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Subject:Country Programmes UpdateReport of:Mercy Ahun, MD, Programme DeliveryAuthored by:Paul Kelly, Director, Country Programmes
Bakhuti Shengelia, Director, Country Grants and RenewalsAgenda item:03bCategory:For DecisionStrategic goal:SG1 - Vaccines, SG2 - Health systems, SG3 - Financing

Section A: Overview

1. Purpose of the report

- 1.1 The purpose of this report is to update the Board on: the implementation and performance of country programmes; the outcome of the work of the Large Country Task Team; and on the possibility that the Democratic Republic of Congo could default on cofinancing commitments. The report outlines achievements and challenges against three of the four GAVI Alliance strategic goals:
 - SG1 Accelerate use of underused and new vaccines;
 - SG2 Contribute to strengthening the capacity of integrated health systems to deliver immunisation;
 - SG3 Increase the predictability of global financing and improve the sustainability of national financing for immunisation.

2. Recommendations

- 2.1 The Secretariat recommends that the Board:
 - **Approve** the continuation of existing vaccine support for Pentavalent and Yellow Fever vaccines for DRC in 2012, in the event that the country is unable to pay its 2010 co-financing arrears for these vaccines by the end of 2011.
- 2.2 The Board may also wish to note that, with respect to India and Nigeria, the Policy and Programme Committee agreed in September that the two countries need a tailored approach for GAVI support and asked the Secretariat to work with these countries and partners to develop a country strategy.

3. Executive summary

3.1 Countries continue to make progress towards the objectives of the Alliance's strategic goals. Based on WHO/UNICEF estimates, average DTP3 coverage increased from 73% to 78% in GAVI eligible countries from 2009 to 2010. The number of countries with at least 90% coverage increased by 27% (from 26 in 2009 to 33 in 2010). However, the preliminary Ethiopia Demographic & Health Survey 2011 report highlights ongoing

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challenges with data quality. The survey indicated that 37% of children completed the required three doses of the pentavalent vaccine, compared to the 2010 WHO/UNICEF estimate of 86%.

- 3.2 The rate of new vaccine introductions in 2010 slowed due to supply issues and the Board's decision to defer new application submissions in 2009. 54 countries implemented health system strengthening programmes with the aim to address crosscutting, systemic sector constraints which impact their capacity to deliver immunisation services successfully. More countries are able to meet co-financing requirements and improve the financial sustainability of their immunisation programmes. The report highlights that large countries as well as under-performing and fragile countries require development of tailored strategies.
- 3.3 The Large Country Task Team on India and Nigeria was formed to identify new and innovative ways of working with these two large countries. The task team brought together a wide range of stakeholders and conducted in-country consultations on future collaboration. Together, India and Nigeria constitute 47% of unimmunised children and 44% of the total birth cohort of GAVI eligible countries, and thus have a significant impact on global immunisation progress. The two countries also have a complex federal structure with large national and sub-national inequities. Both countries are experiencing rapid economic growth and are expected to graduate between 2015 and 2017. The recommendations of the Task Team were discussed at the September PPC meeting. The PPC agreed that these countries need a tailored approach and requested the Secretariat and partners to work with the countries to develop a plan of action with both countries. The multi-agency senior level task team consultation generated very positive support and momentum in both countries. A partnership approach with each country could potentially include targeted TA support, a waiver of the filter for new vaccine introduction and a flexible approach to provision of support to CSOs.
- 3.4 The Secretariat conducted six IRC reviews in 2011: three Annual Progress Report reviews in February, July and September for assessments of a total of 228 country grant renewal requests; 2 new vaccine application reviews in March and April for Meningitis A campaign applications for 3 countries and a June/July round for 75 new vaccine applications. This is the highest number of reviews ever held in a single year since GAVI's inception and was largely managed by two programme staff and consultants. Additional staff have been requested to help manage the review process in the future.
- 3.5 <u>SG1 Accelerate the update and use of underused and new vaccines.</u> By end 2010, eight countries had introduced new vaccines: Pentavalent Cambodia, Georgia and Vietnam. Pneumococcus vaccine Nicaragua; Rotavirus Guyana. Meningitis A Burkina Faso, Niger and Mali.
- 3.6 SG2 Contribute to strengthening the capacity of integrated health systems to deliver immunisation. GAVI currently supports health system strengthening (HSS) in 54 countries. Most of the GAVI-funded HSS programmes have been under implementation for less than three years and have not yet produced significant measurable results. There are promising cases which provide examples of how a systemic approach to addressing health system constraints can contribute to better immunisation outcomes. Many HSS activities experience slow disbursements in part due to fiduciary safeguarding measures introduced under the Transparency and Accountability (TAP) policy. Following the recommendations of the Monitoring IRC, the Secretariat is considering modifications to the implementation of the TAP policy without weakening fiduciary

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controls. In some cases, the HSS programmes exhibit technical design flaws and require reprogramming. The Secretariat is working with Alliance partners to ensure that countries with faltering HSS activities receive adequate technical support to improve programme performance. From 2011 GAVI began transitioning to the Health System Funding Platform (HSFP). It is expected that 8-12 countries (not currently receiving GAVI HSS funding or with ending HSS grants) will apply by December 2011. These applications will be reviewed in early 2012.

