



Report of the GAVI Alliance Board

12-13 June 2012

Subject:	Programme update: Accelerated Vaccine Introduction
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Category:	For Information
Strategic goal:	SG1 - Vaccines & SG4 - Market shaping

Section A: Overview

1 Purpose of the report

- 1.1 The purpose of this report is to provide a summary on the progress of new vaccine rollout supported by the Accelerated Vaccine Introduction (AVI) initiative and progress toward building a platform for future introductions.

2 Recommendations

- 2.1 For information only.

3 Executive Summary

3.1 *Pneumococcal and rotavirus vaccines:*

- (a) In 2012, the GAVI Alliance marked the first simultaneous introduction of both pneumococcal and rotavirus vaccines in Ghana in April. Nine additional countries are expected to launch pneumococcal vaccines (bringing the total to 10) and another seven are planned to introduce rotavirus vaccines (bringing the total to 8) this year. As reported to the Board in Dhaka, however, unprecedented levels of demand for the two vaccines that exceeds available supply will lead to delays in a number of countries, at this point in time anticipated to affect mainly 2013.
- (b) The supply situation remains dynamic. For example, since AVI's recent update to the Programme and Policy Committee (PPC) in April, one manufacturer has confirmed the availability of additional quantities of pneumococcal vaccines (PCV). Furthermore, the WHO has approved the expanded use of the novel two dose PCV presentation with special requirements. Both of these developments could ease supply constraints for pneumococcal vaccines in 2012 and 2013 (see Annex 1 for details).

- (c) For rotavirus vaccine (RV), supply in 2012 and 2013 will be less than anticipated for the two dose product requested by most countries due to issues in scaling-up vaccine production. The manufacturer is making considerable efforts to accelerate an increase in available capacity from Q4 2013 onwards. In 2014, supply for all countries approved to date for both pneumococcal and rotavirus vaccines should be sufficient to support sustainable vaccine introductions. New contracts will be needed to cover forecasted demand for those countries that are anticipated to apply.

3.2 **Other vaccines:**

- (a) With the Board's approval to open funding windows for HPV and rubella vaccines,¹ GAVI has distributed application guidelines for both programmes. In addition, WHO, PATH and GAVI have been working with a wide range of stakeholders from reproductive and adolescent health, education and cervical cancer communities to develop an HPV Demonstration Programme. Progress is being made on rubella following discussions with the Measles Rubella Initiative, as well as input from the GAVI Board retreat in Oslo, and a separate paper is being presented on measles operational strategy for decision.²
- (b) With the launch of pentavalent vaccines in India in December last year and seven additional introductions in 2012-2013, 72³ GAVI countries will have incorporated pentavalent vaccines into their national immunisation programmes.⁴ This means that GAVI support will have ensured that the world's poorest countries are reached with DTP-HepB-Hib vaccines, a monumental achievement for GAVI and the global public health community. From 2011-2015, GAVI expects to help immunise more than 230 million children with the five-in-one vaccine.
- (c) Finally, with WHO working groups, GAVI continues to support yellow fever (YF) and meningococcal A (MenA) campaigns. All 12 high-risk countries have implemented YF campaigns with the exception of Nigeria, expected to apply in 2012. MenA campaigns throughout the sub-Saharan meningitis belt have been initially successful with 90-100% administrative coverage and zero identified vaccine failures.

4 **Context**

- 4.1 AVI was established to project-manage the introduction and the rollout of rotavirus and pneumococcal vaccines. Under the Secretariat's leadership, the AVI Management Team is comprised of members from WHO, UNICEF and the AVI Technical Assistance Consortium (AVI TAC⁵). The team works to empower country decision making on new vaccine introduction; secure predictable financing; balance supply and demand; facilitate country

¹ The former conditional upon receiving a sustainable price for the vaccine.

² See document number 12, Options for Enhancing GAVI's Investment in Measles Prevention.

³ This will increase to 73 if and when South Sudan introduces pentavalent vaccines.

⁴ Six GAVI countries have introduced penta without GAVI support: Ukraine, Bolivia, Cuba, Guyana, Honduras and Nicaragua.

