



Evidence for Malaria Medicines Policy

Outlet Survey Study Design



Annex H – ACTwatch Methodologies

ACTwatch: Outlet Survey

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Recommended citation:

ACTwatch (Population Services International [PSI] and London School of Hygiene and Tropical Medicine [LSHTM]). 2008. Outlet Survey Study Design. PSI, Department of Malaria and Child Survival, *ACTwatch* Group. www.actwatch.info

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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)¹.

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

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;

¹ 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.

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 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 Outlet Survey. The results from this survey will primarily contribute to addressing the first objective, but also help to achieve the second and third objectives. The proposed design will serve as an international template.

II. Outlet Study Research Questions

Key Research Questions:

- 1) What is the availability of antimalarials in the public, private and informal sectors?
 - i. To what extent are antimalarials available?
 - ii. To what extent are non-artemisinin monotherapies and non-artemisinin combination therapies available?
 - iii. To what extent are artemisinin monotherapies available?
 - iv. To what extent are ACTs² available?
 - v. To what extent was there a disruption in stock of antimalarials in the last three months?
 - vi. To what extent is there expired stock of antimalarials?
 - vii. To what extent are acceptable storage conditions maintained for antimalarials?
 - viii. To what extent do outlets offer malaria diagnostic testing?

- 2) What are the prices of antimalarials in the public, private and informal sectors?
 - i. What is the median cost of a full course of an adult treatment of the most popular antimalarial?
 - ii. What is the median cost of a full course of an adult treatment of ACT?
 - iii. How affordable is a full course of an adult treatment of ACT?
 - iv. How affordable is a full course of an adult treatment of ACT relative to the most popular full course adult treatment (non-ACT) for malaria?
 - v. To what extent do providers offer credit to patients for antimalarials?
 - vi. What is the median cost of a full course of an adult treatment of ACT relative to international reference prices?
 - vii. What is the cumulative percentage mark up between retail median price of a full course of an adult treatment of ACT and terminal wholesaler's median price?

- 3) What are the volumes of antimalarial medicines sold or distributed in the public, private and informal sectors?
 - i. What are the volumes of ACTs sold or distributed?
 - ii. What are the volumes of non-artemisinin monotherapies and non-artemisinin combination therapies sold or distributed?
 - iii. What are the volumes of artemisinin monotherapies sold or distributed?

- 4) What are the perceptions of providers and what is their knowledge of antimalarial medicines in the public, private and informal sectors?
 - i. To what extent is a WHO/UNICEF approved ACT or a nationally registered ACT the most popular antimalarial?

² Unless otherwise specified, ACTs will be categorized and reported for each research objective as a) international quality assured ACTs, b) nationally approved ACTs and, c) non-quality ACTs. Results will be presented for each of these three categories.

- ii. To what extent do providers have correct knowledge of the recommended first line treatment for uncomplicated malaria?
 - iii. To what extent do providers have correct knowledge of the recommended dosing regimen of the first line ACT treatment for an adult?
 - iv. To what extent do providers have correct knowledge of the recommended dosing regimen of the first line ACT treatment for a 2 year old child?
 - v. To what extent do providers know at least one danger sign in a child that requires referral to a public health facility?
 - vi. To what extent do customers request specific antimalarials by brand name or generic name?
 - vii.
- 5) To what extent does the population have access to antimalarials?
- i. To what extent do people have access to a full adult course of ACT treatment?
 - ii. To what extent do people have access to a full child course of ACT treatment?
 - iii. To what extent do people have access to any antimalarial treatment?

III. Methodology

PSI will conduct an Outlet Survey in each of the ACTwatch countries to address the aforementioned research questions.

Timeline

The Outlet Surveys will be conducted twice yearly over five years. One survey will be conducted during the peak malaria transmission season and the second survey six months later.

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 patterns³. Peak seasons are estimated using incidence rates (where available), rainfall patterns (Grover-Kopec, 2006⁴) and any other country specific documentation. 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 Outlet 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 Outlet Survey will be conducted in December 2008. A follow-up Outlet Survey will be conducted 6 months later 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 Outlet Survey will be conducted in October 2008. The baseline Household and follow-up Outlet Surveys will be conducted in March 2009. It is not feasible to conduct the surveys in January and February due to heavy flooding. The third round follow-up Outlet Survey will be conducted in October 2009.

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 and Outlet Surveys will be conducted in October/November 2008. The follow-up Outlet Survey will be conducted in April/May 2009.

³ Roll Back Malaria, (2005). Guidelines for Sampling for the Malaria Indicator Survey. ORC: Calverton, Maryland.

⁴ 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.

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 baseline Outlet Survey will be conducted in November/December 2008. The Household and follow-up Outlet Surveys 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 baseline Outlet Survey will be conducted in early October 2008. The Household and follow-up Outlet Surveys will be conducted in February 2009.

Cambodia:

Cambodia has a main rainy season from May to November. The Household and baseline Outlet Surveys will be conducted in November/December 2008. The follow-up Outlet Survey will be conducted six months later in May/June 2009.

Madagascar:

The baseline Outlet Survey and Household Surveys will be conducted between November/December 2008. The follow-up Outlet Survey will be conducted six months later in April/May 2009.

Myanmar:

To be determined.

