

CDC PUBLIC HEALTH GRAND ROUNDS

Global Introduction of New Vaccines: Delivering More to More



Accessible version: <https://www.youtube.com/watch?v=R0CjPYZHIXU>

March 20, 2018



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

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Global Progress



LCDR Anagha Loharikar, MD, USPHS

Medical Officer

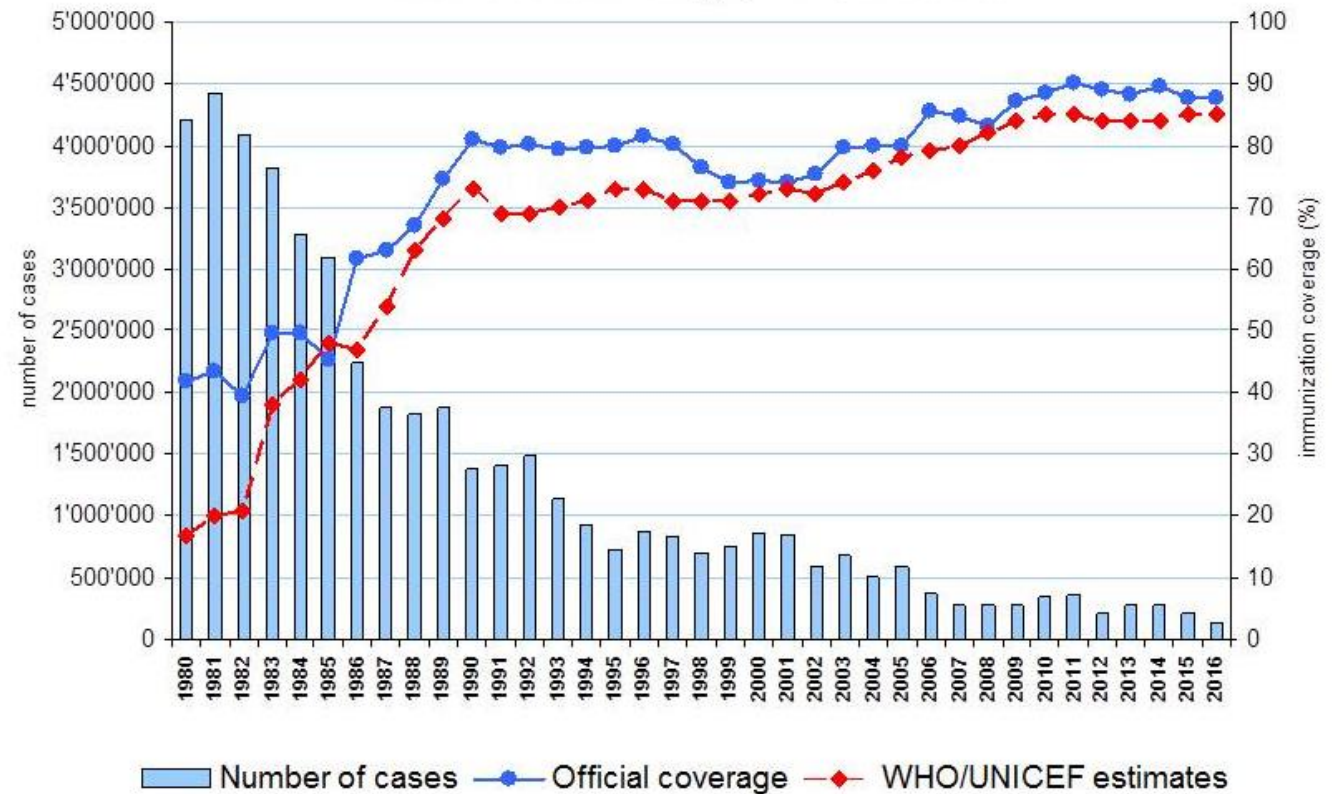
Vaccine Introduction Team, Global Immunization Division

Centers for Disease Control and Prevention

Successful Expanded Program on Immunization (EPI) Initially Targeted Six Diseases

- **World Health Organization (WHO) initiated Expanded Program on Immunization (EPI) in 1974**
 - First six diseases targeted were diphtheria, pertussis, tetanus, measles, poliomyelitis, and tuberculosis
- **Substantial reduction in burden of childhood illness and deaths**

Measles global annual reported cases and MCV1 coverage, 1980-2016



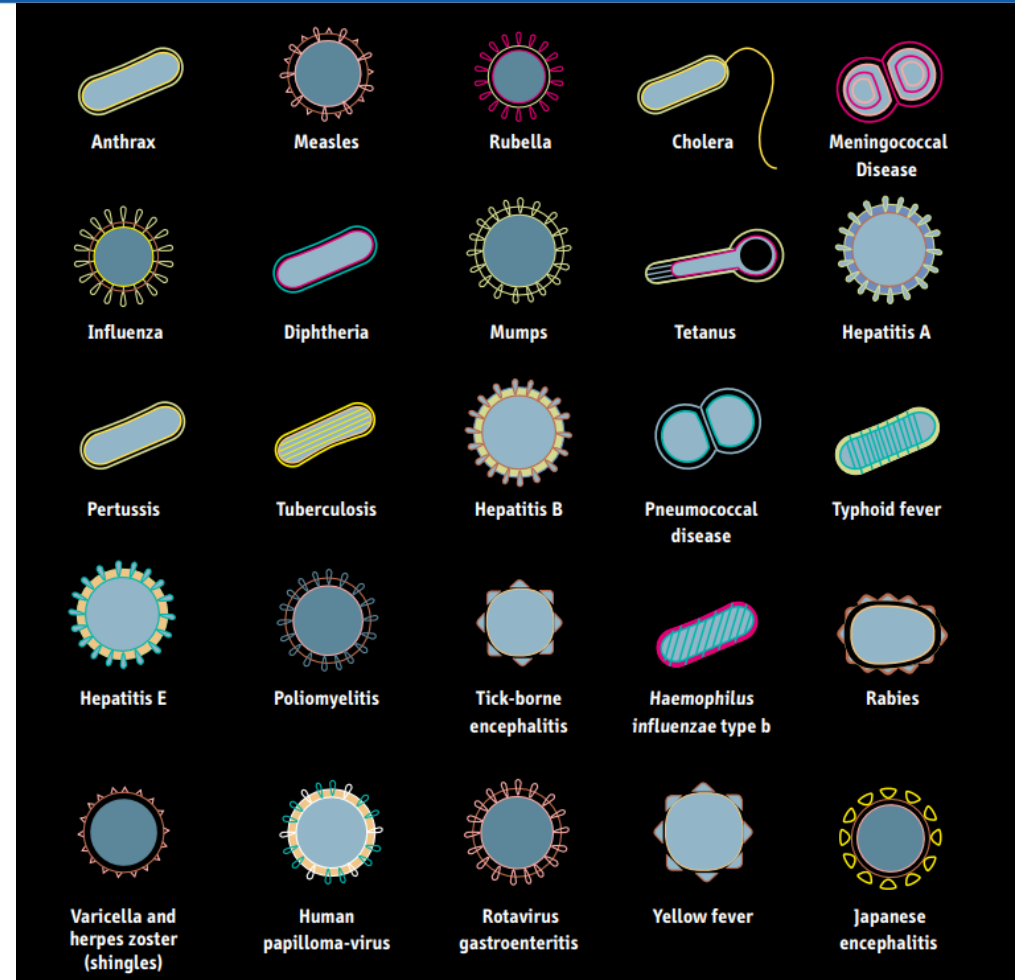
Global Causes of Death in Children Under Age 5 Years

- **An estimated 5.6 million deaths in children under 5 years old each year**
 - 15,000 under-five deaths per day
- **15–25% are attributable to vaccine-preventable diseases**



Vaccines Available to Prevent 25 Infectious Diseases

- Significant advances made in development and introduction of new vaccines
- Licensed vaccines available to prevent 25 infectious diseases



What is a “New” Vaccine?

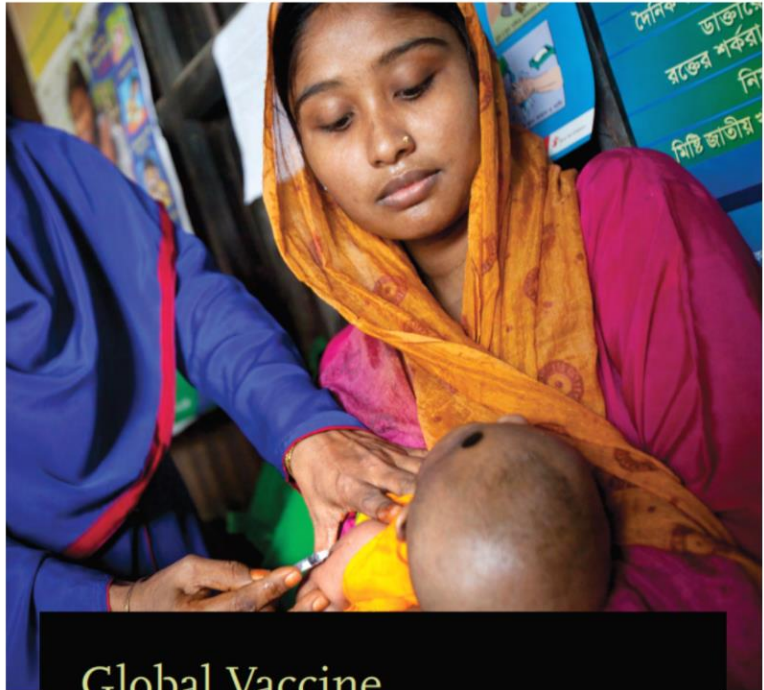
Initial Vaccines	Universally Recommended Vaccines	Vaccines Recommended for Targeted Use
Diphtheria	<i>Haemophilus influenzae</i> type B (Hib)	Yellow fever
Pertussis	Pneumococcal conjugate (PCV)	Japanese encephalitis
Tetanus toxoid	Rotavirus	Typhoid conjugate
Measles	Rubella	Meningococcal
Oral poliovirus (OPV)	Inactivated polio (IPV)	Cholera
Bacille Calmette-Guerin (BCG)	Human papillomavirus (HPV)	Rabies

Why We Need New Vaccines

- 1. Reduce child mortality from vaccine-preventable diseases**
- 2. Prevent and control outbreaks of vaccine-preventable diseases**
- 3. Eliminate and eradicate vaccine-preventable diseases**
- 4. Respond to rapidly increasing antimicrobial resistance**



2011–2020: Decade of Vaccines and the Global Vaccine Action Plan (GVAP) Vision



Global Vaccine
Action Plan

2011–2020

“We envision a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases.”

GVAP Mid-point Progress Targets 2015

NOT
ACHIEVED

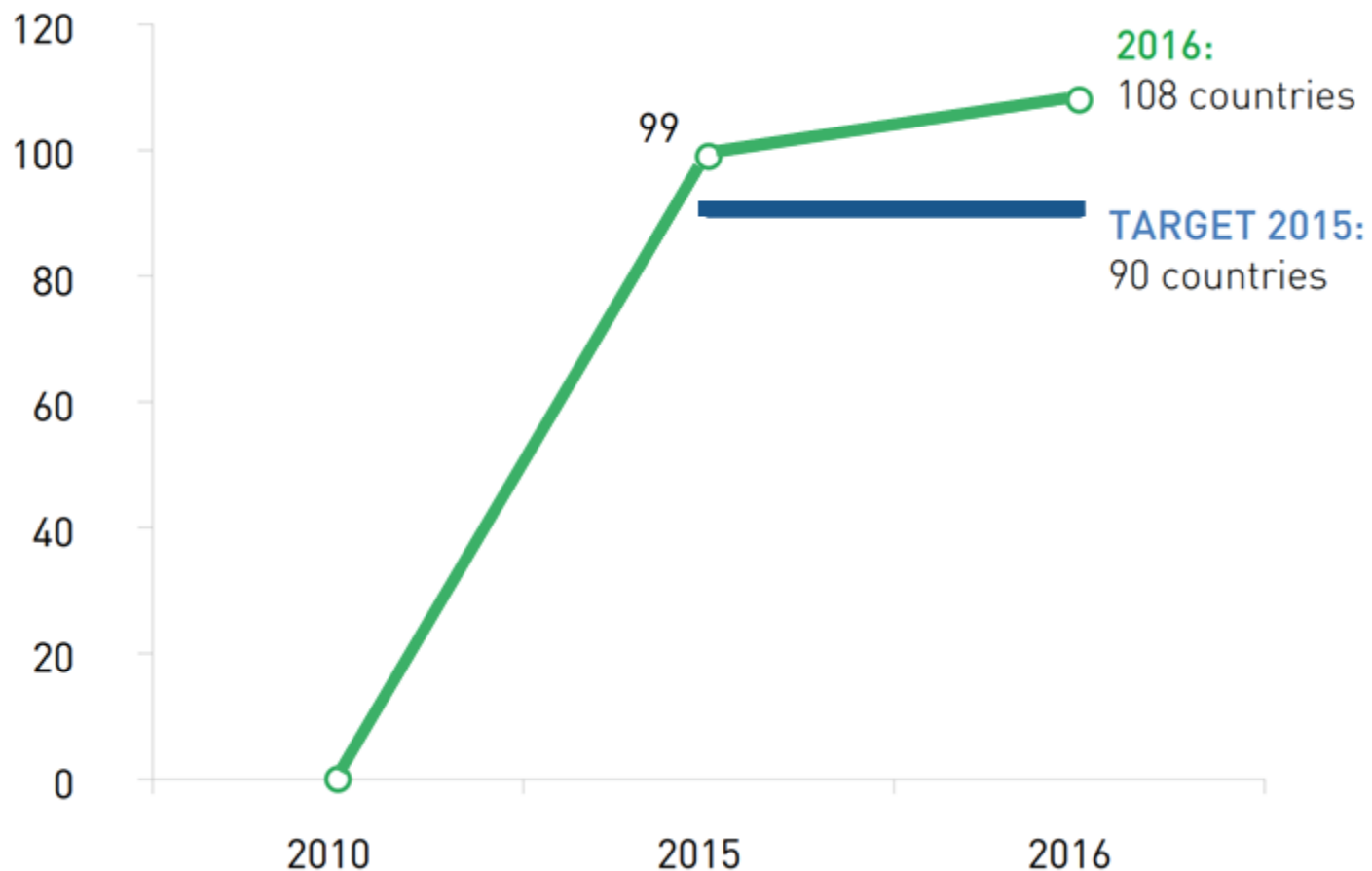
1. **DTP3: All countries >90% national coverage, and >80% in every district by end 2015**
2. **Polio: transmission stopped by end 2014**
3. **Maternal and neonatal tetanus: eliminated by 2015**
4. **Measles: eliminated in 4 regions by end-2015**
5. **Rubella: eliminated in 2 regions by end-2015**

