

Baseline Study to Assess the Extent of Monotherapy Use in the Treatment of Malaria in Liberia: Study Phase 1- Review Study Protocol

Monrovia, Liberia
August 13-17, 2012

Trip Report

Latifa El Hadri, PhD, Program Manager

Abdelkrim Smine, PhD, Consultant

Promoting the Quality of Medicines Program

Implemented by U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1) 301-816-8147
Fax: (+1) 301-816-8374
Email: pqm@usp.org or sb@usp.org

Cooperative Agreement # GHS-A-00-09-00003-00
Sponsoring USAID Missions: USAID/Liberia–PEPFAR and Core Malaria
Grantee: Promoting the Quality of Medicines (PQM) Program
Author(s) Name: Sanford Bradby
Language: English
Date of Publication: November 21, 2012



USAID
FROM THE AMERICAN PEOPLE



PROMOTING THE QUALITY OF MEDICINES

This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00, and the President's Emergency Plan for AIDS Relief (PEPFAR). The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID, PEPFAR, or the United States Government.

Executive Summary

Some of the Core Malaria workplan activities for FY11 funding was to assess the extent of the use of antimalarial monotherapies in Africa, PQM convened a three-day workshop with major stakeholders in Liberia. The Liberian Medicines and Health Products Regulatory Authority (LMHRA) has recently enacted a ban on the use of antimalarial monotherapies, and the proposed study will ultimately shed light on access to monotherapies, compliance with the ban, and the public's perception of the quality of available treatment in both public and private sectors.

The first day of the workshop was dedicated to reviewing the study protocol. The second day was devoted to selecting the study team and defining their roles and responsibilities. The third day, the study team conducted field testing of the survey questionnaires. The revised study protocol has now been submitted for review by the Internal Review Board, the study will be carried out as soon as all administrative and regulatory requirements are fulfilled.

In addition to the workshop, PQM and local partners completed the third round of Minilab[®] activities by sampling and testing antiretroviral (ARV) and opportunistic infection (OI) medicines. A total of 80 samples were collected from Monrovia, and nearly half of the tested samples failed basic tests.

Table of Contents

<u>Acknowledgements</u>	4
<u>Acronyms</u>	5
<u>Background</u>	6
<u>Overview of Activities</u>	6
<u>Conclusion</u>	9
<u>Next Steps</u>	9
<u>Annex 1: List of Participants</u>	10
<u>Annex 2: Agenda</u>	11
<u>Annex 3: Draft Study Protocol</u>	12

About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Medicine Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID’s response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical leadership to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

Acknowledgements

The authors would like to thank:

- The Director of the National Malaria Control Program and his staff for facilitating the workshop and for inviting the major stakeholders to attend the review of the study protocol
- The Managing Director of National Drug Services (NDS) and National AIDS Control Program (NACP) for their willingness to work jointly with PQM
- The Managing Director and the Chair of LMHRA Board for their collaboration and important discussions on improving the implementation of USAID PMI
- The LMHRA quality control laboratory staff for participating in sampling and testing of ARV and OI medicines
- USAID/Liberia staff for their valuable support and collaboration
- Mr. Anthony Boni and Dr. Maria Miralles, USAID/Washington, for their valuable guidance and support
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report

ACRONYMS

ARV	Antiretroviral
DQI	Drug Quality and Information Program
LMHRA	Liberia Medicines and Health Products Regulatory Authority
MOHSW	Ministry of Health and Social Welfare
MQM	Monitoring the Quality of Medicines
NACP	National AIDS Control Program
NDS	National Drug Services
NMCP	National Malaria Control Program
MOH	Ministry of Health
OI	Opportunistic Infection
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

As part of the President's Malaria Initiative (PMI), PQM has been providing technical assistance to Liberia since 2008. PQM assisted in drafting Liberia's medicine regulatory legislation, enacted in 2010, which established the Liberian Medicines and Health Products Regulatory Authority (LMHRA).

In addition, PQM has helped strengthen the medicines quality assurance and quality control (QA/QC) capabilities in Liberia. In collaboration with LMHRA, the National Malaria Control Program (NMCP), and the Ministry of Health (MOH), PQM has conducted three rounds of medicine quality monitoring (MQM) for antimalarials in Liberia and its suburbs. The results of the third round revealed a high failure rate for antimalarials (over 70%). The majority of the failed samples were monotherapies.

PQM has been asked by USAID/Washington to carry out a survey in two African countries (Mali and Liberia) to assess the extent of use of antimalarial monotherapies. PQM selected Liberia because of the results of the third round of MQM.

LMHRA has recently enacted a ban on the use of antimalarial monotherapies, based on the MQM findings. The proposed study will ultimately shed light on access, compliance with the ban, and the public's perception of the quality of available treatment in both public and private sectors. In addition, since the ban was recently issued, this study will serve as a baseline about malaria treatment-seeking behaviors. As needed, a similar survey could be conducted in the future to assess the impact of medicine regulations in changing treatment practices in Liberia.

