Evaluating the additive effect of an indoor residual spraying campaign for reducing the burden of malaria in an Eritrean low-transmission setting

Impact Evaluation Concept Note

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A. Introduction

Despite considerable advances in medical, technological, vector, and biological-based intervention strategies, total malaria control remains an elusive goal in SSA. There are an estimated 300 to 660 million clinical cases of malaria each year (Snow *et al* 2005), with 90% occurring in SSA. Approximately 1 million children (<5 years) in SSA die each year from malaria-related illnesses (Snow *et al.* 2003), constituting nearly 20% of child mortality and 10% of overall mortality (WHO 2006).

Eritrea has long been recognized as a success story with respect to the control of malaria, having greatly reduced the burden using a combination of case management, larval control, ITN distribution strategies, and prompt and effective epidemic response. Despite considerable advances in the reduction of malaria transmission over the last 9 years, malaria elimination has not yet been achieved in Eritrea. In 2007 for example, 85,918 cases of malaria were detected and treated in Eritrea, and 35 deaths were reported; over half of these cases and 60% of the malaria-related deaths came from the western low-land areas of the country. Malaria is the leading cause of death among children under 5 years old in Eritrea. In Eritrea, approximately 70% of the population lives in areas infested with potential malaria vectors, namely *Anopheles gambiae* s.s. and *An. arabiensis* (Shilulu *et al.* 2003).

The integration of combinations of malaria control tools has long been proposed as the most effective approach for malaria control (Ross 1911). It is possible to break transmission between the mosquito vector and humans through the use of such integrated tools (Karch *et al*. 1991, Majori *et al*. 1987, Romi *et al*. 1993, Utizinger *et al.* 2001, Killeen *et al*. 2002, Castro *et al*. 2004). However, the evidence base for this approach needs to be further strengthened. For example, few contemporary studies have been done to evaluate the effectiveness of IRS over and above traditional approaches such as ITN use and larval habitat management in Africa. While several studies have assessed the costs and cost-effectiveness of IRS (Breman *et al.* 2006, Conteh *et al.* 2004, Curtis & Mnzava 2000, Guyatt *et al.* 2002a and 2002b, Goodman *et al.* 2001, Verlé, *et al*. 1999, Goodman & Mills 1999, Kere & Kere 1992), these have largely sought to compare the costs and cost-effectiveness of individual interventions, particularly IRS versus ITNs, rather than to assess the incremental costs and cost-effectiveness of combinations of interventions. A notable exception is Morel *et al*. (2005), who modeled the costs and cost-effectiveness of various combinations of case management regimes, ITNs, and IRS assuming different levels of coverage.

Evidence suggests that multiple vector control strategies may be more beneficial when used in combination, and that IRS can complement other existing malaria control strategies by reducing the reliance on any single intervention alone to reduce the burden of malaria. However, this integrated malaria control approach still needs to be properly tested and evaluated. It is therefore useful to determine the extent to which adding IRS to larval habitat management and ITN use, is useful for long-term community-level malaria control in a low-transmission setting like Eritrea. Integrating entomological, economic, socio-behavioral, and epidemiological data to understand malaria transmission dynamics in relation to interventions, as we propose here, is a vital part of assessing the added value of integrated vector-borne disease control strategies.

B. Study Objectives

This study investigates whether the IRS, in combination with ITNs and larval habitat management (LHM), has an additive cost-effective benefit for reducing malaria related mortality and morbidity in low transmission settings. There are three main components to this impact evaluation: entomological studies, epidemiological studies, and economic assessments of the cost-effectiveness of malaria control interventions. Multiple data collection strategies will be used in this study. The overall objective is to evaluate the impact on reducing malaria parasite infection by adding IRS to an existing package of integrated vector control interventions. A secondary objective is to evaluate the cost-effectiveness of adding IRS, in relation to ITN and LHM alone. This study will address the following questions:

1. What is the additive impact of IRS on malaria prevalence reductions in children and adults?
2. What is the impact of IRS on labor supply and consumption at the household level, over that secured through the use of ITNs and LHM?
3. Does IRS induce an adverse behavioral response from the population such as reduced ITN use or LHM (substitution of ITN and LHM for IRS), and thus reduce the effectiveness of baseline interventions?

Key outcomes include:

1. Malaria parasite prevalence in children and adults
2. Abundance, composition, and infectivity rate of adult mosquitoes
3. Number of hours/days worked/lost to sickness, as a measure of productivity in the workforce.
4. School attendance, as an indicator of inequality in opportunities and long-term labor productivity.
5. ITN use among children and adults.

