Report to the GAVI Alliance Board

4-5 December 2012

Subject:	**Country programme update**
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Section A: Overview

1 Purpose of the report

1.1 The GAVI Secretariat has established a restructured Country Programmes Department that comprises Country Support, Vaccine Implementation (formerly the Accelerated Vaccine Introduction initiative) and Technical Support.[1] This report provides an update on GAVI's work with countries.

2 Recommendations

2.1 This report is for information only.

3 Executive Summary

3.1 The Secretariat has focused on strengthening its Country Programmes Department through the following measures:

(a) An increased number of Country Responsible Officers (CRO) are now in place allowing for more frequent contact with countries. Staff are deepening their understanding of immunisation and development issues in GAVI countries, as well as strengthening relationships with governments and in-country partners. Improved monitoring of GAVI-funded programmes allows the Secretariat to be more proactive in jointly identifying and resolving implementation problems.

(b) The Secretariat has restructured AVI, now integrated into the Country Programmes Department. The new team will have an extended focus on implementation (reflected in the name change to Vaccine Implementation) and on the entire GAVI portfolio of vaccines. A new Director has been added to ensure stronger coordination across the Alliance. The VI team will concentrate on programme rollouts with dedicated specialist support for vaccines implementation and supply chain management.

[1] Effective 1 September.

(c) The Technical Support team will coordinate the implementation of the Alliance's Business Plan activities under Strategic Goals 2 and 3. The main areas of focus include: (a) strengthening health systems to scale up the immunisation programme performance in countries with DTP3 coverage below 70%; (b) addressing systemic bottlenecks causing inequities in immunisation coverage in countries with large equity gaps; (c) supporting countries in integrating national health strategies and multiyear immunisation plans; (d) improving accessibility and effectiveness of GAVI's cash based support for countries; (e) supporting countries in analysing fiscal implications of new vaccine introductions and delivery; (f) monitoring country compliance with GAVI's co-financing policy and supporting them to meet their financial commitments; (g) supporting graduating countries in achieving high programmatic and fiscal performance of their routine immunisation in a financial sustainable manner; and (h) country level advocacy for greater financial sustainability.

3.2 Since the last Board update in June, the Alliance has successfully managed 27 new vaccine introductions. In 2012, a total of 36 rollouts will mark the highest number of new vaccine introductions per year in GAVI's history.[2]

3.3 GAVI's active vaccine programmes have continued to progress in 2012:

(a) **Pentavalent Vaccine:** There were five introductions in 2012 (DPR Korea, Timor Leste, Haiti, Nigeria and Myanmar — a total of 71 since the start of GAVI's programme).[3] By 2013, 72 GAVI countries will have introduced Hib-containing vaccines enabling the Alliance to completely shift focus to increasing coverage; India is extending its rollout to six more states in late 2012/early 2013 and Nigeria will continue its phased-in programme to cover up to 21 states by 2013.[4]

(b) **Pneumococcal Conjugate Vaccine (PCV):** Ten countries are expected to introduce PCV by end 2012 (Ghana, Zimbabwe, Pakistan, Congo Rep, Madagascar, Zambia, Djibouti, Sao Tome & Principe, Tanzania, Angola — for a total of 26 since the start of the programme). The coordinated work of the partners has reduced supply constraints and addressed some of the readiness challenges, thus allowing the Alliance to make considerable headway with its PCV programme. Between 10-20 countries are expected to begin PCV rollouts in 2013.

(c) **Rotavirus Vaccine**: Seven countries are expected to introduce by the end of 2012 (Ghana, Rwanda, Moldova, Yemen, Malawi, Armenia, Tanzania), bringing the total to twelve countries since the start of the programme. Supply limitations, as well as the prevailing country preference for one of the available vaccines, has triggered delays in introductions that will continue throughout 2015; the current estimate for 2013 is 4-7 introductions.[5]

(d) **Conjugate Meningitis A Vaccine**: Four new countries are expected to introduce in 2012 (Benin, Ghana, Senegal, Sudan) and Nigeria,

[2] Expected by the end of December, 2012
[3] Six GAVI countries launched pentavalent without GAVI' support
[4] Pending supply availability and country readiness
[5] At the June Board, GAVI estimated five to seven PCV introductions and two to four rotavirus launches in 2013.

Cameroon and Chad will continue their phased campaigns through the end of the year. The Alliance marks the landmark of 100 million people vaccinated in two years of the MenA programme with Nigeria's Phase II campaign in December. Eight countries will have completed national campaigns, 2010-2012.[6] Campaigns continue successfully and supply remains sufficient even though GAVI is relying on a sole supplier.

(e) **Yellow Fever Vaccine** – Two campaigns are expected to start in 2012 in Cote d'Ivoire and Ghana (12 since the start of the programme). The rollout of campaigns under the initial investment case is nearly completed. With Nigeria's forecasted campaign in 2013, the Alliance will have reached all of the countries at highest risk for epidemics.

(f) **Measles 2nd Dose Vaccine** – Eight countries are expected to introduce by the end of 2012 (Bangladesh, Burundi, Cambodia, Eritrea, the Gambia, Ghana, Myanmar, Zambia — 10 since the start of the programme). Only the 21 GAVI countries that have reached 80% of measles first dose coverage are eligible for GAVI support. The focus of the implementation activities of all partners continues to be on increasing MCV1 coverage in the remaining countries.

3.4 Work is progressing for three new vaccine programmes scheduled to start in 2013 with GAVI's support:

(a) **Human Papilloma Virus Vaccine (HPV)** – Uganda and Rwanda have applied for national introduction of HPV and there is high interest for demonstration programmes. Fifteen countries applied to conduct demonstration projects, compared to the 11 previously forecasted.[7] Applications will be reviewed by an IRC in late November.

(b) **Rubella Vaccine** – Nine countries applied in 2012 for 2013 introduction.

(c) **Measles Vaccine SIA** - Following the Board decision in June 2012, work across the Alliance is underway to support six large countries (Afghanistan, Chad, DR Congo, Ethiopia, Nigeria and Pakistan) at high risk of measles outbreaks with supplemental immunisation activities (SIAs). DRC, Ethiopia and Nigeria submitted applications that will be reviewed by an IRC by end November.

3.5 GAVI remains on track to reach Business Plan targets in terms of number of country introductions for PCV[8], RV[9] and pentavalent[10] by 2015. The annual number of new vaccine programs is expected to increase from 36 in 2012 to 71 in 2014 (see Annex I)[11]. As result of this effort it is expected that the death averted target for the period 2011-2015 (3.9 million) will be achieved.

3.6 WHO/UNICEF estimates of global immunisation coverage showed a one percentage point decline (from 84% in 2010 to an estimated 83% in 2011

[6] Burkina Faso, Mali, Niger, Chad, Cameroon, Benin, Ghana and Senegal will have completed national programmes; Sudan and Nigeria continue phased programmes in 2013.
[7] Strategic Demand Forecast V6
[8] 58 introductions vs. 45 in business plan
[9] 42 vs.35 in business plan
[10] 73 vs. 69 in business plan
[11] Average across 2013-2015

(see Annex II). This decline is mainly due to lower coverage in Nigeria as result of a shortage of DTP vaccine, as well as new survey results in Indonesia and Ethiopia that triggered a downward revision of the estimates.[12] As a consequence, the reported DTP3 coverage in the GAVI eligible countries fell from 76 to 74 percent underscoring the key challenge for the Alliance — reaching the fifth child.

3.7 GAVI is revamping its HSS support model and improvements are already showing results. The total disbursement of HSS funds as of November 2012 is $393 million (81% of total commitments to date). The HSS grant approval rate has started to increase, notably reflecting improved quality of proposals and more effective Technical Assistance (TA) for immunisation programmes. The content of newly approved HSS grants has strong links to the objectives of Strategic Goal 1. The changes in the HSS support model are reflected in the Alliance's 2013-2014 Business Plan. The operational framework for Performance Based Funding (PBF) is being finalized and will be rolled out in January 2013. For this stream of work, the Secretariat is guided by the Technical Advisory Group for Health System Strengthening (TAG-HSS).

