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# Investigating Malaria Test Positivity in Cameroon: Comparing Reported Results to Manual RDT Verification.

A Research Protocol  
CLINTON HEALTH ACCESS INITIATIVE

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### List of abbreviations

|      |                                                                |
|------|----------------------------------------------------------------|
| ACT  | Artemisinin-Based Combination Therapy                          |
| AL   | Artemether-Lumefantrine                                        |
| ASAQ | Artesunate-Amodiaquine                                         |
| CHAI | Clinton Health Access Initiative                               |
| CHW  | Community Health Worker                                        |
| CSI  | Integrated Health Center (Centre de Santé Intégré)             |
| CMA  | Medicalized Health Center (Centre Médicalisé d'Arrondissement) |
| HD   | District Hospital                                              |
| HF   | Health Facility                                                |
| RDT  | Rapid Diagnostic Test                                          |
| TDR  | Test de Diagnostic Rapide (French for RDT)                     |

### SUPPLEMENTS/APPENDICES

1. Health facility registers Image
2. Survey questionnaire
3. In Depth interview questionnaire

## Background and Rationale

The World Health Organization (WHO) recommends a parasite-based test for each patient suspected of having malaria<sup>1</sup>. With the arrival of quality assured malaria RDTs and donor funding in the early 2010s, the use of malaria RDTs steadily has increased in most of malaria endemic Africa<sup>2</sup>. In 2023, over half of all parasite-based diagnosis was conducted through malaria RDTs<sup>3</sup>.

Malaria remains a leading public health challenge in Cameroon, with diagnostic accuracy and data quality among the key barriers to effective case management<sup>4</sup>. The country relies heavily on rapid diagnostic tests (RDTs), with 69% of patients tested using RDTs in 2023<sup>5</sup>. However, very high Test Positivity Rates (TPRs) and supply chain inefficiencies raise concerns about the accuracy of reported malaria cases in Cameroon<sup>6</sup>: Providers may not interpret the test accurately or may report negative RDTs as positive. This could lead to inflated case counts and incidence which distort trends and contribute to observed lack of progress in reducing malaria burden. In addition, administering these patients antimalarials may not address the true cause of illness which can increase the risk to patients for morbidity and mortality. Finally, irrational ACT use may contribute to stockouts as well as wastage and increased risk of developing antimalaria resistance.

Data from the District Health Information System (DHIS2) show that TPR varies widely across Cameroon, with the Southwest reporting rates as high as 89% among public sector health workers, while some regions reporting in the lower 60% range. The Annual Blood Examination Rate (ABER) is highest in the East, Adamawa and Far North regions, ranging between 15-26% (including active testing). The average TPR among Community Health Workers (CHWs) is 83%, significantly higher than in health facilities, with minimal variation between age groups. While it is plausible that CHWs, as first-line responders, test only febrile patients with a high likelihood of malaria, qualitative data suggest that other factors may be influencing these high positivity rates. Key Informant Interviews (KIIs) with malaria experts in Cameroon conducted by CHAI in 2023 for example indicate that financial incentives tied to reporting positive cases could be a factor, leading to potential overreporting of malaria cases<sup>7</sup>.

The high TPR has led to questions around the accuracy of reporting the test results by health worker (HW) and community health workers (CHW). Previous efforts in other low- and middle-income countries have shown discrepancies between reported and ‘true’ TPRs (i.e.,

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<sup>1</sup> WHO Malaria Guidelines 2023

<sup>2</sup> A review of the WHO malaria rapid diagnostic test product testing program (2008–2018): performance, procurement and policy. Jane Cunningham, 2019.

<sup>3</sup> World Malaria Report, WHO, 2024.

<sup>4</sup> Surveillance system assessment report, Clinton Health Access Initiative, Cameroon, 2023.

<sup>5</sup> Cameroon DHIS2, 2023

<sup>6</sup> Surveillance system assessment report, Clinton Health Access Initiative, Cameroon, 2023.

<sup>7</sup> Surveillance system assessment report, Clinton Health Access Initiative, Cameroon, 2023.

using digital solutions to interpret and record RDT results) but provide little guidance on how to explain or address these discrepancies.

In Benin, the proposed approach in which the RDTs are stored, counted and compared to what has been reported in the registers and HMIS has led to significant reductions in reported malaria cases and administered ACTs (an annual reduction of 20-25% in cases and ACT consumption in areas where the approach was implemented). In Cameroon, such reductions could alleviate the stock outs observed among health facilities and CHWs, with 75% of CHWs reporting commodity shortages lasting several months<sup>8</sup>. Data shows that regions with higher stock-out rates tend to have lower testing and treatment rates, suggesting a direct link between commodity availability and malaria service delivery<sup>9</sup>. For example, in the Littoral region, the lowest percentage of tests were conducted using RDTs, yet it had the highest percentage of facilities experiencing stock-outs. This mismatch underscores the urgent need for better stock-tracking mechanisms.

The proposed counting of RDTs could provide accurate near real-time data for (supply chain) managers to monitor and compare the number of RDTs performed and the number of confirmed cases detected monthly against RDT and ACT commodity consumption data. In turn, discrepancies between these data sources could be discussed leading to a more accurate reporting and rationalized use of ACTs, like it did in Benin.

### AIM and Outcomes

The aim of this pilot is to determine the degree of discordance between the RDT positivity rate provided by data obtained from manual and digital counts to that reported in the registers and the national health information system and explore if the approach in which these data sources are compared on a monthly basis would lead to more accurate reporting and rationalized ACT use. Specifically, this involves the following:

- Compare monthly RDT consumption data and volumes/TPRs reported via the registers and HMIS/DHIS2 with manual counts of used RDTs and RDT positives collected from health facilities and CHWs in monthly counts. A digital tool will be used alongside the manual counting process to take pictures of each RDT counted and provide the RDT test result.
- Identify discrepancies between reported and manual RDT counts, TPRs and ACT consumption and discuss these in monthly validation meetings.
- Observe whether discrepancies will disappear over time:

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<sup>8</sup> Cameroon National Malaria Control Program annual report, 2022.