ACHIEVED

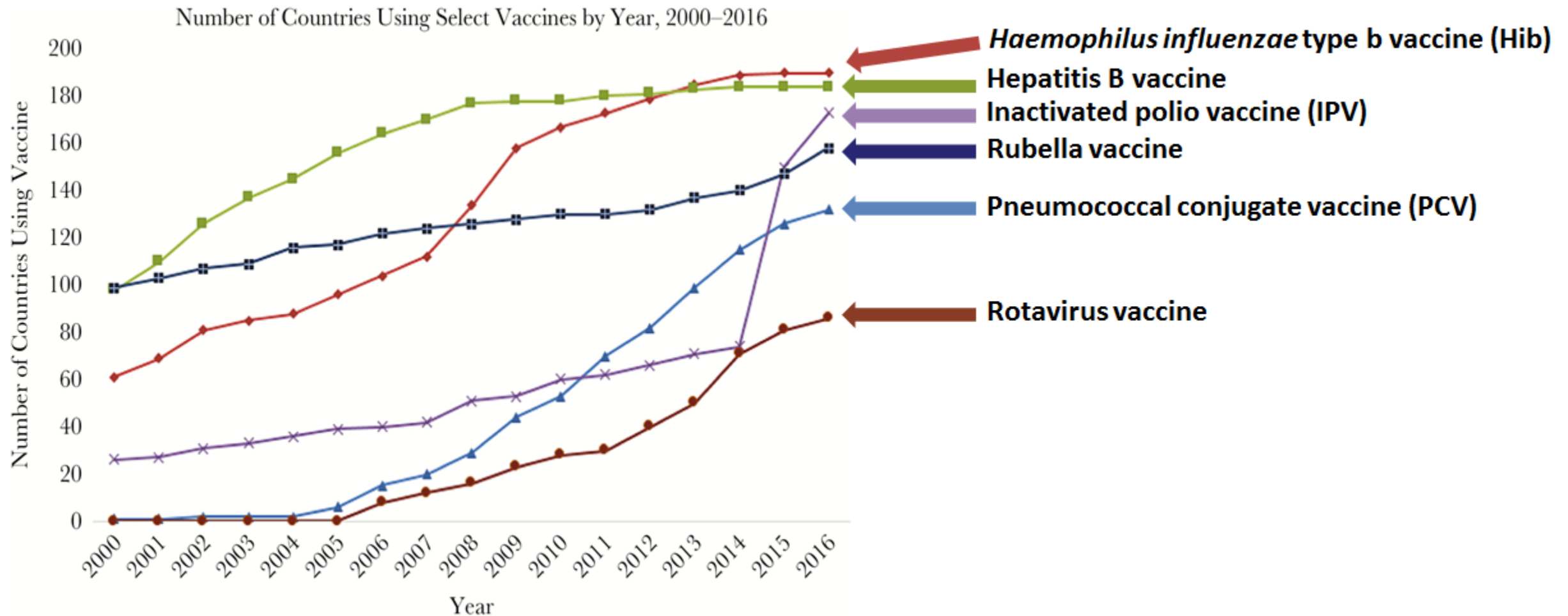
6. **Introduction of new and under-utilized vaccines: At least 90 low- or middle-income countries to have introduced one or more such vaccines by 2015**

New Vaccine Introduction GVAP Target Met

- **GVAP vaccine introduction target has been met and exceeded**
- **Since 2010, 193 vaccines have been introduced in 108 of 138 low- and middle-income countries**

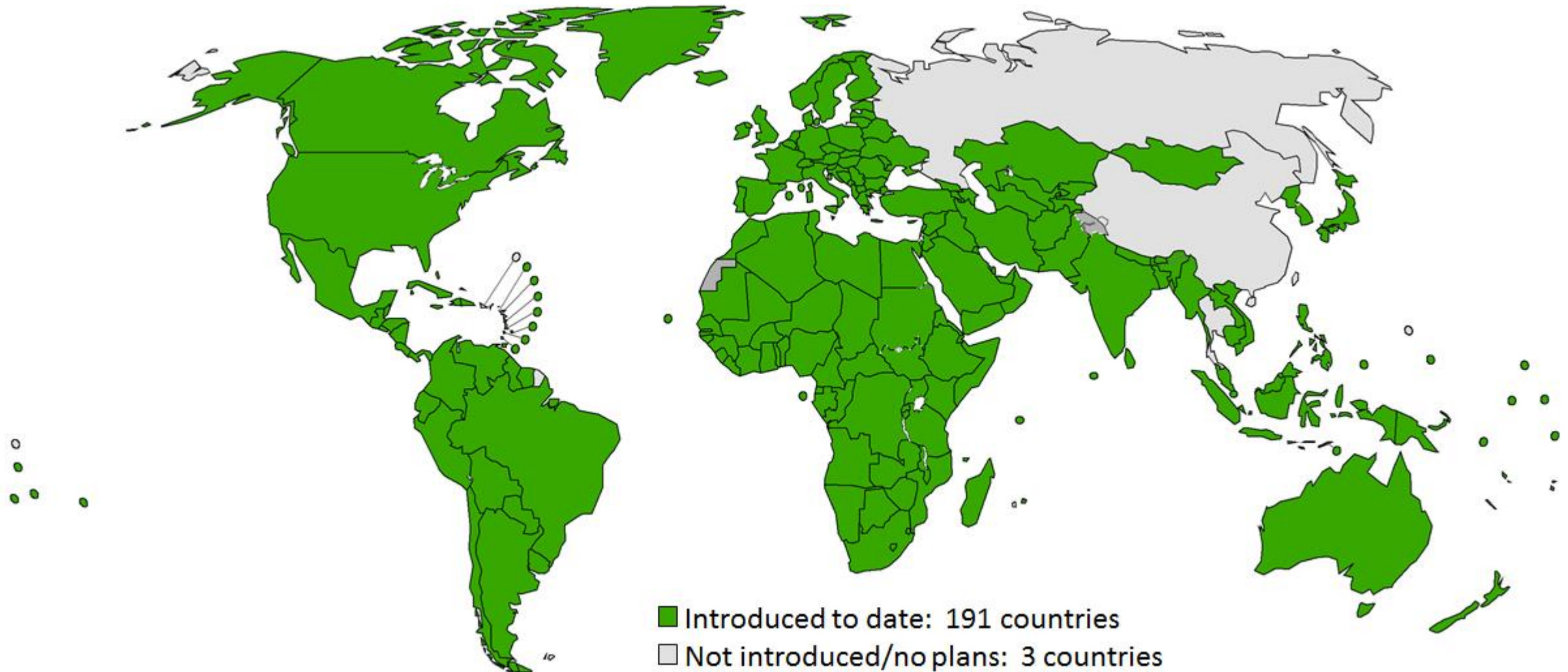


Progress in New Vaccine Introduction



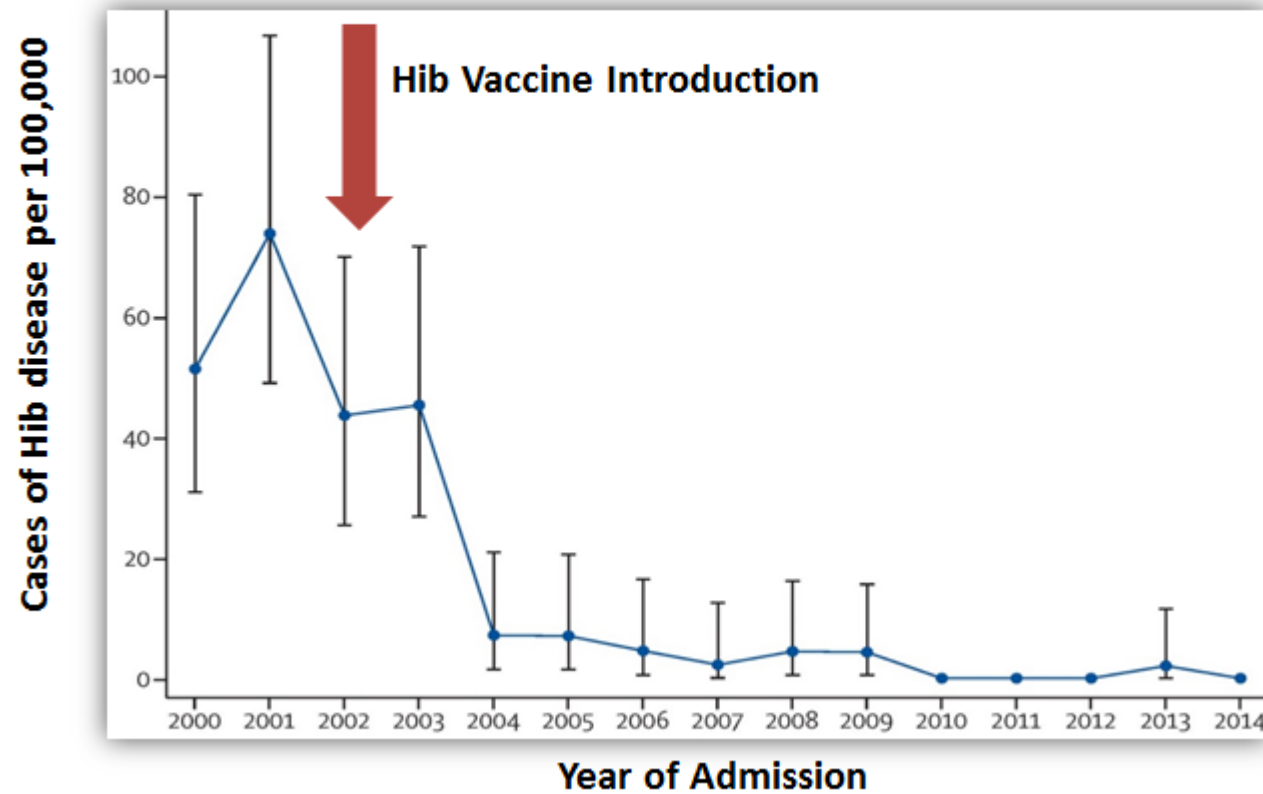
Zipursky S, Patel M, Farrell M, et al. *J Infect Dis.* 2017 Jul 1;216(suppl_1):S15-S23.

Countries with *Haemophilus influenzae* type b (Hib) Vaccine in National Immunization Program



Incidence of Invasive Hib Disease Declines Following Hib Vaccine Introduction in Children Younger than 5 Years

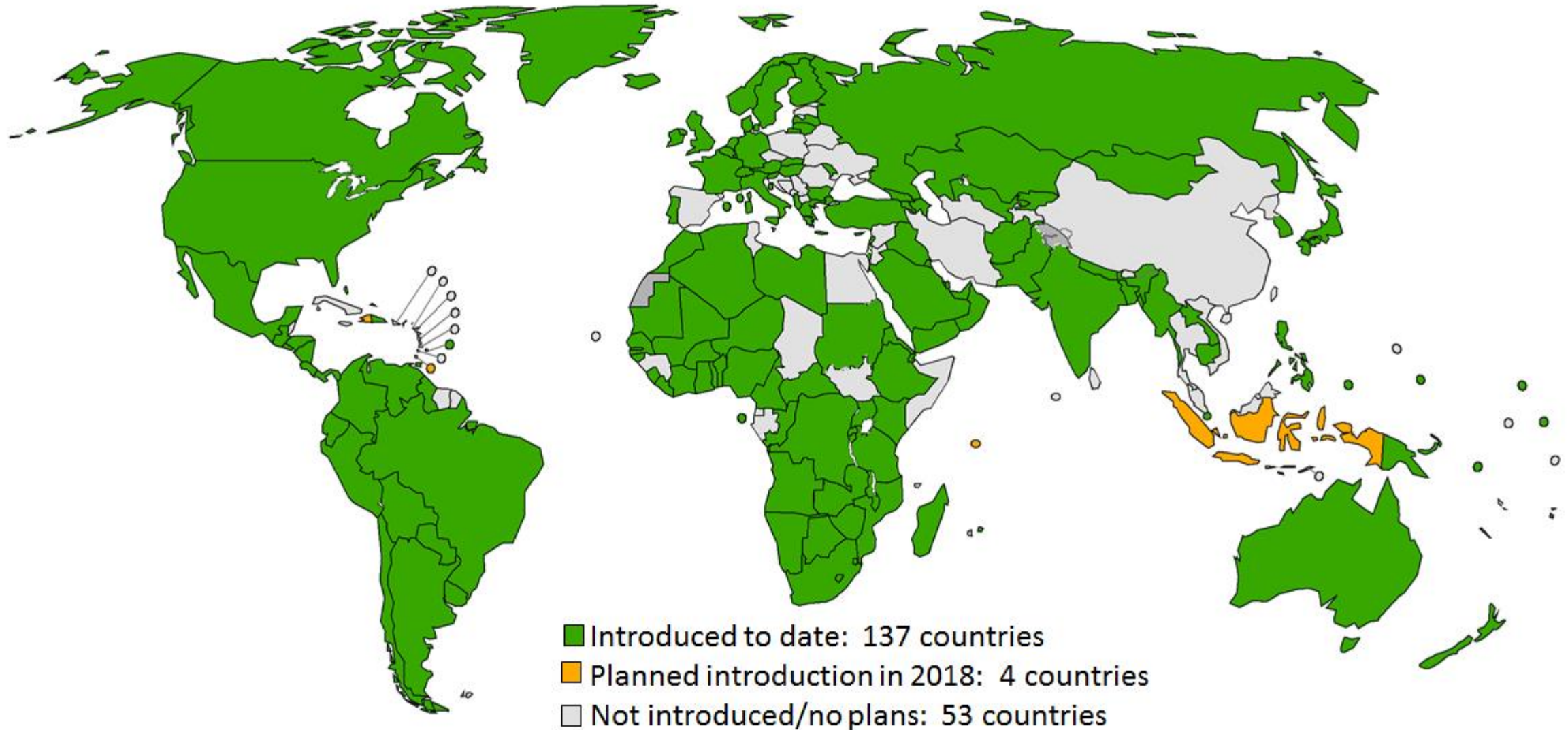
Incidence of Invasive Hib Disease in Children <5 years,
Kilifi, Kenya, 2000–2014