3.8 A new government in DRC has shown a desire to revitalise the country's immunisation programme. The government has cleared its 2010 cofinancing arrears and is determined to pay its 2011 commitment which would open the way for DRC to resume the rollout of PCV beyond the current four provinces. GAVI and partners are working with the government to ensure that it has a strategy for sustainable immunisation financing.

4 Risk implication and mitigation

4.1 Supply constraints, country readiness issues and the persistence of low coverage will be the main causes of missed immunisation opportunities in 2013 and beyond.

4.2 The Alliance partners have worked throughout 2012 to secure additional PCV supply for 2012-2013. A newly closed tender for PCV under the AMC is expected to further increase short-term supply availability for approved and forecasted countries.[13] For rotavirus vaccines, the manufacturer of the two-dose vaccine has installed additional filling lines, and the supplier of the three-dose vaccine is working to improve packaging and characteristics to make the product more compatible with developing world requirements. Unless additional supply is secured, most countries to be approved in the future will have to delay introduction for at least one year, and potentially longer for large countries (such as Pakistan and Bangladesh). The Alliance continues to work to address these challenges through ongoing dialogue with suppliers as well as strong support to countries in their decisions on the timing of introductions and product choices.

4.3 Working closely with partners and countries, GAVI is taking a more coordinated approach in assessing readiness to introduce new vaccines.

[12] The WHO confirms that given the variability in the underlying data, small year to year fluctuations can be expected, but are not statistically significant. In Indonesia and Ethiopia there is no "real" decline in coverage, but a retrospective change in coverage estimates due to newly available data.
[13] Forty-six countries are currently approved for PCV.

The strategy includes focusing on tailored approaches for large and priority countries and a revitalized HSS funding programme to decrease bottlenecks to sustained vaccine uptake. Work is underway to strengthen in-country supply chains, stock management, cold chain capacity and data reliability to address weaknesses in coverage reporting. There will need to be an increase in the country coordination of partner activities, with better feedback mechanisms to adjust implementation strategies moving forward.

5 Financial implications: Business plan and budgets

5.1 Further improvements to country stewardship initiatives and the HSS support model are reflected in the Alliance's 2013-2014 Business Plan. The new Business Plan is significantly different from past years' plans in terms of a greater focus on a selected set of high priority countries (countries with <70% DTP3 coverage and large equity gaps), and better coordination of critical activities under SG1 and SG2 at the country level.

Section B: Content

SG1 – Accelerate the uptake and use of underused and new vaccines

1 Selected Country update

India

1.1 Momentum has been building in GAVI's partnership with India since the CEO update to the June 2012 Board. In addition to Kerala and Tamil Nadu which introduced in late 2011, six states are planning to introduce pentavalent vaccine between Q4/2012 and Q1/2013.[14] Conclusions of the Post Introduction Evaluation (PIE) in Kerala and Tamil Nadu are positive. Supporting factors included good leadership, well trained health workers and high levels of community acceptance. The recent application of WHO's policy[15] on the 10 dose pentavalent vaccine vials has led to a significant reduction in vaccine wastage from 25% to less than 10%. (Historically, India has not applied this policy with the original DTP vaccine.) The Ministry of Health is considering the next phase of pentavalent rollout in nine additional states in 2013 (for a total of 17 out of 35 states), building on the catalytic support provided by GAVI.

1.2 India is finalising a proposal for Health Systems Strengthening, prioritising states with DTP3 coverage less than 60% and focusing on vaccine delivery; intelligence on supply chain management and temperature control; support to strategic communications (especially on demand); and improving evidence-based policymaking for adoption of new vaccines. GAVI assistance will promote innovation and bring resources to areas not supported by other donors. This will enable India to increase immunisation coverage, potentially sustain the gains of polio eradication efforts and prime the system to introduce other new vaccines.

[14] Some of the states' introductions have been delayed by the tight supply situation, however the minimal delays are now resolved with confirmed additional supply

[15] WHO policy (2001) on the use of opened vials helps to reduce wastage by avoiding immediate discarding of unused doses for vaccines with a preservative

1.3 In Q1 2013, the Secretariat will develop a plan in consultation with partners that sets out how GAVI will: support India to scale up pentavalent vaccines nationally; continue advocacy efforts to encourage the government to intensify routine immunisation and plan to introduce new vaccines; and help India affirm its global role in key international fora to step-up the fight against childhood and vaccine-preventable diseases globally.

Nigeria

1.4 The decline of DTP coverage in Nigeria below 50% in 2011 (WHO/UNICEF estimates) is a major cause for concern.[16] Data quality, training and motivation of healthcare staff, as well as vaccine stockouts, continue to threaten successful and sustained vaccine introduction. GAVI and Alliance partners have been working to develop a clear approach to support the government to respond to the challenges. A recent initiative by DFID's Permanent Secretary, Mark Lowcock, to improve coordination and collaboration by development partners is welcome and GAVI is actively engaged.

1.5 In the short term, GAVI has supported Nigeria to reprogramme HSS and ISS funds totaling $52 million to support introduction of new vaccines by: building capacity of frontline health workers in integrated primary healthcare (PHC) services; strengthening Management Information Systems; and upgrading cold chain capacity and supply chain management. The Secretariat is also preparing a longer-term, tailored approach for GAVI support to Nigeria for consultation with partners in Q1, 2013. Possible approaches include: working with and supporting the state level, such as supporting State Governors to establish PHC boards to improve accountability at the state level; supporting renewal of the Ministry's Logistics Working Group, including establishing an "early warning system" to ensure actions are taken in time to prevent stock-outs of basic vaccines; and leveraging strengths of polio eradication networks for enhancing performance of routine immunisation.

Democratic Republic of the Congo (DRC)

1.6 The report to the December 2011 Board highlighted the risk of an overstock of approximately a half million doses of pneumococcal vaccine which could expire during 2013. In May 2012, following an Alliance mission to DRC, the government paid $1,169,087 towards the 2010 co-financing requirement, which removed the country from cofinancing default for 2010. GAVI authorised DRC to use the doses as a one-off activity in Bandundu province.

1.7 In October 2012, the government paid $1,651,243 towards the 2011 co-financing requirement. DRC also transferred $1 million to UNICEF for purchase of traditional vaccines. This is a significant step towards country ownership since this is the first time that DRC has utilised government funds for the procurement of routine vaccines (beyond co-financing). However, DRC remains in arrears in the payment of the 2011 co-financing requirement in an amount of approximately $655,000. DRC is one of six countries

[16] The decline in 2011 is due to both challenges within country systems, but also the significant shortage of DTP vaccine observed in 2011 and partially 2012, more details available on request

identified as a priority for measles SIAs. Its application could be in jeopardy if the country remains in default of its cofinancing obligations.

1.8 The July Monitoring IRC reviewed a DRC proposal to expand introduction of pneumococcal vaccine in Bandundu and three additional provinces, (Kasai oriental, Kasai occidential and Maniema). The expansion plan is based on achievements in the four first provinces (PCV 3 administrative coverage above 70%) as well as the improvement plan submitted following post introduction evaluation and external EPI review recommendations. The IRC recommended the proposal for approval pending the fulfillment of 2011 cofinancing requirements. An in-country task team has prepared a revised Comprehensive Multi Year Plan (cMYP) for immunisation following the EPI review. GAVI will be working with Government and partners to ensure the revised cMYP addresses sustainability of immunisation financing.

1.9 GAVI conducted a country visit to DRC in October 2012 to monitor HSS implementation and financial management; encourage DRC to continue to pay its cofinancing arrears; and to engage in discussions on the draft cMYP. Further GAVI missions are planned for November and December 2012.

Pakistan

1.10 Pakistan introduced PCV10 in October 2012 in Punjab, the country's largest province with approximately 55% of country's total population of around 180 million. The country plans to rollout the vaccine nationally over a period of four months. Pakistan contributes 6.5% of the birth cohort of all eligible countries and is one of the largest recipients of GAVI support. The PCV introduction is a significant achievement given the political and programmatic challenges in the country. There has been a careful effort across the Alliance to monitor Pakistan's readiness to introduce PCV. The next Alliance monitoring mission is planned for December 2012 followed by a Post Introduction Evaluation in Q1 of 2013.