<sup>9</sup> Cameroon DHIS2, 2022

- o Manually and digitally counted RDT volumes and positives converge with what is reported in registers/DHIS2
  - o Manually and digitally country RDTs and RDT positives will converge with reported RDT and ACT consumption volumes
- Assess operational feasibility, costs, and acceptability of the manual RDT storage and count method.

Participating health care workers and CHWs in study sites will be informed about the manual count and asked to store all used RDTs in labeled storage containers that will be provided for this purpose. HCW/CHW are expected to conduct business as usual, interpreting and reporting RDTs per national guidelines and recording the RDT results. At the end of each month, supervisors will collect and count the RDTs. The number of positive and total RDTs will be manually recorded and totals will be compared with the register and DHIS2 reported RDT country and positives.

Primary outcome:

- The primary outcome will be a comparison of the volume and test positivity rate (TPR) from the manual counts by trained supervisors to the TPR recorded in the HMIS (historic, surrounding areas, by CHWs and HF) on a monthly basis over the course of the 6-month intervention.

Secondary:

The secondary outcomes of this study are to:

1. Compare the manually counted RDTs and RDT positives to what was recorded in the registers
2. Compare the manually counted RDTs and RDT positives to the consumption of RDTs and ACTs recorded in the DHIS2 and pharmacy records (i.e., supply log)
3. Compare the costs of implementing the monthly RDT validation with potential savings from reductions in prescription of ACTs
4. Measure the impact of monthly RDT validation exercises on changes in HCWs' subjective norms, attitudes, perceptions and practices related to RDTs
5. Measure the acceptability and feasibility of conducting monthly RDT validation exercises among stakeholders involved

## LITERATURE REVIEW

### 1. Introduction

Malaria remains a major public health burden in Cameroon, contributing to high morbidity and mortality, particularly among children under five and pregnant women. In response to this challenge, parasite-based diagnosis is the standard recommendation by the WHO for testing before malaria treatment<sup>10</sup>. While RDTs have improved access to malaria diagnosis, concerns over accuracy, test interpretation, and data reliability persist. These concerns are as equally expressed for health facilities as CHW settings, where reported malaria test positivity rates are high.

Inconsistent RDT interpretation and errors in manual test recording have been well-documented in sub-Saharan Africa<sup>11</sup>. The introduction of a simple method to count collected RDTs and interpret their results to verify reported test, case and consumption data provides an opportunity to explore whether malaria surveillance data, malaria case management and supply chain practices can be improved in Cameroon.

### 2. Challenges in Malaria Diagnosis and Data Quality

The effectiveness of malaria RDTs depends on the correct interpretation of and compliance to the test result. Numerous studies have shown that health workers often may not conduct the RDT according to the manufacturer's instructions and/or misinterpret the test results, leading to false-positive or false-negative diagnoses<sup>12</sup>. According to Cunningham et al, the most common sources of errors include: (i) Failure to adhere to the correct RDT reading time as specified by manufacturers, leading to result inaccuracies and (ii) Misclassifying faint test lines as negative due to inconsistent lighting conditions or inadequate training.

A study conducted in Uganda found that misinterpretation of RDTs by health workers led to overdiagnosis in 21% of cases, contributing to unnecessary antimalarial use<sup>13</sup>. Another study by Maltha et al revealed that errors in RDT use by end-users were common and related to procedural mistakes, safety issues, and result interpretation<sup>14</sup>. These included delayed

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<sup>10</sup> WHO. (2012). Guidelines for malaria. Geneva: WHO

<sup>11</sup> Maltha, J., Gillet, P., & Jacobs, J. (2010). Accuracy of malaria rapid diagnostic tests. *Malaria Journal*, 9(1), 113.; Mukadi et al., 2014

<sup>12</sup> Cheng, Q., Cunningham, J., & Gatton, M. L. (2014). Systematic review of HRP2 gene deletions in *Plasmodium falciparum*. *Malaria Journal*, 13(1), 283, 2014; Maltha et al., 2010

<sup>13</sup> Karemere, J., et al. (2024). Evaluating the implementation of automated malaria rapid diagnostic test readers in health facilities in the DRC. *American Journal of Tropical Medicine and Hygiene*, 112(1), 10-16

<sup>14</sup> J.Martha, P. Gillet, J. Jacobs. Malaria rapid diagnostic tests in endemic settings *Clinical Microbiology and Infection* Volume 19, Issue 5, May 2013, Pages 399-407.

readings, incorrect sample and buffer volumes, failure to recognize invalid test results, and misinterpretation of faint test lines.

High quality malaria surveillance data is critical for evidence-based decision-making in national malaria control programs. However, in many countries, malaria case data are reported manually, leading to transcription errors, delays, and inconsistencies. A study in DRC found that data discrepancies between RDT results recorded in patient registers and those entered into DHIS2 ranged from 12% to 37%, caused by (i) misinterpretation, (ii) misreporting or (iii) errors in aggregation of the data in registers and DHIS2, highlighting the need for automated diagnostic reporting systems<sup>15</sup>.

### 3. Interventions to improve Malaria Diagnosis

According to Adah et al, an RDT Reader is an automated device designed to enhance the accuracy and reliability of malaria diagnosis by interpreting RDT results through digital image analysis<sup>16</sup>. Functioning as a supplementary tool to traditional visual assessments, the RDT reader captures an image of the test strip and utilizes specialized software to analyze the presence or absence of malaria antigens, thereby reducing human error associated with manual interpretation. Examples of RDT readers are HealthPulse TestNow™, and the Deki Reader™ which are applications that guide users through the RDT process with step-by-step instructions, process control timers, and digital result interpretation. A field study in Côte d'Ivoire, Benin, and Nigeria using the Health Pulse RDT Reader demonstrated a 25% improvement in diagnostic accuracy compared to visual interpretation<sup>17</sup>. A study carried out by Karemere et al evaluated the impact of Deki RDT readers on TPRs and data quality in 155 health facilities across two provinces in the Democratic Republic of Congo (DRC) from 2017 to 2019, comparing TPRs obtained from automated RDT readers, health DHIS2 data, and rainfall patterns to assess trends and reporting discrepancies<sup>18</sup>. Findings revealed that TPRs from automated readers were significantly lower on average than those recorded in HMIS data (22% TPR of reader compared to 69% in the HMIS), suggesting widespread overreporting of malaria cases. Additionally, TPRs recorded by automated readers aligned more closely with seasonal malaria transmission patterns, whereas HMIS-reported TPRs remained consistently high, indicating potential data manipulation. Similar results were observed in a 2022 follow-up study across three additional provinces (Kasai Central, Sud-Kivu, and Haut Katanga), where TPRs from facilities using Deki readers were 30-50% lower than those relying on HMIS-reported data

