FOR INFORMATION

At the request of GAVI Board members, the Secretariat was asked to provide an update on the Accelerated Vaccine Introduction (AVI) initiative

Accelerated Vaccine Introduction Progress Report

The objective of AVI is to drive the sustainable introduction of rotavirus vaccine and pneumococcal conjugate vaccine (PCV) in GAVI-eligible countries. Initial targets were set for 44 countries to launch rotavirus vaccines and 42 countries to launch PCV by 2015[1]. The longer term scope for AVI is to establish an organisational platform to support the introduction of future vaccines[2].

AVI Structure and Management

The management of AVI is conducted by the AVI Management Team (AMT) which consists of representatives of WHO, UNICEF Supply Division (UNICEF SD), UNICEF Program Division (UNICEF PD), and the AVI Technical Assistance Consortium (AVI TAC[3]) led by the GAVI Secretariat. The AMT operates through bi-weekly teleconferences; with more in depth analysis and work carried out by sub teams.[4] (see Annex 1 for more details)

Activities are consolidated between the aforementioned organisations through an integrated workplan and activities are grouped into five high level work streams[5] (see Annex 2):

- Generate informed country decisions
- Ensure sufficient supply
- Secure financing
- Facilitate country introductions
- Establish platform for sustained use

AVI's objective is primarily to deliver health impact through accelerating introduction and uptake of new vaccines. The ability of AVI to achieve this objective is affected by internal and external factors, whose impact is reflected in adjustments to the work plan and if necessary, to the objectives too.

The remainder of this report will provide short briefings on each of the high level work streams referenced above.

[1] In view of the funding situation, the targets may need to be assessed and if necessary changed by the Board
[2] As per the Vaccine Implementation Strategy (VIS) implementation plan endorsed by the Board on 29-30 October 2008, subject to separate approvals of funding. (Section 11 of the Minutes)
[3] A consortium of PATH, Johns Hopkins University (JHU), US Centers for Disease Control and Prevention (CDC) and others
[4] Supplemental information on this and other aspects of AVI operation is available from the Secretariat upon request.
[5] The AVI work streams are synonymous with the outcomes of the Strategic Goal 2 in the GAVI Work-plan

FOR INFORMATION

Generate Informed Country Decisions

Support country level decision-making

Activities to support country level decision-making include generating and disseminating information (e.g. disease burden data, vaccine characteristics, health economics, WHO pre-qualification, supply status, global policy guidance) relevant to local policy makers and technical staff. In addition, AVI provides technical support to countries to assist decision-making (see Annex 3).

The following summarises current introduction status:

- Rotavirus introductions
  - Launched: Bolivia, Nicaragua[6], Guyana, Honduras
  - Eight applications received in September 2009[7]

- Pneumococcal introductions
  - Launched: Gambia, Rwanda
  - Approved by Board 11 countries: Cameroon, Central African Republic, Congo Rep, D.R. Congo, Guyana, Honduras, Kenya, Mali, Nicaragua, Sierra Leone and Yemen.
  - 13 applications received in September 2009

AVI has established a transparent and rigorous methodology for establishing and updating strategic demand forecasts. The methodology has been applied to pneumococcal and rotavirus vaccines (see Annex 4), with country introduction by 2015, summarised in the following table:

Number of GAVI Countries Introducing by 2015	Target	Version 1.0[8]	Version 1.1[9]
Rotavirus	44	57	41
Pneumococcal	42	60	47

Several factors have contributed to the changes in the number of countries forecasted to introduce rotavirus and pneumococcal vaccines. The Board decision on eligibility will result in a reduction in the number of GAVI eligible countries. Further, the requirement for countries to have at least 70% coverage (DTP3) in order to apply for new vaccine support has also affected the forecast.

The current forecast assumes that there are no financial constraints on the introduction of rotavirus and pneumococcal vaccines. Future updates will need to

[6] Nicaragua introduced with a donation from Merck and plan to switch to GAVI supported vaccine in 2010
[7] Applications for countries in Africa and Asia were invited in July 2009 following WHO global recommendation for use of rotavirus vaccines
[8] AVI generated demand forecast prior to November 2009 GAVI Board meeting
[9] AVI generated demand forecast following November 2009 GAVI Board meeting

take into account the projected funding for new vaccine support. The current forecast also does not yet reflect potential changes in country interest in applying for new vaccine support following revisions in GAVI policy, including prioritization. The next revision v2.0 of the strategic demand forecasts will be completed by the SVS sub team following the June 2009 board meeting.

Large Country Activities

An important focus of the informed country decision work stream is the group of the seven 'large countries': India, Nigeria, Pakistan, Indonesia, Bangladesh, Ethiopia and DR Congo. These seven countries constitute 65% of the birth cohort of all 72 GAVI eligible countries. The large country introduction sub-team steers the work relating to large countries (additional details available on request).

The main challenge for the sub team remains India, which has applied and is approved for pentavalent vaccine introduction. Several issues have arisen that will likely delay introduction of pentavalent vaccine in India; including a private legal case being filed, the impact of delays in introducing Hib vaccine on the subsequent introduction of pneumococcal and rotavirus vaccine, being not yet fully understood. A teleconference of stakeholders was held on April 29, 2010 to discuss the status of activities in India, with a follow up planned for July 2010 (more details can be provided upon request).

Generate evidence for decision-making

AVI is conducting a series of studies generating information (safety, immunogenicity, efficacy and health economic data) to inform policy decisions.

