Summary

Social and economic studies continue to play an important role in the Malaria Centre's profile of work. In 2010-11, many of these studies were evaluatory in nature, considering the social and/or economic process and impacts of malaria-related interventions and programmes. Researchers also continued to undertake descriptive social and economic studies, highlighting the social and economic realities of the lives of those affected by malaria, those involved in delivering malaria programmes and those participating in clinical research.

Topics of social and economic research undertaken in 2010-11 reflect a range of areas considered critical to strengthening the implementation of malaria control methods, particularly access to Artemisinin-based Combination Therapies (ACT) and targeting of drugs through malaria Rapid Diagnostic Tests (RDTs). Improving access to effective drugs has been a long-standing recommendation of the WHO, and Malaria Centre members have undertaken a variety of studies to understand the ways people access health care for malaria. Research has also contributed to the design and evaluation of strategies to improve access to antimalarial drugs through public health services, private facilities, retail outlets and community based programmes. This includes evaluation of large-scale interventions, such as the Affordable Medicines Facility – malaria, which is being piloted at the national level in eight countries. Smaller scale studies have contributed to the design and evaluation of supporting interventions being implemented on a smaller scale within malaria endemic countries in order to inform programmes for future scale-up, particularly in terms of feasibility and cost-effectiveness. Improving targeting of precious ACT has become a priority in malaria control, and the WHO's 2010 recommendation for universal parasitological diagnosis before treatment where possible has stimulated interest in how RDTs can be used in low-resource settings. Social and economic studies within the Malaria Centre have designed ways to support the introduction of RDTs in different settings, including at public and private facilities, retail outlets and by community volunteers, incorporating novel social and incentive approaches to encouraging changes in provider and patient behaviour. Large and smaller-scale studies have evaluated the processes and outcomes of such interventions. Understandings of the social and economic realities of patients and the different types of providers operating in pluralistic health systems have been valuable to the design and interpretation of trials addressing access to and targeting of antimalarial drugs for treatment and chemoprophylaxis.

Other key topics that have engaged social and economic researchers in the Malaria Centre revolve

around malaria control strategies for vulnerable groups, particularly pregnant women and children, and methods for assessing safety of ACT. The scale-up of malaria control initiatives in vulnerable groups is central to the WHO's strategy to reduce deaths due to malaria to zero. Pregnant women are a particularly vulnerable group for whom malaria control efforts continue to be poorly delivered. A better understanding of the use and delivery of these services is required, and Malaria Centre members are undertaking a number of studies to assess existing systems and to develop approaches to strengthen malaria control efforts for this group across different country contexts. Children, the most vulnerable group to malaria morbidity and mortality, are the focus of multiple malaria control efforts. Findings of social and economic research carried out by Malaria Centre members have contributed to important policy recommendations for Seasonal Malaria Chemoprevention which has the potential to prevent childhood malaria across areas of the Sahel and Sub-Sahel regions of Africa where 25 million children are at risk. With the wide-scale roll out of ACT across different population groups, including those with comorbidities who are taking other medications, concerns have been raised about the safety of drugs used in real life scenarios. Members of the Malaria Centre have been involved in studies to understand social aspects of ACT safety. These include contributing to novel methods for population level pharmacovigilance involving reporting from non-clinical workers, and understanding the experiences of patients taking ACT together with other drugs, particularly anti-retroviral drugs by those affected by both malaria and HIV. Research has also examined the way safety data are produced within clinical trials, focusing on the process of elicitation of adverse events, which has been found to be mediated by the social circumstances of reporting within a drug trial. More broadly, social research continues to reflect on the experiences of research participants involved in a variety of malaria-related research, contributing to discussions of best practice methods for conducting research in resource-limited settings.

Mobilize Against Malaria (MAM).

***LSHTM Investigators**: Jayne Webster, Caroline Jones, Jane Bruce & Lucy Paintain.*

***External Investigators/Collaborators:** Population Services International, Kenya; KEMRI-Wellcome Trust, Kenya; Family Health International, Ghana; Ghana Social Marketing Foundation, Ghana; Health Partners, Ghana; IntraHealth International, Senegal.*

***Funding Body:** Pfizer Investment in Health.*

Mobilize Against Malaria was implemented between 2007 and 2011 by partners in Ghana, Kenya and Senegal. As Pfizer's signature philanthropic program to reduce malaria morbidity and mortality, the program supported promising models for the effective delivery of Artemisinin-based Combination Therapy (ACT) through private, public and community sectors.

The pilot project demonstrated the viability of improving access to ACT by training Licensed Chemical Sellers in Ashanti Region, Ghana. It demonstrated sustainable approaches to building and maintaining the capacity of community-run health huts in Senegal, and tested the efficacy of healthworker training in Kenya.

Throughout 2012-13, a multidisciplinary team at LSHTM will continue to work with local evaluation partners to facilitate the synthesis of cross-cutting issues emerging from the research, of strategic importance in the development of regional and global policy agendas on the delivery of health services. Cross-cutting evaluation research will focus on contextual evaluation, implementation fidelity, methodological approaches, training efficacy and the development of an evaluation model across the three country settings.

ACTwatch: evidence for malaria medicines policy.

***LSHTM Investigators**: Kara Hanson, Catherine Goodman, Benjamin Palafox, Edith Patouillard, Sarah Tougher, Sergio Torres Rueda & Immo Kleinschmidt*

***External Investigators/Collaborators:** Population Services International.*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

The goal of ACTwatch is to provide a complete picture of the antimalarial markets in Benin, Cambodia, DRC, Madagascar, Nigeria, Uganda and Zambia to enable policymakers and other actors to design interventions to increase availability and decrease the consumer price of quality assured Artemisinin-based Combination Therapy (ACT). Along with conducting nationally representative surveys of pharmaceutical outlets and households, ACTwatch also includes a component that investigates the structure and operation of the distribution chain for antimalarials and Rapid Diagnostic Tests (RDTs) for malaria in each country.

Using a number of different data collection methods, including document review, structured surveys of antimalarial wholesalers, and in-depth interviews with a wide range of stakeholders and businesses at all levels of the distribution chain, this study has developed schematic representations of the antimalarial distribution chains; estimated antimalarial availability among wholesalers; investigated regulatory compliance and enforcement in the private sector; estimated retail- and wholesale-level mark-ups for antimalarials and RDTs; investigated factors affecting drug selection, sales volumes and prices; and compared distribution chains within and between each of the 7 ACTwatch countries.

Data collection for the distribution chain component has been completed in all countries, and a number of country-specific reports are available from the ACTwatch website, www.actwatch.info. Reports of the ACTwatch Outlet and Household Surveys, conducted by Population Services International, are also available from this site.

Benin market.

The impact of retail sector delivery of artemether-lumefantrine on effective malaria treatment of children under five in Kenya .

***LSHTM Investigators**: Catherine Goodman, Simon Brooker & Greg Fegan.*
***External Investigators/Collaborators:** Beth Kangwana, Sarah Kedenge, Abdisalan Noor & Bob Snow (KEMRI-Wellcome Trust Research Programme, Kenya); Andrew Nyandigisi (Division of Malaria Control, Kenya); Jayesh Pandit (Pharmacy and Poisons Board, Kenya).*

***Funding Body:** Wellcome Trust & UK Department for International Development.*

In 2006, Kenya introduced Artemisinin-based Combination Therapy (ACT) through the public sector free of charge, but access remains low. The aim of this study was to evaluate to what extent the provision of pre-packed, subsidised ACT, delivered through private sector retailers, will increase the proportion of children under five, with fever, receiving appropriate anti-malarial treatment. The intervention was implemented by the Division of Malaria Control in collaboration with Population Services International. The study sites were in three districts in Western Kenya: Teso, Butere-Mumias and Busia. Intervention effectiveness was evaluated through a pre-post cluster randomised controlled trial. Baseline data were collected before the intervention and follow up data 9 months after the start of the intervention from both households and retail outlets. The data were collected using six data collection activities: 1) Retail census 2) Household survey 3) Provider survey 4) Mystery shopper 5) Focus group discussions and 6) Documentation of context.

The intervention led to a substantial increase in ACT access, and in ACT coverage for childhood fevers. The vast majority of sales at the target price and correct dose. However, advice given to caretakers by shopkeepers was often inadequate and ACT adherence remained sub-optimal.

IMPACT2: monitoring interventions to improve ACT access and targeting.