- 3.7 SG3- Increase the predictability of global financing and improve the sustainability of national financing for immunisation. The co-financing policy is working well. All countries (except DRC) fulfilled their co-financing commitment for 2010. The total amount co-financed was US\$ 31 million. This is equivalent to 11% of GAVI financial support. DRC is the only country that remains in default of the 2010 co-financing requirements for Pentavalent and Yellow Fever vaccines. The co-financing policy on default will come into effect if they do not pay by the end of the year. The secretariat has sent a reminder letter to DRC on co financing. GAVI's co-financing policy states that 'if a country remains in default for more than one year, the GAVI Board may suspend support for the relevant vaccine until the co-financing arrears are paid in full'.
- 3.8 The Secretariat requests the Board to exempt DRC from suspension and exceptionally approve ongoing vaccine support for Pentavalent and Yellow Fever vaccines for DRC in 2012, in the event that the country is unable to fulfil its commitment by the end of 2011. This will be consistent with a customised approach for countries in special circumstances which is included in the co-financing policy. However, DRC will not be approved for new vaccines or be able to expand current vaccine support (pneumococcal vaccine in four provinces). The Secretariat will continue to work with the country to improve programme sustainability and subsequently update the Board in 2012.
- 3.9 Following the 2011 review of new vaccine applications and of the annual progress reports (APRs), the Independent Review Committee (IRC) made recommendations on policy and programme implementation. The main issues identified by the IRC include: disbursement of country commitments; data quality for immunisation coverage and equity; implementation of HSS grants; and special needs of fragile states. The proposed management response will be submitted to the PPC in April 2012.
- 3.10 Actions underway to address challenges include:
 - Increased funding for Alliance partners to complete Effective Vaccine Management Assessments (EVMs) and monitor implementation of recommendations which has been included in the 2012 business plan.
 - Introduction of a country grant scorecard to improve monitoring of cash programmes and support earlier intervention and target work with partners to re-programme current HSS grants that are significantly delayed.
 - A partnership approach to collaboration with India and Nigeria addressing the specific issues related to progress in immunisation.
 - Targeted strategies to work with countries vulnerable to repeated co-financing defaults, such as DRC and Guinea.

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4. Context

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

- 4.1 In 2010, eight countries introduced new vaccines with GAVI support. The new introduction included pentavalent vaccine in three countries (Cambodia, Georgia and Vietnam); Pneumococcus vaccine in Nicaragua; Rotavirus vaccine in Guyana and Meningitis A Conjugate vaccine was introduced in Burkina Faso, Mali and Niger.
- 4.2 The low number of vaccine introductions were due to two main factors:
 - The GAVI Board decision to defer the approval of the recommendations of the Independent Review Committee for new country proposals at the end of 2009.
 Countries that were planning to introduce new vaccines in 2010 were not approved until the third quarter of the year and the introduction of new vaccines was postponed to 2011;
 - Limited supply of some of the new vaccines, particularly PCV. Several approved countries that had planned to introduce PCV in 2010 were only able to receive the vaccines at the end of the year. Most countries decided to introduce PCV in 2011.
- 4.3 There are multiple operational challenges related to the introduction of new vaccines. Effective Vaccine Management (EVM) assessments revealed a number of critical weaknesses that compromise the efficacy of new vaccine introduction:
 - Damage occurring to vaccines during storage in the cold chain and transportation;
 - Inadequate storage capacities, particularly at the intermediate levels of cold chains;
 - Sub-standard or inadequate vaccine transportation and distribution systems which compromises programme objectives;
 - Serious shortcomings in supervision, monitoring and evaluation, stock management and immunisation reporting.
- 4.4 It is imperative to continue strengthening in-country vaccine management and supply chain capacities in order to ensure better value for money and increase coverage in a sustainable and efficient manner.
- 4.5 Immunisation coverage in GAVI eligible countries is increasing. The DTP3 coverage in 2010 reached 78% (the global coverage was 85%), which is five percentage points higher than in 2009. Notable increases in DTP3 coverage in the past five years have been in the Africa region (AFRO 77% in 2010), and the Western Pacific region (WPRO 96% in 2010). Currently EURO, WPRO and the Americas (AMRO) regions report average DTP3 coverage above 90%.
- 4.6 DTP3 coverage in 39 countries is below the GIVS target of 90%. 12 countries have a DTP3 coverage below 70%, which means that they cannot access GAVI's support to introduce new vaccines (Afghanistan, CAR, DR Congo, Chad, Guinea, Haiti, Liberia, Mauritania, Nigeria, PNG, Somalia and Uganda). The situation worsened in DRC and Uganda as the number of unimmunised children increased in 2010 compared to previous years. Progress in the two large countries with the largest birth cohorts was mixed. In India, the number of unvaccinated children with DTP3 has remained about the same (7.23 million) for the last three years. The proportion of unimmunised children in Nigeria decreased from 2.59 million in 2008 to 1.78 million in 2010. Reports from the Large



Country Task Team (India and Nigeria) and the WHO-led work on Low Performing Countries (DTP3 coverage < 70%) was presented during the September PPC meeting. The recommendations are that GAVI should develop a partnership approach with the two large countries to provide tailored support including targeted technical assistance, a waiver of the filter for new vaccine introduction and a flexible approach to CSO funding (See annex 4 and 5).

4.7 The preliminary 2011 Demographic & Health Survey (DHS) in Ethiopia highlights ongoing challenges with data quality. According to the report, 64% of children received the first dose of pentavalent. Coverage rates for all three of these vaccines have increased since the 2005 DHS estimates. 37% of children completed the required three doses of the pentavalent vaccine. The 2010 WHO/UNICEF estimate indicated that 86% of children completed the required three doses of the /Pentavalent vaccine in 2010. UNICEF and WHO have decided to support the government to conduct a follow up immunisation coverage survey to validate the DHS data. The survey will be completed prior to the release of the Final DHS Report in December 2011.

<u>SG2 – Contribute to strengthening the capacity of integrated health systems to deliver immunisation</u>

- 4.8 Strengthening health systems is an important instrument through which GAVI can achieve sustainable immunisation outcomes and improve immunisation programme performance especially in those countries where coverage rates remain below 70%. GAVI supports health system strengthening (HSS) in 54 countries. Most of these programmes have been under implementation for less than three years and have not yet produced significant tangible results. Some countries (including Afghanistan and Cambodia) report improved immunisation coverage as a result of HSS support. Annex 2 provides examples of HSS implementation where good progress is being made.
- 4.9 GAVI HSS programmes experienced some implementation challenges which pose a risk to their effectiveness. Of the 28 countries reporting implementation progress to the Monitoring IRC (and requesting continued funding), 15 (53%) were approved for ongoing support. Many countries carrying out HSS activities experience funding and implementation delays related to TAP measures, which require immediate attention. Organisational and management processes and weak institutional capacity impede decision making, planning, monitoring, procurement and cash flows.
- 4.10 The Secretariat is working with Alliance partners to ensure that countries with faltering HSS activities can receive technical support to improve programme performance. The Secretariat, in collaboration with WHO, has been implementing a "traffic light" risk monitoring system based on intelligence collected by WHO and GAVI Country Responsible Officers (CROs). Technical assistance may include a situation analysis, development of new design options for reprogramming, monitoring and evaluation activity to gather better intelligence, a policy dialogue event, etc. Currently, 12 countries are identified as the highest priority countries for reprogramming. The Secretariat and WHO will hold quarterly meetings to track the progress of reprogramming and address emerging problems.