1.11 The July 2012, the IRC reviewed a request from Pakistan to resume HSS activities. These activities have been on hold since 2009 due to delays related to compliance with the FMA aide memoir and devolution of the federal health ministry. The IRC sought clarifications primarily relating to the M&E framework but there remain unanswered questions around national and provincial level roles and responsibilities regarding HSS activities following devolution. The Secretariat is working with government and Alliance partners to address these issues.

2 Product updates

Pentavalent Vaccines

2.1 Seventy-two GAVI countries will have incorporated pentavalent into their national immunisation programmes by the end of 2012 (see Annex III).[17] South Sudan is conditionally approved to introduce pentavalent vaccine and, once launched, all GAVI 73 countries will be immunising infants against five

[17] Includes graduating countries

major childhood diseases.[18] Supply continues to be tight and is being closely managed but is not considered a bottleneck to introductions or coverage increases in the future.[19] GAVI estimates that pentavalent coverage will reach 44% at year end versus the 50% 2012 Business Plan target, but by 2015 should reach the target of 76%.

Pneumococcal Vaccine Update

2.2 A total of 46 GAVI-eligible countries are currently approved for pneumococcal vaccine introduction. An additional five countries applied in the 2012 application round and four were recommended for approval by the IRC.[20] Twenty countries are approved for introduction in 2013; however, due to supply constraints, it is currently unclear whether ten of these will be able to introduce next year (see Annex IV). The timing of their introductions depends on the outcome of a tender process that is due to conclude in Q1 2013 as well as the uptake in the large countries which have launched to date.

2.3 Delays have continued to occur in 2012, with many introductions now planned for the last quarter. Only Senegal and Bolivia have postponed for reasons related to the limited supply of their preferred vaccine. GAVI continues to be proactive in increasing information flow and coordination to optimize introduction dates and to match supply with demand.

2.4 GAVI has also been working closely with partners to ensure that the countries adequately meet the additional training requirements linked to the novelty of the two-dose vial without a preservative. The first 2012 PCV10 introductions took place in Q4 in Pakistan, Madagascar and Zambia.

2.4 As previously reported, in several countries which first rolled out PCV, a 'mini catch-up' or 'backlog' of infants under one year of age occurred. An analysis conducted by the Clinton Health Access Initiative[21] (CHAI) in selected countries has now confirmed this resulted in 40% more children being immunised than originally planned during the first six months of the introduction period. In view of the supply shortages, the Alliance partners are working with countries to prioritise the immunisation of new-borns at 6, 10 and 14 weeks of age as per GAVI policy.

2.5 The Vaccine Implementation Management Team (WHO, UNICEF Supply Division & Program Division, AVI TAC, Gates Foundation and GAVI Secretariat) coordinate adjustments to vaccine shipments on an on-going bases. For example, in 2012 three countries required significant adjustments to pneumococcal vaccine shipment plans: Rwanda, after a transition from PCV7 to PCV13 in 2011; DRC after a Board decision to restrict expansion of their programme due to co-financing default, and CAR, in light of its low reported coverage. There has been a concerted effort to ensure there is optimal supply of vaccine in all countries, with a focus on countries which are

[18] Penta protects against Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type B. The GAVI 73 countries includes six countries that have launched pentavalent without GAVI support plus South Sudan which is expected to introduce by 2015 after receiving conditional approval in the 2012 application round.
[19] Penta supply has not limited introductions over the last 5 years, despite the tight situation
[20] Afghanistan and Nepal were recommended for approval; Burkina Faso and Liberia were recommended for approval with clarifications. In addition, Nigeria was recommended for approval for phases 2 and 3.
[21] The Gates Foundation has funded several grants to CHAI in East and West Africa, and shares the data and information through the Vaccine Implementation management team meetings

showing an increase in targeted infants of more than 10% over two years, as well as in (large) countries with >5% disparity between their administrative (country owned) data and the UNICEF/WHO data for DTP3 coverage.

2.6 The cumulative number of introductions and coverage by the end of the Business Plan cycle 2011- 2015 are estimated to be 58 and 43%, respectively (vs. target of 45 and 40% in the Business Plan). Coordinated efforts to increase coverage across the introducing countries should close the gap by 2015.

Rotavirus Vaccine Update

2.7 A total of 28 GAVI-eligible countries are currently approved for the introduction of rotavirus vaccines, and six additional countries were recommended for approval in the latest new vaccine application round. In 2012, seven countries are expected to introduce rotavirus vaccines: Ghana, Rwanda, Moldova, Yemen, Armenia, Malawi and Tanzania (see Annex V). The cumulative number of introductions and coverage in GAVI-eligible countries is 12 and 3%, respectively, by the end of 2012 (vs. target of 21 and 5% in the Business Plan).

2.8 Under the current supply assumptions, the cumulative number of introductions and coverage by the end of the Business Plan cycle (2011-2015) are estimated to be 42 and 22%, respectively (vs. target of 33 and 31% in the Business Plan). It may be possible to reduce the gap in coverage by 2015 with additional supply but this is yet to be determined.

2.9 Reasons for the lagging performance versus targets are primarily due to global supply constraints, and in particular a misalignment between country product preferences and available supply. Thirteen countries that had intended to introduce in 2013 were consulted on their product preference, but all preferred to wait for the two-dose vaccine to become available in late 2013 rather than switch to the three-dose vaccine which could have eased supply constraints. The current projection is now four to seven country introductions in 2013 (i.e. cumulative 16-19 countries by the end of 2013 versus target of 23 in the Business Plan).

2.10 The manufacturer of the two-dose vaccine is making strenuous efforts to accelerate production capacity with the installation of new filling lines,[22] but the time it takes for the validation and registration of this new manufacturing equipment means it will take 36 months to reach peak production. There is currently a gap of between 60 to 80 million doses by 2015.[23] Until more supply is secured, it is likely that most countries to be approved in the future will have to delay introduction for up to a year, and potentially more for the large countries (such as Pakistan and Bangladesh). An analysis is underway to look at possible scenarios to assess the magnitude of the issue.

2.11 In May, the WHO Strategic Advisory Group of Experts (SAGE) endorsed an easing in the strict age limits for rotavirus vaccine administration while emphasizing the need for improved timeliness of vaccination. This shift could

[22] As reported, this is due to 'teething problems' with the filling line of the manufacturer that produces the two- dose vaccine.

[23] Depending on future applicants being approved and introducing as planned. A 60m gap in the total demand in 2011-15 is approximately 25% shortage over the Business Plan period, including future potential applications.

improve coverage rates in the coming years, but will necessitate intensified training of healthcare workers in countries that have already introduced the vaccine.

HPV

2.12 GAVI opened two windows of support for HPV this year: i) GAVI will support national introduction of the vaccine for countries with a demonstrated ability to reach adolescent girls with multiple dose vaccination. Two applications have been received for this window of support: Uganda and Rwanda. Both have introduced the vaccine with a donation and plan to switch to GAVI support in 2014; ii) GAVI will support HPV vaccine demonstration projects for countries lacking experience in delivering multiple dose vaccination in 9 to 13 year olds to determine the feasibility of national introduction. By October 31, 15 countries had applied for demonstration projects in 2013 and 2014. An HPV tender was issued in October this year. Potential issues with HPV supply relate to the vaccine price, early availability of vaccine for early demonstration projects, and a potential imbalance between country preference and product procurement mix. After consultation with partners, GAVI took the decision to allow countries graduating during the course of an HPV demonstration project to make one application to GAVI for national introduction.[24]

2.13 Introduction of HPV vaccines will be challenging, given the new target age group, untested delivery platforms, potential sensitivities around a sexually transmitted virus, low awareness of cervical cancer burden and relatively high operational costs. Successful introduction will require collaboration across various programmes and institutions as well as international organizations active in adolescent, school health, reproductive health, education, cancer control and immunisation programmes. The HPV programme offers a unique opportunity to reach adolescent girls and strengthen integrated services delivered to this target group. To enhance the likelihood of success, the Vaccine Implementation Team has been working closely with the GAVI Alliance partners and non- traditional partners (e.g. UNFPA, UNESCO, UNAIDS, NCI, UICC) to develop programme guidelines and to ensure required technical assistance is available as and where needed.