⁵ A consortium of PATH, Johns Hopkins University (JHU), US Centers for Disease Control and Prevention (CDC) and others. The Bill & Melinda Gates Foundation also participates as an observer.

introductions (monitoring country readiness and supporting implementation) and establish a platform for future vaccines.⁶

5 Next steps

5.1 Key activities for the AVI Management Team planned for 2012 include:

- (a) Continued coordination, planning and information sharing, country by country, for the pre- and post introduction phase of new vaccines:
 - Close and proactive management of the supply and demand situation and communications to countries.
- (b) Transition to a stronger focus on implementation to ensure successful uptake and sustained coverage increases across a widening range of vaccines programmes — penta, YF, MenA, pneumo, rota, HPV and MR — as well as potentially JE and typhoid vaccine introductions that could be approved to start from 2015 and 2017 respectively.

6 Conclusions

6.1 The latest Strategic Demand Forecast⁷ predicts the GAVI Alliance will still reach the Business Plan⁸ target of number of countries expected to introduce PCV and RV by 2015.⁹ However, expected delays in 2013 may affect the ability of GAVI to meet Business Plan targets for number of immunised children and deaths averted, but this may be counterbalanced by increases in overall introductions and further progress with pentavalent and measles vaccines.

Section B: Implications

7 Impact on countries

7.1 GAVI will continue to communicate with approved countries that have not yet introduced vaccines due to supply challenges.¹⁰ New countries applying for PCV and RV in 2012 are being alerted to the supply situation in the application guidelines.

8 Impact on the Business plan/ Budget/ Programme Financing

8.1 The business planning process in 2012 should capture activities and budgets needed to meet the programme objectives and goals for 2013 and 2014, with a specific focus on strengthening alignment between SG1 (vaccines goal) and SG2 (health systems goal) work plans.

⁶ See GAVI Website <http://www.gavialliance.org/about/gavi-business-model/avi/>

⁷ Based on Version 5.0 no supply nor financial constraints

⁸ When this strategy was approved, targets were set at 44 introductions for pneumococcal and 33 introductions for rotavirus vaccines by 2015. These targets were based on version 2.0 of the Strategic Demand Forecast. According to the current strategic demand forecast (v 5.0) which does not take financial or supply constraints into consideration, the Alliance anticipates these targets to increase to 58 and 49 respectively.

⁹ See Appendix I & II

¹⁰ Thirty recently approved countries for rotavirus and pneumococcal vaccines were informed of supply constraints in decision and information letters. GAVI has committed to update countries on supply availability in Q3 2012.

9 Risk implication and mitigation

9.1 *With regard to vaccine supply:*

- (a) The temporary supply/demand imbalance causing a delay in 2013 for recently approved countries cannot be eliminated completely, even with additional contracts. The anticipated supply limitations on new introductions next year could pose a reputational risk to GAVI and undermine donor and country-level confidence in the organization's mission. It is therefore important that GAVI continue to emphasize that the situation is temporary and that the most recently approved countries should be able to introduce no later than 2014.
- (b) Beyond 2013, the supply scenarios from the RV manufacturers and demand scenarios from new applications anticipated are being constantly analysed, and efforts by suppliers and GAVI are planned to secure (and potentially bring forward) timelines for additional capacity. Close follow up with PCV suppliers regarding additional supply is ongoing and recent information indicates an improvement in the situation. One of the key principles in managing supply is to ensure that all countries that have introduced vaccines have adequate supply to sustain immunisation programmes. By end year 2012, GAVI will be supporting 26 countries with pneumococcal vaccine programmes, and 13 countries with rotavirus vaccines.
- (c) GAVI and its partners also are working to optimize the supply to countries to help identify any potential overstock (and under stock) through increased effort to obtain early data on uptake in the months following introduction. A number of countries have monthly data collection systems (which consolidate coverage data at the national level) from which trends can be monitored and may be triangulated with first stock-level data to provide 'real time' analyses. One caution in using this data is the influence of overestimates of the eligible population (e.g. inclusion of other infants out of the target age group) which can lead to inaccuracies.

9.2 *With regard to country readiness:*

- (a) As countries begin to introduce multiple vaccines, immunisation systems (e.g. cold chain capacity, logistics and human resources) may be significantly stretched. A review of the 2011 pneumococcal introductions confirmed that three countries implementing pneumococcal vaccines incurred delays¹¹ due to cold chain expansion as well as training challenges. Chad postponed one phase of its MenA campaign given a serious lack of cold chain capacity.