C. Research Design and Methods

A two-arm cluster-randomized community-controlled trial design will be used to evaluate the impact of IRS on malaria prevalence and related outcomes (Table 1). This evaluation design will measure the additive impact of IRS over current NMCP interventions; effectiveness will be measured as a single difference between treatment and control groups across the range of outcome indicators listed above. The main base of field operations will be Gash Barka Zone. We have chosen to conduct this evaluation in Gash Barka because the NMCP is already rolling out ITNs and LHM, and because of the high burden of malaria, relative to other Zones in Eritrea.

In addition to the impact evaluation results, the epidemiological and entomological data will yield the following: 1) an understanding of spatial distributions of malaria vectors in the low-land areas of Gash Barka (pattern); 2) the identification of household characteristics and human activities that significantly impact human-vector interaction (process); 3) an understanding of which environmental features and human activities are related to malaria disease (prediction); 4) a basis for formulating and testing optimal IRS implementation strategies in relation to ongoing ITN and larval habitat management (prevention); and 5) models for estimating the incremental impact and cost of malaria transmission reductions using IRS over and above existing ITN and larval habitat management strategies (evaluation).

Table 1: Arms of the study

	NMCP+ IRS	NMCP + No IRS
Groups	(Treatment)	(Control)
Sample size	58 villages	59 villages

C.1. Study Site Description

Eritrea has an estimated population of 3.5 million people and is divided into 6 administrative *zobas* (zones); this study will take place in Gash Barka, a mostly rural/agricultural area with typically higher malaria transmission relative to other malariaous zones in the country. The population of Gash Barka zone is 20% of the total population in Eritrea. Altitudes range from below sea level to 3,000 meters country-wide, although altitudes in Gash Barka range from approximately 500 meters to 1500 meters. Temperatures vary widely across Eritrea, although the western lowlands (Gash Barka) are generally associated with extremely hot and dry climatic conditions. The average precipitation in the western lowland is approximately 200 mm per year. *Anopheles arabiensis* and *An. gambiae* s.s., both belonging to the *An. gambiae* complex, form the main vectorial system in Eritrea (Shililu *et al.* 2003b; Shililu *et al.* 2003a; Shililu *et al.* 2004). *Plasmodium falciparum* is the primary species of malaria found in Eritrea, although *P. vivax* has also been reported (Shililu 2001). Malaria transmission is seasonal, with estimates of entomological inoculation rates ranging from zero to 70.6 infective bites per person per year (Shililu *et al*. 2003b). Over 50% of all outpatient and inpatient diagnosed malaria in the country came from the Gash Barka zone in 2007; over 60% of all malaria related deaths also came from Gash Barka in 2007. The same trend also holds true for 2008.

C.2. Intervention and Control Arm Description

C.2.1 Intervention

The intervention involves the control of adult mosquito populations using IRS with the insecticide DDT, the insecticide recommended by the Eritrea National Malaria Control Program. In each intervention village, all households will be sprayed according to the manufacturer's recommended guidelines. The spraying will strive to cover all households, thus ensuring a minimum coverage of 90% of households, and not fall below 80% as per WHO recommendations. Villages in the intervention arm also benefit from existing NMCP vector control interventions (e.g. ITN and larval habitat management).

Monitoring will involve adult mosquito mortality tests and bio-cone assays to assess the level of residual activity as the intervention proceeds. We expect that spraying will occur during the months of July-September. Team members will meet, as already done, to discuss issues and plan information dissemination strategies. The NMCP entomology team is already trained on the proper application techniques, storage, and disposal of contaminated equipment, as IRS is already done on a limited basis.

C.2.2 Control

In the control and intervention arms of the project, the existing NMCP strategy for malaria vector control malaria will be used: ITN and larval habitat management. The NMCP field teams and community health workers will carry out larval habitat inspections and larvicide applications within both the control and intervention villages, per existing protocol.

