CONCEPT NOTE:
Impact Evaluation and Implementation Research of Community-Directed Interventions and Private Sector Approaches to Malaria Control in Seven Nigerian States

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Contents

List of Acronyms

ACT	Artemisinin Combination Therapy
CDD	Community-Directed Distributor
CDI	Community-Directed Intervention
CN	Concept Note
CSS	Community Systems Strengthening
FGN	Federal Government of Nigeria
HNLSS	Harmonized Nigeria Living Standards Survey
ICC	Intra-Cluster Correlation
IE / IR	Impact Evaluation / Implementation Research
IPT	Intermittent Preventive Therapy
ITN	Insecticide-Treated net
MTT	Management and Tracking Tool
MCBP	Malaria Control Booster Project
MIEP	Malaria Impact Evaluation Program
NGO	Non-Governmental Organization
NMCP	National Malaria Control Program
PMV	Patent Medicine Vendor
PPHF	Public Primary Health Facility
PPP	Public-Private Partnership
PSU	Primary Sampling Unit
RDT	Rapid Diagnostic Test
SMOH	State Ministry of Health
WHO	World Health Organization

I. Overview and Background

The World Bank is assisting the Federal Government of Nigeria (FGN) with a Malaria Control Booster Project (MCBP), which is part of the FGNs efforts to improve health and socioeconomic outcomes blighted by malaria and other preventable and treatable diseases. The project, which became effective in May 2007, has two main components: i) strengthening the capacity of the Federal Government to provide malaria control leadership and coordination over the medium and long-term; and ii) strengthening the health system to improve delivery of an integrated package of interventions in the target states. These are: Akwa Ibom, Anambra, and Rivers in the south; and Bauchi, Gombe, Jigawa, and Kano in the north.

In addition to the original US$180 million credit, Additional Financing of US$100 million was approved in June 2009 to further support the Booster Project states in achieving their malaria control objectives. This Additional Financing responds to the FGN's recently updated National Malaria Strategy, specifically to the move towards universal coverage of the population with key malaria prevention and treatment interventions and the greater emphasis placed on diagnostics and health systems development, including at the community level. With regards to the latter, though the government has emphasized community mobilization as a way to increase demand and access to malaria-related health services, and to improve accountability in the health system, there are currently no community-level systems that have been mainstreamed. The Additional Financing, therefore, proposes to support this process, in addition to engaging the local private sector.

Nigeria, where virtually the entire population lives in high-transmission areas, is one of the countries most affected by malaria. With an estimated 57.5 million cases and 225 thousand deaths attributable to the disease, the country accounts for nearly 25% of global malaria-related morbidity and mortality, far more than any other country (WHO, 2008).

The FGN recognizes malaria as both a health and developing priority in the National Economic and Empowerment Strategy (NEEDS). The National Malaria Control Program's (NMCP's) Country Strategic Plan for 2006-2010 aims to halve the burden of malaria by 2010 through a massive scale-up of vector control using LLINs and effective case management of uncomplicated malaria using ACTs. Nigeria is a signatory to the 2000 Abuja Declaration, which committed the country to deploying all necessary resources to achieve coverage rates of 60% for ACTs and LLINs by 2005. The country's recently updated National Malaria Strategy aims for universal coverage of key preventive and curative interventions.

Despite very high volumes of funding (current commitments total approximately USD 1 billion[1]), these targets remain elusive due to health systems constraints. The health system faces a number of limitations which contribute to poor quality and low utilization of health services in general, including: i) a weak public delivery system; ii) challenges in coordination across the three tiers of government (federal, state, and local); iii) human resource constraints; iv) inefficient use of public and private resources; v) heterogeneity in the quality of service delivery, especially in the

[1] Authors' calculation

private sector; and v) insufficient coordination between the public and private sectors (Greer, et al., 2004) (World Bank, 2006) (Oladepo, et al., 2007).

A. Challenges in Malaria Prevention and Treatment

Efforts to control malaria suffer from these problems, and a major challenge faced by the NMCP is the low use of public health care services for malaria prevention and treatment.

Prevention

Of the 89.6 million children living in malaria-endemic areas who are unprotected by ITNs, 25% (22.4 million) are found in Nigeria alone (Noor, Mutheau, Tatem, Hay, & Snow, 2009). Other estimates of the number of unprotected children are even higher. According to the World Health Organization (WHO), only 1% of both children under five and pregnant women in Nigeria sleep under an ITN (WHO, 2008) – suggesting more than 27 million children and nearly seven million pregnant women are unprotected – while results from a 2007 Multiple Indicator Cluster Survey (MICS) give slightly higher usage figures of 3.5% and 3.1% for children under five and pregnant women, respectively (Roll Back Malaria, 2007). For comparison, the corresponding figure across Africa for children under 5 living under stable malaria-endemic conditions, similar to those sound in almost all of Nigeria, is 18.5% (Noor, Mutheau, Tatem, Hay, & Snow, 2009). As a result, an estimated 11% of deaths among pregnant mothers and 29% among children under five are due to malaria (World Bank, 2006). This translates, roughly, to 1.2 maternal deaths and 47.9 deaths in children under five per 1,000 live births annually (World Bank, 2009).

Treatment/Case Management

Coverage of Artemisinin Combination Therapies (ACTs, the recommended first-line anti-malarial class of drugs) is limited, skewed towards the urban sector, and biased against the poor due to the cost of ACTs compared to less expensive (but also less effective) anti-malarials (Oladepo, et al., 2007) (AMFm, 2007). Uptake of ACTs has been slow; using program data, the WHO estimates that use of ACTs relative to estimated fever caces in need of treatment stands at less than 5% (WHO, 2008). An outlet survey carried out by ACTWatch in Nigeria in December, 2008, found only 2.3% of anti-malarials sold or distributed in the past week were the recommended first-line treatment (AL). In contrast, 83.6% were non-artemisinin monotherapies and 9.9% were artemisinin monotherapies, neither of which are recommended for use (ACTWatch, 2008).

