Decade of Vaccines Collaboration

Extraordinary meeting of SAGE to review Global Vaccine Action Plan

16 Feb 2012

Feedback obtained from the consultation process, DoVC progress update and January 2012 Executive Board meeting

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Global consultation process has reached around 700 people from more than 90 countries

More than 100 core members in the 8 Working Groups:

- Delivery, Global Access, Public & Political Support, R&D, Costing & Funding, Health & Economic Benfits, Accountability Framework Indicators, Communications

More than 180 additional individuals participated in the working group discussions

Overall, around 720 participants involved in the global consultation process

- From more than 90 countries
- From more than 220 organizations (government agencies, health professional associations, academic institutions, vaccine manufacturers, development partners, civil society organizations, institutions from the private sector, PDPs

Representatives of the missions to UN briefing on the 19th of January in New York and WHO Executive Board on 20 January 20th

More than 20 consultation events have taken place since the last SAGE meeting (I)

Date	Event	Location	Approximate number of participants	Main Stakeholders
8 November 2011	SAGE consultations	Geneva, Switzerland	15	Policymakers
8 November	Grand Challenges consultation	Delhi, India	21	Countries, academia
17 November2011	Vaccine Symposium consultation	Delhi, India	25	Academia
29-30 November 2011	R&D Working Group meeting	Washington DC, US	57	Academia
1 December 2011	Biotechnology Industry Organization (BIO) consultation	San Francisco, US	16	Manufacturers Private sector
6 December	DoVC Leadership Council meeting		6	Global agencies
8 December 2011	African region Consultation	Windhoek, Namibia	150	Countries, health professionals
9 December 2011	Center for Strategic and International Studies (CSIS) Conference	Washington DC, US	70	Academia
9 December 2011	DoVC Cross Working Group meeting	Washington DC, US	18	Academia
15 December 2011	Civil Society Organizations virtual meeting		17	CSOs
19 December 2011	International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) virtual meeting		17	Manufacturers Private sector
10-11 January 2012	Civil Society Organizations (from various regions) consultation	Louvain, Belgium	24	CSOs
11 January 2012	Civil Society Organizations virtual meeting		12	CSOs

More than 20 consultation events have taken place since the last SAGE meeting (II)

Date	Event	Location	Approximate number of participants	Main Stakeholders
16 January – 1 February 2012	Online consultation		48	Countries (WPRO), CSOs, Academia, Private sector, manufacturers
17 January 2012	US CSOs consultation	Washington DC, US	21	CSOs
17-18 January 2012	Costing Working Group meeting	Washington DC, US	12	Global agencies
19 January 2012	UNICEF and DoVC missions brief	New York, US	35	Countries
20 January 2012	WHO Executive Board Meeting	Geneva, Switzerland	N.a.	Countries
24 January 2012	PDP virtual meeting consultation		12	PDPs
25-26 January 2012	Middle East, Europe and Northern Africa Consultation	Rabat, Morocco	66	Countries Health professionals
2 February 2012	Delivery Working Group virtual meeting		18	Global agencies, countries
17-18 January 2012	Indicators Working Group meeting	Geneva, Switzerland	6	Global agencies
9 February 2012	Civil Society Organizations virtual meeting		15	CSOs
15 February 2012	DoVC Steering Committee	Geneva, Switzerland	16	
16 February 2012	SAGE Extraordinary Meeting	Geneva, Switzerland		

Key themes from consultations

Country ownership (not just governments)	Community engagement	Civil society engagement and capacity building
Need to proactively address vaccine hesitancy	Vaccines as part of comprehensive disease prevention and control	Coordination rather than integration
An accountability framework would be game changing	How to make the GVAP operational?	What happens after the DoVC sunsets?

Feedback on process

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WHO Executive Board: Summary Feedback (1)

Numerous and rich inputs

- 16 **countries** (including on behalf of the EU and member states and on behalf of African member states), and 2 **Civil Society Organizations** (representing over 200 NGOs)

Scope of the GVAP

- **A welcome momentum towards morbidity and mortality and highlights opportunities for**
  - Further steering progress towards achieving MDGs
  - Governments to implement the global vision and strategies into national action plans in line with national priorities
  - Targeted strategies for LMICs
- **Provides opportunities for boosting immunization coverage**

Concerns

- **Anti-vaccination groups endangering vaccination successes**
- **Caution in not recreating the wheel**
  - Existing global and regional goals/targets,
  - Supply, procurement, and financing platforms
  - Global, regional and country coordinating and support mechanisms
- **Need for an accountability framework:**
  - Clear roles and responsibilities of various stakeholders and actors

Executive Board Inputs to the GVAP (2)

Questions Raised

- **Access to vaccines**
  - Clarifying intended role of a "Global Vaccines Access Forum" given existing mechanisms
  - Promoting equitable access and role international financing mechanisms
  - Integrating immunization and achieving synergies with other health programmes
  - Establishing strategies that are based on strong consensus to maximize the support for World Immunization Weeks
- **R&D**
  - Establishing global mechanisms for R&D
  - Supporting Technology Transfer of vaccine production to developing countries
  - Strengthening vaccine prequalification support to be strengthened

