Process Evaluation of the Project on *Defining the Architecture and Management of a Global Subsidy for Antimalarial Drugs*

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Acknowledgments

This process evaluation of the project on *Defining the Architecture and Management of a Global Subsidy for Antimalarial Drugs* was commissioned and funded by the World Bank. The evaluation was conducted as an external assessment by a team of consultants—Dr. Laura Frost (Global Health Insights, LLC), Professor Michael R. Reich (Harvard School of Public Health), Dr. Beth Anne Pratt (Global Health Insights, LLC), and Ms. Anya Levy Guyer (Harvard School of Public Health).

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This report is a process evaluation of the project on *Defining the Architecture and Management of a Global Subsidy for Antimalarial Drugs*, funded by the Bill & Melinda Gates Foundation and managed by the World Bank on behalf of the Roll Back Malaria Partnership. The project's goal was to translate the Institute of Medicine's research report, *Saving Lives, Buying Time*, into an operational plan for a global subsidy for effective combinations of antimalarial drugs. This process evaluation assesses project implementation from August 2006 (when the project grant was approved) to April 2008 (when most project activities ended). The process evaluation documents the steps involved in carrying out project activities and examines how and why the project goal was attained. It concludes with lessons learned for future efforts that seek to translate research reports into operational plans within the global health landscape.

1. Introduction

In 2001, the United States Agency for International Development (USAID) asked the Institute of Medicine (IOM) in Washington, DC, to convene a panel to assess the economics of antimalarial drugs (see Appendix 1 for a timeline of key events). The IOM's Board of Global Health assembled a committee of economists and public health experts with malaria expertise. The Chair of the Committee was Kenneth Arrow of Stanford University, a Nobel Laureate in economics and a founding member of the IOM. After two years of research, the Committee released its report, *Saving Lives, Buying Time,* in July 2004. The report recommended the creation of a global-level subsidy for the new category of antimalarial drugs, artemisinin-based combination therapy (ACT). It recommended the establishment of a global fund that would purchase ACTs from manufacturers at a dollar price per dose and resell it at one-tenth of that price. The subsidized ACTs could be purchased by both the public and private sectors of all malaria-endemic countries. The subsidy would solve two critical problems at the same time: it would enable widespread access to effective antimalarials (to "save lives") and would delay the emergence of resistance to artemisinin (to "buy time"). The Committee believed that a global subsidy would allow ACTs to flow to both the public and private sectors, and would also free up funds that would let countries pursue malaria policies most appropriate to their circumstances (using funds that would otherwise go toward ACT procurement). The Committee also believed that a global subsidy would give the international community leverage to persuade artemisinin manufacturers to stop monotherapy production, which was feared as a source of resistance.

Olusoji Adeyi, Coordinator of Public Health Programs in the World Bank's Human Development Network, read a pre-publication version of *Saving Lives, Buying Time* and believed that the global subsidy recommendation was ground-breaking, addressing in a single stroke the questions of access to treatment, drug resistance, and public-private channels for treatment. He felt it was a simple and elegant idea. Adeyi at this time was serving as chair of the Roll Back Malaria (RBM) Partnership's Working Group on Finance & Resources (RBM FRWG). In its role as chair, the World Bank convened a FRWG meeting in its Washington, D.C. offices in September 2004. The primary topic of the meeting was the *Saving Lives, Buying Time* report.[1] In the meeting, it became clear that there was opposition to the idea, even within the World Bank's Development

Economics Research Group (DEC). To defuse the opposition, Adeyi sought a small grant from the RBM Secretariat (led by Professor Awa Coll-Seck) to hire consultants to further analyze the global subsidy idea. He invited the principal opponent within DEC to identify the consultants and recused himself from the analysis. The study report was published in July 2005 as a DEC Research Working Paper, with the following conclusion:

> "This study finds that a subsidy to ACTs is likely to slow the rate of emergence of resistance to artemisinin and partner drugs, even if such a subsidy were to increase the use of ACTs significantly. This conclusion is robust to alternative assumptions regarding the responsiveness of demand to the lower price for ACTs and a wide range of epidemiological and economic parameters."[2]

The study findings had a profound effect at the World Bank. On July 28, 2005, the former Chief Economist and Senior Vice-President of DEC, Francois Bourguignon, and the former Senior Vice-President for Human Development, Jean-Louis Sarbib, wrote to Kenneth Arrow. They noted that the IOM's recommendations on a global subsidy had clear merit and indicated a willingness to explore its feasibility.

At a conference of donors hosted by the World Bank in Paris in September 2005, RBM asked the World Bank, in its role as co-chair of the FRWG, to develop a detailed proposal on behalf of RBM for the design and operation of the global subsidy. Adeyi, his World Bank team (including Andreas Seiter, a specialist in pharmaceuticals), and other advocates (including Ramanan Laxminarayan from Resources For the Future and Hellen Gelband from the IOM) formed a core group. On behalf of RBM, they sought a grant from the Bill & Melinda Gates Foundation (BMGF) to develop the global subsidy idea from the IOM research report into an operational plan. Both Girindre Beeharry and Daniel Kress of BMGF (both members of the RBM FRWG) saw the merit of the global subsidy idea and said they would consider a proposal to further the idea's development into an operational plan. The World Bank submitted the proposal for the project on *Defining the Architecture and Management of a Global Subsidy for Antimalarial Drugs* (hereafter referred to as the Global Subsidy Project) in May 2006; the grant for $4,085,789 was approved in August 2006 for a 22-month period. It was subsequently extended to March 2009 to ensure the completion of all activities, including this process evaluation.

Two years later, at its 18th Board meeting on 7-8 November 2008 (New Delhi, India), the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) agreed to host and manage the global ACT subsidy for an initial phase in a limited number of countries.[3] The GFATM Board approved an operational plan for the global ACT subsidy through an entity known as the Affordable Medicines Facility for malaria (AMFm). This GFATM Board meeting marked an end to the process of translating the research report into an operational plan for the global ACT subsidy and moved the AMFm into the pre-launch period. The official launch of the AMFm implementation phase is scheduled for April 2009.

2. Description of the Global Subsidy Project

The Global Subsidy Project's goal was to establish a viable plan for a global subsidy for effective combinations of antimalarial drugs.[4] The project had three objectives:

1. To develop a detailed architecture and operational plan for a high-level global subsidy for effective antimalarials, including exit clauses to address situations in which the subsidy might no longer be needed or appropriate.

2. To build a coalition that has the critical mass to generate funding and political support so that the subsidy can become reality.

3. To address questions related to external efforts of the subsidy or external risk factors that could jeopardize the initiative.[5]

The project budget was to cover the costs of hiring qualified consultants to meet these objectives as well as to cover grant management expenses of the World Bank.[6] The work was to be outsourced to a single consulting firm, contracted by the World Bank, and overseen by a Project Management Team consisting of a Task Manager (World Bank Staff), one senior consultant, and one junior consultant.

Following BMGF's approval of the grant, Adeyi assembled a Project Management Team within the World Bank. Andreas Seiter was Task Manager from the end of 2006 to spring 2007, during which time Adeyi provided backup and engaged in networking. In spring 2007, Adeyi took over the reins as Task Manager. A short-term consultant was also hired to assist the work.

In fall 2006, the World Bank initiated the procurement process for consultants and sent out a Request for Proposals. Five major consulting firms submitted proposals. In November 2006, the World Bank, based on a review of the competing proposals, selected Dalberg Global Development Advisors, a relatively new consulting firm that specializes in international development and globalization.[7] The consultants' terms of reference (TOR) specified that the firm would undertake three major tasks:

1) Development of an operational model for a global subsidy of ACTs
2) Coalition building, education, and outreach
3) Analyzing issues and identifying opportunities to prepare the ground for the subsidy

Dalberg began project activities in December 2006, under a one-year contract with the World Bank. Two months later, the RBM Executive Committee approved the creation of a Global ACT Subsidy Task Force (later called the AMFm Task Force). The Task Force's role was to build consensus within the RBM Partnership on key factors related to the global ACT subsidy and present these to RBM Board members in late 2007. Specific areas of work included making recommendations on a series of technical issues, reaching out to stakeholders to create awareness and build support for the subsidy project, reaching

out to donors to mobilize funding, and raising awareness among malaria-endemic countries.[8] The United Republic of Tanzania (Minister of Health David Mwakyusa) and the Netherlands (Harry van Schooten of the Dutch Ministry of Foreign Affairs, on behalf of Rob de Vos, who left to become Ambassador to South Africa) were chosen as co-chairs of the Task Force. At the end of 2007, the Netherlands handed co-chair responsibilities to the U.K. Department of International Development (John Worley). Task Force membership was open to RBM partners. Members included UNICEF, WHO, the World Bank, BMGF, USAID/President's Malaria Initiative, GFATM, the private sector, NGOs, researchers, and other RBM partners. The RBM Executive Director, Awa Coll-Seck, and the RBM Secretariat facilitated and supported this group. The World Bank, through its subcontract to Dalberg, took on the role of Secretariat of the Task Force.

These three groups—the World Bank team, Dalberg, and the RBM AMFm Task Force—were the primary actors involved in the work program for the Global Subsidy Project. While the bulk of project activities ended in April 2008, these actors continued to work on the AMFm until the GFATM Board endorsed the operational plan in November 2008. Dalberg was hired in this April-November 2008 period by the GFATM Secretariat to continue development of the operational plan. The Global Subsidy Project did not fund this April-November 2008 period of work (apart from a consultant assigned to the GFATM Secretariat to work on monitoring and evaluation, and a contribution to an August 2008 meeting of stakeholders in Abuja), so it is not a direct focus of the evaluation.

3. Process Evaluation Methods

3.1 Evaluation terms of reference

The World Bank's terms of reference for this process evaluation were:

a. To assess the extent to which the project has met its stated goals and objectives, and assess the extent to which the project met any explicitly stated modification of those goals.

b. To measure these achievements against the most plausible counterfactual, i.e., what is the most likely scenario if the project had not been undertaken?

c. To describe the approach to the project, including the contents and processes, and assess these against best-in class comparators in development assistance.

The evaluation team included Dr. Laura Frost (consultant) who was project manager and conducted the interviews for the evaluation. Professor Michael Reich (Harvard School of Public Health) was the senior adviser on the evaluation team. Dr. Beth Anne Pratt (consultant) was the project researcher responsible for collecting and assessing all published and unpublished documents. Ms. Anya Levy Guyer (master's student, Harvard

School of Public Health) was the project researcher responsible for the comparator's analysis. The timeline for the evaluation was November 1, 2008 – March 31, 2009.

3.2 Evaluation approach and research questions

Process evaluations do more than assess the outcomes of a project. They are concerned with answering *how* and *why* an intervention was successful or not.[9] This process evaluation therefore sought to document the steps involved in achieving the project's outcome, and assess whether the project was delivered as planned. Our focus was on the work program made possible by the BMGF grant for the Global Subsidy Project. This includes activities undertaken by the World Bank team and Dalberg Global Development Advisors. It also includes activities undertaken by other partners including the RBM AMFm Task Force when their work was made possible by the BMGF grant. The evaluation does not assess either the merit or sustainability of the AMFm, and instead focuses on the *process* in developing the AMFm from research report into operational plan.

Appendix 2 shows the evaluation design, including research questions, indicators, and data sources. The evaluation had five research questions based on the evaluation's terms of reference written by the World Bank team that requested this assessment. The first four research questions are included in this evaluation report. The fifth research question is available in an appendix to this report.

- Research question 1: Was a detailed architecture and operational plan for a high-level global subsidy for effective antimalarials developed? (related to project objective 1)
- Research question 2: Was a coalition of donors and political support built? (related to project objective 2)
- Research question 3: Were questions related to external effects of the subsidy or external risk factors that could jeopardize the initiative addressed? (related to project objective 3)
- Research question 4: What is the most likely scenario if the project had not been undertaken?
- Research question 5: What parallels and differences are there between the process used to translate a research report into an operational plan for the subsidy and other previous similar processes in public health and development?

3.3 Description of methods

To assess the implementation of this project, the evaluation team developed indicators for each research question (see Appendix 2) and used three data collection methods. First, we conducted a literature review on malaria, artemisinin-based combination therapy (ACT), access barriers to ACTs, and theories on translating research to policy. Second, the team collected published and unpublished documents related to the AMFm. Finally, the project manager conducted 35 interviews with people involved in the process of translating the research report into the operational plan.

The interviews were conducted between February 4 and March 23, 2009, through in-person meetings (n=17) and by telephone (n=18). Most interviews lasted between 1-2 hours each, and were conducted with people in international organizations, donors, non-governmental organizations, academic institutions, think tanks, consulting firms, and Ministries of Health in malaria-endemic countries. Interview respondents were chosen from an initial contact list provided by the World Bank, and augmented through snowball sampling. Interview respondents were people working at the global level, or Ministry of Health staff involved in the global-level process of developing the AMFm. We did not conduct an in-depth survey of national-level actors in malaria-endemic countries because of the time and scope of the study. Interviews began with the questions "When did you first hear about the global ACT subsidy?" and "How were you involved in the development of the AMFm?" The interviews then explored each respondent's personal history and experience with the AMFm, their perspective on how the AMFm evolved over time, and their sense of the strengths and weaknesses of the research to policy process. In all the interviews, these questions led to an open-ended discussion of the process of developing the AMFm. We analyzed all interview transcripts and documents using the qualitative methods of thematic and textual analysis.

Evaluating the process of project implementation is difficult because it can involve subjective judgments about particular decisions and actions.[10] Our method was to interview people involved in the process to elicit respondent views on how the components of the project were conducted and how well they were conducted. The problem with this approach is the possibility of biased response or recall. We addressed this through triangulation, drawing on published and unpublished documents related to the AMFm wherever possible.

4. Process Evaluation Results

This section of the report presents the evaluation results for each research question. The results are based on the data collected for the evaluation (interviews and documents). We present this data in case study form in Appendix 3. As we present the evaluation results in this section, we refer in **bold** to relevant page numbers in Appendix 3 where more detailed explanation and data is provided.

4.1 Research Question 1: Was a detailed architecture and operational plan for a high-level global subsidy for effective antimalarials developed?

The first project objective was "to develop a detailed architecture and operational plan for a high-level global subsidy for effective antimalarials, including exit clauses to address situations in which the subsidy might no longer be needed or appropriate."

The evaluation found that the project successfully achieved its first objective. The work program for the Global Subsidy Project resulted in a technical design for a global ACT subsidy (endorsed at the 13th RBM Board meeting on November 28-29, 2007, in Addis Ababa, Ethiopia) **(p. 13)**. The technical design drew from consultations with 168 global stakeholders, 56 endemic country stakeholders in four different countries, and discussions

about the global subsidy in fifteen meetings between March and October 2007 **(p. 13)**. Four background papers were also commissioned, by Dalberg or subcontracted experts between April and November 2007 **(see Appendix 4)**. The work program between November 2007 and April 2008 also contributed to the largely internal GFATM process of developing this technical design into the detailed AMFm architecture and operational plan (approved by the GFATM Board at its 18th Board meeting from on November 7-8, 2008, in New Delhi, India) **(p. 18)**. The technical design and contributions to the GFATM's operational plan were essential to the process of establishing a viable global subsidy program at the GFATM. A lesson learned is that a detailed architecture and operational plan is not possible until the hosting institution (in this case, the GFATM) has been identified. Before this happens, then, technical work should focus more on technical "principles" than detailed operational plans.

Early in the project, the World Bank team and its RBM partners made a decision to develop the global subsidy technical design within an RBM task force established for this purpose—the AMFm Task Force. The fact that the technical design was developed within the AMFm Task Force had three important implications for the work. The first is that there was no one organization—but rather a Task Force—playing the role as "front person" for the work, particularly in the early months as individuals were getting to know each other and identifying priorities for the work program. In this context, working arrangements (and roles and responsibilities) need to be clarified early on in a new partnership **(p. 10)**. But this is not a simple process, for many reasons. The necessary roles and responsibilities may not be clear for a new entity; the partners may be just getting to know each other; the overall organizational home may not be decided. In short, many details are still evolving; as a result, the working arrangements are difficult to define and may require an iterative trial-and-error process.

The second implication is that the process led to strong ownership over the global subsidy within the RBM Partnership, a positive and necessary outcome that is critical for the AMFm in its implementation phase. The third implication is that the consensus-building process meant that compromises on the technical design had to be made, as RBM partners fought over the inclusion of certain interventions ("supporting interventions"). Many felt that supporting interventions were imperative for the successful implementation of the AMFm **(p. 13)**. Others felt that the supporting interventions were overloading IOM's original idea with too many health system issues that, while important, were not central to the AMFm. In the end, many of these interventions were included in the package; AMFm essentially became a combination of the original IOM concept and the "supporting interventions." Further compromises were made once GFATM was selected as the host for the global subsidy, in particular the decision to begin the AMFm with a Phase 1 limited roll-out in selected countries **(p. 15)**. A lesson learned is that consensus building can require compromises be made along the way to achieving an implementable plan for a research report's original idea.

4.2 Research Question 2: Was a coalition of donors and political support built?

The project's second objective was "to build a coalition that has the critical mass to generate funding and political support so that the subsidy can become reality."