The high burden of malaria in Nigeria, alongside inadequate access and uptake of prevention and treatment, hinders households' ability to attain and maintain improved health and socioeconomic status. According to the FGN, malaria impedes human development and is both a cause and a consequence of under-development. Every year, the nation loses over 132 billion Naira (over USD 1 billion) due to treatment costs and absenteeism from work, schools and farms (Oladepo, et al., 2007). Using a willingness-to-pay approach, the economic cost of malaria is estimated at about 12% of GDP, or about 880 billion Naira, per year (Jimoh, Sofola, Petu, & Okorosobo, 2007).

B. Community and Private Sector Approaches to Malaria Control

It has been acknowledged that while malaria control has a public health mandate, the public sector alone is not sufficient to deliver preventive and treatment services to the population. To achieve malaria control targets, the NMCP and State Ministries of Health (SMOHs) are working to better integrate private-sector, community, and non-governmental actors into the public health system to expand effective coverage of life-saving malaria prevention and treatment services. These additional channels for essential public health services would deliver malaria prevention and treatment to vulnerable target populations, including hard-to-reach rural and poor households, and improve utilization patterns through targeted communication efforts.

A number of studies in Nigeria have demonstrated that private sector Patent Medicine Vendors (PMVs) are already the most common source of malaria treatment, with between 36% and 44% of malaria treatment for children under five being purchased from PMV shops (Oladepo, et al., 2007). Another study, however, undertaken in a rural malaria-endemic Nigerian community in the south, found that consumers generally prefer treatment by CHWs over other treatment options, including PMVs (Onwujekwe, et al., 2006). Community-directed interventions (CDIs) have been found to be effective in providing a range of health services, including for malaria control (WHO, 2008).

Despite providing indicative evidence of the effectiveness of community or CDI approaches, as well as of the value of PMV-engagement, for reducing the burden of preventable and treatable diseases such as malaria, pilot interventions to date have not been implemented at scale and accompanied by rigorous impact evaluation and implementation research to provide evidence on: i) what works; ii) in what contexts; iii) under what conditions; iv) impact of interventions on the target population(s); and iv) their impact on the health system at large. However, as competition for the limited resources in the health sector is intense, evidence on what works and which models/innovations perform better are indispensable for policymakers to design more effective policies and programs prior to scale-up.

To enable evidence-based implementation and policymaking, the impact evaluation and implementation research (IE/IR) described in this concept note (CN) will examine the use of CDI mechanisms and public private partnerships (PPPs) with PMVs to reduce both demand and supply-side impediments to the access and appropriate use of malaria preventive measures (such as sleeping under LLINs/bednets or taking IPT when pregnant) and treatment using ACTs. Through exploring how the proposed innovative service delivery channels contribute to effective and cost-effective malaria control, the evaluations will also address broader, system-level questions of novel means of service delivery to improve the coverage and quality of other public health services for vulnerable and poor populations in Nigeria.

II. Why Impact Evaluation?

When resources are limited, policymakers hope to attain priority health targets at the lowest possible cost. Operational impact evaluation is a tool to determine the causal impact of policy innovations and hence can help guide policy decisions by assessing the effectiveness and cost-effectiveness of competing policy options. Evaluation also provides information that can be integral to sustaining a program insofar as information assists in the negotiation of budgets and informs stakeholders and the wider public of progress. In addition, impact evaluation provides information to guide possible mid-course corrections to the program as appropriate.

Given budgetary constraints and the realities of implementation, only policy innovations that have a possibility to be adopted by the national health system should be evaluated. In order to generate germane policy lessons, the innovations should be chosen so that they are i) scalable and ii) conducted under the normal circumstances and capabilities found in the public sector. Rigorous evaluation demands that any observed change in outcomes in areas that receive treatment must be compared with a valid counterfactual that represents the course of events that would have occurred in the treated area in the absence of the intervention, so that the true causal effect may be identified. While there are various methodological approaches to the construction of a valid counterfactual, the most rigorous approach is an experimental design where treatment/control status is assigned to individuals or groups on a randomized basis.

Randomization assures that all units have an equal chance of control or treatment status, and satisfies the conditions of a valid counterfactual comparison. These are: i) all relevant pre-intervention factors / characteristics will be, on average, equal across the treatment and control groups; and ii) the only difference in observed outcomes is due to the intervention and not to any other observed or unobserved factors. The IE/IR described in this CN will use such a randomized treatment/control design to evaluate CDI and PMV interventions of the MCBP CSS component.

The difference between "IE" and "IR" as described in this CN lies in the nature of data to be collected. In both cases, data will be collected on key intermediate and final outcomes of interest. In addition to this data, the three IE states (Akwa Ibom and Anambra in the south and Gombe in the north) will collect detailed information on a number of covariates in order to better understand the impact of the interventions across sub-groups of individuals and households. The four IR state (Rivers in the south and Bauchi, Kano, and Jigawa in the north), on the other hand, will carry out less intensive data collection on a restricted set of covariates. In both IE and IR states, however, interventions will be implemented at scale with random assignment.

Another critical consideration in the design of an impact study is the external validity of the evaluation results. The IE/IR described here will be implemented across seven states spanning five of Nigeria's six geopolitical zones (only the South East zone is not represented). These seven states represented different climactic, epidemiological, socioeconomic, and political climates, thus taken as a whole results should be applicable to Nigeria as a whole.

A. Malaria Impact Evaluation Program

While the causal link between the use of effective anti-malarial services and improved malaria outcomes is well-established, the effectiveness, relative effectiveness, and cost-effectiveness of alternate delivery mechanisms and intervention packages to expand coverage and utilization of malaria and fever related health services, and induce a change in people's health care-seeking behavior, is less well understood.

The World Bank's Malaria Impact Evaluation Program (MIEP) is a multi-country initiative to explore the effectiveness and cost-effectiveness of alternative provision mechanisms for anti-malarial services. Through facilitating in-depth IE/IR, the MIEP seeks to: i) generate high-quality evidence to inform policymaking and programmatic choice; ii) build client and partner evaluation-related capacity; iii) inform future World Bank lending for malaria control; and iv) contribute to the global body of evidence on malaria control across different climactic, epidemiological, socioeconomic, and political contexts.