***LSHTM Investigators**: Catherine Goodman, Katia Bruxvoort, Rebecca Thomson, Harparkash Kaur & Matt Cairns*
***External Investigators/Collaborators:** Salim Abdulla, Admirabilis Kalolella, Emmy Metta, Charles Festo, Boniface Johannes, Happy Nchimbi & Clarence Mkoba (Ifakara Health Institute, Tanzania); Patrick Kachur, Julie Thwing, Denise Roth Allen & Melissa Briggs (Centers for Disease Control and Prevention, USA).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

While a general consensus over the choice of Artemisinin-based Combination Therapy (ACT) as the future malaria therapy has developed, a solid evidence-base for choosing the best ACT deployment strategies to gain optimal impact on malaria morbidity and mortality does not exist. Countries are now beginning to adopt policies to enhance ACT deployment but face tension between the twin goals of: (i) making ACT more readily and speedily accessible to patients, or (ii) targeting ACT to patients shown to have malaria parasitaemia.

The Tanzanian Government has secured funding to address ACT access and targeting on a national scale. Access is being improved through the distribution of subsidised ACT through private facilities and Accredited Drug Dispensing Outlets under the Affordable Medicines Facility-malaria (AMFm). Targeting is being addressed through enhancing microscopy and expanding Rapid Diagnostic Tests (RDTs) to health facilities at every level of the system. This study aims to evaluate these interventions through a pre-post plausibility evaluation in selected regions (Mwanza, Mtwara, Mbeya). The study forms part of the programme of work of the ACT Consortium.

The key objective is to assess the effectiveness of the introduction of RDTs in health facilities, and subsidized ACT in the private sector in terms of coverage, equity, quality, adherence and public health impact, and to explore the socio-cultural context and other factors that influence the implementation and outcome of the interventions. Data collection methods include surveys of households, health facilities and drug shops, studies of adherence and parasitaemia prevalence at health facilities and drug shops and qualitative methods.

Conducting a household survey interview in rural Mwanza, Tanzania.

Evaluation of a pilot ACT subsidy programme in two rural districts in Tanzania.

***LSHTM Investigators**: Catherine Goodman.*

***External Investigators/Collaborators:** Oliver Sabot, Lorrayne Ward, Justin Cohen, Yahya Ipuge & Megumi Gordon (Clinton Foundation, USA); David Bishop (HLSP, UK); Alex Mwita (National Malaria Control Programme, Tanzania); Moses Odhiambo (Steadman Group).*

***Funding Body:** Clinton Health Access Initiative.*

WHO estimates that only 3% of fever patients use recommended Artemisinin-based Combination Therapy (ACT), partly reflecting their high prices in the retail sector from where many patients seek treatment. To overcome this challenge, a global ACT subsidy has been proposed. We tested this proposal through a pilot program in rural Tanzania.

Three districts were assigned to serve as a control or receive the subsidy plus a package of supporting interventions. From October 2007, ACT were sold at a 90% subsidy through the normal private supply chain to intervention district drug shops. Data were collected at baseline and during intervention using interviews with drug shop customers, retail audits, mystery shoppers, and audits of public and NGO facilities.

The proportion of consumers in the intervention districts purchasing ACT rose from 1% at baseline to 44.2% one year later ($p<0.001$), and was significantly higher among consumers purchasing for children under 5 than for adults ($p=0.005$). No change in ACT usage was observed in the control district. Consumers paid a mean price of $0.58 for ACT, which did not differ significantly from the price paid for sulphadoxine-pyramethamine, the most common alternative. Drug shops in population centers were significantly more likely to stock ACT than those in more remote areas ($p<0.001$).

A subsidy introduced at the top of the private sector supply chain can significantly increase usage of ACT and reduce their retail price to the level of common monotherapies. Additional interventions may be needed to ensure access to ACT in remote areas and for poorer individuals who appear to seek treatment at drug shops less frequently.

ACT PROCESS: evaluating the process, context, and impact of interventions to enhance health facilities in Tororo, Uganda.

***LSHTM Investigators**: Clare Chandler, Sarah Staedke & Deborah DiLiberto.*

***External Investigators/Collaborators:** Moses Kamya, Susan Nayiga, Lilian Taaka, Christine Nabirye, Miriam Kayendeke (Infectious Diseases Research Collaboration, Uganda).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

The ACT PROCESS study is a mixed methods evaluation that is running alongside a cluster randomised trial (ACT PRIME) that aims to assess the effect of a health facility intervention on population health indicators.

The ACT PROCESS study aims to provide an in-depth understanding of the way this intervention was delivered, its mechanisms of effect, and how context shapes the outcomes observed.

The project objectives are:

- To develop a comprehensive logic model of the health facility intervention with intervention components mapped through to their intended effects and outcomes.
- To evaluate the process of the health facility intervention implementation including health worker training, health centre management tools, supply of AL and RDTs for malaria, and interactions with local and district stakeholders.
- To develop a rich contextual record of factors that may have affected the health facility intervention outcomes such as other interventions or programmes implemented in the area, changes to malaria case management guidelines, and other environmental, economic, political or individual factors.
- To carry out a limited assessment of the wider expected and unexpected impacts of the HFI at the household, community, private sector, and public health system levels.

Methods for collecting data for the ACT PROCESS study include tape-recorded health worker communication assessments, patient exit interviews, self-filled questionnaires, in-depth interviews, focus group discussions, and a structured contextual record. Data collection started in early April 2011 and is on-going until July 2012.

Independent Evaluation of the Affordable Medicines Facility – Malaria (AMFm).

***LSHTM Investigators**: Kara Hanson, Catherine Goodman, Sarah Tougher, Barbara Willey, Andrea Mann & Becky Thomson.*

***External Investigators/Collaborators:** ICF International; Population Services International; Centre de Recherche pour le Développement Humain, Senegal; Centre International d'Études et de Recherches sur les Populations Africaines, Niger; Komfo Anokye Teaching Hospital, Ghana; Drugs for Neglected Diseases Initiative; Ifakara Health Institute, Tanzania.*

***Funding Body:** The Global Fund to Fight AIDS, Tuberculosis and Malaria.*

The aim of the independent evaluation of Phase 1 of the Affordable Medicines Facility – malaria (AMFm) is to assess whether, and to what extent, the first phase of AMFm achieves its objectives, which are: (i) to increase Artemisinin-based Combination Therapy (ACT) affordability, (ii) to increase ACT availability, (iii) to increase ACT use, including among vulnerable groups, and (iv) to "crowd out" other oral antimalarials by gaining market share. The evaluation results will be summarized in a report to be considered by the Global Fund Board at the end of Phase 1, in November 2012.

The evaluation is being carried out in all 8 operational Phase 1 pilots (Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania mainland, Uganda, and Zanzibar). It is based on a non-experimental design with a pre- and post-test intervention assessment in which each participating country is treated independently as a case study. In each country, a nationally representative survey of outlets stocking antimalarial medicines was conducted at baseline and endline. In addition to measuring the changes in key indicators pre- and post-intervention, the evaluation includes an assessment of the implementation process and a comprehensive documentation of the context both to inform assessments about causality and to aid in generalizability to other settings. Analysis of secondary household survey data is used to assess the effects of the programme on ACT use.

Research on the cconomics of ACT (REACT): Provider and patient surveys to inform the design of interventions to support improved use of ACT in Nigeria.

***LSHTM Investigators**: Virginia Wiseman, Lindsay Mangham & Bonnie Cundill.*

***External Investigators/Collaborators:** Obinna Onwujekwe, Benjamin Uzochukwu, Ogochukwu Ezeoke & Emma Nwala (University of Nigeria, Nigeria).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

In Nigeria, treatment guidelines state that malaria should be symptomatically diagnosed and treated with Artemisinin-based Combination Therapy (ACT) at primary health facilities. Research was undertaken to determine the extent to which patients seeking treatment at primary care facilities and medicine retailers receive the recommended treatment and what factors influence the choice of treatment. A cross-sectional cluster survey of 2,039 respondents exiting public health centres, pharmacies and patent medicine dealers was undertaken in 2009 in urban and rural settings in Enugu State, south-eastern Nigeria.

The results of these surveys showed that although 79% of febrile patients received an anti-malarial, only 23% received an ACT. Many patients (38%) received sulphadoxine-pyrimethamine. A further 13% of patients received an artemisinin-derivative as a monotherapy. An estimated 66% of ACT dispensed was in the correct dose. The odds of a patient receiving an ACT was highly associated with consumer demand (OR: 55.5, $p < 0.001$).

