



Report to the GAVI Alliance Board

21-22 November 2013

Subject:	Country Programmes Update
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Section A: Overview

1 Purpose of the report

- 1.1 This report provides an update on GAVI Country Programmes.

2 Recommendations

- 2.1 This report is for information.

3 Executive summary

- 3.1 The Democratic Republic of Congo (DRC), India, Nigeria and Pakistan continue to be a focus due to the large numbers of unimmunised children, political and systemic complexity, the amount of GAVI funding and the changing epidemiological situation. Intensified engagement and strong commitment from Alliance partners is yielding progress. The Secretariat has increased the number of visits to these priority countries to strengthen the partnership with governments, deepen understanding of the country context and challenges, and improve management of GAVI programmes.
- 3.2 Sustainable domestic financing for immunisation continues to be a challenge for DRC. GAVI's tailored approach for DRC seeks to work with the Government over the next three years to improve budget planning and execution and to break the Government's cycle of GAVI co-financing default. The tailored approach also proposes to increase GAVI investments to rehabilitate the cold chain and vaccine management. Nigeria is finalising a National Routine Immunisation Strategic Plan that provides a harmonised work plan incorporating routine, polio and SIAs. GAVI's tailored approach for Nigeria will support the implementation of the Government's plan. Tailored approach documents for DRC and Nigeria are expected to be finalised by end November. Progress on other tailored

approaches has been staggered due to staff limitations in the Country Support Team and in-country uncertainty (for example, elections in Pakistan and conflict in the Central African Republic). Work on tailored approach for Pakistan and Afghanistan has formally commenced and is in the analysis stage. The next sequence of tailored approaches will include CAR, Haiti and South Sudan.

- 3.3 Institutional arrangements relating to the immunisation programme in Pakistan remain highly fluid. GAVI shares the concerns of other development partners of a serious risk of failure in the routine immunisation (RI) programmes in the country. The Government has established a task force for the preparation of an effective Measles SIA (supplementary immunisation activity). GAVI is working closely with in-country partners to ensure a consistent message on the need for country leadership and clarity in relation to roles and responsibilities and to better harmonise donor efforts.
- 3.4 With the commencement of Measles SIAs, Human Papilloma Virus (HPV) demonstration projects and Measles Rubella (MR) campaigns in the first part of 2013, GAVI now has nine active vaccine programmes. Implementation is on-going in 72 out of the 73 supported countries. By the end of 2013, the Alliance will have started 160 routine immunisation programmes, 32 campaigns and seven HPV demonstration programmes since 2001, with more than 2.4 billion vaccine doses shipped.
- 3.5 The 2012 vaccination coverage estimates released in July by WHO/UNICEF for the 73 GAVI eligible countries¹ indicate that the coverage for the third dose of Pentavalent vaccine (Penta), the pillar of routine immunisation, has reached 43% of the GAVI birth cohort. Coverage is expected to increase significantly in the following years, given that three of the largest countries Indonesia, India and Nigeria have yet to roll out nationally. Revised plans have been submitted by India and Indonesia to accelerate introduction.
- 3.6 The coverage for Pneumococcal Conjugate Vaccine (PCV) has reached 9% for the third dose and Rotavirus (RV) has reached 3% for the last dose.² Of great importance is the fact that in those countries, PCV and RV vaccine coverage has generally reached the corresponding Pentavalent dose coverage³ within 24 months of introduction. This is an encouraging sign indicating the successful integration of the new vaccines into the routine immunisation system.
- 3.7 For RV and PCV, the challenge of vaccine supply constraints remains. While the supply of the 2-dose schedule rotavirus vaccine will remain

1 Coverage estimates are calculated as population weighted-average estimates of coverage among all GAVI 73 countries, regardless of vaccination introduction or vaccine-specific GAVI support. All coverage calculations refer to the total target population in all GAVI 73 eligible countries or, where appropriate in the target countries for regional vaccines.

2 Since two presentations with different schedule are in use, the coverage is referred to the last dose irrespective of the two or three dose schedule

3 One of the rotavirus vaccine schedules is limited to 2 doses

constrained in the near-term, the PCV supply situation has improved following the conclusion of the third tender and all of the 51 approved countries for PCV are expected to be able to receive supplies by the end of 2014. The impact of the various supply constraints on GAVI's performance is amplified as the original coverage targets were set in 2010 without assuming any supply constraints. For Penta, the roll-outs in India and Indonesia began later than were forecast in 2010 which has resulted in the lower than target coverage. Country readiness issues have also caused some delays to PCV and RV introductions.

- 3.8 Following the completion of a benchmarking study undertaken at the request of the Board, to establish whether the Alliance is benefitting from the most cost efficient procurement processes, the results were discussed by the Executive Committee (EC). The EC took note of the findings and welcomed the continued collaboration between UNICEF Supply Division (SD) and the GAVI Secretariat. One of the main results was that the study, which compared UNICEF SD services to other comparable service providers, confirmed that UNICEF SD is the most cost effective organisation to deliver the services provided. Work will now continue on a number of areas identified to further improve the work processes between the Secretariat and UNICEF SD.
- 3.9 Health Systems Strengthening (HSS) disbursements are at \$64 million through September 2013, which exceeds the total 2012 disbursement level and puts GAVI on track to achieve the 2013 target of \$100 million. l'Agence de Medicine Preventive (AMP) and John Snow, Inc (JSI) respectively, will be providing technical support to develop coverage improvement plans in five countries, and enhance Alliance support for new vaccine introductions in three countries. As part of its strengthened focus on results, the Secretariat is drawing on the IHP+ monitoring and evaluation (M&E) framework and working with WHO on defining and implementing "intermediate results" to track health systems performance. These new elements were included in the revised HSS application guidelines, and introduced in 2013.
- 3.10 Support to increase CSO (civil society organisations) engagement in HSS is leading to improved organisation of CSOs at country level and more effective relations with governments. Of the 15 countries approved for HSS funding in 2012, all 15 engaged CSOs in the development of the proposal, primarily through a health sector coordinating committee (HSCC) or equivalent. Ten countries provided specific budgets for CSO-related activities. These activities are for \$30 million, which is over 15% of the total budget for the 15 countries. The main activities will be around immunisation service delivery, empowering communities, cold chain facilities and equipment, and health worker training.
- 3.11 Of the 65 countries required to co-finance their vaccines in 2012, nine⁴ countries defaulted on their payments. As of October 2013, DRC and CAR

4 Afghanistan, Angola, Central African Republic, Congo Republic, Democratic Republic of Congo, Guinea, Niger, Pakistan, Sudan

are the only countries remaining in default. The total amount transferred against the 2012 co-financing commitments to date amounts to approximately \$61 million, accounting for 9% of vaccine support to those countries.

