

# GAVI Vaccine Investment Strategy

## *Executive Summary*



Applied Strategies  
400 S. El Camino Real, Suite 375  
San Mateo, CA 94402  
[www.appliedstrategies.com](http://www.appliedstrategies.com)

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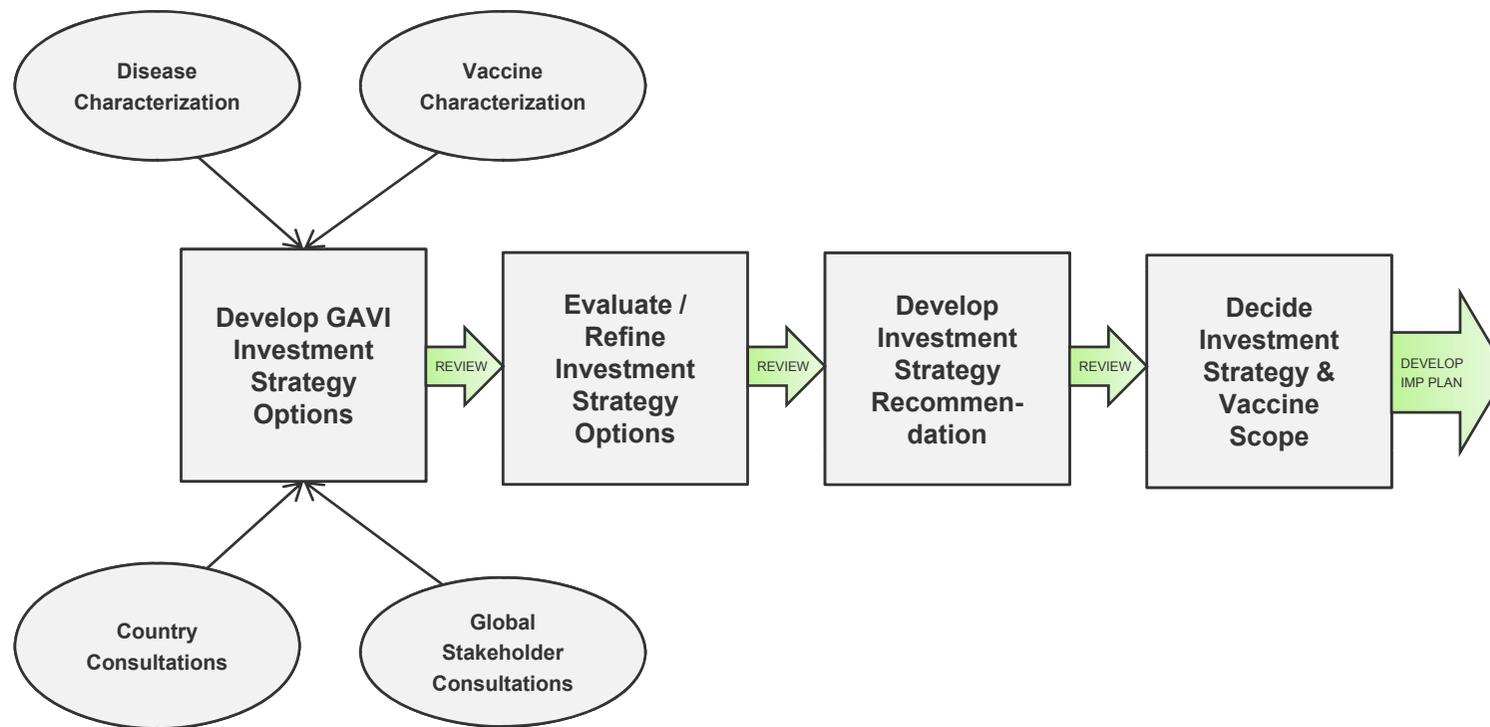
# VIS Executive Summary

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# Project Overview

## PHASE 1 PROCESS





# Project Overview

## PHASE 1 OUTCOMES

### GAVI Alliance Board:

- Endorsed the Reduce Overall Disease Burden portfolio theme and associated vaccines (Cholera, Japanese Encephalitis, Typhoid, Meningitis A, HPV, Rabies, Rubella) for the years 2009-2013
  - Investment in an individual vaccine will be decided on the basis of a costed implementation plan, to be developed in VIS Phase 2
- Agreed that the vaccine investment strategy should be subject to period review and reassessment on the basis of changing information
- Noted that the strategy should monitor the development of vaccines for malaria and dengue and consider accelerated development and pre-introduction activities for these vaccines

*The above decisions do not constitute financial approvals or commitment on behalf of the GAVI Alliance to fund or support any single vaccine.*



# Project Overview

## PHASE 2 PROJECT OBJECTIVES – DISEASE-SPECIFIC

### For Each Disease

- Define vaccination strategy options
- Designate options for full VIS evaluation
- Quantify the vaccine cost and health impact implications of each designated option
- Identify and characterize the country implementation-related costs associated with each designated option
- Determine the optimal financing strategy for GAVI



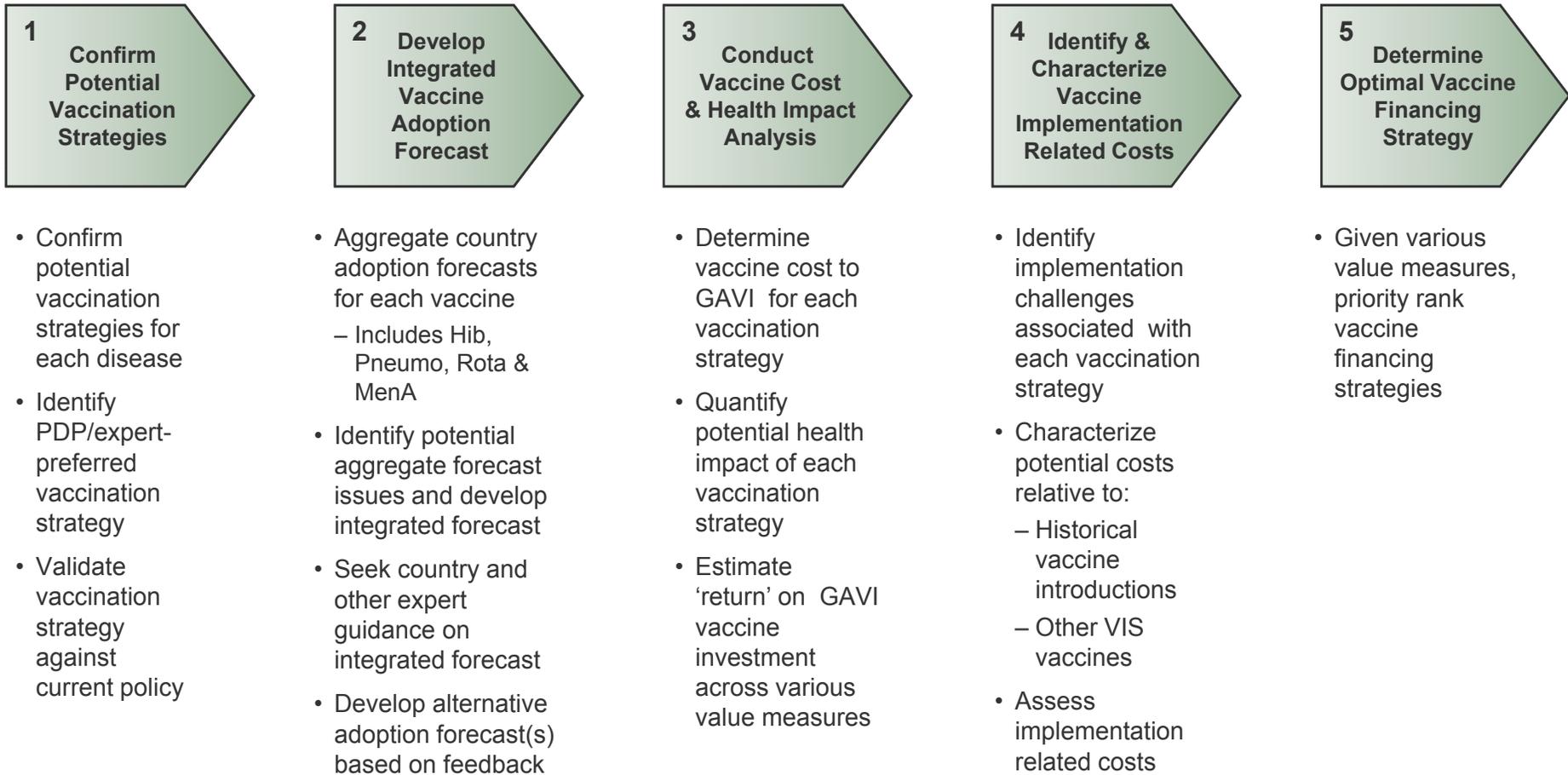
# Project Overview

## PHASE 2 PROJECT OBJECTIVES – PORTFOLIO-SPECIFIC

- Define vaccine portfolio options
- Quantify the vaccine cost and health impact implications of each portfolio option
- Identify and characterize the country implementation-related costs associated with each portfolio option
- Assess the GAVI partner-related costs associated with each portfolio option
- Provide comparative cost and value-measure analyses of the portfolio options to inform recommendation development

# Project Overview

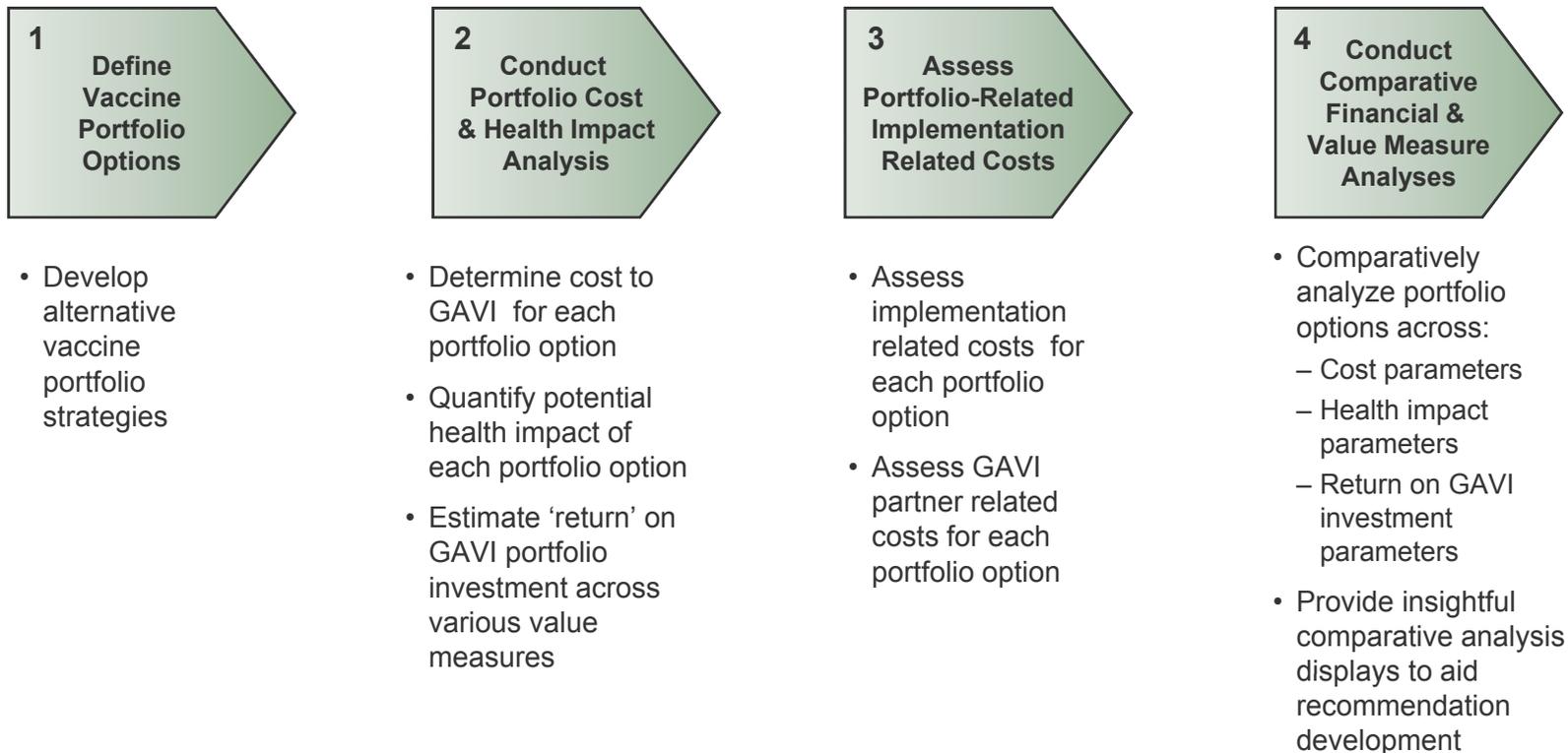
## PHASE 2 PROCESS STEPS – VACCINE-SPECIFIC



Seek WHO, CDC, Industry, PDP, PPP, and Other Expert Validation of Key Project Information and Analysis Assumptions

# Project Overview

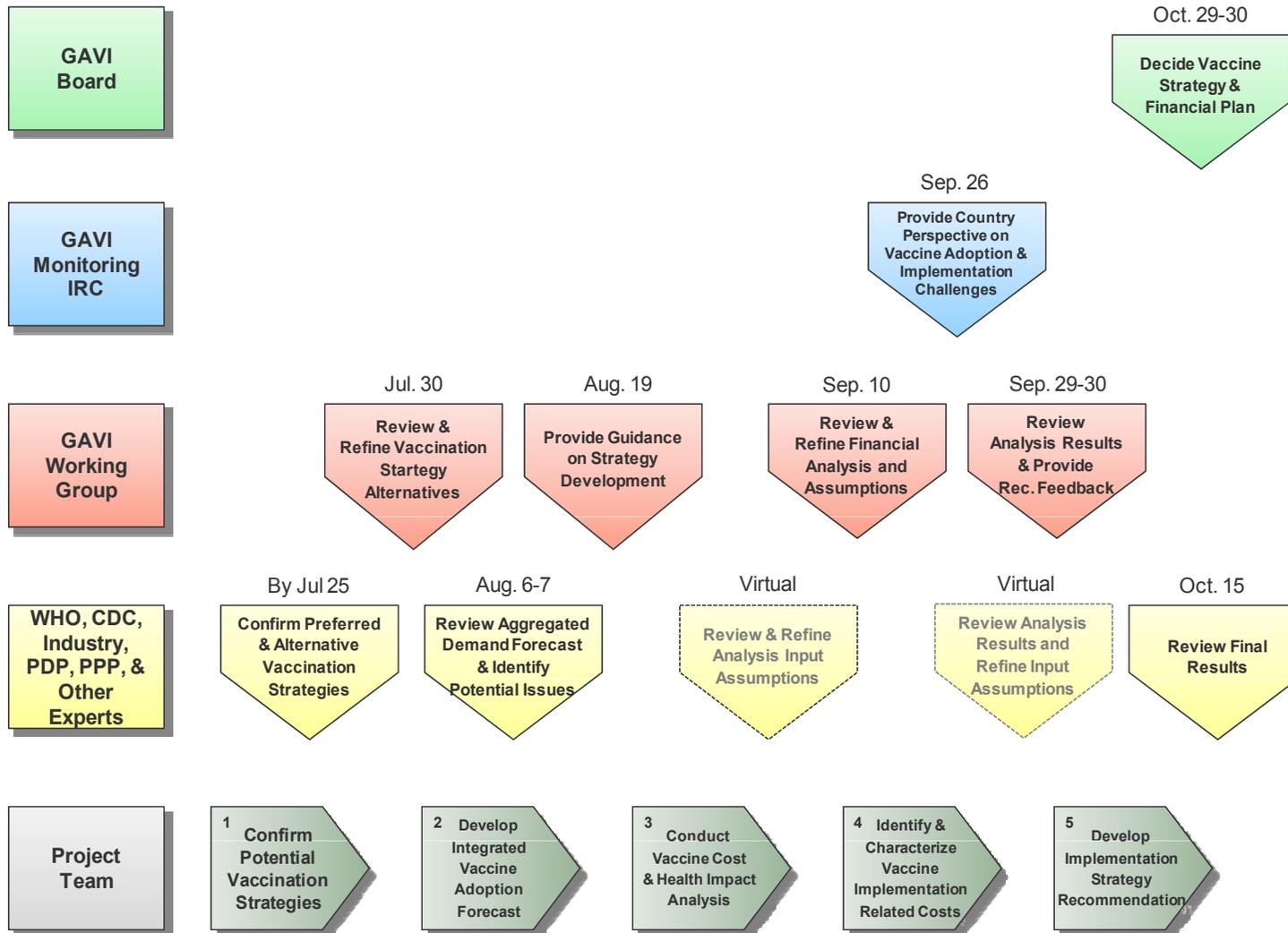
## PHASE 2 PROCESS STEPS – PORTFOLIO-SPECIFIC



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# Project Overview

## PHASE 2 PROCESS





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# Disease & Vaccine Landscape Analysis

## DISEASE CHARACTERIZATION

### Disease Overview

#### DISEASE PATHOGEN, TRANSMISSION & TARGET POPULATION<sup>1</sup>

- Disease Pathogen
  - Japanese Encephalitis (JE) virus is in the Flavivirus genus
- Transmission
  - Transmitted by Culex mosquitoes (*Cx. tritaeniorhynchus*)

### Disease Overview

#### DISEASE IMPACT<sup>1</sup>

- Total Morbidity
  - At least 50,000 cases of JE are reported annually (~12 million asymptomatic cases)
  - This is an underestimation of disease incidence since incidence rates during outbreaks can reach >100 cases per 100,000 population