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¹ Cote d'Ivoire, Cuba, Gambia, Ghana, Guinea Bissau, Indonesia, Madagascar, Myanmar, Nigeria, Sri Lanka, Somalia, Tajikistan



- 4.11 The GAVI Secretariat continued work on the Health Systems Funding Platform (HSFP) in coordination with the Global Fund, World Bank, and WHO. The Platform is being implemented through two streams of work: harmonisation of existing funding and new HSS funding.
- 4.12 New HSS funding through the HSFP is available to countries from August 2011 via two mechanisms: i) a GAVI-Global Fund Request Template based on a jointly assessed national health strategy, and ii) a GAVI-Global Fund Common Application Form. As an interim and bridging mechanism, the Common Proposal Form has been developed for countries which are mid-way in the implementation of their health sector strategic plan. The Common Proposal Form can be used to apply separately either to GAVI, the Global Fund, or both agencies. It is possible that some countries (for example fragile states) will not have the capacity to develop health sector plans and will continue to request funding based on the Common Proposal Form.
- 4.13 Tanzania (common form) and Ethiopia and Vietnam (request template), piloted the application materials in 2011, and have submitted new funding proposals which were reviewed by the IRC in September 2011. Application materials were reviewed by the PPC Cash Based Task Team and jointly approved by the chairs of the GAVI PPC and Global Fund Portfolio Implementation Committee (PIC). The Secretariat currently anticipates 8-12 countries will apply for new funding by the end of 2011.
- 4.14 The IRC, which reviewed the three pilot HSFP proposals made a number of programmatic and procedural recommendations regarding HSS funding under the HSFP. Key recommendations are summarised below:
 - New HSFP applications need to clearly demonstrate linkages with and lessons learned from previous HSS grants;
 - Applications need to explicitly indicate the expected impact of HSS activities on immunisation outcomes and complementarity with the HSS activities funded by other donors;
 - Countries which have undergone a Joint Assessment of the National Health Strategy (JANS) require a different, more 'developmental' approach (i.e. consistent with aid effectiveness principles). The standard GAVI IRC review of applications at the global level does not seem to be the most appropriate mechanism in this context. A country level review in coordination with other partners may be more suitable;
 - The initial pilot of three countries is not sufficient to make final conclusions about how to fund HSS through the HSFP in different country contexts. It is recommended that GAVI continue the process and document lessons learned until sufficient evidence exists to make an informed decision on the most appropriate way to fund HSS through the HSFP.
- 4.15 There are limits to the application of a single approach to HSS provision that meets the requirements of diverse country contexts (e.g. performance based; broader health systems bottlenecks; focused support for low performing/fragile countries). The Secretariat and Platform Partners will continue dialogue to identify the most effective modalities of supporting health system strengthening.
- 4.16 Following the Board's desire to improve the oversight of GAVI's Strategic Goal 2, the Secretariat is setting up an inter-agency technical advisory group for design and implementation of cash based programmes. Draft terms of reference for this group are



being discussed among partners and the group will be formally established by the end of 2011. Such a group is expected to consolidate under one umbrella several current coordination mechanisms (monthly inter-agency HSFP teleconferences, multistakeholder meetings on HSFP, Health System Strengthening Task Force).

4.17 In July 2011, the GAVI Board requested the Secretariat to 'review options for direct support to CSOs'. Terms of reference for a Secretariat-led approach to review options for funding CSOs are attached at Annex 3.

<u>SG3- Increase the predictability of global financing and improve the sustainability of national financing for immunisation</u>

- 4.18 The co-financing policy is working well. Most countries are co-financing at the GAVI required rates. As of 12 October 2011, 50 (98%) countries paid their co-financing commitment² for 2010 only DRC is still in default on its commitments.
- 4.19 The total amount co-financed by the 50 countries that complied with the mandatory co-financing requirement was US\$ 26.1 million in 2010. In addition, eight highly committed countries contributed US\$ 4.9 million to the cost of GAVI vaccine purchases (Benin, Burkina Faso, Mongolia, Papua New Guinea, Togo, Senegal, Yemen and Zambia). These countries started co-financing before they were required to do so.
- 4.20 In 2010, more countries than in previous years co-financed at a higher level than the GAVI minimum (22 countries). In most cases countries co-financed higher levels through the procurement process.
- 4.21 DRC is the only country that is still in default of the 2010 co-financing requirements for Pentavalent and Yellow Fever (US\$1,154,000). The Ministry of Health is in the process of working with the Ministry of Finance on this issue. However, the co-financing policy on default could be invoked if they do not pay by the end of the year. GAVI's co-financing policy states that 'if a country remains in default for more than one year, the GAVI Board may suspend support for the relevant vaccine until the co-financing arrears are paid in full'.
- 4.22 DRC is a one of the poorest countries in the world where years of conflict have left the country deeply impoverished. DRC is a recurrent defaulter and struggles every year to meet its co-financing requirements. The Secretariat requests the Board to exceptionally approve ongoing vaccine support for Pentavalent and Yellow Fever vaccines DRC in 2012, in the event that the country does not fulfil its 2010 commitment by the end of 2011. This will be consistent with a customised approach for countries in special circumstances which is included in the co-financing policy. DRC will not be approved for new vaccines or be able to expand current vaccine support (Pneumococcal vaccine in four provinces). The Secretariat will continue to work with DRC to improve the sustainability of the programme and update the Board in 2012.
- 4.23 The total government spending on vaccines in 2010 (for all countries) reported in the 2010 APR was US\$ 192 million. The average country investment in vaccines per child