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<sup>15</sup> Karemere, J., et al. (2024). Evaluating the implementation of automated malaria rapid diagnostic test readers in health facilities in the DRC. *American Journal of Tropical Medicine and Hygiene*

<sup>16</sup> <https://www.auderenow.org/testnow>.

<sup>17</sup> BMGF & Audere. (2023). Health Pulse RDT Reader Study: Côte d'Ivoire, Benin, Nigeria. *Bill & Melinda Gates Foundation Report*.

<sup>18</sup> Karemere, J., et al. (2024). Evaluating the implementation of automated malaria rapid diagnostic test readers in health facilities in the DRC. *American Journal of Tropical Medicine and Hygiene*, 112(1), 10-16

Reader studies also highlighted high operational costs, the need for internet access to upload results, device maintenance, and user support as major barriers to long-term sustainability. In unpublished work by Ngufor et al<sup>19</sup>, RDTs were read by trained technicians and subsequently stored in field conditions for over a month, after which they were reviewed by an expert panel. The RDT results interpreted in the field and in by the review panel a month later showed few discrepancies and provides evidence that RDTs could be reviewed at a later stage for verification purposes. PMI supported such an approach in Benin, starting in 2022, in which used RDTs are stored and brought to data review meetings where they are counted, their result reviewed and compared to RDT results reported in the registers and the HMIS. This approach led to significant reductions in reported malaria cases and ACT consumption.

#### 4. WHO Guidance and comparing similar approaches

The WHO recommends visual interpretation of RDTs by trained personnel and endorses routine supervisory review and storage of used tests for audit purposes. In its operational guidance for malaria RDTs, WHO outlines a framework for RDT quality assurance that includes periodic cross-checks and supervisor visits to reconcile reported results with physical evidence<sup>20</sup>.

The proposed protocol considers previous work to improve the accuracy of RDT result interpretation and recording through manual and digital counts, and adheres to proposed WHO standards by implementing monthly collection of used RDTs followed by a manual and digital count of used RDTs.

## RESEARCH METHODOLOGY

### Study area

Population density in Cameroon varies substantially between urban and rural areas due to economic opportunities, infrastructure availability, and geographic factors. Urban centers, such as Douala and Yaoundé, have high population densities due to internal migration driven by employment, education, and healthcare access. Conversely, rural areas, particularly in the East and northern regions, exhibit lower densities due to sparse settlements and limited infrastructure<sup>21</sup>. (INS, 2021). Urban areas in Cameroon, such as Yaoundé (6,000-10,000 people/km<sup>2</sup>) and Douala (3,000-5,000 people/km<sup>2</sup>), are significantly more densely populated than rural regions, where densities often fall below 50 people per Kilometer squared<sup>22</sup>. Rural areas experience lower population densities due to subsistence agriculture, lower birth registration rates, and higher emigration toward urban centers<sup>23</sup>.

<sup>19</sup> Malaria rapid diagnostic test (RDT) capture and reporting assessment (MaCRA), Ngufor et al 2023

<sup>20</sup> World Health Organization. (2015). *Malaria Rapid Diagnostic Test Performance: Results of WHO Product Testing*. <https://cdn.who.int/media/docs/default-source/malaria/diagnosis/generic-pf-training-manual-web.pdf>

<sup>21</sup> Institut National de la Statistique (INS). (2021). *Annuaire Statistique du Cameroun 2020*. Yaoundé, Cameroon.

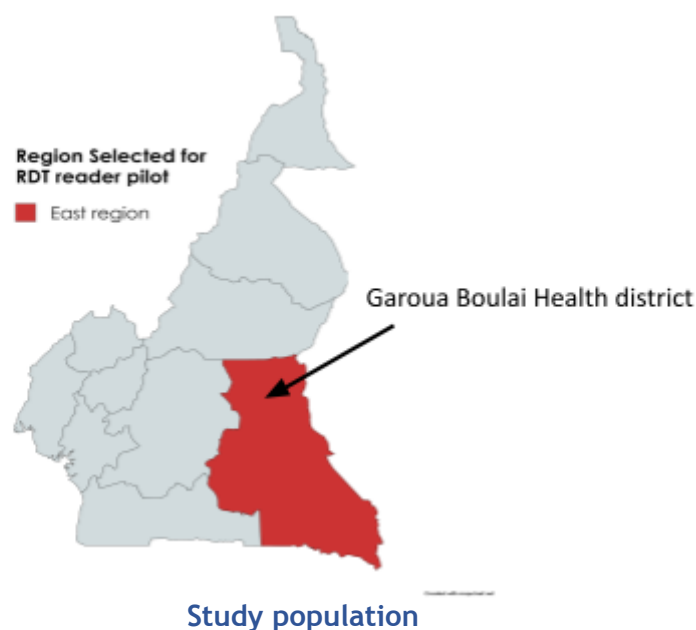
<sup>22</sup> World Bank. (2020). *Urbanization and Population Growth in Cameroon: A Spatial Perspective*. Washington, DC.

<sup>23</sup> Tchindjang, M. (2019). Dynamique des populations et développement territorial au Cameroun. *Revue de Géographie et*

According to national statistics, the East region of Cameroon has one of the lowest population densities in the country, estimated at approximately 7-13 people/km<sup>2</sup> and has one of the highest test positivity rates in the Country. This is attributed to its vast forested areas, limited road networks, and economic reliance on logging and small-scale agriculture. Despite its large landmass, the region has a relatively low urbanization rate, with only a few towns like Bertoua and Batouri serving as regional hubs. Migration patterns in the region are influenced by mining activities and cross-border movement with the Central African Republic.

