Proposal:

Malaria Indicator Survey in the Republic of Sudan in 2012

Principle investigator:

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Contents

Partners

National Statistics and Census Office
World Health Organization
United Nations Children's Fund
United Nation Development Programme
Central Bureau of Statistics
KEMRI/Wellcome Trust Research Programme
Academic institutions

Abbreviations

ACT	Artemisinin-based Combination Therapy
CBS	Central Bureau of Statistics
CQ	Chloroquine
EA	Enumeration Area
ELISA	Enzyme-Linked Immunosorbent Assay
GFATM	Global Fund to Fight AIDS Tuberculosis & Malaria
GIS	Geographical Information System
IDP	Internally Displaced Person
IPT	Intermittent Preventive Treatment
IRS	Indoor Residual Spraying
ITN	Insecticide Treated Net
LLIN	Long Lasting Insecticidal Net
MERG	Monitoring and Evaluation Reference Group
MICS	Multiple Indicators Cluster Surveys
MIS	Malaria Indicator Survey
FMOH	Federal Ministry of Health
NGOs	Non Governmental Organizations
NMCP	National Malaria Control Programme
PSU	Primary Sampling Units
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
SP	Sulphadoxine-Pyrimethamine
WHO	World Health Organization
UNICEF	United Nations Children Fund

1.0 Background

Malaria accounts for a large amount of morbidity and mortality in Africa with clinical cases estimated to be between 250 to 500 million annually and associated with deaths of slightly fewer than one million deaths (Snow et al 2005; Hay et al 2009; WHO 2011). Since 2002, following the establishment of the Global Fund to Fight AIDS, tuberculosis and malaria (GFATM) considerable investment have been put into the scaling up of malaria control intervention in Africa which has led to substantial increase in the coverage of key malaria interventions (WHO 2011; RBM 2010). The main interventions taken to scale are insecticide treated bed nets (ITNs), especially the long-lasting insecticidal nets (LLIN), and artemisinin-based combination therapy (ACT), supported by indoor residual spraying of insecticide (IRS) and intermittent preventive treatment in pregnancy (IPT) in some settings. The protective efficacy of ITNs against malaria has long been established (Lengeler 2004). ITNs impacted on clinical and severe malaria, parasite prevalence, high parasitaemia, splenomegaly and improvement in haemoglobin levels of children (Lengeler 2004). Following the failure of chloroquine and sulphadoxine-pyremethamine as first-line treatment of uncomplicated malaria, almost all malaria endemic countries in Africa have now adopted ACTs as replacement. By 2011, 50% of households in Africa owned at least one ITN, 11% were covered with IRS, while treatments of malaria patients with ACTs steadily increased (WHO 2011).

In Sudan, malaria is a leading cause of morbidity and mortality accounting for 70% of the WHO/Eastern Mediterranean Region cases and deaths respectively (Abdalla et al 2007). Malaria is considered the main cause of fever in children less than 5 years of age. In October 2009 Malaria Indicator Survey (MIS) of Sudan household ownership of nets, ITNs and LLINs were 55%, 41% and 40% respectively while their use by children under the age of five years was 21%, 16% and 16% in similar order respectively. 40% of all fevers that sought treatment and 16% of fevers among children were treated with ACTs (FMoH 2010; Elmardi et al 2011). The survey also showed a worryingly high use of artemether injections (an artemisinin monotherapy and a second line for severe malaria) for treated of uncomplicated malaria. Overall parasiteamia, however, remained low at around 2% of sampled individuals of all ages (FMoH 2010; Elmardi et al 2011). Since the 2009 survey, the NMCP of Sudan has undertaken several measures to increase coverage of interventions and reduce the use of artemisinin monotherapies for uncomplicated malaria. The aim of this survey is to document changes in use of main malaria interventions and improvements in the levels of appropriate malaria case management.