III. What Is To Be Evaluated?

The IE/IR will focus on the Community Systems Strengthening (CSS) component of the MCBP Additional Financing, which proposes to support the process of community engagement through CDI, as well as boosting the capacity of the local private sector through PPPs with PMVs. The service delivery interventions proposed under the CSS component are:

1. *Community-Directed Interventions (CDIs).* This involves training community volunteers on home management of malaria and preventive actions (insecticide-treated net hanging with relevant advice on use, and preventive treatment for pregnant women). Volunteers are selected from small communities linked by family ties (kindreds). They become the health worker in their kindred, providing guidance on malaria prevention and treatment. Volunteers serve people who are related to them through family ties, and are in turn monitored by them, which attenuates incentive and motivation problems associated with volunteering;
2. *Public-Private Partnerships (PPPs).* This involves training Patent Medicine Vendors (PMVs), small private distributors of drugs, in diagnostic procedure and the sale of subsidized ACT (the recommended first line drug) with the right dosage (thereby crowding out less effective drugs, and dispensing effective drugs without waste or pernicious health consequences).

The IE/IR will employ a prospective, randomized design to document changes in both household and provider behavior resulting from the interventions, and to measure impact heterogeneity with respect to household, provider, and community characteristics. The relative and joint effectiveness and cost effectiveness of each of the two proposed innovative health service delivery channels will be evaluated, and compared to the existing regime under which publically funded primary health care services are delivered principally through public sector primary health care facilities (PPHFs).

The IE/IR described in this CN has been developed in close collaboration with the NMCP and the SMOHs of the MCBP states, through an ongoing consultative process which began in May 2007. This research is expected to inform and fill critical knowledge gaps, and facilitate the design of more effective malaria control policy and programs. Furthermore, the IE/IR process will contribute to capacity-building for the NMCP and SMOHs in evidence-based policymaking and program design.

A. Research Questions and Key Indicators

The IE/IR will examine the following primary research questions. These questions have been defined by NMCP and SMOH policymakers, and discussed with the World Bank MCBP Operations Team as well as with Development Partners active in Nigeria.

1. What is the relative and joint effectiveness and cost-effectiveness of the CDI and PPP service delivery channels in improving key health-related and economic outcomes?
2. How does the relative and joint effectiveness and cost effectiveness of the CDI and PPP service delivery channels compare to the existing regime, where publicly-funded anti-malarial care is available primarily through PPHFs?
3. How do the CDI and PPP interventions affect malaria prevention and treatment-related knowledge, attitude, and practice (KAP)?

At the individual level, key indicators will include:

- Proportion of children under five and pregnant women sleeping under an LLIN/ITN the night preceding the survey;
- Proportion of children under five receiving treatment with ACT within 24 hours of the onset of malaria symptoms;
- Proportion of mothers and primary caretakers able to correctly identify the symptoms of malaria, key preventive measures, and appropriate treatment;
- Proportion of pregnant women receiving full courses of IPT.

At the provider (CDD and PMV) level, key indicators will include:

- Proportion of providers reporting stock-outs of key anti-malarial medicines;
- Volume of fever/malaria patients seen by providers, and volume of ACTs dispensed;
- Proportion of providers able to correctly identify the symptoms of malaria, to accurately diagnose (with rapid diagnostic tests, RDTs, where relevant), to describe appropriate preventive measures, and prescribe appropriate treatment.

B. Study Area

The IE/IR will be carried out in all seven MCBP states. All local government areas (LGAs) will be eligible for participation, with the exception of six LGAs in Akwa Ibom, where JHPIEGO is carrying out a study on the use of the CDI approach to prevent malaria in pregnancy.[2]

Public primary health care facilities (PPHFs) play a supporting role in the CDI intervention, hence the unit of implementation for this is the PPHF catchment area. PMVs, on the other hand, are private entrepreneurs with no direct link to PPHFs in their area. The implementation unit for the PPP intervention is, therefore, the political ward.

Table 1 summarizes the study area in each state[3]:

Table 1: Study Area

State	Population	No. of LGAs	No. of PPHFs	No. of Wards
Akwa Ibom	3,920,208	25	272	264
Anambra	4,182,032	21	385	327
Bauchi	4,676,465	20	116	212
Gombe	2,353,879	11	128	114
Jigawa	4,348,649	27	351	280
Kano	9,383,682	44	786	483
Rivers	5,185,400	23	386	319
TOTAL	**34,050,315**	**171**	**2,424**	**1,999**

C. Identification Strategy

The evaluation will use a cluster-randomized experimental design. Randomization ensures that treatment and control groups are as equal as possible, in terms of both observed and unobserved characteristics. This allows us to construct a counterfactual, which in turn allows us to draw unbiased estimates of impact.

To accommodate the implementation context and generate a valid counterfactual, the randomization will be as follows:

1. Primary healthcare facilities (PHFs), the CDI implementation unit, will be randomized into treatment and control groups.

[2] The World Bank study team is engaged in ongoing communication and coordination with development partners active in Nigeria, to ensure that efforts are not duplicated and that one partner's work does not negatively impact or contaminate another's.

3 Population figures from the 2006 census (National Bureau of Statistics); PPHF figures are from 2007 primary healthcare facility census (National Primary Health Care Development Agency). PPHF figures will be updated through a pre-intervention listing activity, described in more detail in section IV.A (Data to Inform Design).

2. Political wards, the PPP implementation unit , will be randomized into treatment and control groups;

This will yield four study arms, each comprising an average of 86 PHFs and 71 wards per state:

1. **Treatment 1: CDI intervention only**
2. **Treatment 2: PPP intervention only**
3. **Treatment 3: CDI *and* PPP interventions**
4. **Control (existing public-sector regime only)**

D. Power calculations

Power calculations are done for a level of significance of 0.05 and a power of 0.80. Since data to ascertain the true value of intra-cluster correlation (ICC) is not currently available, a conservative value of 0.3 is assumed.[4] Annex 1 provides detectable effect sizes for different ICCs and number of individuals sampled per primary sampling unit (PSU).