Meningitis A

2.14 Mass vaccination campaigns will be conducted in four new countries by the end of the year (Benin, Ghana, Sudan and Senegal). Nigeria, Chad and Cameroon are continuing regional campaigns in Q3/Q4 of 2012. More than 50 million people are expected to be reached through this year's campaigns and the Alliance will mark the 100th million person vaccinated in just two years of the programme with Nigeria's phase 2 campaign in December.[25]

2.15 Initial administrative coverage has been high – 92-100%, although rates vary for hard to reach populations, including males 16-29 who are under-served by traditional vaccination programmes.

[24] The national application must be submitted no later than the next application round following completion of the demonstration project.
[25] Includes national campaigns completed in 2010-2011 in Mali, Niger and Burkina Faso.

Yellow Fever

2.16 Ghana and Cote d'Ivoire, the last "high risk" countries defined in the GAVI Alliance original investment case of 2008, are expected to launch yellow fever mass vaccination campaigns in Q3/Q4. Nigeria is expected to conduct a mass campaign in 2013 potentially reaching 60 million people through the end of 2015.[26] Global vaccine supply shortages continue but the situation should improve toward in 2013.

2.17 Next year, the GAVI Alliance Board is expected to consider next steps for yellow fever prevention programmes as part of the overall review of the vaccine investment strategy.[27]

Measles Second Dose

2.18 To date, five of nine countries approved in 2011 for measles second dose support introduced the vaccine into the routine system. Three are expected to introduce before the end of the year. Sao Tome and Principe is forecasted to introduce in 2013.

Measles-Rubella

2.19 With the window for MR support opening in 2012 the first nine countries have applied.[28] Awards for measles and MR vaccines in response to a UNICEF tender confirmed that while there is unlikely to be a vaccine shortage, GAVI must continue close coordination with suppliers in light of unexpected increased demand in 2013. Additionally, India's potential interest in MR could change the situation and must be closely monitored.

Measles SIAs

2.20 Following the Board decision in June, work across the Alliance is underway to support six large countries at high risk of measles outbreaks to apply for supplementary immunisation activities (SIAs). GAVI launched application guidelines for measles SIAs in September 2012. Ethiopia has already submitted an application, and DR Congo and Nigeria are expected to submit applications before the deadline in November. Based on those applications an assessment of the target population and implications of potential changes is required. In order to ensure a successful implementation, GAVI is negotiating a Memorandum of Understanding with the UN Foundation.

3 Special Studies

3.1 AVI Technical Assistance Consortium (TAC)[29] is moving forward studies to document vaccine impact of pneumococcal and rotavirus vaccines. The latest status of the series of studies is provided in Annex VI.

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[26] Nigeria is currently conditional

[27] The Board could approve an expansion of the YF programme to middle and low risk countries. Supported by the WHO, Ministries of Health in Kenya, Rwanda, Tanzania, Ethiopia, Sudan and South Sudan are currently conducting in-country risk assessments to identify specific districts and vulnerable target populations that could most benefit from preventive mass vaccination campaigns or EPI routine immunisation introduction.

[28] Including two countries that have only applied for a vaccine introduction grant to prepare for the integration of MR into routine systems

[29] AVI (now called VI - Vaccine Implementation), TAC is the Technical Assistance Consortium, comprised of Johns Hopkins, US CDC and other institutions led by PATH.

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

4 Health Systems Strengthening

4.1 By November 2012, the total portfolio of approved Health System Strengthening (HSS) grants, which includes the Health System Funding Platform (HSFP), is $485 million. Of this total, $393 million has been disbursed (81%). Since the last Board update, $43 million has been committed and $35 million disbursed. By the end of 2012, the total disbursement for the year may go up from the current $35 million to $70 million (see Annex VII). This would make 2012 the year of highest disbursements of HSS funds in absolute terms since 2008 bringing up the disbursement to approval ratio to 88%.

4.2 Between June and November 2012, the number of countries experiencing disbursement delays decreased from 24 to 17. About one-third of these delays were due to pending country responses to IRC clarifications. These clarifications are expected to be cleared by mid-November. Remaining disbursements delays are due to ongoing financial management assessments or the finalisation of Aide Memoires. The rest of the delays are related to weak implementation capacities, interruptions due to country emergencies (e.g. civil unrest), noncompliance with GAVI financial management requirements and delayed submission of annual audit reports.

4.3 The Secretariat launched the process of revamping its cash based support to countries with the aim of improving its effectiveness, focus on immunisation-specific health system bottlenecks, and overall disbursements of HSS grants. The final outcome of the process will be a new strategy for making HHS more effective in supporting GAVI's mission. The increased number of CROs will also make it possible to have stronger links with countries and thus enhanced coordination between HSS activities, vaccine introductions and country level advocacy.

4.5 This work is being informed by the TAG-HSS, an advisory group to GAVI's CEO, which held its first meeting in September. The meeting focused on four issues: the future of the health system funding platform; rolling out Performance Based Funding (PBF); setting up effective technical assistance and implementation support mechanisms; and incorporating country-by-country approaches in health system strengthening. High-level recommendations from TAG-HSS included: (a) taking a more tailored approach to HSFP; (b) to introduce adjustments to the Board approved model of PBF as it is being rolled out in line with feedback from country consultations; (c) to establish an additional channel for providing timely technical support to countries to complement the work of Alliance Partners. A series of follow-up events and consultations are planned with TAG-HSS to further advance the dialogue on the issues which are critical to GAVI and countries.

4.6 The results of streamlining HSS support processes are already noticeable. As mentioned above, stalled disbursements of about $30 million have been resolved and implementation rates have slightly improved. There has been a significant scale up of reprogramming - between June and November 11

reprogramming requests have been processed with the total value of $42 million. The quality of HSS proposals has been improving: there has been a notable increase in the approval rate of HSS proposals by IRC in the past six months. The February IRC approved only 56% of proposals, while the most recent November IRC approved 100% of proposals. The content of newly approved HSS grants have become much more immunisation-focused compared to earlier generations of HSS grants. A majority of the 2012 approved HSS grants address the issues of supply chain and human resource capacity and other operational barriers that hinder the performance of immunisation programmes.

4.7 The changes introduced in the HSS support model are reflected in the Alliance's 2013-2014 Business Plan. The new Business Plan is significantly different from the earlier versions in terms of a greater focus on a selected set of high priority countries (countries with <70% DTP3 coverage and large equity gaps), and better coordination of critical activities under SG1 and SG2 at the country level.

4.8 Despite some positive changes, the overall disbursement level of HSS is currently below the desired 15-25% of the total GAVI programme funding envelope. Many countries continue to struggle to scale up their routine immunisation systems to deliver better results in terms of higher coverage and greater equity. Country preparedness for new vaccine introduction remains the main cause of IRC's concern when reviewing new funding applications. This will be addressed through the 2013-2014 Business Plan which supports additional technical assistance.

4.09 In July 2012, the Monitoring IRC reviewed Annual Program Reports for 42 ongoing HSS grants. Of the 20 countries requesting the next tranche in 2013, 17 were approved (including nine approved with clarifications).

4.10 In July 2012 the GAVI Executive Committee approved six new HSS proposals with the first year programme funding envelope of $23,886,539 (Afghanistan, Burundi, Comoros, Sierra Leone, Tanzania, and Zimbabwe). Currently, the total first year programme funding envelope (2012 or 2013 programme years depending on the start date of the grant) of all 10 HSS grants approved in 2012 is $32,843,879.

4.11 The latest HSS IRC was held during October 29 – November 2, 2012. GAVI received five new proposals (Burkina Faso, Malawi, Nicaragua, Timor Leste, and Haiti) and one reprogramming proposal from Benin. All five proposals were approved with clarifications. The Benin reprogramming request was recommended for resubmission due to insufficient information.

4.12 Work to prepare for the rollout of PBF is progressing well. The PBF is being rolled out in 10 countries approved for health system strengthening support in January 2013. All countries submitting health system support applications in 2013 will be subject to the PBF unless the country context makes PBF unsuitable (extremely fragile environment, poor health information systems, etc.). Operational guidelines and implementation framework for PBF were developed through extensive consultations with countries, development partners, and TAG-HSS. With the aim to make the PBF model better "fit for purpose," mitigate inherent design risks, and reflect country requirements and

guidance from TAG-HSS, some adjustments have been introduced to the model design as permitted by the Board decision of June 2012.[30] The summary of adjustments to the Board approved PBF model is outlined in Annex VIII. The first round of PBF operations will be used as a learning opportunity to assess effectiveness and relevance of the PBF instrument and fine-tune if necessary. It is understood that the PBF model will not be appropriate for all countries; therefore this learning process will be very useful to refine and better inform our understanding of the relevance of PBF for different contexts.

