



Request for Proposals to Identify and Test Innovative Solutions to Increase Access to Effective Malaria Treatment

I. Overview

The **Clinton Health Access Initiative** ("CHAI") is seeking rigorous and innovative operational research proposals that will test new solutions to improving access to and targeting of effective malaria treatment in order to inform policy and practice at national and global levels. Through funding from the Bill and Melinda Gates Foundation and in collaboration with the Roll Back Malaria Partnership, CHAI is currently supporting a number of operational research projects to advance that goal. This Request for Proposals (RfP) is intended to identify and fund a set of additional high-impact studies that can help to transform malaria treatment policy and practice. In total, \$1.5 million of funding is available for additional studies, with which CHAI hopes to support as many high quality proposals as possible.

The objective of this RfP is to identify and contract additional operational research studies designed to:

1. Develop and test new solutions that address key outstanding impediments to effective and rational malaria treatment in the context of highly subsidized artemisinin-based combination therapies (ACTs); and
2. Facilitate appropriate and substantial changes in policy and practice at the national and global level based on the results of those projects.

Proposals will be accepted from **April 1, 2010 to June 1, 2010.**

A. Background

In response to growing levels of drug resistance to antimalarial monotherapies such as chloroquine and sulfadoxine-pyrimethamine (SP), the World Health Organization (WHO) recommends artemisinin-based combination therapies, (ACTs) as the first-line treatment for uncomplicated malaria in many parts of the world, particularly in Africa and Asia. Prompt treatment with ACTs is essential for reducing the global burden of malaria.

In many African countries, an estimated 60 to 80% of febrile patients seek treatment not from clinics or hospitals, but rather from private drug shops and informal medicine vendors. In 2004, the Institute of Medicine published a report that highlighted the importance of increasing access to ACTs in both the public and private sectors to 1) reduce malaria mortality; and 2) delay the onset of artemisinin resistance. The report concluded that the most effective means of achieving these goals would be to subsidize ACTs at the global level, making them both affordable to poor patients and equally or more attractive than monotherapy alternatives.

The Affordable Medicines Facility-malaria

The global malaria community, under the framework of the Roll Back Malaria (RBM) Partnership, developed the global subsidy concept into a new initiative known as the Affordable Medicines Facility-malaria (AMFm). The Global Fund to Fight AIDS, Tuberculosis, and Malaria is managing the launch and execution of an initial phase of the AMFm in 2010. The AMFm is the financing mechanism which will co-pay the cost of ACTs by approximately 95% at the point of importation for both private and public sector buyers, and thereby increase access to affordable ACTs through both channels.

Nine country applicants¹ are eligible to participate in AMFm Phase I, which will operate from roughly July 2010 to May 2012. The impact of this initial phase will be assessed by an independent evaluation commissioned by the Global Fund. Based on the results of this evaluation of the initial two-year phase, the Global Fund Board will consider whether to discontinue, modify or expand the AMFm in a subsequent phase beyond 2012. For additional information, including “frequently asked questions and responses,” see the Global Fund AMFm website: www.theglobalfund.org/en/amfm.

B. CHAI Malaria Treatment Operational Research Portfolio

Through financing provided by the Bill and Melinda Gates Foundation and in collaboration with other institutions in the Roll Back Malaria Partnership, CHAI is currently supporting a number of ongoing operational research studies. The studies already underway focus on the feasibility of introducing rapid diagnostic tests (RDTs) in the private sector to improve targeting of ACTs, interventions to increase patient adherence to ACTs including through improvements to drug packaging, and the impact of distributor incentives on enhancing access to ACTs in remote areas. Due to the timeline of the AMFm, all studies need to yield results within 18 months of AMFm launch in order to inform the Global Fund board decision in May 2012.