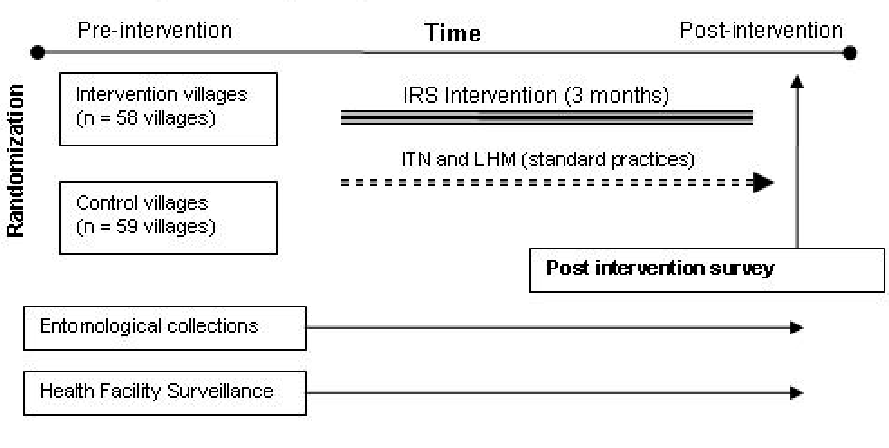
C.2.3 Unit of Randomization

The unit of randomization will be the village in Gash Barka Zoba. Fifty-eight (58) villages within Gash Barka will be randomly assigned to the treatment group, and 59 villages in Gash Barka will be randomly assigned to serve as the control group. As a result of randomization, the villages in each arm will be balanced across a set of important indicators, including population size, environmental factors (altitude, rainfall, temperature and humidity) and ITN coverage.

C.3. Evaluation Plan

This study will use a post-test design to assess the relative effectiveness of the IRS intervention. The intervention will the be implemented for 3 months, after which time a post-intervention household survey will be conducted to ascertain relative changes in impact and outcome indicators between treatment and control groups attributable to the IRS intervention, while controlling for potential environmental and human-behavioral confounders. Before the end of the malaria season (October/November), a household survey will be conducted in treatment and control villages to collect data on malaria, household characteristics, consumption, labor supply, and school attendance. Malaria indicators will include parasite prevalence, fever incidence, and malaria related knowledge. This study will also collect information on behavior (e.g. ITN use, participation in EM activities, sleeping location, and health seeking). Reported reason for denying entrance to IRS agents will also be collected from each household sampled. Secondarily, population based data from the household survey will be compared with facility and community health worker data, especially the number of malaria cases and deaths detected at health facilities and by community health workers within the intervention and control groups, as a retrospective method for assessing effectiveness. Lastly, the effect of the IRS intervention on mosquito populations will be assessed using monthly entomological surveys to assess the relative abundance, composition, and infectivity rate of adult mosquitoes collected in control vs. intervention villages. Figure 1 illustrates the study design and timeline.

Figure 1: Study design overview



C.4. Study Outcomes and Indicators

This study uses epidemiological, entomological, and economic indicators to assess the effectiveness of alternative interventions, over and above ITN use and larval habitat management, for reducing the burden of malaria.

We will test the following hypotheses:

1. IRS will lead to lower prevalence of malaria in residents of intervention villages, relative to residents in control villages, where ITN use and larval habitat management is the standard malaria control practice.
2. Labor supply of adults will increase as will household consumption, and the same will happen with school attendance by children, as malaria prevalence declines.

3. The abundance of infectious mosquitoes will be lower in intervention villages, as compared to control villages.
4. The number and proportion of malaria cases seen in health facilities and as detected by community health workers within intervention villages will be lower than that observed in control villages.
5. The incremental cost-effectiveness of IRS for reducing malaria parasite prevalence and malaria related morbidity is higher than the use of ITN and larval habitat management alone.
6. The effectiveness of ITN and larval habitat management alone will be hampered by behavioral response to the decline in mosquito density.

The primary malaria impact indicators to be used in this evaluation are:

- Malaria parasite prevalence, defined as the proportion of individuals testing positive for malaria parasite infection
- Malaria related morbidity, defined as the number of cases presenting at health facilities with malaria parasite infection and clinical symptoms of malaria disease.