4 Risk implication and mitigation

4.1 See risk register presented to the GAVI Board.

5 Financial implications: Business plan and budgets

5.1 As country tailored approaches are developed, levels of GAVI's support to individual countries may be reconsidered. For example the HSS ceiling could be reassessed based on country demand, as was the case for DRC. Discussions are also beginning about the possibility of further linking GAVI support for SIAs to activities strengthening routine immunisation. Such activities could entail additional costs. For example if evaluations are required following each SIA additional cash support to countries and/or technical assistance from partners may be required.

Section B: Content

6 Country Programmes coordination and oversight

6.1 Work to prepare and support new vaccines introduction and integration into effective routine systems continued to ramp up in the second half of 2013. The three main cross-Alliance management groups meet regularly to review implementation of the Business Plan and resolve constraints.

6.2 The Vaccine Implementation Management team (VIMT) and its product specific subgroups ensures oversight and guidance to vaccine implementation with a more active focus on country readiness, supply, safety surveillance, cold chain assessment and risk management.

6.3 The SG2 Management Team (SG2MT) oversees the timeliness and quality of provision of technical assistance for GAVI Health Systems Strengthening as well as development of coverage and equity improvement plans. WHO have completed six coverage improvement plans with five to be completed by the end of 2013. UNICEF has commenced or completed an equity assessment in nine out of ten countries.

6.4 The Immunisation Financing and Sustainability task team (IF&S) continues to oversee the implementation of activities to increase and sustain allocation of national resources to immunisation.

6.5 GAVI has been consolidating new partnerships. For example, through the Matching Fund, Lions Club International will target support to the measles and rubella activities planned in Ghana, Nigeria, Bangladesh, Senegal, Tanzania and Burkina Faso. GAVI is facilitating Lions engagement with governments and partners during the country SIA planning phase.

- 6.6 The need to deepen country engagement and revise business processes that are no longer fit for purpose are increasing staff workload. In addition, the contract/Decision Letter process, including dose and target calculations, for over 200 funded country programmes; building engagement between GAVI and the Global Polio Eradication Initiative (GPEI) to deliver the Polio Endgame strategy; development and implementation of the end to end supply chain strategy; and consultation and implementation of the future engagement strategy with graduating countries, will all continue to be resource intensive.

7 GAVI and Fragile States – a country by country approach

- 7.1 GAVI's Fragile States policy was approved by the Board in December 2012. Following application of the framework included in the policy, 11 countries were identified for development of a tailored approach. The development of each tailored approach is led by the relevant Country Responsible Officer and undertaken closely with Secretariat/Alliance colleagues and through consultation with Government and key in-country development partners.
- 7.2 Progress on other tailored approaches has been staggered due to staff constraints in the Country Support Team and in-country uncertainty (elections in Pakistan; conflict in CAR). DRC and Nigeria are expected to be finalised by end November. Work on Pakistan and Afghanistan has formally commenced and is in the analysis stage. Tailored approaches should be finalised in early 2014. Work on CAR, Haiti and South Sudan will commence in Q4.
- 7.3 Remaining countries include Chad, Cote d'Ivoire, Guinea, and Somalia. While work has not formally begun to document a tailored approach, engagement with these countries is already reflecting a more creative and flexible approach. For example the Alliance is consulting with the Government in CAR on what support is required to maintain immunisation services in conflict-affected areas; supporting Chad to programme unallocated HSS funds to implement its coverage improvement plan; and providing technical support for Haiti to develop an implementation strategy to transition the cold chain to solar power. These activities will subsequently be reflected in GAVI tailored approach documents for these countries.

8 Country Issues

- 8.1 **Democratic Republic of Congo (DRC):** the number of children unvaccinated for DTP3 in DRC, exceeds 700,000 (2012)⁵. WHO/UNICEF estimates indicated national DTP3 coverage of 70% in 2011 while the Government's administrative coverage was reported above 90%. This raises concerns about the reliability of data. An EPI review conducted in

⁵ UNPD surviving infants, WHO/UNICEF coverage, 2012

2012 highlighted many systemic failures in the routine immunisation services. These included poor vaccine management, frequent vaccine shortages, insufficient storage capacity at the central and the intermediate levels, large numbers of health workers with inadequate knowledge of immunisation, weak management capacity at operational level and unreliable data collection and health information systems. DRC faces measles outbreaks, and sustainable domestic financing for immunisation also continues to be a challenge.

- 8.2 GAVI's tailored approach for DRC will attempt to respond to these challenges by working with the Government over the next three years to improve budget planning and execution to break the cycle of GAVI co-financing default and to build financial sustainability of the immunisation programme. The approach is expected to be finalised by end November following consultation with the Government, the Alliance and other development partners. Priority areas for GAVI engagement in DRC over the period 2013 to 2017 will include (i) strengthening provision of immunisation services by targeted HSS support to the Provinces with the highest numbers of low immunisation coverage, improving the management capacity of Provincial and Health Zone management teams (ii) support to improve the supply chain and vaccine management system through the implementation of the national logistics rehabilitation plan and (iii) strengthening data quality for improved decision-making by using HSS funds to develop and implement a data quality improvement plan with support from WHO and other Technical and Financial Partners and iv) supporting the Government to meet GAVI cofinancing commitments and to build financial sustainability of the immunisation programme.
- 8.3 **India:** In September 2013 the full NTAGI (National Technical Advisory Group for Immunisation) approved the national scale up of pentavalent vaccine. The Health Ministry's efforts to obtain NTAGI endorsement for the expansion are commendable given the complex environment, including recent negative press on HPV phase IV research, pentavalent vaccines and court cases challenging the safety of pentavalent vaccines (NB: to date no causal relationship between the vaccine and the reported adverse events following immunisation has been established). The Ministry is currently making the necessary budgetary allocations to match the ambition. A budget proposal is expected to be presented shortly to the Mission Steering Group, (a cabinet sub-committee) for approval. India is preparing an application for GAVI support for a phased roll out in 2014 in the remaining 27 states. In order to build up capacity for AEFI surveillance, it is understood that India will roll out in a phased manner slightly slower than previously planned, starting in Q3, 2014. As usual the roll out plan will consider the varying human resources, training, infrastructure and surveillance capacity in the different states. Production capacity is not expected to cause delays.
- 8.4 In April 2013, the IRC reviewed India's HSS proposal and recommended it be approved. The proposal amount of \$107 million over three years has identified 12 states with DTP3 coverage less than 60%. Key areas for

