FIVE-YEAR EVALUATION OF THE GLOBAL FUND – STUDY AREA 3: HEALTH IMPACT

Inception Report

Revised June 20, 2007

Five-Year Evaluation of the Global Fund—Study Area 3: Health Impact
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Five-Year Evaluation of the Global Fund – Study Area 3: Health Impact

1. Introduction

This Inception Report is the first deliverable for Study Area 3: Health Impact, under contract GVA-520-C-07-045-00 with the Global Fund. In the contract the report is described as: "The contractor will deliver an inception report on April 20, 2007 outlining the timeline, team structure and working methodology of the evaluation." The requested information is presented below, as well as other information that elucidates the approaches taken by the Team and the progress made so far.

2. The Team Structure

The Health Impact Evaluation Team (the Team) that will carry out the activities related to Study Area 3: Health Impact of the Five-Year Evaluation of the Global Fund (the Evaluation) consists of five partners:

Macro International
The World Health Organization
Johns Hopkins University Bloomberg School of Public Health
Harvard University, School of Public Health
African Population and Health Research Center

Macro International is the prime contractor and is in charge of the general contract administration, reporting and management. Technical direction for the contract is provided by WHO.

Representatives from each organization constitute the Steering Committee which is scheduled to have monthly meetings, mainly through teleconference, to ensure that all Team members are fully up-to-date on events and approaches and to share experiences that will be of value to other partners.

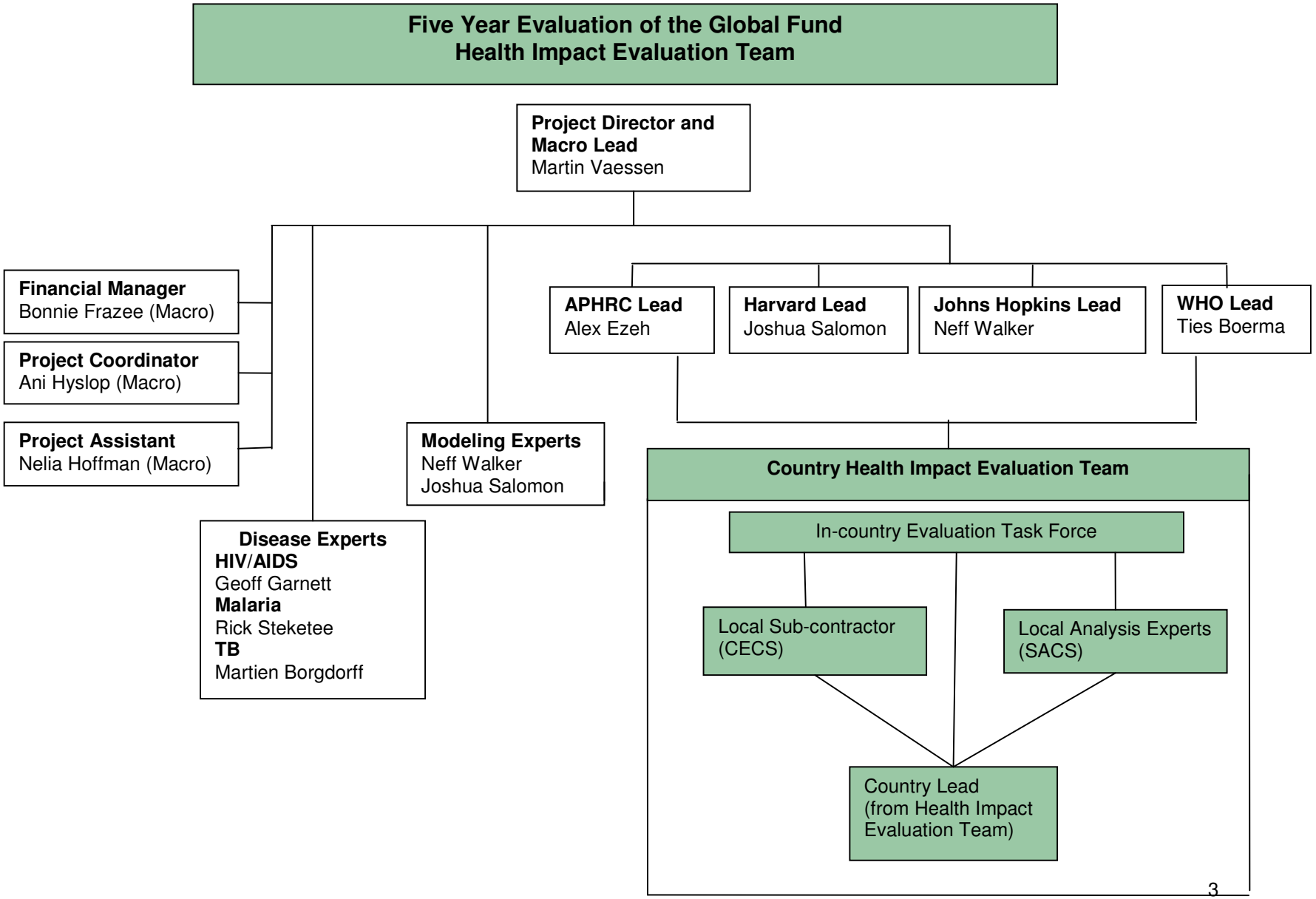
In addition to these five organizations, three disease experts have been hired as consultants to ensure that the Team has access to the latest technical developments in the areas of HIV/AIDS, malaria and tuberculosis.

An organization chart that shows the relationships between the partners and the in-country evaluation stakeholders and assigns responsibilities to the principal specific individuals is presented below.

In addition to the Team that was contracted by the Global Fund, In-Country Evaluation Task Forces will be created and will form an integral part of the team through their direct involvement in and direction of country-specific activities.

Each participating partner will draw on relevant staff in their organizations to help the In-Country Evaluation Task Force and local analysts and subcontractors to carry out the specific activities related to the country Health Impact Evaluation Work Plan.

Finally, local analysts and subcontractors will also be engaged as needed and carry out the local activities that are decided upon for each country, bearing in mind available data and the possibility of funding for necessary additional data collection activities. All local implementing staff will effectively form the core of each country team.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APHRC Lead
Alex Ezeh
Harvard Lead
Joshua Salomon
Johns Hopkins Lead
Neff Walker
WHO Lead
Ties Boerma
Country Health Impact Evaluation Team
In-country Evaluation Task Force
Local Sub-contractor (CECS)
Local Analysis Experts (SACS)
Country Lead (from Health Impact Evaluation Team)

3. General Performance Schedule and Work Plan

Appendix 1 contains a detailed general work plan for the Evaluation activities. This plan will be further refined and adapted on the basis of the experiences that are gained with the different countries.

Appendix 2, *Guidance Note: Process and Expected Outcomes,* provides more information about the general approaches to be followed during this Evaluation, and is meant as a document that is shared with country counterparts prior to the first visit to ensure that everyone has a good grasp of the scope and intent of the planned country Health Impact Evaluation.

The main milestones of the general work plan can be summarized as follows:

Develop draft protocols	March – April 2007	Completed
Invite country participation	April 2007	Completed
April-June 2007 Carry out first country visits and develop country Work Plans and subcontracts	April – June 2007	In progress
Multi-country Workshop for SACS countries	June 18-20, 2007	In progress
Data collection	June 2007 – February 2008	Planned
Data analysis	August 2007 – May 2008	Planned
Information dissemination	April – June 2008	Planned

Country specific activities will vary in their timing by country, but all should ultimately be completed in June 2008. Until specific country Work Plans have been developed for all countries, no further detail can be provided. The country Work Plans will be contained in the Management and Oversight Report that will be presented on July 15, 2007.

4. Assignment of Country Responsibilities

The key to accomplishing the extensive activities envisaged in the Health Impact Evaluation in a timely manner implies that the different Team members will each take primary responsibility for one or more countries. The countries are divided into two groups, according to the contract: (1) Comprehensive Evaluation Country Studies (CECS) countries of which there are eight and (2) Secondary Analysis Country Studies (SACS) countries of which there are 12. These groups of countries were given various different names during the Partners in Impact Forum, but in this document we use the terms by which theses countries are designated in the contract.

During the first meeting of the Steering Committee on March 26-27, 2007 at Macro, the primary responsibility for assisting countries with their impact evaluations was decided upon as follows:

CECS countries:

Burkina Faso	WHO
Cambodia	WHO
Ethiopia	Johns Hopkins University
Haiti	Macro
Malawi	APHRC
Peru	Harvard University
Tanzania	WHO
Zambia	WHO

SACS countries:

Benin	APHRC
Burundi	APHRC
DRC	APHRC
Ghana	APHRC
India	WHO
Kyrgyzstan	Johns Hopkins University
Moldova	WHO
Mozambique	Harvard University
Nepal	Macro
Rwanda	Harvard University
South Africa	Macro
Vietnam	Johns Hopkins University

The country assignments were largely based on the level of familiarity of the different team members with the different countries and their access to and experience and familiarity with local staff and resources. Each partner in charge of a CECS country or countries will contact the relevant Country Coordinating Mechanism and other contacts provided by the Global Fund to arrange for a first visit to the country to start the process of developing the Work Plan and selecting local subcontractors that will actually be doing the local work.

Introductory letters addressed to the chair of the Country Coordinating Mechanism were sent out on April 11 (the day that Macro received the signed contract from WHO) notifying the countries of the partner assigned to their countries (examples for CECS and SACS countries are found in Appendix 4).

5. Basic Evaluation Methodology

a. Description of the Team's basic approach

The basic approach to this evaluation is to study trends in the important indicators related to HIV/AIDS, malaria and tuberculosis and to relate those trends to any changes in the service environment and behaviors and to changes in the financial allocations to the different diseases. This approach reflects the basic philosophy that changes in funding should have an effect on services and that changes in services should have an effect on outcomes. The approach was developed and discussed during the March 26-27 Steering Committee Meeting and further refined thereafter through consultation with Team members. The approach is described in *Data Collection Design and Methods* (Appendix 3)

b. Evaluation process

The process to be followed in the country studies is described in *Guidance Note: Process and Expected Outcomes* (Appendix 2) and consists of four phases.

Phase 1: Planning (April – July 2007)

During which a detailed Country Health Impact Evaluation Work Plan is developed and an inventory of all relevant data sources is made. The first multi-country workshop will be held during this time.

Phase 2: Data collection (June 2007 – February 2008)
Focuses on compiling existing data and data collection activities in Comprehensive Evaluation Country Studies countries.

Phase 3: Data analysis (August 2007 – May 2008)
Analysis of existing and new data is conducted. The second multi-country workshop will be held during this time.

Phase 4: Information dissemination (April – June 2008)
The final country Health Impact Evaluation Report is disseminated to in-country stakeholders and submitted to Macro.

c. CECS and SACS country approach

The 20 countries involved in the Evaluation have been designated as Comprehensive Evaluation Country Studies (CECS) countries or Secondary Analysis Country Studies (SACS) by the Global Fund. CECS countries are those eight countries where significant additional funding is available for additional data collection activities, while SACS countries are those where the evaluation would largely take place on the basis of existing information.

The Team decided that rather than employing this distinction to the letter, all countries would basically start with the same protocol and might do additional data collection as possible, including potential collection funded by other donors. Thus, there could be variable support for data collection across the different countries, depending on the identified needs for additional data collection and the line between CECS and SACS countries could become less sharp than envisaged. Much will depend on the capabilities in SACS countries to attract other donor funds, as primary data collection was not budgeted for SACS countries, as that was not requested in the RFP.

This thinking has not led to a re-assignment of resources to the two types of countries for additional data collection, but is more a state of mind that will guide the work in the different countries. Given the limited funds available for additional data collection and the elevated cost of such activities, funding from other donors may also be tapped to fill in some of the funding gap that will likely be identified. (See also 7).

d. Capacity building plan

As a result of this Evaluation, both human capacity and technical resources will be developed which will increase local and international capacity to conduct future Health Impact Evaluations and other disease-related analyses. In terms of human capacity, a cadre of analytical experts will be trained to conduct similar evaluations for the country in the future or for other countries. In addition the Impact Evaluation Task Force will be established and encouraged to continue existing following the end of the Evaluation. The deliverables for the Evaluation can be grouped as those that build the capacity of the country to conduct analyses by creating new data, cataloguing existing data, and

validating existing data and those that build global capacity to conduct future Health Impact Evaluations by developing the necessary reference materials.

Deliverables that Increase Country Capacity

- Data source logbook
- Document library
- New data collection
- Data validation study

Deliverables that Increase Global Capacity

- Impact Model Platform which includes the documents *Guidance Note: Process and Expected Outcomes* and *Data Collection: Design and Methods* (see p.12 of Annex 2 for details)

Two formal workshops have been established in the implementation plan for SACS countries, one in June, 2007 to develop the country Evaluation Work Plan and one in April 2008 on modeling. There are no other formal capacity building activities in the work plan, but it is foreseen that some of the country analytic work may also be done with groups of countries participating at some central level and with considerable oversight and help and this should further help build capacity.

Areas where capacity building should be evident fairly early on should be during the record review. During this process people will learn the strengths and shortcomings of their systems and how to best process and analyze the data that become available. This experience should be invaluable for future work.

Analytical capacity will also be increased considerable through working with the Contractor's team diseases and analytic experts.

The role of the Impact Evaluation Task Force (IETF) in capacity building is important in that this body provides the first line of oversight and can help guide the work done by the local counterparts with the help of the contractor. One issue that has to be borne in mind is that the quality of the IETF membership may vary somewhat by IETF and that the contractor had little or no say in the establishment of the IETF's. However, during each visit by contractor staff there should at least be an attempt to meet with the IETF at the end of the visit to provide them with a detailed update of the activities and to enlist their help where necessary. This process itself will help make the IETF more aware of the problems that are encountered and the solutions that are offered, and thus make a substantial contribution to the capacity building of this body.

6. Workshops

In the original plans of the Team, two multi-country workshops were included for representatives from Secondary Analysis Country Studies (SACS) countries, to facilitate work in those countries in the most efficient manner. The first such workshop has now been scheduled for June 18-20 in Kenya. The purpose of this workshop is to review existing data sources and develop country Health Impact Evaluation Work Plans.

In the April 11 letter CCM's were asked to provide the Team with the names of two outstanding local analysts who will be invited to attend this workshop and who are in a position to dedicate about one year of time to the activities related to this evaluation.

7. Country Implementation Approach

The general working methodology will be very much as described in the Team's proposal and is presented in the draft documents *Guidance Note: Process and Expected Outcomes* (Appendix 2) and *Data Collection: Design and Methods* (Appendix 3). These documents will be shared with the countries early on. The approach will incorporate measures to help ensure country ownership of the evaluation process and results. These measures include:

1. establishing initial contact with the country through the CCM chair and its designees;
2. eliciting from the CCM nominations for analytic experts to conduct the evaluation analysis in SACS countries and approving the hiring of contractors in SECS countries;
3. ensuring that the Impact Evaluation Task Force is functional
4. working with the CCM and the Impact Evaluation Task Force to approve the Evaluation Work Plan;
5. helping the Impact Evaluation Task Force and CCM to identify additional funding sources for filling data gaps
6. having the Impact Evaluation Task Force be responsible for facilitating and reviewing the evaluation work;
7. ensuring that the Impact Evaluation Task Force and CCM and other stakeholders participate in the dissemination of evaluation results.