¹¹ Three countries incurred delays: Burundi (12 months), Malawi (14 months) and Honduras (seven months)

- (b) GAVI and its partners are working closely with countries to follow-up on recommendations and activities identified as part of the effective vaccine management (EVM) assessment. The AVI team also continues to update its country readiness dashboard, a tool to track and monitor early warning signs in introduction planning that might predict approved countries' vulnerabilities to managing large-scale vaccination rollouts. However, coordinated action by countries and partners will be required to ensure system readiness is not a bottleneck to future introductions and sustained vaccine implementation.

10 Legal and governance implication

- 10.1 None. For information only.

11 Consultation

- 11.1 This report was developed with input from the AVI Management Team (AMT).

12 Gender implications / issues

- 12.1 N/A

13 Implication for the Secretariat

- 13.1 In early 2012, GAVI's CEO announced a re-alignment within the Secretariat to bolster country focus and vaccine delivery. To this end, the AVI staff within the Secretariat will move to Country Programmes once a new Managing Director is in place. The Secretariat will also strengthen AVI's capacity by dividing senior responsibilities between a technical advisor and a programme director, as well as by moving Strategic Demand Forecasting in-house.

Annex 1: Vaccine updates

1. Pneumo Vaccine Update – Progress to date

- 1.1 A total of 46 countries are currently approved for introduction of PCV.¹² To date, 17 countries have introduced PCV (2009 – two; 2010 – one; 2011–13; 2012– one to date). In 2012 a total of 10 (one to date and nine additional) countries are anticipated to introduce. See appendix I for details.
- 1.2 An analysis of the countries that have already introduced PCV suggests it took on average seven to eight months to introduce from the time the PCV products were available¹³ to launch in GAVI countries. This is the time taken for planning, training and other readiness activities.
- 1.3 GAVI will review the Annual Progress Reports for the year 2011 and analysis carried out by CHAI¹⁴ on ‘mini catch up’ or ‘backlog’ to identify possible trends in uptake rates in the first year of introductions. These reports will provide the first official data on coverage in countries and also include country reported stock levels as of 1 January 2012 which could be used to assess any need for adjustments of 2012 quantities and will provide the basis for approval of 2013 quantities.
- 1.4 First supply agreements under the Advance Market Commitment (AMC) were signed in March 2010, and manufacturers have agreed to supply additional doses in 2012 and 2013 as part of the AMC Capacity Development Period. Based on the total volumes contracted under the AMC to date, 82M doses are available in 2013 and 96M are available annually from 2014. With the increasing demand for PCV, a third Call for Offers will be issued in Q3 2012 to contract additional doses for the longer term.
- 1.5 In addition, at the time of writing this report, both manufacturers verbally confirmed potential access to additional supply for 2012 and 2013 under certain conditions, which could lead to additional introductions. An update on the status of introducing countries will be presented to the Board during its meeting.
- 1.6 WHO has now confirmed that the preservative-free vaccine presentation PCV10 can be rolled out in GAVI countries with the specific training materials, intensified training programs and the distribution of fridge stickers in place before vaccine introduction.¹⁵ Rigorous survey-based assessment of training effectiveness must also be implemented six months after vaccine rollout. The post-assessment will inform the need for potential re-training of vaccinators.

¹² Nigeria was approved for phase 1 of its introduction while phase 2 and 3 remain conditionally approved.

¹³ PCV vaccines must be deemed AMC eligible by the AMC Independent Assessment Committee to be available for procurement under the AMC. PCV 10 (in 2 dose vials and preservative free) received WHO prequalification - with conditions, in March 2010 and was deemed AMC eligible in April, 2010. PCV 13 was prequalified and subsequently deemed AMC eligible in August 2010.

¹⁴ In Kenya, Ethiopia and Malawi

¹⁵ The two dose presentation of a preservative-free liquid vaccine has not been previously used in United Nations vaccination programmes.

Data from studies in Ethiopia and Kenya on the PCV10 two dose presentation have shown no unexpected adverse events from inappropriate use, but did report waning in the understanding of how the vaccine should be discarded if not used within six hours.