SG3 – Increase the predictability of global financing and improve the sustainability of national financing for immunisation

5 Co-Financing

5.1 The overall performance of GAVI's co-financing programme suggests that financial sustainability is increasing in many countries. At the end of 2011, all countries except Angola, CAR, DRC and Togo, had fulfilled their 2011 co-financing commitment. Since then, Angola, CAR and Togo have paid their co-financing obligations. DRC is the only remaining country in default. The total amount co-financed by the 62 countries towards the 2011 requirement was $38 million. This is equivalent to 7% of GAVI's financial support to these governments.

5.2 In 2011, 25 countries, both non-graduating and graduating, co-financed at a higher level than the GAVI minimum. This is a strong signal that many countries are demonstrating a stronger political commitment to immunisation and that the value added of the support provided by the Alliance is leveraging an increasingly greater amount of domestic resources.

5.3 After four years of the programme, GAVI perceives positive trends in the implementation of the co-financing policy (Annex IX presents the co-financing evolution in dollar amounts since the first year of implementation). Countries' contributions have significantly increased from the first year of the policy in 2008. This is driven by various factors: increasing number of countries co-financing; new vaccines being rolled out; better compliance of countries with co-financing policies; and increasing frequency of countries co-paying voluntarily above the required amount.

5.4 According to the information in the countries' Annual Progress Reports, the average government financing of vaccines per capita amounts to US$ 3.8 (US$ 4.61 without India). GAVI observes a general trend of higher government investment per child with rising GNI per capita. Three countries from the Americas: Honduras, Guyana and Bolivia provide very positive examples of a significantly higher government investment in vaccines per child (the highest among the GAVI-countries) compared to other countries with a similar GNI per capita (see Annex IX). These countries are early introducers of new vaccines and financial sustainability is a top priority.

[30] Although there were concerns with the certain design risks associated with the PBF model the Board during its November meeting in Dhaka, agreed that it was important to move forward with the implementation and to make adjustments as needed as the performance based funding is rolled out.

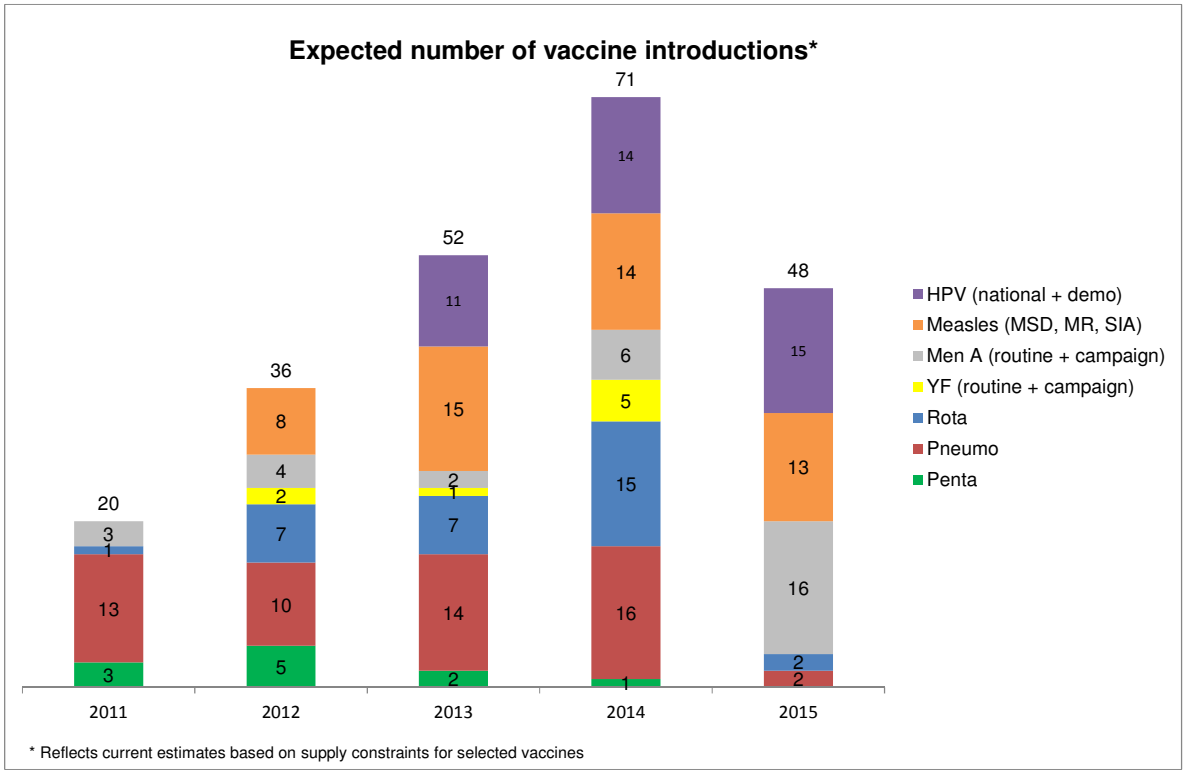
Malawi and Nicaragua are also investing significant funds in vaccines as compared to their GNI per capita.

5.5 In January 2012, the Immunisation Financing and Sustainability (IF&S) task team identified six graduating and four underperforming countries as priorities. The task team has visited five graduating countries; Congo Republic, Republic of Moldova, Bhutan, Mongolia and Georgia. Angola is the only country not visited (the visit was postponed due to the presidential election and is expected to be conducted in Q4). During the multi-partner missions to these countries, specific country action plans to support the graduation processes were finalized. All four underperforming countries, Guinea-Bissau, CAR, DRC and Guinea have already been visited. Weeks after the multi-partner visits to Guinea-Bissau and CAR, these governments fulfilled co-financing requirements.

5.6 The sustainability of GAVI's impact is necessary on both financial and programmatic components. However there are some graduating countries which experience serious programmatic performance challenges increasing the risk of sustainability of immunisation results. Until now GAVI's work with graduating countries tend to focus on financial performance only. However with emergence of the risk of programmatic sustainability, the Secretariat is preparing a draft of a new framework for engagement with graduating countries which will focus on a broader set of systemic issues that determine both the financial and programmatic performance and sustainability. The draft framework will be widely circulated for consultations among the Alliance partners before finalisation.

Section D: Annexes

Annex I. Increasing number of vaccine program introductions by year 2011 – 2013, this data includes the impact of supply constraints



Source: Vaccine Implementation team product managers, based on readiness and supply constraint assumptions as of November 6th 2012; data does not include any forecast Japanese Encephalitis and Typhoid conjugate introductions