The studies conducted by AVI TAC are on track per the last update (see Annex 5). To gain technical community consensus on what constitutes serotype replacement and the factors that drive shifts in observed invasive disease due to specific serotypes, the WHO, in collaboration with AVI TAC, is undertaking a systematic review of all available data and a series of consultations with experts in the field. The process begins with a technical expert meeting in July 2010 and is expected to culminate in a report to SAGE with recommendations for countries on how to evaluate and interpret serotype changes.

Ensure Sufficient Supply

Understanding the dynamics of demand for pneumococcal and rotavirus vaccines in GAVI-eligible countries within the context of available funding and production capacity is critical to AVI meeting its stated objective. Clear identification and measurement of demand drivers are also essential to guide GAVI financial planning; advocacy and communication efforts with partner countries, donors, and manufacturers; as well as to assist partner organizations responsible for ensuring adequate country preparedness.

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The method used to establish strategic demand forecast by the SVS sub-team provides useful tools to understand the dynamics of demand. As a result of the work of the Strategic Vaccine Supply sub-team, GAVI and its partners now have: the latest versions of projected demand for pneumococcal and rotavirus vaccines; a more in-depth understanding of key assumptions; the ability to run scenarios; a clear identification and listing of conditions that need to be met for demand to materialize.

In addition, there are several issues that may have an impact in the near future on demand from countries for new vaccines that have been identified, including:

- timing of the IRC round and synchronization with the revised eligibility policy to ensure eligible countries have a chance for application before implementation of the policy to maintain the current demand dynamics.[10]
- timing of PCV13 prequalification which will impact the ability to start the Pneumo roll-out as Synflorix availability is currently restricted to Kenya.
- timing of developing countries manufacturers entrance in the market to create an environment for potential price reductions.

PCV product availability

The main updates regarding PCV supply are as follows:

- Advanced Market Commitment (AMC) provisional supply agreements signed week commencing March 23rd 2010. Annual quantities committed to were 30 million doses for GSK and Pfizer from 2012 and 2013 respectively, for a 10 year period; supply prior to this amounts to 51.4M.
- AMC Independent Assessment Committee have deemed PCV10 meets the AMC Target Product Profile.
- PCV10 (GSK) in 2 dose vials without preservative is WHO prequalified as of March 2010. The pre-qualification is limited to Kenya until successful completion of a 12 month assessment of programmatic issues in two demographic surveillance sites.
- PCV 13 (Pfizer[11]) in 1 dose vial is on track for projected pre-qualification as of Q3 2010.

The first delivery of PCV10, under the terms of the AMC, is expected in Kenya Q3 2010. For more details on supply including pipeline see Annex 6.

Rotavirus Vaccine Product Availability

[10] The number of years financial support or 'ramp down' following actual year of graduation is being clarified in the co-financing paper to the June 2010 board meeting

[11] Pfizer have made PCV 7 available in vials as opposed to prefilled syringes; however this only has impact in Gambia and Rwanda where the vaccine was donated in pre-filled syringes.

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Two WHO prequalified rotavirus vaccines are available for procurement by GAVI. Currently, the PAHO Revolving Fund is procuring vaccine for GAVI-eligible countries in the America's region with financial support from GAVI. A price for rotavirus vaccines for GAVI-eligible countries outside of the America's region has not been established. Following the approval by the GAVI Alliance Board of at least one application for rotavirus vaccines UNICEF Supply Division will issue a tender to cover future supply needs. The formation of a Procurement Reference Group (PRG) for rotavirus vaccines is now underway (see Annex 7).

Allocation of Supply in Case of Shortage

In situations where demand exceeds supply, AVI has developed a procedure to determine the allocation of scarce vaccines between the approved countries to ensure equity and transparency in the allocation (a copy of the allocation process may be obtained from Head AVI upon request). The goal of this procedure is to generate a ranking of GAVI Board approved countries to inform the sequence in which countries will receive vaccine allocations in the circumstance of supply shortage.

A likely shortage is expected this year compared to the volumes demanded from approved countries for Pneumococcal Conjugate Vaccines (PCV). Since vaccines have specific characteristics, a vaccine-specific allocation framework was developed for PCV (full details are available on request). This will be applied to manage the 2010-2011 demand from the approved countries.

Secure Financing

The GAVI Alliance High Level Meeting on Financing Country Demand took place in The Netherlands on 25-26 March, co-convened with the First Meeting of the Global Fund Third Replenishment on 24-25 March. The high level meeting focussed attention on the potential impact of pneumococcal and rotavirus vaccines on the Millennium Development Goals, in particular MDG 4. It informed current and potential donors of the resource mobilisation challenges that need to be overcome urgently in order to satisfy rising country demand for the vaccines and to make a tangible impact on child mortality by 2015. The next steps for fund raising are being aligned with a meeting later in 2010 which is likely to be a full scale donor pledging conference in Q4. AVI partners were major contributors to the evidence base publication used in The Hague.

AVI provides support to GAVI's resource mobilization efforts in several ways. The strategic demand forecasts for the current vaccine portfolio (including rotavirus and pneumococcal vaccines) provide data on numbers of immunised children. This data is used to derive:

- cases averted and future lives saved using modelling
- GAVI's financial projections.

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In light of the resource mobilization needs, AVI TAC resources initially intended to generate country demand through local advocacy have been largely reprogrammed to provide support to the GAVI External Relations Office (ERO). AVI TAC has 'embedded' staff within the GAVI secretariat office supporting Media & Communications office, Advocacy and Donor Relations. AVI has established relationships with stakeholders, external experts, networks and coalitions, all of whom can be called upon to support GAVI objectives in increasing funding for new vaccines.