As of January 2009, two funding commitments—from DFID and UNITAID—had been secured, providing enough funding for the subsidy for Phase 1.[11] The work program did not build a coalition of donors, but instead created the infrastructure that led to a funding commitment from DFID (a key participant in the AMFm development process) **(p. 17)** and UNITAID (a new player on the global health scene) **(p. 15, 18)**. A lesson learned is about the timing of fundraising. Until decisions about the operational plan and hosting arrangements had been reached, any attempts to secure funds were difficult as donors wanted to know first *who* and *what* they were funding. Donors often want to be involved in decisions about what they are funding, so it is important to involve them (at least informally) early on in the process. In addition, the changing context (such as the emergence of UNITAID on the global health scene) can benefit the process, and advocates should be strategic to take advantage of these changes.

The project did build a coalition of political support for the AMFm within the global health community by the end of the Global Subsidy project activities (April 2008), but this effort required intense effort and time by Dalberg, the World Bank team, BMGF, members of the IOM Committee, the RBM Secretariat, and other members of the AMFm Task Force. Project activities that proved successful in coalition building included an effort to "rebrand" the global subsidy that led to the name AMFm **(p. 11)**, and bringing in experts to the process when they were needed (such as Rob de Vos **(p. 9)**, Brad Herbert **(p. 13)**, Ricki Orford **(p. 14)**, and Todd Summers **(p. 16)**). The Clinton Foundation's HIV/AIDS Initiative (CHAI) with their partners in Population Services International (PSI) and the Tanzanian Government implemented small pilots of the ACT subsidy, which provided evidence to inform some of the discussions between proponents and opponents of the subsidy, but this research was funded by a separate BMGF grant and not part of the Global Subsidy project activities **(p. 12-13)**. In all, the Global Subsidy Project involved consultations with 168 global stakeholders, 56 endemic country stakeholders in four different countries, and discussions about the global subsidy in fifteen meetings between March and October 2007 **(p. 13)**. AMFm Task Force members and Dalberg carried out these consultations and meetings; most served the dual purpose of outreach and gaining feedback on the global subsidy technical design.

The process of coalition building showed that language matters when defining policy problems and solutions. Many people did not initially understand the concept of a global subsidy for ACTs, in part because it was based on economic reasoning, and this caused some public health people and policymakers to ignore the concept or misunderstand it **(p. 16)**. "Rebranding" the Global Subsidy as the Affordable Medicine Facility for Malaria was an important strategy in making these ideas more acceptable to certain audiences. The work program probably could have communicated the idea more effectively to non-economist audiences throughout the process by using language familiar to them (for example, GFATM language) and by presenting the ideas in formats that they could digest

(rather than large powerpoint decks). In addition, bringing the right people into the process, at the right time, is critical to success. A final lesson is that many global health actors will not buy in to a new idea until operational research has been conducted. The findings from operational research are important for coalition building as well as for refining strategies for implementation.

Despite the overall success in coalition-building, some groups opposed the AMFm because they did not believe it is the most effective tool to "save lives" and "buy time." Critics came from many different stakeholder groups. Two powerful opponents were Richard Feachem (formerly Executive Director of the GFATM) **(p. 4, 11)** and the U.S. President's Malaria Initiative **(p. 11)**. Criticisms became more sophisticated over time, and have included the following concerns: whether the global subsidy is essentially a subsidy to pharmaceutical companies; whether it is feasible or correct to provide the subsidy to private sector buyers; whether the private sector is needed to solve the malaria problem; whether the subsidy would reach the poorest of the poor; whether the idea would work in field implementation; whether the global subsidy was the best or most efficient way to spend scarce resources (time and money) in malaria control **(p. 9, 14)**. In their early coalition-building work, Dalberg, the World Bank team, and core partners did not anticipate these kinds of opposition to the global subsidy concept. At the same time, people who raised concerns often felt their views were not welcomed or listened to, and this alienated some stakeholders **(p. 9)**. The experience shows that new ideas—like the global subsidy idea—are often met with opposition from existing stakeholders for various reasons. Advocates must plan for the need to provide justification for their idea. An in-depth stakeholder analysis done early on could have helped the Global Subsidy Project prepare for the opposition that emerged and helped them create better strategies to address the concerns and build a coalition. An informal mapping of stakeholders was conducted midway through the project and helped to secure RBM Board approval of the AMFm at its meeting in November 2007. A more extensive analysis was successfully conducted later on in the process of developing the AMFm (after the end of the Global Subsidy Project work program) and the same technique could have been employed much earlier **(p. 16)**.

In short, the project did not begin with a clear sense of which groups in global health were stakeholders for the AMFm, and when and how they should be involved in the process of creating the global subsidy. Some stakeholders, such as CIDA **(p. 14)** and technical partners in malaria-endemic countries **(p. 17)**, became involved later on in the process. These groups then raised concerns about issues such as whether the AMFm would reach the "poorest of the poor" and whether the subsidy idea would work in the field. Overall, the work program would have benefited from an earlier environmental scan of key actors and stakeholder analysis, which would have helped identify who to involve in the process, and when and how to involve them.

Despite some opposition to the idea of a global subsidy, the work team achieved their goals of coalition building and mobilizing political support, in ways that helped establish the initiative. Consensus-building efforts rarely lead to unanimous support. These efforts require effective leaders who know when to end the consensus process and move forward

with the coalition of supporters that has been built. In the case of the AMFm, advocates created a forward momentum that opponents (including the US government and northern NGOs **(p. 18)**) decided not to block. Whether critics of the AMFm will support the initiative in its implementation stage is yet to be seen.

4.3 Research Question 3: Were questions related to external effects of the subsidy or external risk factors that could jeopardize the initiative addressed?

The third (and final) project objective was to "address questions related to external effects of the subsidy or external risk factors that could jeopardize the initiative." In their terms of reference, Dalberg asked was to select questions for analysis that would:

- Provide analysis of related questions of particular concern to stakeholders,
- Identify possible unintended adverse effects of the subsidy and define possible mitigation plans, and
- Identify other opportunities for enhancing malaria control that are created or made more attractive by the existence of the subsidy.

Between February and November 2007, the work program under the Global Subsidy Project achieved this project objective through analyses undertaken by Dalberg, or by experts subcontracted by Dalberg. Appendix 4 summarizes the four background papers and one workshop that were conducted to address external effects of the subsidy or external risk factors that could jeopardize the AMFm. Operational research in Tanzania was also conducted to address some of these issues, but this was funded by a separate BMGF grant to the Clinton Foundation HIV/AIDS Initiative (CHAI) in partnership with Population Services International (PSI) and the Tanzanian National Malaria Control Program **(p. 12-13)**.

4.4 Research Question 4: What is the most likely scenario if the project had not been undertaken?

The process evaluation's fourth research question assesses the main achievements of the project in relation to the most plausible counterfactual. Specifically, the evaluation asked: What is the most likely scenario—in terms of access to effective antimalarial drugs ("saving lives") and increasing the useful lifespan of artemisinins and future first-line antimalarials ("buying time")—if the Global Subsidy Project had not been undertaken?

In order to answer this question it is necessary to define: 1) the scenario made possible by the Global Subsidy Project, and 2) the most plausible counterfactual scenario. In defining the first scenario, we have already shown that the Global Subsidy Project was essential in the eventual establishment of the AMFm at the GFATM. But the AMFm has not yet entered the implementation stage. Thus, any comparison to a counterfactual scenario requires us to make the assumption that the AMFm will, starting in 2010, be globally implemented (following Phase 1 in 2009-2010).

The most plausible counterfactual requires estimating what today's context of malaria control will look like in 2010. This is a scenario that is quite different from the setting in 2002, when the IOM Committee began its work. Research results emerging from ACTWatch (a PSI research project that monitors the availability and affordability of ACT in eight countries) suggest that ACT prices are decreasing in some countries. In the Democratic Republic of Congo (DRC) for example, ACTs have decreased to $4 for a full adult course[12] (from earlier estimates of $10). These prices, however, are still high and will impede access unless they continue to trend downward over the next year. In the DRC, for example, ACTs are today almost seven times more expensive than SP. In this counterfactual scenario, there is increasing access to ACTs in the public sector in most malaria-endemic countries. This has been made possible from funds provided by the GFATM, the U.S. President's Malaria Initiative (PMI), UNITAID, and the World Bank Booster Program. Furthermore, as malaria-endemic countries continue their efforts to achieve the 2010 Abuja Declaration targets, malaria prevention technologies such as insecticide treated bed nets (and to a lesser extent, indoor residual spraying), have been increasingly scaled up. Finally, in the counterfactual scenario, reports of resistance to ACTs have begun to emerge. For example, a recent report confirms cases of ACT resistance in Cambodia.[13] Artemisinin monotherapy continues to circulate on the market, as do substandard or counterfeit ACTs.

Studies by Laxminarayan et al and the Clinton Foundation HIV/AIDS Initiative (CHAI) have compared the "no subsidy" and "global subsidy" scenarios. The Laxminarayan et al study[14] assesses whether a global subsidy for ACTs would save lives and reduce malaria (compared with a scenario of "no subsidy" in which artemisnin monotherapy or partner monotherapy would be used) and, if so, at what cost **(p. 5)**. They compare several scenarios including: no global subsidy, partial global subsidy, full global subsidy, and a two-year delayed global subsidy (where the full ACT subsidy would be introduced in year 3). The "delayed global subsidy" is the scenario that is the closest match to the scenario made possible by the Global Subsidy Project. The study found that a delayed subsidy would result in fewer deaths compared with the "no subsidy" scenario but at the risk of greatly exacerbating resistance brought on by the use of artemisinin monotherapy and partner monotherapy prior to the introduction of the global subsidy. The authors recommend that a global ACT subsidy be introduced immediately on all eligible drug combinations in order to delay resistance and "buy time" for further research and development of new antimalarial drugs.

Two recent studies by CHAI compare demand for ACTs without the AMFm and demand for ACTs with a global roll-out of the AMFm in 2010 (comparing aggressive, conservative, and moderate roll-out scenarios).[15] These studies suggest that even with increased funding to country-level donation programs and end-user subsidy programs, the private sector is unlikely to gain market share by 2011. They also find that in 2012, in a scenario without the AMFm, worldwide demand for ACTs will range from 179 to 198 million treatments. Demand will be 57-64% of global need. In a world with the AMFm, demand in 2010 could range from 222 to 445 million treatments, and could equal or exceed global need. The study authors point out that three variables have a great influence on demand estimates: the total antimalarial market size, the rate at which

countries start participating in the AMFm, and the rate of change in the market share of subsidized ACTs within participating countries. The authors conclude that the AMFm has the potential to dramatically increase access to ACTs.

Advocates for the AMFm have recognized from the beginning that it is not a "magic bullet" and is meant to serve as one strategy, among many, that will make ACT treatment more affordable, available, and effective to poor people in developing countries. An important aspect of the AMFm is that it is the only intervention to tackle the issue of drug resistance and price simultaneously. Several people interviewed for this evaluation argued that in light of recent reports of ACT resistance in Cambodia, the greatest contribution the AMFm can make is to "buying time" and they view global scale-up of the AMFm as urgent and essential for fulfilling this purpose.[16] The AMFm plan is an innovative idea, and an important one. Through consensus-building work in the RBM Partnership, many actors in the malaria community have collectively decided that the AMFm is a worthwhile experiment to invest in, at least in a Phase 1. It has the potential to be one among many ongoing efforts to "save lives" and "buy time."

5. Discussion of Results and Lessons Learned

The evaluation results demonstrate that overall, the three project objectives were achieved despite some continuing opposition to the AMFm within the global health community. The technical design, contributions to the GFATM's operational plan, and coalition building for funding and political support were all essential elements in the process of creating a new program to provide a global subsidy for ACTs at the GFATM.

5.1 Facilitating Factors

This process evaluation documented the steps involved in attaining the project goal and identified six key factors that explain the Global Subsidy Project's success.

5.1.1 The power of a good idea

The first factor is the global subsidy idea itself. The IOM Committee recommended the global subsidy as a "Good Idea" that could solve several problems at one time. The subsidy would at the same time enable widespread access to effective antimalarials (to "save lives") and delay the emergence of resistance to artemisinin (to "buy time"). The global subsidy idea is the only intervention in malaria control to tackle the issues of drug resistance and price simultaneously. Many of the people that were interviewed for the evaluation described their attraction to the idea, and stated that it was both "simple" and "elegant."[17]

5.1.2 Policy champions

The second factor relates to the presence of policy champions to propel the idea forward. The World Bank team—particularly Olusoji Adeyi—was an early policy champion for the global ACT subsidy. Previous studies in public policy and public health have pointed

to the importance of policy champions. Frost & Reich examine the role of policy champions in providing access to health technologies. [18] Kingdon, who studied the agenda-setting process for public policy, calls champions "policy entrepreneurs" who are willing "to invest their resources—time, energy, reputation, and sometimes money—in the hope of a future return. That return might come to them in the form of policies of which they approve, satisfaction from participation, or even personal aggrandizement in the form of job security or career promotion."[19] By the time the Global Subsidy Project work program had begun, a small, core group of policy champions had formed around Adeyi. This group expanded throughout the process, but remained small enough to function effectively. These policy champions represented different sectors—international organizations, foundations, think tanks, and donor countries (but not implementing agencies). All of them devoted their energy, time (often volunteer time), and in some cases reputation. As core members of the AMFm Task Force they were instrumental in pushing the work program forward. Throughout the process they kept an unwavering focus on their goal of establishing a global subsidy initiative.

5.1.3 Resources

Policy champions need resources to conduct their work and achieve successful outcomes. With the funding for the Global Subsidy Project ($4 million) from BMGF, the policy champions were able to launch the work program. This funding allowed the policy champions another key resource—a consulting firm (Dalberg Global Development Advisors) who worked full-time on grant activities from December 2006 to April 2008. Dalberg was an increasingly useful resource over time as their expertise grew and as the individuals involved in the World Bank team, the consulting firm, and the AMFm Task Force grew to know each other and established a working arrangement. Also critical to the work program were those AMFm members who volunteered their time and the RBM Secretariat that devoted significant staff time to the work program. These resources were used to create the technical document and outreach necessary for the coalition building and political mobilization that contributed to the initiative's establishment at the GFATM.

5.1.4 Legitimacy

Another important resource was the AMFm Task Force that was established by the RBM Partnership a few months after the Global Subsidy Project began. The Task Force—which included the early policy champions of the global subsidy, the RBM Secretariat, and other RBM partners—was established by RBM in early 2007 to steer the work forward. Task Force membership was open to all RBM partners, and this gave the global subsidy "institutional legitimacy" in the malaria community. The early policy champions felt that Kenneth Arrow could give the idea "academic legitimacy," the World Bank could give the idea "policy legitimacy," and bilateral donors like the Dutch and U.K. governments could give "political legitimacy," but that widespread ownership for the idea was needed within the malaria community if the concept was going to become a reality. Locating the work program within the AMFm Task Force did lead to a strong

sense of ownership for the global subsidy initiative within the RBM Partnership and malaria community, despite continued criticism for the initiative from some partners.

5.1.5 Organizational learning

Another important factor in the success of the Global Subsidy Project was that the groups involved in project implementation were learning and adapting to new developments as the process moved forward. For example, early in the project, the World Bank team and Dalberg realized that more attention in the work program needed to focus on engaging stakeholders, so Dalberg shifted more funding to this work and brought in outside experts to help change the tone of consultation and to focus more explicitly on advocacy and coalition-building.[20] Over time, the project team—the World Bank team, Dalberg, and the AMFm Task Force—honed outreach strategies and learned to bring in the right people at the right time in the process.

5.1.6 Political opportunities

The fourth factor was that the project team took advantage of political opportunities that arose in the global health context throughout the process. Kingdon refers to these opportunities as a "policy window."[21] Luck played its part in the changing context, but the project team used strategies to take advantage of the emerging political opportunities. One of these opportunities was the change of leadership at the GFATM in April 2007. While Richard Feachem had been a vocal opponent of the global subsidy, the situation changed when Michel Kazatchkine became Executive Director of GFATM in April 2007. Kazatchkine was favorable to the idea, and this provided a new opportunity for a hosting institution. The emergence of UNITAID in 2006 was also an important opportunity for the project team. These developments enabled global subsidy advocates to find an institutional home for the subsidy initiative and secure financing.

5.2 Problems encountered

This evaluation also identified some problems that the project team encountered in the process of project implementation. While these problems did not keep the Global Subsidy Project from reaching its goal, some issues led to time delays in the process while others may have consequences for AMFm's implementation phase.

5.2.1 Stakeholder alienation

One problem was that some stakeholders were alienated from the process, starting from the beginning of project activities. These individuals and groups felt that their concerns were not being adequately heard or were not welcomed by the advocates for the global subsidy. One reason for this problem is that early policy champions for the global subsidy did not fully anticipate the range of opposition to the global subsidy concept that emerged, nor did they anticipate the pockets of intense opposition. They were frustrated with many of the concerns raised by stakeholders and believed these concerns were based on a misunderstanding of the subsidy idea, personal or organizational interests, or deep-

rooted ideologies about the private sector. They did not begin the work program prepared with strategies to explain and justify the global subsidy idea to the wider stakeholder group.

5.2.2 Inadequate planning and stakeholder analysis

The project team did not have a clear sense from the beginning of the work program about who were the AMFm stakeholders, and a plan for how and when these stakeholders should be involved in the process. Some of the stakeholders came into the process late, including technical staff in malaria-endemic countries. It took time to understand their perspectives and concerns about the global subsidy. The project team had also not mapped the range of organizational positions on the subsidy idea, and was therefore not fully prepared to discuss stakeholder concerns. A stakeholder analysis (by the team or by outside experts)—that mapped stakeholders, their positions, and their power—conducted as an early project activity would have addressed this problem. Such an analysis was carried out later in the process of developing the AMFm and this proved essential to designing specific outreach strategies.