The results identified major problems in the choice of treatment for malaria, and the need for interventions that target consumer preferences as well as seek to improve health service provision. The REACT study is working with the Malaria Control Programme in Enugu State to develop and evaluate innovative demand and supply-side interventions that aim to improve access to a confirmed malaria diagnosis, raise awareness about the recommended antimalarials and promote appropriate treatment for malaria.

Research on the economics of ACT (REACT): qualitative situation analysis to inform the design of interventions to support improved use of ACT in Nigeria.

***LSHTM Investigators**: Virginia Wiseman, Lindsay Mangham & Clare Chandler.*

***External Investigators/Collaborators:** Obinna Onwujekwe, Ogo Exeoke Nkoli Ezumah & Benjamin Uzochukwu (University of Nigeria, Nigeria).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

The adoption of ACT as the first line treatment for uncomplicated malaria in Nigeria has concentrated attention on the role of testing for appropriate diagnosis for malaria. There are calls at both national and global level for malaria treatment to be based on a test result, but it is still unclear how these tests can be incorporated into treatment seeking and practices of health providers. This study explored both community and providers' perceptions and experiences with malaria tests in south east Nigeria.

The study was conducted in an urban (Enugu) and a rural (Udi) area of Nigeria. A total of 18 focus group discussions were conducted with 179 community members and 26 in-depth interviews were conducted with public and private health providers involved in prescribing medicines in the study area.

Most people had experienced malaria tests and both providers and community members identified this as an important step to distinguish malaria from other illnesses with similar symptoms and to give appropriate treatment. However, in practice antimalarial treatment was often used presumptively, without a positive test result. The logic of test-directed treatment was undermined by cost of testing and a lack of facilities but above all concerns over the reliability of negative test results, with community members and providers observing inconsistencies between results and symptoms, and providers attributing inaccurate results to incompetencies of technicians. Recognition of malaria symptoms was deemed most important in determining the use of antimalarial drugs.

To tackle these issues, the REACT project designed intervention packages targeted at providers and community members. The core message of test-directed Artemisinin Combination Treatment is supported by provision of Rapid Diagnostic Tests, interactive learning and integration with other components of care for providers, and a school-based peer education programme with community-oriented malaria event to increase awareness and demand amongst care seekers. These interventions are being evaluated with a 3-arm cluster randomised trial.

Research on the economics of ACT (REACT): patient and provider surveys to inform the design of interventions to support improved use of ACT in Cameroon.

***LSHTM Investigators**: Virginia Wiseman, Lindsay Mangham & Bonnie Cundill.*

***External Investigators/Collaborators:** Wilfred Mbacham, Olivia Achonduh, Joel Ambebila, Albertine Lele, Theresia Metoh, Sarah Ndive, Ignatius Ndong, Rachel Nguela, Akindeh Nji, Barnabas Orang-Ojong & Joelle Pamen-Ngako (University of Yaoundé I, Cameroon).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

The objective of the provider and patient surveys was to investigate the quality of malaria case management in Cameroon 5 years after Artemisinin-based Combination Therapy (ACT) was adopted as the first-line antimalarial. Patterns of treatment were examined in different types of facility, and the factors associated with being prescribed or receiving an ACT were investigated.

A cross-sectional cluster survey was conducted among individuals of all ages who reported seeking treatment for a fever as they exit public and private health facilities and medicine retailers. Prevalence of malaria was determined using Rapid Diagnostic Tests (RDTs) in consenting patients.

Among the patients, 73% were prescribed or received an antimalarial, and 51% were prescribed or received an ACT. Treatment provided to patients significantly differed by facility type: 65% of patients at public facilities, 55% of patients at private facilities and 45% of patients at medicine retailers were prescribed or received an ACT. The odds of a febrile patient being prescribed or receiving an ACT were significantly higher for patients who asked for an ACT, were physically examined by the health worker, had not previously sought an antimalarial for the illness and sought treatment at a public or private facility. Malaria was confirmed in 29% of patients, and 70% of patients with a negative malaria test were prescribed or received an antimalarial.

The results of these surveys showed that malaria case management could be improved, and symptomatic diagnosis is inefficient because two-thirds of febrile patients do not have malaria. As the Cameroon Government plans to extend malaria testing it will be important to promote the rational use of ACT. The REACT study is working with the National Malaria Control Programme to develop and evaluate provider training interventions that can support the roll out of RDTs.

Research on the economics of ACT (REACT): qualitative situation analysis to inform the design of interventions to support improved use of ACT in Cameroon.

***LSHTM Investigators**: Virginia Wiseman, Lindsay Mangham & Clare Chandler.*

***External Investigators/Collaborators:** Wilfred Mbacham, Abanda Ngu Njei & Olivia Achonduh (University of Yaoundé, Cameroon).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

In response to widespread overuse of antimalarial drugs, the World Health Organisation changed guidelines in 2010 to restrict the use of antimalarials to parasitologically confirmed malaria cases. Malaria Rapid Diagnostic ests (RDTs) have been presented as a means to realize the new guidelines, and National Malaria Control Programmes, including that of Cameroon, are developing plans to introduce the tests to replace microscopy or clinical diagnosis at public health facilities across the country.

We aimed to understand how malaria tests and antimalarial drugs are currently used as part of social interactions between health workers and patients at public and mission health facilities in Yaoundé and Bamenda and surrounding districts in the Northwest region of Cameroon. In May to June 2010, we held 17 focus group discussions with 146 health workers involved in clinical care from 49 health facilities.

Clinicians enacted malaria as a 'juggling' exercise, involving attention to pathophysiology of the patient as well as their desires and medical reputations, utilising tests and medicines for their therapeutic effects as symbols in the process of care. Parasites were rarely mentioned in describing diagnostic decisions.

These enactments of malaria contrast with evidence-based guidelines emanating from WHO, which assume the parasite is the central driver of practice. If RDTs are to be taken up in practice, public health practitioners need to pay careful attention to the values and priorities of health workers and patients if they are to work with them to improve diagnosis and treatment of febrile illnesses. The REACT project has designed an interactive intervention with health workers to support the uptake of RDTs, being tested in a cluster randomised trial.

Implementing the inSCALE project in Uganda: Innovations at scale for community access and lasting effects.

***LSHTM Investigators**: Betty Kirkwood, Raghu Lingham, Anna Vassall, Frida Kasteng & Seyi Soremekun.*

***External Investigators/Collaborators:** Sylvia Meek, James Tibenderana & Karin Kallander (Malaria Consortium, UK); Zelee Hill & Daniel Strachan (Institute of Child Health – University College London, UK).*

***Funding Body:** The Bill & Melinda Gates Foundation.*

As a way of improving access to treatment for sick children, several African countries are investing in Community Health Workers (CHWs) to deliver the integrated Community Case Management (iCCM) package. Here CHWs are trained to identify, refer and/or treat children with malaria, diarrhoea, and pneumonia, which together contribute to more than 50% of the childhood illnesses in sub-Saharan Africa. However, CHW programs have been faced with challenges of scale up while maintaining effectiveness, largely due to problems of ruptures in medicine supplies, lack of community involvement, shortfalls in training materials, lack of refresher training and supervision, high attrition and low performance of CHWs.

The inSCALE project ("Innovations at scale for community access and lasting effects") is a Malaria Consortium-led project in collaboration with the LSHTM aiming to evaluate innovative technology and community-based engagement solutions to improve motivation and retention of CHWs, and thus improve the appropriate treatment of children under five years of age.

At the Uganda site we plan two approaches:

Community: The community approach will use a village health 'club' setting, where CHWs and club members can work together to identify and address child health and CHW challenges – and by doing so increase the local visibility and standing of the CHW and the community support of the iCCM programme.

Technology: The technology approach aims to improve the CHW experience through increased supervisory and peer support, using affordable mobile phones. CHWs and their supervisors will receive phones with built-in applications allowing data submission, feedback, motivational messaging and job aides, whilst allowing unlimited calls and SMS amongst CHWs and their supervisors.

These two innovations will be evaluated in a 3-arm cRCT in mid-western Uganda, the results of which will contribute to advocacy efforts aiming to demonstrate the feasibility of increasing and sustaining coverage of the iCCM programme nationally.

Website: http://www.malariaconsortium.org/inscale/

Discussing the inSCALE project with community stakeholders in a village in mid-Western Uganda.

