GAVI Vaccine Investment Strategy

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Rising to the challenge
GAVI Alliance Partners' Forum
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GAVI ALLIANCE

Background

- Individual investment cases until 2008
  - Heb B, Hib, Penta, yellow fever, polio, maternal/neonatal tetanus, measles, rotavirus, pneumococcal vaccines
- First comprehensive vaccine investment strategy in 2008, prioritised
  - Men A, HPV, Rubella
  - JE, Typhoid (when available)
  - Malaria, Dengue (radar)

Disease & Vaccine Landscape Analysis (2008)

DISEASE CHARACTERIZATION

JE

Disease Overview

DISEASE PATHOGEN, TRANSMISSION & TARGET POPULATION[1]

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

JE

Disease Overview

DISEASE IMPACT[1]

- 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

JE

Disease Overview

NON-VACCINE PREVENTION & TREATMENT INTERVENTIONS[8]

- 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

JE

Disease Overview

INEQUITIES

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

and

JE

Disease Overview

0 = None Reported Data Not Available or Non-Endemic

DISEASE BURDEN IN GAVI-ELIGIBLE COUNTRIES – MORBIDITY[3-6]

Country	WHO Region	Morbidity (Annual Cases)	Morbidity Rate (Cases/100,000)
Bangladesh	SEARO	15,606	10
Bhutan	SEARO	65	10
India	SEARO	115,492	10
Indonesia	SEARO	23,015	10
Korea, DPR	SEARO	2,404	10
Myanmar	SEARO	4,884	10
Nepal	SEARO	2,758	10
Sri Lanka	SEARO	1,947	10
Timor-Leste	SEARO	109	10
Pakistan	EMRO	7,967	5
Lao PDR	WPRO	198	4
Viet Nam	WPRO	2,979	4
Cambodia	WPRO	489	4
Papua New Guinea	WPRO	213	4
Afghanistan	EMRO		
Angola	AFRO		
Armenia	EURO		
Azerbaijan	EURO		
Benin	AFRO		
Bolivia	AMRO		
Burkina Faso	AFRO		
Burundi	AFRO		
Cameroon	AFRO		
Central African Republic	AFRO		
Chad	AFRO		
Comoros	AFRO		
Congo, Dem. Rep.	AFRO		
Congo, Rep.	AFRO		
Côte d'Ivoire	AFRO		
Cuba	AMRO		
Djibouti	EMRO		
Eritrea	AFRO		
Ethiopia	AFRO		
Gambia, The	AFRO		
Georgia	EURO		
Ghana	AFRO		

Country	WHO Region	Morbidity (Annual Cases)	Morbidity Rate (Cases/100,000)
Guinea	AFRO		
Guinea-Bissau	AFRO		
Guyana	AMRO		
Haiti	AMRO		
Honduras	AMRO		
Kenya	AFRO		
Kiribati	WPRO		
Kyrgyzstan	EURO		
Lesotho	AFRO		
Liberia	AFRO		
Madagascar	AFRO		
Malawi	AFRO		
Mali	AFRO		
Mauritania	AFRO		
Moldova, Rep. of	EURO		
Mongolia	WPRO		
Mozambique	AFRO		
Nicaragua	AMRO		
Niger	AFRO		
Nigeria	AFRO		
Rwanda	AFRO		
São Tomé and Principe	AFRO		
Senegal	AFRO		
Sierra Leone	AFRO		
Solomon Islands	WPRO		
Somalia	EMRO		
Sudan	EMRO		
Tajikistan	EURO		
Tanzania, United Rep. of	AFRO		
Togo	AFRO		
Uganda	AFRO		
Ukraine	EURO		
Uzbekistan	EURO		
Yemen	EMRO		
Zambia	AFRO		
Zimbabwe	AFRO		

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JE

Disease Overview

0 = None Reported Data Not Available or Non-Endemic

DISEASE BURDEN IN GAVI-ELIGIBLE COUNTRIES – MORTALITY[4-7]

