



Report to the GAVI Alliance Board

11-12 June 2013

Subject:	Country Programmes Update (including Health and immunisation systems strengthening)
Report of:	Hind Khatib-Othman, Managing Director, Country Programmes
Authored by¹:	Stefano Malvoti, Director, Vaccine Implementation, and Alan Brooks, Special Adviser for Immunisation
Agenda item:	11
Category:	For Information
Strategic goal:	SG1 - Vaccines, SG2 - Health systems, SG3 - Financing

Section A Overview

1 Purpose of the report

1.1 This report provides an update on GAVI's country programmes.

2 Recommendations

2.1 This report is for information.

3 Executive Summary

3.1 The fourth quarter of 2012 and first five months of 2013 have been periods of rapid transition and intense work for GAVI's country programmes. New or updated collaboration mechanisms for supporting countries (e.g. a Strategic Goal 2 Management Team) have been rolled out to facilitate alignment across partners and implementation of the Business Plan. The Secretariat has increased its focus on active programme and grant management, including strengthening co-ordination between Transparency and Accountability Policy-related activities and Country Responsible Officer (CRO) grant management. A new Partnership Framework Agreement is being implemented that sets out the legal relationship between GAVI and countries and will speed formalisation of GAVI funding decisions.

3.2 DR Congo, India, Nigeria and Pakistan continue to require intensive engagement because of the complex operating environments, the large numbers of unimmunised children and the number of vaccine implementation activities. The Secretariat has begun to implement the

¹ With contributions from Paul Kelly and Bakhuti Shengelia

December 2012 Board policy on fragile states and is developing the first country-tailored approaches, commencing with DRC, Nigeria and Pakistan. The Secretariat is working with GAVI's Civil Society Organisation (CSO) Constituency to strengthen country-level civil society networks and platforms. CSO engagement, such as participation in country Inter-agency Coordinating Committees/Health System Coordinating Committees (ICC/HSCC), is increasing in the 14 countries where GAVI is providing support.

- 3.3 Demand remains very strong for GAVI-supported vaccines with associated increases in coverage. Implementation of the nine vaccine programmes supported by the Alliance led to introductions by seven countries² in the first five months of 2013. Up to 45 additional introductions are projected through the remainder of 2013. Pentavalent uptake in India is accelerating while Indonesia is expected to begin rapidly scaling up in the second half of 2013 using domestically produced pentavalent vaccine. HPV demonstration programmes and Measles-Rubella campaigns have successfully started. Challenges persist on the supply side affecting scaling up of Rotavirus and Pneumococcal Conjugate vaccines and requiring active management. On-going discussions with suppliers and assessments of country readiness are assisting to optimise the use of available supplies.
- 3.4 The Secretariat has contracted with a firm to benchmark GAVI's vaccine procurement arrangements as requested in December 2012 by the Board. The results are anticipated by September, in advance of the next Board meeting.
- 3.5 There are an increasing number of reported Adverse Event Following Immunisation (AEFI's) resulting from the growing number of vaccines administered, but not necessarily caused by the vaccines. This has caused some concerns at governmental and public opinion levels particularly in Asia. Reactions in countries, regardless if unfounded, could be a risk to GAVI's long term performance. Adverse Events are tracked closely by Alliance partners leading to coordinated responses, while further efforts are envisaged to strengthen proactive support to countries as they manage these incidents in the future.
- 3.6 In addition the Secretariat is working with Alliance members on a number of other cross-programme initiatives aimed, for example, at specifying the complementary role that GAVI could play to the Global Polio Eradication Initiative, at defining the best way in which supplementary immunisation activities can contribute to strengthening routine immunisation services, and at redesigning the end-to-end vaccine supply chain. We anticipate seeking further guidance from GAVI stakeholders on these topics in the coming months.

² Mozambique, Uganda, Kiribati introduced PCV, Georgia introduced RV, Somalia introduced Pentavalent, Kenya started its HPV demonstration project, Burundi started Measles Second Dose, Rwanda started MR

- 3.7 As of April 2013, the total portfolio of approved HSS grants since 2007 is US\$611 million, of which US\$425 million has been disbursed, reflecting increases from US\$512 million and US\$410 million, respectively, in December 2012. Cash programmes represented 12% of total spending in 2012. All three new HSS proposals reviewed by the Independent Review Committee in April 2013 were recommended for approval or approval with clarifications.
- 3.6 Of the 65 countries required to co-finance their vaccines in 2012, nine countries are in default in their payments versus four at the same point the previous year, however, seven of those countries made some level of contributions. Only Afghanistan and Guinea have not yet made any contributions towards their co-financing requirements during 2012. The total amount transferred against the co-financing commitments by the 63 countries was approximately US\$47 million in 2012, accounting for 8% of the vaccine support to those countries. An additional US\$5 million has been transferred by the defaulting countries since January 2013 against 2012 requirements.

4 Risk implication and mitigation

- 4.1 See risk register regularly presented to the GAVI Board.

5 Financial implications: Business plan and budgets

- 5.1 Activities are progressing within the budget approved through the Business Plan, or otherwise approved by the Executive Committee or Board (e.g. vaccine support). The notable exception is related to support for Measles supplementary immunisation activities (SIAs). The Executive Committee in March 2013 has clarified the age eligibility for GAVI's support to Measles SIAs and with revised country projections increased the financial estimates by approximately US\$31 million from US\$107 million estimated in June 2012, to the current estimate of US\$138 million. New, additional financing from Canada of approximately US\$20 million for Measles was also committed, matched by the Bill and Melinda Gates Foundation.
- 5.2 Once the country tailored approaches are developed, levels of GAVI's support to individual countries may be reconsidered. For example the HSS ceiling could be adjusted on a country by country basis. Discussions are also beginning about the possibility of further linking GAVI support for SIA's to activities strengthening routine immunisation. Such activities could entail additional costs. For example if evaluations are required following each SIA it could require additional cash support to countries and/or technical assistance from partners.