### Disease Overview

#### NON-VACCINE PREVENTION & TREATMENT INTERVENTIONS<sup>2</sup>

- Non-Vaccine Prevention
  - Reduction in cultivation, use of pesticides and centralized pig production may help to prevent the spread of JE, but there is no proof to support these prevention efforts
- Treatment Interventions

### Disease Overview

#### INEQUITIES

- Inequity of Poor
  - Japanese Encephalitis mainly strikes poor rural communities in 14 poor countries of Southeast Asia and the Western Pacific

### Disease Overview

#### DISEASE BURDEN IN GAVI-ELIGIBLE COUNTRIES – MORBIDITY<sup>3-6</sup>

Country	WHO Region	Morbidity (Annual Cases)	Morbidity Rate (Cases/100,000)	Country	WHO Region	Morbidity (Annual Cases)	Morbidity Rate (Cases/100,000)
Bangladesh	SEARO	15,606	10	Guinea	AFRO		
Bhutan	SEARO	65	10	Guinea-Bissau	AFRO		
India	SEARO	115,492	10	Guyana	AMRO		
Indonesia	SEARO	23,015	10	Haiti	AMRO		
Korea, DPR	SEARO	2,404	10	Honduras	AMRO		
Myanmar	SEARO	4,884	10	Kenya	AFRO		
Nepal	SEARO	2,758	10	Kiribati	WPRO		
Sri Lanka	SEARO	1,947	10	Kyrgyzstan	EURO		
Timor-Leste	SEARO	102	10	Lesotho	AFRO		
Pakistan	EMRO	7,967	5	Liberia	AFRO		
Lao PDR	WPRO	198	4	Madagascar	AFRO		
Viet Nam	WPRO	2,379	4	Malawi	AFRO		
Cambodia	WPRO	489	4	Mali	AFRO		
Papua New Guinea	WPRO	213	4	Mauritania	AFRO		
Afghanistan	EMRO			Moldova, Rep. of	EURO		
Angola	AFRO			Mongolia	WPRO		
Armenia	EURO			Mozambique	AFRO		
Azerbaijan	EURO			Nicaragua	AMRO		
Benin	AFRO			Niger	AFRO		
Bolivia	AMRO			Nigeria	AFRO		
Burkina Faso	AFRO			Rwanda	AFRO		
Burundi	AFRO			São Tomé and Príncipe	AFRO		
Central African Republic	AFRO			Senegal	AFRO		
Chad	AFRO			Sierra Leone	AFRO		
Comoros	AFRO			Solomon Islands	WPRO		
Congo, Dem. Rep.	AFRO			Somalia	EMRO		
Congo, Rep.	AFRO			Sudan	EMRO		
Côte d'Ivoire	AFRO			Tajikistan	EURO		
Cuba	AMRO			Tanzania, United Rep. of	AFRO		
Djibouti	EMRO			Togo	AFRO		
Eritrea	AFRO			Uganda	AFRO		
Ethiopia	AFRO			Ukraine	EURO		
Gambia, The	AFRO			Uzbekistan	EURO		
Georgia	EURO			Yemen	EMRO		
Ghana	AFRO			Zambia	AFRO		
				Zimbabwe	AFRO		

### Disease Overview

#### DISEASE BURDEN IN GAVI-ELIGIBLE COUNTRIES – MORTALITY<sup>4-7</sup>

Country	WHO Region	Mortality (Annual Deaths)	Mortality Rate (Deaths/1,000,000)	Country	WHO Region	Mortality (Annual Deaths)	Mortality Rate (Deaths/1,000,000)
Bangladesh	SEARO	4,882	31	Guinea	AFRO		
Bhutan	SEARO	19	31	Guinea-Bissau	AFRO		
India	SEARO	34,648	31	Guyana	AMRO		
Indonesia	SEARO	6,905	31	Haiti	AMRO		
Korea, DPR	SEARO	721	31	Honduras	AMRO		
Myanmar	SEARO	1,465	31	Kenya	AFRO		
Nepal	SEARO	827	31	Kiribati	WPRO		
Sri Lanka	SEARO	584	31	Kyrgyzstan	EURO		
Timor-Leste	SEARO	33	31	Lesotho	AFRO		
Pakistan	EMRO	2,390	15	Liberia	AFRO		
Cambodia	WPRO	147	11	Madagascar	AFRO		
Lao PDR	WPRO	60	11	Malawi	AFRO		
Papua New Guinea	WPRO	64	11	Mali	AFRO		
Viet Nam	WPRO	894	11	Mauritania	AFRO		
Afghanistan	EMRO			Moldova, Rep. of	EURO		
Angola	AFRO			Mongolia	WPRO		
Armenia	EURO			Mozambique	AFRO		
Azerbaijan	EURO			Nicaragua	AMRO		
Benin	AFRO			Niger	AFRO		
Bolivia	AMRO			Nigeria	AFRO		
Burkina Faso	AFRO			Rwanda	AFRO		
Burundi	AFRO			São Tomé and Príncipe	AFRO		
Cameroun	AFRO			Senegal	AFRO		
Central African Republic	AFRO			Sierra Leone	AFRO		
Chad	AFRO			Solomon Islands	WPRO		
Comoros	AFRO			Somalia	EMRO		
Congo, Dem. Rep.	AFRO			Sudan	EMRO		
Congo, Rep.	AFRO			Tajikistan	EURO		
Côte d'Ivoire	AFRO			Tanzania, United Rep. of	AFRO		
Cuba	AMRO			Togo	AFRO		
Djibouti	EMRO			Uganda	AFRO		
Eritrea	AFRO			Ukraine	EURO		
Ethiopia	AFRO			Uzbekistan	EURO		
Gambia, The	AFRO			Yemen	EMRO		
Georgia	EURO			Zambia	AFRO		
Ghana	AFRO			Zimbabwe	AFRO		

\* WHO, expert, PDP, PPP reviewed

# Disease & Vaccine Landscape Analysis

## DISEASE IMPLICATION SUMMARY\*

Category		Cholera	HPV	JE	Rabies	Rubella	Typhoid
Vulnerable Populations		<10yo & elderly most vulnerable	Pre-sexually active females	<15yo	5 – 15yo most vulnerable	WCBA for Congenital Rubella Syndrome	2-15yo must vulnerable
Inequity of Poor		Yes	Yes	Yes	Yes	Yes	Yes
Gender Inequity	Do genders suffer differently?	No	Yes	No	No	No	No
	Prevalence greater in one gender?	No	Yes (♀)	No	Yes (♂)	Yes (♀)	No
	Adverse affects in pregnant women?	Yes	No	No	No	Yes	No
Long-Term Sequelae	Severe	-	✓	✓	-	✓ (CRS)	-
	Moderate	-	-	-	-	-	-
	Mild-None	✓	-	-	✓	-	✓

\*♀<sub>Pg</sub> = Pregnant Women; ♂ = males; WCBA = women of childbearing age; Severe Long-Term Sequelae = > 5% of cases result in neurological complications (e.g., meningitis); Moderate Long-Term Sequelae = less impact but long-term (> 1yr) (e.g. deafness); Mild Long-Term Sequelae = rare severe cases or mild long-term effects (e.g., decrease in fertility)

# Disease & Vaccine Landscape Analysis

## VACCINE CHARACTERIZATION

**Vaccine Landscape**  
**LICENSED VACCINES**

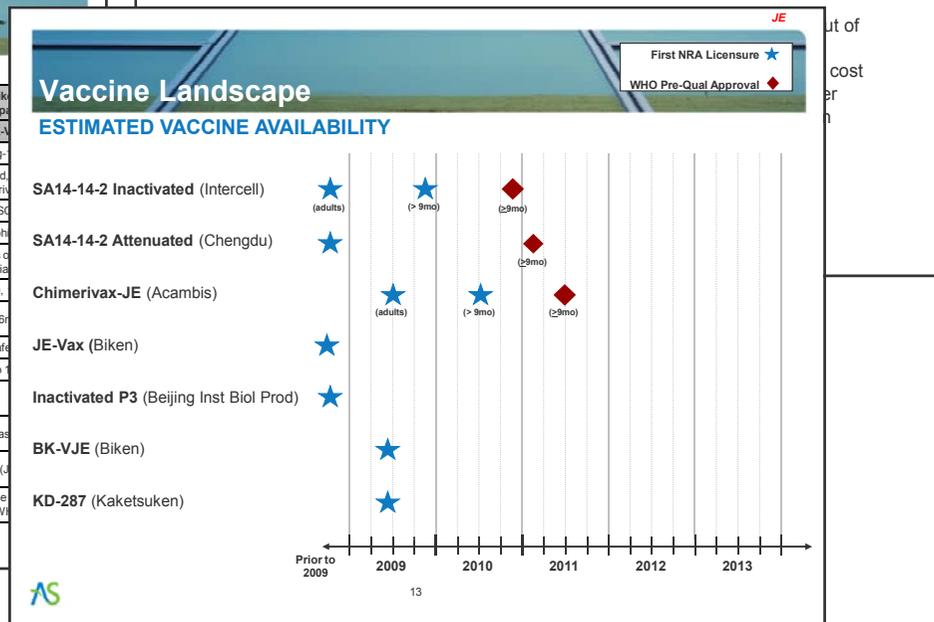
Supplier (1 Partner)	Chengdu (Wuhan, Lanzhour, Shanghai Inst for Biol Products) <sup>9</sup>	Biken (GreenCross, NIPM, GPO, NIHE) <sup>10</sup>	Beijing, Inst of Biol
Vaccine	SA14-14-2 Attenuated	JE-Vax	Inactivated
Strain / Antigen	SA 14-14-2 strain	Beijing strain	P3 Str
Adjuvant / Platform	Live, attenuated, primary hamster kidney cell culture derived	Inactivated, mouse brain-derived	Inactivated, prim kidney cell cult
Administration Route	SQ	SQ	SQ
Formulation	Lyophilized	Lyophilized	Liqui
Presentation	1 & 5-dose vials	1 dose vial	2, 5, 10-dos
	1 dose at 9mo; boost 1 yr later	2 doses at 1-3 yrs (0, 1mo); boost after 1yr	2 doses at 12 m; at 2, 4, 12 m

**Vaccine Landscape Analysis**  
**COST EFFECTIVENESS LITERATURE SUMMARY (IV)**

- Analysis of JE in Cambodia showed JE to cause 7,339 DALYs over 10 years, costing \$28 (Range: \$0-\$347) (out of pocket only) per case treated. The cost-effectiveness of SA 14-14-2 vaccine in a 2009 population cohort (1-10 yo and 9-mo) over 10 years, demonstrated that the total cost per case treated was \$1,660, and loss of earning related to long-term sequelae was \$154,935-169,878. Vaccination prevented 3,099 cases and 403 deaths, saved \$92,752 in out of pocket medical expenses, \$42 per DALY averted, and \$5,093 per death averted.<sup>17</sup>

**Vaccine Landscape**  
**VACCINES IN CLINICAL DEVELOPMENT**

Supplier (1 Partner)	Intercell AG (Biological E, WRAIR) <sup>11</sup>	Acambis (Sanofi-Pasteur) <sup>12</sup>	Kaketsuken (Japan) <sup>9</sup>	Bik (Japa)
Vaccine	SA14-14-2 Inactivated	Chimerivax-JE	KD-287	BK-V
Strain / Antigen	SA14-14-2 strain	SA14-14-2 strain	Beijing-1 strain	Beijing-
Adjuvant / Platform	Inactivated, Vero cell-derived	Live, attenuated, chimeric Vero cell-derived-YF	Inactivated, Vero cell-derived	Inactivated, deni
Administration Route	IM	SQ	SQ	SQ
Formulation	Liquid	Lyophilized	Lyophilized	Lyoph
Presentation	multi-dose vials; pre-filled syringe	multi-dose vials	1 dose vials or multi-dose vials	1 dose vials o via
Dosing Schedule	2 doses (0, 1mo or 1yr)	1 dose	3 doses (0, 1, 6-24mo)	3 doses (0,
Target Population for Licensure	≥ 9mo	≥ 9mo	≥ 6mo	≥ 6r
Safety	No major safety concerns	No major safety concerns	No major safety concerns	No major safe
Efficacy	Comparable Immunogenicity	Comparable Immunogenicity	up to 100%	up to 1
Expected Duration of Protection				
Stage of Development	Ph 3 (adults); Ph 2 (1-3 yo)	Ph 3 (adults); Ph 2 (age <15)	Phase 3	Phas
Estimated Licensure Date	4Q08 (adults) 4Q09 (> 9mo)	2009 (adults) 2010 (≥ 9mo)	2009 (Japan)	2009 (J
Estimated WHO Prequalification Date	4Q10	2011	Assume will not seek WHO PQ	Assume seek W

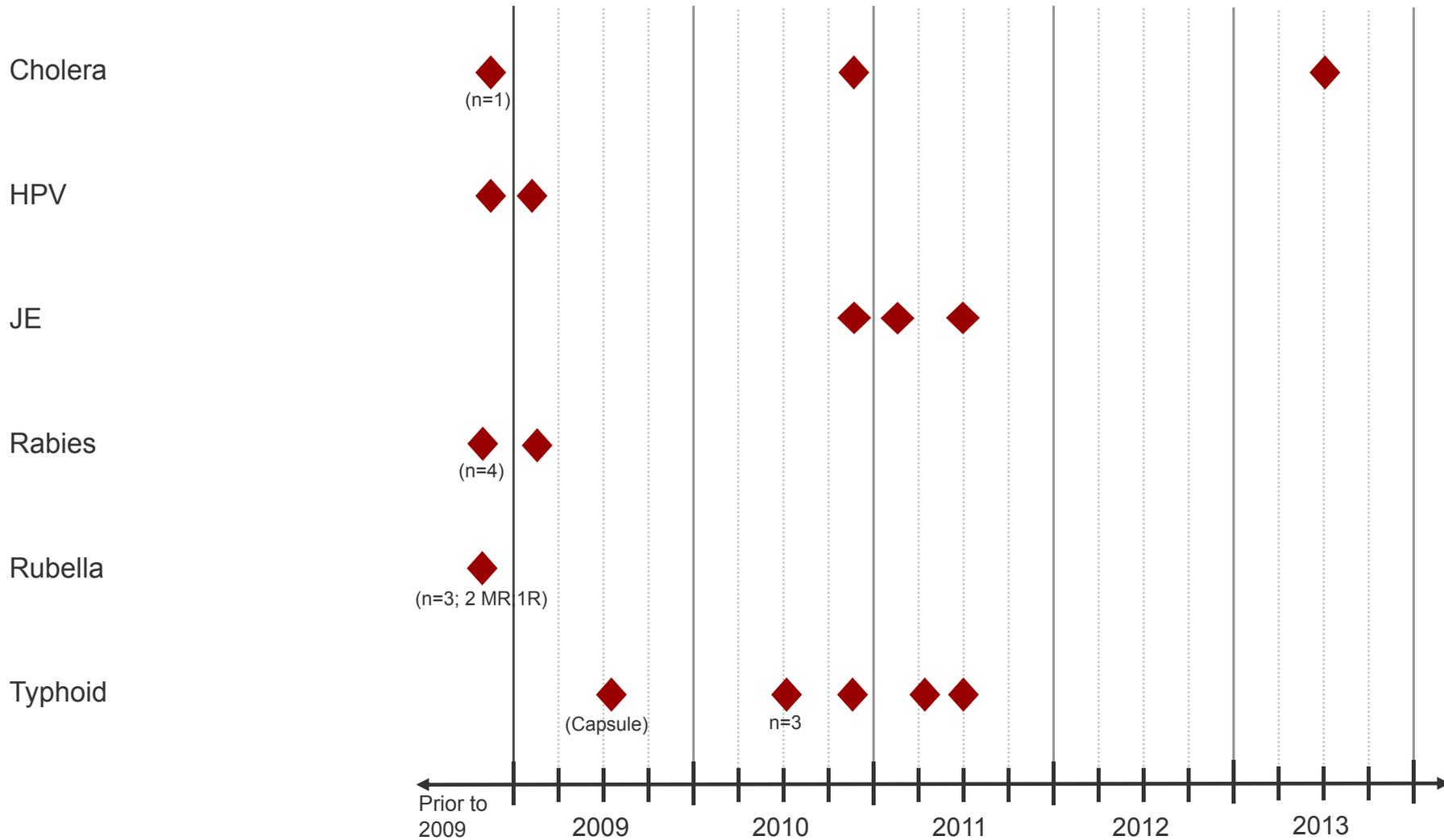


\* Supplier, expert, PDP, PPP reviewed

# Disease & Vaccine Landscape Analysis

WHO Pre-Qual Approval 

## VACCINE AVAILABILITY



\* WHO, supplier, expert, PDP reviewed

# Disease & Vaccine Analysis

## VACCINE IMPLICATION SUMMARY \*

Category	Cholera	HPV	JE	Rabies	Rubella	Typhoid
Impacts MDG4	√	-	√	-	-	-
Impacts MDG5	√	√	-	-	√	-
Integrates into EPI	-	-	√	-	√	√
Integrates into IMCI	√	-	√	-	√	√
Integrates into IMAI	-	√	√	-	-	√
Integrates into Other Existing Health Programs	Maternal Health Programs	Maternal Health Programs	-	-	Maternal Health Programs	-

\*IMCI = Integrated Management of Childhood Illness (WHO)

IMAI = Integrated Management of Adolescent and Adult Illness (WHO)



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# Vaccine Policy and Strategies

## POLICY SUMMARY\*

### Current Vaccination Policy

Disease:

Policy Type Source	Category	Policy Statement
Summary Report of an Expert Meeting & Recommendations of WHO • J Health (2007)	Usage Strategies	Use of oral cholera vaccines (OCV) in crisis situations - Can be used where high-level commitment by all stakeholders and national authorities has been secured - The current WHO prequalified vaccine is not recommended once an outbreak has occurred Use of OCV in endemic settings

### Current Vaccination Policy

Disease:

Policy Type Source	Category	Policy Statement
WHO Technical Information • HPV vaccines: Technical information • Oral Cholera in Context: What Next Meeting, Cairo, Egypt, 31, 2005 • State of vaccines development	Usage strategies	If a two-dose schedule could be used, or if HPV vaccines could be given at an earlier age with other vaccines (e.g. at school entry or even in infancy), vaccine delivery could be greatly facilitated.