Expected Role of WHO

- Setting norms and in providing technical support to member states
- Preserving an independent role on setting immunization policies
- Facilitating country and regional level production of vaccines
- Being at the core of the GVAP development as the normative lead in global health
- Actively coordinate research in the areas of new vaccine developments

Revised Global Vaccine Action Plan (GVAP) – Vision, Guiding Principles and Goals

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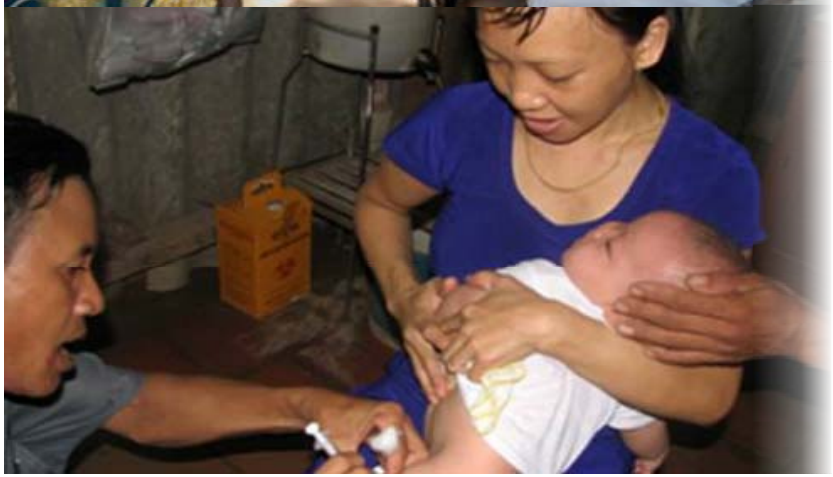

"We envision a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases.

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

Decade of Vaccines vision

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DoV Guiding Principles (I)

Changed from. DRAFT 3 based on recommendations from DoVC Steering Committee

Country ownership

- Countries have primary ownership and responsibility for establishing good governance and providing effective and quality immunization services for all. This means ownership by all stakeholders within a country, not just governments

Shared responsibility and partnership

- Maintaining active immunization against vaccine-preventable diseases is a personal and community responsibility that transcends borders

Equitable access

- Equitable and affordable access to immunization is a core component of the right to health

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DoV Guiding Principles (II)

Integration

- Strong immunization systems, which are part of the broader health systems and closely coordinated with other primary health care delivery programmes, are essential for achieving immunization goals

Sustainability

- Informed decisions and implementation strategies, appropriate levels of financial investments, and improved financial management and oversight are critical to ensure the sustainability of immunization programmes

Innovation

- The full potential of immunization can be realised only through learning, continuous improvement, and innovation in R&D and across all aspects of immunization

We have ambitious goals for this decade

Changes to goals vs. DRAFT 3 recommended by DoVC Steering Committee

Goals

1. A world free of polio

2. Neo-natal tetanus is eliminated

3. Measles is eliminated in at least five WHO regions and an eradication date is defined

4. Rubella and congenital rubella syndrome are eliminated in at least two WHO regions

5. Vaccines in national immunization programmes reach 90% coverage globally and 80% in every district or equivalent administrative unit, within 5 years of introduction

6. By 2015 at least 200 vaccine introductions have occurred

7. New vaccines and technologies for high-burden diseases are developed, licensed, and introduced

8. Immunization contributes to reaching a reduction of under 5 mortality rates of 2/3 by 2015 and exceeding that by 2020 (compared to 1990)

Revised Global Vaccine Action Plan (GVAP) – Outcomes and Actions

Together, six outcomes will lead to DoV goals

Outcomes of a successful decade

- All countries commit to immunization as a priority
- Individuals and communities understand and demand immunization
- The benefits of immunization are equitably extended to all people
- Strong immunization systems that are an integral part of a well functioning health system
- Immunization programmes have sustainable access to long-term financing and quality supply
- Country, regional and global R&D efforts maximize the benefits of immunization

DoV goals

Vaccines in national immunization programmes reach 90% coverage globally and 80% in every district...

By 2015 at least 200 vaccine introductions have occurred

New vaccines and technologies for high-burden diseases are developed, licensed, and introduced

A world free of polio

Neo-natal tetanus is eliminated

Measles is eliminated in at least five WHO regions and an eradication date is defined

Rubella and congenital rubella syndrome are eliminated in at least two WHO regions

Immunization contributes to reaching a reduction of under 5 mortality rates of 2/3 by 2015 and exceeding that by 2020

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What will be different or further emphasized?

Further emphasizing critical components of GIVS...