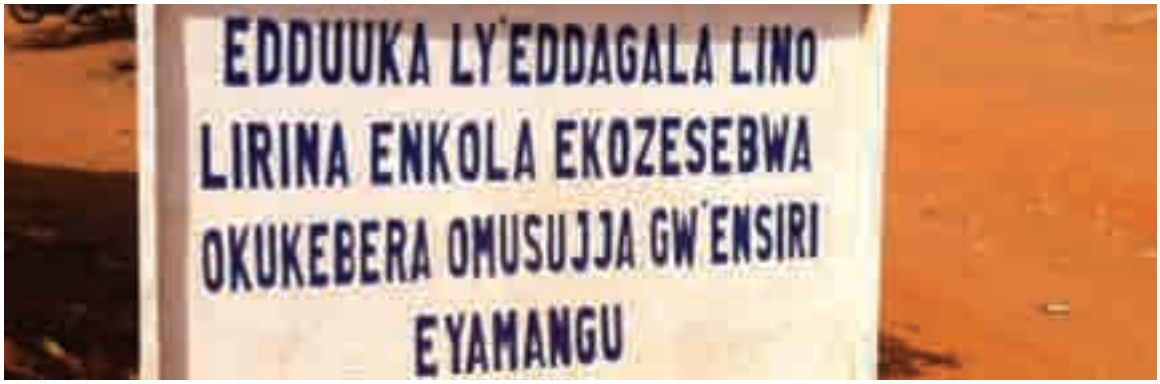
The amount and value of work time of community medicine distributors in community case management of malaria among children under five years in the Ejisu-Juaben District of Ghana.

***LSHTM Investigators**: Kristian Hansen.*

***External Investigators/Collaborators:** Peter Agyei-Baffour & Edmund Browne (Kwame Nkrumah University of Science and Technology, Ghana); Pascal Magnussen (DBL Centre for Health Research and Development, Denmark).*

***Funding Body:** Kwame Nkrumah University of Science and Technology & University of Copenhagen.*

The contribution of Community Medicine Distributors (CMD) to prompt health service delivery in areas described as 'hard-to-reach' is important but the value of their work time remains unknown. This study attempted to estimate the value (opportunity costs) of 54 CMDs work time involved in Community Case Management of malaria (CCMm) in a rural district in Ghana. Time spent by CMDs on CCMm activities was recorded for a period of 12 months to determine their work time. Opportunity costs of time were valued using different proxy measures such as national minimum wage and average labourer wage from common economic activities in the area. The CMDs spent an average of 4.8 hours (95% CI: 3.9; 5.3) on all CCMm related activities per day. The value of time related to CMD work ranged from GHS4.8 (US$5.3) to GHS21.6 US$23.7] per week depending on time valuation approach. The estimated opportunity cost of time using any method was much higher than the money incentives actually paid by the CCMm programme to CMDs. The value of work time and the forgone income of CMD in CCMm are high and yet there are no regular and sustainable incentives provided for them.



This advertisement, which reads 'This drug shop has a fast/ quick way of testing for malaria', was assembled by a drug shop vendor who was given RDTs to sell by the ACT Consortium Project in Mukono, Uganda.

Qualitative evaluation of the introduction of malaria RDTs and a new referral system at registered drug shops in Mukono district, Uganda.

***LSHTM Investigators**: Clare Chandler, Eleanor Hutchinson, Kristian Hansen, Sham Lal & Sian Clarke.*

***External Investigators/Collaborators:** Anthony Mbonye (Ministry of Health, Uganda); Pascal Magnussen (DBL Centre for Health Research and Development, Denmark).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

This qualitative study is running alongside a cluster randomised trial that has introduced malaria RDTs, subsidised Artemisinin-based Combination Therapy (ACT) and a new referral system to registered drug shops in Mukono district, Uganda. We aim to understand more about the processes involved with the introduction of RDTs at drug shops, specifically (1) to evaluate how RDTs and subsidized ACT are perceived and incorporated into practice by drug shop vendors and their clients, (2) to document and describe the referral process from drug shops to health facilities in Mukono from the perspective of patients, drug shop sellers and health workers and (3) to contribute to the current policy and research debates of involving the private sector in health service delivery. We have carried out 21 focus group discussions with drug shop vendors, clients and health facility staff and questionnaire interviews with patients on day 10-14 after visiting drug shops are ongoing. We are also carrying out a discourse analysis to describe the cultural context in which drug shops operate by analysing the ways in which words, phrases and narratives (discourse) are used to name, represent and create particular concepts and images of drug shops and drug shops vendors in Uganda. We will focus on media and government discourses, locating them within the wider context of the relationship between public and private sector health providers in Uganda.

Research on the economics of ACT (REACT): an evaluation of the effectiveness and cost-effectiveness of two interventions designed to support the roll-out of malaria Rapid Diagnostic Tests (RDTs) and improve the rational use of Artemisinin-based Combination Therapy (ACT) in Enugu State, Nigeria.

***LSHTM Investigators**: Virginia Wiseman & Lindsay Mangham.*

***External Investigators/Collaborators:** Obinna Onwujekwe, Ogochukwu Ezeoke, Emmanuel Nwala, Jane Enemuo, Eloka Uchegbu & Benjamin Uzochukwu (University of Nigeria, Nigeria).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

The Government of Nigeria recommends that patients presenting with malaria symptoms should be tested using microscopy or RDTs prior to treatment, and that confirmed cases of malaria should be treated with ACT. With limited access to testing, symptomatic treatment of malaria has been the mainstay, though the Government of Nigeria plans to introduce RDTs. It is feared that without supporting interventions, many patients will not receive care in line with the national malaria policy.

This study aims to design, implement and evaluate two interventions to improve the care of patients presenting with malaria symptoms at primary health facilities in the public sector and at pharmacies and patent medicine dealers.

A 3-arm cluster randomized trial is ongoing and will assess the effectiveness and cost effectiveness of: (i) a provider intervention versus expected standard practice in malaria diagnosis and treatment; (ii) combined provider plus school-based intervention versus expected standard practice; and (iii) the combined provider plus school-based intervention versus provider intervention alone. RDTs will be introduced in all arms of the trial. The primary outcome is the proportion of patients attending facilities that report a fever or suspected malaria and receive treatment according to malaria guidelines. This will be measured by surveying patients (or caregivers) as they exit primary health centres, pharmacies and patent medicine dealers. Costs will be estimated from both a societal and provider perspective using standard economic evaluation methodologies. Cost-effectiveness will be presented in terms of the primary outcome and a range of secondary outcomes, including changes in provider and community knowledge.

Research on the economics of ACT (REACT): an evaluation of the effectiveness and cost-effectiveness of provider interventions improve the rational use of Artemisinin-based Combination Therapy (ACT) in Cameroon.

***LSHTM Investigators**: Virginia Wiseman, Lindsay Mangham, Bonnie Cundill & Clare Chandler.*

***External Investigators/Collaborators:** Wilfred Mbacham, Olivia A Achonduh, Akindeh Mbuh Nji & Abanda Ngu Njei (University of Yaoundé I, Cameroon).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

Governments and donors all over Africa are searching for sustainable, affordable and cost-effective ways to improve the quality of malaria case management. Widespread deficiencies have been reported in the prescribing and counselling practices of health care providers treating febrile patients in both public and private health facilities. Cameroon is no exception with poor adherence to national guidelines, the frequent selection of non-recommended antimalarials and the use of incorrect dosages.

This study aims to design, implement and evaluate interventions to improve the care of patients presenting with malaria symptoms at public and mission health facilities. The evaluation will determine the effectiveness and cost-effectiveness of introducing provider training alongside Rapid Diagnostic Tests. Two training courses have been designed. Both courses will equip providers with the basic knowledge and practical skills needed to effectively diagnose and treat malaria, while the enhanced course also uses interactive methods and additional activities to promote changes in prescribing practices.

A 3-arm cluster randomized trial is ongoing. The primary outcome is the proportion of patients attending facilities that report a fever or suspected malaria and receive treatment according to malaria guidelines. This will be measured by surveying patients (or caregivers) as they exit public and mission health facilities. Costs will be estimated from a societal and provider perspective using standard economic evaluation methodologies. Cost-effectiveness will be presented in terms of the primary outcome and a range of secondary outcomes, including changes in provider knowledge.

Packets of drugs.

The Good Use of ACT and Rapid Diagnostic Tests (RDTs) - (GUARD) study.