Purpose of Trip

The purposes of this trip were to:

- Finalize the baseline monotherapy study protocol with the major stakeholders
- Plan the implementation stage of the study in the field
- Select a study team and define their roles
- Conduct one round of sampling and testing antiretrovirals (ARVs) and opportunistic infections (OI) medicines
- Debrief USAID/Liberia

Source of Funding

This trip was funded by Core Malaria and the President's Emergency Plan for AIDS Relief (PEPFAR) through USAID/Liberia.

Overview of Activities

Debriefing USAID/Liberia

Participants: Randolph Augustin, Soukeynatou Traore, and Kaa Williams, USAID/Liberia; Latifa El Hadri, PQM

Dr. El Hadri met the USAID team and shared the agenda of the planned activities for the trip. The Mission expressed the need to have the monotherapy study included in the Liberia work

plan and to provide more information on the study. They also requested that the Core Malaria and PMI activities be together in one work plan.

PQM shared with the main activities conducted by PQM's consultant, Mr. Ben Botwe, including training LMHRA inspectors in medicines regulations inspections and inspection report writing, helping LMHRA draft the letter to ban monotherapy treatment, and coordinating the advertisement for the LMHRA Managing Director (MD) position.

To complete the third round of MQM, PQM informed the group that LMHRA and PQM will be collecting medicines to treat HIV, including both ARVs and OIs. The collected samples will be tested using Minilab[®] basic tests followed by compendial testing on failed samples.

At the end of the meeting, PQM shared with the potential FY13 activities and discussed the challenges that the LMHRA lab is facing in conducting routine QC activities.

Monotherapy Study

1. Review and validate the study protocol

PQM staff, Dr. Smine and Dr. El Hadri, organized a workshop with all key local stakeholders to review the original draft of the study protocol developed by PQM. Representatives from the Ministry of Health (MOH), LMHRA, Board of Pharmacists, National Malaria Control Program (NMCP), National Drug Services (NDS), and the World Health Organization (WHO) office in Liberia attended the workshop and contributed to the protocol review (see *Annex 1* for the complete list of participants).

All participants agreed that the study is needed and its findings will help NMCP better understand the extent of the use of antimalarial monotherapy. The participants finalized the objectives of the study and discussed all pertinent elements of the study according to the meeting agenda (see *Annex 2* for the agenda). The attendees also reviewed all of the questions included in the health facilities and household survey questionnaires. In light of the stakeholders' remarks and recommendations, Dr. Smine and Dr. El Hadri updated the protocol and questionnaires.

2. Select the study team and define roles

In coordination with NMCP, LMHRA, and MOH, PQM selected staff from these entities and invited them to attend a training session on the field questionnaire. During the training session, PQM and NMCP defined the responsibilities for each team member. Both PQM and NMCP agreed to lead the study and be in charge of data entry and analysis when the study is done.



The revised study protocol and questionnaires were reviewed by data collectors during the second day of the workshop. The staff from MOH and NMCP has field experience in conducting survey studies; staff from LMHRA has knowledge about medicines stores and health facilities. The objectives of the study were clearly discussed, and all questions in the questionnaires were reviewed by the data collectors. Dr. Smine and Dr. Hinneh (of NMCP) facilitated the review and discussion of all issues related to conducting the surveys in households and health facilities. The participants also agreed on all definitions to be used in the context of this study. The protocol and the questionnaires were updated after the data collectors' review (see *Annex 3* for the revised questionnaires).

3. Field testing of the survey questionnaires

On the third day of the workshop, the trained data collectors were split to four groups of three staff each and went to different neighborhoods to field test the questionnaires. Data collectors reached fifteen household and health facilities. After the field testing, each group was asked to comment on how the survey went and how easy or difficult it was to collect data. All groups reported that the survey went very well. The groups did not find any major challenges in collecting data using the questionnaires. However, they suggested making minor changes to certain questions and contributed to finalizing both questionnaires.

The final study protocol was submitted by PQM to the director of NMCP, and NMCP subsequently submitted it to the MOH. The MOH recommended minor changes to the protocol. The NMCP will now submit the protocol for review by the Internal Review Board. The study will be carried out as soon as all administrative and regulatory requirements are fulfilled.

Minilab[®] activities

In collaboration with NMCP, LMHRA, and staff from the Ministry of Health and Social Welfare (MOHSW), PQM collected antimalarial samples from Monrovia and its suburbs and tested them using Minilab[®] basic tests. The majority of failed samples were tested using compendial methods. The preliminary results showed that 70% of tested samples were substandard.

To complete this round, Dr. Sonpon Blamo Sieh, Program Manager of the National AIDS Control Program (NACP) requested that PQM and LMHRA test the following medicines:

1. Zidovudine + Lamivudine + Nevirapine
2. Tenofovir + Lamivudine + Efavirenz
3. Zidovudine
4. Ciprofloxacin
5. Cotrimoxazole
6. Metronidazole

A total of 24 ARVs and 56 OI medicines were collected and tested using Minilab[®] basic tests. Nearly half of collected samples failed. The failed samples are pending confirmatory testing due to technical problems with the major lab equipment including the HPLC, Dissolution tester, and UV- vis spectrophotometer. To address some of the issues, PQM provided technical assistance via a representative from Agilent and Copley Scientific. However, lab staff were unable to implement the technical guidance on their own.