Section B Content

1 Context

Country Programmes

1.1 The Secretariat has been in a period of rapid transition and intense work. Work processes are being revised to reinforce core roles, particularly managing grants. Increased numbers of Country Responsible Officers (CROs) allow for closer country engagement, there is more regular monitoring of HSS implementation and the introduction of the new Partnership Framework Agreement (PFA) will speed formalisation of GAVI funding decisions. There are also strengthened means of co-ordinating support to countries (for example the Vaccine Implementation Management Team has been re-chartered, and a cross-Alliance Management Team has been established to monitor implementation of Business Plan activities under Strategic Goal 2). These approaches will improve iteratively, including through the Grant Application Monitoring and Review (GAMR) redesign process.

Countries

1.2 Democratic Republic of Congo (DRC)

(a) Completion of the national introduction of Pneumococcal vaccine is expected to be complete by October 2013. In 2012, DRC paid US\$3.5 million for GAVI co-financing which removed the country from default for 2010 and 2011. DRC's co-financing obligation for Yellow Fever and Pentavalent vaccines for 2012 was US\$2.6 million, of which only US\$1.2 million was paid in March 2013. As such, DRC is in default for 2012. DRC has allocated around US\$10.5 million for vaccines and campaigns in its 2013 health budget, however this is approximately US\$2.7 million less than the \$13.2 million needed for DRC to meet commitments: 2012 co-financing arrears (US\$2.6 million); the 2013 co-financing requirement (US\$3.4 million); and traditional vaccines and campaigns (estimated around US\$7.2 million).

(b) As part of the development of a tailored approach to GAVI support in DRC, the Secretariat is working with the Government to develop a plan to improve sustainability of immunisation financing.

1.3 India

- (a) Pentavalent vaccine has now been introduced with GAVI support in eight states. Delhi State has self-financed the introduction of Pentavalent. In May the Government submitted a request for GAVI assistance to scale-up the vaccine nationally. Reports of Adverse Events Following Immunisation (AEFI) in Kerala and Tamil Nadu have raised concerns in these states about vaccine safety. Following investigations, the national AEFI expert committee concluded that there was no causal relationship with vaccines. These incidents have highlighted the need for stronger AEFI reporting and management of communications, with support to the Government from GAVI partners, to allay public fears and misperceptions about vaccine safety.
- (b) India's HSS proposal was recommended for approval with clarifications by the IRC in April 2013. The three year (2013-2015), US\$ 107 million proposal targets 12 states with DTP3 coverage less than 60%. Activities include: vaccine logistics and supply chain management; demand generation through routine immunisation and innovation in behaviour change communications; and leveraging polio infrastructure to strengthen routine immunisation. India is expected to submit its response to the clarifications by end June 2013.

1.4 Nigeria

- (a) The deteriorating state of Nigeria's immunisation programme has generated a high level political response and a commitment from development partners to better coordinate their support. The Government is developing a harmonised work plan which incorporates routine, polio and supplementary immunisation activities, as well as improved coordination and accountability mechanisms.
- (b) Nigeria introduced Pentavalent vaccine in 14 states in 2012. Seven states commenced introduction in February 2013 with the remaining 16 states expected to start from June 2013. Nigeria is scheduled to introduce PCV from Q4, 2013 depending on supply availability. In March 2013, the EC approved support for Nigeria to undertake Measles and Yellow Fever preventive campaigns in 2013.
- (c) The Secretariat, in consultation with the government and partners, is developing a tailored approach to support Nigeria's efforts to improve immunisation. Likely areas for attention include strengthening supply-chain and funding for outreach services at local levels; direct GAVI engagement at the state level; and promoting coordination and complementary approaches between polio eradication and routine immunisation.

1.5 Pakistan

- (a) Pneumococcal vaccine introduction has continued since the national launch in Punjab Province in October 2012. The security situation has delayed the original roll-out schedule by around three months which is now expected to be complete by the middle of 2013. Training and readiness assessments are on-going to ensure safe and effective introduction.
- (b) Since October 2012, there have been over 20,000 suspected measles cases reported with more than 500 deaths (case fatality ratio = 2.5%). An Alliance mission to review the measles situation in February 2013 concluded that the high disease incidence across the country was due to failure to vaccinate and poor routine immunisation resulting in an accumulation of susceptible children. In March 2013 the Government submitted a Measles SIA application for support for children 9 months to 5 years, commencing mid-June 2013. The Government intends to mobilise both national and international support to cover the remaining target group of 5-10 years. The application was recommended for approval (with clarifications) by the IRC in April 2013.
- (c) GAVI is working with Government and partners to address concerns about the local capacity to conduct an effective national campaign and to link the measles campaign to a longer term strategy to strengthen routine immunisation. On 1 May 2013 the Executive Committee deferred a decision on the IRC recommendation to 10 June 2013.

1.6 GAVI and fragile states – a country by country approach

- (a) GAVI's Fragile States policy was approved by the Board in December 2012. Following application of the framework included in the policy, 11 countries³ have been identified for development of a tailored approach. Development will be undertaken in close consultation with government and key in-country partners. The Secretariat will take a sequenced approach rather than developing all 11 country tailored approaches at once. Sequencing helps balance resource implications for the Country Programmes Department and also allows the Secretariat to learn lessons and refine the process over time. Work has commenced on DRC, Nigeria and Pakistan and it is planned that documents would be finalised in the second half of 2013. Work on Chad, Haiti and South Sudan is expected to commence from Q3. Overall progress and impact will be included in the Country Update at future PPC/Board meetings.

³ Afghanistan, CAR, Chad, Cote d'Ivoire, DRC, Guinea, Haiti, Nigeria, Pakistan, Somalia, South Sudan

1.7 Strengthening CSO engagement in HSS

(a) In September 2011, Catholic Relief Services, on behalf of the GAVI CSO Constituency, was contracted by GAVI to manage a programme of support to CSOs to promote active engagement in HSS. Catholic Relief Services is currently working in 14 countries⁴ to build CSO capacity to contribute to development of country HSS applications as well as to the broader policy dialogue. All 14 countries have started to increase CSO participation in the ICC/HSCC. Five of these countries were approved for new GAVI HSS support in 2012 with increasing involvement of CSO partners in implementation arrangements.

1.8 GAVI's role in the polio eradication effort

(a) In December 2012, the Board approved *GAVI playing a complementary role to the Global Polio Eradication Initiative (GPEI) in the polio eradication effort, specifically through routine immunisation within GAVI's strategy and mission using existing structures, processes, and procedures*. The Secretariat, based upon input from Alliance partners and GPEI, has drafted a document proposing GAVI's approach to playing a complementary role. It will be discussed under Board agenda item 07.

