

Prototype Help Guide Heuristics for Malaria Elimination in African Most Populous Country

*Michael Ekholuenetale**

Department of Epidemiology and Medical Statistics, College of Medicine, University of Ibadan, Nigeria

**Corresponding author: Michael Ekholuenetale Federal Housing Estate, Gwarinpa, FCT, Abuja, Nigeria. Tel: +234 (0) 7033019224; 08184776016; Email: mic42006@gmail.com*

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Abstract

Long-Lasting Insecticidal Nets (LLIN) have been proven as a highly effective method for preventing malaria infection and reducing possible morbidity and mortality. Widespread distribution of LLIN has been supported prominently by Global Fund which has yielded rapid increase in LLIN ownership. Albeit, translating the large ownership of LLIN into use has become a nightmare for many passionate public health experts in Nigeria. To achieve this, community-based, multicenter, cluster randomized controlled trial using a mixed methods approach is suggested. A baseline assessment phase and an intervention and evaluation phase will be adopted. Stakeholder engagement, community dialogue, town announcements, radio jingles and compound meetings methods will be used to create awareness in the study communities.

Keywords: Behavior Change Communication; Epidemic; ITN/LLIN; Malaria

Background

According to World Health Organization (WHO) estimates, a total of 216 million cases of malaria were reported in 2016, an increase of approximately 5 million cases over the previous year. The global tally of malaria deaths touched 445 000 deaths, about the same number reported in 2015 [1]. The WHO African Region continues to account for about 90% of malaria cases and deaths worldwide. Fourteen countries in sub-Saharan Africa face nearly 80% of the global malaria burden [1]. The disease is more severe in pregnant women and children under 5 years old. In 2016, approximately half (54%) of individuals at risk of malaria in sub-Saharan Africa used ITN which is the foremost malaria prevention method [1]. Timely diagnosis and treatment is effective in preventing mild cases of malaria from growing into severe disease and death. Across sub-Saharan Africa region, household ownership of at

least one ITN has increased from 50% in 2010 to 80% in 2016. The proportion of households with enough nets (one net for every two people) remains inadequate, at 43% in 2016 [1].

The prevailing inadequate ownership Long Lasting Insecticidal Net (LLIN), low utilization of LLIN and poor skilled health care by children and women alike has reinforced the need for intervention programmes targeting Universal Health Coverage (UHC), which is embedded in the third Sustainable Development Goal (SDG-3) to ensure healthy lives and promote the well-being for all at all age [2]. UHC includes the full spectrum of essential, quality health care services from health promotion to prevention, treatment, rehabilitation and palliative care. Malaria has a history of being a recurring public health problem and a life-threatening disease particularly in endemic areas due to its prevalence and fatality rate, while accounting for approximately one-quarters of childhood mortality in Africa [1]. Though all age groups are susceptible to malaria, it is perceived as the main health problem among women and children. This supports the goal of WHO to end the malaria epidemic by 2030 through its commitment to invest in changing people's health care seeking behavior [3].

Awareness creation remains the prominent approach in changing the health care seeking behaviour of individuals. Broadly, it is reported that availability of treatment commodities will only have impact when individuals understand the value, as in the saying that “when the purpose of a thing is not known, abuse is inevitable”. Behaviour change communication helps in promoting the awareness and knowledge of people in health care programmes. Unfortunately, low utilization of key anti-malaria commodities has been commonly reported in areas where there is a lack of awareness of malaria control strategies [4]. Poor knowledge of the causes and preventive measures of malaria has led to low use of malaria preventive measures rural residence [5]. In addition, perception has become another factor that hampers individual's choices regarding malaria prevention and treatment. Women's perception and interpretation of disease has been reported to influence treatment choices, especially for malaria condition. Some symptoms of malaria have been misinterpreted by traditional methods and often traditional medicine is used for treatment [6]. The overall knowledge of malaria prevention practices across large populations is low, which implies that the knowledge about the prevention, cause, symptom and treatment of malaria has not improved sufficiently to achieve substantial results particularly among the rural dwellers [7].

