Household Survey Study Design

ACTwatch: Household Survey

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I. Background

Goal

The goal of *ACTwatch* is to increase effective treatment rates of malaria by generating and disseminating evidence and recommendations to policymakers on methods to increase availability and decrease the consumer price of artemisinin-based combination therapy (ACTs)[*].

ACTwatch comprises a partnership which includes Population Services International (PSI), United States Pharmacopeia (USP), London School of Hygiene and Tropical Medicine (LSHTM) and AC Nielson. *ACTwatch* is being implemented in Africa (Benin, Nigeria, DRC, Uganda, Zambia and Madagascar) and Southeast Asia (Cambodia and Myanmar).

Objectives

ACTwatch partners will achieve the goal through three primary objectives which will provide policy makers with evidence and actionable policy recommendations in the following areas:

1. levels and trends in the availability, price, quality, volume, provider perceptions, and knowledge of antimalarial medicines at different outlets;
2. the different components which contribute to the consumer price of antimalarials, and the influence current policies have on market prices, particularly the mark-ups from import to outlet; and
3. consumer treatment-seeking behavior, determinants of behavior and the relative volumes of specific antimalarials consumed.

A crosscutting fourth objective will be to prepare and execute country-specific advocacy plans and disseminate the information internationally to ensure that the evidence is effectively translated into policy.

Research Components:

These three objectives will be met through evidence provided from four different research studies implemented through the *ACTwatch* partnership. Recommendations based on this evidence will be used to guide policy makers and partners on methods to increase availability and decrease the consumer price of ACTs. These research studies are summarized as follows:

1. **Outlet Study**: to monitor levels and trends in the availability, price and volume of antimalarials, as well as to examine providers' perceptions and knowledge of antimalarial medicines at different outlets;
2. **Drug Quality**: to conduct quality assurance and quality control activities on a sample of antimalarials on the market;
3. **Market Supply Chain**: to measure wholesaler and provider volumes and the components of the consumer price of antimalarials, as well as current policy

[*] ACTs will be defined as: (1) ACTs listed in the WHO/UNICEF procurement list and (2) ACTs that are nationally registered that may or may not be on the WHO/UNICEF procurement list

influences on the market, specifically, on mark-ups from import to outlet. This will be updated annually;

4. **Household Study**: will be conducted twice during the 5-year study period to monitor consumer treatment-seeking behavior and volumes of specific antimalarials consumed.

This document outlines the research questions, indicators, data collection methods and procedures for the Household Survey. The results from this survey will primarily contribute to addressing the third objective, but will also provide household level data required by the supply chain and drug quality assurance research components of *ACTwatch*. The proposed design will serve as an international template.

II. Malaria Treatment Background

The Roll Back Malaria (RBM) target for malaria treatment is that "80% of individuals suffering from malaria should have access to and be able to use correct, affordable, and appropriate treatment within 24 hours by 2010"[†]. Current rates of effective treatment remain extremely low across sub-Saharan Africa and Southeast Asia. The key challenges to achieving the RBM case management target include: 1) increasing the speed of treatment response to fever in children under five in Africa and diagnosis-seeking in Asia (24 hours), 2) improving access to ACTs for those who need it most, 3) reducing dependence on/preference for antimalarial monotherapies and 4) improving effective treatment, that is, receiving ACTs within 24 hours of fever onset and accurate age/weight specific treatment and regimen adherence.

The majority of the disease burden for malaria exists in sub-Saharan Africa and most vulnerable groups include children under five. There are estimated to be 300 to 500 million episodes of clinical malaria each year with the majority occurring in sub-Saharan Africa. It is estimated that about 1 million children under five in sub-Saharan Africa die each year from malaria-related illnesses, constituting nearly 25% of overall child mortality[‡]. In Southeast Asia, global antimalarial drug resistance has been in existence for 30 years and the first data on ACT drug resistance is already emerging there. In contrast to sub-Saharan Africa, there is little immunity in the population due to lower transmission rates, which mean that all age groups are at risk and activities which expose individuals to transmission sites tend to drive the epidemiological pattern. For this reason, presumptive treatment is not recommended for any age group and all fevers need diagnostic confirmation prior to treatment[§].

[†] "The Abuja Declaration," *Roll Back Malaria Partnership,* Website, 25 April 2000, July 2007 <http://www.rbm.who.int /docs/abuja_declaration_final.htm>.
[‡] WHO 2006
[§] CNM 2004

III. Study Rationale

Policymakers need to understand the extent to which policies aimed at increasing access to ACTs and reducing demand for antimalarial monotherapies ultimately affect rates of effective treatment. Solely measuring supply of ACTs does not guarantee a resulting increase in effective treatment. A range of factors affecting demand must be understood in order to achieve the ultimate goal of increased rates of effective treatment. Such factors include rapid recognition of and appropriate response to fever, informed demand for ACTs, correct age/weight specific treatment and adherence to the appropriate treatment regimen.

Household surveys not only measure the impact of policies and interventions affecting supply, but can also provide valuable information on the relative importance of different types of outlets in providing antimalarials from a consumer standpoint. Absolute and relative volume estimates for different antimalarials can be derived by measuring the percentage of fevers treated with specific antimalarials. Repeated Household Surveys ultimately allow the impact of all supply- and demand-side interventions on rates of effective malaria treatment to be measured.

Household Surveys can also facilitate an understanding of the determinants of appropriate treatment-seeking behavior. The at-risk population can be divided into two sub-population groups of users and non-users and analyzed to identify significant determinants and population characteristics that differentiate users and non-users of effective treatment. For example, there could be a significant association between a caregiver being confident that she is capable of treating malaria (self efficacy determinant) and/or knows that malaria can kill a child under five (knowledge determinant) and seeking treatment within 24 hours. Psychometric validated multi-item scales can be used to capture multidimensional concepts that influence behavior. The significant determinants can provide evidence for communication interventions in order to maximize the likelihood of increasing the practice of the desired behavior.

IV. Research Objectives

This study aims to monitor and evaluate treatment-seeking behavior by target populations and identify potential determinants of effective treatment or malaria diagnostic testing that will provide evidence to inform policy recommendations.

The survey is restricted to fevers occurring in the previous two weeks since the recall period beyond this time point is questionable. Although the RBM indicator states that treatment should be sought within 24 hours, 48 hours has also been included since 48 hours is a more realistic timeframe that still prevents progression to severe disease. The denominator for 24 and 48 hours in these indicators includes all individuals reporting fever[**].

Specifically, the research objectives for the Household Survey are:

1. Determine the proportion of target populations being treated within 24 and 48 hours with appropriate antimalarial treatments and adhering to the correct dose.

[**] Kangwana, B.B; Goodman, C; Fegan, G; Noor, A.M.; Akhwale, W.S.; & Snow, R.W. The Impact of Retail Sector Delivery of Artemether-Lumefantrine on Effective Malaria Treatment of Children under five in Kenya. Proposal.

2. Determine the proportion of target populations who have used a malaria diagnostic test (microscopy or rapid diagnostic tests) within 24 and 48 hours of onset of fever to confirm symptoms of malaria.

3. Determine the proportion of confirmed malaria cases among target populations who received antimalarials within 24 and 48 hours of onset of fever.

4. Determine the proportion of the target population with fever in the last two weeks who received ACTs within 24 and 48 hours of onset of fever.

5. Determine the proportion of the target population receiving artemisinin-based drugs as a monotherapy.

6. Determine the proportion of the target population receiving non-artemisinin drugs as a monotherapy.

7. Determine the proportion of the target population who received any antimalarial and adhered to the full course.

8. Determine where treatment is sought among the target population with fever in the past two weeks.

9. In sub-Saharan Africa, identify determinants of effective treatment. Determinants include theoretical constructs such as knowledge, availability and perceived threat.

10. In Southeast Asia, identify determinants of diagnostic blood testing. Determinants include theoretical constructs such as knowledge, availability and perceived threat.

11. Determine access of target populations to antimalarials within a defined geographic area.

12. Measure the proportion of the target population who know they should respond to fever the same or next day.

13. Determine the proportion of the target population who know that fever is the main symptom of malaria.

14. Measure equity of access to antimalarials across socio-economic quintiles.

15. Determine the relative volumes of different antimalarials consumed among target populations.

16. Determine price and affordability of antimalarials to target populations.

Follow-up survey rounds will additionally measure the impact of interventions, including policy changes, on treatment-seeking behavior, rates of effective treatment and adherence.

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V. Indicators

A list of key indicators has been developed after consideration of relevant RBM monitoring and evaluation reference group indicators[††]; Global Fund indicators[‡‡], and AMFm subsidy monitoring and evaluation frameworks[§§]. These indicators will be monitored across a minimum of two time points in the eight countries under the *ACTwatch* project. These indicators aim to monitor any changes in access to effective anti-malarial treatment, treatment seeking behaviour and knowledge of malaria within households. Standardizing outcome measures will allow for data to be compared across countries and will also ensure that the studies provide the policy makers with the relevant information they require for policy implications at both the international and country level (Annex 2).