Facilitate Country Introduction

For the PCV and rotavirus vaccine introductions, the lessons learned through the introduction of pentavalent vaccines and from the WHO process of Post Introduction Evaluations (PIE) are continually being incorporated. Vaccine specific system strengthening is required in terms of disease and Adverse Events Following Immunization (AEFI) surveillance, Expanded Program on Immunization (EPI) training, vaccine and cold chain management. This is being addressed through a series of activities carried out by WHO and UNICEF PD. Activities are summarized in Annex 8.

It is widely recognized and communicated that the volumetric demand on cold chain capacity will increase especially due to the introduction of pneumococcal and rotavirus vaccines. Cold chain capacity therefore is and will remain a priority issue for AVI. An AVI sub team focuses on the cold chain and vaccine management matters. The team has done a detailed analysis of country cold chain capacity, with priority on in-depth analysis of the central cold storage and district level capacity for the first introducing countries.

At this stage, central store level capacity has been well mapped, district level mostly (~70%) mapped, whilst information on service delivery level capacity remains to be consolidated. Preliminary analysis shows that some 72% of countries have sufficient central store level cold chain to immediately launch one vaccine and [1]50% of countries sufficient for two vaccines by 2015[12]. Countries are undertaking the process of expansion of their national cold storage capacity with the support of different bilateral donors. This process does not always follow the expected time frame in all countries, alternatives to the central cold storage expansion such increasing frequency of distribution, using sub-national storage capacities are being suggested to overcome the challenges (see Annex 9 for more details on AVI and other cold chain & logistic activities).

Establish Platform for Sustained Use

AVI builds capacities to support the introduction of future vaccines beyond pneumococcal and rotavirus vaccines. For scientific and economic studies, AVI partners work with local investigators and institutions to strengthen local capacity.

[12] WHO/IVB, presented at NUVI Meeting, Montreux 16-18 June 2009

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AVI has developed innovative tools and approaches based on the state-of-the-art in forecasting. This tool is applicable to both current and future vaccines.

Throughout the AVI workplan activities, best practices are being identified that can be used for both current and future vaccine platforms. Examples of elements of the platform being built by AVI or future vaccine introductions include:

- A single, common modelling platform able to accommodate nine different vaccines with an increasing number of interrelations between assumptions.
- A launch-readiness scorecard[13] to assess country capacity to introduce new vaccines.
- Study protocols, methodologies, and trial sites for investment cases to be built for future vaccine introductions.
- Establishing links to coalitions that will provide support to efforts to accelerate access to new vaccines (e.g., World Pneumonia Day Coalition, Diarrhoea Disease Call to Action Coalition, country-level coalitions).
- Development of replicable advocacy and communication strategies employed to broaden constituencies of support at global, regional, and country level, calling for policies and resources to be allocated for new vaccine introduction.
- AVI project management processes and consortium operational structures that serve as a model for future vaccine introductions.

These elements of the platform, together with proactive extraction of lessons learnt from introducing Hib, pneumococcal and rotavirus vaccines, serve to strengthen GAVI's capacity to rapidly introduce new vaccines in the future, including vaccines approved as part of the Vaccine Investment Strategy (human papillomavirus (HPV), Japanese encephalitis, rubella, and typhoid vaccines) and make informed policy decisions on new vaccines going forward.

Annexes

1. AMT Sub Teams
2. AVI Integrated Work Plan – 2009-10 Objectives
3. WHO & UNICEF PD Activities to Generate Informed Country Decisions
4. Latest SDF forecasts with assumptions
5. Special Studies carried out by AVI TAC
6. Pneumococcal Vaccine Supply Status
7. Rotavirus Vaccine Supply Status
8. WHO & UNICEF PD Activities to Facilitate Country Introductions
9. Cold Chain & Logistics

[13] Also referred to as 'dashboard'

ANNEX 1

AMT Sub Teams

Sub Team	Lead	Role
Strategic Vaccines Supply (SVS)	S. Malvolti, PATH	Forecast demand and supply , identify gaps Run scenarios to identify opportunities and risks Provide input into critical activities to achieve forecast Link forecast with operational plan
Large Countries (LC)	G. Mayers, WHO	Large countries strategy and operational support Perform influencer mapping exercise Develop country specific strategies Advocate to build in-country support
Cold Chain and Logistics (CCL)	S. Kone, WHO	Provide in-depth, country-level analysis of CCL status for new vaccine introduction Identify cold chain expansion needs and logistic constraints within countries Document best practices in countries regarding management of CCL Mobilize technical and financial support required to overcome in-country constraints
Special Studies (SS) *Planned*	O. Levine, Johns Hopkins University	Provide external insight to fill knowledge gaps and avoid overlaps Assist with technical A&C Integrate findings into AVI project
Advocacy & Communication (A&C) *Planned*	J. Wecker, PATH (a.i)	Disseminate information to countries Build coalitions/alliances to generate local advocacy Support GAVI Secretariat in A&C efforts at global level