2.0 Malaria Monitoring and Evaluation

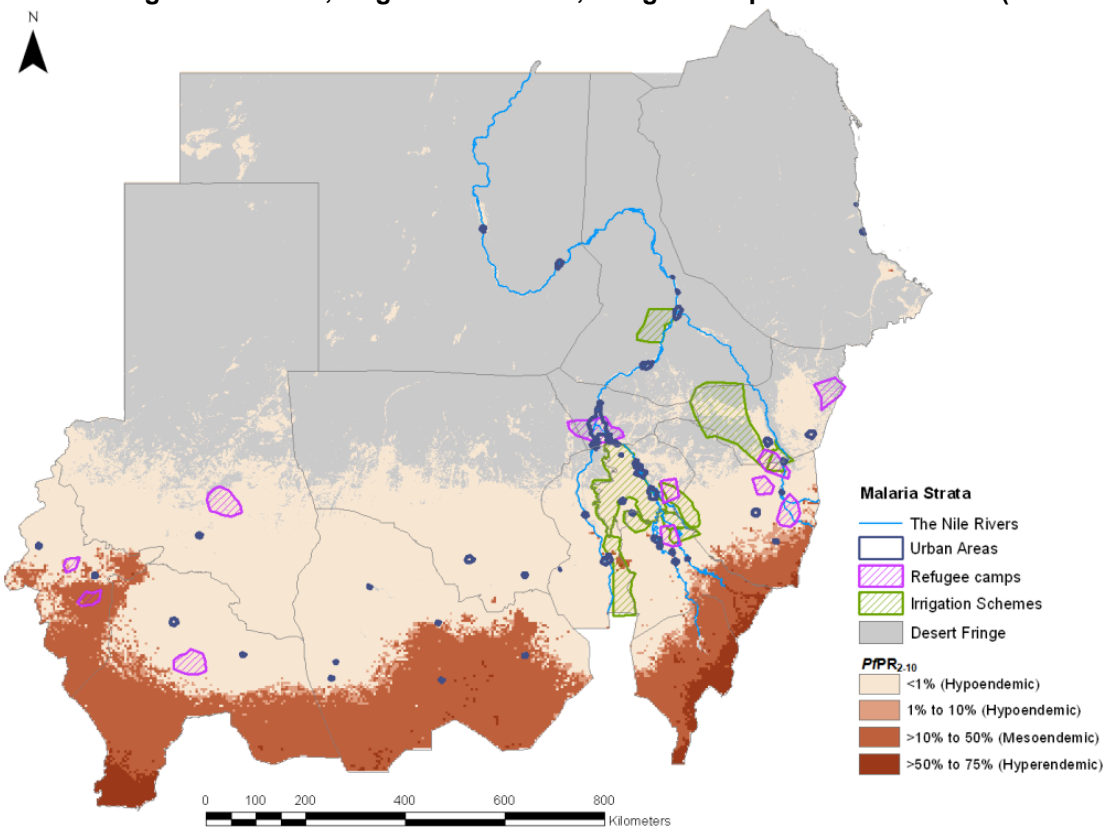
Monitoring the progress of indicators aimed at controlling malaria and the parasitological and clinical consequences of increased intervention coverage are fundamental requirements of all National Malaria Control Programmes. First there is a recognition that for efficient planning there is need for evidence for optimum resource planning and allocation. Secondly, it is now required that for national programmes that rely on donor funding to secure continued support, they provide progress on key indicators. Finally, most developing countries are now signatories to the Millennium Development Goals and the Roll Back Malaria projects both of which have clear time-fixed targets that require evidence-based approaches in documenting progress towards key targets and indicators. Therefore, in 2002, the RBM Monitoring and Evaluation Reference Group (MERG) was established to advice the RBM Partnership Board on monitoring and evaluation of RBM initiatives at all levels. The RBM-MERG identified national cluster randomized household surveys as the main source of information on the progress of key malaria indicators. This stand-alone household surveys are aimed at collecting data at the national and regional levels from a representative sample of respondents to support national malaria control programs and international health organizations to make evidence based decisions in malaria control. It is

recommended that MIS surveys are done during the high malaria transmission season to provide programmatically relevant information on the key indicators. To help countries undertake national MIS, the RBM-MERG (http://www.rollbackmalaria.org/mechanisms/merg.html#MIS) has provided detailed guidelines on survey design, sampling and implementation, which form the basis of this proposal.