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² UNICEF SD has not received the payment from Guinea yet. However, the Secretariat received a letter from The World Bank stating that they will finance all vaccines requirements for 2010 for Guinea. For this reason Guinea is considered as fulfilling their commitments.



was around US\$ 4 per child. The analysis included 64 countries³. The results range from an investment of US\$ 0.03 per child in Eritrea to US\$ 60 in Bolivia. 31 out of 64 countries invested less than US\$ 3.00, with eight countries not having any government expenditure on vaccines (DRC, Djibouti, Guinea, Guinea-Bissau, Liberia, Myanmar, Somalia and Zimbabwe). Each of these countries are fragile or under stress. The majority of countries (58) provide less than US\$ 20.00 per child, after which we observed a significant gap until a 'high spending' group of countries in the range of US\$ 40.00 to US\$ 60.00. This group included Azerbaijan, Georgia, Nicaragua, Guyana, Honduras and Bolivia – all of which are graduating countries, with the exception of Nicaragua.⁴

5. Next steps

5.1 Following the 2011 review of new vaccine applications and of the annual progress reports (APRs), the Independent Review Committee (IRC) made recommendations on policy and programme implementation. The main issues identified by the IRC include:

Disbursement of country commitments

 Slow grant disbursement and implementation delays especially in HSS programmes are largely due to the financial management procedures under the TAP requirements. The Monitoring IRC recommends streamlining the TAP policies, including introduction of a differentiated approach to countries depending on their specific risk profile, and fostering various partnership arrangements with relevant agencies which can help the countries to strengthen their financial management and accounting practices.

Quality of data on immunisation coverage and equity

- The Monitoring IRC pointed to unreliability of administrative coverage data in countries with weak health information systems and lack of independent immunisation coverage surveys. The IRC recommends increased collaboration with in-country development partners for strengthening the routine health information systems and implementing regular immunisation coverage surveys where needed.
- There are persistent equity gaps in immunisation coverage across socio-economic groups in selected countries. The Monitoring IRC recommends greater focus on analysis of health system constraints and other socio-economic determinants of inequity in immunisation coverage, and addressing them more effectively through health system strengthening efforts in collaboration with other partners.

³ The following countries were excluded due to missing APR or missing data in the APR: Haiti, Timor Leste, Sierra Leone, Bhutan, India, Cuba, Kiribati and Ukraine.

⁴ Note the data for government expenditures is drawn from country APRs and should be interpreted with caution and seen in the context of other data sources. Due to the data quality, the Secretariat relies on UNICEF SD/PAHO reporting for monitoring of co-financing compliance and not the APR. Reviewing the indicators requested in the APRs and improving the quality of the data is a priority activity for 2012.

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Implementation of HSS grants and special needs of fragile states

- Some HSS programmes experience implementation challenges and need to be reprogrammed. The IRC recommends that the Secretariat facilitate reprogramming of under-performing HSS programmes with technical support from in-country development partners.
- The IRC notes that fragile states experience much greater difficulties in implementing and sustaining their immunisation programmes. The IRC recommends the development of a special policy with regard to fragile states, including states with humanitarian emergencies.
- 5.2 Some of the recommendations have already been taken on board. The implications of the others are still being discussed. The Secretariat will prepare a management response to the recommendations in consultation with partners. The proposed management response will be submitted to the PPC in April 2012.
- 5.3 The Secretariat will continue supporting directly and through other Alliance partners effective vaccine management assessments and implementation of their recommendations in countries with supply chain limitations. Application of EVM tools will be encouraged and approval of new vaccine introduction proposals will be based on the evidence of the performance of the supply chains. The increased number of applications for new vaccines received in 2011 and the initiation of the new health system platform has implications for Programme Delivery. As a more tailored approach is taken to supporting a number of priority countries, additional Secretariat staff will be required.
- 5.4 GAVI Alliance partners will work with India and Nigeria to develop a country-specific partnership approach. The Secretariat will also work on a policy for under-performing and fragile countries.
- 5.5 The Secretariat is working on measures to address slow disbursements of cash-based programmes. The Secretariat will consider more country-specific and risk-based approaches in application of the TAP policy. The development of the grant monitoring scorecard and possible increase in resourcing for PD (recommended by Director Internal Audit to the July 2011 Board), will partially provide focused monitoring of programmes which should lead to earlier intervention to rectify implementation problems. It is envisaged that one Country Responsible Officer (CRO) would manage an average portfolio of 4 to 6 countries.
- 5.6 Lessons learned from the three pilot HSFP applications, and a WHO-led review of the experience of countries that have applied through the HSFP in 2011 will influence GAVI's approach to health systems strengthening. Work will focus on ensuring GAVI-funded programmes show a clear link to immunisation outcomes.
- 5.7 The Secretariat is working with partners to agree an appropriate approach to HSFP implementation following the decision by the Global Fund to extend its deadline for Round 11 applications (including HSFP) until at least 1 March 2012. The Board's decision on introduction of performance-based approaches to HSFP as recommended by the Performance-Based Funding Task Team will also need to be integrated into HSFP processes in 2012.

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5.8 The Secretariat and partners will work to develop an appropriate approach to support countries vulnerable to recurrent co-financing defaults, such as DRC and Guinea. The Secretariat and partners will work to design incentives for graduating countries that are willing to accelerate their graduation process by co-financing higher levels. Several countries had mentioned their interest in providing higher levels of co-financing.

6. Conclusions

6.1 Progress in country towards the strategic goals of the Alliance is variable. While the aggregate level performance is satisfactory there are countries where immunisation coverage levels remain below 70%. In countries with relatively high coverage, internal equity is an issue and most countries have not achieved the target of 80% DTP3 coverage in all districts. Low performing countries also tend to have the weakest health systems. Supporting introduction of new vaccines needs to be underpinned with appropriate health system support; adopting more country tailored approaches; encouraging country self-reliance and financial sustainability; and maintaining due diligence in managing fiduciary risks will remain among the main principles for the work of the GAVI Secretariat. GAVI needs a tailored country approach to address the specific needs in India and Nigeria. Recurrent defaulting countries like DRC will need additional support.