For the CDI intervention (Treatment 1), we consider two key intermediate outcomes: i) NET, the proportion of children under five sleeping under an ITN/LLIN; and ii) DRUG, the proportion of fever cases treated with ACT within 24 hours. For the PPP intervention (Treatment 2) we consider DRUG only. For the joint intervention (CDI *and* PPP interventions, Treatment 3) we consider both DRUG and NET.

Akwa Ibom State

- *Treatment 1: CDI intervention only.* Of the 272 PPHFs in the study area, 136 will be randomly assigned to the CDI intervention. The mean of NET and DRUG in Akwa Ibom are 13.5% and 2.28%, respectively. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size 7.06% in NET and 2.25% in DRUG.
- *Treatment 2: PMV intervention only.* Of the 264 wards in the study area, 132 will be randomly assigned to the PMV intervention. The mean of DRUG in Akwa ibom is 1.2%. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size on DRUG of 2.28 percentage points.
- *Treatment 3: CDI and PMV interventions.* For the joint intervention, we consider 61 intervention clusters and 61 pure control clusters. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size of 10.54 percentage points in NET and 3.36 percentage points in DRUG.

Anambra State

[4] Data from the 2009 Harmonized Nigeria Living Standards Survey (see section IV.A on Data to Inform Design) will be used to calculate ICCs when it becomes available.

- *Treatment 1: CDI intervention only.* Of the 385 PPHFs in the study area, 192 will be randomly assigned to the CDI intervention. The mean of NET and DRUG in Anambra are 12.2% and 0.5%, respectively. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size 5.69% in NET and 1.23% in DRUG.
- *Treatment 2: PMV intervention only.* Of the 327 wards in the study area, 163 will be randomly assigned to the PMV intervention. The mean of DRUG in Anambra is 0.5%. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size on DRUG of 1.33 percentage points.
- *Treatment 3: CDI and PMV interventions.* For the joint intervention, we consider 81 intervention clusters and 82 pure control clusters. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size of 8.76 percentage points in NET and 1.89 percentage points in DRUG.

Gombe State

- *Treatment 1: CDI intervention only.* Of the 128 PPHFs in the study area, 64 will be randomly assigned to the CDI intervention. The mean of NET and DRUG in Gombe are 11.8% and 4.12%, respectively. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size 9.71% in NET and 3.89% in DRUG.
- *Treatment 2: PMV intervention only.* Of the 114 wards in the study area, 57 will be randomly assigned to the PMV intervention. The mean of DRUG in Gombe is 1.7%. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size on DRUG of 4.12% percentage points.
- *Treatment 3: CDI and PMV interventions.* For the joint intervention, we consider 28 intervention clusters and 29 pure control clusters. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size of 14.68 percentage points in NET and 5.88 percentage points in DRUG.

IV. Data Collection and Sampling

Information used for the evaluation of the Nigeria MCBP CSS interventions will derive from two principal sources: i) health management information system (HMIS) data streams for routine facility-based data (HMIS enhancements are proposed for pilot testing during the first year of intervention); and ii) dedicated surveys for population, community, provider, and facility-based data. Table 2 details the data sources to be used in further informing design and at baseline and follow-up.

Table 2: Data

	Household and community data	Facility and provider Data	Routine administrative data
Data to inform design	2009 Harmonized Nigeria Living Standards Survey	2010 pre-intervention listing, including collection of basic data on PMVs and kindred groups	Health Management Information System (HMIS)
Baseline	2010 dedicated surveys	2010 dedicated surveys	HMIS
Follow-up	2011 dedicated surveys	2011 dedicated surveys	"Enhanced" HMIS

A. Data to Inform Design

Through collaboration with the National Bureau of Statistics, a malaria module was included in the 2009 Harmonized Nigeria Living Standards Survey (HNLSS). Indicators span a range of categories, including: i) knowledge of and attitude towards malaria and its prevention; ii) use of mosquito nets; iii) diagnosis and treatment-seeking behavior; iv) cost of illness (direct and indirect); and v) use of preventive therapy by pregnant women. HNLSS data will be used to ensure balanced sampling which is representative of the population in each participating state.

A pre-intervention listing is currently underway, to collect basic information (including GPS coordinates and approximate populations of PPHF catchment areas) in preparation for the CSS interventions. This listing will cover PPHFs, communities and the kindreds within them, PMVs, and Community Laboratories (which are used in some instances for malaria diagnosis). Data collected through this activity will be used for intervention planning, implementation, monitoring and supervision, and evaluation.

B. Baseline and Follow-Up Data Collection

A random sample of ten households linked to each PPHF catchment area in both treatment and control areas will be surveyed at baseline and then again approximately one year later. The household survey will comprise 13 sections, including: i) Roster; ii) Education, including school attendance; iii) Labor; iv) Housing; v) Assets and Household Enterprise; vi) Transfers, Other Income, and Subjective Wealth; vii) Consumption; viii) Malaria; ix) Health Status, Utilization, and Satisfaction; x) Mental Health; xi) Risk; xii) Willingness-to-Pay; xiii) Biomedical module, including tests for anemia and malaria parasitemia. Across the seven states, total sample size will be approximately 24,240 households in each round (baseline and follow-up). Sample size per state per round is given in table 3 below.

To account for community effects, a community survey will be administered to a randomly selected community in the catchment area of each PPHF, both in treatment and control areas. This will include the following sections: i) Direct Observation; ii) Demography; iii) Basic Services; iv) Social Capital and Empowerment; v) Economic Activities; vi) External Shocks; vii) Prices. Across the seven states, total sample size will be approximately 2,424 communities in each survey round. Sample size per state per round is given in table 3 below.

To better understand existing public sector service delivery, and its interaction with the innovative service delivery channels proposed as part of the CSS, a PPHF survey will be administered to *all* PPHFs in both treatment and control areas. This will include the following sections: i) General Information & Facility Characteristics; ii) Administration and Management; iii) Human Resources; iv) Laboratory Facilities; v) Records; vi) Community Outreach; vii) Services; viii) User Fees; iv) Universal Precautions; x) Equipment; xi) Drug Storage and Availability; xii) Governance and Accountability / Organizational Determinants. Total sample size will be approximately 2,423 in each round (sample size per state per round is given in table 3 below).