CHAI’s overarching malaria treatment goal is to ensure that *all people with malaria* receive and appropriately use a *complete dose* of ACT. This goal is naturally broken down into four key objectives that are the focus of CHAI’s operational research portfolio:

- Access – All people with malaria are able to obtain an effective anti-malarial in a short period of time and pay a reasonable price for that treatment;
- Equity – All people, regardless of socioeconomic status, have access to high quality treatment and services;
- Targeting – ACTs are provided to patients with confirmed malaria and appropriate alternative treatment/care is provided to those with other illnesses;
- Appropriate Use – All patients receive the full appropriate dose for their age/weight and complete the treatment according to recommendation;

The AMFm independent evaluation will measure a number of core indicators, including: 1) changes in the price of co-paid ACTs; 2) changes in the availability of co-paid ACTs; 3) Changes in the market share of ACTs compared to undesirable antimalarials. However, the evaluation will not measure some of the secondary indicators above related to effective malaria case management (e.g., targeting, equity, appropriate use); and it will not assess potential interventions to improve the core or secondary indicators. As such, additional operational research is needed to generate a comprehensive package of evidence to inform the Global Fund Board’s decision on the future of the

¹ Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania (mainland), Uganda, and Zanzibar.

AMFm in 2012. For more detail on the core evaluation of the AMFm, please visit the Global Fund AMFm website referenced above.

[Request for Additional Innovative Research Projects](#)

Through this RfP, CHAI will commission as many additional studies as possible to complement the existing projects and test solutions to other major barriers to effective malaria treatment access. Proposed studies may be conducted in only one country or several. All proposed studies must meet the core principles of the research portfolio, including:

1. **Solution-oriented:** CHAI is not interested in studies that further define a problem. All studies must test solutions that could substantially improve outcomes in one or more of the four portfolio objective areas;
2. **Policy-relevant:** Studies must have the potential to have a direct and immediate impact on global as well as national policy and practice;
3. **Robust:** Studies must be rigorous and rely on an evidence based approach that can reliably inform policy by making a strong case that estimated effects can be attributed to the intervention and not to confounding variation. Projects should employ methods to establish causality as best they can;
4. **Innovative and Transformative:** Studies must test interventions that are additional to current common practice and that could result in a substantial rather than marginal improvement in outcomes; and
5. **Efficient:** Studies must yield robust and scientifically credible results in time to inform the Global Fund evaluation and must minimize costs at all stages.

This RfP is deliberately designed not to be prescriptive, but rather to provide an opportunity for a broad range of actors to propose creative ideas that may not have been considered by the global malaria community. To this end, CHAI encourages applications from actors that have worked partly or fully outside of malaria research and that draw on disciplines beyond public health. Proposed studies should be fully additional to not only existing evidence and practice, but also other research currently ongoing in this area. Applicants will therefore want to familiarize themselves with the efforts of initiatives such as the ACT Consortium. Additional information can be found at www.actconsortium.org.

The AMFm is designed to use existing public and private delivery channels to increase ACT access. Applicants are encouraged to propose solutions that build on this approach to resolve further barriers to access. Studies that test entirely new delivery mechanisms will not be excluded, but will have to strongly demonstrate the potential for the intervention to be scalable and sustainable to be approved.

In developing its research portfolio, CHAI has consulted extensively with experts and implementers in the malaria community. This includes an Expert Advisory Group composed of nine prominent researchers and policymakers that CHAI has established to guide the selection, design, and analysis of studies within the portfolio. Through this process, CHAI has identified a number of topics that could lead to important changes in policy. These include:

- Effective, cost-efficient and scalable interventions to improve the performance of frontline health workers (including those in the public, private for-profit and private not-for-profit sectors) and outcomes;
- Optimal strategies to change patient behavior related to malaria diagnosis and treatment;

- Strategies to increase equity of ACT access and outcomes (e.g., adherence);
- Strategies to improve stocking/inventory at all levels in the public and private sector supply chain;

In addition, the Global Fund and RBM Partners have developed a paper which articulates Implementation Science Priorities for AMFm, attached as *Annex B*.

We welcome proposals on these topics. However, applicants are in no way restricted to proposing studies that are directly or indirectly related to these issues.

