

**Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women.**

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## Abstract/Executive Summary

There is renewed effort to scale up intervention that have contributed in reducing the malaria burden in endemic area especially sub-Sahara Africa such as use of Long-Lasting Insecticidal Nets (LLIN), Intermittent Preventive Treatment in children (IPTc), and test, treat and track (TTT). However, there is need for malaria mass drug administration (MDA) of the whole population which could drastically reduce the parasite level and pave the way for elimination. Though, Seasonal Malaria Chemoprophylaxis (SMC) is adopted for selected localities in Ghana, the impact of such interventions could be enhanced, if combined with MDA at baseline to reduce the parasite load. IPT of children in southern Ghana has demonstrated a parasite load reduction from 25% to 1%. In a pilot mass test, treat and track study in Ghana, we achieved coverage of more than 75% in target communities and reduced asymptomatic parasitaemia by 24% from July 2017 to July 2018. There is need to generate more data that will support evidence decision-making on what potions to adopt for scale up. Some of the questions that need to be answered through the present study included, does MDA affect prevalence of malaria parasitaemia and/or anaemia in under 15 and pregnant women? This study will generate evidence on the impact of implementing MDA on malaria prevalence and acquired malaria partial immunity to inform decision-making in Ghana.

## Introduction/Rationale

Malaria continues to pose a serious burden to local populations in sub-Sahara Africa, with Nigeria and Ghana reporting the highest absolute increase in malaria cases in 2018 compared to 2017 [1]. There has been consistent effort to scale up interventions that work such as preventing man-vector contact using mosquito nets, intermittent preventive treatment (IPT), seasonal malaria chemoprophylaxis (SMC) and Test, Treat and Track (TTT) for febrile patients [2]. However, asymptomatic malaria, believed to be an important reservoir that fuels malaria transmission in endemic communities in Africa has not been specifically targeted for malaria control[3, 4]. Currently, there is renewed interest in using mass drug administration (MDA) or mass testing, treatment and tracking (MTTT) to target asymptomatic malaria in endemic communities in Africa, which if implemented could pave the way towards malaria elimination [5-7]. MTTT using RDTs has been demonstrated to be feasible and effective in reducing the asymptomatic malaria burden in endemic communities in Ghana [6, 8]. However, not much has been done in implementing malaria mass drug administration in Ghana. It is therefore important to determine the impact of malaria MDA on an endemic community in the Eastern Ghana. This will provide evidence for decision making by the National Malaria Control Programme (NMCP). Some of the questions that need to be answered included, does MDA affect malaria asymptomatic and symptomatic prevalence under 15 and maternal and/or prevalence of anaemia? Is there a possibility of a re-bounce in malaria especially in under 5 children following malarias MDA? *The aim of this study is to generate evidence on the impact of implementing MDA on malaria prevalence and acquired malaria partial immunity to inform decision-making in Ghana.*

## Literature Review

Rapid scale-up of malaria control interventions in the past decade led to a reasonable decrease in the burden of malaria [1]. The challenges involved with translating research scenarios into implementation are enormous and needs to be clearly understood. *In an era with decreasing funding for the health system [9], it is important to understand not only the economic impact of MDA in the health of pregnant women and under 15 children but also its effect on the partial immunity of the population.* Interventions focused on clearing the parasites in asymptomatic individuals in combination with intensive use of other control measures could pave the way for pre-elimination of malaria in endemic communities [3], especially in an era when the SAR-var-2 virus is ravaging countries across the world. It is important to generate data on the trends on the population acquired anti-malarial immunity over time following MDA. This information could be very important for national malaria control programmes for decision-making and planning scale-up of malaria MDA, either nationally or regionally.

Several studies in Ghana have demonstrated very high levels of asymptomatic malaria in both under five and school age children who have a higher risk of coming down with clinical malaria or continue to serve as a transmission reservoir [10-13]. IPT of children in a community in the southern parts of the country reportedly reduced the parasite load by 90 % in two years [8]. It has been demonstrated that IPT using SP impacted the production of protective antibodies against malaria[14]. Immuno-suppression has also been reported from experimental studies of artemisinin-derivatives[15]. In Ghana [16], malaria incidence during the post-intervention period with SP was increased by 62% in infants who received six monthly artesunate + amodiaquine, but this rebound was not seen in children aged one year or more at the time of drug administration. This rebound effect has been observed where the IPT intervention targeted only children leaving out the adults who could be asymptomatic but transmitting. Though this study targets the entire population, the effect of MDA on malaria prevalence will be evaluated in under 15 children and pregnant women. While there are concerns that eliminating the parasite in an endemic community could lead to a rebound or fatalities should the parasites be reintroduced, malaria passive case detection and management will therefore continue to be through the health facilities in the study areas. A recent study in Mali demonstrated that implementing SMC does not affect acquired immunity in children following four rounds [17].

In a pilot scale-up study of MTTT in the Pakro subdistrict of Ghana, a coverage of more than 79% and a reduction in asymptomatic malaria prevalence of 24% was achieved, and a reduction of 67% in severe anaemia following 3-rounds of MTTT interventions over 1-year only [6]. These results could be further improved if the sub-microscopic parasitaemia is targeted through malaria MDA.

## Aims or Objectives of study

### Primary objective

The main aim of this study is to determine the impact of implementing malaria MDA on malaria prevalence in under 15 children and pregnant women.

### *Secondary objectives*

To determine the prevalence of asymptomatic malaria parasitaemia in population within the Pakro sub district

1. To assess the effect of scaling up malaria MDA on malaria antibodies over time in asymptomatic participants.
2. To determine the effect of malaria MDA on health of children and pregnant women.
3. To assess the effect of malaria MDA on febrile illnesses in under 15 children

## **Methodology**

### **Study Design:**

This is a clinical intervention study to be undertaken within a 24-month framework in 8 communities in the Eastern Region of Ghana. This trial employs a parallel design randomized at the community level with two arms – two intervention arms and a control arm. It is designed to compare the baseline to evaluation findings following the interventions[13]. Interventions will be implemented at the community level. An intervention in this study entails testing with RDTs and treatment of all participants with ACTs. Eight interventions and surveys will be undertaken. *The use of RDTs during each intervention is to determine the prevalence across season.* The study will be conducted in two arms - arm 1 will constitute the MDA intervention communities, while arm 2 will constitute the control communities.

1. Arm 1 (MDA intervention arm) will include four communities (Homedakrom, Otiakrom, Kojokrom and Nsakyi): mass treatment of all participants with ACTs by CHWs. *While malaria parasites can be cleared from infected individual during an MDA intervention, infected mosquitoes could still refuel transmission shortly after such intervention.in this light, we will undertake the first two interventions within 2 months to reduce the chances of reinfection. The third intervention will take place in month six while the subsequent interventions will take place every three months).* Every participant will however be tested to determine the malaria prevalence before each MDA intervention. All participants are treated irrespective of test result. Between intervention community health workers (CHWs) will test and treat febrile cases. This is to further clear residual parasitaemia in the population. Febrile cases in this study refer to participants with symptoms such as fever, vomiting, muscle pain, headache, cough, convulsion and skin rashes etc.
2. Arm 2 (control arm) will include three communities (Oboadaka, Pepewani, Takyikrom and Amanfrom): two rounds of mass screening with RDTs, and treatment of those who test positive with ACTs by CHWs (one at baseline and one at evaluation). Between interventions community health workers (CHWs) will test and treat febrile cases at home. Testing and treatment of participants in the

control arm will not affect the result since the interventions occurs two years apart. Results from Arm 1 will be compared to Arm 2. If participant become febrile at any time, they will be tested and treated if confirmed positive for malaria or referred to the health facility for further investigation.