ANNEX 2

AVI Integrated Work Plan – 2009-10 Objectives

Work Stream	Objectives
Generate Informed Country Decisions	Generate health and economic impact data Generate efficacy, immunogenicity and safety data Present vaccine data to decision makers Support country level decision making Assess country readiness Set up global and regional decision support policies
Ensure Sufficient Supply	WHO prequalify PCV and rotavirus vaccines Build sufficient manufacturing capacity Make price and supply agreements with suppliers Develop strategic supply strategy Ensure vaccine presentations are appropriate for developing countries
Secure Financing	Assess financing needs Secure donor financing Secure country financing
Facilitate Country Introduction	Ensure availability of sufficient in-country cold chain capacity Prepare country immunization and health systems Enhance vaccine management capability Train health care professionals Support community level social mobilization
Establish Platform for Sustained Use	Enhance regionally appropriate surveillance systems Monitor safety of the vaccines post-introduction Evaluate impact of immunization Adjust implementation based on impact on disease Document and disseminate learnings Develop contingency communication plans

ANNEX 3

WHO & UNICEF PD Activities to Generate Informed Country Decisions

Topic	Country/Region	Activity	Status	Timing
Disease Burden	Inter-Country Program	IBD/rotavirus sentinel sites ongoing in Bangladesh, Bhutan, India, Indonesia, Myanmar, Nepal, Sri Lanka.	Ongoing	Year Round
	Mongolia and Viet Nam	Hepatitis B sero-survey	Ongoing	Oct 2009 - Nov 2009
Applications & cMYPs* ***comprehensive multi-year plans**	Afghanistan and Yemen	In Afghanistan Workshop on cMYP. In Yemen and Afghanistan Technical Assistance in developing their cMYP	**Completed**	March 2009
	Armenia, Azerbaijan, Georgia, Moldova, Kyrgyzstan, Tajikistan and Uzbekistan	Technical support provided to development cMYPs. Consultancies conducted to assist countries in costing and financing of cMYPs	On-going	April 2010
	Inter-Country Program	Workshop on Updating Comprehensive Multi-year Plan on Immunization and Reporting on Implementation of GAVI Support Program in Eligible Countries was conducted	**Completed**	March 2010
	India	Finalizing cMYP for Universal Immunziation Program in India (2010-2017). Draft currently awaits MOH approval	Ongoing	June 2010
	Bangladesh	Finalized preparation of cMYP.	Awaiting Gov. clearance	March 2010
	Solomon Islands, Papua New Guinea, Viet Nam	Technical support in analysing and reviewing GAVI APRs	**Completed**	April-May 2010
Reporting (Annual Progress Reports APRs)	AFRO/ESA:	Pre review of the 2009 APRs before submission to GAVI.	**Completed**	April-May 2010
	AFRO/C: Angola, Burundi, Congo, DRC, CAR, Cameroon, STP and Chad	Peer review workshop organized by IST Central in Douala, from 6 to 9 April 2010	**Completed**	April 2010
	All EMRO GAVI Countries	Pre review of the APR 2009 before submission to GAVI	**Completed**	April 2010
	EURO: Inter-Country Program	Workshop on Updating Comprehensive Multi-year Plan on Immunization and Reporting on Implementation of GAVI Support Programs in Eligible Countries conducted.	**Completed**	March 2010
	SEARO: All GAVI countries	Support provided for the drafting of GAVI APRs	On-going	April-May 2010