***LSHTM Investigators**: Shunmay Yeung, Clare Chandler, Patricia Tabernero & Mikhael De Souza.*

***External Investigators/Collaborators:** Chea Nguon, Ouk Rada & Mam Boravann (National Malaria Control Programme, Cambodia); Henrietta Allen (Population Services International).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

The role of malaria Rapid Diagnostic Tests (RDTs) in the private sector has recently become a hot topic for expansion of appropriate diagnosis and treatment of malaria. However programmatic experience is very limited. In Cambodia RDTs have been socially marketed alongside Artemisinin-based Combination Therapy (ACT) since 2004. However little was known about how they were being used in practice. We undertook the Good Use of ACT and Rapid Diagnostic tests (GUARD) study in collaboration with the National Malaria Control programme and other partners in Cambodia in 2010-2011. We used a mixed methods approach including a private provider census survey, RDT user assessment, RDT quality assessment; mystery client study, chemical analysis of drugs and focus group discussions. In all, 217 providers in 12 health centre catchment areas were included. The census survey showed that only 59% of the 203 providers who sold antimalarials, also sold RDTs. Qualitative findings suggested that providers distinguish their roles as selling drugs ("lout tnam") or diagnosing and treating ("pinit pchier bal"), and that RDTs seem to be at the margins rather than central to these practices. The mystery client findings suggested that providers were often reluctant to sell antimalarials without a prior blood test, and that the sale of "drug cocktails" is still very popular. Challenges were identified in the manual use of RDTs, including difficulties with the blood pipette, insufficient waiting time and unsafe disposal of the used lancets. Providers also reported some problems in interpreting results. When asked about alternative diagnoses for patients with negative RDTs, the most common diagnosis reported by providers was "typhoid", and a third said that they would provide antibiotics. The results of the study are being used to modify aspects of the programme in Cambodia, and will hopefully be useful for other malaria-endemic countries that are considering the roll-out of RDTs in their private sectors.

Village Malaria Worker Access to Treatment (VIMWAT) study.

***LSHTM Investigators**: Shunmay Yeung & Edith Patouillard.*

***External Investigators/Collaborators:** Chea Nguon & Poly Teng (National Malaria Control programme, Cambodia).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

Community health workers have been identified as a means to increase prompt access to appropriate management of malaria, through parasitological diagnosis using Rapid Diagnostic Tests (RDTs) and Artemisinin-based Combination Therapy (ACT). There has also been interest in expanding their role to the management of childhood illnesses. However, evaluations of these programmes are lacking.

In Cambodia, the national malaria control programme introduced a network of Village Malaria Workers (VMWs) in 2004. VMWs are community volunteers who perform RDTs and treat confirmed malaria cases with ACT, with some having an "expanded role" to treat children under 5 years presenting with diarrhoea and/or acute respiratory infections using Oral Rehydration Solution (ORS) and/or antibiotics.

The VIMWAT study is a pragmatic evaluation of the VMW programme. It aims to evaluate their effectiveness at delivering prompt access to appropriate diagnosis and treatment of malaria to the most vulnerable populations and feasibility and impact of expanding their role. It employs mixed methods, including:

- A three-arm cohort study of 1,152 households (~ 5,000 individuals) to document treatment seeking behaviours and associated costs over time for populations living in villages with VMWs offering RDT and ACT only, populations in villages with VMWs offering RDT, ACT, ORS and antibiotics and populations without access to VMWs.
- Epidemiological and economic cost study of the VMW programme from a provider perspective.

Fieldwork started in August 2011 and is expected to be completed mid-2012.

Willingness-to-pay for Rapid Diagnostic Tests (RDTs) and ACT medicines into the private sector. Costumer survey in registered drug shops in Mukono district, Uganda.

***LSHTM Investigators**: Kristian Hansen, Bonnie Cundill, Shunmay Yeung & Sian Clarke.*

***External Investigators/Collaborators:** Deborah Pedrazzoli (Health Protection Agency, UK); Anthony Mbonye (Ministry of Health, Uganda); Pascal Magnussen (DBL Centre for Health Research and Development, Denmark).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

Many people seek treatment for malaria in drug shops as their first point of care, and the role of the private sector in providing access to prompt effective antimalarial treatment is increasingly recognised by malaria control programmes.

However, parasitological diagnosis to guide malaria treatment is not usually offered in these outlets. Rapid Diagnostic Tests (RDTs) are easy to perform with minimal training, and could feasibly be performed in drug shops, but it is not known how much customers would be willing to pay for an RDT.

The bidding game technique was used to elicit the willingness-to-pay (WTP) for an RDT and a course of Artemisinin-based Combination Therapy (ACT), with and without RDT confirmation, during exit interviews with drug shop customers seeking treatment for fever in Mukono District, Uganda. The geometric mean WTP for an RDT was US$0.53, and US$1.82 for a course of ACT. Customers indicated WTP for an ACT would increase to US$2.05 should the RDT have proved positive. In conclusion, the WTP for RDTs and ACT were considerably lower than prevailing and estimated end-user prices under AMFm. Additional measures may be needed to increase uptake of ACT in drug shops and to restrict sale of ACT to parasitologically confirmed malaria.

"Bringing treatment to the people" - emerging geographies of care and the role of rapid diagnostic tests in access to malaria treatment in Bo District, Sierra Leone.

***LSHTM Investigators**: Uli Beisel & Wenzel Geissler.*

***External Investigators/Collaborators:** Jorgen Stassijns (Médecins Sans Frontières, Belgium).*

***Funding Body:** Leverhulme Trust.*

In collaboration with Médecins Sans Frontières (MSF) in Belgium this project conducted one month of qualitative research in Bo District, Sierra Leone. From 2007-11 MSF ran an outreach malaria control project in rural, hard-to-reach communities; 50 medically untrained community malaria volunteers (mainly local farmers) were trained to use rapid diagnostic tests to diagnose *falciparum* malaria and administer Artemisinin-based Combination Therapies. MSF's project aimed to increase access to malaria care for population groups that had thus far not been able to seek biomedical care due to their distance to health care facilities. This research project aimed to assess the community responses, social implications and changed geographies of care and access to malaria treatment in the project area. MSF's project was highly successful in increasing access to malaria diagnosis and treatment for vulnerable populations, and the results of the qualitative interviews and observations underlined that on-going medical training and regular supervision of the volunteers was crucial. Furthermore, the results emphasise the importance of establishing long-term and local institutional support for such capacity building projects with medically untrained and unpaid volunteers. The application of Rapid Diagnostic Tests in non-medical settings through health volunteers is only sustainable and effective in improving malaria diagnosis and treatment if projects are conceived from the beginning as medical education and capacity building projects.

Cost-effectiveness analysis of introducing RDTs for malaria diagnosis as compared to microscopy and presumptive diagnosis in public health centres in Ghana.

***LSHTM Investigators**: Kristian Hansen, Chris Whitty & Shunmay Yeung.*

***External Investigators/Collaborators:** Evelyn Ansah (Ghana Health Service, Ghana).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

Overprescription of antimalarials occurs in public health centres in Ghana both where microscopes are available and where diagnosis is done presumptively due to lack of parasitological testing facilities. The present research project assessed the cost-effectiveness of introducing malaria Rapid Diagnostic Tests (RDTs) in three public health centres in Dangme West district, Ghana. Suspected malaria patients attending a health centre with a microscope were randomly assigned to a diagnosis by either RDT or microscopyand subsequent treatment by health centre staff whereas patients visiting two health centres without a microscope were randomly assigned to diagnosis by an RDT or based on clinical signs. Costs of offering diagnostic services and outpatient services were collected through visits to the health centres. An exit survey among suspected malaria patients and follow-up visits in their homes captured household cost of treatment-seeking. The measure of effect was the number of correctly treated patients as determined by a double read blood slide. The cost per correctly treated patient in the health centre with a microscope was at a similar level among patients diagnosed by an RDT and by a microscopy. In the health centres without a microscope, the cost per correctly treated patient was considerably lower among patients diagnosed by an RDT arm as compared to those diagnosed by clinical signs.

Introducing Rapid Diagnostic Tests (RDTs) into the private health sector: a cost-effectiveness analysis among registered drug shops in Mukono district, Uganda.