The Impact Evaluation Task Force is the body that is in formal charge of the studies. Ensuring that all IETF's are fully functional will be a challenge as they have been established in a rather *ad hoc* manner and little control has been exercised over their membership. Much of the membership is decided upon on an institutional basis and, while that is logical, may not render the best possible IETF. However, the IETF will have to approve the work plans and as such has ultimate say over what is going to happen.

The contractor will attempt to meet with the IETF during each visit of its staff, to inform the IETF of what is going on and to get their advice. Thus contact with the IETF will be continuous and it will be further strengthened during the production of the final country report that also will need to be approved by the IETF. Whether the IETF will continue as an active body after this exercise is really outside the scope of this contract and no financial or human resources were set aside in our proposal to ensure continued existence of the IETF.

8. Performance Management

It is clear that in a complicated endeavor, as is the Five-Year Evaluation of the Global Fund, there will be expected and unexpected events that may affect the timely completion of activities in each country. This is not a characteristic that is reserved for Global Fund activities; as it occurs with all substantial activities that are carried out in some of the more difficult countries to work in.

Macro and its partners have extensive experience in this area. At the same time, the remedies for non-performance are limited: one can exhort local staff in charge to do better and faster work and oftentimes this does help the situation considerably. The earlier such calls are made the better, so it will be necessary to closely follow the activities planned in a country to gauge progress and develop necessary interventions.

In many instances, however, remedial measures will mean provision of more technical assistance than planned, which has cost implications, of course. Alternatively, different local staff may have to be found to complete the work, but in all cases it is likely that more oversight and technical assistance will need to be provided.

Particularly if time frames are immovable, we have to foresee that some countries will need considerable intervention. That is what experience tells us. Hopefully we are wrong.

It is not worthwhile to develop a detailed intervention plan for each country as it is not known in which areas the interventions will be necessary. The secret is to monitor and evaluate progress and to step in when judged necessary. Country ownership is also an important issue, and one cannot at the first sign of trouble intervene and take the work out of the hands of the assigned experts, particularly as they were designated by the IETF. Collaboration is the word that has to be operative throughout this work and with each country.

9. Link between SA2 and SA3

The Five-Year Evaluation of the Global Fund has been divided into three sections of which two of them involve country-level studies: SA2: Global Fund Partnership Assessment and SA3: Health Impact. Eleven of the 20 Health Impact countries are also involved in the Partnership Assessment (all 8 CECS and Kyrgyzstan, Nepal, and Viet Nam).

Study areas 2 and 3 are quite different, both in content and in the time dedicated to complete the basic studies. SA2 activities are scheduled to be finished by February 2008, while SA3 activities will go until the middle of 2008. Thus, there is a limited time that SA2 and SA3 will be operational in the same countries, prior to the development of the final synthesis report. We see the linkage between SA2 and SA3 as one that can inform where SA3 can find data that are relevant for the evaluation, because SA2 will identify all the actors working in the area. It will be another major source of information for gauging the efforts that have gone into the Global Fund work and thus, contribute significantly to the evaluation. Much of this work is scheduled for the final synthesis report, but sources of possible information should be identified as soon as possible.

10. The Role of Other Donors

The extensive activities that are necessary to carry out a high quality impact evaluation for the countries chosen for this exercise, may imply more extensive data collection than can be financed out of the funds available for local subcontracts.

In the Team's experience, it will be possible to secure additional funding from donors other than the Global Fund to pay for some of these additional activities. Additionally, according to the advice received from the Global Fund staff during the Partners in

Impact Forum, participating countries may also be able to dedicate some of the Global Fund grants that are earmarked for monitoring and evaluation to part of the work that will be carried out under this impact evaluation.

The detailed country Work Plans that will be developed will form the basis on which to decide whether additional funding is required and should be sought. It is expected that such funding will mostly be obtained for the eight priority countries, but it should not be discounted for the 12 other countries, where more financial support may be needed to carry out all planned activities to the highest level.

11. Ethical Considerations

All Macro studies are submitted to the Macro Institutional Review Board (IRB) for approval as well as to the local IRB's. This is a Macro policy. In the case of the Five-Year evaluation, IRB approval will be especially needed for the record reviews and the follow-up of people on ARV's and DOTS. However, Macro will obtain approval for the larger study package, that for the CECS countries, so that SACS countries will automatically be covered.

At the local level, Macro and the IETF have to ensure that the terms approved by the IRBs are adhered to in full during the execution of the work. Particularly, those activities that tend to work with individual people who have been identified with a specific disease need to strictly follow the established protocols that will be put in place to protect the identity of the concerned subjects from people who should not know their disease status.

12. Concluding Remarks

The Five-Year Impact Evaluation of the Global Fund – Study Area 3: Health Impact is well underway. The immediate activities that are underway or completed are:

- A meeting of the Steering Committee took place on March 26-27 to discuss the study protocols and other issues related to the implementation of the work
- Development of the evaluation guidance is well advanced (Third draft completed)
- Country responsibility has been assigned to individual partners (Completed)
- Initial contact with countries has been made (Countries contacted on April 11, 2007. Sample letters included in Appendix 4.)
- Visits to all CECS have been completed and draft Country Evaluation Work Plans are being developed for IETF approval.
- All Country Evaluation Work Plans are expected to be completed by July 15, as planned
- Work has started on the development of the questionnaire that will be used for the district-level household survey as well as on the instrument that will be used to obtain data for the census of district health facilities, as described in the *Data Collection Design and Methods* document.
- Sampling issues are also being addressed and discussed, to ensure that proper sampling procedures are implemented in the field.

The table below summarizes the activities in the countries:

	Lead Partner	1st Country Visit	Analysts Nominated
CECS countries:			
Burkina Faso	WHO	May 7-10	
Cambodia	WHO	June 5-8	
Ethiopia	JHU	May 7-13	
Haiti	Macro	May 1-4	
Malawi	APHRC	May 1-4	
Peru	Harvard	June 4-7	
Tanzania	WHO	May 28-31	
Zambia	WHO	April 11-13	
SACS countries:			
Benin	APHRC		
Burundi	APHRC		
DRC	APHRC		
Ghana	APHRC		
India	WHO		
Kyrgyzstan	JHU		
Moldova	WHO		
Mozambique	Harvard		
Nepal	Macro		
Rwanda	Harvard		
South Africa	Macro		
Vietnam	JHU		

Appendix 1.

Health Impact Evaluation Work Plan

Activity	Lead	2007										2008						
		M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Health Impact Evaluation Management																		
Steering Committee Management Meetings	MV	28	17	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Send Introductory Letters	MV		11															
Develop:																		
Health Impact Evaluation Guidance Note	TB		30															
Data Collection Design Methods	TB		30															
Country Work Plan Template	TB		30															
District Household Survey Package	MV				30													
District Health Facility Census Package	TB				30													
Model Health Impact Platform	PN/JS															X	X	X
Submit:																		
Inception Report	MV		20															
Management and Oversight Report	MV					15												
Initial Progress Report	MV						28											
Mid-term Progress Report	MV									12								
Final Progress Report	MV												28					
Draft Impact Evaluation Report	MV														30			
Final Impact Evaluation Report	MV																30	
Collaborate on *Final Five-Year Evaluation Synthesis Report* (continues through Oct 2008)	MV													X	X	X	X	X
12 Secondary Analysis Countries																		
Phase 1: Planning																		
Identify in-country analytic experts	Leads			10														
Multi-Country Health Impact Workshop I (June 18-20; Nairobi Kenya)	PN/JS/AE				20													
Country Health Impact Evaluation Work Plan	Leads					15												
Compile Data; Completing:	Experts					X	X	X										
Data Source Logbook								15										
Indicator Database								15										
Phase 3: Data analysis																		

Activity	Lead	2007										2008						
		M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Analyze existing data	Experts								X	X	X	X	X					
Multi-Country Workshop II Modeling Workshop	PN/JS/AE														X			
Phase 4: Information dissemination																		
In-country dissemination of draft report															X			
Draft country Health Impact Evaluation Report	Experts														X			
Final country Health Impact Evaluation Report	Experts																X	
8 Comprehensive Evaluation Study Countries																		
Phase 1: Planning																		
Country Visit 1 (introduction, work planning)	Leads		X	X														
Identify in-country expert	Leads		X	X	X													
Country Health Impact Evaluation Work Plan	Leads				30													
Compile Data; Completing:	Experts				X	X	X	X										
Indicator/Data Source Map																		
Data Source Logbook								15										
Indicator Database								15										
Phase 2: Data collection																		
Country Visit 2 (finalizing primary data collection plans)	Leads			X	X													
Collect Data	Experts				X	X	X	X	X	X	X	X	X					
Phase 3: Data analysis																		
Analyze existing data	Experts						X	X	X	X	X	X	X	X				
Multi-Country Workshop II Modeling Workshop)	PN/JS/AE														X			
Phase 4: Information dissemination																		
In-country dissemination of draft report	Experts														X			
Draft country Health Impact Evaluation Report	Experts														X			
Final country Health Impact Evaluation Report	Experts																X	

Appendix 2.

Multi-Country Health Impact Evaluation of the Scale-up to Fight AIDS, TB and Malaria
with Special Reference to the Global Fund

GUIDANCE NOTE: PROCESS AND EXPECTED OUTPUTS

March 2007

Five-Year Evaluation of the Global Fund—Study Area 3: Health Impact
Macro International Inc.
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This document provides general guidance to the country health impact evaluations conducted as part of the Five year evaluation of the Global Fund, Health Impact Study Area 3. Twenty countries have been invited to be part of this process, including eight countries with where additional funding for primary data collection is available through the Evaluation Study Consortium (also referred to as the Macro Team). This Consortium consists of Macro International (the primary contractor), African Population and Health Research Centre (Nairobi), WHO (Department of Measurement and Health Information Systems, Geneva), John Hopkins University (School of Public Health), and Harvard University (School of Public Health). In addition, the Consortium includes expertise in the three diseases and health financing. There are four phases in the country evaluation of health impact: planning, data collection, data analysis and data dissemination. The time frame is such that the final product, the country evaluation report, will be ready by May 2008. This document describes the country activities in the four phases. An additional document will focus on data collection and analysis protocols to be used in the evaluation and describe in greater detail the measurement and analytical issues.

Background

The overall objective of the Five-Year Impact Evaluation is to comprehensively assess the collective impact that Global Fund and other national and international partners have achieved on reducing the disease burden of HIV, tuberculosis and malaria. Evaluation research is a critical element of the scale-up against the AIDS, TB and malaria. The evidence that appropriately designed and implemented evaluations can provide is important for two principal reasons. First, evaluation data can convincingly demonstrate the impact of resources invested. In many respects, the current global commitment to scale up services represents a grand experiment by the respective funding partners. It has been argued that widespread morbidity in many developing countries impedes development prospects. Such arguments combined with the overwhelming human tragedy, particularly in Sub-Saharan Africa, have resulted in an unprecedented increase in resources for the three diseases. If the impact is not documented in a convincing manner, then it may become increasingly difficult to secure future funding for the same objectives. Secondly, the evidence base for designing effective packages of interventions against the three diseases is limited. Although many cost-effectiveness studies have been conducted, there is much that is still not understood about both specific interventions and packages of interventions, particularly when going to scale.

The primary purpose of the evaluation is not only to assess what the morbidity and mortality changes have been brought about by Global Fund support. Instead, the Impact Evaluation takes a broader approach in which health impact is defined as the measurement or estimation of overall program effect on disease morbidity and/or mortality, brought about by all control initiatives and programs combined irrespective of their financing source(s), in a country or region. Direct attribution of Global Fund-specific investments to reductions in disease burden will not be attempted. Where possible, however, the share of Global Fund contributions relative to overall investments, and to other major contributors, will be assessed.

This approach recognizes that, in many countries, the Fund is not the single major international investor. As a financial instrument, any discernable impact that would be produced will only be accomplished through partnerships with multiple actors, including

the country itself. Therefore, the impact evaluation sets out to assess overall impact on the three diseases and the contribution of the Global Fund without direct attribution.

It must also be taken into account that the Global Fund investments are relatively recent. Any potential impact of Global Fund-supported activities will depend on the amount of funds disbursed and the length of time that they have been available to work on-the-ground. Data collection for the Five Year Evaluation will need to be complete by early 2008. At that time, less than 30% of grants (Rounds 1 to 5) will have completed a full five years of implementation. These factors suggest that health impact should be estimated in countries with widespread coverage of interventions supported by the Fund, relatively large influx of resources and at least several years of grant implementation.

The focus will be at the country level involving twenty countries that have received significant Global Fund funding. All countries will produce a thorough analysis of the current situation and trends, based on existing data, validation of data and supplementary new data collection. For all countries the Evaluation Study Consortium has resources to provide technical assistance through either country visits or workshops and validation of existing data. For eight impact evaluation country studies the Evaluation Study Consortium has resources to directly fill identified data gaps through primary data collection and analysis during 2007 and early 2008 in close partnerships with country institutions. These countries were selected by the Global Fund TERG following the Partners in Impact Forum 12-14 March 2007.

All evaluation activities will involve a country evaluation task force that will lead the work to ensure local ownership, maximum participation, integration of the evaluation work into ongoing activities, and enhance sustainability. In a second group of 12 impact evaluation country studies, the main investments will focus on detailed analysis of existing data, supplemented by small investments in validation studies and capacity building through workshops and technical assistance. Additional resources may become available for data collection from other sources. Workshops will be organized to bring together country expertise in the three diseases and evaluation, international experts on the three diseases and the evaluation study consortium (referred to as the Macro Team).

Basic approach

The basic approach of the evaluation is to document changes in the burden of the three diseases and systematically relate those changes to trends in behaviours, service coverage and utilization, and trends in health financing. This type of scientific inference used for policy making in the field of health has been referred to as adequacy evaluation[1]. Reductions in disease burden will also be examined through an equity lens, comparing trends in impact and in service coverage by major socioeconomic and demographic characteristics within countries.

The Impact Evaluation Study not only aims at making the best possible assessment of the collective impact of the Global Fund and partners on the burden of the three diseases, but also aims to lay the foundation for improved monitoring and evaluation in

[1] Victora CG, Habicht JP, Bryce J. Evidence based public health: moving beyond randomized trials. AJPH 2004, 94: 400-405.

the future. First, the evaluation will have direct benefits for the health information systems in countries involved in the evaluation. The evaluation efforts will rely on a range of data collection efforts, including surveys, surveillance, research studies, service and administrative records.