- Focus on mortality, morbidity and economic impact
- Country ownership
- Demand generation
- Comprehensive strategy, from R&D to delivery, access and public and political support
- Comprehensive disease prevention and control / focus on surveillance

... And adding new elements

- An accountability framework with defined indicators and stakeholder responsibilities
- Innovation as a guiding principle
- From Reaching Every District to Reaching Every Community
- Supply-side interventions to ensure sustainable access
- Broader stakeholder participation

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Outcome 1: all countries commit to immunization as a priority

Establish and sustain commitment to immunization	• Ensure up-to-date vaccine legislation in all countries, including provisions for public funding and for monitoring and reporting. • Develop comprehensive national immunization plans that are part of overall national health plans through a bottom-up process including all stakeholders. • Set ambitious but attainable country-specific targets within the context of morbidity and mortality reduction goals. • Scrutinise, defend, and more closely follow immunization budgets and immunization programme activities.
Convince decision makers of the value of immunization	• Explore models to promote collaboration between evidence generators and evidence users. • Articulate and highlight equity arguments for immunization. • Articulate and highlight economic arguments for immunization. • Include immunization in the agendas of governing body meetings at all levels and in other social, health and economic forums
Strengthen local decision-making	• Create or strengthen independent bodies that guide country decision-making (for example, NITAGs). • Develop more effective ways for national regulatory agencies (NRAs), health sector coordination committees (HSCCs), and interagency coordination committees (ICCs) to support immunization programmes. • Create regional forums and peer-to-peer exchange of information, best practices, and tools. • Create expanded, more transparent mechanisms for aggregating, sharing, and using information to monitor commitments.

Outcome 2: individuals and communities understand and demand immunization

Promote the benefits of immunization	• Proactively communicate the risks and benefits of immunization to address vaccine hesitancy. • Utilise social media tools and lessons from commercial and social marketing efforts. • Leverage new mobile and Internet-based technologies. • Include immunization in the basic education curriculum. • Conduct communications research.
Create incentives to stimulate demand	• Create incentives for immunization while respecting the autonomy of beneficiaries (for example, cash or in-kind transfers, bundling of services, media recognition). • Conduct social research.
Build advocacy capacity	• Train healthcare workers on effective communication techniques, esp. to address vaccine hesitancy and to respond to reports of serious adverse events following immunization in order to maintain trust and allay fears. • Create national or regional advocacy plans that involve CSOs. • Build capacity of CSOs. • Recruit new voices, including those of educators, religious leaders, traditional and social media personalities, family physicians, community health workers, and trained immunization champions (among others). • Link global and national advocacy efforts with social and professional networks at community level.

Outcome 3: the benefits of immunization are equitably extended to all people

Reach Everyone	• Recast "Reaching Every District" to "Reaching Every Community" • Develop or coordinate with existing national-identification-number systems to improve immunization information and tracking and to inform outreach or targeted strategies. • Introduce appropriate new vaccines in national immunization programmes • Establish a life course approach to immunization planning and implementation, including new strategies to ensure equity across the life span. • Prevent and respond to vaccine-preventable diseases during disease outbreaks, humanitarian crises, and in conflict zones. • Conduct operational and social science research to identify successful strategies to reduce inequities and improve the quality and delivery of immunization services. • Engage underserved and marginalised groups to develop locally tailored, targeted strategies for reducing inequities.
Engage communities	• Develop and empower community health workers to use information to identify and serve missed populations (for example, provide incentives and equip the workers with mobile technology). • Take advantage of community structures to enhance communication and deliver services (for example, traditional birth attendants, birth registries). • Involve CSOs in community outreach and planning. • Develop new approaches to community engagement for urban and peri-urban areas.

Outcome 4: strong immunization systems that are an integral part of a well functioning health system

Develop comprehensive & coordinated approaches	• Ensure that global vaccine programmes focus on eradication and elimination goals (for example, polio and measles campaigns) are incorporated into national immunization programmes and do not operate independently. • Ensure that new vaccine deployment is accompanied by comprehensive plans to control targeted diseases.
Strengthen programme monitoring and surveillance programmes	• Improve the quality of immunization administrative coverage data and promote its analysis and use at all administrative levels to improve programme performances. • Develop and promote the use of new technologies for collection, transmission and analysis of immunization data. • Further strengthen and expand disease surveillance systems to generate information for decision-making, monitoring the impact of immunization and changes in disease epidemiology. • Strengthen mechanisms for disease and post licensure surveillance.
Build capacity of frontline workers	• Ensure that immunization and other primary health care programmes have adequate human resources. • Increase levels of in-service and post service training for human resources, and develop new, relevant curricula that approach immunization as a component of comprehensive disease control. • Promote coordinated training and supervision of community-based health workers.
Strengthen infrastructure and logistics	• Improve cold-chain capacity and logistics, as well as waste management. • Minimise the environmental impact of energy, materials, and processes used in immunization supply systems, both within countries and globally. • Staff supply systems with adequate numbers of competent, motivated, and empowered personnel at all levels. • Establish information systems that help staff accurately track the available supply.

Outcome 5: immunization programmes have sustainable access to long-term funding and quality supply

Increase total amount of funding	• Establish a commitment for governments to invest in immunization according to their ability to pay and the expected benefits. • Engage new potential funding partners. • Diversify sources of funding—including the private sector, insurance companies, and patients as part of the contribution to prevention-and-service-delivery programmes. • Continue to leverage innovative funding mechanisms.
Increase affordability for middle-income countries	• Explore differential pricing using non-traditional market-segmentation frameworks • Explore pooled negotiation or procurement mechanisms for lower middle-income countries
Improve allocation of funding in low- and middle-income countries	• Strengthen budgeting and financial management in-country to better integrate financial and health care planning and priority setting. • Coordinate funding support from development partners and other external sources. • Evaluate and improve funding support mechanisms on the basis of their effectiveness in reaching disease goals. • Base funding on transparency and objectivity in order to ensure the sustainability of programmes. Promote the use of cost and cost-benefit arguments in fund raising, decision making, and defence of immunization funding. • Explore pay-for-performance funding systems.
Secure quality supply	• Develop regulatory and legal structures and capability investments that ensure secure high-quality vaccine supply and that increase innovation and manufacturing capabilities. • Build and support networks of suppliers to share best practices and to improve capabilities and quality control. • Expand activities to improve communication and coordination among countries, vaccine manufacturers, and public-sector organisations.