Table 1: Timing of Outlet Survey

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

*baseline Household Surveys are also conducted at the same time

Stratification

Stratification is 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.

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.

Sample Size

To guide the sampling, an estimated sample size is provided to determine how many outlets would be needed to provide statistically robust conclusions.

This survey will measure differences in indicators over time and between outlet types. It will measure a) differences over time for a given outlet type (e.g. changes in ACT availability in drug shops at baseline versus ACT availability in drug shops at follow-up), and b) differences between outlet types within each stratum at a given point in time (e.g. differences in ACT availability between public health facilities versus availability in Type One pharmacies at baseline). Denominators for this survey are the numbers of outlets at a particular time. The required sample size for each year of the program is therefore calculated using the formula:

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

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 = the design effect in case of multi-stage cluster sample design

Assumptions are as follows:

P_1 = the value of the key outcome indicators at time 1= 40% (40% is used to maximize the sample size and ensure that a 20% difference can be detected as the true value is unknown)

P_2 = the expected value of the indicator at the second instance (time 2). A 20% difference will be detected (assuming that a 20% 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,

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

Deff = estimated at 3.

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

A minimum of 291 of each outlet type is needed in order to detect a statistically significant difference of 20% in indicators (80% power, 95% significance, design effect estimated at 3 to address one staged cluster sampling, P_1 is the hypothesized value of the indicator at year one [40%], P_2 is the hypothesized value of the indicator at time 2 [60%]).

The estimated sample size needed to take into account indicators that address changes in the price of ACTs is also considered in the following formula:

$$n = \frac{n_1}{P_u * P_r}$$

Where $[P_u]$ is outlets with antimalarials and $[P_r]$ is the proportion of outlets with an ACT. This is the final estimated sample size needed to ensure sufficient power to detect changes in price of an ACT.

Assumptions are as follows:

n = desired sample size for monitoring pricing indicators

$n_1 = 291$, that is, where design effect is estimated at 3; α to 5%; and β to 20%; a 20% difference. P_u = the proportion of outlets with an ACT. This value is unavailable in most countries, so an estimate of 10% is used to provide guidance on the sample size.

P_r = the proportion of outlets with an antimalarial. As all interviewed outlets are those that have stocked an antimalarial within the past 3 months, this value = 100%.

Using these assumptions, a total of 2910 ACTs must be audited to detect a 20% difference in antimalarial prices. Assuming an average of 2 ACTs per outlet that carries ACTs, a total sample size of 1455 outlets will be needed. Given financial and geographic constraints, it is unlikely that a sufficient number of all outlets will be achieved in a single commune to detect differences in prices of ACTs at the baseline. Therefore, a booster sample will be required.

Sampling

The proposed study design for this project is an adaptation of the World Health Organization (WHO)/Health Action International (HAI) methodology to measure the price, availability and affordability of medicines across countries⁵. An adaptation of this methodology was chosen because sentinel site selection, based on the WHO/HAI methodology, does not permit for the extrapolation of results to form a complete picture of the antimalarial medicines market, nor does it allow for significant comparisons between outlet types. The adapted methodology is outlined in this section.

⁵ The HAI guidelines recommend monitoring indicators in six geographic areas across four service delivery sectors: (1) public sector hospitals and clinics, (2) the formal commercial sector, (3) the unlicensed commercial sector, and (4) 'other' not-for-profit organizations (where present). Selection of survey facilities, for generating data on prices to patients in both the private and public sectors, uses a sampling approach which selects one central area, the major urban centre (usually the capital of the geographical area (e.g. country, province or state), combined with three other administrative areas chosen randomly from a list of areas that can be reached within one day's travel from the central area. In each of the four identified areas, at least five public health facilities are selected, including the main public hospital. The choice of private sector pharmacies sampled is based on their proximity to the public health facilities surveyed; at least five pharmacies per survey area should be included. Private sector not-for-profit facilities (e.g. a nongovernmental organization) will also be selected if they are present, applying the same methodology. This results in a basic sample size of up to 120 outlets, assuming no sub-national stratification. This sampling approach has sufficient power to test for differences in levels and trends that are of national policy significance (HAI, 2003, 2006).

Sampling Approaches

Two different sampling approaches are used to address the research objectives. The first sampling approach is for all outlet types that have the potential to sell or provide antimalarials. The second sampling approach is for a booster sample of public health facilities and Part One pharmacy outlets. Employing both approaches will provide a sufficient sample size to detect differences of statistical significance in availability of ACTs across the five main types of outlets. The main outlet categories to be compared are: 1) public health facilities and community based health workers as appropriate⁶, 2) Part One pharmacies, 3) drug shops, 4) grocers and 5) other informal outlets (e.g. kiosques). The data collection for both of these sampling approaches will take place at the same time.

Sampling of All Outlets

Given that a complete sampling frame does not exist for potential antimalarial outlets such as grocers, drug shops and other informal outlets, the following sampling approach will be employed. For this approach, a sampling frame of all sub-districts within each stratum will be developed. Sub-districts are administrative units⁷ that host a population size of approximately 10,000 to 15,000 inhabitants. By using the sub-district as the sampling unit, we expect to achieve the minimum sample size needed to detect changes between the most commonly found antimalarial outlets within each stratum. For each stratum, a minimum of 19 sub-districts will be selected probability proportional to size—a sampling technique in which the probability that a particular sub-district will be selected within a stratum is proportional to sub-district population (so that larger sub-districts have a greater chance of being selected). The selection of 19 sub-districts is based on the principles of Lot Quality Assurance Sampling (LQAS) (see Annex for further detail).