- 1.7 Under the current assumptions, a number of countries planning introduction in 2013¹⁶ may face a delay of up to one year. However there should be at least five introductions in 2013. The number of additional introductions will depend on the amount of additional supply that can be made available as well as the actual timing of introduction and the speed of roll-out, especially in large countries, i.e. Pakistan in 2012, and Nigeria and Bangladesh in 2013.
- 1.8 The Pneumo/Rota Operational Working Group continues to provide the essential close coordination and improved information flow around pre and post-launch activities, day-to-day operational issues and actions. The two products are being launched in many countries 'back to back' and, in fact, there are currently 15 countries that are launching pneumo and then rota¹⁷ within 24 months.
- 1.9 The challenges of the first months of the Democratic Republic of Congo (DRC)'s introduction of pneumococcal vaccine highlight the ideal of having real time data on progress of uptake.¹⁸ GAVI's Board recommended a restriction of their pneumo programme (limiting vaccine use in the four states/provinces) until DRC settled co-financing arrears for penta and yellow fever, which the country has now done. In the interim, the country reported an overstock of PCV based on initial demand off-take in the four provinces. The overstock is now calculated to be reduced by 67% and the remaining doses will be used in an additional province subject to the Secretariat's approval.

2. Rotavirus Vaccine Update – Progress to date

- 2.1 In the first half of 2012, countries began planned vaccine introductions in Yemen, Ghana, Moldova, and Rwanda. Four additional countries are expected to launch in 2012. Taking into account the previous years' introductions in PAHO countries and in Sudan, 13 countries will be implementing rotavirus vaccine programmes with GAVI's support by year end.
- 2.2 Two manufacturers with prequalified products signed long-term agreements for rotavirus vaccine supply for 2012-2016. Supply is adequate to meet the demand of eight countries launching in 2012, but less than anticipated due to issues with scale up of one manufacturer's filling line. In 2013, two to five countries will potentially be able to launch the vaccine, out of 15 additional

¹⁶ 10 countries in total: 3 countries postponed from 2012 to 2013 due to unavailable supply, 2 countries that chose to postpone to 2013 and 5 countries that from their application planned introduction in 2013.

¹⁷ A few countries may decide to launch Rota first then Pneumococcal (e.g. Sudan)

¹⁸ In Q1 2012 there was a report of possible freeze damage in DRC, there has been specific follow up by UNICEF and WHO to complete an assessment: refresher training to staff on temperature monitoring augmented by the use of freeze tags™ technology has been implemented, as well as a recommendation for a continuous temperature monitoring systems to be installed. UNICEF has officially communicated that no vaccines have been damaged.

countries approved to date.¹⁹ The situation is expected to improve in late 2013 with the manufacturer making strong efforts to accelerate production capacity increase. GAVI and UNICEF are working closely to track progress toward the goal of supplying approved countries rotavirus vaccine supply in the latter part of next year.

- 2.3 As with pneumococcal vaccines, obtaining *real time* or *more timely* data on the coverage levels reached in the country's first year(s) of rotavirus vaccination programmes would help in managing shipments during a supply constraint situation. Initial administrative data from Sudan shows 86% coverage for first dose (rota1), and 74% for the second (rota2), compared to 100% for penta1 and 95% for penta2. Currently, the strategic demand forecast predicts rotavirus vaccine uptake will be 5% less than the penta²⁰ coverage. Variances from this assumption will have an impact on the demand and will have to be taken into account in future demand supply modeling.
- 2.4 Last month, the WHO Strategic Advisory Group of Experts (SAGE) endorsed an easing in the strict age limits for rotavirus vaccine administration while emphasizing the need for improved timeliness of vaccination. This could improve coverage rates in the coming years, but will necessitate intensified communication and training to health care workers in countries that have already introduced the vaccine. Furthermore, there is a need to ensure adequate surveillance to address real or perceived potential adverse events.²¹

3. HPV Update

- 3.1 Following the board decision to fund HPV vaccines subject to the negotiation of an acceptable reduction in vaccine price, the sub-team continued to meet and guidelines for country applications for national introductions have been disseminated to countries. GAVI is forecasted to support up to six nationwide introductions by end of 2015. In order to receive GAVI support for HPV, the country must have demonstrated their ability to deliver a complete multi-dose series of vaccines to at least 50% of the target vaccination cohort in an average size district (preferably comprising urban and rural areas) using a strategy similar to the one proposed for national HPV vaccine delivery. Those countries that cannot demonstrate this ability are being encouraged to apply for a demonstration project. Of note, HPV vaccines will only be supplied pending offers of an acceptable price from manufactures during the tender process.
- 3.2 Design of the demonstration projects is under development through a series of workshops soliciting technical partner, country and donor input. These projects will assist countries in 'learning by doing' before moving to national introduction.

¹⁹ Fourteen countries approved to launch in 2013; Guinea-Bissau was recently approve by the IRC in February for 2014.

²⁰ The quantities of Rota approved to countries are not based on a penta proxy.