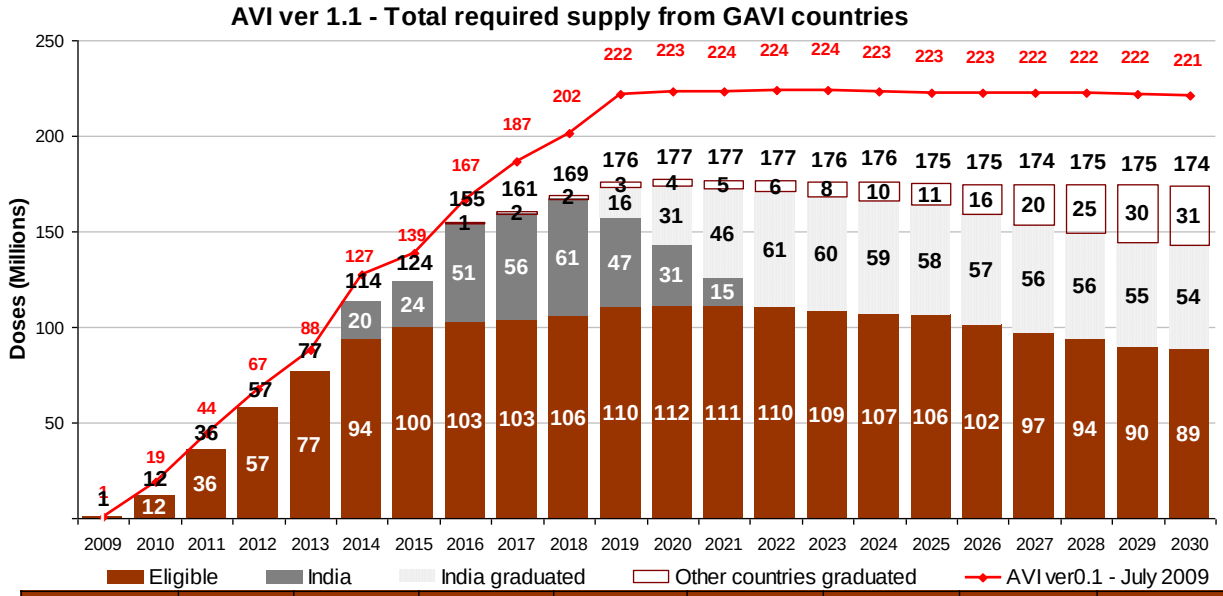
ANNEX 3

Topic	Country/Region	Activity	Status	Timing
NITAGs (Advisory groups) NITAGs contd.	Tunisia and Lebanon	Joined the Global Initiative (Sivac) formed to strengthen the NITAGs	**Completed**	Jan-Feb 2010
	Inter-Country Program	Participation of WHO EURO specialist in SIVAC workshop "Providing information, tools and training to support the evidence-based decision making process in National Immunization Technical Advisory Committees" that was held in Agence de Médecine Préventive (AMP)	**Completed**	Jan 2010
	Inter-Country Program	Regional input provided to the development of outcome indicators for NITAGS through participation in WHO HQ videoconferences.	On-going	Jan-April 2010
	Tunisia and Lebanon	Joined the Global Initiative (Sivac) formed to strengthen the NITAGs	**Completed**	Jan-Feb 2010
	AMRO: Almost all countries	Almost all countries have been holding meetings at least twice a year. Joined the Global Initiative (SIVAC) formed to strengthen NITAGs.	Completed	Jan-Feb 2010
Surveillance	EURO: Armenia, Azerbaijan, Georgia, Moldova, Kyrgyzstan, Tajikistan, Ukraine and Uzbekistan	Contracts with National Coordinators for implementation of rotavirus and bacterial meningitis surveillance in 2010 developed. Procurement of essential laboratory equipment and reagents continues. Monthly reporting of surveillance data from countries to the Regional Office continues. General coordination of surveillance networks is being provided.	Completed	February-April 2009
	AMRO:	Technical support to improve data quality for rotavirus and IBD surveillance in following countries – Bolivia, Ecuador, El Salvador, Honduras, Panama,	Ongoing	2010
	SEARO: Nepal	International surveillance review on EPI, VPD, AFP	Ongoing	June 2010
	EURO: Inter-Country Programme	Contracts for implementation of Regional Reference Laboratories on Rotavirus and Invasive Bacterial Diseases have been developed. Transportation of specimens from national rotavirus laboratories to the reference laboratory has been arranged.	Completed	February-April 2009
	WPRO: Cambodia, Laos, Mongolia, PNG	Technical support to conduct rotavirus surveillance activities	Ongoing	Year Round
Global Policy	Global	Revised position paper on WHO global rotavirus vaccine recommendation issued in December 2009 and distributed globally.	Completed	Feb 2010

ANNEX 4

Latest SDF forecasts with assumptions

Pneumo vaccine



	2009	2010	2011	2012	2013	2014	2015	2009-2015
Introductions	2	15	11	10	4	4	1	47

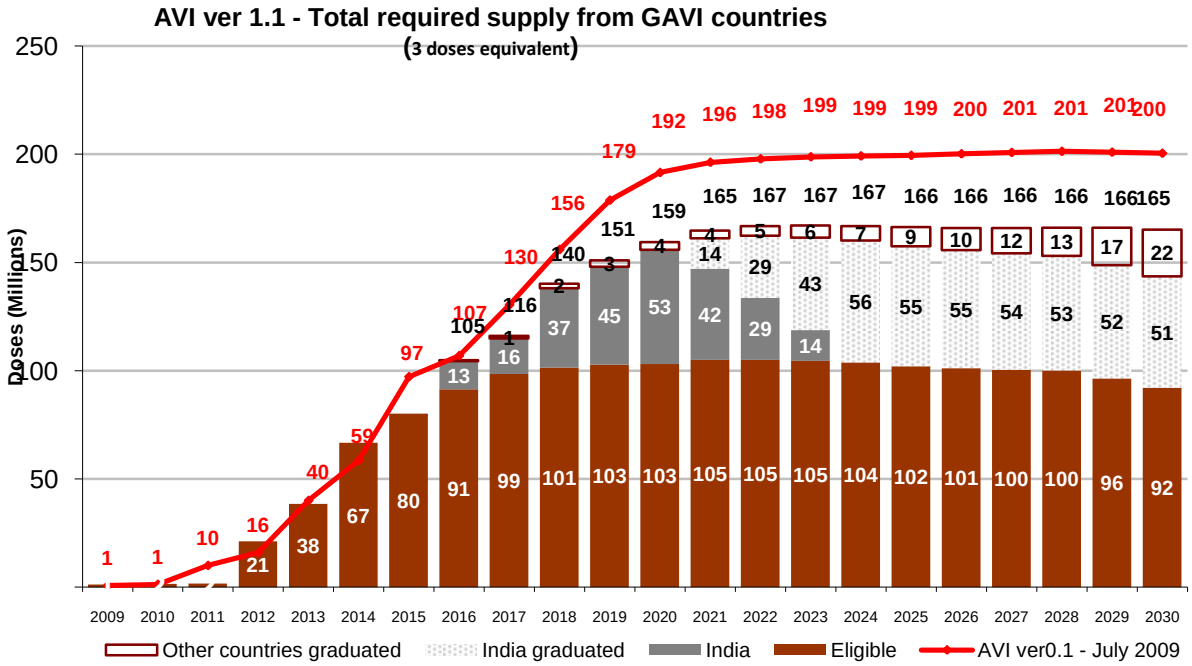
PCV Strategic Demand Forecast version 1.1 Assumptions

