THE ADVANCE MARKET COMMITMENT FOR PNEUMOCOCCAL VACCINES

PROCESS AND DESIGN EVALUATION

APPENDIX

FEBRUARY 15, 2013

DALBERG GLOBAL DEVELOPMENT ADVISORS

The Advance Market Commitment for Pneumococcal Vaccines
Process and Design Evaluation

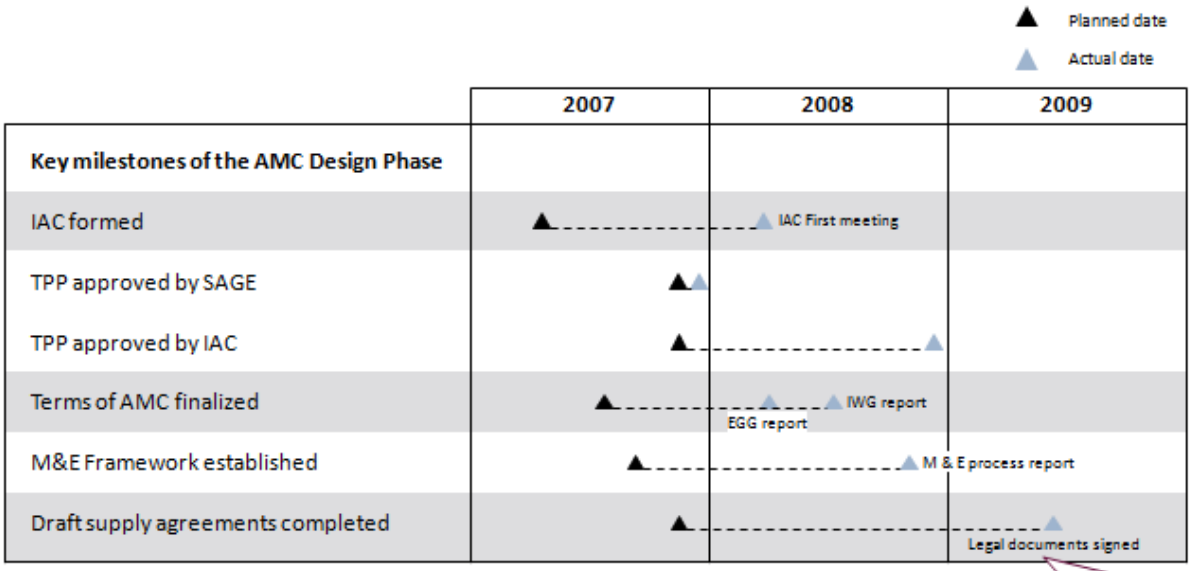
Appendix
February 15, 2013

Contents

Appendix

Appendix I. Timelines and inputs to design process analysis

Figure 1: Major sources of delay in the design process



Sources: AMC Website [accessed 10/01/12]; Interviews, presentation for donor meeting in Rome 8th March 2007

Figure 2: Timeline of consultations conducted during the Pneumococcal AMC design phase

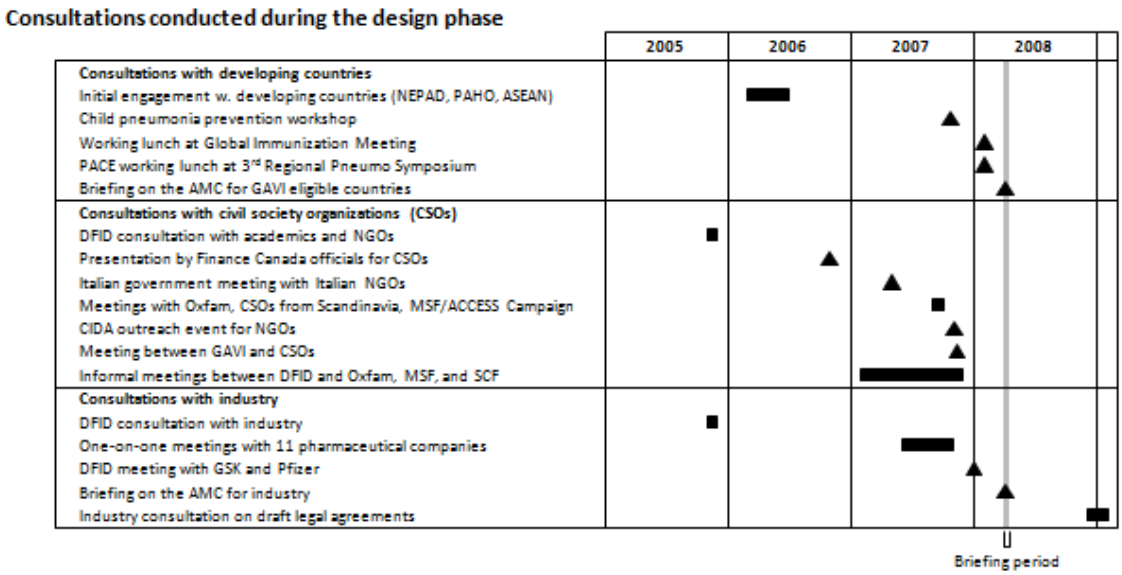


Figure 3: Breakdown of committee or working group members by their area of expertise

Number of people in each expertise area ☐ 0 ☐ 1-3 ☐ ≥ 4

Committee or Working Group	Expertise Area						
	Global Health	Vaccines	Epidemiology	Economics	Industry	Developing countries[1]	Implementation (incl. procurement)
Disease Committee	1	1	0	1	2	8	0
TPP Committee	2	5	2	1	1	3	0
Economic Expert Group	1	0	0	6	1	4	0
Implementation Working Group	2	0	0	4	1	1	3

[1] Developing countries is a stakeholder category defined in the Consultation & Advisory Process Document published by the AMC

Source: Consultation & Advisory Process Document; EEG Final Report; Interviews; Dalberg analysis