All participants will be tested to determine the prevalence. This is meant to allow for comparison across sites. Hospital data will also be assessed to determine the impact of the interventions on prevalence of symptomatic malaria parasitaemia in the communities.

Monitoring visits to ensure proper implementation of the activities of CHWs will be undertaken monthly. During each visit, RDT and ACT stocks will be replenished, and the PI will have a meeting with the CHWs, review what was done and document challenges as well as ensure adherence to SOPs. This intervention study will determine the impact of MDA on malaria prevalence in endemic communities. This is the first study of malaria MDA to be undertake in the Eastern Region of Ghana. The challenges faced during implementation will be documented during monitoring. Focus group discussions (FGDs) and in-depth interviews will be organised to obtain additional information from the community and stakeholders such as the NMCP, Regional and District units of the Ghana Health Service. This study will be undertaken in collaboration with the NMCP.

### **Study participants:**

Community entry activities to sensitise the chiefs and the general population will be conducted at the beginning of the study through meetings and durbars (Ansah et al., 2015; Ahorlu, et al., 2009). Once the community leaders and the population have accepted the project, the households will be numbered and participants per household will be registered during a household census. All households will be given a unique identification code. Everyone within the household will be assigned a code that links them to a particular household and community (Ndong et al., 2019). After obtaining consent from the household heads, the children will be enrolled but individual assent and consent will be obtained from the other adolescents and adults in the household. The intervention study will target all the household members. The primary outcome will be based on data from all enrolled participants. The effect of the interventions on secondary outcome 1 will be observed in all children aged 2 months to 14 years randomly and pregnant women. In addition, selected under 15 children and pregnant women will have in addition to the other data, their Hb readings taken to assess the level of anaemia. The effect of the interventions on secondary outcome 2 will be observed in all under 15 children and pregnant women. Furthermore, the effect of the intervention on secondary outcomes 3 and 5 will be observed in all participants while the effect of secondary outcome 4 will be observed in pregnant women. We hypothesize that within the study population, the prevalence of asymptomatic parasitaemia should drop by 90% by the end of the first year and by 95% by the end of the second year. This is estimated based on the findings of Ahorlu et al., 2011. In the same light we expect that anaemia should drop by the same proportion.

### **Intermittent preventive treatment for the household members**

Trained community health workers (CHWs) will conduct house-to-house testing all children (from 2 months old) and adults residing in the selected communities for the presence of malaria parasites using RDTs. This is to determine the prevalence in both arms. All participants will be treated in arm 1 irrespective of results while only the positive cases will be treated in arm 2. For molecular studies, 200ul (two drops) of blood will be collected on filter paper. Treatment using ACTs will be conducted following the Ghana National Malaria Treatment Guidelines and followed-up for four days (day 1, 2, 3 and 7). Participants who receive the treatment will be observed for 30 minutes to ensure that they retain the drug. Those who vomit within this period will have the treatment repeated. Since it is required that patients eat before taking the drug, and household members may not have food when they are tested, some will have to take the medicine later after eating. This means that some of the treatment will be unobserved. However, the research team will pass round to cross check whether participants are adhering to treatment as prescribed. They will ask to see the drug package to ensure that the participants are taking the treatment correctly. This also serves as assurance to the population that the research team cares.

### **Questionnaire:**

The questionnaire will include questions about malaria treatment, prevention and control measures practiced by the household members.

### **Timely treatment of suspected febrile malaria cases in the community:**

Two Community Health workers (CHWs) will be selected from each community in both study arms and trained. The CHWs will be provided with the protocol, RDTs and ACTs to serve their communities. Between one MDA intervention and the next, the trained community members will provide prompt home-based treatment for participants reporting signs and symptoms of malaria and confirmed to be carrying the parasite using RDTs. This will be done using national malaria management protocol. The research team will conduct monthly monitoring visits to assess the CHWs activities, provide guidance as well as replenish their stocks. There is a need to visit the health facilities that service the community to enable tracking and linking of medical records with study participants.

### **Surveillance Phase**

Given that the parasite prevalence in the intervention site has greatly reduced and following the recommendations of the malaria case management working Group on Malaria, we will switch to surveillance over the next one year. During the surveillance phase, we will trace each confirmed case in the health facilities in the intervention communities to their household and neighbourhoods, test using RTDs and treat all confirmed positive cases. Serological technique will be used to *screen* samples for anti-malarial resistance markers using a targeted deep sequencing panel of drug resistance markers for *Plasmodium falciparum* that include chloroquine resistance transporter (*pfcr*) and *kelch13*.

### **Sample size:**

This study aims to enrol an entire population estimated at 1600 participants from 4 intervention communities (Homadakrom, Otiakrom, Kojokrom and Nsakyi) (arm) 1 and 1500 from three control communities (Oboadaka,

Takyikrom and Amanfrom) (arm 2) in the in the Pokrom sub district of the Akwapim South Municipal Health Directorate. This population was obtained from this district health Directorate following data from a head count from 2016 census.

**Inclusion criteria:**

To be included in the study, the participant must be aged 2 months and above and be resident in the communities for the period of the study. Willingness to participate will be proven by a completed and signed consent or assent form. Administrative authorization will be obtained from the Ghana Health Service.

**Exclusion criteria:**

If an individual intends to stay less than one year in the study site or would be absent at some time because he/she is schooling in a boarding school or has a life-threatening illness (excluding malaria). However, all individuals including those with clinical malaria signs who are present during surveys will be tested and treated.

**Data collection:**

Following consent, blood will be drawn from a finger prick by trained community health workers. All participants will be tested for the presence of malaria parasites using RDTs. All participants in arm 1 will be treated while only positive cases in arm 2 will be treated. Additionally, blood will be collected on filter paper to enable molecular characterization. All samples will be stored at NMIMR. To test for anaemia in children under 15 and pregnant women, a portable automated Hemocue photometer will be used to determine the concentration of Haemoglobin. Anaemia in this study is defined as Hb levels less than 10g/dl. Participants with severe anaemia (Hb less than 7g/dl) will be referred to the Health Centre for follow up. Questionnaires will be used to collect data on malaria treatment, prevention, and control measures at the level of the household.

**Malaria prevalence**

All participants confirmed to be positive for malaria using RDTs will be treated with artemisinin-based combination therapy (ACTs). Sampled blood spots on filter paper will be air dried and stored individually in small Ziploc bags with a desiccant and transferred to the laboratory. Plasmodium spp detection will be performed using a real time polymerase chain reaction (PCR) in routine use with an ABI ViiA7qPCR instrument 8.