5.2.3 Insufficient communication

A third problem is that the project team did not always "package" materials for outreach or education efforts in the most effective manner. People involved in the process report receiving stacks of paper on the global subsidy (too much to read) in language that did not always make sense to them (too difficult to understand). A more explicit focus in the work program on appropriate communications and packaging could have made outreach activities more effective.

5.2.4 A delayed focus on implementation issues

Some stakeholders felt the issues they raised about field-level realities were not given adequate consideration through the process and are only now being addressed. The work program for the Global Subsidy Project focused around RBM, GFATM, and UNITAID Board meetings. The project team believed that a focus on these Boards was critical to achieving their overall goal. But the result was that some key field-level concerns (such as the role of local manufacturers in the AMFm or the level of the copayment) are only now being addressed in the AMFm pre-launch period. This situation was inevitable in part given both time and resource constraints. One way that these concerns could have been addressed earlier was to involve people with field-level expertise on the Global Subsidy project team from the beginning (this was done later when Ricki Orford of PSI was asked to joined the GFATM Secretariat and Dalberg team in Geneva). Another strategy would be to conduct the technical work on the global subsidy in the field where local concerns become more clear and pressing.

5.4 Lessons Learned

This process evaluation assessed the implementation of the Global Subsidy Project and identified lessons for future efforts to translate a research report into an operational plan. Overall, we have found that the process of translating a research report into an operational plan is a political as well as a technical process. The process is complex and time-consuming and requires effective strategies to propel an idea forward. In the evaluation report, we have identified the following specific lessons:

- Facilitating factors in translating a research report to an operational plan include a "Good Idea," policy champions, resources, legitimacy, organizational learning, and political opportunities.

- A detailed architecture and operational plan is not possible until the hosting institution has been identified. Before this happens, then, the technical work may need to focus more on technical "principles" than detailed operational plans.

- The consensus-building process can require compromises to a research report's original idea.

- Working arrangements (and roles and responsibilities) need to be clarified early on in a new partnership. But this is not a simple process, for many reasons. The necessary roles and responsibilities may not be clear for a new entity; the partners may be just getting to know each other; the overall organizational home may not be decided. In short, many details are still evolving; as a result, the working arrangements are difficult to define and may require an iterative trial-and-error process.

- Until decisions about the hosting arrangement are reached, any attempts to secure funds are difficult as donors want to know first *who* and *what* they are funding. Donors often want to be involved in decisions about what they are funding, so it is important to involve them (at least informally) early on in the process.

- A changing context (such as the emergence of UNITAID on the global health scene) can benefit the process, and advocates should be strategic to take advantage of these changes.

- Language matters when defining policy problems and solutions. Reframing a policy problem or solution (through rebranding, for example) can be an effective strategy.

- Bringing the right people into the process, at the right time, is critical to success.

- Many global health actors will not buy into a new idea until operational research has been conducted. The findings from operational research are important for both coalition building and designing implementation strategies.

- Fully incorporating field-level concerns into operational plans is difficult when the work program is focused at the global level. Innovative solutions need to be considered and tried.

- New ideas—like the global subsidy idea—are often met with opposition. Advocates must plan for the need to provide justification for their idea. An in-depth stakeholder analysis done early on can help the project team create effective strategies and activities.

- Consensus-building efforts rarely lead to unanimous support. These efforts require effective leaders who know when to end consensus building, how to find effective compromises, and when to move forward with the coalition of supporters that has been built.

6. Conclusions

This process evaluation found that the Global Subsidy Project's work program was essential to achieving the goal of establishing a viable, funded, global subsidy entity (the AMFm) at the GFATM. Specifically, the work program was based on a "Good Idea" and had policy champions and sufficient resources to propel the work forward. The actors conducting the work activities sought legitimacy in different organizations, demonstrated organizational learning, and took advantage of political opportunities in a changing global health context.

The evaluation also demonstrates that the process of translating the IOM research report into the AMFm operational plan is a complex task requiring political as well as technical strategies. The global ACT subsidy was a new idea in global health, and was met with individual and organizational perspectives that are deeply rooted in experience with implementation, as well as ideology and politics. As such, the translation process was as much a political as technical task and coalition building for political support became the core project activity. Under the work program, actors used a set of strategies that were successful in bringing stakeholders into the coalition. Other aspects of the coalition building process were less successful, leading to delays in the timeline and stakeholder alienation in some cases (with possible implications for AMFm's implementation phase). Conducting an in-depth stakeholder analysis early in the process of translating a new idea like the global ACT subsidy into an operational plan can help the project team plan better and save time in shaping coalition-building strategies from the beginning of project activities. It can also guide a project team in timing project activities and bringing in the right people at the right time to conduct these activities.

In sum, navigating the process of translating a research report into an operational plan in the global health landscape requires a powerful idea and an equal amount of determination, political savvy, planning, openness to new ideas, a willingness to make compromises, and adaption to new circumstances.

End Notes

[1] The session is available online at http://info.worldbank.org/etools/docs/voddocs/632/1289/lo.htm.
[2] Ramanan Laxminarayan, Mead Over, and David Smith, "Will a global subsidy of new antimalarials delay the emergence of resistance and save lives?" (World Bank Policy Research Working Paper 3670, July 2005).
[3] GFATM, *Report of the affordable medicines facility for malaria – Malaria Ad Hoc Committee* (Decision GF/B18/7, 18th Board Meeting, New Delhi, India) November 7-8, 2008.
[4] World Bank, *Project Proposal: Defining the Architecture and Management of a Global Subsidy for Antimalarial Drugs* (Proposal to the Bill and Melinda Gates Foundation) May 24, 2006: 4.
[5] The original project proposal lists objective 3 in two different ways. On page 4, it is listed as "to address questions related to external effects of the subsidy or external risk factors that could jeopardize the initiative." On page 6, it is listed as "to identify other opportunities for enhancing malaria control that are created or made more attractive by the existence of the subsidy." We write the objective as it is first stated in the project proposal (on page 4).
[6] World Bank, *Project Proposal.*
[7] Interview #19 by author (Laura J. Frost).
[8] The World Bank, *Defining Architecture and Management of a Global Subsidy for Antimalarial Drugs and Building a Coalition that has Political Weight and Financial Power to Implement It: Terms of Reference for a Consulting Project* (Washington, DC: World Bank).
[9] Allan Steckler and Laura Linnan, eds, *Process Evaluation for Public Health Interventions and Research* (San Francisco, CA: Jossey-Bass, 2002).
[10] Steckler and Linnan.
[11] Interview #3 by author (Laura J. Frost).
[12] Population Services International, *Baseline Outlet Survey Report, DRC* (ACTWatch Evidence for Malaria Medicines Policy, March 2009), http://www.actwatch.info.
[13] William Rogers, Rithy Sem, Thong Tero, Pharath Chim, Pheaktra Lim, Sinuon Muth, Dong Socheat, Fréderic Ariey, and Chansuda Wongsrichanalai, "Failure of artesunate-mefloquine combination therapy for uncomplicated Plasmodium falciparum malaria in southern Cambodia," *Malaria Journal* 8 (2009).
[14]Ramanan Laxminarayan, Mead Over, and David Smith, "Will a global subsidy of new antimalarials delay the emergence of resistance and save lives?" (World Bank Policy Research Working Paper 3670, July 2005); Ramanan Laxminarayan, Mead Over, and David L. Smith, "Will a global subsidy of new antimalarials delay the emergence of resistance and save lives?" *Health Affairs* 25 (2006): 325-336.
[15] Clinton Foundation HIV/AIDS Initiative, *Global Forecast of ACT Demand: Initial Report* (Boston, MA, CHAI, 2008); Clinton Foundation HIV/AIDS Initiative, *An Analysis of Global ACT Demand under the Affordable Medicines Facility for malaria (AMFm)* Boston, MA, CHAI, 2008).
[16] Interviews #4, #10, and #23 by author (Laura J. Frost).
[17] Interviews # 4 and #18 by author (Laura J. Frost).
[18] Laura J. Frost and Michael R. Reich, *Access: How do good health technologies get to poor people in poor countries?* (Cambridge, MA: Harvard Center for Population and Development Studies, 2008).
[19] John W. Kingdon, *Agendas, Alternatives and Public Policies* (Boston: Little, Brown, 1984), 129.
[20] Interviews #10 and #21 by author (Laura J. Frost).
[21] Kingdon.

Appendix 1: Timeline for the Process of Developing the IOM Research Report into the AMFm Operational Plan

This timeline records key events in the process of developing the IOM's research report on the global subsidy, *Saving Lives, Buying Time*, to an operational plan for the Affordable Medicines Facility for malaria (AMFm). The timeline also includes developments in the global health landscape related to malaria control and financing mechanisms. These developments are provided in the timeline in italics.

2001

- USAID commissions Board on Global Health at the US Institute of Medicine (IOM) to look into innovative financing strategies for malaria treatments in response to increasing resistance to existing medicines.

2002

- Board on Global Health at the US Institute of Medicine (IOM) convenes a committee exploring innovative financing strategies for malaria treatments in response to increasing resistance to existing medicines.
- *GFATM established.*
- *Roll Back Malaria Partnership Secretariat restructured.*
- *WHO endorses adoption of ACTs as the first-line treatment for uncomplicated P. falciparum and establishes prequalification mechanisms for manufacturers of artemisinin compounds and ACTs.*

2003

- ***December**: RBM issues draft technical document to establish Malaria Medicines and Supply Service (MMSS) within RBM to aid on procurement of drugs, including ACTs, and malaria supplies in general. Consultation starts.*

2004

- ***January:** GFATM begins reprogramming all approved grants to procure ACTs, rather than CQ or SP, in areas where there is demonstrable resistance to the latter.*
- ***April:** World Bank Booster Program launched.*
- **July:** IOM releases the report *Saving Lives, Buying Time* calling for a global subsidy of ACTs. Soji Adeyi, of the World Bank, takes a personal interest in the report.
- **September**: World Bank sponsors RBM Finance and Resources Working Group meeting in Washington, D.C. (Sept. 8-9) and initiates study into the economic and

epidemiological costs and benefits of initiating a global subsidy on ACTs in relation to counterfactual proposals.

2005

- *All Party Parliamentary Group on Malaria (APPGM) launched in UK to promote and lobby within parliament on better UK government financing of global malaria activities.*
- **July:** Laxminarayan, Over, and Smith publish DEC working paper on global ACT subsidy.
- **September:** World Bank holds donors' conference in Paris (Sept 8-9) to discuss Booster Program for Malaria. RBM Finances and Resources Working Group asks World Bank to develop detailed proposal for the design and operation of a global ACT subsidy to be submitted to BMGF.

2006

- ***January:*** *WHO appeals to manufacturers to cease marketing oral AMT and to promote quality ACTs*
- **February:** *Health Affairs* publishes Laxminarayan, Over and Smith article on the Global ACT subsidy, originally a DEC working paper.
- ***April:*** *WHO Global Malaria Program provides technical briefing to 25 pharmaceutical companies involved in production and marketing of AMTs. 15 agree to stop marketing AMTs over short term, 10 refuse to say.*
- **May:** World Bank submits proposal to BMGF, on behalf of RBM, to develop the design and operation of a global ACT subsidy.
- **August:** BMGF approves World Bank proposal, on behalf of RBM, to develop the design and operation of a global ACT subsidy. The grant for $4, 085,789 was approved for 22 months.
- ***September:*** *UNITAID founded to develop innovative financing mechanisms for reducing the price of drugs for HIV/AIDS, Malaria and TB.*
- **November:** Dalberg awarded contract by World Bank to produce technical design for the global ACT subsidy, to conduct outreach, and to undertake additional analyses.
- **December:** Dalberg begins the work program for translating the IOM proposal into an operational plan.

2007

- ***Clinton*** *HIV/AIDS Initiative (CHAI) expands work to include increasing access to ACTs.*
- **January:** RBM Expert Workshop and Consultative Forum held in Amsterdam (Jan.18-19), hosted by the Dutch government, leading to the endorsement and creation of a RBM task force (the RBM Global ACT Subsidy Task Force) to steer the AMFm project.

- **February:** RBM Executive Committee approves the creation of the Global ACT Subsidy Task Force, co-chaired by Harry van Schooten (Dutch government) and David Mwakyusa (Minister of Health, Tanzania).
- **March:** AMFm discussed and consultation held by the MMV Access and Delivery Advisory Committee meeting in Amsterdam (Mar. 6).
- **April:** AMFm discussed and consultation held at the African Health Ministers' Conference in Johannesburg (Apr. 10-13).
- **May:** 12th RBM Board Meeting held in Geneva (May 10-11). RBM Global ACT Subsidy Task Force agrees upon and submits outline technical proposal, process and timeline to RBM Board. RBM Board approves objectives and principles for technical design document.
- **Summer:** Global ACT subsidy rebranded "AMFm" and term "subsidy" changed to "buyer copayment." The name of the RBM Global ACT Subsidy Task Force is changed to the AMFm Task Force.
- **July:** Dalberg submits draft technical design for the AMFm.
- **August:** WHO convenes informal consultation with manufacturers, national health authorities of countries that have made successful progress at AMT withdrawal, technical experts and WHO technical resource people.
- **September:** 3rd RBM Harmonization Working Group (HWG) holds meeting in Geneva (Sept. 10-11). The HWG is briefed on the ACT subsidy and asked to consider what role it can play in it, with the agreement to carry out a needs assessment at the country level with financing from Malaria No More.
- **September:** AMFm discussed and consultation held at GFATM Policy and Strategy meeting in Geneva (Sept. 19-21).
- **September:** MMV in partnership with the Ugandan Ministry of Health hold a workshop on Improving Access to ACTs in which AMFm is discussed (Sept. 26- Oct. 3).
- **October:** Operational research begins in Tanzania piloting the subsidy in 3 rural districts. Research is financed by BMFG, implemented by CHAI and Population Services International (PSI) in partnership with Tanzania's National Malaria Control Programme (NMCP).
- **October:** Evidence presented to APPMG in the House of Commons leading to UK parliamentary endorsement of AMFm (Oct. 9).
- **October:** AMFm discussed and consultation held at the RBM Procurement and Supply Chain Management Working Group meeting in Washington, D.C (Oct. 11).
- **October:** World Malaria Forum held in Seattle (Oct. 16-18). A high-level meeting on the sidelines of the Forum leads to a decision that GFATM will move forward with plans for hosting the AMFm.
- **November:** 13th RBM Board Meeting held in Addis Ababa (Nov. 28-29). Technical design document submitted by RBM AMFm Task Force. Board of RBM partnership endorses Task Force's work and invites Global Fund to host and manage the AMFm as a

business line. GFATM Board agrees to consider the possibility of managing AMFm as business line.

- **November:** World Bank extends Dalberg's contract for 6 months to help support Task Force's work.
- **December:** UNITAID Board agrees that the UNITAID Secretariat should explore ways in which UNITAID might be involved in the AMFm.
- **December 2007 – January 2008:** RBM AMFm Task Force works on outstanding implementation challenges as brought up at RBM Board meeting in Addis Ababa.

2008

- **February:** RBM AMFm Task Force Meeting in London (Feb. 1) sponsored by DFID to address the remaining implementation challenges.
- **February:** RBM Harmonization Working Group (HWG) meeting in Geneva (Feb. 18-19). HWG presents AMFm country readiness assessment to the RBM Executive Committee which initially refuses to accept it until revisions take place
- **April:** 17th GFATM Board Meeting held in Geneva (Apr. 28-29) agrees to have the GFATM secretariat host and manage the AMFm as a business line.
- **April**: Dalberg hired directly by the Global Fund to work with GFATM Ad Hoc Committee on the AMFm.
- **April:** 7th UNITAID Board Meeting in Brasilia, Brazil agrees to support in principle the development of the AMFm and discuss working with GFATM in a number of potential roles, including that of donor.
- **May:** 14h RBM Board Meeting held in Geneva (May 15-16) asks AMFm Task Force to continue to work with Global Fund and other partners on outstanding challenges while Global Fund Secretariat prepares implementation plan for final GFATM Board approval.
- **June:** MMV holds symposium in Accra on *Expanding Reach of ACTs in the Private Sector: Dialogue with Countries* (Apr. 28-29) at which AMFm is discussed.
- **August:** RBM AMFm Task Force meets in Geneva (Aug. 19) to discuss and hone the AMFm implementation plan hosted by RBM Secretariat.
- **August:** PSI and Society for Family Health, Nigeria host a country consultation in Abuja (Aug. 5-6) in order to meet with country level technical partners and other stakeholders
- **September:** Millennium Development Goals Malaria Summit in New York City launches global Malaria Action Plan, developed by RBM partnership (Sept. 25). At the Summit, Prime Minister Gordon Brown announces that the United Kingdom will contribute £40 million to the AMFm.
- **September:** Resources for the Future holds consultative forum on the AMFm in Washington D.C. (Sept. 26-28)
- **October:** The Artemisinin Enterprise (AE) holds a conference in York, UK looking at global ACT supply and ways to interface AE's efforts with that of AMFm (Oct. 8-10).