Though awareness or knowledge is one facet of a complex interplay of factors in malaria prevention and treatment, it is a major prerequisite for instigating behaviour change and could likely inform attitudes about malaria health care behaviours. This factor could also be responsible for the case of Nigeria with wretch pattern or trend. The current Nigeria Multiple Indicator Cluster Survey (MICS), reported the prevalence of households with at least one ITN (64.5%), prevalence of utilization of ITN among under-5 children and household members (49.1% and 40.9% respectively) [8]. Malaria has the highest prevalence, about 50%, in children age 6-59 months in the South West, North Central, and North West regions, while the least prevalence (27.6%), in children age 6 to 59 months was reported in the South East region [8]. Similar trend in malaria previously resulted to a call which brought African Heads of State together in Abuja where a target was set for malaria reduction, specifically among pregnant women and children under-5 years which were marked to benefit from appropriate protective measures such as ITN/LLIN, key anti-malaria commodities among others in the Roll Back Malaria Programme (RBM) [9]. Therefore, we hope to provide additional mechanisms that will be useful in planning and implementing interventions for the utilization of key anti-malaria commodities and increase malaria knowledge in Nigeria. The focus of the

intervention will be consistent with the National Malaria Strategic plan to contribute in reducing the malaria burden towards pre-elimination levels.

Theoretical/conceptual framework

This study will apply the theoretical framework for assessing health care services utilization and prominently explains the relevance of the; i.) features of the health care services supply mechanism, ii.) changes in medical technology and social norms influencing the description and treatment of disease, and iii.) individual determinants of the use of health care services [10]. Utilization of health care services is currently getting large attention, which appears to arise from the occurrence of several related societal beliefs and perceptions such as the rising consensus that everyone has right to health care irrespective of their ability to afford the health care; the public opinion that the vulnerable population including the disadvantaged and rural residents lack quality health care in contrast to the better-off population; high demand regarding the extent to which health care can improve the overall health status of the population; and total distress consequent upon the crisis in health care, stimulated by high cost and poor satisfaction of the available and assessable services. Improved support for health care utilization is linked to understanding that health care distribution can be enhanced by developing new policies targeted to alleviate the challenges in health care system.

Furthermore, the utilization of health care services is prominently regarded as a type of individual-level behavioural factor. Interestingly, behavioural sciences have made efforts to describe individual behaviour as a function of the attributes of the person himself; attributes of the location of residence; and other associations of the individual and environmental factors. Unfortunately, more attention is commonly placed on the individual characteristics than the environmental effect. Therefore, it is important that intervention on health care services utilization consider both environmental and individual-level factors. The theoretical framework by Andersen and Newman [10] helps to explain some major trends and patterns in health care services utilization. An assessment of relative importance of the model components will be tested for the different types of malaria prevention and treatment services. In addition, an approach for evaluating the utility of different individual-level factors of health care services utilization will be used to achieve a situation of equitable distribution of health care services in the project states.