In each of the 19 sub-districts, all outlets that have the potential to sell or provide antimalarials to a consumer will be sampled. To ensure that all potential outlets are included, a census of all outlets will be conducted in each of the selected sub-districts. An outlet is defined as any point of sale or provision of a commodity to an individual. Outlets include, but are not limited to: 1) public health facilities, 2) Part One pharmacies⁸, 3) drug shops, 4) grocers and 5) other informal outlets. Outlets are not restricted to stationary points of sale and may include mobile units or individuals. For the purpose of this study, outlets such as bars, hardware shops and salons are excluded.

⁶ Community health workers may be appropriate in countries in which there is a significant presence of community based health workers. Inclusion of community health workers and how they are included will be determined on a country by country basis.

⁷ “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.

⁸ The presence of public health facilities and Part One pharmacies in the sub-district will be confirmed using Ministry of Health information (see procedures section for more detail).

Booster Sample: Sampling of Part One Pharmacies and Public Health Facilities

Public health facilities (e.g. tertiary care facilities, district/provincial level facilities, smaller health posts and centers, and community health workers) and Part One pharmacies are government regulated pharmaceutical outlets. These facilities typically service a large number of patients; however, few of these outlet types are expected to be found in any given sub-district. Given few public health facilities and Part One pharmacies are expected to be found at the sub-district level and given their importance as antimalarial distribution points, a booster sample of public health facilities and Part One pharmacies will be taken. Since a complete sampling frame for both public health facilities and Part One pharmacies is available (they are registered with every country's Ministry of Health), these listings will be utilized to create a sampling frame. The sampling frame will be used to both confirm their locations within the selected sub-district and identify additional facilities located at the district-level of the selected sub-district.

The Ministry of Health sampling frame will be organized by stratum appropriate to each country context. All public health facilities and Part One pharmacies located at the district level of the selected sub-districts, will be listed in the sampling frame in each stratum. Those public health facilities and Part One pharmacies that are located in other districts will not be included in the sampling frame. Selection of these facilities in the selected districts will be conducted in the following manner--

Public health facilities:

- All tertiary care facilities and district/provincial level facilities will be purposely selected.
- Smaller health posts and centers will be selected via simple random sampling.
- Community health workers will be selected via simple random sampling.

Part One pharmacies:

- Part One pharmacies will be selected via simple random sampling.

Pilot Study

A pilot study using the census only methodology will be conducted in every country, across an entire sub-district. The objectives are to understand the denominator of potential outlets, the time taken to survey a sub-district, and to define the outlet types. The pilot will also identify and address any unanticipated challenges for the full study. The pilot is a key component of this research, as it will address the feasibility of conducting a complete audit of every potential antimalarial outlet in the suggested geographic areas.

Country-specific information will be collected to ensure that outlets are categorized in a meaningful and consistent manner for comparability. Attention will be given to understanding country differences and similarities between outlets. Differences will be highlighted in country-specific study designs. Although some differences in outlet types are expected, we will strive to categorize outlets in a relatively standard manner across countries.

IV. Indicators

The following indicators will be measured through the Outlet Survey. Results will be presented for the five outlet types within each strata, as appropriate, and nationally.

Indicator Table 1: Availability, Price, Volumes, Knowledge & Provider Perceptions

1. Availability
i. Proportion of outlets that had antimalarials in stock at the time of survey visit
ii. Proportion of outlets that had non-artemisinin monotherapy or non-artemisinin combination therapy in stock at the time of survey visit
iii. Proportion of outlets that had artemisinin monotherapy in stock at the time of survey visit ♣ - <i>modified</i>
iv. Proportion of outlets that had ACTs in stock at the time of survey visit ♣ 'ACTs' will be categorized as follows: <i>WHO/UNICEF approved ACTs</i> <i>Nationally registered ACTs</i> <i>Non-WHO/UNICEF/Nationally registered ACTs</i>
v. Proportion of outlets reporting no disruption in stock of antimalarials in the last three months ♣ - <i>modified</i>
vi. Proportion of outlets with expired stock of ACTs ◆
vii. Proportion of outlets that maintain acceptable storage conditions for antimalarials ◆ - <i>modified</i>
viii. Proportion of outlets that have either rapid diagnostic tests or microscopic blood testing facilities
2. Price
i. Median cost of a full adult course of the most popular antimalarial
ii. Median cost of a full course of an adult treatment of ACT 'ACTs' will be categorized as follows: <i>WHO/UNICEF approved ACTs</i> <i>Nationally registered ACTs</i> <i>Non-WHO/UNICEF/Nationally registered ACTs</i>
iii. Median cost to patient of a full course of an adult treatment of ACT relative to minimum daily wage of a government unskilled worker ♣ - <i>modified</i> 'ACTs' will be categorized as follows: <i>WHO/UNICEF approved ACTs</i> <i>Nationally registered ACTs</i> <i>Non-WHO/UNICEF/Nationally registered ACTs</i>
iv. Median cost to patient of a full course of an adult treatment of ACT relative to cost of the most popular full course adult treatment (non-ACT) antimalarial ♣ - <i>modified</i> 'ACTs' will be categorized as follows: <i>WHO/UNICEF approved ACTs</i> <i>Nationally registered ACTs</i> <i>Non-WHO/UNICEF/Nationally registered ACTs</i>
v. Proportion of outlets that offer credit to consumers for antimalarials
vi. Median cost to patient of a full course of an adult treatment of ACT relative to international reference prices ◆ 'ACTs' will be categorized as follows: <i>WHO/UNICEF approved ACTs</i> <i>Nationally registered ACTs</i> <i>Non-WHO/UNICEF/Nationally registered ACTs</i>
vii. Cumulative percentage mark up between retail median price of a full course of an adult treatment of ACT and terminal wholesaler's median price. ◆ ✨ 'ACTs' will be categorized as follows:

