IMPACT CASE STUDY

Improving policies and practice for malaria management, prevention and control

KEMRI/Walter Reed
Project-Kisumu Field Station

KEMRI/Walter Reed Project

INDEPTH Network
Better Health Information for Better Health Policy

The Kombewa Health and Demographic Surveillance System (HDSS), of the KEMRI/Walter Read Project grew out of the Kombewa Clinical Research Center in 2007 and has since established itself as a platform for the conduct of regulated clinical trials, nested studies and local disease surveillance. The HDSS is located in a rural part of Kisumu County, Western Kenya, and covers an area of about 369 km2 along the north-eastern shores of Lake Victoria. A dynamic cohort of 141, 956 individuals drawn from 34,718 households forms the HDSS surveillance population.Following a baseline survey in 2011, the HDSS continues to monitor key population changes through routine biannual household surveys. The intervening period between set-up and baseline census was used for preparatory work, in particular Global Positioning System (GPS) mapping. Routine surveys capture information on individual and households including residency, household relationships, births, deaths, migrations (in and out) and causes of morbidity (syndromic incidence and prevalence) as well as causes of death (verbal autopsy). The Kombewa HDSS platform is used to support health research activities, that is clinical trials and epidemiological studies evaluating diseases of public health importance including malaria, HIV and global emerging infectious diseases such as dengue fever. Formal data requests and proposed collaborations can be submitted at Kombewadssdata@usamru-k.org

INDEPTH Network
Better Health Information for Better Health Policy

INDEPTH is a global leader in health and population research, providing robust answers to some of the most important questions in development. The lack of a reliable information base to support the identification, prevention and treatment of health problems is a major hurdle to addressing the high burden of disease in low- and middle-income countries. INDEPTH — through its global network of 52 health and demographic surveillance system (HDSS) sites run by 45 research centres in 20 countries across Africa, Asia and the Pacific region — is the only organisation in the world capable of developing that information base. It tracks a total population of over 3.8 million people, providing high quality longitudinal data not only about the lives of people in low- and middle-income countries (LMICs), but also about the impact on those lives of development policies and programmes. Kombewa Health and Demographic Surveillance System (HDSS) is a member of INDEPTH Network.

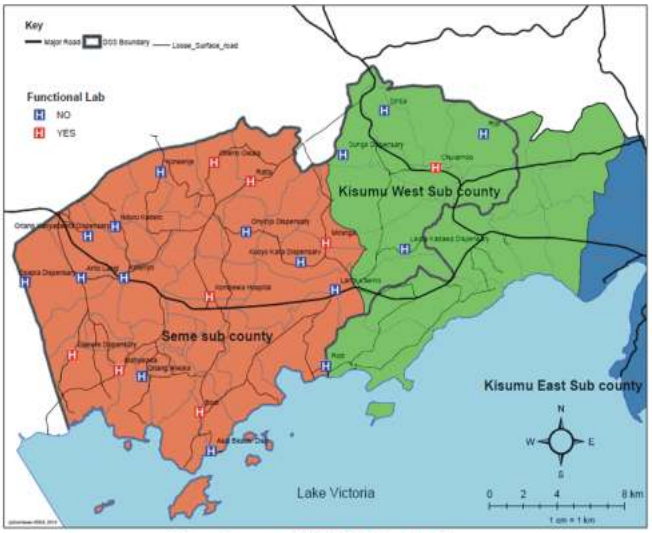
Summary of the Impact

The KEMRI/Walter Reed Project is a collaboration between the U.S. Army Medical Research Directorate – Kenya (an overseas activity of the Walter Reed Army Institute of Research) and the Kenya Medical Research Institute which dates back to the inception of KEMRI in 1979. The KEMRI/WRP Kisumu Field Station is comprised of five major programmes on four campuses: the Malaria Diagnostic Center (MDC), the Kombewa Clinical Research Center, the Vector Biology/Entomology and Malaria Drug Resistance Laboratories, and the Basic Science Laboratory (BSL) complex). Collectively, these activities have made significant contributions towards improving policies for malaria management in Kenya and beyond. The Kombewa health and demographic surveillance systems (HDSS) is housed at the Kombewa Clinical Research Center and provides a platform for the conduct of clinical trials, syndromic surveillance for common diseases, surveillance of health behaviours and preventive measures and nested prospective surveillance studies.