To complete confirmatory testing on failed samples and in order to avoid any hindrance to the lab's routine activities, there is a need to have a local service contractor assist the lab in solving mechanical and technical issues.

Meeting with Malaria and HIV Program Managers

Drs. El Hadri and Smine met with Mr. Sonpon and Mr. Jons and briefed them on PQM activities in Liberia. Both expressed their gratuities to USAID/Liberia for supporting them in MQM and for supporting LMHRA in conducting its regulatory functions. They emphasized that all medicines procured via WHO and Global Fund should be subject to quality testing and subsequent routine testing to ensure that their quality is maintained. PQM agreed with their proposal and explained the guidelines needed to comply with WHO and Global Fund QA policies for medicines and diagnostics. Dr. Smine stressed that QC of procured goods—including medicines, rapid diagnostic tests, and insecticide-treated nets—is mandatory for all primary recipients of Global Fund money used to purchase medicines and diagnostics. Further discussions were carried out on how to transform the policies into practice and how to develop implementation plans in accordance with those guidelines and standards.

Next Steps

By December 2012:

- PQM will work with NMCP to finalize the budget required to conduct the monotherapy study
- PQM and NMCP will set up a timeline for conducting the surveys, compiling and entering data, and analyzing surveys data
- PQM will assist the LMHRA QC lab in solving lab equipment issues
- The LMHRA QC lab will submit the testing results of ARVs and OI medicines to PQM after fixing lab equipment
- PQM will communicate with NMCP and NACP to develop an action plan for complying with WHO and Global Fund QA policy

Conclusion

PQM convened a successful three-day workshop with major stakeholders in Liberia and was able to review the drafts of the study protocol and the related questionnaires. The revised documents have been submitted for review by the Internal Review Board and the study will be carried out as soon as all administrative and regulatory requirements are fulfilled.

PQM and local partners also completed the third round of Minilab[®] activities by sampling and testing antiretroviral (ARV) and opportunistic infection (OI) medicines. Nearly half of the tested samples failed basic tests. The LMHRA QC lab staff was unable to complete confirmatory testing on failed samples due to the malfunctioning of major lab equipment. PQM is assisting the lab to address these technical issues.

**Survey to assess the availability and the extent of use of
monotherapy in the treatment of malaria in Liberia**

Review of the Study Protocol

**Cape Hotel, Monrovia / Liberia
August 13, 2012**

List of Participants

No.	Name of organization	Contact Person
1	World Health Organization	Dr. Moses Jeroulun
2	Plan Liberia	Felecia Nuwulo
3	Research Unit/MOH/SW	Luke Bawo
4	M&E Unit/MOH/SW	George Jacobs
5	SCMU/MOH/SW	James Gbandalai
6	Pharmacy Division	Rev. Tijily Tayee
7	LMHRA	Clarvina Parker
8	Siap/MSH	David Sumo
9	Mentor Initiative	Isaac Ziah
10	Pire- University of Liberia	Dr. Steve Kennedy
11	USAID DELIVER	Jayne Waweru
12	Department of Preventive Services	Hon. Tolbert Nyeswah
13	Department of Curative Services	Hon. Saye Dahn Bawoo
14	M&E NMCP	Jonathan Enders
15	USP PQM	Latifa El Hadri and Karim Smine

Survey to assess the availability and the extent of use of monotherapy in the treatment of malaria in Liberia



The Cape Hotel – Monrovia
Monday August 13, 2012

Objectives of the Meeting

- Review and finalize the study protocol
- Select the study area within Monrovia and its suburbs
- Identify study team
- Set the time line for the implementation of the study in the field

Program Agenda

09:00 – 10:00	Registration	
10:00 – 10:15	Introduction	Participants
10:15 – 10:30	Introduction of the study protocol, objective of the meeting	NMCP
10:30 – 10:40	Remarks Pharmacy Division	Tijli Tyee Director
10:40 – 11:45	Remarks by PMI/USAID	Randolph Augustine
10:45 – 11:50	Opening remarks by LMHRA	TBD
10:50 – 11:55	Remarks by M&E – Research Dept. MOH &SW	Mr. Luke Bawo
11:00 – 11:30	Coffee Break	
11:30 – 12: 30	Review of the Study Protocol (Household Questionnaire)	Smine
12:30 – 13:30	Lunch	
13:30 – 14:00	Finalize Household questionnaire	El Hadri
14:00 – 15:30	Review and Finalize the Medicine's outlets questionnaire	
15:30 – 15:45	Coffee Break	
15:45 – 17:30	Agreement about the study area, study approval, study team, timeline and partners involvement	NMCP
17:30	Closing remarks	El Hadri

Baseline Survey Study to assess the extent of use of monotherapy in the treatment of malaria in Liberia

Study Protocol

Abdelkrim Smine, Ph.D.