WHO/UNICEF approved ACTs
Nationally registered ACTs
Non-WHO/UNICEF/Nationally registered ACTs

3. Volumes

- i. Total volume of ACTs sold or distributed in the last week as a proportion of the total volume of all antimalarials sold or distributed in the last week
 'ACTs' will be categorized as follows:
WHO/UNICEF approved ACTs
Nationally registered ACTs
Non-WHO/UNICEF/Nationally registered ACTs
- ii. Total volume of non-artemisinin monotherapies and non-artemisinin combination therapies sold or distributed in the last week as a proportion of the total volume of all antimalarials sold or distributed in the last week
- iii. Total volume of artemisinin monotherapies sold or distributed in the last week as a proportion of the total volume of all antimalarials sold or distributed in the last week

4. Knowledge & Provider Perceptions

- i. Proportion of providers that report a WHO/UNICEF approved ACT or a nationally registered ACT is the most popular antimalarial
- ii. Proportion of providers that correctly state the recommended first line treatment for uncomplicated malaria ◆
- iii. Proportion of providers that correctly state the dosing regimen for an adult of the first line treatment ACT ◆
- iv. Proportion of providers that correctly state the dosing regimen for a two year old of the first line treatment ACT ◆
- v. Proportion of providers that can list at least one danger sign in a child that requires referral to a public health facility
- vi. Proportion of providers that agree with the statement 'Most customers request an antimalarial by brand name or generic name'
- vii. Proportion of providers that agree with the statement 'I decide which antimalarial medicine most customers receive'

Symbols:

♣ AMFm core indicator

◆ AMFm supplementary indicator

⚙ This indicator requires the extension of the WHO/HAI Medicines price survey questionnaire to include national wholesalers. This indicator will be answered using complementary data from the Market Supply Chain research

Access Indicators

Measuring Population Access to ACTs: Approach One

Sampling 19 geographic areas has the additional benefit of permitting the production of an access indicator, i.e. the proportion of the national population that lives in geographic areas of defined population size, with a given level of antimalarial availability.

The following indicators measure the proportion of the population living in areas that have access to antimalarials, based on minimum standards. In the table below, an access indicator will report the proportion of the population living in areas in which at least one provider is present that carries an adult and child dose of an internationally registered and/or nationally approved ACT.

The following indicators will be measured through the Outlet Survey. Results will be presented by outlet types within each strata, as appropriate, and nationally. For minimum standards to be met, two criteria must be met: 1) the outlet type must exist and 2) it must carry an international or/and nationally approved ACT.

Indicator Table 2: Measuring Population Access to ACTs and Other Antimalarials

5. Access Indicators
i. Proportion of the population living in areas that achieve coverage standards of availability for a full course of an adult treatment of ACT Minimum Standards:
At least one outlet in the sub-district with any WHO/UNICEF approved full course adult treatment of ACT
At least one public health facility in the sub-district with any WHO/UNICEF approved full course adult treatment of ACT
At least one Part One pharmacy in the sub-district with any WHO/UNICEF approved full course adult treatment of ACT
At least one drug shop in the sub-district with any WHO/UNICEF approved full course adult treatment of ACT
At least one outlet in the sub-district with any nationally registered full course adult treatment of ACT
At least one public health facility in the sub-district with any nationally registered full course adult treatment of ACT
At least one Part One pharmacy in the sub-district with any nationally registered full course adult treatment of ACT
At least one drug shop in the sub-district with any nationally registered full course adult treatment of ACT
ii. Proportion of the population living in areas that achieve coverage standards of availability for a full course of a child treatment of ACT Minimum Standards:
At least one outlet in the sub-district with any WHO/UNICEF approved full course child treatment of ACT
At least one public health facility in the sub-district with any WHO/UNICEF approved full course child treatment of ACT
At least one Part One pharmacy in the sub-district with any WHO/UNICEF approved full course child treatment of ACT
At least one drug shop in the sub-district with any WHO/UNICEF approved full course child treatment of ACT

At least one outlet in the sub-district with any nationally registered full course child treatment of ACT
At least one public health facility in the sub-district with any nationally registered full course child treatment of ACT
At least one Part One pharmacy in the sub-district with any nationally registered full course child treatment of ACT
At least one drug shop in the sub-district with any nationally registered full course child treatment of ACT
iii. Proportion of the population living in areas that achieve coverage standards of availability for any antimalarial
Minimum Standards:
At least one outlet in the sub-district with any antimalarial
At least one public health facility in the sub-district with any antimalarial
At least one Part One pharmacy in the sub-district with any antimalarial
At least one drug shop outlet in the sub-district with any antimalarial
iv. Proportion of the population that has access to WHO/UNICEF approved ACT
v. Proportion of the population that has access to nationally registered ACT