### Current Vaccination Policy

Disease:

Policy Type Source	Category	Policy Statement
WHO Position Paper • Weekly Epi. Record, No. 34/95, 2006, 81: 331-340	Vaccine considerations	• Ideally, the mouse brain-derived vaccine should be gradually replaced by new generation JE vaccines.
	Usage strategies	• The most effective immunization strategy in JE-endemic settings is a one-time catch-up campaign, followed by incorporation of the JE vaccine into the routine immunization program. This approach had a greater public health impact than either strategy separately.
SAGE Recommendation • Weekly Epi. Record, No. 21, 2006, 81: 209-220	Programmatic recommendations	• JE immunization should be integrated into the EPI programs in all areas where JE constitutes a public health problem.
	Usage strategies	• SAGE acknowledged that immunization is the most appropriate and cost-effective means of controlling JE. • SAGE recommended that JE immunization strategies be guided by evidence of the burden of disease, the impact and safety of immunization and the ability to integrate JE vaccination into the EPI program.
SAGE Recommendation • Weekly Epi. Record, No. 21, 2006, 81: 209-220	Programmatic recommendations	• As the JE vaccine is currently not pre-qualified for procurement, SAGE recommended that countries introducing JE vaccine assure licensure and monitoring of the product against international standards.
	Usage strategies	• Interference with the immune response to other vaccinations, the number of doses required and the duration of protection need to be assessed. Efforts to continue measuring incidence of acute encephalitis syndrome and to confirm diagnoses need to be sustained.

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### Current Vaccination Policy

Disease:

Policy Type Source	Category	Policy Statement
WHO Position Paper	Vaccine considerations	• Human RIG (HRIG) is preferred but purified equine RIG or F(ab) <sub>2</sub> products should be used where HRIG is not available or affordable. • It is imperative that production and use of nerve tissue-based vaccines (NTVs) be discontinued as

### Current Vaccination Policy

Disease:

Policy Type Source	Category	Policy Statement
WHO Position Paper	Vaccine considerations	• The RA 27/3 based rubella vaccine should be used in all countries where control or elimination of congenital rubella syndrome (CRS) is considered a public health priority.

### Current Vaccination Policy

Disease:

Policy Type Source	Category	Policy Statement
WHO Position Paper • Weekly Epi. Record, No. 6, 2008, 83: 49-60	Vaccine considerations	• Two typhoid vaccines, parenteral Vi polysaccharide and live, oral Ty21a, should now replace the old and relatively reactogenic heat-phenol or acetone inactivated whole-cell vaccine. • Although the Vi and the Ty21a vaccines provide appreciable levels of protection and have a good record of safety, improved vaccines against typhoid fever are desirable. Such vaccines should confer higher levels and more durable protective immunity in all age groups, including those aged <2 years, preferably without the need for booster doses.
	Target population	• Immunization of school-age and/or preschool-age children is recommended in areas where typhoid fever in these age groups is shown to be a significant public health problem, particularly where antibiotic-resistant <i>S. Typhi</i> is prevalent.
	Usage strategies	• Countries should consider the programmatic use of typhoid vaccines for controlling endemic disease. In most countries, this will require only vaccination of high-risk groups and populations. • Given the epidemic potential of typhoid fever and observations on the effectiveness of vaccination in interrupting outbreaks, vaccination is also recommended for outbreak control. • The selection of delivery strategy (school or community-based vaccination) depends on factors such as the age-specific incidence of disease, subgroups at particular risk and school enrollment rates, and should be decided by the concerned countries.
	Programmatic recommendations	• Priority should be given to strengthening surveillance systems. • All typhoid fever vaccination programs should be implemented in the context of other efforts to control the disease, including health education, water quality and sanitation improvements, and training of health professionals in diagnosis and treatment.
SAGE Recommendation • Weekly Epi. Record, No. 1, 2006, 83: 1-16	Usage strategies	• Countries should decide on the selection of populations and age groups to target, and on the delivery strategy, which will depend on the local context. • Countries should select typhoid vaccines depending on the capacity of the local Expanded Program on Immunization and other logistic and cultural factors and should utilize opportunities coupled with other public health interventions in specified age groups.

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\* WHO reviewed

# Vaccine Policy and Strategies

## VACCINATION STRATEGIES

### Decision Framework Status

#### CHOLERA

GAVI VIS Decision Framework      Vaccination Strategies for Financial Planning Purposes

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### Decision Framework Status

#### JE

GAVI VIS Decision Framework      Vaccination Strategies for Financial Planning Purposes

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### Decision Framework Status

#### RABIES

GAVI VIS Rabies Decision Framework      Support Strategies for Financial Planning Purposes