For each of the indicators subgroup analysis will be undertaken to present outcomes by socioeconomic group, treatment source (outlet type) and geographic areas (strata), as appropriate for each indicator. Presenting the outcomes by wealth quintile should reveal the extent to which there is equity in the use of antimalarials among target populations. Differences between geographical areas will be used to ascertain if those most at risk have access to affordable and effective treatment.

[††] Roll Back Malaria, MEASURE Evaluation, World Health Organization, UNICEF (2006). Guidelines for Core Population Coverage Indicators for Roll Back Malaria: To Be Obtained from Household Surveys. MEASURE Evaluation: Calverton, Maryland.

[‡‡] Global Fund to Fight AIDS, Tuberculosis and Malaria (2006). Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria, Second Edition. The Global Fund: Geneva.

[§§] Affordable Medicines Facility – malaria (2007), Monitoring & Evaluation Framework and Operational Research. Technical Proposal to Increase Access to Malaria Medicines.

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The indicators to be measured in sub-Saharan Africa are:

Access and Utilisation
The proportion of children under five with fever in the past 2 weeks who received antimalarial treatment within 24 and 48 hours of fever onset[***] ▫▼●
The proportion of children under five with fever in the past 2 weeks receiving antimalarial treatment by type of drug within 24 and 48 hours of fever onset ●*WHO/UNICEF registered ACT* ●*Nationally registered ACT* *Non-artemisinin monotherapy* ●*Artemisinin monotherapy*
The proportion of children under five with fever in the past 2 weeks who sought treatment by source[†††] ◘ *Public health facility* *Pharmacy* *Drug Shop* *Community Health Worker* *Other*
The proportion of caregivers of children under five with fever in the past 2 weeks who chose treatment source by reason *Proximity* *Good reputation* *Inexpensive treatment* *Qualification of staff* *Availability of drugs* *Provides credit for purchases*
The proportion of children under five with fever in the past 2 weeks who received antimalarial drugs by source *Already present in house* *Public Health Facility* *Pharmacy* *Drug Shop* *Community Health Worker* *Other*

[***] This indicator is the standard RBM and Global Fund indicator which reports on prompt treatment of suspected malaria with any antimalarial. The two week recall period is standard, and it is usual to ask about fever rather than malaria because of the reliance on presumptive rather than clinical diagnosis (which would involve use of microscopy or rapid diagnosis tests). Although the RBM indicator states that treatment should be sought within 24 hours, 48 hours has also been included as this could still be considered prompt.

▫ Roll Back Malaria, MEASURE Evaluation, World Health Organization, UNICEF (2006). Guidelines for Core Population Coverage Indicators for Roll Back Malaria: To Be Obtained from Household Surveys. MEASURE Evaluation: Calverton, Maryland.

▼ Global Fund to Fight AIDS, Tuberculosis and Malaria (2006). Monitoring and Evaluation Toolkit: HIV/AIDS, Tuberculosis and Malaria, Second Edition. The Global Fund: Geneva.

♦ Proposed indicator based on RBM MERG recommendations.

● Affordable Medicines Facility – malaria (2007), Monitoring & Evaluation Framework and Operational Research. Technical Proposal to Increase Access to Malaria Medicines.

[†††] Treatment source will be defined by the category of health facility/outlet types that exist in each country, e.g. public, mission and commercial health facilities, pharmacies and other retail outlets, community based health workers, traditional healers and other sources. Reporting indicators by treatment source will allow assessment of any changes in treatment seeking patterns, for example whether there is a shift from public to private facilities or vice versa.

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The proportion of all child under five with fever treated with an antimalarial *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
The proportion of all people over five with fever treated with an antimalarial *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
The proportion of children under five with fever in the past 2 weeks having a confirmed malaria diagnosis within 24 and 48 hours of fever onset♦
The proportion of confirmed malaria cases among people over five with fever in the past 2 who received antimalarials within 24 and 48 hours of fever onset
The proportion of children under five with fever in the past 2 weeks taking antimalarials who adhered to the full treatment dose (defined by the number of days) ●
Proportion of people over five with fever in the past 2 weeks taking antimalarials who adhered to the full treatment dose
The proportion of caregivers of children under five with fever in the past 2 weeks who received an antimalarial they requested from a provider
The proportion of caregivers of children under five with fever in the past 2 weeks who received an antimalarial recommended by a provider
The proportion of children under five with fever in the past 2 weeks that were treated with any antimalarial across socio-economic quintiles
The proportion of the population within a defined geographic area that have access to a source of *WHO/UNICEF registered ACT* *Nationally registered ACT*
The proportion of caregivers with children under five who know where to obtain antimalarials
Price
Household cost of fever episode treated with an antimalarial (for all completed episodes)
Volumes
Relative volumes of antimalarials consumed by children under five with fever in the past 2 weeks *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
Relative volumes of antimalarials consumed by people over five with fever in the past 2 weeks *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
Knowledge
The proportion of caregivers of children under five who know that fever is the main symptom of malaria.
The proportion of caregivers with children under five who know to respond to fever the same or next day
The proportion of caregivers with children under five who know that compliance with the full treatment dose is important for effectiveness
The proportion of caregivers with children under five who have heard of the most common ACT brand [list country specific brand] and know what it is
Effectiveness of antimalarials
The proportion of caregivers of children under five who believe that the following antimalarials are the most effective malaria treatment for adults *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
The proportion of caregivers of children under five who believe that the following antimalarials are the

most effective malaria treatment for pregnant women *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
The proportion of caregivers of children under five who believe that the following antimalarials are the most effective malaria treatment for children under five *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
Correct utilizations of antimalarials
The proportion of caregivers with children under five who store partial doses of antimalarials to use again
The proportion of caregivers with children under five with fever in the past 2 weeks who used antimalarials prior to the expiration date
Exposure
The proportion of caregivers who have been exposed to antimalarial communications

The indicators to be measured in Southeast Asia are:

Access and Utilisation
The proportion of confirmed malaria cases among all age groups with fever in the past 2 weeks who received antimalarials within 24 and 48 hours of fever onset ●
The proportion of all age groups with fever in the past 2 weeks receiving antimalarial treatment by type of drug within 24 and 48 hours of fever onset ●*WHO/UNICEF registered ACT* ●*Nationally registered ACT* *Non-artemisinin monotherapy* ●*Artemisinin monotherapy*
The proportion of all age groups with fever in the past 2 weeks who sought treatment by source ◘ *Public health facility* *Pharmacy* *Drug Shop* *Community Health Worker* *Other*
The proportion of all age groups with fever in the past 2 weeks who chose treatment source by reason *Proximity* *Good reputation* *Inexpensive treatment* *Qualification of staff* *Availability of drugs* *Provides credit for purchases*
The proportion of all age groups with fever in the past 2 weeks who received antimalarial drugs by source *Already present in house* *Public Health Facility* *Pharmacy* *Drug Shop* *Community Health Worker* *Other*
The proportion of children under five treated with an antimalarial ●*WHO/UNICEF registered ACT* ●*Nationally registered ACT* *Non-artemisinin monotherapy* ●*Artemisinin monotherapy*
The proportion of all age groups treated with an antimalarial ●*WHO/UNICEF registered ACT* ●*Nationally registered ACT*

Non-artemisinin monotherapy ●*Artemisinin monotherapy*
The proportion of all age groups with fever in the past 2 weeks having a confirmed malaria diagnostic test within 24 and 48 hours of fever onset •
The proportion of all age groups with fever in the past 2 weeks taking antimalarials who adhered to the full treatment dose (defined by the number of days)●
The proportion of all age groups with fever in the past 2 weeks who received an antimalarial they requested from a provider
The proportion of all age groups with fever in the past 2 weeks who received an antimalarial recommended by a provider
The proportion of all age groups with fever in the past 2 weeks that were treated with any antimalarial across socio-economic quintiles
The proportion of the population within a defined geographic area that have access to a source of *WHO/UNICEF registered ACT* *Nationally registered ACT*
The proportion of all age groups who know where to obtain antimalarials
Price
Household cost of fever episode treated with an antimalarial (for all completed episodes)
Volumes
Relative volumes of antimalarials consumed by all age groups with fever in the past 2 weeks *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
Knowledge
The proportion of the adult population who know that fever is the main symptom of malaria.
The proportion of the adult population who know to respond to fever the same or next day
The proportion of the adult population who know that compliance with the full treatment dose is important for effectiveness
The proportion of the adult population who have heard of the most common ACT brand [list country specific brand] and know what it is
Effectiveness of antimalarials
The proportion of the adult population who believe that the following antimalarials are the most effective malaria treatment for adults *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
The proportion of the adult population who believe that the following antimalarials are the most effective malaria treatment for pregnant women *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*

● Affordable Medicines Facility – malaria (2007), Monitoring & Evaluation Framework and Operational Research. Technical Proposal to Increase Access to Malaria Medicines

▪ Roll Back Malaria, MEASURE Evaluation, World Health Organization, UNICEF (2006). Guidelines for Core Population Coverage Indicators for Roll Back Malaria: To Be Obtained from Household Surveys. MEASURE Evaluation: Calverton, Maryland.