Hib: *Haemophilus influenzae* type b

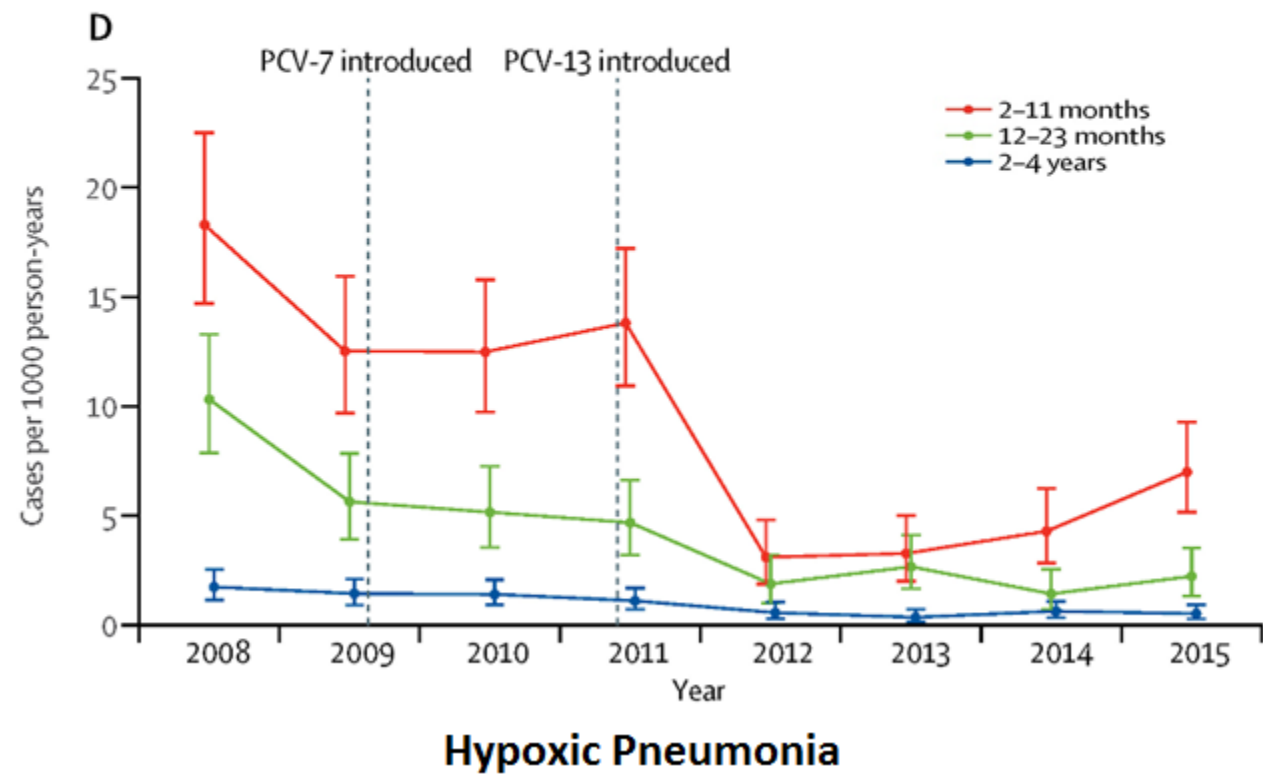
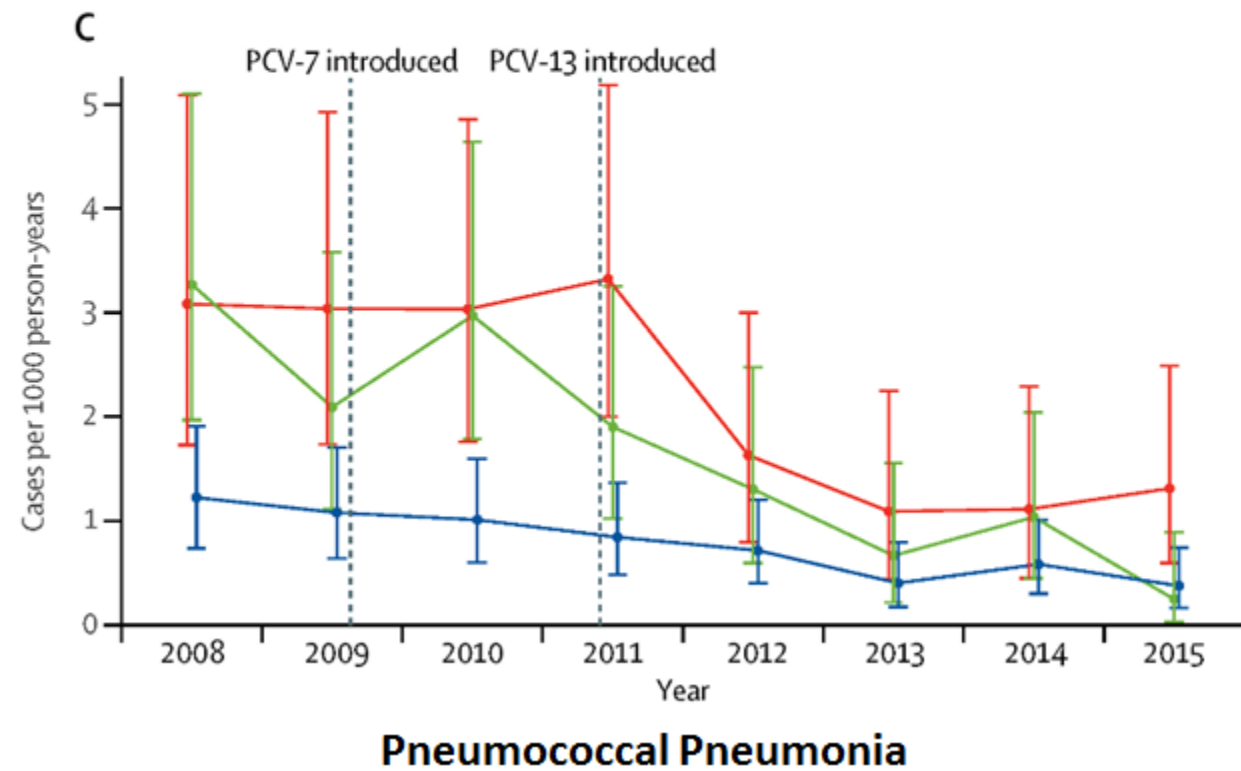
Hammit LL, Crane RJ, Karani A, et al. *Lancet Glob Health*. 2016 Mar;4(3):e185-94

Countries with Pneumococcal Conjugate Vaccine (PCV) in National Immunization Program



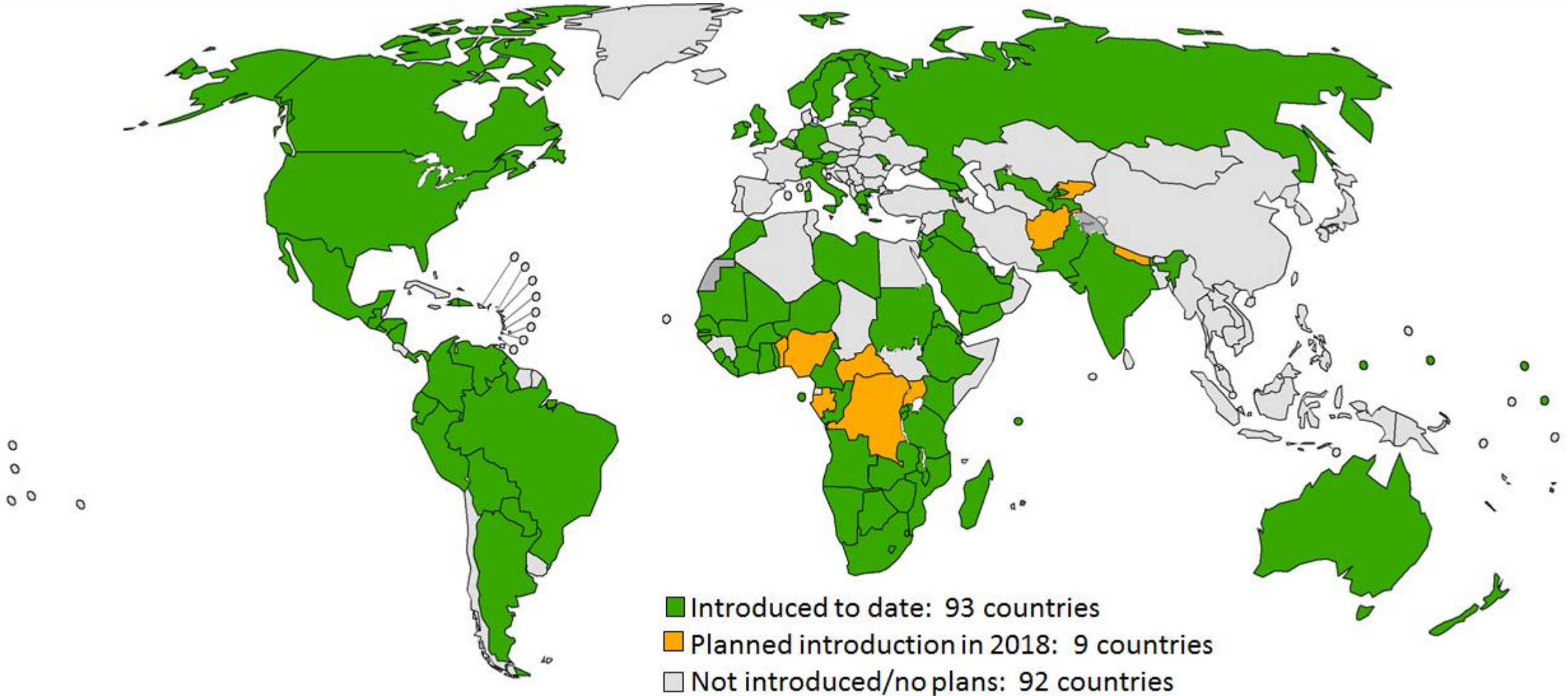
Reduction in Annual Pneumonia Incidence Following PCV Introduction in The Gambia

Incidence of Radiological Pneumonia with Pneumococcal Pneumonia and Hypoxic Pneumonia in the Basse Health and Demographic Surveillance System, 2008–2015, by Age Group

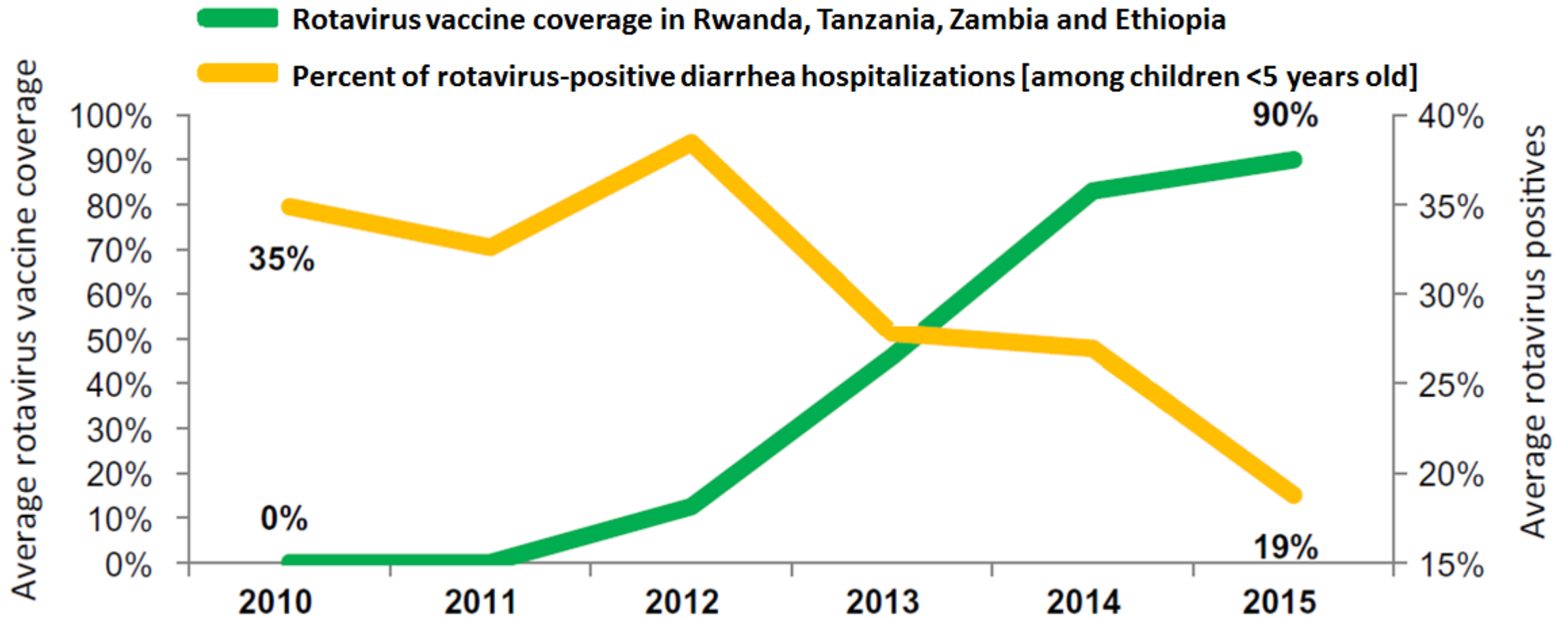


Mackenzie GA, Hill PC, Sahito, MS, et al. *Lancet Infect Dis*. 2017 Sep;17(9):965-973.

Countries with Rotavirus Vaccine in National Immunization Program

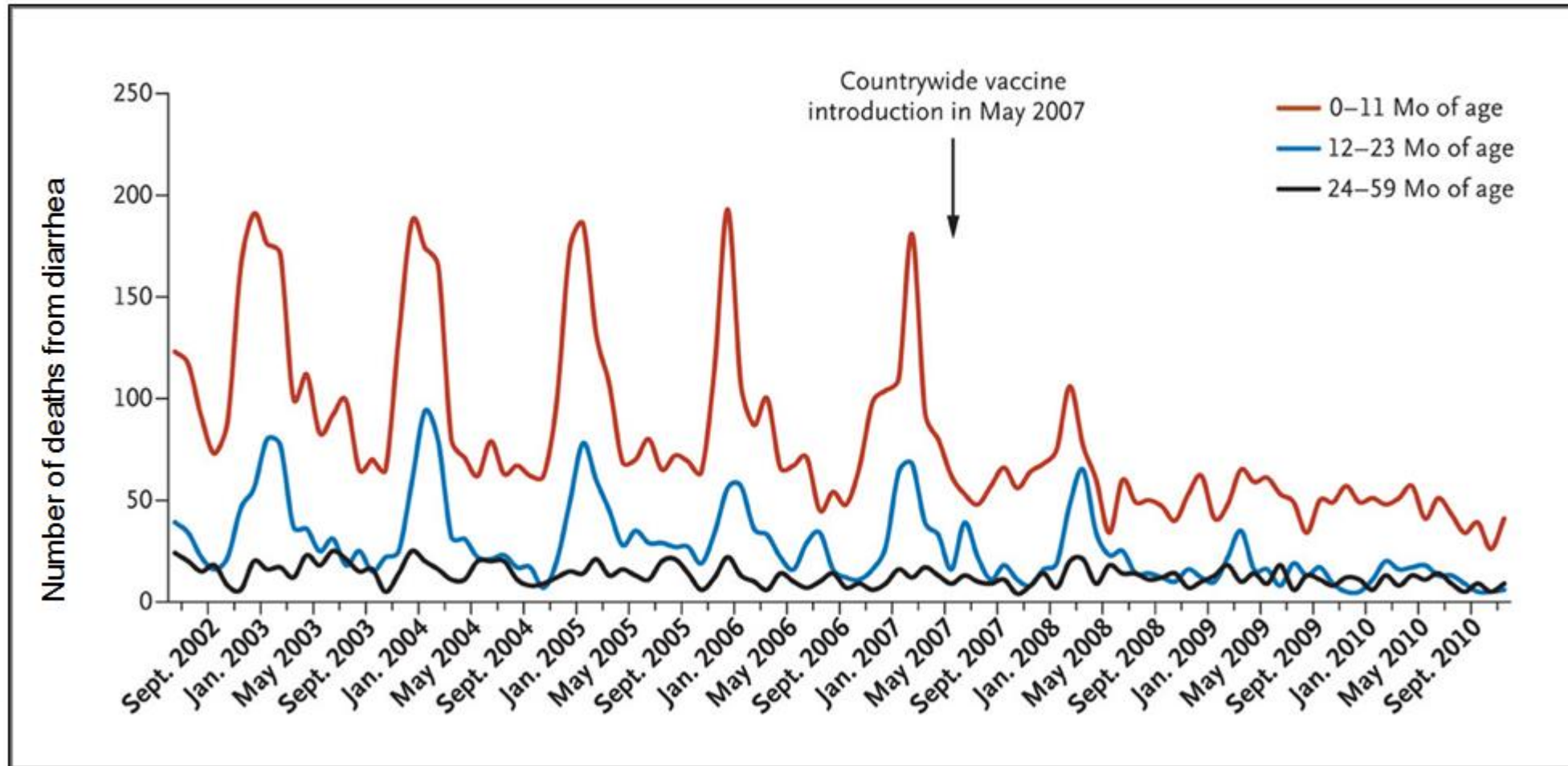


Decrease in Rotavirus-positive Cases with Increasing Rotavirus Vaccine Coverage in Four African Countries, 2010–2015

