OGUN STATE HEALTH RESEARCH ETHICS COMMITTEE (OGHREC) RESEARCH PROTOCOL SUBMISSION

Title: Evaluation of Foldscope & Microfluidics Diagnostics as a low-cost point of care (POC) for Community-led Schistosomiasis Control: A Pilot Study

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List of Abbreviations

CHEW: Community Health Extension Worker

FGD: Focus Group Discussion

FGS: Female Genital Schistosomiasis

HIYH: Health in Your Hands

HPV: Human Papillomavirus

KII: Key Informant Interview

LGA: Local Government Area

NPV: Negative Predictive Value

NTD: Neglected Tropical Disease

OGHREC: Ogun State Health Research Ethics Committee

PPV: Positive Predictive Value

WHO: World Health Organization

Protocol/Proposal Summary

This study aims to evaluate the effectiveness of the Foldscope, a low-cost paper microscope, for diagnosing *Schistosoma haematobium* in urine samples within rural Nigerian communities, particularly in rural Ogun state. The project will assess diagnostic accuracy, community acceptability, and feasibility of implementation through collaboration with local community health extension workers (CHEWs) and volunteers.

The study will compare Foldscope-based microscopy workflow with conventional methods, focusing on the effectiveness and accuracy of this diagnostic tool paired with a reusable microfluidic device for trapping eggs in urine. Additionally, we will measure feasibility and community acceptability using a mixed-methods approach including focus group discussions and key informant interviews.

The research will be conducted in selected rural communities of Abeokuta North and Odeda LGAs, near the Oyan River Dam in Ogun State, with a sample size of 365 participants. The

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study employs a cross-sectional design with both quantitative and qualitative components to evaluate the diagnostic tool's performance.

The expected benefit is the development of a sustainable, community-based diagnostic solution that could improve schistosomiasis surveillance in resource-limited settings, potentially transforming community-based disease detection and treatment strategies.

Chapter 1: Introduction

Background

Schistosomiasis is a significant public health issue in Nigeria, particularly in rural areas where access to low-cost diagnostics and treatment is limited by numerous barriers. Urogenital schistosomiasis is prevalent in rural areas where people rely on natural freshwater, with transmission depending on the abundance of the primary snail host (Ezeh et al., 2019). While *Schistosoma haematobium* infection is currently diagnosed mainly via traditional light microscope inspection of expensive polycarbonate membrane filtered urine, the Foldscope presents an opportunity to provide low-cost, portable diagnostics, potentially transforming community-based disease detection and treatment strategies (Ephraim et al., 2015). However, there is a need to evaluate the use of the Foldscope for this purpose in the hands of community health extension workers (CHEWs) in rural settings, to better understand how this may be incorporated into control strategies. Additionally, there is no current suitable option for sample preparation that is cost-effective and does not require electricity. In the present study, we aim to fill these gaps in current knowledge.

Statement of the Problem

Studies have found the highest prevalence rates of schistosomiasis in school-aged children and young women, and a high prevalence of urogenital schistosomiasis in Nigeria in many endemic states despite ongoing mass drug administration with praziquantel (Ezeh et al., 2019; Archer et al., 2024; Faust et al., 2021; Mtethiwa et al., 2015). Classic symptoms include hematuria, abdominal pain, and fatigue (WHO, 2023). Of particular concern is the development of female genital schistosomiasis (FGS), which can harm female reproductive organs and increase the risk for infertility, and HPV infection. FGS has been highly associated with bladder cancer, particularly squamous cell carcinoma and cervical cancer, which is associated with high rates of HPV infection in patients with FGS (Chatterji et al., 2024).

Geographical, financial, social and educational barriers currently prevent adequate diagnosis and screening in hyper-endemic (>50% endemicity) zones of schistosomiasis in Nigeria, including Ogun state (Ezeh et al., 2019). Traditional testing methods require trained personnel, costly lab equipment, and centralized facilities, making them less accessible. In rural communities, long travel distances to healthcare facilities and high costs associated with services deter individuals from seeking diagnosis (Van et al., 2020; Dawaki et al., 2015). This is exacerbated by limited awareness of schistosomiasis, limited recognition of the presenting symptoms by healthcare workers, as well as social stigma surrounding the presenting symptoms, leading to delays in seeking healthcare for those affected (Faust et al., 2020; Van et al., 2020; Dawaki et al., 2015). Local scholars point to a gap between policy-making and control measures for schistosomiasis, as well as a lack of clarity about the number of people affected by S. haematobium infection in endemic areas, making epidemiological data difficult to determine (Ezeh et al., 2019).

Justification/Significance of the Study

Commented [UE2]: An important justification is that schistosomiasis has been targeted for elimination as a public health problem by WHO by 2030. Therefore low-cost community participatory diagnostics POC for test and treat is urgently need particularly in communities where MDA has been stop or where prevalence is <10%. See WHO recommendation #2 (WHO 2022, Oluwole et al 20220. See attached papers

As schistosomiasis poses multifactorial challenges, a community-based, low-expense solution for diagnosing Schistosoma haematobium in urinary samples is needed. Schistosomiasis has been targeted for elimination by the WHO by 2030. Low-cost community participatory diagnostics and POC solutions for testing and subsequential treatment is urgently needed particularly in communities where MDA has been stopped or where prevalence is <10%, according to WHO recommendations and guidelines on control of schistosomiasis (WHO 2022, Oluwole et al 2022). The project aims to work with local health workers in Foldscope-based microscopy, comparing its diagnostic accuracy, cost-effectiveness, and community acceptability to conventional microscopy methods. By empowering communities to diagnose schistosomiasis in a way that would reduce financial and travel barriers, this initiative aims to contribute to schistosomiasis control efforts.

We will also assess the use of a reusable microfluidic device capable of trapping Schistosoma haematobium eggs (Xiao et al., 2016) as the slide containing the urine sample, in order to evaluate the utility of trapping the eggs from urine mechanically as opposed to relying on centrifugation or expensive filtering, which relies on expensive equipment. To enhance the impact and scalability of this project, we aim to partner with national, state, and local leadership in Nigeria, and individuals already engaged in relevant public health and research initiatives, to build on existing work that has been done.

We propose to evaluate the effectiveness of the Foldscope microscope and a microfluidic slide as diagnostic tools in Nigerian regions impacted by *Schistosoma haematobium*, in communities near the Oyan River Dam in Ogun State, where there is a recorded high burden of this disease (Akinwale, 2010; Ekpo, 2012). Findings from this study could aid in further research to inform

the development of scalable diagnostic strategies for rural settings incorporating accessible tools, communication, and education into control efforts.