The proportion of the adult population who believe that the following antimalarials are the most effective malaria treatment for children under five *WHO/UNICEF registered ACT* *Nationally registered ACT* *Non-artemisinin monotherapy* *Artemisinin monotherapy*
Correct utilizations of antimalarials
The proportion of the adult population who store partial doses of antimalarials to use again
The proportion of the adult population with fever in the past 2 weeks who used antimalarials prior to the expiration date
Exposure
The proportion of the adult population who have been exposed to antimalarial communications

VI. Methodology

Timeline

PSI will conduct a baseline and follow-up Household Survey in each of the *ACTwatch* countries to address the aforementioned research questions.

The surveys will take place during or within 6 weeks of the end of the rainy season based on RBM-MERG MIS guidelines for countries with endemic malaria transmission patterns[‡‡‡]. Peak seasons are estimated using incidence rates (where available), rainfall patterns (Grover-Kopec, 2006[§§§]) and any other country specific documention. Considerations related to existing research plans and feasibility of data collection are also factored in when planning baseline surveys. The baseline survey will take place in 2008-2009 and the follow-up survey will take place in 2010-2011. The specific timing of the Household Survey is planned as follows:

Nigeria:
Southern Nigeria experiences malaria transmission throughout the year. Northern Nigeria experiences a peak in transmission between June and September. The baseline Household Survey will be conducted in June/July 2009.

DRC:
The majority of the country experiences malaria transmission all year, apart from a small area in the south (centre-south stratum) that experiences a dry season between July and September, resulting in a decrease in transmission around that time. Even though this area is geographically small, it is heavily populated. The baseline Household Survey will be conducted in March 2009. It is not feasible to conduct the surveys in January and February due to heavy flooding.

[‡‡‡] Roll Back Malaria, (2005).Guidelines for Sampling for the Malaria Indicator Survey. ORC*:* Calverton, Maryland.
[§§§] Web-based climate information resources for malaria control in Africa, (2006), Grover-Kopec, E.K., Blumenthal, M.B., Ceccato, P., Tufa Dinku, J.A., & Connor, S. J., *Malaria Journal*, **5**:38.

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Benin:
Benin has a main rainy season from April to July and a shorter season from September to October. In December, there is a dry season where malaria incidence is reduced. There are no geographical differences related to rainfall patterns. The baseline Household Survey will be conducted in April 2009.

Zambia:
Zambia has a main rainy season from November to March. There is a dry season from May to September. Data collection is not feasible late January to February due to heavy flooding. The Household Survey will be conducted in March 2009.

Uganda:
Malaria cases reported by the Ministry of Health (2007) show peaks in January, February, June and August. The rainy seasons are December to February and May to July. In northern Uganda, transmission is highest between May and November. The Household Survey will be conducted in February 2009.

Cambodia:
Cambodia has a main rainy season from May to November. The Household Survey will be conducted in November 2008.

Madagascar:
The baseline Household Survey will be conducted between November and December 2008.

Myanmar:
To be determined.

Table 1: Timing of Household Survey

	Baseline	**Follow-up**
Nigeria	June/July 2009	June/July 2011
Madagascar	November/December 2008	November/December 2010
Cambodia	November 2008	November 2010
Benin	April/May 2009	April/May 2011
DRC	March 2009	March 2011
Uganda	February 2009	February 2011
Zambia	March 2009	March 2011

Stratification

Stratification in based on a number of factors: epidemiological transmission, geographical differences, and/or known resistance. Discussions with country stakeholders, donor commitments and financial constraints are also taken into consideration. Rationale for this stratification is provided for each country. Further detail is given in the country specific study designs.

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Nigeria:
Nigeria will be stratified according to malaria epidemiology, geographical differences and cultural variation. The four main strata are: upper north, lower north, southwest and southeast/south.

DRC:
DRC will be stratified according to geopolitical, social and economic considerations given that malaria transmission is endemic throughout the year. The four strata are: north-east, north-west, center-south and Kinshasa (the capital).

Uganda:
Uganda is stratified according to epidemiology. The first stratum comprises of areas with low endemicity, while the second stratum comprises of areas with high and medium endemicity.

Zambia:
Since malaria is endemic throughout the country, Zambia is stratified according to rural and urban areas, given the large differences in the distribution of the health care system between the two. While urban areas depend on both the private and public sectors for drug provision, the rural areas are mostly dependent on the public sector with limited private sector involvement.

Cambodia:
Cambodia has been divided into zones to address containment and elimination of *P. falciparum* parasites with an altered response to artemisinins. The first zone represents those areas where multi-drug resistant (MDR) parasites have been identified. The second zone represents those areas where MDR parasites are suspected and further research is being undertaken. The third zone represents the remaining provinces in Cambodia where malaria parasites are found, but no MDR parasites have yet to be identified. Based on this, the country will be divided into two strata. The first strata will include Zones 1 and 2, and the second strata will include Zone 3.

Benin:
No stratification is employed for Benin.

Myanmar:
To be determined.

Study population

The unit of analysis in this survey is directly related to the study indicators. Some indicators call for analysis at the individual level (e.g. % of children with fever in the past two weeks who received treatment within 24 and 48 hours).Other indicators are calculated with the caregiver or the adult population as the unit of analysis (e.g. % of caregivers/adult population who know that fever is the main symptom of malaria).

In sub-Saharan Africa, the target population is women with children under five who have had a fever in the last two weeks. Inclusion criteria: 1) female, 2) identify themselves as a primary caregiver in the household of a child that is 5 years or younger.

In South-East Asia, the target population is all household members who have had a fever in the last two weeks. In case children between the ages of 0-15 have had a fever in the last two weeks, the full questionnaire will be administered to the caregiver of that child.

Sampling

Multi-staged cluster sampling will be used to randomly select the target population. A sampling frame of all sub-districts within each stratum will be developed. Sub-districts are administrative units[****] that host a population size of approximately 10,000 to 15,000 inhabitants. For each stratum, a fixed number of sub-districts will be selected using a probability proportional to size (PPS) sampling technique whereby the probability that a particular sub-district will be selected within a stratum is proportional to the population of that sub-district. Sub-districts will serve as the primary sampling units.

At the second stage of selection, enumeration areas (EAs) will be selected using PPS. A fixed number of EAs will be selected within each of the sub-districts - the number will vary depending on the sample size required for each stratum.

At the third stage of selection, a fixed number of households will be randomly selected in each of the EAs. Given that a list of housing/dwellings is unlikely to be available, the EA will be divided into 4-5 smaller sub-clusters. In each sub-cluster, a starting address/or house on a random road (in case there is no address) will be randomly selected. Interviewers will then follow the right hand rule method to select the remaining households to be contacted. This will capture the diversity of the EA and also to some extent reduce the effective cluster size.

At the household level in sub-Saharan Africa, all eligible caregivers aged 15-49 in the household with children under five reporting a fever in the past 2 weeks, will be administered the full interview. Other adult members, including household heads, will be asked to complete the household and screening questionnaire and, if applicable, the case management questionnaire. In Southeast Asia, all eligible adults with fever in the past two weeks will be administered the full interview.

Sample Size

The calculation of sample size required for this study is based on the fact that its main aim is to produce tables for: 1) monitoring of indicators over time and 2) segmentation purposes. Each table requires a specific approach to computing sample size. Therefore, this proposal

[****] "Administrative" units are the most common and usual term to describe these geographical, health or political boundary areas, such as counties, wards, parishes, communes, districts, provinces, regions, states, prefectures and arrondissements. In each country, the definitions of these administrative units will be based on the organisation of the public health system in that country. In some countries, the public health system is organised according to existing administrative geographical or political boundaries, or alternatively, based on specific sub-divisions defined by the Ministry of Health.

will determine the minimum required sample size for each table and take the maximum sample size for each country specific study.