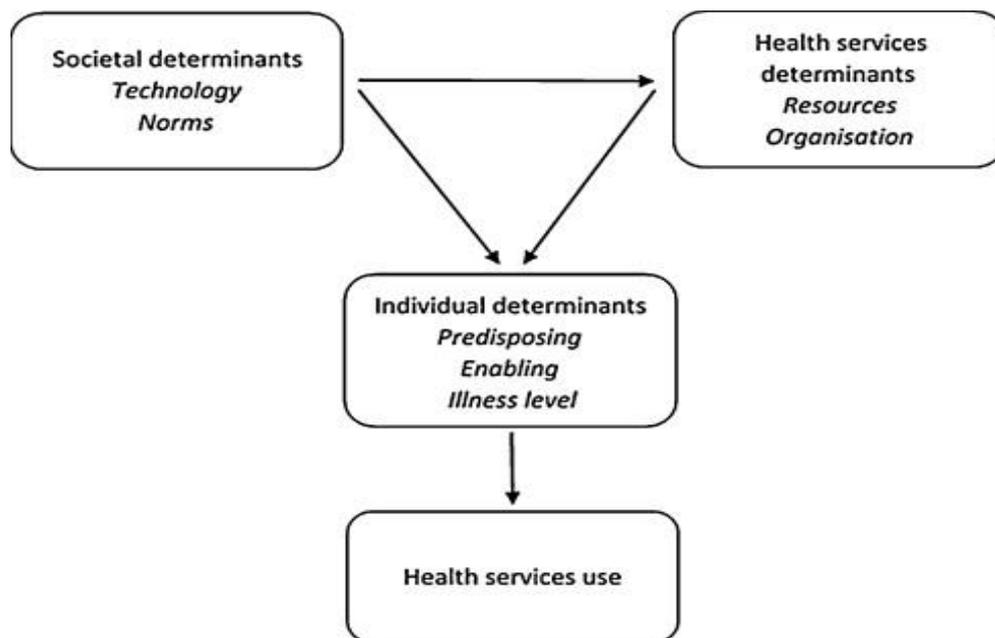


Figure 1: Theoretical framework for assessing health services utilization.

More so, the four dimensions of access framework proposed by O'Donnell [11] and Peters *et al.* [12]; will be used in this study. This includes availability, acceptability, geographical and financial accessibility which could stem from demand and supply sides factors. Demand side factors relate to the ability to use health care services at individual, household or community levels. Nonetheless, supply side factors relate to inadequacies in health care system that hampers service utilization by individuals, households and communities members. In this regard, some demand side factors will include costs of services such as indirect costs related to transport, awareness on health care services, cultural norms, perceptions and gender inequalities.

Strategies to increase the utilization of effective interventions of health care utilization in developing countries could be expensive. This will require directing spending on the most effective programmes and interventions and that the geographic distribution of these programmes does not completely mismatch that of the population. Causal and logical indicators are necessary conditions to address challenges in health care access to ensure that effective health care is generally available. However, individuals must be willing to use effective preventive and treatment interventions. Figure 2 will help to raise the demand for health care especially within resource-constrained settings.

The quality of health care is the core of all four dimensions of access to health care services, as it becomes a crucial component of each dimension and is prominently linked to the technical ability of health care services to change individual's health. There are several notable individual and household levels distal factors connected to health care service access. In spite of the efforts to provide access to health care in resource-constrained settings, significant proportions of key populations have shortfall in access. Majority of the disadvantaged in these settings experience a disproportionate burden of diseases, yet having limited access to health care services, whether measured by geographic accessibility, availability, financial accessibility, acceptability, or quality of care. However, basic understanding of the dimensions and factors of access to health care services, and intervention to improve services for the disadvantaged and vulnerable is needed for

improving utilization. The issue require to design ways to ensure that vulnerable populations demonstrate improvements in health care access particularly the hard-to-reach communities.

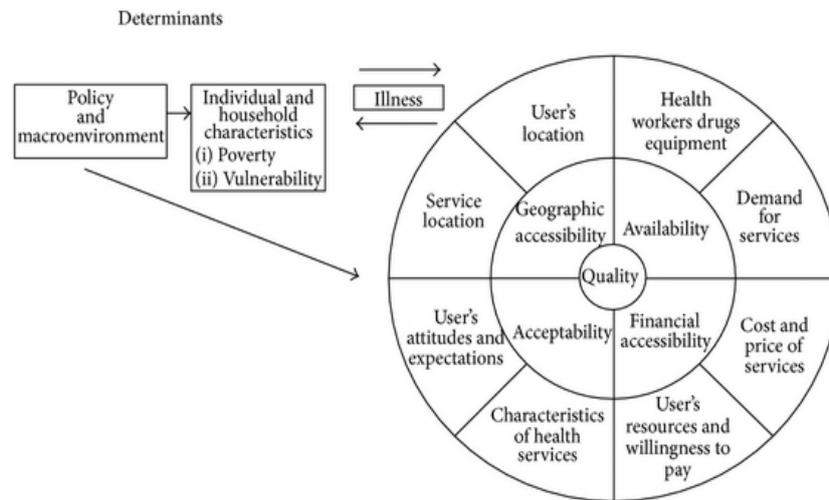


Figure 1: Conceptual framework for assessing access to health services.

Project objectives

The goal will be to reduce malaria incidence in Nigeria by strengthening the availability and/or use of key anti-malaria commodities among under 5 children and women of reproductive age.