Country	WHO Region	Mortality (Annual Deaths)	Mortality Rate (Deaths/1,000,000)
Bangladesh	SEARO	4,682	31
Bhutan	SEARO	19	31
India	SEARO	34,648	31
Indonesia	SEARO	6,905	31
Korea, DPR	SEARO	721	31
Myanmar	SEARO	1,465	31
Nepal	SEARO	827	31
Sri Lanka	SEARO	584	31
Timor-Leste	SEARO	33	31
Pakistan	EMRO	2,390	15
Cambodia	WPRO	147	11
Lao PDR	WPRO	60	11
Papua New Guinea	WPRO	64	11
Viet Nam	WPRO	894	11
Afghanistan	EMRO		
Angola	AFRO		
Armenia	EURO		
Azerbaijan	EURO		
Benin	AFRO		
Bolivia	AMRO		
Burkina Faso	AFRO		
Burundi	AFRO		
Cameroon	AFRO		
Central African Republic	AFRO		
Chad	AFRO		
Comoros	AFRO		
Congo, Dem. Rep.	AFRO		
Congo, Rep.	AFRO		
Côte d'Ivoire	AFRO		
Cuba	AMRO		
Djibouti	EMRO		
Eritrea	AFRO		
Ethiopia	AFRO		
Gambia, The	AFRO		
Georgia	EURO		
Ghana	AFRO		

Country	WHO Region	Mortality (Annual Deaths)	Mortality Rate (Deaths/1,000,000)
Guinea	AFRO		
Guinea-Bissau	AFRO		
Guyana	AMRO		
Haiti	AMRO		
Honduras	AMRO		
Kenya	AFRO		
Kiribati	WPRO		
Kyrgyzstan	EURO		
Lesotho	AFRO		
Liberia	AFRO		
Madagascar	AFRO		
Malawi	AFRO		
Mali	AFRO		
Mauritania	AFRO		
Moldova, Rep. of	EURO		
Mongolia	WPRO		
Mozambique	AFRO		
Nicaragua	AMRO		
Niger	AFRO		
Nigeria	AFRO		
Rwanda	AFRO		
São Tomé and Principe	AFRO		
Senegal	AFRO		
Sierra Leone	AFRO		
Solomon Islands	WPRO		
Somalia	EMRO		
Sudan	EMRO		
Tajikistan	EURO		
Tanzania, United Rep. of	AFRO		
Togo	AFRO		
Uganda	AFRO		
Ukraine	EURO		
Uzbekistan	EURO		
Yemen	EMRO		
Zambia	AFRO		
Zimbabwe	AFRO		

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* WHO, expert, PDP, PPP reviewed

Disease-specific summaries can be found in the disease analysis presentations posted on GAVI's website
http://www.gavialliance.org/vision/strategy/vaccine_investment/index.php

Disease & Vaccine Landscape Analysis (2008)

VACCINE CHARACTERIZATION

JE

Vaccine Landscape

LICENSED VACCINES

Supplier (1 Partner)	Chengdu (Wuhan, Lanzhour, Shanghai Institute for Biol Products)[9]	Biken (GreenCross, NIPM, GPO, NIHE)[10]	Beijing, Inst of Biolo
Vaccine	SA14-14-2 Attenuated	JE-Vax	Inactivate
Strain / Antigen	SA 14-14-2 strain	Beijing strain	P3 Stra
Adjuvant / Platform	Live, attenuated, primary hamster kidney cell culture derived	Inactivated, mouse brain-derived	Inactivated, prim kidney cell cultu
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 1yo	2 doses at 12 mo at 2, 6

JE

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.[17]

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JE

Vaccine Landscape

VACCINES IN CLINICAL DEVELOPMENT

Supplier (1 Partner)	Intercell AG (Biological E, WRAIR)[11]	Acambis (Sanofi-Pasteur)[12]	Kaketsuken (Japan)[9]	Biken (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-1
Adjuvant / Platform	Inactivated, Vero cell-derived	Live, attenuated, chimeric Vero cell-derived-YF	Inactivated, Vero cell-derived	Inactivated, deriv
Administration Route	IM	SQ	SQ	SQ
Formulation	Liquid	Lyophilized	Lyophilized	Lyophi
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, 1
Target Population for Licensure	≥ 9mo	≥ 9mo	≥ 6mo	≥ 6m
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 WH