Sample Size Calculations for Monitoring

Monitoring: Monitoring studies compare values of given indicators at different times. The sample size calculation for monitoring purposes in sub-Saharan Africa is based on the key outcome indicator *"the proportion of children under five with fever in the past 2 weeks who used any antimalarial within 24 and 48 hours of the onset of fever".* The sample size in Southeast Asia for monitoring purposes is based on the key outcome indicator *"the proportion of all age groups with fever in the past 2 weeks who sought a malaria diagnostic test within 24 and 48 hours of the onset of fever".* The required sample size for each year of the program is therefore calculated using the formula:

$$n = \frac{deff \times \left[Z_{1-\alpha}\sqrt{2P(1-P)} + Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)}\right]^2}{(P_2-P_1)^2}$$

Where:
n = desired sample size
P_1 = the hypothesized value of the indicator at year X (time 1)
P_2 = the expected value of the indicator at year X+1 (time 2)
$P = (P_1+P_2)/2$
Z_α = the standard normal deviate value for an α type I error
$Z_{1-\beta}$ = the standard normal deviate value for a c type II error
Deff is the design effect in case of multi-stage cluster sample design

Assumptions are as follows:

P_1 is the value of the key outcome indicators at time 1. These values vary by country:

	Reference	% of Children under Five with Fevers Treated with Antimalarial same/Next Day (P1) [††††], [‡‡‡‡], [§§§§]
Benin	DHS 2006	42.0%
DRC	DHS 2007	17.3%
Madagascar	DHS 2003-2004	34.0%[*****]
Nigeria	DHS 2003	24.6%
Uganda	DHS 2006	28.9%
Zambia	DHS 2007	20.5%
		% of Target Population with Fevers who Sought Malaria Diagnosis Same/Next Day (P1)

[††††] Demographic and Health Survey: http://www.measuredhs.com/
[‡‡‡‡] Zambia National Malaria Indicator Survey (2006). Zambia Ministry of Health.
[§§§§] Cambodia National Malaria Baseline Survey 2004, National Institute of Public Health, Cambodia (NIPH) Malaria Consortium.
[*****] DHS (2004) reports 34% of children under 5 with a fever in the previous 2 weeks receiving an antimalarial to treat their fever. In the absence of any reliable figures on the percentage receiving such treatment within 48 hours, the full 34% figure is used (ie 100% of children given an antimalarial receive the medication within 48 hours) in order to obtain the largest possible sample size needed.

Cambodia		10.0%

P_2 is the expected value of the indicator at the second instance (time 2). A 10% difference will be detected (assuming that a 10% point increase is the minimum necessary to justify the importance in public health policy terms).

$P = (P_1 + P_2)/2$,

$Z\alpha = 1.96$ (5% significance) is the standard normal deviate value for an α type I error,

$Z1 - \beta = 0.84$ (80% power) is the standard normal deviate value for a c (or 1 − β) type II error, and

Deff = estimated at 2.

The table below presents minimum sample size required per strata for monitoring of the two aforementioned indicators, respective to each country. Values of n for different levels of P_1 and P_2-P_1, setting the design effect to estimated 2; α to 5%; and β to 20%. Differences of 10% change per are calculated. For stratified samples the number of required sample size is used for each stratum and national estimates are calculated based on the number of strata per country.

Sample Sizes for Monitoring

Country	**% of Children under Five with Fevers Treated with Antimalarial within 48 Hours (P1) %**	**Required Households with a Child under Five with Fever, by Strata**	**Number of Strata**	**Minimum Sample Size**
Benin	42.0	779	1	779
DRC	17.3	542	4	2,168
Madagascar	34.0*****	743	2	1,486
Nigeria	24.6	652	4	2,608
Uganda	28.9	702	2	1,404
Zambia	20.5	594	2	1,188
	% of Target Population with Fevers Who Sought Malaria Diagnosis Same/Next Day			
Cambodia	10.0	398	2	796

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Sample Size Calculations for Segmentation Analysis

Segmentation studies compare values of a given behavioural determinant (e.g. knowledge, perceived affordability of antimalarials) between users (e.g. those that seek treatment for fever within 48 hours or those who seek diagnostic tests) and non-users among the population at risk. 'Users' in this instance include "the proportion of children under five with fever in the past 2 weeks who used any antimalarial within 48 hours of the onset of fever" or "the proportion of all age groups with fever in the past 2 weeks who sought a malaria diagnostic test within 48 hours of the onset of fever".

Segmentation analysis takes into account not only the level of use, but also the level of the target population who report seeking treatment or diagnostic tests. Segmentation analysis will only be conducted on a sub-sample of the population that reported they had fever in the last two weeks.

Given the objectives of segmentation, sample size is only calculated for national level estimates. Sample size for segmentation studies are computed in using the following main steps.

1) The required number n_1 of users among the population at risk will be determined using an adapted version of the monitoring formula. Unlike the previous monitoring formula, P_1 refers to the percentage of users that are positive for the given behavioural determinant (users) while P_2 refers to the percentage of non-users that are positive for the same behavioral determinant (non-users). All other parameters remain similar. The required sample size for step one for segmentation is therefore calculated using the formula

$$n = \frac{deff \times \left[Z_{1-\alpha}\sqrt{2P(1-P)} + Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)} \right]^2}{(P_2 - P_1)^2}$$

Where:
n = desired sample size
P_1 to the percentage of users that are positive for the given behavioural determinant (users)
P_2 to the percentage of non-users that are positive for the given behavioural determinant (non-users)
$P = (P_1+P_2)/2$
Z_α is the standard normal deviate value for an α type I error
$Z_{1-\beta}$ is the standard normal deviate value for a c type II error
Deff is the design effect in case of multi-stage cluster sample design

Assumptions are as follows:

P_1 is the expected value of the indicator among users that are positive for the given behavior determinant. Given that P_1 values are unknown, 42.5% for all countries is taken as this will maximize sample sizes when calculating sample size for a 15% difference.

A 15% difference will be detected between users and non-users.
$P = (P_1 + P_2)/2$,
Z_α = 1.96 (5% significance) is the standard normal deviate value for an α type I error,
$Z_{1-\beta}$ = 0.84 (80% power) is the standard normal deviate value for a c (or 1 − β) type II error, and
Deff = estimated at 2.

Values of n for different levels of P_1 and P_2-P_1, setting the design effect to estimated 2; α to 5%; and β to 20%. Differences of 15% change per are calculated. Segmentation will not be stratified as monitoring indicators are, and the value obtained is the minimum sample size needed in total for segmentation analysis. A sample size of 347 is obtained.

2) The final required sample size then takes into account the required number of subjects at risk [i.e. who report having a child under five with fever, or adults having fever in the last two weeks]. The sample size is also derived by taking into account the proportion of people that behave (among those at risk) [P_u] and the proportion of people at risk (among general target population) [P_r]. The required sample size is computed using the formula:

$$n = \frac{n_1}{p_u * p_r}$$

Assumptions are as follows:

n = desired sample size for segmentation
n_1 = 347, that is, where design effect is estimated at 2; α to 5%; and β to 20%; a 15% difference between users and non users.
P_u is the value of the proportion of people that behave. These values vary by country:

	% of Children under Five with Fevers Treated with Antimalarial within 48 Hours (P1)
Benin	42.0%
DRC	17.3%
Madagascar	34.0%*****
Nigeria	24.6%
Uganda	28.9%
Zambia	20.5%
	% of Target Population with Fevers Who Sought Malaria Diagnosis Same/Next Day (P1)
Cambodia	10.0%

P_r = 100%, given that the main questionnaire is only administered to respondents who report having a child under five with fever or adults having fever in the last two weeks.

	Minimum Sample Size for Segmentation
Benin	827
DRC	1,995
Madagascar	1,550
Nigeria	1,411
Uganda	1,201
Zambia	1,698
Cambodia	1,735

Using final sample sizes calculations from monitoring and segmentation analysis, the largest sample size is taken to ensure monitoring of key indicators and segmentation analysis.

	Final Sample Size: Number of Households Needed with an Eligible Respondent
Benin	827
DRC	2,168
Madagascar	1,545
Nigeria	2,608
Uganda	1,404
Zambia	1,693
Cambodia	1,735

Estimated Total Number of Households Required for Screening

These values are adjusted for 10% refusal, but not for filtering processes. In order to determine the number of households an interviewer needs to visit to find sufficient caregivers with children under 5 with fever in the last two weeks (or adults with fever as per the protocol for Southeast Asia), the required number of households an interviewer will need to approach will be inflated to account for the fact that not all households will have children under five/adults with fever in the last two weeks. The estimated number of households that will need to be approached will be inflated by about 30%-40%, as per estimated households with a child with fever in the last 2 weeks.

Population	% of Children under Five with Fevers in Past 2 Weeks (%)	Estimated # of Households Needed to Find Sample (n)
Benin	28.6	3,181
DRC	31.0	7,743
Madagascar	20.6	8,250
Nigeria	31.6	9,079
Uganda	40.9	3,777
Zambia	29.2	6,441
	% of the Population with Fevers in Past 2 Weeks (%)	
Cambodia	11.4	16,742

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VII. Questionnaires

The following tools will be used for the household survey:

Section 1: Household Identification (to be completed by interviewer)
Section 2: Screening Questionnaire: Household Member Information (preferably to be complete by head of household; representatives will be used if household head is unavailable)
Section 3: Household Information (preferably to be completed by head of household)
Section 4: Treatment Seeking and Case Management (to be completed by: all household members with fever in the past 2 weeks or their caregivers if under 16 (SE Asia) or the caregivers of all children under 5 with fever in the past 2 weeks (Africa). Will be completed once for each case of fever.)
Section 5: Caregiver's Knowledge (to be completed by all eligible respondents interviewed for Section 4. Will be administered once per respondent.)
Section 6: Case Management for persons aged 5 years and older (to be completed by all household members aged 5 or above with fever in the last 2 weeks. Caregivers will be interviewed for children ages 5-15. Will be administered once for each case of fever.)