Chapter 2: Research Objectives

2.1 General Objective

The central objective is to evaluate the use of Foldscope-based microscopy in an endemic area within a community of known high prevalence, comparing its diagnostic accuracy, cost-effectiveness, and community acceptability to conventional microscopy methods. With collaboration from local leadership, we aim to evaluate:

- The effectiveness of the Foldscope (Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy)
- Feasibility (using a mixed-methods approach)
- Community acceptability & barriers of this Foldscope-based microscopy workflow in the diagnosis of genitourinary schistosomiasis caused by *Schistosoma haematobium*

2.2 Specific Objectives

1. To determine the effectiveness of Foldscope microscopy for *Schistosoma haematobium* detection, as measured by sensitivity, specificity, PPV, NPV, and accuracy of this diagnostic tool, as well as the level of agreement between trained lab scientists and CHEWs using the Foldscope.
2. To assess community feasibility of implementation, and opportunities for educational interventions for community health extension workers (CHEWs).

3. To assess acceptability and barriers encountered using the Foldscope in this clinical setting vs. conventional methods, as measured by focused group discussions (FGDs), structured in-depth interviews, and key-informant interviews (KIIs) with community leaders and current control effort leaders.

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Chapter 3: Research Methods

METHODOLOGY

3.1 STUDY DESIGN

This is a mixed methods cross-sectional study aimed at evaluating Foldscope-based microscopy against conventional diagnostic methods. All samples will be examined with the current gold standard in addition to the experimental process. It will also incorporate qualitative research components to assess community perceptions and implementation feasibility.

3.2 METHODOLOGY BY OBJECTIVE

3.2.1 EFFECTIVENESS OF THE FOLDSCOPE

INCLUSION CRITERIA

This study will include individuals aged 5 years or older with a history of freshwater exposure, recent travel from endemic areas, or hematuria/urinary symptoms. Must be able to provide

informed consent (or guardian consent for minors). Capable of providing a urine sample of at least 30 mLs.

EXCLUSION CRITERIA

Any clinical criteria deemed inappropriate for study inclusion by the screening clinician will be considered exclusion criteria.

STUDY SETTING

This study will be conducted in Ogun State, within Imala Odo and Imala communities near Oyan River Dam. These two areas have been evaluated for prevalence of schistosomiasis, and 72% prevalence was found in Imala Odo (Ekpo, 2012). Ogun State has been selected due to the presence of key collaborators at the Federal Medical Center Abeokuta and Sightsavers, who have prior experience with prevalence studies in rural communities. We have chosen Imala Odo and Imala based on recent measures of high prevalence in Imala Odo (greater than 90% from unpublished report) and decreasing prevalence in Imala, following conversations with local parasitologist and schistosomiasis expert, Dr. Uwem Ekpo. The duration of the study will be at least eight days (Allowing ample time for methodology) visiting Imala and Imala Odo and the surrounding area in July-August 2025.

Sample Size Determination

First, we assessed the current average prevalence of schistosomiasis in Oyan River Dam communities as 52% based on the existing literature (Akinwale, 2010; Ekpo, 2012). The formula for calculating the required sample size for sensitivity estimation in a diagnostic accuracy study was applied as follows,

assuming a finite number of population of 1600 individuals since we are focusing on two communities with a limited population:

$$N = \frac{Z^2 * Se * (1 - Se)}{d^2 * P}$$

Where:

- N = Minimum required number of infected individuals
- Z = Standard normal deviate corresponding to a 95% confidence level (1.96)
- Se = Expected sensitivity of the diagnostic test (assumed 80% or 0.80)
- d = Desired precision (5% or 0.05)
- P = Prevalence of infection in the study population (52% or 0.=52)

Substituting values:

$$N = \frac{(1.96)^2 * 0.80 * (1 - 0.80)}{(0.05)^2 * 0.52}$$

$$N \approx 473$$

To adjusted for a finite population of 1600, we will apply to finite population correction:

$$Nadjusted = \frac{N}{1 + (N / Npopulation)}$$

Substituting:

$N_{adjusted} = \frac{473}{1 + (473/1600)} = 365$

Thus, we will aim to recruit 365 people for this study.

Assumptions and Considerations:

- The expected sensitivity of the Foldscope is assumed to be 80% based on preliminary estimates.
- The 52% prevalence is a liberal estimate that represents historically high infection rates (Ekpo, 2012) observed in Oyan Reservoir communities, but this is likely far higher than the existing situation today in Imala, while Imala Odo likely faces much higher prevalence. There is a lack of existing up-to-date data in this region, so we are using this number to reflect an approximate average for the region based on existing data.
- A 5% precision margin aligns with standard diagnostic accuracy study methodologies.
- The study is primarily focused on sensitivity estimation; specificity assessment is exploratory and may be limited due to the high prevalence of infection.

Thus, we will aim to recruit 365 people to be included in this study.

Assumptions:

- The expected sensitivity of the Foldscope is assumed to be 80% based on preliminary estimates
- The 52% prevalence represents an approximate average for the region based on existing data
- A 5% precision margin aligns with standard diagnostic accuracy study methodologies
- A 10% buffer will be added to account for potential dropout rates, meaning 400 in total as a goal for recruitment, meaning 50 people per day over an 8 day period.
- No adjustments have been made for dropout rates or misclassification errors; however, a small recruitment buffer may be considered if needed.

To ensure a statistically robust estimate of sensitivity, the study will recruit 365 participants from these Oyan Reservoir communities.

SAMPLING METHODS

Participants will be selected via convenience sampling. Over the course of two days at each study site, participants will be recruited by community mobilizers and Health In Your Hands (HIYH) team members/affiliates to attend a screening clinic. The screening clinic will be set up at the physical location of the community leadership's choosing and may include sites such as the local primary school or community meeting center. Participants who present to the screening clinic will be assessed to determine if they meet inclusion criteria. Those meeting inclusion criteria will be asked to provide a urine sample. Participants may collect the urine sample at a nearby restroom with adequate privacy or complete the collection at home and return with their sample, per patient preference. Each urine sample will be assigned a unique identifier with the associated name and contact information held securely in a separate location for diagnostic follow-up.