The Underpinning Research

Context:

The KEMRI/Walter Reed Project Kisumu Field Station is comprised of four campuses:



Kombewa HDSS Study Area

- The Malaria Diagnostic Center (MDC) is one of the largest malaria diagnostic centers in sub Saharan Africa. The center leads the global effort in improving malaria diagnostics through basic and advanced malaria microscopy training for research and Ministry of Health personnel, malaria microscopy quality assurance training, and preparation of standardized malaria blood films for training and testing laboratory technicians and for developing and managing quality assurance programs.
- The Kombewa Clinical Research Center is a dedicated unit for conducting regulated clinical trials of malaria therapeutic and vaccine candidates in development. One highlighted achievement is the participation as a site in the multi-center trial of dispersible Coartem® for pediatric use; the data from this study led to licensure and implementation of dispersible Coartem® as the first line antimalarial in children. Another highlight was the evaluation of IV artesunate in adults which led to the registration of the product for use in severe malaria in Kenya and availability of the product under IND in the United States.
- The KEMRI/WRP Vector Biology/Entomology and Malaria Drug Resistance (MDR) Laboratories are housed at the KEMRI Center for Global Health Research in Kisian. The MDR program focuses on monitoring patterns of resistance to antimalarial compounds from malaria isolates collected throughout Kenya.
- The Headquarters building in Kisumu houses the Basic Science Laboratory (BSL) complex and administrative functions. The BSL program supports the KEMRI/Walter Reed Project's broader mission by providing molecular and immunological readouts to vaccine and antimalarial drug development programs. The laboratory supports development of diagnostic platforms for infectious diseases, disease surveillance and outbreak investigations and builds capacity for young Kenyans participating in various areas of research including molecular biology and immunology.

Capacity Development in Quality Malaria Diagnostics (2004 to present)

The gold standard for diagnosis of malaria remains microscopic identification of Plasmodium parasites in stained blood films[1]. Despite the fact that microscopy remains the gold standard and reference method for diagnosis of malaria in routine patient care and in research studies evaluating therapeutics, vaccines and diagnostic technologies in development, diagnostic errors still persist. These errors commonly include false positives and negatives, species misclassification and inaccurate density estimation. In order to improve accuracy and reliability of microscopic diagnosis, and reduce symptom-based diagnosis, the WHO proposed that microscopy training be standardized and that objective competency/proficiency benchmarks and robust quality assurance (QA)/quality control (QC) systems be established. The KEMRI/WRP Malaria Diagnostic Center has been at the forefront in advancing this agenda through microscopy training workshops offered to healthcare, research and clinical laboratory personnel from throughout sub-Saharan Africa and the world. To date, a total of 1,665 professionals have been trained in a total of 76 workshops since 2004 in malaria diagnostics and malaria QA. The emphasis of this training is accurate identification of true negative slides (specificity), detection of low-density infections (sensitivity), correct classification of Plasmodium species (species identification) and accurate estimation of parasite densities (burden).

Conduct of Regulated Clinical Trials, Testing Candidate Antimalarial Therapeutics and Vaccine Candidates (1995 to date)

The KEMRI/WRP Kisumu Field Station has been rated as a mature all purpose trial site[2]. Since its inception, the site has contributed significantly to malaria control efforts through successful execution of several ICH/GCP compliant clinical trials focused on treatment and prevention of malaria [3-5]. For example in 2007, the site participated in a multi-center trial of a new dispersible tablet formulation of artemether-lumefantrine for the treatment of young children with uncomplicated malaria. This trial was carried out because of the need for alternative antimalarial formulations that offered increased ease of administration and compliance for infants and children. The six-dose regimen of the new dispersible tablet formulation was found to be as efficacious and safe as the conventional crushed tablet formulation in infants and children[3]. The site also successfully conducted a phase II, open-label, non-randomized pharmacokinetic clinical trial of intravenous artesunate. The objective of the trial was to show the pharmacokinetic (PK) profile of intravenous artesunate in Kenyans infected with uncomplicated falciparum malaria. The overall goal of the project was to provide a well-validated, efficacious, and safe product licensed by the US Food and Drug Administration (FDA) for the treatment of severe malaria which would be available for use in the USA. The trial results showed that intravenous artesunate could provide much higher peak concentrations of artesunate when compared to concentrations achieved with oral therapy[6]. Another major milestone was participation in the first clinical trial of the RTS,S/AS01 malaria vaccine which demonstrated a reduction in episodes of both clinical and severe malaria in children 5 to 17 months of age by approximately 50%[7, 8]. Prior studies conducted at the center, evaluating safety and efficacy of various candidate vaccines marks the site's commitment and key role in the long journey towards development of a malaria vaccine.