Promoting the Quality of Medicines

Implemented by U.S. Pharmacopeia

12601 Twinbrook Parkway

Rockville, MD 20852 USA

Tel: (+1-301-230-3274)

Email: AZS@usp.org

Cooperative Agreement # GHS-A-00-09-00003-00

Funding Source: Malaria Core Fund

Grantee: Promoting the Quality of Medicines (PQM) Program

Author(s) Name: Abdelkrim Smine

Language: English

Date of Publication: March, 2012



USAID
FROM THE AMERICAN PEOPLE



This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00. The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID or the United States Government.

About USP PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

Abstract

In its continued efforts to assist developing countries reduce the burden of malaria, the United States Agency for International Development (USAID) has commissioned The Promoting the Quality of Medicines (PQM) to conduct a localized survey study to assess the extent of use of antimalarial monotherapies in two African countries. After discussion with the USAID mission and the country partners, PQM decided to conduct the survey study in Liberia.

The study protocol described in this document has been finalized with The National Malaria Control Program (NMCP), The Liberian Medicines and Health Products Regulatory (LMHRA) and The Board of Pharmacy of Liberia. The protocol and the agreement to conduct this baseline survey in Liberia were also endorsed by the world health organization representative who participated on the review and validation of the study protocol. PQM and NMCP explained the objectives and trained selected staff from partner institutions on how to use the questionnaires of this protocol to collect data from households and health facilities. After the training, the questionnaires were field-tested by conducting a survey of six households, six health facilities and four medicines stores in Monrovia. The questionnaires of this protocol were again reviewed and finalized after being field-tested in Monrovia.

Key Words

Survey, monotherapy, malaria, antimalarial medicines, Artemisinin Combination Therapy (ACT), Access, Drug quality

Definitions:

The following definitions were made and approved by PQM and the study partners in the contest of this survey study only.

- **Medicines outlets:** Means all facilities where malaria medicines could be received or purchased by patients. This includes health facilities and medicines stores.
- **Health facilities:** Means all facilities where a malaria patient could get a confirmed diagnosis about malaria infection. This includes all public and private health care centers, hospitals and clinics.
- **Medicines stores:** Means all types of pharmacies, medicine shops where antimalarial medicines are sold
- **Clinical Diagnosis:** A diagnosis provided by a trained health professional, not confirmed with rapid diagnostic test or blood smear

TABLE OF CONTENT

Abstract	02
.....
Definitions.....
..02	
Acronyms.....
.....	04
Background.....
.....	05
Introduction	06
.....
Pharmaceutical Sector in Mali	07
.....
Methodology of the	
Study.....	07
Objectives	07
.....
Overview of the study methodology	08
.....
Selection of Geographical Study Area	08
.....
Selection of Medicines Outlets	09
.....
Selection of Households	09
.....
Selection Criteria of household respondent	09
.....
Data Collection	09
.....
Data Entry	10
.....
Ethical approval	10
.....
Annex-1: Consent form for household respondent	11
.....
Annex-2: Consent form for health facilities/medicines stores respondent	12
.....

Annex-3: Household Questionnaire13

Annex-4: Health Facilities and Medicines stores Questionnaire15

Annex-5: Medicine’s list for household questionnaire17

Annex-6: Medicine’s list for health facilities & medicines stores questionnaire18

ACRONYMS

ACT	Artemisinin Combination Therapy
DQ	Drug Quality
EML	Essential Medical List
HAI	Health Action International
LMHRA	Liberian Medicines and Health Products Regulatory Authority
NDS	National Drug Services
NMCP	National Malaria Control Program

NMP	National Medicines Policy
MOH-SW	Ministry of Health and Social Welfare
MQM	Medicines Quality Monitoring
PQM	Promoting the Quality of Medicines
QA	Quality Assurance
QC	Quality Control
RBM	Roll Back Malaria
SP	Sulfadoxine Pyrimethamine
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Baseline Survey Study to assess the extent of use of monotherapy in the treatment of malaria in Liberia

1. Background

Malaria is still considered as a major public health burden in sub-Saharan Africa. The world health organization (WHO) estimates that about 40 % of the world population living in developing countries is still under risk from malaria. This disease kills an estimated 1.5 to 2.7 million in the world each year. About one million Children under five die each year with malaria and nine out ten of that child death occurs in Sub-Saharan Africa.

In addition to the loss of human lives, malaria constitutes an economic burden because the disease immobilizes affected people for many days and block children from going to schools. Malaria affects the social development and contributes to decreasing the economic growth of affected populations.