Within the East region, Garoua-Boulai health district exhibits distinct population distribution patterns. Garoua-Boulai, located on a major trade route near the border with the Central African Republic, has a relatively higher population density due to its role as a commercial and transit hub. Refugee settlements in Garoua-Boulai further contribute to localized population clustering, and offers a blend of urban and rural settlements<sup>24</sup>. Due its unique disposition, this study will be carried out in the Garoua Boulai health district in the East region in Cameroon. This district is considered relatively safe and accessible given the security situation and logistics constraints within the region.

#### Map of Cameroon highlighting study area



All health workers (n=32 - 2 per HF) and CHWs (n=31) in the Garoua Boulai health district will be approached for consent and included in the study. We anticipate collecting a minimum of

Aménagement, 50(2), 120-140.

<sup>24</sup> UNHCR. (2022). Cameroon Refugee Situation Update. Geneva, Switzerland.

2121 tests conducted during the study period in outpatients and 1292 tests conducted in the community by polyvalent CHWs.

### **Inclusion/Exclusion Criteria**

**PARTICIPANTS-** health workers in participating health facilities and CHWs in health areas (catchment) tasked to conduct the malaria RDT in patients suspected of having malaria

#### **INCLUSION CRITERIA:**

- All RDTs conducted in outpatients suspected of having malaria by participating CHWs in the targeted health area
- All RDTs conducted by participating healthcare workers on patients at the HFs
- All healthcare workers and community health workers that provided consent to participate in the study

#### **EXCLUSION CRITERIA:**

- RDTs conducted by CHWs on pregnant women (Because tests from pregnant women carried out by CHWs are not recorded in the DHIS2) or in patients
- Nonconsenting HCWs

### **Study Design**

This is an observational pilot conducted over six months in the Garoua-Boulai Health District. It will involve 16 health facilities and 31 CHWs routinely performing malaria testing. The selected district was selected because (i) historic testing data would suggest we could easily meet the sample size of 2121 tests in a period of 6 months in the HFs, (ii) the research team already has ongoing operations in the district, (iii) CHWs carry out Integrated Community case management (ICCM). In collaboration with district health officials and the nurse in charge of the participating health facilities, the health workers, supervisors and the community health workers in the district that conduct malaria RDTs will be invited to a short training in which the study will be explained. The health workers will be informed of the manual count of the RDTs and equipped with containers for storage of the used RDTs. They will be requested to store the used RDT readers be it positive or negative. Supervisors will collect the stored readers monthly for the manual and digital review and counting. Discrepancies will be communicated back to nurses in charge of the participating health facilities after each count. The supervisors and the district health official will participate in the monthly count process, facilitated and chaired by the research team (at least for the first few months). Participants

in the counting process will receive brief training on manual RDT result interpretation by the research team and use of the digital tool (a mobile app downloaded on a phone).

### Sampling calculation

We hypothesize that the TPR recorded in the registers differs from the TPR found through the manual count and used the anticipated difference in our sample size calculations. We calculated sample size requirements based on a cluster randomized two-sample unpaired t-test for the comparison of two proportions using standard formulae (Hayes and Bennett, 1999). We fixed the Type 1 error at 5% and the power at 80%. Prior to the intervention we assume the TPR to be 65% in HFs and 95% in CHWs. We hypothesize that this, as a result of our intervention, will decrease to 40% in HFs and 50% in CHWs. We accordingly calculated separate sample sizes for HFs and CHWs based on the baseline and expected proportions. Since we will be sampling HFs and CHWs, we expect that there will be clustering effects in the populations that these Point Of Care serve. As such, we took clustering into account by applying a design effect based on the total population (i.e. total number of tests) that these POCs cover over six months (the assumed sampling time period) - using 2023 testing data for all HFs and CHWs in East region. We used an ICC of 0.05. Based on these assumptions and calculations, the maximum sample size required for HFs and CHWs respectively is 2121 and 1292 tests. We aim to sample from 16 HFs and 31 CHWs over a single district in the East region to control unknown confounders and differences in behavior/population between HFs and CHW catchment populations.

### Tools for data collection

Data will be collected through a review of routine health records, one survey and in depth interviews to assess the introduction of the counting on performance, diagnostic accuracy, and stock management outcomes. The routine health records include the registers, which will be filled by health care workers (health facility and CHWs), and the DHIS2, metadata on test results, RDT and ACT consumption data and timestamps for each test. During the data validation meetings, the aggregated results of the manual and digital count and the health records will be recorded and stored in a cloud-based system. For the digital count, we will use a customized Audere 'Healthpulse' Android mobile app on a phone provided by the research. The user is instructed to open the app and prompted to take a picture of the RDT result window. The Audere app is trained to interpret and provide the result of the RDT picture to the end user. The aggregated digital and manual count will be compared and any discrepancies will be reviewed and resolved by the supervisor, the district health official and the research team.

A survey will be conducted among the participating health workers on their perceptions of malaria RDTs. In depth interviews will be conducted with all stakeholders involved in the data validation meetings to explore feasibility of the validation meetings post study. The research

team will also collect data on the financial and human resources required to conduct the RDT counts.

### Study Outcome Measures

The primary outcome of the study will be the RDT volume and TPRs obtained from the manual count compared with the RDT counts TPRs recorded in the HMIS, health facility registers, and CHW records. This will provide insights into potential discrepancies in malaria diagnosis and reporting accuracy.