II. Application Instructions

The application instructions are designed to be simple, with the emphasis on the potential of your proposed project to inform policy and practice; and on the rigor and feasibility of your study design. You are required to submit either a Microsoft Word® or PDF document. Applications should be concise (no more than 10 pages, 11 point font, single spaced) and should contain the following seven sections:

1. Organization and contact information
2. Project background and purpose
3. Study design (objectives and methodology)
4. Impact on policy and dissemination strategy
5. Country alignment and engagement
6. Proposed budget and timeline
7. Research and project management experience

We do not expect fully developed study protocols, however we do require that research questions and study methodologies are clear and demonstrate that a feasible and rigorous operational research project can be successfully completed within the timeframe and budget outline.

Applications must be received by the deadline of June 1, 2010 via email to:
malaria.treatment.solutions@gmail.com.

1. Organization and contact information

Please provide the name of the organization that will manage the proposed study, partner organizations involved (if applicable), project title, submission date, and name, email address, and phone number of a contact person who can answer questions about the proposed project. References to academic publications are welcome but not required.

2. Project background and purpose

Include a brief project background describing the nature of the problem you are seeking to address, informed by existing literature. You should clearly identify the solution(s) that the project will test, where you plan to conduct this research and at what scale, and how it will impact the malaria treatment barrier being addressed.

Address the following questions in your background/purpose statement:

- a) Why is the proposed research problem a *key outstanding barrier* to access to safe and effective malaria treatment?
- b) What, if any, are the existing interventions that are implemented or planned to address this barrier and why are these insufficient?
- c) How is the proposed solution(s) to this barrier, *innovative*? How is it *additional* to and go beyond the interventions of the core AMFm model or other ongoing research activities in the field?
- d) Where (in what countries) do you plan to implement this study and at what scale?
- e) Why is this a *practical* and *cost-effective* intervention, and how can it be feasibly *taken to scale* if it proves to be effective in addressing key challenges to the AMFm?
- f) How can your idea lead to major, not incremental, *shifts in policy and practice* at global and national levels?
- g) What is the *scientific basis* for your idea and how will your research adhere to local and international *scientific and ethical standards*?

3. Study design (objectives and methodology)

As described previously, the study design does not need to be presented as a fully developed protocol, but it should clearly describe the three aspects below.

Objectives

- a) What are the hypotheses being tested?
- b) In what ways do the hypotheses being tested relate to a key barrier to effective malaria treatment?

Methodology

The study methodology should measure the change in outcomes that can be attributed to the specific intervention(s). The proposed methodology should be feasible, appropriate, and well suited to answer the study questions. It should also be rigorous in that it meets accepted standards of evidence for impact attribution². Specifically, the methodology should address:

- a) How will you test the study hypotheses?
- b) Why is the proposed research design best suited (among feasible alternatives) to test the study hypotheses?
- c) How will the study address confounding factors, selection bias, spillover effects, Hawthorne effects, contamination of control groups, and any other issues that might affect the net change in outcomes?
- d) How does the study address challenges to scaling up and sustaining the program?

² For example, see the International Initiative for Impact Evaluation (3ie)'s **Principles for Impact Evaluation**: <http://www.3ieimpact.org/doc/principles%20for%20impact%20evaluation.pdf>. See also the discussion of impact attribution in chapter 4 of the Network of Networks Impact Evaluation Initiative guidance document: <http://www.worldbank.org/ieg/nonie/guidance.html>

Note: If the study uses quantitative methods, the proposal should include a power calculation, demonstrating the ability of the research design to answer questions with a high level of statistical precision.

4. Impact on policy & dissemination strategy

- a) How will answers to these hypotheses influence malaria policy and/or programs?
- b) What is your proposed dissemination strategy?
- c) What are the major challenges you anticipate for translating the results of this research into policy? How do you propose to address these challenges?

5. Country alignment and engagement

One of CHAI's operating principles is to support local and government priorities in the countries where we work. What is your plan to engage with national policymakers, implementers, and researchers in the target countries? Demonstrating a robust plan for country engagement will be a substantial bonus for proposed projects.

6. Proposed budget and timeline

Please populate the project budget template that can be found in *Appendix A*. In narrative, please state the total proposed budget amount and include a paragraph providing an overview of the budget and the primary cost drivers. Please also describe the proposed timeline for the study in order to have results by January 2012. You can provide this timeline via narrative or through a project/GANTT chart.