1.9 Emerging private sector support

(a) The Secretariat has initiated a number of consultations with private sector organisations with exciting potential to provide technical support to GAVI eligible countries under the GAVI Matching Fund. Two projects have been initiated so far. In Mozambique, Vodafone is trialling a project to improve coverage and stock management through a mobile-based information system capturing data on births and immunisations. LDS Charities, the humanitarian agency of the Church of Jesus Christ of Latter-day Saints, supported the double roll-out of Pneumococcal and Rotavirus vaccines in Ghana last year with a social mobilisation campaign for immunisation.

2 Strategic Goal 1: Accelerate the uptake and use of underused and new vaccines

2.1 At the end of 2012, the GAVI Alliance had six active vaccine programmes. Implementation had begun in 71 of the currently 73 supported countries for a total of 131 introductions into routine immunisation and 21 campaigns. More than a billion doses have been shipped to the eligible countries since GAVI began providing vaccines in 2001. Coverage across all 73 GAVI countries as per the end of 2012 is estimated to be 43% for third dose of Pentavalent reflecting the fact that Indonesia and most of India and Nigeria have yet to introduce.

⁴ Burkina Faso, DRC, Ethiopia, Ghana, Kenya, Malawi and Pakistan in 2011; plus Chad, Guinea, Haiti, India, Liberia, Nigeria, and Uganda in 2012.

- 2.2 At the December 2012 GAVI Alliance Board the Secretariat was requested to “benchmark GAVI’s vaccine procurement arrangements” with focus on the activities performed by UNICEF Supply Division. UNICEF indicated that it encouraged the undertaking of a benchmarking study of fees for procurement services to ensure that the Alliance gets the best deal in terms of cost and quality. Following that request, the GAVI Secretariat has initiated a project aimed at comparing the different vaccine procurement activities currently performed on behalf of the Alliance with ones performed by other similar service providers. UNICEF SD has been kept aware of the process and goals and confirmed its collaboration. Through a competitive selection process, an agency has been identified to support the Secretariat in its work and the benchmarking project has started during the month of May. The evaluation is expected to be completed by September with results and recommendation to be shared at the next Board in November. Because of the several links this evaluation is kept aligned with the end-to-end Supply Chain redesign project.
- 2.3 In 2013 GAVI has started two new vaccine programmes: Human Papilloma Virus (HPV) demonstration programmes (the first GAVI-supported national introduction is planned in 2014) and Measles-Rubella. Support for Measles Supplementary Immunisation Activities (SIAs) are planned to start from late May, taking to nine the number of vaccine programmes supported by the Alliance. One additional country (Somalia) has introduced Pentavalent vaccine with GAVI support taking the total to 72 out of a total 73 countries currently supported. In the first months of the year eight countries introduced new vaccines⁵. Throughout 2013, we anticipate 33 new introductions into routine programmes, 14 campaigns and six HPV demonstration programmes requiring in excess of 500 million vaccine doses. This level of activity is unprecedented for the Alliance.
- 2.4 For the Strategic period 2011-2015, all 73 GAVI supported countries are projected to have started at least one vaccine programme. Total shipments are projected to exceed two billion doses. Over the 2011-2015 period we foresee the start of 137 new routine programmes, 50 new campaigns and 29 HPV demonstration programmes. Progress of key vaccine programmes against GAVI’s Strategic Plan targets as of the end of 2012 was estimated to be:
- (a) Pentavalent: 43% against a target of 50%;
 - (b) Pneumococcal: 10% against a target of 17%; and
 - (c) Rotavirus: 3% against a target of 5%.
- 2.5 These results are slightly lower than those presented to the December 2012 Board. The key drivers of these results are:

⁵ Three additional countries are anticipated to introduce vaccines between mid-May and the time of the GAVI Board, Angola (Pneumococcal), Somalia (Meningitis A), and Ethiopia (Measles SIA)

- (a) Supply constraints affecting primarily Rotavirus vaccine for the entire 2011-2015 period are due to a mismatch between product preferences and supply availability. PCV supply will also be constrained until at least the beginning of 2014 as result of limited total manufacturing capacity available from the two suppliers and to a lesser extent because of recent production problems with one of the manufacturers. The impact of these constraints on GAVI's performance is amplified because the original targets were set in 2010 without assuming any supply constraint.
 - (b) Delays in country introductions vs. original 2010 approved plans primarily concerning Pentavalent roll-out in large countries (India, Nigeria, and Indonesia).
- 2.6 More active programme management across the Alliance is allowing us to mitigate the constraints above. This includes management and monitoring of supply to optimise allocation, coordination of in-country pre-introduction activities, increased deployment of technical assistance in countries including involvement of new and private partners to remove bottlenecks potentially delaying introductions, and proactive management of vaccine wastage.
- 2.7 With increasing attention to vaccine safety globally, utilisation of new vaccine products and more people than ever benefitting from vaccination, the absolute number of Adverse Events Following Immunisation (AEFIs) reported in many countries is increasing. Although a very small number of serious reactions are known to occur from vaccines, most AEFI reflect coincidental health problems, anxiety or errors in vaccine administration. This has led, often as a result of political concerns, to considering suspending or temporarily suspending some of our programmes (e.g. Pentavalent in India and Sri Lanka respectively). Effective and rapid communication about serious AEFI's is important to ensure that any true safety issue can be promptly identified and an appropriate response implemented by GAVI partners and the Secretariat. Closer communication and coordination across the Alliance and more proactive management in the rare instances where adverse events arise has been ensured by building upon the Global Vaccine Safety Blueprint infrastructure and mobilising in country partners. This has resulted in a rapid assessment of arising situations and issuing of required guidance from WHO to support country responses.
- 2.8 GAVI and Supplementary Immunisation Activities (SIAs)
 - (a) GAVI is supporting a growing number of SIAs (campaigns), such as Yellow Fever, Meningitis A, Measles-Rubella, Measles, and in the future Japanese Encephalitis. Because of its processes and governance GAVI is best suited to support planned, preventive SIAs, while others are better positioned to support campaigns aimed at responding to outbreaks (e.g. Measles & Rubella Initiative; Yellow Fever International Coordinating Group; direct partner support to countries).