In Liberia, Malaria is endemic and the entire estimated population of more than 3.9 million is at risk of the disease. Children under five and pregnant women are the most affected groups. In Liberia, malaria accounts for over 38% of outpatient attendance and 42.30% of in-patient death. Since 2005, with funding from the Global Funds and since 2008 with funding from USAID-PMI, some progress has been made in terms of the use of more effective malaria control and prevention strategies based on WHO Roll Back Malaria recommendations. All donors programs are supporting the MOH-SW to increase the availability of Insecticide Treated Nets (ITN), expand Indoor Residual Spraying (IRS), expand Intermittent Preventive treatment of pregnant women, improve the case management of malaria patients and improve early diagnostic and treatment with quality medicines.

According to the Liberia Malaria Indicator Survey (LMIS) 2011, the prevalence of malaria in children under five is 28%. The major vectors for malaria are *An. gambiae* s.s, *An. funestus*, *An. melas*. The major parasite species are, *P falciparum* (>90%), *P. ovale* and *P. malariae*.

The Ministry of Health and Social Welfare supported by donors has put in place a malaria strategic plan (2009-2013). The main target of this strategic plan is to reduce malaria mortality by 50% by 2013. This target is supposed to be reached by developing countries by 2010 according to RBM-Abuja declaration.

As it is the case of most health systems in Liberia, the pharmaceutical sector has been devastated by the war. MOH&SW supported by USAID and other partners is engaged in building medicine's quality assurance and quality control capabilities. PQM has assisted the Liberian regulatory authority committee in drafting the medicine's legislation which was enacted in 2010. The Liberian Medicines and Health products Regulatory Authority (LMHRA) has been established and is slowly starting to build drug quality control capacity and establish drug regulations. The Liberian pharmaceutical market is almost uncontrolled, medicines are being sold by illegal shops all over the country and recent studies by PQM have shown that drug quality is still a major issue in Liberia.

Malaria treatment with good quality, accessible and affordable medicines of assured quality is a key objective of malaria control measures in Liberia.

The proposed study to assess the extent of use of antimalarial monotherapies in Liberia will ultimately shed light on access, the compliance and the perception of the public on the quality of available treatment in both public and private sector.

1.1. Introduction

In its continued efforts to assist developing countries reduce the burden of malaria, the United States Agency for International Development (USAID) has commissioned The Promoting the Quality of Medicines (PQM) of the United States Pharmacopeia (USP) to conduct a localized survey study to assess the extent of use of antimalarial monotherapies.

Following discussion about the objectives of this study with the National Malaria Control Program (NMCP), the Liberian Medicine's and Health products Regulatory Authority (LMHRA), the Board of Pharmacists in Liberia, and the enthusiasm received by PQM from all Liberian partners, PQM decided to choose Liberia as one of the two African countries where this survey will take place.

In the World Malaria report (2010), WHO reported that 25 countries mostly in Africa are still up to November 2010, authorize the commercialization of monotherapies for malaria treatment. WHO has banned the use of artemisinin based medicines in form of monotherapy. The resistance of Plasmodium falciparum to artemisinin combination therapy (ACT) has already been confirmed in Thailand-Cambodia border in 2009 (world malaria report-2010). WHO continues to recommend that artemisinin based medicines must be used in combination with other medicines based on efficacy studies in each country.

The drug resistance threatens all efforts of prevention and control measures to reduce the burden of Malaria in Africa. The global targets to control malaria (2010 to 2015) are to extend the prevention, the diagnosis and the prompt and adequate treatment to all affected population. To reach these objectives, all countries must pay very close attention to malaria treatment at all levels of the health delivery systems. All antimalarial medicines available in public and private sectors must be of assured quality and must be used according to strict national treatment guidelines.

In Liberia and because of the impact of long years of devastating war, most health systems have collapsed. The MOH & SW is working in close collaboration with donors and international partners to build and strengthen health systems. PQM with support of USAID-PMI has been assisting Liberia building quality assurance and quality control of medicines. The rationale about choosing Liberia is that this survey study is highly needed, and if conducted, new regulatory actions could be taken based on the finding of this study. Similar survey could be conducted after a year or two to re-assess the situation based on the actions which will be taken based on the findings of this survey. In addition, very recently the Ministry of Health and Social Welfare has issued a ban of use of antimalarial monotherapy in Liberia. This study will constitute a baseline of the extent of use of monotherapy in Liberia and its findings will help the NMCP and LMHRA take the appropriate actions to enforce the ban and reduce the availability and use of monotherapy especially in the private sector.

This study will not only shed light on the extent of use of monotherapy to treat malarial in Liberia and the public perception about the access and the availability of medicines in the public and the private sectors, but will also build staff capacity in conducting field research to address important public health challenges.