Measuring Population Access to ACTs: Approach Two

Given that a Household Survey will be conducted at the same time as the peak season Outlet Survey, this provides us with the opportunity to measure access to ACTs in an alternative fashion. Household respondents will be selected at random from villages that are located within the Outlet Survey sub-districts. GIS coordinates will be used to mark the locations of the selected households. As part of the Household Survey, caregivers with children under five will be asked questions related to how far they would be willing to travel to obtain antimalarials, how far have they traveled and from which outlet type.

Based on these procedures the following data will be collected:

- 1) GIS coordinates illustrating the location of outlets with known ACT availability
- 2) GIS coordinates illustrating the location of the selected households
- 3) Average distance caregivers travel to obtain antimalarials
- 4) Population size of the enumeration unit (e.g. village)

The access indicator is determined in the following manner: Using data on the distance a caregiver is willing to travel/has traveled, a catchment area can be drawn around the selected village. Should an ACT-carrying outlet 'fall' within this catchment area, the village population is considered to have access to ACTs. This procedure is repeated for all the villages selected for the Household Survey.

Using this procedure, an access indicator will be produced to answer the question: What is the proportion of the population that has access to international registered and/or nationally approved ACTs? The denominator is the total population size of the selected villages in a given sub-district. Among these villages, the numerator is the total population that has access to an ACT-carrying outlet.

V. Questionnaire

A drug audit sheet and set of structured questions on provider knowledge and perceptions will be used (this is referred to as the drug audit sheet from here on). The drug audit sheet will be used to collect data on outlet identification and characteristics, availability, price, stock and expiry date of antimalarial medicines and is based on the WHO/HAI Medicine Price Data Collection form. It will be translated into the local language.

VI. Procedure

As highlighted in the sampling section of this document, two sampling approaches will be used in this study. The sampling addresses how all outlet types will be sampled in the 19 sub-districts, within each stratum. The booster sampling approach illustrates how public health facilities and Part One pharmacy outlets will be selected using a sampling frame based on Ministry of Health information, within the districts of the selected sub-districts in each stratum. The following section describes the procedures for conducting the Outlet Survey and the universal procedures used to collect the drug audit sheet data.

Before data collection, initial lists of all registered facilities in the selected sub-districts and corresponding districts from the Ministry of Health or other national or lower level health departments will be obtained. This list will include all public health facilities and Part One pharmacies. Where possible, other outlets will be identified initially from lists provided by NGOs or other organisations. Field workers will make a note of all these outlets that are located in the sub-district and ensure that they are included in the census at the sub-district level. For those public health facilities and Part One pharmacies located at the corresponding district level, sample selection will be conducted as described in the sampling section: all tertiary care health facilities and district/provincial care facilities will be selected; smaller health posts/centers, community health workers and Part One pharmacies will be selected via simple random sampling. Fieldworkers will record the locations of these outlets in advance of the field visit given data collection in the sub-district and district level will be conducted simultaneously.

The list of known outlets will be supplemented by visiting the areas and confirming the list with local leaders. The field worker will also contact the relevant authority in the sub-district area to enquire about places that typically or even occasionally, stock antimalarials. Field workers will also confirm the list of known public health facilities and Part One pharmacies with key informants in that area. In addition, a snowballing technique will be used where providers of known outlets will be asked to identify other outlets within the local area. All identified outlets within the selected sub-districts will then be mapped.

The field workers will then proceed to every outlet and known public health facility and Part One pharmacy to enquire about the availability of antimalarials. Field workers will visit each outlet and position it using a Global Positioning System (GPS) unit. One longitudinal and latitudinal reading will be taken for each outlet. Once the information has been recorded, a screening question will be asked to determine if the outlet should be audited and the provider interviewed: The screening question is: 'Do you currently provide or sell antimalarial medicines today'? The type of outlet will be recorded. In case the outlet does not currently have any antimalarials, the field worker will ask the outlet owners or assistants about the location of other outlets in the area that may typically or occasionally stock antimalarials. Records of these outlets and their location will be added to the list of known locations of the public health facilities and Part One pharmacies in the sub-district.

In this manner, the field workers will conduct a census of all the outlets in the sub-district, by visiting all the outlets they come across in the sub-district. Field workers will use key

informants living or working in the sub-district to ensure no outlets are missed and they will draw on existing Ministry of Health information regarding known public health facilities and Part One pharmacies. The field worker will also ensure that he/she goes to the public health facilities and Part One pharmacies that have been listed as being present in the sub-district.

Once an exhaustive census has been conducted in the sub-district, the field workers will then proceed to the additionally selected Part One pharmacies and public health facilities that are located in the district level. The same audit procedures describe in the next section will be used.

Outlets that are Closed Down or Out of Stock

Records will be kept of closed outlets. If outlets are not permanently 'closed down' interviewers will try to make call-backs to these outlets. The number of call-backs will vary by location and country (for further information see the country-specific study designs) In case outlets are out of stock, the provider section of the questionnaire will be administered.