The content of the questionnaires will be based on the RBM Monitoring and Evaluation Reference Group's Malaria Indicator Survey. Questions on household expenditure on medicines will be based on the WHO Household Survey on Access to and Use of Medicines.

Section One: Household ID

Contains information on the household location, identification numbers, date and time of interview. This section will be completed for all households the interviewer approaches.

Section Two: Screening Form

The screening questionnaire will be used to list all the usual members and visitors of the selected households. Basic characteristics (age, gender, members with fever in the last two weeks) will be collected on each resident living in the household. This will be administered to the household head (if he/she is likely to know which members had fever in the last two weeks) or another suitable member, such as a primary caregiver. The objectives of the screening form are:

1) To identify respondents [caregivers with children under five or adults with fever in the last two weeks] who are eligible to answer the main questionnaire.
2) To identify members of the household who are not eligible to complete the main questionnaire, but reported fever in the last two weeks (e.g. adult males in sub-Saharan Africa). These members will complete a short additional case management form.

Section Three: Household Questionnaire

The household questionnaire will collect socio-economic and wealth asset data. The household questionnaire will be completed by the household head or another suitable respondent, such as a primary caregiver. One household questionnaire will be completed per household.

Section Four: Treatment Seeking and Case Management

The case management questionnaire will be completed to estimate how quickly treatment was sought, whether diagnostics were used, what treatment was used and from which source. Access to money to treat fevers and access to credit from providers will be assessed and the reasons for choosing each source and type of treatment is also ascertained.

Section Five: Caregiver's Knowledge

The Caregiver's Knowledge form will be completed once by each caregiver in the household who has cared for a child under 5 with a fever within the past 2 weeks. It includes the following sub-sections:

1) Demographic characteristics of the respondent.
2) Exposure to media and communication activities
3) Knowledge of malaria, antimalarials, and sources of treatment.
4) Attitudes and perceptions related to the behaviour of interest (i.e. seeking treatment within 48 hours of onset of fever in children under five or taking a malaria diagnostic test). Determinants will be developed using formative research[†††††] within each country and may include concepts such as perceived severity of malaria and locus of control.

Questions in sub-sections 1-3 will be standard for all countries. Sub-section 4 will differ for each country, given the use of formative research to develop the concepts. In Southeast Asia, these determinants related to the target populations' attitudes and perceptions of malaria diagnostic blood testing. In Sub-Saharan Africa, determinants will relate to the target population's attitudes and perceptions related to seeking treatment within 48 hours of onset of fever in children under five.

Section Six: Supplementary Case Management form for Sub-Saharan Africa

In Sub-Saharan Africa a supplementary case management form will be administered to all members of the household who had a fever within the past 2 weeks (care givers will be interviewed on behalf of children aged 5-15) to estimate how quickly treatment was sought,

[†††††] Qualitative research will be conducted with the target population to generate multi-items scales related determinants of treatment seeking behaviors and define their measurement for use in the standardized household questionnaire. Using formative research to generate items by the target population will confirm the importance of the dimensions of treatment seeking behavior or diagnostics. This will improve the conceptual validity and clarity and the cultural relevance of the determinants being measured in the questionnaire. This formative research will be conducted during the inception phase of the research project and the results will be used directly in the development of the questionnaires. See study design for further background and annex for the qualitative guidelines.

whether diagnostics were used, what treatment was used and from which source. One case management form will be completed for each individual with fever.

Translation

The questionnaires will be translated into the local language and pre-tested with a small group of respondents to check for comprehension of questions as well as procedures for conducting interviews. The questionnaires will be back translated to check for the quality of the translation.

Antimalarial Guides

To help respondents identify the type(s) of antimalarials consumed, a photo-illustrated guide will be used to aid in the identification of anti-malarial treatments.

VIII. Procedures

Selection of Households

In a selected EA, interviewers will first determine if a list of households exists. In case a list does not exist, interviewers will proceed to the selected area and confer with the village leader or municipal agent to determine the EA boundaries. Within each of the EAs, the EA will be further divided into small sub-clusters of equal size and geographical boundaries and each sub-cluster will be clearly marked. Along with the markings, the estimated number of households (as provided by key informants) in each sub-cluster will also be specified. The entire sample for the EA will be distributed across the sub-clusters as per the country sample size specifications. Within each sub-cluster, the selection of the household will be done with the help of a household contact sampling interval (Household interval = Total number of households/Total number of interviews). For example, if the total number of households is 900 and the total number of households to be contacted is 18, then the household interval will be 900/18 = 50. If the first contact is conducted in the 5^{th} household then the next interview will be in the 55^{th} household.

Field workers will position each household using a Global Positioning System (GPS) unit. One longitudinal and latitudinal reading will be taken for each household. GPS coordinates will also be used to determine the distance of the household to the nearest antimalarial outlet or health facility.

Administration of Screening Form

At each randomly selected household, the interviewer will give information on the study and ask to interview the head of the household or another member who will be able to list all household members and whether or not they had fever in the last two weeks. Prior to administering the screening form, the household head will be provided with information on the study and gain permission to administer the screening form. Verbal consent will be required to administer the screening form.

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The screening form will be used to gather information about eligible respondents. In sub-Saharan Africa, the screening questionnaire will be used to ascertain if any child in the household experienced fever in the last two weeks. In Southeast Asia, the screening questionnaire will be used to ascertain if any members of the household had a fever within the past 2 weeks (caregivers will be interviewed on behalf of children aged 0-15).

Call-backs

In case no one is available for the screening interview or no one is home when the interviewer visits the household, the interviewer will proceed to the next household.

In case no eligible respondents are identified to complete the main questionnaire, the interview will thank the head of the household for his/her time and proceed to another household. In case an eligible respondent is identified, but not at home during the time of the interview, the interviewer will make one call-back in an attempt to interview the eligible respondent. If the eligible respondent is not available after the call-back, the interviewer will proceed to the next household.

Administration of Household Questionnaire and Consent

The household questionnaire will be administered to the household head or his/her representative. If the head of the household is not available, then the interviewer will identify another appropriate household member, such as the main caregiver.

Prior to administering the household questionnaire, written consent will be gained from the household head or his/her representative and verbal consent from all other interviewees. In case the household head is illiterate, verbal consent will be obtained. All verbal consent will be witnessed by a field worker. Once consent has been given, the Household questionnaire will be used to gather information on the household assets.

Administration of the Case Management Questionnaire

In sub-Saharan Africa, the case management questionnaire will be administered to all members of the household who had a fever within the past 2 weeks (caregivers will be interviewed on behalf of children aged 5-15). All eligible respondents will be administered the Case Management questionnaire using verbal consent procedures.

Administration of the Knowledge, Attitudes and Perceptions Questionnaire

All eligible respondents in the household identified through the screening questionnaire will be invited for an interview. For each eligible respondent, the interviewer will give information on the study and the respondent will be asked to give verbal consent. The interviewer will administer the questionnaire in a private area in the household or nearby.

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Figure One: South East Asia Flow Chart