Section B: Implications

7. Impact on countries

- 7.1 As new vaccines become available, the requirements for country cold chain will increase as well. More efforts will be required from countries to ensure that their vaccine management efforts are linked to their general logistics management and capacities are adequate for immunising as many children as needed with minimum wastage. Countries need support from WHO and UNICEF to improve vaccine and logistics management.
- 7.2 Moving to provision of health system strengthening through HSFP will require greater harmonisation of development partners around country health system strategies. The role of the Ministries of Health as stewards of such harmonisation and alignment process is very important.
- 7.3 It is critical that countries improve the performance of their financial management and procurement systems so that fiduciary risks can be minimised.

8. Impact on GAVI Stakeholders

8.1 The Secretariat will be working closely with Alliance partners, especially WHO to provide closer monitoring of HSS/HSFP implementation. This will be reflected in the business plan for 2012.

9. Impact on the Business Plan / Budget / Programme Financing

- 9.1 The September EC meeting approved the following from the Monitoring and Proposals review this year:
 - 135 requests for active grant renewals;
 - 50 new vaccine grant requests for 2012-2014.

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9.2 Implications for supporting countries to implement these programmes have been included in the 2012 Business Plan.

10. Risk implications and mitigations

- 10.1 The increased number of applications for new vaccines raises the risk that countries' supply chain capacities may not be able to handle the increased volumes. In order to reduce the risk there is a recommendation to increase funding through the 2012 business plan for Alliance partners to complete and follow up EVMs.
- 10.2 The financial management and accounting requirements under the TAP policies in 2009 are likely to continue to cause implementation delays. This risk is particularly relevant for the introduction of new funding for health system strengthening programmes under HSFP. The Secretariat is investigating options to streamline TAP procedures and make them more tailored to country-specific risks, so that disbursements do not get suspended in countries with minor financial management and accounting issues. The TAP team estimates that most of the discrepancies in financial management reporting which are regularly subject to requests for clarifications arise from currency conversion issues which can be considered minor. One option which is currently being investigated is the request for a joint financial reporting in both US\$ and local currency. This is expected to address about 50% of requests for clarifications and thus reduce the number of outstanding clarifications.

11. Legal or governance implications

11.1 The recommendation and other information contained in this paper do not have legal implications.

12. Gender implications / issues

- 12.1 The GAVI gender policy, (2008) and the WHO study, (2010), on gender and immunisation point at two major gender issues for country programming. One is the gender related barriers in accessing vaccination services that are linked to cultural, social and economic situations resulting in inequity in coverage rates between different populations groups within a country. This may imply that men and women have different roles in bringing their children to the vaccination services and will require further gender analysis. Thus specific actions such as targeting men or health staff or measures to facilitate for women may be required. The GAVI Information Note for HSFP; Gender-related Barriers to Vaccination Services provides guidance.
- 12.2 Another gender issue is the right to equal access to vaccinations by boys and girls. Recent evidence from the global WHO study, discussed at SAGE 2010, demonstrates that sex disparities are not a major problem, as anticipated when the gender policy was written. GAVI analysis of 2010 APRs confirmed the WHO study; 79% of the countries report equal access to immunisation services for boys and girls. The remaining 21% either do not report on gender equity or acknowledge that data does not exist. However, as part of a health system, all health information data in the future need to be disaggregated by sex as well as by other equity parameters in order to discover and monitor any inequity trends.



13. Implications for the Secretariat

- 13.1 The development of the grant monitoring scorecard and possible increase in resourcing for the Secretariat will provide for more focused monitoring of programmes which should lead to earlier intervention to rectify vaccine introduction readiness and HSS implementation problems. Additional human resources will be needed to implement the recommendations of the report on large countries (India and Nigeria) and a more customised approach to countries particularly fragile countries and underperforming countries.
- 13.2 The Secretariat is undertaking an end-to-end independent review of the application and approval process for new vaccines and review. This may lead to streamlining of tools for the application and progress reporting requirements.



Annex 1 – Statistical Annex

Figure 1: GAVI Commitments through 2016 for eligible countries

US\$ 7.2 billion committed to countries

As at 30 September 2011

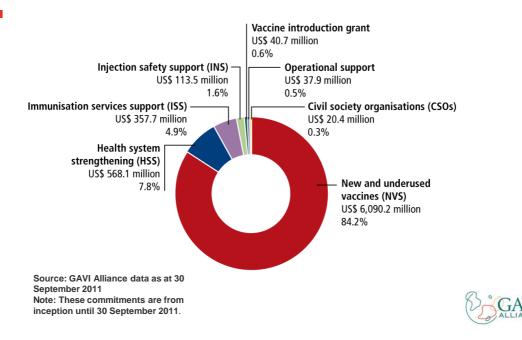


Figure 1 illustrates the relative size of the commitments through 2016 for GAVI's support windows. The committed support to New and Underused Vaccines (NVS) represents approximately 84% of the committed funds. Health Systems Strengthening (HSS) and Immunisation Services Support (ISS) constitute approximately 8% and 5% of the committed funds respectively.