Administration of Drug Audit Sheet

For outlets where antimalarial medicines are sold, the field worker will give information on the study and ask to interview the main provider. If there are multiple providers working in a single outlet, one provider will be interviewed at random. Prior to administering the drug audit sheet, the provider will be asked to give consent using the informed consent procedures described in the Annex. Once consent has been given, full details on each available antimalarial medicine will be gathered through the drug audit sheet.

Initially, data collection will be done using paper questionnaires. Paper questionnaires will provide hard-copy documentation of the data and will allow it to be easily verified. The use of paper questionnaires will ensure consistency between countries, as participating countries in Southeast Asia may not be able to use Personal Digital Assistants (PDAs) due to the local script. The use of paper questionnaires will also streamline the training of interviewers in data collection procedures.

In the future, it is anticipated that data collection will be done with PDAs, ensuring ease of data entry, optimal data quality and audit efficiency. "Intelligent" PDA audit forms that include various quality checks and built-in skip patterns will be developed and uploaded onto each PDA, along with a number of data backup and transfer tools and procedures. It may still not be feasible to use PDAs in Southeast Asia due to the local script, in which case, standard paper interviews will be continue to be conducted.

VII. Data Collection Team

An independent research agency will be responsible for data collection. Data collection will be undertaken by a team of field workers and team leaders, supervised by PSI staff serving as quality controllers. The number of interview teams and team leaders will vary per country. The field workers and team leaders will be responsible for conducting the census in the selected areas (i.e. going to all the outlets that have the potential to stock antimalarial medicines), and conducting interviews at the outlets. Team leaders and PSI quality controllers will also perform spot checks by randomly visiting selected areas and auditing a few of the outlets in these areas, so that the quality of the work of field workers may be verified.

PSI quality controllers will be responsible for ensuring that interviews are conducted correctly and that outlets included in the survey conform to the criteria. Quality controllers will also be responsible for checking completed questionnaires (or checking downloaded PDA information) and ensuring that the information is valid and correct during the field collection. They will also play a key role in ensuring that an accurate census of establishments was conducted. In cases where outlets were missed, the quality controller will be responsible for conducting the interview which conforms to the aforementioned procedures. Any missed outlets will be communicated to the selected data collection agency.

VIII. Training

All fieldworkers will undergo training prior to the Outlet Survey. Two trainings will be conducted before implementing the Outlet Survey.

A five-day regional training on PDA and GPS will be conducted by PSI's geographical mapping expert. The training will focus on handling the PDA for data collection, designing and implementing a PDA-based survey, using the basic functions of PDA programming software (Visual CE), managing data collected with PDAs, and the use GPS devices.

A second five-day training will be provided to train team leaders, field workers and quality controllers on how to identify antimalarial medicines, including the differences between ACTs and non-ACTs, trade names and generics, packaged and loose tablets, and the various formulations. Field workers will first be trained on the paper questionnaire, followed by the pre-programmed PDA. Training will also educate fieldworkers on the purpose of the study, the importance of consent and how to administer both the consent forms and questionnaires.

After the training, the pre-programmed PDA will also be tested by field workers for a period of up to two weeks in each country to ensure that data collection and information is accurate.

IX. Pilot Test in Sub-districts

An important part of the Outlet Survey will be to pilot the drug audit sheet and the methodology.

Prior to commencing the field work, field workers will attempt to audit and collect a range of antimalarials that are on the market. The objective of this will be to complete the country specific drug audit sheet in advance, given that there are a wide range of antimalarials on the market. This information will then be uploaded into the PDAs before commencing the data collection. It is appreciated that a number of other types of antimalarial drugs will be found during the data collection. These will be recorded and programmed into the PDAs for future rounds. As the rounds of data collection carry on, it is expected that this sheet will contain an exhaustive list of antimalarials.

When field workers are collecting different type of antimalarials, they will also be asked to take photos of the outlet types and develop definitions of them as it relates to the country-specific situation. These photos and definitions will then be used during the training to help field workers determine what outlet types they are going to and how they should be classified. Below is an example from Cambodia. Selected outlets and definitions are presented. Photos (not shown) are provided to illustrate the outlet types.

Example from Cambodia: Definitions of Selected Outlet Types

Drug shops: Smaller than a pharmacy, these outlets are not licensed by the Ministry of Health. They typically sell medicines from a house and store drugs in small cupboards. Drug shops are commonly found in village areas and can also be market stalls in which medicines are sold. They do not have a pharmacy signboard.

Grocery stores: These are usually small businesses, whereby the front of a house is used to sell goods, including food, beverages and household products.

Mobile provider: Found mostly in rural areas, these providers have medical training. They provide medical treatment including distribution of antimalarial products. They travel by motorcycle and are not stationary. They may sell health products to stores or to individuals. Mobile providers typically work within a radius of their home or a base venue and will be identified by asking village chiefs. GPS data will be collected on the location of the respondent's home or base venue.

During the interview training, the audit drug audit sheet will be translated as needed, and then pre-tested. In particular, the provider questionnaire will be pre-tested to check for comprehension of questions, ease or difficulty of statements, confidence in response, level of discomfort and social desirability.