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    graph LR
      A[Offer Vaccine Financing to GAVI-Eligible Countries] --> B[PEP Only]
      A --> C[Provide Alternative Investment Support]
      A --> D[Don't Support in 2009 - 2013]
      B --> B1[Develop & implement pilot programs in 2-3 countries]
      B --> B2[Monitor & evaluate impact and develop recommendations]
      C --> C1[Pilot Regional Bite Center & District Hospital Studies to Demonstrate Impact of GAVI Support]
      C --> C2[Pilot Rabies Education Programs to Demonstrate Reduced Disease Burden Impact]
      C --> C3[Fund RIG Capacity Building in GAVI Countries To Eliminate Shortages and Reduce Treatment Costs]
      C1 --> C1a[Develop educational programs aligned with national rabies prevention control strategies]
      C1 --> C1b[Implement pilot programs in 2-3 countries]
      C1 --> C1c[Monitor & evaluate impact and develop recommendations]
      C2 --> C2a[Accelerate tech transfer of RIG to emerging suppliers]
      C2 --> C2b[Motivate supplier capacity development]
      C3 --> C3a[Accelerate tech transfer of RIG to emerging suppliers]
      C3 --> C3b[Motivate supplier capacity development]
  
```

★ Phase 2 Analysis scope

### Decision Framework Status

#### HPV

GAVI VIS Decision Framework      Vaccination Strategies for Financial Planning Purposes

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### Decision Framework Status

#### RUBELLA

GAVI VIS Decision Framework      Vaccination Strategies for Financial Planning Purposes

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### Decision Framework Status

#### TYPHOID

GAVI VIS Decision Framework      Vaccination Strategies for Financial Planning Purposes

Vaccine*	Doses	Cohort	DOP
IM Vi PS IM Vi-DT	1 1+B	2 - 15yo	3yrs
		2 - 15yo	≥5yrs
Oral Ty21a IM Vi PS IM Vi-DT	3 1 1+B	5 - 15yo	7yrs
		5 - 15yo	3yrs
IM Vi-DT	★	2 - 15yo	≥5yrs
IM Vi-DT	2	Infants	NA

★ Phase 2 Analysis scope

\*Ty21a - Vivotif  
PS - polysaccharide  
Vi-DT - conjugate

\* WHO, CDC, PDP and other expert reviewed

# Vaccine Policy and Strategies

## VACCINATION STRATEGY SUMMARY

Vaccine	Vaccination Strategy Components			
	Routine	Catch up campaign	Periodic campaign	Other
Cholera			1-15yo or 1-49yo every 3 years	2M dose annual stockpile
HPV	10yo females			
JE	EPI with boost after 12mo	1 – 15yo		
Rabies				Post-exposure vaccination with immunoglobulins
Rubella	1 yo with MR	± 1 – 19yo	2 <sup>nd</sup> dose every 4 years	20 – 29 yo females or 15-39yo females (child bearing age)
Typhoid	EPI with Boost after 12mo	± 1 – 15yo	2 – 15yo or 5 – 15yo every 3 years	



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# Vaccine Need, Adoption, & Demand Forecasts

## DEFINITIONS

- Vaccine Need
  - Identifies the GAVI-eligible countries that suffer from a specific disease, either because of high mortality or high morbidity
- Vaccine Adoption Forecast
  - Identifies which countries are likely to adopt which vaccines and when
- Vaccine Demand Forecast
  - Determines how many treatments and doses are required given a country adoption forecast



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# Vaccine Need

## VACCINE NEED BY DISEASE

### Country Vaccine Need

Disease: **CHOLERA** Vaccine Need: 32  
VISP Scope: 31

- Assumed to be endemic<sup>1</sup> if the estimated country morbidity is  $\geq 25,000$  or morbidity rate is  $\geq 100$  cases/100,000 annually (International Vaccine Institute, Jul08)

### Country Vaccine Need

Disease: **Japanese Encephalitis (JE)** Vaccine Need: 14  
VISP Scope: 13

- JE is the most important form of viral encephalitis in Asia (WHO position paper, Aug06); Pakistan has also been included based on evidence of JE (PATH JE Team)

### Country Vaccine Need

Disease: **RUBELLA** Vaccine Need: 72  
VISP Scope: 46

- Rubella occurs worldwide with the greatest burden of congenital rubella syndrome (CRS) occurring in developing countries (WHO position paper, May00)

Category (# out of 72)	GAVI-Eligible Country Vaccine Need							
	AFRO (36 of 36)			AMRO (6 of 6)	EMRO (6 of 6)	EURO (8 of 8)	SEARO (9 of 9)	WPRO (7 of 7)
Least Poor (2 of 12)	Cameroon			Bolivia Guyana Honduras	Djibouti	Armenia Azerbaijan Georgia Ukraine	Indonesia Sri Lanka	Kiribati
Intermediate (4 of 16)	Ghana Kenya	Nigeria Zimbabwe	Cuba Nicaragua	Pakistan	Kyrgyzstan Moldova Tajikistan Uzbekistan	India Korea DPR	Mongolia PNG Viet Nam	
Poorest (18 of 31)	Benin Burkina Faso Chad Comoros Ethiopia Gambia Guinea Guinea-Bissau	Lesotho Madagascar Malawi Mali Mauritania Mozambique Niger Rwanda	Sao Tome & Principe Senegal Sierra Leone Tanzania Togo Uganda Zambia	Yemen		Bangladesh Bhutan Myanmar Nepal	Cambodia Lao Solomon Islands	
Fragile (7 of 13)	Angola Burundi CAR	Congo DR Congo Côte d'Ivoire	Eritrea Liberia	Haiti	Afghanistan Somalia Sudan	Timor-Leste		

BLUE: Countries with rubella vaccine program in place (n=14)  
ORANGE: countries not eligible based on MCV coverage rates <80% (n=12)

Source: WHO

Category (# out of 72)	GAVI-Eligible Country Vaccine Need							
	AFRO (36 of 36)			AMRO (6 of 6)	EMRO (6 of 6)	EURO (8 of 8)	SEARO (9 of 9)	WPRO (7 of 7)
Least Poor (2 of 12)	Cameroon			Bolivia Guyana Honduras	Djibouti	Armenia Azerbaijan Georgia Ukraine	Indonesia Sri Lanka	Kiribati
Intermediate (4 of 16)	Ghana Kenya	Nigeria Zimbabwe	Cuba Nicaragua	Pakistan	Kyrgyzstan Moldova Tajikistan Uzbekistan	India Korea DPR	Mongolia PNG Viet Nam	
Poorest (18 of 31)	Benin Burkina Faso Chad Comoros Ethiopia Gambia Guinea Guinea-Bissau	Lesotho Madagascar Malawi Mali Mauritania Mozambique Niger Rwanda	Sao Tome & Principe Senegal Sierra Leone Tanzania Togo Uganda Zambia	Yemen		Bangladesh Bhutan Myanmar Nepal	Cambodia Lao Solomon Islands	
Fragile (7 of 13)	Angola Burundi CAR	Congo DR Congo Côte d'Ivoire	Eritrea Liberia	Haiti	Afghanistan Somalia Sudan	Timor-Leste		

### Country Vaccine Need

Disease: **Human Papillomavirus (HPV)** Vaccine Need: 60  
VISP Scope: 60

- Cervical cancer is the most common cancer affecting women in developing countries (HPV vaccines: technical information for policy-makers and health professionals, WHO, Dec07); the current countries in scope represent countries with high rabies incidence or

### Country Vaccine Need

Disease: **RABIES** Vaccine Need: 49  
VISP Scope: 49

- The vast majority of deaths due to rabies occur in Asia and Africa (WHO position paper, Dec07); the current countries in scope represent countries with high rabies incidence or

### Country Vaccine Need

Disease: **TYPHOID** Vaccine Need: 25  
VISP Scope: 24

- Typhoid fever continues to be a public health problem in many Asia, Africa and Latin American developing countries (WHO position paper, Feb08); high disease burden countries were defined by incidence rates > 100 cases/100,000 annually (SAGE, background paper, Nov07)

Category (# out of 72)	GAVI-Eligible Country Vaccine Need						
	AFRO (8 of 36)			AMRO (0 of 6)	EMRO (2 of 6)	EURO (3 of 8)	SEARO (8 of 9)
Least Poor (2 of 12)						Indonesia (25%) Sri Lanka	
Intermediate (8 of 16)	Zimbabwe			Pakistan (25%)	Kyrgyzstan Tajikistan Uzbekistan	India (25%)	PNG Viet Nam <sup>1</sup>
Poorest (12 of 31)	Comoros Lesotho	Madagascar Malawi	Mozambique Zambia			Bangladesh Bhutan Myanmar Nepal	Cambodia Lao
Fragile (3 of 13)	Angola			Afghanistan		Timor-Leste	

<sup>1</sup> Using locally produced vaccine; will not seek GAVI financing support

Source: SAGE & IVI Typhoid Team

\* WHO, CDC, PDP, PPP, and other expert reviewed

# Vaccine Need

## VACCINE NEED BY COUNTRY (I)

Country	Cholera	HPV	JE	Rabies	Rubella	Typhoid
Afghanistan				√	√	√
Angola	√	√		√		√
Armenia		√		√	MMR	
Azerbaijan				√	MMR	
Bangladesh	√	√	√	√	√	√
Benin		√		√	√	
Bhutan		√	√ <sup>75%R</sup>	√	√	√
Bolivia		√		√	MMR	
Burkina Faso	√	√		√	√	
Burundi	√	√			√	
Cambodia	√	√	√	√	√	√
Cameroon		√		√	√	
CAR	√	√		√		
Chad	√	√		√		
Comoros		√			√	√
Congo, DR	√	√		√	√	
Congo, Rep.		√			√	
Côte d'Ivoire		√		√	√	
Cuba		√		√	MMR	
Djibouti	√	√			√	
Eritrea		√			√	
Ethiopia	√	√		√		
Gambia	√	√			√	
Georgia		√		√	MMR	
Ghana	√	√		√	√	
Guinea	√	√			√	
Guinea-Bissau		√				
Guyana		√			MMR	
Haiti		√		√	√	
Honduras		√		√	MMR	
India	√ <sub>25%</sub>	√	√ <sup>1</sup>	√	√	√ <sub>25%</sub>
Indonesia	√ <sub>25%</sub>	√	√ <sup>75%R</sup>	√	√	√ <sub>25%</sub>
Kenya		√		√	√	
Kiribati					MR	
Korea, DPR		√	√	√	√	
Kyrgyzstan		√		√	MR, MMR	√

√# = subnational

# Vaccine Need

## VACCINE NEED BY COUNTRY (II)

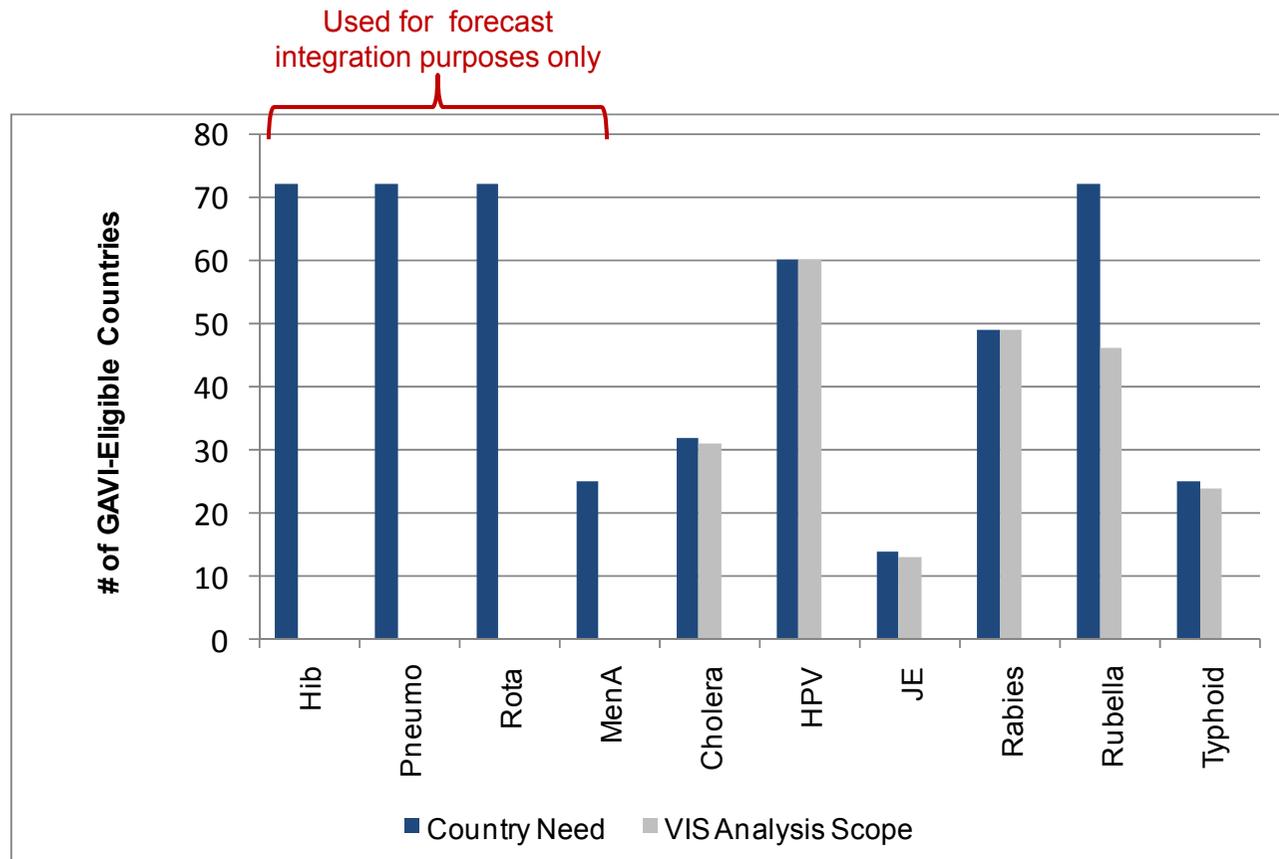
Country	Cholera	HPV	JE	Rabies	Rubella	Typhoid
Lao PDR		√	√	√		√
Lesotho		√			√	√
Liberia	√	√				
Madagascar		√		√		√
Malawi	√	√		√	√	√
Mali		√		√	√	
Mauritania		√				
Moldova		√			MMR	
Mongolia		√			√	
Mozambique	√	√		√	√	√
Myanmar	√	√	√	√	√	√
Nepal	√	√	√ <sub>60%R; 40%C</sub>	√	√	√
Nicaragua		√		√	MR, MMR	
Niger	√	√			√	
Nigeria	√			√		
Pakistan	√ <sub>25%</sub>		√ <sub>25%R</sub>	√	√	√ <sub>25%</sub>
PNG		√	√ <sub>40%R</sub>		√	√
Rwanda		√		√	√	
São Tomé	√				√	
Senegal		√		√	√	
Sierra Leone	√	√			√	
Solomon Island		√			√	
Somalia	√					
Sri Lanka		√	√	√	MR	√
Sudan	√			√		
Tajikistan				√	√	√
Tanzania	√	√		√	√	
Timor-Leste			√		√	√
Togo	√	√		√	√	
Uganda	√	√		√	√	
Ukraine		√		√	MMR	
Uzbekistan				√	MMR	√
Viet Nam	√ <sup>1</sup>	√	√ <sub>100%R; 70%C</sub>	√	√	√ <sup>2</sup>
Yemen					√	
Zambia	√	√		√	√	√
Zimbabwe		√		√	√	√

√# = subnational

24 <sup>1</sup>Adopted in ~1997 with locally produced vaccine; will not seek GAVI financing support;  
<sup>2</sup>Using locally produced vaccine; will not seek GAVI financing support

# Vaccine Need

## VACCINE NEED VS. VIS ANALYSIS SCOPE



### Need vs. Analysis Scope Rationale

Cholera

- Viet Nam uses local vaccine

JE

- India adopted without GAVI

Rubella

- 14 countries have programs
- 12 countries not currently eligible

Typhoid

- Viet Nam uses local vaccine



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A banner image featuring a blue sky, a green field, and a single acacia tree on the right. The text 'Vaccine Adoption' is overlaid in white on the left side.

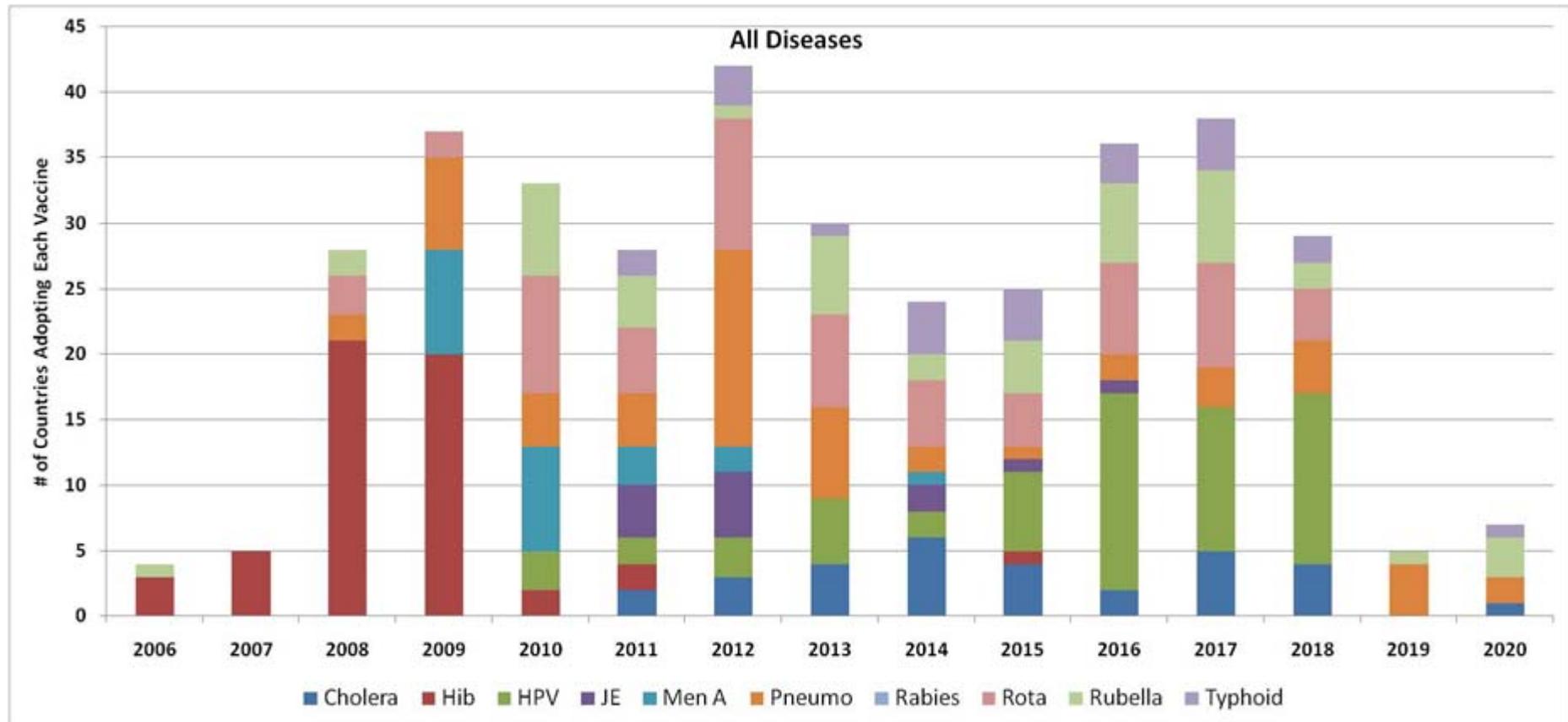
# Vaccine Adoption

## ADOPTION FORECAST DEVELOPMENT PROCESS

- Gathered individual vaccine adoption forecasts from PDPs and vaccine experts
  - Aggregated forecasts across all 10 vaccines (Hib, pneumo, rotavirus, menA, cholera, HPV, JE, rabies, rubella, typhoid)

# Vaccine Adoption

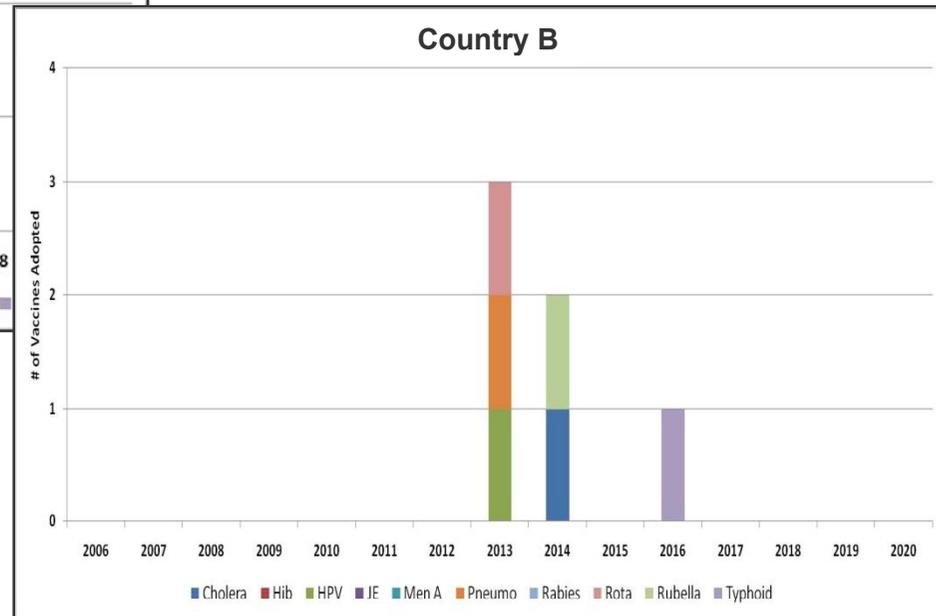
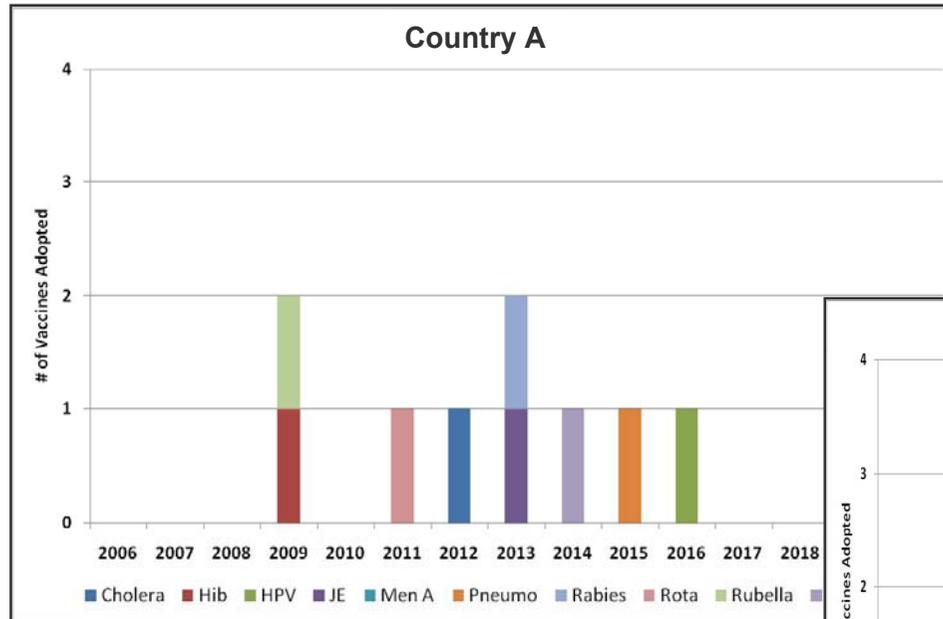
## AGGREGATED ADOPTION FORECAST



# Vaccine Adoption

## AGGREGATED FORECAST – BY COUNTRY

**EXAMPLES**



*When examined at country level, the aggregated forecast was clearly aggressive, and perhaps unrealistic*

A banner image featuring a blue sky, a green field, and a single acacia tree on the right. Two white diagonal lines cross the image from the top corners towards the center.

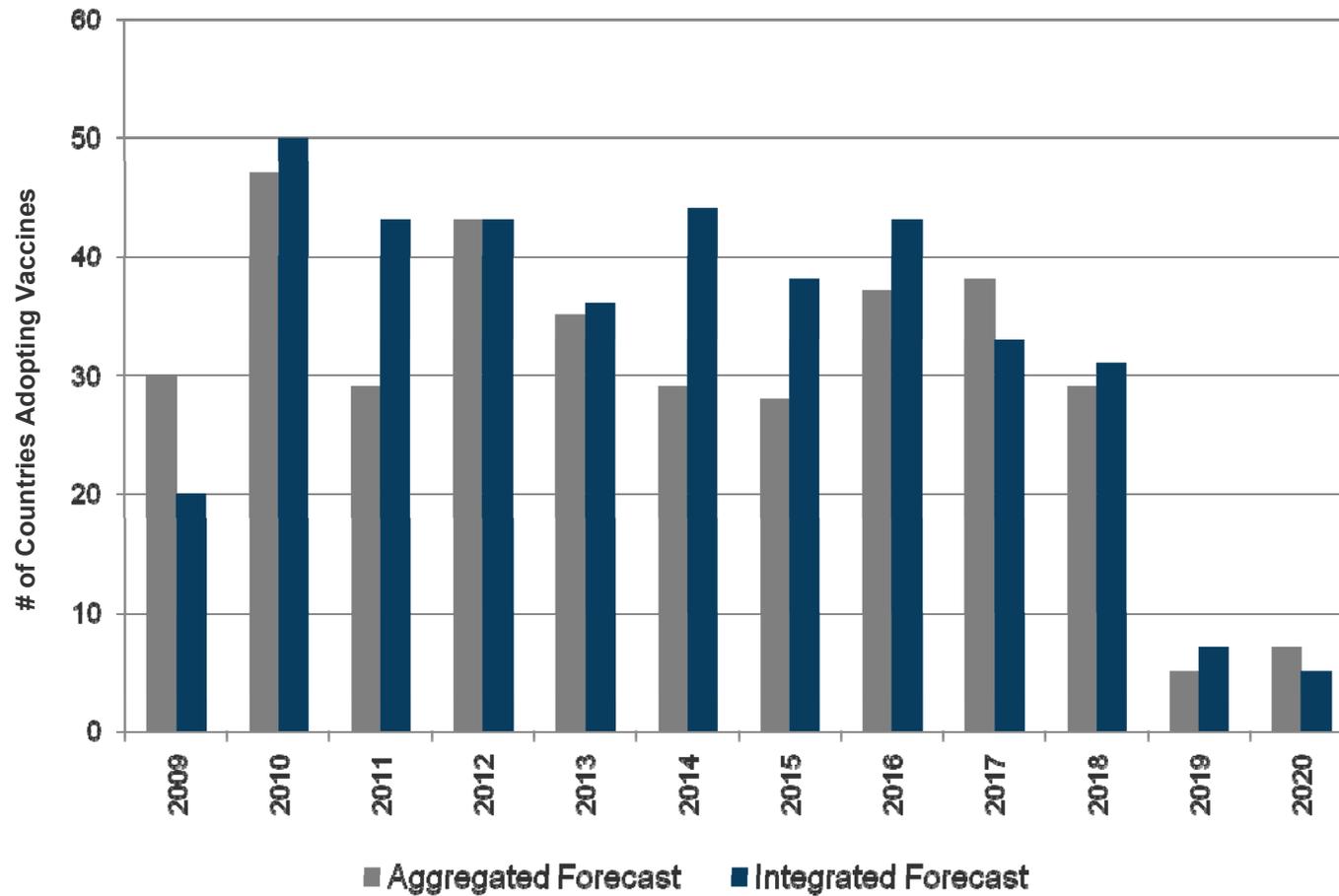
# Vaccine Adoption

## ADOPTION FORECAST DEVELOPMENT PROCESS (continued)

- Gathered individual vaccine adoption forecasts from PDPs and vaccine experts
  - Aggregated forecasts across all 10 vaccines (Hib, pneumo, rotavirus, menA, cholera, HPV, JE, rabies, rubella, typhoid)
- Held meeting with WHO, UNICEF, CDC, PDPs and vaccine experts representing all 10 diseases
- Discussed and modified the aggregated adoption forecast to create an *Integrated Adoption Forecast*
  - ‘Rule-of-thumb’ applied: one vaccine adopted per year, except for rubella (switch from MCV to MR) & rabies (vaccine delivery in rabies centers for post-bite subjects) since these are considered underutilized vaccines that generally do not require setting up new immunisation programmes and could be added without much delay

# Vaccine Adoption

## INTEGRATED VS. AGGREGATED FORECAST





# Vaccine Adoption

## POST-INTEGRATED FORECAST DEVELOPMENT PROCESS

- Vetted Integrated Adoption Forecast with GAVI Country Support Team
  - Agreed forecast was very aggressive
  - Disagreed with some country-specific adoption profiles
  - Suggested we seek country feedback to create a “Country-Influenced” adoption forecast
- GAVI sent letter to countries requesting non-binding adoption forecast
  - Asked to designate interest in adopting current and VIS vaccines
  - If interested in adopting, asked to specify earliest likely adoption year
  - Have received 32 responses to date

# Vaccine Adoption

## COUNTRY ADOPTION SURVEY – RESPONDENTS TO DATE

	AFRO (36)	AMRO (6)	EMRO (6)	EURO (8)	SEARO (9)	WPRO (7)	Total
Least Poor (12)	Cameroon	Bolivia			Indonesia Sri Lanka		4
Intermediate (16)	Kenya	Nicaragua	Pakistan	Moldova Uzbekistan	Korea	Viet Nam	7
Poorest (31)	Benin Burkina Faso Comoros Guinea Madagascar Mali Sao Tome & P Senegal Togo Uganda				Bangladesh Bhutan Myanmar Nepal	Cambodia	15
Fragile (13)	Angola Burundi Congo DR Congo Cote d'Ivoire				Timor Leste		6
<b>TOTAL</b>	<b>17</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>8</b>	<b>2</b>	<b>32</b>

# Vaccine Adoption

## COUNTRY ADOPTION SURVEY – INPUT TO DATE

Vaccine	Already Adopted?	Plan to Adopt in Year													Do Not Plan to Adopt Because:			Adoptions out of 32 total	Responses out of 32 total	