Specific outcomes will include the following:

| S/N | Type of Outcomes | Outcome                                                                                                    | Methods of measurement                                                                                                                                                                                                                                                                                    |
|-----|------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | Primary          | The volume and proportion of RDT results reported as positive                                              | On a monthly basis, RDT counts and RDT positives recorded through the manual count will be compared to RDT count and TPR recorded in the registers (by health facility and CHWs attached to that facility) and what was recorded in the DHS2 for that facility and for the CHWs attached to that facility |
| 2   | Secondary        | The proportion of RDTs reported as positive in months prior to intervention and in surrounding HF and CHWs | TPR calculated during the monthly validation meetings will be compared to the TPR found in the DHIS2 of HF in surrounding districts and in the TPR of intervention HF and CHWs attached to that HF in the same month in the three previous years.                                                         |
|     |                  | The total number of positive RDT found in the manual count and the total volume of ACTs administered       | The total count of positive RDTs during the monthly validation meeting for each HF and CHWS attached to the HF will be compared to the total count of ACTs administered at that HF and by CHW attached to that HF during the same period, as recorded in the institution's supply log.                    |

|  |  |                                                                                 |                                                                                                                                                                                              |
|--|--|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  | Total costs associated with monthly RDT counts                                  | Collection and analysis of cost data, including personnel costs, travel expenses, and other project-related expenses will be used to estimate the total costs associated with the RDT counts |
|  |  | HCWs subjective norms, attitudes, perceptions and practices regarding RDT usage | A survey will be administered to participating HCWs to understand their subjective norms, attitudes, perceptions and practices regarding RDT                                                 |
|  |  | Acceptability and feasibility of implementing monthly RDT validation exercises  | In-depth interviews will be conducted with HCWs, health officials to understand their perceptions of the acceptability of the monthly validation processes                                   |

### Potential Risks

We do not foresee direct risks to participants in the study. One potential risk would be in health outcomes if fewer ACTs are administered. In Benin, where the manual count has already been rolled out, no significant impacts were recorded related to increases in morbidity and mortality in the intervention areas. The proposed intervention would not deviate from existing national guidelines in which ACTs should only be administered to patients with a parasite-based positive diagnosis (i.e., microscopy or RDT).

Loss or damage of RDT cassettes before validation is a potential risk to the study fidelity. As a mitigation, an SOP for proper storage of RDT cassettes will be provided to participating health workers for the safe handling and retention. Regular checks, especially in the first few months will also be conducted to ensure adherence to storage protocols.

### Participant Enrollment and informed consent

To ensure compliance with study protocols, monthly CHW and health facility supervision visits will be conducted throughout the study period. These visits will serve to verify all used RDTs are stored and labelled appropriately using the designated collection devices, to troubleshoot any issues around RDT storage, to copy (or bring) the registers for the review period, and to transport the cassettes for the count. Informed, written consent will be obtained from all participants involved in the in depth interviews and qualitative survey. Participants will be

informed that their participation is entirely voluntary and that they are under no obligation to participate if they do not wish to. They will be assured that no negative consequences will result from their decision to either participate or decline. They will also be informed that they have the right to withdraw from the study at any point, without facing any repercussions. Confidentiality will be maintained throughout the study.

Since all participants are expected to be literate, written consent will be feasible and preferred. Should any exceptions arise, alternative methods of obtaining consent (such as oral consent witnessed by a third party) will be considered, ensuring the process remains ethical and transparent.

### **Data collection and SUBJECT CONFIDENTIALITY**

Strict measures will be taken to ensure the confidentiality of all data collected during the study. All quantitative data collection activities will be carried out using smartphones equipped with Open Data Kit (ODK) tools and the research team will be trained on the data collection processes. The tools will be implemented using a smartphone which will be provided to all research assistants.

Participant confidentiality will be maintained during the intervention. No patient identifying information will be collected. Results will be reviewed in aggregate by CHWs and health facility Data will be stored in secured registers. The data will only be accessible to the Data Manager and the PI. It will be reviewed regularly to ensure quality and completeness. Only fully de-identified data will be provided to other study personnel or statisticians. Only fully de-identified data will be shared.

In Depth Interviews with participants will be conducted in designated private spaces. If a private space is not available, an alternate location will be used to maintain confidentiality. Interviews will be audio recorded, transcribed verbatim in English language. Personal identifiers such as names and phone numbers will only be collected during the informed consent process and will not be recorded during interviews. The names of health facilities will be collected during data collection for identification purposes but will be excluded during data cleaning to ensure confidentiality.

To minimize risk of disclosure to others and discrimination or stigmatization, measures will be taken to avoid loss of confidentiality. A unique identification number will be assigned to all participants. Access to the completed study instruments and databases will be limited to the project manager, project lead, and data analysts. All data files will be password - protected.

## Data analysis

### 1. Quantitative analysis

The primary outcome will be assessed with a chi-squared test to analyze whether the difference between reported TPR and counted TPR is significantly significant. This will include outcomes for an average across all surveyed points of care (POCs), disaggregated by HFs and CHWs, and compared between baseline (pre-intervention) and endline (after six months of the intervention).

We will further investigate the difference and change in TPR by constructing a mixed effects linear regression model with the POC-month as the unit of analysis and TPR as the outcome variable. The model will include a binary indicator to exhibit pre/post intervention (implementation of the RDT check), a binary variable to indicate intervention group (i.e. "reported" or "counted" TPR), a dummy variable to exhibit month since introduction of the intervention, and a random effect variable for POC type to account for clustering. 95% confidence intervals will be fit around the TPR per POC-month.

To determine whether changes in TPR were due to changes in provider behavior or changes to the DHIS2 data, the ratio of TPRs from the health facility register to the RDT cassettes will be plotted over the six months of the intervention and compared to the change in TPR reported from the DHIS2 data.

The costs of implementing the RDT validation will be summed across all categories and averaged across the health facilities. The number of ACT courses averted in the intervention district will be calculated and costed using the schedule obtained from the MOH. The cost of implementing the RDT validation will be compared to the costs averted through reductions in ACT consumption.

### 2. Qualitative analysis

Qualitative analysis of the in-depth interviews and survey will follow a structured thematic approach. The themes will be identified from interviews with HCWs to understand their perceptions of the acceptability of the manual counting and validation processes. Audio recording will be conducted in English and/or French and then translated and transcribed to English text. All transcripts will be validated by project teams to ensure data quality. Analysis will be conducted using NVIVO software, where relevant codes will be identified. Thematic analysis will be conducted on the coded transcripts and the excerpts will be synthesized into a report.