The PPHF survey includes a health worker module, which comprises the following sections: i) General Information; ii) Training and Services; iii) Working Conditions; iv) Compensation and Assets; v) Monitoring and Supervision; vi) Community Support; vii) Satisfaction; viii) Knowledge and Quality of Care; ix) Organizational Determinants; x) Job Comparison. This module will be administered to a randomly selected clinical health worker in each facility.

Finally, the key providers involved in the innovative service delivery arms will be surveyed. The CDD survey will include the following sections: i) General Information; ii) Training and Services; iii) Economic Activities; iv) Working Conditions; v) Monitoring and Supervision; vi) Support; vii) Selection and Retention; viii) CDD Knowledge and Quality of Care; ix) Drug Procurement, Storage, and Availability; x) Job comparison. The CDD survey will be administered to two randomly selected CDDs in each intervention PPHF catchment area (as malaria control CDDs represent a new type of health worker introduced by the intervention, CDDs will not be present in control areas). Total sample size will be approximately 4,848 households in each round (sample size per state is given in table 3 below).

The PMV survey will include the following sections: i) General Information; ii) Training and Service; iii) Economic Activities; iv) Working Conditions; v) Monitoring and Supervision; vi) PMV Association and Community Support; vii) Satisfaction; viii) PMV Knowledge and Quality of Care; ix) Drug Procurement, Storage, and Availaiblity; x) Job Comparison. The PMV survey will be administered to four randomly selected PMVs in both treatment and control wards. Total sample size will be approximately 7,998 in each round (sample size per state is given in table 3 below).

Table 3: Survey Sample Sizes

State	Household	Community	PPHF	CDD	PMV
Akwa Ibom	2,720	272	272	272	1056
Anambra	3,850	385	385	385	1308
Gombe	1,280	128	128	128	458
Sub-total for IE states	*7,850*	*785*	*785*	*785*	*2,822*
Bauchi	1,160	116	116	116	848
Jigawa	3,510	351	351	351	1,120
Kano	7,860	786	786	786	1,932
Rivers	3,860	386	386	386	1,276
Sub-total for IR states	*16,390*	*1,639*	*1,639*	*1,639*	*5,176*
TOTAL	**24,240**	**2,424**	**2,425**	**2,425**	**7,998**

C. Routine Administrative Data

Routine administrative data on malaria case management will be collected through the existing malaria HMIS with tools developed by the NMCP. Information is collected on basic patient data, diagnosis, treatment, IPT, LLIN distribution, and malaria-related deaths. Given the importance of such routine data in ongoing monitoring and evaluation of interventions, certain enhancements to the existing HMIS are under consideration for roll-out during the first year of intervention (i.e. between baseline and follow-up surveys). These are:

1. *Management and Tracking Tool (MTT).* The MTT is a simple, user friendly Excel-based tool to extend the reach of the HMIS to the innovative service delivery channels introduced by the CDI and PPP interventions. This will incorporate basic automated data analysis. The MTT will initially be piloted in purposively selected LGAs to assess whether the tool is successful in capturing needed data, as well as to gauge demand and capacity for further scale-up of the tool.

2. *Text message-based reporting.* Building on the successful use by the NMCP of text messaging to monitor and manage mass LLIN distribution campaigns, this widely used technology is proposed for routine reporting by PMVs (and possibly CDDs) on basic indicators such as diagnostic tests performed, number of persons treated, and quantity of drugs distributed. As with the MTT, this mHealth-type intervention will initially be piloted in purposively selected LGAs to assess its potential and gauge demand and capacity for further scale-up.[5]

[5] mHealth can be defined as the use of mobile communications and network technologies for healthcare (3G Doctor Blog, 2010).

V. Timeline and Budget

Table 4 provides an indicative timeline from the present on.

Table 4: Timeline

Activity	**Dates**
Instrument development	February-August 2010
Ethical clearance	May-August 2010
Preliminary listing for randomization and implementation	August-October 2010
Training and pilot testing for baseline	September-October 2010
Baseline data collection	November 2010-January 2011
CDI & PMV interventions	February 2011-January 2012
Routine program monitoring	February 2011-January 2012
Baseline report	July 2011
Training and pilot testing for follow-up	September-October 2011
Follow-up data collection	November 2011-January 2012
Final IE/IR report	September 2012

Table 5 provides an indicate budget in USD per round of data collection in both the IE states (Akwa Ibom, Anambra, and Gombe) and IR states (Bauchi, Jigawa, Kano, and Rivers).

Table 5: Budget Per Survey Round

	IMPACT EVALUATION STATES			
	Survey	Estimated Unit Cost	Estimated No. of Units	Total Estimated Cost
Akwa Ibom	Household	100	2,720	272,000
	Community	25	272	6,800
	PMV	25	1,056	26,400
	CDD	25	544	13,600
	PPHF*	80	272	21,760
			Sub-total	*340,560*
Anambra	Household	100	3,850	385,000
	Community	25	385	9,625
	PMV	25	1,308	32,700
	CDD	25	770	19,250
	PPHF*	80	385	30,800
			Sub-total	*477,375*
Gombe	Household	100	1,280	128,000
	Community	25	128	3,200
	PMV	25	458	11,450
	CDD	25	256	6,400
	PPHF*	80	128	10,240
			Sub-total	*159,290*
	** Includes health worker module*			
			IE TOTAL	***977,225***

	IMPLEMENTATION RESEARCH STATES			
	Survey	Estimated Unit Cost	Estimated No. of Units	Total Estimated Cost
Bauchi	Household	40	1,160	46,400
	Community	10	116	1,160
	PMV	10	848	8,480
	CDD	10	232	2,320
	PPHF*	32	116	3,712
			Sub-total	*62,072*
Jigawa	Household	40	3,510	140,400
	Community	10	351	3,510
	PMV	10	1,120	11,200
	CDD	10	702	7,020
	PPHF*	32	351	11,232
			Sub-total	*173,362*
Kano	Household	40	7,860	314,400
	Community	10	786	7,860
	PMV	10	1,932	19,320
	CDD	10	1,572	15,720
	PPHF*	32	786	25,152
			Sub-total	*382,452*
Rivers	Household	40	3,860	154,400
	Community	10	786	7,860
	PMV	10	1,932	19,320
	CDD	10	1,572	15,720
	PPHF*	32	786	25,152
			Sub-total	*222,452*
			IR TOTAL	***840,338***

Estimated data collection costs for all seven states are summarized in Table 6.