support include: vaccine logistics and supply chain management; an electronic system to monitor real time vaccine stock flows and temperatures; demand generation through innovation in behaviour change communications; strengthening the evidence base for improved policy making; and leveraging polio infrastructure to strengthen routine immunisation. India has requested the funds be managed by WHO/UNICEF/UNDP. As the systems are strengthened and routine coverage improves in these states, India will be able to introduce new vaccines.

- 8.5 GAVI is enhancing the co-ordination of vaccine advocacy in India. In close collaboration with local Alliance partners, a GAVI-India Advisory Council will be launched by the CEO in Q1 of 2014. The Advisory Council will comprise eminent and well respected Indians drawn from a variety of backgrounds such as political, academic, industry (non-vaccine), and media who will be expected to advocate positively for immunisation. These 'thought leaders' will be supported by a media strategy to advocate for immunisation and position it as a cornerstone for child survival. GAVI is also exploring a more proactive approach to respond to poor and one-sided journalism on immunisation issues, through active engagement with Indian media leaders.
- 8.6 **Nigeria:** Despite DTP stock outs contributing to the drop in DTP3 coverage in 2011 (47%) and 2012 (41%), the successful roll out of pentavalent vaccine (28 out of 36 states plus the Federal Capital Territory, Abuja, by October 2013) is expected to result in improved coverage rates. Administrative data shows a significant increase for the first seven months of 2013 (85%). The Government has worked with partners to develop a National Routine Immunisation Strategic Plan (NRISP) that provides a harmonised work plan which incorporates routine, polio and supplementary immunisation activities. The NRISP is to be launched on 11 November 2013. An accountability framework, as well as an improved coordination and accountability mechanism, will accompany the NRISP. Nigeria is scheduled to introduce PCV in Q4 2014. In March 2013, the GAVI Alliance Executive Committee (EC) approved support for Nigeria to undertake Measles and Yellow Fever preventive campaigns in 2013. The first phase of the measles campaign was also conducted in 19 northern states from 5–9 October, with coverage varying across the states with an average of approximately 90%. The second phase will take place from 2-6 November.
- 8.7 GAVI's tailored approach for Nigeria will be finalised by end November following consultation with the Government at federal and state levels, as well as with Alliance and other development partners. Priority areas for GAVI engagement in Nigeria during 2014 will be (i) the continuation of new vaccine support (NVS) based on the Comprehensive Multiyear plan (cMYP); eligibility criteria will be applied flexibly to enable quicker roll out of critical antigens; (ii) the continuation of HSS support based on requests from the country, earmarking parts of the funding for critical areas such as supply chain and data quality; (iii) a higher emphasis on accountability and

transparency from the federal and state levels supporting the government to achieve a higher rate of cash transfers and incentivising political commitment ownership; and (iv) strengthening routine immunisation through the Polio Eradication Initiative (PEI).

- 8.8 **Pakistan:** Results of the recent Pakistan Demographic and Health Survey 2012-13 indicate a lower DTP3 coverage level than estimated by WHO/UNICEF (54% compared to 81%), with provincial coverage rates ranging from 16% in Baluchistan to 66% in Punjab Province.
- 8.9 Following the General Elections held in May, the Ministry of National Health Regulation and Service (MoNHRSC) has been identified as the executing partner of GAVI Alliance for both HSS and EPI support. The Federal EPI programme reports to the MoNHRSC. Despite this, institutional arrangements relating to the immunisation programme remain highly fluid. GAVI shares the concerns of other development partners of a serious risk of failure in the routine immunisation in the country. GAVI is working closely with in-county partners to ensure a consistent message on the need for country leadership and clarity in relation to roles and responsibilities and to better harmonise donor efforts.
- 8.10 In June 2013, the Executive Committee approved the application from the Federal EPI programme to undertake a nationwide preventative measles SIA. The Government established a Task Force to manage the measles SIA and to ensure that an effective evaluation is undertaken in order to document how routine immunisation is strengthened. Preparatory steps for the SIA have commenced (for example UNICEF Supply Division has clarified that 67 million vaccines will be released in batches between November 2013 and January 2014). The Secretariat is monitoring preparations of the SIA and will participate in meetings of the Task Force where possible.
- 8.11 Since the introduction of PCV10 in Punjab Province in October 2012, Sindh and Azad Jammu and Kashmir have also introduced PCV10. Khyber Pakhtunkhwa (KP) Province's introduction was delayed to September following its failure to pass the WHO assessment of programme readiness. Following the introduction in KP, over 90% of the country will have access to PCV10. The remaining province Baluchistan is expected to roll out in December. The dates of the roll out in FATA and AJK are unsure due to security concerns. A Post Introduction Assessment is scheduled for Q1 2014.
- 8.12 In April the IRC endorsed a resumption of HSS activities following assessment of Pakistan's 2011 Annual Progress Report (for example strengthening the link between the work plan and the monitoring and evaluation framework). The IRC also approved (with clarification) an application to extend CSO Type B support until end-2014. Both programmes of support have since commenced. GAVI continues to investigate the provision of future HSS and CSO support, including through co-financing or parallel financing options with the World Bank.