## RESULT DISSEMINATION PLAN

The findings from this study will be disseminated through multiple channels to ensure broad stakeholder engagement and to inform future malaria control strategies. National and regional dissemination will include presentations to the Cameroon National Malaria Control Program (NMCP), Ministry of Health, and regional health directors. These presentations will focus on how manual counting impacts malaria diagnosis, stock management, and surveillance data accuracy. Additionally, briefing sessions will be organized with district health teams and CHWs to review results and discuss operational implications.

On the academic front, study findings will be submitted for publication in a peer-reviewed journal such as Malaria Journal or PLOS Global Public Health. Policy briefs summarizing key findings and recommendations will be shared with global malaria stakeholders, to advocate for potential scale-up this model in malaria-endemic settings.

At the community and health worker level, feedback workshops will be conducted with participating health workers and CHWs to review results and discuss implementation challenges. User-friendly summary reports and infographics will be developed to facilitate knowledge-sharing among frontline health workers. By leveraging these dissemination strategies, the study aims to maximize its impact on malaria control policies, diagnostic practices, and health system strengthening efforts.

## SUPPLEMENTS/APPENDICE

## Appendix 1: Image of consultation register

| Signes et Symptômes/<br>Signs and Symptoms | Diagnostic/<br>Diagnosis | Examens demandés/<br>Investigations | Résultats des examens<br>demandés /<br>Results of requested<br>tests | Traitements /<br>Treatment | Diagnostic de<br>confirmation /<br>Confirmatory<br>diagnosis | Mise en<br>Observation/<br>Hospitalisation/<br>Ambulatoire /<br>Ambulatory<br>observation/<br>Hospitalisation | N° Quittance/<br>Indigence /<br>Receipt No/<br>Impecuniosity | Référence /<br>Referral | Observations |
|--------------------------------------------|--------------------------|-------------------------------------|----------------------------------------------------------------------|----------------------------|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|-------------------------|--------------|
| 14                                         | 15                       | 16                                  | 17                                                                   | 18                         | 19                                                           | 20                                                                                                            | 21                                                           | 22                      | 23           |
|                                            |                          |                                     |                                                                      |                            |                                                              |                                                                                                               |                                                              |                         |              |
|                                            |                          |                                     |                                                                      |                            |                                                              |                                                                                                               |                                                              |                         |              |

| Signes et Symptômes/<br>Signs and Symptoms | Diagnostic/<br>Diagnosis | Examens demandés/<br>Investigations | Résultats des examens<br>demandés /<br>Results of requested<br>tests | Traitements /<br>Treatment | Diagnostic de<br>confirmation /<br>Confirmatory<br>diagnosis | Mise en<br>Observation/<br>Hospitalisation/<br>Ambulatoire /<br>Ambulatory<br>observation/<br>Hospitalisation | N° Quittance/<br>Indigence /<br>Receipt No/<br>Impecuniosity | Référence /<br>Referral | Observations |
|--------------------------------------------|--------------------------|-------------------------------------|----------------------------------------------------------------------|----------------------------|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|-------------------------|--------------|
| 14                                         | 15                       | 16                                  | 17                                                                   | 18                         | 19                                                           | 20                                                                                                            | 21                                                           | 22                      | 23           |
|                                            |                          |                                     |                                                                      |                            |                                                              |                                                                                                               |                                                              |                         |              |
|                                            |                          |                                     |                                                                      |                            |                                                              |                                                                                                               |                                                              |                         |              |

## Appendix 2: KAP Questionnaire for participating health workers

|   | Label: English | Type  | Choice list | Hint: English |
|---|----------------|-------|-------------|---------------|
|   | Identification |       |             |               |
| 1 |                | Start |             |               |

|    |                                                                                                                                                                                     |            |                |                                |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|----------------|--------------------------------|
| 2  |                                                                                                                                                                                     | End        |                |                                |
| 3  |                                                                                                                                                                                     | Today      |                |                                |
| 5  | Interviewer unique identifier                                                                                                                                                       | number     |                |                                |
| 6  | Region                                                                                                                                                                              | select_one | East           |                                |
| 7  | District                                                                                                                                                                            | select_one | district_list  |                                |
| 8  | Health facility                                                                                                                                                                     | select_one | facility_code  |                                |
| 10 | Sex                                                                                                                                                                                 | select_one | Sex            |                                |
| 11 | Age (years)                                                                                                                                                                         | number     |                |                                |
|    | <b>Thank you for your willingness to participate in this study. We are interested in understanding more about malaria, and how you diagnose and treat malaria in this facility.</b> |            |                |                                |
| 12 | What is your current occupational category?                                                                                                                                         | select_one | occupation     |                                |
| 13 | What are your qualifications?                                                                                                                                                       | select_one | qualifications |                                |
| 14 | What year did you graduate (or complete studies) with this qualification?                                                                                                           | number     |                | (yyyy)                         |
| 15 | How many years of experience have you had in this occupational category?                                                                                                            | number     |                | (If less than 1 year, enter 0) |
| 16 | In what year did you start working in this health facility?                                                                                                                         | number     |                | (yyyy)                         |

|                                                                                                    |                                                                                                                                    |                 |                |                                                                                                         |
|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------|---------------------------------------------------------------------------------------------------------|
| 17                                                                                                 | In an average week, how many hours do you work in this facility?                                                                   | number          |                | (If hours per week are not consistent, average out the number of hours per month and divide this by 4.) |
| <b>Now I would like to ask you a few more questions about diagnosing malaria.</b>                  |                                                                                                                                    |                 |                |                                                                                                         |
| 18                                                                                                 | In your current position, and as a part of your work for this facility, do you personally diagnose (test) and/or treat malaria?    | select_one      | diagnose_treat |                                                                                                         |
| 19                                                                                                 | If no, is it possible that you might be called on to diagnose malaria in patients in the future?                                   | select_one      | yes_no_idk     |                                                                                                         |
| 20                                                                                                 | How frequently do you, personally, administer malaria RDTs in this facility? Administering an RDT means that you perform the test. | select_one      | frequency      |                                                                                                         |
| 21                                                                                                 | How frequently do you, personally, use RDT results in deciding how to treat patients?                                              | select_one      | frequency      |                                                                                                         |
| 22                                                                                                 | How frequently do you, personally, record the RDT results in either the OPD or laboratory register?                                | select_one      | frequency      |                                                                                                         |
| <b>I would now like to ask you some questions about your knowledge and perceptions of malaria.</b> |                                                                                                                                    |                 |                |                                                                                                         |
| 23                                                                                                 | What do you think is the cause of malaria?                                                                                         | select_multiple | malaria_causes | Do not prompt. Select all that apply. Then ask: Anything else?                                          |