Dalberg

Figure 4: The role of partner organizations during the design process

	PROCESS	OUTCOME
Development of TPP	• Conducted by WHO Department of Immunization, Vaccines and Biologicals (based on WHO's core mandate of setting norms for areas of public health) • Used established WHO processes (including appointment of experts through SAGE and SAGE validation of the TPP)	• Process completed on time (~6 months as specified in the TOR)
Procurement strategy	• Preliminary analysis conducted by external consulting firm • Final design proposed by IWG, consulted and negotiated with UNICEF, and approved by AMC Donors	• Despite UNICEF's initial reluctance, the AMC procurement strategy differed from UNICEF's standard practices in : o Requirements to make an offer o Requirement to supply o Early consideration for award o Potentially annual tenders o Request for supply to begin max. 5 years into future o Duration of supply agreements 10-15 years o Firm contracting element in all SAs o Tail price ceilings predetermined
Fund structure & procedure to underwrite donor pledges	• Bilateral agreements with donors negotiated by the World Bank	• Fund structure and payment arrangements accommodated diverse authorization schemes and donor payment preferences
Country eligibility and graduation policy	• After the GAVI Board approved the new country eligibility and graduation policies, a recommendation to mitigate the impact on the AMC was coordinated between the AMC stakeholders and the Programme and Policy Committee, and presented to GAVI Board for approval	The GAVI Board approved: • Grandfathering the AMC deal, increasing PCV peak demand to 208 million doses (from 166 million doses) • Offering a final application round for graduating countries • Temporary suspending raising DTP coverage filter to 70%

Sources: TOR for TPP development, Timeline in AMC website, Summary of Rome AMC Donors Meeting March 8th 2007, Interviews, Presentation to update industry on AMC before next call for offers prepared by UNICEF Supply Division on June 27th 2012 ; Paper on Next Steps on the Pneumococcal AMC on 2 June 2010; interviews

Dalberg

Appendix II. Implementation Analysis

This analysis contains two parts:

- Part A presents an evaluation of the Pneumococcal AMC's implementation progress using a newly created series of indicators along four dimensions: effectiveness, transparency, timeliness, and responsiveness to changes in context and external factors.
- Part B gives an assessment of the existing annual Monitoring & Evaluation (M&E) framework, along with suggested new indicators that may improve the insights provided by the AMC's M&E activities over the next nine years[i] of the AMC.

In August 2007, the Monitoring & Evaluation group of the AMC Donor Committee commissioned the "Report of the Monitoring and Evaluability Study" for the Pneumococcal AMC, which was published in November 2008. The study was carried out by a consulting team from Goss Gilroy Inc. and funded by the Canadian International Development Agency (CIDA) and Department for International Development (DFID), with input from GAVI.[ii] Activities included in the reports' framework included conducting the AMC Baseline Study (conducted in 2009 by the Swiss Centre for International Health), annual monitoring of the AMC and complementary activities, the current process (and design elements) evaluation, and outcome evaluations to be conducted every four years, the first of which was originally scheduled for 2013. Given the early timing and broad scope of the Goss Gilroy report, it did not dictate specific details regarding which metrics should be measured or methods employed in the annual M&E process. The metrics from the Monitoring & Evaluation group are described below in Part B, and are different from the benchmarks measured in the AMC Baseline Study.

Part A. Alternative Framework for Monitoring and Evaluating Implementation

This section proposes tracking metrics categorized under the aforementioned four headings, which more directly address how much progress the implementation of the AMC has made in achieving the AMC objectives. In some cases, however, these new indicators are subject to data availability and may be difficult to obtain.

There are multiple ways through which to measure progress; the criteria proposed are simply one method of monitoring and evaluating the AMC's implementation progress.

Criteria	Question	Indicator	Status	Evidence/Results/Values
Effectiveness	1. Is gap between demand and supply being closed?	Doses shipped in 2012 / forecasted demand		SDF v5.0 – Estimated demand for 2012 = 34 million doses; (SDF v3.0 was 40 million doses) Shipments until end of August 2012 = 29.34 million doses; estimated shipments until end of 2012 = 49.1 million doses

[i] End of the AMC defined to be end of year 2021, when the last, existing 10-year contract expires.

[ii] DFID and CIDA, "Report of the Monitoring and Evaluability Study," Advance Market Commitment for Pneumococcal Vaccines, November 13, 2008, Foreword.

Criteria	Question	Indicator	Status	Evidence/Results/Values
				Demand Predicted for 2012 / Doses Shipped in 2012 SDF v5.0: 34 m / Aug. 2012: 29.3 m; SDF v3.0: 40 m / Dec. 2012: 49.1 m Source: http://www.unicef.org/supply/index_gavi.html
	2. Are multiple firms participating so that the market is healthy and robust?	Number of firms participating in the AMC		GSK and Pfizer
	3. Are prices being reduced below the cap ($3.50)?	Tail price included in bids		All bids with tail price = $3.50. Not expected to decrease until a 3rd manufacturer enters the market
Transparency	1. Has the GAVI Alliance published the GAVI Strategic Demand Forecast on the AMC Website annually and as soon as the necessary information is available from the last procurement cycle and relevant GAVI Alliance Board meeting?	Maximum time between SDF publishing		SDF v0.1 published on 7 August 2009 SDF v2.0 presented to the GAVI Board in December 2010, but not published to reflect changes in eligibility and graduation policies SDF v.3.0 published on 11 March 2011 SDF v 4.0 approved in July 2011, but not published (procurement cycle in process) SDF v5.0 published on 13 August 2012 Source: 2012 AMC annual report
	2. Have all IAC actions, decision and deliberations (including minutes of AMC Eligibility Determination Meetings) been disclosed on the AMC Website by the AMC Secretariat?	Fraction of all IAC meetings of which meetings minutes are published on the AMC Website		Meeting minutes published: 3 November 2008, 11 December 2008, 16 April 2010, 23 August 2010
	3. Has each AMC Annual Report followed the guidelines from the legal agreements, including: • Key events in the implementation of the AMC, with particular reference to timelines, plans and projections, • Data relating to new trials for the relevant vaccine and new investment in production capacity for the relevant vaccines targeted at GAVI Eligible Countries, • Updates on mortality data, burden of disease, and related projections, • Updates on the implementation activities to support the introduction and use of the relevant vaccines including in respect of the GAVI Co-Financing Policies	Fraction of annual reports that include timeline for procurement cyde (SDF publication, call for offers, entry into supply agreements) & calendar of vaccine introductions		Timeline for call for offers and SA included Actual & planned SDF publication date included No calendar for introductions in 2009-2010 report (too early); calendar included in the others
		Fraction of annual reports that include data relating to new trials for the relevant vaccine and new investment in production capacity for the relevant vaccines targeted at GAVI Eligible Countries		PCV vaccine pipeline discussed in annual report 2010-11 No information about manufacturer investment in production capacity is included in any annual report
		Fraction of annual reports that include updates on mortality		Not included in any Pneumococcal AMC annual report; pneumonia mortality data is included in GAVI