Table 6: Summary of estimated data collection costs

State	Baseline	Follow-up	Total
Akwa Ibom	340,560	340,560	681,120
Anambra	477,375	477,375	954,750
Gombe	159,290	159,290	318,580
Sub-total for IE states	*977,225*	*977,225*	*1,954,450*
Bauchi	62,072	62,072	124,144
Jigawa	173,362	173,362	346,724
Kano	382,452	382,452	764,904
Rivers	222,452	222,452	444,904
Sub-total for IE states	*840,338*	*840,338*	*1,680,676*
TOTAL	**1,817,563**	**1,817,563**	**3,635,126**

Annex 1: Minimum Detectable effect sizes under different ICCs and sample sizes per cluster

AKWA IBOM STATE

Treatment 1: CDI intervention only. Of the 272 PPHFs in the study area, 136 will be randomly assigned to the CDI intervention. The mean of NET and DRUG in Akwa Ibom are 13.5% and 2.28%, respectively. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size 7.06% in NET and 2.25% in DRUG. Tables A1 and A2 provide detectable effect sizes for NET and DRUG, respectively, for different ICCs and number of individuals N sampled per primary sampling unit.

Table A1: Alternate detectable effect sizes – Akwa Ibom Treatment 1 (NET)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0519	0.0367	0.0300	0.0259	0.0232
0.0500	0.0568	0.0442	0.0391	0.0362	0.0344
0.1000	0.0614	0.0506	0.0464	0.0442	0.0428
0.1500	0.0656	0.0562	0.0527	0.0509	0.0498
0.2000	0.0696	0.0614	0.0584	0.0568	0.0559
0.2500	0.0734	0.0661	0.0636	0.0622	0.0614
0.3000	0.0770	0.0706	0.0683	0.0672	0.0665
0.3500	0.0804	0.0747	0.0728	0.0718	0.0711
0.4000	0.0837	0.0787	0.0770	0.0761	0.0756
0.4500	0.0868	0.0825	0.0809	0.0802	0.0797
0.5000	0.0899	0.0861	0.0847	0.0841	0.0837

Table A2: Alternate detectable effect sizes – Akwa Ibom Treatment 1 (DRUG)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0165	0.0117	0.0095	0.0083	0.0074
0.0500	0.0181	0.0141	0.0124	0.0115	0.0110
0.1000	0.0196	0.0161	0.0148	0.0141	0.0136
0.1500	0.0209	0.0179	0.0168	0.0162	0.0159
0.2000	0.0222	0.0196	0.0186	0.0181	0.0178
0.2500	0.0234	0.0211	0.0203	0.0198	0.0196
0.3000	0.0245	0.0225	0.0218	0.0214	0.0212
0.3500	0.0256	0.0238	0.0232	0.0229	0.0227
0.4000	0.0267	0.0251	0.0245	0.0242	0.0241
0.4500	0.0277	0.0263	0.0258	0.0255	0.0254
0.5000	0.0286	0.0274	0.0270	0.0268	0.0267

Treatment 2: PMV intervention only. Of the 264 wards in the study area, 132 will be randomly assigned to the PMV intervention. The mean of DRUG in Akwa ibom is 1.2%. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size on DRUG of 2.28 percentage points. Table A3 provides detectable effect sizes for different ICCs and number of individuals N sampled per primary sampling unit.

Table A3: Alternate detectable effect sizes – Akwa Ibom Treatment 2 (DRUG)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0168	0.0119	0.0097	0.0084	0.0075
0.0500	0.0184	0.0143	0.0126	0.0117	0.0111
0.1000	0.0199	0.0164	0.0150	0.0143	0.0138
0.1500	0.0212	0.0182	0.0171	0.0165	0.0161
0.2000	0.0225	0.0199	0.0189	0.0184	0.0181
0.2500	0.0237	0.0214	0.0206	0.0201	0.0199
0.3000	0.0249	0.0228	0.0221	0.0217	0.0215
0.3500	0.0260	0.0242	0.0235	0.0232	0.0230
0.4000	0.0271	0.0255	0.0249	0.0246	0.0244
0.4500	0.0281	0.0267	0.0262	0.0259	0.0258
0.5000	0.0291	0.0278	0.0274	0.0272	0.0271

Treatment 3: CDI and PMV interventions. For the joint intervention, we consider 61 intervention clusters and 61 pure control clusters. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size of 10.54 percentage points in NET and 3.36 percentage points in DRUG. Tables A4 and A5 detectable effect sizes for NET and DRUG, respectively for different ICCs and number of individuals N sampled per primary sampling unit.

Table A4: Alternate detectable effect sizes – Akwa Ibom Treatment 3 (NET)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0775	0.0548	0.0447	0.0387	0.0347
0.0500	0.0849	0.0660	0.0583	0.0541	0.0514
0.1000	0.0917	0.0755	0.0693	0.0660	0.0639
0.1500	0.0980	0.0840	0.0788	0.0760	0.0743
0.2000	0.1040	0.0917	0.0872	0.0849	0.0835
0.2500	0.1096	0.0988	0.0949	0.0929	0.0917
0.3000	0.1149	0.1054	0.1020	0.1003	0.0992
0.3500	0.1200	0.1116	0.1087	0.1072	0.1062
0.4000	0.1249	0.1175	0.1149	0.1136	0.1128
0.4500	0.1297	0.1231	0.1209	0.1197	0.1190
0.5000	0.1342	0.1285	0.1265	0.1255	0.1249