(b) The Secretariat is modifying the New and Underutilised Vaccine (NVS) application guidelines for 2013 onwards. It will require all SIA applications to articulate the way activities related to a planned SIA will strengthen routine immunisation and/or primary health services. WHO and partners have supported studies and documentation of SIAs demonstrating how they may strengthen routine services which can inform such a requirement. Immunisation strengthening activities as part of an SIA may have financial implications that GAVI could look to governments and in-country partners to support. Requiring coverage surveys and/or evaluations could also have financial implications. The Secretariat anticipates consulting further with Alliance partners on ways that GAVI can support routine immunisation strengthening systematically as part of support to planned SIAs.

3 SG2 – Contribute to strengthening the capacity of integrated health systems to deliver immunisation

3.1 As of April 2013, the total portfolio of approved HSS grants since 2007 is US\$611 million, of which US\$425 million has been disbursed. In December 2012, these figures were US\$512 million and US\$410 million, respectively. The trend of increased disbursements from 2012 continues: US\$36 million was disbursed in the 4th quarter of 2012 alone, and US\$14 million so far in 2013, with a target of US\$100 million for 2013. Cash programmes represented 12% of total spending in 2012.

3.2 The latest HSS IRC was held from April 5 – 12, 2013. GAVI received three new proposals (India, Papua New Guinea and Rwanda), three annual programme updates with a request for the next tranche of funds (Bangladesh, Lao PDR and Nepal), and APR clarifications and a CSO Type B extension request from Pakistan. All submissions, including the three new proposals, were recommended for approval or approval with clarifications.

3.3 The Secretariat continues the overhaul of its HSS support model as part of the broader change process which involves a range of cross cutting areas within GAVI's business model. HSS support is being more closely linked to immunisation outcomes. The Secretariat draws on advice from the Technical Advisory Group for Health System Strengthening (TAG-HSS) and consultations carried out with key internal and external stakeholders.

3.4 Some of the key programmatic areas being implemented in the area of HSS include:

- (a) Setting up an inter-agency Management Group to coordinate Business Plan activities under Strategic Goal 2;
- (b) Development of new and more streamlined HSS application guidelines and forms; and
- (c) Rolling out Performance Based Funding (PBF) in the 15 countries approved for HSS support in 2012.

- 3.5 The Secretariat conducted a desk review of the currently active HSS grants (See Annexes 3 and 4 for additional details). The key highlights from this analysis are as follows:
- (a) In new generation HSFP grants, starting from 2012, countries prioritise activities which are very closely linked with immunisation;
 - (b) Cash utilisation is improving but still remains low in countries with unstable governments and volatile internal security problems;
 - (c) The majority of 17 reprogramming requests approved by GAVI during 2010-2012 are designed to lead to improved immunisation outcomes;
 - (d) In many countries implementing old generation HSS grants improved immunisation outcomes are observed but it is hard to attribute to the HSS grants.
- 3.6 GAVI intends to include in its country-specific HSS grant monitoring and evaluation frameworks intermediate HSS results and indicators, in addition to the core immunisation specific indicators set for Strategic Goal 2. These intermediate results and indicators will enable GAVI to better assess and monitor the impact of its HSS grants, and thereby mitigate methodological challenges related to measuring GAVI's contribution on immunisation-specific outcomes, which are affected by many confounders.

4 Strategic Goal 3: Increase the predictability of global financing and improve the sustainability of national financing for immunisation

- 4.1 Of the 65 countries required to co-finance their vaccines in 2012, nine countries are in default in their payments versus four at the same point the previous year. Only Afghanistan and Guinea did not make any contributions towards their co-financing requirements during 2012. The remaining seven paid arrears from the previous year and/or made partial payments towards their 2012 requirement. This suggests that while they are currently in default, it is anticipated that the Secretariat and partners will be able to support a number to come out of default in the coming months. The total amount transferred against the co-financing commitments by the 63 countries was approximately US\$47 million in 2012, accounting for 8% of the vaccine support to those countries. Since then, Angola has come out of default; Pakistan is currently in the process of coming out of default; while DRC, Sudan and Republic of Congo have made additional partial payments against its 2012 co-financing requirements. Those additional payments transferred throughout 2013 amounted an additional US\$5 million to the US\$47 million already transferred in 2012.

Section C Annexes

Strategic Goal 1. Vaccine Implementation

Annex 1 – Sources and definitions of performance metrics*

Indicators	2011 and before	2012	2013	2014-onwards
# of countries introduced/ing	<i>Vaccine Impl. team</i>	<i>Vaccine Impl. team</i>	<i>Vaccine Impl. team</i>	<i>SDF v.7 base case**</i>
Coverage	<i>WHO Progress report</i>	<i>SDF v.7 base case**</i>	<i>SDF v.7 base case**</i>	<i>SDF v.7 base case**</i>
No of people immunised/to be immunised	<i>WHO Progress report</i>	<i>SDF v.7 base case**</i>	<i>SDF v.7 base case**</i>	<i>SDF v.7 base case**</i>

* Data up to 2011 are actuals. 2012 figures are projections and are subject to change

** Supply constrained scenario for PCV and rota

Definitions:

- **Introduction:** First dose delivered, including ceremonial launch. This also applies to campaigns.
- **Coverage:**
 - o Numerator: number of people reached with last dose of series in the last year – irrespective of age and irrespective of funding.
 - o Denominator: target population in GAVI 73 for global vaccines in the last year

Annex 2. Vaccine Implementation

2.1 Pneumococcal Conjugate Vaccine (PCV)

2.1.1. Key programme statistics⁶ (programme start date 2009)

	Actuals	Forecasts			
	Programme start - 2011	Year 2012	Year 2013 ⁷	2011-2015 (BP Period)	Programme start - 2015
No. of countries	16	8	19	~54	~57
Coverage ⁸	4%	~10%	~20%	~41%	~41%
No. vaccinated	4M	~7M	~14M	~78M	~79M

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.1.2. Key programme facts

(a) **Supply constraints** are expected to be eased once the on-going tender is concluded, however, based on the latest supply estimates, it is still foreseen that a number of countries approved for 2013 introduction will be delayed to at least 2014. UNICEF Supply Division (SD) is seeking to complete the tender as quickly as possible, manage the impact of supply shortages, and planning for clear and timely communication to countries on supply availability to ensure the maximum use of available doses.