DATA COLLECTION TOOLS AND ADDITIONAL TECHNIQUES

At least 30 mL of urine must be collected from each participant. Of this, 10 mL will be used for the current gold standard diagnostic technique, microfiltration with 12mm, 12 micrometer pore size polycarbonate membranes, followed by microscopic evaluation with standard light microscopy at a 20x and 40x objective. For the gold standard microscopy, we will bring a microscope, generator (if necessary), and a Schistosomiasis urine filtration kit to the screening clinic location to expedite testing and diagnosis. The remaining urine sample will be used in the experimental arm of the study, utilizing our novel microfluidic device and Foldscope

microscope. CHEWs and clinicians recruited via the methodology described in the “community feasibility” section will conduct processing and diagnosing of urine samples in experimental arms. Prior to participating in the experimental arm, participating CHEWs and clinicians will receive educational training on how to utilize the microfluidic device and Foldscope, as outlined in the “Community Feasibility” section below. During the experimental arm, each CHEW or clinician will have access to a Foldscope, light module, 50x, 150x, and 340x lenses, and a phone provided by the HIYH team to assist in visualization. Using these tools, each participant will provide a “positive” or “negative” determination of schistosomiasis infection per sample based on the positive identification of one or more eggs. Compared to the gold standard light microscopy, the sensitivity, specificity, positive predictive value, and negative predictive value of the experimental arm will be calculated.

3.2.2 COMMUNITY FEASIBILITY

STUDY POPULATION

This population will include community health extension workers or other clinicians who spend the majority (>50%) of their work hours serving rural communities. Further inclusion criteria include the clinical qualifications to diagnose and treat schistosomiasis infections and willingness to participate in both phases of the pilot study. The duration of the study will be at least two days during the period of July-August 2025.

EXCLUSION CRITERIA

Exclusion criteria include individuals who (1) do not hold clinical qualifications to diagnose or treat schistosomiasis, (2) do not work predominantly in a rural community, (3) do not agree to

participate in either the processing, diagnostics, or post-participation qualitative interview, (4) cannot provide informed consent, or (5) cannot understand provided verbal or written education materials due to language barriers.

STUDY SETTING

This study will be conducted in Ogun State, within Imala Odo and Imala communities, or additional near Oyan River Dam.

SAMPLE SIZE DETERMINATION

Participants will engage in the experimental arm as described in the above "Effectiveness of the Foldscope" section as well as a qualitative follow-up session. Based on published literature, the appropriate number of participants for qualitative data collection is 10-20(Sharma et al., 2024). Thus, we will aim to recruit 10-20 CHEWs or clinicians who will engage in both project components. As we are not comparing the accuracy of Foldscope diagnostics between participants, but rather as an average relative to the gold standard, no minimum sample size is necessary beyond what is needed for qualitative data accuracy.

SAMPLING METHODS

Participants will be recruited via convenience sampling. Community health workers and local clinicians will be recruited from Imala, Imala Odo, and surrounding communities, as deemed appropriate and facilitated by local partners or affiliates.

DATA COLLECTION TOOLS AND ADDITIONAL TECHNIQUES

Participants should expect to spend at least one full day participating in the study. This includes screening and diagnosing urine samples with Foldscope microscopy as well as participating in a qualitative, in-depth structured interview with a HIYH team member. At the beginning of their participation, they will receive no more than 1 hour of education and direct instruction on the proper utilization of the Foldscope. They may ask HIYH team members for further logistical support during the course of the experiment, but they may not receive assistance in making a positive or negative determination of schistosomiasis presence in the sample.

Following participation in the experimental arm, each participant will participate in an in-depth structured interview with a member of the HIYH team. This interview is expected to last between 30-60 minutes. In-depth structured interview questionnaires may be found in the appendix.

Each CHEW/clinician participant will receive compensation upon completion of both the diagnostic and qualitative components. Compensation per day of participation will be 150% of Ogun state's daily rate for CHEWs.

3.2.3 ACCEPTABILITY AND BARRIERS

STUDY POPULATION

This population includes adults residing in Imala or Imala Odo, CHEWs or clinicians in Imala, Imala Odo, or surrounding areas, or other stakeholders with a vested interest, knowledge, or experience working with schistosomiasis diagnosis, control, or treatment in Ogun state.

INCLUSION CRITERIA

Must be able to provide informed consent and have time for a discussion.

EXCLUSION CRITERIA

Unable to provide informed consent.

STUDY SETTING

Participation will largely occur in the communities of Imala and Imala Odo, in conjunction with screening clinics. However, should the need for additional or key informant interviews arise, the HIYH team may travel to meet the participant at their preferred location.

SAMPLE SIZE DETERMINATION

In this format of conducting FGDs in qualitative health research, 7-10 individuals in a group for at least two discussions is advisable based on data and theme saturation as well as the practicality of group size (Vasileiou, 2018). Thus, we will aim for a number slightly higher to ensure adequate participation, at 8-12 individuals for each FGD.

SAMPLING METHODS

Participants will be collected via convenience sampling. 8-12 participants will be recruited for each focus group discussion. A minimum of one CHEW/clinician focus group and one community member focus group will be conducted. Additionally, a minimum of one focus group of leadership involved in combating this neglected tropical disease will be conducted. A maximum of three each may be conducted as determined by recruitment outlook.

DATA COLLECTION TOOLS AND ADDITIONAL TECHNIQUES

The goal of this study component is to further understand community perception of the Foldscope, determine cultural or practical barriers as perceived by community members or CHEWs/clinicians, and attempt to solve barriers that may arise.

Following participation in the study, CHEWs may elect to participate in a focus group discussion. The focus group discussion guide may be found in the appendix.

Adults living in Imala or Imala Odo, regardless of their prior participation in the study, may elect to participate in a focus group discussion. The focus group discussion guide may be found in the appendix.

Should the HIYH team identify **key informants** during the study who may provide valuable input or insight, the HIYH team will request that they participate in an in-depth structured interview. Sample interview questionnaire may be found in the appendix. Example key informants include, but are not limited to, community leaders, state NTD coordinators, local government lab technicians, or local Medical Officers of Health.

We aim to conduct a thematic analysis of focus group data using Dedoose. Dedoose is a cloud-based qualitative data analysis software that facilitates the coding, organization, and interpretation of qualitative and mixed-methods research data. Researchers can use Dedoose to import transcripts, categorize themes, apply codes, and conduct text analysis to identify patterns across interviews, focus groups, and any recorded responses from methods described above. The platform's interactive visualizations, co-occurrence matrices, and descriptor tools allow for in-depth comparisons across participant groups. Additionally, Dedoose supports collaborative coding, enabling multiple researchers to work simultaneously on data analysis while maintaining

audit trails and inter-rater reliability checks to ensure consistency. Relative frequency of themes, direct quotations, and proportion of themes according to profession will be examined.