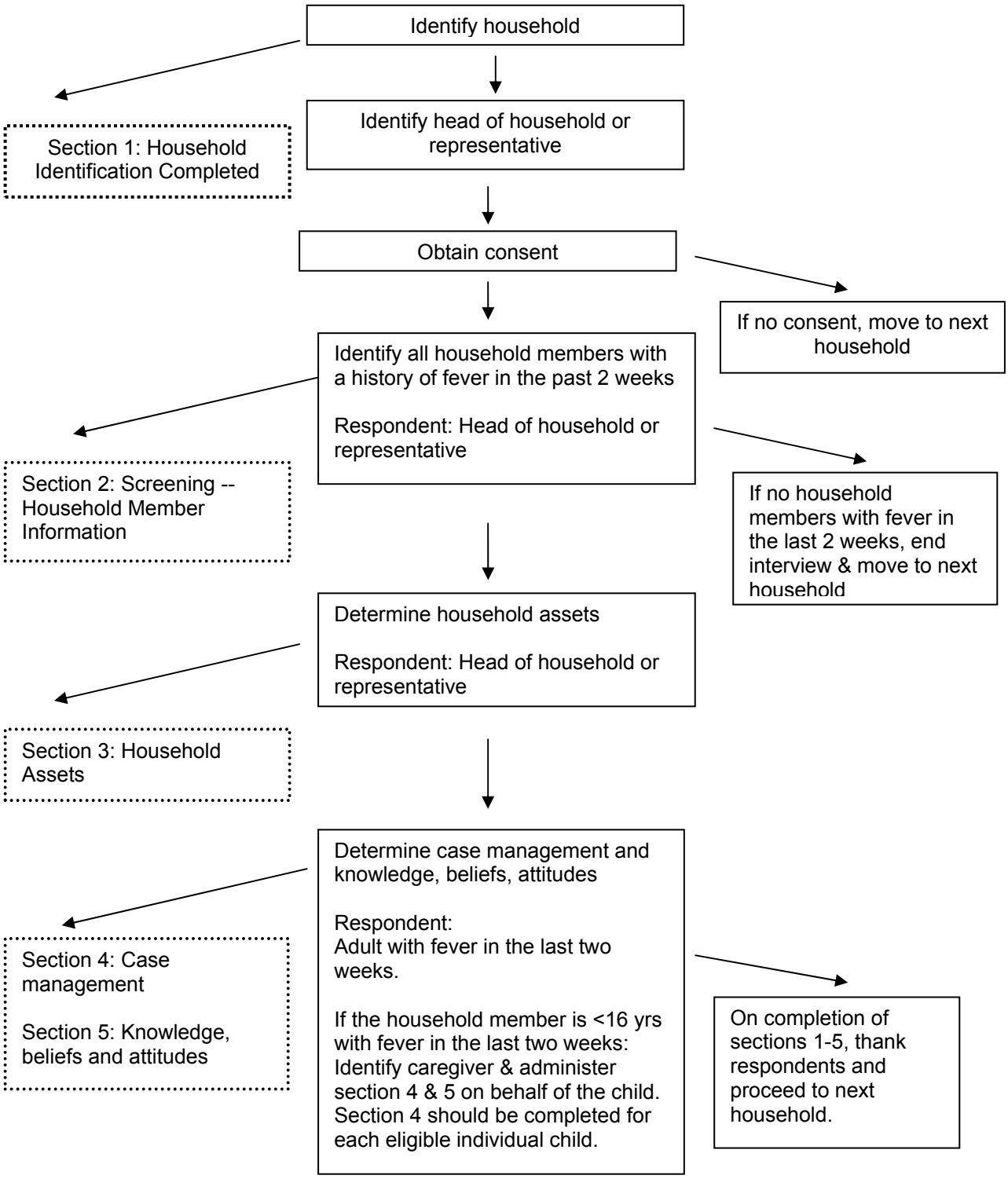

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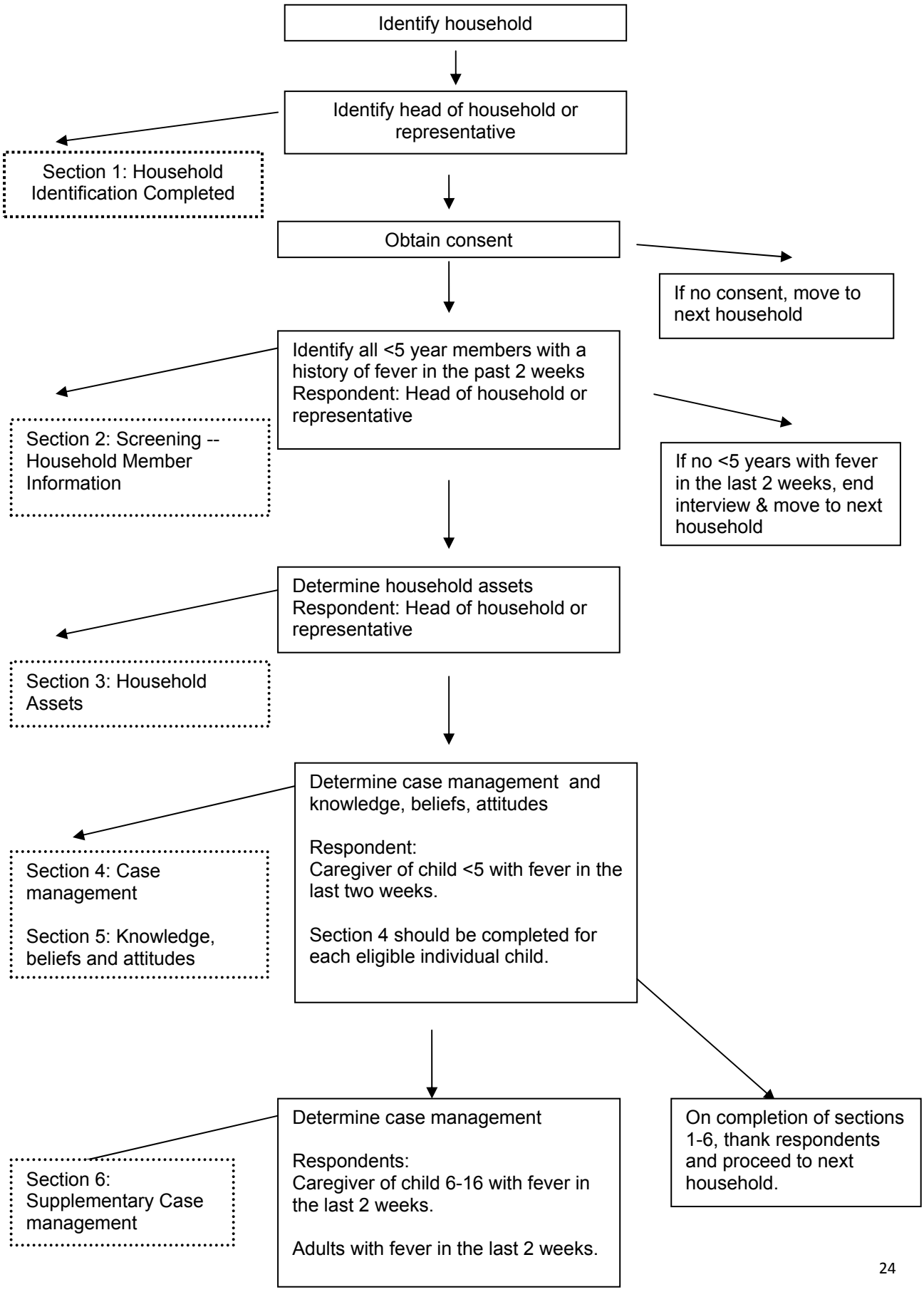
Figure Two: Sub-Saharan Flow Chart



Timing of Data Collection:

Data collection will take place according to when eligible respondents are most likely to be at the household.

Refusal Rates

Records will be kept of refusal rates and incomplete interviews and substitutions/call-backs.

IX. Data Collection Team

An independent research agency will be responsible for data collection. PSI research teams will be instructed to ensure that field workers have experience collecting data. Field workers should also be fluent in the local dialects spoken in the chosen sub-districts.

Data collection will be undertaken by a team of interviewers and team leaders, supervised by PSI staff serving as quality controllers. The number of interview teams and team leaders will vary per country. The interviewers will be responsible for identifying households for interview and conducting interviews at the household. The quality controllers and team leaders will be responsible for ensuring that interviews are conducted correctly and that respondents included in the survey conform to the criteria. Team leaders are responsible for the management of data collection.

X. Data verification and Validation in the Field

During data collection, a quality control process will be implemented to ensure quality of the data collection. Throughout the survey, questionnaires will be reviewed at the end of each day by the team leaders to ensure all entries are completed appropriately. Team leaders will scrutinize for filter errors and non-response/missing data. Any tools with incomplete or questionable entries will be sent back to be re-filled the next day. In 10% of the interviews in the Household Survey, interviewers will be accompanied by the team leader to monitor their performance and see where any improvements can be made. Also, a random sample of 5% of interviewees in each area will be re-interviewed by team leaders (back-checking). The team leaders will conduct partial interviews to ensure concordance in responses. The data collection team will also be provided with detailed instructions on how to administer the questionnaire.

XI. Training

Team leaders, quality controllers and interviewers will be trained on the following:

1) purpose of the study and *ACTwatch*,
2) procedures to identify households within each sub-cluster (second-stage cluster-level sampling of households),
3 how to determine eligible respondents and which respondents are eligible for the main questionnaire,
4) importance of consent, how to administer both the consent forms and ensure confidentiality of interviews,

5) administering the household/screening questionnaire, main questionnaire and case management form. Specifically, training on the instruments will focus on how to complete questions related to household listings, eligibility, treatment seeking behavior, scaled items and skip patterns,
6) Use of GPS and application to the survey.

A field pretest of all survey procedures will be conducted to determine the feasibility of the proposed methodology in each country. Each team will practice performing the household listing, conducting interviews and testing procedures. This will also serve to pre-test the questionnaires, to check for comprehension of questions, ease or difficulty of statements, confidence in response, level of discomfort and social desirability. The results from the pre-test will be used to adapt the questionnaires or country-specific study designs. Any adaptations will be based on the information gathered during the pilot, and may include the time taken to interview respondents, the number of eligible households and refusal rates.