9 Strategic Goal 1: The Vaccine Goal

- 9.1 With the commencement of Measles SIAs, Human Papilloma Virus (HPV) demonstration projects and Measles Rubella (MR) campaigns in the first part of 2013, the GAVI Alliance now has nine active vaccine programmes. Implementation is on-going in 72 out of the 73 supported countries. By the end of 2013, the Alliance will have started 160 routine immunisation programmes, 32 campaigns and seven HPV demonstration programmes since 2001, with more than 2.4 billion vaccine doses shipped.
- 9.2 Updates on Penta, PCV and RV vaccines, GAVI's three largest vaccine programmes follow. An update on additional GAVI supported vaccine programmes is provided in Annex A.
- 9.3 Pneumococcal Conjugate Vaccine (PCV)

Key programme statistics (programme start date 2009)

	Actuals	Forecasts		
	Programme start - 2012	Year 2013	2011-2015 (Strategy Period)	Programme start - 2015
No. of countries	24	16	~54	~57
Coverage ⁶	9%	~18%	~37%	~37%
No. vaccinated ⁷	11M	~13M	~73M	~74M

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

- (a) As of October 2013, eight countries introduced PCV (Angola, Kiribati, Lao PDR, Moldova, Mozambique, North Sudan, Uganda and Zambia) and a further eight are expected to introduce by the end of the year: Afghanistan, Azerbaijan, Bolivia, Burkina Faso, Mauritania, Niger, Papua New Guinea and Senegal. By 2015, 57 introductions are expected, above the target of 45. The coverage is forecast to remain below target and is expected to reach 37% by 2015 (vs. 40% target). This is mainly due to introduction delays related to supply constraints, including those related to a production issue that has delayed the introductions in Bangladesh and Nigeria by approximately one year, as well as country readiness factors, including cold chain expansion and/or rehabilitation, logistics, training and funding. Despite these temporary setbacks, 73 million children are forecast to be vaccinated with PCV in the period 2011-2015.

⁶ For PCV, RV and Penta coverage in the related tables, weighted average coverage for all GAVI 73 countries, regardless of GAVI support. Coverage estimate indicated for 2011-2015 reflects the coverage for the last year of the time period (i.e. do not represent cumulative coverage estimates). Coverage estimate indicated for Programme start-2011 reflects the coverage for the last year of the time period (i.e. 2011).

⁷ Estimates include only those immunised with GAVI support.

- (b) In July 2013 the third tender for PCV under the Advance Market Commitment (AMC) was concluded with the two eligible manufacturers committing to supply a total of 500 million additional doses in long-term supply agreements easing the supply constraints for both products. In the short term, a temporary production issue with PCV10⁸ is still affecting the introductions in Bangladesh and Nigeria resulting in postponement until Q4 2014. Alliance partners are working with industry to address supply issues and are carefully managing the available supply to prevent any programme interruptions in countries. Even with this issue, all of the 51 currently approved countries are expected to be able to receive PCV supplies by the end of 2014.
- (c) 2012 WHO/UNICEF Estimates of National Immunisation Coverage (WUENIC) data demonstrated that countries are able to successfully introduce PCV into their routine systems, with PCV3 coverage generally in line with DTP3 coverage by the second year of implementation.

9.4 Rotavirus Vaccine (RV)

Key programme statistics (programme start date 2008)

Actuals		Forecasts		
Programme start – 2012		Year 2013	2011-2015 (Strategy Period)	Programme start – 2015
No. of countries	12	~8	~32	~35
Coverage	3%	~7%	~20%	~20%
No. vaccinated	4M	~4M	~33M	~34M

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

- (a) In 2013, Georgia and Gambia introduced Rotavirus vaccine, the latter being the first to use the 3-dose schedule vaccine. Six more countries are yet to introduce in the last quarter: Haiti, Djibouti, Ethiopia, Zambia, Burkina Faso, and Burundi. By 2015, 35 country introductions are anticipated, exceeding the strategic plan target of 33. The coverage is expected to reach 20% in 2015 as opposed to the projected target of 31%. This is a consequence of delays in introductions due primarily to supply constraints, and due to the fact that the target was set without anticipating supply constraints.

⁸ The manufacturer has confirmed that the root causes have been identified and production has been resumed, but the capacity that was lost during the process will not be recovered.

- (b) The supply-demand mismatch persists. The supply of the 2-dose schedule vaccine, preferred by GAVI supported countries, (due to its smaller cold chain footprint, presence of Vaccine Vial Monitor (VVM) and dosing schedule) continues to be limited, although there have been encouraging developments in the last few months. Thanks to accelerated production, the manufacturer will be able to deliver 10% more than the previously estimated; supply capacity is expected to double by 2015. However, despite this increase, the supply of the 2-dose schedule vaccine will remain constrained in the near-term. The 3-dose schedule vaccine remains available for earlier introduction, but demand has so far been limited. Additional doses were awarded to the 3-dose manufacturer in May, to meet the demand of three recently approved countries (including the Gambia which successfully introduced in August).
- (c) 2012 WUENIC data confirms strong performance in Latin America, with Guyana, Honduras and Nicaragua reaching RV last dose coverage of 87-98%. These early experiences show that, RV coverage can reach the same level as DTP3 in 2-3 years with timely immunisation.
- (d) In May 2013, the Government of India and an Indian manufacturer announced positive Phase 3 clinical results for a new 3-dose schedule Rotavirus vaccine. Local licensure for this vaccine is expected in 2014. Projected timing for WHO pre-qualification is being followed closely.

9.5 Pentavalent Vaccine (DTwP+HepB+Hib)⁹

Key programme statistics (programme start date 2001)

	Actuals	Forecasts		
		Year 2013	2011-2015 (Strategy Period)	Programme start – 2015
No. of countries	70	~2	~11	~73
Coverage	43%	~49%	~70%	~70%
No. vaccinated ¹⁰	155M	~36M	~196M	~288M

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

⁹ Pentavalent vaccine refers to countries receiving GAVI support for Pentavalent vaccine and does not include countries receiving only Hepatitis B or only Hib vaccine support.