- **October:** 5th RBM HWG meeting in Geneva (Oct. 28-29) discusses AMFm and the way in which could support it. There is some disagreement as to whether or not HWG should be involved with the final decision stating that the a partner should be contracted to manage the AMFm, working with RBM directly through the HWG
- **November:** 18th GFATM Board Meeting held in New Delhi, India (Nov. 7-8). The Board endorses the policy framework and implementation plan and grants approval to host.
- **November:** Pre-Launch period begins (November 2008-April 2009). Official launch of the AMFm was scheduled for April 2009. The AMFm's Phase 1 was scheduled to end in 2010.

Appendix 2:
Evaluation Design

Evaluation research questions	Indicators	Data sources
Research Question 1: Was a detailed architecture and operational plan for a high-level global subsidy for effective antimalarials developed? (related to project objective 1)		
1a: Was a detailed architecture and operational plan for a high-level global subsidy for effective antimalarials developed, including exit clauses?	• An architecture & operational plan was completed **(See evaluation document, p. 7)**	• Documents related to the AMFm Interviews with AMFm stakeholders
1b: Who developed the architecture and operational plan? What activities did these actors undertake, and how did these activities affect their ability to complete the architecture and operational plan?	• Number and scope of activities undertaken (including consultations and background papers commissioned) **(See evaluation document, p. 7)**	• Documents related to the AMFm Interviews with AMFm stakeholders
Research Question 2: Was a coalition of donors and political support built? (related to project objective 2)		
2a: Was a coalition of donors built who were i) willing to fund the subsidy, and ii) willing to work together on the subsidy?	• Presence of coalition of key donors in global health with the goal of working together on the subsidy **(See evaluation document, p. 7-8)** • Financial resources committed by donors for the subsidy **(See evaluation document, p. 8)**	• Documents related to AMFm • Media reports related to the AMFm Interviews with AMFm stakeholders
2b: What are the perceptions of the global subsidy for antimalarial drugs idea by key groups in global health? How do these perceptions match the project's view of the subsidy idea? Key groups include: i) donors; ii) NGOs in donor & recipient countries; iii) Ministries of Health in recipient countries; iv) international organizations; v) academics; vi) manufacturers, etc.	• Perceptions of key groups in global health about the subsidy idea **(See evaluation document, p. 8-9)** • Perceptions of project team about the subsidy idea **(See evaluation document, p. 8-9)**	• Documents related to AMFm • Media reports related to the AMFm Interviews with AMFm stakeholders
2c: Has the project managed these perceptions in terms of	• Number and scope of meetings and individual	• Documents related to AMFm

educating key groups in global health about the benefits of the subsidy and what it can and cannot achieve; engaging key groups in global health who have negative perceptions about the subsidy idea, and addressing their concerns and potential resistance; and gaining adoption within the broader political environment (specifically persons with responsibility for health services) in donor and recipient countries?	consultations held with key groups to build political coalition **(See evaluation document, p. 8-9)** • Quality of materials provided to potential stakeholders **(See evaluation document, p. 8-9)** • Scope of strategies designed to build political support **(See evaluation document, p. 8-9)**	especially meeting reports/transcripts • Media reports related to the AMFm • Interviews with AMFM stakeholders
Research Question 3: Were questions related to external effects of the subsidy or external risk factors that could jeopardize the initiative addressed? (related to project objective 3)		
3a: Were questions related to external effects of the subsidy or external risk factors that could jeopardize the initiative addressed?	• Meetings on these questions held **(See evaluation document, p. 9-10)** • Written analyses of these questions completed **(See evaluation document, p. 9-10)** • Number of these questions addressed **(See evaluation document, p. 9-10)**	• Documents related to the AMFm • Interviews with AMFm stakeholders
Research Question 4: What is the most likely scenario if the project had not been undertaken?		
4a: What is the most likely scenario if the project had not been undertaken? (Assess the achievements in relation to the most plausible counterfactual)	• Malaria mortality/morbidity data for the different scenarios (where it exists) **(See evaluation document, p. 10-11)** • ACT demand data for the different scenarios (where it exists) **(See evaluation document, p. 10-11)** • Resistance data for the different scenarios (where it exists) **(See evaluation document, p. 10-11)** • Qualitative description of the different scenarios **(See evaluation document, p. 10-11)**	• Documents related to the AMFm Interviews with AMFm stakeholders

Research Question 5: What parallels and differences are there between the process used to translate a research report into an operational plan for the subsidy and other previous similar processes in public health and development?		
5a: What parallels and differences are there between the process used to translate a research report into an operational plan for the subsidy and other previous similar processes in public health & development?	• Parallels and differences between the AMFm translation process and the translation process in previous similar examples in public health & development **(See comparators report)**	• Theoretical literature about translation • Documents related to the AMFm • Documents on similar efforts in development assistance • Interviews with key actors in other efforts • Interviews with AMFm stakeholders

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Appendix 3:
A Case Study of the Process of Developing the Affordable Medicines Facility for Malaria (AMFm)

This case study describes the process of translating the IOM research report on the global subsidy, *Saving Lives, Buying Time*, to an operational plan for the Affordable Medicines Facility for malaria (AMFm) between 2001 and 2008. It is based on data from published and unpublished documents, and in-depth interviews with 35 people involved in the process.

1. Introduction

In July 2004, the Board on Global Health of the U.S. Institute of Medicine (IOM) released a report called *Saving Lives, Buying Time* that recommended the creation of a global-level subsidy for the new category of antimalarial drugs, artemisinin-based combination therapy (ACT). It recommended the establishment of a global fund that would purchase ACTs from manufacturers at a dollar price per dose and resell it at one-tenth of that price. The subsidized ACTs would be accessible by both the public and private sectors of all malaria-endemic countries. The subsidy would at the same time enable widespread access to effective antimalarials (to "save lives") and delay the emergence of resistance to artemisinin (to "buy time"). Four and a half years later, the Board of the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) approved a policy framework and implementation plan that will operationalize the global ACT subsidy through an entity known as the Affordable Medicines Facility for malaria (AMFm). The Board also reaffirmed its decision to host and manage the AMFm for an initial phase in a limited number of countries.[1] This case study documents the process of translating the idea of a global ACT subsidy into the AMFm operational plan during this four and a half year period.

Specifically, the case study explores the complex process of moving forward with a new idea within the global health landscape. It details the strategies that a core group of policy champions used to engage stakeholders, allay fears, generate political will, secure financing, create ownership, and negotiate operational details. It looks at both obstacles and opportunities encountered by policy champions throughout this policy process and shows how these led to both compromises and considerable achievements. The case therefore focuses on the *process* of developing the AMFm rather than the *content* of the AMFm operational plan. It does not assess the implementation of the AMFm, which has not yet occurred. It also does not examine the work following the GFATM Board decision in November 2008 to fine-tune the operations of the AMFm, as these efforts are not yet complete.

2. Malaria and its treatment

Malaria is a parasitic infection spread from person to person by the bite of the female *Anopheles* mosquito. Every year, malaria parasites infect approximately 250 million people, over half of whom children.[2] Over half of the world's population currently lives in malaria-endemic countries, many of which are classified as "less developed" and already face considerable human and economic development challenges.[3] There are four types of human malaria; *Plamodium falciparum* is the most deadly and is also the type most common to sub-Saharan Africa. Morbidity from *P. falciparum* has widespread consequences for both the health systems and economies of developing countries.

In the early 1950s, chloroquine was introduced as the primary first-line drug for malaria. Affordable and available, it continues to be a widely used treatment in many malaria-endemic countries But *P. falciparum* resistance to chloroquine is now so extensive that chloroquine is no longer considered an effective treatment for this type of malaria.[4] In response to widespread resistance to chloroquine, many countries in the 1980s and 1990s began to substitute sulphadoxine-pyrimethamine (SP) as a cost-effective alternative. SP, like chloroquine, is affordable, available, and commonly prescribed throughout both the public and private sectors in Africa. But SP resistance has been increasing and the World Health Organization (WHO) now only recommends the drug for intermittent preventive treatment in pregnant women.[5]

Presently, the only treatment for which *P. falciparum* malaria has not developed significant resistance is artemisinin, a drug derived from the Chinese plant *Artemisia annua*. In order to preserve artemisinin's effectiveness and extend the life of other, less effective antimalarials, WHO recommend that artemisinin derivatives be used in combination with another partner drug (such as lumefantrine, amodiaquine, SP, or mefloquine).[6] These combination antimalarials are known as artemisinin-based combination therapies, or ACTs. Currently, WHO lists ten companies that make artemisinin-based antimalarials that the agency says are acceptable, in principle, for procurement by UN agencies. These companies include both western manufacturers such as Sanofi Aventis and Novartis, as well as a number of Indian generic producers.[7] There are about a dozen other manufacturers of ACTs, including local manufacturers in Kenya, Cameroon, Ghana, and Uganda.[8]

In April 2002, WHO endorsed the adoption of ACTs as a first-line treatment for uncomplicated *P. falciparum* malaria in countries with significant resistance to chloroquine. To further encourage the transition to ACTs, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) in 2004 began reprogramming all approved grants to procure ACTs in areas where there is demonstrable resistance.[9] But two key barriers to widespread ACT access are affordability and availability. A single dose of ACT can cost up to twenty times more than a dose of chloroquine or SP, due to the high cost of producing the combination therapy.[10] Until August 2007, Coartem® (manufactured by Novartis) was the only WHO-prequalified fixed-dose combination on the market.[11] Prequalification meant that Coartem® was the primary drug of choice for public-sector procurement and for use in clinical trials. The production process of ACT is

complex and involves the long growing cycle of *Artemisia*, the artemisinin extraction process, and the difficulties of combining artemisinin with a partner drug. This coupled with high demand for Coartem® by international and public sector procurement agencies, led to increasing Coartem® shortages once the reprogramming of GFATM grants got underway.

There are also concerns about emerging resistance to artemisinin. Artemisinin monotherapy (AMT) circulates on the market in many countries, threatening the lifespan of artemisinin. Substandard or counterfeit ACTs are also available and increase the probability of parasite mutation and resistance. A recent report confirms cases of ACT resistance in Cambodia.[12] In May 2007, the World Health Assembly passed a resolution requiring member states to withdraw oral AMT from the public and private sectors, to promote the use of quality ACTs, and to take measures to prevent counterfeits from being produced and distributed. Some countries continue to allow AMT to be marketed and as of August 2007, 67 companies continued to produce and market AMT.[13] There is an increasing sense of urgency among members of the global health community to find innovative solutions to high ACT prices and supply-side uncertainty, and to delay resistance to artemisinin.

3. The Institute of Medicine Committee on the Economics of Antimalarial Drugs *(2001-July 2004)*

In 2001, the United States Agency for International Development (USAID) asked the Institute of Medicine (IOM) in Washington, D.C. to convene a panel to assess the economics of antimalarial drugs. The committee's task would be to "recommend steps that could be taken to maximize the influence of both new and established antimalarial drugs while postponing the development of drug resistance."[14] USAID was interested in two key areas: 1) ensuring that new and existing antimalarial drugs were affordable to the people who needed them, and 2) ensuring that antimalarial drugs were engineered, produced, packaged, and delivered in ways that encouraged adherence to prescribed regiments.[15] USAID wanted to know how to extend the life of SP as an effective antimalarial drug and how to make artemisinins more affordable. IOM wanted to focus on the broader question of how to make antimalarial drugs more affordable.[16] After a year of discussions between the two groups, it was decided that the Committee would focus its attention on the affordability of antimalarial drugs. During the period of discussion between USAID and the IOM, WHO had made a recommendation that artemisinins should be used in combination with other antimalarials to protect the compound from drug resistance.[17]

In 2002, the IOM's Board on Global Health convened a committee—the IOM Committee on the Economics of Antimalarial Drugs—to examine the questions posed by USAID. The chair of the Board on Global Health was Dean Jamison, Professor of Public Health and Education at the University of California in Los Angeles. He asked his former PhD advisor, Kenneth Arrow of Stanford University, a Nobel Laureate in economics and a founding member of the IOM, to be chair of the Committee. As Arrow states, "they convinced me quite quickly to be Chair. I like challenges and had done nothing in this

area of malaria and global health, so I thought this would be an interesting challenge."[18] Jamison also asked Hellen Gelband and Claire Panosian to staff the Committee; they were responsible for project management and writing the report. Jamison, Arrow, and their colleagues then assembled the members of the Committee, seeking a balance between economists and public health experts with malaria expertise.

The Committee held a series of meetings in Europe and the United States, invited experts to present their work, and commissioned studies. While USAID provided initial funding for the Committee's proceedings, the Bill & Melinda Gates Foundation (BMFG) later became a co-sponsor. The idea for a global subsidy for antimalarial drugs, accessible by the public and private sectors, emerged early in Committee proceedings. Jamison, for one, had been considering the idea since his work at the World Bank, where he learned the challenges of addressing procurement problems at the country level.[19] Likewise, in his research and discussions on malaria before the Committee was even constituted, Arrow learned that the private sector plays a key role in the distribution and delivery of antimalarials, particularly in Africa.[20] He knew that these distribution and delivery issues would be central to the Committee's discussions.

After weighing the advantages and disadvantages of both targeted and broad subsidies, as well as subsidies administered at country and global levels, the Committee concluded a broad subsidy at the global level for ACTs would be more efficient and equitable than targeted subsidies or subsidies at the national or end-user levels.[21] It recommended the establishment of a global fund that would purchase ACTs from manufacturers at a dollar price per dose and resell it at one-tenth of that price. The subsidized ACTs would be accessible by both the public and private sectors of all malaria-endemic countries. The subsidy would at the same time enable widespread access to effective antimalarials (to "save lives") and delay the emergence of resistance to artemisinin (to "buy time"). The Committee argued that a global subsidy allowed ACTs to flow to both the public and private sectors, and also freed up countries to pursue malaria policies most appropriate to their circumstances without having to divert funds better used for other interventions toward ACT purchase. The Committee also believed that a global subsidy would give the international community leverage to force artemisinin manufacturers to stop monotherapy production. The Committee spent time assessing a number of different alternatives before recommending the global subsidy as a solution to the challenges of making ACTs more affordable and staving off resistance to artemisinin compounds.[22]

The Committee presented its recommendations in a report called *Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance*, released in July 2004. Prior to the release of the report, Arrow presented the Committee's findings to USAID staff members by phone. USAID accepted the recommendation but took no steps to take the idea forward. The GFATM, which had recently been established in 2002, did not respond favorably to the report's recommendations. Richard Feachem, the Executive Director of the GFATM, wrote a letter to Arrow stating that the global subsidy was not necessary because it already existed in the form of the GFATM. He argued that the private sector could apply for subsidized ACTs from the GFATM (with a 100% subsidy) through the national-level country coordinating mechanism.[23] Feachem may have also been

concerned that a new global subsidy entity could potentially take resources from the GFATM.[24] With this kind of opposition, it was clear that the global subsidy idea needed a sponsor to propel it forward.

4. The emergence of policy champions *(July 2004-December 2006)*

In mid-2004, Olusoji Adeyi, Coordinator of Public Health Programs in the World Bank's Human Development Network, received a prepublication version of *Saving Lives, Buying Time*. He was leaving for vacation so he put the report in his bag and forgot about it. Later, sitting on the beach in North Carolina, he removed the report and read it. As he recounts, "the idea of a global ACT subsidy struck me as an incredibly bright and simple idea. I wanted to get back to the office right away to start working on it."[25]

Adeyi at this time served as co-chair of the Roll Back Malaria (RBM) Partnership's Working Group on Finance & Resources (FRWG). The RBM Partnership, established in 1998 by WHO, UNICEF, UNDP, and the World Bank, is made up of partners from multilateral organizations, OECD donor countries, malaria-endemic countries, the GFATM, NGOs, foundations, the private sector, and researchers and academics. RBM also has sub-regional networks and a set of working groups, including the FRWG. In its role as co-chair, the World Bank convened a FRWG meeting in its Washington, D.C. offices in September 2004.The primary topic of the meeting was the *Saving Lives, Buying Time* report. In the meeting, participants raised the concern as to whether the subsidy, by encouraging greater use of ACTs, would lead to increased resistance of the only effective antimalarial currently on the market.[26]

Adeyi decided to seek a grant from the RBM Partnership and commission a study to examine this question. Instead of participating in the study team, he invited Mead Over to participate. Over was a senior economist at the World Bank and one of the meeting participants that expressed apprehension about increased resistance. The two other members of the study team were Ramanan Laxminarayan, a member of the IOM Committee and Fellow at Resources for the Future in Washington, D.C., and David Smith, a staff scientist at the Fogarty International Center, National Institutes of Health. The study's specific objective was to explore the effects of a global subsidy on both ACT demand and potential drug resistance.