Malaria outcome indicators to be used in this evaluation are:

- Entomological inoculation rate (EIR) per village, defined as an estimate of the number of infectious bites per person per unit time (Note: if EIR is not logistically feasible, we will use the abundance of infectious mosquitoes per village and the sporozoite rate in villages, as two separate indicators)
- Disability adjusted life year (DALY)
- Use of ITN coverage rate, defined as the proportion of residents sleeping under an ITN the night before the survey
- IRS coverage rate, defined as the proportion of houses sprayed in last 12 months

Socio-economic outcome indicators will include:

- Household consumption
    - Food
    - Medical expenses (monthly and annual)
    - Educational expenses
    - Transport
- Labor supply (all members of the household)
    - Hours and days worked inside the home and outside the home during the last week/month
    - Number of days of work lost due to illness
    - Number of days/hours of work lost due to the caring of children<5 and other members of the household
- School attendance (if schools open)
    - Days at school during the last week
    - Hours of study during the last week
    - Number of days of school lost due to illness
    - Number of days/hours of school lost due to the caring of other members of the household

C.5. Sampling Design

A two-stage cluster design will be used to generate a probability sample of households within the study area for each of the survey domains (control versus intervention groups). Detailed sampling frames consisting of a count of all households within primary sampling unit (PSU -

village) are currently available from the NMCP. PSUs will consist of villages within the study area of Gash Barka, divided into intervention and control villages. To maximize sampling efficiency, 58 PSUs will be selected for each survey domain at the first stage, with 15 households selected from each PSU at the second stage, thereby obtaining a total sample size of 1,740 houses (after adding non-response, the total number of houses is equal to 1,914). The list of eligible PSUs for the study was provided by the NMCP. All households within each selected PSU will be enumerated by the Orotta School of Medicine to create the second stage sampling frames for households. Enumeration of households within each PSU will also allow data to be weighted during analysis if needed. For the second stage, 17 households (ultimate sampling units) will be systematically (systematic random sampling) selected within each enumerated PSU. Data will then be collected at the household level. Survey fieldwork will be conducted just following/during the rainy season in September, 2009.

C.6. Sample Size and Power Calculations

A sample size of 870 households in the treatment group (58 villages, 15 households per village) and the same number in the control group will allow the detection (at a 5% level of significance) of a reduction of 10.47% points in malaria parasite prevalence from a baseline of about 15-20% with 80% power. This assumes that the intra-cluster correlation is 0.2. The total sample size is 1,740 households. Adding 10% to account for non-response yields a total sample size of 1,914 houses. Given that there are approximately 4.5 individuals per household, the total sample of individuals will be 8,613.

C.7. Data Collection Activities

C.7.1 Entomological Data Collection

Adult mosquitoes will be collected over a two month period in selected intervention and control villages; 8 houses will be selected for collections and traps will run for 7 days at each house. Adult mosquitoes will be collected using CDC light traps. Locations of adult sampling sites will be recorded by GPS. We expect to conduct adult mosquito sampling monthly within the study area to obtain reliable data on the species composition, distribution, and densities of host-seeking mosquitoes. Simple random sampling will be used to select the houses for adult mosquito collections; house selections will be drawn from a complete listing of households within the selected village. The number of children and adults who reportedly slept in the house the previous night, as well as characteristics about the house (e.g. house construction type, presence of eaves/screens, etc) will be noted. Biting rates will be calculated from CDC light trap-collected mosquitoes as the total number of mosquitoes collected in the house with a human blood-meal, divided by the number of persons who slept in the house during the night. This is a standard method for assessing host contact, which we have validated against landing catches at sites along the Kenyan coast. Laboratory processing will involve dissecting anopheline mosquitoes to look for *P. falciparum* circumsporozoite protein in salivary glands to determine sporozoite rates (Wirtz *et al*. 1987). Combined with estimates of mosquito contact, the sporozoite rates will allow us to calculate and track temporal and spatial variation in EIRs (Beier *et al*. 1994). Malaria agents and community members will be trained to set-up, operate and empty traps.

C.7.2. Household Survey

A modified MIS style questionnaire will be administered to one resident adult at randomly selected households in both the control and intervention villages at the completion of intervention. Socio-economic data will include the household roster, and modules on consumption, assets, education, participation in community activities, and labor supply.