²¹ See document number 14, continued funding for special studies

They will also aim to provide an opportunity to select other appropriate healthcare interventions related to adolescent health and cancer control and test the synergies and the practicality and usefulness of their integration with vaccine delivery. GAVI estimates that a country will require approximately two years between the start date of a demonstration project and possible national introduction.

4. Measles-Rubella Update

- 4.1 By 2015, MR vaccine is expected to be introduced in 32 GAVI eligible countries through wide-age (9 months-14 years) campaigns, immediately followed by routine introduction into the EPI programme funded by the countries themselves. There is only one supplier with a WHO prequalified product, with a current production capacity of 130m²² doses per year. The manufacturer has been meeting 90% of the global demand for MR vaccines for many years. The situation remains actively monitored as GAVI seeks to increase its supply security with a potential second supplier and as a possible request from India for new vaccine support would limit the number of MR campaigns in other countries.
- 4.2 GAVI Secretariat management now participates in the Measles Rubella Initiative weekly calls, and discussions are on-going to review the level of strategic and operational collaboration. Following the Board Retreat in April, the GAVI Secretariat is also providing an options paper on GAVI engagement on Measles to the Board for decision.²³

5. Yellow Fever Update

- 5.1 To date, the 12 highest risk countries have introduced yellow fever vaccines through preventive campaigns and Nigeria expects to apply for GAVI support in the coming months for a 2013 launch. Two preventive campaigns (Phase II) are planned for 2012 in Ghana and Cote d'Ivoire. In January 2012, Senegal, Ghana and Cameroon reported YF outbreaks and more than 1.4 million doses were distributed through the GAVI-funded YF emergency stockpile. Global vaccine supply shortages continue but the situation should improve toward the end of 2012.
- 5.2 The WHO has been working on a new strategic framework for the yellow fever prevention programme for 2012-2020 to be submitted to the GAVI Secretariat in June. The plan is expected to recommend an expansion of the YF programme to middle and low risk countries. Supported by the WHO, Ministries of Health in Kenya, Rwanda, Tanzania, Ethiopia, Sudan and South Sudan are currently conducting in-country risk assessments to identify specific districts and vulnerable target populations that could most benefit from preventive mass vaccination campaigns or EPI routine immunization introduction.

²² This can be increased to 180-200m ds with 6 months notice.

²³ See document number 12, Options for Enhancing GAVI's investment in Measles.

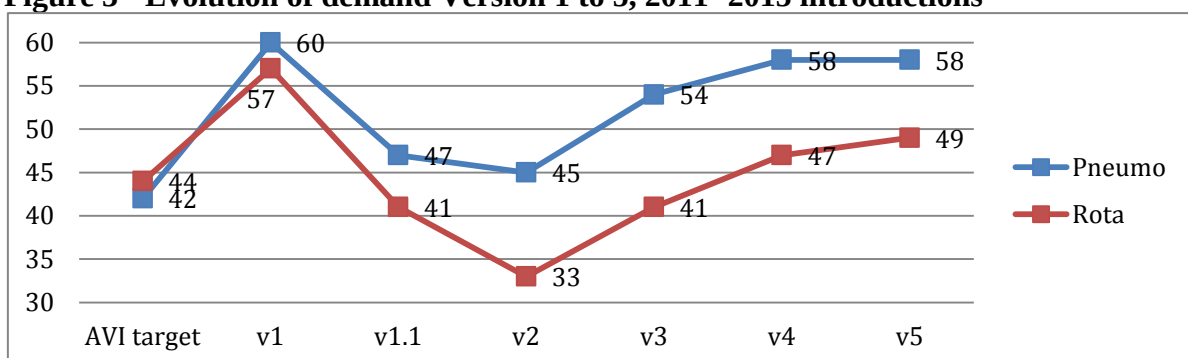
6. Meningitis A Conjugate Vaccine Update

- 6.1 To date, six countries have launched Meningitis A vaccine campaigns (MenAfriVac) supported by GAVI funding. Burkina Faso, Mali and Niger completed national programmes last year. Initial administrative coverage is high – 92-100%, although rates vary for hard to reach populations, including males 16-29 who are under-served by traditional vaccination programmes. Chad, Nigeria and Cameroon launched regional campaigns in 2011 and will continue with these programmes in other districts this year. Benin, Ghana, Senegal and Sudan will begin mass campaigns in late 2012 with MenAfriVac™ progressively reaching more than two dozen countries across the African meningitis belt 2012-2016.