Topic	Assumptions
Finance & support	GAVI support based on revised eligibility approved by November 2009 board (prev. slide) One round of applications in September 2010, 2 rounds p.a. from 2011 NVS support at country level (no separate state support) Once approved, GAVI commitment to countries ensures 5 years protection from graduation Graduation over 3 years with linear decline of co-financing share Financing available for product purchase & introduction costs (AMC / GAVI / local gov't) confirmed after prioritization work Sustainable co-financing prices (also after 2010 policy revision) PAHO single price clause not impacting negatively intention to introduce from manufacturers
Demography	Surviving Infants based on 2008 UN population prospect, medium variant for population, birth & infant mortality rates (Cameroon & Congo based on more updated country census)
Products	All products WHO pre-qualified, meet or exceed AMC profile and have suitable presentation Mix of international and developing countries suppliers ensures no capacity constraint; first dev' countries products to become available in 2015 India preference for introduction with I – some countries as India may have different schedule local manufacturer can be derogated in the first years Schedule = 6, 10 and 14 weeks of age with DTP or Pentavalent / No Booster – some countries as India may have different schedule Presentation = 1-dose and 2-dose liquid vials
Introduction	Introduction timing as per WHO NUVI calls; at least 12 months after application; separated by 24 months from other introductions unless documented input Impact of GAVI Board decision only partially reflected (too early for all countries to have changed their introduction strategies) – several countries losing eligibility may anticipate application to 2010 Approval pause limited to 6 months and resolved by June GAVI Board with countries "paused" / waiting for clarification continuing their pre-introduction activities 15 Countries introducing during 2010 depending on Synflorix PQ date

ANNEX 4

	India phased introduction financed locally beyond GAVI cap – 11 states (10 states introducing Penta + Orissa pilot) to introduce in 2014, remaining states after 2 yrs Nigeria cannot apply for NVS because of low coverage, then loses eligibility Pakistan introduce in Sept. 2011
Coverage	Reference coverage: DTP2 linear extrapolation based on DTP3/1 WHO/UNICEF estimates Projected coverage: based on standard AVI coverage projections rules
Uptake	Time to match reference coverage aligned with HepB/Penta analogue (Pneumo introduced with same schedule as Penta): 24 months for small countries / 36 for medium/large countries (>1 mln SI) / 48 months for very large countries (>3.5 mln SI)
Logistic	Wastage = 10% based on WHO policy (higher than policy to discount 2 doses presentation) Buffer stocks = 25% of 1 year full supply (@ target coverage), phased if necessary Cold chain up scaling and ongoing financing available at central & local level in all countries

Rota vaccine



	<2011	2011	2012	2013	2014	2015	2009-2015
Introductions	4	1	12	7	10	7	41

ANNEX 4

Rotavirus Vaccine Strategic Demand Forecast version 1.1 Assumptions

Topic	Assumptions
Finance & support	GAVI support based on revised eligibility approved by November 2009 board (prev. slide) One round of applications in September 2010, 2 rounds p.a. from 2011 NVS support at country level (no separate state support) Once approved, GAVI commitment to countries ensures 5 years protection from graduation Graduation over 3 years with linear decline of co-financing share Financing available for product purchase & introduction costs (donors / GAVI / local gov't) confirmed after prioritization work Sustainable co-financing prices (also after 2010 policy revision) PAHO single price clause not impacting negatively intention to introduce from manufacturers
Demography	Surviving Infants based on 2008 UN population prospect, medium variant for population, birth & infant mortality rates (Cameroon & Congo based on more updated country census)
Products	All products WHO pre-qualified & have acceptable presentation for countries Mix of international and developing countries suppliers ensures no capacity constraint: Rotarix and RotaTeq currently available, first dev' countries products to be available by 2014 Schedule = 3 doses (6,10, 14 weeks of age) for RotaTeq, 2 doses for Rotarix (6, 10 weeks of age) – some countries as India may have different schedule Presentation = single dose
Introduction	Introduction timing as per WHO NUVI calls; applications submitted often together with Pneumo up to 3 years in advance vs. expected introduction date Impact of GAVI Board decision only partially reflected (too early for all countries to have changed their introduction strategies) Approval pause limited to 6 months and resolved by June GAVI Board with countries "paused" / waiting for clarification continuing their pre-introduction activities India phased introduction financed locally beyond GAVI cap – 10 states (10 states introducing Penta) to introduce in 2016, remaining states after 2 yrs Nigeria cannot apply for NVS because of low coverage, then loses eligibility
Coverage	Reference coverage: DTP2 linear extrapolation based on DTP3/1 WHO/UNICEF estimates Projected coverage: based on standard AVI coverage projections rules
Update	Time to target coverage based on HepB/Penta analogue (Rota introduced with a different schedule from Penta so uptake is slower): 30 months for small countries / 42 for medium/large size (>1 mln SI) / 54 months for very large countries (>3.5 mln SI)
Logistic	Wastage = 5% (base on 1 dose presentation) Buffer stocks = 25% of 1 year full supply (@ target coverage), phased if necessary Cold chain up scaling and ongoing financing available at central & local level in all countries