Before implementing the survey, one sub-district will be randomly selected for the pilot study. In this sub-district the aforementioned procedures will be implemented to determine the feasibility of the proposed methodology in each country. The results from the pilot will

be used to then adapt the country specific study designs. Any adaptations will be based on the information gathered during the pilot, and may include the types and numbers of outlets found, the time taken to go to all outlets in a given area and interview providers, and refusal rates.

X. Ethical Issues

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

Confidentiality: Results will not be linked to individual providers or outlets. 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 outlets will be emphasized during training of data collection staff. Field workers 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 providers. 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. Verbal consent will be obtained prior to the survey. All verbal consent will be witnessed by a field worker. For the Outlet Survey, verbal consent will be obtained from the fieldworker interviewees. Verbal as opposed to written consent will be obtained since the pilot showed that providers tend to be very cautious of inspectors and suspicious of having to sign documents that may be used to identify them or their outlet/facility.

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.

XI. Data Management

Quality controllers and team leaders will follow data safeguarding procedures during data collection. These include the daily transfer of data from each questionnaire or PDA onto laptops and/or memory cards, maintaining a data collection monitoring sheet (daily number of outlets audited by each field worker/PDA and codes of outlets visited in each area), and backing up of data so as to have a copy of each record.

The software that will be used to develop the PDA data entry forms is Visual CE, a Windows Mobile compatible software package that is designed for these types of surveys where multiple PDAs will be involved in data collection.

The data collected through the PDA audit forms will be uploaded into a central Microsoft Access database which will allow for the required data merging, cleaning, and validation processes. Data consistency will be evaluated by checking for coding and filter errors, incorrect non-responses, range checks and any other irregularities.

From the Access database, data will be exported to the SPSS software package which will be used for the analysis. The attribute data for each outlet – each equaling one record in the table – will be fully labeled along with its value codes.

In the case of the Southeast Asia countries and others using paper questionnaires, all data will be manually entered into SPSS.

A trained local PSI staff member will be responsible for data importing and for initial data cleaning and validation. Preparing data for the analysis and data management related to the GIS component of the study will be done by the PSI central and regional research teams.

XII. Analysis Plan

Data collected during the survey will first be processed in SPSS and Health Mapper. PSI has established an agreement with the World Health Organization's Public Health Mapping and GIS unit [http://www.who.int/health_mapping/en/] that gives us access to the WHO HealthMapper software application, a mapping tool that is specifically designed to manage, map, and analyze public health data, as well as to the WHO's global database of geographic information.

The first set of indicators described in this study design (Indicator Table 1: Availability, Price, Volumes, Knowledge & Provider Perceptions) will be calculated on the basis of outlet type, per stratum and nationally. Outlet types will not be aggregated in the analysis. For the national averages, we will apply weighted averages based on the population size of the sub-district. Indicators will be calculated as specified in the indicator table (in preparation). In some cases, simple frequencies based on the numerators and denominators will be provided. In other cases, more complex analysis will be used.

Accessibility indicators (Indicator Table 2: Measuring Population Access to ACTs and Other Antimalarials) will be calculated using the LQAS decision rule table.

Data analysis and reporting will also entail mapping of both coverage and access variables.

Annex 1: Rationale and Background on LQAS

Below is an outline of the rationale for the use Lot Quality Assurance Sampling (LQAS) for *ACTwatch* to monitor the accessibility of internationally registered and nationally approved ACTs by the population. An overview of important terms and concepts related to LQAS is also provided.

LQAS methodology was originally developed in the 1920s to control the quality of output in industrial production processes (Lanata & Black, 1998). This was achieved by utilising small sample sizes. Since industrial production is done in batches or lots, the sampling strategy was developed to classify lots into 'acceptable' or 'unacceptable' according to preset quality levels, minimising the risk of misjudgment. To satisfy the statistical assumptions of this method, the selection of each individual unit to be sampled within a lot has to be done following a random sampling process. The number of sampling units selected in each lot is typically recommended at 19. This method does not provide an estimate for the lot sampled, it only classifies it as acceptable or unacceptable.

What are 'Lots'?

The use of LQAS methodology has been advocated for health monitoring. In health applications of LQAS, *lots* have been defined as population areas or catchment areas of health facilities. An ideal lot is the smallest unit that can provide meaningful information to health planners or policy makers when evaluating a health programme. For a given lot, it is assumed that the sampling units within the lot have had similar exposure to the health programme under study. Given the objectives of *ACTwatch*, and the need for national and international policy level decision-making, lots have been defined as large geographical areas which differ in terms of malaria endemicity, urbanization or known multi-drug resistance. Sampling units have been defined as sub-districts within the large geographical area. These 'lots' essentially mirror the stratification of each country. For example, in Uganda there are two lots, geographical areas defined in terms of high malaria endemicity versus low malaria endemicity; in Zambia there are two lots, urban and rural areas; while in Cambodia there are also two lots, but defined as geographical areas with known antimalarial drug resistance versus a geographical area with suspected antimalarial drug resistance.

Sampling Units

For LQAS, it is important that the probability of selecting the sampling unit is drawn randomly, ensuring that the probability of selecting the sampling unit has been equal for all similar units within the lot. The sampling unit has to provide useful information to evaluate a health programme. Examples of sampling units utilised in other research contexts include a pregnant woman for the use for prenatal services, and a woman aged 12-49 for the use of family planning methods. For the purpose of *ACTwatch* and the need to address national coverage of antimalarials, the sampling unit is defined as sub-districts hosting a population size of 10,000-15,000. All sub-districts will be located in the sampling frame and selected

using probability proportional to size. A sampling frame with the complete listing of sampling units is used.