Table A5: Alternate detectable effect sizes – Akwa Ibom Treatment 3 (DRUG)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0247	0.0175	0.0143	0.0123	0.0110
0.0500	0.0270	0.0210	0.0186	0.0172	0.0164
0.1000	0.0292	0.0241	0.0221	0.0210	0.0204
0.1500	0.0312	0.0268	0.0251	0.0242	0.0237
0.2000	0.0331	0.0292	0.0278	0.0270	0.0266
0.2500	0.0349	0.0315	0.0302	0.0296	0.0292
0.3000	0.0366	0.0336	0.0325	0.0320	0.0316
0.3500	0.0382	0.0356	0.0346	0.0341	0.0339
0.4000	0.0398	0.0374	0.0366	0.0362	0.0359
0.4500	0.0413	0.0392	0.0385	0.0381	0.0379
0.5000	0.0428	0.0409	0.0403	0.0400	0.0398

ANAMBRA STATE

Treatment 1: CDI intervention only. Of the 385 PPHFs in the study area, 192 will be randomly assigned to the CDI intervention. The mean of NET and DRUG in Anambra are 12.2% and 0.5%, respectively. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size 5.69% in NET and 1.23% in DRUG. Table A6 and A7 provide detectable effect sizes for NET and DRUG, respectively, for different ICCs and number of individuals N sampled per primary sampling unit.

Table A6: Alternate detectable effect sizes – Anambra Treatment 1 (NET)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0418	0.0296	0.0241	0.0209	0.0187
0.0500	0.0458	0.0356	0.0315	0.0292	0.0277
0.1000	0.0495	0.0408	0.0374	0.0356	0.0345
0.1500	0.0529	0.0453	0.0425	0.0410	0.0401
0.2000	0.0561	0.0495	0.0471	0.0458	0.0450
0.2500	0.0592	0.0533	0.0512	0.0501	0.0495
0.3000	0.0620	0.0569	0.0551	0.0541	0.0536
0.3500	0.0648	0.0603	0.0587	0.0578	0.0574
0.4000	0.0674	0.0634	0.0620	0.0613	0.0609
0.4500	0.0700	0.0665	0.0652	0.0646	0.0643
0.5000	0.0724	0.0694	0.0683	0.0678	0.0674

Table A7: Alternate detectable effect sizes – Anambra Treatment 1 (DRUG)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0090	0.0064	0.0052	0.0045	0.0040
0.0500	0.0099	0.0077	0.0068	0.0063	0.0060
0.1000	0.0107	0.0088	0.0081	0.0077	0.0074
0.1500	0.0114	0.0098	0.0092	0.0088	0.0086
0.2000	0.0121	0.0107	0.0101	0.0099	0.0097
0.2500	0.0127	0.0115	0.0110	0.0108	0.0107
0.3000	0.0134	0.0123	0.0119	0.0117	0.0115
0.3500	0.0140	0.0130	0.0126	0.0125	0.0124
0.4000	0.0145	0.0137	0.0134	0.0132	0.0131
0.4500	0.0151	0.0143	0.0141	0.0139	0.0138
0.5000	0.0156	0.0149	0.0147	0.0146	0.0145

Treatment 2: PMV intervention only. Of the 327 wards in the study area, 163 will be randomly assigned to the PMV intervention. The mean of DRUG in Anambra is 0.5%. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size on DRUG of 1.33 percentage points. Table A8 provides detectable effect sizes for different ICCs and number of individuals N sampled per primary sampling unit.

Table A8: Alternate detectable effect sizes – Anambra Treatment 2

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0098	0.0069	0.0056	0.0049	0.0044
0.0500	0.0107	0.0083	0.0074	0.0068	0.0065
0.1000	0.0116	0.0095	0.0088	0.0083	0.0081
0.1500	0.0124	0.0106	0.0099	0.0096	0.0094
0.2000	0.0131	0.0116	0.0110	0.0107	0.0105
0.2500	0.0138	0.0125	0.0120	0.0117	0.0116
0.3000	0.0145	0.0133	0.0129	0.0127	0.0125
0.3500	0.0152	0.0141	0.0137	0.0135	0.0134
0.4000	0.0158	0.0148	0.0145	0.0143	0.0142
0.4500	0.0164	0.0155	0.0153	0.0151	0.0150
0.5000	0.0169	0.0162	0.0160	0.0159	0.0158

Treatment 3: CDI and PMV interventions. For the joint intervention, we consider 81 intervention clusters and 82 pure control clusters. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size of 8.76 percentage points in NET and 1.89 percentage points in DRUG. Tables A9 and A10 provide detectable effect sizes for NET and DRUG, respectively, for different ICCs and number of individuals N sampled per primary sampling unit.

Table A9: Alternate detectable effect sizes – Anambra Treatment 3 (NET)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0644	0.0455	0.0372	0.0322	0.0288
0.0500	0.0705	0.0548	0.0485	0.0450	0.0427
0.1000	0.0762	0.0628	0.0576	0.0548	0.0531
0.1500	0.0815	0.0698	0.0655	0.0632	0.0618
0.2000	0.0864	0.0762	0.0725	0.0705	0.0694
0.2500	0.0911	0.0821	0.0789	0.0772	0.0762
0.3000	0.0955	0.0876	0.0848	0.0833	0.0825
0.3500	0.0998	0.0928	0.0903	0.0891	0.0883
0.4000	0.1038	0.0977	0.0955	0.0944	0.0938
0.4500	0.1078	0.1023	0.1005	0.0995	0.0989
0.5000	0.1115	0.1068	0.1052	0.1043	0.1038

Table A10: Alternate detectable effect sizes – Anambra Treatment 3 (DRUG)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0139	0.0098	0.0080	0.0069	0.0062
0.0500	0.0152	0.0118	0.0104	0.0097	0.0092
0.1000	0.0164	0.0135	0.0124	0.0118	0.0114
0.1500	0.0176	0.0150	0.0141	0.0136	0.0133
0.2000	0.0186	0.0164	0.0156	0.0152	0.0149
0.2500	0.0196	0.0177	0.0170	0.0166	0.0164
0.3000	0.0206	0.0189	0.0183	0.0180	0.0178
0.3500	0.0215	0.0200	0.0195	0.0192	0.0190
0.4000	0.0224	0.0210	0.0206	0.0203	0.0202
0.4500	0.0232	0.0221	0.0216	0.0214	0.0213
0.5000	0.0240	0.0230	0.0227	0.0225	0.0224

GOMBE STATE

Treatment 1: CDI intervention only. Of the 128 PPHFs in the study area, 64 will be randomly assigned to the CDI intervention. The mean of NET and DRUG in Gombe are 11.8% and 4.12%, respectively. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size 9.71% in NET and 3.89% in DRUG. Tables A11 and A12 provide detectable effect sizes for NET and DRUG, respectively, for different ICCs and number of individuals N sampled per primary sampling unit.