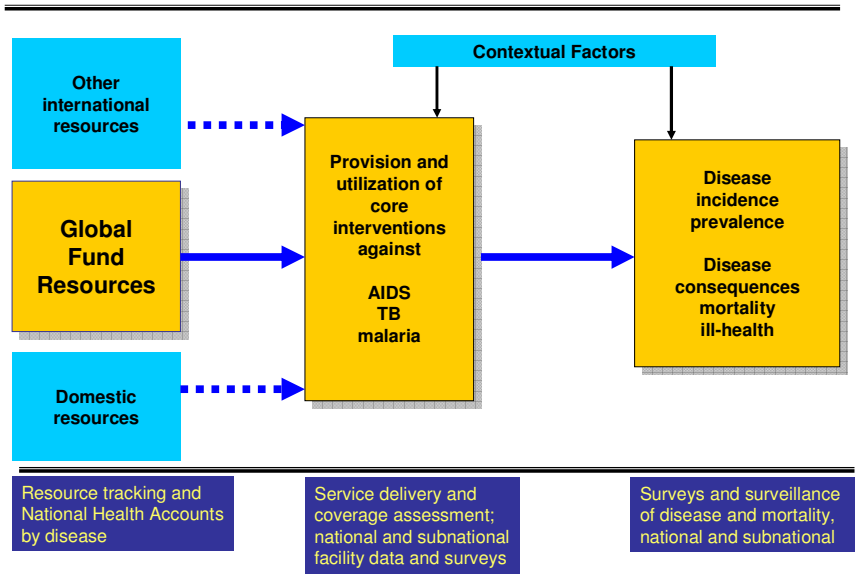
Recipient countries are encouraged to strengthen these types of data collection as part of implementing their Global Fund grants in a way that not only informs the 2008 Evaluation but also strengthens the country health information system. A link of the Impact Evaluation Study with general efforts such as the Health Metrics Network or PEPFAR efforts to support country health information systems strengthening and country capacity is critical.

Second, the evaluation will, based on lessons learned from countries participating in the evaluation, develop a model platform, including consensus on a set of tools and processes that can be used in assessing disease impact for the three diseases among Global Fund grant recipients and in other countries. One desirable post-evaluation outcome of the Impact Evaluation Study is that countries will be better equipped to use their Global Fund grants for systematically improving monitoring and evaluation work.

Data limitations will affect the extent to which the Impact Evaluation can reach conclusions about the impact of scaling-up against the three diseases. Health information systems are often weak and fragmented in countries with highest disease burden and high levels of external financial support. Given the recent nature of intervention scale-up in most of these countries, data availability will limit the power to accurately measure and evaluate disease trends. Data collection in the context of the evaluation can only partially overcome these limitations. Such data will form a basis for evaluation of progress towards the three diseases and MDGs in general in future years. Furthermore, the Impact Evaluation is expected to galvanize efforts to strengthen health information systems in the coming years, which will be instrumental for future impact evaluations.

The basic framework for the Impact Evaluation as specified in the Global Fund Request fro Proposals is shown below. Detailed frameworks for the specific diseases will be developed as appropriate. The core indicators are shown in Annex 1.

Figure 1
Basic Framework for 2008 Impact Evaluation
With Data Sources



Phase 1: Planning (month 0-4)

The first output of the work will be a comprehensive inventory of all available data following the design laid out in the framework, which will specify the key indicators and identify current data sources within the country. The mapping will be done by a small team of country experts in the field of evaluation and health, with a focus on the three diseases[2]. In-country partners will be asked to assist in this process. In some cases a country visit by the Macro Team will be used to identify key country actors and provide guidance in the mapping exercise.

In the first phase, an Impact Evaluation Task Force with broad representation from in-country stakeholders and partners will be established and a country evaluation work plan developed. The Impact Evaluation Task Force is a multi-disciplinary technical body of up to a dozen experts and will be chaired by a national leader in the field of evaluation. The Task Force will have representation from major stakeholders and technical experts in-country, including selected representatives from:

- Principal recipients in country*:* Global Fund Country Coordinating Mechanism (CCM), Ministry of Health, Ministry of Finance and Planning, NGOs, National Networks, etc.
- Evaluation and research expertise*:* Subcontracting agency, academic institutions, private research institutions, national bureau of statistics, health statistics section within the Ministry of Health.
- In-country partners*:* CDC/PEPFAR, UNAIDS, WHO, UNICEF, civil society, NGOs, key donors etc.

[2] In several countries the mapping exercise was initiated prior to the Partner in Impact Forum. The results are available from http://www.theglobalfund.org/en/about/terg/announcements/impact_forum/default.asp and will be summarized in a forthcoming workshop report.

Task Force responsibilities

- Developing the Impact Evaluation Work Plan in collaboration with the Evaluation Study Consortium.
- Advising on the delegation of impact evaluation activities as defined in the Impact Evaluation Work Plan, including technical work, administration and oversight of activities, supervision and quality assurance, etc.;
- Mobilizing in-country institutions and partners for data collection and analysis work, as appropriate.
- Providing regular debriefings on the progress of the impact evaluation to the CCM, in the event that the CCM is not represented on the Task Force.
- Assisting in the preparation of milestones to be provided to the Consortium
- Reviewing the results and final report.

The goal is to maintain a country-driven approach in every phase and aspect of the evaluation. In this respect, the role of the Impact Evaluation Task Force will be critical, as it will both strive for the best possible evaluation and try to ascertain the greatest country benefits in terms of capacity building and sustainability.

It is envisioned that a small team with representation of key institutions and subcontractors will lead the evaluation work in each country under the supervision of the Task Force.

In some countries country task forces with limited technical assistance will be able to rapidly draw up a work plan and propose subcontractors to the Macro Team. This will particularly be the case for countries for which the Macro Team has core resources for supplementary data collection. Other countries will be invited to participate in a three-day evaluation planning workshop. At this workshop, countries are expected to produce their mapping of data sources, gaps and ways to fill the gaps, and the Evaluation Study Consortium will present standard evaluation protocols for data collection and analysis for possible use by the countries to fill data gaps and enhance the evaluation[3]. At the workshop there will be a review of the available data for consistency, level of aggregation, and possible biases that may invalidate the data. Based upon this review of the initial indicator compilation, a work plan will be defined to clean, refine and validate the data to produce a final data set showing trends in the key indicators. This process will focus on ensuring that data sets have consistent measures and outputs (e.g., same age structure, identical questions for indicator surveys, same testing protocols). . Over the course of the workshop, each country team will work with Macro Team staff to produce country-specific Impact Evaluation Work Plans using the standard protocols adapted to the local situation. The workshop will be held mid 2007. The products of the workshop will be reviewed by country Task Force within one month of the workshop.

[3] The Evaluation study consortium is working with various external references groups in the three disease areas, along with other technical advisers from UN agencies and other technical partner organizations to agree on standard data sets that each country will produce for the evaluation. These standard data sets will build on the various international indicators for each disease area, but will include additional data that will be used to help assess and model the impact of scaled up interventions. In addition to the standard data sets, the contracting team, again working with various technical partners, is developing standard study protocols that can be adapted and used by the country evaluation team in their plans to help fill data gaps, validate the completeness or quality of existing data, or to provide more in-depth information about a particular topic.

The work plan should be completed within five months. The Macro Team as well as external disease experts, such as reference groups for the three diseases and monitoring and evaluation groups, , will review the country evaluation work plans. Based upon this review, countries should have one final, approved plan by latest 1 August 2007.

Proposed Contents of the Impact Evaluation Work Plan

Background
- Description of the Impact Evaluation Task Force's membership, involvement and responsibilities;
- Data and information gap assessment (for disease and health financing tracking);
- Description of relevant indicators for impact evaluation (e.g., disease burden, health finance tracking, and service provision/utilization)

Investment plan to fill targeted data gaps;
- Implementation milestones and timelines to mark discrete points of progress and payment schedules;
- Ethical considerations and procedures to obtain approval, where necessary;
- Data management plan for all steps of data collection and storage through dissemination of transparent data sets;
- Supervision plan including quality assurance measures;
- Analysis plan including modeling and estimation;

Technical assistance and capacity building
- Technical assistance plan including identification of types of assistance required, and sources of expertise, from in-country, South-South collaboration, and other sources;
- Capacity-building plan with objective measures of skills and systems strengthening;
- Sustainability plan detailing the steps needed to take to sustain the use of tools and processes for future impact evaluations in the country;

Detailed budget and description of financial management processes;

The role of disease partners in the planning phase. Disease partners in-country will be greatly relied upon during the planning phase. First, in order that HIV, TB and malaria experts comprehend the intended objectives of the impact evaluation, the basic document on *Data collection design and methods* (March 2007) will be sent to the Task Force, including disease partners, prior to the Macro Team's first visit. Then, during the Macro Team's first visit, an informative session on the impact evaluation design will be held with the Task Force to discuss the overall evaluation design, including highlighting the basic data requirements needed to meet the objectives. Following the informative session, the Macro Team will consult with disease experts individually to discuss in detail the availability and accessibility of the specific data, the periodicity, the coverage, the level of aggregation, and the format (electronic vs. paper). For information regarding record reviews of routine program data, the main partners will include the National TB Program, the National Malaria Programme, disease departments in the Ministry of Health, and various HIV initiatives that oversee the collection of VCT, ARV, PMTCT and ANC data. In some cases civil society is involved, such as in Burkina Faso where an NGO oversees the VCT data. For information regarding national surveys, the National

Statistical Office or other survey institution will be consulted. For information on local studies and demographic surveillance sites, research institutions and civil society organizations will be consulted regarding relevant studies, for example, research conducted on quality of care, patient follow-up, other pilot projects, etc. All consultations with individuals or institutions serve as important exchanges between the Macro Team and the local experts to determine how best their past or on-going activities might be incorporated into the impact evaluation at a national level, or at a district level if activities concern the districts selected for the comprehensive district assessment.

Phase 2: Data collection (month 3-12)

The second phase will focus on data collection activities. These may include additional data collection on household surveys, conduct of small scale surveys, mortality records reviews, review and validation of clinical data, follow-up studies of treatment cohorts, etc., depending on data needs and opportunities. The evaluation study consortium will develop protocols for specific studies in consultation with experts around the globe. Data collection will be integrated into planned and existing mechanisms to the extent possible, and contribute to national health information systems along the lines of the Health Metrics Network framework. If, for instance, a DHS is planned for 2007 (or the initial months of 2008) the country evaluation team and Task Force will collaborate with the survey steering committee to determine if additional data collection is possible (e.g., a survey module, additional blood collection or nested follow up study). If the USG/CDC team in-country has invested in an ARV treatment impact study, then those data will be used. Or if the country service statistics strengthening efforts initially focus on a specific province, evaluation activities will aim to support that effort to the extent possible. In several countries no direct funding is available from the Evaluation Study Consortium for extensive additional data collection. Other sources of funding will however be explored.

Filling gaps, a multi-pronged approach

The principal gap that the current design aims to fill across countries is up-to-date service and coverage information. The present design focuses on collecting information at the district level, where services are scaled-up to various degrees relative to each other. Therefore, a district approach will afford not only key coverage information that can be linked to health facility data, but it will also provide a snapshot of the most recent scenario. Recent information is important because the rapid pace of the scale-up means even many 2005 estimates have significantly changed. Further, the data collection instruments to be used in the district assessment will provide comparable measures to a full-scale national survey, such as DHS, but are short enough that they can be implemented in cost and time efficient fashion. In short, at the district level is where impact, especially after a relatively recent intervention period, can be best measured-- that is, in an area concentrated enough to detect change and large enough to determine if it is significant.

In addition, gaps will be clearly identified as a result of national and district record reviews where retrospective archival data will be compiled for the 10-year period, 1998-2007. Obvious gaps in terms of periodicity and coverage will indicate where future efforts must be made to improve M&E.

Finally, the Evaluation Team and the Task Force are taking an inventory of on-going or planned data collection efforts and will piggy-back as feasible. Often, however, data collection field work for a national survey is not timed within the relatively narrow period available for data collection (approximately July 2007-February 2008).

The second phase will also focus on systematic gathering and assessment of available data from clinical and population-based sources. Following the agreement on the work plan, all documents and data specified in the mapping process will be compiled in greater detail. This compilation will result in a country logbook containing all documents related to the data sources, as well as a database that compiles the disaggregated indicator data from these sources. The database will contain all indicators disaggregated by geographic region, sex, age, and economic status where available. The country evaluation focal point will work with the Country Coordinating Mechanism and evaluation team to ensure access to all data. The initial country logbook and the indicator database will be the second set of country outputs and this work should be completed by month 6 of the evaluation or within 2 months of the planning workshop (for countries participating in the workshop).

There will be some funds available for small-scale validation studies, especially as they relate to the validity of clinical measures such as provision of ART, and treatment of malaria and TB. The output of these studies can then be used to correct routine reporting data.

Data collection will be the responsibility of sub-contractors. The kind of arrangement depends on the type of data collection and country situation:

- For household surveys, the National Bureau of Statistics is generally the most experienced and capable organization in-country. Local surveys may be carried out by a university or research institution, a local NGO with survey expertise or a private organization. In many cases, survey-based data collection will piggyback onto an ongoing survey mechanism such as the DHS. In such cases, the same local subcontractor will be contracted to conduct, for example, a follow-up study of a select sample of households.
- For service statistics, the involvement of the Ministry of Health is essential but another organization in-country will be subcontracted to carry out the work. This may involve a university or research institution, local NGO with analytical expertise or private organization. Linking with the experience and partners working for PEPFAR, TB programmes and malaria programmes will also be essential.
- In case of service availability and quality, collaboration with local partners and the Ministry of Health will be essential, since results should be integrated into a country database of information on the health system. These should include partners within both the public and private sectors.
- If possible, National Health Accounts will be done with teams that have been engaged in previous exercises. These may have involved university or research institutions, WHO, World Bank, local NGOs or international NGOs and Ministries of Health and Finance. The involvement of UNAIDS and major bilaterals will also be crucial. Similar contracting procedures as in previous NHAs will be used if feasible.

Specific data collection efforts regarding quality of services, cost of service delivery, and access of specific populations may be addressed as follows:

1) Quality of services. Quality of services indicators will be obtained from the health facility census using data collection instruments based on the Service Availability Mapping (SAM) questionnaires. One instrument is a district questionnaire that takes inventory in the district of the type and number of facilities, type and number of health service providers, type and number of patient beds, blood transfusion services, various lab services, communication and technology resources, injection and sterilization practices, donor assistance, some basic payment and social marketing questions, and some general coverage information on interventions such as IMCI, ANC, HIV counseling and testing, PMTCT, STI diagnosis and treatment, family planning, drug and supply management, ART, immunizations, indoor residual spraying coverage in district, and others. The second facility census instrument is the facility questionnaire. It provides information on patient flow, specific amenities of the facility, availability of disease guidelines, functioning diagnostic resources, sterilization equipment, qualifications of the staff, recent training opportunities for the staff, availability of drugs and commodities, specific laboratory tests conducted, and provision of various interventions. To operationalize 'quality of services' in the analysis there will be a quality index constructed using several of the quality dimensions listed above (see Hong et al. 2006 as an example of how a quality index might be constructed). Perception of quality by the end-user is an important element in assessing quality of services. However, given the subjective nature of information obtained from, for example, exit-interviews, this type of information would be best interpreted in its local context and less meaningful in a large-scale impact evaluation.[4]

2) The cost of delivery. Information on fees for specific patient services will be collected with the aim to provide needed information for constructing national health accounts. Likewise, some household expenditure information on various health services will be collected with the household survey. This information will be used to generate national estimates (distribution key).