ANNEX 5

Special Studies carried out by AVI TAC

No.	Study	Location	Vaccine	Recent Deliverables	End Date*
Optimization of dosing/delivery studies					
I.1	Landscape analysis of PCV dosing schedules	Desk based; multiple sites	All pneumococcal vaccines	Protocol developed 6/2009	4/2010
I.2	Impact of breastfeeding and age of administration on immunogenicity of rotavirus vaccine	Pakistan	Rotarix	Protocol submitted 11/2009	12/2010
I.3	Mathematical modelling of rotavirus and PNC transmission patterns (also considers herd immunity and safety)	Desk based		Meeting with modellers 9/2009	9 / 2010
I.4	Global review of rotavirus strain prevalence	Desk based; multiple sites	Live oral rotavirus vaccines	Final report and draft publication 1/2010	
Herd Immunity Studies					
II.1	Assessment of population and indirect effects of rotavirus vaccine introduction	Bangladesh	Rotarix	Covered under Rota ADIP	TBC
Effectiveness Studies					
III.1a	Assess impact of national introduction of rotavirus & PNC vaccines: case-control studies on rotavirus vaccine effectiveness	Bolivia	Rotarix	Protocol submitted 6/2009	6/2011
III.1b		Nicaragua	Rotateq	First infant enrolled 9/2009	12/2010
III.1c		South Africa	Rotarix	Protocol approved 12/2009	2/2012
III.1d	Assess impact of national introduction of rotavirus & PNC vaccines: case-control studies on PCV effectiveness		PCV	Protocol submitted 9/2009	4/2012
III.1e				Protocol submitted 9/2009	4/2012
III.1f	Interrupted time-series analysis of combined PCV/ rotavirus vaccine effectiveness		PCV / rota vaccines	Not due yet	6/2012
III.2	Development of PNC vaccine impact assessment manual and case-control study protocol	Desk based; multiple sites	Pneumococcal vaccines	Delayed	12/2010
Demonstration Projects to Measure Costs and Benefits					
IV.1	Assessment of the economic impact of national introduction of rotavirus and PNC vaccines through collection and evaluation of associated health care and societal costs	South Africa, Honduras, Bolivia & Peru	PCV7 and rotavirus vaccines	Not due yet	12/2010
Cost-Benefit Analysis and Acceptability					
V.1	Creation, maintenance and training on web-based tools for cost-effectiveness analyses	Desk-based: multiple sites	Not vaccine specific	Delayed	12/2010
Safety					
VI.1	Post-marketing safety monitoring of the oral rotavirus vaccines	Bolivia, Honduras	Rotateq	Delayed	12/2010
* Indicative; no cost extensions may be required					

ANNEX 6

Pneumococcal Vaccine Supply Status

Wyeth (Pfizer) launched PCV7 (Prevenar) in 2001 and it is commercialised worldwide, however it was not made available for sale to UNICEF. On September 25th, Wyeth obtained a positive opinion from EMEA for their new vaccine Prevenar PCV13, with US licensure expected in 2010 and WHO pre-qualification (PQ) by Q4 2010. GSK launched PCV10 (Synflorix) in Europe in 2009 and their 2 dose was WHO pre-qualified March 2010.

PCV Pipeline Overview[14]

Vaccine & Manufacturer	**GAVI[15] Presentation & Form**	**Licensure Status** In country of origin WHO pre-qualification status	**SAGE Recommend-ation AMC**	**Expected to meet AMC Target Product Profile**	**Next Steps**
Prevenar, PCV7 Pfizer/Wyeth	1 dose pre-filled syringe (pfs) 1 dose vial	US 2001 WHO 'recommended for use' only Awaiting PQ	YES[16]	NO	None
Synflorix, PCV10 GSK	2 dose vial without preservative 1 ds	EU Jan 2009 WHO PQ approved March 2010 WHO PQ'd Oct 2009		YES	Available for supply
Prevenar 13 PCV13 Pfizer/Wyeth	1 dose vial (presentation details not known)	US approval expected mid-2010 WHO PQ expected Q3 2010		YES	IAC approval for procurement
Shanta, Panacea, Serum Institute India, Biomanguinhos , Intercell, Merck	Not specified	Development timelines information indicates earliest licensure 2015+		To be determined	WHO prequalification

All manufacturers can register for the Pilot Pneumo AMC, the mechanism which aims to link financing and procurement to promote long term availability of pneumococcal conjugate vaccines in appropriate quantity and price for GAVI eligible countries.

[14] Publicly available information from industry, WHO, AVI assessments
[15] Presentation & form likely to be supplied to GAVI
[16] The recommendation on pneumococcal conjugate vaccines are based on data from PCV-7/9 available and applies to other products provisional to establishing non-inferiority to PCV7/9 and subject to some variations in scheduling and indications for specific products

ANNEX 7

Rotavirus Vaccine Supply Status

Two rotavirus vaccines are already approved and marketed, GSK's Rotarix and Merck's Rotateq. Both companies should be able to supply the product and AVI is working to ensure countries can make informed decisions to introduce following the recent SAGE recommendation to expand the use of rotavirus vaccine in national immunization programs of all countries (5 June 2009). Current applications for RCV make it likely that introduction will be earliest 2010 and likely 2011 subject to funding and prioritization.

Rotavirus Vaccine Pipeline Overview

Vaccine & Manufacturer	**GAVI[17] Presentation & Form**	**Licensure Status** In country of origin WHO pre-qualification status	**SAGE Recom-mendation**	**Next steps**
Rotarix GSK	1 ds 1.5ml oral vaccine 'tube (2 ds schedule)	EU Q2 2006 WHO PQ March 12th 2009	YES Global recommend-ation 5 June 2009	Likely to be a call for offers of supply for a time horizon of 1-3 years (depending on demand levels across this period)
Rotateq Merck	1 ds dose 2ml oral vaccine 'tube' (3 ds schedule)	US Q1 2006 WHO PQ EMRO, EURO Dec 2008, pending for rest of World		
DCVMN[18] Including Shanta, Serum Institute India, Bharat, Biopharma, Biomanguinhos	Not specified	Development timelines information indicates earliest projected licensure 2012-3		developing country suppliers critical for price reduction (lower margin model)

As for PCV, developing country manufacturers are expected to offer rotavirus vaccines in the medium to long term, currently expected earliest in 2012-13[19].