Outcome 6: country, regional and global R&D efforts maximize the benefits of immunization

Improve capabilities	• Build capacity and human resources in developing countries to conduct R&D. • Increase networking among research centres for efficient building of partnerships between high-, middle- and low-income countries' institutions. • Recruit scientists from disciplines not previously engaged in vaccine research.
Invest in R&D enablers	• Engage with end users to prioritise vaccines and innovations according to perceived demand and added value. • Adopt best practices in portfolio and partnership management for R&D.
Implementation and operational research	• Research the use of more effective information through modern communication technologies. • Conduct representative epidemiological, immunological and operational studies and studies of vaccine impact to guide cost-effective analysis. • Perform operational research on improved delivery approaches for life course immunization and vaccination in emergency situations. • Perform research on interference effects and optimum delivery schedules.
Vaccine manufacturing technology Research	• Promote greater access to technology, know-how, and intellectual property for adjuvants and their formulation into vaccines. • Develop nonsyringe delivery mechanisms and vaccine packaging that best suit the needs and constraints of countries' programmes. • Develop thermostable vaccines. • Develop new bioprocessing and manufacturing technologies. • Develop a global, regulatory, science research agenda.
Vaccine discovery research	• Research on the fundamentals of innate and adaptive immune responses, particularly in humans. • Research on immunologic and molecular characteristics of microbes • Improve current understanding of the causes of variation in human-population response to vaccines.

Benefits, costs and funding

Objective is to quantify benefits, costs and funding requirements to achieve ambitious goals

Return on Investment

Funding gap

Benefits	Costs	Funding
Health & economic benefits of routine vaccination (9 vaccines only)	**Costs of routine vaccination (18 vaccines)**	**Projected funding for routine vaccination (18 vaccines)**
Health & economic benefits of Accelerated Disease Control initiatives not assessed	**Costs of Accelerated Disease Control initiatives**	**Projected funding for Accelerated Disease Control initiatives**
Health & economic benefits of Research & Development not assessed	Costs associated with Research & Development	*Research & Development funding not assessed by this work*

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Three primary scope considerations

	Benefits analysis	Costing analysis
Country scope	**81 countries included in the benefits analysis scope** • 73 GAVI countries • 8 other countries defined as lower-middle-income countries by the World Bank (2011)	**94 countries included in the costing and funding scope** • 73 GAVI countries • 21 other countries defined as lower-middle-income by the World Bank (2011)
Vaccine scope	• **Yellow Fever** • **Hep B** • **Hib** • **HPV** • **JE** • **MenA** • **Pneumo** • **Rota** • **Rubella**	• Penta (DTP-**HepB-Hib**) • **HPV** • **JE** • **MenA** • **Pneumo** • **Rota** • **Rubella** • **Yellow Fever** • TB (BCG) • Measles • Rubella • Non-Penta DTP-HepB-Hib options* • Measles 2nd dose • Polio (OPV & IPV) • Cholera • Dengue • Malaria
Time period	**All cost, funding and health and economic outcomes projection analyses were conducted using 2010 as the baseline year and building projections for the period 2011–2020**	

Note: Detailed country list available in appendix

Adding new vaccines and increasing coverage drives benefits and costs

Vaccine	Global coverage rates (%) 2011	→	2020
TB (BCG)	88	→	93
Penta	50	→	92
Pneumo	6	→	89
Rotavirus	2	→	77
Malaria	0	→	75
Dengue	0	→	49

- **Sustaining currently high coverage rates of traditional vaccines**
- **Scale-up and increased utilization of existing and underutilized vaccines**
- **Successful development, licensing & introduction of new vaccines**

1. Polio coverage in 2020 accounted for in Penta assuming Penta switch to Hexa

GVAP Page 24-25 and Appendix 3, Pages 38-57

Health and economic benefits analysis

Benefits	Costs	Funding
Health & economic benefits of routine vaccination (9 vaccines only)	**Costs of routine vaccination (18 vaccines)**	**Projected funding for routine vaccination (18 vaccines)**
Health & economic benefits of Accelerated Disease Control initiatives not assessed	**Costs of Accelerated Disease Control initiatives**	**Projected funding for Accelerated Disease Control initiatives**
Health & economic benefits of Research & Development not assessed	Costs associated with Research & Development	*Research & Development funding not assessed by this work*

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Overview of our approach to health benefits analysis

Vaccinated persons	x	Disease Impact Data	=	Future deaths averted
Coverage rates x Target population by country		Different disease impact models to determine deaths averted per 1,000 immunized persons per country for 9 different diseases		Estimate of potential lives saved by vaccine for 9 different diseases