Selecting the Sample Size

To select the number of sampling units, the method requires that an upper and lower level of performance be determined for each health programme to be evaluated. The sample size will be selected to ensure that lots with an actual performance level above the upper level of performance will have a good probability of being classified as acceptable, and lots with an actual performance level below the lower level of performance will have good probability of being classified as unacceptable.

The sample size should be large enough that the policy maker has a high probability of identifying lots that are at or above the upper level of performance and a high probability of identifying lots that are at or below the lower level of performance.

Use of 19

For the purpose of *ACTwatch*, we have relied on a sample size of 19 as this is the statistical point at which errors least effect survey results. A random sample of 19 will provide an acceptable precision of at least 92% on dichotomous data. It is also used because of the flexibility it provides. With a sample size of 19, the upper level of performance can be changed for any variable and we still have a fairly low risk of judging lots incorrectly. With a smaller sample size, if we wanted to change thresholds after data collection, this increases the chance of making errors when assessing lots. To avoid making these errors, the only other option would be to collect additional data. However, little is added to the precision of the measure by using a sample larger than 19. Sample sizes less than 19, however, see a rapid deterioration in the precision of the measure.

Decision Rules

Judgment regarding whether a lot is acceptable or below expectation is based on a *decision rule*. A decision rule is the maximum number of sampling units in a lot which can be classified as “unacceptable” if the whole lot is to remain acceptable. Decision rules are based upon thresholds that reflect: 1) the minimum standard that must be met in order for a lot to be “acceptable” (the *upper threshold*), and 2) the cut off point below which a lot is deemed to be “below expectation” (the *lower threshold*).

For example, an upper threshold of 80 percent and a lower threshold of 50 percent imply that lots with coverage at or above 80% are “acceptable,” while lots with coverage at or below 50% are “below expectation.” The corresponding decision rule for these thresholds is 19:6, where 19 is the sample size and six is the maximum number of observations which can be classed as “unacceptable” if the whole lot is to remain acceptable. In other words, an entire lot is considered “good” or “acceptable” if data indicate that at least 13 out of 19 randomly selected sampling units are acceptable. The percentages are generated using the LQAS decision table.

To further illustrate this concept for *ACTwatch*, in each lot, 19 sub-districts will be selected. A census of all outlets that have the potential to sell antimalarials will be conducted. If at least 13 or more sub-districts are found to have at least one outlet that has internationally registered or nationally approved ACTs in stock, it will be concluded that the stratum has “acceptable” (adequate) coverage of the internationally registered or nationally approved ACTs. If fewer than 13 sub-districts have at least one outlet with internationally registered ACTs in stock (more than six), this would imply that the stratum is not acceptable.

Annex 2: Consent Form & Information Sheet

CONSENT FORM – INTERVIEWS

ACTwatch

OUTLET SURVEY

(To be read to/ read and signed by the outlet proprietor or representative)

Why are we conducting this research?

This is a study to determine the availability of antimalarials. The results will be used to improve the availability of appropriate medicines and treatment for malaria in <<Country X>>. We hope to hold discussions with you. We feel that your experience providing antimalarial medicines to the community can contribute much to our understanding and knowledge of how we can improve malaria treatment.

I would like to ask you a number of questions about:

- The type of medicines you stock
- From where you get your supplies
- If you have had any stock outs

In addition, I would like to ask your permission to check and see what antimalarial medicines are available in this outlet. I would just ask for you to show me the current antimalarial medicines you have available and I can make a note of this.

How long will the interview take?

The interview with you should take approximately 30 minutes. The audit should take about 10 minutes to one hour (depending on the availability of antimalarials).

Are there any disadvantages or advantages involved in taking part?

There are no individual benefits to taking part, but in answering our questions you will help us improve our understanding of how to increase the availability of malaria treatment for the benefit of everyone living in << country >>. Unfortunately, we are not in a position to assist with financial or other problems that we come across, nor can we provide malaria treatment to your shop/facility.

However, we hope that you will participate since your views are important for the study and the results from the study will improve the availability of antimalarials.

Who will have access to the information I give?

We are not here to inspect your business and no information about this specific outlet will be passed on to the regulatory authorities. We will not share individual information about you or other participants with anyone beyond our research team. Your name, address or any other information that could identify you personally is not being recorded. The knowledge gained from this research will be shared in summary form, without revealing individuals' identities. We will share this information with other interested organizations or individuals who may find the information useful in improving availability of malarial treatment.

What will happen if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree, you can change your mind at any time. You can refuse to answer any specific questions, or stop the interview at any time. If you chose not to answer a question, stop the interview or even not participate at all in the study it will not affect your working conditions today or in the future.

What if I have any questions?

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

<<Name of Country Project Coordinator>>

CONSENT FORM – INTERVIEWS

**Outlet Survey
(To be read to the available provider)**

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

please tick **The interviewee agrees to be interviewed**

Signature/Mark: _____ **Date** _____

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

THE PROVIDER SHOULD NOW BE GIVEN AN INFORMATION SHEET TO KEEP