7. Build a platform — demand forecasting

- 7.1 AVI TAC provides twice yearly strategic demand forecasts (SDF) covering all GAVI's current vaccine portfolio and Vaccine Investment Strategy (VIS) vaccines. The SDFs estimate volumes of doses required per year over a 20 year period and assumes no financial or supply constraints. This information is then used to inform estimates of potential health impact, GAVI financial projections, and to inform discussions on required supply.
- 7.2 SDF version 5.0 was endorsed by the AMT and the Secretariat in March and includes the outcome of 2011 Board decisions on applications as well as the IRC that convened in February 2012. See table below.
- 7.3 The accelerated uptake of pneumococcal and rotavirus vaccines is especially pronounced as compared to the speed of pentavalent vaccine uptake in GAVI countries. In the five years following the first GAVI supported introduction of pentavalent, only 11 countries had introduced the vaccine. The current forecast projects 58 and 49 countries to introduce pneumo and rota in the same period.

Figure 3 - Evolution of demand Version 1 to 5, 2011 -2015 introductions



8. Build a platform — Special Studies

- 8.1 Using evidence generated from the AVI Special Studies Team, AVI TAC continues to work closely with national and global immunisation decision makers to provide the epidemiologic and economic evidence base needed to make timely and informed decisions on vaccination programmes.
- 8.2 Since the last AVI update to the Board, the Special Studies Team has presented data and perspectives to the April SAGE meeting session that weighed the benefits and risks of removing the age restrictions for rotavirus vaccination.
- 8.3 AVI TAC is working with specific countries introducing new vaccines to conduct studies to document vaccine impact and provides technical expertise to countries to assist in research initiatives. Recent progress includes the completion on a rotavirus vaccine effectiveness study in Nicaragua showing protection consistent with other studies in Asia and Africa. Analysis has started in the South Africa study to assess the impact of the introduction of rotavirus and pneumococcal vaccines, with final results expected mid-2012.
- 8.4 After identifying a research agenda for the consortium's next phase of work at a Special Studies retreat in December 2011, the consortium submitted to the Secretariat proposals for studies identified as pressing research and policy questions on rotavirus and pneumococcal vaccine introduction.²⁴

9. Build a platform – country and global advocacy and communication

- 9.1 AVI TAC teams based in PATH Geneva and in Johns Hopkins University in Baltimore are progressing strategies in support of timely in-country decision-making for new vaccines. The teams are targeting their activities on two levels: across all GAVI eligible countries and, secondly, with an intensive focus on six countries (Bangladesh; Burkina Faso; Kyrgyzstan; Myanmar; Tanzania and Zambia)²⁵ to solicit country voices to advocate for sustained vaccination programmes. The teams are working closely on other ongoing GAVI initiatives including the 2012 Partners Forum and generating content, resources and opportunities for GAVI advocacy and communication priorities.
- 9.2 AVI TAC launched a specific sub-team focused on rotavirus vaccine advocacy and communications issues. The working group, comprising members from PATH, WHO, UNICEF and GAVI, is specifically tasked with preparing countries for introduction. The working group has launched a web-based “one-

²⁴ See document number 14, Continued funding for special studies.

²⁵ Criteria for selection included countries representing at least three WHO regions, identified from: countries that have not yet applied; approved countries with a demonstrated need for support in delivering on commitments made; graduating countries that need support in sustaining the use of vaccines; identified gaps in technical and advocacy and communications capacity around rotavirus and/or vaccine introduction, and/or major advocacy opportunities or synergies that could be leveraged during 2012–2013; countries demonstrating ‘Amplification Capacity’ – meaning the capacity or potential to influence neighboring countries; under-five deaths attributable to rotavirus and/or pneumococcal infection and resonance among GAVI Country Resource Officers (CRO) and other staff within the GAVI Secretariat.