¹⁰ Estimates only include children vaccinated with GAVI support

- (a) In 2013 two countries introduced as forecasted: Somalia in April and Indonesia in August. Nigeria started the final phase of its roll out on time in July with positive reports. India, which started phased introduction in 2011, has rolled out in nine states to date, and has submitted an accelerated roll out plan for all remaining states in 2014. The last remaining GAVI country, South Sudan, plans to introduce in Q1 2014. By 2015, 73 introductions are foreseen, compared to a target of 69. The coverage is forecast to reach 70% in 2015 versus the target of 77%. Slower phased implementation in India versus the original plan established in 2011 is the main reason for coverage projections being below target.
- (b) For the largest countries which are in the process of rolling-out Pentavalent vaccine, a coordinated effort from the Alliance partners is assisting to ensure timely achievement of their plans or, as in the case of India and Indonesia, to support recent requests to accelerate their rollouts. In the other GAVI countries the emphasis is on increasing coverage, with special focus on those with DTP3 coverage under 70%.
- (c) For Pentavalent vaccine, a progressive switch towards the use of the 10-dose vial (with a lower cold chain footprint and price per dose, but higher wastage) has led this presentation to account for 70% of use in 2014. In response to this change the Alliance has increased its focus on wastage and introduced in the guidelines a benchmark wastage of 15% based on 2011 country Annual Progress Reports (compared to the 25% indicative wastage rate from WHO). Latest 2012 APR data confirmed wastage for this presentation to be on average 15%.
- (d) The availability of multiple presentations also allows for more strategic use: piloting of the combined use of both 1-dose and 10-dose vials within a single programme, is currently being explored to support countries in their effort to optimise cost, coverage, cold chain footprint and wastage. This is underpinned by growing programmatic data from partners work on EVMs (Effective Vaccine Management) assessments, PIEs (Post Introduction Evaluations), EPI Reviews and other sources to establish improved programmatic understanding of new vaccine introduction.

10 GAVI and Supplementary Immunisation Activities (SIAs)

- 10.1 GAVI is supporting a large number of planned, preventative campaigns with vaccines including measles, rubella, meningitis A and yellow fever. Beginning in mid-2013 and continuing through early 2014, the Secretariat is working with partners to (i) document best practices, prioritise approaches and provide additional guidance to different categories of countries in order to improve the use of campaigns to strengthen RI; (ii) support efforts to make evidence-based revisions to GAVI's vaccine application guidelines and procedures in order to incentivise and support RI strengthening in campaigns; and (iii) build support for these efforts within the wider immunisation community by understanding and

addressing the concerns of stakeholders in relevant organisations. Work to date by GAVI partners suggests that for campaigns to strengthen RI, specific activities must be embedded in the planning for the campaign and be underpinned with dedicated resources. The activities, resources and expectations of what can be achieved are also likely to vary with the strength of the underlying immunisation programme and health system.

- 10.2 The Secretariat has modified the New and Underutilised Vaccine (NVS) application guidelines for 2013 to strengthen routine immunisation during planned campaigns. According to the guidelines, *“country applications should describe how the campaign activities will contribute to strengthening routine immunisation services and achieve high campaign coverage”*. This applies to applications for any vaccine to be delivered through a campaign. Applications must include specific activities to (i) be undertaken as part of the planning and implementation of the campaign that will strengthen routine immunisation services; and (ii) assess, via a rigorous and independent survey, or comparable approach, the level of coverage achieved through the campaign. Countries are also strongly encouraged to evaluate the implementation of the routine strengthening activities completed during the campaign.
- 10.3 The Secretariat, working with a consultant, has contacted partners to start the dialogue and determine appropriate field research or case studies. The process of documenting the experience of Ethiopia, where the most recent GAVI-funded Measles SIA included RI strengthening activities, has begun. Additional case studies, with a mix of different characteristics, are anticipated in the coming months. As findings become available, the Secretariat anticipates working with partners to identify appropriate fora, for example through regional meetings, to build international support for campaigns strengthening RI.

11 Safety and Surveillance

- 11.1 Although most adverse events following immunisation (AEFI) reports are of coincidental health problems unrelated to the vaccines, a very small number of serious vaccine reactions are known to result from specific vaccine administration. They are usually associated with errors administering the vaccines and can increase immunisation anxiety. The introduction of new vaccines and the increased number of doses administered often results in increased attention on vaccine safety issues. In several countries, there have been reports of a number of serious AEFI. Those reports, on occasion have also generated a public debate and led decision makers to consider precautionary measures such as temporary suspensions of vaccine use.
- 11.2 Within the GAVI Alliance, WHO has responsibility for following up with countries on AEFI reports and ensuring that safety issues are promptly identified and addressed. In collaboration with national authorities, local and international experts, AEFI are thoroughly investigated and for some conditions of interest, such as intussusception and rotavirus vaccines,

special studies have been implemented. When there is sufficient evidence that serious AEFI are not causally related to vaccination, support is provided to national authorities to communicate available evidence and prevent unnecessary disruption of immunisation activities. Within the framework of the Global Vaccine Safety Initiative, the WHO's Essential Medicines Department plays a leading role in surveillance and response to serious AEFIs. During the first part of 2013, activities have been implemented, in coordination with the Vaccine Implementation Management Team, in response to two alleged Penta vaccine AEFI in India and Vietnam. A coordinated response including global and local communication, information sharing, and technical support to the countries ensured minimal disruption to the programmes.

12 Vaccine Supply Chain

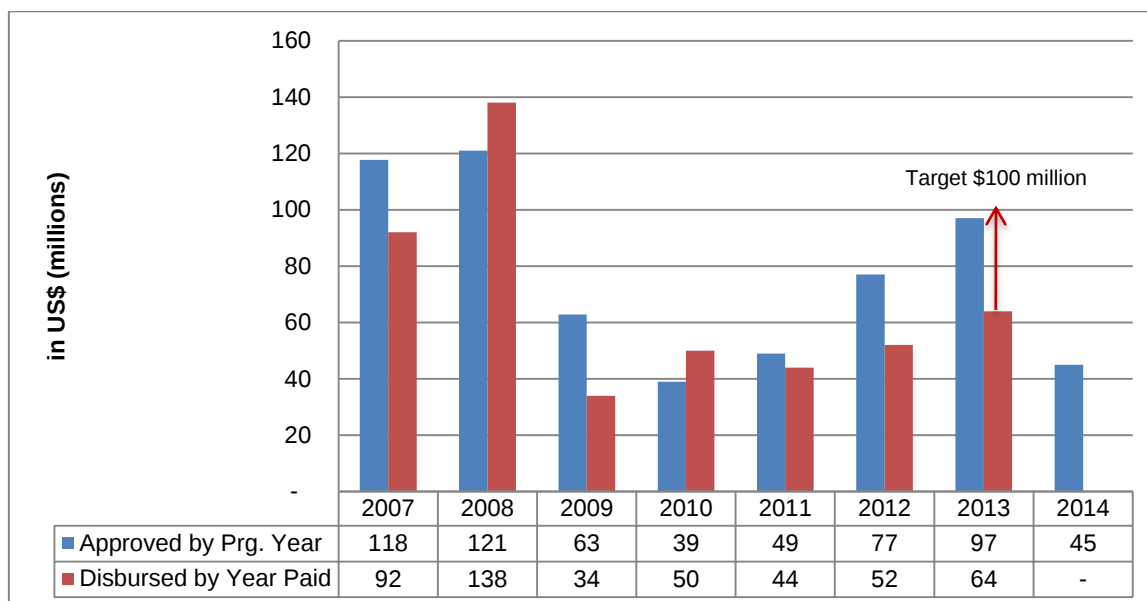
- 12.1 The increased GAVI expenditure on vaccines over the years has not always been matched by a sufficient strengthening of the supply systems that deliver them to their final point of use. In 2012, in recognition of the importance of strong supply chains to protect the GAVI vaccine investment and to help the Alliance meet its collective goals, the GAVI Board requested the Secretariat start work on a strategic initiative to strengthen the end-to-end vaccine supply chain. This was presented to the PPC in October 2013 and now, will be further advanced and brought to the April 2014 PPC.