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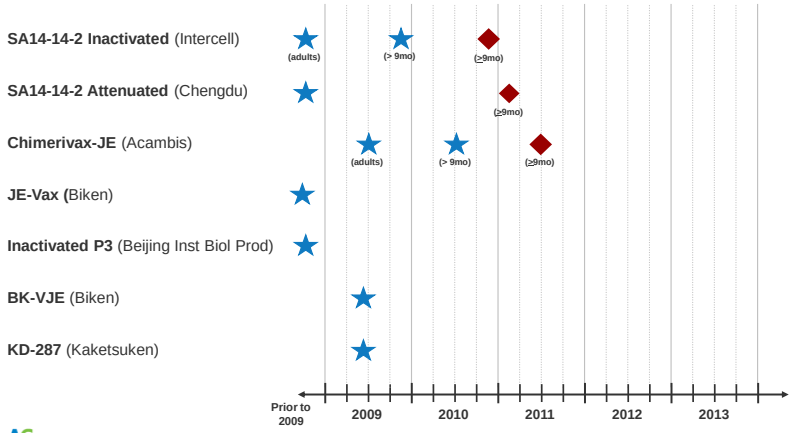
JE

Vaccine Landscape

First NRA Licensure ★
WHO Pre-Qual Approval ◆

ESTIMATED VACCINE AVAILABILITY



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GAVI ALLIANCE

* Supplier, expert, PDP reviewed

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Prioritise among vaccines – Criteria used by board to prioritise vaccines for vaccine investment strategy (VIS)

Health Impact

- Deaths averted
- < 5 deaths averted
- Cases averted

Costs

- GAVI vaccine cost
- GAVI cost per death averted
- GAVI cost per case averted

Strategic Considerations

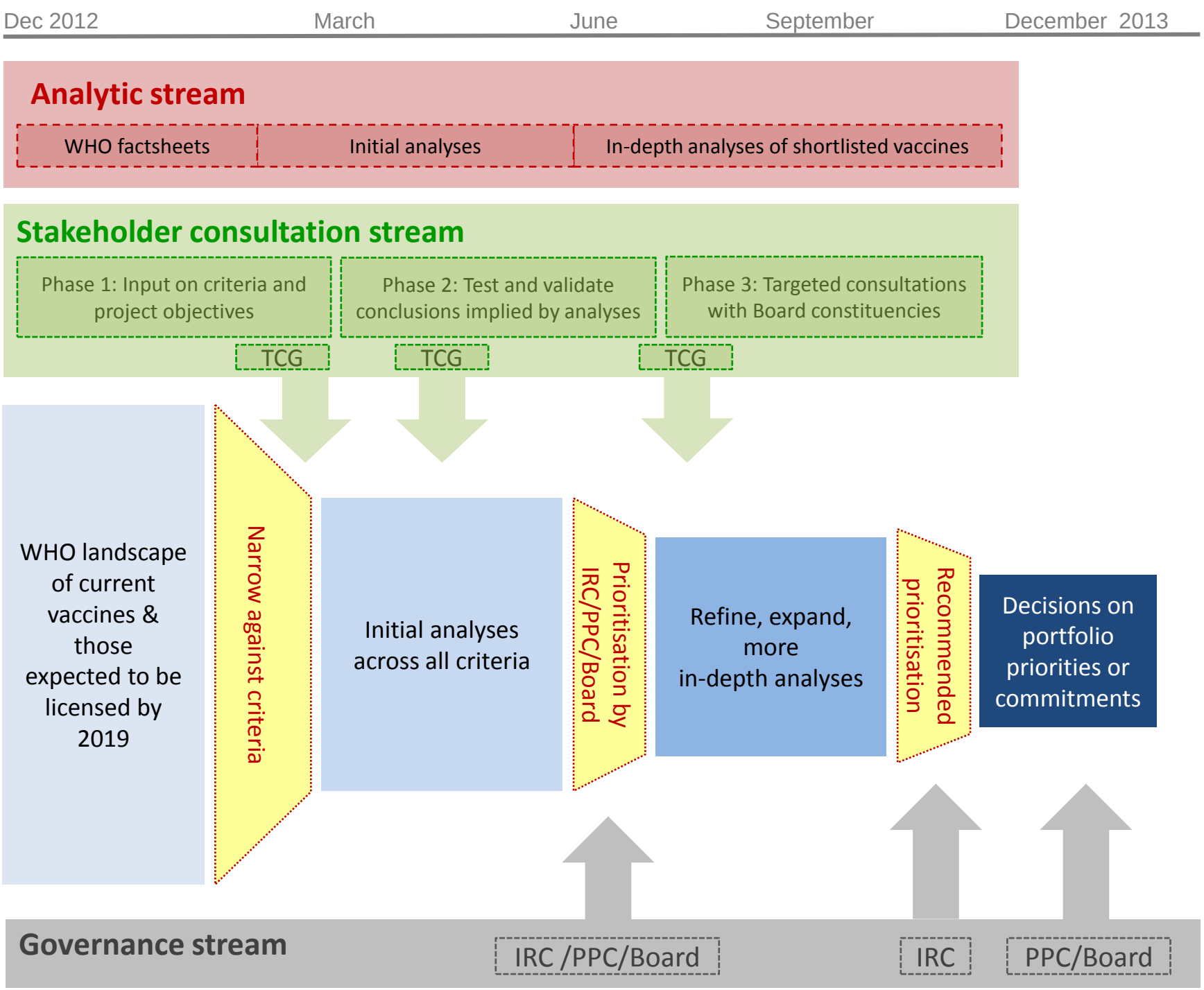
- Integrates with EPI schedule
- Focuses on highly effective vaccines
- Addresses inadequate current interventions (treatment/prevention)
- Addresses inequity for the poor
- Addresses gender inequity