***LSHTM Investigators**: Kristian Hansen, Sian Clarke & Sham Lal.*

***External Investigators/Collaborators:** Anthony Mbonye (Ministry of Health, Uganda); Pascal Magnussen (DBL Centre for Health Research and Development, Denmark).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

It is common in Uganda for people to seek treatment for malaria in drug shops as their first point of care. Parasitological diagnosis to guide malaria treatment is not usually offered in drug shops. Since Rapid Diagnostic Tests (RDTs) are easy to perform and have high accuracy in many settings, these tests could feasibly be offered in drug shops. The present research is designed as a cost-effectiveness study alongside a cluster-randomised trial in Mukono district, Uganda, where drug shops will either offer RDT diagnosis or presumptive diagnosis. Societal cost of interventions will be collected incorporating the cost related to deployment of the interventions and the provider cost of treatment in public health facilities if patients proceed to seek care. In addition, interviews with a sample of drug shop customers will be done to capture the household cost of treatment-seeking for fever including the direct costs of transport, diagnosis and drugs and opportunity cost of lost time. The effectiveness measure is 'correctly treated patient' defined as a research blood slide positive patient receiving an Artemisinin-based Combination Therapy (ACT) or a blood slide negative patient not receiving an ACT. The collected data will be used to estimate the incremental cost and effects of introducing RDTs in private, registered drug shops as well as to perform various decision tree and sensitivity analyses incorporating factors like adherence, provider compliance and accuracy of the test.

Mother and child in The Gambia.

Introducing rapid diagnostic tests into community-based management of malaria: a cost-effectiveness analysis among community medicine distributors in two areas of high and low transmission in Uganda.

***LSHTM Investigators**: Kristian Hansen, Sian Clarke & Sham Lal.*

***External Investigators/Collaborators:** Richard Ndyomugyenyi (Ministry of Health, Uganda); Pascal Magnussen (DBL Centre for Health Research and Development, Denmark).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

Universal access to diagnostic testing for malaria is recommended by the World Health Organisation. Rapid Diagnostic Tests (RDTs) provide a simple means of confirming malaria diagnosis in remote locations where community health workers after limited training may be able to perform RDTs and treat accordingly. Alongside a cluster-randomised trial, data have been collected for a cost-effectiveness analysis of introducing RDTs to improve malaria diagnosis and treatment by Community Medicine Distributors (CMDs) in two sub-counties with contrasting transmission in Rukungiri District, Uganda. Societal cost of two interventions will be collected: (1) having CMDs perform an RDT followed by treatment with artemisinin-based combination therapy (ACT) or referral and (2) CMDs treating presumptively with ACT or referral. The cost to be collected include the cost related to deployment of the interventions and the provider cost of treatment in public health facilities if patients proceed to seek care or are referred there by the CMDs. In addition, interviews with a sample of patients treated by CMDs will be done to capture the household cost of treatment-seeking for fever including the direct costs of transport, diagnosis and drugs and opportunity cost of lost time. The effectiveness measure was 'correctly treated patient' defined as a research blood slide positive patient receiving an ACT or a blood slide negative patient not receiving an ACT. The collected data will be used to estimate the incremental cost and effects of introducing RDTs among CMDs as well as to perform various decision tree and sensitivity analyses incorporating factors like adherence, compliance to RDT result by CMDs and accuracy of the RDT.

Development of programme friendly rapid assessment tools to identify and quantify the major barriers to the scale up and use of interventions for the control of malaria in pregnancy.

***LSHTM Investigators**: Jayne Webster, Jane Bruce & Lucy Paintain.*

***External Investigators/Collaborators:** Jenny Hill, Rukhsana Ahmed, Feiko ter Kuile (Liverpool School of Tropical Medicine, UK); Kassoum Kayentao, Sory Diawara, Samba Diarra (Malaria Research and Training Centre, Mali); Stephanie Dellicour, Meghna Desai & Peter Ouma, (KEMRI-CDC, Kenya); Din Syafruddin (Eijkman Institute of Molecular Biology, Indonesia).*

***Funding Body:** The Bill & Melinda Gates Foundation through the Malaria in Pregnancy Consortium.*

In order to support global efforts to scale up malaria control interventions, greater attention must be given to implementation research in order to understand the obstacles to progress at the level of local decision makers. Innovative rapid assessment approaches that explore the link between health care utilisation patterns and specific elements of the delivery system are needed in order to support programme managers maximise the outputs of current investment levels.

We are using a combination of integrated survey techniques to assess barriers at the levels of 'access', 'delivery' and 'use'. Strengths and weaknesses of the study methods will be examined and used to illustrate how they provide complementary information to improve programme performance. These comprehensive methods will be scaled down to provide essential rapid assessment tools. Findings have highlighted blockages in delivery of preventative interventions, methodological anomalies in the way in which we are currently assessing coverage of interventions, and the strengths and weakness of survey techniques in providing information for programme improvement.

In a second phase of the study findings of the above will be used to 1) develop streamlined second generation survey tools, 2) routine data collection for delivery of MiP interventions through ANC will be examined and described, 3) enhanced data collection indicators, and tools will be implemented and the completeness, accuracy, validity and utility of the data evaluated.

Intermittent Screening and Treatment (IST) or Intermittent Preventive Therapy (IPT) for control of Malaria in Pregnancy (MiP) in Indonesia.

***LSHTM Investigators**: Jayne Webster & Jane Bruce.*

***External Investigators/Collaborators:** Jenny Hill, Rukhsana Ahmed, Eve Worral & Feiko ter Kuile (Liverpool School of Tropical Medicine, UK); Din Syafruddin, Jeanne Poespoprodjo & Puji Budi Asih (Eijkman Institute of Molecular Biology, Indonesia).*

***Funding Body:** UK Department for International Development; Medical Research Council, UK; Wellcome Trust Joint Global Health Trial Scheme.*

A range of implementation research sub studies will be used to investigate the current status of the programme for prevention of malaria in pregnancy, and the feasibility, acceptability and cost effectiveness of possible new strategies. The study will run alongside a randomised control trial and will involve structured observations, in-depth interviews and focus group discussions.

Currently in Indonesia women are tested for malaria on their first visit to antenatal clinics, and if positive are treated with dihydroartemisinin-piperaquine (DHA-PQ) in 2nd and 3rd trimester and quinine in 1st trimester. During subsequent visits they are only tested if they present with symptoms. This strategy for Single Screening and Treatment (SST) will be compared with Intermittent Screening and Treatment (IST) where women are tested on every scheduled visit to ANC, and with Intermittent Preventive Treatment (IPTp), where women receive a preventive treatment on scheduled visits to ANC but no testing. The implementation research will focus on these 3 strategies of SST, IST and IPT.

Scale-up of Malaria in Pregnancy (MiP) interventions.

***LSHTM Investigators**: Jayne Webster.*

***External Investigators/Collaborators:** Jenny Hill & AnneMieke van Eijke (Liverpool School of Tropical Medicine, UK); Rick Steketee (MACEPA); PATH, USA.*

***Funding Body:** The Bill & Melinda Gates Foundation through the MiP consortium.*

Despite clear documented evidence on the burden of malaria in pregnant women and proven effective interventions, as adopted/recommended in African Regional and country policies, coverage of malaria prevention in pregnant women in many malaria-endemic African countries remains unacceptably low.

We have adopted a 2 stage approach to address this problem. In stage 1 we are conducting reviews and secondary data analyses to clarify the issues and problems experienced across countries, including variations by sub-regions. In the second stage we plan to systematically identify and actively address the coverage barriers at country level. In order to facilitate the second stage we are developing an assessment and decision making tool.

Economic analysis for the Malaria in Pregnancy (MiP) Consortium.

***LSHTM Investigators**: Kara Hanson, Silke Lutzelschwab & Jayne Webster.*

***External Investigators/Collaborators:** Elisa Sicuri (CRESIB, Barcelona); Azra Ghani & Patrick Walker (Imperial College, UK); Feiko ter Kuile & Jenny Hill (Liverpool School of Tropical Medicine, UK).*

***Funding Body:** The Bill & Melinda Gates Foundation.*

Sitting within the Public Health Impact activity of the Malaria in Pregnancy Consortium (MiPc), the objectives of the economics contributions are: a) to estimate the economic burden of MiP; b) to assess the cost and cost-effectiveness of new prevention and case management interventions; c) to estimate the cost of scaling up new MiP interventions.

The economic burden of malaria in pregnancy will be estimated using a variety of methods, including cross-sectional household and facility surveys, exit surveys, and modelling approaches. Cost-and cost-effectiveness analyses will be conducted alongside both prevention and case management trials. Information to support decision making will be provided by modelling the costs and affordability to national governments of implementing MIP interventions, and exploring the costs of alternative approaches to their targeting and delivery.

In collaboration with Azra Ghani, the project has supported the development of a model of malaria in pregnancy which will be used to explore the applicability of potential prevention strategies to various settings with different underlying epidemiological and economic characteristics.