The researchers modeled a number of different scenarios, including no subsidy, partial subsidy, full subsidy, and a two-year delayed subsidy. They concluded that any promptly implemented subsidy of ACTs—whether full or partial—would have a significant effect on the number of deaths averted. A two-year delay in implementing the subsidy, however, would lead to increased use of both cheaper artemisinin monotherapy and partner drug monotherapy and greatly amplify the risk of widespread artemisinin resistance. The authors recommended that a global ACT subsidy be introduced immediately on all eligible drug combinations in order to delay resistance and "buy time" for further research and development of new antimalarial drugs. The authors first published their results in a World Bank working paper (July 2005)[27] and later in *Health Affairs* (February 2006).[28] The study reinforced the sense of urgency among Adeyi, IOM

Committee members, and other advocates for moving forward rapidly on the global ACT subsidy. It also helped gain adoption for the idea within the World Bank.[29]

In September 2005, the World Bank held a donors' conference in Paris. The meeting centered around the World Bank's new Booster Program for Malaria Control in Africa and discussion of its framework for action in the Africa region.[30] This effort represented the Bank's renewed attention to malaria control and Adeyi had played a key role in its design. One session at the meeting was devoted to *Saving Lives, Buying Time*. This session proved to be an important opportunity to educate senior staff from donor agencies about the global ACT subsidy idea. The main opposition that arose in the forum was from supporters of insecticide-treated bednet programs who were concerned that the subsidy might shift money away from efforts to scale-up bednets.[31]

Also at this Paris meeting, RBM asked the World Bank, in its role as co-chair of the FRWG, to develop a detailed proposal on behalf of RBM for the design and operation of a global ACT subsidy. Adeyi welcomed this request as he felt RBM could bring institutional legitimacy to the global ACT subsidy idea, provide a forum within which the operational plan could be developed, and lead to widespread ownership of the global subsidy.[32] RBM itself was not at the time in a position to move the work forward. It was about to embark on the Change Initiative, facilitated by Boston Consulting Group, which was a comprehensive redesign of RBM to improve effectiveness. Adeyi agreed to develop the proposal but needed to find funding for the work. The Bill & Melinda Gates Foundation (BMGF) said it would consider a proposal, and asked that it include architecture (what does the organizational structure look like), analytics (what are additional questions that need to be examined), and advocacy (what are the strategies for advocating for this).[33] Girindre Beeharry, who was the point person within BMGF on the Medicines for Malaria Venture (MMV) drug portfolio, was interested in how to get prices of new antimalarials down so they could compete with SP in the private market and achieve health impact.[34] Given this focus on affordability and the private antimalarial drug market, his interest in the global ACT subsidy was growing. The World Bank team submitted a Letter of Interest to BMGF in early 2006 and then submitted the proposal in May. The grant for $4,085,789 was approved in August 2006 for a 22-month period.

The stated goal of the work under the BMGF grant was to establish a viable plan for a subsidy of effective combinations of antimalarial drugs.[35] It would prepare the ground for the subsidy itself, which would make the drugs accessible to the poor, and prevent the premature development of resistance to artemisinins. The project had three objectives:

1. To develop a detailed architecture and operational plan for a high-level global subsidy for effective antimalarials, including exit clauses to address situations in which the subsidy might no longer be needed or appropriate.
2. To build a coalition that has the critical mass to generate funding and political support so that the subsidy can become reality.
3. To address questions related to external effects of the subsidy or external risk factors that could jeopardize the initiative.

The grant was to cover the costs of hiring qualified consultants to meet these objectives as well as to cover grant management expenses of the World Bank. The work was to be outsourced to a single consulting firm, contracted by the World Bank, and overseen by a Project Management Team consisting of a Task Manager (World Bank Staff), one senior consultant, and one junior consultant. Adeyi, at the time, was working on a major report on noncommunicable diseases and did not have time to be Task Manager for this project. Andreas Seiter, who had eighteen years experience in the pharmaceutical sector and had been a Pharmaceutical Fellow at the World Bank, took on the role of Task Manager. Adeyi continued to provide backup and engage in networking during this period. The RBM FRWG was to provide technical assistance, as well as convene an Advisory Committee on behalf of the project.[36]

Following approval of the grant, the World Bank initiated the procurement process for consultants and sent out a Request for Proposals. The World Bank received five proposals from major consulting firms. Dalberg Global Development Advisors, a consulting firm that specializes in international development and globalization, won the contract. Dalberg's terms of reference outlined three tasks: development of an operational model for a global subsidy of ACTs (defined as the consulting firm's "main task"); coalition building, education, and outreach; and, analyzing issues and identifying opportunities to prepare the ground for the subsidy.[37] Some members of the RBM community were unhappy with the selection of Dalberg, and wondered why they had been chosen. The firm had only recently been established (in 2001) and did not have a long track record in the field of global health. And unlike some of the other consulting firms bidding for the project, they did not have previous experience working on malaria. But for these very same reasons, Dalberg had a lot to prove to the global health community, and they began the work in December 2006 with enthusiasm.

By the end of 2006, a small group of policy champions had started to form around the global subsidy idea including Adeyi, Beeharry, Laxminarayan, and Hellen Gelband of the IOM. This group of policy champions believed that the World Bank could act as policy sponsor of the global ACT subsidy, but that they also needed a political sponsor. In the summer of 2006, the group went out to lunch with Rob de Vos, the Dutch government's Deputy Director General of Foreign Affairs, to discuss the subsidy idea. At that time, the Dutch Foreign Affairs staff had been internally discussing subsidized procurement because of global discussions around advanced market purchases (AMCs) and the International Finance Facility for Immunization (IFFIm).[38] The Dutch government had also been a member of the RBM Partnership Board and de Vos, who had suffered from malaria, had a personal interest in the global ACT subsidy idea.[39] Given these factors, the Dutch government agreed to host a RBM FRWG meeting in Amsterdam (with the World Bank team and Dalberg carrying out the logistics) that would bring together the RBM Partnership community and begin to drive the idea of the global subsidy forward.

5. Developing a technical design for the global ACT subsidy within the RBM Partnership *(January 2007-November 2007)*

5.1 RBM FRWG meeting in Amsterdam

In January 18-19, 2007, the RBM FRWG held the two-day Expert Workshop and Consultative Forum on a High-Level Buyer Subsidy for Artemisinin-Based Combination Therapies in Amsterdam. The meeting was attended by representatives of the IOM Committee (including Kenneth Arrow), World Bank, the U.S. President's Malaria Initiative (PMI), UNITAID, WHO, GFATM, UNICEF, MMV, Drugs for Neglected Diseases initiative (DNDi), BMGF, malaria-endemic and donor countries, NGOs, and the private sector.[40]

The first day of the Amsterdam meeting involved four concurrent breakout sessions on operational research, local market and supply chain issues, provider and patient behavior, and subsidy design and organization. The purpose of these sessions was "to establish a common expert platform for the proposed ACT subsidy."[41] The goal was not to debate market sizing, demand forecasting, or other antimalarial drug issues not specific to the global ACT subsidy. The meeting organizers felt that there were other ongoing efforts to address these issues.[42]

Many of the people who arrived to the meeting in Amsterdam were surprised by the first day's agenda. They expected to discuss the assumptions behind the subsidy (for example, the assertion that most poor people access antimalarials in the private sector), and debate whether the global subsidy was a feasible, effective, or equitable idea. These issues surfaced in the breakout sessions. For example, the session on operational research reportedly "found it important to discuss whether…the global subsidy should exist or not."[43] There were questions in the breakout sessions on topics ranging from regulatory and taxation issues to the impact of the subsidy on morbidity and mortality indicators, from consumer and provider preferences, to diversion of funds and the establishment of accountability structures, from the role of civil society organizations to incentives for producers. These differing expectations of the meeting's purpose set a challenging tone for its first day.

Participants in the Amsterdam meeting included two broad groups of people. One group consisted of the core group of policy champions, many of whom had been developing the subsidy idea since 2004 when *Saving Lives, Buying Time* was released. Many of these advocates had been working hard, often without support and on their own time, to get internal adoption for the global subsidy from their organizations. They were ready to move forward and urgently. They were excited about the subsidy idea, and convinced that it was the right way forward given the research that Arrow and the IOM Committee had put into it. Their strategy was to provide a forum on key issues related to the global subsidy, but not to debate the "yes" or "no" of moving forward.

The other group represented the meeting participants who did not know much about the global subsidy and came to Amsterdam to learn more about it. A number of these people

were very attracted, in principle, to a global ACT subsidy but were cautious about fully endorsing the idea without further debate. Others had read *Saving Lives, Buying Time* and were opposed to its recommendation to work through private sector distribution channels. One concern that participants raised was whether the global subsidy was essentially a subsidy to pharmaceutical companies, providing manufacturers a disincentive for lowering ACT prices. Others voiced concerns about whether it was feasible or correct to provide the subsidy to private sector buyers (a group of people felt the private sector was not needed to solve the problem). Yet other participants, many of whom supported the subsidy idea, felt that additional interventions were needed to make the subsidy idea work in the field. These interventions included pharmacovigilance, social marketing, and monitoring and evaluation. Some of these participants discounted the global subsidy idea because no operational research had been done on the idea, and they were not convinced that it would work in practice. A final category of concerns was from participants who questioned whether a global subsidy initiative was the best or most efficient way to spend scarce resources (time and money) at a time when other malaria control efforts were being scaled-up to meet the goal agreed in the Abuja Declaration of 2000 to halve malaria mortality in Africa by 2010.

Many of the participants who raised questions at the meeting felt that their views were not welcomed or heard at the forum. The advocates of the global subsidy, on the other hand, were frustrated with what they viewed as ideological responses to a new idea that required new thinking. Both groups described the meeting as "heated."[44] On the meeting's second day, the Deputy Director General of the Dutch Ministry of Foreign Affairs, Rob de Vos, worked hard to find some consensus. De Vos, in the words of one meeting participant, was a "skilled diplomat, a negotiator."[45] Many meeting participants reported that the actions of de Vos salvaged the meeting in the end. As one person said, "He created a slight change in the group from 'no' to 'yes' and this was a critical moment for moving forward."[46]

The conflict experienced at the Amsterdam meeting was a difficult beginning to the global ACT subsidy's journey from research report to operational plan. In the view of some participants, the meeting served to cement key groups' opposition to the global ACT subsidy. Some of these groups never changed their views on the subsidy and continued to oppose it.[47] Yet it provided a forum for groups to express their views. It also demonstrated to the policy champions and Dalberg that the technical and political challenges involved in moving forward with the global ACT subsidy were complex. As one person reflected, "we realized that trying to get an architecture and operational plan in place was premature because there was no consensus in the RBM community on the global ACT subsidy. And outreach to donors was also premature. We couldn't ask for funding until there was consensus on what we were trying to implement."[48] Dalberg realized that more of their attention needed to be on engaging stakeholders, so they shifted more funding to this work and brought in outside experts (including Brad Herbert, formerly chief operating officer of the GFATM) to help change the tone of consultation and to focus more explicitly on outreach and coalition-building.[49]

5.2 The RBM Global ACT Subsidy Task Force

One result of the Amsterdam meeting was the creation of an RBM task force, called the Global ACT Subsidy Task Force, to steer the work forward. The RBM Executive Committee approved the creation of this task force in February 2007. The Task Force's role was to build consensus within the RBM Partnership on key factors related to the global ACT subsidy and present these to RBM Board members later in the year. Specific areas of work included making recommendations on a series of technical issues, reaching out to stakeholders to create awareness and build support for the subsidy project, reaching out to donors to mobilize funding, and raising awareness among malaria-endemic countries.[50] The United Republic of Tanzania (Minister of Health David Mwakyusa) and the Netherlands (Harry van Schooten of the Dutch Ministry of Foreign Affairs) were chosen as co-chairs of the Task Force. Other members included the core group of advocates for the global ACT subsidy along with a number of RBM partners. Task Force membership was open to all RBM partners. The RBM Executive Director, Awa Coll-Seck, and the RBM Secretariat facilitated and supported this group. The World Bank, through its subcontract to Dalberg, took on the role of Secretariat for the Task Force. So while Dalberg's line of reporting was to the World Bank, their work happened within the context of the Task Force with a focus on responding to issues that emerged from Task Force proceedings. Thus, there was no one organization—but rather a Task Force—playing the role as "front person" for the work program. Many actors report that this arrangement was at times challenging for both the consultants and the Task Force members, particularly when key decisions needed to be made. This was particularly the case in the early months of the Task Force's work. As the individuals grew to know each other, Dalberg's consultants came up to speed on the brief, and the specific priorities in the work program became clear, the working arrangement reportedly became easier.

Following the formation of the Task Force, work on the subsidy involved a number of parallel activities, both formal and informal. The formal activities revolved around the RBM Board meetings in May and November. These meetings required reports and presentations that responded to decisions and requests from Board members. The Task Force held half-day conference calls every other week to seek consensus on issues related to the technical design of the global subsidy. This flurry of activity around Board meetings seemed inefficient to some Task Force members. However, most Task Force members were volunteering their time to the global ACT subsidy work, and squeezing their work on reports and presentations into their normal work schedules. The role of Dalberg in supporting the Task Force's work was, therefore, particularly crucial for moving the technical design forward. The RBM Secretariat also provided the equivalent of one full time person to the work program, which was also invaluable. In spring 2007, Adeyi took over the reins of Task Manager within the World Bank. Along with the other core policy champions, he was central to the Task Force proceedings. Informal activities also occurred during this period, with many Task Force members—particularly the core group of policy champions—working behind the scenes and engaging in daily phone and email conversations to strategize on ways forward and to explain key components of the technical design to RBM partners and members of the Board.[51]

For the 12th RBM Board Meeting on May 10-11, 2007 in Geneva, the Task Force was required to submit an outline technical proposal, process, and timeline of the global subsidy to the RBM Board. At the meeting, Mwakyusa updated the Board on the work of the Task Force and next steps. Ian Boulton of GlaxoSmithKline (and private sector representative on the RBM Board) gave a presentation outlining the way the subsidy would work and laying out six design principles. The RBM Board approved the objectives and principles for the technical design document. In the meantime, other RBM working groups began to discuss the way to synchronize their work with that of the Task Force. The Board asked the Task Force to address nine specific issues in a more detailed technical design document: product eligibility, quality assurance, supply and demand alignment, costing breakdowns, structures needed to support the subsidy, the cost of switching from co-blistered to co-formulated drugs, funding, hosting, and communication plans. The Board requested that the Task Force include representation by distributors in endemic countries. It also stated "ownership of the process by countries is important."[52]

As previously mentioned, many people involved in the process during the early period of the project characterized the work program as disorganized. Exacerbating this situation was the fact that certain individuals and groups continued to be vocal in their opposition to the global subsidy idea. Shortly after leaving the GFATM in spring 2007, Richard Feachem was strongly critical of the global subsidy in a Financial Times article. He stated, "It's not just getting the design right—we should not be doing it."[53] He argued that even with the subsidy, ACT prices would still be unaffordable for many poor people. People may start a course of treatment but then stop because they could not afford the rest of the treatment, and this would lead to drug resistance. He also stated that the global subsidy would undermine pharmaceutical innovation on antimalarial drugs and distract ongoing work toward malaria targets. Finally, he argued that the subsidy's policy champions had created a picture of consensus for the global subsidy, when in fact serious criticisms had not been addressed. PMI also continued to raise concerns about the global subsidy. As Bernard Nahlen, deputy coordinator of PMI later stated to the National Journal Magazine, "The U.S. Government has been consistent from day one on this, which is, there needs to be some evidence for this. You have to go to a few countries and try this out and see if it's going to work. Nobody has all the answers to this. To propose one particular model to solve all these problems, I think, is going far out on a very thin limb."[54] Some representatives of northern NGOs continued to oppose the global subsidy because it would work through private sector distribution and delivery channels.

The core group of policy champions in the Task Force knew they needed to design specific strategies to reach out to the subsidy's opponents. One strategy was to deliberately reach out to each RBM Board member for discussion on the global subsidy. Another strategy was a "rebranding" effort. In the Amsterdam meeting and subsequently, it became clear that people had a negative reaction to the word "subsidy" and a new, more acceptable term was needed. The Task Force proposed and narrowed down a few names for a global subsidy entity, and Coll-Seck and Adeyi ultimately chose the name Affordable Medicines Facility for malaria, or AMFm. The Task Force began to use the word "buyer co-payment" instead of "subsidy" in all of its writing and discussions. The Task Force also changed its name to the "AMFm Task Force." A third strategy was to

ask southern representatives from Ministries of Health and NGOs to advocate for the global subsidy when discussing the concept with their northern counterparts. While only a handful of southern representatives had been involved in the process thus far, advocates report that there had been support from many Ministries of Health and southern NGOs for the initiative.[55]

5.3 Operational research in Tanzania

A fourth strategy came from a new group to the process, the Clinton Foundation's HIV/AIDS Initiative (CHAI). CHAI in 2007 had decided to start working on antimalarial drug access issues and was considering what role the group could play in the development of the AMFm. They believed that one way to break the deadlock between the advocates and the opponents of the AMFm was to test the idea out in the field. Using funds from an existing BMGF grant on malaria, they quickly designed a project that would pilot the subsidy in Tanzania (they decided to do the pilot in May, had a design ready in August, and began the study in October). CHAI, Tanzania's National Malaria Control Programme (NMCP), and Population Services International (PSI) implemented the project. The pilot's specific objective was to assess the effect of a global subsidy on the price and uptake of ACTs. While a number of other pilot projects on subsidized ACTs had taken place in Africa, this was the first intervention in which the supply chain from wholesaler to drug seller was left untouched. The project started in October 2007 and focused on drug shops in two districts, Kongwa and Maswa. CHAI procured the ACTs and sold them to a reputable national pharmaceutical wholesaler who then distributed the drugs through normal channels. The drugs were packaged with a suggested retail price of $1 printed on the label. PSI supplied the packaging intervention along with an array of supporting interventions such as social marketing and other IEC activities. The Government of Tanzania and PSI partnered to train shopkeepers in the pilot districts on appropriate dispensing. Data was collected in November 2007 and March 2008.[56] The subsequent findings of the study played a role in shaping the direction of the technical document and the Task Force's work in 2008, as we discuss below.