		No Date	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Product Profile	DB Unknown	NA or Low DB			
Hib	16	1	12	2	1														32	32
Pneumo			4	9	9	6		1											29	29
Rota		1	1	2	12	3	2	1	2	2									26	26
Rubella	2	1		4	3	3		2											15	15
Rabies	3	1	3	4	1	1							1						14	14
HPV		2		2	4	2	1			1	1						1		13	14
MenA	1	1		2	1	3	1	1									1	1	10	12
Typhoid			3	1	1		2		1					1			1		9	10
JE	2	1	4		1	1													9	9
Cholera			1	1	2	1	2									1		1	7	9
	24	8	28	27	35	20	8	5	3	3	1	0	2	0	1	3	2			



# Vaccine Adoption

## INTEGRATED VS. COUNTRY SURVEY FORECAST INSIGHTS

- A “country influenced” adoption forecast was determined to be comparable to the Integrated forecast
  - Country-specific survey results were either more aggressive, similar, or more conservative than the Integrated Adoption Forecast
  - Aggregated across all countries, the country influenced forecast was similar to the integrated forecast
- Nevertheless, the Integrated Forecast is perceived to be aggressive, so an additional, more conservative adoption forecast was developed



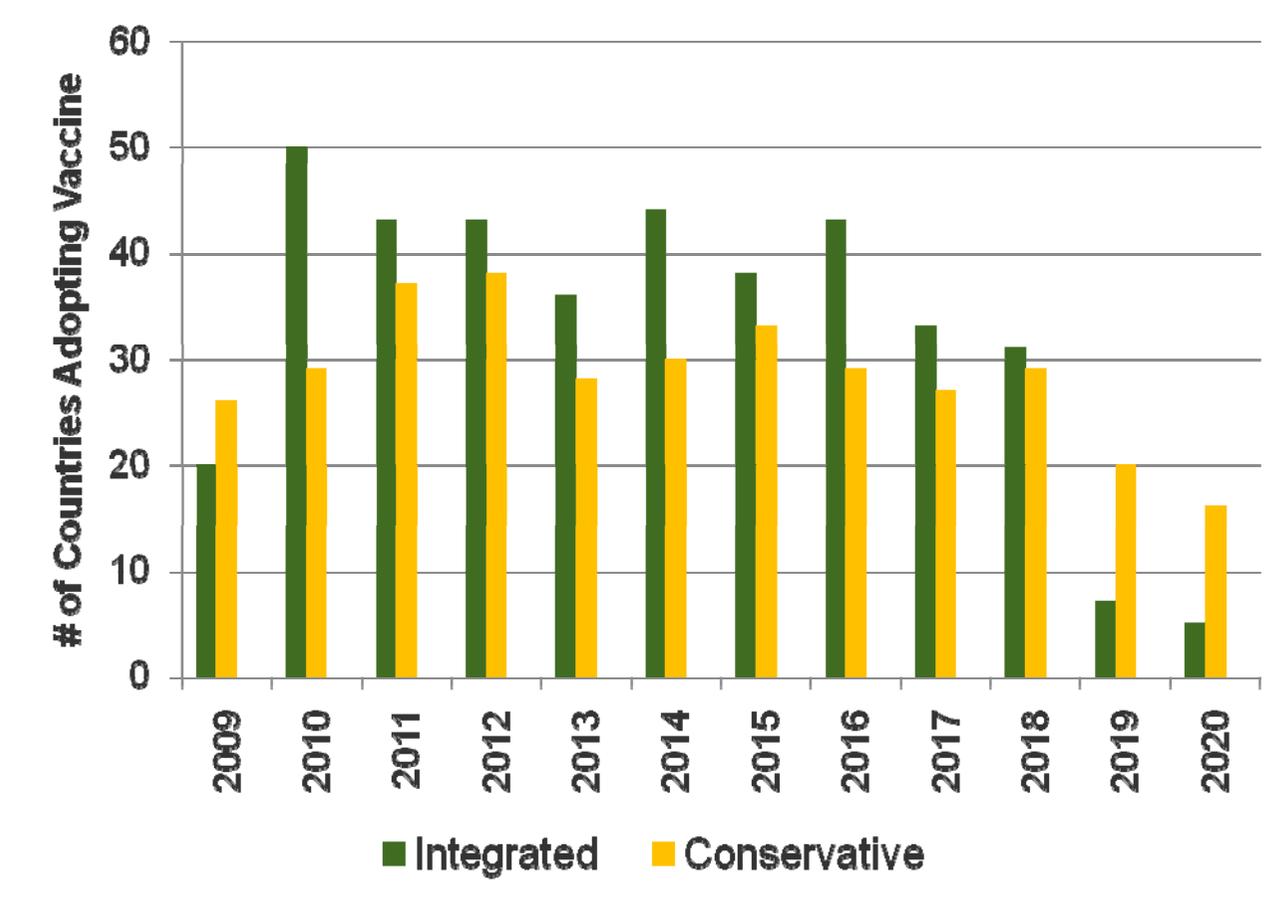
# Vaccine Adoption

## CONSERVATIVE FORECAST DEVELOPMENT PROCESS

- Began with Integrated Forecast
- Applied Conservative Forecast Rules
  - Hib forecast same as Integrated Forecast, wherever possible
  - No more than 1 new vaccine adoption every three years (UNICEF “rule of thumb”)
    - Rabies and Rubella considered underutilized vaccines, so do not follow every three year rule, therefore, same as Integrated Forecast, where possible
    - If two or more vaccines still in same year:
      - Country survey results dictate vaccine priority order
      - If country survey results not available, Integrated Forecast results dictate vaccine priority order
      - If still multiple vaccines in same year, current GAVI vaccines take priority over new vaccines

# Vaccine Adoption

## INTEGRATED VS CONSERVATIVE ADOPTION FORECAST



A banner image featuring a blue sky, a green field, and a single acacia tree on the right. Two diagonal lines, resembling structural beams, cross the image from the top corners towards the center.

# Vaccine Adoption

## INTEGRATED VS CONSERVATIVE ADOPTION FORECAST IMPLICATIONS

- All vaccine and portfolio analyses were conducted given both the integrated and conservative forecast
- Although the conservative forecast resulted in lower vaccine cost forecasts and metric values, it did not lead to a change in the prioritisation of vaccines and composition of portfolio options
- The Integrated Adoption Forecast was chosen as the “planning” forecast, representing:
  - *A ‘worst case’ scenario from a financial perspective*
  - *A ‘best case’ scenario from a public health perspective*



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The header features a landscape image with a blue sky, green grass, and a single acacia tree on the right. Two diagonal lines cross the image from the top corners towards the center. The text 'Vaccine Demand' is overlaid in white on the left side.

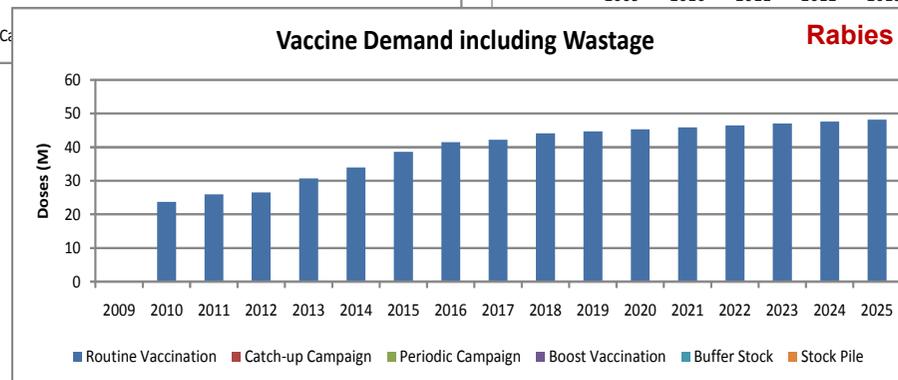
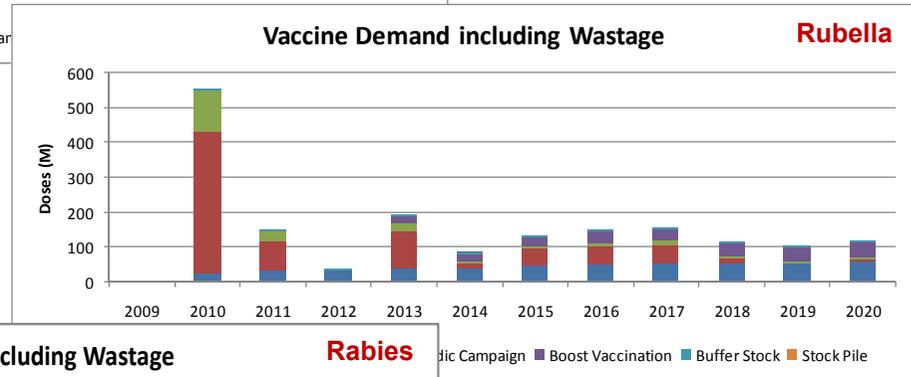
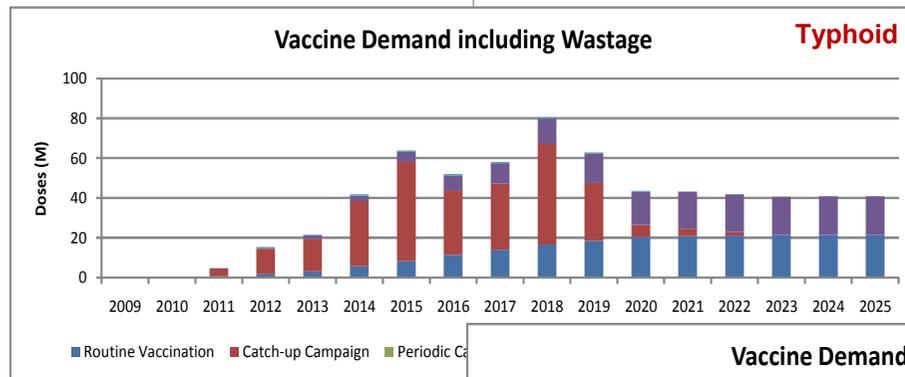
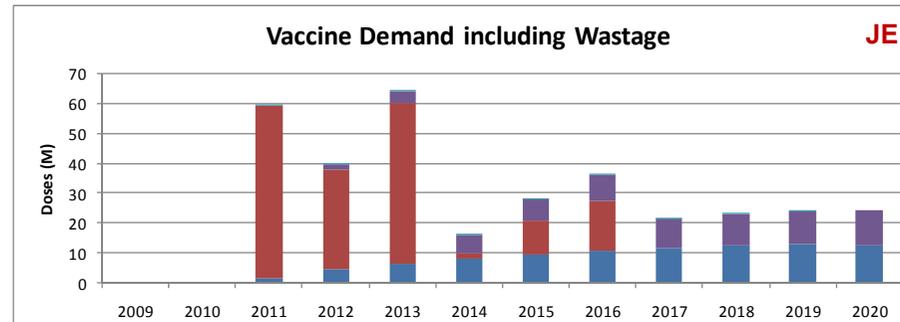
# Vaccine Demand

## METHODOLOGY

- Vaccine Demand Forecast = function of:
  - 1<sup>st</sup> Vaccine Availability (WHO Pre-Qual date)
  - Country Adoption Forecast
  - Country Vaccine Coverage Rates
  - Vaccine Doses/Treatment
  - Vaccine Wastage Factors
  - Country Time to Peak Coverage or Campaign Duration

# Vaccine Demand

## DEMAND FORECASTS



\* WHO, UNICEF, CDC, PDP and other expert reviewed



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# Vaccine Cost & Health Impact Analysis Methodology

## TOTAL VACCINE COST – METHODOLOGY

- Total Vaccine Cost = function of:
  - Vaccine Demand Forecast
  - Vaccine Price Forecast by Vaccine
  - Vaccine Product Share

Provides  
Weighted  
Average  
Vaccine Price

### EXAMPLE

Low Vaccine Price Forecast

Vaccines	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Vaccine A	\$0.75	\$0.75	\$0.75	\$0.75	\$0.75	\$0.75	\$0.50	\$0.50	\$0.50	\$0.50	\$0.50
Vaccine B				\$0.70	\$0.70	\$0.70	\$0.50	\$0.50	\$0.50	\$0.50	\$0.50
Vaccine C							\$0.70	\$0.70	\$0.70	\$0.70	\$0.70

Low Vaccine Price Distribution Assumptions

Vaccines	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Vaccine A	100%	100%	100%	95%	95%	95%	85%	80%	80%	80%	80%
Vaccine B				5%	5%	5%	5%	5%	5%	5%	5%
Vaccine C							10%	15%	15%	15%	15%

<b>Weighted Average Low Price Forecast</b>	<b>\$0.75</b>	<b>\$0.75</b>	<b>\$0.75</b>	<b>\$0.75</b>	<b>\$0.75</b>	<b>\$0.75</b>	<b>\$0.52</b>	<b>\$0.53</b>	<b>\$0.53</b>	<b>\$0.53</b>	<b>\$0.53</b>
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\* PDP, PPP, and Industry reviewed; industry input kept confidential

# Vaccine Cost & Health Impact Analysis Methodology

## VACCINE COST TO COUNTRY

- Vaccine Cost to Country = function of:
  - Demand Forecast
  - GAVI Country Co-Pay
  - *Total Vaccine Product Cost (when GAVI support ends)\**

**Country Copay by GAVI Financing Tier**

Last GAVI Financing Year:

	Co-pay for Country in terms of Years since Vaccine Adoption <sup>1</sup>											
	0	1	2	3	4	5	6	7	8	9	10	11
Least Poor <sup>2</sup>	\$0.15	\$0.17	\$0.20	\$0.23	\$0.26	\$0.30	\$0.35	\$0.40	\$0.46	\$0.53	\$0.61	\$0.70
Intermediate	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15
Poorest	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15
Fragile	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15	\$0.15

<sup>1</sup> Co-pay is for second or greater GAVI vaccine; Country co-pay is not impacted by inflation

<sup>3</sup> Grows at 15% per year until it meets or exceeds vaccine price.

\* *Least poor countries should be paying for Rubella vaccines within 5 years of adoption (\$0.30 co-pay > \$0.28 vaccine price per dose)*

# Vaccine Cost & Health Impact Analysis Methodology

## VACCINE COST TO GAVI

- Total Cost to GAVI = function of:
  - Vaccine Demand Forecast
  - Weighted Average Vaccine Price
  - Country Co-Payment
  - Vaccine Equipment Costs
  - Vaccine Shipping & Insurance

### Vaccination Equipment Cost

Autodisable Syringe (\$/dose):	0.05
Reconstitution Syringe/Needle (\$/dose):	0.10
Safety Box (\$/dose):	0.01

### Other vaccine Costs

Shipping & Insurance (\$/dose):	0.05
---------------------------------	------

# Vaccine Cost & Health Impact Analysis Methodology

## HEALTH IMPACT – VALUE MEASURES

Value Measure	Benefit	Concern
Potential Deaths Averted	<ul style="list-style-type: none"> <li>• Common measure of vaccine impact on infectious diseases</li> <li>• Important variable in tracking impact on MDGs</li> </ul>	<ul style="list-style-type: none"> <li>• Mortality often under-reported, especially in developing countries</li> <li>• Generally estimated from country trials and extrapolated to rest of world, therefore, may not accurately reflect regional/disease burden differences</li> </ul>
Potential Cases Averted	<ul style="list-style-type: none"> <li>• Common measure of vaccine impact on infectious diseases</li> <li>• Important variable in tracking impact of disease on morbidity, especially in diseases with long-term sequelae</li> </ul>	<ul style="list-style-type: none"> <li>• Morbidity often under-reported, especially in developing countries</li> <li>• Generally estimated from country trials and extrapolated to rest of world, therefore, may not accurately reflect regional/disease burden differences</li> </ul>
Cost per Potential Death or Case Averted	<ul style="list-style-type: none"> <li>• Important measure for evaluating return on investment</li> </ul>	<ul style="list-style-type: none"> <li>• Subject to strengths/ weaknesses associated with estimates derived for deaths &amp; cases averted (above) as well as estimates on cost of the intervention</li> </ul>

# Vaccine Cost & Health Impact Analysis Methodology

## POTENTIAL DEATHS AVERTED

- Total Potential Deaths Averted = function of:
  - Vaccine Demand Forecast
  - Doses/Treatment

Provides  
Subjects  
Vaccinated

- Deaths Averted per 1000 Vaccinated
- <5yo Deaths Averted per 1000 Vaccinated

# Vaccine Cost & Health Impact Analysis Methodology

## GAVI COST PER DEATH AVERTED

- GAVI Cost per Death Averted = function of:
  - Vaccine Cost to GAVI
  - Total Potential Deaths Averted

# Vaccine Cost & Health Impact Analysis Methodology

## POTENTIAL CASES AVERTED

- Total Potential Cases Averted = function of:
  - Demand Forecast
  - Doses/Treatment
  - Cases Averted per 1000 Vaccinated

Provides  
Subjects  
Vaccinated

# Vaccine Cost & Health Impact Analysis Methodology

## GAVI COST PER CASE AVERTED

- GAVI Cost per Case Averted = function of:
  - Vaccine Cost to GAVI
  - Total Potential Cases Averted

# Vaccine Cost & Health Impact Analysis Methodology

## MODEL INPUT SUMMARY

*\*Used a weighted average Deaths & Cases averted to account for vaccine differences in the model* **CHOLERA**

### Vaccine Evaluation Summary

#### ANALYSIS INPUT SUMMARY (II)

VARIABLE	VACCINATION STRATEGY					RATIONALE/SOURCE
	Periodic Campaign				Stockpile	
	Dukoral	Reformulated Bivalent				
	5-15yo	5-49yo	1-15yo	1-49yo	1-49yo	
Doses per Treatment	2					Established dosing schedule based on published data; current WHO recommendation

**HPV**

### Vaccine Evaluation Summary

#### ANALYSIS INPUT SUMMARY (II)

VARIABLE	VACCINATION STRATEGY		RATIONALE/SOURCE
	Routine Vaccination (10yo fm)	Catch-up Campaign (11-14yo fm)	
Doses per Treatment	3		Based on Gardasil (Merck) & Cervarix (CSK) package insert

**JE**

### Vaccine Evaluation Summary

#### ANALYSIS INPUT SUMMARY (II)

VARIABLE	VACCINATION STRATEGY					RATIONALE/SOURCE
	Rapid Impact		Delayed Impact			
	Routine Vx (Surviving Infants)	Catch-up Campaign (2-19yo)	Mass Campaign (20-29yo fm)	Routine Vx (Surviving Infants)	Mass Campaign (15-31yo fm)	
Doses per Treatment	1					Routine: single dose + boost, based on package inserts; Campaigns: single dose
Proxy Coverage Rate	MCV	90% MCV	80%	MCV	50%	WHO (P. Strebel) and CDC (S. Reef)
Time to Peak Coverage	1					Assume a switch from M to MR for routine, and ≤ 1yr duration for campaigns
Deaths Averted (per 1000 vaccinated)	0					No mortality associated with rubella
Years to Deaths Averted	-					NA
% Deaths Averted < 5yo	-					NA
Cases Averted (per 1000 vaccinated)	TBD					
Years to Cases Averted	0					Immunoprotection after 1 dose
% Cases Averted < 5yo	100%					Assume vaccines provide life-long protection
Average Cost per Case	\$55,000					Median lifetime cost estimate to treat a child with CRS (Hinman, et al., Bull WHO, 2002, 80:264-270)

**RABIES**

### Vaccine Evaluation Summary

#### ANALYSIS INPUT SUMMARY (II)

VARIABLE	VACCINATION STRATEGY		RATIONALE/SOURCE	
	Routine Vx	Periodic Campaign		
	Infants	2-15yo	5-15yo	
Doses per Treatment	Ty21a	-	3	Ty21a vaccine (Vivotif)
	Vi-PS	-	1	Vi polysaccharide vaccine
	Vi-DT	1 + boost	1 + boost	Source: V. Reddy, Shanitha
Proxy Coverage Rate	Ty21a	50% MCV	50% MCV	NI estimate
	Vi-PS	86% MCV	86% MCV	NI estimates; using weighted average to account for vaccine differences
	Vi-DT	50% MCV	50% MCV	Proxy for DTP2 (within 3% across GAVI countries)
Time to Peak Coverage	1			Assume campaign duration is for 1yr
Time Between Campaigns (yrs)	Ty21a	-	3	Based on duration of protection and need to vaccinate new cohorts
	Vi-PS	3	3	Based on duration of protection and need to vaccinate new cohorts
	Vi-DT	-	-	Routine and catch-up campaigns only
Deaths Averted* (per 1000 vaccinated)	Ty21a	-	0.5	NI estimate
	Vi-PS	-	0.2	NI estimate
	Vi-DT	1.7	-	NI estimate
Years to Deaths Averted	0			Assumes immunoprotection after 1 <sup>st</sup> dose
% Deaths Averted < 5yo	100%			Infants only; 2-4yo only (3/15 of 2-15yo); and ≥ 5yo only
Cases Averted* (per 1000 vaccinated)	Ty21a	-	50.4	NI estimate
	Vi-PS	-	21.6	NI estimate
	Vi-DT	171	-	NI estimate
Years to Cases Averted	0			Assumes immunoprotection after 1 <sup>st</sup> dose
% Cases Averted < 5yo	100%			Infants only; 2-4yo only (3/15 of 2-15yo); and ≥ 5yo only
Average Cost per Case	\$99			NI estimate; median of cost studies done in all Asian sites (\$15 - \$182); SAGE paper; Nov07

**RUBELLA**

### Vaccine Evaluation Summary

#### ANALYSIS INPUT SUMMARY (III)

VARIABLE	VACCINATION STRATEGY					RATIONALE/SOURCE
	Rapid Impact		Delayed Impact			
	Routine Vx (Surviving Infants)	Catch-up Campaign (2-19yo)	Mass Campaign (20-29yo fm)	Routine Vx (Surviving Infants)	Mass Campaign (15-31yo fm)	
Doses per Treatment	1					Routine: single dose + boost, based on package inserts; Campaigns: single dose
Proxy Coverage Rate	MCV	90% MCV	80%	MCV	50%	WHO (P. Strebel) and CDC (S. Reef)
Time to Peak Coverage	1					Assume a switch from M to MR for routine, and ≤ 1yr duration for campaigns
Deaths Averted (per 1000 vaccinated)	0					No mortality associated with rubella
Years to Deaths Averted	-					NA
% Deaths Averted < 5yo	-					NA
Cases Averted (per 1000 vaccinated)	TBD					
Years to Cases Averted	0					Immunoprotection after 1 dose
% Cases Averted < 5yo	100%					Assume vaccines provide life-long protection
Average Cost per Case	\$55,000					Median lifetime cost estimate to treat a child with CRS (Hinman, et al., Bull WHO, 2002, 80:264-270)