The specific objectives of the project are as follows:

- I. To explore the utilization of key anti-malaria commodities by under 5 children and women of reproductive age in Nigeria, particularly those living in rural or the hard-to-reach communities;
- II. Based on Objective 1, to design and implement a set of multi-faceted community-led interventions to increase children and women's accessibility and utilization of key anti-malaria commodities in randomly selected rural communities in three States of the country;
- III. To evaluate the effectiveness of the implemented multi-faceted interventions by comparing baseline and endline indicators of access and use of anti-malaria commodities between the intervention-receiving communities and the control communities (not receiving the intervention);
- IV. To use the study findings to modify Nigerian policy and programmes aimed at reducing malaria incidence especially within the country's rural areas.

Key Research Questions

The specific questions that will be addressed are as follow:

1. What proportion of pregnant women use an LLIN?
2. What proportion of children under five years of age use an LLIN?
3. What proportion of children under five years of age who have fever correctly use malaria treatment (ACTs)?

4. What proportion of women of reproductive age use Intermittent Preventive Therapy in pregnancy (IPTp)?
5. How often do children in Sahelian states use Seasonal Malaria Chemoprophylaxis (SMC) during high transmission?
6. Are LLIN sufficiently available in households?
7. Are LLIN sufficiently hung in households?
8. Are key anti-malaria commodities (ACT, RDT, SP and Artesunate Injectable) sufficiently available in health facilities?
9. Do health providers have the skills for case management including the Integrated Community Case Management (ICCM)/Integrated Management of Childhood Illness (IMCI)?
10. Do women of reproductive age have the knowledge of the symptoms and appropriate treatment of malaria?
11. Do women seek prompt treatment for their children on recognition of the symptoms of malaria?
12. Do women adopt any preventive measure against malaria including the use of Intermittent Preventive Therapy in pregnancy (IPTp) and Seasonal Malaria Chemoprophylaxis (SMC) in Sahelian states?
13. What demand factors (cultural beliefs/norms, perception, traditional medicine acceptability) account for low use or non-use of evidence-based malaria prevention and treatment in rural communities within Nigeria?
14. What supply factors (health providers, availability and affordability of key malaria commodities) account for low use or non-use of evidence-based malaria prevention and treatment in rural communities within Nigeria?

Methods

Study design

We will use community-based, multicenter, cluster randomized controlled trial using a mixed methods approach. The project will be conducted in three stages. Namely:

1. A scoping study (formative phase);
2. Intervention phase;
3. Evaluation of the intervention and knowledge translation.
4. The study will be done over 36-months in selected communities. The intervention and control communities shall as much as possible share similar socio-demographic and economic characteristics. Surveys about malaria prevention, knowledge and treatment will be conducted at the scoping study (baseline) and at end of the project to test the effectiveness of the intervention.

Study Area

This study will be conducted in all states in Nigeria which currently has a population of over 180 million, making it the sixth largest in the world after Brazil, Indonesia, USA, India and China. Nigeria has 36 States and a Federal Capital Territory and 774 Local Government Areas (LGAs). It is grouped into six geo-political zones/regions, namely: North West, North East, North Central, South East, South West and South-South.

Study phases

Phase 1: Scoping study

Quantitative approach

The quantitative instruments will include household questionnaire and site inventory assessment checklist. This will be used to investigate the supply factors in the use or nonuse of malaria care services. A stratified multistage random cluster sampling will be used to select communities from Local Government Areas (LGAs). All ever-married women aged 15 to 49 years in each household to be visited who have under-5 children will be eligible for interview for the use of anti-malaria commodities for members of households. In addition, health facilities will be assessed to determine availability of key anti-malaria commodities using a standard checklist. All quantitative instruments will be designed and pre-tested to ensure that they are consistent to will sufficiently answer research questions.

Qualitative method

Qualitative data collection to engage these various stakeholders, educate communities member about the project as follows:

Sensitization

Meetings will be held at community-level to explain to the rural dwellers the purpose of the study and the benefits they will receive from participation in the intervention. Each meeting will end with an opportunity for asking and answering questions. Informed verbal and written consent will be sought from the parents or guardians of children who meet the entry criteria for the study.

Key Informants Interviews

We will conduct interviews with the communities and health facilities stakeholders to determine their views on availability and use of anti-malaria commodities and how to improve its use. Their views will be incorporated in the design of the project implementation.