XII. Pilot Test of Questionnaire in Sub-districts

Before implementing the survey, the scaled items will be piloted on a minimum sample of 200 respondents per country. The objective of the pilot test is to determine the psychometric properties of the scaled items. This will also enable an additional pilot of the aforementioned procedures. Selected sites for the pilot will in close proximity to field offices.

XIII. Ethical Issues

Sources of data collected for this study include interview data. Any data collected during this study will be used for the aforementioned research objectives.

Ethical Procedures: Prior to the survey, ethical approval will be obtained according to national guidelines. Where relevant, letters will be sent to district health authorities or district officers. These letters will explain the study and its purpose. In the EAs, the field team leaders will meet with any relevant officials at the district health authorities and present a copy of ethical approval, the information sheet and verbally discuss the planned field work. During these discussions, concerns or queries about the survey may be voiced. Once authorities have been briefed and approval has been gained, a representative from the district health authority may escort the team leader to the relevant village elders, chiefs and/or local leaders. They will be given a copy of the information sheet and ethical approval together with a verbal explanation. Queries and concerns will be addressed during this time and verbal approval will be sought to go ahead with the survey. The health authorities and community leaders will have access to the team throughout the survey so any concerns that arise during the survey can be addressed to the team leader.

Confidentiality: Every effort will be made to protect the confidentiality and the identity of participants. The importance of confidentiality and the protection of the identity of respondents will be emphasized during training of data collection staff. Interviewers will be trained to advise all participants not to share any information found during the field work.

Individual consent: During the surveys, consent will be obtained from the necessary individuals. Information sheets and consent forms will be translated into the local dialect. A copy of the information sheet will be left for the households. The information sheet will include an introduction, the purpose of the study, how questions will be administered, the risks and benefits to those who participate, that the data collected will be confidential and that participation is purely on a voluntary basis. Written consent will be gained from the household head or his/ her representative and verbal consent from all other interviewees. All verbal consent will be witnessed by the interviewer.

Participants will be able to drop out at anytime during the survey and do not have to respond to questions they do not wish to. However, reasons for not participating or not answering questions will be obtained. Great efforts will be made to ensure that participant's confidentiality will be maintained at all times. This includes restricting access of all data to the investigators and data entry clerks when need be, as well as using individual identification numbers on software programs for data analysis.

Training for those involved in administering consent: All fieldworkers will undergo training prior to the study, as explained in the training sub-section. Training will educate fieldworkers on the purpose of the study, the importance of consent and how to administer both the consent forms and questionnaires.

XIV. Data Management:

Data will be collected through paper questionnaires.

Data Storage

All data collected from the survey will be cleaned before and after data entry and will be stored on PCs and USB drives at PSI's country offices. Copies will be sent to the Principle Investigator of *ACTwatch*. All data on computers will be secured through the use of passwords. Field notes and hard copies of the questionnaires will be stored in locked filing cabinets on site. All data entered into software will only have individual identification numbers. Access to any of these materials will be limited to investigators and when necessary clerks for data entry purposes.

Data will be entered into a customized data entry programs (ACCESS). ACCESS is a relational database that reduces data entry errors by up to 80% due to built in logical checks. These programs will be designed to be as similar as possible to the hard copies. Copies of the cleaned data will be made available in the ACCESS format which will have enough identifying information on the address of each household and its GPS location to allow a return/ panel survey on the same respondents if necessary. The datasets will be converted to SPSS for data analysis.

XV. Analysis Plan

Weighting

Due to the disproportional allocation of the sample to the different strata, sampling weights will be applied during analysis. Estimates of proportions and means will be calculated using SPSS's '*complex analysis'* commands.

In order to create weights, the following data will be collected for each stratum. This is also needed for countries without stratification.

- The population of each stratum
- The list of all sub-districts within each stratum and their population size
- The list of EAs within each selected sub-district and their population size
- The number of households per selected EA

Baseline Survey:

Key behavioral indicators will be reported using descriptive analysis. Proportions or means of behavioral indicators and behavioral perceptions will be reported.

Psychometric properties of scaled items: The psychometric scaled items will be analyzed using pilot data and data from the field test. Pilot data analysis will include reliability analysis, exploratory factor analysis and multi dimensional scaling. Any items with inter-item correlations less than .40 will be potentially dropped from the latent construct. Items which result in a decrease in Cronbachs alpha of .70 will also be removed. The reliability of constructs will be confirmed using data from the field test.

Socio Economic Status: Socioeconomic wealth quintiles will be created using information on asset ownership, housing quality, income sources and education status. Principal components analysis (PCA) will be used to construct a household wealth asset index and classify households into wealth quintiles.

Relative volumes of specific antimalarials consumed: This will be derived from the proportion of the target population that used specific antimalarials to treat a fever in the past 2 weeks. Calculations will be based on whether the respondent took the full course and the number of tablets they took. This can then be extrapolated to the total population in the country or sampled areas and over a larger time period, for example a year[‡‡‡‡‡].

For example, if SP has been used to treat fever:

1) Proportion of population who used SP = 10%
2) On average respondents took 5 tablets
3) Total population is 1,000,000
4) = 500,000 SP consumed in past 2 weeks.

[‡‡‡‡‡] As this extrapolation involves combining two confidence intervals to calculate volumes to the total population and over an increased timeframe it may not be possible to determine if changes in volumes of antimalarials consumed over time are statistically significant.

Access to antimalarials: Access to antimalarials will be calculated in a Geographic Information System (GIS) application, using available population data at the time of analysis. The location of outlets with known antimalarial availability (derived from the outlet survey) and population data will be displayed together with relevant spatial information. For example, the transportation network, administrative boundaries, protected areas, lakes and other environmental features if deemed relevant will be highlighted. A catchment area will be drawn around selected geographic areas to determine the proportion of the population who 'fall' within this catchment area and have access to an outlet stocking antimalarials.

Segmentation Analysis: Determinants of treatment-seeking behavior will be analyzed based on multiple logistic regression in which explanatory variables will be dropped if found not to significantly contribute to the explanation of the variance in the behavior of interest. Odds ratio of involvement in the behavior of interest will be reported for each significant explanatory variable. Analysis of Variance (ANOVA) will be employed to estimate the adjusted means or proportions of each explanatory variable by the behavior of interest. Each explanatory variable will be assessed in ANOVA with the behavior of interest serving as the group variable and other significant explanatory variables serving as covariates.

Follow-up Household Survey rounds:

For subsequent household rounds (two-time-point data) tables will be produced to monitor the prevalence and trend of behavioral indicators and related perceptions, and to evaluate the impact of communication interventions. Separate UNIANOVA models will be run for each variable of interest (i.e., behavioral indicators, determinants of behavior) adjusting for socio-demographic characteristics (i.e., age, education, residence, socio-economic status, etc.).

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Annex 1

Indicator Definitions

Core Indicators	Definition: Numerator	Definition: Denominator
1. Proportion of target population with a fever who received any antimalarial within 24 and 48 hours of onset of fever (sub-Saharan Africa and Southeast Asia)[§§§§§]	Number of target population with fever in last 2 weeks who received any antimalarial within 24 and 48 hours of onset of fever	Number of target population with fever in last 2 weeks
2. Proportion of target population with fever in the past 2 weeks having a confirmed malaria diagnosis within 24 and 48 hours of onset of fever (sub-Saharan Africa)[******]	Number of target population with fever in the past 2 weeks having a confirmed malaria diagnosis within 24 and 48 hours of inset of fever	Number of target population with fever in the past 2 weeks
3. Proportion of target population with fever in the past 2 weeks who sought a malaria diagnostic test within 24 and 48 hours of the onset of fever (Southeast Asia)	Number of target population with fever in the past 2 weeks who sought a malaria diagnostic test within 24 and 48 hours of inset of fever	Number of target population with fever in the past 2 weeks
4. Proportion of confirmed malaria cases among target population who received antimalarials within 24 and 48 hours of onset of fever (sub-Saharan Africa and Southeast Asia)	Number of confirmed malaria cases in target population receiving antimalarials within 24 and 48 hours of onset of fever	Number of target population receiving any antimalarial drug within 24 / 48 hours of onset of fever
5. Proportion of target population with fever in the past 2 weeks who received WHO/UNICEF registered ACT within 24 and 48 hours of onset of fever (sub-Saharan Africa and southeast Asia)	Number of target population with fever in last 2 weeks who received WHO/UNICEF registered ACT within 24 and 48 hours of onset of fever	Number of target population with fever in last 2 weeks

[§§§§§] This indicator is the standard RBM and Global Fund indicator which reports on prompt treatment of suspected malaria with any antimalarial. The two week recall period is also standard, and it is usual to ask about fever rather than malaria because of the reliance on presumptive rather than clinical diagnosis (which would involve use of microscopy or rapid diagnosis tests). A 24 hour treatment period is used, as specified in the RBM indicators.