3.3 Data Analysis

3.3.1 Diagnostic Accuracy Data

The following metrics will be calculated using a 2×2 contingency table in GraphPad Prism:

- Sensitivity = (TP/(TP + FN)) * 100
- Specificity = (TN/(TN + FP)) * 100
- PPV = (TP/(TP + FP)) * 100
- NPV = (TN/(TN + FN)) * 100
- Accuracy = (TP + TN)/(TP + TN + FP + FN) * 100
- Kappa statistic (κ) = (Po - Pe)/(1 - Pe)
- McNemar's test will be applied to compare performance between methods
- **Level of agreement between trained lab scientists and CHEWs will be assessed**

rism:

Gold Standard	Foldscope Positive	Foldscope Negative	Total
Positive (True Cases)	TP (True Positives)	FN (False Negatives)	TP + FN

Negative (Non-Cases)	FP (False Positives)	TN (True Negatives)	FP + TN
Total	TP + FP	FN + TN	N (Total Cases)

- Kappa statistics will be used to determine the level of agreement between the Foldscope and the gold standard diagnostic approach.
- McNemar's test will be applied to compare the performance of Foldscope versus gold standard microscopy.

Equations:

Sensitivity = (TP/(TP + FN)) * 100

Specificity = (TN/(TN + FP)) * 100

PPV = (TP/(TP + FP)) * 100

NPV = (TN/(TN + FN)) * 100

Accuracy = (TP + TN)/(TP + TN + FP + FN) * 100

κ = (Po - Pe)/(1 - Pe)

Calculations:

1. Sensitivity (True Positive Rate)

Sensitivity = (TP/(TP + FN)) * 100

Measures the proportion of true infections correctly identified by the Foldscope.

2. Specificity (True Negative Rate)

Specificity = (TN/(TN + FP)) * 100

Measures the proportion of uninfected individuals correctly identified as negative.

3. Positive Predictive Value (PPV)

PPV = (TP/(TP + FP)) * 100

Indicates the likelihood that a positive Foldscope result truly represents an infection.

4. Negative Predictive Value (NPV)

NPV = (TN/(TN + FN)) * 100

Indicates the likelihood that a negative Foldscope result truly represents an absence of infection.

5. Diagnostic Accuracy

Accuracy = (TP + TN)/(TP + TN + FP + FN) * 100

Represents the overall proportion of correctly classified cases.

6. Agreement (Kappa Statistic, κ)

κ = (Po - Pe)/(1 - Pe)

Where:

- PoPo = Observed Agreement (proportion of TP and TN combined)
- PePe = Expected Agreement due to chance

7. McNemar's Test

- Used to compare the Foldscope's performance against the gold standard, testing whether the proportion of false positives and false negatives differs significantly.

All calculations will be performed using GraphPad Prism's Contingency Table and Agreement Analysis tools.

3.7.2 Qualitative Data Analysis

A thematic analysis of qualitative data will be conducted to explore perceived feasibility, acceptability, and barriers to implementing Foldscope-based diagnostics in community settings. Dedoose software will be used to facilitate coding, categorization, and pattern recognition in transcribed focus group discussions (FGDs), key informant interviews (KIIs), and structured interviews with community health extension workers (CHEWs) and other stakeholders. A deductive and inductive coding approach will be applied, incorporating predefined themes (e.g., usability, training needs, perceived accuracy) while allowing for emergent themes identified during coding. Coding reliability will be enhanced through inter-rater agreement, with discrepancies resolved through discussion. Stakeholder perspectives (e.g., CHEWs vs. community members) will be compared to identify variations in diagnostic feasibility and acceptability. Sentiment analysis will be performed to assess overall attitudes toward Foldscope implementation. Findings from FGDs and KIIs will be triangulated with diagnostic accuracy results to explore how perceived usability and feasibility correlate with Foldscope performance metrics. Descriptive statistics (e.g., frequency of themes, coding matrices) will be used to quantify qualitative findings where applicable. This approach will provide a comprehensive understanding of diagnostic implementation challenges and inform future scale-up strategies for community-based schistosomiasis control.

3.8 Exploratory Environmental Mapping Component (Pilot Project)

In collaboration with local partners Daniel Amao (videographer and drone operator) and Olubukola Adelakun (snail habitat researcher), an exploratory environmental analysis component will be piloted alongside the core diagnostic project. The goal is to evaluate whether remote

sensing—via drones and satellite imagery—can assist in identifying areas of elevated schistosomiasis risk through environmental mapping of snail habitats.

Preliminary activities will include:

- Acquiring satellite images of the Oyan Reservoir region from open-access platforms such as Earth.ESA or evaluating high-resolution providers such as MAXAR
- Applying and testing/adapting the AI-based modeling approach described by Wood et al. (2019), which uses satellite vegetation signatures to predict suitable snail habitats for *Bulinus* species, the intermediate host of *Schistosoma haematobium*
- Comparing predicted high-risk vegetation zones with historical schistosomiasis incidence data in Ogun State
- Conducting drone-based field validation in selected areas to assess the feasibility of real-time, community-driven mapping in partnership with local collaborators, with prior community leadership permission

This pilot aims to assess whether these remote sensing techniques could contribute to future, sustainable, community-led surveillance of high-risk transmission zones. If the model is predictive, we can evaluate integration into future work to complement diagnostic studies.

Hypothesis: Remotely-sensed vegetation and water body patterns can serve as indirect indicators of *Schistosoma*transmission risk, informing community-level prevention strategies in endemic regions.

ETHICAL CONSIDERATIONS

Ethical approval is sought from **Ogun institutional and ethical review boards.** Written informed consent will be secured from all participants (or guardians for minors). Community health worker participants will be informed of the aims of the study, which will entail them answering a set of questions. Written consent will be collected for anybody participating in qualitative data collection, as well. The option to not participate will be fully communicated. For patients participating, the notification will be given that we are examining their urine and that their health information will be kept fully confidential. Written informed consent will be obtained from each respondent and participants will not be coerced in any way. They will be given the choice to participate or not in the study and the free will to withdraw at any time if they so choose with no negative consequences and appropriate clinical care maintained. No names will be written on consent forms or questionnaires by the research team, so respondents can be assured of confidentiality. Image data stored securely on encrypted, password-protected devices with no mention of names.