Focus Groups Discussion

We will conduct Focus Groups Discussion (FGDs) with various categories of individuals to elicit their views on availability and use of anti-malaria commodities and feedback such views into the planning and design of the intervention. In particular, we will seek ways during the FGDs to determine how to include individual's perspectives through all phases of the implementation process.

Community Conversations

Initial Community Conversations (CC) with community leaders in the identified project communities. During CC, we will bring together the decision-makers and leaders in each community to discuss the project ideas and intentions. We will introduce the project objectives and request them to identify ways the communities would help to solve the problems. The idea behind community conversation will be to ensure that the communities identify the problems themselves and suggest solutions. This way, not only will the communities participate fully in the project activities, they would also owe the project and sustain its implementation over time.

Stakeholders' Engagement

We will pay advocacy visits to policymakers or decision-makers that will be identified to explain the project objectives and activities and to ensure that they support the project with resources to undertake on the use of anti-malaria commodities.

Implementation tools

The scoping study will apply the Equitable Impact Sensitive Tool (EQUIST) and Knowledge Translation (KT) approach. The Knowledge Translation Platform (KTP) will utilize production of policy briefs on malaria epidemic, advocacy visits to key stakeholders and decision makers in the LGAs, State Ministry of Health, Federal Ministry of Health, and health practitioners for a, print and electronic media, the intervention communities' partners and research publication. The analysis will identify why disadvantaged individuals, such as those in rural areas do not use anti-malaria commodities and highlight social equity dimensions health care use. It will also include an analysis of how the combination of evidence-based high impact interventions and health system strengthening strategies can produce the best results for the project.

Phase 2a: Design and implementation of the intervention

Intervention design workshop

On completion of the scoping study, we will organize an intervention workshop to design the intervention using the findings from the scoping study. The intervention workshop will also serve to disseminate Phase 1 research findings so as to build support for the project among critical stakeholders.

Intervention design

The intervention will consist of; behaviour change communication to encourage people to use health facilities for malaria treatment; provision of key anti-malaria commodities; home visits to assist community members for net hanging and community-led activities aimed at promoting services utilization; strengthening the knowledge of health providers on treatment of malaria.

Social behavior change communication

State-wide campaigns will be used to educate people on the importance of LLIN and disabuse their minds of wrong beliefs about its use. At community level, community conversation will be conducted on the project and centred on reasons for poor utilization of recently distributed LLIN. A radio jingle in "Pidgin English" which is the general spoken language in Nigeria; on LLIN use and care will be developed and field tested prior to the intervention; this was then adopted for this intervention. Town announcement services will also be used to create awareness of anti-malaria commodities and use respectively. These will be possible channels to reach large populations with information on the importance of LLIN and anti-malaria commodities utilization.

Home visits on the hanging of LLIN

Community Volunteers (CV) will be employed in home visits among rural communities. Where LLIN are available but not hanged, CV will assist the household to air the LLIN outside and return to hang same. Information, Education and Communication (IEC) materials will be developed and given to the CV during household visits as a medium for behaviour

change communication. A supervisory checklist will be used to monitor intervention activities by different levels of supervisors.

Key anti-malaria commodities

The supply of key anti-malaria commodities will be coordinated through the primary health care centres. As the nearest health care point for the rural people, all malaria drugs and incentives for malaria treatment package during pregnancy will be done through PHCs. However, for communities without PHCs, private health facilities will be used but with close monitoring during the intervention period.

Phase 2b.: Monitoring and evaluation of the intervention

A strong Monitoring and Evaluation team will directly supervise and evaluate the project. In brief, both output and outcome indicators will be used to monitor the achievements of the specific objectives of the project. A logical framework will be designed that will capture each research objective, the expected outcomes, the indicators for measurement, means of verification and the identification of the specific reporting project official. Both quantitative as well as qualitative measures will be used to capture the results of the project. Through triangulation of the qualitative and quantitative results, a more comprehensive assessment of the results of the project and the intervention will be obtained. The indicators for measuring the success of the project will be identified at three levels: indicators for the formative research phase (Phase 1), indicators for the intervention phase (Phase 2), and indicators of the translational research phase.