3.0 Malaria in the Republic of Sudan

The predominant human malaria across Sudan is *Plasmodium falciparum,* however *P. vivax* is less common but poorly characterized clinically and epidemiologically. Transmission is maintained largely by *Anopheles arabiensis*, with focal contributions by *An. gambiae* and *An. funestus.* The World Malaria Report (2011) shows that malaria incidence was around 1000 cases per 100 000 population annually with a case fatality rate of about 6 deaths per 100,000 (WHO 2011). These estimates, however, are associated with un-quantified amount of uncertainties and are based largely on data from routine health information or extrapolated from observation from sentinel sites. For this reason, regular national malariometric surveys remain an important source, not only in progress in scale up of interventions but also of understanding the impact on disease burden.

Figure 1: A malaria stratification map of Sudan showing endemicity classes estimated from age-corrected *Plasmodium falciparum* parasite rates (*Pf*PR$_{2-10}$), aridity defined from thresholds of enhanced vegetation index, irrigation schemes, refugee camps and urban areas (Noor et al 2012).



The Republic of Sudan has historically been classified as covering a wide range of malaria endemicities (El Gaddal, 1986). In the recent National Malaria Strategy malaria risks are classified into six strata: very low risk desert fringe, riverine risks along the Nile, irrigated area risks South

and East of Khartoum, urban malaria risks, risks specific to internally displaced persons (IDPs) of which there are an estimated 3.5 million, and the remaining areas as seasonal transmission (NMS 2006). This map was further improved by using the parasite survey data from the MIS of 2005 and 2009 within a Bayesian geostatistical framework to produce an empirical map of malaria risk which also show the distribution of refugee camps, irrigation schemes, the desert and urban areas (Figure 1, Noor et al 2012).

4.0 Malaria control in the Republic of Sudan

The history of organized malaria control efforts in Sudan goes back to the beginning of the last century when A. Balfour managed to eradicate malaria from Khartoum in 1904 (Malik et.al. 2006). Now, a fully functional National Malaria Control Program (NMCP) is under the Directorate General of Preventive Medicine and Primary Health Care at the federal level, supporting malaria units at the State levels. The Programme consists of more than 50 technical staff, engaged in the planning, supervision, monitoring and evaluation of various activities related to vector biology and control, preparedness and control of epidemics, quality assurance, treatment; drugs and case management, training; capacity building and research, multiple prevention, State affairs, administration and finance. The main partners supporting the NMCP include the WHO, UNICEF and United Nation Development Programme, project-based partners supporting sub-national initiatives on the Egyptian border along the river Nile, Khartoum and White Nile States. Over 40 NGO partners work in Sudan and many have a specific interest in malaria.

The Global Fund for Malaria (GFATM) is the main source of funding for malaria control in Sudan. Since 2005, the GFATM has disbursed over 100 million USD in funding for malaria control in the Republic of Sudan. The other main sources of support are the financial commitment from national government, state contributions, locality governments and the private sector. Since the last MIS, a a revised and uodated national malaria strategy for the period 2011 – 2016 has been developed which doesn't recommend IPTp as a suitable control intervention in Sudan while at the same time aiming for universal parasitolgical diagnosis of malaria at all level of health facilities (FMoH 2010).

The strategic approaches adopted by Sudan follow largely those advocated as part of global RBM initiatives promoted during the Abuja Declaration including vector control with insecticide treated nets (ITN), Indoor Residual Spraying (IRS) and other measures, effective prompt case-management, epidemic detection and containment and supporting communications and behavioral change initiatives. These packages of interventions have been driven at State levels, modified depending upon resources, partners and objectives. Since the split with the higher malaria risk South Sudan and following the transmission intensity estimates of the MIS 2009 intermittent presumptive treatment of malaria in pregnancy is no longer a control strategy in the Republic of Sudan. A renewed emphasis on parasitological diagnosis of malaria at all levels of the health sector and improvements in malaria surveillance and epidemic detection and response has been outlined (FMoH 2010).