Work is being carried out alongside trials in 12 countries from 4 continents and fieldwork will commence during 2010.

Cost-effectiveness of malaria microscopy and rapid diagnostic tests versus presumptive diagnosis: implications for malaria control in Uganda.

***LSHTM Investigators**: Kristian Hansen.*

***External Investigators/Collaborators:** Vincent Batwala (University of Science & Technology, Uganda); Pascal Magnussen (DBL Centre for Health Research and Development, Denmark); Fred Nuwaha (Makerere University Uganda).*

***Funding Body:** Makarere University School of Public Health; UK Department for International Development; Centre for Health Research and Development.*

Current Ugandan National Malaria treatment guidelines recommend parasitological confirmation either by microscopy or Rapid Diagnostic Test (RDT) before treatment with artemether-lumefantrine (AL). The cost-effectiveness of these strategies has not been assessed at rural primary care centres. Three health centres were randomized to three diagnostic arms (microscopy, RDT and presumptive diagnosis) each in a district of low and high malaria transmission intensities in Uganda. Patients presenting with fever at outpatients departments were enrolled from March 2010 to February 2011. Costing was performed from the societal perspective and following the standard step-down costing method and the ingredients approach. Effectiveness was measured as the number and proportion of patients correctly diagnosed and treated. The Incremental Cost-Effectiveness Ratio (ICER) of introducing RDT diagnosis instead of presumptive diagnosis was US$5.0 while the ICER of microscopy versus presumptive diagnosis was US$9.61. The ICERs of RDT and microscopy diagnosis varied by transmission setting, but RDT diagnosis remained the most cost-effective option of the two in both settings. With a global campaign to reduce the costs of AL and RDT, the Malaria Control Programme and stakeholders need a strategy for malaria diagnosis because as the cost of AL decreases, presumptive treatment is likely to become more attractive.

Eliciting harms data from trial participants: how perceptions of illness and treatment mediate recognition of relevant information to report.

***LSHTM Investigators**: Clare Chandler & Sarah Staedke.*

***External Investigators/Collaborators:** Karen Barnes & Elizabeth Allen (University of Cape Town, South Africa); Adiel Mushi, Isolide Massawe & Martha Lemnge (National Institute of Medical Research, Tanzania); Ushma Mehta (South Africa); Lasse Vestergaard (University of Copenhagen, Denmark).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

There is no consensus on ideal methodology for eliciting participant-reported harms in clinical trials, but the extent and nature of data detected depend on the types of questions asked. This gives potential for measurement error and undermines meta-analyses of adverse effects.

Participants in two (South African and Tanzanian) antiretroviral/antimalarial interaction trials were asked about their health and treatments by general enquiries followed by checklists. Those reporting differently between these methods were invited to an in-depth interview and focus group discussion. Health narratives were analysed to investigate accuracy and completeness of the case record form data and to understand reasons for differential reporting.

Using checklists generally increased the sensitivity of detection of medical histories, concomitant medications and adverse events compared to open enquiries, though trial participants deliberately withheld some further information, revealed through the interviews. We identified the following barriers to reporting: poor memory, perception of the significance of the event or treatment to the participant, perceived relevance of the event or treatment to the trial or medical consultation, perceived consequences of reporting, and problems with naming concomitant treatments. These barriers were underpinned by psycho-social constructs concerned with being a trial subject and perceived responsibility for reporting. Differing perceptions between South Africans and Tanzanians about whether it is the participant or investigator who takes responsibility for reporting were influenced by the distinct trial contexts.

Our current aim is to work towards consensus about the design of appropriate and feasible harms data elicitation methods within the malaria clinical research community.

Designing adverse event forms for real-world reporting: participatory research in Uganda.

***LSHTM Investigators**: Clare Chandler & Sarah Staedke.*

***External Investigators/Collaborators:** Emma Davies, David Lalloo & Dianne Terlouw (Liverpool School of Tropical Medicine, UK); Simeon H Innocent (Cambridge University, UK); Charles Kalumuna (Malaria Surveillance Programme, Uganda); Ane Haaland (University of Oslo/Haaland Communication).*

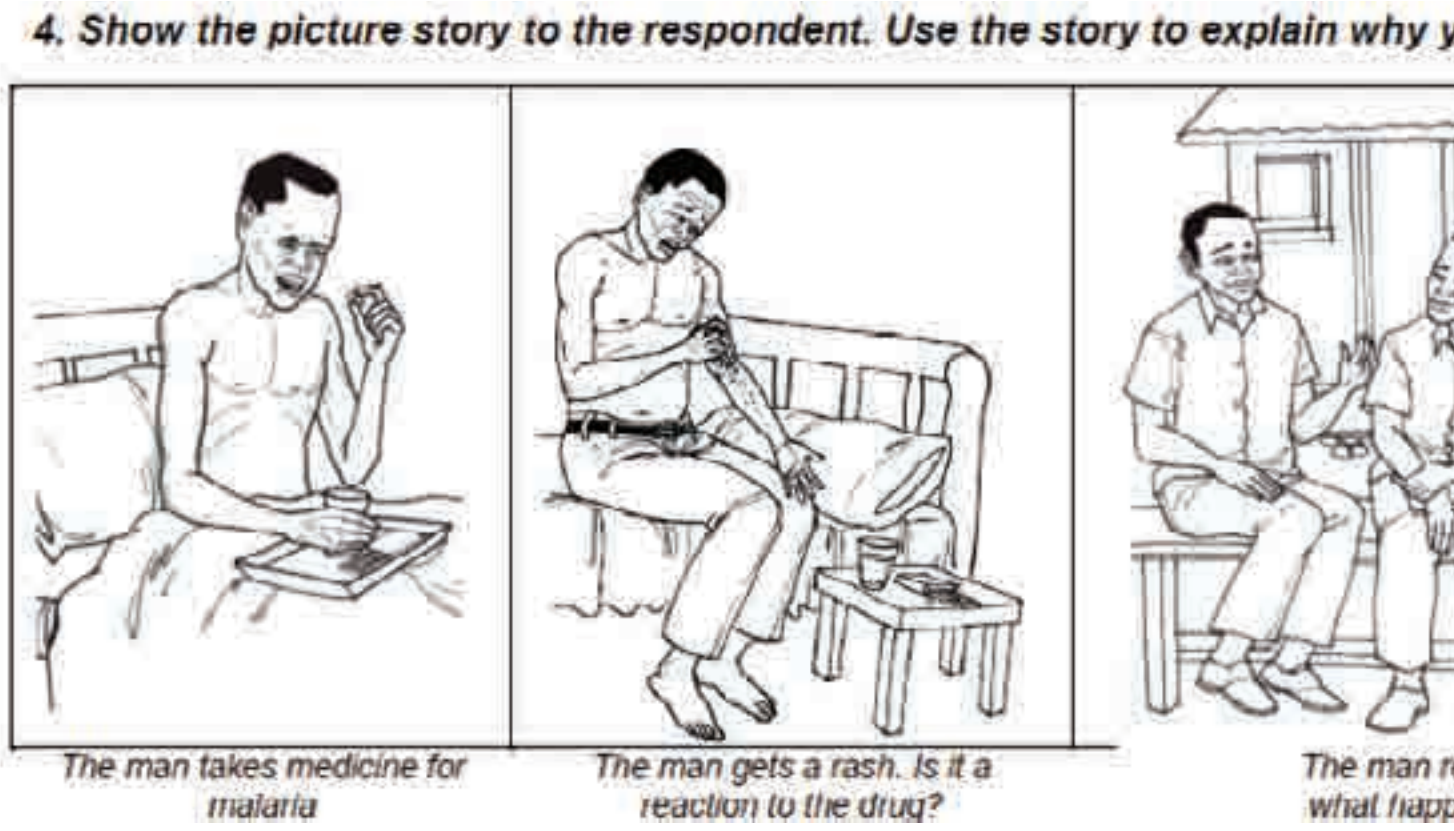
***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

The wide-scale roll-out of Artemisinin-based Combination Therapy (ACT) for the treatment of malaria should be accompanied by continued surveillance of their safety, as standard good practice. Post-marketing pharmacovigilance relies on passive and active adverse event reporting by clinicians, but as a large proportion of treatments are provided by non-clinicians in many low-resource settings, the effectiveness of such PV systems is limited. To facilitate reporting, adverse event report forms should be easily completed; however, most commonly used forms are challenging for lower-level health workers and non-clinicians to complete. Through participatory research, we sought to develop user-friendly adverse event report forms designed to capture information on events associated with ACT.