In April, UNICEF SD was informed of production issues that will reduce by 14 million doses the total 2013 available supply of one of the two products. While the root causes have been identified and production has been resumed, the capacity lost during the investigation process will not be recovered. With stringent management of the available supply, including utilisation of buffer stocks, it is expected that this will not lead to interruptions to programmes utilising the affected product in countries which have already introduced the vaccine and that smaller countries will be able to continue with their introductions as planned. However, it is anticipated that Uganda's planned scale up to cover all districts may be delayed by 2-6 months provided that the country is ready to introduce, while the introductions in Bangladesh and Nigeria will need to be postponed until the second half of 2014.

(b) Issues related to country-level readiness have presented challenges for the introduction and scale-up of PCV in some of the larger countries. Alliance partners are actively reviewing country readiness and coordinating technical assistance with the aim of identifying and proactively resolving implementation issues with the support of the partners working at the country level.

(c) In December 2012, The United Republic of Tanzania became the second GAVI supported country to **simultaneously introduce PCV and Rotavirus**

⁶ See Annex 1 for definitions and sources

⁷ Number vaccinated assumes 17 additional countries introduce in 2013

⁸ Coverage estimates are for the last year of the time period (i.e. do not represent cumulative coverage estimates)

vaccines, with the EPI programme utilising lessons learned during a study tour to Ghana, the only other country to have carried out a similar joint introduction.

2.2. Rotavirus Vaccine

2.2.1. Key programme statistics⁹ (programme start date 2008)

	Actuals	Forecasts			
	Programme start – 2011	Year 2012	Year 2013	2011-2015 BP Period	Programme start – 2015
No. of countries	5	7	~8	~36	~36
Coverage ¹⁰	1%	~3%	~7%	~21%	~21%
No. vaccinated	2M	~2M	~5M	~35M	~35M

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.2.2. Key programme facts

(a) The **supply shortage of the 2-dose schedule vaccine¹¹**, preferred by GAVI supported countries due to its smaller cold chain footprint, presence of Vaccine Vial Monitor (VVM) and dosing schedule, is the key challenge for the programme. Based on the manufacturer’s latest estimates on supply capacity, the 2-dose schedule vaccine will remain constrained in supply through 2016, a further worsening of the supply picture compared to our last update, and thus will not be available for new applicants for introduction before 2016 at the earliest. Alliance partners continue engagement with the manufacturer of the 2-dose schedule vaccine to increase supply and optimise utilisation of available supply.

(b) The **3-dose schedule vaccine** is available for earlier introduction, but there has been limited country demand so far. The Alliance partners continue active engagement and discussions with the manufacturer including advice for development of future product presentations to adapt to developing countries’ needs. GAVI is discussing with countries the supply situation and trade-offs between speed of introduction and product choice, actively supporting them in their decisions and implementation planning.

(c) **Early adopter countries** -- Bolivia, Honduras and Nicaragua – have shown strong performance, with rotavirus vaccine coverage reaching 80%, 98% and 98% respectively in 2011. Despite lower coverage in the earlier years of introduction likely due to the implementation of age restrictions, the coverage in these countries is now at the same level as DTP3 coverage.

⁹ See Annex 1 for definitions and sources

¹⁰ Coverage estimates are for the last year of the time period (i.e. do not represent cumulative coverage estimates)

¹¹ E.g. One county was required to postpone introduction from 2012 to 2013 -due to supply constraints whereas 13 others were approved for introduction as of January but will only be able to access supplies from Q4 2013

(d) In January 2013, WHO issued an updated position paper on rotavirus vaccines¹² recommending age restrictions to be removed in countries where disease burden is high and delays in vaccinations and deaths from rotavirus are common. The implementation of the new guidelines may lead to an increase in coverage but may also make supply constraints even tighter.

2.3 Pentavalent Vaccine (DTP+HepB+Hib)¹³

2.3.1. Key programme statistics¹⁴ (programme start date 2001)

	Actuals	Forecasts			
	Programme start – 2011	Year 2012	Year 2013	2011-2015 BP Period	Programme start – 2015
No. of countries ¹⁵	65	5	~2	~11	~73
Coverage ¹⁶	40%	~43%	~50%	~68%	~68%
No. vaccinated	130M	~31M	~36M	~189M	~291M

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.3.2. Key Programme Facts

(a) With the programme having reached all GAVI eligible countries, the emphasis is now focused on **increasing coverage and managing wastage** across all countries and in particular those under 70% DTP3 coverage. For the largest countries which have yet to complete their roll-out, a coordinated effort from the partners is on-going to assist the countries in timely achievement of their roll-out schedule:

- India – review of introductions to date in key states, track progress and plans regarding the sequence of roll out across the 35 states, active follow up on specific reports of adverse events following immunisation in 2 of the states.¹⁷
- Indonesia – track milestones of the phase III registration studies and licensure by National Regulatory Authority (estimated in Q3 2013) for the locally produced Pentavalent vaccine; support for prelaunch activities, and assessment of alternative scenarios for acceleration of the roll out¹⁸

(b) A more strategic use of **new vaccine vials presentations**¹⁹ now available from manufacturers allows consideration of new scenarios in the effort to reach

¹² Updated WHO position paper on rotavirus vaccines: <http://www.who.int/wer/2013/wer8805.pdf>

¹³ Pentavalent vaccine refers to countries receiving GAVI support for Pentavalent vaccine and does not include countries receiving only Hepatitis B or only Hib vaccine support.

¹⁴ See Annex 1 for definitions and sources.

¹⁵ Includes the 6 countries that introduced without GAVI support

¹⁶ Coverage estimates are for the last year of the time period (i.e. do not represent cumulative coverage estimates)

¹⁷ GAVI and partners are working with goal to understand the time frame, for complete introduction

¹⁸ Indonesia has a plan to complete by mid-2016, the country is assessing feasibility to introduce in a shorter time frame

¹⁹ 10ds, 5ds 2ds 1ds and auto disable compact prefilled devices

the most difficult children. For instance, use of multiple presentations in large countries may allow a potential optimisation between cost (per dose), cold chain footprint, wastage and coverage. As the data from 2012 becomes available with feedback from the 30 countries using the 10 doses vials, future programmatic decisions will be informed by more solid data²⁰.