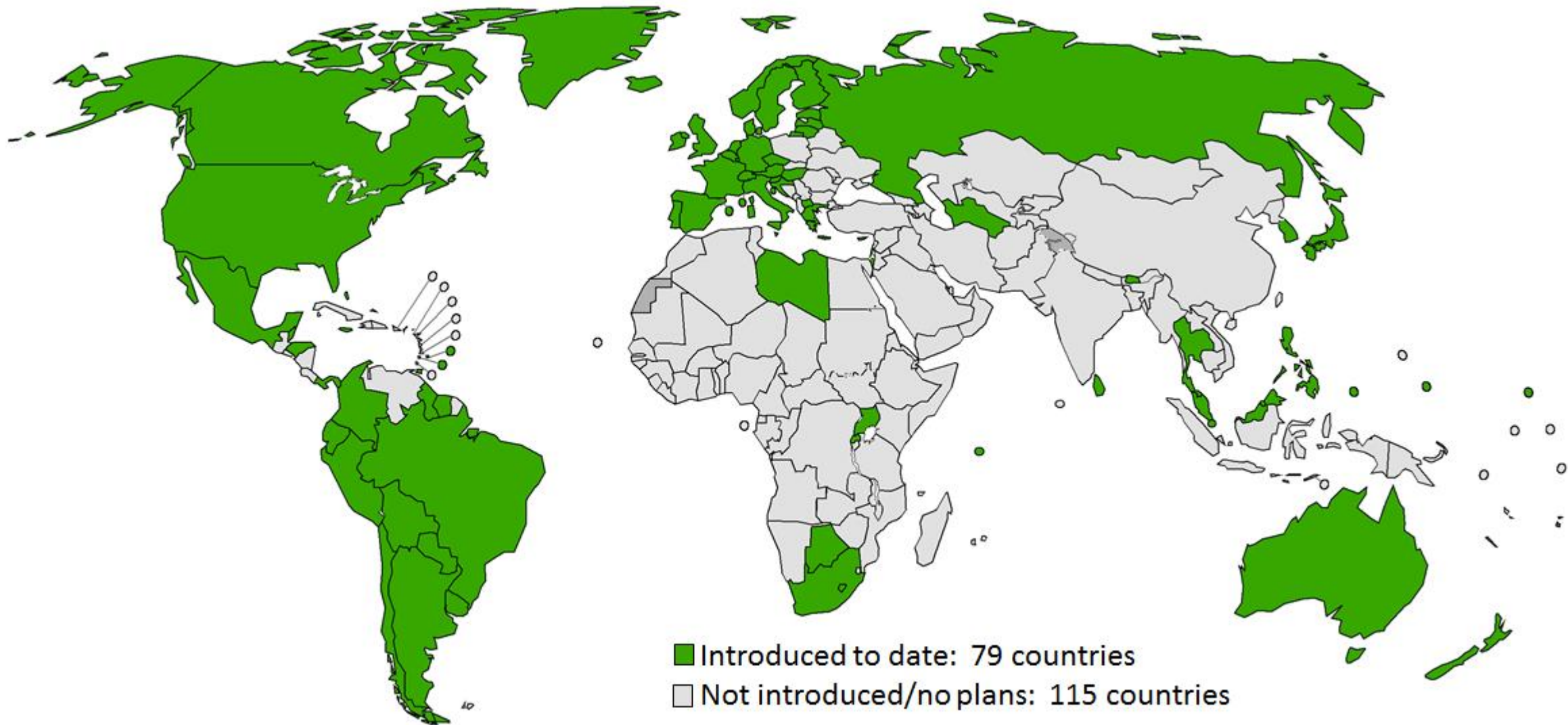


Dramatic Reduction in Diarrheal Deaths Following Rotavirus Vaccine Introduction in Mexico

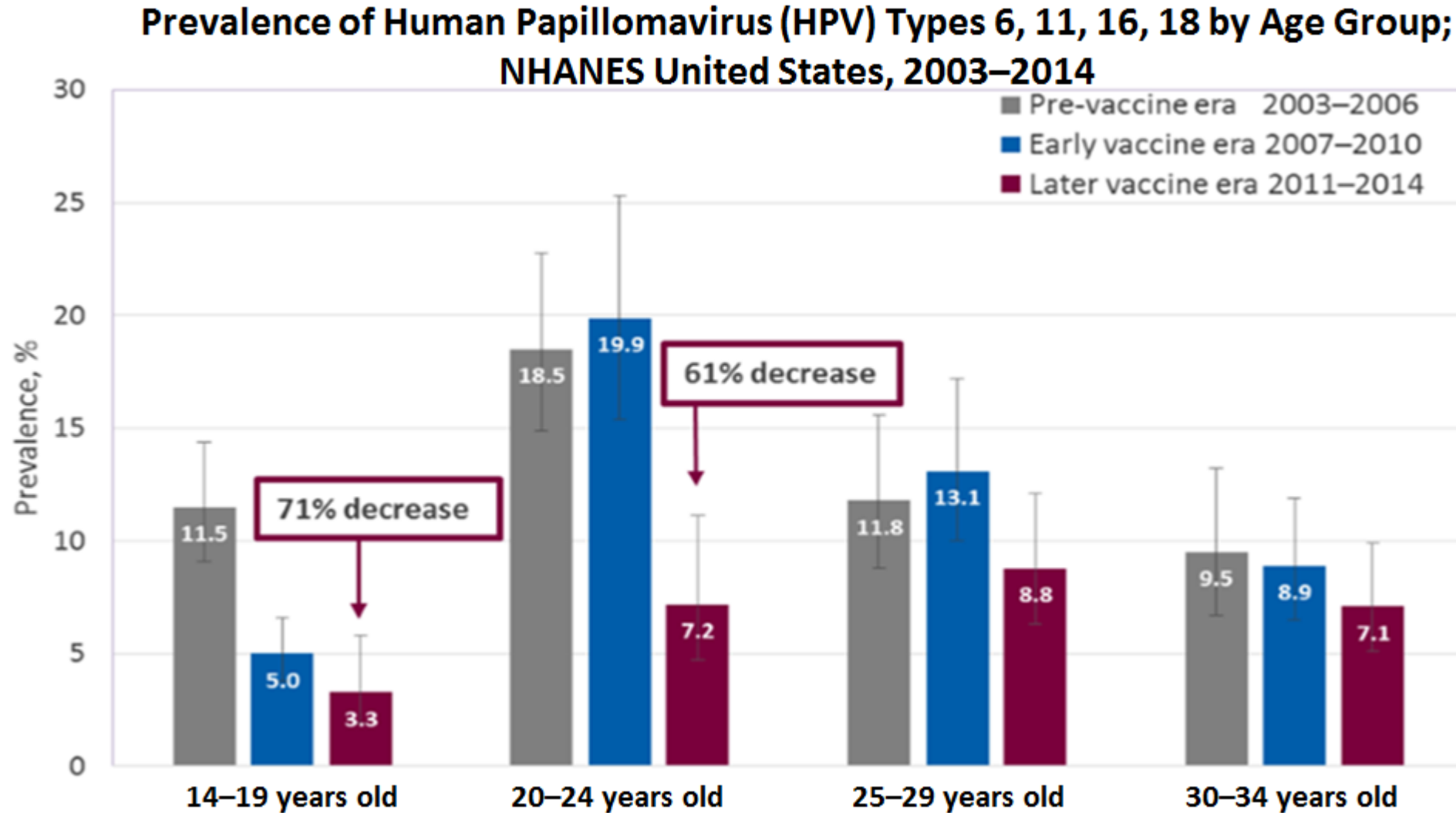
Number of Diarrhea-related Deaths among Children <5 years age, Mexico, 2002–2010



Countries with Human Papillomavirus (HPV) Vaccine in National Immunization Program



Substantial Decline in Prevalence of HPV Types 6, 11, 16, 18 Following HPV Vaccine Introduction



Efforts of Global Partners to Improve Vaccine Introduction in Low- and Middle-income Countries

➤ **World Health Organization (WHO)**

- Vaccine prequalification
- Global recommendations and policies



**World Health
Organization**

➤ **United Nations Children's Fund (UNICEF)**

- Communication and social mobilization
- Vaccine procurement



➤ **Gavi, the Vaccine Alliance (Gavi)**

- Donor funding for eligible countries
- Eligibility determined by country gross national income
- Vaccine market shaping through forecasting and assuring demand



Estimated Impact of Vaccine Introduction in Gavi-eligible Countries

- **By 2020, all or nearly all Gavi-eligible countries are projected to have introduced the following nine vaccines where recommended:**

Hepatitis B

Rotavirus

Meningococcal serogroup A

Hib

Rubella

Japanese encephalitis

PCV

Yellow fever

Measles second dose

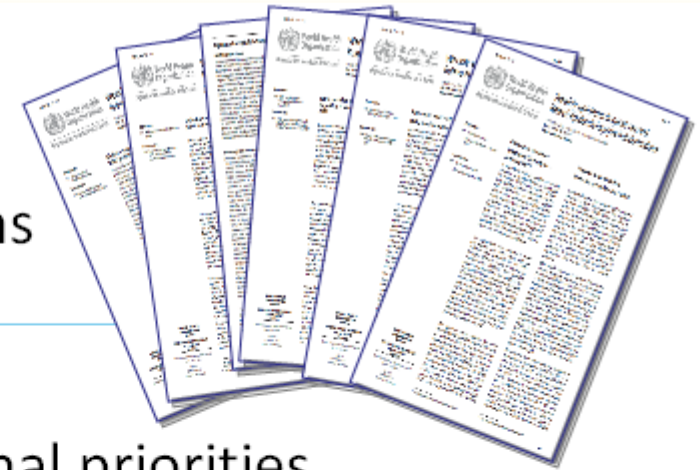
- **Estimated 23.3 million deaths will be averted by vaccines during 2011–2020, in 73 Gavi-eligible countries**

WHO Immunization Policy Framework and Decision-making on Vaccine Introduction

Global

Strategic Advisory Group of Experts
(SAGE)
on Immunization

Global policy
recommendations



Regional

Regional Immunization
Technical Advisory Group
(RITAG)

- Identifies regional priorities
- Sets regional policies and strategies

National

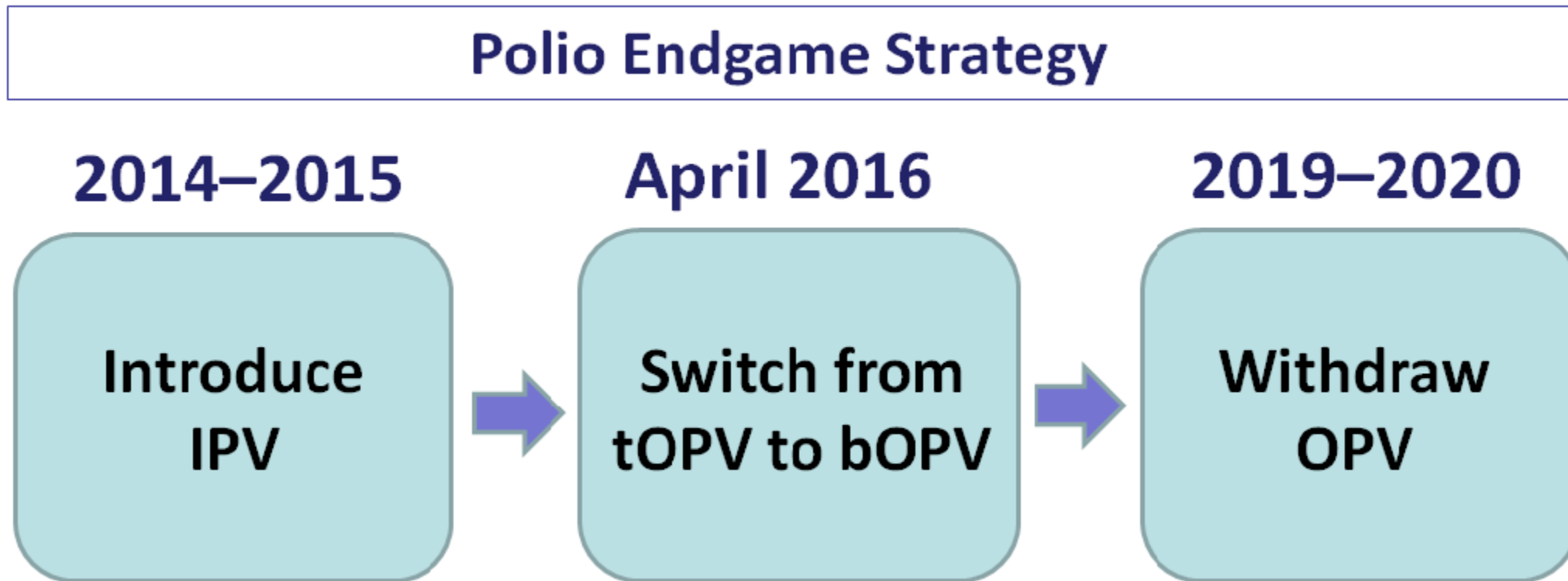
National Immunization
Technical Advisory Group
(NITAG)

Makes immunization policy
recommendations to national
health authorities

Vaccine Supply Security and Procurement Can Hinder New Vaccine Introduction

- **Recent supply shortages of rotavirus, PCV, IPV and HPV vaccines**
 - Vaccine markets and limited numbers of manufacturers
 - Increasing demand and inaccurate supply forecasting
- **Countries may use programmatic modifications to address supply constraints**
 - Fractional doses of vaccines
 - Phased introductions
- **Increasing vaccine manufacturing in middle-income countries can reduce price and increase supply**

Global Mandates Can Facilitate Vaccine Introduction



Outbreaks of Vaccine-Preventable Diseases

- **Require additional resources for vaccination campaigns**
 - Cholera outbreaks in Haiti, Zambia, and Yemen
 - Yellow fever outbreaks in Angola and Brazil
- **May necessitate the use of vaccines before licensure**
 - Ebola in West Africa
- **Can occur during a humanitarian crisis**
 - Diphtheria among Rohingya refugees in Bangladesh



Increasing Antimicrobial Resistance Necessitates Global Support for New Vaccine Introduction

- **PCV introduction has prevented resistant infections and led to reduction in antibiotic use**
- **Newer typhoid conjugate vaccine available**
 - Prequalified by WHO – January 2018
 - Gavi-endorsed funding support for eligible countries
 - Potential for high impact on prevention and control of antimicrobial-resistant typhoid fever

Additional New and Pipeline* Vaccines across the Lifespan

Infants and young children

- Japanese encephalitis
- Meningococcal A
- Measles 2nd dose
- Rubella
- Varicella
- Hepatitis A
- Malaria
- Dengue
- Enterotoxigenic *E. coli*
- *Shigella*
- Group A *Streptococcus*