3) Access of specific populations. The household survey will provide certain individual background characteristics which can be linked with coverage information collected in the same questionnaire. For example, estimates of bednet or VCT coverage can be generated by wealth status, by urban/rural residence, by geographic area, by sex, by age, and by religion, ethnicity or other country-specific characteristics of import. Furthermore, it is planned to link the household coverage information with the facility service provision information, using georeference points. This will potentially provide information on pockets of populations that do not have adequate access to adequate services such as TB diagnostic and treatment services.

The role of disease partners in the data collection phase. The close collaboration with national disease partners is essential in the data collection phase. For example, for compiling required data from the national record reviews, national disease partners will either agree to complete the standard compilation of data using in-house resources, or else provide technical orientation for the person contracted for the task. Partners will be relied upon not only to provide access to the data, but also to provide expert information relevant to the data being collected (e.g., precise definition of data or indicators being collected, information on geographical coverage, etc.). Since routine data at the national

[4] Hong, R., Montana L., Mishra V. 2006. Family Planning Services as a determinant of use of IUD in Egypt. BMC Health Services Research. 6:79. http://www.biomedcentral.com/1472-6963-6-79

level is typically aggregated by facility, district and/or region, it usually does not include any personally identifiable information. In any case, confidentiality will be verified and dealt with according to national policy on research ethics. Regarding validation of data, it will be made explicit from the beginning that data collected is for the purpose of the evaluation objectives, and only data that the partner institution consents to be released may be published. In Burkina Faso, for example, the National AIDS Committee is the secretariat for a validation body that meets periodically to review and approve any HIV-related data disseminated by the government. Only those data will be used in the evaluation. Likewise, for primary data collection in districts, close collaboration with disease partners will be necessary. The standard district survey instruments for households and facilities will be shared with national disease partners for country adaptation. It will also be necessary that partners approve and are involved with data collection at selected facilities in the district. For example, only programmatic personnel will have access to patient registers and will thus facilitate necessary data collection at this level. As made clear in background documents and further emphasized during technical discussions, no person-identifiable data will be collected at all for this evaluation. If necessary, ethical approval will be obtained according to national procedures; other than the time it could take for the ethics committee to meet and review the research (committees typically meet once a month), this is not seen as an obstacle to the impact evaluation activities.

Phase 3: Data analysis (month 5-15)

During the third phase, which partly overlaps with Phase 2, data analysis will be the main activity. Data from the different sources will be brought together and analyses conducted for each of the three diseases. Country involvement and capacity building will be at two levels. First, the Macro partner responsible for the country impact evaluation will work closely with at least two analysts from the country throughout the study period to ensure consistent country inputs and to build capacity. The country partners should have an analytical background and may come from a university, statistical office, ministry or private sector. The Country Impact Evaluation Task Force will be involved in the selection of the country analytical partners. The extensive experience of the Macro Team in working with country staff in analysis will also be utilized to select country partners.

It is anticipated that each country will have produced a full data set for the country by latest February 2008, which includes all relevant data agreed upon in the work plan. Specific analytical work is however expected to be conducted in the preceding months, so that new data can simply be added on to the analysis. Some Phase 2 work may still be going on and supplement the data set as data become available. Analyses on the time trends in the key indicators will be the basis of the initial country report, as well as production of epidemic curves and estimates of cause-specific mortality trends, coverage and exposure to interventions, possibly supported by financial data. The data set will also serve as the basis for the disease-specific and overall modeling efforts as well as the country final evaluation report.

At this point the country evaluation team should also review the planned analysis and if necessary produce an updated planned set of analyses for evaluating the impact. This proposed set of analyses should be provided to the Macro Team for external review by

contractor team members who will also consult representatives of the reference groups of the three disease areas.

In some countries, where considerable additional data collection is taking place, technical assistance will be given during the analysis. This may include workshops involving a greater number of staff in the analysis will be held on each occasion. For the majority of countries, there will be an analysis and modeling workshop, which is scheduled for April 2008. At the workshop countries will produce all tables for the final report.

The country evaluation teams will produce draft country reports, including analyses of trends and basic overall modeling by April 1, 2008. These reports will be presented and reviewed at the second SACS country workshop at the end of April 2008.

The role of disease partners in data analysis phase. Impact estimation efforts will be done in close consultation with national and international disease partners. Input from both parties is critical for the final analysis: input from the national partners is needed since they are the experts on their data and the context it represents; input from international partners is necessary because they have expertise in estimative methods using data from different countries and will be to provide insights into cross-country comparisons. Furthermore, having both national and international disease experts involved-- both coming from different perspectives regarding data but working towards a common analysis-- will provide a unique opportunity for sharing information, with the expectation that 'capacity building' will work in both directions.

Following the evaluation, agreement with partners will be sought such that anonymous data is archived according to international meta- and microdata standards and be made available to researchers for further analyses. Coordinating technical assistance for carrying-out standard archiving procedures is not in this project's terms of reference and budget, but further resources are being sought through Paris 21 networks as an effort towards achieving sustainability (see for example, http://www.internationalsurveynetwork.org/home/index.php).

Phase 4: Final report and dissemination (month 13-15)

Each country draft report will be reviewed by both the Macro Team's country manager as well as by disease area experts. Based on the review, the country manager will work with the country evaluation team to produce a final report. This collaborative process will be designed to ensure consistency of methods and comparability of the 20 country final evaluation reports. Final reports will be reviewed and approved by the both the country evaluation teams and the Macro Team prior to their final submission to the TERG / Global Fund in June 2008. An outline of the contents of a country report is shown below.

An in-country dissemination workshop will be part of the final phase of the comprehensive country evaluation effort. This will be preceded by discussions and reviews with the Impact Evaluation Task Force. All relevant stakeholders in-country will be invited to attend the workshop.

Country impact evaluations will focus on the diseases funded from active Global Fund grants. The Country Impact Evaluation Reports will incorporate at least the following sections/sub-sections:

Country Impact Evaluation Reports - draft outline

I. Overview

II. Description of Core Indicators

- Disease burden (mortality and morbidity)
- Bevaiours (as appropriate)
- Health service provision/utilization measurements
- Health financing information

III. Data and Methods

- Data sources: Census, vital registration, population-based surveys, health service statistics, health and disease records including disease surveillance systems, facility and district surveys, modeling and estimates, health finance tracking
- Data quality: data collection methods, timeliness, periodicity, representativeness, disaggregated by major background characteristics
- A comparison of data collected and compiled for the evaluation with those reported to the Global Fund in routine reporting cycles
- Detailed Explanation of Data Gaps Filled: What gaps were filled? How were they filled? Are efforts sustainable?
- Modeling and Estimation: models including unit of analysis, model parameters, and sample description; potential weaknesses and limitations in data quality and coverage and any other factors which may influence model outcomes; assumptions built into the proposed model, the type of model to be used, and sensitivity analyses or other tests to be conducted; how and to what extent results should or should not be generalized to populations beyond the sample.

IV. Situation and Trends

- Trends for 3 diseases
- Health service provision/utilization for 3 diseases
- Health financing contributions for 3 diseases i.e., proportional contributions of Global Fund, PEPFAR, other partners, private and public sources

V. Impact Evaluation

- Estimated impact of collective investments on burden of each disease and related service provision/utilization.
- Contribution analysis of major partners, by disease e.g., Global Fund, other major external donors, domestic investments and civil society
- Modeling disease burden and impact scenarios

VI. Discussion results in country context

- Equity issues*
- Further country specific observations, especially as they are relevant to linking with Study Areas 1 & 2.
- Generalizing results and limitations of results

VII. Recommendations for the Future

- Sustainability Plan: data availability, log book, future data collection
- Health information system strengthening
- Global Fund programme interventions

*** Equity Issues**

Attention to equity issues is fundamental to a better understanding of health outcomes in populations. Any national level analysis such as this impact evaluation should strive to detect and bring to light systematic differences by examining health outcomes by gender, economic, political, ethnic and geographical distributions.

One of the durable products from this evaluation will be a standard suite of tools and approaches that constitute a “model impact platform.” The design of this platform will be

informed by the results of the country impact evaluations. The overall goal in developing the model platform will be to offer guidance for future evaluation studies in countries in terms of available data sources, priorities for new data collection, analytic methods, reporting of results, data transparency, and effective collaborative strategies.

The Macro Team envisions that the model impact platform will include the following components:

- Overview of the general impact evaluation framework, including a list of essential indicators stratified by disease, and categorized by different levels of priority, as well as general guidance on building collaborative partner networks for evaluation within countries.
- Template for mapping types of data sources to specific indicators.
- Template for preparing a country data source logbook and document library.
- Instruments and protocols for implementing data collection activities including surveys and laboratory measurements as appropriate.
- Guidelines and user-friendly programs for statistical analyses of specific data types as appropriate.
- Disease models used in estimation of unobserved quantities where relevant.
- Standardized tools and guidelines for developing national health accounts, and particularly disease specific subaccounts.
- Database tools for archiving and sharing of data collected during the evaluation.
- Templates for presenting tables and figures summarizing findings on key indicators.
- Template for preparing country impact evaluation reports.

Efforts will also be made to support the development of a number of additional outputs which include a logbook of data collection efforts, document library and data archive. The systematic documentation of information will be one of the outputs of the Impact Evaluation. There are three dimensions. First, there will be a log book of data collection efforts. Health Metrics Network and WHO have been working such a tool for countries and the Impact Evaluation will provide the opportunity to take it to countries, field test and adapt it, while documenting all relevant information for the Impact Evaluation.

Second, there will be a document library. In many countries it is difficult to access relevant publications. The Impact Evaluation Study will not only make a major effort to gather all relevant information and reports, but also turn those into pdf or other format files and make those available to the wider public. This will also be part of the same piece of software that Health Metrics Network and WHO are developing for the log book. The software will be made available to all countries, and populated with data collection efforts (with metadata) and reports to the extent possible. Linking with the International Household Survey Network database has already been established.

Third, access to data used in the Impact Evaluation Study will be ensured by assisting countries in developing a data archive. It is beyond the scope of the Evaluation to set up country data archives, particularly because such archives need a major investment in training and maintenance. The Macro Team however with its extensive experience in data archives will provide advice to countries on developing data archives and in countries where there is demand try to link the host country with donors that have an interest in supporting such an effort.

Annex 1
Overview of Indicators and Data Sources

Types of Information

There is general consensus around the types of indicators that are relevant for HIV/AIDS, TB and malaria[5]. Table 1 shows key indicators that have been proposed for each disease at different levels of the evaluation framework. In several instances, it is necessary to fall back on proxy indicators, because of measurement or data availability problems with the indicator of greatest interest. Specific definitions of the indicators are not included here but can be found in the Global Fund toolkit for most indicators. We also provide more detailed information below in sections on each specific disease.

Indicators by Framework Level and Disease				
	HIV/AIDS	**Tuberculosis**	**Malaria**	**Other**
Mortality	**Outcomes of interest:** Mortality rates due to HIV/AIDS Proportion of all deaths attributable to HIV/AIDS Survival rates of people on ART (annual and within year 1) Proxy indicators: All cause (young) adult mortality rates	**Outcomes of interest:** Mortality rates due to TB Proportion of all deaths attributable to TB Survival rates for people on TB treatment (HIV negatives)	**Outcomes of interest:** Malaria-specific mortality rates **Proxy indicators:** All cause under-5 mortality rates (under-2 mortality)	**Outcomes of interest:** All-cause mortality rates and trends
Morbidity	**Outcomes of interest:** HIV incidence and prevalence by age and sex; and among risk populations Quality of life measures for people receiving ART (working status, health state) **Proxy indicators:** HIV prevalence among women attending antenatal	**Outcomes of interest:** Incidence and prevalence of active tuberculosis by age and sex Annual risk of tuberculosis infection **Proxy indicators:** Case notification rates	**Outcomes of interest:** Incidence of malaria cases, prevalence of malaria infection, and severity of malaria **Proxy indicators:** Anemia prevalence in under fives Parasite prevalence among children Incidence of clinical malaria cases in	**Outcomes of interest:** Healthy life year measures (e.g. disability-adjusted life years)

[5] WHO, World Bank, UNICEF, UNAIDS, US Global AIDS Coordinator, USAID, CDC, The Global Fund, Measure Evaluation. 2006. *Monitoring and Evaluation Toolkit HIV/AIDS, Tuberculosis and Malaria.* Second Edition. http://www.theglobalfund.org/pdf/guidelines/pp_me_toolkit_en.pdf

Indicators by Framework Level and Disease				
	HIV/AIDS	**Tuberculosis**	**Malaria**	**Other**
	clinics		under fives Incidence of severe malaria or blood transfusion in facilities	
Coverage	VCT, PMTCT, ART, condom use in higher risk sex, care and support orphans	Case detection rate (estimated) DOTS success rate	Bednet use by children, pregnant women Indoor residual spray coverage in eligible households IPT during recent pregnancies Treatment for suspected malaria cases	Coverage of other interventions (MCH, chronic diseases)
Availability (population and district levels)	Care and support in facilities for AIDS cases VCT, PMTCT, ART readiness	TB treatment	Malaria treatment Bednet ownership by households	Health service capacity (health workers, infrastructure, basic drugs and commodities)
Finances	Relative contribution Global Fund, other partners etc. Expenditure by subcomponent	Relative contribution Global Fund, other partners etc.	Relative contribution Global Fund, other partners etc.	General health financing

Mortality

General and cause-specific mortality reductions are the primary goal of the scale-up against the three diseases. A range of data sources will need to be considered based on the specific country situation:

- Vital registration, civil registration and sample registration data: if there is a system that generates vital statistics with cause-specific mortality data by age and sex, the Macro Team will focus on obtaining trends for the three diseases from this source. In most high-mortality countries there are no vital statistics generated by civil registration systems, but it will be worthwhile to assess the quality of urban civil registration data, which may provide some information on trends. Some countries, such as China and India, may have sample registration data that are useful.
- Demographic surveillance studies and epidemiological population-based studies: an increasing number of countries, including several candidate countries for this evaluation, have established demographic and health surveillance sites which are often located in rural areas. Most demographic surveillance sites use verbal autopsy to ascertain the probable cause of death which could be used for trend data.
- Household surveys, with or without verbal autopsy: child, and in some countries adult, mortality trends can be obtained from surveys. The introduction of verbal

autopsy for all recent deaths would be a valuable addition to a national household survey, given the recent improvements in development of standardized verbal autopsy instruments, although there will be very few countries with a previous survey with such data.

- Hospital mortality statistics: the trends in hospital mortality due to the three diseases have only limited value, as many biases may play a role, but if there is information about the direction and magnitude of the biases, then such studies should be considered.
- Clinical follow-up studies: an important indicator of TB program impact is the treatment success rates, which includes survival status of those on treatment. Such data may be useful for assessment of survival rates, although additional efforts are needed to assess the completeness of the mortality data. Also for HIV/AIDS, efforts should be made to systematically measure the survival status of those on ARV therapy.