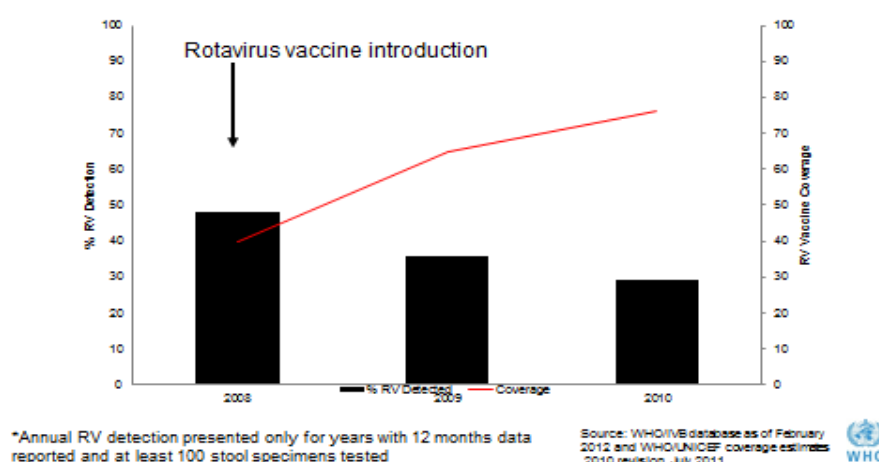
stop-shop” to deposit and access communication, training, and background information on rotavirus and rotavirus vaccines designed to support partners and countries with communication activities. Key communication issues of concern include intussusception/AEFI, age of administration, and training.

10. Build a platform – Surveillance

- 10.1 WHO estimates that more than 18 GAVI countries have based country vaccine introduction decisions on local surveillance data. A summary of the latest data from the WHO coordinated surveillance networks is circulated via bimonthly bulletins for Rotavirus (RV) and Invasive Bacterial Vaccine Preventable Diseases (IB-VPD) surveillance supported by GAVI. These bulletins present data for January through June of 2011, as reported by Member States including many GAVI-eligible countries.
- 10.2 Data from Bolivia (see figure 4 below) which is consistent with those from several other countries, shows a trend of lower rotavirus detection after the introduction of the vaccine. This ‘impact’ data is important as it provides local decision makers evidence of the results of implementing the vaccine in the national immunisation programme. It is to be noted that the vaccinated children were all <1 year old while surveillance data is for <5 years olds’, which means these data likely *underestimate* the impact of vaccination.

Figure 4

% Rotavirus (RV) Detection in Children <5 Years of Age Hospitalized with Diarrhoea and RV Vaccine Coverage, Sentinel Surveillance, Bolivia, 2008-2010*



- 10.3 As reported in earlier AVI updates, while the data from the RV network is relatively robust, further work is needed to improve the quality and consistency of data emerging from the IB-VPD surveillance network. Training of laboratory staff is ongoing and in November a global laboratory external quality assurance (EQA) programme was conducted in 61 hospital, national, and reference laboratories. Currently, WHO is distributing new laboratory manuals

and companion poster to aid in the laboratory identification of the vaccine preventable bacteria, as well as lab posters to assist in the appropriate collection of clinical specimens from meningitis cases.

11. Build a platform – Cold Chain & Logistics

- 11.1 As previously reported in AVI updates, cold chain at the national level has not been a major bottleneck to date to the introductions of new vaccines²⁶ mainly thanks to good planning and timely investments made in several countries, and coordinated by WHO and UNICEF. However in many countries there may be an over-reliance on 'coping mechanisms' such as increasing frequency of vaccine shipments. Without further investments in cold chain capacity beyond the regional, national and regulatory level, related human resources and the number of service delivery points, the quality of vaccine introductions will suffer, with potentially increased wastage, stock outs and lower coverage results.
- 11.2 GAVI partners, the WHO, PATH and UNICEF have recently completed a preliminary analysis of supply chain readiness on the basis of actual inventory data in 21 GAVI priority countries.²⁷ The initial results of this new review suggest that several of these countries (seven) face some constraints at the national level and almost half (nine) have constraints at the regional level. At the district level, the initial review confirms that almost all countries will have to overcome limitations, either with the need to invest in additional capacity at that level or to explore alternative approaches. The service delivery cold chain capacity (at the facility level) is adequate in the short-term, but in the mid and longer term additional service points will be needed to increase vaccine coverage. Overall, there is a need to re-equip and/or replace aging equipment and to transition from kerosene/gas to reliable energy sources, e.g. solar direct drive.
- 11.3 The vaccine suppliers have recently been able to develop new presentations with smaller cold chain foot prints such as 10-dose vials and smaller one dose vials for pentavalent vaccines. The introduction of these presentations in 2011 and 2012 has freed up capacity in existing cold chain systems, although some are expected to increase wastage rates, so there are some trade-offs.
- 11.4 However, the increasing number of multiple vaccine introductions needs to be reflected in a corresponding increase in investments in cold chain capacity, human resource capacity and number of service points. Unless these investments are made in advance, weak cold chain systems will impede successful vaccine delivery in the coming years. Thus, GAVI is exploring shoring up cold chain and logistics requirements through funds from the Health System Strengthening Programme.