Objective of 2013 vaccine investment strategy

- Identify new, priority investments in vaccines, licensed by 2019, for the GAVI Alliance to achieve its mission and goals in the most efficient and cost-efficient means while adhering to its operating principles
  - Evidenced based portfolio approach
  - Foundation for strategic planning and fundraising
  - Inform country, partner and industry plans

Development of portfolios

- Disease prioritization – build upon 2008 analysis and updated global burden of disease analyses
- Vaccine landscape (WHO)
- Consult countries, industries and experts
- Initial analyses against criteria
- Develop initial portfolio recommendation for Board review


Dec 2012
March
June
September
December 2013
Analytic stream
WHO factsheets
Initial analyses
In-depth analyses of shortlisted vaccines
Stakeholder consultation stream
Phase 1: Input on criteria and project objectives
Phase 2: Test and validate conclusions implied by analyses
Phase 3: Targeted consultations with Board constituencies
TCG
TCG
TCG
WHO landscape of current vaccines & those expected to be licensed by 2019
Narrow against criteria
Initial analyses across all criteria
Prioritisation by IRC/PPC/Board
Refine, expand, more in-depth analyses
Recommended prioritisation
Decisions on portfolio priorities or commitments
Governance stream
IRC /PPC/Board
IRC
PPC/Board

How vaccines will be considered

Strategic considerations

- Integrates with EPI schedule
- Focuses on highly effective vaccines
- Addresses inadequate current interventions (treatment/prevention)
- Addresses inequity for the poor or gender
- Public health context of disease

Health impact

- Burden of disease
- Deaths and under 5 deaths averted
- Cases averted
- DALYs averted (morbidity)

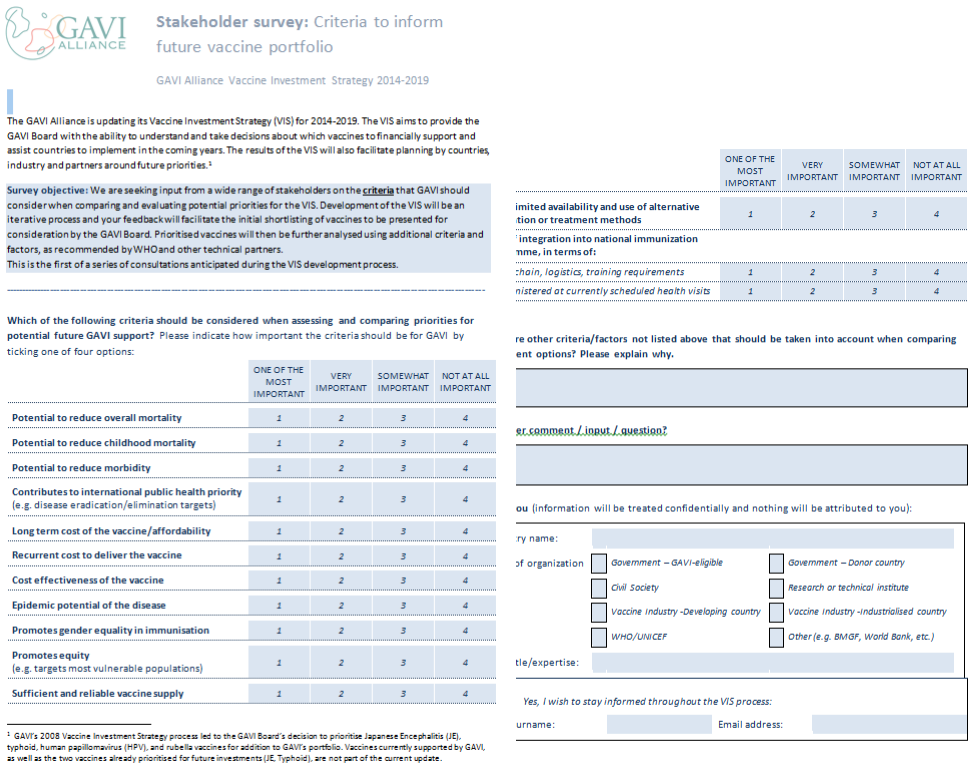
Costs

- Vaccine and implementation
- Per case and death averted, per DALY averted
- Complementary economic and fiscal space analyses