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Modeled disease burden data to generate 'deaths averted per 1,000 vaccinated' metric

6 different models for 9 different vaccines; standardized inputs where ever possible

Disease	Model source	Underlying disease burden data
Hepatitis B	CDC, WHO	Pre-vaccination HBsAg serosurvey data (many countries)
Hib, Pneumococcal & Rotavirus	JHU (Lives Saved Tool)	WHO/CHERG 2008 under-5 pneumonia deaths (many countries) x pre-vaccination proportion radiographic pneumonia cases due to Hib or Pnc (probe studies in 4 countries) & WHO/CHERG 2008 under-5 diarrhea deaths (many countries) x pre-vaccination proportion severe gastroenteritis due to rotavirus infection (many countries
Human papillomavirus	Harvard	Pre-vaccination restrospective surveys of women with invasive cervical cancer with use of molecular techniques to determine the proportion due to HPB and due to specific HPV genotypes (many countries)
Yellow fever	GAVI (LRCI)	Pre-vaccination 1993 study modeling the impact of vaccination in Nigeria during 1991-2026. Model based on many disease burden studies in Nigeria (one country, little comparable data elsewhere). Only epidemic disease burden considered. Impact based on marginal increase in coverage since year prior to start of GAVI support.
Meningococcal meningitis	GAVI (LRCI)	Based on a pre-vaccination prospective hospital surveillance study in Niger conducted during 1981-1996 (one country, little comparable data elsewhere)
Japanese encephalitis	PATH	Based on a 2011 review of population-based surveillance studies. Some pre-vaccination some post-vaccination) (several countries)
Rubella	UK Health Protection Agency Centre for Infections, CDC, WHO	Pre-vaccination retrospective rubella serosurveys to determine age-specific incidence (many countries)

Key assumptions and considerations

- 6 different peer-reviewed disease impact models used with documented assumptions but different constraints
- Indirect benefits not included
- Subjects assumed to receive full vaccination course
- Vaccinations assumed to have been received on time
- Impact shown in year of vaccination, but protective effects of vaccination calculated over period of mortality risk for each disease
- Probability of dying and of being vaccinated independent and uniformly distributed in the target population
- Coverage of one vaccine does not impact on coverage with other vaccines
- LiST leverages 2008 cause of death data
  - New data to be integrated in February or March

Note: Impact shown by year of vaccination but protective effects of vaccination calculated over period of mortality risk for each disease

Value of Statistical Life Concept

The value of a statistical life (VSL) is based on the income a typical individual is willing to trade off to reduce the risk of death.

- Value is derived from trade-offs between financial reward and increased risk of mortality
- Based on wage-risk and stated preference studies.

Considered the "Full Income" approach, this approach values not only lifetime productivity, but also the benefits of living longer with better health.

Copenhagen Consensus of 2008 supported this approach as a method to value the economic benefits of health interventions and it is used as a policy tool in countries around the world to place value on interventions that save lives (EPA, DOT)

Only values averted deaths, not averted morbidity.

Our analysis adjusts for the reality that poorer people tend to take more risks for less money

Draft—for discussion only

Vaccine Cost Analysis Segmentation

	Procurement Costs	Delivery + On-going Cold Chain Costs	Capital Cold Chain Costs
ADCs (Campaigns)	Measles, Polio, Rubella, MenA, Tetenus, YF		Incremental capital cold chain costs assumed to be negligible for campaigns
Traditional Non-GAVI Routine EPI Portfolio	TB (BCG) Measles 1st Dose Rubella Mumps Polio OPV DTP-containing HepB-Containing	TB (BCG) Measles 1st Dose Rubella Mumps Polio OPV DTP-containing HepB-Containing	
GAVI Routine EPI Portfolio	YF Hib-Containing Measles 2nd Dose Pneumo Rota MenA	YF Hib-Containing Measles 2nd Dose Pneumo Rota MenA	
Other Routine Vaccine Portfolio	HPV (routine non-EPI) Cholera (routine campaign) Dengue (routine) JE (routine + catch-up) Malaria (routine) Polio IPV[2] (routine) Typhoid (routine)	HPV (routine non-EPI) Cholera (routine campaign) Dengue (routine) JE (routine + catch-up) Malaria (routine) Typhoid (routine)	HPV (routine non-EPI) Cholera (routine campaign) Dengue (routine) JE (routine + catch-up) Malaria (routine) Typhoid (routine)

[1]DTP, Hep-B, DTP-HepB
[2]Polio IPV delivery costs assumed to be included in penta delivery costs for hexavalent vaccines; IPV standalone vaccines not included in delivery cost analysis

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Vaccine Procurement Costing - Key Assumptions

Traditional Non-GAVI Vaccines		GAVI Vaccine Portfolio		Other Vaccines	
DTP HepB Hib DTP-HepB	DTP-Hib TB BCG Measles Polio OPV	Pentavalent Yellow Fever MSD Rubella	MenA Pneumo Rota HPV	JE Cholera Typhoid	Dengue Malaria Polio IPV
• All vaccines introduced prior to 1990 per WHO Immunization monitoring database[1]		• Country vaccine introduction dates per GAVI SDF v4.0 or ADF v4.0 demand forecasts		Country vaccine introduction dates per: • GAVI SDF v4.0 demand forecasts for JE and typhoid conjugate • PGA v1.0 for cholera and dengue • MVI forecast for malaria • BMGF forecast for Polio IPV	
• Price forecast based on historic UNICEF and PAHO pricing information		• Price forecast based on historic UNICEF and PAHO pricing information and GAVI/BMGF price forecasts		• Price forecast based on best available market intelligence	