1.2. Pharmaceutical Sector Liberia

Country Profil	Liberia
Total population	3.9 million
Life expectancy	55-59
Health expenditure per capita \$ US	8.31
Individual expenditure per capita \$ US	0.3
Number of registered pharmacists	52
Number of Pharmacists per 10,000 habitants	0.14
Number of Physicians in Liberia	261
Number of Physicians per 10,000 habitants	0.65
Total Number of Licensed Pharmacies	256
National Health Policy	2006, revised on 2011
National Medicines Policy	2005, revised on 2011
Essential Medical List	2009

- The National Health Policy adopted in 2006 and revised in 2011
- The National Drug Policy established in 2005, revised in 2011
- The National Drug Authority (Liberian Medicines and Health Products Regulatory Authority) established in 2010.
- The National Quality Control Laboratory is under LMHRA. It was established in 2010-2011 and its capacity is being strengthened by the support of USAID and PQM.
- The Malaria Indicator Survey was revised and released on July 2012
- There are no pharmaceutical manufacturers in Liberia
- Most of medicines in Liberian market are imported from India, China and also enter from neighboring countries. Medicines from Europe and US are very expensive in Liberia.
- The pharmaceutical market in Liberia is poorly controlled

2. Methodology of the proposed study

2.1 Objectives of the study

The main objective of this survey is to assess the extent of use of antimalarial monotherapy to treat malaria and try to understand the major reasons leading to such treatment seeking behavior. The survey study is sought to answer the following questions;

- What is the extent of use of antimalarial medicines in form of monotherapy?
- Are the artemisinin combination therapy (ACT) (artesunate-Amodiaquin) medicines available in the public and private sectors?
- Are ACTs available and affordable in the private sector?

- Are malaria patients and health professionals well aware about national malaria treatment protocols?
- Are health professionals well aware about the ban about the use of antimalarials in form of monotherapy?

2.2. Overview of the study methodology

The study will consist of conducting two types of surveys to answer the questions under the specific objectives of this study;

- 1- A household survey will cover at least 300 households. In this survey, trained data collectors will interview a household representative using a standard questionnaire to collect general data about malaria infection, treatment seeking behavior, public perceptions about access to malaria medicines, public perceptions about quality of medicines in rural and urban selected areas. The questionnaire is designed to be simple, short and contains easy to answer questions.

The number of households is adopted from WHO type of household survey methodology and will be determined using statistical approaches based on the size of the population in the districts where the survey will be conducted. The ministry of health estimates that the average household is made of five people in Liberia. The population size will be estimated using the last demographic data available and corrected to reflect the population growth up to date.

- 2- A survey of a significantly representative number of antimalarial medicines outlets in the study area. The outlets will consist of public and private health facilities and medicines stores as defined below. A significant number of medicines outlets will be randomly selected based on the mapping of all existing outlets in the selected study areas. Data collectors will use questionnaire to collect data about availability, cost, storage conditions and the health professional's knowledge about national treatment guidelines. Data about existing health facilities will be provided by the Ministry of Health. Data about medicines stores will be provided by LMHRA. Additional mapping in remote areas outside Monrovia will be conducted and updated in the study areas.

2.3. Selection of geographical study area

Based on the review of the study protocol and survey questionnaires, and based on the need for data about the objectives set for this baseline study, it was decided that the survey will be conducted in selected districts in Monteserrado, Nimba and Grand Gedeh counties. The number of households and the medicines outlets to be surveyed will be balance based on the population sizes and the total number of medicines outlets in the selected districts of three counties. The

choice of these study areas was determined based on NMCP need for data in these specific areas and the budget available for this study.

2.4. Selection of medicine's outlets

The survey of medicines outlets from public and private sectors will be conducted in a number of facilities to be representative of the study area. The NMCP, LMHRA, NDS and the Board of Pharmacists will assist PQM staff contribute to determining a subset of health facilities as well as medicines stores based on partner's knowledge about the antimalarial distribution systems.

2.5. Selection of households to be part of the study

The selection of the households to be surveyed will follow the WHO standardized method in conducting surveys measuring access and use of medicines. The households will be selected randomly using approved and accepted methods previously used by similar surveys conducted by NMCP. The number of households will be based on the size of the population, and the distribution of selected households using a health facility as reference point.

2.6. Selection criteria of household respondent

Interviewers will be trained to use judgment in selecting respondents. Respondents will be selected if they met at least three of the following criteria:

- Main health care decision maker
- Most knowledgeable about health of household members
- Most knowledgeable about health expenditures of the household
- Most knowledgeable about health utilization by household members
- Designated care giver for sick household members

2.7. Data collection

The survey team will be made of at least three staff each. In each team will include one staff from LMRHA. Each team will have a leader. Three senior supervisors will oversee and monitor all steps of data collection, review and analysis. All those involved in this study have contributed to the reviewing and finalizing the study protocol and the survey questionnaires. The team leaders will check all completed questionnaires at the end of each day of data collection. Upon completion of the survey, the survey supervisors will conduct a quality control check of all completed questionnaires. It was decided that the entire data collection will be done in ten days. The primary study managers from NMCP and PQM will review and approve the collected data before data entry.

2.8. Data Entry

Survey data will be entered by trained data entry staff with experience in data entry procedures. Data analysis and reporting will be done by the study managers from PQM and NMCP using existing and specific computerized tools.

The final study report will undergo the formal review and approval process by the NMCP, LMHRA, PQM and USAID before sharing it with other key stakeholders.