4.4 Benefits and Risks

Benefits:

- Immediate diagnosis and treatment for infected participants
- Potential development of improved diagnostic tools for the community
- Knowledge generation to benefit schistosomiasis control programs

Risks:

- Minimal discomfort during urine sample collection
- Potential breach of confidentiality (mitigated by strict data protection protocols)

4.5 Compensation and Incentives

- CHEW/clinician participants will receive appropriate compensation upon completion of both the diagnostic and qualitative components
- Community participants will not receive direct financial compensation but will benefit from free screening and treatment if infected

Chapter 5: Result Dissemination

5.1 Notification of Results

5.1.1 Individual Results

- Individual test results from urine samples will be communicated within hours (estimated 10-20 minutes)
- Positive cases will be referred for standard treatment following national guidelines.
- Participants will receive appropriate counselling about their results

5.1.2 Stakeholder Notification

- Meetings with community health workers and local health leaders
- Written summaries in local languages and English to enhance accessibility
- Reports to relevant health authorities and partner organizations

5.2 Anticipated Products and Impact

- Standardized Foldscope diagnostic protocol
- Training materials for health workers
- Documented themes of feasibility to inform future efforts
- Documented themes of community acceptability and barriers
- Data for image analysis algorithms for schistosomiasis detection

5.3 Dissemination Plan

- Application for National Geographic's level 1 grant for Freshwater Storytelling for a 2026 media project
- Peer-reviewed journal submissions with open access, with credit to all parties involved
- Regional and international conference presentations
- Reports to relevant Nigerian health authorities

5.4 Timeline

First phase (April 2025):

- Establish communication and collaboration with national, state, and local government leadership
- Engage community leaders, NTD coordinators, and health workers
- Communicate goals and methods

Second phase (July 2025):

- Train community health workers in microscopy techniques

- Assess diagnostic accuracy vs conventional methods
- Gather qualitative data on feasibility and potential improvements
- Assess infection etiology education and clinical algorithms
- Address usability, training, and logistical challenges
- Optimize protocols for image acquisition, interpretation, and reporting

Third phase (August-December 2025):

- Data analysis
- Manuscript preparation
- Dissemination activities

5.5 Data Sharing and Accessibility

- De-identified datasets will be shared following ethical guidelines and data privacy regulations
- Results will be published in open-access journals to ensure information can be used and scaled up by local or international efforts

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APPENDIX

1. ***Participant Demographics Questionnaire***

2. ***CHEW/Clinician In-Depth Interview Guide***
3. ***General Focus Group Discussion Guide***
4. ***CHEW/Clinician Focus Group Discussion Guide***
5. ***Key Informant Stakeholders Interview***
6. ***Schistosomiasis Urine Screening Informed Consent Form***
7. ***CHEW/Clinician Experimental Participation Informed Consent Form***
8. ***Focus Group Discussion Informed Consent Form***
9. ***Budget***

1. PARTICIPANT DEMOGRAPHICS QUESTIONNAIRE

Instructions:

Thank you for taking the time to complete this survey. This project is led by Health in Your Hands Diagnostics, a group of medical students working closely with doctors and researchers in Abeokuta. The goal of this study is to understand how the Foldscope, a low-cost paper microscope, can be used to help diagnose schistosomiasis. Schistosomiasis is a parasitic worm that lives in freshwater like rivers or lakes. It can infect the urinary tract, such as the bladder, and cause uncomfortable symptoms. Chronic infection increases the risk of cancer. Today, we will be asking you questions about yourself and any symptoms you might have. This survey is expected to take 15 minutes. You can stop at any time, and if you don't feel comfortable answering any questions, please let me know and we will skip it. Do you have any questions before we begin?

1. What is your age?
    a. 5-10 years old
    b. 11-17 years old
    c. 18-30 years old

d. 31-50 years old

e. 51-65 years old

f. More than 65 years old

2. Where do you live?

   a. Imala Odo

   b. Imala

   c. Other: _____

3. How often do you get in freshwater, such as a river or lake?

   a. Never

   b. Once a month

   c. A few times a month

   d. A few times a week

   e. Every day

4. What types of things do you use the river or lake for? Select all that apply.

   a. Washing laundry

   b. Cleaning household items

   c. Bathing

   d. Collecting water

   e. Fishing

   f. Swimming for fun

   g. Religious or cultural reasons

   h. Other: _____

5. When you get in the water, do you notice any plants or vegetation in the water near you?

   a. Yes, lots of it

   b. Yes, there's some

   c. No

d. I'm not sure

6. Before participating in this study, had you heard of schistosomiasis? Did this affect your water activities?
    a. Yes, I knew what it was and avoided getting in the water because of it at least some of the time.
    b. Yes, I knew what it was, but it did not affect how I used the river or lake.
    c. No, I did not know what schistosomiasis was
7. Have you ever been treated for schistosomiasis, either by a medical provider or through mass drug administration?
    a. Yes, multiple times
    b. Yes, but only once
    c. No
    d. I'm not sure
8. In the past two weeks, have you had any of the following symptoms? Select all that apply:
    a. Painful urination (pain or burning when you pee)
    b. Blood in the urine (pee that looks red or dark-coloured)
    c. Frequent urination (needing to pee often)
    d. Difficulty with urination (feeling like it's hard to pee)
    e. Pelvic pain (pain in your lower abdomen, below your belly button)
    f. Incontinence (having a hard time holding your pee or peeing when you don't want to)
    g. Flank pain (pain in your middle back at the bottom of your ribs)
9. If you ever had any of the symptoms listed above, how likely would it be that you'd go to the local clinic for testing and treatment?
    a. Very likely
    b. Possibly
    c. Probably not

d. Definitely not

10. If you were diagnosed with schistosomiasis and given the medication for free, how likely would you be to take it?
    a. Very likely
    b. Possibly
    c. Probably not
    d. Definitely not

2. CHEW/CLINICIAN IN-DEPTH STRUCTURED INTERVIEW GUIDE

Introduction

My name is _____, and I am a member of the Health in Your Hands team. We are a group of students working closely with researchers in Abeokuta to understand schistosomiasis in your community. Thank you for taking the time to talk with me today. The goal of this interview is to discuss your experience using the Foldscope this morning and explore any feedback you might have. This interview is expected to take about 30 minutes. You can stop at any time, and if you don't feel comfortable answering any questions, please let me know and we will skip it. Do you have any questions before we begin?

Instructions

Ask each question in the order provided. Subquestions may be used as probes or to guide the participant's focus, as needed. A translator should be provided for those who would like to interview in their preferred language.

1. How often do you see patients who you suspect might have schistosomiasis?
    a. (Prompts, after respondent's initial expression) Daily? Weekly?
    b. Do people present to the clinic with these concerns in the first place?

    c. Do you consider schistosomiasis infection ever in people presenting with urinary symptoms?