|                                                                                                       |                                                                                                                                                                                |                 |                    |                                                                |
|-------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|----------------------------------------------------------------|
| 24                                                                                                    | How can someone protect himself or herself against malaria?                                                                                                                    | select_multiple | malaria_prevention | Do not prompt. Select all that apply. Then ask: Anything else? |
| 25                                                                                                    | What signs or symptoms would lead you to think that a person has malaria?                                                                                                      | select_multiple | malaria_symptoms   | Do not prompt. Select all that apply. Then ask: Anything else? |
| 26                                                                                                    | What are the main danger signs of malaria?                                                                                                                                     | select_multiple | malaria_danger     | Do not prompt. Select all that apply. Then ask: Anything else? |
| 27                                                                                                    | As a healthcare provider, what makes you certain that a patient has malaria?                                                                                                   | select_multiple | malaria_diagnosis  | Do not prompt. Select all that apply. Then ask: Anything else? |
| <b>Now I'm going to ask you about trainings that occurred off-site, away from your place of work.</b> |                                                                                                                                                                                |                 |                    |                                                                |
| 28                                                                                                    | Have you received any pre-service or in-service training, training updates, or refresher trainings <b>off site</b> on topics related to diagnosis and/or treatment of malaria? | select_one      | yes_no             |                                                                |
| 29                                                                                                    | If yes, what types of off-site trainings on malaria diagnosis and treatment have you received?                                                                                 | select_multiple | training_type      | Do not prompt. Select all that apply. Then ask: Anything else? |
| 30                                                                                                    | Have you received any pre-service or in-service training, training updates, or refresher trainings <b>off site</b> in administering malaria RDTs?                              | select_one      | yes_no             |                                                                |
| 31                                                                                                    | If yes, what types of off-site trainings on malaria RDTs have you received?                                                                                                    | select_multiple | training_type      | Do not prompt. Select all that apply. Then ask: Anything else? |

|                                                                                                                                                                                                   |                                                                                                                                 |            |                       |        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|------------|-----------------------|--------|
| 32                                                                                                                                                                                                | In what year did you last receive training off site to administer a malaria RDT?                                                | number     |                       | (yyyy) |
| <b>I would now like to ask you about trainings that occurred on-site at your place of work.</b>                                                                                                   |                                                                                                                                 |            |                       |        |
| 33                                                                                                                                                                                                | Have you received on the job mentorship including onsite job training related to diagnosis and/or treatment of malaria?         | select_one | yes_no                |        |
| 34                                                                                                                                                                                                | Have you received on the job mentorship including onsite job training related to administering malaria RDTs?                    | select_one | yes_no                |        |
| 35                                                                                                                                                                                                | In what year did you last receive training on the job mentorship or onsite job training to administer a malaria RDT?            | number     |                       | (yyyy) |
| <b>I would like to ask you some questions about supervision you have personally received. This supervision may have been from a supervisor either from this facility or outside the facility.</b> |                                                                                                                                 |            |                       |        |
| 36                                                                                                                                                                                                | Have you received technical support or supervision in your work that touched on malaria diagnosis or treatment?                 | select_one | yes_no                |        |
| 37                                                                                                                                                                                                | If yes, when was the most recent time you received technical support or supervision related to malaria diagnosis and treatment? | select_one | supervision_frequency |        |

|                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                      |            |        |        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------|--------|
| 38                                                                                                                                                                                                                                                                                                                                                                            | In what year was the most recent time you received technical support or supervision related to malaria diagnosis and treatment in your work?                         | number     |        | (yyyy) |
| 39                                                                                                                                                                                                                                                                                                                                                                            | How many times in the past six months has your work on malaria diagnosis or treatment been supervised or have you received technical support?                        | number     |        |        |
| 40                                                                                                                                                                                                                                                                                                                                                                            | The last time you were personally supervised or received technical support for malaria diagnosis or treatment, did your supervisor observe you administering an RDT? | select_one | yes_no |        |
| <b>In the next set of questions, I'm going to ask you whether you agree, disagree or feel uncertain about the statement that I read to you, and how strongly you feel this way. You can answer that you strongly disagree, somewhat disagree, somewhat agree or strongly agree. If you don't know or are uncertain, you can respond that you don't know or are uncertain.</b> |                                                                                                                                                                      |            |        |        |
| 41                                                                                                                                                                                                                                                                                                                                                                            | I believe that I can administer/perform a malaria RDT correctly.                                                                                                     | select_one | likert |        |
| 42                                                                                                                                                                                                                                                                                                                                                                            | It is easy to administer malaria RDTs in this facility.                                                                                                              | select_one | likert |        |
| 43                                                                                                                                                                                                                                                                                                                                                                            | I have enough time to administer malaria RDTs correctly in this facility for all patients who need them.                                                             | select_one | likert |        |
| 44                                                                                                                                                                                                                                                                                                                                                                            | I have enough time to wait for the RDT results and use them to inform the treatment that I prescribe for this patient                                                | select_one | likert |        |