*Anti PfEMP1 response*

Total plasma IgG levels will be measured as to a recently described panel [19] of microsphere bead coupled proteins consisting of 39 P. falciparum derived antigens and tetanus toxoid using the Luminex platform. The panel included VAR2CSA and 35 HIS-tagged CIDR proteins representing all three main groups of PfEMP1. Specifically, 19 different sequence variants of CIDR $\alpha$ 1, 12 different variants of CIDR $\alpha$ 2-6 and 4 different CIDR $\delta/\gamma$  domain proteins produced in

Drosophila Sf9 cells will be included. In addition, the protein array included circumsporozoite protein 1 (CSP1), merozoite surface protein 1 (MSP1) and apical membrane antigen 1 (AMA1). The Luminex-based assays will be performed at NMIMR of the University of Ghana, where the equipment and technique are available.

### **Inhibition of Binding Assay**

Functional activity of antibodies is defined as their ability to inhibit adhesion of infected erythrocytes to different proteins and assessed by inhibition of binding assay. Briefly, target proteins will be coated as spots on a Petri dish, incubated overnight at 4°C, and blocked with bovine serum albumin–PBS. Late-stage IEs will be blocked in bovine serum albumin at room temperature and incubated with samples at 37°C. Cells will be added to receptor-coated wells in duplicate and incubated for RT-PCR. Non adherent IEs will be washed using a shaker washing system. Bound IEs will be fixed with glutaraldehyde, stained with Giemsa, and quantified as the mean number of IEs per square millimeter counted in images acquired with a Mi5 microscope. The percentage of inhibition will be determined relative to the well without test sample. Inhibitory activity will be attributed to samples for which the percentage of inhibition is >20% [20].

### *Parasites molecular characterization*

A mixed trizol will be used to determine var gene transcripts. PfEMP1 expression phenotypes will be determined by quantitative PCR. Var gene type specific primers will be used to determine the transcript level of var genes in relation to two internal control genes seryl-tRNA synthetase and aldolase. Individual RT-PCR reactions will be performed using a Rotorgene® thermal cycler (Corbett Research) according to a standard procedure 11 at NMIMR.

### **Statistical Analysis**

**Baseline Comparison of Patients:** Summary statistics (proportions for categorical variables and means or medians with variances or IQRs for continuous variables) and graphs will be used to detect presence of outliers or unusual observations, and to assess validity of assumptions for statistical tests. Participants will be compared between the two study arms (Intervention communities and control communities) with respect to baseline demographic, clinical and parasitological characteristics. Statistical analysis of the above comparisons for continuous variables will be based on graphs, t-test (or Wilcoxon test), and ANOVA (or Kruskal-Wallis test). Categorical variables will be compared using chi-square tests. All analyses will be performed for the whole population in each arm.

**Primary objective:** outcomes of primary objective asymptomatic parasitaemia will be compared over time and between intervention arms using chi-square tests (or fisher exact tests) and logistic regression (or conditional logistic regression). Adjustments for potential confounders including patient's age and use of ITN and baseline temperature will be considered. In addition, these outcomes will also be compared over time using Cochrane Armitage test of trends.

**Secondary objectives:** symptomatic parasitaemia at the hospitals and symptomatic parasitaemia picked up at the community compared over time and between intervention arms using chi-square tests (or fisher exact tests) and logistic



regression (or conditional logistic regression). Comparisons of anaemia in children <15 years across time and study arms will be assessed through Cochran Armitage test of trends and using chi-square tests (or Fisher exact tests) respectively. A binomial logistic regression will be used to test impact of intervention on febrile illnesses.

### **Problems Anticipated:**

It is anticipated that ACTs and RDTs supplies could delay. In order to avoid this, we have approached the national Malaria control programme so that we could obtain drugs through the Eastern Regional Store. We anticipate the number given to houses in the communities could be erased and so we have house data also linked to the name of the household head. This could enable us to trace the houses.

### **Project Management:**

The PI will carry out day to day implementation and supervisions of all aspects of the project. The Research assistant helps in facilitating project logistics. The statistician will oversee data entry and analysis. The volunteers are community members that assist in data collection while the driver facilitates movements.

### **Quality Assurance:**

In order to ensure the quality of data collected, 20 volunteers will be trained and 14 will be selected for the project. The questionnaires will be pretested and corrections effected. All data collected will be cross checked and signed by the Research Assistant (RA) in the field. In the case of discrepancy, the data sheet will be returned to the collector for rectification. All data will be transferred to the NMIMR. To avoid loss of data, all data from the field will be recorded in the paper based CRF and transferred to the data management unit. All ACTs (AL or AA) and RDTs will be procured from the National Malaria Programme through the Eastern Region medical store or from licensed suppliers recommended by the NMCP. The expiry dates for all procurements made will be verified.

**Ethical Considerations:** (i.e. consent procedures, confidentiality, privacy, risks and benefits, etc.)

#### *Consent Procedure*

We will obtain consent at different levels. Administrative authorization will be obtained from the Ghana Health Service. There will be community consent given by the chiefs, households consent given by the head or parents/caretakers for children below 18 years, individual assent for 12-17 years old and consent for adults in each household. People from 18 years old are considered as Adults.

#### *Privacy and confidentiality*

All information/samples obtained from participants will be kept confidential and will not be released to a third party. This information will be stored in a secure location at the Epidemiology Department of NMIMR. Two individuals – the PI and the head of the statistics unit will have access to the data. During the study data collectors will have access to the data to enable tracing of household members. Some staff of Epidemiology Department of NMIMR may be authorized to access the data for research purposes only, such as malaria prevalence studies in asymptomatic individuals. Findings will be published with no reference to any personal identifiers. The data collected will be stored for a period of five years at NMIMR. Anonymised data will be made publicly available through an open access data repository.

## **Expected Outcome/Results**

### **Primary outcome**

The difference in asymptomatic malaria parasitaemia prevalence in children <15 years and pregnant women in arm 1 compared to arm 2.

### **Secondary outcomes**

1. The difference in prevalence of anaemia in children <15 years and pregnant women in 1 arm compared to arm 2.
2. The difference in febrile illnesses in children <15 years and pregnant women in the intervention arm compared to the control arm (arm 2)
3. The difference in symptomatic malaria cases attending health facilities in arm 1 compared to arm 2.
4. The proportion of pregnant women testing positive at first antenatal clinic and subsequent visits in arm 1 and arm 2.
5. The difference in prevalence of anti-plasmodium antibodies between baseline and evaluation in arm 1 and arm 2.