Annex II. Vaccine coverage WHO/UNICEF for 2011, reported June 2012

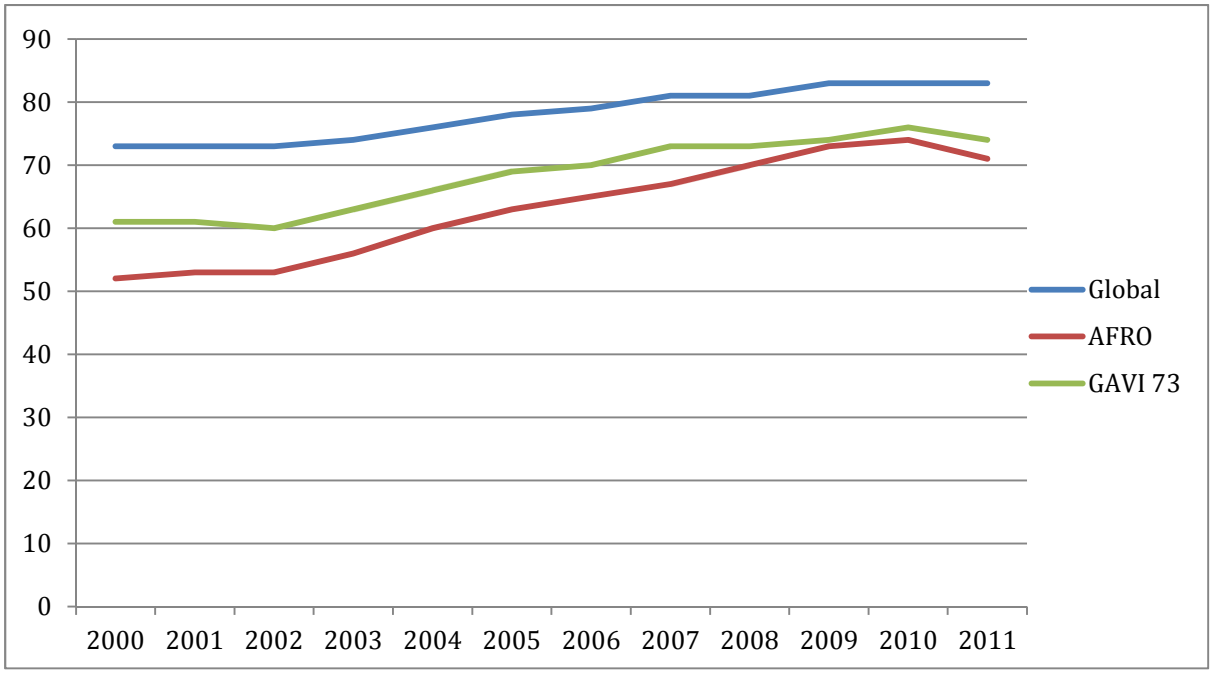
DTP3 country coverage changes due to availability of new survey results

	2011 estimates	2012 estimates		Percentage points decline	2011 Surviving infants
	For 2010	For 2010	For 2011		
Indonesia	83%	63%	63%	-20%	4.2m
Ethiopia	81%	50%	51%	-30%	2.4m
Cameroon	84%	68%	66%	-18%	0.65m

DTP3 country coverage with > 10% point reported drop in coverage

	2010	2011	Percentage points decline	2011 Surviving infants
Chad	35%	22%	-13%	0.45m
Cote d'Ivoire	85%	62%	-23%	0.63m
Nigeria	69%	47%	-22%	5.8m

% DTP3 coverage trends over time, WHO / UNICEF Joint Report 2011



Annex III. Pentavalent Vaccine Introductions: 2009 – 2013

Year	Country	Status	Number of Launches	Cumul. No.
<2010			59*	59*
2010	Georgia	Introduced in January	3	62
	Cambodia	Introduced in April		
	Vietnam	Introduced in June		
2011	Moldova	Introduced in July	3	65
	Azerbaijan	Introduced in August		
	India	Introduced in December		
2012	Haiti	Introduced in April	5	70
	Nigeria	Introduced in June		
	Korea	Introduced in July		
	Timor Leste	Introduced in October		
	Myanmar	Introduced in November		
2013	Somalia	Planned for Janurary-February	2	72
	Indonesia	Planned for July		
2014	South Sudan	Applied in 2012 for 2014 launch**	1	73
* Six not supported by GAVI				
** Conditional status				

Annex IV. Pneumo Vaccine Introductions: 2009 – 2013

Year	Country	Status	No. of Launches	Cumul No.
2009	Gambia	Switched to PCV13 in June	2	1
	Rwanda	Switch to PCV13 in August		2
2010	Nicaragua	Introduced in December	1	3
2011	Guyana	Introduced in January	13	4
	Yemen	Introduced in January		5
	Kenya	Introduced in January		6
	Sierra Leone	Introduced in January		7
	Mali	Introduced in March		8
	Congo, DR	Introduced in April		9
	Honduras	Introduced in April		10
	Central African Republic	Introduced in July		11
	Benin	Introduced in July		12
	Cameroon	Introduced in July		13
	Burundi	Introduced in September		14
	Ethiopia	Introduced in October		15
	Malawi	Introduced in November		16
2012	Ghana	Introduced in April*	10	17
	Zimbabwe	Introduced in June*		18
	Pakistan	Introduced in October		19
	Congo Rep	Introduced in October		20
	Madagascar	Introduced in November		21
	Zambia	Planned for November		22
	Djibouti	Planned for November		23
	Sao Tome & Principe	Planned for November		24
	Tanzania	Planned for December		25
	Angola	Planned for December		26
2013	Kiribati	Planned for May	11	27
	Armenia	Planned for 2013 – month tbc		28
	Georgia			29
	Guinea Bissau			30
	Mozambique			31
	Uganda			32
	Azerbaijan	Dependent on product selection		33
	Bolivia	First shipment available Q4 2013 - introduction month tbc		34
	Niger			35
	Senegal			36
	Sudan North			37
TBC	Bangladesh	Introduction dependent on supply - to update in Q1 2013	9	38
	Haiti			39
	Lao			40
	Lesotho			41
	Mauritania			42
	Moldova			43
	Nigeria (phase1)			44
	Papua New Guinea			45
	Togo			46

Annex V. Rotavirus Vaccine Introductions: 2009 – 2013

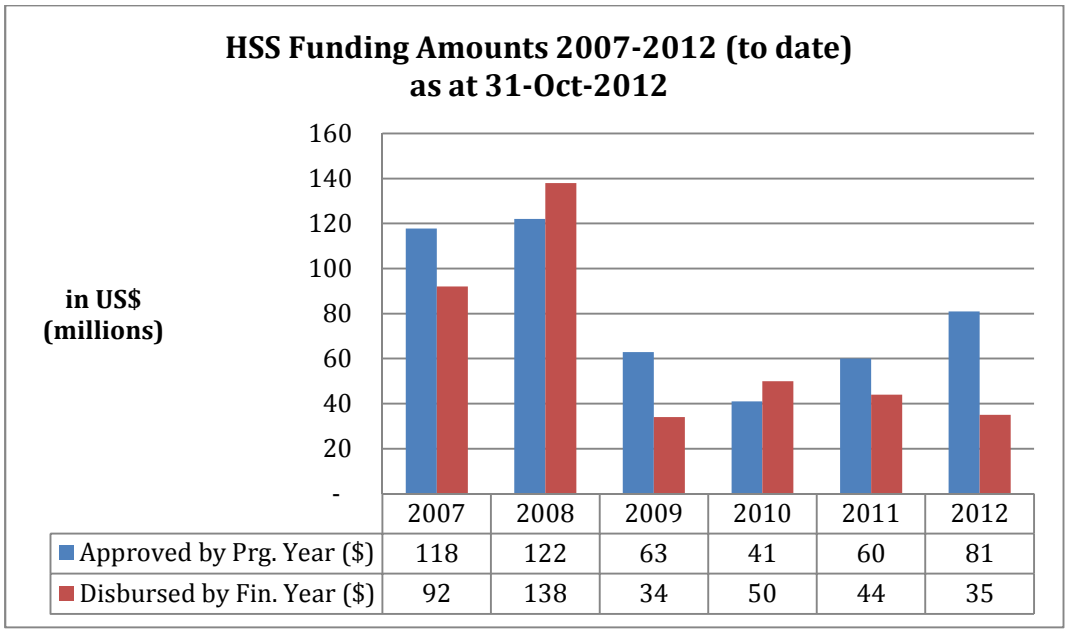
Year	Country	Product	Status	Number of Launches	Cumul No.
2008	**Bolivia**	2 dose	Introduced in July	**1**	**1**
2009	**Honduras**	2 dose	Introduced in December	**1**	**2**
2010	**Nicaragua**	3 dose	Introduced in 2006 based on a donation from supplier	**2**	**3**
	Guyana	3 dose	Introduced in April		**4**
2011	**Sudan**	2 dose	Introduced in July	**1**	**5**
2012	**Ghana**	2 dose	Introduced in April*	**7**	**6**
	Rwanda	3 dose	Introduced in May*		**7**
	Moldova	2 dose	Introduced in July		**8**
	Yemen	2 dose	Introduced in August		**9**
	Malawi	2 dose	Introduced in October		**10**
	Armenia	2 dose	Planned for November		**11**
	Tanzania	2 dose	Planned for December*		**12**
2013 / 2014	**Angola**	2 dose	Vaccine deliveries in late 2013 with a few exceptions; exact timing of introduction to be confirmed	**4-7 out of 15**	**16-19**
	Burundi	2 dose			
	Cameroon	2 dose			
	CAR	2 dose			
	Congo Rep	2 dose			
	Djibouti	2 dose			
	Ethiopia	2 dose			
	Georgia	2 dose			
	Haiti	2 dose			
	Madagascar	2 dose			
	Niger	2 dose			
	Sierra Leone	2 dose			
	Togo	2 dose			
	Zambia	2 dose			
	Zimbabwe	2 dose			
	Guinea-Bissau	2 dose		**1**	**17-20**