*\*Used a weighted average Deaths & Cases averted to account for vaccine differences in the model* **TYPHOID**

### Vaccine Evaluation Summary

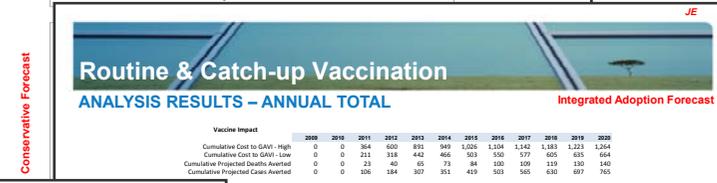
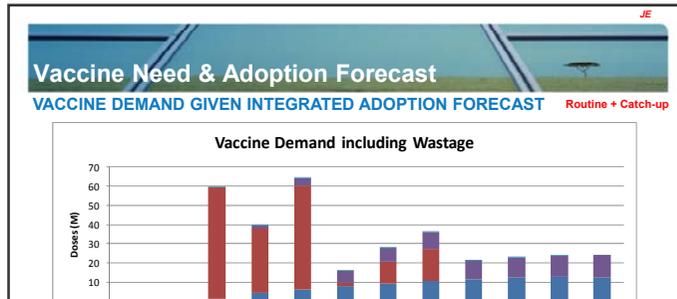
#### ANALYSIS INPUT SUMMARY (II)

VARIABLE	VACCINATION STRATEGY			RATIONALE/SOURCE
	Routine Vx	Periodic Campaign		
	Infants	2-15yo	5-15yo	
Doses per Treatment	Ty21a	-	3	Ty21a vaccine (Vivotif)
	Vi-PS	-	1	Vi polysaccharide vaccine
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Proxy Coverage Rate	Ty21a	50% MCV	50% MCV	NI estimate
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Time Between Campaigns (yrs)	Ty21a	-	3	Based on duration of protection and need to vaccinate new cohorts
	Vi-PS	3	3	Based on duration of protection and need to vaccinate new cohorts
	Vi-DT	-	-	Routine and catch-up campaigns only
Deaths Averted* (per 1000 vaccinated)	Ty21a	-	0.5	NI estimate
	Vi-PS	-	0.2	NI estimate
	Vi-DT	1.7	-	NI estimate
Years to Deaths Averted	0			Assumes immunoprotection after 1 <sup>st</sup> dose
% Deaths Averted < 5yo	100%			Infants only; 2-4yo only (3/15 of 2-15yo); and ≥ 5yo only
Cases Averted* (per 1000 vaccinated)	Ty21a	-	50.4	NI estimate
	Vi-PS	-	21.6	NI estimate
	Vi-DT	171	-	NI estimate
Years to Cases Averted	0			Assumes immunoprotection after 1 <sup>st</sup> dose
% Cases Averted < 5yo	100%			Infants only; 2-4yo only (3/15 of 2-15yo); and ≥ 5yo only
Average Cost per Case	\$99			NI estimate; median of cost studies done in all Asian sites (\$15 - \$182); SAGE paper; Nov07

\* WHO, UNICEF, CDC, PDP and other expert reviewed

# Vaccine Cost & Health Impact Analysis Methodology

## MODEL OUTPUT SUMMARY



	2009 - 2020
Total Projected Deaths Averted (x1000)	140
Total Projected Deaths Averted of < 5yo (x1000)	93
Total Cases Averted (x1000)	765
Total Savings from Cases Averted (\$M)	96
Total GAVI Cost (\$M) - High	1,264
- Low	664
Total Cost (\$M) - High	1,324
- Low	724

**Insights & Conclusions**  
GAVI FINANCIAL ANALYSIS SUMMARY

**Integrated Adoption Forecast**

	Projected Deaths Averted (x1000)	Projected 5-Yo Deaths Averted (x1000)	Cases Averted (x1000)	Cost Savings (\$M)	Cost to GAVI (\$M)**	Cost to Country (\$M)**	Total Cost (\$M)**	GAVI Cost/Death Averted	GAVI Cost/Case Averted	GAVI Cost/\$ saved
IE Routine Vaccination	74	74	464	551	532	534	535	\$4,358	\$93	\$5.28
IE Routine Vaccination with Catch-up	140	93	765	186	5974	565	\$1,034	\$6,987	\$5,274	\$13.32

**Conservative Adoption Forecast**

	Projected Deaths Averted (x1000)	Projected 5-Yo Deaths Averted (x1000)	Cases Averted (x1000)	Cost Savings (\$M)	Cost to GAVI (\$M)**	Cost to Country (\$M)**	Total Cost (\$M)**	GAVI Cost/Death Averted	GAVI Cost/Case Averted	GAVI Cost/\$ saved
IE Routine Vaccination	23	23	140	516	585	58	591	\$1,099	\$605	\$5.35
IE Routine Vaccination with Catch-up	65	35	322	145	5320	524	\$595	\$6,854	\$564	\$7.35

**Annual Impact**

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total Cost - High (\$M)	0	0	372	243	300	41	82	84	43	46	46	47
Total Cost - Low (\$M)	0	0	200	153	154	27	42	52	35	33	35	35
Cost to GAVI - High (\$M)	0	0	364	237	290	58	77	78	38	41	41	41
Cost to GAVI - Low (\$M)	0	0	211	107	124	24	37	47	27	28	29	29
Cases Averted - High (\$M)	0	0	9	6	10	3	5	6	4	5	5	6
Cases Averted - Low (\$M)	0	0	6	6	10	7	5	6	4	5	5	6
Cost to GAVI - High (\$M)	0	0	351	229	277	55	71	70	34	36	36	36
Cost to GAVI - Low (\$M)	0	0	199	98	109	21	31	40	22	23	24	24
Cases Averted - High (\$M)	0	0	9	6	10	3	5	6	4	5	5	6
Cases Averted - Low (\$M)	0	0	9	6	10	3	5	6	4	5	5	6
Equipment Cost (\$M)	0	0	10	6	10	3	5	6	4	4	4	4
Insurance Cost (\$M)	0	0	3	2	3	1	1	2	1	1	1	1
With Averted (x1000)	0	0	23	16	25	7	12	15	10	10	10	10
With Averted if 5yo (x1000)	0	0	8	7	11	7	9	11	10	10	10	10
Cases Averted (x1000)	0	0	106	78	124	44	68	84	61	65	67	67
5-Yo Cases Averted (\$M)	0	0	16	11	17	5	8	10	7	7	7	7
Costs Demanded (\$M)	0	0	60	40	64	16	26	36	22	23	24	24
Costs Demanded without Wastage (\$M)	0	0	54	36	58	14	25	33	20	21	22	22
Total Vaccinations (\$M)	0	0	54	36	58	14	25	33	20	21	22	22

# Vaccine Cost & Health Impact Analysis Methodology

Vaccination Strategy	Total Vaccine Cost (\$M)	GAVI Vaccine Cost (\$M)	Country Vaccine Cost (\$M)	Deaths Averted (x1000)	<5 Deaths Averted (x1000)	Cases Averted (x1000)	GAVI Cost (\$)/ Death Averted	GAVI Cost (\$)/ Case Averted
<b>Cholera</b> 1-15yo Campaign Every 3 Years	\$1,480	\$1,227	253	130	33	6,654	\$9,462	\$184
<b>Cholera</b> 1-49yo Campaign Every 3 Years	\$3,198	\$2,659	\$538	132	10	6,046	\$20,075	\$440
<b>HPV</b> Routine 10yo Female Vaccination	\$1,293	\$1,261	\$31	707	n/a	870	\$1,784	\$1,449
<b>JE</b> Routine Infant Vaccination with boost after 12 mos + 1-15yo Catch-up Campaign	\$1,034	\$974	\$60	140	93	765	\$6,967	\$1,274
<b>Rabies</b> Post-Exposure Prophylaxis	\$2,945	\$2,882	\$63	483	24	n/a	\$5,970	n/a
<b>Rubella (rapid impact)</b> Routine 1yo Vaccination with boost at 4yo + 2-19yo Campaign + 20-29yo WBCA Campaign	\$884	\$608	\$276	74*	31*	417*	\$8,222*	\$1,459*
<b>Rubella (delayed impact)</b> Routine 1yo Vaccination with boost at 4yo + 15-39yo WBCA Campaign	\$540	\$370	\$170	22*	13*	110*	\$16,742*	\$3,363*
<b>Rubella Incremental</b> From Delayed to Rapid	\$344	\$238	\$106	52*	18*	307*	\$4,577*	\$775*
<b>Typhoid</b> Routine Infant Vaccination with boost after 12mos	\$211	\$182	\$29	154	154	15,485	\$1,182	\$12
<b>Typhoid</b> Routine Infant Vaccination with boost after 12mos + 1-15yo Catch-up	\$529	\$459	\$70	178	160	18,093	\$2,579	\$25
<b>Typhoid</b> 2-15yo Campaign Every 3 Years	\$443	\$364	\$79	39	8	4,248	\$9,259	\$86
<b>Typhoid</b> 5-15yo Campaign Every 3 Years	\$510	\$432	\$78	36	n/a	3,855	\$11,985	\$112



# VIS Executive Summary

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# Implementation Cost Analysis Methodology

## PROCESS STEPS



- Identify country implementation cost categories, beyond vaccine procurement,



- For each vaccine, identify typical and unique country vaccine implementation challenges
- For each vaccine, identify potential synergies with:
  - Traditional EPI vaccines
  - Currently supported GAVI vaccines
  - Potential new GAVI supported vaccines
- Aggregate synergies across all vaccines



- Given challenges, assess implementation costs relative to traditional EPI vaccine implementation



- For each vaccination strategy, determine actual potential implementation associated cost

Seek WHO, UNICEF, CDC, PDP and Other Expert Validation of Key Project Information and Analysis Assumptions

# Implementation Cost Analysis Methodology

## STEP 1: COST CATEGORY IDENTIFICATION

- Thoroughly reviewed literature and other publically available information to identify potential cost categories
- Initial cost category draft reviewed with WHO implementation cost experts
- Based on WHO consultation, chose GIVS model\* cost categories

Cost Categories	Category Examples
Cold Chain	<ul style="list-style-type: none"> <li>• cold boxes, cold rooms &amp; ice packs</li> <li>• cold chain equipment (e.g., refrigerators, freezers, generators, voltage stabilizers)</li> <li>• maintenance &amp; running costs</li> </ul>
Waste Management	<ul style="list-style-type: none"> <li>• incinerators &amp; recurrent costs</li> </ul>
Transport	<ul style="list-style-type: none"> <li>• purchasing vehicles</li> <li>• cost of operating &amp; maintaining vehicles</li> <li>• fuel costs</li> </ul>
Personnel Training	<ul style="list-style-type: none"> <li>• development &amp; production of training materials</li> <li>• training course costs (e.g., instructor fees)</li> <li>• travel cost reimbursement</li> </ul>
Communication, Education, Social Mobilization	<ul style="list-style-type: none"> <li>• communication strategy and materials development</li> <li>• staff and volunteers recruiting, training &amp; support costs</li> <li>• media costs (e.g., radio, TV, newspaper, booklets, flyers)</li> <li>• social mobilization program costs</li> </ul>
Monitoring & Evaluation, Surveillance	<ul style="list-style-type: none"> <li>• strategy development support</li> <li>• monitoring program costs (e.g., SOPs, immunization cards, coverage surveys, training)</li> <li>• surveillance program costs (e.g., computer hardware, lab equipment, personnel, training)</li> </ul>
Service Delivery	<ul style="list-style-type: none"> <li>• outreach immunization services (e.g., additional personnel at district and health facility levels)</li> </ul>

\* Wolfson LJ, Gasse F, et al., Estimating the costs of achieving the WHO-UNICEF Global Immunization Vision and Strategy, 2006-2015. Bull World Health Organ 2008;86:27  
<http://www.who.int/bulletin/volumes/86/1/07-045096/en/index.html>

# Implementation Cost Analysis Methodology

## GIVS MODEL BACKGROUND\*

- The GIVS model is designed to provide input on:
  - Cost-effectiveness analyses of new vaccines in broad groups of countries
  - Vaccine-specific GAVI Investment cases (or alternative submissions that the GAVI Board may request),
  - The GIVS update in 2010,
  - Cost analysis of new vaccine(s) introduction globally or by region
  - Scenario analyses for the above



# Implementation Cost Analysis Methodology

## STEP 2: IMPLEMENTATION CHALLENGES & SYNERGIES PROCESS

- Vaccine-specific “typical” and “unique” implementation challenges were solicited from WHO, UNICEF, CDC, PDPs and other experts during Seattle Demand Forecasting Workshop and further refined by ASC in consultation with experts
- In Seattle, experts also developed a list of potential implementation synergies associated with introducing their respective vaccine, which was further refined by ASC in consultation with experts

# Implementation Cost Analysis Methodology

## STEP 2: IMPLEMENTATION CHALLENGES ASSESSMENT

**Cholera**

Implementation-Associated Cost Analysis  
UNIQUE IMPLEMENTATION CHALLENGES

Challenge Category	Unique Implementation Challenges
Dis	

**Rubella**

Implementation Associated Cost Analysis  
UNIQUE IMPLEMENTATION CHALLENGES

Vaccine	Unique Implementation Challenges
D	<ul style="list-style-type: none"> <li>Awareness of CRS potentially limited based on under reporting</li> </ul>

**HPV**

Implementation-Associated Cost Analysis  
UNIQUE IMPLEMENTATION CHALLENGES

Challenge Category	Unique Implementation Challenges
Vaccination Strategy	<ul style="list-style-type: none"> <li>Non-EPI vaccination schedule required                             <ul style="list-style-type: none"> <li>School-based delivery - more difficult to reach age cohort &gt;10yo</li> <li>New immunization cards required</li> </ul> </li> <li>Increased costs due to transport of immunization teams into schools or community outreach sites</li> </ul>
Perception Management	<ul style="list-style-type: none"> <li>Requires high level of community sensitization including teachers and healthcare workers</li> <li>Significant misperceptions need to be overcome                             <ul style="list-style-type: none"> <li>Cost prohibitive vaccine</li> <li>Poor school enrollment in low income countries</li> <li>Vaccination affects fertility</li> <li>Vaccine approved for use in males</li> </ul> </li> </ul>
Program Integration	<ul style="list-style-type: none"> <li>Requires coordination with MoE (for school-based programs)</li> </ul>
Health Impact	<ul style="list-style-type: none"> <li>Measuring impact of HPV vaccine requires over 20 years</li> </ul>

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**JE**

Implementation Associated Cost Analysis  
UNIQUE IMPLEMENTATION CHALLENGES

Challenge Category	Unique Implementation Challenges
Vaccination Strategy	<ul style="list-style-type: none"> <li>Both licensed vaccines have limited duration of protection requiring revaccination</li> </ul>

**TYPHOID**

Implementation-Associated Cost Analysis  
UNIQUE IMPLEMENTATION CHALLENGES

Challenge Category	Unique Implementation Challenges
Vaccination Strategy	<ul style="list-style-type: none"> <li>Non-EPI vaccination – animal (mostly dog) bite driven vaccination strategy</li> <li>Potential need to integrate vaccination strategy with other rabies control programs</li> <li>Vaccination strategy needs to include patient access via rabies 'dog bite treatment centers at central as well as district hospitals</li> <li>Continued advocacy required to support promotion of:                             <ul style="list-style-type: none"> <li>The use of economical and safe multistite ID post exposure prophylaxis</li> <li>Discontinuation of production and use of nerve tissue based vaccines</li> </ul> </li> <li>Major vaccine shortage for safe cell culture based vaccines</li> <li>Severe bite cases require vaccination and rabies immunoglobulin (RIG)                             <ul style="list-style-type: none"> <li>Major RIG shortage</li> </ul> </li> </ul>
Vaccination Access Via Rabies Bite Centers	<ul style="list-style-type: none"> <li>Significant facility and staff training upgrades required (e.g. wound wash stations)</li> <li>Need to promote and train medics overcome resistance to ID vs. IM vaccine administration</li> </ul>

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# Implementation Cost Analysis Methodology