Figure 2 - New Vaccine Introduction Dynamics

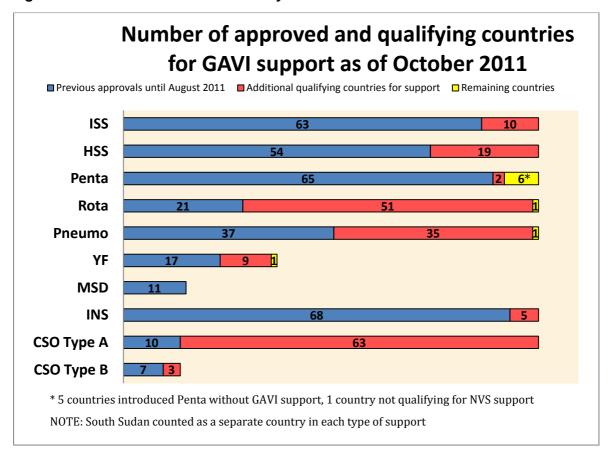
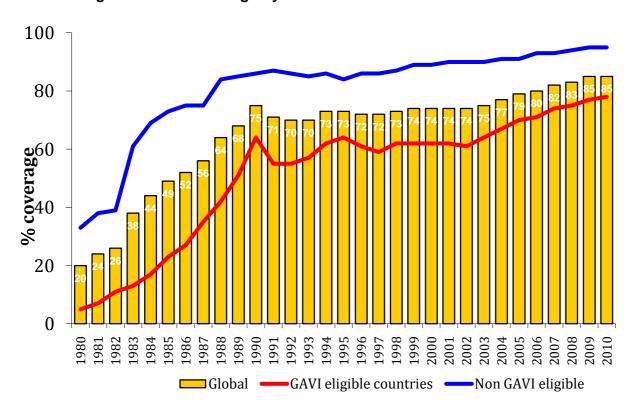


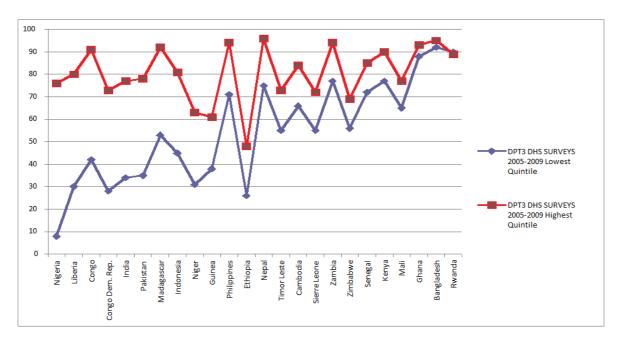
Figure 3: DTP3 Coverage Dynamics





Source: WHO/UNICEF coverage estimates 2010 revision - July 2011. Figure from WHO/IVB

Figure 4: DTP3 coverage inequality by socio-economic groups in selected countries (lowest-to-highest quintile comparison. Source: DHS)



The countries presented are those that had two consecutive DHS surveys in the last 6 years. GAVI supported countries differ significantly in terms of their equity performance.

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Annex 2: Health System Strengthening – Country Examples

Cambodia

Cambodia was the first country to be approved for the first GAVI HSS round in 2006 (one year support), and later approved for a long term funding (2007-2015) for the total amount of USD 10,315,500.

The 2010 Annual Progress Report indicates that there has been a 20% improvement in immunisation coverage from 2007 until 2010 in 10 HSS Operational Districts. Of the 11 HSS ODs only one has DPT3 coverage less than 80% (compared to 9 at baseline). GAVI funds are used for ensuring basic health services to selected districts. In the original HSS application the 2015 target for EPI was 90%, but this has been shifted upwards following improved performance in recent years and to contribute to CMDG by the year 2015. The DHS Preliminary report indicates that MDG 4 goal in Cambodia has now been achieved. Cambodia's national DTP3 coverage has increased from 82% in 2007 to 92% in 2010, during the period of GAVI support.

Sri Lanka

The APR report indicates that there are barriers and constraints which prevent Sri Lanka from providing maternal and child health services in an equitable manner. Some of them are directly related to the difficult terrain of the central hill-country which makes accessibility to health services very difficult. The 20 year long conflict too has caused many difficulties in maintaining Primary Health Care Services especially to those that are constantly shifting as Internally Displaced Persons (IDPs).

The goal of the GAVI HSS in Sri Lanka is to accelerate the reduction of MCH related morbidity and mortality in underserved areas particularly those affected by the conflict, through improvement of coverage and quality of MCH services. Sri Lanka focused on three key areas for utilisation of HSS funds: 1) Human resource development; 2) Renovation and reviving of PHC centres and posts at village levels in the conflict affected areas 3) Establishing strong supervision to support and promote good quality MCH and immunisation service delivery.

PHC centres have been renovated and equipped in ten underserved districts in the Northern areas since 2008 (82% renovations are complete), and training is provided for PHC Staff (about 900 Public health midwives) for immunisation services as well as other PHC services. Training programmes were conducted in the project districts on Adverse Events Following Immunisation (AEFI). Training centres in the Northern provinces as well as other regions (total of 6 centres) were repaired using GAVI HSS funds. The performance appraisal tool was developed and used for PHC staff by the Family Health Bureau.

As a result of this training and other programmes conducted the immunisation coverage in the areas reached 70% by 2010 (target is to reach 95% by the end of GAVI HSS in 2012).

Nepal – introducing HSFP

By investing in national health strategies, the GAVI Alliance has an opportunity to ensure immunisation and health systems support form a critical component of a country's national health plan. The JANS, combined with the Comprehensive Multi Year Plan for immunisation (cMYP) can help ensure that immunisation objectives are included in national health strategies, and that immunisation related indicators are integral to measuring country performance.

GAVI was invited to provide inputs to Nepal's annual health sector plan for 2011-2012, and we highlighted the need to address stagnation in immunisation coverage, improve equity by reaching the migrant population in urban slums, and upgrade cold chain and related infrastructure to introduce Pneumococcal and Rotavirus vaccines.



The Platform enables GAVI to engage at the highest level, working across ministries to mainstream immunisation issues and challenges into health sector planning. In contrast, GAVI's current portfolio of HSS investments is seen in countries as a GAVI-specific 'project'.

GAVI is able to leverage support from in-country partners for implementing immunisation services. For example, 'stagnating immunisation coverage' merits a discussion at the Joint Annual Review and solutions are offered collectively by all partners.

GAVI will no longer require GAVI-specific progress reporting, but will use country reporting prepared following joint government-donor annual reviews. However the content and the format of the joint report shall be acceptable to GAVI as well and will demonstrate the performance of immunisation programmes as part of the overall health system performance.

Report to the GAVI Alliance Board

Annex 3 - Review options for direct support to CSOs

At its July 2011 meeting, the GAVI Board requested the Secretariat, concurrently with the evaluation of CSO support in 2011, to review options for direct support to CSOs for service delivery and advocacy and submit to the PPC for its recommendation to the Board.