4.1 ITN, IRS and larval control

The current national malaria strategy aims to achieve over 90% coverage of relevant vector control and malaria diagnosis and treatment interventions across all target populations (FMoH 2010). This will be supported by a Communication for Behavioral Impact (COMBI) Plan, which aims to raise awareness of malaria and its control among the general population. Under the COMBI plan, strong private sector participation will be encouraged. Between 2001 and 2004 it was estimated that approximately 550,000 ITN had been distributed through the private sector. In 2003 116,500 ITN were distributed by UNICEF and WHO (NMCP, SA) and in 2004 UNICEF provided 145,000 LLINs

using funds from JICA. To date, the total number of LLINs distributed all over the country through the government is over 12 million including 7.1 million distributed since 2008, of which 2 million were distributed in 2010 after the MIS 2009 largely through global fund support. During the 2000 MICS, 23.1% of children less than 5 years slept under a net during the night preceding the survey but only 1.9% slept under an ITN (UNICEF, 2007). The MIS undertaken in 10 states in October 2005 showed that 43% of children slept under a net the previous night, but only 7.8% slept under LLIN. According to the MIS 2009 16% of children under five years slept under LLIN with household ownership of LLIN above 40% (FMoH 2010a

Indoor residual spraying (IRS) in large irrigated schemes in epidemic prone areas is promoted and the insecticides predominantly used are pyrethroids. Moreover, special programme for IRS is under implementation in north of the country to form as a belt protecting Egypt from malaria and malaria vector in collaboration with the Egyptian Government under the Gambiae project. The use of IRS has been documented in Gezira State, Kenana Sugar Cane area, New Halfa, Northern State and the Abohamad area in River Nile State. In 2008 the NMCP estimated that a total of 456,337 households had been sprayed. There has been the use of larviciding (with Temephos EC 50%) in urban centres and limited use of *Gambusia* fish for biological control of mosquito larvae. In 2011, over half a million household were sprayed covering about 94% of the targeted households.

4.2 Providing prompt effective treatment

Health care is provided at three levels: the primary care level constituting 95% of all formal health care facilities (including PHC unit, dressing stations, dispensaries and health centres); the secondary referral level (including general or rural hospitals); and the tertiary level (provincial or specialist hospitals). Primary health care facilities, excluding health centres, are under the responsibility of the local administrative councils and responsible to the State Ministry of Health (SMoH). Secondary care facilities and health centres are under the exclusive control of the State Ministry of Health. Public health care services in Sudan is payable for both diagnosis and treatment exception is the emergency health care.

From June 2004, co-blister artesunate +sulfadoxine/pyrimethamine (AS+SP) was adopted as the first-line treatment for uncomplicated malaria with Artemether-Lumefantrine reserved as second-line treatment for treatment failures (Malik et al., 2006). Responsibility for drug procurement is with the Federal Central Medical Drug Supply agency through tendered purchase from international companies, but still the private sector plays an important role as well as the international donors and funds. Since 2010, almost 5 million treatment doses of AS+SP were procured and distributed in all states free of charge through GFATM and UNICEF funding mechanisms. By 2008, the efficacy of AS+SP and were 96.1% and 90.4% respectively. To expand access to appropriate malaria treatment, attempts to scale up home-based management has been made in Sudan with some degree of success (Elmardi et.al. 2009). The National Malaria Strategy 2011-2016 highlights the need to expand this approach during the next phase of malaria control by improving the practice of home and community-based malaria care by training and providing medicines to village or community health workers (FMoH, 2010)

Priori to 2010, diagnosis of malaria in majority of primary health care units was based on clinical symptoms. However, most major main urban centres laboratories have historically performed blood slide examination. Since 2010, a total of 2759 rural health facilities or a total of 79% of the targeted facilities were supplied with rapid diagnostic tests (RDTs) for malaria. During the 2009 MIS 19% of the surveyed population reported experiencing a fever in the two weeks prior to the survey. 16% of patients sought treatment within 24 hours of which 44.5% of fevers were treated with antimalarials but only 19.5% with the AS+SP, which is the first line treatment for uncomplicated malaria.

5.0 Objectives of the Malaria Indicator Survey of 2012

To collect baseline data to monitor progress and to provide evidence for further investment and implementation of national malaria strategy by collecting information on the coverage of malaria indicators and the prevalence of malaria infection.

5.1 Specific objectives:

1. To examine the status of (ITN, ACT and IEC) coverage and use among children under five and/or pregnant women in the Republic of Sudan.
2. To measure the prevalence of malaria parasite in all age groups using rapid diagnostic tests (RDTs) and microscopy.
3. To build capacity of the national malaria control programme and its partners in the implementation of MIS.
4. To provide strategic orientation of malaria control programmes using the results of the MIS.