13 Strategic Goal 2: The Health Systems Goal

- 13.1 The Secretariat continues to improve its HSS cash support model which is now closely linked to immunisation outcomes. As of September 2013, GAVI has committed a total of US\$ 884 million for HSS grants from 2007 through 2017. Total HSS approvals from 2007-2014 are US\$ 609 million, of which US\$ 474 million has been disbursed (see figure 1). The trend of increased disbursements continues in 2013, with a target of US\$ 100 million in disbursements to more than 25 countries, which represents a doubling of the 2012 disbursement level. Cash programmes represented 12% of total spending in 2012 and is forecasted to be 19% in 2013.¹¹

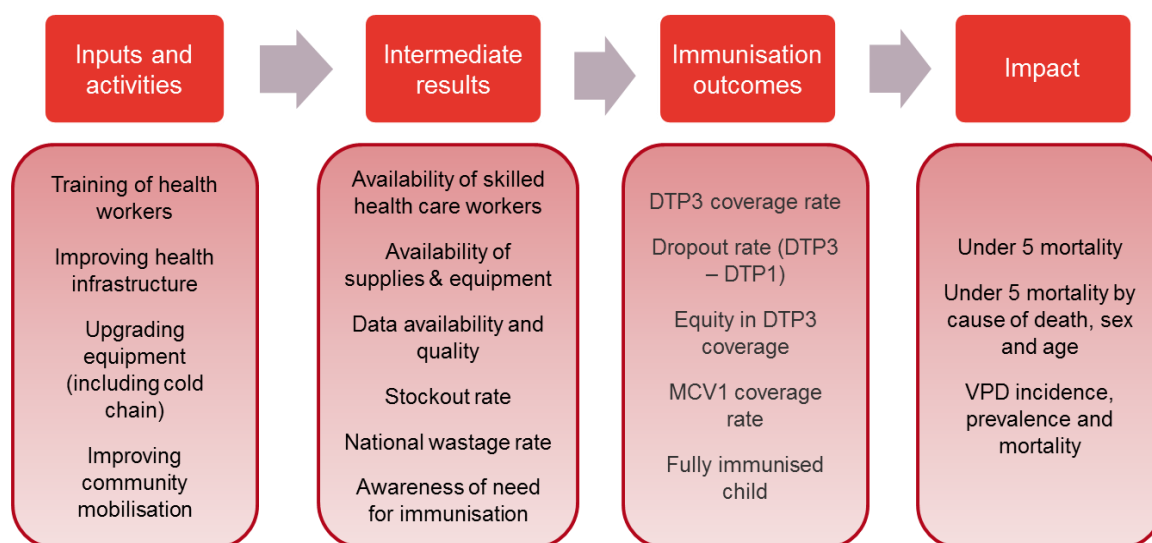
¹¹ Cash programmes include funds for HSS, ISS, CSO, HPV demo projects, vaccine introduction grants, and operational costs for campaigns.

Figure 1. HSS Grant approvals and disbursements for 2007-2014, as of 30 September 2013



- 13.2 Following the discussions of the GAVI Board at the March 2013 retreat, and with advice from the Technical Advisory Group for Health System Strengthening (TAG-HSS), the Secretariat is working to better invest resources to address key bottlenecks and is exploring HSS resource allocation options that take into account country context and performance, balancing needs with performance. The Secretariat is working with TAG-HSS on a document outlining GAVI's HSS approach, which will be shared with the Board in 2014. The paper will provide a clear rationale and evidence for continuing investment in health systems strengthening and a series of recommendations to improve the quality and impact of GAVI's investments in this area. Recommendations will seek to define more clearly the scope, purpose and impact of GAVI's spending on HSS.
- 13.3 As part of a strengthened focus on results, the Secretariat is drawing on the IHP+ M&E framework and has been working with WHO on "intermediate results" for health systems performance. Intermediate results are now incorporated in a revised results chain and M&E framework for HSS grants. The results chain is intended to demonstrate a clear link between proposed HSS activities and intermediate results to immunisation outcomes (see figure 2) and was included in the 2013 revised GAVI HSS application materials. The Secretariat revised the application materials through a consultative process with partners.

Figure 2. Results chain, showing intermediate results



- 13.4 The Secretariat is also working to strengthen the M&E frameworks of the 18 Phase 1 PBF (performance based funding) countries¹² and to incorporate intermediate results in order to better assess and monitor the performance of these HSS grants. The Secretariat will conduct implementation research on PBF that will contribute to enhancing the ability of the Secretariat and country partners to learn from, revise, and strengthen how PBF is operationalised as well as to enhance the effectiveness of the PBF approach.
- 13.5 WHO has completed six country coverage improvement plans with five more to be completed by end 2013. A new partner, l'Agence de Medicine Preventive (AMP), has commenced work to develop coverage improvement plans in another five countries. UNICEF has also commenced or completed an equity assessment in 9 out of 10 countries which will lead to the development of plans to address disparity in access and utilisation of immunisations services. GAVI support for the implementation of coverage or equity plans will be through provision of HSS or as part of a country-tailored approach (where appropriate), to complement other ongoing efforts at country level.
- 13.6 Support to increase CSO engagement in HSS is leading to improved organisation of CSOs at country level and more effective relations with Government. Of the 15 countries approved for HSS funding in 2012, all 15 engaged CSOs in the development of the proposal, primarily through a health sector coordinating committee (HSCC) or equivalent. Of these countries, 13 indicated in their proposal that CSOs would be involved in the implementation of the grant.