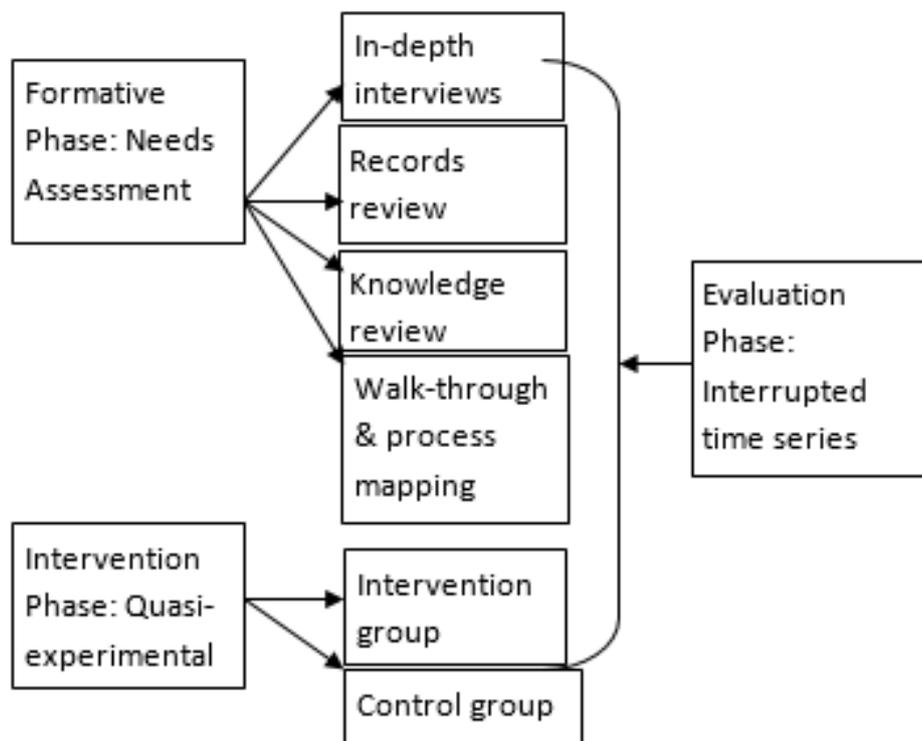


Figure 1: Procedural framework for project phases.

Data source and sample size

Primary data will be required for this study. In addition, data will be extracted from records in health facilities to examine history of malaria case management at the health facilities. The sample size formula below is applied for the scoping study as follows:

Sample Size Estimation

The sample size formula is applied as follows:

$$n_1 = \{[p_1q_1 + p_0q_0] (Z_{\alpha/2} + Z_{\beta})^2\} / (p_1 - p_0)^2$$

p_0 = utilization of key malaria commodities for children and/or women in the control arm (assumed to be -5 reduction in the percentage in the experiment site)

p_1 = utilization of key malaria commodities for children and/or women in the experimental arm

z_{α} = Two-sided standard normal variate at 95% level of significance = 1.96

z_{β} = Statistical power at 80% = 0.84;

$$n_1 = n_2$$

n_1 = no of study participants in the experimental group

n^2 = no of study participants in the control group

We assume 50% since there is no data from this study geographical location which reported the utilization of key anti-malaria commodities for children and/or women in the rural communities.

Thus;

$$n^1 = (0.50 \times 1 - 0.50 + 0.45 \times 1 - 0.45) (1.96/2 + 0.84)^2 / (0.50 - 0.45)^2$$
$$(0.25 + 0.2475) (3.3124) / 0.0025$$

$$n^1 = 659$$

$$n^2 = 659$$

Sample size = 1,318

Using design effect = 2.0

Minimum sample size = 2,636

There will be 2,636 participants in each study site.

Selection of Communities

Multi-stage random sampling approach will be used to select communities at formative research, and will involve two stages: Firstly, rural Local Government Areas (LGAs) will be randomly selected from the study states. Secondly, communities in randomly selected rural Local Government Areas (LGAs) will be selected randomly. All ever-married women of reproductive age in each household of the selected communities who have under-5 children will be eligible for interview; to investigate the knowledge of malaria, ownership and utilization of LLIN and determine their prevention and treatment of malaria using recommended mechanisms. This will be continued until the optimum sample size is obtained.