Criteria	Question	Indicator	Status	Evidence/Results/Values
	and activities to forecast demand, • Data relating to the procurement of the relevant vaccine?	data, burden of disease, and related projections		Annual Progress Reports
		Fraction of annual reports that include dates on the implementation activities to support the introduction and use of the relevant vaccines including in respect of the GAVI Co-Financing Policies and activities to forecast demand		Information on the Accelerated Vaccine Introduction (AVI) included in 2009-10 annual report with activities and timing Events in partnership with introducing governments included in 2010-11 annual report Coordination of introductions discussed in annual report 2011-12, but no specific activities with dates
		Fraction of annual reports that include annually contracted volumes (including the capacity development period)		Allocation of doses by year from 2010-2022 included
	4. Has the Remaining AMC Offer Amount been published on the AMC Website on each anniversary of the entry into of the Offer Agreement?	Number of announcements published on the website		2010, 2011, and 2012 data available at http://www.gavialliance.org/library/gavi-documents/amc/
Timeliness	1. Has the AMC Secretariat scheduled an AMC Eligibility Determination Meeting as soon as reasonably possible after receipt by the AMC Secretariat of the Application for AMC Eligibility?	Number of Eligibility Determination Meetings that were scheduled within six weeks after product obtained PQ (the six-week threshold was defined in annual report 2009-2010)		GSK PQ in March 10, applied to AMC in March 2010, AMC approval April 2010 Pfizer applied to AMC Jan 2010, PQ in Aug 2010, AMC approval Aug 2010
	2. Has UNICEF issued a Call for Supply Offers within 20 IBRD Business Days following the publication of the GAVI Strategic Demand Forecast as specified in the legal agreements?	Number of Calls for Supply Offers issued within 20 IBRD business days following the publication of SDF		1st Call for SO issued on 4 September 2009 (20 days after SDF v0.1) 2nd Call for SO issued on 8 April 2011 (20 days after SDF v3.0) 3rd Call for SO issued August 2012 (on par with publication of SDF v5.0, published 13 Aug 2012)
	3. Has UNICEF entered into Supply Agreements within 90 IBRD Business Days from receiving Supply Offers as specified in the legal agreements (40 days to assess offers + 20 days to reach agreement + 30 days to enter into a SA)?	Actual vs. Planned date for finalizing supply agreements		1st tender – March 2010 provisional SA (actual) vs. 18 February 2010 (planned) 2nd tender – 12 Dec 2011 (actual) vs. 9 September 2011 (planned). The procurement timeline was delayed account for demand from newly approved countries in round May 2011 Source: annual reports

<table>
<tr><th>Criteria</th><th>Question</th><th>Indicator</th><th>Status</th><th>Evidence/Results/Values</th></tr>
<tr><td rowspan="4">Responsiveness to changes in context and external factors</td><td rowspan="2">1. Are new entrants being incentivized to enter the market by being provided with sufficient expected individual demand?</td><td>Awarded quantity as a % of total quantity forecasted in five-year time</td><td></td><td>47% and 49% awarded in rounds 1 and 2
UNICEF did not award full quantities to incentivize manufacturers to accelerate the development of new vaccines, to contribute to the creation of a healthy market with multiple suppliers, and to enhance the possibility to access lower long-term prices through future offers.
Source: annual reports, SDFs</td></tr>
<tr><td>% of funds available for new entrants after the third call for Supply Offers</td><td></td><td>By the time new manufacturers enter the market it is likely that only 30% of the funds will be available. Monitoring this indicator will help inform decisions about the allocation of funds after the entry of DCVMs.</td></tr>
<tr><td rowspan="2">2. Have manufacturers entering into a Supply Agreement used existing manufacturing headroom to fill orders for their product and mitigate product shortage during the Capacity Development period?</td><td>Million doses contracted during the Capacity Development period compared to SDF predictions</td><td></td><td>SDF v3.0 14 mil. In 2011
SDF v5.0: 34 mil. In 2012, 74 mil. In 2013
Sufficient doses have been contracted to meet the needs of SDF v5.0
<table>
<tr><th>Year</th><th>Demand predicted (SDF v3, v5)</th><th>Doses contracted</th></tr>
<tr><td>2011</td><td>14 m</td><td>28.9 m</td></tr>
<tr><td>2012</td><td>40 m; 34 m</td><td>67 m</td></tr>
<tr><td>2013</td><td>71 m; 74 m</td><td>77 m</td></tr>
</table>
Source: 2011-12 annual report</td></tr>
<tr><td>Number of countries postponing vaccine introduction due to insufficient supply</td><td></td><td>2 in 2012 and potentially more in 2013
Source: 2011-12 annual report, UNICEF interviews</td></tr>
<tr><td>3. Has the AMC appropriately adapted to GAVI's new country eligibility and graduation policies?</td><td>Percentage change in peak forecasted demand with respect to AMC reference (200 mil. doses) with GAVI's new eligibility and graduation policies before and after GAVI's "grandfathering" of the AMC deal</td><td></td><td>-17% vs. +4%
(166 mil. without grandfathering; 208 mil. with grandfathering)
Source: "Next steps on the Pneumococcal AMC: Accounting for the New Context," prepared for GAVI Alliance Board Meeting, 16-17 June 2010</td></tr>
</table>