2.4. Human Papilloma Virus Vaccine (HPV)

2.4.1. Key programme statistics²¹ (Programme start date 2013)

	Forecasts		
	Year 2013	2011-2015 BP Period	Programme start – 2015
No. of countries	~6 demo, 0 national	~29 demo, ~10 national	~29 demo, ~10 national
No. vaccinated	~0.1M	~0.5M	~2M

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.4.2. Key programme facts

(a) The GAVI Secretariat has worked extensively with traditional and new partners **to define terms and conditions of the HPV programme**. In particular the Secretariat is working to define an **HPV programme results framework** to establish targets in collaboration with the Alliance partners. Challenges and concerns related to introduction of a relatively costly immunisation intervention targeting adolescents to prevent later onset of cancer were taken into account in programme design.

(b) Over the past months, the Secretariat has focused its efforts on coordination for **technical assistance** to meet the needs of both countries getting ready to implement the programme and those countries planning to apply for support in 2013. Review of each country work plan and updated timelines to test solidity of their planning is currently on-going to ensure successful demonstration projects.

(c) Special efforts are focused on directing technical assistance in the area of (i) evaluation of programme **outcomes**; (ii) assessment of feasibility of **integration** of HPV vaccination with other adolescent interventions; and (iii) country development of a national **comprehensive strategy for cervical cancer prevention and control**. These areas are key to the HPV demonstration programme success and represent a great challenge for the Alliance in the light of issues related to identification and size of the target population as well as coordination and collaboration challenges within a large group of stakeholders (school/adolescent health, immunisation, cancer, reproductive and women health etc.)

²⁰ There is growing programmatic data from partners work on EVMs (Effective Vaccine Management) assessments, PIEs (Post Introduction Evaluations), EPI Reviews and other sources to establish improved programmatic understanding of new vaccine introduction

²¹ See Annex 1 for definitions and sources

(d) The Alliance has been working to secure **vaccine supply** through UNICEF SD. The HPV tender has been concluded and supply is available for approved countries.

2.5. Yellow Fever Routine and Campaign Programmes

2.5.1. Key programme statistics²² (programme start date 2001)

	Actuals	Forecasts			
	Programme start – 2011	Year 2012	Year 2013	2011-2015 BP Period	Programme start – 2015
No. of countries	11 (campaigns)	0	~2 (campaign)	~2 (campaigns)	~13 (campaigns)
	17 (routine)		~1 (routine)	~9 (routine)	~26 (routine)

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.5.2. Key Programme Facts

(a) The **success of Nigeria’s preventive campaign** programme is crucial. The country has a population at risk of more than 66M (40% of its total population) as it has not conducted any preventative campaigns in the past 30 years. Moreover, outbreaks were reported in 19 of the 22 states between 1986 and 1991 with a total of 16,320 cases reported and 3,633 deaths. In order to ensure the effective implementation of the preventive campaigns WHO is supporting the Federal Minister of Health to prioritise states based on risk level. Technical support for the elaboration of macro and micro plans will be provided as soon as the dates of the campaigns are decided so as to make sure the key components of the campaign, (e.g. social mobilisation, logistics, waste management, AEFI surveillance) are timely and appropriately implemented.

(b) **Ghana** conducted a Yellow Fever preventive campaign in 40 districts in November 2011 and 15 districts in September 2012 to prevent outbreaks in areas of the country at highest risk of the disease. Ghana’s health authorities achieved high coverage rates in the 2011 campaign — over 100% and reported wastage rate of only 2.4%. As result, to-date, no outbreaks have been reported in the vaccinated areas.

(c) **Low routine immunisation coverage** in some countries, especially those that have conducted successful campaigns, requires focused actions aimed at strengthening the EPI programmes.²³ The situation is especially concerning in the high risk countries (priority "A") where **districts that were not targeted for preventive campaigns** may now require such intervention due to changes in disease epidemiology and distribution of the vector leading to a change of their

²² See Annex 1 for definition and sources

²³ Analysis on-going to determine if low coverage is due to countries limiting routine programmes in high-risk areas only.

risk profile. Update of the risk assessments and coordinated Alliance efforts will be important to address this challenge.

(d) The **global supply** of Yellow Fever vaccines continues to be very tight, specifically in the short to medium term exposing the programme to risk of supply shortages in particular in the event of large outbreaks.²⁴

2.6. Meningococcal A Conjugate Vaccine – Campaign Programme

2.6.1. Key programme statistics²⁵ (programme start date 2010)

	Actuals Programme start – 2011	Forecasts			
		Year 2012	Year 2013	2011-2015 BP Period	Programme start – 2015
No of countries ²⁶	6	4	~2	~18	~19
No. vaccinated	54M	~54M	~52M	~220M	~240M

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.6.2. Key Programme Facts

(a) Although administrative coverage for the MenA campaign is generally reported as very high (74-104% on average), **several post-campaign surveys confirmed a slightly lower coverage** — 10-15 points less than the administrative numbers - raising questions on the need for additional activities.²⁷ This situation is a consequence of challenges in vaccinating some cohorts – in particular males from 16 – 29 and some remote areas. Countries are changing social mobilisation tactics to reach this target of the population. Security issues in Nigeria’s also slowed vaccination coverage in the Borno and Yobe states at the end of the 2012 campaign season as well. In January, the country conducted a “mop-up” campaign to reach this targeted area.

(b) **Other strains of Meningitis** still cause a significant burden in the belt. Outbreaks of the W135 subgroup were reported in 42 districts in 10 countries in the second half of 2012. Through the GAVI-funded stockpile, more than 5 million doses of meningitis polysaccharide quadrivalent vaccine were made available to respond to these meningitis outbreaks in 2010-2012.