Disease incidence, prevalence and severity

There are various population- and clinic-based sources of data on morbidity:

- Household surveys may include testing for HIV infection, malaria parasites, anemia and possibly TB infection using interferon assays.
- Clinical surveillance information includes data from sentinel surveillance of pregnant women attending antenatal clinics for HIV, and TB disease notification rates. It would be possible to include surveillance of malaria cases, but only if there is consistent information on whether or not they are lab-confirmed.
- Target population surveillance and surveys provide a further source of data on epidemiology of the three diseases. For example, in concentrated HIV epidemics, surveillance and surveys of high-risk populations such as sex workers and injecting drug users provide the main source of data on prevalence of infection.

Coverage of interventions

The main sources of data on coverage of interventions are household surveys and service records. If service data are of good quality, reconciliation of data from both sources is the best way to obtain an estimate of coverage:

- Household surveys: VCT, PMTCT, orphan care and support, ART, bednet ownership and use, recent IRS in eligible households, malaria treatment patterns, other health services.
- Service recording and reporting: VCT, PMTCT, ART, TB success rate.; records of home-based services

Service availability and quality

In most cases administrative records are not adequate to assess service availability and quality, and facility visits will be required:

- Health facility surveys and censuses: minimum standards for ART, VCT, PMTCT, care and support, TB treatment, malaria control, other interventions.

- Community services assessments: public and private sector outlets of specific interventions (bednets, condoms etc.), NGOs for vulnerable populations, including orphans

Funding and Expenditure

Data on funding and expenditure can be obtained from a comprehensive review of data from different sources, including the public and private sector:

- National Health Accounts, with sub-accounts for the different diseases.
- General health financing data.
- Global Fund statistics.
- Other major partners' resource statistics.

Appendix 3.

Multi-Country Health Impact Evaluation of the Scale-up to Fight AIDS, TB and Malaria
with Special Reference to the Global Fund

DATA COLLECTION: DESIGN AND METHODS

March 2007

Five-Year Evaluation of the Global Fund—Study Area 3: Health Impact
Macro International Inc.
In Partnership with:
World Health Organization • Johns Hopkins Bloomberg School of Public Health
Harvard University School of Public Health • African Population and Health Research Center

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1 Background

The general principles and steps for countries participating in the Global Fund 5-year health impact evaluation study has been described in a document "Guidance for the Global Fund 5 year country health impact evaluation studies: process and expected outputs". This document provides further specification of the design of the multi-country evaluation study. This document should form the basis for the development of a country work plan and associated subcontracts for data collection, data preparation and analysis. It is important to keep in mind that data collection and analysis will all take place in a very participatory manner, so that the evaluation study supports capacity building and health information system strengthening. The evaluation study will contribute to future monitoring and evaluation work in the countries involved through the development of a model evaluation platform, as described in the basic guidance document.

The Global Fund Impact Evaluation Study Team[6] has engaged international expertise in the development of the standard data requirements for the evaluation, including external reference groups in the three disease areas, along with other technical advisers from UN agencies and other technical partner organizations. The resulting standard data sets will build on the various international indicators for each disease area, and will include additional data that are necessary to help assess and model the impact of scaled up interventions.

To obtain the standard data sets, the Evaluation Study Team, again working with various technical partners, is developing standard study data collection protocols that can be adapted and used by the country evaluation teams in their data collection plans. These study protocols will be geared towards meeting the individual needs of countries and can play several roles, including facilitating the collection of new data to fill data gaps, assessment of data quality and proper use of existing data. The country situation in terms of existing data, ongoing and planned data collection efforts and ability to raise additional funds is of particular relevance. In a subset of the 20 countries the Evaluation Study Team has limited additional resources available to support the collection of additional data.

This document first describes some of the measurement and analytical considerations that have guided the development of the minimum data requirements for the evaluation study. This is followed by a summary of the data requirements for the three diseases, to ensure that the core indicators are covered and that disaggregation to assess trends and equity is possible in a standardized manner. For purposes of this evaluation emphasis will be given to data covering the period 1998-2007. The second part presents the study protocols for the three disease areas and health systems effects in general. The protocols have been divided into five major groups, including national record reviews, household surveys, comprehensive district studies, special supplementary studies and national health accounts.

[6] The Team consists of MACRO (primary contractor), Africa Population & Health Research Centre (APHRC), Johns Hopkins University, Harvard University and WHO.

2 Measurement and analytical issues

2.1 HIV/AIDS

2.1.1 Measurement

Mortality data on HIV/AIDS are generally derived from models with HIV prevalence data as the main empirical input. HIV-associated mortality trends may be available from longitudinal community studies, but there are relatively few of those. If such studies exist for the period 1998-2007, a country impact evaluation should consider supporting the processing and analysis of mortality data to obtain recent trends. The Evaluation Study Team will also look into ways to obtain cause-specific mortality data, if only to lay a solid foundation for the assessment of future trends and use retrospective data to assess trends. Potential data sources include household surveys with the addition of a verbal autopsy module for recent deaths (e.g., in the last 2-3 years), follow-up surveys of household deaths identified in censuses or surveys (e.g. economic surveys), urban civil registration systems and hospital or mortuary studies. A survey would allow trend analysis for the three years preceding the surveys if the sample size is sufficiently large, taking into account recall bias. Hospital studies have major biases but if detailed data can be obtained on trends in admission and discharge practices and accurate data on cause of death distribution by age and sex, it is worthwhile to consider such studies.

Survival analysis will be important to assess the impact of antiretroviral treatment (ART). In most countries, such data are not readily available and the quality is often poor because different criteria are used by different clinics. The evaluation should aim to work with a select set of clinics to ascertain survival rates. Such a study may be done in close collaboration with partners such as CDC, based on previous work done on survival analyses of people on ARVs for specific clinics.

The best sources of data on *HIV prevalence* in generalized epidemics are population-based surveys, provided response rates exceed 70%. Where two household surveys with HIV testing are available, this set of information provides a unique opportunity to assess trends, but only a few countries will have such data. The presence of one national population-based survey, however, will still provide a wealth of information on the distribution of HIV in the population, the extent of bias in clinic-based surveillance systems, and incidence patterns. Data on trends in HIV prevalence can be obtained from antenatal clinic-based surveillance systems, particularly if the same clinics have been used over time. Additional work is often needed to obtain prevalence data by age, which allows an assessment of trends in young pregnant women. For this evaluation study, long-term trends will be assessed (1998-2007) and, if possible, clinic characteristics will be taken into consideration to assess selection biases. The effects of the introduction of PMTCT will be given special attention. Direct estimates of HIV incidence are only available from longitudinal community studies, but indirect estimates will be derived from age-specific prevalence patterns and mortality estimates. In this impact evaluation, the Evaluation Study Team will work with countries to obtain all currently available information on HIV prevalence. Where feasible, new data collection will be undertaken in

connection with ongoing activities such as surveys that are already planned for the evaluation period.

In concentrated epidemics, where HIV prevalence among pregnant women is less than 1%, the focus of the study will be on ascertaining levels and trends in high-risk populations such as sex workers, injecting drug users and men who have sex with men. Special attention will be paid to how high-risk populations are defined and their sizes are estimated.

Both service statistics and household surveys are data sources on coverage of interventions, such as ART, VCT, PMTCT, and interventions aimed at the prevention of sexual transmission. Care and support interventions for orphans may be included if significant funding is directed to such programmes. In all cases, it will be necessary to carefully validate service data, so the design of special validation studies will be an important component of each country impact evaluation plan.

2.1.2 Analytical approach

The basic analytic approach to estimating the impact of the scale-up on HIV/AIDS will be to document the trends in the key indicators related to the course of HIV/AIDS (incidence, prevalence and mortality), the change in coverage of prevention interventions and sexual behaviour (e.g., coverage of PMTCT, VCT coverage, availability and usage of condoms, age of sexual debut, number of partners), indicators of treatment and care (e.g., ART coverage, support to orphans and vulnerable children) and trends in financial resources available. These trends will be disaggregated by age, sex, geographic region, wealth and other relevant categories where possible.

Many of these indicators and outcomes are directly measurable and comparisons of time trends are straightforward. Other key indicators, such as HIV incidence and mortality are less readily measurable and will have to be estimated using simple epidemiological models. For this work, we will promote the use of the standard modeling and estimation tools that have been developed by UNAIDS and its partners under the direction of the UNAIDS reference group. These will include using the software tools EPP[7] and Spectrum[8] to translate prevalence trends into estimates of incidence and AIDS mortality as well as estimated need for treatment and PMTCT. All of the possible evaluation countries have been trained previously in using these and other software tools by UNAIDS, WHO and their partners. Therefore there should be little difficulty in supporting the use of these tools for the evaluation and this will serve to strengthen national-level capacity with tools that will be part of the on-going estimation and evaluation process within countries. Where necessary, such work needs to take into account the latest available population-based HIV prevalence data derived from national surveys rather than those derived from sentinel surveillance sites.

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[7] Brown T, Grassly NC, Garnett G, Stanecki K. Improving projections at the country level: the UNAIDS Estimation and projection Package 2005. *Sexually Transmitted Infection* 2006**, 82**: iii34-iii40.

[8] Stover J, Walker N, Grassly NC, Marston M. (2006). Projecting the demographic impact of AIDS and the number of people in need of treatment: updates to the Spectrum projection package. *Sexually Transmitted Infections,* 2006, **82**: iii45-iii50.

A key issue in determining trends in the indicators will be to ensure that the indicator measurements over time are truly comparable. While a few countries will have multiple nationally representative household data that will produce comparable indicator measurements over time, for many countries and indicators, this will not be the case. Rather, indicators will have changed over time (e.g., condom use at last high risk sex, versus consistent condom use) and care will have to be taken to create comparable time trends. For many countries this will mean that trends can only be measured for certain areas of the country (e.g., in the capital city, or urban areas) and for other countries there will be no trend data of any type for some indicators. In each case, the analysis will build on what data are available, using the key indicators where possible, but substituting other available information if needed. An example of this type of approach can be found in the recent published issue of *Sexually Transmitted Infections*[9] where trend analyses were performed for a group of high prevalence countries. For some of the countries, there were sufficient data to perform clear trend analyses and show that prevalence and estimated incidence had fallen[10] and this could be related to behavioral changes, while for other countries fewer data were available and the conclusions that could be drawn were much weaker.[11]

These data, along with the trends in the financial resources available and details on spending in countries will be used to build plausible inferences about the relationship between increased spending for HIV programs and changes in the key outcome and coverage indicators. Where possible these analyses will look at geographic, age, sex and other breakdowns.

2.2 Tuberculosis

2.1.1 Measurement issues

Direct data on the mortality or epidemiology of tuberculosis are relatively uncommon in high-burden countries. While some data sources are discussed below, assessment typically relies on the two indicators reported by tuberculosis control programs, case detection rate and treatment success rate. Together, these two pieces of information may be used to estimate the impact of tuberculosis control efforts in terms of reductions in disease frequency or mortality, and form the basis for definition of targets and reporting on progress against the epidemic. Given the lack of data on the relationship between these indicators and epidemiological outcomes, however, more direct, population-based estimates of tuberculosis frequency or mortality would be a valuable complement, if such data can be collected.

Mortality. Some data on tuberculosis mortality are available for the 64 countries reporting complete vital registration data to WHO, and the development of new verbal autopsy methods (e.g., a module for deaths in the last 24 months) show promise

[9] Walker N, Ward H, Miller R (Ed.s). UNAIDS: trends in HIV/AIDS epidemics. Special issue of *Sexually Transmitted Infections* 2006, **82**.
[10] Mahova A, Gregy S, Dube S, et al. HIV prevalence and trends from data in Zimbabwe, 1997-2004. *Sexually Transmitted Infections* 2006, **82**, i42-i47.
[11] Hladik W, Shabbir I, Jelaludin A, et al. HIV/AIDS in Ethiopia: where is the epidemic heading? *Sexually Transmitted Infections* 2006, **82**, i32-i45.

in measuring deaths in other countries. In addition, direct measurement of survival of patients on treatment should be possible based on program records, although high default rates may compromise the quality of the estimates. Furthermore, these numbers are of unclear relevance to the unknown number of patients not under treatment. These data are routinely compiled in the annual global reports on tuberculosis surveillance and control. Where necessary, the data will be obtained directly from program records in the countries participating in this evaluation, through collaboration with country partners. It should be possible in some countries to present these data disaggregated by sub-national units or along other relevant dimensions.

Incidence and prevalence. Direct measurement of the incidence of active tuberculosis is not feasible. Although notified cases have been used as a proxy measure of incidence or as one input to imputed incidence estimates for purposes of broadly characterizing the current status of the epidemic, trends in case notifications are difficult to interpret for purposes of impact assessment. This is particularly true in countries where levels of ascertainment are changing over time, due for example to the implementation of new reporting systems or modalities. Direct measurement of the prevalence of smear-positive pulmonary tuberculosis is possible through national prevalence surveys, which may be available in some countries as a baseline measurement. Given the time and expense required, however, new prevalence surveys may not be feasible although they need to be considered specifically for this evaluation.

Annual risk of infection. Though used extensively in the past, annual risk of infection is no longer a central element in routine tuberculosis surveillance, in part because of methodological challenges in interpreting results of tuberculin skin test surveys. If measured reliably, however, risk of infection would provide useful and timely information for program evaluation, since it captures the secondary benefits of treatment in terms of reduction in the transmission of tuberculosis infection and would be expected to respond more rapidly to effective program implementation than prevalence or mortality. The tuberculin skin test has historically been the mainstay of efforts to measure prevalence of infection, but presents a number of methodological challenges due to its limited specificity. Recent advances in the diagnosis of latent tuberculosis infection may present a promising new opportunity to measure changes in risk of infection as an indicator of program impact. Where and when feasible, we will consider the measurement of prevalence of tuberculosis infection in children as an additional data collection avenue for this impact evaluation.

Programme indicators. The most important measures of intervention coverage for tuberculosis have been estimates of the detection rate for smear-positive cases, and measures of the treatment success rate. The case detection rate is estimated as the number of notified smear-positive cases divided by the estimated incidence of smear-positive TB. This indicator has been used to define targets for tuberculosis control, but direct measurement of the denominator is not feasible in most places. An alternative to the case detection rate has been suggested (Borgdorff 2004), which uses prevalence (as measured in population surveys) as the denominator. While this “patient diagnostic rate” has the advantage of reducing the reliance on imputed quantities for monitoring purposes, it has the disadvantage of being expensive to implement. Countries with existing population prevalence surveys would be ideal settings in which to make use of this metric.

The other major indicator that has been used for monitoring progress against tuberculosis has been the treatment success rate. Like the survival probability for patients on treatment (as discussed above), this indicator should be readily available for all of the countries in the evaluation, since it is part of the routine reporting of tuberculosis control programs.

2.2.2 Analytical approach

The standard international approach to outcomes assessment (cf. Dye et al. 2005) relies primarily on the two indicators of programme delivery, treatment success and case notification rate. As noted above, treatment success rates for cohorts of patients are measured by all DOTS programmes, and these data are readily available. Case notification rates are analyzed based on the assumption that changes in notifications are attributable to either changes in tuberculosis incidence or changes in programmes' detection of incident cases (the case detection rate). By generating a comprehensive set of estimates for tuberculosis incidence, changes in the national case detection rate are calculated, and trends in this aspect of programme performance can be monitored. Though estimates of tuberculosis incidence in many countries necessarily rely on weak epidemiological data (Dye 1999), this method has the advantage of producing consistent estimates of case detection for every country in the world over time. This approach could conceivably be adapted to avoid some of the problems involved in directly estimating tuberculosis incidence, for example by using empirical data on known determinants of tuberculosis to control for changes in incidence, thereby isolating changes in case detection.