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## Work Plan

| Activity             | Year one |   |   |   |   |   |   |   |   |    |    |    | Year Two |    |    |    |    |    |    |    |    |    |    |    |
|----------------------|----------|---|---|---|---|---|---|---|---|----|----|----|----------|----|----|----|----|----|----|----|----|----|----|----|
|                      | 1        | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13       | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| Ethical Clearance    | √        |   |   |   |   |   |   |   |   |    |    |    |          |    |    |    |    |    |    |    |    |    |    |    |
| Purchase of material | √        |   |   |   |   |   |   |   |   |    |    |    |          |    |    |    |    |    |    |    |    |    |    |    |
| Training             |          | √ |   |   |   |   |   |   |   |    |    |    |          |    |    |    |    |    |    |    |    |    |    |    |
| Data collection      |          | √ | √ | √ | √ | √ | √ | √ | √ | √  | √  | √  | √        | √  | √  | √  | √  | √  | √  | √  | √  | √  | √  | √  |
| Data analysis        |          |   | √ | √ | √ | √ | √ | √ | √ | √  | √  | √  | √        | √  | √  | √  | √  | √  | √  | √  | √  | √  | √  | √  |
| Dissemination        |          |   |   |   |   |   |   |   |   |    |    |    |          |    |    |    | √  | √  | √  | √  | √  | √  | √  | √  |

## Budget and Budget Justification

| Item                                | specification                                                                                                                                                                                                                                                                                                                                            | Cost (€) |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| RDTs                                | RDTs: 6500 RDTs are required for baseline and evaluation while $1550 \times 6 = 9300$ RDTs are required for the remaining interventions. This gives $9300 + 6500 = 15800$ RDTs. Total cost $15800 \times \$0.419 = 6620$                                                                                                                                 | 6620.2   |
| Treatment                           | Artemether lumefantrine (AL) for both adults and children. The number of treated cases will be decreasing over time.<br>We will obtain 15,800 doses of ACTs @ €0.5 each = €7,900                                                                                                                                                                         | 7,900    |
| Hemocue photometer                  | Hb levels will be assessed to determine anaemic status.<br>Children under 15 up to 33 % of the population, giving a total of 1230<br>Hb meter ( $11 \times €100$ ) = €1100, cost of HB strips = $€0.5 \times 990 \times 8 = 3,960$ . Total = 2015                                                                                                        | 5,060    |
| Consumables/ materials              | Gloves = €300<br>Tissue = €100<br>Cotton = €100<br>zip-lock bags = € 100<br>safety boxes = €100<br>silica gel = €100,<br>filter paper = €500<br>rubber bags for filter paper = €50<br>Alcohol = €200<br>Alcohol dispenser = €100<br>Total = €1650                                                                                                        | 1,650    |
| Incentives for Under 15 children    | Biscuits<br>Cost is $€0.15 \times 990 \times 8 = €1,188$                                                                                                                                                                                                                                                                                                 | 1,188    |
| Data analysis                       | Statistician will coordinate data collection, entry and conduct analysis<br>Data entry = 2500<br>Data analysis = 1500                                                                                                                                                                                                                                    | 4,000    |
| Community entry                     | Meetings and durbars with chiefs<br>Introduction to eight community leaders $€20 \times 8 = €160$                                                                                                                                                                                                                                                        | 160      |
| Questionnaire administration        | Questionnaires will be administered to participants enrolled in the study<br>8 days for Research Assistant, 8 days for the PI and 8 days for the driver. The cost is as follows (Drivers ( $€30 \times 8 \times 8$ ) = €1920, Research Assistant = ( $€35 \times 8 \times 8$ ) = €2,240, PI ( $€70 \times 8 \times 8$ ) = €4480 giving a total of €8,640 | 8,640    |
| Laptop                              | laptop                                                                                                                                                                                                                                                                                                                                                   | 750      |
| Study of hospital admission records | To study admission trends over the intervention period €1500                                                                                                                                                                                                                                                                                             | 1500     |

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |        |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| Communication           | Communication credit enable the team liaise with the volunteers on home-based management.<br>Each volunteer will be given a monthly communication credit of €1.5 over two years ( $€1.5 \times 17 \times 24 = \text{€}504$ ) while the PI will require $€25 \times 24 = \text{€}600$ .                                                                                                                                                                                                                                   | 1,104  |
| Bags for the volunteers | These are required for transport of materials<br>Therefore, we have $16 \times €25 = €400$                                                                                                                                                                                                                                                                                                                                                                                                                               | 400    |
| Personnel               | 14 community volunteer (2 from each community) conduct community-based management of malaria following the protocol. Every three months the CHWs are given an allowance<br>For a total of 4 interventions, we have $14 \times €15 \times 4 = €1320$                                                                                                                                                                                                                                                                      | 1320   |
|                         | Census and mapping the study site                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 447    |
|                         | 4 interventions visits<br>Each intervention will last 6 days, giving 48 in total. Daily allowance for CHWs ( $€5 \times 48 \text{ days} \times 14$ ) = €3,360, Food during data collection = $€3 \times 48 \text{ day} \times 14 = €2,016$ , driver ( $€30 \times 48$ ) = €1,440, Research Assistant = ( $€35 \times 48 \text{ days}$ ) = €1,680, PI ( $€70 \times 48 \text{ days}$ ) = €3,360, giving a total of <b>€11,856</b> .                                                                                       | 11,856 |
|                         | Monitoring visits<br>Since 8 of the 24 months will be involved in the intervention, monthly monitoring will take place 16 times over the 16 remaining months. The cost is calculated as follows - driver ( $€30 \times 16$ ) = €480, Research Assistants ( $€35 \times 16$ ) = €560 and the PI ( $€70 \times 16$ ) = €1,120 giving a total of €2,160                                                                                                                                                                     | 2,160  |
|                         | Training<br>A two-day training work will be organized for the research team in the field. The PI, RA and driver will spend one extra day in the planning the event.<br>Daily transport during training for 14 CHW = $€5 \times 14 \times 2 \text{ days} = €140$ , food for participants $€3.5 \times 2 \text{ days} \times 14 = €98$ , resource persons @ $€70 \times 2 \times 2 \text{ days} = €280$ , Driver @ $€30 \times 3 \text{ days} = €90$ , RA @ $€35 \times 3 \text{ days} = €105$ , PI @ $€70 \times 3 = 210$ | 818    |
|                         | Salaries<br>Dr. Ndong Ignatius Cheng (12% FTE) = $€1200/\text{month} \times 24 = €28800$<br>Prof. Collins Ahorlu (5% FTE) = $€600/\text{month} \times 24 = €14,000$<br>Research Assistant (100%) = $€400/\text{month} \times 24 = €9,600$                                                                                                                                                                                                                                                                                | 52,600 |
| Rechargeable lamp       | Most of the communities are farming communities where participant leave for their farmers very early in the morning. Some visits will be done in the evening when all then members are at home. 11 Rechargeable for work in the night ( $€17 \times 7$ ) = 119                                                                                                                                                                                                                                                           | 119    |
| Transport               | Car hiring, fuel for censor, interventions and monitoring<br>€10,000                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 10,000 |
| Molecular Analysis      | To determine the effect MDA on <i>anti-Plasmodium</i> antibodies, ELISA and PCR will be conducted.                                                                                                                                                                                                                                                                                                                                                                                                                       | 40,000 |

|              |  |                |
|--------------|--|----------------|
| <b>Total</b> |  | <b>153,212</b> |
|--------------|--|----------------|

## CONSENT INFORMATION SHEET

**Title: Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

Principal Investigator: Dr. Ndong Ignatius Cheng

Address:

Epidemiology Department,  
Noguchi Memorial Institute for Medical Research  
University of Ghana  
P. O. Box LG 581 Legon  
Tel: +233 561817573  
Email: NCheng@noguchi.ug.edu.gh