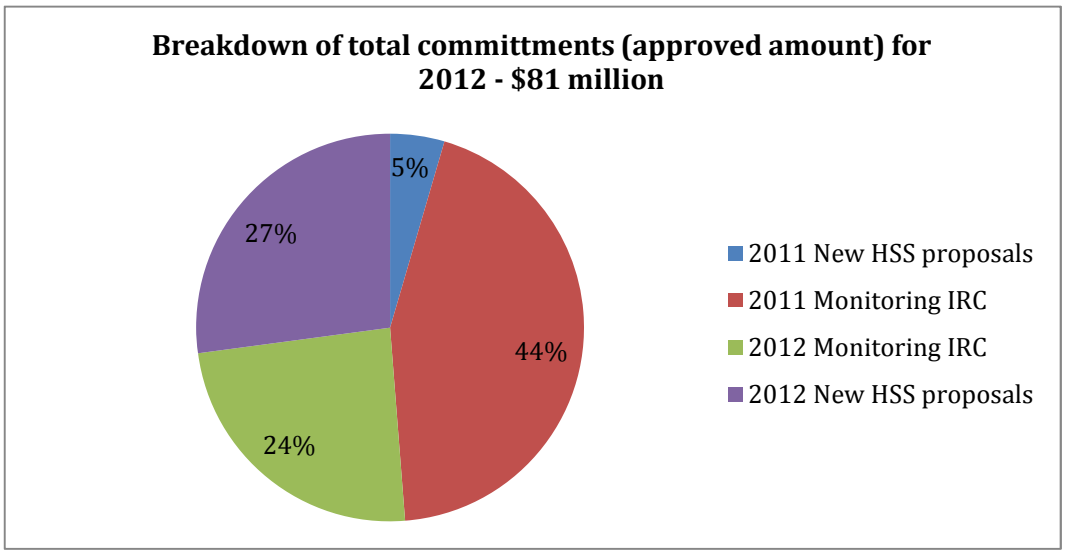
* Ceremonial launch; National introduction in the month following

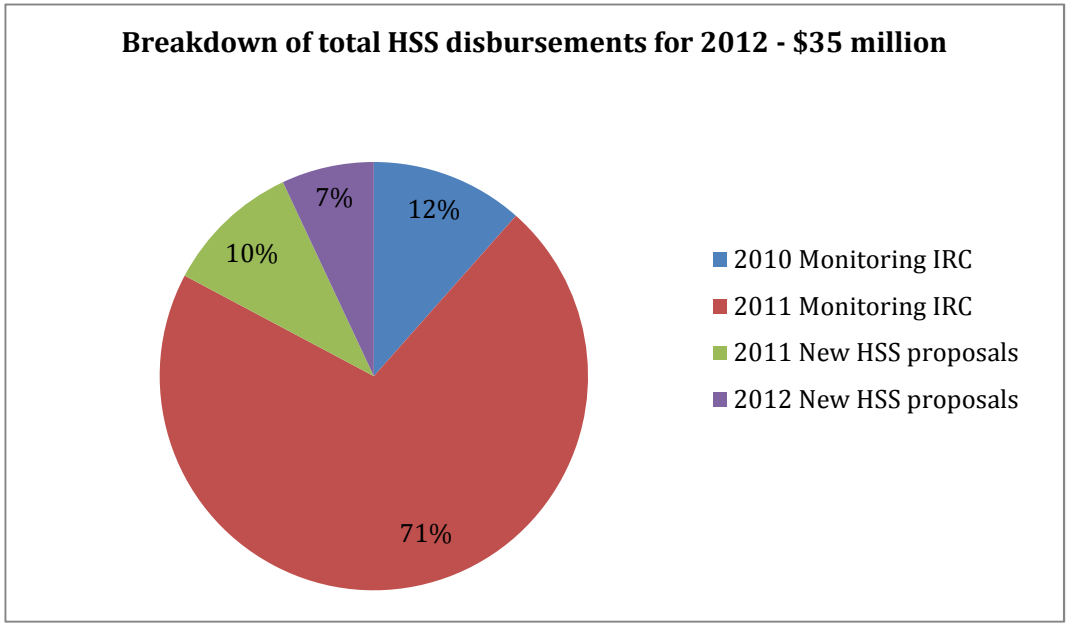
Annex VI. AVI TAC Special studies update

Study	Activities since June 2012
I.1. Landscape analysis of PCV dosing	Seven-paper supplement is nearing completion for submission to *Pediatric Infectious Diseases Journal*. Major findings are that both 3+0 and 2+1 schedules provide protection against IPD, NP colonization, pneumonia and induce herd effects. However the dosing regimens are not identical with respect to timing of immunogenicity, consequently dosing regimen choices should consider local disease epidemiology and vaccine programs.
I.2. Impact of breastfeeding on rotavirus vaccine (Pakistan)	Recruitment of all infants was completed in July 2012, with follow-up visits to be completed by the end of November. Data analysis has been planned and study results are expected in April 2013. Poster presentations of two abstracts were given at 10th Rotavirus Symposium, 19-20 September 2012.
I.3. Rotavirus transmission models	Publication of two papers in *PLoS One*: Models indicate lower rotavirus vaccine efficacy observed in some settings are driven primarily by reduced immunogenicity of the vaccine and reduced protection conferred by natural infection among low socio-economic status (SES) populations. Implications: Modifications to the vaccine or the vaccination program could generate considerable reductions in severe rotavirus gastroenteritis.
I.4. Rotavirus strain review	Study is closed and was published in April 2012 in *Vaccine*. Implications: Comprehensive, up-to-date information on rotavirus strain surveillance in pre-rotavirus vaccine era useful background to examine the impact of rotavirus vaccine introduction on future strain prevalence.
III.1a. Effectiveness pentavalent rotavirus vaccine (Bolivia)	Presentation to NUVI in May 2012: Effectiveness, impact and safety of rotavirus vaccination in Bolivia. Manuscript has been submitted for journal review. First study from a low-income country showing that a monovalent vaccine (Rotarix) is broadly effective against many strains. Results assured the Bolivian Ministry of Health that rotavirus strain emergence is natural and unrelated to vaccine use.
III.1b. Effectiveness pentavalent rotavirus vaccine (Nicaragua)	Publication in *Pediatrics* offering the first evidence of the duration of protection of the pentavalent rotavirus vaccine against severe rotavirus disease after routine use of the vaccine in a developing-country setting and showing protection of a magnitude consistent with other such studies in Asia and Africa. Presentation at 10th Rotavirus Symposium 19-20 September 2012.
III.1c. Rotarix® effectiveness (South Africa)	Measuring effectiveness in HIV-infected and HIV-uninfected children. Enrollment has been extended to a 3rd rotavirus season to achieve sample size needs, and preliminary results are expected in April 2013.
III.1d. Effectiveness of PCV7 against IPD (S Africa)	Preliminary findings reveal that even in a routine use setting, with high pneumococcal transmission and using a novel schedule PCV is highly effective for HIV-uninfected children but insufficiently so for HIV-infected children. Publication in *Vaccine* discussed effects of study on changes to PCV dosing schedule made by South African NAGI.
III.1e. Effectiveness of PCV against pneumonia (South Africa)	Measuring effectiveness in HIV-infected and HIV-uninfected children. Enrollment continues in order to meet the required sample size. Preliminary results are expected by April 2013.
III.1f. Pneumo/Rota time series (S Africa).	Data collection will be completed December 2012 and preliminary results are expected September 2013.
III.2. Hib conjugate vaccine impact manual	Manual has been published (October 2012) and is available on the WHO website. A presentation on the manual was made at NUVI meeting in May 2012.
IV.1. Economic impact of RV and PCV (Ghana and The Gambia)	Assessment of the economic impact of The Gambia's introduction of PCV was completed and two manuscripts are in preparation. Ghana data analysis is expected to be complete in Quarter 4, with a peer review journal submission in early 2013.
V.1. Web-based tools for cost-effectiveness analyses	Workshop on economic evaluation for vaccine decision-making was held 6-7 June 2012 with participants from seven francophone African countries. Participants acknowledged value in utilizing economic evaluation as part of the decision-making process in their countries, both for future vaccine introduction and vaccine program.