Nonetheless, in light of the difficulties in estimating incidence, other methods have been proposed to complement the approaches described above. The proposed patient diagnostic rate indicator, unlike case detection rate, uses prevalence rather than incidence as the denominator for notified cases. This presents two major advantages: on a practical level, data on tuberculosis prevalence are more common than data on incidence, making the metric more empirically-based; on a logical level, a programme performance indicator should measure detection of tuberculosis irrespective of whether the patient is a newly incident case or a prevalent case from a previous year. This method can be applied in those countries where longitudinal prevalence data are available (most notably China).

Unlike prevalence, measuring annual risk of infection (ARI) provides a composite indication of the transmission of tuberculosis over time, in the course of one study. It has been calculated by testing a population of children of mean age *a* for tuberculosis infection, yielding a prevalence rate *p*. If ARI is assumed to be constant over the time period in question, its value at the midpoint between the birth of the cohort and the study can be calculated as follows:

$$\mathrm{ARI}_{a/2} = 1 - (1 - p)^{1/a}$$

It is possible to envisage some modifications to the traditional approach. ARI calculations, for example, have traditionally been based on tuberculin surveys of children. In practice, interpretation of the tuberculin test is limited by inconsistent

definitions of infection; confounding from environmental mycobacteria, BCG vaccination, and ‘boosting’ from repeat testing; and increasing selection bias in BCG scar-negative children. IFN-□ testing could be substituted for tuberculin. In addition, ARI could be modeled at individual ages, rather than grouping all ages together to yield a mean ARI.

2.3 Malaria

2.3.1 Measurement issues

For highly-endemic areas of sub-Saharan Africa, all-cause under-5 mortality rate is recommended as the primary malaria indicator to be monitored by countries[12]. This is best measured by nationally representative household surveys, such as DHS and MICS, in addition to national census data and in some cases supported by longitudinal demographic surveillance studies.

Cause-specific mortality is difficult to obtain, but for African countries that are approaching the Abuja targets of 60% coverage with ITNs and prompt effective treatment, it becomes relevant to evaluate the trend in malaria-attributable mortality, and link those with all-cause under-5 mortality trends. In most countries with malaria no such data exist and the use of verbal autopsies is proposed to fill the data gap. Verbal autopsies may be used in household surveys, community demographic surveillance systems and epidemiological studies although these may underestimate the true impact because of limited specificity and sensitivity. In combination with hospital data, they may provide an idea of the relative importance of malaria, although the ability to detect trends in malaria mortality may be limited. Outside of Sub-Saharan Africa, vital registration and health facility records may provide a reliable indication of malarial deaths, if not fully complete then at least as a trend indicator.

In view of the documented reductions in childhood anaemia in response to malaria prevention or treatment in endemic Sub-Saharan Africa settings, childhood anaemia is proposed as an additional impact indicator for endemic Sub-Saharan African settings[13]. Although anaemia is not a specific indicator of malaria, in very young children (below 60 months or in the most endemic settings below 24 or 36 months) malaria may account for a large proportion of especially moderate-to-severe anaemia. Anaemia prevalence can be measured precisely through household surveys such as the national DHS, and it may be included in the laboratory component of focal malaria indicator surveys.[14] Care should be taken, in areas of seasonal malaria transmission, not to infer time trends between subsequent surveys if these are done during different seasons.

The prevalence of parasite infection is not a key indicator, because it does not in itself indicate the malaria disease burden, due to the high prevalence of asymptomatic infection. Conversely, successful interventions may reduce malaria morbidity and mortality without immediately producing major reductions in parasite prevalence. Nevertheless, parasite prevalence in children is worth further exploration as an additional survey-based indicator in both Sub-Saharan Africa settings (provided measurement occurs during the malaria transmission season) as well as outside Sub-Saharan Africa (where due to lower endemicity and less acquired clinical immunity in the population, parasite infection may more closely correlate with morbidity). Recent malaria indicator surveys have assessed parasite prevalence and shown very large differences

[12] Malaria indicators for monitoring of progress towards the MDGs include the malaria prevalence rate in the general population (where prevalence is replaced by incidence, a more relevant measure of acute malarial morbidity) and malaria-related death rate in children under-five, as well as the more general MDG indicators under-5 mortality rate and infant mortality rate.

[13] RBM MERG Task Force on Malaria-related Anemia, *Meeting Minutes,* 27-28 October 2003 (http://rbm.who.int/merg).

[14] WHO/RBM. Malaria Indicator Survey (MIS) (http://rbm.who.int/merg).

between urban and rural and rich and poor populations. The Impact Evaluation will aim to detect trends in countries with more than one survey.

For Sub-Saharan Africa, the use of service-based data as a measure of impact over time is very limited. On the one hand, only a minority of malaria cases reach the formal health system, leading to gross underreporting. On the other hand, presumptive diagnosis in clinics may lead to over-reporting, while the high prevalence of asymptomatic parasitemia undermines the potential benefit of confirmatory parasitological testing. Outside Sub-Saharan Africa, malaria cases notified in the service statistics may indicate the time trend in malaria incidence, provided that reporting completeness is stable over time.

Mortality should be reported together with the coverage of malaria interventions, in particular the use of insecticide-treated mosquito nets (ITNs), the coverage of prompt and effective antimalarial treatment by children under-5, the use of intermittent preventive treatment (IPT) by pregnant women and the coverage of indoor spraying.

These coverage indicators are measured in DHS, malaria indicator surveys and MICS. During 25 DHS surveys (2004-06) and 22 MICS (2005-06) included malaria modules. An analysis is ongoing[15]. Malaria indicators surveys are being conducted and scheduled for many countries. Malaria in pregnancy research groups may be able to provide trend data on birth weights.

Table: Malaria Impact Indicators and Method and Time Frame of Measurement

Indicator	Setting	Measurement	Time frame
All-cause under-5 mortality	SSA	National household surveys: DHS & MICS. Malaria indicator survey	Retrospective, ideally measured every 5 years. Demonstration of impact may lag up to 5 years.
Malaria mortality in DSS	SSA/ All	Demographic surveillance systems	Continuous, but due to small scale, trend detection will still require at least 5 years[16].
Malaria mortality in HIS	Outside SSA	HIS	Continuous & immediate
Malaria incident cases in HIS	Outside SSA	HIS	Continuous & immediate
Anemia in under-5's	SSA	Household surveys: DHS & MICS. Malaria indicator survey	Cross-sectional, ideally measured every 2 years. Impact detectable within 1-2 years.
Parasite prevalence	All	Malaria indicator survey, done during malaria transmission season.	Cross-sectional, ideally measured every 2 years. Impact detectable within 1-2 years.

HIS = health information system; SSA = sub-Saharan Africa; DSS = demographic surveillance system.

[15] UNICEF is leading the coverage analysis, determinants of coverage for Zambia data is done by Amara Robinson (Lusaka)

[16] Korenromp EL *et al.*. 2003 Measurement of trends in childhood malaria mortality in Africa: an assessment of progress toward targets based on verbal autopsy. *Lancet Inf.Disease*, **3**: 349-58.

Additional resources to strengthen malaria monitoring in countries in the context of the evaluation could be spent on investments in community surveys with additional support to DHS, MICS or other national surveys with health data collection etc. (including laboratory component, where possible) and support of efforts to evaluate and strengthen the service statistics (also referred to as Health Management Information System): e.g., evaluation of completeness of case and death reporting in order to better adjust reported numbers, set-up of sentinel sites in selected areas to achieve more complete reporting, linking of service statistics against community-based data from DSS sites (where existing), in particular for in-depth analysis of cause-specific mortality.

2.3.2 Analytical approach

The time trends in all-cause mortality and intervention coverage together are used to model the trend in malaria-specific mortality (and morbidity) in children under 5 years of age in malaria endemic areas. This will require data about the effectiveness of the main interventions, including bed nets, IPT, indoor spraying, and treatment, which will be obtained from existing reviews of other studies.

Data on coverage levels and distribution and linkages with biomarkers can be used to evaluate the intervention effects. Currently, two types of models are used, including the intervention impact model (derived form the Lancet child survival series) and a MARA based model malaria distribution models, used to estimate the number of people at risk.

2.4 Health system components

The impact evaluation will also aim to assess the penetration of the main scale-up interventions within the country, especially at the district level. For some key interventions, it is useful to simply evaluate the penetration of the intervention by district, e.g., social marketing programmes for condoms. It could also be assessed to what extent specifically the Global Fund and other major efforts have penetrated into districts. For other interventions, it would be relatively straightforward to map service delivery points and assess availability by including district population data, e.g., for ARV therapy, PMTCT. Such service availability mapping will build on national databases and records on service delivery points for specific services. Linking the supply of services to the coverage is of particular relevance. This would require a district household survey.

If appropriate, a district census with facility visits can be implemented to validate or develop comprehensive information on service availability. In some countries pre-existing databases with geo-coordinates of health facilities can be used as a basis, allowing the Impact Evaluation Study to focus on validation or complementing the database with recent data.

Several of the interventions related to the scale-up go beyond the district's health facilities. Detailed information on the role, coverage and quality of services of organizations providing care and support to households affected by AIDS, orphans and vulnerable children and others is needed to evaluate the extent to which these services are reaching their intended audiences with effective interventions.

National Health Accounts will provide the general context in which to analyze disease-specific expenditures, specifically HIV/AIDS. A time series will be generated starting 2 years prior to entry of GFATM funds up to the time of the latest available reported/audited health expenditures. The percentage of total health expenditure going to HIV/AIDS, TB and malaria will be obtained from a beneficiary analysis, more specifically from the fully distributional disease-specific table developed from the overall health account. Tracking of the sources used to finance HIV/AIDS and other diseases will be done by constructing a financing source by disease matrix. Health expenditures will be divided into prevention and treatment categories using International Classification for Health Accounts definitions. An analysis of additionality as recently defined and tested in joint work between WHO, UNAIDS, PHR Plus and the Thai Government will be undertaken. Expenditures by disease will also be reported per capita and per outcome indicator. A particular classification problem is the attribution of specific expenditures to tuberculosis or to HIV/AIDS because tuberculosis is considered as an opportunistic illness of HIV/AIDS. For purposes of this evaluation, GFATM grants to countries classified or counted as tuberculosis (or to HIV/AIDS for that matter) will provide the basis for disentangling contributions of different approaches. More specifically, grants will be examined and GFATM expenditures will be attributed based on the performance indicator chosen (e.g. whether TB or HIV indicator).

The expenditure on the three diseases may also be assessed through a health expenditure module in household surveys, providing insights on catastrophic expenditure. This is however a major undertaking and unlikely to be implemented as a specially planned activity during the period of the evaluation due to the need for large samples where tuberculosis expenditures are concerned.

2.5 Modeling Approach

In addition to trends analyses, estimation modeling will be conducted to link service delivery coverage with morbidity and mortality impact in individual countries and using pooled data from all countries. The evaluation team remains committed to working with the appropriate reference groups from UNAIDS, the Stop TB Initiative, and Roll Back Malaria to ensure that the most appropriate methods are used in the modeling work and to ensure that the capacity within country programs to do these types of analyses is increased. Participants from the evaluation countries will be invited to participate in a modeling workshop in the spring of 2008 during which the modeling approach for each country will be standardized.

For individual countries, we assume that the primary modeling in the area of HIV and AIDS will use existing models and approaches that have been promoted by the United Nations and other partners such as PEPFAR and have been used in the countries. These would be EPP and SPECTRUM, in most countries with generalized epidemics, and either EPP and SPECTRUM or Asia Epidemic Model in countries with concentrated epidemics. All of these models have been developed under the aegis of the UNAIDS reference group for modeling and projections and all countries have been trained in their use. This approach builds on and strengthens countries' existing analytical capacity and will allow us to evaluate the impact of treatment on mortality.

The cross-country modeling work for HIV and AIDS will use a slightly different modeling approach that has more behavioural parameters and lets us more accurately assess the impact of various interventions on the course of the epidemic. This work will be done in conjunction with Geoff Garnett and his team at Imperial College which is the secretariat of the UNAIDS reference group. The specific techniques and modeling approach are described in detail in a special issue of the journal *Sexually Transmitted Infections*.[17] This modeling will be done for individual countries, where sufficient data exist and in a pooled modeling analysis.

For tuberculosis, we aim to minimize reliance on epidemiologic models by gathering sufficiently detailed empirical data on service delivery and epidemiology to enable more direct estimation, for example, of deaths averted based on trends in diagnosis and treatment of cases in DOTS programs combined with assessment of treatment outcomes in DOTS and non-DOTS programs. Nevertheless, we anticipate that certain country-specific and pooled statistical analyses will be useful in order to make inferences about trends in the time series data that are compiled for this evaluation. As in the case of HIV/AIDS, we expect that for both TB and malaria, the evaluation teams will work with the technical advisors (Martien Borgdorff for TB and Rick Steketee for malaria) and the appropriate reference groups to develop consistent analytic methods that can be used for estimation of reductions in disease burden due to increased interventions as well as modeling approaches appropriate for cross-country comparisons.

[17] Walker N, Ward H, Miller R. (Ed.s). UNAIDS: Trends in HIV/AIDS epidemics. Special issue of *Sexually Transmitted Infection*s. April 2006, **82**, supplement 1.

3 Standard data requirements

3.1 HIV/AIDS

HIV prevalence data

- Surveillance data from antenatal clinics by age (single year if possible, 5-year age groups as minimum) and by clinic. For each data point we also need the number of women tested and the testing algorithm used.
- Prevalence data from nationally representative studies by age by sex by region (at least urban rural breakdown). These data may also be disaggregated by other variables of interest such as wealth or education.
- *For countries with concentrated or low-level epidemics:*
- Prevalence from more at risk populations such as sex workers or men who have sex with men by clinic and by age. Again data need to be presented at the clinic level, with information about the testing algorithm and the sample size.
- Local level longitudinal studies of different populations

Anti-retroviral therapy data

- Number of people on ART (for each year) by sex and age.
- Follow-up data on compliance and survival of people treated. For this data there should be enough information to judge how representative these data are for the total population of people placed on ART. Also the drug regime should be included if possible.
- Loss to follow up and deaths by year, age and sex of those on or starting treatment

Prevention of mother-to-child transmission

- Number of women given PMTCT interventions by year and by type of intervention (e.g., nevirapine short course, AZT + Nevirapine, other).
- Also here one might have the whole cascade of indicators related to PMTCT
    a. number of women offered testing
    b. Number of women counselled
    c. Number of women tested
    d. Number of HIV-positive women provided therapy
    e. Number of women on various feeding options (e.g., exclusive breastfeeding, replacement feeding)

Provision of co-trimoxazole as prophylaxis

- Number of exposed children (but no confirmed HIV status) receiving Cotrim during the last year, by age and sex, for all years.
- Number of confirmed HIV+ people receiving Cotrim by age and sex for each year.