Ethical Clearance

The ethical clearance approval needed for the project will be obtained from the National Health Research Ethics Committee (NHREC) after the submission of the study protocol. The reliability and validity of the questionnaires will be conducted using standard methods. We will use various mechanisms to ensure high quality of data to be collected by avoiding sampling errors. We will adopt careful selection and training of field workers or interviewers since data collection process will include collecting personal data. Furthermore, we will match interviewers with respondents based on gender: some questions may be of a sensitive or personal nature, and respondents would feel more comfortable sharing this kind of

information with someone of the same sex. Therefore, men would interview men, and women would interview women.

Wealth-Related Tertial Measurement

A list of household assets including floor types; roof and wall materials; access to sanitation and potable water; type of cooking fuel; ownership of radio; television; bicycle; motorcycle; refrigerator amongst others will be used to measure wealth scores using Principal Components Analysis (PCA) approach. Based on the analysis of household assets, PCA will provide plausible and defensible weights for an index of assets to serve as a proxy for household wealth status. By definition, the first principal component variable across individuals or households has a mean of zero and a variance of λ , which corresponds to the largest eigenvalue of the correlation matrix of x . The first principal component y yields a wealth index that assigns a larger weight to assets that vary the most across households so that an asset found in all households is given a weight of zero. Weights (effectively defined by factor scores) for each asset will be computed. Thus, the wealth index takes into account the distribution of assets in order to reflect each household's economic conditions. Based on the weighted wealth scores, households will be grouped into wealth tertile; poor (low), middle and rich (high)

Analytical Approach

Quantitative data from the scoping study will be analysed using summary statistics, plots and inferential statistics such as mean and median tests, correlation and regression. Furthermore, comparisons across study communities will be computed between intervention and control sites to test for significant differences. Considering the cluster nature of the study communities, the effect of cluster design will be adjusted for during the analyses. For models involving test of association, we will check for multi-collinearity among explanatory variables examining the Variance Inflation Factor (VIF), diagonal elements in the variance-covariance (τ) matrix for correlation between -1 and 1 , and diagonal elements for any elements close to zero. If the results of the tests provide reasons for concern, collinearity will be treated by standard techniques to ensure that models provide robust and valid results. However, qualitative data will be collected by recording, transcription and analysed thematically. Microsoft Excel, ATLAS ti version 7.5.4 and Stata version 14 (StataCorp, College Station, TX) will be used to analyse the data.

Quality assurance

Data collection and management

There will be a quality assurance officer to ensure that all implementation and evaluation activities follow standard operating procedures. Quality assurance will include monitoring the process of obtaining consent, data collection, and retrieval of completed survey instruments, data management, and the secure storage of study materials. Furthermore, field supervisors will monitor the survey administration undertaken by field workers and make random and regular visits to assess the quality of data collection and review completed questionnaires. Only authorized staff with appropriate training will have access to the databases and perform data entry. All databases will be password protected. Each data form will be entered by two data entry clerks in a database of the same structure using two different computers. Entries will be compared for discrepancies using statistical software. Any discrepancies will be corrected by crosschecking against the corresponding original questionnaire. Checks (validation rules) will be implemented in different fields of the database. Data will also be

queried electronically to ensure the correct data are entered under the correct variables for each section of the form/questionnaire. A log of all data changes will be kept. Questionnaires will be kept in a locked filing cabinet.

Activities	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q 4
Definition of roles and responsibilities amongst project team and set up of a project management committee												
Recruit project staff including community volunteers amongst others												
Development of the Study Guides												
Draft questionnaires and interview schedules and Validation												
Determine sites and samples and obtain ethics clearance												
Development of field guide (including field notes and attention to gender equity)												
Preparing practical materials for field work (car rental, supplies, etc.)												
Quantitative Survey												
Qualitative Study (Interviews, FGDs and Community Conversations)												
Data Analysis												
Report Writing												
Workshop on the dissemination of scoping study results, intervention design and Equitable Impact Sensitive Tool (EQUIST) and knowledge translation												
Selection of intervention communities												
Mid-Term Evaluation												

Final Evaluation													
Policy briefs													
Media briefs													
Scientific publications													
Website													
Dissemination meetings for FMOH, SMOH, NGOs, LGAs, Community Stakeholders, Media & Donors													

Table 1: Gantt chart for project.

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