## STEP 2: IMPLEMENTATION SYNERGIES ASSESSMENT

### Cholera

POTENTIAL IMPLEMENTATION SYNERGIES

	Traditional	HepB	Hib	YF	Pneumo	Rota	MenA	HPV	JE	Rabies	Rubella	Typhoid
Cholera												
HPV												
JE												

### Rabies

POTENTIAL IMPLEMENTATION SYNERGIES

	Traditional	HepB	Hib	YF	Pneumo	Rota	MenA	Cholera	HPV	JE	Rabies	Rubella	Typhoid
Rabies													
Rubella													
Typhoid													

### Implementation Cost Analysis Methodology

#### STEP 3: POTENTIAL IMPLEMENTATION SYNERGIES – SUMMARY

	Traditional	HepB	Hib	YF	Pneumo	Rota	MenA	Cholera	HPV	JE	Rabies	Rubella	Typhoid
Cholera									√				√
HPV								√					√
JE													
Rabies													
Rubella													
Typhoid								√	√				

*Traditional = Routine EPI vaccines includes Bacillus Calmette-Guérin (BCG), Diphtheria-tetanus-pertussis (DTP), measles containing vaccines (MCV), oral polio (OPV), Tetanus toxoid (TT)*

**Vaccine-Specific Synergies**

- Leverages traditional EPI systems for routine
- Potential to integrate with meningo-encephalitis WPR and SEAR that include Hib and pneumo
- Potential to increase immunization coverage CDIBP's live attenuated SA 14-14-2 vaccine v

**Other Synergies**

- No other synergies were identified

ing and surveillance (rotavirus)  
 cination programs (cholera, HPV)

h education and clean water & sanitation initiatives  
 ansion of adolescent health programs  
 and maternal health programs  
 d initiatives



# Implementation Cost Analysis Methodology

## STEP 3: RELATIVE COST ASSESSMENT PROCESS

- Leveraging implementation challenges and synergies insights, ASC assessed implementation costs of each vaccine under consideration relative to traditional EPI implementation costs (i.e., higher, similar, lower)
- Final cost assessment developed in consultation with experts

# Implementation Cost Analysis Methodology

## STEP 3: RELATIVE COST ASSESSMENT

### Cholera

#### RELATIVE COST ASSESSMENT

Implementation Cost Categories	Incremental Vaccine Implementation Cost Relative to Traditional EPI Costs	
	Periodic Campaigns (1 or 5 - 15yo or 1 or 5 - 49yo every 3 years)	
Cold Chain		

### JE

#### RELATIVE COST ASSESSMENT

Implementation Cost Categories	Incremental Vaccine Implementation Cost Relative to Traditional EPI Costs	
	Routine (infants + 1 yr boost)	Catch-up Campaign (1 - 15yo)
Cold Chain		
Waste Management	• Typical	• Large short-term capacity need given size of

### Rabies

#### RELATIVE COST ASSESSMENT

Implementation Cost Categories	Incremental Vaccine Implementation Cost Relative to Traditional EPI Costs	
	Post-Exposure Prophylaxis	
Cold Chain	<ul style="list-style-type: none"> <li>• Potentially significant impact where supply prior to GAVI support was insufficient to meet demand, especially in newly established regional rabies dog bite treatment centers                             <ul style="list-style-type: none"> <li>- Need for vaccine &amp; RIG vial management and usage, particularly in small decentralized dog bite treatment centers</li> </ul> </li> </ul>	
Waste Management	• Less than typical given animal bite-driven demand	
Transport	• Less than typical given regional rabies bite centers usually serving large populations where animal bites are more common	
Training of Personnel	• More than typical given IM to ID route of administration transition in rabies dog bite treatment centers and potential increased use of RIG	
Communication, Education, Social Mobilization	• More than typical given significant impact on disease burden with educational awareness on bite prevention	
Monitoring & Evaluation, Surveillance	• Typical, given the need to strengthen systems for monitoring and evaluation given current under reporting of rabies cases	
Service Delivery	• Less than typical given regional rabies dog bite treatment centers	

### Rubella

#### RELATIVE COST ASSESSMENT

Implementation Cost Categories	Incremental Vaccine Implementation Cost Relative to Traditional EPI Costs		
	Routine (1yo)	Catch-up Campaign (2-19yo)	Catch-up Campaign (15-39yo or 20-39yo females)
Cold Chain	• Less than typical given		

### Typhoid

#### RELATIVE COST ASSESSMENT

Implementation Cost Categories	Incremental Vaccine Implementation Cost Relative to Traditional EPI Costs	
	Periodic Campaigns (2-15yo every 3 yrs or 5-15yo every 3 or 7 years)	
Cold Chain		
Waste Management	• Large short-term capacity need given cohort age ranges	

### HPV

#### RELATIVE COST ASSESSMENT

Implementation Cost Categories	Incremental Vaccine Implementation Cost Relative to Traditional EPI Costs	
	Routine (10yo)	Catch-up Campaign (11 - 14yo)
Cold Chain	• Less than typical (fewer subjects in 10yo vs. birth cohort)	• Short-term capacity need
Waste Management		
Transport	• More than typical due to both school & community delivery requirements	• Significantly greater short-term capacity need due to both school & community delivery requirements
Training of Personnel	• Common route of administration (IM), but significant disease training required	
Communication, Education, Social Mobilization	• More than typical due to high level of community sensitization required and need for school based and community education	
Monitoring & Evaluation, Surveillance	• More than typical given cervical cancer disease impact cannot be measured for ~20 years or more	
Service Delivery	• More than typical due to need to reach schools and clinics	

# Implementation Cost Analysis Methodology

## STEP 4: ACTUAL COST ASSESSMENT PROCESS

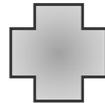
- The most notable implementation costing resources (GIVS\*, WHO-UNICEF Guidelines, PATH AIM) provide:
  - Costing methodology with examples based on historical expenses and benchmarks (e.g. x% of y expense)
  - Overall costs assessment for a specific vaccine portfolio implemented over a specified time period
- It is difficult to extract benchmarks that can be applied to the implementation cost assessment of another individual vaccine or vaccine portfolio
- However, the GIVs model provides a robust methodological foundation by which to assess VIS vaccines by leveraging proxy disease and vaccine characteristic data

\* Wolfson LJ, Gasse F, et al., *Estimating the costs of achieving the WHO-UNICEF Global Immunization Vision and Strategy, 2006-2015*. Bull World Health Organ 2008;86:27  
<http://www.who.int/bulletin/volumes/86/1/07-045096/en/index.html>

# Implementation Cost Analysis Methodology

## STEP 4: GIVS MODEL METHODOLOGY – ROUTINE\*

**Total Average Marginal Systems Scale-Up Cost**



**Total Average Marginal Delivery Scale-Up Cost**



**Total Average Marginal Scale-Up Costs**

Cost Categories
Cold Chain
Waste Management
Transport
Personnel Training
Communication, Education, Social Mobilization
Monitoring & Evaluation, Surveillance

Cost Categories
Service Delivery**

- Costs are calculated by determining the difference between the immunization system as is and the immunization system given the adoption of a new routine vaccine
- Underlying data assumptions are both vaccine and country-specific and are based mainly on historical immunization data, country FSPs, WHO ICE-T, investment case projections, and various standard planning and financial variables
- The overall cost is the sum of the individual country costs per dose which are then multiplied by the VIS demand forecasts to produce an annual country-specific and aggregate implementation cost forecast

\*\* Incremental cost added when vaccination strategy requires additional visits outside of the EPI schedule; assumes 10 minute health visits

\* Wolfson LJ, Gasse F, et al., *Estimating the costs of achieving the WHO-UNICEF Global Immunization Vision and Strategy, 2006-2015. Bull World Health Organ* 2008;86:27 <http://www.who.int/bulletin/volumes/86/1/07-045096/en/index.html>

# Implementation Cost Analysis Methodology

## VIS PROXY ASSUMPTIONS – ROUTINE VACCINATION\*

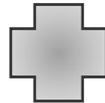
Disease	GAVI VISP Cohorts	Marginal System Scale-Up (GIVS Model)		Marginal Delivery Scale-Up (WHO: Adams)	
		Doses/Tx	Proxy Cohort	Doses Outside EPI schedule	Service Delivery Cost
HPV	10 yo females	3	HPV (11 yo females)	3	Country specific estimates of cost for 10 minute health facility visit (USD 2004)
JE	Infants (<1 yo)	2 (boost included)	JE (< 1yo)	0	
Rubella	Surviving Infants (1 yo)	2 (boost included)	Rubella (1st & 2 <sup>nd</sup> dose Measles)	1	
Typhoid	Infants (<1 yo)	2 (boost included)	Typhoid (< 1yo)	0	

\* Lara Wolfson provided guidance where possible; initial analysis provided by GIVS programmer Richard Schwab

# Implementation Cost Analysis Methodology

## STEP 4: GIVS MODEL METHODOLOGY – CAMPAIGNS\*

**Total Average Marginal  
Systems Scale-Up Cost**



**Total Average Marginal  
Delivery Scale-Up Cost**



**Total Average  
Marginal Scale-Up  
Costs**

Cost Categories
Cold Chain
Waste Management
Transport
Personnel Training
Communication, Education, Social Mobilization

Cost Categories
Per Diem

\* Wolfson LJ, Gasse F, et al., Estimating the costs of achieving the WHO-UNICEF Global Immunization Vision and Strategy, 2006-2015. Bull World Health Organ 2008;86:27 <http://www.who.int/bulletin/volumes/86/1/07-045096/en/index.html>

# Implementation Cost Analysis Methodology

## VIS PROXY ASSUMPTIONS – CAMPAIGNS\*

Disease	GAVI VISP			GIVS Model
	Cohorts	Campaign Frequency	Doses/Tx	Cost Per Dose Disease Proxy
<b>JE</b>	1-15 yo	Once, upon introduction	1	Measles
<b>Rubella</b>	2-19 yo	1	1	Measles
	15-39 yo females	1	1	Tt (WCBA)
	20-29 yo females	1	1	
	<b>Cholera</b>	5-15 yo	Every 3 yrs	2
1-15 yo	Every 3 yrs	2		
5-49 yo	Every 3 yrs	2		
1-49 yo	Every 3 yrs	2		
<b>Typhoid</b>	2-15 yo (50%)	Every 3 yrs	1	Measles
	2-15 yo (50%)	Every 3 yrs	2	
	5-15 yo (25)	Every 3 yrs	3	
	5-15 yo (50)	Every 3 yrs	1	
	5-15 yo (25%)	Every 3 yrs	2	
	1-15 yo	Once, upon introduction	2	

\* Lara Wolfson (WHO) provided guidance where possible; initial analysis provided by GIVS programmer Richard Schwab

# Implementation Cost Analysis Methodology

## STEP 4: ACTUAL COST ASSESSMENT

### Portfolio Option ('A')

ANNUAL COUNTRY IMPLEMENTATION COST FORECAST *Integrated Adoption Forecast 2009-2020*

### Portfolio Option 'B'

ANNUAL COUNTRY IMPLEMENTATION COST FORECAST *Integrated Adoption Forecast 2009-2020*

### Portfolio Option 'C'

ANNUAL COUNTRY IMPLEMENTATION COST FORECAST *Integrated Adoption Forecast 2009-2020*

Disease	Country Implementation Costs (\$M)											Total (\$M)
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	
HPV Routine	0	4	7	11	20	26	39					
JE Routine + Catch-up	0	0	30	29	40	39	52					
Routine + boost	0	0	5	18	29	39	46	54				
15-39yo Catch-up	0	0	24	11	11	1	6	12				
Rubella Delayed	0	66	30	16	42	36	44					
Routine + boost	0	14	16	18	32	35	38					
15-39yo WCBA	0	51	13	0	10	1	5					
Typhoid Routine + Catch-up	0	0	8	19	26	52	68					
Routine + boost	0	0	3	19	19	34	31					
15-39yo WCBA	0	0	5	9	7	18	18					
<b>Total Partner Costs</b>	<b>\$0</b>	<b>\$69</b>	<b>\$75</b>	<b>\$76</b>	<b>\$128</b>	<b>\$153</b>	<b>\$203</b>	<b>\$2</b>				

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Country Implementation Costs (\$M)						
	2012	2013	2014	2015	2016	
1						
7	11	20	26	39	90	
30	29	40	39	52	67	
5	18	29	39	46	54	
24	11	11	1	6	12	
30	16	42	36	44	50	
16	16	32	35	38	45	
13	0	10	1	5	4	
67	\$57	\$102	\$102	\$135	\$206	

Disease	Country Implementation Costs (\$M)											Total (\$M)
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	
	7	11	20	26	39	90	136	191	238	272	1,033	
	30	29	40	39	52	67	60	64	67	67	516	
	5	18	29	39	46	54	60	60	67	67	452	
	24	11	11	1	6	12	0	0	0	0	64	
	8	19	26	52	68	78	111	132	129	139	762	
	3	10	19	34	31	71	89	108	122	135	845	
	5	9	7	18	18	7	21	24	7	4	120	
	6	6	7	8	9	10	10	10	10	10	90	
	60	17	110	42	65	71	90	62	57	64	838	
	16	16	32	35	38	45	49	53	56	59	414	
	35	1	71	6	23	22	35	8	0	4	357	
	9	0	7	1	4	3	8	1	1	1	67	
	\$111	\$83	\$203	\$166	\$233	\$315	\$406	\$460	\$501	\$553	\$3,241	

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### Portfolio Option Summary

COUNTRY IMPLEMENTATION COST SUMMARY *Integrated Adoption Forecast 2009-2020*

Cost	Portfolio Option 'A'	Portfolio Option 'B'	Portfolio Option 'C'
Routine Vaccination-Related Costs (\$M)	1,898	2,542	2,542
Campaign-Related Costs (\$M)	162	281	609
Other Vaccination-Related Costs (\$M)	n/a	n/a	90
<b>Total Country Imp Costs (\$M)</b>	<b>\$2,060</b>	<b>\$2,823</b>	<b>\$3,241</b>

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\* Lara Wolfson (WHO) provided guidance where possible; initial analysis provided by GIVS programmer Richard Schwab

Disease-specific and portfolio-specific summaries can be found in the disease and portfolio analysis presentations, respectively, posted on GAVI's website [http://www.gavialliance.org/vision/strategy/vaccin\\_investment/index.php](http://www.gavialliance.org/vision/strategy/vaccin_investment/index.php)

# Implementation Cost Analysis Methodology

Vaccination Strategy	Total Vaccine Cost (\$M)	GAVI Vaccine Cost (\$M)	Country Vaccine Cost (\$M)	Deaths Averted (x1000)	<5 Deaths Averted (x1000)	Cases Averted (x1000)	GAVI Cost (\$)/ Death Averted	GAVI Cost (\$)/ Case Averted	Country Imp Costs (\$M)