6.0 Methodology

The survey shall cover all 17 states in Sudan and will target a nationally representative sample of households which will provide precise estimates of core malaria control indicators at the national and state levels and for urban and rural populations. According to the national census of 2008, these 17 states had a combined population of 30.58 million residing in 4,800,770 households of which 34.5% were urban. Projected estimates to 2011 obtained from the Central Bureau of Statistics show that population increased to just over 35 million.

6.1 Sample size estimation and sample selection

In developing the sampling strategy a number of key features of Sudan must be borne in mind: human settlement is extremely unevenly distributed in space and largely congruent with availability of water; malaria risks are likely to be markedly different between States (Figures 1, 2a; 2b); and where malaria risks are low and/or very seasonal the spatial description of community-level malaria prevalence will be markedly heterogeneous. Consequently, recent information on prevalence of key indicators and population distribution are required. The selected key indicator for sampling was the '*proportion of women who were pregnant in the last one year who slept under a net the night before survey*'. The estimate for this indicator, the proportion of pregnant women in the last 12 months and the mean household size were obtained from the MIS of 2009 and the national census of 2008.

6.1.1 Multi-stage probability and spatial sampling

The sampling for the Sudan MIS 2012 was based on the approach recommended by the RBM-MERG and had two stages. In the first stage, the traditional household cluster sample design (equation 1) was used to define the overall sample size as follows:

$$n = (4\,(r)\,(1 - r)\,(f)\,(1.1)) / ((e*r)^2\,(p)\,(n_h)) \quad \text{.....equation 1}$$

where

n = the required sample size for the KEY (rarest) indicator,
4 = a factor to achieve the 95 percent level of confidence,
r = the predicted or anticipated prevalence (coverage rate) for the key indicator, in this case the proportion of women who were pregnant in the last 12 months sleeping under a net the night before survey which was estimated at 21% in the MIS 2009.
1.1 = the factor necessary to raise the sample size by 10 percent for non-response,
f = the design effect *(deff)*, 1.5 was selected for the purposes of this survey
e = the margin of error to be tolerated (0.12 as advised in the MIS sampling manual)
p = the proportion of the total population that the smallest group comprises (5% of the population was pregnant in the last 12 months as measured in the MIS 2009)
n_h = the average household size (this was 5.9 from the 2008 national census)

Based on this sampling approach, a total of 5,875 households will be required to provide precise estimates of the key indicator at the national and state levels and for urban and rural populations. At an average of 20 households per cluster, therefore, 290 clusters would be selected for the 2012 Sudan MIS (Table 1). To ensure that we have a sufficient number of clusters for malaria mapping per state, a minimum of 10 clusters per state was targeted and an additional ten clusters were redistributed across those states where sample sizes was less than 10. In total 300 clusters and 6000 households were selected for survey.

These clusters were then allocated into urban and rural categories proportionately within each state. For example in Blue Nile state, the proportions of households that are urban are 0.25 and rural are 0.75 according to the projection to 2011. In the sample, 10 clusters in Blue Nile state will be surveyed of which 3 (10x0.25) will be urban and 7 (10x0.75) will be rural. The Central Bureau of Statistics (CBS) will then select the actual clusters from a national sampling frame based on probability proportional to size.

Table 1: Summary of sample design and sample size based on 2011 estimates derived from projections of the 2008 national census

State	Total households	Proportion households urban	Proportion households rural	Proportion of households	Proportion of sample households	No of sample clusters	No of final sample of clusters	Sample clusters Urban	Sample clusters Rural
Blue Nile	158641	0.25	0.75	0.03	173	9	10	3	7
Gadarif	280444	0.27	0.73	0.05	288	14	14	4	10
Gezira	700516	0.1	0.9	0.11	656	32	32	3	29
Kassala	349367	0.3	0.7	0.06	350	17	17	5	12
Khartoum	1062361	0.8	0.2	0.18	1065	53	53	42	11
North Darfur	374321	0.2	0.8	0.06	365	18	18	4	14
North Kordorfan	516326	0.2	0.8	0.10	575	29	29	6	23
Northern	133686	0.17	0.83	0.02	140	7	10	2	8
Red Sea	228158	0.46	0.54	0.04	233	12	12	5	7
River Nile	215086	0.28	0.72	0.04	238	12	12	3	9
Sinnar	257272	0.22	0.78	0.05	265	13	13	2	11
South Darfur*	775381	0.29	0.71	0.10	606	30	30	9	21
South Kordorfan	374321	0.25	0.75	0.04	259	13	13	3	10
West Darfur*	251330	0.19	0.81	0.05	272	13	19	4	15

White Nile	341048	0.32	0.68	0.06	359	18	18	6	12
Total	**6018258**	**0.34**	**0.66**	**1.00**	**5845**	**290**	**300**	**102**	**198**

*The sample sizes for East Darfur state will be drawn from the clusters allocated to South Darfur while for Central Darfur will come from that of West Darfur once we have data from the Central Bureau of Statistics.