[1] http://www.who.int/immunization_monitoring/data/data_subject/en/

Delivery & Cold Chain Costing Key Assumptions

Service Delivery Costing	Vaccine Delivery Costing
• **Service Delivery** = costs to deliver immunization services • Includes human resources, program management, training/capacity building, social mobilization, surveillance… • Leveraged data from 58 country-submitted multi-year plans costing and financing tools (cMYPs) • Extrapolated to other countries using average unit costs and typologies • For HPV, Malaria, Dengue, Typhoid…used external studies to augment cMYP data (e.g. PATH introduction study for HPV)	• **Vaccine Delivery** = cost to store and transport vaccines to service delivery points. • Includes cold chain equipment, cold chain overheads, vehicles and transport • Leveraged WHO global forecasting tool for cold chain equipment and applying logistics indicators derived from country-submitted multi-year plans (cMYPs). • For HPV, Malaria, Dengue, Typhoid…used external studies to augment cMYP data (e.g. PATH introduction study for HPV)

Costing Scenarios – differences among 3 scenarios

Cost Category	Scenario Assumption		
	Base Case	Low Case	High Case
Routine Immunization Procurement	• GAVI Adjusted Demand Forecasts (ADF v4.0) and country introduction timing • PAHO pricing for non-GAVI LMICs	• GAVI Strategic Demand Forecasts (SDF v4.0) • All new vaccine introductions delayed by 2 years	• No change from Base Case
Routine Immunization Delivery	• cMYP data driven cost assumptions • Low range for incremental delivery cost benchmark	• No change from Base Case	• Includes annual growth in HR costs • High range for incremental delivery cost benchmark

Overview of our approach to Accelerated Disease Control vaccine and delivery costing

Scope

- Polio (OPV)
- Measles
- MenA (Conjugated)
- Tetanus (TT/Td)
- Rubella (MR)
- Yellow Fever

Vaccine and Delivery Costing

- Leveraged available vaccine cost and delivery cost forecasts from global SIA programmes (e.g., GPEI, Measles Initiative)
- Aligned cost scope with broader DoV effort

Scenario analysis

- Base case: Used base forecast from SIA programme forecast
- Low case: No changes from base case
- High case: Revised pricing based on UNICEF Supply Division estimates; included Technical Support costs

DECADE of VACCINES COLLABORATION

Costing Scenarios – differences among 3 scenarios

Cost Category	Scenario Assumption		
	Base Case	Low Case	High Case
ADC Procurement & Delivery Costs	• ADC programme forecasts	• No change from Base Case	• Revised pricing based on UNICEF SD estimates for ADC vaccine procurement • Includes technical support costs

Overview of our approach to routine immunization vaccine costs and delivery costs funding

Country / Government Funding

- Use **current** baseline of **government funding** and **assume** immunization funding grows at same rate as projected **GDP growth**
- For GAVI countries, assume **countries will fully meet procurement co-funding** % commitments through 2020

GAVI Alliance Funding

- Assume **GAVI remains fully funded** and continues to meet current level of funding support for procurement of vaccines within GAVI-eligible countries **through 2020**

Other Development Partner Funding (beyond GAVI)

- **No other Development Partner funding** included in this analysis *(aside from contributions through GAVI Alliance)*

DECADE of VACCINES COLLABORATION

Overview of our approach for Accelerated Disease Control vaccine costs and delivery costs funding

Country / Government Funding

- Use current baseline of government funding and assume growth in government funding flows for immunization grows at same rate as projected GDP growth

GAVI Alliance Funding

- For GAVI supported campaigns (i.e. MenA, Yellow Fever and Rubella), funding was assumed to cover the full costs of the vaccines and supplies
- For operational costs, it was assumed that GAVI will provide funding at least equivalent to current levels (i.e.US$0.30 per targeted person)

Other Development Partner Funding (beyond GAVI)

- Other Development Partner funding not included in this analysis *(aside from contributions through GAVI Alliance)*

R&D costs - caveats

R&D costs are highly uncertain and difficult to project

Existing data on R&D costs is limited

- Data on current funding levels for a subset of "neglected" diseases (source: G-Finder)
- Data on cost projections for BMGF-supported candidates (source: BMGF Risk-Adjusted Portfolio model)
- Based on these two sources, a high-level projection of vaccine product development costs can be made for the G-Finder diseases

The cost projections we are about to show you do NOT include:

- The full cost of the R&D actions recommended in the GVAP, including:
  - Cost of operational research
  - Cost of technology development (e.g., thermostable vaccines, IT-based immunization systems)
  - Cost of basic research
  - Cost of vaccine development for vaccines not outlined in G-Finder (such as universal flu vaccine, hepatitis C, cytomegalovirus, respiratory syncytial virus, Epstein-Barr virus, Group A streptococcal, encephalitic alphaviruses)