Household data will be used to generate variables related to age, gender, consumption and asset holding, investment in human capital, labor supply, economic valuation of health benefits, ITN use, LHM participation, history of malaria within the household, treatment seeking patterns, travel history, and nocturnal activities of household occupants (i.e. activities that may reduce the likelihood of ITN use). This activity will also focus on identifying and quantifying individuals in the house who travel, how often they travel, and at what time during the day and year they are most likely to travel. Parasite prevalence and febrile illness data will be collected from all household residents greater than one month old. For all household residents, a small sample of blood will be taken from the finger (by standard finger-prick methods using a sterile lancet) for the rapid diagnosis of malaria using rapid diagnostic test kits. For individuals testing positive, a second drop of blood will be taken to make thick/thin blood films for confirming parasite infection status and parasite density. Blood slides will be transported to Barentu Zonal Referal Hospital Laboratory and NMCP headquarters in Asmara for staining and microscopic evaluation. Two separate microscopists will examine blood-slides (100 thick film fields x 1,000x), one in Gash Barka and 1 in Asmara, to determine parasite infection status, parasite species, and densities of asexual stages and gametocytes. Individuals testing positive for parasites will be treated with the recommended first-line anti-malarial drugs used in Eritrea. A community health worker/public health technician will provide anti-malarial drug treatment. The parent/guardian will be responsible for administering the treatment and team members will be present to observe the first dose of treatment. The Orrota School of Medicine will be responsible for administering household surveys; community health workers and public health technicians will be hired as needed for data collection. Locations of selected villages will be recorded by GPS.

C.7.3. Health System Surveillance

Confirmed cases of malaria will be identified at health facilities and from community health workers serving control and intervention villages, and when possible, the location of residence, employment status, and travel history collected from patients, at monthly intervals throughout the study. This information will help establish where malaria is coming from, while controlling for secular drift associated with rainfall, temperature, demographic characteristics, and malaria control strategies operating in the area.

C.7.4. Economic Data Collection

The cost analysis of IRS control activities will quantify and value all relevant resources necessary for program implementation and management of the IRS intervention. Cost-analysis (CA) is a necessary precursor to more complete economic evaluations such as cost-effectiveness analysis (CEA), which evaluates program costs relative to their health consequences. The overall goal of the cost analysis is to organize and value resources so policy makers are fully aware of the financial and economic costs of implementation of IRS control activities relative to existing interventions (e.g., ITNs, larval habitat management). Using the existing sample frame, cost data will be collected during the intervention phase of the project to assess the cost of IRS in relation to existing malaria control strategies such as ITN use and larval habitat management. Cost analysis data will be combined with data collected as part of the cross-sectional survey to estimate individual and household cost data.

Intervention costs will be evaluated by examining the program budget, monthly maintenance costs, equipment and materials cost, consultancy costs, person-hours per month to undertake the intervention and monitoring. If data are not available for specific items used and not included in our current program budget, we will consult with NMCP program managers to price resources. The cost of existing ITN programs in Eritrea will be obtained from the NMCP. Questions related to economic activity and willingness to pay for malaria control will be asked of respondents as part of the household survey. Data on life expectancy, gross domestic product per household by administrative area, and relative wealth of areas will come from the Eritrean Central Bureau of Statistics. Demographic data and individual-level cost data will come from household cross-sectional surveys. Data on causes of death and rates of malaria infection detected by community health workers and at health facilities will be obtained.

C.8. Data Analysis

Teams will standardize their field and laboratory methods and resulting datasets to aid comparisons between control and intervention villages. Monthly reports and summaries will be produced to allow tracking of data. This will facilitate exploratory and descriptive analyses as a foundation for testing the hypotheses. Descriptive statistics will be used to summarize adult mosquito data, malaria parasite data, and household occupant characteristics, by location within the study area. Mosquito density will be calculated for households and villages within the study area. Multivariate regression analysis will be used to test the direction and magnitude of the effect of environmental and human ecological factors on the abundance of water adult mosquitoes. Calculating indices of aggregation for the adult mosquito species, using Taylor's power regressions and variance to mean ratios, will determine the extent of clustering or over-dispersion between control and intervention villages. All analyses will control for village level characteristics and location.

Malaria parasite prevalence in household residents at pre, mid, and post-intervention will serve as the primary indicator for measuring the impact of the intervention. At the individual level, malaria parasite prevalence for each sampling method will be calculated as the proportion of sampled individuals with any parasitemia out of all sampled individuals. Malaria parasite prevalence will also be calculated at the household level as the proportion of households with any resident with any parasitemia out of all households surveyed. Empirically estimated standard errors (using the Huber-White-Sandwich estimator) will be obtained for population point estimates of parasite prevalence, using the household as the clustering unit. Multivariate logistic regressions and random effects models will be used, while controlling for transmission season, location, and mosquito density.

For the analysis of the economic data we will start by comparing mean outcomes across villages in each of the treatment groups and in the control village. This will allow us to estimate the effect of IRS on labor supply, consumption, and schooling. Using village characteristics as conditioning variables potentially helps the analysis by reducing small sample bias and the intra-cluster correlation (contributing to a decrease to the standard errors of our estimates). Therefore, as a supplement to the simple mean comparison described above, we will perform regressions of household outcomes on indicators for treatment and control, and several village characteristics.