Following situation analysis, we undertook workshops with community medicine distributors and health workers in Jinja, Uganda, to develop a reporting form based on experiences and needs of users as well as communication and visual perception principles. Participants practised with the forms and gave feedback for revisions of subsequent versions. We then conducted a series of 8 pretesting sessions with 77 potential end users using scenarios to test and refine passive and active versions of the form.

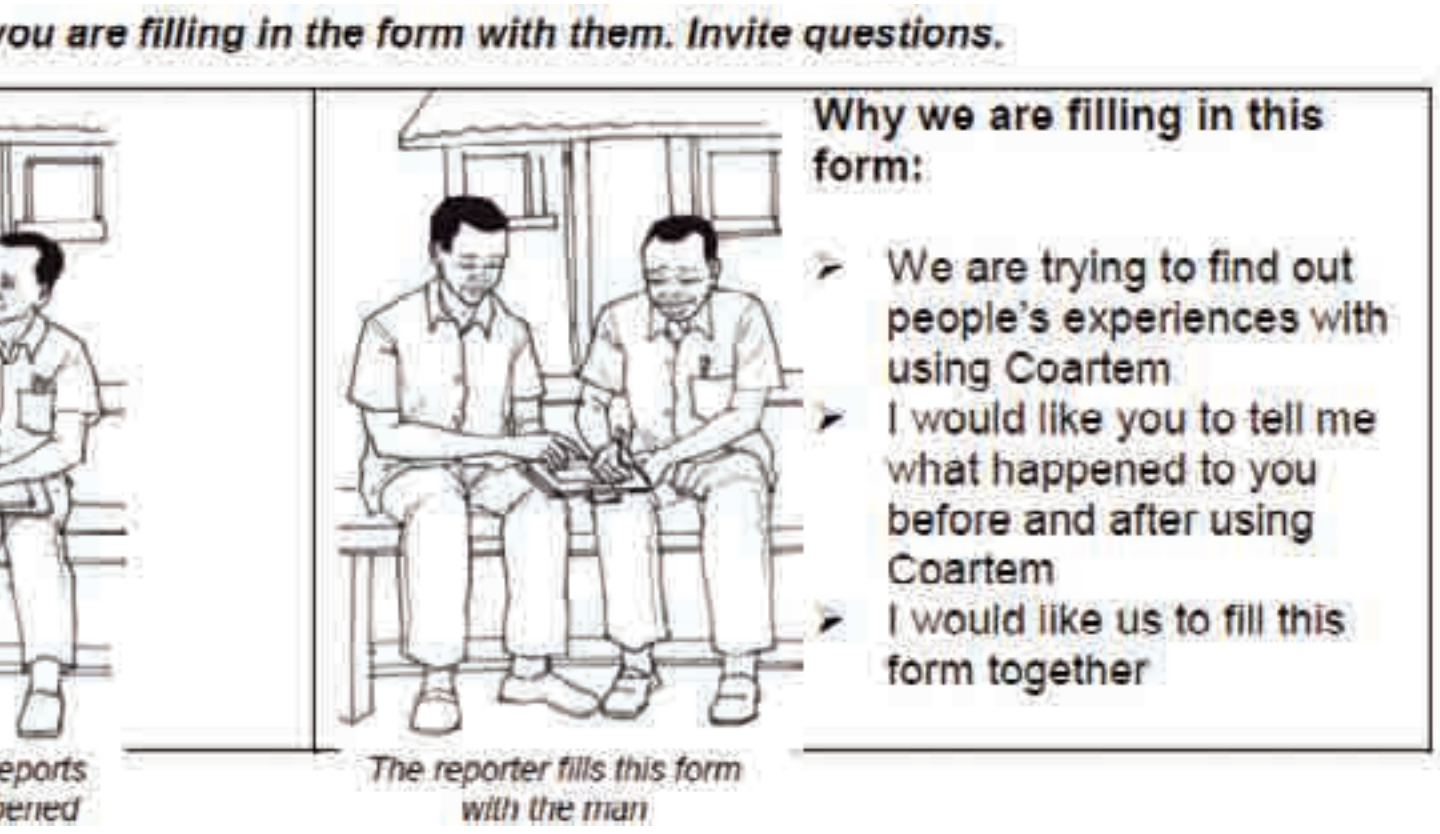
The development process resulted in a form that included a pictorial storyboard to communicate the rationale for the information needed, and a diary format to record the drug administration and event details in chronological relation to each other. Successive rounds of pretesting used qualitative and quantitative feedback to refine the form, with the final round showing over 80% of the form completed correctly by potential end users.

We developed novel adverse event report forms that can be used by non-clinicians to capture pharmacovigilance data for anti-malarial drugs. The participatory approach was effective for developing forms that are intuitive for reporters, and motivating for respondents. The forms or their key components could be adapted for use in other low-literacy settings to improve quality and quantity of drug safety reports as new medicines are scaled-up.



Above: Community medicine distributors working to design an adverse event reporting form that encourages their respondents to give the full story of the 'event'.

Below: Final version of a story board developed through participatory research, to communicate to low-level health workers and respondents the purpose of the adverse event reporting form.



Understanding perceptions of malaria and malaria treatment amongst HIV-positive individuals in Muheza, Tanzania: a qualitative study.

***LSHTM Investigators**: Clare Chandler & Joanna Reynolds.*

***External Investigators/Collaborators:** Lasse Vestergaard (University of Copenhagen, Denmark); Peter Mangesho & Martha Lemnge (National Institute for Medical Research, Tanzania).*

***Funding Body:** The Bill & Melinda Gates Foundation through the ACT Consortium.*

Acknowledging the double burden of malaria and HIV co-infection faced by many in sub-Saharan Africa, we designed a qualitative study to explore perceptions of taking antimalarial medication concomitantly with Anti-Retroviral Therapy (ART) amongst HIV-positive people, in Muheza, Tanzania. We sought to understand these perceptions, and how they influence attitudes towards malaria prevention and treatment seeking, and conducted the study alongside a clinical observation trial of the efficacy and safety of taking ART concomitantly with Artemisinin-based Combination Therapy (ACT) for malaria. As a secondary research question, we also sought to explore with participants their experiences of participating in the clinical observation trial and the meaning attached to it.

We conducted 13 Focus Group Discussions (FGDs) and 10 In-Depth Interviews (IDIs) between July and November 2011, with HIV-positive and negative participants of the clinical observation trial, trial staff and health workers from the surrounding health service in Muheza. The FGD and IDI transcripts are being analysed in relation to each research question, and analysis will be completed by mid-March, 2012. It is hoped the findings will help address gaps in existing knowledge around perceptions of taking ART and antimalarial medication concomitantly, informing practice in how to minimise the risks related to co-infection of HIV and malaria. Furthermore, we hope to contribute to understanding of the ethical dimensions of conducting trials in developing country settings and how to better align participants' and researchers' expectations and experiences of the research process.

Boys playing in The Gambia.

The costs of large-scale administration of Seasonal Malaria Chemoprevention (SMC) in Central Senegal.

***LSHTM Investigators**: Catherine Pitt, Badara Cisse & Paul Milligan.*

***External Investigators/Collaborators:** Mouhamed N'Diaye & Oumar Gaye (Université Cheikh Anta Diop, Senegal); El Hadj Ba (Institut de Recherche pour le Developpement, Dakar, Senegal); Lesong Conteh (Imperial College London, UK).*

***Funding Body:** The Bill & Melinda Gates Foundation.*

In March 2012, the World Health Organization recommended Seasonal Malaria Chemoprevention (SMC) as an additional malaria control tool. This is the first study to assess the costs of SMC on a large scale; preliminary results on the financial costs of SMC were presented to WHO in 2011. We evaluated the financial and economic costs of delivering SMC in a population of approximately 175,000 children aged 3 to 120 months in 45 health posts across four districts of central Senegal in 2010. Implementation was led by the Ministry of Health. At each health post, Community Health Workers (CHWs) travelled door-to-door in pairs to administer sulphadoxine-pyramethamine and amodiaquine tablets over the course of several days in each of the three main months of the malaria season. The financial and economic costs were found to be lower than in previous studies, which is likely attributable to economies of scale, as this was a much larger study, but also to the leading role of the Ministry of Health in implementation, and the economies of scope achieved in extending the usual age range of SMC from children under five to children under ten. The SMC tablets themselves and the incentive payments to CHWs were the key cost drivers. Analyses are ongoing and will also include an assessment of the cost-effectiveness of SMC.