¹² The 18 Phase 1 PBF countries include 15 countries approved in 2012 (see next footnote below) and 3 countries approved in 2013 (Mozambique, Papua New Guinea and Rwanda).

- 13.7 Ten out of the 15 countries provided specific budgets for CSO-related activities. These activities are for \$30 million, which is over 15% of the total budget of \$175 million for these 15 countries. This may not include all funding to CSO-related activities; countries such as Haiti and Liberia, where CSOs have a significant role in the health sector, did not specify a budget for CSO-related activities in the GAVI HSS proposal. Actual funding allocations and expenditures will be reported by countries in 2014. The main types of CSO-related activities through these HSS grants are: immunisation service delivery (including facility-based and outreach services); empowering communities (including community mobilisation, awareness raising, demand generation and advocacy); cold chain facilities and equipment; and health worker training. For example, Afghanistan's grant proposal indicated over 70% of budget for implementation by CSOs, including increasing cold chain capacity, procurement of cold chain equipment, and training over 5,500 community health workers. Meanwhile, Burundi proposed to contract over 200 community based organisations with performance initiatives linked to ensure children were receiving the full course of immunisation.

14 Strategic Goal 3: The Financing Goal

- 14.1 Regarding co-financing, of the 65 countries required to co-finance their vaccines in 2012, nine countries were in default of their payments at the end of the year versus four at the same point the previous year. As of October 2013 DRC and CAR remain in default. Both countries have paid their arrears from previous year during 2012 and made additional partial payments against its 2012 co-financing requirements during 2013. The total amount transferred against the co-financing commitments to date amounts to approximately 61 million, accounting for 9% of vaccine support to those countries.
- 14.2 Following the release of the 2012 gross national income (GNI) per capita information by the World Bank in July of this year, three additional countries, Papua New Guinea, Nicaragua and Uzbekistan, moved into the graduating countries grouping and will therefore not be eligible for new GAVI support starting from January 2014.

Section C: Annexes

Annex A: Strategic Goal 1: Vaccine Implementation

15 This annex provides an update on the additional GAVI supported vaccine programmes. PCV, RV and Penta updates are reported in the main paper in sections 9.3, 9.4 and 9.5.

15.1 Human Papilloma Virus Vaccine (HPV)

Key programme statistic (Programme start date 2013)

	Forecasts		
	Year 2013	2011-2015 (Strategy Period)	Programme start – 2015
No. of countries	~7 demo, 0 national	~27 demo, ~7 national	~27 demo, ~7 national
No. vaccinated ¹³	~0.1M	~1.8	1.8M

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

- (a) In 2013, Kenya, LAO PDR, Malawi and Sierra Leone started an HPV demonstration programme and three more are planned in Ghana, Madagascar and Niger. Approximately 85,000 girls will be immunised against HPV through the demonstration projects.
- (b) The number of countries interested in the HPV demonstration programme has exceeded expectations, with 15 applications for the first round and 12 in 2013. Rwanda was approved for national programme support and will shift from donated supply to GAVI funded supply in 2014, while Uganda and Uzbekistan applied in 2013 for introduction in 2015.
- (c) The GAVI Secretariat has worked with traditional and new partners to adjust HPV programme guidelines in light of lessons learnt following the first round of approved programmes. An HPV programme results framework has been established with related targets for the demonstration programme component. Targets for the national programme will be set next year as the first round of demonstration countries will have completed at least one year of implementation.
- (d) The Alliance, led by the WHO, has recently focused its efforts on coordination for technical assistance to meet the needs of countries getting ready to implement the programme and those countries planning to apply for support in 2013. Minimal delays are currently expected in introduction timelines.

¹³ Estimates only include girls vaccinated with GAVI support.

- (e) Special efforts are focused on directing technical assistance to (i) programme evaluation (ii) assessment of feasibility of integration of HPV vaccination with other adolescent interventions; and (iii) country development of a national comprehensive strategy for cervical cancer prevention and control. These areas are key to the success of the demonstration programmes and will help to address complex issues of accurate target population estimates as well as coordination and collaboration between a larger, more diverse group of stakeholders (e.g. cancer, adolescent health, education, and immunisation). Experience to date suggests that the demonstration programme concept is working as intended and helping to identify the programme areas that need strengthening, before countries commit to national HPV vaccine introduction.

15.2 Yellow Fever Routine and Campaign Programmes

Key programme statistic (programme start date 2001)

	Actuals	Forecasts		
	Programme start – 2012	Year 2013	2011-2015 (Strategy Period)	Programme start – 2015
No. of countries	12 (campaigns) 17 (routine)	1 (campaign)	~4 (campaigns) ~5 (routine)	~13 (campaigns) ~22 (routine)
No. vaccinated (routine)	64M	~8.7M	~44M	~93M
No. vaccinated¹⁴ (campaigns)	69M			

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

- (a) By the end of 2013, preventive campaigns will have been organised in 13 WHO designated “high-risk” countries in Africa. Six of the 13 countries conducted partial vaccination with the proportion of districts covered during the campaign ranging from 52% to 100%.¹⁵ In November 2013, Nigeria is expected to conduct mass vaccination programmes targeting a population of 9.5 million. Sudan, is expected to begin preventive campaigns during the first six months of 2014. Timing and speed of roll-out is heavily influenced by the continuing vaccine supply shortage.

¹⁴ 2015 onwards is subject to the outcome of the Vaccine Investment Strategy 2014. Nigeria and Sudan are approved; targets are being confirmed

¹⁵ Source : WHO 2013 report Addendum to the strategic Framework for YF Immunisation Initiative in Africa 2012-2020

- (b) As of 2012, all 13 “priority A” countries, and 10 of the 21 “B and C priority” countries have introduced YF into their routine immunisation programmes.¹⁶ However routine coverage for YF remains low in some countries, especially those that have conducted successful campaigns. No new applications for routine immunisation have been received by GAVI since 2009 to date. Activities are on-going to identify the causes for this and define a corrective plan.