2. When you suspect a patient has schistosomiasis, what do you do?
    a. Do you do any type of screening test, such as urine or stool?
    b. Do you offer treatment based on symptoms alone without further screening?
3. What challenges do you face when trying to diagnose or treat patients who you suspect might have schistosomiasis?
    a. Are there any tools you wish you had access to in order to manage these patients?
    b. Do patients have concerns about the cost of diagnosis or treatment?
    c. Are there any cultural concerns about being diagnosed with schistosomiasis, like shame or stigma?
4. What were your initial thoughts about the Foldscope when you first heard about it?
5. Before trying the Foldscope, did you have any expectations about how easy or hard it would be to use?
    a. If easy, have you used a microscope in the past?
6. Tell me what you thought about the education session we provided prior to you using the Foldscope.
    a. Did you feel like we provided too much, not enough, or the right amount of training?
    b. Was there anything you feel like we left out or that you were confused by?
    c. Was there anything we said or did that was really helpful?
7. When you first used the Foldscope, tell me your initial impressions.
    a. Was it harder or easier to use than you expected?
    b. If you were confused about anything, how quickly were you able to figure it out? Did you figure it out on your own or ask for help?
8. As you continued to use it, did your impressions of it change at all?
    a. Did it get easier or harder as you got more experience with it?

9. Were there any aspects of the process that felt confusing or difficult to use?
    a. Filtration?
    b. Knowing how to do basic movements around the slide?
    c. Knowing how to focus on the slide?
    d. Identifying what was an egg and what wasn't?
10. Were there any aspects of the process that you worked very well?
11. Would you see yourself using the Foldscope to screen patients in your clinic if you had access to one?
    a. If so, what concerns might you have, if any?
12. Compared to your usual management of patients with suspected schistosomiasis, would access to the Foldscope make management easier or harder? Why?
13. The goal of this project is to equip people like you with access to Foldscopes so that you can screen and diagnose patients in your clinic. Knowing this, do you have any recommendations for how we could improve the process, design, or education before we expand the project to a larger number of people?

3. GENERAL FOCUS GROUP DISCUSSION GUIDE (OPTIONAL)

Procedural Note:

A general focus group discussion may be conducted with community members or other local stakeholders should the need to further investigate any themes arise. Considering this, the general focus group is being listed as "optional."

Introduction:

Thank you for taking the time to attend this focus group. This project is led by Health in Your Hands Diagnostics, a group of medical students working closely with doctors and researchers in Abeokuta. The goal of this study is to understand how the Foldscope, a low-cost paper microscope, can be used to help diagnose schistosomiasis. Schistosomiasis is a parasitic worm that lives in freshwater like rivers or lakes. It can infect the urinary tract, such as the bladder, and cause uncomfortable symptoms. Chronic infection increases the risk of cancer. Today, we will be asking this group questions about medical care here in (Imala/Imala Odo) as well as barriers that you might have to access care. This focus group is expected to take between 30-45 minutes. Please remember to respect one another's privacy and not share any information discussed with people outside of this group. We would love to hear from each of you, but if there are ever questions that you do not feel comfortable answering, you do not have to share. You can end participation at any time without any penalty. Does anyone have any questions?

Instructions

Ask each question in the order provided. Subquestions may be used as probes or to guide the participant's focus, as needed. Allow ample time for thoughtful engagement with each question before deploying probes or moving to the subsequent question. A translator should be provided for those who would like to conduct the interview in their preferred language.

1. To start, if you know what schistosomiasis is, can you raise your hand?
2. Can someone who knows what schistosomiasis is explain it to the group?
    a. Facilitator: take note of how they are describing it/any inaccuracies
3. (If many people are familiar) How do people in this community view [KT1] schistosomiasis?
    a. Is it something you think about?
    b. How would you feel if you were diagnosed with it?

4. Many local governments participate in a program called “mass drug administration” where they provide medication to children and adults in the community to try to control schistosomiasis. Has anyone ever participated in this before?
    a. Can you describe your experience?
    b. Did you have any concerns about the program?
5. As an alternative to mass drug administration, we are working on finding an easy way for your local clinic to diagnose schistosomiasis with a microscope and treat only people who test positive. If this was available, what would your thoughts be?
    a. Do you think you would like this option better or worse than MDA?
    b. Are there any hesitations or concerns you have about this?
6. Schistosomiasis can cause urinary symptoms such as pain with peeing or blood in your pee. Some women may find these symptoms embarrassing, even though they’re very common. Would shame or embarrassment affect the likelihood that you’d go to the clinic for these symptoms?
    a. If so, do you have any ideas for how to help with this?
    b. Would you be more likely to get tested if you could provide a urine sample at home instead of in the clinic?
7. We know that sometimes accessing care can be challenging. What barriers do you have to getting medical care?
    a. Facilitator: Please probe financial, transportation, logistical (eg. clinic hours, staff), or cultural (eg. social stigma)
    b. Do you have any ideas to help with these barriers?
    c. Are there any ways that the Foldscope specifically could avoid these barriers?

4. CHEW/CLINICIAN FOCUS GROUP DISCUSSION GUIDE

Introduction:

Thank you for taking the time to attend this focus group. This project is led by Health in Your Hands Diagnostics, a group of medical students working closely with doctors and researchers in Abeokuta. The goal of this study is to understand how the Foldscope, a low-cost paper microscope, can be used to help diagnose schistosomiasis. Schistosomiasis is a parasitic worm that lives in freshwater like rivers or lakes. It can infect the urinary tract, such as the bladder, and cause uncomfortable symptoms. Chronic infection increases the risk of cancer. Today, we will be asking this group questions about medical care here in (Imala/Imala Odo) as well as barriers that you might have to access care. This focus group is expected to take between 30-45 minutes. Please remember to respect one another's privacy and not share any information discussed with people outside of this group. We would love to hear from each of you, but if there are ever questions that you do not feel comfortable answering, you do not have to share. You can end participation at any time without any penalty. Does anyone have any questions before we begin?

Instructions:

Ask each question in the order provided. Subquestions may be used as probes or to guide the group's focus, as needed. Allow ample time for thoughtful engagement with each question before deploying probes or moving to the subsequent question. A translator should be provided for those who would like to conduct the interview in their preferred language. *NTD coordinator team members, LGA coordinator, Director of Public Health, Lab scientists

1. Who do you think would benefit the most from having access to the Foldscope?
2. Do you think access to the Foldscope would be an improvement from current clinical practice?
3. What would make the Foldscope more useful or relevant?
4. How do people in your community generally view schistosomiasis?

5. If community members knew that they could get screened for schistosomiasis at the clinic, what reasons would they have to come or not come to get screened?
    a. What would be the best way to inform community members that this screening option would be available? Word of mouth, flyers, radio?
6. Outside of schistosomiasis, what challenges do people here have accessing healthcare?
7. When you used the Foldscope, what were your perceptions of it?
8. Some women may feel embarrassment or shame about urinary symptoms. Is this something that you think might interfere with the community's willingness to get tested for schistosomiasis?
9. If you had access to the Foldscope in your clinic, how would you fit it into your work?
10. Are there any challenges or hesitations that you'd have about using the Foldscope in your clinic?
    a. Do you have any ideas for solutions to these?
11. Have past health programs faced resistance in this community? If so, why?