Acknowledgements

Costing & Funding forecasts

- Logan Brenzel (The Bill & Melinda Gates Foundation)
- Santiago Cornejo (GAVI Alliance)
- Eliane Furrer (GAVI Alliance)
- Lauren Franzel (PATH)
- Gian Gandhi (UNICEF)
- Patrick Lydon (WHO)
- Carol Marzetta (Applied Strategies)
- Helen Saxenian (Independent Consultant)
- Sandy Wrobel (Applied Strategies)
- Consultancy services provided by Applied Strategies and The Boston Consulting Group

Health & economic benefits analysis

- Dagna Constenla (John Hopkins University)
- Peter Hansen (GAVI Alliance)
- Lisa Lee (GAVI Alliance)
- Orin Levine (John Hopkins University)
- Sachiko Ozawa (John Hopkins University)
- Meghan Stack (John Hopkins University)
- Damian Walker (The Bill & Melinda Gates Foundation)

R&D Costing analysis

- Lee Hall (The National Institutes of Health)
- Margie McGlynn (IAVI)
- Gina Rabinovich (The Bill & Melinda Gates Foundation)
- Saara Romu (The Bill & Melinda Gates Foundation)
- David Shoultz (The Bill & Melinda Gates Foundation)

Accountability framework

DoV accountability framework should have 3 elements

1. **Indicators to measure progress and targets against these indicators**
2. **Clear definitions of stakeholder responsibilities and commitments**
3. **Process and responsibilities for monitoring progress**

Framework defined at a high-level in GVAP, but detailed definition required post-WHA

	1 **Indicators to measure progress and targets against these indicators**	2 **Clear definitions of stakeholder roles and commitments**	3 **Process and responsibilities for monitoring progress**
Pre WHA	• Indicators to monitor progress towards overall DoV goals and each outcome • Targets for GVAP goals	• High-level description of responsibilities by stakeholder group (Appendix in Draft 3 of GVAP) *Completed and included in GVAP*	• Leadership council decision on high-level process
Post WHA	• Establish baseline to measure progress against outcome indicators • Indicators to monitor progress against specific actions	• Specific stakeholder responsibilities aligned to each action • Stakeholder commitments to meet funding requirement and implement each action	• Detailed processes for tracking progress defined and launched

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Three levels of indicators for tracking progress

	# of Indicators	Audience	Targets?	Example
				Defined in GVAP
1 **Indicators for DoV goals**	**7**	**WHA and global leaders**	**Yes**	# of vaccine introductions
2 **Indicators for DoV outcomes**	**28**	**Global immunization community**	**No – measure progress against a baseline**	% routine EPI vaccines financed by government
3 **Indicators for specific actions**	**?**	**Implementers**	**TBD**	Country has emergency preparedness and response plan

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Process followed to define indicators for GVAP

Step 1: Developed long-list of potential indicators based on inputs from consultations

Input on indicators solicited during:

- Southern Africa consultation
- Middle East, Europe and Northern Africa Consultation
- Europe CSO consultation and monthly CSO teleconferences
- R&D working group meeting
- Etc.

Long-lists included in GVAP Draft 2

Step 2: Benchmarked existing accountability mechanisms

Organizations benchmarked:

- Every woman, Every child
- PMNCH
- ALMA
- GAVI Business Plan
- WHO / UNICEF Joint Reporting Form
- Countdown to 2015
- Roll Back Malaria
- MDG monitoring
- International Health Partnership

1:1 and group discussions with experts on what works, doesn't work and potential relevance to DoV

Step 3: Convened working group to recommend short list of indicators for GVAP

Working group members:

- Tony Burton (WHO)
- Daniel Thorton (GAVI)
- John Grove (BMGF)
- David Brown (UNICEF)
- Dragoslav Popovic (UNICEF)
- Chung-Won Lee (CDC)

Selection criteria:

- Relevance to outcome
- Relevance to countries
- Ease of measurement
- Objectivity

Draft—for discussion only

27 indicators recommended to track progress

	Proposed outcome Indicators	
Outcome 1: All countries commit to immunization as a priority	• Presence of up to date legislation that includes establishment of a national immunization plan for effective delivery of vaccines • Presence of independent technical advisory group that meets defined criteria • Number of WHO recommended vaccines in national immunization schedule • % of target population immunized with 3 doses of DTP containing vaccine • % of target population immunized with other WHO recommended vaccines	GVAP Page 9
Outcome 2: Individuals and communities understand and demand immunization	• Indicator(s) capturing knowledge, attitudes, beliefs, and practices on immunization - TBD • Indicator based on analysis of media coverage on immunization (immunization week and rest of year) – TBD	GVAP Page 11
Outcome 3: Benefits of immunization extended equitably	• % of districts (or lowest possible administrative level) with less than 80% coverage with 3 doses of DTP containing vaccine against baseline • % progress against baseline for coverage with 3 doses of DTP containing vaccine by dominant pattern(s) of deprivation for country (as defined by countries) • % of children protected at birth against tetanus (PAB) at district level (or lowest possible administrative level)	GVAP Page 14