2.9. Ethical approval

This survey study will go through all required review and approval by the Internal Review Board and the Ethical Review Committee of the ministry of health. All participants in the household and medicines outlets will be correctly informed and should agree and sign the consent forms (Annex 1 and 2) before they will be interviewed.

Household Informant Consent Form

Dear Participant,

You have been identified as the most knowledgeable respondent in your household. We would like to interview you. This survey is conducted by The Malaria Control Program and the Liberian Medicines and Health Products Regulatory Authority of Liberia.

The survey will be carried out by professional interviewers from (MOH, NMCP, LMHRA and NDS).

The interview will take approximately 15 minutes and you will be asked questions about:

- Malaria infection and treatment of members of your household,
- The sources and types of malaria medicines used in your household

The information you provide will only be used to understand the malaria treatment in Liberia.

The information you provide is totally confidential and will not be disclosed to anyone. It will only be used for research purposes. Your name, address, and other personal information will be removed from the questionnaire, and only a code will be used to connect your name and your answers without identifying you.

Your participation is voluntary and you can withdraw from the survey after having agreed to participate. You are free to refuse to answer any question that is asked in the questionnaire. If you have any questions about this survey you may ask me or contact (NMCP – Contacts details) or (Designated Investigator).

Signing this consent indicates that you understand what will be expected of you and are willing to participate in this survey.

Respondent: _____

Interviewer: _____ Date: ____ / ____ / ____

Health Facility Consent Form

Dear Participant,

Your facility has been selected to be part of our survey to assess the availability, access and use of antimalarial medicines in Liberia. Your valuable contribution to our study will help your ministry of health to make better decisions in its efforts to control the burden of malaria. This survey is conducted by the National Malaria Control Program of Liberia and the Liberian Medicines and Health products regulatory Authority.

The survey will be carried out by professional interviewers from (MOH, NMCP, PQM, NDS and LMHRA).

The interview will take approximately 20 minutes and you will be asked questions about:

- Antimalarial medicines use, purchase and storage in your facility
- Malaria patient’s treatment seeking behavior

The information you provide will only be used to understand the issues related to access and use of antimalarial medicines.

The information you provide is totally confidential and will not be disclosed to anyone. It will only be used for research purposes. Your name, the name and address of your facility, and other information will be removed from the questionnaire, and only a code will be used to connect your facility to your answers without identifying you.

Your participation is voluntary and you can withdraw from the survey after having agreed to participate. You are free to refuse to answer any question that is asked in the questionnaire.

If you have any questions about this survey you may ask me or contact (NMCP – Contacts details) or (Designated Investigator).

Signing this consent indicates that you understand what will be expected of you and are willing to participate in this survey.

Respondent: _____

Interviewer: _____ Date: ___ / ___ / ___

Baseline Survey study about the extent of use of antimalarial Medicines in form of monotherapy in Liberia

Household Survey Questionnaire

File Number

.....
.....
.....
...

Number	Question	Response/Action
Before asking any question, please fill out the consent form; have it signed by the member of the household		

to be interviewed. Indicate how far is this household from the reference health facility		
Household Profile:		
1.1. Name of Monitoring Staff: Date		
1.2. Household respondent:		
1.3. Address:		
1.4. County: District		
Q001	Has anyone in your family had malaria in the past?	YES [] NO []
Q002	How did you know that you or your family member had malaria?	➤ Self-diagnosis [] ➤ Clinical diagnosis [] ➤ Confirm diagnose [] ➤ Other []
Q003	Who are those in your household that often get sick of Malaria?	➤ Under five years [] ➤ Above five years [] ➤ Pregnant women [] ➤ Others specify []
Q004	What did you usually take/give to treat malaria?	Use malaria Medicine's list Use Medicine packages display
Q005	Where did you usually get or buy your malaria medicines?	
Q006	Why did you use these medicines to treat yourself/your household member?	
Q007	Do you have any malaria medicine in your house?	YES [] NO [](go to Q009)
Q008	Can I see your malaria medicines?	Use Malaria Medicine's list Note and check the medicines
Q009	At home, where do you usually keep your malaria medicines?	
Q010	How easy is it to find the medicine to treat malaria?	
Q011	How many tablets/capsules did you buy/receive to treat yourself/member of your household?	
Q012	Did you take all of the tablets/capsules that you got when you were sick?	YES [] NO []

Q013	<p>How much time does it take to reach the following health care facilities or providers that are closest to your household?</p> <p>a. Public health facility []</p> <p>b. Private health facility []</p> <p>c. Medicine Store []</p> <p>d. General Community Health Volunteer []</p> <p>e. Street Drug sellers []</p> <p>f. Traditional healer []</p> <p>H. Others, specify []</p>	<p>➤ Less than 15 min [A]</p> <p>➤ 15 min to 1 hour [B]</p> <p>➤ More than 1 hour [C]</p>
Q014	How much do you pay for malaria treatment?	
Q015	What is the best antimalarial medicine you know about?	<p>Use Malaria Medicines List</p> <p>Use display box of medicines</p>
Q016	Why you consider that as the best malaria medicine?	