Older children and adolescents

- Tetanus adolescent dose

Older Adults

- Zoster

Pregnant women

- Influenza
- Group B *Streptococcus*
- Respiratory syncytial virus

*Vaccines shown in blue are in varying stages of development

Progress Made in New Vaccine Introduction but Need for Sustained Efforts

- **Extensive progress in introducing new vaccines in low- and lower middle-income countries, meeting GVAP target**
 - Largely due to support from international partners and donors
 - Significant reductions in vaccine-preventable disease and mortality
- **Many factors affect the timing and prioritization of vaccine introduction**
 - Vaccine supply constraints and global mandates
 - Outbreaks and humanitarian crises
 - Increasing antimicrobial resistance
- **Need for continued support of implementation to sustain health gains and work toward remaining GVAP targets**

Global Progress

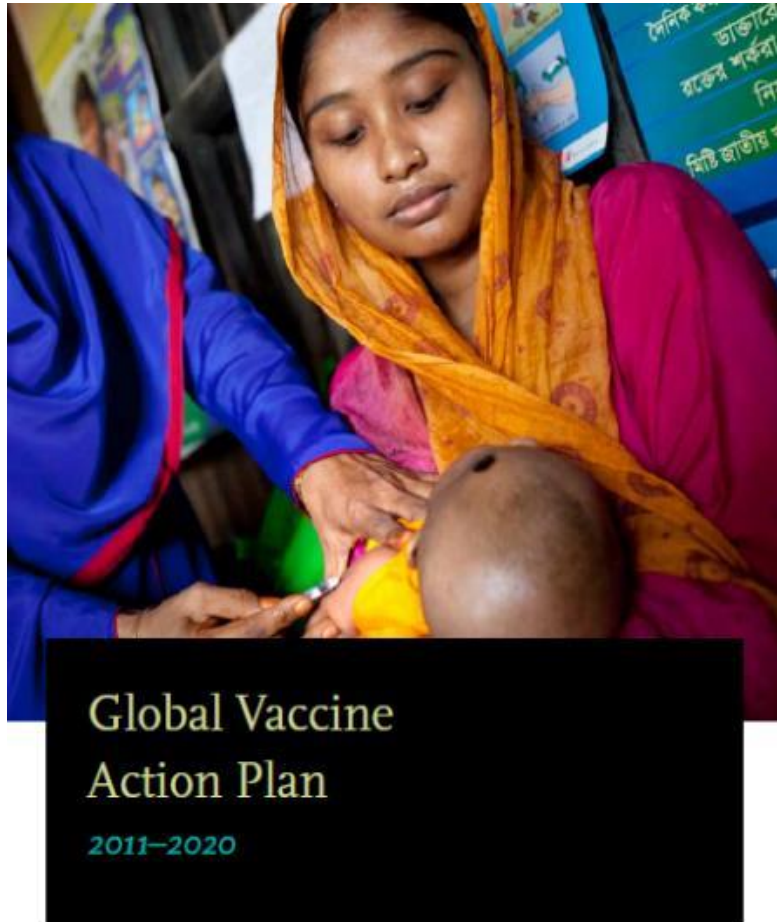


Carsten Mantel, MD, MPH

Managing Director, MMGH Consulting GmbH, CH-Zürich

*Senior Advisor Immunization, Department of Infectious Disease Epidemiology,
Robert Koch Institute, D-Berlin*

Global Vaccine Action Plan (GVAP) Mission



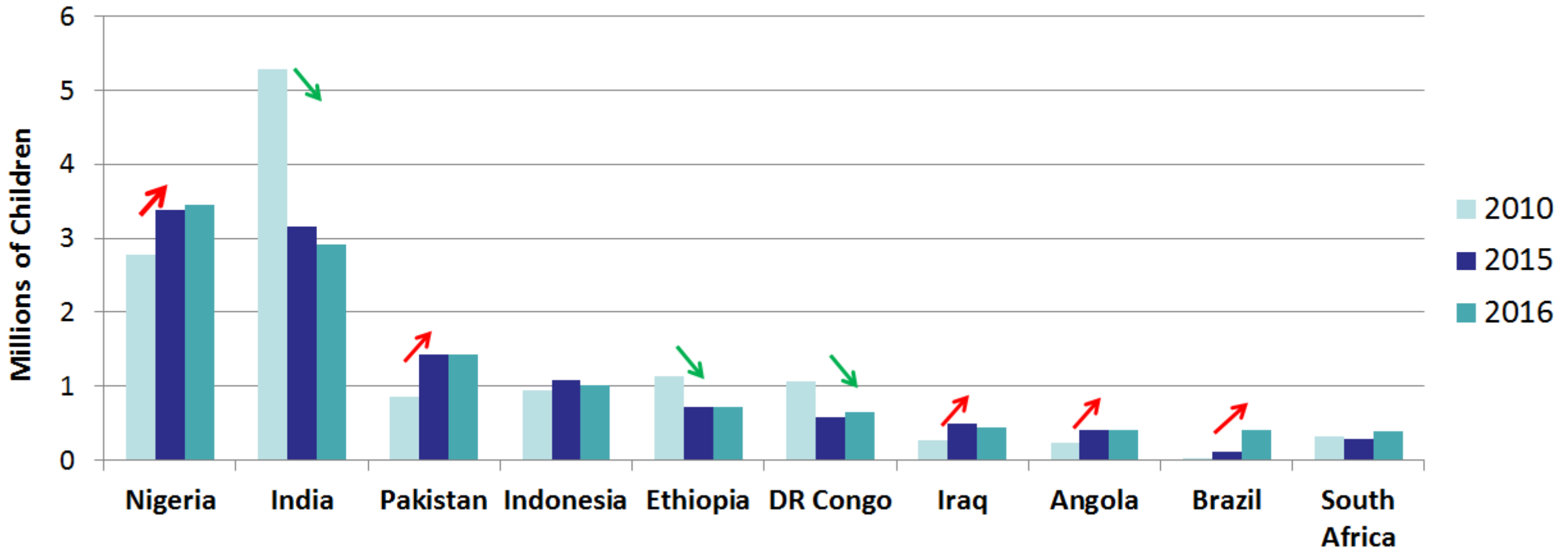
"The mission of the Decade of Vaccines is to extend, by 2020 and beyond, the full benefits of immunization to all people, regardless of where they are born, who they are, or where they live..."

Vaccines and Equity—The Challenge Across Countries

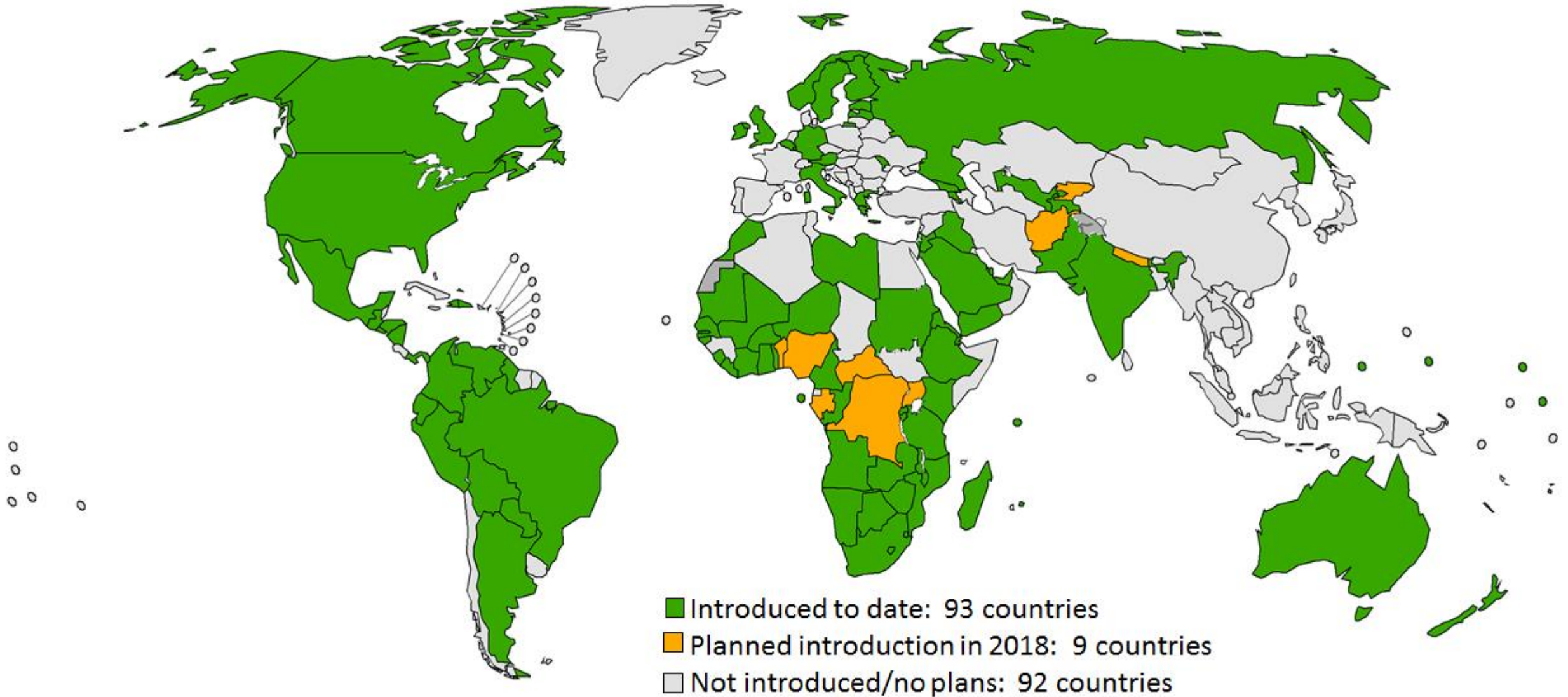
- **Inequity in new vaccine access across countries remains**
- **We are still not reaching every child everywhere**
 - Nearly 1 in 10 infants worldwide has not received **any** DTP vaccine (12.9 million infants)
 - The global coverage of DTP3 is stagnating at around 86%
 - Most of the unvaccinated and under-vaccinated children live in 10 large countries
- **Rotavirus vaccine use is delayed in Asia**
- **Middle-income countries are lagging in new vaccine introduction**

Numbers of Unvaccinated Children Falling in Some but Not All Large Countries

Number of Unvaccinated Children in Top 10 Countries with Most Unvaccinated (DTP3)

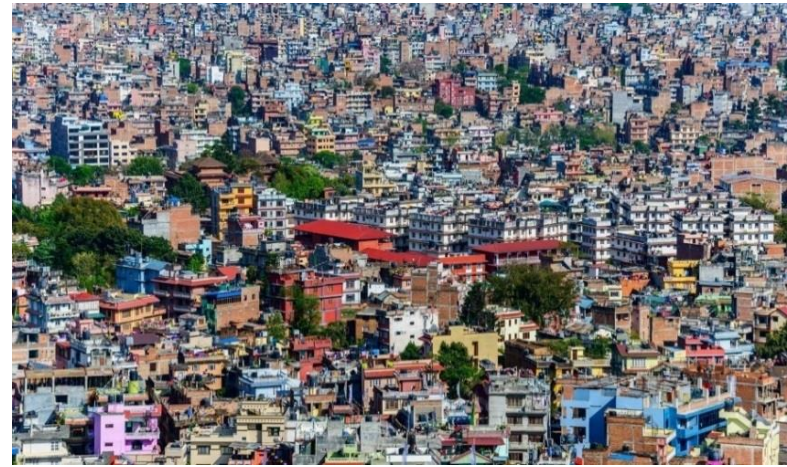


Delay in Introducing Rotavirus Vaccine in Parts of Asia and Europe



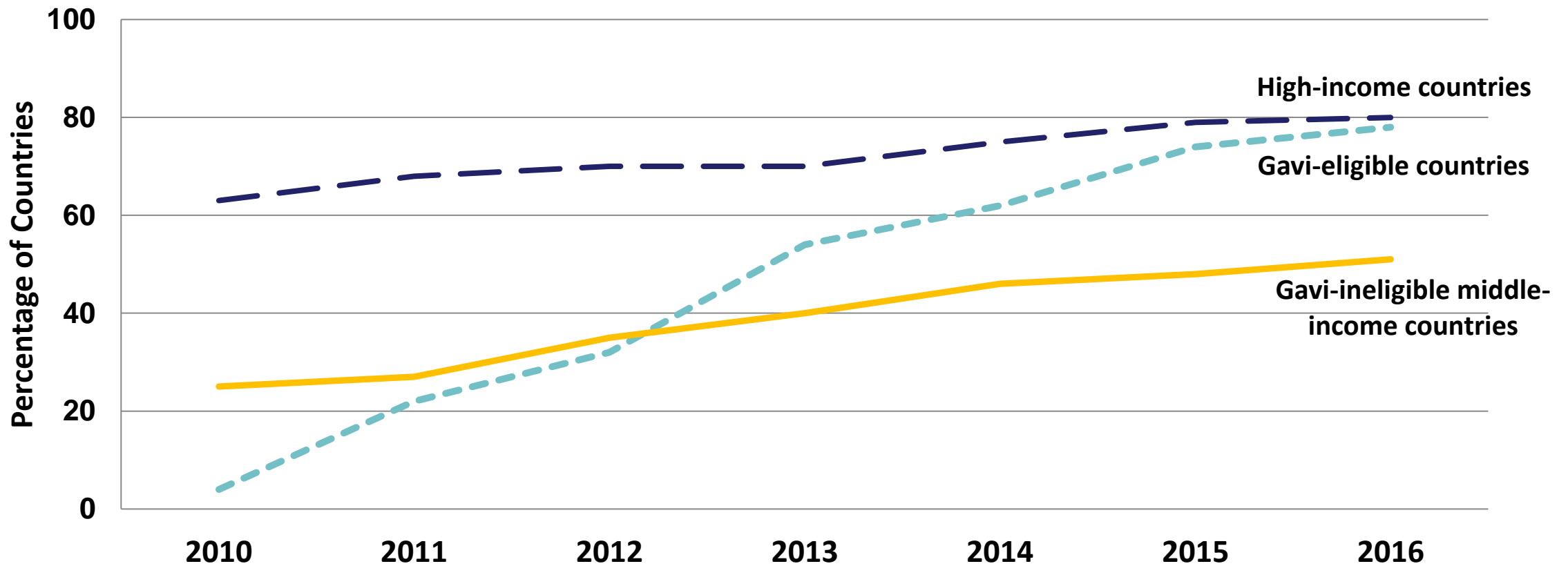
Challenges for Middle-Income Countries (MICs)

- About two-thirds of the world's poor now live in MICs
- For children, the largest fraction without access to new vaccines are born in MICs
- About one quarter of vaccine-preventable deaths occur in the MICs that are excluded from or are soon to lose donor support
- 20 MICs are expected to transition from Gavi support by 2020



Introduction of PCV Slower in Middle-Income Countries

Comparison of PCV Uptake in High-income, Gavi-eligible and Gavi-ineligible Countries, 2010–2016