Part B. Review of existing M&E framework and proposal for additional indicators

The M&E framework developed during the AMC design phase in 2007 tracks indicators that yield raw numbers without providing benchmarks, targets, or projected timelines for comparison or context. Without such comparison points, it is difficult to draw inferences about or assess the relative success or appropriate speed of the AMC implementation in order to improve future efforts. Furthermore, many of these data points change very little or not at all year by year, are redundant, not publically available, or difficult to locate. With the addition of more in-depth measurements that compare annual data points against previously set targets or relevant benchmarks, AMC implementers can more effectively interpret the results and draw implications at closer to real-time regarding the progress of the AMC. Moreover, segmenting metrics by potential causal contributors or by phases is also likely to yield more actionable data that can inform decisions. These metrics will help create accountability and allow implementers to better identify areas for improvement, quickly create solutions to course-correct, or build upon previous successes.

The chart below presents an assessment of current indicators as well as suggestions for potential additional indicators to use.

Current Indicators	Assessment	Potential New Indicators
Progress towards objectives		
Goal: To reduce morbidity and mortality from pneumococcal diseases and, specifically, to prevent an estimated 7 million childhood deaths by 2030 1. Cumulative number of cases of IPD averted due to pneumococcal vaccination in GAVI-eligible countries 2. Cumulative number of future deaths averted due to pneumococcal vaccination in GAVI-eligible	• Information should be available publically and easily accessible, perhaps prior to the 2014 Outcome Evaluation. Updates and information on both of these metrics are difficult to locate on GAVI-related websites, and are not reported on GAVI's M&E spreadsheet[3] • Only one mention of cumulative number of deaths averted can be found on GAVI website; we recommend this be included in the AMC annual reports as well	• Efficiency in reduction of mortality rates (e.g. measure changes in cost per DALY to immunize against pneumococcal disease) • Changes in disease burden of pneumococcal disease per GAVI-eligible country and for all GAVI-eligible countries • Percentage of future deaths averted relative to baseline of predicted future deaths from pneumococcal-related diseases

[3] "Pneumo AMC Annual Monitoring: Indicator Matrix," last updated 25 November 2011.

countries		
Objective 1: Accelerate the development of new vaccines 1. Cumulative # of TPP candidates 2. Median time between key milestones in the development of TPP candidates 3. Cumulative # of AMC-eligible PCVs	• Overall, indicators are helpful and provide insight on progress towards Objective 1 • Difficult to determine progress without clear targets for each in accordance to short and long term goals (aim for oligopoly vs. natural monopoly) and the specificities of the market or vaccine • Targets needed for desired # of TPP candidates and timeline, which would help indicate whether the AMC has been successful or not in accelerating R&D, given # of capable producers, difficulty of producing PCV, and timeline for R&D • To better draw inferences from these data, goals can be set for # of new entrants every 5 years, desirable maximum # of manufacturers, or percentage of TPP candidates that receive approval • GAVI can ask countries to voluntarily and confidentially report on current progress and expected timeline as part of the registration process to improve its understanding and decision making • GAVI can also ask companies to self-report on their projected timeline for the development of TPP candidates, perhaps when they first register with the AMC	• Targeted number of TPP candidates vs. actual number • Compare the median time between key milestones in development of TPP candidates against previously estimated timelines by companies; measure any increases in speed of development • Amount of time (months/years) of delays reported by DCVMs; measure actual manufacturer entry date against expected entry date
Objective 2: incentivizing manufacturers to expand capacity 1. Total # of doses of TPP vaccines offered to UNICEF SD per year for GAVI-eligible countries	• Since the baseline is 0, there is no benchmark or target rate against which to measure the ramp up rate of doses PCV offered to UNICEF	• Differences in number of doses between contracted and offered amounts and the respective targets set • Differences between the supply offered, supply contracted, and supply purchased by UNICEF

2. # doses of TPP vaccine contracted under AMC by year		• Difference between the number of doses contracted and number requested by UNICEF (or forecasted demand) • Track changes in investment in dedicated PCV capacity expansion relative to original projected expenditures on PCV capacity • Total manufacturing capacity for PCV; total manufacturing capacity for GAVI PCV after non-GAVI markets are considered (e.g., use market intelligence efforts and voluntary reporting to gather information)
Objective 3: accelerating vaccine uptake in-country 1. Number and cumulative number of countries (and children within countries) in the different application phases of GAVI support for PCV (submission, needing clarifications, and approval) 2. GAVI-eligible countries planning the introduction TPP vaccines 3. Cumulative number of doses of TPP vaccine shipped to GAVI-eligible countries 4. PCV3 coverage in GAVI eligible countries 5. Time in years to reach 80% PCV coverage	• Segment the number of countries in each phase of application for GAVI support • Compare to number of doses requested by country based on demand • In addition to measuring rate of coverage, note key issues/delays; coordinate and monitor complementary activities to resolve issues • Clarify what "80% PCV coverage" refers to, e.g. all GAVI-eligible countries or per country measurements	• Time interval between country application and GAVI approval; time between country approval and roll-out of PCV (1st and 3rd doses of PCV); compare timeliness against preset targets • Frequency and timeliness of communications between country and GAVI during the application phase; measure against preset goals • Conduct brief surveys on country feedback on PCV application process • Timelines of country introduction against set targets • Track and differentiate between causes of delays for country introductions (e.g. country readiness vs. supply shortage) • Changes in wastage rates per country • Number of countries delaying

		introductions due to supply shortages • Number and percentage of GAVI-eligible countries at 80% PCV coverage