[******] This is intended to provide some evidence on the extent to which target populations have a confirmed malaria diagnosis, rather than presumptive treatment based on fever. However, careful interpretation of this indicator is required since, this will be based on recall of the caregiver rather than diagnostics conducted during the interview.

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Core Indicators	Definition: Numerator	Definition: Denominator
6. Proportion of target population with fever in the past 2 weeks who received nationally registered ACT within 24 and 48 hours of onset of fever (sub-Saharan Africa and southeast Asia)	Number of target population with fever in last 2 weeks who received nationally registered ACT within 24 and 48 hours of onset of fever	Number of target population with fever in last 2 weeks
7. Proportion of target population with fever in the past 2 weeks receiving non-artemisinin monotherapy within 24 and 48 hours of onset of fever (sub-Saharan Africa and southeast Asia)	Number of target population with fever in last 2 weeks receiving non-artemisinin monotherapy within 24 and 48 hours of onset of fever	Number of target population with fever in last 2 weeks
8. Proportion of target population with fever in the past 2 weeks receiving artemisinin based drugs as a monotherapy (sub-Saharan Africa and southeast Asia)[††††††]	Number of target population with fever in last 2 weeks receiving artemisinin based drugs (either as a monotherapy or combination therapy)	Number of target population with fever in last 2 weeks
9. Proportion of all target population with fever in the past 2 weeks treated with an antimalarial within 24 and 48 hours of onset of fever (sub-Saharan Africa and southeast Asia)	Number of target population with fever in last 2 weeks treated with an antimalarial within 24 and 48 hours of onset of fever	Number of target population with fever in last 2 weeks
10. Proportion of target population with fever in the past 2 weeks who sought treatment by source (sub-Saharan Africa and southeast Asia)	Number of target population with fever in the past 2 weeks who sought treatment by source	Number of target population with fever in last 2 weeks who received any antimalarial drug
11. Proportion of target population with fever in the past 2 weeks who chose treatment source by reason (sub-Saharan Africa and southeast Asia)	Number of target population with fever in the past 2 weeks who sought treatment source by reason	Number of target population with fever in last 2 weeks who received any antimalarial drug

[††††††] This indicator is intended to provide information on the use of artemisinin monotherapies and provide measures for reporting on the extent to which artemisinin monotherapies have been crowded out.

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Core Indicators	Definition: Numerator	Definition: Denominator
12. Proportion of target population with fever in the past 2 weeks who received antimalarial drugs by source (sub-Saharan Africa and southeast Asia)	Number of target population with fever in the past 2 weeks who received antimalarial drugs by source	Number of target population with fever in last 2 weeks who received any antimalarial drug
13. Proportion of target population with fever in the past 2 weeks who received an antimalarial recommended by a provider (sub-Saharan Africa and southeast Asia)	Number of target population with fever in the past 2 weeks who received an antimalarial recommended by a provider	Number of target population with fever in last 2 weeks who received any antimalarial drug
14. Proportion of target population with fever in the past 2 weeks who received an antimalarial they requested from a provider (sub-Saharan Africa and southeast Asia)	Number of target population with fever in the past 2 weeks who received an antimalarial they requested from a provider	Number of target population with fever in last 2 weeks who received any antimalarial drug
15. Proportion of target population with fever in the past 2 weeks who used antimalarial drug prior to the expiration date (sub-Saharan Africa and southeast Asia)	Number of target population with fever in the past 2 weeks who used antimalarial drug prior to the expiration date	Number of target population with fever in last 2 weeks who received any antimalarial drug
16. Household cost of fever episode treated with an antimalarial (for all completed episodes (sub-Saharan Africa and southeast Asia)	Median household cost of fever episode treated with an antimalarial	Number of households with target population with fever in the past 2 weeks for all completed episodes
17. Volumes of antimalarials consumed by target populations with fever in the past 2 weeks by type of antimalarial (sub-Saharan Africa and southeast Asia)	Volumes of antimalarials consumed by target populations with fever in the past 2 weeks by type of antimalarial	Number of target population with fever in the past 2 weeks who received any antimalarial drug and completed the full course of antimalarial received
18. Proportion of target populations with fever in the past 2 weeks that were treated with any antimalarial across socio-economic quintiles (sub-Saharan Africa and southeast Asia)	Number of target population with fever in last 2 weeks who received any antimalarial by socio-economic quintile	Number of target population with fever in last 2 weeks

Annex H – ACTwatch Methodologies

Core Indicators	Definition: Numerator	Definition: Denominator
19. Proportion of population within a defined geographic area that have access to a source of antimalarials by type of antimalarial (sub-Saharan Africa and southeast Asia)	Number of people within the catchment area of a provider with antimalarials	Total population
20. Proportion of target population who know where to obtain antimalarials (sub-Saharan Africa and southeast Asia)	Number of target population who know where to obtain antimalarials	Number of target population
21. Proportion of target population who know they should respond to fever the same or next day (sub-Saharan Africa and southeast Asia)	Number of target population who know to respond to fever the same or next day	Number of target population
22. Proportion of target population who know that fever is the main symptom of malaria (sub-Saharan Africa and southeast Asia)	Number of target population who know that fever is the main symptom of malaria	Number of target population
23. Proportion of target population who know that compliance with the full treatment dose is important for effectiveness (sub-Saharan Africa and southeast Asia)	Number of target population who know that compliance with the full treatment dose is important for effectiveness	Number of target population
24. Proportion of target population who have heard of ACT and know what it is (sub-Saharan Africa and southeast Asia)	Number of target population who have heard of ACT and know what it is	Number of target population
25. Proportion of target population who store partial doses of antimalarials to use again (sub-Saharan Africa and southeast Asia)	Number of target population who store partial doses of antimalarials to use again	Number of target population
26. Proportion of target population who received any antimalarial and adhered to the full course (defined by number of days (sub-Saharan Africa and southeast Asia)	Number of target population with fever in last 2 weeks who received any antimalarial and took the antimalarial over the specified number of days	Number of target population with fever in last 2 weeks who received any antimalarial drug

Annex H– ACTwatch Methodologies

Core Indicators	Definition: Numerator	Definition: Denominator
27. Proportion of target population who believe that a specific antimalarial is the most effective malaria treatment for adults (sub-Saharan Africa and southeast Asia)	Number of target population who believe that a specific antimalarial is the most effective malaria treatment for adults	Number of target population
28. Proportion of target population who believe that a specific antimalarial is the most effective malaria treatment for pregnant women (sub-Saharan Africa and southeast Asia)	Number of target population who believe that a specific antimalarial is the most effective malaria treatment for pregnant women	Number of target population
29. Proportion of target population who believe that a specific antimalarial is the most effective malaria treatment for children under five (sub-Saharan Africa and southeast Asia)	Number of target population who believe that a specific antimalarial is the most effective malaria treatment for children under five	Number of target population
30. Proportion of target population who have been exposed to antimalarial communications (sub-Saharan Africa and southeast Asia)	Number of target population who have been exposed to antimalarial communications	Number of target population

Annex 2:

Definitions of Behavioral Constructs

'Opportunity' refers to defined community and service factors that promote or inhibit recommended behaviors. Opportunity constructs are derived from Diffusion of Innovation theory and health promotion. The determinants include measures of availability, quality of care, brand appeal, brand attributes and social norms. Many of these determinants of behavior cannot be effected directly through communications and are addressed through supply side interventions (e.g. product packaging, branding and distribution).

'Ability' refers to an individual's skill or proficiency at solving problems, given the opportunity and motivation setting. Ability constructs come from social psychology theories and the determinants include knowledge, self-efficacy and social support.

Motivation describes how a person has self-interest in changing his or her behavior, given the opportunity and ability. These constructs may relate to awareness of the behavior and its benefits and costs, or emotional reactions to related past events. Motivational determinants that are most proximate to behavior may include personal risk assessment and outcome expectations.

Annex 3:

CONSENT FORM – INTERVIEWS

ACTwatch

HOUSEHOLD SURVEY
(To be read to/ read and signed by the household head or representative)

I have had the study explained to me. I have understood all that has been read and had my questions answered satisfactorily. I understand that I can change my mind at any stage and it will not affect the benefits due to me or the household members.

please tick **I agree to be interviewed**

Signature/ Mark: _____ **Date** _____

Participant's Name: _____ **Time:** _____
(please print name)

I certify that I have followed the study information sheet to explain this study to the participant, and that s/he understands the nature and the purpose of the study and consents to participate in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Signature: _____ **Date** _____

Designee/investigator's Name _____ **Time:** _____
(please print name)

THE HOUSEHOLD HEAD OR REPRESENTATIVE SHOULD NOW BE GIVEN AN INFORMATION SHEET TO KEEP