Table A11: Alternate detectable effect sizes – Gombe Treatment 1 (NET)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0714	0.0505	0.0412	0.0357	0.0319
0.0500	0.0782	0.0608	0.0538	0.0499	0.0474
0.1000	0.0845	0.0696	0.0639	0.0608	0.0589
0.1500	0.0903	0.0774	0.0726	0.0701	0.0685
0.2000	0.0958	0.0845	0.0804	0.0782	0.0769
0.2500	0.1010	0.0910	0.0875	0.0856	0.0845
0.3000	0.1059	0.0971	0.0940	0.0924	0.0915
0.3500	0.1106	0.1029	0.1001	0.0988	0.0979
0.4000	0.1151	0.1083	0.1059	0.1047	0.1040
0.4500	0.1195	0.1135	0.1114	0.1103	0.1097
0.5000	0.1237	0.1184	0.1166	0.1157	0.1151

Table A12: Alternate detectable effect sizes – Gombe Treatment 1 (DRUG)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0286	0.0202	0.0165	0.0143	0.0128
0.0500	0.0313	0.0244	0.0215	0.0200	0.0190
0.1000	0.0339	0.0279	0.0256	0.0244	0.0236
0.1500	0.0362	0.0310	0.0291	0.0281	0.0274
0.2000	0.0384	0.0339	0.0322	0.0313	0.0308
0.2500	0.0405	0.0365	0.0350	0.0343	0.0339
0.3000	0.0424	0.0389	0.0377	0.0370	0.0366
0.3500	0.0443	0.0412	0.0401	0.0396	0.0392
0.4000	0.0461	0.0434	0.0424	0.0420	0.0417
0.4500	0.0479	0.0455	0.0446	0.0442	0.0440
0.5000	0.0496	0.0475	0.0467	0.0464	0.0461

Treatment 2: PMV intervention only. Of the 114 wards in the study area, 57 will be randomly assigned to the PMV intervention. The mean of DRUG in Gombe is 1.7%. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size on DRUG of 4.12% percentage points. Table A13 provides detectable effect sizes for different ICCs and number of individuals N sampled per primary sampling unit.

Table A13: Alternate detectable effect sizes – Gombe Treatment 2

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0303	0.0214	0.0175	0.0152	0.0136
0.0500	0.0332	0.0258	0.0228	0.0212	0.0201
0.1000	0.0359	0.0296	0.0271	0.0258	0.0250
0.1500	0.0384	0.0329	0.0308	0.0297	0.0291
0.2000	0.0407	0.0359	0.0341	0.0332	0.0327
0.2500	0.0429	0.0387	0.0371	0.0364	0.0359
0.3000	0.0450	0.0412	0.0399	0.0392	0.0388
0.3500	0.0470	0.0437	0.0425	0.0419	0.0416
0.4000	0.0489	0.0460	0.0450	0.0445	0.0441
0.4500	0.0507	0.0482	0.0473	0.0469	0.0466
0.5000	0.0525	0.0503	0.0495	0.0491	0.0489

Treatment 3: CDI and PMV interventions. For the joint intervention, we consider 28 intervention clusters and 29 pure control clusters. With ICC=0.3, using a sample of ten households per cluster, we can detect a minimum effect size of 14.68 percentage points in NET and 5.88 percentage points in DRUG. Tables A14 and A15 provide detectable effect sizes for NET and DRUG, respectively, for different ICCs and number of individuals N sampled per primary sampling unit.

Table A14: Alternate detectable effect sizes – Gombe Treatment 3 (NET)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.1080	0.0763	0.0623	0.0540	0.0483
0.0500	0.1183	0.0919	0.0813	0.0754	0.0716
0.1000	0.1277	0.1052	0.0966	0.0919	0.0890
0.1500	0.1366	0.1170	0.1097	0.1059	0.1036
0.2000	0.1449	0.1277	0.1215	0.1183	0.1163
0.2500	0.1527	0.1376	0.1322	0.1294	0.1277
0.3000	0.1601	0.1468	0.1421	0.1397	0.1383
0.3500	0.1673	0.1555	0.1514	0.1493	0.1480
0.4000	0.1741	0.1637	0.1601	0.1583	0.1572
0.4500	0.1807	0.1716	0.1684	0.1668	0.1659
0.5000	0.1870	0.1790	0.1763	0.1749	0.1741

Table A15: Alternate detectable effect sizes – Gombe Treatment 3 (DRUG)

ICC/N	5.0000	10.0000	15.0000	20.0000	25.0000
0	0.0433	0.0306	0.0250	0.0216	0.0193
0.0500	0.0474	0.0368	0.0326	0.0302	0.0287
0.1000	0.0512	0.0422	0.0387	0.0368	0.0357
0.1500	0.0547	0.0469	0.0440	0.0424	0.0415
0.2000	0.0580	0.0512	0.0487	0.0474	0.0466
0.2500	0.0612	0.0551	0.0530	0.0519	0.0512
0.3000	0.0642	0.0588	0.0570	0.0560	0.0554
0.3500	0.0670	0.0623	0.0607	0.0598	0.0593
0.4000	0.0698	0.0656	0.0642	0.0634	0.0630
0.4500	0.0724	0.0687	0.0675	0.0668	0.0665
0.5000	0.0749	0.0717	0.0706	0.0701	0.0698

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