Survey study about the extent of use of antimalarial Medicines in form of monotherapy

Healthcare Facilities & Medicine's Stores Survey Questionnaire

File Number:

Number	Questions	Response /Action
<i>Before asking any question, please fill out the consent form; have it signed by the person to be interviewed. Also fill out the Data form and collect all information about the health facility you are about to survey.</i>		
Facility Profile: 1.1. Name of Monitoring Staff Date of Visit..... 1.2. Name of Facility, 1.3. Status: Health Care Facility [<input type="checkbox"/>] Medicines Store [<input type="checkbox"/>] 1.4. Is This Facility Registered with LMHRA / Pharmacy Board YES [<input type="checkbox"/>] NO [<input type="checkbox"/>] 1.5. County District		
Q001	What is your function in this facility?	
Q002	Are you a? Physician [<input type="checkbox"/>] Assistant physician [<input type="checkbox"/>] Nurse [<input type="checkbox"/>] Midwife [<input type="checkbox"/>] Pharmacist [<input type="checkbox"/>] Assistant pharmacist [<input type="checkbox"/>] Others [<input type="checkbox"/>] - specify	
Q003	What medicines you use to treat malaria patients?	List name of medicines below
Q004	How do you dispense the medicines to malaria patients?	Note all protocols by age groups;
Q005	What was the approximate range	➤ Under 5 years [<input type="checkbox"/>]

	of age of patient (s) seeking Malaria treatment	<ul style="list-style-type: none"> ➤ Above 5 years [] ➤ Pregnant Women []
Q006	How do you usually know that the patient has malaria?	
Q007	What are all antimalarial medicines you have in your facility?	Use Medicine's List
Q008	Where do you usually buy/get antimalarial medicines?	<ul style="list-style-type: none"> ➤ NDS [] ➤ Importer/wholesaler [] ➤ Wholesaler [] ➤ Others, specify []
Q009	How do you dispose of damaged and/or expired medicines?	<ul style="list-style-type: none"> ➤ Incineration by NDS [] ➤ Burning in open air [] ➤ Burying underground [] ➤ Others, specify []
Q010	Did you have any stock out of antimalarial medicines in the last three months?	YES [] NO []
Q011	Where do you store your antimalarial medicines?	
Q012	Does the facility meet storage standards? (completed by surveyor)	YES [] NO []
Q013	What is the most used antimalarial medicine in your facility?	Use medicine's list
Q014	What is the antimalarial medicine that is often bought in this facility?	Use medicine's list
Q015	Why this (these) medicines are highly used by patients	
Q016	What is the price of different malaria treatment?	
Q017	Do you know about your National malaria's Standard treatment guidelines?	YES [] NO []
Q018	Have you heard about the ban about using antimalarial in form of monotherapy?	YES [] NO []

ANTIMALARIAL DATA COLLECTION FORM

for
Household Questionnaire

Antimalarial by API	Brand name	Q004	Q008	Q015
Amodiaquine suspension 50 ml/5ml				
Amodiaquine tablet 200 mg				
Artemether injection				
Artemether tablets				
Artemether/Lumefantrine tablets				
Artesunate injection				
Artesunate suppositories				
Artesunate tablets/capsules				
Artesunate/Amodiaquine				
Artesunate /Mefloquine				
Atovaquone-Proguanil tablets				
Atovaquone-Proguanil tablets				
Chloroquine syrup				
Chloroquine injection				
Chloroquine tablets				
Dihydroartemisinin sachet				
Dihydroartemisinin tablets				
Dihydroartemisinin-Piperaquine tablets				
Doxycycline tablets/capsules				
Halofantrine suspension				
Halofantrine tablets				
Mefloquine tablets				
Proguanil tablets 100 mg				
Quinine drops				
Quinine injection				
Quinine suspension				
Quinine tablets				
Sulfadoxine-Pyrimethamine				
Herbal medicine				

--	--	--	--	--

ANTIMALARIAL DATA COLLECTION FORM
for
Health Facilities & Med. Stores Questionnaire

Antimalarial by API	Brand name	Q007	Q013	Q014
Amodiaquine suspension 50 ml/5ml				
Amodiaquine tablet 200 mg				
Artemether injection				
Artemether tablets				
Artemether/Lumefantrine tablets				
Artesunate injection				
Artesunate suppositories				
Artesunate tablets/capsules				
Artesunate/Amodiaquine				
Artesunate /Mefloquine				
Atovaquone-Proguanil tablets				
Atovaquone-Proguanil tablets				
Chloroquine syrup				
Chloroquine injection				
Chloroquine tablets				
Dihydroartemisinin sachet				
Dihydroartemisinin tablets				
Dihydroartemisinin-Piperaquine tablets				
Doxycycline tablets/capsules				
Halofantrine suspension				
Halofantrine tablets				
Mefloquine tablets				
Proguanil tablets 100 mg				
Quinine drops				
Quinine injection				
Quinine suspension				
Quinine tablets				
Sulfadoxine-Pyrimethamine				
Herbal medicine				