### General Information about Research

This study is implementation research. We are trying to find out how something that has work for a small population can work in a normal community with a large population like your community. The research is looking at ways to reduce the level of malaria in your community. Malaria is caused by something called the malaria parasite. When the mosquito bites you it passes the parasite that causes malaria into your blood. Everybody in your community can suffer from malaria especially pregnant women and children. When the parasite that causes malaria enters the blood of some adults, sometimes they may not have malaria. These adults have something in their blood that protects them against the malaria parasite. So as an adult, you may sometimes carry the parasite but will not be ill of malaria. Children suffer more from malaria, because they do not have that thing that fights malaria in their blood, so anytime they have the malaria parasite they will have malaria. When you treat malaria in the children and pregnant women and even those people who are ill, you remove the malaria parasite from their blood. But the parasite is still found in the blood of the people in your community who carry the parasite but are not ill. So, if you do not have that thing which will protect you from malaria and the mosquito bites a person around you who has malaria, it will carry the parasite. If the mosquito comes and bites you, it will transfer the parasite to you. This will make you to become ill again. We will like you to participate in this study so that we can remove the parasite from the blood of many of the people living in your community. How are you going to do this? You and every member of your household will be tested. Whether you have malaria parasite or not we will treat you free, and we will follow up to see whether you have side effects such as vomiting, dizziness, weakness etc. If you do this, then you will remove the malaria parasites from the blood of those people who are not ill. If everybody takes part, then you can reduce the effect of malaria in your community and the money you are using to treat malaria every year can be used to do other things in the house.

**Nature of Research:**

You will be participating in this mass testing, and treatment of everybody and follow up of everybody. In the first two months, we will test and treat everybody two time, then we will start testing and treating people every three months over a period of two years. However, at any time, when you have malaria in the community, you will go to the community volunteer and the person will test you with a fast test and treat you if you are carrying the parasite that causes malaria. When the research team comes to your house, you will allow them to collect 200ul of blood (two drops of blood) and test to find out whether you have malaria. But if you have signs and symptoms of malaria and you do not have malaria the volunteer will send you to the Health Centre for check up by the Medical personnel. You will also be asked questions on the things you do at home to prevent malaria such as use of mosquito net etc. At the end of the work, we will have to bring some people together and discuss with them (focus group discussion) and also interview some people. We will audio tape interview and focus group discussions so that we listen to it again and write out what they people were saying that can help our work. Nobody's identity will be linked to what they said. After use, the tapes will be stored for five years before being thrown away.

**Participant involvement*****Duration of the study:***

This study will last for two years. All members of the community will be tested and treated two times in the first two months and then every three months. The rapid test and treatment for malaria that will be used in this study will be the same as those used by the National Malaria Control Programme.

***Potential Risks***

When your finger is pricked, you will have some pain. But this is only for a short time. Also, when you take the malaria medicine you may vomit. If this happens, the drug will be repeated. You may also feel weak, dizziness, have stomach upset, body weakness, etc in the course of treatment.

***Possible Benefits***

The level of malaria in your community could possibly drop and so many children will not be absent from school because of malaria. Your families will be able to use the money that you spend on malaria on other items needed by the family. Results from this work will help the National Malaria programme to be able to expand this programme to the whole of Ghana.

***Cost***

The participant will not incur any cost in the cost of this project. All tests and treatment are free.

***Compensation***



Except for the free treatment given to all participants, there is not compensation of any kind. However, we will be providing some biscuits for children below 5 years when they are tested.

### ***Confidentiality***

To the best of our ability, we will protect information about you and store it in a safe location at NMIMR for a period of five years and after that will be discarded. You will not be named in any reports and your name will not be released to any third party. Some staff of Epidemiology Department of NMIMR may sometimes look at your records for research purposes only. For this to happen, the person must have written permission from the Head of Department, co-signed by the data management unit head for a specified purpose under a project that has been cleared by the Noguchi IRB.

### ***Voluntary Participation and Right to Leave the Research***

Participation in this project is voluntary and you can leave the study at any time.

### ***Outcome and Feedback:***

Data collected from you will be analysed and we will tell you the results. After the study is completed we will come and tell community members how malaria is in this community. We will also share the results with the district health service, the regional Health service and the National Malaria Programme.

### ***Sharing of participant Information/Data:***

The data collected is owned by Noguchi Memorial Institute for Medical Research. The data from this study will be shared with the National Malaria Control Programme and published.

***Funding information:*** No external Funding. This study is being funded from own resources with the support of the National Malaria Control Programme (NMCP).

### ***Storage of samples***

Data collected will be stored at Noguchi Memorial Institute of Medical Research for a period of 5 years. Before any study is done on stored blood samples collected on filter paper ethical clearance will be obtained from IRB.

### ***Provision of the information and consent for participants***

You will be given a copy of the information sheet and the consent after signing or thumb printing to keep.

### **Contacts for Additional Information**

Dr. Ndong Ignatius Cheng  
Epidemiology Department,  
Noguchi Memorial Institute for Medical Research  
University of Ghana  
P. O. Box LG 581 Legon  
Tel: +233 561817573  
Email: [NCheng@noguchi.ug.edu.gh](mailto:NCheng@noguchi.ug.edu.gh)

Prof. Abraham Kwabena Anang, PhD

Director  
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T: +233 302 940422  
C: +233 244835872  
Email: [Anang@noguchi.ug.edu.gh](mailto:Anang@noguchi.ug.edu.gh)

## CONSENT FORM

**STUDY TITLE: Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

### PARTICIPANTS' STATEMENT

I acknowledge that I have read or have had the purpose and contents of the Participants' Information Sheet read and all questions satisfactorily explained to me in a language I understand (English, Ewe, Twi). I fully understand the contents and any potential implications as well as my right to change my mind (i.e. withdraw from the research) even after I have signed this form.

Do you agree that if your child is select in the subgroup study, his/her blood samples could be stored at NMIMR for 5 years for further research concerning malaria in your community?

Yes ☐ No ☐

Do you agree to participate in audio tape interviews and focus group discussion **of 8-10 persons**, if selected?

Yes ☐ No ☐

I voluntarily agree to be part of this research.

Name or Initials of Participant..... ID Code  
.....

Participants' Signature .....OR Thumb Print.....

Date:.....

### INTERPRETERS' STATEMENT

I interpreted the purpose and contents of the Participants' Information Sheet to the afore named participant to the best of my ability in the (English, Ewe, Twi) language to his proper understanding (*tick language used*).

All questions, appropriate clarifications sort by the participant and answers were also duly interpreted to his/her satisfaction.

Name of Interpreter.....

Signature of Interpreter.....  
.....

Date:

Contact Details. Dr. Ndong Ignatius Cheng, Tel: 0561817573, Email: NCheng@noguchi.ug.edu.gh

### STATEMENT OF WITNESS

I was present when the purpose and contents of the Participant Information Sheet was read and explained satisfactorily to the participant in the language he/she understood (English, Ewe, Twi) (*tick language used*)

I confirm that he/she was given the opportunity to ask questions/seek clarifications and same were duly answered to his/her satisfaction before voluntarily agreeing to be part of the research.