Process indicators related to manufacturers

Manufacturers 1. Total number of AMC-registered manufacturers 2. Number of AMC-registered manufacturers whose Product Summary File was accepted by WHO QSS for prequalification review 3. Number of applications for AMC Eligibility 4. Number of failed applications for AMC eligibility	• These measurements overlap and are a bit redundant (e.g. only manufacturers who have entered the WHO PQ process can apply for AMC eligibility)	• Measure the timeline of each phase: 1) AMC-registration, 2) approval or rejection of TPP candidate, and 2) determining AMC eligibility; track whether this timeline is compliant with that in the AMC Procedures Memorandum • Frequency and turnaround time of communications (letters, notices, etc.) between manufacturers and the relevant GAVI parties • Track whether and if so, by how much TPP candidates exceed the PCV TPP requirements (define new scale for measuring qualification vs. over-qualification, etc.) • Number of consultations (presentations or meetings, live or via teleconference) with manufacturers
Strategic Demand Forecast (provision of predictability for manufacturers) 1. Number of Strategic Demand Forecast (SDF) published	• Tracking the number of forecasts alone does not yield any actionable insight regarding the implementation process • Determine whether the publishing of SDFs should be more or less frequent	• SDF consistency, i.e. percentage changes in SDFs over time • SDF accuracy, i.e. percentage difference between SDF predictions and actual demand; include both country-by-country (e.g. percentage of countries within 10% of predicted demand) and overall

		• Solicit and record evaluation of and reaction to SDFs by manufacturers in terms of usefulness and dependence on SDFs during manufacturer capacity and investment planning
Supply Agreements 1. # of Call for Supply Offers issued 2. Number of Pneumo Procurement Reference Group (PRG) Meetings 3. # of Provisional Supply Agreements (PSA) signed 4. # of Supply Agreements (SA) signed 5. Number of AMC Registered Manufacturers who have entered into PSA/SA		• Solicit feedback from manufacturers on appropriate frequency of calls for supply offers (can be one time basis) • Track the timeliness of PRG meetings, i.e. time between calls for supply offers and meetings • Number of SA as percentage of PSA
IAC 1. Number of IAC meetings 2. Number of Applications for Inflation review received 3. Number of IAC intervention in dispute resolution 4. Number of IAC Selection and Oversight Panel Meetings	• These raw numbers do not give a clear indication of the efficacy of the IAC, include targets	• Feedback from stakeholders regarding their evaluation of the IAC's dispute resolutions • Level of transparency of IAC's resolution process; number, detail, and timeliness of external communications on decision-making process and final decisions (e.g. are the meeting minutes transcribed or largely filtered?) • Adherence to timeline of eligibility determination or resolution process, including meeting minutes publication
Media and Communications		
1. Record of updated material	• Currently, it is difficult to locate all AMC-related press	• Level of transparency of AMC-related

2. Total number of press releases 3. Total number of events where the AMC was presented	releases and materials (e.g. a search in GAVI press releases with the filter "pneumococcal vaccine support" or similar phrases yields zero results); consolidate all relevant press releases	operations (e.g. measure level of disclosure, accuracy and scope, clarity, ease of access, and perception of transparency level) • Frequency and number of communications or consultations (direct responses to inquiries, criticisms via letter, publications, or conferences)with CSOs • CSO/public feedback on and reaction to AMC-related press releases (e.g. are press releases detailed, objective, and do they address key concerns?)
Partners' performances		
World Bank 1. Total amount received from fixed payment donors 2. Total amount received from on-demand donors 3. Cumulative receipts from AMC donors 4. Total estimated required amounts communicated by GAVI to the World Bank through the Semi Annual Estimates (SAE) 5. Estimated amounts to be requested by the World Bank to AMC donors based on the SAE in the next 36 months 6. Total amount disbursed by the World Bank to GAVI	• Metrics do not offer insight on the efficiency or effectiveness of this process • These finance metrics are dependent on factors covered above (e.g. doses contracted and price); therefore, improvements can be made by tracking the effectiveness of WB functions and timeliness of such payments	• GAVI's overheard and cost data related to implementation of AMC • Measure efficacy and costs of complementary activities by GAVI • Timeliness of disbursements (e.g. measure time between GAVI communication to WB and completion of its fiduciary duties) • Timeliness of WB and UNICEF functions • Fees paid to the World Bank vs. costs for best alternative • Level of transparency and communications of these metrics (e.g. measure level of disclosure, accuracy and scope, clarity, ease of access, and perception of transparency level) • Accuracy of the Semi Annual Estimates (SAE)

UNICEF 1. Total Cash Disbursement to UNICEF procurement accounts 2. Total amount of Procurement fees paid to UNICEF 3. Total amount paid for the Firm Order Commitments (FOC) 4. Total amount required in the Promissory Notes	• The current indicators do not provide insight on effectiveness of implementation or UNICEF	• PCV doses offered and contracted; compare to demand forecasted (based on both GAVI and UNICEF SDFs) • Ask manufacturers for feedback on (to rate) UNICEF's ability and efficacy in providing clarity and predictability on country demand • Timeliness of cash disbursements by GAVI to UNICEF
Delivery of PCV		
1. Number of GAVI countries approved for the introduction of pneumo vaccines 2. On-time delivery performance 3. Actual weighted average price of each vaccine for the year and projected weighted average price for the following year 4. Total fulfillment costs 5. Number of vaccines rejected per year as a % of the aggregate annual shipments for each vaccine product 6. Report on co-financing	• No data on weighted average price; this data is crucial and should be gathered for both total price and GAVI's contribution per vaccine dose (currently not available on UNICEF site) • For on-time delivery, include the agreed upon timeline and actual timeline for comparison • Set target for costs (e.g. a range or decreases over time) or benchmark against other comparable vaccines • Co-financing terms should be made available as soon as possible; include list of countries and how much each is paying	• Segment relevant delays by causes: delays due to country readiness and delays due to supply constraints • Include GAVI cost measurements for implementation (GAVI overhead, fees, etc.) • Devise and track metrics on complementary activities (e.g. costs, timeline, impact) Pricing • Bid price and changes in bid price • Actual bid price compared GAVI forecasted or target price points • Monitor price per vaccine segmented by total price, paid by GAVI vs. paid by country; compare to targets by year

Appendix III. Description of inputs to pricing structure and price point analysis

To estimate the returns that manufacturers are earning under the AMC, and whether they would have participated in the initiative under different scenarios, we have developed a Microsoft Excel model to simulate their cashflows given a set of basic assumptions.