Cost data will be analyzed to assess the unit and incremental costs of ITN use and larval habitat management in relation to adding IRS. This information will be compared to the costs of ITN distribution and re-impregnation and to the costs of case management for uncomplicated and severe malaria in control and intervention villages. An ingredients approach will be used to calculate unit costs. Resource categories will be assessed independently to identify the more costly components to running larval control, ITN distribution, or IRS. The primary resource categories include: personnel, equipment and supplies (e.g., protective clothing, insecticide, larvicide), vehicles and transportation, training, community sensitization, initial capital investments (for buildings, spraying equipment, and hiring staff), and overhead. Identifying the relative contribution of resource categories to the total cost of each intervention is useful for improving resource allocation decisions and overall program efficiency. To facilitate calculation of these measures, cost interview guides should be developed for NMCP workers who will spend time on IRS, ITN distribution and larval control activities in order to determine person-hours needed to conduct the respective components of the interventions. Both financial (e.g. reflecting actual market prices) and economic costs (reflecting the true opportunity costs of donated inputs and volunteer time) will be analyzed and compared to assess issues of affordability and sustainability. The annual financial costs of capital inputs will be assessed as their replacement value divided by their expected useful life (e.g., 10 years for spray pumps, 5 years for vehicles). The total cost of IRS, larval control and ITN distribution programs will be compared to standard ITN and larval control programs to determine the incremental cost associated with more costly, but potentially more effective, interventions, resource utilization costs, and the cost of each intervention resource category. As well, we will examine the proposed costs of the intervention versus what we actually spend in the field. All cost analyses will be divided to illustrate the costs incurred at the start of the project versus maintenance costs after program has been operational for a period of time. The analysis will emphasize the provider perspective, but we will also assess the direct (e.g., savings to individuals and households from medical treatment averted) and indirect costs (e.g., the value of lost work time from illness and care-seeking) to individuals and households. Once data are collected, we will explore the possibility of conducting a Cost effective analysis of IRS, ITN, and larval control programs relative to ITN and larval control alone. Incremental program costs will be compared to a measure of program effectiveness such as mosquito density and parasite infection rates (per data collected as part of entomological monitoring and household surveys). Program effectiveness will also be expressed in terms of disability-adjusted life years (DALYs), a common effectiveness measure used in existing economic studies of malaria control (Breman *et al.* 2006, Coleman *et al*. 2004, Utzinger *et al*. 2001, Goodman *et al*. 1999).

D. Organizational Plans

The National Malaria Control Program in Eritrea will be the lead institution for this study, with support coming from the World Bank personnel and external consultants. The Orotta School of Medicine will coordinate and implement the household survey. An external consultant will be placed in the field as per IE standard practice to: assist the government in the implementation of the IE, provide technical supervision and ensure lack of contamination between treatments and control groups. Communication will be maintained with NMCP, the Orotta School of Medicine, and the Eritrean MoH throughout the project. To help team members communicate and coordinate activities during the project, the World Bank will continuously monitor, support and manage the activities both in Gash Barka and at the NMCP headquarters in Asmara on a bi-weekly basis, as per a research protocol. As well, the NMCP and Orotta School of Medicne will link closely with the World Bank to store, access, and share data and reports. Specifically, the NMCP and the World Bank will: 1) monitor team performance and activity with monthly progress reports, to be uploaded onto a server at the World Bank; 2) share and maintain training materials and data files both in Eritrea and at the World Bank; 3) keep electronic records of project management models and research designs; and 4) house all data at the World Bank and NMCP, with the understanding that any project investigator interested in reviewing or perusing the data will be allowed to do so.