Name:.....

Signature..... OR Thumb Print .....

Date:.....

#### INVESTIGATOR STATEMENT AND SIGNATURE

I certify that the participant has been given ample time to read and learn about the study. All questions and clarifications raised by the participant have been addressed.

Researcher's name.....

Signature .....

Date.....

## **PARENTAL CONSENT INFORMATION SHEET**

**Title: Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

**Principal Investigator:** Dr. Ndong Ignatius Cheng

**Address:**

Epidemiology Department,  
Noguchi Memorial Institute for Medical Research  
University of Ghana  
P. O. Box LG 581 Legon  
Tel: +233 561817573  
Email: NCheng@noguchi.ug.edu.gh

### **General Information about Research**

This study is an implementation research. We are trying to find out how something that has worked for a small population can work in a normal community with a large population like your community. The research is looking at ways to reduce the problem that malaria is causing in your community. Malaria is caused by the malaria parasite. When your child has malaria, the malaria parasite is found in your blood. When the mosquito bites your child, it transfers the malaria parasite into the blood of your child. This parasite will cause malaria in the child. Everybody in your community can suffer from malaria especially pregnant women and children. Your child suffers more because your child does not have the protection that can stop malaria in adults, so anytime your child has the malaria parasite in his/her blood, he/she will have malaria. As an adult you may sometimes carry the parasite but will not have malaria. This is because you have the protection that can stop malaria even if you have the parasite. When your child or a pregnant woman or those people who are ill take medicine for malaria, the malaria parasite is removed from their blood. But the parasite is still found in your community, in the blood of the people who have that thing that can stop malaria when they have the parasite (that is, those people who carry the parasite but are not ill). Since your child does not have that thing that stops malaria when adults carry the parasite, if the mosquito bites your child, it will transfer the parasite to the blood of your child. This will make your child to become sick again. We will like that your child participates in this study so that we can remove the parasite from the blood of many of the people living in your community. Your child and every member of your household will be tested. Following the test everybody will be treated, and followed up to see whether you have side effects such as stomach upset, dizziness, weakness etc. If your child or any

member of your community does this, then we will remove the malaria parasite from the blood of those people who are not ill. If everybody participates in this research then you can reduce the effect of malaria in your community and the money you are using to treat malaria every year can be used to do other things in the house.

### **Nature of Research:**

You will be participating in this mass testing, and treatment of everybody and follow up of everybody. In the first two months, we will test and treat everybody two time, then we will start testing and treating people every three months over a period of two years in this community. However, when your child has fever, you will go to the community volunteer and the person will test your child with a fast test and treat if your child is carrying the malaria parasite. When the research team comes to your house, you will allow them to collect 200ul of blood (two drops of blood) and test to find out whether your child has malaria. But if your child has signs and symptoms of malaria and he/she does not have malaria the volunteer will send your child to the Health Centre for check up by the medical personnel. Some children will be selected for a subgroup study. If your child is selected for the subgroup study, apart from malaria test, we will also collect additional four drops of blood from him/her on a filter paper. The filter papers will be stored for a period of five years. This will be used for two things 1) If you have malaria parasites and the drugs cannot treat you then we will also use the blood on the filter paper to find out what is wrong and 2) To check whether the thing that protect children against malaria (partial immunity) as they grow above 5 years is affected over time as the malaria parasites are removed from the blood of all the people in the community. Before using the stored samples, the researchers will seek ethical approval from NMIMR-IRB. You will also be asked questions on the things you do at home to prevent your child from having malaria such as use of Long-Lasting Insecticidal Nets (LLIN) etc. At the end of the work we will have to bring some people together and discuss with them (focus group discussion) and also interview some people. We will audio tape interview and focus group discussions so that we listen to it again and write out what they people were saying that can help our work. Nobody's identity will be linked to what they said. We will tape the discussions so that we listen to it again and write out what they people were saying that can help our work. After use, the tapes will be stored for two years before being thrown away.

### **Participant involvement**

#### ***Duration of the study:***

This study will last for two years. All members of the community will be tested and treated two times in the first two months and then every three months. The rapid test and treatment for malaria that will be used in this study will be the same as those used by the National Malaria Control Programme.

### ***Possible Risks***

When your child's finger is pricked, your child will feel some pain. But this is only for a short time. Also, when the child takes the malaria medicine your child may vomit. If this happens within 30 minutes after taking the medicine the treatment will be repeated. Your child may also feel weak during treatment.

### ***Possible Benefits***

The number of people with malaria could possibly reduce and so many children will not be absent from school because of malaria. Your families will be able to use the money that you spend on malaria on other items needed by the family. Results from this work will help the National Malaria Control Programme to be able to expand this programme to the whole of Ghana.

### ***Cost***

The participant will not incur any cost in the cost of this project. All tests and treatment are free.

### ***Compensation***

Except for the free treatment given to those who test positive, there is no compensation of any kind. However, we will be providing some biscuits for children below 5 years when they are tested.

### ***Confidentiality***

To the best of our ability we will protect information about your child and store it in a safe location at Noguchi Memorial Institute for Medical Research (NMIMR) for a period of five years. Your child will not be named in any reports and his/her name will not be released to any third party. Some staff of Epidemiology Department of NMIMR may sometimes look at your child's records for research purposes only.

### ***Voluntary Participation and Right to Leave the Research***

Participation in this project is voluntary and your child can leave the study at any time.

### ***Outcome and Feedback:***

Data collected from your child will be analysed and we will tell you the results. After the study is completed, we will come and tell community members how malaria is in this community. We will also share the results with the district health service, the regional Health service and the National Malaria Programme.

### ***Storage of sample***

The data will be stored for a period of five years at NMIMR. Any time another researcher wants to use the data collected on filter papers ethical clearance will be obtained from the NMIMR.

### ***Voluntary Participation and Right to Leave the Research***

Participation in this project is voluntary and your child enrolled into the cohort study can leave the study at any time.

***Funding information:*** No external Funding. This study is being funded from own resources with the support of the National Malaria Control Programm (NMCP).

### ***Provision of the information and consent for participants***

You will be given a copy of the information sheet and the parental consent form after signing or thumb printing to keep.

### **Contacts for Additional Information**

Dr. Ndong Ignatius Cheng  
Epidemiology Department,  
Noguchi Memorial Institute for Medical Research  
University of Ghana  
P. O. Box LG 581 Legon  
Tel: +233 561817573  
Email: [NCheng@noguchi.ug.edu.gh](mailto:NCheng@noguchi.ug.edu.gh)

Prof. Abraham Kwabena Anang, PhD  
Director  
Noguchi Memorial Institute for Medical Research  
University of Ghana  
P. O. Box LG 581 Legon  
T: +233 302 940422  
C: +233 244835872  
Email: [Anang@noguchi.ug.edu.gh](mailto:Anang@noguchi.ug.edu.gh)

### **Your Child's Rights as a Participant**

This research has been reviewed and approved by the Noguchi Memorial Institute for Medical Research Institutional Review Board). If you have any questions about your child's rights as a research participant you can contact the +233-302-916438 for the NMIMR-IRB.