Consultation at the Partners Forum

- Survey on **criteria** that GAVI should consider when evaluating potential priorities

Please participate and give us your feedback!



GAVI ALLIANCE

Stakeholder survey: Criteria to inform future vaccine portfolio

GAVI Alliance Vaccine Investment Strategy 2014-2019

The GAVI Alliance is updating its Vaccine Investment Strategy (VIS) for 2014-2019. The VIS aims to provide the GAVI Board with the ability to understand and take decisions about which vaccines to financially support and assist countries to implement in the coming years. The results of the VIS will also facilitate planning by countries, industry and partners around future priorities.[1]

Survey objective: We are seeking input from a wide range of stakeholders on the **criteria** that GAVI should consider when comparing and evaluating potential priorities for the VIS. Development of the VIS will be an iterative process and your feedback will facilitate the initial shortlisting of vaccines to be presented for consideration by the GAVI Board. Prioritised vaccines will then be further analysed using additional criteria and factors, as recommended by WHO and other technical partners.
This is the first of a series of consultations anticipated during the VIS development process.

Which of the following criteria should be considered when assessing and comparing priorities for potential future GAVI support? Please indicate how important the criteria should be for GAVI by ticking one of four options:

	ONE OF THE MOST IMPORTANT	VERY IMPORTANT	SOMEWHAT IMPORTANT	NOT AT ALL IMPORTANT
Potential to reduce overall mortality	1	2	3	4
Potential to reduce childhood mortality	1	2	3	4
Potential to reduce morbidity	1	2	3	4
Contributes to international public health priority (e.g. disease eradication/elimination targets)	1	2	3	4
Long term cost of the vaccine/affordability	1	2	3	4
Recurrent cost to deliver the vaccine	1	2	3	4
Cost effectiveness of the vaccine	1	2	3	4
Epidemic potential of the disease	1	2	3	4
Promotes gender equality in immunisation	1	2	3	4
Promotes equity (e.g. targets most vulnerable populations)	1	2	3	4
Sufficient and reliable vaccine supply	1	2	3	4

[1] GAVI's 2008 Vaccine Investment Strategy process led to the GAVI Board's decision to prioritise Japanese Encephalitis (JE), typhoid, human papillomavirus (HPV), and rubella vaccines for addition to GAVI's portfolio. Vaccines currently supported by GAVI, as well as the two vaccines already prioritised for future investments (JE, Typhoid), are not part of the current update.

	ONE OF THE MOST IMPORTANT	VERY IMPORTANT	SOMEWHAT IMPORTANT	NOT AT ALL IMPORTANT
imited availability and use of alternative tion or treatment methods	1	2	3	4
integration into national immunization nme, in terms of:				
chain, logistics, training requirements	1	2	3	4
nistered at currently scheduled health visits	1	2	3	4

re other criteria/factors not listed above that should be taken into account when comparing ent options? Please explain why.

er comment / input / question?

ou (information will be treated confidentially and nothing will be attributed to you):

ry name:

of organization: *Government – GAVI-eligible*; *Government – Donor country*; *Civil Society*; *Research or technical institute*; *Vaccine Industry -Developing country*; *Vaccine Industry -Industrialised country*; *WHO/UNICEF*; *Other (e.g. BMGF, World Bank, etc.)*

tle/expertise:

Yes, I wish to stay informed throughout the VIS process:

urname: Email address:

Thank you very much for your participation! Please use the box at the information desk to hand in your survey response or pass it to any GAVI Secretariat staff member

For more information, contact the GAVI Alliance Secretariat: VIS@gavialliance.org

Next steps following a potential 2013 Board decision

- WHO position paper on vaccine use (if not yet available) and prequalification of vaccines
- Secure adequate price
- Develop country application guidelines
- Open GAVI funding window to enable countries to apply

Thank you

GAVI/2011/Ed Harris