6.2 Development of survey questionnaires and manuals

The survey questionnaires and manuals will be based largely on the 2009 MIS data. Instead of the three questionnaires used in 2009, only two survey questionnaires (household and members) will be used. Because IPTp is no longer a policy in Sudan, the women's questionnaire will be dropped and some of details on pregnancy will be transferred to the household and members questionnaires.

6.2.1 Questionnaires

The household questionnaire will be used to list all usual members and visitors of the selected households. For each household member the following data will be collected: age, sex, education, and relationship to the head of the household. Pregnancy and birth status of women aged 15 to 49 years in the last 12 months will be documented in the household questionnaire. The household questionnaire also collects data on household head's education level and household assets to assess household socio-economic status. Information on the household ownership of mosquito nets and their use by household members will also be recorded. Data on household exposure to indoor insecticide spraying (IRS) and information-education-communication (IEC) activities will be collected (Annex 2A).

The household members' questionnaire will record information on all household members and will capture information on whether they had fever in the last 14 days and whether they sought treatment for the fever in that time; sources of treatment and drugs used (Annex 2B). All consenting individuals will then be examined for parasitaemia and temperature measurements will be taken to ascertain fever at the time of interview. This will be followed by a section detailing recent travel history and net use while travelling and the final section will capture information on malaria infection status for each assenting individual who will examined for parasitaemia first using RDTs; thick and thin blood smears. Individuals who test positive for parasite infection using the RDT test will be treated with nationally recommended antimalarial drugs. Likely severe malaria cases will immediately be referred to the nearest health facility.

6.3 Training and Pre-test activities

During the first week of October 2012, after the development of the draft set of survey tools, representatives of all 17 states will be trained in Khartoum for a period of one week. Training will be undertaken on general interviewing skills, administration of consent forms, filling of questionnaires, collection of blood samples and the appropriate treatment of individuals found positive for malaria. Team members will also be trained in the use of global positioning systems for mapping of households. During this period, data entry supervisors will also be trained in the details of the questionnaires. A set of clusters in Khartoum, which will be excluded from the actual surveys, will be selected for testing of the survey tools. The Principal Investigator will then evaluate all filled questionnaires again and correction of mistakes made during pre-testing and any necessary adjustments to the survey tools resulting from the pre-test will be undertaken.

The trained state coordinators will then act as trainers of field workers and this process, supervised and facilitated by the NMCP, will run concurrently for a period of one weeks in each state beginning the third week of October. Each state will then pilot the questionnaires in the state capital. Before the beginning of the actual survey, the consultant will evaluate some of the questionnaires from the pre-testing exercise undertaken in each state and advice on where

additional training is required. Laboratory technicians who will be responsible for malaria testing in the field and undertake the reading of slides will be trained also in the first week of October in Khartoum.

6.4 Administrative preparation and community sensitization

A community sensitization exercise will be undertaken in the two weeks before survey in the print, radio and television media by the NMCP of the FMoH. With technical help from the WHO consultant, a detailed kit of media materials will be prepared. The sensitization message will cover the risk malaria poses to population health, the efforts the government is undertaking to fight malaria, the need for information on the burden of the disease and hence the importance of the malaria indicator survey. Listeners will be encouraged to support and participate in the survey and will be assured that those who were found to have malaria will be treated with effective drugs. Local administration, health NGOs and women associations will also be engaged to spread by word of mouth the impending malaria survey and to drum up support in their local communities. From past experience in Sudan, most people tend to their chores outside the house in the early part of the day and often many household members are absent. To minimize this all community elders in the selected clusters will be contacted before the survey and will be asked to mobilize members of the village to be present during the day of survey.