5.4 Finding an institutional home for the AMFm

While Task Force members and Dalberg were developing the technical plan, talks had begun on institutional hosting arrangements for the AMFm. Some of the advocates of the AMFm believed that finding an organization to "own" and "host and manage" the subsidy was a matter of urgency.[57] Until there was an owner, they argued, it would be difficult to convince donors to provide funding (because the donors would not know who they were funding). The Task Force debated several different hosting arrangements, including situating the AMFm within an existing organization (UNICEF, WHO, UNITAID, the GFATM) or contracting out to the private sector. While under Richard Feachem, the GFATM had been opposed to the global ACT subsidy, the situation changed when Michel Kazatchkine became Executive Director in April 2007. Kazatchkine was favorable to the global subsidy idea, and this provided a new hosting opportunity. Dalberg developed a set of criteria for making the hosting decision, but the

decision was ultimately made in a high level meeting on the sidelines of the World Malaria Forum in Seattle, in October 2007. Senior staff from the major agencies expressing an interest in hosting the AMFm attended the meeting, which was facilitated by Brad Herbert, consultant to Dalberg and former chief operating officer of the GFATM. It was decided here that the GFATM was the most suitable host and Kazatchkine said he would take the idea to the GFATM Board.[58] At its 16th Board Meeting on November 12-13, 2007 in Kunming, China, the GFATM stated in a decision point that it "supports in principle the objectives and principles of AMFm; and the idea of investigating with no presumptive decision the appropriateness of hosting the AMFm as a Global Fund business line, considering the complementarities and synergies of the Global Fund's objectives and business model with many design elements of the AMFm."[59]

5.5 The RBM Board endorses the AMFm technical design

At its 15th Board meeting on November 11-12, 2007 in Addis Ababa, Ethiopia, the RBM Board discussed the technical design for the AMFm. The design was centered on the global ACT subsidy recommended in the *Saving Lives, Buying Time* report but also included five supporting interventions that emerged from the consensus-building process in RBM: national policy and regulatory preparedness, wholesaler incentives and pricing, public education and awareness, provider training, and national monitoring and quality preparedness. The technical design drew from consultations with 168 global stakeholders, 56 endemic country stakeholders in four different countries, and discussions about the global subsidy in fifteen meetings between March and October 2007.[60] Four background papers were also commissioned, by Dalberg or subcontracted experts between April and November 2007.[61] In the Board meeting, CHAI also presented the first results from the operational research in Tanzania. The research found that stocking of ACTs in drug shops increased during the intervention, as did the uptake of ACTs, and there was an indication that SP stocking decreased at least in one district. The mean price of subsidized ACT was almost equal to that of SP, and drug sellers and consumers were increasingly better informed about the treatment.[62] At the same time, there were some significant differences in success between the two pilot districts, as well as large differences in stocking levels between rural and urban levels. The research found that the poorest patients in the two districts were far less likely to use drug shops to obtain antimalarials. This finding led to a vigorous discussion among advocates and critics of the global subsidy over the issue that the poorest patients were unlikely to benefit from the subsidy.[63]

The Board endorsed the technical design and instructed the Task Force to work closely with the GFATM in order to help prepare it to host and manage the subsidy. RBM's decision in Addis Ababa meant that it publically embraced the AMFm. The Board did, however, insist that the Task Force work over the next year to address five outstanding implementation challenges deemed important to stakeholders and critical to secure GFATM approval.[64] These were pharmaceutical standards and treatment guidelines, supporting interventions, developing a business plan for managing the AMFm, supplier sourcing and forecasting, and resource mobilization.[65] The Board also reiterated the need for a better communications plan, more extensive understanding of drug seller behavior, additional research on markets outside of Anglophone Africa, improved planning for

diagnostics, and reassurance that the AMFm would work to strengthen existing procurement and supply structures in participating countries. In spite of these continuing questions, the Board's "[c]onsensus was to take the risk and go ahead with the AMFm knowing you can fine tune as you go along. AMFm, after all, is only one part of a larger set of solutions." The Board asked donors to enter into consultation with the Task Force about possible financial contribution.[66] The World Bank renewed Dalberg's contract for another six months to support the Task Force's work.

6. From RBM technical design to GFATM operational plan *(November 2007-November 2008)*

6.1 The GFATM works with the RBM AMFm Task Force to develop a business plan and policy framework

In the period after the November 2007 RBM Board decision, the focus of the work shifted away from RBM toward the GFATM Board. The technical design needed to be aligned with GFATM policies and made more concrete. Within the GFATM Secretariat, the Global Strategy team—headed by Christina Schrade—had responsibility for developing a business plan for the AMFm for consideration by the GFATM Board. The GFATM Secretariat asked the RBM AMFm Task Force for support in developing the business plan. Together, the Task Force and the GFATM Secretariat created workstreams on the implementation challenges raised by the RBM Board to provide feedback to the GFATM Secretariat in 2008. Task Force members also felt that a person with implementation experience would be a valuable asset to the GFATM Secretariat and Dalberg as they drew up a business plan and policy framework. The World Bank team asked Ricki Orford of PSI to join the team in Geneva for six weeks; his involvement was funded by the BMGF grant.

The Task Force was restructured for this new period of work. By the end of 2007, Harry van Schooten had left the Dutch Ministry of Foreign Affairs and handed his co-chair responsibility to John Worley of the U.K. Department of International Development (DFID). The RBM Partnership had emerged from its Change Initiative, and Awa Coll-Seck played an increasingly important leadership role in the Task Force. On February 1st, 2008, DFID sponsored a meeting where the leaders of each workstream reported back on their results. This meeting was critical in making progress on the implementation challenges outlined in the November 2007 RBM Board meeting. The meeting had some new participants who voiced concerns about the global subsidy. Representatives from the Canadian International Development Agencies (CIDA), for example, raised concerns about whether the subsidized ACTs would reach the poorest of the poor. Instead of the subsidy, they argued for more support to community health workers to reach these poor groups.[67] In addition, participants continued to disagree on a number of technical issues, including critical supply side problems from the manufacturing perspective. Some participants felt that the concerns they had been voicing over the course of the previous year's meetings had either not been fully understood or deprioritized. They were worried that too much attention in the Task Force had been given to Board meeting preparations, and not enough to the technical details of the subsidy.[68] Other stakeholders, many of

whom had spent a good part of the previous year working on the technical design, felt that these participants were "voicing 11th hour questions…even if these were valid concerns, they were coming in late."[69] In spite of these difficulties, the Task Force pushed ahead in order to prepare for the GFATM hosting decision.

6.2 UNITAID expresses an interest in collaborating with the GFATM on the AMFm

The work of the Task Force in early 2008 was also critical in helping to secure crucial financing from UNITAID. UNITAID is an international medicine purchasing facility, created in 2006 through the efforts of France, Brazil, the UK, Chile, and Norway to finance reduced prices for AIDS, tuberculosis, and malaria drugs, mostly through a levy on airline tickets applied to flights departing from participating countries. In December 6-7, 2007 in Geneva, staff from the RBM Secretariat presented the AMFm at the 6th Board meeting of UNITAID. The presentation led the Board to instruct its Secretariat to begin exploring ways in which UNITAD might be involved in the AMFm, including as donor.[70] The UNITAID Secretariat then prepared a working paper describing the AMFm in terms of UNITAID's key objectives. In early April 2-3, 2008, at the 7th UNITAID Board meeting in Brazil, the UNITAID Board welcomed the work done on the AMFm and offered its support, in principle, to further its development. The Board asked its Secretariat to "further define, in relation to the GFATM and RBM, options for UNITAID's areas of involvement…and prepare a proposal to the Board setting out the framework for collaboration."[71]

6.3 The GFATM agrees to host and manage the AMFm

In March 2008, the GFATM Secretariat presented a business plan for managing the AMFm to the GFATM Policy and Strategy Committee (PSC). Later in April 28-29, 2008 in Geneva, the GFATM Board agreed at its 17th Board meeting to host and manage the AMFm as a business line, once a policy framework and implementation plan were developed. The Board asked that the framework and plan incorporate a set of guiding principles and offer "practical solutions, in consultation with technical partners, to remaining technical issues (including identification of strategies to maximize access to ACTs by the most vulnerable and poorest and ensuring patient safety)."[72]

The guiding principles included the stipulation that the AMFm be implemented through a Phase 1, a one-year phased launch in selected countries. This reflected a compromise made by AMFm advocates in order to appease the concerns of the U.S. about testing the initiative in a smaller group of countries. This differs substantially from the IOM Committee's recommendations in *Saving Lives, Buying Time* which argues that a broad, global roll out of the subsidy is required to crowd out traditional antimalarials (to "save lives") and artemisinin monotherapy (to "buy time"). Full roll out of the AMFm would remain pending until the GFATM Board could review the results of an evaluation to be presented at its April meeting in 2010. The principles also addressed a number of other issues raised during the past sixteen months of consultations, including the need to achieve sustainable financing separate from existing GFATM grant-making activities, the

importance of linking closely with pre-existing national malaria control programs and partner organization activities, the necessity of funding and advocating for supporting interventions, the imperative to undertake responsible negotiations with manufacturers in terms of price and quality issues, and the obligation of the AMFm to focus on the most vulnerable populations.[73] The GFATM instructed its Secretariat to begin discussions with UNITAID and other partners to resolve issues such as annual financial contributions, demand forecasting, and drug price and co-payment negotiations.[74] The PSC went on to present the plan to the 14th RBM Board meeting from May 15-16, 2008 in Geneva. It highlighted to the Board and to the Task Force the outstanding issues and requested that "as a first step the Task Force focus its outreach efforts on mobilizing support from the GFATM and UNITAID Board members" in order to ensure successful adoption.[75]

Dalberg's work on the AMFm, funded by the BMGF grant to the World Bank on behalf of RBM, ended at this time and the GFATM Secretariat hired them to help draw up the policy framework and implementation plan and manage relationships with RBM and other partners. The Task Force continued to work with the GFATM and other partners on outstanding challenges while the GFATM Secretariat prepared an implementation plan for final GFATM Board approval in November.

6.4 The AMFm Ad Hoc Committee is established at the GFATM

In the April 2008 meeting, the GFATM Board requested that an AMFm Ad Hoc Committee be established to oversee and guide the GFATM Secretariat's work. Todd Summers of BMGF was asked to be chair of this Committee and Eyitayo Lambo, former Minister of Health in Nigeria, was asked to be vice-chair. The Board specified that membership of the Ad Hoc Committee should include partners and potential donors, including UNITAID, and invited nominations for membership.

Summers came from a background in HIV advocacy and knew the complex stakeholder processes of the GFATM well due to his work at BMGF and previous consulting work. He knew that AMFm advocates faced a number of challenges in getting final GFATM Board approval on the AMFm, including: 1) many Board members did not understand what the global ACT subsidy was or were suspicious of the word "subsidy"; 2) current documents on the AMFm did not explain the subsidy in GFATM language; 3) most of the people on the Board knew more about HIV than either TB or malaria; 4) some people on the Board had deeply held views (for example, about the private sector) that were counter to the spirit of the AMFm.[76] Summers, along with colleagues at BMGF, Dalberg, and other policy champions, conducted a stakeholder analysis and devised strategies to address these challenges. They reached out to Board members one-on-one, talked about their concerns, and discussed the AMFm concept in GFATM language. Their outreach efforts also included daily phone and email conversations with GFATM constituencies to share information about the AMFm. The challenge of the outreach work was to balance the political interests of Board members with the operational needs of the AMFm program.

6.5 Country consultations with stakeholders begin

Back in May 2007, the RBM Board had stated that ownership of the development process by countries is important.[77] The AMFm was brought up and discussed at the April 2007 African Health Minister's Conference in Johannesburg and had been the subject at several MMV workshops in Africa in 2007 and 2008. Yet by early 2008, the project had conducted no systematic country consultation either among Ministers of Health or among technical experts working within National Malaria Control Programs.

This changed when the RBM Secretariat asked Eyitayo Lambo, former Minister of Health in Nigeria and a past chair of the RBM Partnership Board, and Dorothée Kinde-Gazard, former Minister of Health in Benin, to brief African Ministers of Health on the AMFm and collect their feedback. They contacted Ministers and senior health officials in 40 countries. They found that there was "strong political will in countries" for the AMFm and that they wanted the initiative "today, not tomorrow."[78] In addition, the people interviewed said that as they were now familiar with the GFATM application processes and financing mechanisms, the AMFm application and grant management process would not be so daunting.[79] Interviewees did voice concern about how local manufacturers would fit into the AMFm, and that funding could be disrupted or time-limited, and that there had been very little engagement with relevant stakeholders at the country level thus far. There was also some doubt about the current state of ACT access, even in the absence of the subsidy, and a request for more advocacy, information, and needs assessments.

In August 2008, PSI and the Society for Family Health in Nigeria hosted a country consultation in Abuja to address remaining implementation challenges. Participants included technical partners within malaria-endemic countries and other country-level stakeholders, including directors of African drug regulatory authorities.[80] The meeting organizers formed five sub-groups on the following topics: monitoring and evaluation, resource mobilization, country preparedness/country selection criteria, procurement and supply management, and reaching the poor. Following the country consultation, the Task Force continued work on these topics. At a meeting in Geneva on August 19, 2008, the Task Force drew up a list of 25 countries as potentially eligible for inclusion in AMFm's Phase 1. Countries were included if they had moderate-to-high malaria mortality and multi-year experience with large-scale deployment of ACTs. In Geneva, a number of papers on reaching the poor were presented in order to help persuade skeptical stakeholders that the co-payment would lead to uptake of ACTs among the poorest population quintiles.[81] At this point, the Task Force allocated all outstanding challenges directly to the established RBM Working Groups.[82]

6.6 The United Kingdom pledges funds to the AMFm

Soon after, the first financing commitment for the AMFm was secured. In September 2008, at the Millenium Development Goals Summit in New York City, Prime Minister Gordon Brown announced that the United Kingdom would contribute 40 million British pounds to the AMFm. DFID had been involved in the process of developing the AMFm

since the Amsterdam meeting in January 2007. Its involvement grew in late 2007 when John Worley of DFID became co-chair of the Task Force. The U.K.'s All Party Parliamentary Group on Malaria (APPGM) also helped lay the groundwork for this commitment. In October 2007, the group had carried out a thorough consultation, addressing how the AMFm works, the ways in which the AMFm differs from existing malaria grants, and the role of supporting interventions. It acknowledged the weaknesses of the subsidy idea and addressed the risks of donor investment in the AMFm. These risks included: the diversion of investment in the public sector delivery mechanisms; development of resistance to ACT with scaled-up unmonitored use; lack of cost competition; suppression of diversification among manufacturers and disincentives for innovation; price mark-ups by middle men at the expense of the end-user; sustainability of ACT delivery once the AMFm ends; and access by the poorest of the poor. Nevertheless, the APPGM ascertained that the risks of not investing in the AMFm were greater than the flaws of the subsidy idea.[83] The APPGM, therefore, created a degree of political ownership in the UK that facilitated the country in becoming the first donor to commit funding to the AMFm.

6.7 The GFATM Board approves a policy framework and implementation plan for the AMFm and UNITAID commits funding

In New Delhi on November 7-8, 2008, the GFATM Board in its 18th Board meeting approved the policy framework and implementation plan for the Affordable Medicines Facility for malaria (AMFm). The Board also reaffirmed its decision to host and manage the AMFm in a Phase 1 in a limited number of countries. One critical board member, the United States, abstained from voting but did not attempt to block the AMFm's Phase 1. According to the U.S. Government position, the "delegation's primary concerns were whether implementation of the AMFm is consistent with the Global Fund's mandate as a financing organization rather than an implementing entity; whether the AMFm will be able to achieve its stated objectives; and the number of staff the Global Fund will require to manage the AMFm, should it go to Phase 2 implementation." Still the U.S. noted that they were "pleased that the Ad Hoc Committee had taken these concerns into consideration and made changes…to begin to address these issues…[and] that the Ad Hoc Committee recommended that companies continuing to market artemisinin tablets alone for treatment of malaria will not be eligible for the AMFm subsidy."[84] At a RBM Board meeting held at the same time, the Board felt that the AMFm Task Force's work was finished and recommended its dissolution.[85]

Later in November, the UNITAID Board decided to commit up to $130 million for the AMFm's Phase 1, pending clarification of a number of outstanding issues. The Board planned to meet on January 29, 2009 to make a final decision about the commitment (it voted in January to approve the commitment).

7. AMFm's pre-launch and Phase 1 begins *(November 2008-December 2010)*

With an operational plan for the AMFm in place at the GFATM, and enough funding for Phase 1 committed by DFID and UNITAID, the process of developing the AMFm had ended and the AMFm pre-launch period had begun (and continues into April, 2008). The GFATM operational plan that will guide the AMFm in Phase 1 is a different document than IOM's *Saving Lives, Buying Time* or RBM's technical document. However, in all three documents, the "spirit" of the original idea remains the same. All three center on a copayment provided at the top of the supply chain that serves to bring the end-user price of ACT down in order to drive traditional antimalarials and artemisinin monotherapy from the market through distribution in the public and private sector. In March 2009, the World Bank and the GFATM agreed that Olusoji Adeyi, the early policy champion of the global ACT subsidy, would take leave from the World Bank to head the AMFm at the GFATM.