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27 indicators recommended to track progress

Changed from. DRAFT 3 based on recommendations from DoVC Steering Committee

	Proposed outcome Indicators	
Outcome 4: Strong immunization systems that are an integral part of a well-functioning health system	• Planning cycles or targets of immunization plans are aligned with national health plans • Indicator for missed opportunities in immunization – TBD • DTP1 – DTP3, DTP1 - measles dropout rate • # of Stock-outs of any vaccine or syringes at the national and district level • % of mothers and babies who received postnatal care visit within two days of childbirth • % births attended by skilled health personnel (alternative HR indicators under discussion) • Number of independent data reviews conducted in the last 24 months	GVAP Page 17
Outcome 5: Sustainable long-term funding and quality supply	• % of routine immunization costs financed through government budgets • % of immunization financing gap (as projected in cMYP) met by development partners • For GAVI-countries: % of co-financing requirements met and % of supported vaccines that continue to be funded post-graduation • Number of suppliers for each vaccine type (a. WHO prequalified, b. others) • All countries have access to a quality, affordable supply of universally recommended vaccines within 5 years of initial licensure in any country	GVAP Page 20
Outcome 6: R&D efforts maximize the benefits of immunization	• Progress towards a first generation universal influenza vaccine • Licensure and launch of vaccine or vaccines against one or more major diseases not currently vaccine preventable, such as dengue, Hepatitis C, CMV, RSV, leishmaniasis, hookworm and Group A Strep • Proof of concept for a vaccine that shows 75% efficacy for AIDS, TB, or malaria • Licensure & launch of thermostable rotavirus and measles vaccines • Licensure & launch of at least one new platform delivery technology	GVAP Page 23

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Most recommended indicators can leverage existing data

	Proposed Indicators	Source	Ease of Measurement
All countries commit to immunization as a priority	Legislation on immunization	**New**	Mid
	Independent technical advisory group	JRF	High
	# WHO recommended vaccines in schedule	JRF	High
	% coverage with 3 doses DTP	WHO/UNICEF Est.	High
	% cover with other recommended vaccines	WHO/UNICEF Est.	High
Individuals/communities understand/demand imm.	Knowledge, beliefs, and attitudes on immunization	**New**	Low
	Media coverage of immunization	**New**	Mid
Benefits of immunization extended equitably	% districts (or lowest admin. level) above 80% DTP3 coverage	WHO/UNICEF Est.	High
	% progress in DTP3 coverage by other dominant pattern of deprivation	**New**	Low
	% of children protected at birth at district level (or lowest admin. level)	WHO/UNICEF Est.	High
Strong immunization systems that are an integral part of a well-functioning health system	Planning cycles/plan targets aligned with national health plans	**New**	Mid
	Indicator for missed opportunities in immunization – TBD	**New**	Low
	DTP1 – DTP3, DTP1 - measles dropout rate	WHO/UNICEF Est.	High
	# of Stock-outs of any vaccine or syringes at national or district level	JRF	High
	% of mothers and babies who received postnatal care	EW, EC[1]	High
	% births attended by skilled health personnel	EW, EC[1]	High
	Number of independent data reviews conducted in the last 24 months	**New**	Mid
Sustainable long-term funding and quality supply	% of routine immunization costs financed through government budgets	JRF	Mid
	% financing gap met by development partners	WHO	Mid
	For GAVI-countries: % of co-financing/graduation requirements met	GAVI	High
	All countries have access to a quality, affordable supply	**New**	
	# of suppliers for each vaccine type (a. WHO prequalified, b. others)	WHO	Mid
R&D efforts maximize the benefits of immunization	Progress towards a first generation universal influenza vaccine	**New**	
	Licensure and launch of vaccine or vaccines against one or more major diseases not currently vaccine preventable	**New**	
	Proof of concept for vaccine w/ 75% efficacy for AIDS, TB, or malaria	**New**	High
	Licensure & launch of thermostable rotavirus and measles vaccines	**New**	
	Licensure & launch of at least one new platform delivery technology	**New**	

1. Every Women, Every Child

High level stakeholder responsibilities for all groups are defined in the GVAP

GVAP Appendix 2
Page 34-37

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Next steps for defining the accountability framework

1

Indicators to measure progress and targets against these indicators

- Finalize goal and outcome-level indicators for inclusion in GVAP
- Develop action-level indicators in conjunction with specific responsible stakeholders
- Detail methodology for each indicator
- Establish baseline for each indicator
- Develop plan to improve data quality

2

Clear definitions of stakeholder roles and commitments

- Finalize high-level stakeholder responsibility section of GVAP
- Develop detailed stakeholder responsibilities for each action
- Mobilise stakeholders to commit to each action

3

A process for monitoring progress

- Finalize general language on accountability framework in GVAP
- Leadership council to decide on final process for tracking progress

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Conclusions and next steps

Immediate next steps

Feb 16th:	**SAGE Reviews GVAP Draft 3**
Feb 17th:	**Steering Committee Meets**
Feb 24th:	**Leadership Council Teleconference**
Feb 27-28	**Americas consultation**
First week of March:	**WHO and DoVC Missions brief in Geneva**
Early March:	**Final GVAP submitted to WHO for WHA**