(c) Currently **one single manufacturer** supplies GAVI for meningitis conjugate A. This situation exposes the programme to a continuing risk of continuity of supply.²⁸

2.7. Measles Second Dose

²⁴ See paper from Market Shaping for more information on long-term supply

²⁵ See Annex 1 for definitions and sources

²⁶ Includes the 6 countries that introduced without GAVI support

²⁷ Cameroon, 84% verbal, 63% with cards; Niger, 90.9 verbal and 68.8 with cards

²⁸ See paper from Market Shaping for more information on long-term supply

2.7.1. Key programme statistics (programme start date 2007)

Actuals		Forecasts			
Programme start - 2011		Year 2012	Year 2013 ²⁹	2011-2015 BP Period	Programme start – 2015
No. of countries	2	6	~3	~17	~19
No. vaccinated	7M	~3M	~7M	~36M	~41M

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.7.2. Key Programme Facts

(a) **Some of the countries eligible for Measles second dose are not exploiting the opportunity** of GAVI support to consider inclusion in their routine system despite WHO position paper encouraging countries to provide a second dose of Measles vaccine, either through routine or SIA. Information and advice from the Measles & Rubella Initiative is increasing to sensitise countries with high Measles first dose coverage to consider introducing a second dose through routine.

(b) Another challenge is in informing decisions for countries that will opt to **switch their Measles second dose for MR**. Programmatically and logistically, it is more practical to have both doses of the same vaccine type, although this would present additional financial challenges to countries.

2.8. Measles SIAs

2.8.1. Forecasted performance (programme start date 2013)

	Forecasts		
	Year 2013	2011-2015 BP Period	Programme start – 2015
No. of countries	~4	~6	~6
No. of vaccinated	~56M	~85M	~85M

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.8.2. Key Programme Facts

(a) The June Board in 2012 approved opening of a **window to allow six large countries** (Afghanistan, Chad, DR Congo, Ethiopia, Nigeria and Pakistan) at high risk of measles outbreaks to apply for SIA before the rollout of MR and not later than 2017. The opening of this Measles SIA window resulted in closer

²⁹ For 2013, number of countries are only those introducing in 2013, but number vaccinated are all 9 countries that receive GAVI support in 2013 (support for VietNam and DPRK have ended).

interaction with countries and partners, including Measles & Rubella Initiative and donors. This has also resulted in emphasis with the countries and all stakeholders on the importance of strengthening routine immunisation through Measles SIA. Using SIAs to strengthen routine immunisation remains an opportunity for all partners to seize upon and a challenge to implement.

(b) In the time since the Board submission, there have been changes in **target population assumptions** (which at the time of the Board were based on immunising only children under age 5), as well as changes in the data provided to the Secretariat about the expected epidemiological landscape with the distribution of cases shifting to an older age group, resulting in countries (Ethiopia and DRC) requesting support for a larger target age range (up to 15 years). At the Executive Committee meeting in March 2013 a decision was taken to limit the target population to those under 5 years of age. The SAGE meeting in November is expected to provide guidance on target age ranges for future Measles SIAs.

(c) **GAVI Alliance processes** are set-up to support routine or planned campaigns but not to respond to rapidly evolving epidemiological situations, including those triggered by outbreaks, where response-times are much shorter and not compatible with the ones of the Alliance governance. Arrangements to support to Ethiopia and Pakistan in particular have proven especially challenging. All partners have collaborated to make the country requested timing possible.

2.9 Measles Rubella

2.9.1. Forecasted performance (programme start date 2013)

	Forecasts		
	Year 2013	2011-2015 BP Period	Programme start – 2015
No. of countries ³⁰	~6	~24	~24
No. vaccinated	~85M	~193M	~193M

All forecasted data are subject to changes as consequence of revision of historical coverage data, progression of the programme and revised forecast assumptions

2.9.2 Key Programme Facts

(a) Currently there is **only one MR supplier** that is also the largest supplier of Measles to date.³¹ This situation exposes the programme to a risk of continuity of supply made higher in reason of the close interdependency between global Measles and MR demand. While the current supply situation is sufficient, uncertainty regarding India plans for introduction of the MR vaccine can put further strains on the global supply. Communication between Alliance partners to coordinate global supply / demand balance and timely and accurate forecast to suppliers and communication to countries are critical to prevent shortages.

³⁰ 2 of the 8 countries, Nepal and Lao PDR receive vaccine introduction grant from GAVI to introduce MR into routine.

³¹ See paper from Market Shaping for more information on long-term supply

(b) **Coordination of regional / country strategies and GAVI support for Measles and Rubella** is important to minimise implementation challenges. With almost all of the regions having regional elimination goals by 2020 at the latest, countries may seek support to immunise wider age groups. GAVI may anticipate growing requests to include wider target age groups in SIAs, and/or countries will need to coordinate GAVI's support with that from other sources for older ages. In this context, countries may be reluctant to introduce Rubella fearing a risk of shift in the age of infection with Rubella to older age groups leading to a paradoxical increase in Congenital Rubella Syndrome, even though Rubella is not as highly transmissible as Measles. SAGE in November is expected to make recommendations on both fronts.

Annex 3: Country cases of HSS programmes

Box 3.1: The case of Afghanistan

HSS was first implemented in *Afghanistan* in 2007 with a grant for US\$ 34 million. According to WHO/UNICEF official estimates published in 2012, the increase in DTP3 coverage in that period was from 63% in 2007 to 66% in 2011. Afghanistan is planning to conduct an end of grant evaluation for their first HSS grant. A new HSS grant is starting in 2013, covering the period 2013-2014 with US\$ 18 million. Due to the conflict context in the country, 70% of health activities are implemented by NGOs and to a very large degree also by the private sector. GAVI's HSS investment focuses on working closely with NGOs and the private sector to expand coverage for immunisation and maternal and child health services. Proposed activities also include training and placement of community health workers. Given the focus on partnerships, there is also a strong emphasis on performance-based management. An innovative monitoring and evaluation plan, which includes engaging an independent contractor to monitor implementation of the basic service package, is proposed.

Box 3.2: The case of Cambodia

In *Cambodia*, GAVI's HSS grant amounts to US\$ 10 million over 2008-15. From 2007 to 2011, national DTP3 coverage increased from 82% to 94% (WHO/UNICEF official estimates published in 2012). The grant focused on performance-based management, financial management and IMCI in 10 low- performing districts of the country.