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Appendix 4
Work completed for project objective 3
by Dalberg Global Development Advisors and subcontractors

Description	Key Questions Addressed	Authors and Delivery Date
Background papers		
Summary of Field Research (Senegal, Burkina Faso, Cameroon, Uganda)	• What is the price transmission in the public and private sectors of subsidized antimalarials? • What is the availability of the subsidized ACTs in the various distribution channels? • What are the observed markups along the supply chain?	• Senegal study: Institut de Recherche pour le Développement (October 2007) • Country Visit Report in Burkina Faso and Cameroon: Dalberg (April 2007) • Drug Supply Chain in Uganda: Dalberg (February 2007)
Monitoring & Evaluating and Operational Research	• What are the existing indicators that are relevant to the AMFm? • What are the core and supplementary indicators that comprise the M&E framework? • What are the plans to undertake intensive M&E in the sentinel countries? • How will the M&E and operational research be implemented? (ie timing, scope and coordination of the activities) • What are the costs of conducting M&E and operational research for the AMFm?	Dalberg with support from the London School of Hygiene and Tropical Medicine (November 2007)
Analysis of Complementary Supply Chain Interventions	• What are the challenges in the current antimalarial supply chain? • What are the incentives of the supply chain players? • What are the secondary incentives higher up in the distribution channels that could induce a higher volume flow, lower markups and higher availability of ACTs?	May Ongola and Prashant Yadav, a study conducted for Dalberg (September 2007)
Estimating Private-Sector Demand for Antimalarials in Willingness-to-Pay Estimates	• What are the drivers of demand for ACTs? • What is the actual demand for ACT treatments at different price points? • What is the price elasticity (willingness to pay) of ACT demand?	May Ongola and Prashant Yadav, a study conducted for Dalberg (September 2007)
Workshop		
Developing a Toolkit for Introduction of ACTs via an AMFm	• How can elements of the subsidy design and plan be translated into practical operational guidance? • What type of practical support can be given to implementers for the introduction of low-cost ACTs?	Various workshop presenters (September 14, 2007/Geneva)

Source: Dalberg Global Development Advisors

APPENDIX 5

From Idea to Initiative: Comparing the Development of the Affordable Medicines Facility-Malaria and the Advance Purchase Commitment for Pneumococcal Vaccine*

How does an idea get developed into a proposal and subsequently translated into a functioning initiative? This Appendix addresses this question by comparing two similar processes that resulted in two new programs. The Affordable Medicines Facility-malaria (AMFm) was launched mid-April 2009 at the Global Fund to Fight AIDS, TB, and Malaria; and the pneumococcal vaccine Advance Market Commitment (AMC) was announced by the World Bank in early April 2009. Both the AMFm and the AMC are derived from ideas initially generated by researchers working outside of an implementing institution and were subsequently developed over the course of the last decade. Assessing them in parallel allows us to compare the two initiatives' development processes. In addition, the similarities revealed by the assessment allow us to identify some general features of global policy development done collaboratively by individuals working in implementing and non-implementing agencies.

One concept useful in considering the goals and strategies of both the AMFm and the AMC is the concept of a global public good. A global public good is a benefit that is accessible to all and whose benefits are quasi-universal, reaching across population groups, continents and generations.[1] The AMFm was conceived to address dual targets of 1) creating wider access to effective malaria treatment ("saving lives"), and 2) delaying the development of resistance to artemisinin by the malaria parasite ("buying time"). The benefits of the AMFm, therefore, should accrue to a wide array of peoples across the globe. Likewise, the AMC concept was designed to transcend the limiting effect that a profit motive has on vaccine development, leading manufacturers to focus on diseases of the developed world where strong market opportunities exist. Over the last decade, it has become increasingly recognized that protecting and promoting global public goods necessitates "global cooperation beyond the capability of any single actor or nation state,"[2] particularly in the case of disease control.

This cooperation, in turn, necessitates new forms of policy and program development and management that integrate public and private sector actors. These actors can also be subdivided along other lines. In this discussion, another distinction is made between implementers and non-implementers. In general terms, implementers are those whose activities are intended to *actively change* the circumstances of a particular problem or set of problems. Non-implementers are those working on the problems from a research or academic perspective. "Research" and "academic" are used (interchangeably) to encompass two key components: first, an overarching interest in *advancing knowledge* about concepts and issues; and second, a *particular approach* to studying and proposing solutions to problems based on theoretical inquiry and scientific methodology.

* This report was compiled independently by Anya Levy Guyer on behalf of the evaluation team and as part of her master's thesis at Harvard School of Public Health.

Few frameworks exist for evaluating public policy development at the global level; a framework based on policy analysis and process evaluation frameworks used at local, national and international levels is proposed in order to allow systematic comparison of the development of the AMFm and AMC.*

Ultimately, this analysis shows that while both the AMFm and AMC processes resulted in the creation of a program, the AMFm process was more successful in creating a program that effectively integrates solutions to a set of intertwined goals. The analysis also shows that inter-disciplinary and academic processes can generate workable ideas to promote global public goods. However, generating a good idea for addressing a problem of global public goods does not necessarily result in effective or timely implementation. The complexity of the network of global stakeholders involved in generating and sustaining global programs necessitates a similarly complex network to promote an idea. This network is made up of idea generators, policy champions and institutions – each category leads the process of translating the idea into an initiative in different ways and at different points in time.

Analytical Framework

The question this paper asks has two parts. The first part asks how a general idea for a solution to a problem gets developed into the specifics of a policy proposal. It then goes on to ask: how is a proposal on paper then translated into a functioning initiative? These two phases of development are related and inter-connected, but can have different outcomes. Analyzing the AMFm and AMC requires addressing both components:

1. *Development of the initial idea into a policy proposal:* Both the AMFm and the AMC originated from ideas initially developed through research. The contribution of academic research to policy development is the topic of much investigation and debate. (In clinical medicine, adopting research into general practice is estimated to take, on average, 17 years.[3]) In a study of health policy development in Mexico, Trostle, Bronfman and Langer note: "Many research results DO influence decisions, but this influence is sometimes unpredictable, and often broad or diffuse."[4] As will be described in detail below, the initial ideas for both programs came from sources that did not have either a mandate or the capacity to do program development. Many ideas that are proposed in these settings never get beyond the theoretical "this could be a good idea" stage. Thus a primary question is: How does this process occur?

   Examination of this phase also offers us the chance to consider additional questions specific to developing ideas generated by academic research: Does originating from a non-implementing agency help or hinder the process of development into workable policy? Or is it simply an identifying feature, not a determinant of the successes or challenges of the process? How does this process occur?

* International and global are not used interchangeably. International connotes interactions among individual nations, while global is used to refer to those issues and efforts that transcend national borders and international political relations.

2. *Promotion of the policy proposal to implementers:* Because the ideas behind the AMFm and AMC came from people working in an academic research environment, they did not necessarily have time, skills or access to the global policy processes that would enable implementation. Thus once the policy proposal was adequately outlined, a second process was necessary to present the ideas to implementing agencies, as well as to other potential stakeholders and supporters.

   This raises questions that have been raised by other studies of policy development: What are the roles of the idea generators and the idea promoters in this aspect of program development? How do they interact with each other and with outside parties? How do implementing agencies and other relevant stakeholders get engaged in the process? The two cases examined here provide an opportunity to examine them in the specific context of policy relating to global public goods.

Combining two theoretical models allows us to address the complexity of this policy development and implementation process. First, Kingdon's "policy windows" model accounts for the elements of time, chance and opportunity. According to Kingdon's construction, policy adoption occurs when a "window" opens between three independent "streams." The problem stream represents the recognition of a certain situation as something that can be changed or addressed; the policy stream contains the specific ideas that are regarded as 'good advice' at a given time; and the political stream comprises the wider political environment. At certain moments, "policy windows" open among the three streams, allowing them to coincide, at which point new policy initiatives can be created to address a particular problem. These windows can, in some situations, be opened "manually" from one of the streams, but the three must be working in concert for changes to occur and be sustained.

What Kingdon's model lacks, however, is the need for coordination among players at various institutions and levels that characterize the global public goods environment. Evans and Davies' policy transfer network model "links a particular form of policy development (policy transfer), micro-decision making in organizations, macro-systems and global, transnational and international systems."[5] They write: "Policy transfer networks are an *ad hoc*, action-oriented phenomenon set up with the specific intention of engineering policy change. They exist only for the time that a transfer is occurring. By implication, policy transfer networks matter because without them other policies might be adopted."[6] That is, there are always alternative policy options available (including doing nothing) and so a network of policy champions must be created for a particular policy alternative to be pushed through.

Combining these two approaches enables us to identify, in both the AMFm and AMC cases, the global structures into which the proposals were presented and the roles played by a diverse set of agents in a policy transfer network, as well as the element of the complex temporal context addressed in Kingdon's analysis.

Evaluating a process entails assessing both the steps and the outcome. In assessing the development processes of these two initiatives, the following key elements will be compared and used as indicators of the success of the processes:

- Success in establishing the proposed program
- Timeline and efficiency of development process
- Stakeholders engaged
- Skeptics/critics assuaged or sidelined
- Institutional support secured
- Resources secured
- Political support secured
- Prospects for long-term sustainability

The process of creating programs does not happen accidentally – people must initiate and conduct the various activities listed above, such as engaging stakeholders (including critics) and securing resources for the present and for future sustainability. However, the people involved in driving or shepherding any process are constrained and shaped by the institutions in which they work. Therefore, in addition to the steps and outcomes of a process, additional factors to examine are the strategic actions of:

- Process drivers (people who champion the initiative)
- Process facilitators (people who create political space for the process drivers or otherwise support the initiative's development)

Combining these ten indicators can provide a framework for an overall analysis of the success of a process of developing a research idea into a policy initiative. Comparing our analyses of the AMFm and AMC enables us to draw conclusions about their relative success as well as key factors that promote the translation of research ideas into policy initiatives.

Case 1: The Affordable Medicines Facility-malaria

Malaria, according to the World Health Organization (WHO), caused between 189 and 327 million cases of acute illness in 2006, causing approximately 881,000 deaths, primarily among children.[7] In the 20th century, the advent of options for treatment and prophylaxis, combined with mosquito control efforts, temporarily decreased malaria mortality, particularly in areas where malaria was seasonal. However, in recent years this trend has reversed, due to, among other factors, the development of resistance of malaria parasites to the commonly-used anti-malarial drugs, the development of resistance among mosquitoes to insecticides, and the limited capacities of health systems in many affected countries.[8]

The speed at which malaria parasites develop resistance to new types of anti-malarial drugs has also increased. Quinine resistance was first identified in 1910. The first reports of chloroquine resistance, which became available beginning in the mid-1940's, came after 12 years of use. Drugs discovered and introduced subsequently generated resistance more quickly: sulfadoxine/pyrimethamine resistance was noted within about six months in some areas; mefloquine lasted about 5 years; and in mid-1990's, resistance to atovaquone was reported about 6 months after it was introduced.[9] Currently, the most effective anti-malarial medications are those that are derived from *Artemisia annua*, a plant native to China. Artemisinin-based drugs, particularly those that are produced in combination with other anti-malarial compounds, are effective at treating malaria throughout the world.[10]

Because malaria is primarily a problem of poor countries, antimalarial medication is not perceived by the for-profit pharmaceutical industry as a profitable area for research and development of new compounds. Therefore, by the mid 1990's it became apparent that there were virtually no new antimalarial products in the research and development pipeline.[11] Around the same time, however, new concerns about the possible widening range of mosquitoes due to climatic changes, combined with a general increase in interest in global health, served to raise the profile of malaria as a target for intervention. One emphasis of recently introduced or scaled-up interventions is a focus on creating access to effective malaria treatment with a particular focus on artemisinin-based medications. However, a central challenge for health and development agencies working in malaria-affected areas is how to increase widespread access while preventing the development of artemisinin-resistance. This is particularly important because new drugs currently under development are unlikely to be available for at least the next decade.

Forestalling the development of resistance to artemisinin among malaria parasites is therefore crucial to ensure that effective malaria remedies exist in the near-term. In response to this challenge, and in light of the growing morbidity and mortality burdens created by malaria across the world, in 2004 the U.S. Institute of Medicine (IOM) released a commissioned report entitled *Saving Lives, Buying Time.*[12]

IOM is explicitly not an implementing agency. It is a sub-agency of the American private non-profit National Academy of Sciences (NAS), which defines itself as a "society of

distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare."[13] While commissioned by the U.S. Congress to do scientific inquiry on issues of national interest, the National Academies can also take commissions from non-governmental agencies and can initiate its own inquiries into topics it deems of national importance. According to Dr. Harvey Fineberg, the president of IOM, the goal of all of IOM's work is to inform policy and programming for the betterment of human health.[14]

Produced by a commission of academics and public health specialists chaired by Nobel Prize-winning Stanford economist Kenneth Arrow, *Saving Lives, Buying Time* proposed a global subsidy for ACT "to facilitate widespread use of artemisinins while, at the same time, to preserve their effectiveness for as long as possible."[15] The plan that the report's authors had concluded was "the most economically and biomedically sound means to meet this challenge" was for the global community to "provide sufficient funds to encourage investments by manufacturers, guarantee purchases of ACTs and generally stimulate a robust world market…through a visible, centralized mechanism, ideally using existing national and international organizations (e.g., UNICEF [United Nations Children's Fund], WHO [World Health Organization]), which can quickly take on the task."[16] The authors further recommended that within five years the global community should allocate between $300 and $500 million for "a global subsidy near the top of the distribution chain [that] will stabilize demand and create incentives for ACT production, resulting in lower prices."[17]

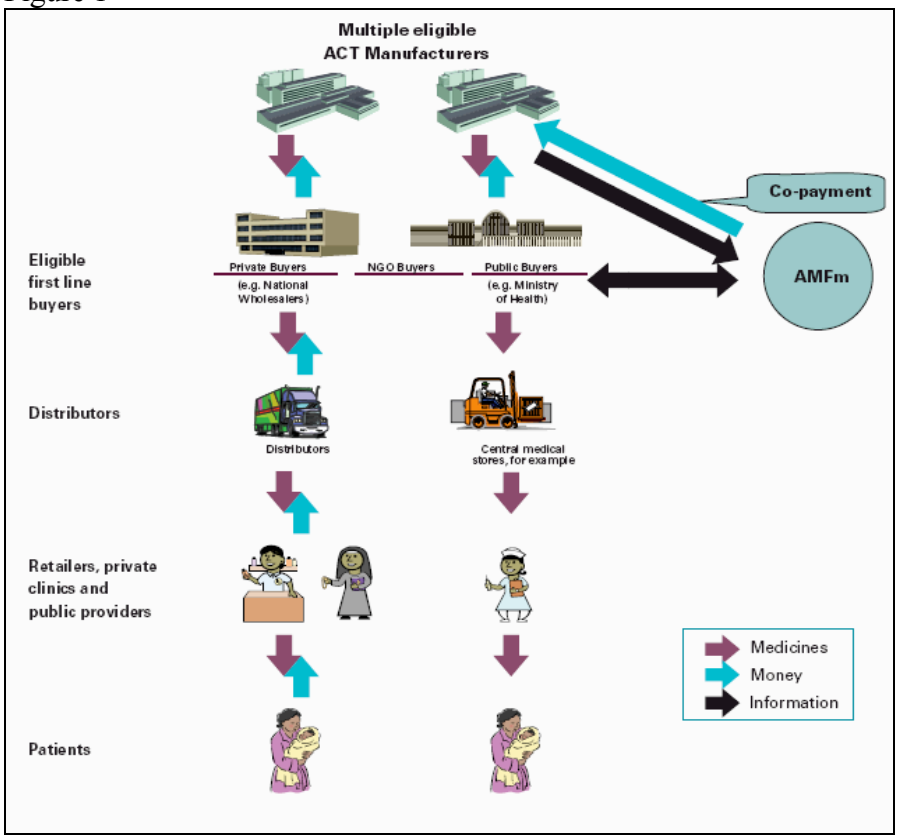
This report was initially commissioned at the request of the United States Agency for International Development (USAID). However, when the panel finished its inquiry and submitted its report, the recommendations were not well received by USAID (indeed, the U.S. President's Malaria Initiative (PMI) has been critical of developments based on the report). As is described in detail in the main body of this Process Evaluation Report, one of the people who received a pre-publication copy of the report was Olusoji Adeyi, coordinator of the Public Health Programs in the Human Development Network at the World Bank. Adeyi was struck by the report and came to believe that the global subsidy recommendation was a ground-breaking way to address, in a single stroke, the questions of access to treatment, drug resistance, and public-private channels for treatment. He found the proposal to be "simple and elegant", and initiated a coalition within and outside the Bank to translate into reality the idea of the subsidy.[18]

As outlined in greater detail in Appendix 3, Adeyi's team at the World Bank, with the endorsement of IOM and the report's authors, painstakingly convened and convinced additional possible stakeholders among members of the Roll Back Malaria Partnership and elsewhere to support the report's core idea. The initial group included Ramanan Laxminarayan at Resources For the Future, Hellen Gelband at the IOM, Girindre Beeharry at the Bill and Melinda Gates Foundation (BMGF), and Awa Coll-Seck, Executive Director of the Roll Back Malaria Partnership (RBM). The BMGF provided the World Bank with a grant on behalf of the Roll Back Malaria Partnership to develop specifications to transform the idea into a functional architecture and operational plan. Dalberg Global Development Advisors was awarded a contract to generate a proposal for an architecture. This proposal

was reviewed through a series of formal and informal meetings and consultations; ultimately a critical mass of supportive individuals and organizations was assembled, an institutional home at the Global Fund to Fight AIDS, TB and Malaria (GFATM) was secured and an operational plan developed.