## PARENTAL CONSENT FORM

**STUDY TITLE: Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

### PARTICIPANTS' STATEMENT:

I acknowledge that I have read or have had the purpose and contents of the Participants' Information Sheet read and all questions satisfactorily explained to me in a language I understand (English, Twi, Ewe). I fully understand the contents and any potential implications as well as my right to change my mind (i.e. withdraw from the research) even after I have signed this form.

I voluntarily agree that my child be part of this research.

If your child is selected for the subgroup study the samples could be stored at NMIMR for 5 years. Before any study is conducted on those sample by another researcher ethical approval will be obtained from NMIMR.

Do you agree                      Yes ☐                      No ☐

Name or Initials of Participant..... ID Code .....

Participants' Signature .....OR Thumb Print.....

Date: .....

### INTERPRETERS' STATEMENT

I interpreted the purpose and contents of the Participants' Information Sheet to the afore named participant to the best of my ability in the (English, Twi, Ewe) language to his proper understanding (*tick language used*).

All questions, appropriate clarifications sort by the participant and answers were also duly interpreted to his/her satisfaction.

Name of Interpreter.....

Signature of Interpreter.....

Date: .....

Contact Details. Dr. Ndong Ignatius Cheng, Tel: 0561817573, Email: NCheng@noguchi.ug.edu.gh



STATEMENT OF WITNESS

I was present when the purpose and contents of the Participant Information Sheet was read and explained satisfactorily to the participant in the language he/she understood (English, Twi, Ewe) (*tick language used*).

I confirm that he/she was given the opportunity to ask questions/seek clarifications and same were duly answered to his/her satisfaction before voluntarily agreeing to be part of the research.

Name:.....

Signature..... OR Thumb Print .....

Date:.....

INVESTIGATOR STATEMENT AND SIGNATURE

I certify that the participant has been given ample time to read and learn about the study. All questions and clarifications raised by the participant have been addressed.

Researcher's name.....

Signature .....

Date.....



## CHILD ASSENT INFORMATION SHEET

Title: **Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

**Principal Investigator:** Dr. Ndong Ignatius Cheng

**Address:**

Epidemiology Department,  
Noguchi Memorial Institute for Medical Research  
University of Ghana  
P. O. Box LG 581 Legon  
Tel: +233 561817573  
Email: NCheng@noguchi.ug.edu.gh

### General Information about Research

This study is implementation research. We are trying to find out how something that has work for a small population can work in a normal community with a large population like your community. The research is looking at ways to reduce the level of malaria in your community. Malaria is caused by something called the malaria parasite. When the mosquito bites you it passes the parasite that causes malaria into your blood. Everybody in your community can suffer from malaria especially pregnant women and children. I am asking you to take part in this research study because I am trying to learn more about *malaria parasites in people who carry the parasite but are not ill*. This will take *two years*

### Nature of the Research

If you agree to be in this study, you will be asked question on the prevention of malaria in your home, we will collect 200ul (two drops of blood samples) from you and tested for malaria. If you are positive, you will be treated. Some children between the ages 2 months to 15 years will be selected for a subgroup study. If you are selected for the subgroup study, apart from testing for malaria, we will also collect additional four drops of blood from you on a filter paper. The filter papers will be stored for a period of five years. This will be used for two things 1) If you have malaria parasites and the drugs cannot treat you then we will also use the blood on the filter paper to find out what is wrong and 2) To check whether the thing that protect children against malaria (partial immunity) as they grow above 5 years is affected over time as the malaria parasites are removed from the blood of all the people in the community. Before using the stored samples, the researchers will seek ethical approval from IRB.

### Participant involvement

**Duration of the study:** You will be participating in mass testing, and treatment and follow up of everybody. In the first two months, we will test and treat everybody two time, then we will start testing and treating people every three months over a period of two years in this community. The rapid test and treatment for malaria that will be used in this study will be the same as those used by the National Malaria Control Programme.



***Potential Risks***

When your finger is pricked, you will have some pain. But this is only for a short time. Also when you take the malaria medicine you may vomit so the drug will be repeated. You may also feel weak, dizziness, have stomach upset, body weakness, etc in the course of treatment.

***Possible Benefits***

The level of malaria in your community could possibly drop and so many children will not be absent from school because of malaria. Your families will be able to use the money that you spend on malaria on other items needed by the family. Results from this work will help the National Malaria programme to be able to expand this programme to the whole of Ghana.

***Cost***

The participant will not incur any cost in the cost of this project. All tests and treatment are free.

***Compensation***

Except for the free treatment given to those who test positive, there is not compensation of any kind. However, we will be providing some biscuits for children when they are tested.

***Confidentiality***

To the best of our ability we will protect information about you and store it in a safe location at NMIMR for a period of five years and after that will be discarded. You will not be named in any reports and your name will not be released to any third party. Some staff of Epidemiology Department of NMIMR may sometimes look at your records for research purposes only. For this to happen, the person must have written permission from the Head of Department, co-signed by the data management unit head for a specified purpose under a project that has been cleared by the Noguchi IRB.

***Voluntary Participation and Right to Leave the Research***

Participation in this project is voluntary and you can leave the study at any time.

***Outcome and Feedback:***

Data collected from you will be analysed and we will tell you the results. After the study is completed we will come and tell community members how malaria is in this community. We will also share the results with the district health service, the regional Health service and the National Malaria Programme.

***Sharing of participant Information/Data:***

The data collected is owned by Noguchi Memorial Institute for Medical Research. The data from this study will be shared with the National Malaria Control Programme and published.

***Funding information:*** No external Funding. This study is being funded from own resources with the support of the National Malaria Control Programme (NMCP).



***Storage of samples***

Data collected will be stored at Noguchi Memorial Institute of Medical Research for a period of 5 years.

Before any study is done on stored blood samples collected on filter paper ethical clearance will be obtained from NMIMR-IRB

***Seeking parental approval***

Please talk about this study with your parents before you decide whether or not to participate. I will also ask permission from your parents before you are enrolled into the study. Even if your parents say “yes” you can still decide not to participate.

***Provision of the information and consent for participants***

You will be given a copy of the information sheet and the consent after signing or thumb printing to keep.

**Contacts for Additional Information**

Dr. Ndong Ignatius Cheng  
Epidemiology Department,  
Noguchi Memorial Institute for Medical Research  
University of Ghana  
P. O. Box LG 581 Legon  
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Noguchi Memorial Institute for Medical Research  
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P. O. Box LG 581 Legon  
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C: +233 244835872  
Email: [Anang@noguchi.ug.edu.gh](mailto:Anang@noguchi.ug.edu.gh)

**Your rights as a Participant**

This research has been reviewed and approved by the Noguchi Memorial Institute for Medical Research Institutional Review Board). If you have any questions about your child's rights as a research participant you can contact +233-302-916438 for the NMIMR-IRB.



## CHILD ASSENT FORM

**STUDY TITLE: Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

### PARTICIPANTS' STATEMENT

I acknowledge that I have read or have had the purpose and contents of the Participants' Information Sheet read and all questions satisfactorily explained to me in a language I understand (English, Twi, Ewe) (*tick language used*). I fully understand the contents and any potential implications as well as my right to change my mind (i.e. withdraw from the research) even after I have signed this form.