Pricing: Dalberg's model has built on the analysis done by the Implementation Working Group (IWG)

As part of its work, the IWG modeled companies' NPVs under different conditions/assumptions

APPENDIX D: NPV VALUES FOR DIFFERENT SCENARIOS

NPVs for 100 Million Dose Annual Capacity Plant; $7.00 AMC Price, with a $3.50 AMC subsidy and a $3.50 tail price; 10 Year Supply Commitment (in millions)
The 100 million dose commitment gives the firm nominal AMC Funds of $750 Million, based on a 200 million dose target by 2030

Cost Estimates			Demand Realization				
Capital Costs (Mil.)	Annual Fixed Costs (Mil.)	Variable Costs Per Dose	100%	75%	50%	25%	15%
NPV of Firm Profits							
$110	$35	$0.65	$1,396	$1,352	$1,157	$595	$307
$110	$35	$1.00	$1,231	$1,193	$1,010	$520	$262
$110	$35	$1.75	$880	$851	$723	$360	$166
$200	$35	$1.75	$809	$779	$651	$288	$94
$200	$50	$2.50	$301	$362	$230	$50	($77)
$300	$50	$2.50	$301	$282	$200	($27)	($157)
$300	$50	$2.75	$184	$165	$102	($80)	($189)
$400	$50	$2.75	$104	$88	$22	($160)	($269)
$400	$50	$3.50	($248)	($264)	($274)	($320)	($365)
$400	$50	$4.00	($483)	($482)	($472)	($427)	($429)
NPV of Spending							
Total Spending			$2,476	$2,409	$2,091	$1,311	$945
GAVI Spending			$1,787	$1,730	$1,448	$756	$455
Country Co-Payment			$145	$140	$117	$61	$37
Net DALYs Averted							
Using 10-Valent Vaccine			44	37	25	11	5
Using 13-Valent Vaccine			49	41	28	13	6
Dollar Cost per Net DALY							
Using 10-Valent Vaccine			$56	$66	$83	$119	$188
Using 13-Valent Vaccine			$50	$59	$73	$103	$156
Dollar Cost per DALY							
Using 10-Valent Vaccine			$36	$40	$45	$54	$65
Using 13-Valent Vaccine			$33	$37	$42	$51	$61

Dalberg aims to update this analysis based on new information and approaches

New information
- Actual UNICEF round 1 and 2 supply contracts with GSK and Pfizer
- Updates to the Strategic Demand Forecast
- Information on GSK's and Pfizer's capacity investments

Updated approach
- Our analysis will estimate supplier IRRs, not NPVs, to understand not just their go/no go decisions but the scale of their returns
  - Approach supported by interviews with companies, ex-industry members, and consultants

Caveats
- Dalberg has not been able to obtain the precise IWG model used to produce the table at left
- Charles River Associates has provided an earlier iteration of the model, though with different inputs and outputs from the final version
- Where possible/reasonable, we have tried to incorporate its logic

Source: IWG July 2008 report; Dalberg interviews

Dalberg

Worth noting is that instead of an NPV framework used by the AMC's Implementation Working Group (IWG) report, our analysis will use an Internal Rate of Return (IRR) approach. This measure considers what discount rate would be required to offset an investment's initial costs with later positive cashflows.[iv] The IRR is useful in that it serves as a way of simplifying the complex cashflows of different investments into a single number to allow comparisons.[v] While NPV and IRR frameworks represent

[iv] As a technical complication, investments whose profit streams swing back and forth between positive and negative may have multiple valid IRRs; in our analysis we have selected the one most applicable in each given scenario.

[v] As an example of the limits of NPV analysis, consider the case of two investments with an NPV of $100 million over one year. The first requires one billion dollars to earn, for a return of 10%; the second $10 million, for a return of 1000%. The second is significantly more attractive, but one can only tell this by considering the relative returns of the two.

different perspectives, the two feed into each other: an investment with an IRR of 10% is equivalent to one with an NPV of zero at a 10% discount rate.

Our model makes the following set of baseline assumptions:

Dalberg model assumptions (1/2)

Assumptions tested in sensitivity analysis

Assumption	Range Tested	Range source
Tail price	$1.00-4.00	Current AMC ceiling; potential alternatives
Total supplier AMC-related investments (capital expenditures, clinical trials, etc.)	$100-500M	Supplier press releases; IWG report; supplier interviews
COGS	$1.00-4.00	IWG report
% of demand forecast realized	75-100%	Dalberg interviews

Source: IWG report, July 2008; GAVI/AMC website; price/cost model provided to Dalberg by Charles River Associates; Net Resources International

Dalberg model assumptions (2/2)

Assumptions held fixed in sensitivity analysis

Category	Assumption	Value
Market shape	**Demand curve**	Uses the Strategic Demand Forecast v5.0
	Date of DCVM entry	2017
	1st and 2nd round tenders	Contracts awarded to as per GAVI/AMC website
	3rd round tender contract	46M doses – enough to satisfy demand through end of 2016 Split 50%/50% between MNC's
	4th round tender contract	Remainder of supply forecast Split 80%/10%/10% between DCVM,MNC-1, and MNC-2
	Include post-AMC demand?	No; only considers direct incentives provided by the AMC
Costs	**Capex investment duration**	MNCs: Over 7 years, DCVMs: Over 10 years *(evenly spread)*
	Annual fixed cost of plant operation	$28M; scaled value from IWG report to reflect lower peak volumes and lower overall average rate due to use of headroom during capacity development period
	Supply outage	No
	Cost growth (inflation)	1.5%
	Supplier NPV discount rate	10%
	IRRs adjusted for inflation	No; IRRs and NPVs are reported in nominal values
Revenues	**AMC subsidy**	$3.50 per dose on the first 21% of each contract, up to 2000 doses
	Tail price inflation adjustment	Matches cost growth; at 1.5%
	Include post-AMC revenues	No; only considers revenue from the 2000 AMC doses

Source: IWG report, July 2008; GAVI/AMC website; price/cost model provided to Dalberg by Charles River Associates

Dalberg

Appendix IV. Additional design elements.