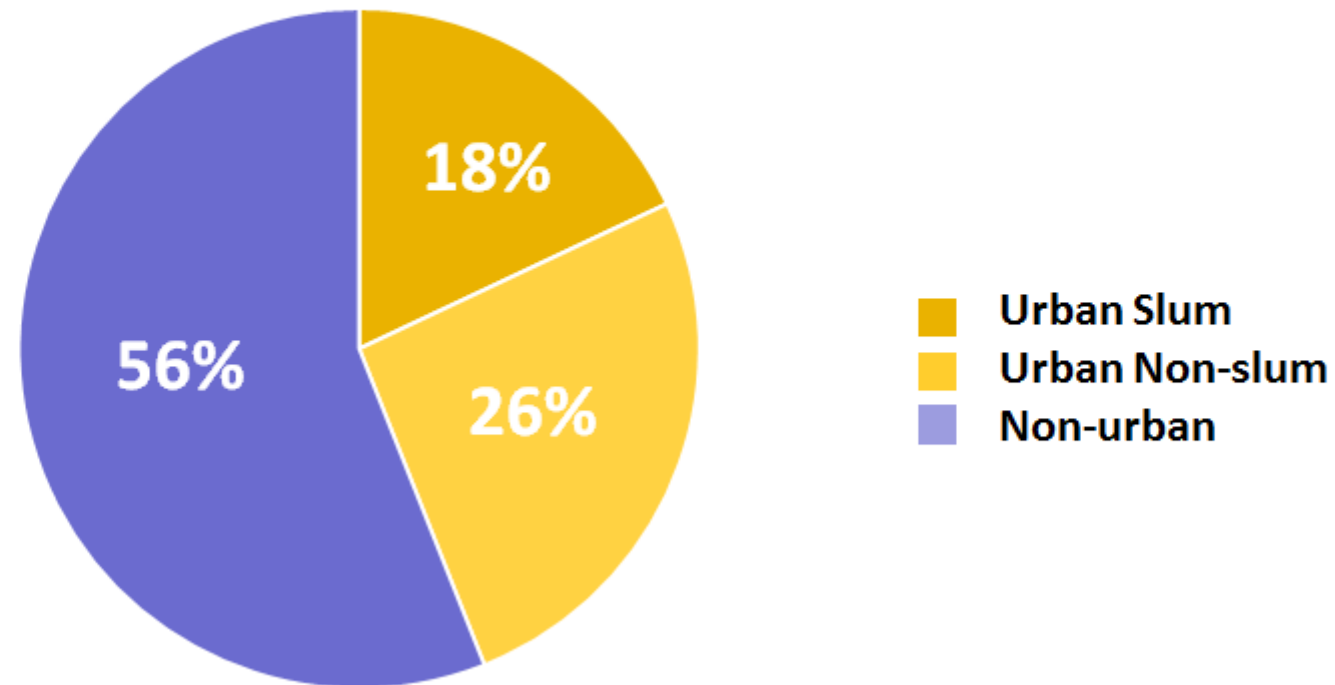


Vaccines and Equity – The Challenge Within Countries

- **Inequity in vaccine delivery within countries is associated with:**
 - Conflicts, fragile situations, or humanitarian emergencies
 - Residence (urban or rural), with low coverage in urban slums and remote rural communities
 - Nomadic populations and ethnic minorities
 - Economic status (wealth quintiles)
 - Education (of mothers)
 - Gender
 - Vaccine hesitancy

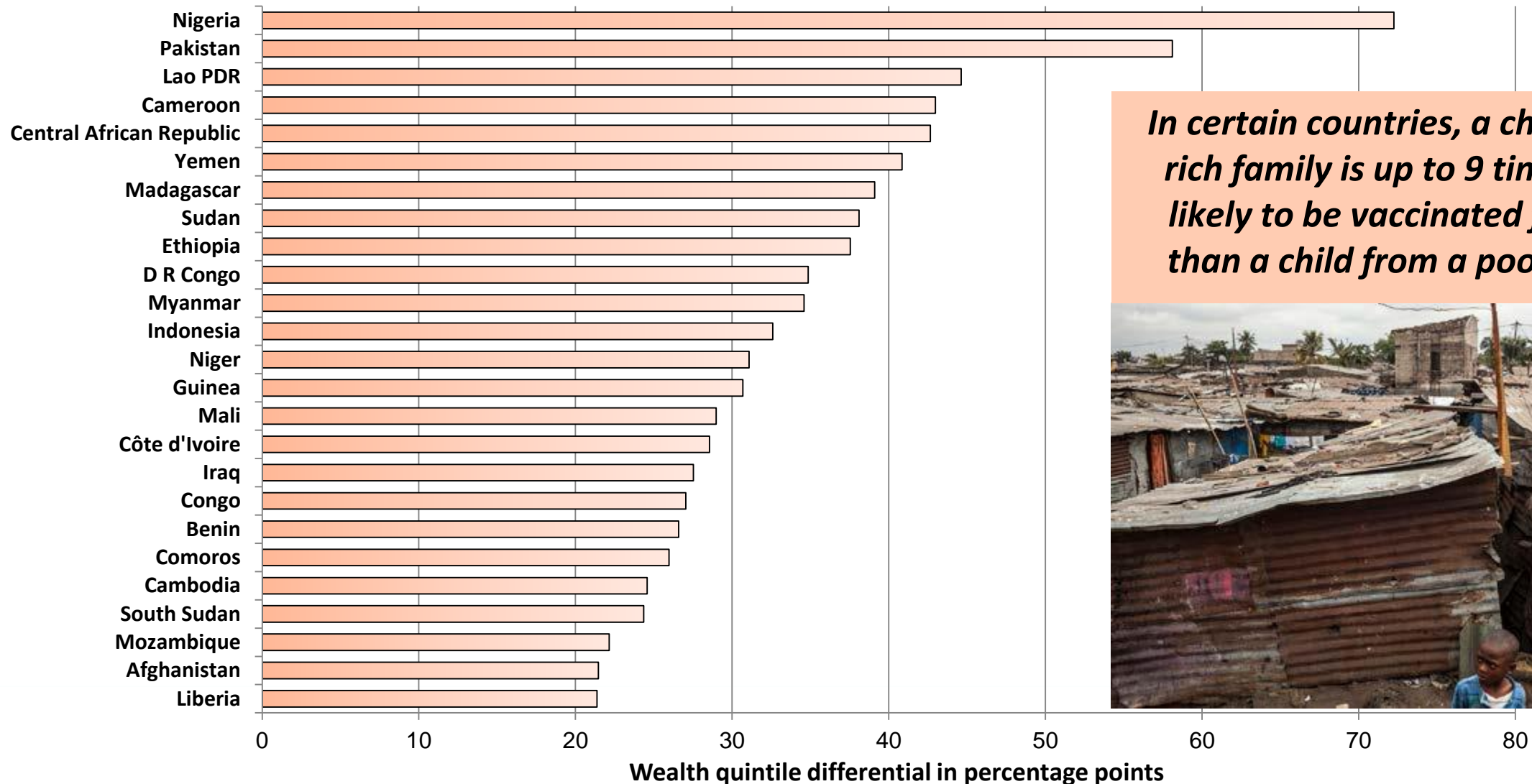
Increasing Proportion of Unimmunized Live in Cities and Urban Slums

Distribution of Unimmunized or Under-immunized (DTP3) in Top 10 Countries



Many Countries Show High Levels of Inequity

Differential in DTP3 coverage between highest and lowest wealth quintile



In certain countries, a child from a rich family is up to 9 times more likely to be vaccinated for DTP3 than a child from a poor family.



New Vaccines and Equity—The Response

➤ **Renewed global focus on equity across countries**

- GVAP equity monitoring and response (WHO, UNICEF, World Bank)
- Gavi coverage and equity strategy 2016–2020
- Global Routine Immunization Strategies and Practices (GRISP)
- Middle-income country strategy

➤ **Increasing access to the unvaccinated within countries**

- Governments often have difficulties in reaching these populations—or lack political will
- Community-based organizations play an important role in reaching the unimmunized and in increasing vaccine access and coverage—also related to new vaccines (e.g., IPV, HPV)
- New approaches to reach urban poor (slums), nomadic, marginalized populations
- New delivery and access strategies in crisis and humanitarian emergencies

Gavi 2016–2020 Strategy Includes Equitable Uptake and Coverage

Mission	<i>To save children's lives and protect people's health by increasing equitable use of vaccines in lower-income countries</i>			
Principles	<ul style="list-style-type: none"> ▪ Country-led ▪ Globally engaged ▪ Integrated ▪ Collaborative ▪ Community-owned ▪ Catalytic & sustainable ▪ Innovative ▪ Accountable 			
Goals	Accelerate equitable uptake and coverage of vaccines	Increase effectiveness and efficiency of immunisation delivery as an integrated part of strengthened health systems		
	1 <ul style="list-style-type: none"> ▪ Coverage and equity ▪ Introduction and scale-up of new vaccines ▪ Flexible response to special needs of fragile countries 	2 <ul style="list-style-type: none"> ▪ Integrated comprehensive immunisation programmes ▪ Supply chains, health information systems, demand generation and gender sensitive approaches ▪ Engagement of civil society, private sector and other partners 		
	Improve sustainability of national immunisation programmes	Shape markets for vaccines and other immunisation products		
	3 <ul style="list-style-type: none"> ▪ National and sub-national political commitment ▪ Allocation and management of national human and financial resources ▪ Sustained performance after graduation 	4 <ul style="list-style-type: none"> ▪ Adequate and secure supply ▪ Appropriate and sustainable prices ▪ Incentivise development of suitable and quality products 		

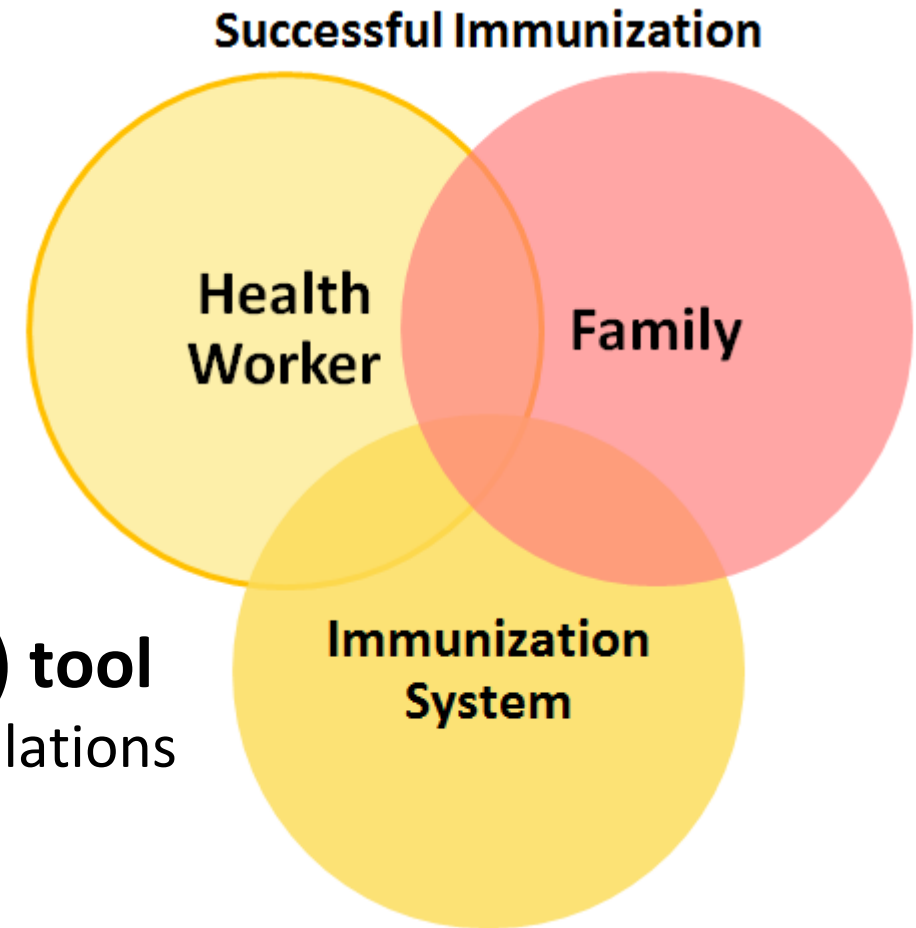
New Vaccines and Equity—The Response

Middle-Income Country Strategy 2015–2020

Goal	Enhance sustainable access to vaccines for populations in middle-income countries to meet GVAP targets			
Objective	Raise and sustain equitable immunization coverage and enable new vaccine introductions			
Focus areas	<p>① Strengthened decision making for timely and evidence-based immunization policy and programmatic choices</p>	<p>② Increased political commitment and financial sustainability of immunization programs</p>	<p>③ Enhanced demand for and equitable delivery of immunization services</p>	<p>④ Improved access to affordable and timely supply</p>
Strategic enablers	<p>Country commitment to and investment in immunization Coordination among international and local partners International and national advocacy & country-to-country peer learning Strong monitoring & evaluation efforts</p>			

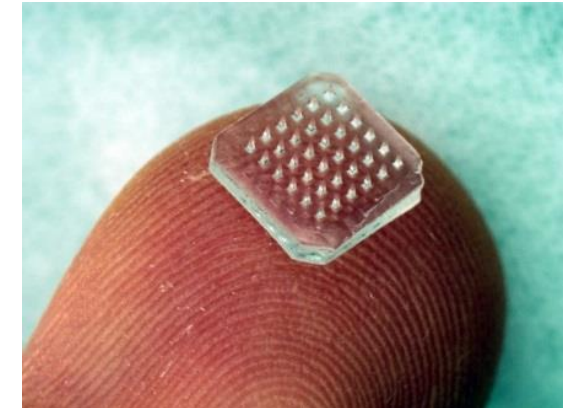
New Vaccines and Hesitancy—The Response

- **Efforts to address misperceptions and vaccine safety concerns**
 - Targeting and training health workers
 - Identifying key influencers
 - Preparing Web and social media information
 - Informing the public about decisions
- **Tailoring Immunization Programmes (TIP) tool**
 - Toolkit for responding to vaccine-hesitant populations



New Vaccine Products and Technologies Ensure Reach of Those Most in Need

- **Innovative vaccine products (thermostable, low multidose, monodose/prefilled, fractional dosing)**
- **Innovative packaging (reduced volume)**
- **Improved cold chain equipment**
- **Innovative delivery technologies (intradermal devices, cPADs, microarray patches, electroporation, integrated reconstitution devices)**