E. Data Management

At the NMCP, Dr. Tewolde will provide leadership for the data management and analysis, with support from the World Bank and external consultants. Researchers at the World Bank and external consultants will work closely to develop synergistic strategies for maximizing resources and standardizing data management protocols. All data forms and records collected during this research will be held in a secure location by Drs. Tewolde and Pedro Carneiro for the duration of the project. Confidentiality of all respondents will be assured through the replacement of any personal information with unrelated unique identifiers as needed. STATA® and ArcGIS® software will be used to store and clean all data. As previously described, household survey data, entomological data, and geographic datasets will be constructed during the proposed research. Each dataset will be converted to ".dbf" for integration into the GIS and STATA database for analytical purposes. These data will be made available only to project personnel and will be distributed via request, per a research protocol. At the completion of the project, data will be made available more widely within the institutions participating in this project. Hardcopy datasets will not be distributed. The master GIS database, which includes all data, will be made available to key personnel as needed throughout the project. Data sharing agreements will not be required for members of the research team or members of institutions affiliated with this project. Prior to dissemination, the PI and project leaders will approve all requests for datasets. No co-authorship requirements will be required from disseminated data. At the onset of the project, the World Bank team members and external consultants will work with the NMCP to develop protocols for proper data security, tracking, and auditing procedures.

F. Training Component and Capacity Building

This project seeks to promote academic development of students and scientists interested in translational public health evaluation research, as well as build capacity of Eritrea NMCP scientists, Orotta School of Medicine students, and community health workers conducting malaria control, evaluation research, surveillance, and health policy. We will link student and community health worker training directly to the research under the project. We will use public health technicians (and PHT students) and medical students to collect household survey and entomological data, as this approach was highly successful during the bed net surveys conducted in 2003.

G. Timeframe

This study begins in May 2009 and will end in January 2010. The horizon of the evaluation can be expanded to include the 2010 malaria season. In that case, the study will have two phases. The decision to include phase 2 will be made on the basis of the phase 1 results. Below is a timeline of major activities of the first phase:

Project Period (November 2008 – Jan 2010)	***2008***		***2009***									***2010***
Months	**Nov**	**Dec**	**Jan**	**Feb**	**May**	**Jun**	**Jul**	**Sept**	**Oct**	**Nov**	**Dec**	**Jan**
Procurement of entomological materials and light-traps	■	■	■	■								
Randomization of intervention and control villages					■							
Sampling frame development					■							
Implementation of the IRS intervention						■	■					
Training of data collectors								■				
Household survey									■	■		
Entomological data collection									■	■		
Laboratory work and data entry										■	■	
Data analysis											■	■
Dissemination of results												■

H. Key Personnel

World Bank Research Team: The Technical Coordinating Group for the Malaria Impact Evaluation Program (MIEP) includes the World Bank Malaria Booster Program (MBP), the Malaria Implementation Resource Team (MIRT), the Africa Impact Evaluation Initiative (AIM, AFTRL), the Development Impact Evaluation Initiative (DIME) of the World Bank Research Group (DECRG), and academic partners from Harvard University, the Institute for Fiscal Studies/University College London (IFS/UCL), London School of Hygiene and Tropical Medicine (LSHTM) and Tulane University School of Public Health and Tropical Medicine.

Eritrea Research Team: The evaluation is a collaborative effort between the Eritrea Malaria Control Program in the Ministry of Health, Orotta School of Medicine, the WB health project team and the MIEP. Project supervision and harmonization with the country sector strategy will be provided by the project TTL, Rianna Mohammed (AFTH1). Overall supervision of the impact evaluation design and analysis will be provided by Arianna Legovini (impact evaluation TTL, AFTRL), Jed Friedman and Edit Velenyi (DECRG). Eritrea management and coordination of the impact evaluation will be provided by Dr. Tewolde Ghebremeskel (Eritrea NMCP), Afeworki Araya and Selam Mehretab. The Lead Researcher will be Dr. Pedro Carneiro (University College London and Institute for Fiscal Studies), and co-investigators Dr. Tewolde Ghebremeskel (MOH), Professor Andemariam Gebremichael (Orotta School of Medicine), Professor Jacob Mufunda (Orotta School of Medicine), Arianna Legovini (WB), Son Nguyen (WB), Dr. Joseph Keating (Tulane University School of Public Health and Tropical Medicine), Rianna Mohammed (WB), Abdoulaye Sy (Berkeley). Abdoulaye Sy will serve as field coordinator to provide in-country research assistance to the NMCP team.

J. Informed Consent

Informed consent/assent will be required of all individuals participating in this study. For minors, assent will be required, as well as consent from the parent or guardian. A standard consent/assent form will be used, which will be approved by Eritrean and World Bank Institutional Review Boards prior to the onset of the study. As well, members of the team will visit all selected villages prior to the data collection teams to inform village elders and interested community members as to the purpose of the study, the proposed activities, the data collection procedure and to answer any questions. In this way, we will minimize refusal to participate and maximize community participation during the intervention and data collection phases.

K. References

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