GFATM's board approved the final proposal in November 2008, paving the way to begin implementation. The first phase of the AMFm was expected to last for two years, with a co-payment fund of about $225-233 million and additional funds for "supporting interventions" at the country level. By March 2009, UNITAID and the British Government Department for International Development (DFID) had made firm pledges to the co-payment fund of AMFm. The government of the Netherlands and BMGF had also signaled intentions to contribute to the co-payment fund. A secondary, global, roll-out of the AMFm was expected to disburse up to $2 billion dollars over five years.[19] Its proposed structure is presented in Figure 1, drawn from the AMFm technical design document.[20] Essentially, the AMFm will provide a direct subsidy to approved manufacturers of approved ACTs. They, in turn, provide the drugs at a lower, subsidized cost through their normal supply chains in either the public or the private sector. The subsidy incentivizes manufacturers to focus on production of ACT, rather than cheaper, but resistance-prone, monotherapies. It also drives down the cost of ACT to the consumer, whether that is a government health system or drug-sellers in rural villages.

Figure 1



Case 2: Advance Market Commitments

The second process we examine is the creation of an Advance Market Commitment (AMC) for the pneumococcal vaccine. The general concept behind an AMC (sometimes also called an Advance Purchase Commitment) is to create demand, backed by purchasing power committed by donors, for products that primarily benefit developing countries. An initial AMC proposal was published in 2000 by Michael Kremer, an economist at Harvard University and the Brookings Institution. In that and subsequent articles, Kremer and colleagues started to flesh out the concept and technical requisites of the AMC idea, which had arisen from discussions at WHO and the International AIDS Vaccine Initiative (IAVI) about how to incentivize for-profit vaccine manufacturers to conduct research into a vaccine against HIV or AIDS.[21]

In 2003, the Center for Global Development (CGD) convened a "Pull Mechanisms Working Group" to "explore the feasibility of advance guarantee agreements as a tool for stimulating research, development and production of vaccines for neglected developing-country diseases."[22] Funding for the working group's activities was provided by BMGF. Like IOM, CGD is a research institution that makes policy recommendations but is not itself a program implementer. It describes itself as "an independent, nonprofit policy research organization that is dedicated to reducing global poverty and inequality and to making globalization work for the poor."[23]

The Pull Mechanisms Working Group, co-chaired by Kremer, Ruth Levine from CGD and Alice Albright from The Vaccine Fund, included more than 20 economic, public health, legal, industry and policy experts from universities, government agencies, consulting firms, law firms and foundations. Their report, *Making Markets for Vaccines,* was issued in April 2005.[24] It offers a detailed model, along with sample contracts, outlines of technical requirements for vaccine producers and financial requirements for donors and other specifics.

The report's guidelines for addressing "the lack of market-based incentives for pharmaceutical companies to complement…existing efforts with the R&D necessary to move promising vaccine candidates from the lab through to scaled-up manufacturing"[25] were legitimized by the level of detail of the proposal, the data marshaled as evidence, the academic and political affiliations of the members of the commission, and the statements of support for the proposal, printed as blurbs on the back of the report, from, among others, British Prime Minister Tony Blair, Ethiopian Prime Minister Meles Zenawi and Patty Stonesifer, the president of BMGF. The involvement of stakeholders from the various potential implementing organizations and governments of recipient countries served two functions: some stakeholders became policy champions within their organizations and advocated for it after the conclusion of the working group's commission; others were not active champions but created opportunities for the advocates to present the proposal in various settings.

The CGD report was presented to, among other possible supporters, the finance ministers of the G7 in June 2005. The ministers charged the Italian minister of economy and finance, Guilio Tremonti, with examining the proposal further. Background papers and

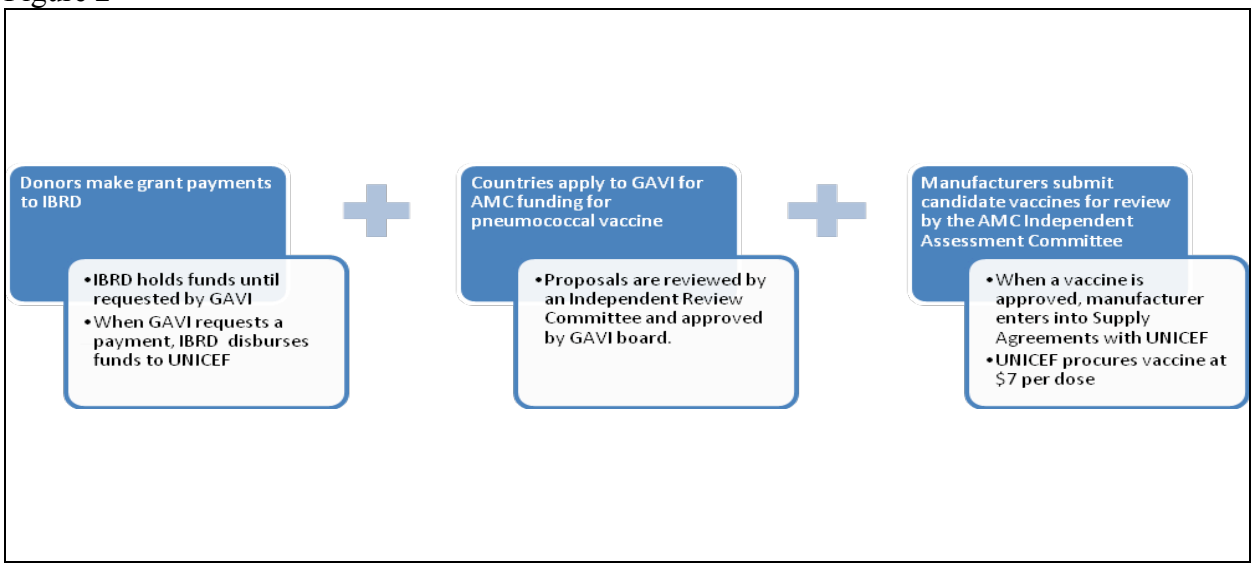
the final analysis were "the fruit of a collective work carried about by a team"[26] whose members included staff from the Italian Ministry of the Economy and Finance, the World Bank, a strategic consulting company and several academics, including Kremer. In December 2005 Tremonti presented his conclusion: "The AMC initiative is feasible and stands as an innovative and effective tool in the fight against global disease and poverty."[27] At the G7 finance ministers' meeting, they announced an agreement to develop a pilot project to test the concept of the advance market commitment and asked the World Bank and GAVI to coordinate it jointly.

A consultation process to further develop technical specifications was launched in January 2006, designed to coordinate simultaneous efforts by several sub-committees.[28] The "Disease Expert Committee" was charged with selecting a candidate vaccine effort to focus on as the pilot project – their recommendation to focus on streptococcus pneumonia, or pneumococcus, was made in February 2006. Pneumococcus is estimated to be the cause of over 1.5 million deaths from meningitis or pneumonia annually, and a vaccine targeting the types of pneumococcus most prevalent in the developing world was in the late stages of development and clinical testing.[29] A technical working group then met several times over the course of the year to integrate the specifics of pneumococcal vaccine and AMC structures, resulting in an official launch in February 2007. At that point, management of the pilot was transferred to an Independent Assessment Committee (IAC) while two committees, an economic expert group and a target product profile (TPP) committee, continued defining programmatic details. The IAC issued a call for membership applications in May 2007 and held its first selection panel in October of that year. At the end of the year, the TPP was approved by WHO's Director-General, and UNICEF issued a written declaration of interest in the project.

Throughout 2008, the working groups continued to meet and compile their reports. In December 2008, with reports having been submitted on the economics of the project, as well as recommendations and guidelines for implementation and monitoring and evaluation, and with funding commitments from several G8 governments, the IAC approved a TPP for *streptococcus pneumoniae*. The Global Alliance for Vaccines and Immunization (GAVI) took on the role of administering the proposal review process for the AMC, while the World Bank's IBRD was designated the financial manager (a decision that was endorsed by the Board of Executive Directors during their meeting in March 2009).[30] IBRD will provide "standard financial management and administrative services regarding donor contributions, AMC commitments, and disbursements."[31] The final structure for the pilot AMC is outlined, very generally, in Figure 2. GAVI reviews proposals submitted by countries to integrate the pneumococcal vaccine into their other immunization activities. If the proposal receives approval, GAVI makes a recommendation to IBRD to release funds to UNICEF on behalf of the country. UNICEF then sources vaccines and provides them to the country for distribution. Financial commitments of up to $1.5 billion to this AMC, for the previously developed but not widely distributed pneumococcal vaccine, have been made by the governments of Italy, Britain, Canada, Russia and Norway, as well as the Gates Foundation.[32]

One significant compromise made for the purposes of the pilot AMC was the selection of pneumococcal vaccine, a vaccine that was pre-existing. Other options considered by the Disease Expert Committee included HIV/AIDS, human papilloma virus, malaria, rotavirus and tuberculosis. While recognizing that all these diseases have major public health implications, pneumococcus was selected for the pilot AMC because the existence of vaccines gave it "the ability to demonstrate quickly that the AMC concept works and because of their potential impact on the health of the target populations."[33] The committee also noted that a second pilot AMC would eventually be necessary to test the concept for early-stage development. In this case, the use of an AMC is incentivizing widespread production and distribution of vaccine for developing countries. However, the initial purpose of AMC's also included an emphasis on incentivizing research and development for neglected diseases.

Figure 2



Discussion

With the details of the two cases in mind, the AMFm and AMC can now be systematically compared for each of the proposed process indicators. In Table 1 each indicator is listed, along with specific questions that comprise it. The two processes are placed side-by-side and a brief assessment offered for each indicator.

Comparing the individual indicators shows one key difference: the AMFm process was ultimately more successful than the AMC process because the program created is directly in line with the initial goals of the proposal. The current structure of the AMFm should, if it proves effective, address both challenges initially identified: increasing access to drugs while protecting against the development of resistance to artemisinin. The AMC, however, is addressing only one of its initial two targets: it will, if it proves effective, expand access to new vaccine products, but it will not be able to demonstrate whether the same incentive structure can also promote research and development.

Another key difference is the point at which the initial idea was taken up by a policy research institute. In the case of the AMFm, the idea for the subsidy was generated by a policy research group convened to address a particular set of challenges. The particulars of an AMC, however, were initially floated by an individual researcher, and it took about three years before a research institute convened a formal working group to flesh out the idea into architecture.

Once both proposals had been developed by multi-disciplinary research groups, however, the processes became fairly similar. Comparing them, therefore, sheds more light on key elements for success of processes like these in the early 2000's. Emanating from well-regarded research groups, associated with academic integrity and political acceptability, afforded immediate authority to the ideas presented. The authority of IOM, and in particular of Arrow, along with the "simplicity and elegance" of its strategy, earned it an effective policy champion in Adeyi; for the AMC, although the idea originator Kremer continued to act as a vocal advocate, policy champions from the World Bank, DFID, industry and management consultancy came from the CGD working group. Successfully promoting the ideas beyond the idea stage, therefore, required having policy champions both within and outside research institutions. Academics' commitment to a proposal gives the idea its initial authority; but policy champions are required to shepherd ideas through the maze of institutions, agencies and political systems that can facilitate development to an articulated policy initiative that can be implemented.

Both the AMFm and AMC ideas, originating as they did from theoretical approaches, also needed significant technical input from consulting groups, stakeholders and relevant implementing agencies. Both reports did include technical and financial recommendations. However, skeptics were concerned that, when translating a theoretical approach into a practical program, on-the-ground realities and complications would prove insurmountable impediments to implementation.

Table 1: Process indicators		
Indicator	***AMFm***	***AMC***
1. Success in establishing the proposed program: a. Does it exist? b. Is it fully supported in the short-term? c. Is it designed to fulfill all the goals of the initial proposal?	a. Yes b. Yes c. Yes Overall: Successful	a. Yes b. Yes c. No Overall: Partially successful
2. Timeline and efficiency of development process a. How long did it take? b. Were there significant gaps between steps?	a. Five years from IOM report release b. Some gaps but process was ongoing Overall: Mostly efficient	a. Three years from Kremer's first article; four years from CGD report release b. Yes, especially before report Overall: Partially efficient
3. Stakeholders engaged a. Early enough in process? b. Took on responsibilities? c. Effectively executed responsibilities?	a. Yes and no b. Yes c. Yes Overall: Partially successful	a. Yes b. Yes c. Yes Overall: Successful
4. Skeptics/critics assuaged or sidelined a. At what point? b. Were any swayed enough to switch positions?	a. Initially sidelined, subsequently engaged b. Some Overall: Partially successful	a. Unknown b. Unknown Overall: Unknown, but partial success assumed based on outcome of process
5. Institutional support secured		

Table 1: Process indicators		
Indicator	***AMFm***	***AMC***
a. Institution agrees to house program b. Institutional leadership publicly supports initiative	a. GFATM b. Yes Overall: Successful	a. GAVI and IBRD b. Yes Overall: Successful
6. Resources secured a. Donors commit new resources	a. Yes for Phase 1 Overall: Successful	a. Yes for pilot Overall: Successful
7. Political support secured a. Representatives of donor governments publicly express support b. Representative of beneficiary governments publicly express support	a. Yes (European but not U.S.) b. Yes, co-chair Overall: Successful	a. Yes (European, but not U.S.) b. Yes Overall: Successful
8. Prospects for long-term sustainability a. Evaluation plans established b. Donors commit to long-term support c. Additional donors being cultivated	a. Yes for Phase 1 b. Pending evaluations c. Unknown Overall: Partially successful	a. Yes for pilot b. Pending evaluations c. Unknown Overall: Partially successful
9. Process drivers (people who champion the initiative)	Yes – at World Bank, RBM, IOM, BMGF, Dutch and UK governments, GFATM	Yes – at CGD, GAVI
10. Process facilitators (people who create political space for the process drivers or otherwise support the initiative's development)	Yes – at World Bank, RBM, GFATM	Yes – G7 finance ministers

At this point in both processes, BMGF served as a critically important facilitator by providing the research agencies with financial support to conduct these translational steps. BMGF's interest in supporting market-based solutions to global health challenges, and willingness to take risks on these ideas, enabled both programs to materialize at a point when the costs involved in facilitating the process would have been difficult to overcome for other institutions.

Once the ideas were shown to have traction in the face of potential obstacles, the next step was to present them to potential implementing institutions and to secure an institutional home for the proposed program. At this point, the commitment of the policy champions is critical. Kingdon writes: "There is a long process of softening up the system….Thus [champions], who broker people and ideas, are more important than inventors."[34] Kingdon describes champions as people "who are willing to invest their resources – time, energy, reputation, money – to promote a position in return for anticipated future gain in the form of material, purposive or solidary benefits."[35]

Among the important characteristics of a successful champion, according to Kingdon, are standing within the network, meaningful political connections outside the network, willingness and skill to negotiate, and, above all, persistence. The willingness of the policy champions to promote the AMFm and AMC was derived from their strong commitments to what they saw as the theoretical validity of the ideas. Thus they were willing to shepherd the proposals through the series of presentations, technical reviews, advocacy activities and other necessary steps. Among the steps the policy champions took, garnering visible support from political players as well as potential donors and beneficiaries, assisted them to maintain momentum and secure support from implementing institutions.

Securing an institutional home is an exceedingly critical element. The ideas for the AMFm and AMC were generated outside of implementing organizations, meaning that they did not have an immediately available infrastructure in which to develop. This gap necessitated a long process of building political support among multiple potential stakeholders who could jointly identify and agree on the proper institutional home. Then a second process had to take place to build political support within the identified institution. Although these processes required a long period of advocacy, it would have required much longer to create an entirely independent institution for either program. Although locating the programs with existing institutions necessitated generating internal political support, it ultimately shortened the period of setting up operations and administrative structures for managing donor funds. Aligning with existing structures, such as GFATM and GAVI, lends additional legitimacy to the ideas and provides current donors to those organizations with a sense of security when supporting the new entity.

Comparing the AMFm and the AMC reveals both benefits and liabilities that arise in implementing ideas for development initiatives that are generated by research institutes. These are outlined in Table 2.

Table 2: Benefits and Liabilities of Independent Proposal Development	
Inherent Element	**Effect**
Carefully constructed, theoretically sound policy designed to respond to complex, multi-faceted challenges	**Benefit**
Research-based process allows for detailed critiques that might be more difficult in a siloed institution or one with immediate targets for implementation	**Benefit**
Prestige and objectivity associated with academic research	**Benefit**
Developed outside an institutional home	**Liability**
Requires additional development to address technical dimensions of implementation and real-world complications	**Liability**
Requires strong and committed policy champions to manage the politics involved	**Liability**

Thus, there are both benefits and liabilities inherent in developing initiatives based on ideas generated through theoretical and research processes. Future evaluations and analyses of implementation will determine the extent to which the AMFm and the pneumococcal vaccine AMC actually meet the goals set for them, as well as their impact on the problems which they were designed to address. Learning from the processes, in the meantime, can assist academic and implementing institutions to better understand the ways in which they interact and the key aspects necessary to promote future collaborations. Ultimately, good ideas can come from anywhere. Coming from an academic process lends authority to the theoretical validity of the idea, but necessitates additional considerations to ensure that it is feasible and can be applied in practice. This involves creation of an effective policy transfer network. A network enables the integration of expertise from multiple disciplines and sectors, coordination among implementing institutions and, above all, builds support among political, donor and beneficiary stakeholders. This network support provides a foundation from which a small group of policy champions, willing to devote significant time and effort to translating the idea to an initiative, can get to work. With financial support from a donor willing to risk funds on developing ideas, such as BMGF, the policy champions can succeed in taking the ideas all the way into implementation.

End Notes

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