|                                                                                            |                                                                                                                                                             |                 |                  |                                                                |
|--------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------|----------------------------------------------------------------|
| 45                                                                                         | I believe that the malaria RDTs can accurately diagnose malaria in my patients.                                                                             | select_one      | likert           |                                                                |
| 46                                                                                         | I regularly have all the supplies that I need in order to administer a malaria RDT correctly.                                                               | select_one      | likert           |                                                                |
| 47                                                                                         | I have reference material (job aids, protocols, other materials) available to me that I can consult if I am unsure how to administer/perform a malaria RDT. | select_one      | likert           |                                                                |
| <b>I would like to ask you some questions about what you know about malaria diagnosis.</b> |                                                                                                                                                             |                 |                  |                                                                |
| 48                                                                                         | Which method do you prefer to use to diagnose malaria: microscopy, malaria RDTs or clinical signs and symptoms (presumptive diagnosis)?                     | select_one      | diagnosis_method |                                                                |
| 49                                                                                         | Do you take blood from the finger or a vein for a malaria RDT?                                                                                              | select_one      | RDTblood         |                                                                |
| 50                                                                                         | Is there a way to know if an RDT test is working correctly? If so, how?                                                                                     | select_one      | RDTConclusive    |                                                                |
| 51                                                                                         | Is it possible for a patient to have a positive RDT test even if they do not currently have malaria?                                                        | select_one      | yes_no_idk       |                                                                |
| 52                                                                                         | What should you do if there is no C line after the test has been implemented and the correct amount of time has passed?                                     | select_multiple | nocontroline     | Do not prompt. Select all that apply. Then ask: Anything else? |
| 53                                                                                         | Is it possible for a patient to have a negative RDT test when they actually have a malaria infection?                                                       | select_one      | yes_no_idk       |                                                                |

|                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                         |            |               |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|------------|---------------|--|
| 54                                                                                                                                                                                                                                                                                                                                                                                 | Under what circumstances should you treat a patient with an antimalarial even if their RDT returns a negative result?   | select_one | Treatnegative |  |
| <b>For this section, I would like to ask how you feel about malaria RDTs compared to microscopy for diagnosing malaria. When I refer to patients, please think about young children. You can answer that you strongly disagree, somewhat disagree, somewhat agree or strongly agree. If you don't know or are uncertain, you can respond that you don't know or are uncertain.</b> |                                                                                                                         |            |               |  |
| 55                                                                                                                                                                                                                                                                                                                                                                                 | I use malaria RDTs to diagnose malaria because the patients at this health facility expect me to use them.              | select_one | likert        |  |
| 56                                                                                                                                                                                                                                                                                                                                                                                 | I use malaria RDTs to diagnose malaria because my coworkers at this health facility expect me to use them.              | select_one | likert        |  |
| 57                                                                                                                                                                                                                                                                                                                                                                                 | I use malaria RDTs to diagnose malaria because my supervisor expects me to use them.                                    | select_one | likert        |  |
| 58                                                                                                                                                                                                                                                                                                                                                                                 | I use malaria RDTs to diagnose malaria because the national malaria treatment guidelines require me to use them.        | select_one | likert        |  |
| 59                                                                                                                                                                                                                                                                                                                                                                                 | I use malaria RDTs to diagnose malaria because I believe that they are the best way to diagnose malaria in my patients. | select_one | likert        |  |
| 60                                                                                                                                                                                                                                                                                                                                                                                 | I believe that malaria RDTs are and microscopy are equally accurate for diagnosing malaria.                             | select_one | likert        |  |

|                                                                                                               |                                                                                                                                                                                   |                 |                |                                                                |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|----------------|----------------------------------------------------------------|
| 61                                                                                                            | I believe that showing patients or their caregivers a <b>positive</b> malaria RDT result helps explain (or justify) why I am prescribing treatment with an antimalarial medicine. | select_one      | likert         |                                                                |
| 62                                                                                                            | I believe that showing patients or caregivers a <b>negative</b> malaria RDT result helps explain (or justify) why I am not prescribing treatment with an antimalarial medicine.   | select_one      | likert         |                                                                |
| 63                                                                                                            | I worry that a malaria RDT test might be wrong if a patient has fever but the RDT is negative.                                                                                    | select_one      | likert         |                                                                |
| 64                                                                                                            | I worry <b>more</b> that a negative malaria RDT test might be wrong if the patient is a child than if the patient is an adult.                                                    | select_one      | likert         |                                                                |
| <b>I would like to ask about options you have for diagnosis and treatment of cases that are RDT-negative.</b> |                                                                                                                                                                                   |                 |                |                                                                |
| 65                                                                                                            | If an RDT is negative, I have diagnostic tests for other diseases at this facility that I can use to try to find the cause of illness.                                            | select_one      | likert         |                                                                |
| 66                                                                                                            | If an RDT is negative, I have medicines at this facility that I can use to treat the patient other than antimalarials.                                                            | select_one      | likert         |                                                                |
| 67                                                                                                            | In what months of the year is malaria more common (more of a problem) in this facility?                                                                                           | select_multiple | malaria_season | Do not prompt. Select all that apply. Then ask: Anything else? |

|                                                                                                     |                                                                                                                     |            |                  |  |
|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|------------|------------------|--|
| 68                                                                                                  | During the months when malaria is more common, do you prefer to use RDTs or signs and symptoms to diagnose malaria? | select_one | diagnosis_choice |  |
| 69                                                                                                  | During the months when malaria is less common, do you prefer to use RDTs or signs and symptoms to diagnose malaria? | select_one | diagnosis_choice |  |
| <b>Thank you very much for participating in this survey. We will now move to the RDT checklist.</b> |                                                                                                                     |            |                  |  |

### Appendix 3. In Depth questionnaire-

#### Name and Title, role in study

1. Please provide general impressions on the study- what went well and what did go well
2. Could manual and digital counts help improve quality of malaria surveillance data? Please explain
3. Could manual and digital meetings help improve malaria case management? Please explain
4. Could manual and digital counts help improve stock management practices of malaria commodities? Please explain
5. Could the counts reduce stock outs of RDTs and/or ACTs? Please explain
6. Would you recommend a manual count, using the digital tool, or both? Please explain
7. What would you change about the process to collect and perform the RDT counts
8. Would you recommend continuing the counts outside of the study?
9. Do you have any other feedback for the study team?