Some elements that were contentious during the design phase have turned out to be uncontroversial or have not been fully tested yet

	Issue	Assessment
Inflation procedure	• The AMC accounts for inflation by updating the tail price ceiling based on changes in the OCED Total GDP Deflator	• Difficult to assess impact, as the inflation procedure has not been used • GSK has expressed a preference for a more automatic and predictable adjustment process
Demand scale-up mechanism	• The AMC's contracts included provisions for the Capacity Development Period (CDP), where suppliers provided doses ahead of schedule to facilitate country scale-up	• CDP appears to be a successful case of flexibility being included with AMC contracts • However, some interviewees argue that could have been done faster and more smoothly: in 2011 46 million doses were contracted for, but only 32 actually purchased
5-year bid cap	• Firms may not bid to supply more doses than 5-year forward demand	• Not cited as significant issue in interviews
10-year supply commitment requirement	• Manufacturers are required to provide doses to GAVI through long-term 10-year contracts • GAVI has option, but not requirement, to purchase doses	• Difficult to assess impact on price without counterfactual • Manufacturers have indicated dissatisfaction with long-term exposure to demand risk; may factor in risk premium into price bids

Source: Pneumococcal AMC Inflation Review Application Process; AMC Donor Response to EEG Report; Dalberg interviews and analysis

Dalberg

Annex I. Evaluation Terms of Reference

The evaluation will address the following questions broken-down into four major categories:

Design structure, elements and assumptions

1. Given the AMC's objectives, to what extent do the binding legal agreements provide a clear incentive to industry to accelerate the development of vaccines meeting the Target Product Profile and bring forward their availability?
2. To what extent do specific AMC design elements (including but not necessarily limited to those listed below) contribute to the AMC objectives:
    a. AMC Price
    b. Tail price cap
    c. Sequential bidding process
    d. Bid cap set at 5-year forward peak demand
    e. Assessment of peak demand at 200 million doses and allocation of AMC funds
    f. 10-year supply commitment requirement
    g. 3-year purchase guarantee (deescalating % of committed doses)
    h. Inflation procedure
3. To what extent is the Target Product Profile used for the pilot AMC an appropriate standard for product development?
4. To what extent have assumptions underpinning the AMC at the time of its design proved to be robust and appropriate over time, including those related to the supply landscape, country demand, GAVI funding and vaccine cost?
5. To what extent is the AMC management structure – such as the placement of the AMC within the context of the GAVI Alliance, and the setup of an Independent Assessment Committee – relevant to the achievement of the AMC objectives?

Design Process

1. To what extent was the AMC Donor Committee an effective and efficient way to oversee the AMC design phase?
2. To what extent was the role of different partner organizations appropriate, effective and efficient during the design phase?
3. To what extent were expert and stakeholder consultations[vi] adequate during the design phase?
4. To what extent were the estimated costs of setting up and implementing the AMC in terms of finances and staff allocation reasonable and appropriate?

Implementation Process

1. To what extent has the AMC been implemented as designed? What elements have been most difficult or require adjustment, if any?

[vi] All consultations undertaken during the design phase of the AMC are reported in the Consultation and Advisory Process available on the AMC website: http://www.gavialliance.org/library/documents/amc/consultation-and-advisory-process/

2. To what extent has management by the implementing agencies of the AMC been efficient, effective, transparent, timely and appropriately responsive to changes in context and external factors?
3. In what phases of the implementation process have the greatest costs been incurred? To what extent are on-going support costs reasonable and appropriate?
4. To what extent has the oversight process (e.g. IAC) been adequate?
5. To what extent have the complementary activities identified as necessary to stimulate demand and support the introduction of pneumococcal vaccines in GAVI eligible countries (including communication and outreach activities) been conducted as planned?

Future AMCs

1. What lessons can be drawn at this stage from the design and implementation of the pneumococcal AMC to help inform if and how future AMCs should be designed and implemented?

In capturing key lessons learned, the evaluation should actively explore and document the following:

1. Critical success factors
2. Barriers in design or implementation that may adversely affect the AMC's effectiveness
3. Positive and negative unintended consequences of the design and implementation of the pilot AMC

Annex II. List of persons interviewed

Name	Organization	Title	Date
Donors			
Greg Widmyer	Bill & Melinda Gates Foundation	Senior Programme Officer; member of the PRG	9/19/2012
Melanie Galvin	MicroNutrient Initiative	Asia Regional Director; former donor representative from the Canadian International Development Agency	9/27/2012
Carlo Monticelli	European Investment Bank; Italian Ministry of Economy and Finance	Director General; Director of International Financial Relations; former Italian donor representative	10/3/2012
Seb Ling	DFID	Global Funds & Development; Former DFID representative	10/18/12[vii], 6/2012
Saul Walker	The World Bank	Senior Health Specialist; former DFID representative	10/18/12[§]
Sally Waples	DFID	Head of Ministerial Support Team	10/18/12[§]
Chris Athayde	DFID	Deputy Head, Evidence Into Action	10/18/12[§]
Leone Gianturco	Italian Ministry of the Economy and Finance; International Financial Relations Division.	Senior Economic and Financial Advisor; former AMC donor board member; former AMC Advisory Group member	6/2012
Hannah Kettler	Bill & Melinda Gates Foundation	Economist & Senior Program Officer on the Global Health Advocacy Team; former donor representative; former AMC Advisory Group member	6/2012
Technical Experts and Advisors			
Sandy Wrobel	Applied Strategies Consulting	Chief Executive Officer	9/25/2012
Craig Shaffer	Applied Strategies Consulting	VP, Applied Analytics and Technology Development	10/5/2012
Angeline Nanni	Aeras	Director of Market Access; former Director of Vaccine Finance & Supply of PneumoADIP, John Hopkins University	9/21/2012

[vii] Interviews conducted via email.