²⁶ The WHO estimates that of the 72 GAVI-eligible countries, 63-67% have sufficient capacity to introduce either pneumo or rota vaccines, while 50% would have sufficient storage space to introduce *both* vaccines over the coming years.

²⁷ Quality data at the sub-national level is scarce. Until now, WHO and GAVI have estimated country readiness through a modelling approach which gives a rough indication of whether the country is likely to face constraints.

Appendix I. Pneumo Vaccine Introductions – 2009 - 2013

Year	Country	Product	Status	No.	Cumul No.
2009	Gambia	PCV7	Switched to PCV13 in June	2	1
	Rwanda	PCV7	Switch to PCV13 in August		2
2010	Nicaragua	PCV13	Introduced December	1	3
2011	Guyana	PCV13	Introduced January	13	4
	Yemen	PCV13	Introduced January		5
	Kenya	PCV10	Introduced January		6
	Sierra Leone	PCV13	Introduced January		7
	Mali	PCV13	Introduced March		8
	Congo, DR	PCV13	Introduced April		9
	Honduras	PCV13	Introduced April		10
	Central African Republic	PCV13	Introduced July		11
	Benin	PCV13	Introduced July		12
	Cameroon	PCV13	Introduced July		13
	Burundi	PCV13	Introduced September		14
	Ethiopia	PCV10	Introduced October		15
	Malawi	PCV13	Introduced November		16
2012	Ghana	PCV13	Introduced April 2012 (with Rota)	10	17
	Djibouti	PCV13	Planned June 2012		18
	Madagascar	PCV10	Planned July 2012		19
	Pakistan	PCV10	Planned July 2012		20
	Congo Rep	PCV13	Planned July 2012		21
	Zambia	PCV10	Planned July 2012		22
	Zimbabwe	PCV13	Planned July 2012		23
	Angola	PCV13	Planned October 2012		24
	Sao Tome	PCV13	Planned October 2012		25
	Tanzania	PCV10	Planned December 2012		26
	Mozambique	TBC	TBC likely in 2013	6	27
	Senegal	TBC	Postponed to 2013		28
	Sudan North	TBC	Postponed to 2013		29
	Bolivia	TBC	Postponed to 2013		30
	Niger	TBC	Postponed to 2013		31
	Kiribati	TBC	Postponed to 2013		32
2013	Armenia	TBC	Approved for introduction in 2013	5	33
	Azerbaijan				34
	Georgia				35
	Moldova				36
	Uganda				37
	Bangladesh	TBC	Recommended for approval for introduction in 2013	9	38
	Guinea Bissau				39
	Haiti				40
	Lao				41
	Lesotho				42
	Mauritania				43
	Nigeria (phase1)				44
	Papua New Guinea				45
	Togo				46

Appendix II. Rota Vaccine Introductions – 2008/09 - 2013

Year	Country	Product	Status	No. of Launches	Cumul No.
2008-9	Bolivia	2 ds schedule	Introduced	3	3
	Honduras	2 ds schedule	Introduced		
	Guyana	3 ds schedule	Introduced		
2010	Nicaragua	3 ds schedule	Introduced in 2006 based on a donation from Merck	1	4
2011	Sudan	2 ds schedule	Introduced July	1	5
2012	Ghana	2 ds schedule	Introduced April (with Pneumo)	8	13
	Yemen	2 ds schedule	Planned July		
	Rwanda	3 ds schedule	Introduced May		
	Moldova	2 ds schedule	Planned June		
	Armenia	2 ds schedule	Planned August		
	Ethiopia	2 ds schedule	TBD		
	Georgia	2 ds schedule	Planned Sept		
	Malawi	2 ds schedule	Planned Oct		
2013	Tanzania*	TBD	Expected to introduce in 2013 ²⁸	14	27
	Burundi				
	Congo Rep				
	Haiti				
	Angola				
	Cameroon				
	Niger				
	Djibouti				
	Madagascar				
	CAR				
	Togo				
	Sierra Leone				
	Zambia				
	Zimbabwe				

²⁸ Pending the availability of additional supply.

*Tanzania applied for a 2013 launch but has now requested a late 2012 introduction (simultaneous with pneumococcal vaccines)