15.3 Meningococcal A Conjugate Vaccine – Campaign Programme

Key programme statistics (programme start date 2010)

	Actuals	Forecasts		
	Programme start – 2012	Year 2013	2011-2015 (Strategy Period)	Programme start – 2015
No of countries ¹⁷	10	2	~21	~21
No. vaccinated	~103M	~56.9M	~267M	~286M

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

- (a) In 2013, Nigeria and Sudan will continue phased campaigns reaching an additional 34 million. Ethiopia will launch a new campaign, targeting an additional 19 million people in October 2013. Gambia will conduct a campaign in November targeting 1.3 million. By 2015, the GAVI Alliance expects to have reached all 21 countries in the meningitis belt, with a total of 267 million individuals vaccinated against Meningitis A. For reasons of country readiness, some campaigns have been delayed and others have opted to extend phases for multi-year programmes. The remaining five countries included in the original investment case will introduce preventive campaigns in 2016.
- (b) The deployment of Men A Conjugate vaccine has been successful so far. Analysis of surveillance data from the meningitis case-based surveillance systems in Burkina Faso, Mali and Niger, suggest that vaccine introduction has substantially reduced the number of reported meningococcal serogroup A cases in the vaccinated areas. Burkina Faso data showed significant reductions in the rate of meningococcal serogroup A disease.¹⁸ In order to reach some remaining population cohorts,¹⁹ specifically males aged 16–29 years, and some remote areas, countries are changing their social mobilisation approaches.

¹⁶ WHO/UNICEF- A Strategic Framework for the Yellow Fever Immunisation Initiative 2012-2020

¹⁷ Includes the 6 countries that introduced without GAVI support

¹⁸ Joint WHO/UNICEF Progress Report January – December 2012, Meningitis A Conjugate vaccine Immunisation Campaign.

¹⁹ Cameroon, 84% verbal, 63% with cards; Niger, 91% verbal and 69% with cards.

15.4 Measles Second Dose

Key programme statistics (programme start date 2007)

	Actuals	Forecasts		
	Programme start – 2012	Year 2013 ²⁰	2011-2015 (Strategy Period)	Programme start – 2015
No. of countries	8	~3	~26	~28
No. vaccinated²¹	10M	~7M	~40M	~45M

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

- (a) During 2013, three more countries will introduce measles second dose into their routine system: Burundi, Zambia and Sao Tome and Principe. Tanzania was approved for support in 2013 and will introduce routine Measles second dose from January 2014.
- (b) Historically, some of the countries eligible to introduce a second dose of measles into their immunisation schedule have not been availing GAVI support. In the last year increased advocacy by GAVI, WHO and other partners has resulted in countries applying during 2013 that were not initially forecasted, such as Mozambique, Malawi and Papua New Guinea. A total of six countries have applied this year for measles second dose support.

²⁰ For 2013, number of countries are only those introducing in 2013, but number vaccinated are all 9 countries that receive GAVI support in 2013 (support for Viet Nam and DPRK have ended).

²¹ Estimates include direct and catalytic support

15.5 Measles Supplementary Immunisation Activities (SIAs)

Forecasted performance (programme start date 2013)

	Forecasts		
	Year 2013	2011-2015 (Strategy Period)	Programme start – 2015
No. of countries	~322	~6	~6
No. of vaccinated²³	~53M	~80M	~80M

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

- (a) In 2013, three of the four countries approved for measles SIA targeting children up to five years of age will be conducting the campaigns: Ethiopia, DRC and Nigeria; Pakistan is likely to postpone the SIA to Q1 2014 for better preparation. Ethiopia conducted their SIA from 29 May-2 June, and the coverage survey is being finalised. DRC started their phased campaign in September (to continue to the end of July 2014). Nigeria conducted their campaign in the Northern States in October and will be reaching the Southern States in November. Two more countries remain eligible to perform measles SIAs in the period 2014-2017: Chad and Afghanistan. Nigeria is also eligible for another SIA until 2017. Both Chad and Afghanistan have submitted their applications, and Chad plans to conduct the campaign in 2014, while Afghanistan plans to conduct the campaign in 2015. However, discussions are continuing with Afghanistan on the possible introduction of rubella vaccine.
- (b) The security of vaccine supply remains an issue, with the current sole supplier of WHO pre-qualified MR being also the largest supplier of Measles vaccine. The vast majority of both MR and Measles orders are shipped by this supplier which puts strain on the logistics and warehousing systems and in some cases necessitates the prioritisation of some shipments over others. High volatility of demand with large scale unexpected requests for tens of millions of doses of measles vaccines exacerbates the existing problems. Global, regional and country partners are working to better coordinate and plan the timing of large SIAs to ensure supply is available.

²² Pakistan 2013 introduction possibly delayed to Q1 2014

²³ Estimates include direct and catalytic support

15.6 Measles Rubella

Forecasted performance (programme start date 2013)

	Forecasts		
	Year 2013	2011-2015 (Strategy Period)	Programme start – 2015
No. of countries²⁴	~4	~25	~25
No. vaccinated²⁵	~70M	~214M	~214M

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

- (a) In March, Rwanda became the first country to conduct a GAVI-supported MR campaign, reaching more than five million children aged nine months to 14 years of age. According to the post campaign coverage survey, the country achieved 97.5% coverage. The campaign was also used to provide HPV (already in country) for the appropriate age cohorts and vitamin A. Rwanda is expected to introduce MR vaccine into the routine system from January 2014 fully financing the programme. Ghana also conducted the campaign in September. By the end of 2013, Cambodia and Senegal are also expected to have conducted SIAs. Bangladesh planning on a November campaign has faced some challenges for financial disbursement in-country and is likely to postpone the campaign to Q1 2014. Vietnam's MR campaign and subsequent routine introduction has been delayed due to local regulatory registration requirements. Six more countries have applied this year for MR campaigns including Yemen who were conditionally approved last year.

²⁴ two countries, Nepal and Lao PDR receive vaccine introduction grant from GAVI to introduce MR into routine.

²⁵ Estimates include direct and catalytic support