Microarray Patch

Improved Packaging and Presentation Reduces Stress on Supply Chains



Initial rotavirus vaccine
lyophilized, no VVMs
Full course: 330 cm³

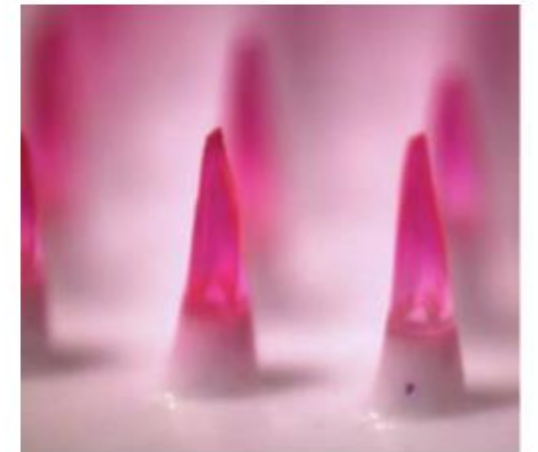
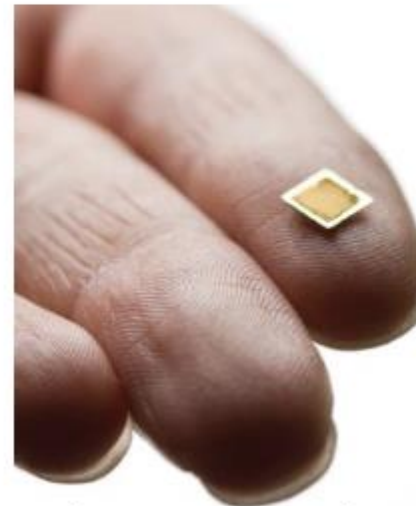
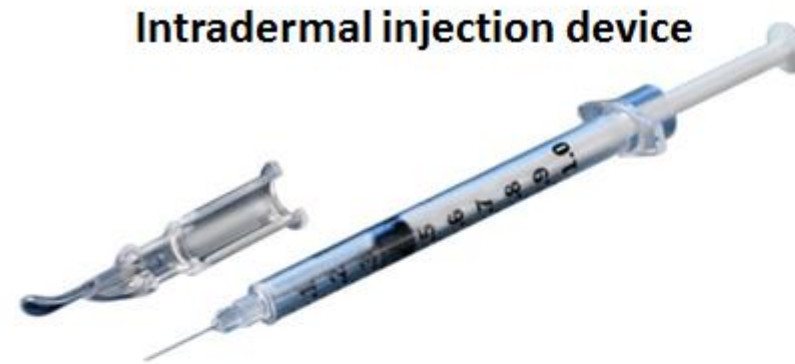


Second generation
rotavirus vaccine,
VVMs, liquid
Full course: 170.6 cm³



Latest rotavirus
vaccine, VVMs.
Full course: 34 cm^{3*}

New Vaccine Delivery Technologies



Compact pre-filled auto-disable injection device (cPAD)

Microarray vaccine patch

Microarray vaccine patch

Improving The Cold Chain



New Vaccines: Strengthening Routine Immunization

- Increased focus on immunization, more advocacy and visibility
- Opportunities for change in routine practices
- Enhanced training
- Improved vaccine management (e.g., demand forecast, supply and logistics, cold chain)
- Improved data quality, collection, recording and reporting
- Strengthened vaccine preventable disease surveillance
- Improved adverse events reporting and management



Scannable vaccine record

New vaccines: Delivering More to More Increasing Vaccine Access to More Populations Across The Life Course

➤ New vaccines and life-course approach in immunization programs

- Birth dose
- EPI infant services
- Second-year-of-life visit
- Pre-school vaccination

➤ Regular joint child health visits



New Vaccines: Delivering More To More

Deliver More New Vaccines In A More Integrated Way

➤ New vaccines delivered through non-immunization services and platforms

- Antenatal services and maternal immunization (influenza, tetanus)
- School-based delivery (HPV)
- Adolescent health programs (HPV)
- Services for the elderly (PCV, influenza)
- Disease-related services, e.g., diabetics and influenza



Reducing Missed Opportunities for Vaccination



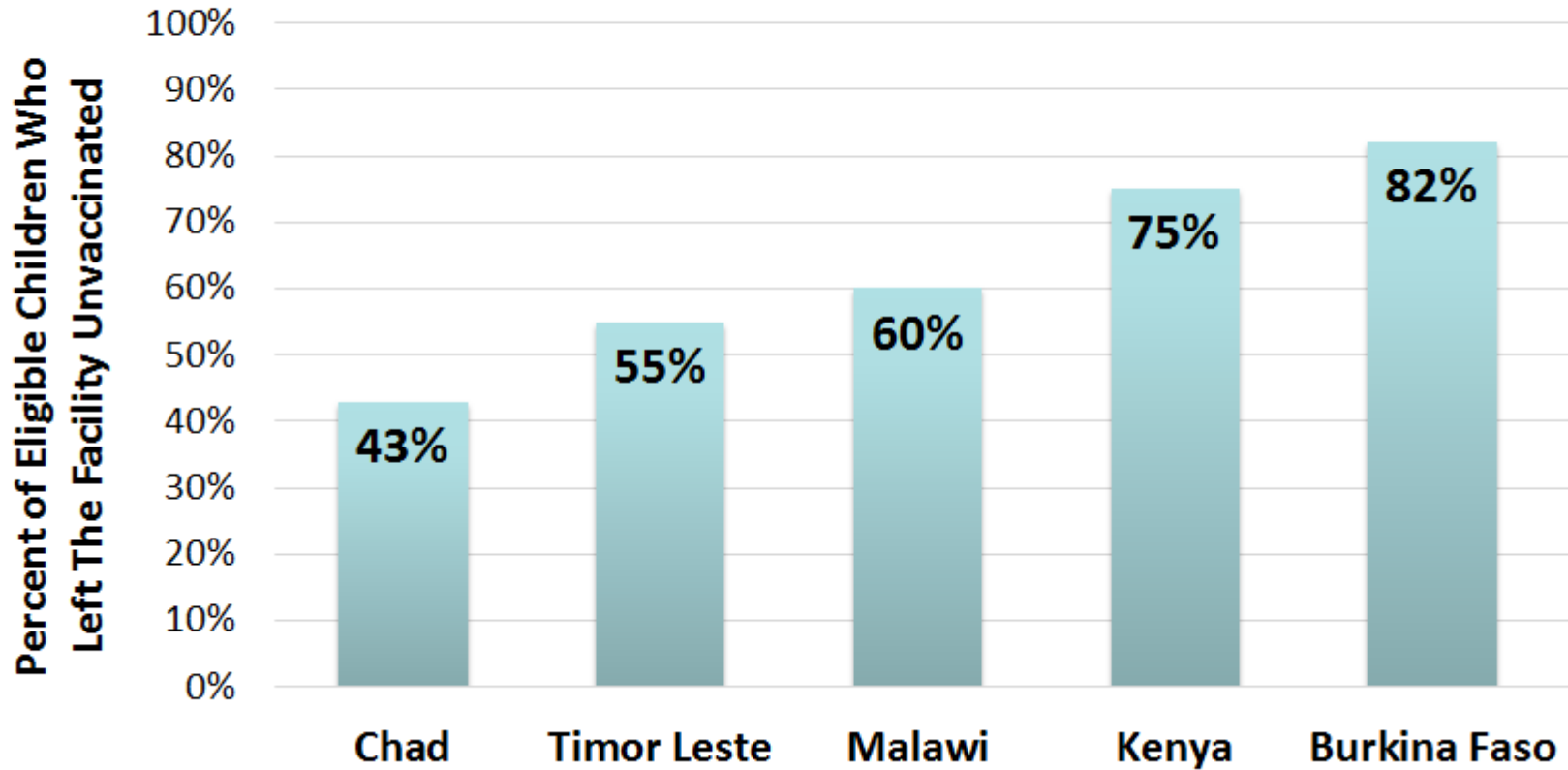
A missed opportunity to vaccinate is...

any visit to a health service by a child (or adult) who is **eligible** for vaccination, that **does not result in the person receiving** all the vaccine doses for which he or she is eligible



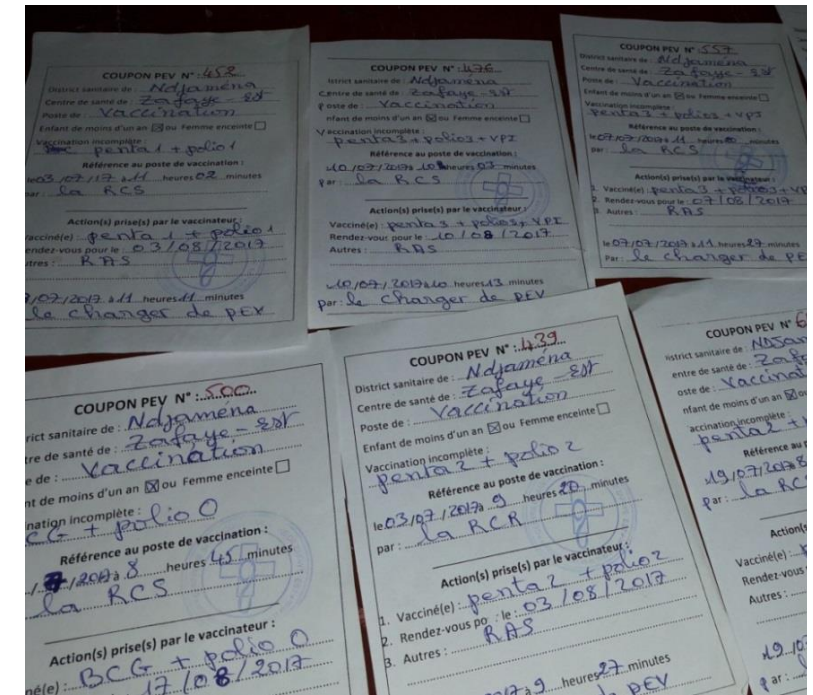
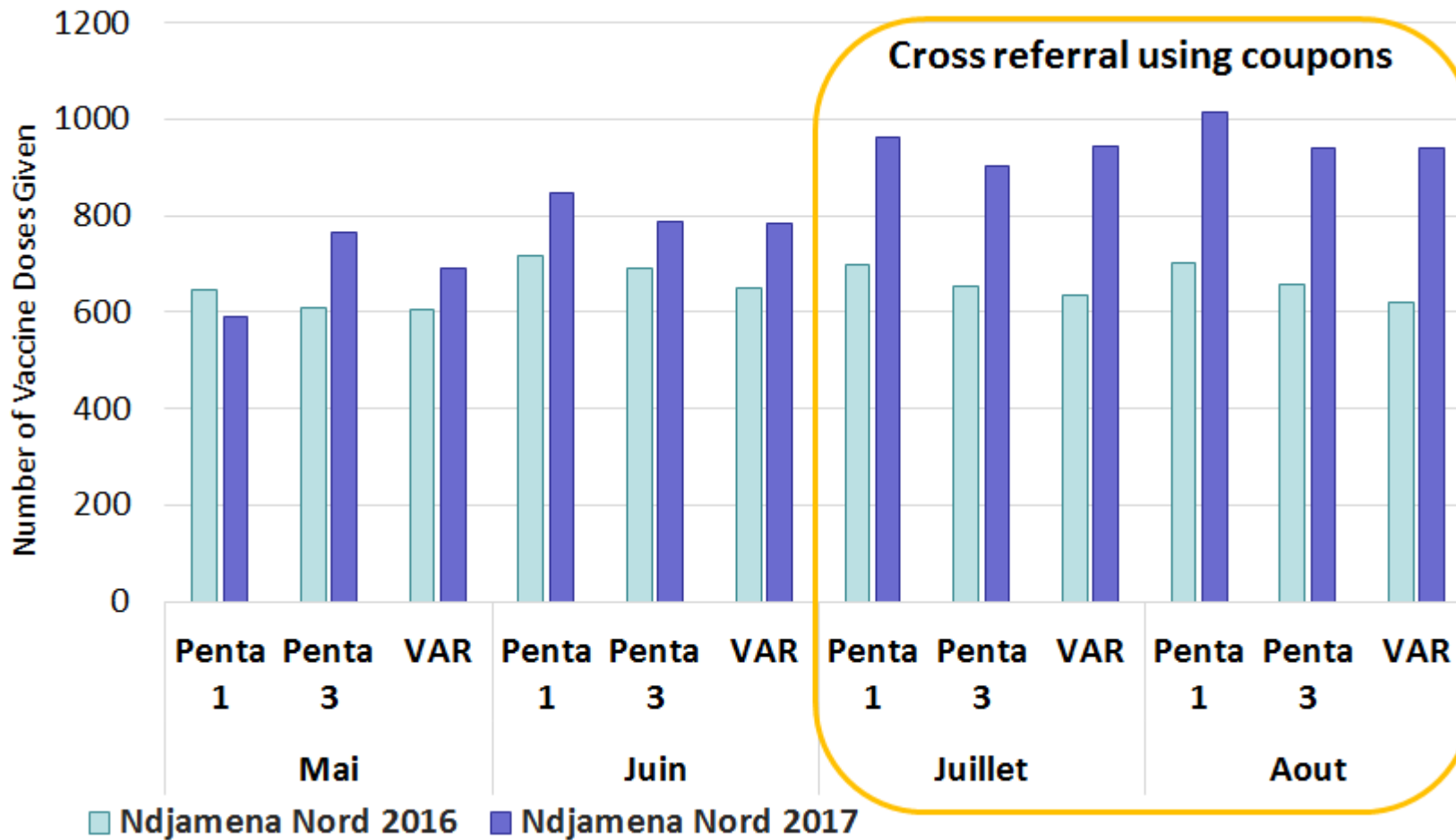
Many Eligible Children Leave Health Facility Without Being Vaccinated

Eligible Children Who Left a Health Facility Unvaccinated, By Country, 2016



In Chad, 15 Simple Strategies Reduced Missed Opportunities and Increased Vaccinations

Comparison of the Number of Vaccine Doses Given in Four Districts in Chad, May–August 2016, 2017



One strategy was simply issuing vaccination coupons to cross-refer children who visited for other reasons

New Vaccines Linked with Other Health Interventions Will Take Us Further

➤ Other interventions delivered together with (new) vaccines

- Deworming (albendazole)
- Vitamin A
- Long lasting impregnated nets
- Chemoprophylaxis
- Nutrition interventions
- Water, sanitation, and hygiene

➤ New collaborative approach to integration



Overburdened alone, or share the load together?



Financial and Economic Considerations

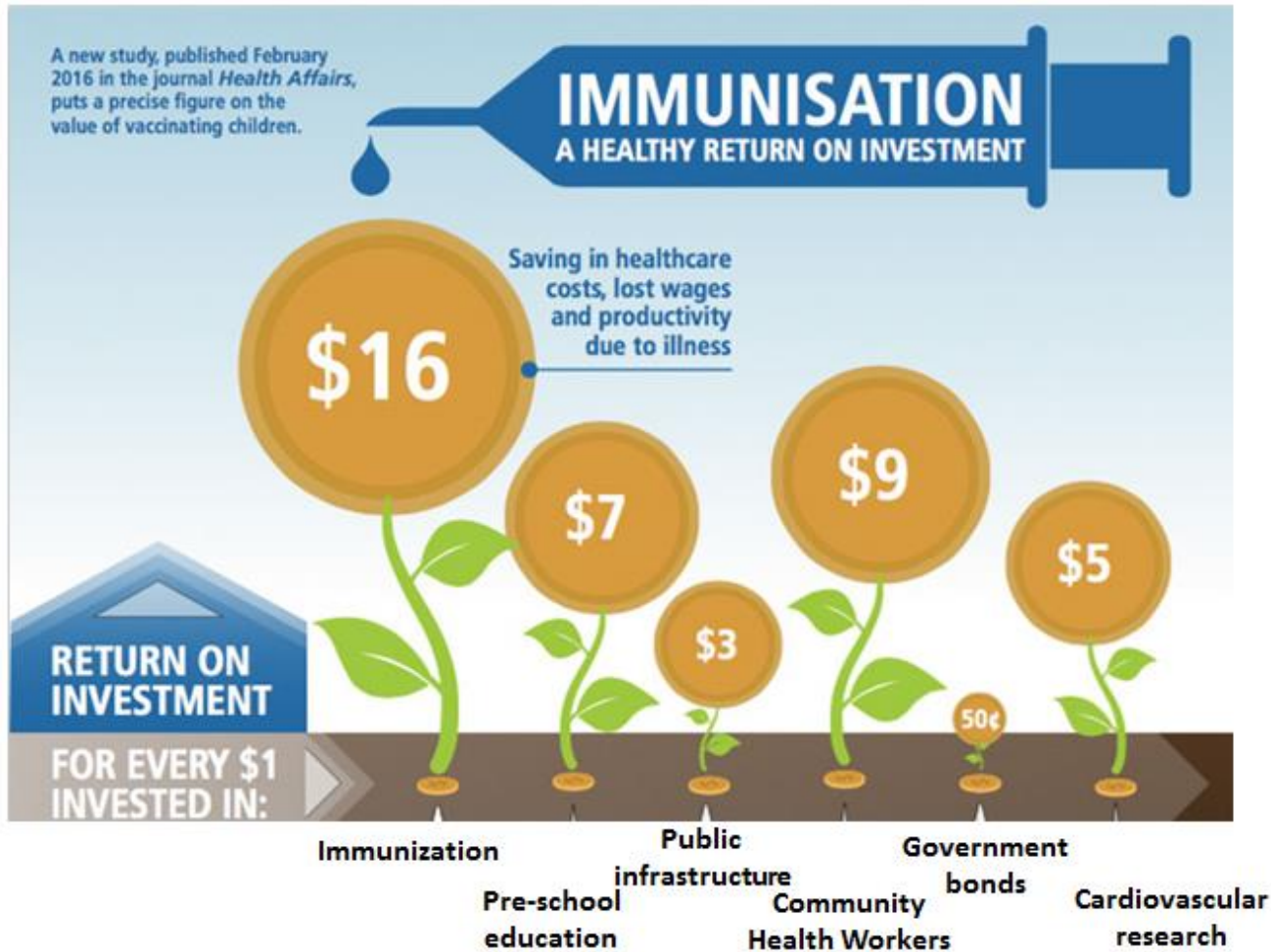


Craig Burgess, MD, MSc, MBA

Senior Technical Advisor

JSI Training and Research Institute Inc.