<b>Cholera</b> 1-15yo Campaign Every 3 Years	\$1,480	\$1,227	253	130	33	6,654	\$9,462	\$184	<b>\$425</b>
<b>Cholera</b> 1-49yo Campaign Every 3 Years	\$3,198	\$2,659	\$538	132	10	6,046	\$20,075	\$440	<b>\$888</b>
<b>HPV</b> Routine 10yo Female Vaccination	\$1,293	\$1,261	\$31	707	n/a	870	\$1,784	\$1,449	<b>\$1,033</b>
<b>JE</b> Routine Infant Vaccination with boost after 12 mos + 1-15yo Catch-up Campaign	\$1,034	\$974	\$60	140	93	765	\$6,967	\$1,274	<b>\$516</b>
<b>Rabies</b> Post-Exposure Prophylaxis	\$2,945	\$2,882	\$63	483	24	n/a	\$5,970	n/a	<b>\$90</b>
<b>Rubella (rapid impact)</b> Routine 1yo Vaccination with boost at 4yo + 2-19yo Campaign + 20-29yo WBCA Campaign	\$884	\$608	\$276	74*	31*	417*	\$8,222*	\$1,459*	<b>\$838</b>
<b>Rubella (delayed impact)</b> Routine 1yo Vaccination with boost at 4yo + 15-39yo WBCA Campaign	\$540	\$370	\$170	22*	13*	110*	\$16,742*	\$3,363*	<b>\$511</b>
<b>Rubella Incremental</b> From Delayed to Rapid	\$344	\$238	\$106	52*	18*	307*	\$4,577*	\$775*	<b>\$327</b>
<b>Typhoid</b> Routine Infant Vaccination with boost after 12mos	\$211	\$182	\$29	154	154	15,485	\$1,182	\$12	<b>\$643</b>
<b>Typhoid</b> Routine Infant Vaccination with boost after 12mos + 1-15yo Catch-up	\$529	\$459	\$70	178	160	18,093	\$2,579	\$25	<b>\$763</b>
<b>Typhoid</b> 2-15yo Campaign Every 3 Years	\$443	\$364	\$79	39	8	4,248	\$9,259	\$86	<b>\$218</b>
<b>Typhoid</b> 5-15yo Campaign Every 3 Years	\$510	\$432	\$78	36	n/a	3,855	\$11,985	\$112	<b>\$197</b>



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- Board Recommendation 81



# Partner Cost Analysis Methodology

## PARTNER COST ASSESSMENT PROCESS (I)

- Leveraged current GAVI Work Plan budget for Strategic Goal #2, to derive proxy cost multipliers from the pneumococcal and rotavirus vaccine implementation cost data
- First segmented SG2 Work Plan line items into one of three categories
  - **"Country-related" Costs:** include activities that were specific to a given number of countries and diseases (e.g., surveillance systems support for pneumo and rotavirus in GAVI countries)
  - **"Disease-related" Costs:** costs which benefit the Pneumococcal and Rotavirus programs but are not country specific (e.g., regional estimation and dissemination of pneumococcal and rotavirus vaccine impact and disease burden data)
  - **"Portfolio-related" costs:** include activities that could be applicable to additional diseases and an expanded AVI platform (e.g. global and regional policies developed to assist countries in making vaccine-introduction decisions)
- Once costs were segmented, the cost multiplier was derived by calculating the annual budget associated with each segment and then applying the appropriate divisor:
  - Country costs were divided by the number of countries underlying the cost estimate
  - Disease costs were divided by 2 (Rota and Pneumo)
  - Portfolio costs were not divided further



# Partner Cost Analysis Methodology

## PARTNER COST ASSESSMENT PROCESS (II)

- Once multipliers were determined, they were applied to the three VIS portfolios:
  - The proxy country cost was multiplied by the # of countries in each portfolio
  - The proxy disease cost was multiplied by the # of diseases in each portfolio
  - The proxy portfolio cost was applied as a fixed cost to each portfolio with a 5% incremental increase for each new disease in the GAVI portfolio
- Key assumptions guided the application of multipliers
  - Country-related costs were assumed to be one-time “introduction costs” and were not repeated after the year of introduction.
  - Disease-related costs were treated as “time-limited” introduction costs and only applied to the first three years of disease introduction
  - Portfolio-related costs were begun 1 year prior to introduction at 50% of the estimated cost and scaled down to 50% of estimated cost in the final year

*Note: This is an indicative costing exercise that may not completely account for economies of scale or appropriately recognize disease-specific funding that may already be in place*

# Partner Cost Analysis Methodology

## PARTNER COST ASSESSMENT

	Partner Cost Category	GAVI Partner Costs (\$M)												
		2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	TOTAL
Portfolio A	Country-Related Costs	0	7	5	4	5	4	7	11	8	8	1	2	60
	Disease-Related Costs	0	4	6	6	2	0	0	0	0	0	0	0	17
	Portfolio-Related Costs	19	38	40	40	40	40	40	40	38	38	36	18	426
	<b>Total Portfolio Cost</b>	<b>\$19</b>	<b>\$48</b>	<b>\$50</b>	<b>\$49</b>	<b>\$47</b>	<b>\$44</b>	<b>\$47</b>	<b>\$51</b>	<b>\$46</b>	<b>\$46</b>	<b>\$37</b>	<b>\$20</b>	<b>\$503</b>

	Partner Cost Category	GAVI Partner Costs (\$M)												
		2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	TOTAL
Portfolio B	Country-Related Costs	0	7	6	5	6	7	8	12	9	10	1	2	72
	Disease-Related Costs	0	4	8	8	4	0	0	0	0	0	0	0	23
	Portfolio-Related Costs	19	38	41	41	41	41	41	41	40	40	38	19	443
	<b>Total Portfolio Cost</b>	<b>\$19</b>	<b>\$48</b>	<b>\$55</b>	<b>\$54</b>	<b>\$51</b>	<b>\$49</b>	<b>\$50</b>	<b>\$54</b>	<b>\$49</b>	<b>\$50</b>	<b>\$39</b>	<b>\$21</b>	<b>\$537</b>

	Partner Cost Category	GAVI Partner Costs (\$M)												
		2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	TOTAL
Portfolio C	Country-Related Costs		11	11	6	10	12	10	13	10	11	1	2	97
	Disease-Related Costs		6	9	9	4								28
	Portfolio-Related Costs	20	40	43	43	43	43	43	43	41	41	38	19	459
	<b>Total Portfolio Cost</b>	<b>\$20</b>	<b>\$56</b>	<b>\$64</b>	<b>\$59</b>	<b>\$57</b>	<b>\$55</b>	<b>\$53</b>	<b>\$56</b>	<b>\$51</b>	<b>\$53</b>	<b>\$39</b>	<b>\$21</b>	<b>\$584</b>

### Proxy Cost Segment Multipliers:

Country-Related Activities:	\$503,749	per country
Disease-Related Activities:	\$1,880,611	per disease
Portfolio-Related Activities:	\$34,578,824	for portfolio



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# Portfolio Analysis Results

## PORTFOLIO ANALYSIS

### Portfolio Option ('A')

#### PORTFOLIO DEFINITION

Disease	Decision	Vaccination Strategy	Rationale
HPV	Routine 10yo Female Vaccination		Disease burden impact portfolio Severe long-term sequelae Access to current or pending Vaccination strategy Consensus vaccination Disputed

### Portfolio Option ('A')

#### METRIC SUMMARY – BY STRATEGY

Strategy	Total Vaccine Cost (\$M)	GAVI Vaccine Cost (\$M)	Country Vaccine Cost (\$M)	Deaths Averted (x1000)	<5 Deaths Averted (x1000)	Cases Averted (x1000)	GAVI Cost (\$)/Death Averted	GAVI Cost (\$)/Case Averted	Long-Term Sequelae	Country Imp. Costs (\$M)	Wt. Avg. Country Imp. Cost (x)
HPV Routine 10yo Female Vaccination	\$1,293	\$1,261	\$31	707	n/a	870	\$1,784	\$1,449	Severe	\$1,033	\$16.35

### Portfolio Option ('A')

#### ANNUAL COUNTRY IMPLEMENTATION COST FORECAST

Disease	Country Implementation Costs							
	2009	2010	2011	2012	2013	2014	2015	2016
HPV Routine	0	4	7	11	20	26	39	9
JJE Routine + Catch-up	0	0	30	29	40	39	52	6
Rubella Delayed	0	68	30	18	42	36	44	5
Rubella + boost	0	14	16	15	32	35	39	4
15-39yo WBCA	0	51	13	0	10	7	5	4
<b>Total Partner Costs</b>	<b>\$0</b>	<b>\$69</b>	<b>\$67</b>	<b>\$57</b>	<b>\$102</b>	<b>\$102</b>	<b>\$135</b>	<b>\$20</b>

### Portfolio Option ('A')

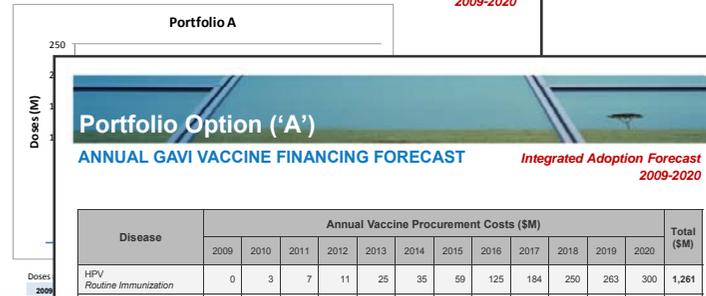
#### TOTAL PORTFOLIO COST

Cost Component	Cost
GAVI Vaccine Cost (\$M)	2,606
Country Vaccine Co-Pay Cost (\$M)	261
<b>Total Vaccine Cost (\$M)</b>	<b>\$2,867</b>
Country Implementation Cost (\$M)	2,060
Partner Associated Cost (\$M)	454
<b>TOTAL COST (\$M)</b>	<b>\$5,381</b>

Deaths Averted (x1000)	<5 Deaths Averted (x1000)	Cases Averted (x1000)	GAVI Cost (\$)/Death Averted	GAVI Cost (\$)/Case Averted
869	106	1,745	\$2,998	\$1,493

### Portfolio Option 'A'

#### DEMAND FORECAST



### Portfolio Option ('A')

#### ANNUAL GAVI VACCINE FINANCING FORECAST

Disease	Annual Vaccine Procurement Costs (\$M)												Total (\$M)
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	
HPV Routine Immunization	0	3	7	11	25	35	59	125	184	250	283	300	1,261

### Portfolio Option ('A')

#### ANNUAL GAVI PARTNER COST FORECAST

Disease	GAVI Partner Costs (\$M)												Total (\$M)						
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020							
HPV Routine	0	4	7	11	20	26	39	9	5	4	5	4	7	11	8	8	1	2	60
JJE Routine + Catch-up	0	0	30	29	40	39	52	6	20	20	7	0	0	0	0	0	0	0	61
Rubella Delayed	0	68	30	18	42	36	44	5	30	30	30	30	30	30	30	30	15	333	
Rubella + boost	0	14	16	15	32	35	39	4	30	30	30	30	30	30	30	30	30	30	333
15-39yo WBCA	0	51	13	0	10	7	5	4	\$55	\$54	\$42	\$34	\$37	\$41	\$38	\$38	\$31	\$17	\$454

# Portfolio Analysis Results

## PORTFOLIO DEFINITIONS

Portfolio Option 'A'	Portfolio Option 'B'	Portfolio Option 'C'
<ul style="list-style-type: none"> <li>• <b>HPV</b> <ul style="list-style-type: none"> <li>– Routine Vaccination</li> </ul> </li> <li>• <b>JE</b> <ul style="list-style-type: none"> <li>– Routine Vaccination + Boost</li> <li>– 1-15yo Catch-up</li> </ul> </li> <li>• <b>Rubella Delayed Impact</b> <ul style="list-style-type: none"> <li>– Routine Vaccination + Boost</li> <li>– 15-39yo Women of Childbearing Age (WCBA) Catch-up</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>HPV</b> <ul style="list-style-type: none"> <li>– Routine Vaccination</li> </ul> </li> <li>• <b>JE</b> <ul style="list-style-type: none"> <li>– Routine Vaccination + Boost</li> <li>– 1-15yo Catch-up</li> </ul> </li> <li>• <b>Rubella Delayed Impact</b> <ul style="list-style-type: none"> <li>– Routine Vaccination + Boost</li> <li>– 15-39yo WCBA Catch-up</li> </ul> </li> <li>• <b>Typhoid</b> <ul style="list-style-type: none"> <li>– Routine Vaccination + Boost</li> <li>– 1-15yo Catch-up</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>HPV</b> <ul style="list-style-type: none"> <li>– Routine Vaccination</li> </ul> </li> <li>• <b>JE</b> <ul style="list-style-type: none"> <li>– Routine Vaccination + Boost</li> <li>– 1-15yo Catch-up</li> </ul> </li> <li>• <b>Typhoid</b> <ul style="list-style-type: none"> <li>– Routine Vaccination + Boost</li> <li>– 1-15yo Catch-up</li> </ul> </li> <li>• <b>Rabies</b> <ul style="list-style-type: none"> <li>– Post-Exposure Prophylaxis</li> </ul> </li> <li>• <b>Rubella Rapid Impact</b> <ul style="list-style-type: none"> <li>– Routine Vaccination + Boost</li> <li>– 20-29yo WCBA Catch-up</li> <li>– 1-19yo Catch-up</li> </ul> </li> </ul>

# Portfolio Analysis Results

## PORTFOLIO COST SUMMARY

*Integrated Adoption Forecast  
2009-2020*

Cost Component	Portfolio Option 'A'	Portfolio Option 'B'	Portfolio Option 'C'
GAVI Vaccine Cost (\$M)	2,606	3,065	6,185
Country Co-Pay Cost (\$M)	261	331	499
<b>Total Vaccine Cost (\$M)</b>	<b>\$2,867</b>	<b>\$3,396</b>	<b>\$6,684</b>
Country Implementation Cost (\$M)	2,060	2,823	3,241
Partner Cost (\$M)	503	537	584
<b>TOTAL COST (\$M)</b>	<b>\$5,430</b>	<b>\$6,756</b>	<b>\$10,509</b>

# Portfolio Analysis Results

## PORTFOLIO METRIC SUMMARY

*Integrated Adoption Forecast  
2009-2020*

Metric	Portfolio Option 'A'	Portfolio Option 'B'	Portfolio Option 'C'
Total Projected Deaths Averted (x1000)	869	1,046	1,582
Total Projected Deaths Averted <5yo (x1000)	106	266	308
Total Cases Averted (x1000)	1,745	19,838	20,145
GAVI Cost per Death Averted (\$)	\$2,998	\$2,929	\$3,910
GAVI Cost per Case Averted (\$)	\$1,493	\$155	\$307

# Portfolio Option Summary

## PORTFOLIO SUMMARY

## *Conservative Adoption Forecast 2009-2020*

Cost	Portfolio Option 'A'	Portfolio Option 'B'	Portfolio Option 'C'
GAVI Vaccine Cost (\$M)	842	965	3,695
Country Vaccine Co-Pay Cost (\$M)	175	193	351
Total Vaccine Cost (\$M)	1,017	1,158	4,047
Total Projected Deaths Averted (x1000)	200	240	718
Total Projected Deaths Averted <5yo (x1000)	46	80	117
Total Cases Averted (x1000)	572	4,617	4,906
GAVI Cost per Death Averted (\$)	\$4,207	\$4,023	\$5,149
GAVI Cost per Case Averted (\$)	\$1,471	\$209	\$753

# Portfolio Option Summary

## PORTFOLIO SUMMARY *Without India*

*Integrated Adoption Forecast  
2009-2020*

Cost	Portfolio Option 'A'	Portfolio Option 'B'	Portfolio Option 'C'
GAVI Vaccine Cost (\$M)	2,100	2,456	3,785
Country Vaccine Co-Pay Cost (\$M)	179	234	329
Total Vaccine Cost (\$M)	\$2,279	\$2,690	\$4,114
Total Projected Deaths Averted (x1000)	667	818	1,058
Total Projected Deaths Averted <5yo (x1000)	100	238	259
Total Cases Averted (x1000)	1,460	16,725	16,911
GAVI Cost per Death Averted (\$)	\$3,149	\$3,005	\$3,578
GAVI Cost per Case Averted (\$)	\$1,439	\$147	\$224



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## Board Recommendation

The Board is asked to:

- Consider at a minimum, prioritizing Portfolio A (HPV, JE and Rubella) for the 2009 – 2020 time period, with potential financial implications of \$2.6 billion (\$1.1 billion for 2009 – 2015). Fundraising targets would be set accordingly.

*OR*

- Prioritize Portfolio B (HPV, JE, Rubella and Typhoid) for the 2009 – 2020 time period, with potential financial implications of \$3.1 billion (\$1.3 billion for 2009 – 2015). Fundraising targets would be set accordingly.\*

*AND*

- Set aside \$12 million (if Portfolio B is endorsed) or \$18 million (if Portfolio A is endorsed) for operations research on specific vaccine strategies

\* GAVI Working Group-preferred portfolio