5. KEY INFORMANT STAKEHOLDER INTERVIEW GUIDE

Procedural Note

Key informant interviews should be conducted when there is a need for more thematic exploration in a specific area or access to individuals with unique or specialized knowledge. This interview guide is semi-structured and serves as a foundation for thematic exploration. Questions and probes should be adjusted or added according to the unique knowledge or qualifications of the key informant.

Introduction

My name is _____, and I am a member of the Health in Your Hands team. We are a group of students working closely with researchers in Abeokuta to understand schistosomiasis in your community. Thank

you for taking the time to talk with me today. The goal of this interview is to understand the unique perspective that you have as a [insert role title here] and how that may help us better understand schistosomiasis in your community.. This interview is expected to take about 30 minutes. You can stop at any time, and if you don't feel comfortable answering any questions, please let me know and we will skip it. Do you have any questions before we begin?

Instructions

Ask each question in the order provided. Subquestions may be used as probes or to guide the participant's focus, as needed. A translator should be provided for those who would like to conduct the interview in their preferred language.

1. In your work, how do you encounter schistosomiasis currently?
    a. Adjust accordingly for job (eg. clinician, community leader, NTD coordinator, etc)
2. What is the perception of schistosomiasis among the people you serve (eg. patients, fellow community members)?
    a. Do people know what schistosomiasis is?
    b. Does knowledge of schistosomiasis change how people interact with potentially contaminated water, such as in the river or lake?
3. When someone has symptoms of female genital schistosomiasis, like pain with urination, what do they commonly do?
    a. Do they typically present to a local clinic? Is a local or cultural medical provider preferred?
    b. Is shame or embarrassment a concern when seeking treatment?
    c. Is ease of access to clinical care a concern when seeking treatment?

4. What challenges do patients face when trying to receive a diagnosis for their schistosomiasis? What about treatment for their schistosomiasis?
5. What were your initial thoughts about the Foldscope when you first heard about it?
6. Compared to the usual management of patients with suspected schistosomiasis, would access to the Foldscope make management easier or harder? Why?
7. In your role as [insert job title], do you have any specific or unique insights into schistosomiasis in your community?
    a. This can address any spectrum of responses, from exposure to diagnosis/treatment
8. The goal of this project is to equip clinicians in local clinics with access to Foldscopes so that they can screen and diagnose patients in the clinic. Knowing this, do you have any recommendations for how we could improve the project before we expand the project to a larger number of people?

6. SCHISTOSOMIASIS URINE SCREENING INFORMED CONSENT FORM

INFORMED CONSENT FORM

For Participation in Schistosomiasis Urine Screening

Study Title: Foldscope & Microfluidics: Accessible Diagnostics for Community-led Schistosomiasis Control

Principal Investigator(s): Dr. Tope Olubodune

Institution/Affiliation: Federal Medical Center, Abeokuta

Contact Information: olubodunetope@gmail.com

Introduction

You are invited to participate in a study where you will receive free screening for urinary schistosomiasis infection. Before you decide whether to participate, please read the following information carefully. Feel free to ask any questions you may have.

Purpose of the Study

The goal of this study is to understand how the Foldscope, a low-cost paper microscope, can be used to help diagnose schistosomiasis. Schistosomiasis is a parasitic worm that lives in freshwater like rivers or lakes. It can infect the urinary tract, such as the bladder, and cause uncomfortable symptoms. Chronic infection with schistosomiasis increases the risk of cancer.

What Will Happen During the Study?

- You will be asked to provide a urine sample for schistosomiasis testing.
- The sample will be analyzed using the Foldscope as well as via a light microscope, the gold standard for schistosomiasis diagnosis.
- The procedure is non-invasive and will take approximately 10-20 minutes.
- If your test result is positive, you will be referred for further voluntary evaluation and treatment.

Potential Risks and Benefits

- Risks: The risks associated with providing a urine sample are minimal. There may be minor discomfort related to sample collection.
- Benefits: You will receive free schistosomiasis screening, which may help detect the infection early. If you test positive, you will be directed to appropriate voluntary treatment options.

Confidentiality

- Your test results will be kept confidential and used only for research and health monitoring purposes.
- No personal identifying information will be included in any reports or publications.
- Only the research team will have access to your data.

Voluntary Participation

- Your participation is **completely voluntary**. You may choose to withdraw at any time without any consequences.
- You do not have to answer any questions that make you uncomfortable.

Questions & Contact Information

If you have any questions about this study, you may contact Dr. Tope Oludoun at olubodunetope@gmail.com. If you have concerns about your rights as a participant, you may contact the Ethics Committee at Federal Medical Center, Abeokuta.

Consent Statement

I have read and understood the information above. I voluntarily agree to participate in this focus group discussion.

Participant's Name:

Participant's Signature:

Date:

Researcher's Name:

Researcher's Signature:

Date:

7. CHEW/CLINICIAN EXPERIMENTAL PARTICIPATION INFORMED CONSENT FORM

INFORMED CONSENT FORM

For Participation in Foldscope Diagnostics Experiment and Structured Interview

Study Title: Foldscope & Microfluidics: Accessible Diagnostics for Community-led Schistosomiasis Control

Principal Investigator(s): Dr. Tope Olubodune

Institution/Affiliation: Federal Medical Center, Abeokuta

Contact Information: olubodunetope@gmail.com

Introduction

You are invited to participate in a study consisting of two phases. In the first phase, you will be asked to identify schistosomiasis eggs in urine samples using the Foldscope microscope. In the second phase, you will be asked to participate in a structured interview with a member of the research team. Before you decide whether to participate, please read the following information carefully. Feel free to ask any questions you may have.

Purpose of the Study

The goal of this study is to understand how the Foldscope, a low-cost paper microscope, can be used to help diagnose schistosomiasis. Schistosomiasis is a parasitic worm that lives in freshwater like rivers or lakes. It can infect the urinary tract, such as the bladder, and cause uncomfortable symptoms. Chronic infection with schistosomiasis increases the risk of cancer.

What Will Happen During the Study?

- Phase One:
    - You will participate in a brief educational session on how to use the Foldscope
    - You will be presented with de-identified urine samples and asked to process and screen the samples for schistosomiasis using the Foldscope. You will provide a "positive" or "negative" result for each sample. All results will be confirmed by the research team using gold-standard screening.
- Phase Two:
    - You will participate in an in-depth interview with a member of the research team.
    - This interview is expected to take between 30 and 60 minutes.
    - You will be asked questions about your experience in Phase One.