Annex VII. Breakdown of HSS commitments and disbursements





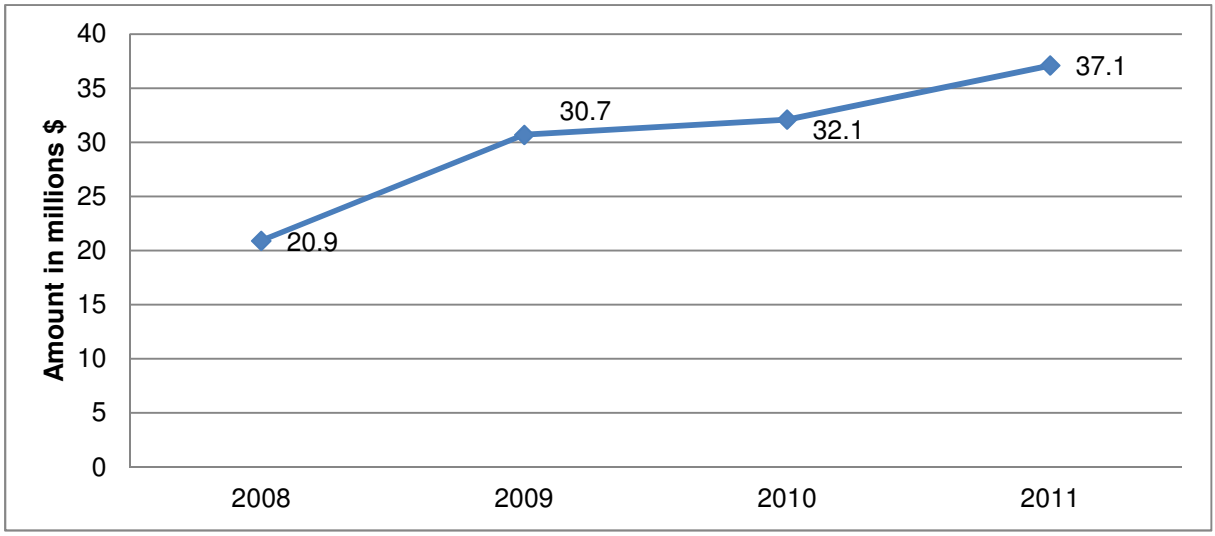


Annex. VIII.

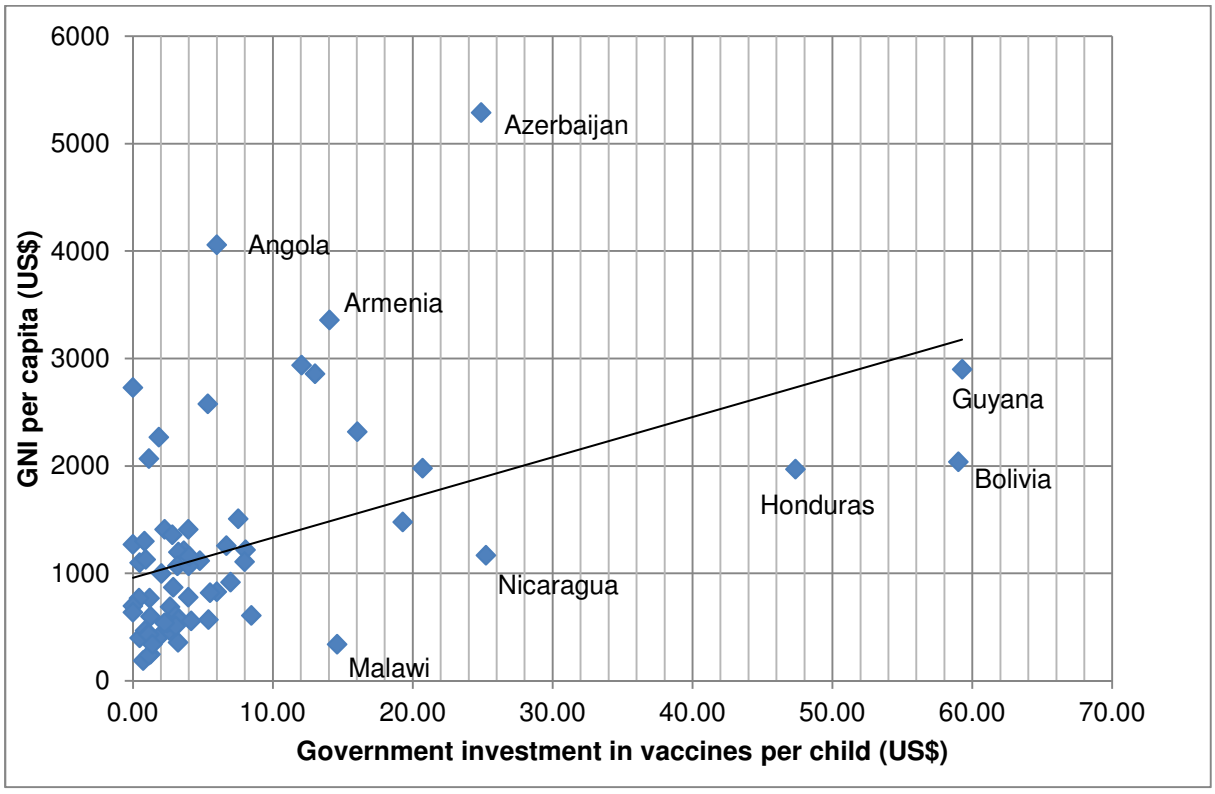
Summary of adjustments to the Board approved PBF model

Design elements	Board-approved PBF model	Proposed Adjustments
Fixed payments	20%, 40%, 60% of country ceiling based on country category.	80% of country ceiling for all countries
First year payments	100% of country ceiling.	No change
Maximum funding possible for Category A countries for best performance	100% of the ceiling	120% of the ceiling
Maximum funding possible for Category B and C countries for best performance	Above 100% of the ceiling, unlimited (but modeled to be realistic)	No change
Trigger for performance payments for Category A countries	1. Maintaining or increase DTP3 coverage. 2. District-level equity indicator.	1. Remaining above 90% threshold for DTP3 coverage 2. No change for equity indicator.
Performance payment for Category A countries	Up to 80% of ceiling	Up to 40% of country ceiling.
Trigger for performance payments for Category B and C countries	Increase in DTP3 & Measles coverage	No change
Payment per additional child immunised (Category B and C)	If DTP3 coverage increases, $20 per additional child immunised with DTP3; plus $20 per additional child immunised with first dose of measles containing vaccine, if measles coverage increases	Change from $20 to $30
Conditions attached to the use of performance payments	Untied but cannot be used for co-financing requirements.	In addition, explicitly state that funds have to be used in the health sector and in line with TAP requirements.
Conditions attached to the use of fixed portion	Investment in the national health strategy and other activities in line with HSFP.	Investment in activities programmed in the grant application. Must address health system bottlenecks for immunisation and be aligned with the national strategy.
Conditions for payment of the fixed portion	Board paper does not explicitly state conditions, although understanding is that payment would be linked to progress on grant implementation.	Explicitly link payment to progress on grant implementation using a specified number (3-5) of country-specific HSS intermediate output indicators programmed in the grant.
Source of performance data	Country reported	No change
Verification of country-reported data.	WHO/UNICEF estimates	In addition, use surveys in years available but recognizing that this is not often the case until GAVI has a plan to support surveys. GAVI IDQAs being rolled out will provide an indication of data quality but cannot be used for verification of country reported data for payments.
Measuring equity	Inter-district variation	No change
Monitoring implementation progress (implication for the fixed payment in the adjusted model)	Ongoing monitoring of grant implementation + APR	No change

Annex IX. Amount co-financed per year



Government vaccine financing per capita according to GNI per capita



*Excluded are the following countries: DPRK, Myanmar, Somalia, Cuba, Ukraine, South Sudan and Kiribati.