High Return on Investment and Economic Benefits

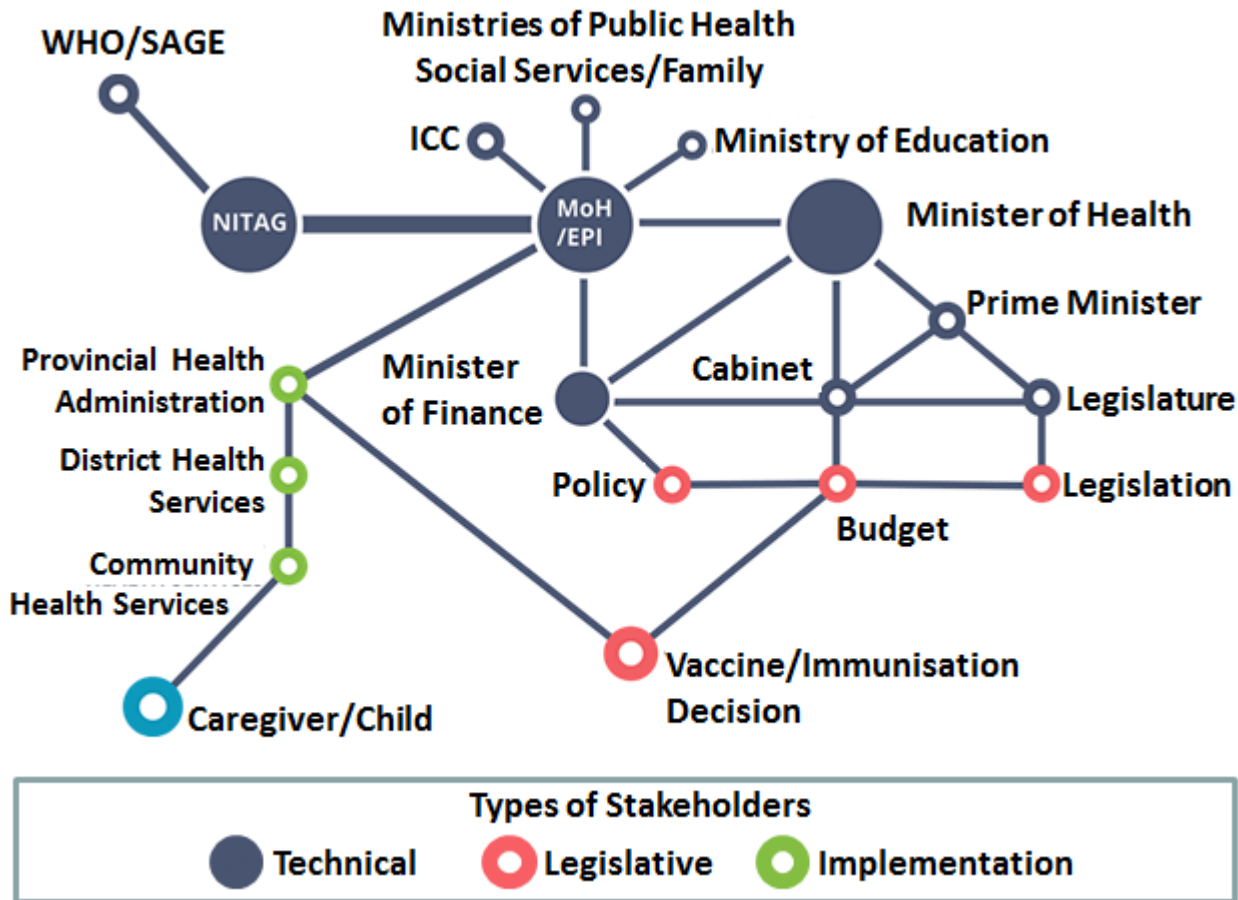


- **For every \$1 invested, immunizations pay back:**
 - \$16 from costs associated with illness and lost productivity
 - \$44 from costs associated with broader economic impact of illness
- **New vaccines against pneumonia (Hib, PCV) and diarrhea (rotavirus) are significant contributions to this investment**

Vaccines Are Cost-Effective and An Attractive Investment

- **Vaccines are cost-effective**
- **Most traditional and new vaccines cost less than:**
 - \$100 per disability-adjusted life year averted (DALY)
 - 3 times gross domestic product (GDP) per capita
- **Variability in cost effectiveness is due to context (e.g., disease burden in population, delivery mechanisms)**
- **Vaccines are an attractive investment for essential health packages**
 - Vaccines are often more cost-effective than other basic health interventions

New Vaccine Context: Understanding Complex Decision-Making



➤ Stakeholders

- Political, finance, civil society, and private
- NITAG, Interagency Coordinating Committee (ICC), Ministry of Health, Ministry of Finance

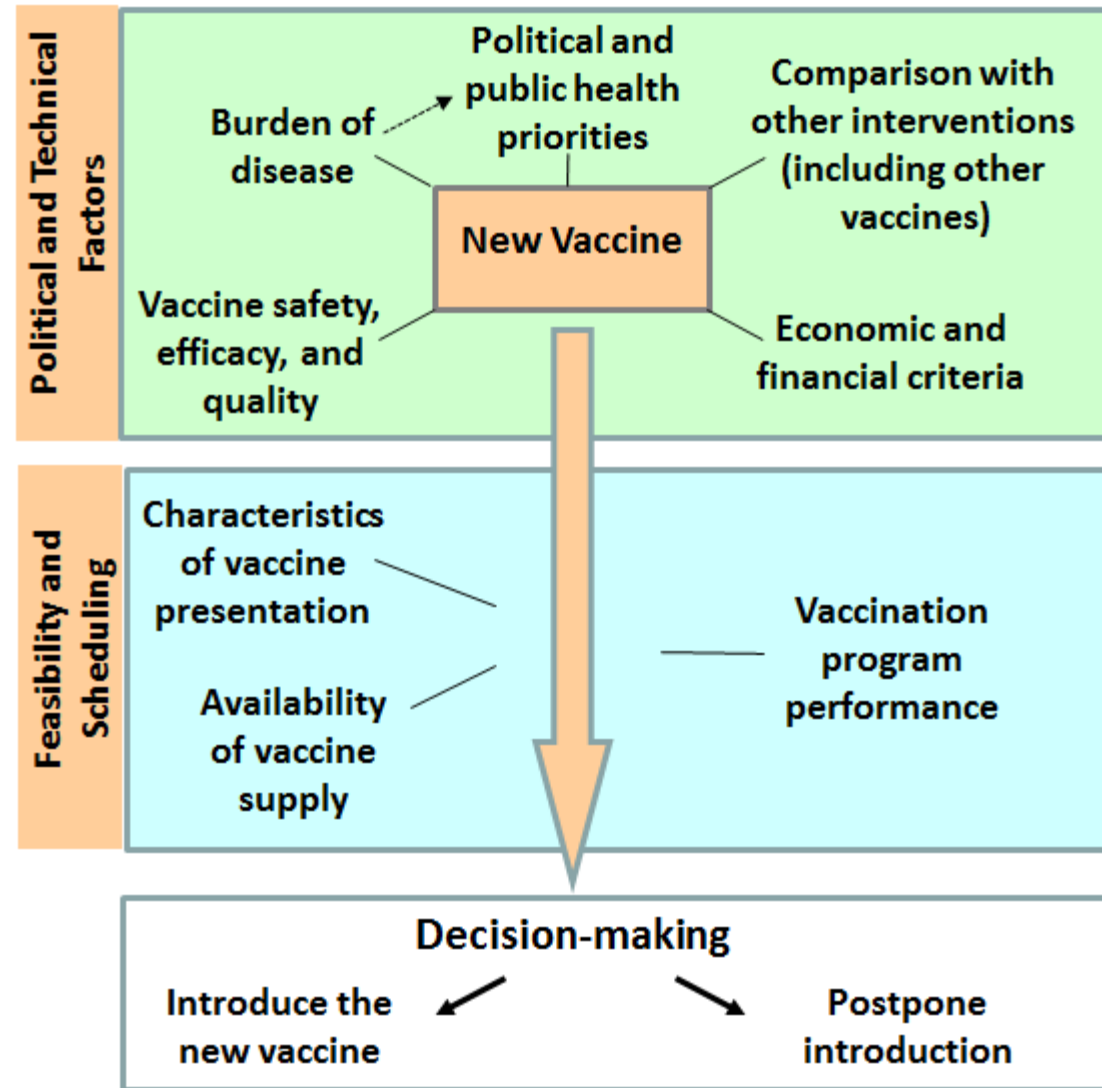
➤ Decentralized decision-making

- Decisions on budget and planning to districts

➤ Views on sustainability differ

- Economist and community views

New Vaccine Context of Decision-Making



New Vaccine Context of Integration Into System

- **New vaccines need to fit into:**
 - Essential health packages
 - Integrated delivery platforms
 - Planning and budgeting
- **Evidence needed for decisions**
 - Economics, disease burden, delivery, cold chain
- **Decision-making about how, where, and when**
- **Decisions need compromise and trade-offs**
- **Communicating results and opportunities**
 - Raises awareness and demand, and reduces hesitancy



Cost to Fully Immunize a Child Is Rising and New Vaccine Prices Are Major Contributor

- **Vaccine prices are main cost driver in immunization programs**
 - Price for all recommended vaccines increased by 68 times during 2001–2014
- **Most increases in cost are driven by the price of newer vaccines**

Year	Vaccine Prices	Vaccines
2001	\$0.67	6 initial antigens (OPV, DTP, measles, BCG)
2014	<p>\$32.09 fully immunized boy (11 antigens)</p> <p>\$45.59 fully immunized girl (11 antigens + HPV)</p>	<p>11 antigens in total</p> <p>6 initial antigens + Hepatitis B, PCV, rubella, rotavirus, IPV, and <i>Haemophilus influenzae</i> type b (Hib)</p>

New Vaccine Delivery

- **Increasing cost per child immunized, as coverage increases (e.g., harder to reach)**
- **Increasing use of campaigns to deliver in certain contexts**
- **Investing in delivery systems is crucial if vaccines are to:**
 - Reach those with greatest disease burden (equity)
 - Maximize cost-effectiveness
 - Protect investment in new vaccines



After Vaccines, The Main Cost Driver Is Systems Related

Estimated Systems Costs (Service Delivery and Supply Chain) from Decade of Vaccines Work, 2011–2020

Service Delivery

41% Human resources
15% Program management
4% Disease surveillance
2% Social mobilization,
communication and advocacy
2% Training and capacity building



Supply Chain and Logistics

23% Cold chain equipment
and overheads
9% Vehicles and transport
5% Human resources

New Vaccine Cost Considerations

- **Equity:** link to health sector, primary health care, Reaching Every District or Community plans
- **Multiple shared costs:** staff, transport, facilities
- **Effectiveness of delivery:** timeliness, safety, and strategy (outreach, fixed post, school-based, workplace, campaigns, child health days)
- **Community participation:** sustainability, acceptability and uptake
- **Tools, repository, and community of practice for costing and financing:** www.immunizationeconomics.org and www.immunizationfinancing.org

New Vaccine Budgeting

- **Realistic budgets—
a political process that
needs better evidence**
- **‘On’ budget or ‘off’ budget?**
- **What is affordable when:**
 - Expenditure on health is low?
 - There are competing priorities?
 - Delivery of routine vaccines is incomplete?

Country Classification	2014 Average Health Expenditure Per Capita (US\$)	Number of countries
Low income	\$37	31
Lower middle-income	\$92	54
Middle income	\$290	103

Transitioning from Gavi and Global Polio Eradication Initiative (GPEI) Support

- **Transition plans require dialogue with broad health systems planners**
- **Address country management of logistics and supply need**
- **Plan and budget for future new vaccines**
- **Focus on domestic resource mobilization**
- **Sustainability and capacity of institutions**



New Vaccine Financing – What to Ask Before Starting

- **Key questions for countries to ask**
- Is the financing really additional?
 - Is there a 'hidden' cost to new financing?
 - Is the funding predictable and sustainable?
 - How flexible is the financing?
 - Will funding flow equitably?



New Vaccine Financing – Finding the Funding

➤ **Domestic resources for funding**

- Tax (“sin”/earmark), risk pooling, user fees, national trust funds, loans, budget support, universal health care advocacy for health budget 5% GDP

➤ **Reducing costs of vaccines through pooled procurement for vaccines**

- Gavi, Vaccine Independence Initiative (VII), accessing UNICEF prices, and PAHO Revolving Fund

➤ **Increasing efficiency to lower spending**

- Decrease vaccine wastage and drop out, integration, increase social mobilization

Strengthening New Vaccine Introduction

- **National decision-making** requires increasing awareness and **use of evidence** (disease burden, economics, systems) and **understanding politics**
- **Translating global policy making to national action** requires context-specific approaches and an understanding of stakeholders
- New vaccine introduction has a role to play in **economic development as well as disease control** with very **positive return on investment**

New Vaccine Implementation: The Way Forward

- **Improve integration of service delivery at all levels**
 - Optimize vaccination schedules and broaden life-course approach
 - Reduce missed opportunities for vaccination
 - Use opportunities for 'collaborative' integration of immunization with other programs and sectors
- **Reduce inequity in immunization across and within countries**
 - Implement GVAP, Reaching Every District or Community (focus on hard to reach)
 - Strengthen country immunization delivery systems and reduce vaccine hesitancy
 - Improve presentation and packaging and new delivery technologies
- **Reinforce alignment between immunization, global health, and development agendas**
 - e.g., sustainable development goals and universal health coverage