6.5 Composition of survey management and field team

Overall, the survey management team will be composed of an international consultant; a national consultant; 7 national coordinators; 17 state coordinators; 17 state supervisors; and 217 field team members.

The role of the international consultant will, in collaboration with the national malaria programme and national consultant, be responsible for general survey oversight; develop a scientifically sound survey protocol; design the survey sample; develop survey tools; field manuals; budget; electronic data entry forms; provide training to trainers of trainees; supervise data entry; undertake data analysis and writing of survey report. The national consultant will work closely with international consultant to achieve the aforementioned tasks; ensure of overall successful implementation of survey; participate in data analysis and report writing.

The national coordinators will assist the consultants in all aspects of survey preparation and management; they will be in charge of the actual survey implementation; management of survey budget; hiring of survey teams; procurement of survey materials; storage of survey questionnaires and samples; revision and clearance of the field work; management of data entry; and will participate in the data analysis and report writing. The national coordinators will also be primarily responsible for the dissemination of survey results.

The state coordinators will act as trainers of the survey field teams and in collaboration with the state supervisors will be in-charge of day-to-day management of the survey. The will also act as the bridge between the field teams and the national level management team. They will be responsible for daily checking of questionnaires and proper storage of survey materials; briefing of survey teams each day prior to start of survey and will ensure appropriate inventory and registration of survey questionnaires; RDTs; slides; and filter papers before they handed over to the relevant teams for analysis.

The state supervisors will be responsible for the identification and hiring of field surveyors with help of state coordinators; organize and participate in training of survey team at state level; ensure all relevant state level departments are on- board; in collaboration with state coordinator are in charge of day to day management of survey and daily checking of questionnaires and proper storage of survey materials; maintain daily contact with state coordinators.

Each field team will consist of 7 persons comprising 1 supervisor; 2 interviewers; 2 nurses or equivalent; and 2 laboratory technicians resulting in 31 field teams. Survey teams will visit a selected cluster every two days. The supervisor will ensure that all survey procedures are followed and field teams conduct household interviews appropriately. The supervisor will also check that all questionnaires have been correctly coded and filled before departing the cluster. The supervisor will be responsible for ensuring that callbacks are attended to. He/she will be responsible for handing over the questionnaires and other survey materials to the state supervisors. The supervisor, the state supervisors and the state coordinators will maintain a complete registry of these materials.

6.6 Field work and quality control

The survey will begin in the last week of October 2012 and will continue for a period of 21 days. For some of the large and sparsely populated states extra survey days may be needed. At the end of each survey day, all questionnaires, RDTs and blood slides will be submitted to the state coordinators for review and storage. The state coordinators will review the survey team's daily submissions and suggest corrections where necessary. The international consultant and national coordinators will also visit the states and observe each survey team as they perform interviews for a few selected households and advise on appropriate corrections. At the end of every five days, the state coordinators will submit completed questionnaires to the NMCP office in Khartoum where a central data entry system will be established. The slides will be retained at the state for initial analysis and by the end of November will be submitted to the national level for a second reading and general quality control. An international expert microscopist will be responsible for quality assurance of the slide reading.

6.7 Malaria testing

To minimize the inconvenience and pain caused during the collection blood samples, only a single finger prick will be used for RDT and blood slides. The first drop will wiped off from the finger using a swab dipped in methylated spirit, the second drop will be applied to the RDT; the third sets of drops will be used to prepare a thick and thin blood films and the fourth set of drops for the filter papers. All leftover materials used for the collection of blood samples, such as lancets and swabs will be carried from the household in a special biohazard box and appropriately disposed of at the end of the survey day.

6.7.1 Parasite prevalence

Presently there are several HRP-2 tests available that appear to have very good performance in detecting *P. falciparum* and *P. vivax* antigens. Notable is CareStart Malaria HRP2/pLDH (Pf/PAN) COMBO (Access Bio, Inc) and First Response Malaria Ag (pLDH/HRP2) COMBO (Premier Medical Corporation Ltd.) which in a both the first and the second review by WHO and FIND was reported to be among the highest performing RDTs (WHO, 2009; 2011). Due to ease of procurement, CareStart Malaria HRP2/pLDH will be used during the Sudan 2012 MIS. All RDT positive cases detected during the household survey will be given, by a qualified nurse or equivalent, an appropriate age-weight specific treatment course of AS+SP as per national standard treatment guidelines and a referral note if their condition does not improve to the nearest health centre.