[17] Presentation and form likely to be supplied to GAVI
[18] Developing Country Vaccine Manufacturer's Network
[19] AVI TAC

ANNEX 8

WHO & UNICEF PD Activities to Facilitate Country Introductions

Topic	Country/Region	Activity	Status	Timing
Cold Chain	Global	Global data base on cold chain updated	On-going	2010-15
	EMRO: Afghanistan	Technical support in the area of logistic forecasting tool to update cMYP	**Completed**	March 2010
	AMRO: Argentina, Ecuador, Guatemala	Assessment of existing storage capacity for introduction of new vaccines and training of national staff in cold chain operations	Ongoing	Feb-Jun 2010
	WPRO: Viet Nam, Solomon Islands, Papua New Guinea	Assessment of cold chain requirement for new vaccine introduction as part of c-MYP exercise in	**Completed**	March-April 2010
	SEARO: Nepal	Developed proposal and TORs to complete cold chain replacement plan	Awaiting Governmen t clearance	To be initiated June 2010
	EURO: Tajikistan	Vaccine management assessment (EVSM)	**Completed**	April 2010
	Global	Pilot and final testing of EVM cold chain training module in Tunisia. Train the trainers in Egypt.	On-going	Q2 2010
Waste Management	AFRO: Rwanda	Consolidation of a planned national assessment of HCWM activities with a focus on immunization activities.	Ongoing	May 2010
	EURO: Kyrgyzstan	HCWM monitoring pilot project implementation	**Completed**	March 2010
Vaccine Management	AFRO: Rwanda	Consolidation of a planned national assessment of HCWM activities with a focus on immunization activities.	Ongoing	May 2010
	AMRO: Bolivia, Nicaragua, Paraguay	Vaccine stock management introduction software pilot testing	**Completed**	Jan-Mar 2010
	EURO: Kyrgyzstan	HCWM monitoring pilot project implementation	**Completed**	March 2010

ANNEX 8

Topic	Country/Region	Activity	Status	Timing
Post-Introduction Evaluations	AFRO: Rwanda	PIE of introduction of PCV7	**Completed**	April 2010
	AFRO: Tanzania	Full EPI Review, including PIE of pentavalent introduction and readiness for HPV donation	Planned	May 2010
	EURO: Uzbekistan	Evaluation conducted in collaboration with UNICEF Immunization Programme Management Review	Ongoing	April 2010
	SEARO: india	1. Hep B vaccine uptake assessment study conducted in 5 states in December 2009. 2. Analysis complete and final report of the assessment to be available in early May	Ongoing	April 2010
Training	EURO: Inter-Country Programme	MLM training materials were revised in line with recommendations provided by the Experts' Meeting from October 2009.	**Completed**	March 2010
	SEARO: India	1. RI training of Medical Officers in 10 States where single antigen Hepatitis B vaccine has been introduced - approx 3,000 trained during the period. 2. 5,500 flip charts disseminated for orientation of Health Workers on Hep B.	On going	June 2010
Vaccine Supply, Demand and Allocation	Global	Participated in GAVI/AVI supply allocation for Pn, review Target Product Profile, GAVI Prioritization Task Team, chair in the GAVI PRG Hib, HepB and YF-containing vaccines.	Ongoing	Ongoing

ANNEX 9

Cold Chain & Logistics

The WHO vaccine volume calculator was revised to include monograms (abacus) for estimating the adequate cold storage and transport capacities for in-country vaccine distribution and storage. Districts with more than 10,000 annual births may require a minimum of 3-6 refrigerators for a two-month stock level depending availability of electricity. In-depth analysis is required by country, based on the size of the districts to develop concrete action plans for what can be done to reach the required capacity levels.

In the mid-to-long term there significant amounts of work are still to be done. Larger and lighter vaccine carriers are being prequalified for transporting and storing vaccines at service delivery. Bigger refrigerators are required to fill the gap between the current small size refrigerators and the cold rooms used at national and sub-national stores.

Activities to address this are being carried out by AVI through the CCL sub-team as well as by the WHO Optimize project (funded by BMGF); both are involved in new activities such as piloting new cold chain evaluation methodology and vaccine management tools as well as pilots for use of mobile phone technology for vaccine store management.

Table 1: The current national immunization schedule, plus new vaccines under consideration

Currently Available Vaccines						
Vaccine	**Total doses**	**Age and interval**	**Number of doses**	**Packed volume per dose cc**	**Waste Multiplication Factor**	**Packed volume per fully immunized child cc**
BCG	1	Birth	1	1.2	2	2.4
OPV	3	6, 10, 14 weeks	3	2	1.33	8.0
DTP or DTP-HepB-Hib	3	6, 10, 14 weeks	3	12.9	1.05	40.6
Measles	1	9 months	1	2.5	1.67	4.2
Tetanus (pregnant women)	2	During pregnancy	2	3.0	1.33	8.0
New Vaccines to be considered						
Pneumococcal	3	6, 10, 14 weeks	3	12.9	1.05	40.6
Rotavirus	2	6,10 weeks	2	17.1	1.05	35.9
			TOTAL			**139.7 cc**