Behavioural and knowledge indicators

- Condom use rate of the contraceptive prevalence rate, and population age 15-24 with comprehensive correct knowledge of HIV/AIDS
- Percentage of young people 15-24 who both correctly identify ways of preventing the sexual transmission of HIV and who reject major misconceptions about HIV.

- Percentage of general population receiving an HIV test
- Percentage of women and men age 15-49 who had sex with more than one partner in the last 12 months, of all people surveyed age 15-49 who report being sexually active in the last 12 months.
- Percentage of young women and men age 15-19 who never had sex
- Percentage of young women and men age 15-24 who never had sex in the last year of those who ever had sex.
- Percentage of young people age 15-24 reporting consistent use of condom with non-regular sexual partners in the past year.
- Percentage of IDUs who have adopted behaviors that reduce transmission of HIV, i.e. who both avoid sharing non-sterile injecting equipment and use condoms.
- Percentage of young persons age 15-24 who have had sex before age 15.
- Percentage MARS who received HIV testing in last 12 months and who know results
- Percentage MARS who both correctly identify ways of preventing sexual transmission of HIV and who reject major misconceptions about HIV transmission
- Percentage of sex workers (male and female) reporting use of condom with most recent client.
- Percentage of men reporting the use of a condom the last time they had anal sex with a male partner.
- Percentage of injecting drug users who have adopted behaviors that reduce transmission of HIV, i.e. who both avoid using non-sterile injecting equipment and use condoms, in the last 12 months.

Coverage of prevention activities (examples, as activities differ by country)

- Number of facilities offering services by year. Do this for major prevention services (e.g., Schools providing education related to HIV and AIDS, Number of VCT clinics)
- Number of people reached yearly by VCT by age and sex with geographic breakdowns
- OVC support by geographic region
- Treatment for STIs

Modelled outputs from EPP/Spectrum or similar package

- AIDS mortality by age (5 year bands) and sex
- Estimated treatment needs (ART, Cotrimoxazole for prophylaxis, PMTCT) by age

3.2 Tuberculosis

Treatment outcomes data

- Routine program data on cohort treatment outcomes (proportion cured, completed treatment, failed, died, defaulted, transferred out)

  Disaggregated by age, sex, DOTS vs. non-DOTS, new cases vs. re-treatment, HIV-positive vs. HIV-negative, MDR vs. non-MDR, smear-positive vs. smear-negative, by calendar year and by sub-national entity
- Validation study on treatment outcomes – follow up cases treated during last 1 to 2 years

Case notifications

- Routine program data on reported tuberculosis cases
  Disaggregated by age, sex, DOTS vs. non-DOTS, new cases vs. re-treatment, HIV-positive vs. HIV-negative, MDR vs. non-MDR, smear-positive vs. smear-negative, by calendar year and by sub-national entity

Diagnostic intensity indicators

- Numbers of registered TB suspects, numbers sputum tested, number cultured, number DST, number other diagnostic testing (e.g. radiography) and test results by age, sex, calendar year and sub-national entity

TB-HIV

- Number of TB patients tested for HIV and test results (by age, sex, calendar year and sub-national entity)
- Number of HIV-positive TB patients started on ARVs (by age, sex, calendar year and sub-national entity)
- Number of HIV-positive TB patients started on cotrimoxazole (by age, sex, calendar year and sub-national entity)
- [For HIV indicators, include number of HIV-infected individuals, e.g. in VCT, tested for tuberculosis, and number receiving INH prophylaxis

Prevalence of infection

- Results from all recent (since 1995) tuberculin skin test surveys with detailed tabulations of induration size stratified by BCG scar status, age, sex and sub-national entity (where relevant)
- In selected countries with recent baseline, repeat tuberculin skin test surveys recommended
- Where feasible, nested IGRA (IFN-□ release assays) testing in same samples as new tuberculin skin testing

Prevalence of active pulmonary tuberculosis

- Results from all recent (since 1995) tuberculosis prevalence surveys with detail on testing modes and results on all tests (i.e. X-ray, smear, culture), disaggregated by HIV status, treatment history, age, sex and sub-national entity (where relevant)
- New prevalence surveys following above specifications where feasible.

3.3 Malaria

Impact

- All cause under five mortality trends from households surveys
- Malaria mortality trends in local DSS by age group; outside Africa malaria mortality in hospitals
- Number of blood transfusions to children under five years of age over time in hospitals (by facility, region, district)
- Mean birthweight trends in selected hospitals over time
- Aneamia by age in children 6-59 months by background characteristics (urban-rural, education, wealth quintile)

- Parasite prevalence by age and sex and background characteristics (urban rural, education, wealth quintile), if available

Bednets
- Household survey data on children and pregnant women sleeping under bednets by background characteristics; household ownerships; insecticide treatment status
- Availability of bednets; social marketing of nets

IPT
- Household survey data on use of antimalarial prophylaxis during the last pregnancy among women; type of drugs, number of times, by background characteristics
- Service delivery: IPT implementation at facility level, drug availability in clinic and pharmacy

Anti-malarial treatment practices
- Household survey data on treatment of children with fever in the last 2 weeks with antimalarials by background characteristics, sex and age
- Service delivery: availability ACT, 1st and 2nd line drugs, lab facilities (blood slide, anaemia), trained health worker, guidelines for treatment

Indoor spraying
- Household survey questions on coverage of indoor spraying by background characteristics
- District level record reviews on trends in spraying activities; stock of DDT

3.4 Health systems

Coverage of maternal and child health interventions
- Coverage of other interventions by background characteristics, measured through surveys complemented facility statistics: immunization coverage, coverage of maternal and neonatal care, family planning, treatment of acute childhood illnesses, nutritional intervention (vitamin A, iodine, breastfeeding)

Service delivery
- Availability of basic maternal and child health services, that meet a minimum a standard: trained health worker, guidelines, drugs and commodities in stock, diagnostic capabilities, equipment present and working
- Availability of basic chronic disease treatment services: trained health worker, guidelines, drugs and commodities in stock, equipment present and working

General NHA (total expenditure on health, with a special focus on external financing sources and particularly the contribution by GFATM)
- Records of government executed budgets (ministry of health, other ministries, autonomous government units-social health insurance), by programmes (preventive/public health/curative/administrative/...), by input (current/capital), tracking external resources financing
- Household survey expenditure on health results (average health expenditure and utilization (by provider and by function, frequency, …)

- Donors contribution to health (whether transferring through an agent to execute the purchasing or directly to providers)
- Estimates of NGOs spending on health, firms/corporations spending on health, private health insurances spending on health
- Public and private health care providers expenditure (with source of revenue when possible) and utilization
- Pharmaceutical imports/exports/production and pharmaceutical purchases
- Health related National Accounts statistics (final consumption, value added, …)
- Business or Economic surveys for facility expenditure information, by input, by type of facilities, total output, volume of sales, …

Disease-specific NHA (percentage of total health expenditure, with special focus on external funding, going to HIV/AIDS, TB and malaria)

- Facilities survey (district assessment): proportion of inpatient hospital days with discharge diagnosis of HIV/TB/Malaria/other, with patients information (age, sex, social welfare)
    - expenditures of hospitals and health centers (private and public); if not available, budgets
    - proportion of outpatient visits due to malaria/HIV/TB/others by age and sex; if not available (n/a), total number of outpatient visits; if n/a, total number of health centers and private clinics (if n/a, registered number of private practitioners)
    - proportion of hospital days/discharges due to HIV/TB/malaria /others by age and sex; if not available (n/a), total number of discharges; if n/a, total number of beds and occupancy rates by hospital (public/private)
    - if financial difficulty is the reason for defaulting, probe for indebtedness and selling of assets and other indicators of financial catastrophe
    - workplace HIV programmes expenditures; orphan care expenditures
    - disease-specific expenditures
- Disease control programme specific expenditures
- Pharmaceutical purchases through central medical stores(public) and IMS data (private) for malaria/TB/HIV/others
- Proportion of outpatient visits due to malaria/HIV/TB/others; if not available (n/a), total number of outpatient visits; if n/a, total number of health centers and private clinics (if n/a, registered number of private practitioners))
- proportion of hospital days/discharges due to HIV/TB/malaria/others; if not available (n/a), total number of discharges; if n/a, total number of beds and occupancy rates by hospital (public/private)
- Expenditures of hospitals and health centers (private and public); if not available, budgets
- Household survey expenditure on health results (average health expenditure and utilization (by provider and by function, frequency…..)

4 Standard study protocols

The study protocols have been grouped into five categories: national record reviews, household surveys, comprehensive district assessment, special studies and national health accounts. For each category there will be a set of brief documents outlining the specifics, which will be further supported by detailed protocols, building upon internationally accepted norms and standards, if necessary. This document describes the basic features of the protocols.

4.1 National record reviews

HIV/AIDS	TB	Malaria	General
HIV surveillance data	TB outcome, notification, HIV-TB	Blood transfusion	Health workforce
ART, PMTCT, VCT reports	Diagnostic intensity		Health financing (see 4.4)
Distribution: condoms, ARVs	Distribution: drugs	Distribution: bednets, ACT	
Mortality by cause	Mortality by cause	Mortality by cause	

A systematic review of records at the national level will focus on the ten-year period 1998-2007. The basic guidance on the information to collect and collate is provided by the data requirements section. In some cases the information has already been put together in a database or report and will be easy to put together. In other cases it will mean going back to records and reports received by the national level. The Evaluation Study needs detailed information and all information should be in electronic format. Often this may imply clinic level or individual level information. The Evaluation Study Team will develop standard data entry forms (e.g. in Excel, CS Pro or other commonly used software package), which can be adapted in countries as needed.

HIV/AIDS

- HIV/AIDS surveillance data should be broken down by sentinel clinic with details on the location of the clinic and results by age, supplemented by details on how the samples were tested. If surveillance focuses on risk populations, details on how the population was identified and sampled are essential. In addition, all other sources of HIV prevalence data, such as research studies and prevalence surveys should be included with age and sex-specific data.
- For service-based interventions, such as ART, PMTCT and VCT, data are needed on enrolment and outcome by clinic level, with details on location, type of clinic etc. It would also be useful to obtain quantitative trend data on the coverage of preventive interventions, such as school AIDS education programmes, workplace programmes, programmes for high risk populations or high transmission areas etc., if available.
- The compilation of import, local production and distribution data on condoms and ARV (by type of drug, including research-based industry and generic drugs) is useful to support the data on coverage.

Tuberculosis

- District reports are generally the basis for a national level report on a core set of TB data and statistics, including case notifications (routine program data on reported tuberculosis cases), treatment outcomes data (proportion cured, completed treatment, failed, died, defaulted, transferred out) disaggregated by age, sex, DOTS vs. non-DOTS, new cases vs. re-treatment, HIV-positive vs. HIV-negative, MDR vs. non-MDR, smear-positive vs. smear-negative, and by sub-national entity. The goal is to gather all data for the last ten years in an electronic file by district or similar geographic unit.
- District level data on TB-HIV such as the number of TB patients tested for HIV and test results and number of HIV-positive TB patients started on ARVs should also be collated (details see data requirements)
- If data are available on the diagnostic intensity, such as numbers of registered TB suspects, numbers sputum tested, number cultured, number DST, number of other diagnostic testing (e.g. radiography) and test results, these should also be compiled (by age, sex, calendar year and sub-national entity).
- If data are available, trends in the importation, production and distribution of specific TB drugs (rifampicin, other?) should be compiled.

Malaria

- Trends in the number of blood transfusions to children under five years may provide an idea of the number of admissions with severe anaemia due to malaria in hospitals (by hospital, district, and region). If data on birth weight are available these should be included.
- Annual national distribution figures of bednets and ACT can be used to support coverage and service provision data.

Causes of death

Sources of mortality data by cause (and age and sex) differ between countries. If civil registration data are available, such data need to be compiled for the last ten years with special attention for AIDS, TB and malaria. Any information on under-registration of deaths needs to be included. If data from special studies are available, it will be useful to try to compile those data in a systematic manner and request further analysis if needed. In some cases, it may be useful to invest in assisting a research study team in reducing backlogs in data processing or analysis. A third source of cause of death data are hospital data.

If data quality is considered good enough to detect trends over time, it may be worthwhile to invest in setting up a database with data by hospital, or if that is not possible by district. Data should be broken down by age group and sex. Information on admission trends is also needed to assess possible changes over time that may affect cause-specific mortality trends. It is also important to document coding practices

4.2 National surveys

HIV/AIDS	TB	Malaria	General
Coverage of services		Coverage of services	Coverage interventions
HIV prevalence	TB prevalence	Anemia, parasitemia	
		Under 5 mortality	
Cause of death	Cause of death	Cause of death	
	Tuberculin skin test		

National household surveys are the preferred method to evaluate trends in disease prevalence or consequences (AIDS and malaria) and coverage indicators, with detailed information about equity. To implement a household survey like DHS may require as much as one year preparation and generally needs to be incorporated in country health information plans. Also, disease-specific surveys such as AIDS or malaria indicator surveys or a tuberculosis prevalence survey need special preparation. Therefore, as a general principle, the evaluation study should build upon ongoing or planned national surveys. Additional questions or modules to inform the evaluation should be added if time allows. It should also be explored if a survey planned for 2008 could be moved forward in time to provide data for the evaluation.

Changes in cause-specific mortality are a key outcome indicator for the evaluation study. Apart from countries with civil registration data it will be difficult to ascertain cause of death trends. Longitudinal community studies may give some insights, and most countries do not have such long term data. A national cause of death survey using standardized verbal autopsy tools would fill the current information gap but would not be able to provide trend information. If there is an opportunity to conduct a national cause of death survey, this should be considered, specifically because it would put the country monitoring system in a very good position for future monitoring, not only for monitoring and evaluation of the scale up against the three diseases but also for all other common diseases and conditions. A cause of death survey ideally build upon a sample of households with recent deaths as identified in a census or large-scale economic or other survey.

For tuberculosis a tuberculin skin test survey is recommended if a previous survey has been conducted, allowing an assessment of trends over time. The methodology for the new survey should be the same as that used in the previous survey. In general this implies a survey of school children. The number of children included in the survey should be adequate to provide a national, urban and rural estimate.

4.3 Comprehensive district assessment

HIV/AIDS	TB	Malaria	General
Facility census	Facility census	Facility census	Facility census
Household survey coverage of services		Household survey coverage of services	Household survey coverage of services
Record review ART (individual), PMTCT and VCT clinics	Record review TB district level (individual), HIV,ART		
Follow-up treatment outcomes	Follow-up treatment outcomes		
Hospital record review: admissions, mortality	Hospital record review: admissions, mortality	Hospital record review: admission, mortality, blood transfusions, birth weight	
High transmission area assessments; schools; workplaces		Outlets bednets; indoor spraying records	

The comprehensive district assessment will be a key data collection and analysis instrument of the Evaluation Study. It includes four core and two optional components. The four core components are a health facility census, a household coverage survey, record reviews of specific services, and a follow-up study of treatment outcomes. The optional components are a hospital records review and assessment of non-health sector sources of supply.