It is also proposed that all sampled individuals will also have a thick and thin blood smear prepared and examined from the same finger stick blood sample for an independent assessment of

infection. The smears will be stained in 4% Giemsa solution for 30 minutes and labeled slides transported to each state headquarters. Thick blood films will be read using a light microscope with x 100 oil-immersion lens and x 10 eyepiece. One hundred high power fields will be examined before a slide is considered negative. For all positive blood slides, the asexual stage of *Plasmodium* parasites will counted against 200 leukocytes and expressed as parasites/µl of blood by multiplying this number by a factor of 40 assuming a mean white blood cell count of 8000 cells/µl. Slides will be read by two independent microscopists and any discrepancies will be further reviewed by a third independent expert microscopist. The first reading of the slides will be undertaken at the state by qualified microscopists and will be transported to Khartoum for a second reading by a selected set of independent expert microscopists.

6.8 Data entry and analysis

Trained data entry personnel will be used to capture information from the survey questionnaires using customized data entry screens developed in Microsoft Access 2007. Double entry of the data will be undertaken in a central place at the NMCP offices in Khartoum. Once entered data will be checked for consistencies by the data manager and necessary corrections will be made. The results of the blood slides and filter papers will be recorded in customized forms with members ID in. The international consultant will undertake analysis of the survey data and a final report will be published by the 21st December 2012.

6.9 Dissemination strategy

After approval of the survey results, data will be disseminated in terms of a published report that will be put online on the NMCP web page. A public launch of the survey results will also be done nationally and in each state. Where relevant, some of the survey results could be disseminated via peer-reviewed journal publications. The NMCP will be fully responsible for the dissemination exercise.

6.10 Ethical considerations & ethical review

Ethical clearance and consent to conduct interviews will be obtained from Ethical Committee, Ministry of Health and individuals interviewed respectively. Measures will be taken to ensure the respect, dignity and freedom of each individual participating in the study. During training of the interviewers, emphasis will be placed on the importance of obtaining informed consent (orally) and the avoidance of any kind of coercion. Where children below 15 years are involved, an informed consent will be obtained from the household head; the mother or other guardians. To ensure confidentiality, all household members will be identified by a unique code and the main investigator or the state, national coordinators only can access personal data. Informed consent will be obtained from study subjects before conducting interviews. The respondent will be adequately informed about all relevant aspects of the study including its aim, procedures attendant risk and hazards and the potential. The respondents will be informed that their participation was strictly on a voluntary basis. Those seen positive for malaria using the RDT will be treated on the spot using nationally recommended antimalarial drugs. During the procees of drawing the blood samples, a strict protocol will be followed to ensure that respondents are not unduly inconvenienced and they and the survey teams are not exposed to any danger of infection

7.0 Budget for the Sudan MIS 2009

Budget input	Total in USD
International consultant	19,220
Training of ToTs at national level	17,486
Training of surveyors at state level	105,748
Training of laboratory technicians as ToTs in Khartoum	5,976
Per diems and wages of survey team during field work	192,894
Sampling frame and sample selection by CBS	103,880
Transportation	198,180
MIS lab supplies and equipment	92,498
Advocacy and community sensitization	15,000
Dissemination	3,000
TOTAL	**761,027**

8.0 Time for the Sudan MIS 2012

Month		July				August					September					October					November					December				
WK #		0	1	2	3	4	5	6	7	8	9	10	11	12	13	11	13	14	15	16	13	14	15	16	17	18	19	20	21	
Tasks																														
1	Complete Draft of Survey Proposal & Questionnaires																													
2	Submission of protocol for ethical review																													
3	Programming of data entry forms																													
4	Training of Trainers and Pretesting																													
5	Training of Laboratory Technicians																													
6	Training of Survey Teams at State level																													
7	Pre-testing at State level																													
8	Social Mobilization																													
9	Data collection																													
10	Analysis of Slides at State																													
11	Data Merging and Cleaning at HQ																													
12	Report Writing- Preliminary																													
13	Presentation of Draft Report																													
14	Review of Draft Report																													
15	Printing of Final Report																													
16	Procurement of equipment																													

9.0 References

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10.0 Annex 1 Questionnaires

Attached separately.