Note: In accordance with guidelines for the use of funding provided by the Bill and Melinda Gates Foundation, overhead costs cannot surpass 15% for NGOs and 10% for academic institutions.

7. Research and project management experience

Provide brief background descriptions of your proposed study staff, including Principal Investigators (PIs) and key project managers. In addition, describe the experience and/or capacity of your institution, and explain why it is well suited to support the implementation and management of this research project. Attach CVs for all investigators and relevant staff members.

III. Proposal Evaluation Criteria

Proposals will be reviewed and evaluated according to the following eight criteria.

- *Tackles a relevant challenge* – How well does the proposal address a key need in malaria treatment access, equity, targeting, or appropriate use and present a scientific basis for the proposed approach?
- *Innovative* – Does the proposed solution offer a creative or unconventional approach to the problem?
- *Effective, cost-efficient and scalable* – Is the proposed intervention a potentially effective, cost-efficient solution to the issue that can practically be taken to scale?
- *Credibly demonstrates effect* – Does the study apply a rigorous methodology that will provide a credible evidence base to inform policy?
- *Potential for significant policy impact* – Does the proposal test solution(s) in a manner that could rapidly lead to appropriate changes in policy and/or practice at global and national levels? Does the proposed research go beyond just analyzing and describing a problem?

- *Country alignment and engagement* - Does the proposal merit a bonus for its proposed local engagement plan?
- *Efficiency* – Is the design and budget capable of generating robust results by January 2012 (in time to input into the Global Fund evaluation)? Is the budget clearly designed to maximize value for money?
- *Organizational capacity* – Does the institution have the requisite experience and a proven track record for leading and managing rigorous research?

IV. Proposal Review Process

All submitted proposals will be reviewed and initially screened to ensure alignment with the core principles of CHAI’s research portfolio. Proposals that make it past this stage will be reviewed in detail by a panel of independent health and malaria experts who will judge them against the seven criteria outlined above. The top ranked applicants will then be contacted and contracts negotiated and signed based on the final budget levels of the qualifying projects.

Submissions with unsuccessful projects will receive notice that their project was not selected. CHAI will not be able to provide specific feedback as to why an individual proposal was not selected.

V. Schedule

Event	Date
Begin accepting admissions	April 1, 2010
Q&A teleconference	May 14, 2010, 9am EST
Application deadline	June 1, 2010
Successful applicant(s) notified	July 15, 2010

VI. Additional Information/Frequently Asked Questions

A. Eligibility

Submissions are invited from a variety of organizations, including international and local non-governmental organizations, business, academic institutions, government agencies, and independent researchers. We encourage researchers/research organizations to partner with governments or other implementing organizations with existing plans for innovative interventions that have not yet been evaluated. We will also accept applications from researchers or implementing organizations who intend to design, implement, and evaluate a new intervention.

B. Privacy

Except as described in the proposal review process, CHAI shall not externally publish or distribute applicant or proposal information.

C. Questions and Q&A session.

We will host a Q&A session via teleconference on May 14, 2010 prior to the application deadline on June 1, 2010. Applicants interested in participating in this call are asked to confirm their attendance and submit questions regarding this RfP in advance of the call via email to malaria.treatment.solutions@gmail.com. Any updates to this RfP can be found at <http://www.rollbackmalaria.org>.

D. Applicant tips

- Ensure the proposed approach is solution-oriented and does not just quantify a problem.
- Attempt to keep your budget as limited as is feasible to complete the research. CHAI has very high standards of cost-efficiency and will consider budgets with extraneous or high costs to be a major negative factor in proposal selection. This includes overhead rates (e.g., proposals with overhead rates exceeding 20% may be immediately discarded).
- The research methodology must be rigorous, and rely on an evidence based approach that can inform policy by credibly demonstrating causality. Proposals with vague descriptions or ambiguous testing methodologies will not be funded. By example, we consider Randomized Control Trials (RCTs) to be a standard, although we do not expect all proposals to utilize this methodology.
- The research findings should be relevant both within and beyond the countries where the work is being conducted (i.e., the research should have both in country and global validity with the potential to inform national and global policy).