Do you agree that if you are select for the subgroup study, your blood samples could be stored at NMIMR for 5 years for further research concerning malaria in your community?

Yes ☐ No ☐

I voluntarily agree to be part of this research.

Name or Initials of Participant..... ID Code  
.....

Participants' Signature .....OR Thumb Print.....

Date:.....

### INTERPRETERS' STATEMENT

I interpreted the purpose and contents of the Participants' Information Sheet to the afore named participant to the best of my ability in the (English, Twi, Ewe) language to his proper understanding (*tick language used*).

.

All questions, appropriate clarifications sort by the participant and answers were also duly interpreted to his/her satisfaction.

Name of Interpreter.....

Signature of Interpreter..... Date: .....

Contact Details. Dr. Ndong Ignatius Cheng, Tel: 0561817573, Email:  
[NCheng@noguchi.ug.edu.gh](mailto:NCheng@noguchi.ug.edu.gh)



STATEMENT OF WITNESS

I was present when the purpose and contents of the Participant Information Sheet was read and explained satisfactorily to the participant in the language he/she understood (English, Twi, Ewe) (*tick language used*).

I confirm that he/she was given the opportunity to ask questions/seek clarifications and same were duly answered to his/her satisfaction before voluntarily agreeing to be part of the research.

Name:.....

Signature..... OR Thumb Print .....

Date:.....

INVESTIGATOR STATEMENT AND SIGNATURE

I certify that the participant has been given ample time to read and learn about the study. All questions and clarifications raised by the participant have been addressed.

Researcher's name.....

Signature .....

Date.....



## **Data Collection Instruments**

### **Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

#### **Interview Guide for In-depth Interview – Assistant Physician**

1. What are some of the key health problems of this community?
2. a. What is the leading health issue of which cases are reported to the health facility?  
b. (Probe: What do you think is the cause of it?)
3. What does it take for patients to access treatment in your health facility?  
b. What difficulties do patients face in accessing treatment?
4. Has there been any form of intervention to address Malaria prevalence in this community apart from the Mass Testing, Treatment and Tracking Intervention (MDA)?
5. a. Before the MTTT intervention, how was the malaria prevalence in this community?  
b. (Probe:- Has there been a change, during this MDA intervention?)
6. a. How would you respond to the argument that Malaria treatment is the highest revenue generator in your facility?  
b. (Probe:- How has the MDA affected revenue generation?)
7. In your opinion, what aspect of the MDA impresses you the most?
8. a. In your opinion, what do you think is the shortfall of the MDA intervention?  
b. (Probe:- What can be done to improve the MDA?)
9. Would you like the MTTT to continue? Probe:- Why?
10. Any further comments?





**Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

**Interview Guide for In-depth Interview – District Director**

1. What are some of the key health problems of your catchment area?
2. a. What is the leading health issue that tops the list on the DHMS?  
b. (Probe: What do you think is the cause of it?)
3. a. Has there been any form of intervention to address Malaria prevalence in your district in the past 2 years?  
b. (Probe: What is the intervention about?)
4. a. Do you know about the mass drug administration (MDA) going on in the Pokrom Sub-district?  
b. (Probe:- What can you say about it?)
5. a. Before the MDA intervention, how was malaria prevalence in the District?  
b. (Probe:- Has there been any change in the past year that the MDA is in progress?)  
c. Explain the change
6. a. How would you respond to the argument that malaria treatment is the highest revenue generator in your district?  
b. How has the MDA intervention affected revenue generation?
7. a. In your own view, would you like the MDA to continue in the Pokrom sub district and possibly be extended to the whole of your district?  
b. (Probe:- Explain your response in 7a above)
8. Any further comments?



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**Interview Guide for In-depth Interview – REGIONAL DIRECTOR/NMCP**

**PERSONNEL**

1. What are some of the key health problems in the region?
2. a. What is the leading health issue that tops the list the DHMS?  
b. (Probe: What do you think is the cause of it?)
3. a. Has there been any form of intervention to address Malaria prevalence in the region in the past 2 years?  
b. (Probe: What were the intervention about?)  
c. Is there any plans from the Government to introduce an intervention to reduce the Malaria prevalence in your region? What is the intervention about?
4. a. Do you know about the mass drug administration (MDA) going on in the Pokrom Sub-district?  
b. (Probe:- What can you say about it?)
5. a. Before the MDA intervention, how was the prevalence in the District?  
b. (Probe:- Has there been any change in the past year that the MDA is in progress?)  
c. Explain the change.
6. a. How would you respond to the argument that malaria treatment is the highest revenue generator in your region?  
b. How has the MDA intervention affected revenue generation?
7. a. In your own view, would you like the MDA to continue in the Pokrom sub district and possibly be extended to the whole of your region or country?  
b. (Probe:- Explain your response in 7a above). Any further comments?



**Determining the impact of malaria mass drug administration on malaria prevalence in under 15 children and pregnant women in the Pokrom sub district of Ghana**

**Interview Guide for Focused Group Discussion – Community Members**

1. What are some of the key health problems of this community?
2. Has there been any form of intervention to address malaria prevalence in your community?
3. Before the Mass drug administration (MDA) intervention, how was the malaria situation in this community?
4. Before the MDA intervention, how frequent have you or any member of your family suffered from malaria?
  - b. When was the most recent time you or any member of your family member suffered from malaria?
  - c. How was malaria managed?
  - d. What was the details of the cost involved? Probe –transport, consultation, test and treatment.
  - e. How much time do other family member spent taking care of patients with malaria?
  - f. How does this spent on taking care of malaria patient affect your daily activity or family income?
5. At what stage would you report a malaria situation at the health center?
6. Based on Q4 above, what is the difference between the period before the MDA intervention and now?
7. In your opinion, what aspect of the MDA intervention impresses you the most?
8. In your own opinion, what do you dislike about the MDA intervention?
9. How has the MDA intervention benefitted your family especially in relation to the health of your children? (Probe for financial benefits)
10. In your view, what can something be done to improve the MDA intervention to help the whole community?
11. In general, what can you say about the volunteers who come to do the Malaria testing?



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**Interview Guide for Focused Group Discussion – Health Workers**

11. What are some of the key health problems of this community?
12. a. What is the leading health issue of which cases are reported to the health facility?  
b. (Probe: What do you think is the cause of it?)
13. Has there been any form of intervention to address Malaria prevalence in this community apart from the Mass drug administration (MDA) intervention?
14. a. Before the MDA intervention, how was the malaria prevalence in this community?  
b. (Probe:- Has there been a change, during this MDA intervention?)
15. a. How would you respond to the argument that Malaria treatment is the highest revenue generator in your facility?  
b. (Probe:- How has the MDA affected revenue generation?)
16. In your opinion, what aspect of the MDA impresses you the most?
17. a. In your opinion, what do you think is the shortfall of the MDA intervention?  
b. (Probe:- What can be done to improve the MDA?)
18. Would you like the MDA to continue? Probe: Why?