The comprehensive district assessment will be conducted in 8-10 randomly selected districts in the country. The sample frame of districts will be selected from a stratified list of districts: urban - rural, or in some cases by zones or regions/provinces.

Facility census

The facility census will comprise all public and private health facilities. Pharmacies will also be included. Data collection will focus on assessment of the availability of key services against the three diseases, but also include general information on infrastructure, expenditure and health workers. Pre-existing lists of facilities (obtained from national staff, district staff or WHO) will be used as a starting point. The GPS coordinates will be taken from all facilities to help the district develop a database for future management of services and monitoring and evaluation. The data collection tool will be based on the WHO Service Availability Mapping questionnaire, with adaptation for the evaluation study and with inputs. PDAs may be used for data entry to facilitate

data processing. A facility census in an average district is expected to take about 10 working days for one team of 2-3 people.

The facility census will provide a full picture of services that meet a minimum standard. The main criteria for the minimum standard are presence of a trained health worker, equipment, commodities and drugs, laboratory support and guidelines for treatment. This includes ARV therapy, PMTCT, counseling and testing, TB control and malaria control.

District coverage survey

A district coverage survey will provide information on coverage of the basic interventions against HIV/AIDS and malaria and also provide information on related interventions. The information collected will be in line with national indicators and international initiatives and includes PMTCT and counseling and testing coverage, exposure to preventive interventions and risk behaviour, care and support for households affected by HIV/AIDS; bednet ownership and use, fever treatment practices, indoor spraying and IPT. In addition information will be gathered about coverage of immunization and maternal and neonatal care. The questionnaire will be brief and in line with international standards. The use of PDA will be explored.

Simple sampling methods will be used to obtain a sample of households. This may be based on an improved version of the "EPI 30 cluster" sampling method or use of GPS to select households after more extensive listing. The current targeted sample size is 500 households, but this is subject to further discussion.

Record review

For a selected number of services an in-depth record review will be conducted. Clinic registers and sometimes individual medical records will be examined and standard variables will be extracted for further analysis and validation of district and national summaries.

For ART this will include information on age, sex, date of enrolment, regimen, most recent visit, lab parameters, defaulter, mortality etc. to allow a cohort analysis. The information will be obtained from clinic registers in all ART clinics in the district, while adequate measures will be taken to protect the patients' identity. For PMTCT this will include at each antenatal clinic the number of women counseled, tested, given results, HIV status, and ARV prophylaxis given by month. For VCT the information focuses on the number of people reached monthly by service delivery point, by age, sex and marital status.

The TB monitoring system aims to gather individual level data at the district level. The assessment will focus on the district and clinic level. First, a randomly selected number of clinics will be visited and the numbers of patients by age and sex and selected key variables will be copied. This information is used to verify the completeness and accuracy of the district register. Second, individual level data from the district register will be entered into an electronic database focusing on age, sex, dates, clinic, treatment outcome and other relevant variables (see Standard Data Requirements section).

Data collection at the district level will aim to identify diagnostic intensity: number of registered TB suspects, number of sputum tested, number of sputum cultured, number DST, number other diagnostic testing (e.g. radiography) and test results by age, sex, and calendar year. This may require visiting laboratories.

In addition, special attention will be paid to HIV-TB. At the district level data on the number of TB patients tested for HIV and test results (by age, sex, calendar year, clinic), number of HIV-positive TB patients started on ARVs (by age, sex, calendar year, clinic), number of HIV-positive TB patients started on cotrimoxazole (by age, sex, calendar year, clinic) will need to be collected.

Follow-up treatment outcomes

The follow-up study aims to assess the outcome of treatment, with particular attention for defaulters. Up to three ARV clinics and three TB clinics will be selected.

For ARV patients who have not attended for a period of 3 months an effort will be made to assess the reasons for not attending. Thirty patients will be randomly selected and the follow-up will be done by the clinic staff responsible for ART home follow-up in the clinic or district. Data will be collected on survival status and reason for defaulting.

For TB 30 patients from each clinic will be randomly selected among those who have been on treatment for the period of X months prior to the date of visit. This may include defaulters, those who completed treatment and those who are on treatment but have not been seen in the last 3 months. Data will be collected on survival status, health status and if appropriate reason for defaulting.

Hospital record review

A hospital record review should only be done if the records are in good shape and data can be extracted on admissions and discharges, including cause of death for a prolonged period of time, preferably 1998-2007. If a hospital outside the district caters for the district population, it should be visited for possible inclusion. A standard data entry protocol will be available from the Evaluation Study Team.

Non-health services

If substantial scale-up and specifically Global Fund resources are allocated to HIV prevention activities outside of the health services, the assessment should explore if the delivery and coverage of such services can be assessed. Coverage may best be assessed through the district survey.

Data on service delivery can be obtained from civil society organization in the districts, e.g. care and support activities to families affected by HIV/AIDS or orphans and vulnerable children. Data on preventive activities can be obtained by identifying the five areas in the district with the highest HIV transmission rates (according to key informants) and assessment of the availability of key interventions such as media messages, posters, condoms, STD control, VCT, peer educators etc. A similar approach could be used to assess the delivery of preventive interventions in schools (using a sample of

schools) and workplaces (focusing on the largest workplaces, e.g. with at least 50 workers). Standard protocols for such data collection are available and can be adapted to meet local needs.

4.4 National Health Accounts

National level

Government spending need to be collected from executed expenditure records and not budgets, for Ministry of Health, other ministries, and other governmental units including social health insurance. Information should be collected by programs (preventive/public health/curative/administrative/...), by input (current/capital), tracking sources of funding (government revenues/external resources). Disease control program specific expenditures will also be necessary for estimating expenditure by HIV/AIDS, TB, malaria and other.

Statistics on pharmaceutical imports, exports, production and purchases can be collected from central statistical office for retail sale, health institution for pharmaceutical purchases, trade commissions, central medical stores (public), and IMS data (private). This is necessary to estimate total pharmaceutical consumption, as well as pharmaceutical purchases for malaria/TB/HIV/others.

National Accounts statistics could provide data on final consumption in health and value added in health (for triangulation or direct use). Health care facilities (private/public) records can inform on expenditure and utilization. Business or economic surveys publish statistics on facility information expenditure, by input, type of facilities, total output, and volume of sales.

For disease-specific expenditure estimates, it is necessary to get information on:
- the proportion of outpatient visits due to malaria/HIV/TB/others (if not available, total number of outpatient visits, total number of health centers and private clinics, or registered number of private practitioners should be collected to cross with district assessment survey that will be conducted);
- the proportion of hospital days/discharges due to HIV/TB/malaria/others (if not available, total number of discharges, total number of beds and occupancy rates by hospital (public/private) should be collected to cross with district assessment).

Expenditures of hospitals and health centers (private and public).

National surveys

For expenditure tracking, survey results on average health expenditure, utilization by provider and by function, frequency should be collected.

Sub-national/district data

In the selected districts data collection on budgets and expenditures should be considered as it may add to the district study and to the NHA. These could include:

- Expenditures by provider (private and public), by NHA function Revenue/Sources of funds by provider (HH payments, subsidies, …)

- Revenue by district (if decentralized)
- Outpatient visits due to malaria/ HIV/TB/others by age, sex, and social-welfare Hospital days/ discharges due to HIV/TB/malaria /others by age, sex, and social-welfare

Hospitals and health centers (private and public) will be surveyed for expenditure information (or budgets if expenditure is not available), possibly disease-specific expenditures.
Utilization will be surveyed at outpatient level through the number of outpatient visits due to malaria/HIV/TB/others by age, sex and social welfare (or if not available, total number of outpatient visits, total number of health centers and private clinics, registered number of private practitioners); at inpatient level through the proportion of hospital days/discharges due to HIV/TB/malaria/others by age, sex and social welfare (if not available, total number of discharges, total number of beds and occupancy rates by hospital (public/private)).
Revenue by district will also be tracked if financing system is decentralized.

Additionally, the assessment can probe for indebtedness and selling of assets and other indicators of financial catastrophe, workplace HIV programs expenditures, orphan care expenditures

4.5 Special studies

These will be defined based upon country needs and after assessment of the extent to which the data generated by these studies can be used to inform the evaluation study.

Appendix 4. April 11, 2007 Introductory Letter to a CECS (Cambodia)

April 11, 2007

Dr. Michael O'Leary
CCM Chairperson
WHO Office Cambodia
P.O Box 1217
Phnom Penh
Kingdom, Cambodia

Re: Five-Year Evaluation of the Global Fund: Health Impact (Study Area 3)

Dear Dr. O'Leary

It is our pleasure to follow up on the letter you received from Dr. Rolf Korte, in which he communicated the decisions of the Global Fund regarding the Five-Year Evaluation of the Global Fund, including the list of countries that are scheduled to participate in this evaluation and the Health Impact Evaluation Team that was chosen by the Global Fund to collaborate with countries on their Health Impact Evaluations.

The Team that will assist countries with the Health Impact Evaluation is constituted by five reputable organizations with extensive international experience in areas of relevance to the successful execution of this evaluation. The Team also constitutes an independent body and as such will function with full objectivity in the work ahead.

The Team is led by Macro International and consists of the following organizations and principal individuals:

Macro International	Martin Vaessen M.A.
World Health Organization	Dr. Ties Boerma
Johns Hopkins Bloomberg School of Public Health	Dr. Neff Walker
Harvard University School of Public Health	Dr. Joshua Salomon
African Population and Health Research Center	Dr. Alex Ezeh

One of the first activities of the Team was to divide up the country responsibilities to ensure that work can start in all countries in a timely fashion, given the extremely tight time frame and the large number of countries involved in this evaluation.

> Primary responsibility for the Health Impact Evaluation activities in Cambodia has been assigned to the World Health Organization.

At this stage, the Team is pulling together the proposed methodologies for the Health Impact Evaluation. These methodologies are meant to ensure that activities which are carried out in one country are similar to those carried out in another. This will promote effective use of the data for cross-country evaluation purposes and make the country work more efficient by providing some basic thinking and tools that can be adopted and adapted by the local agencies that will actually implement this evaluation at the country level.

Shortly you should receive a communication from the World Health Organization to arrange for a first visit to your country. The proposed terms of reference for the visit are:

1. To meet with Cambodia's Global Fund Five Year Evaluation Task Force to discuss the Health Impact Evaluation

2. To discuss the Health Impact Evaluation process, expected outcomes, linkages and possible contributions with key actors in data and statistics in the country, including (but not limited to):

    - Bureau of Statistics,
    - Ministry of Health (health statistics / information unit, AIDS, TB and malaria programmes)
    - Monitoring and evaluation staff of civil society organizations
    - Relevant departments at university and research institutions
    - Representatives of key international organizations that invest in monitoring and evaluation or are closely linked to the scale up of interventions against the three diseases.

3. To develop a country work plan with a small core group of experts designated by the Task Force, including outlining of possible subcontracts for components of the country work plan

We are excited about the prospect of contributing to a scientific evaluation of the Global Fund and look forward to working with you and all relevant agencies in Cambodia, to make this work a success.

Sincerely,

Martin Vaessen, Project Director

Ties Boerma, Technical Director

Cc:

Dr. Sin Somuny
Dr. Kheng Sim
Dr. Lim Yi
Dr. Or Vandine
Dr. Sinath Ouksophea

April 11, 2007

April 11 2007 Introductory Letter to a SACS (Ghana)

April 11, 2007

Mr. Louis Agbe
Ghana CCM Chairperson
Country Coordinating Mechanism-CCM Gh.
PMB CT380, Cantonments
Accra-GHANA

Re: Five-Year Evaluation of the Global Fund: Health Impact (Study Area 3)

Dear Mr. Agbe,

It is our pleasure to follow up on the letter you received from Dr. Rolf Korte, in which he communicated the decisions of the Global Fund regarding the Five-Year Evaluation of the Global Fund, including the list of countries that are scheduled to participate in this evaluation and the Health Impact Evaluation Team that was chosen by the Global Fund to collaborate with countries on their Health Impact Evaluations.

The Team that will assist countries with the Health Impact Evaluation is constituted by five reputable organizations with extensive international experience in areas of relevance to the successful execution of this evaluation. The Team also constitutes an independent body and as such will function with full objectivity in the work ahead.

The Team is led by Macro International and consists of the following organizations and principal individuals:

Macro International	Martin Vaessen M.A.
World Health Organization	Dr. Ties Boerma
Johns Hopkins Bloomberg School of Public Health	Dr. Neff Walker
Harvard University School of Public Health	Dr. Joshua Salomon
African Population and Health Research Center	Dr. Alex Ezeh

One of the first activities of the Team was to divide up the country responsibilities to ensure that work can start in all countries in a timely fashion, given the extremely tight time frame and the large number of countries involved in this evaluation.

> Primary responsibility for the Health Impact Evaluation activities in Ghana has been assigned to African Population and Health Research Center.

At this stage, the Team is pulling together the proposed methodologies for the Health Impact Evaluation. These methodologies are meant to ensure that activities which are carried out in one country are similar to those carried out in another. This will promote effective use of the data for cross-country evaluation purposes and make the country work more efficient by providing some basic thinking and tools that can be adopted and adapted locally.

The work needs to be carried out locally, and we will be looking for at least two highly qualified technical experts with a background in analysis who will contribute to the study during the next 12 months. The exact duration will be determined after development of the detailed work plan. These experts need to have a good grasp of the issues surrounding data on HIV/AIDS, malaria and tuberculosis and have the capacity to conduct further analysis of existing data as well as contribute to some potential new activities.

Please nominate two technical experts who can carry out this work and submit their names and contact information to Martin Vaessen by April 30, 2007. With the agreement of the Health Evaluation Impact Team, Macro will arrange a consultancy agreement directly with the individual to carry out the work. We'd be happy to answer any questions to assist in the selection process of the country technical experts.

The two technical experts will be invited to a workshop (June 18-20, 2007; venue to be determined) which will be attended by representatives from other countries as well as the Health Evaluation Impact Team staff. During this workshop, the experts will work with the Team to develop a detailed work plan for Ghana. The technical experts will be required to do some preparatory work for the workshop (a template for which will be provided in early May). The background information that was provided by Ghana at the Partners in Impact Forum in Glion, Switzerland in March of this year will be an important starting point for determining what work will render the most useful results.

We expect that the technical experts will be working closely with local offices of major agencies such as:

- Bureau of Statistics,
- Ministry of Health (health statistics / information unit, AIDS, TB and malaria programmes)
- Monitoring and evaluation staff of civil society organizations
- Relevant departments at university and research institutions
- Representatives of key international organizations that invest in monitoring and evaluation or are closely linked to the scale up of interventions against the three diseases.

We are excited about the prospect of contributing to a scientific evaluation of the Global Fund and to further capacity building in Ghana and look forward to receiving your nominations shortly so that we can properly plan for the June workshop.

We are excited and challenged by this assignment and look forward to an effective and close collaboration.

Sincerely,

Martin Vaessen, Project Director

Ties Boerma, Technical Director

Cc:

Dr. Alex Ezeh
Dr. Jaochim Saweka
Dr. Warren Naamara
Dr. Derek Aryee
Dr. George Amofa
Dr. Taaivi Erkkola
Dr. Frank Bonsu