Approach

The Programme Delivery Department will lead the review of options for direct support to CSOs, including consultation, identifying possible options, drafting option papers. This work will be guided by a reference group that includes representatives of recipient governments, GAVI's civil society constituency, Alliance partners and Secretariat staff. The Secretariat will periodically update the PPC Chair on issues and progress of the review.

Scope

The review reference group will:

- Analyse strengths and weaknesses in GAVI's current approach to providing funding support for CSOs.
- Consider alternative options to GAVI's current approach of providing funding to CSOs.
- Consider how GAVI can support CSOs to provide immunisation services in underperforming and fragile countries.
- Test possible options for direct support to CSOs to ensure that proposed options for direct support to CSOs: contribute to achieving the objectives of the GAVI Alliance Strategy 2011-2015; are consistent with GAVI's commitment to the Paris Principles for aid effectiveness; and are simple to administer and involve a level of transaction costs that are acceptable to all partners.
- Ensure that options take into account and are consistent with the CSO Evaluation and the work of the IRIS Task Team (as far as is practicable).

Timing

It is proposed that the review would be submitted for PPC consideration in May 2012 and, if appropriate, for Board approval in June 2012.

Membership

2 Country government representatives, 2 country CSO representatives; GFATM; WHO; UNICEF GAVI CSO Constituency communications focal point

GAVI Secretariat (Programme Delivery, External Relations, Policy and Performance, Governance and Legal, TAP, Finance)

SAVI ALLIANCE

Report to the GAVI Alliance Board

Annex 4 - Country context India

India, with a birth cohort of over 26 million has the largest birth cohort among GAVI eligible countries and accounts for more than 20% of child deaths worldwide. India's national 2010 DTP3 coverage is estimated at 72% (WHO-UNICEF estimates of National Immunization Coverage); however vaccination coverage varies considerably from state to state, with lower coverage concentrated primarily in a few northern States. Many of the larger states in India have populations larger than many other GAVI-eligible countries

Given India's size and presence of a strong vaccine manufacturing base, the GAVI Board has always considered its support to India differently than for other countries. Under Phase I (2000-05), support to India was capped at \$40 million. Recognising that \$40 million for a country the size of India was small relative to the needs, the GAVI Board raised the cap to \$100m for Phase II. However, in November 2007, and based on assumptions of India taking advantage of ISS and HSS funds in 6 states and new vaccine support (initially for DTP-Hep B and then Pentavalent over 2008-2011), the GAVI Board subsequently approved an additional \$250 million increasing the GAVI phase II "cap" for India from \$100m to \$350m. The GAVI Board has always taken note that the country (unlike most developing countries), finances most of its health budget but recognises the role catalytic support can play in accelerating adoption new initiatives like use of injection safety equipment.

Experience of GAVI support to India to date has been mixed. GAVI support for injection safety and Hepatitis B monovalent vaccine was positive and has catalysed the adoption of a national policy and nationwide scale up of both the commodities. However, while injection safety was scaled up within 2 years, there were implementation challenges, and scale up plans for Hep B mono took over 8 years. India now procures the vaccine locally with its own resources. Despite a successful application for pentavalent in 2009, the Government of India scaled down initial plans and introduction in the two approved states of Tamil Nadu and Kerala will commence when supplies are available in November.

Key findings

With the introduction of the National Rural Health Mission (NHRM), India has dramatically increased public expenditure on health. During the period 2005-2009, absolute dollar values of government health spends have more than doubled from around \$5 billion to \$13 billion. As of 2009, government spending on health was at 1.2% of GDP, while health as a share of total government expenditure increased from 3.3% (2005) to 4% (2009).

The Routine immunisation programme is almost 100% financed by the country. The vaccine budget, however, remains a small part of the health budget at less than 3%.

The new 12th Five-Year Plan (still in development) aims towards universal health coverage for India's 1.2 billion citizens over the coming decade and will provide a conducive framework for further increases of budgetary allocations and firming up India's commitment to immunisation. There are strong and vibrant academic and expert groups engaged in the process of developing the new health plan.

When technical consensus exists, the Gol has been able to move forward with introduction of new vaccines (i.e. introduction of JE and Rubella vaccines and injection safety).

India is showing encouraging results with its Polio eradication efforts. Extensive investments have been made and important lessons can be learned and synergies can be created in hard to reach areas.

Report to the GAVI Alliance Board

India has recently (late 2010) introduced a phased plan for a second dose of measles vaccine (MCV2) coverage via catch up campaigns (poor performing states) and routine immunization (well performing states).

The recent decision by the GoI to expand their scale up of pentavalent vaccine from 2 states to potentially 6 states will provide immunisation to more than 2 million additional children. The decision to include additional states (from the initial intent to limit it to two states) was based on expression of interest from state governments.

Challenges indentified

India still faces weak technical and managerial capacity in the UIP, as outlined in the National Vaccine policy issued in April 2011.

Gaps still exist in key areas for vaccination programmes (e.g., demand forecasting, logistics & cold chain management, high wastage rates with multi-dose vial vaccines) as evidenced by various analyses⁵, ⁶, ⁷

There is considerable heterogeneity in vaccine coverage rates among and within states. Coverage in urban slums is an emergent issue for the Gol.

India lacks a robust surveillance system for vaccine preventable diseases. The national vaccine policy recognises the need for strengthening surveillance capacity⁸

There is a lack of robust evidence, operational research and strong processes for both policy decisions and implementation³.

The National Technical Advisory Group on Immunisation has made new vaccine recommendations, however its independence and transparency is sometimes challenged.

Capacity to introduce new vaccines in low performing states has been questioned by some, including politicians and a vocal civil society concerned about the impact of introduction of new vaccines on the system and government resources.

There are small but highly vocal activist groups and politicians who continue to challenge the introduction of new vaccines into the UIP, sometimes with misleading or erroneous data. Both government and partners fully recognise that response to date to such activist groups in India needs improvement. Positive messages to build support around vaccines and immunisation more generally are also needed.

Additional efforts are needed to engage advocates at both the state and national level, particularly to strengthen accountability and improve uptake.