Coverage surveys, data quality audits and independent evaluations throughout the life of the grant have confirmed that GAVI HSS has contributed to increased coverage and utilisation of services. At the commencement of the grant in 2008, only one out of 10 target districts had coverage for DTP3 above 80%. At the end of 2011, 9 out of the 10 districts had achieved greater than 80% coverage. Other measurable improvements include the following:

- DTP–hepB, Hib3 coverage in 10 target districts increased from 74% at baseline to 83% in 2011.
- Coverage for hepatitis B vaccine birth dose-24 hours in the 10 target districts increased from 25% at baseline to 96% in 2011.
- IMCI consultation for under-five year olds in the 10 target districts increased from 0.33 in 2008 to 1.53 in 2011.
- Immunisation at fixed facilities increased from 25% in 2007 to 45% in 2011.
- The number of districts that have reached targets in performance contracts increased from 1 at baseline to 10 in 2011.

Box 3.3: The Case of Ethiopia

Ethiopia's prospects for achieving MDGs are promising, with MDG4 (reduced child mortality) on track for 2015. Under-five mortality has declined from 123 deaths per 1,000 live births in 2005 to 88 in 2011. Ethiopia is one of the largest recipients of GAVI funding, with a total US\$ 374.9 million disbursed by the end of 2012, of which US\$ 76.5 million for a first HSS grant, which supported the Health Sector Development Programme (HSDP) III for the period 2007-2009, later extended to 2012.

The first HSS grant has substantially contributed to the implementation of the Health Extension Programme, as part of the national strategy to expand access to primary health care. A new US\$ 75 million HSFP grant was approved in 2012, covering the implementation of the HSDP IV (2010/11 – 2014/15). It will be channelled through the MDG Pool Fund. It aims at supporting innovative and evidence-based interventions that are identified as potentially gap-filling in the areas of cold chain management, strengthening and building the capacity of the health workforce, involving civil society organisations (CSOs) and initiating m-Health and electronic medical recording systems with the intent to reach unreached communities throughout the country.

Ethiopia's reporting to GAVI in the annual progress report has been inadequate. Direct follow-up with country is being undertaken, including an evaluation of the first grant being planned. This will help to inform the implementation of the new grant.

Much still needs to be done to improve immunisation outcomes. Although the reported full immunisation coverage has increased significantly from 22.3% in 1999/2000 to 75% in 2010/11, it is plateauing. Furthermore, while administrative data reported 87% coverage for DTP3 in 2011, WHO/UNICEF estimates were 51%. A national immunisation coverage survey was conducted in 2012 to clarify these discrepancies, strongly supported by partners, notably with active engagement of the Bill and Melinda Gates Foundation. It shows a sharp drop-out between DTP1 (80%) and DTP3 (65%). There are clear concerns of data quality in Ethiopia and efforts are underway to improve data quality.

Box 3.4: The case of DRC

DRC's grant of USUS\$ 56.8 million, which covers the period 2007-2013, focuses on areas ranging from strengthening institutional capacity at national, provincial and health zones levels, to reaching every district (RED) strategy and supporting services delivery in 65 health zones. The GAVI grant has also seen front-line health workers receive bonus payments as incentives to retain them in difficult access areas. The grant was reprogrammed in 2012 because of the delay in implementation to incorporate current challenges of the national immunisation programme. From 2007, the year of the first HSS funding to DRC, to the present, DTP3 coverage has fluctuated: from 70%, down to lower levels in two intervening years and back to 70% in 2011 (WHO/UNICEF revised estimates 2011).

Nonetheless, challenges have delayed programme implementation, namely a slow internal disbursement of funds through a collapsing banking system, and the subsequent requirement to initiate aide memoire and reprogramming requests. The increase in immunisation coverage was mainly related to an improvement in access to health services and complementarity of GAVI support with other health interventions. The role of a coordination mechanism to follow up on results linked to the disbursement of funds has been weak and needs strengthening. GAVI is working with the government and partners to strengthen the financial management mechanisms before the next tranche can be disbursed.

On a positive note, the aide memoire signed in 2011 saw the creation of a fiduciary agency and management unit together with partners, funded by GAVI to ensure effective management of the HSS funds. DRC is the only country where GAVI is funding such a mechanism. CSOs are also important partners in implementation. They are supported directly by GAVI to mobilise their communities and support HSS implementation activities in low-performing health zones. DRC is eligible for new HSS funding of USUS\$ 100 million for five years.

Annex 4: Analysis of 15 HSFP grants approved in 2012**HSFP grant analysis**

Strategic focus (extent to which proposals are aligned with national policies or plans, demonstrate a balance between systems and downstream service implementation, and are focused on immunisation outcomes):

- 15 out of 15 proposals have a strong immunisation focus, with frequent investment areas being cold chain, RED/REC strategies, information systems and performance based management.
- 15 out of 15 proposals demonstrate close links of activities and strategies to national health policies and/or plans.
- However, only 24% of the proposals strike an even balance between systems/policy development and service implementation, with the vast majority focusing on downstream implementation and capital investments.

Equity:

- Many of the HSFP proposals demonstrate focus on either geographic (59%) or socio-economic equity (53%). Although the majority of countries have an equity strategy (53%), in 47% of proposals there is some plan to make equity measurements.

Data quality:

- In the majority of cases, countries plan to validate outcomes through coverage surveys (56%) and/or data quality systems (81%). All in all, 13 out of 15 proposals plan either a coverage survey or DQA/S activity in the HSFP plan cycle. In nine of these countries, HSFP grants will fund coverage survey and/or DQA/S activity.

Monitoring and evaluation:

- There is a high level of aligned M&E planning (76%) and planning review (65%) with M&E frameworks clearly linked to immunisation outcomes (76%). Although the majority of proposals have some level of geographic targeting, in only 18% of proposals could it be established that some form of baseline assessment would be conducted in these specific areas.

Demand-side strategy:

- 88% of proposals demonstrated a reasonable balance of demand- and supply-side strategy. In 56% of cases, there was some indication of direct channeling of funds to CSOs or the private sector. 50% of proposals described some form of performance-based management system for public, private or CSO sector agencies.

Research and evaluation:

- The weak evidence base for HSFP is underscored by the fact that only 47% of countries have any form of research agenda, and only 29% identify a mid-term or end of programme evaluation in the text or work plan.

Technical cooperation:

- While not required, 43.8% of HSFP countries identified a clear technical cooperation plan with funding sources.

Annex 5. Co-financing amount paid by countries as share of GAVI support