Potential Risks and Benefits

- Risks: As you will be processing human urine samples, there is the possibility that you will come into contact with pathogens. You will be provided with proper personal protective equipment prior to the study.
- Benefits: Your participation will help contribute valuable insights to help us better understand schistosomiasis in your community.

- Compensation: You will be compensated ₦20,000/day for your participation.

Confidentiality

- Your responses will be kept confidential. You will not be personally identified in any reports or publications.
- The discussion will be recorded for research purposes. Only the research team will have access to these recordings.
- You are asked to respect the privacy of other participants by not sharing what is discussed outside of the group.

Voluntary Participation

- Your participation is **completely voluntary**. You may choose to withdraw at any time without any consequences.
- You do not have to answer any questions that make you uncomfortable.

Questions & Contact Information

If you have any questions about this study, you may contact Dr. Tope Oludoun at olubodunetope@gmail.com. If you have concerns about your rights as a participant, you may contact the Ethics Committee at Federal Medical Center, Abeokuta.

Consent Statement

I have read and understood the information above. I voluntarily agree to participate in this focus group discussion.

Participant's Name:

Participant's Signature:

Date:

Researcher's Name:

Researcher's Signature:

Date:

8. FOCUS GROUP DISCUSSION INFORMED CONSENT FORM

INFORMED CONSENT FORM

For Participation in a Focus Group Discussion

Study Title: Foldscope & Microfluidics: Accessible Diagnostics for Community-led Schistosomiasis Control

Principal Investigator(s): Dr. Tope Olubodune

Institution/Affiliation: Federal Medical Center, Abeokuta

Contact Information: olubodunetope@gmail.com

Introduction

You are invited to participate in a focus group discussion as part of a research study. Before you decide whether to participate, please read the following information carefully. Feel free to ask any questions you may have.

Purpose of the Study

The goal of this study is to understand how the Foldscope, a low-cost paper microscope, can be used to help diagnose schistosomiasis. Schistosomiasis is a parasitic worm that lives in freshwater like rivers or lakes. It can infect the urinary tract, such as the bladder, and cause uncomfortable symptoms. Chronic infection with schistosomiasis increases the risk of cancer.

What Will Happen During the Focus Group?

- You will take part in a group discussion with approximately 8-12 participants.
- The discussion will last about 30 minutes.
- A facilitator will guide the discussion using a set of prepared questions.
- The session will be audio-recorded for research purposes, but no names will be included in the final report.

Potential Risks and Benefits

- Risks: There is minimal risk associated with this study. However, as with any group discussion, there is a possibility that others may repeat what was said outside of the session. While we will encourage confidentiality, we cannot guarantee that all participants will maintain it.
- Benefits: Your participation will help contribute valuable insights to help us better understand schistosomiasis in your community.
- Compensation: You will be compensated ₦20,000/day for your participation.

Confidentiality

- Your responses will be kept confidential. You will not be personally identified in any reports or publications.
- The discussion will be recorded for research purposes. Only the research team will have access to these recordings.
- You are asked to respect the privacy of other participants by not sharing what is discussed outside of the group.

Voluntary Participation

- Your participation is **completely voluntary**. You may choose to withdraw at any time without any consequences.
- You do not have to answer any questions that make you uncomfortable.

Questions & Contact Information

If you have any questions about this study, you may contact Dr. Tope Oludoun at olubodunetope@gmail.com. If you have concerns about your rights as a participant, you may contact the Ethics Committee at Federal Medical Center, Abeokuta.

Consent Statement

I have read and understood the information above. I voluntarily agree to participate in this focus group discussion.

Participant's Name:

Participant's Signature:

Date:

Researcher's Name:

Researcher's Signature:

Date:

9. BUDGET

Subject Category	Details	# of subject	# of Days	Per Person Rate (NGN)	Total NGN (Calc)	Cost (USD)	Cost (NGN)
Gold Standard Sample Prep Kit	Urine filtration kits for diagnostics (500 count)	1				$600.00	₦960,000
Standard Light Microscope	Essential for comparison with Foldscope	1				$500.00	₦800,000
Portable Generator	Power source for light microscope in field	1				$100.00	₦160,000
CHEW Compensation	2 CHEWs × 8 days @ ₦20,000/day	2	8	₦20,000	₦320,000	$200.00	₦320,000
Lab Scientists	2 Lab Scientists × 8 days @ ₦25,000/day	2	8	₦25,000	₦400,000	$250.00	₦400,000
Field Supervisor/ Doctor	1 Supervisor × 8 days @ ₦30,000/day	1	8	₦30,000	₦240,000	$150.00	₦240,000
State NTD Coordinator	1 person × 6 days @ ₦35,000/day	1	6	₦35,000	₦210,000	$135.00	₦210,000
Local NTD Coordinators	2 persons × 6 days @ ₦30,000/day	2	6	₦30,000	₦360,000	$230.00	₦360,000
Mobile Phone Equipment	3–4 locally sourced phones for image capture	4				$190.00	₦304,000
PPE & Field Supplies	Gloves, masks, cooler, table, containers, etc.					$200.00	₦320,000
Field Transport	Vehicle rental and driver (reduced local transport)					$500.00	₦800,000
Unforeseen field expenses	Misc.					$100.00	₦160,000
Lodging & In-Country Travel	Accommodations and domestic travel					$500.00	₦800,000
Team Travel (Intl + Local)	Airfare and internal movement for U.S.-based team	2				$2,900.00	₦4,640,000

Dissemination	Stakeholder meetings, briefings, conference preparation	$210.00	₦336,000
Publication (Open Access)	Covered in-kind by Dr. Kristi Tebo	In-kind	In-kind
Foldscope Kits	Provided in-kind by Stanford / Foldscope Instruments	In-kind	In-kind
TOTAL		$9,500.00	₦15,200,000

OGHREC Ethics Review Fee – Budget Justification Note

Based on the OGHREC (Ogun State Health Research Ethics Committee) reviewed fee structure (November 2024), external research projects with a total budget exceeding ₦10 million (approx. $6,250 USD at ₦1,600/USD) are required to pay an ethics review fee of 1% of the total project budget, with a minimum fee of $200 USD.

As a group conducting a U.S.-based research project with a total budget of $9,500 USD (approx. ₦16,000,000), this study falls into that category. Therefore, the required OGHREC fee is:

- 1% of $10,000 = $100, which is below the minimum.
- Thus, the applicable fee is the minimum of $200 USD (₦320,000).