Owen Barder	Center for Global Development	Senior Fellow & Europe Director; former AMC Advisory Group member	10/22/2012
Paul Wilson	Columbia University	Assistant Professor at the Mailman School of Public Health	8/15/2012
Christopher Snyder	Dartmouth University	Professor; former EEG member	8/20/2012
Andrew Jones	Clinton Health Access Initiative	Manager of Malaria Financing; former Senior Programme Officer of Accelerated Vaccine Introduction at GAVI; former IWG member	8/20/2012
Ruth Levine	Hewlett Foundation	Director, Global Development and Population; former co-chair of AMC Working Group at Center for Global Development, former AMC Advisory Group member, IWG co-chair, and EEG member	9/28/2012
Jonathan Levin	Stanford University	Professor; former IWG member	10/1/2012
David Fleming	Seattle & King County Department of Public Health	Public Health Director and Health Officer; former co-chair of EEG and IWG	10/2/2012
Michael Kremer	Harvard University	Gates Professor of Developing Societies; former co-chair of CGD AMC Working Group, former member of EEG and IWG	10/2/2012
John Hurvitz	Covington & Burling LLP	Partner; former AMC Advisory Group member	10/11/2012
Orin Levine	Bill & Melinda Gates Foundation	Director of Vaccine Delivery; former Executive Director of PneumoADIP, Johns Hopkins University; former AMC Advisory Group member	12/5/2012
GAVI Alliance and Secretariat			
Johanna Fihman	GAVI Alliance	AMC Senior Programme Assistant, Policy and Performance; Programme Manager for Accelerated Vaccine Initiative	8/22/2012
Aurelia Nguyen	GAVI Alliance Secretariat	Director of Policy & Market Shaping	9/13/2012
Nina Schwalbe	GAVI Alliance Secretariat	Managing Director	9/14/2012
Jon Pearman	GAVI Alliance Secretariat	Acting Director of Vaccine Implementation; Director of	9/20/2012

		Accelerated Vaccine Initiative; member of the PRG	
Kate Harris	GAVI Alliance	Senior Manager, Program Funding	9/20/2012
Lauren Franzel	GAVI Alliance	Lead, Strategic Vaccine Supply at PATH; member of the PRG	9/21/2012
Tania Cernuschi	GAVI Alliance	Senior Manager Accelerated Vaccine Initiative; former AMC Manager (2007-2009)	9/24/2012
Eliane Furrer	GAVI Alliance	Senior Programme Officer, Policy and Performance	9/26/2012
Ariane McCabe	GAVI Alliance	Senior Manager, External Relations	9/26/2012
Marina Krawczyk	GAVI Alliance	Project Manager, External Relations	10/4/2012
Partner Organizations			
Carsten Mantel	WHO	Medical Officer, Group Leader for New and Underutilized Vaccines; member of the PRG	9/26/2012
Joachim Hombach	WHO	Senior Adviser in the Department of Immunisation, Vaccines and Biologicals	10/2/2012
Susan McAdams	World Bank	Director of Multilateral and Innovative Financing; former AMC Advisory Group member, former IWG member	10/9/2012
Shirmila Ramasamy	World Bank	Counsel, Corporate Finance, Legal Vice President	10/18/2012
Shanelle Hall	UNICEF Supply Division	Director of Supply Division; former AMC Advisory Group member	6/2012
Ann Ottosen	UNICEF Supply Division	Contracts Manager of the Vaccine Center; former IWG member	10/18/2012
Meredith Shirey	UNICEF Supply Division	Chief of Vaccine Center; former IWG member	10/18/2012
Manufacturers			
Adel Mahmoud	Princeton University	Professor; former President of Merck Vaccines	10/9/2012
Suresh Jadhav	Serum institute of India Ltd., Pune; GAVI Board	Executive Director; Alternate Member	10/10/2012, 6/2012
R. K. Suri	Panacea Biotec Ltd.	Chief Executive Biologicals	10/15/2012

Lynn Bodarky	Pfizer	Senior Director Developing World	10/15/2012, 6/2012
Susan Silbermann	Pfizer	Head of Vaccines	Scheduled (11/12/2012)
Eunice Miranda	GSK	Director of Supranationals, Government Affairs and Public Policy; Director of Biologicals	10/26/2012
Jean Stephenne	GSK	Special Advisor to the CEO A. Witty, former President and General Manager	11/30/2012
Luciana Leite	Instituto Butantan	Director, Centro de Biotecnologia	11/9/2012
Morena Makhoana	The Biovac Institute	Chief Executive Officer	11/13/2012
Xiaoming Yang	China National Biotec Group Company Ltd.	President and Chief Executive Officer	11/20/2012
Ying Tang	China National Biotec Group Company Ltd.	Director, International Cooperation Department	11/20/2012
James Connolly	Aeras	President and Chief Executive Officer; former Executive Vice President and General Manager of Wyeth Vaccines	12/7/2012
Civil Society Organizations and External Experts			
Laurent Gadot	French Ministry of Health	Health economist; formerly at Médecins Sans Frontières Access Campaign	9/11/2012
Rohit Malpani	Oxfam America	Special Advisor for Campaigns	10/10/2012
Jens Plahte	Plahte J. Plahte Research & Consulting	Independent Researcher and Consultant	10/11/2012