Opportunities identified

Significant infrastructure and lessons learned from successes and investment in polio can be leveraged to achieve synergies with routine immunisation, including in the hard to reach areas. Experience with surveillance of acute flaccid paralysis conducted by WHO/NPSP (National Polio Surveillance Programme), can also be leveraged.

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 $^{^{\}rm 5}$ India Universal Immunization Program Review, WHO 2009

⁶ Coverage Evaluation Survey All India Report, UNICEF 2009

⁷ Vaccine Wastage Assessment, UNICEF April 2010

National Vaccine Policy. Ministry of Health and Family Welfare. April 2011



India offers a conducive technical and scientific environment for operations research to complement the data generated in the system and to support fine tuning of policies and strategies. These opportunities could be leveraged alongside the introduction of pentavalent vaccine to help build a platform of evidence for further scale-up and evidence of feasibility of introduction of future vaccines.

Public-private partnerships have shown promise in addressing service delivery issues in some areas. Stakeholders felt this was an area for further exploration. For-profit private sector strengths can also be leveraged to strengthen capacity in the public sector. There is more openness to civil society, more generally to help in addressing health disparities.

Further opportunities identified during the consultation included increasing human resources and training, especially at the community level; the appointment and training of a large cadre of community mobilisers (Accredited Social Health Activists or ASHAs) political support from the minister on health, use of technology such as ICT, stronger civil society and technical support provided by external partners.

There is a desire to take advocacy and communication to a higher level, as recognised by the national vaccine policy. Some partners and Indian civil society are already conducting advocacy and communication activities at national and targeted state levels, and supplementing current activities may have significant impact in building stronger public and political support at all levels.



Annex 5 - Country context Nigeria

Nigeria is the 2nd largest GAVI Country after India with a birth cohort of over 6 million. There is considerable inter-state variation and inequities⁹ in immunisation coverage, though Nigeria has made progress since 2006 and WHO-UNICEF recently raised their estimate of Nigeria's 2010 DTP3 coverage to 69%. After an unsuccessful bid for pentavalent and pneumococcal vaccines in 2009, Nigeria successfully applied for Meningococcal A vaccine in March 2011, was recommended for approval by the IRC in July 2011 for pentavalent and also received conditional approval for pneumococcal vaccine. The latter new vaccine applications were made possible through the temporary waiver of the 70% coverage filter for new vaccines by the Board in November 2010, pending further work on GAVI's proposed new mechanism, Performance-based Financing.

Key findings

Administrative data indicates that routine immunisation coverage has improved significantly in almost all states over the past five years, but there continues to be considerable variation between and within states.

Nigeria experienced a slow implementation of cash support (GAVI Immunisation Services Support (ISS) and Health Systems Support (HSS)) due to competing priorities and a lack of clarity around how programme and financial management were to be organised between the Federal Ministry of Health and National Primary Health Care Development Agency (NPHCDA). NPHCDA is a para-statal body which oversees implementation of programmes at state and district levels. These issues have since been resolved and are being finalised in an Aide Memoire between GAVI and the Government of Nigeria.

ISS has played a critical role in bolstering routine immunisation and has been especially effective at local government authority levels.

GAVI new vaccine support for Yellow Fever, Meningitis A (for which Nigeria was approved in March 2011), and (pending approval on September 24) Pentavalent is highly valued and appreciated. Introduction of new vaccines will be phased over a period of three year, starting in 12 high performing states drawn from all geopolitical zones in the country and in the Federal Capital Territory, Abuja.

Civil society groups (led by the Health Reform Foundation of Nigeria) played a major role in advocating for the passage of Nigeria's National Health Bill which remains to be signed by President Goodluck Jonathan. The Bill (when signed into law) is expected to significantly increase funding for basic health services (including immunisation) and to increase the accountability of states and local government authorities, which are ultimately responsible for funding and implementing immunisation programmes at the sub-national level and whose performance to date has been decidedly mixed.

Traditional leaders and faith based groups are playing an increasingly important role as advocates for immunization and polio eradication. Generally, civil society can play a bigger advocacy role in Nigeria.

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⁹ Analysis of the 2008 Demographic and Health Surveys reveal a nearly 10-fold difference in rates of complete immunization between the wealthiest and poorest quintile.

Report to the GAVI Alliance Board

Challenges identified

Vaccine security continues to be a challenge in Nigeria, with timely procurement hampered by late release of budgeted funds. There is a major DTP and BCG stock out currently in the country. The 2011 stock out was a consequence of a "perfect storm" of events including (i) the utilisation in Q1of funds originally intended for routine immunisation for polio and measles outbreaks (ii) a global DTP shortage and (iii) significant delays in the passage of the 2011 budget due to the national elections which prevented the timely release of budgeted Q2 funds for routine immunisation.

The releases of funds from national to state and LGA level does not necessarily cover funding needs for vaccine an immunisation programmes due to the way financial authority is delegated the lower levels of the system. Leveraging funds from state and LGA levels has therefore proved to be a challenge.

Cold chain capacity at the lower levels is a major challenge, especially in light of the introduction of new vaccines which will require additional and better storage capacities for the introduction to be successful.

Opportunities identified

Nigeria's commitment to improving immunisation has probably never been higher. There is strong political will emerging at the highest levels of government with dedicated and qualified technical staff engaging at national and state levels, and a growing number of advocates in the private sector and civil society. This growing commitment, however, may not yet have reached the critical mass necessary for Nigeria to "go it alone" in immunisation. GAVI support to Nigeria, therefore, remains instrumental to improve immunisation programmes and introduce new vaccines.

Polio eradication efforts continue to absorb much of the attention and focus of the government and partners and much of the polio progress seen in 2010 is considered at risk. There is however opportunity for greater synergies between polio eradication efforts, routine immunisation and new vaccine introduction in Nigeria, including technical assistance, surveillance, data quality and monitoring.

GoN is proposing to set up a Primary Health Care Development Fund which is a pooled funding mechanism where the federal MoH together with the states and the LGs pool funding for primary health care activities. The funding mechanism will also be open for support from development agencies.