ROLE OF THE SECRETARIAT AND OTHER NETWORKS

The KEMRI/Walter Reed Project Kisumu is a member of the INDEPTH Network and therefore receives support through training of staff linked to the demographic surveillance system. The Network also provides training for scientists in data management and analysis. Through the Malaria Clinical Trials Alliance (an INDEPTH Network project aimed to strengthen clinical trial capacity of member sites), the Kombewa Reseach Center received the state of the art x-ray machine and other laboratory equipment in preparation for the phase III of the RTS,S/AS vaccine trial. One staff member was also sponsored by INDEPTH for the Masters programme in Clinical Trials.
Other collaborators: Kenya Ministry of Health.

Malaria Culture and Molecular Lab, Monitoring Resistance Patterns to Antimalarial Compounds (2002 to date)

The Malaria Drug Resistance Laboratory (MDR) uses genetic analyses, *in vitro* tests and *in vivo* efficacy studies as comprehensive surveillance tools to monitor emergence and spread of antimalarial drug resistance. The MDR provides useful data on prevalence and patterns of drug resistant parasites to advise the Kenya MOH on malaria treatment and prevention strategies. In addition, the MDR provides data to the U.S. Department of Defence (DoD) on existing and emerging parasite antimalarial resistance to inform policy and improve safety of U.S. Military Service Members working in Africa. The MDR conducts *in -vivo* and *in-vitro* studies to evaluate the efficacy of the current first- and second- line antimalarial combination therapies (artemether/lumefantrine (AL) and artemisinin derivatives) using molecular markers of artemisinin drug resistance previously described in South East Asia (SEA)[9].

Basic Science Laboratory (2004 to date)

The Basic Science Laboratory conducts molecular and immunological analyses in support of malaria vaccine, therapeutic and diagnostic studies[9]. Work completed by the Basic Science program at KEMRI/WRP has made significant contributions to the fields of malaria immunology and vaccine development by contributing to the understanding of how excessive host immune responses contribute to more severe illness due to malaria[10, 11]. The BSL team has contributed to the body of knowledge about the RTS,S malaria vaccine candidate by demonstrating that: i) individuals vaccinated with the RTS,S have reduced parasite diversity during infection and ii) the immune response induced by RTS,S provides protection against multiple circulating strains of *P. falciparum* parasites rather than targeted protection against a single strain.

Details of the Impact

The critical research on malaria led by KEMRI/WRP has had major impacts scientifically, on capacity building of African scientists and on policy with regard to treatment and management of malaria in Kenya and other contexts globally.

Supporting Quality Malaria Diagnostics (2004 to date)

Under an ethically approved Blood Collection Protocol (BCP), the MDC has been able to collect parasitized and non-parasitized malaria blood samples for preparation of quality standardized malaria blood films. These catalogued, standardized films are used for teaching and testing malaria microscopists; they also provide a platform for structured development and evaluation of emerging diagnostic technologies. Through this protocol, the MDC has also been able to establish a slide library with thousands of catalogued reference malaria blood films.

The Center offers the following malaria diagnostic training courses: two week basic malaria microscopy training, one week microscopy refresher training, three- day Rapid Diagnostic Test (RDT) training, malaria microscopy QA training, five -week mentorship programs for facilitators in new training centers, two- day proficiency testing, and a one- week tailored malaria microscopy training, depending on the request made[12].

The MDC has also supported KEMRI/WRP clinical trials evaluating therapeutics, candidate malaria vaccines and malaria diagnostic devices by providing high quality malaria microscopy allowing quality endpoint evaluation. In addition, the MDC has a library of validated blood films prepared during trails. The MDC and clinical trials teams have also worked together to test various™ diagnostic devices, including the Fio smart reader (Deki Reader), which is a mobile telephone software device application that provides step-by-step guidance in RDT processing and reading, capture of patient information, capture and storage of Malaria Rapid Test (mRDT) image and data transmission via the local mobile phone network [13].

The main impact of the activities at the MDC has been to establish competency and improve malaria diagnosis for both clinical research and patient care utilization. To date over 1300 individuals from Kenya, 350 from other SSA countries and 15 from outside of Africa have completed basic malaria microscopy training and this has improved malaria diagnostic capacity, competency and quality. Proficiency testing is conducted six months after the initial two week training to confirm that the skills are still being maintained. The MDC has also assisted in establishing training centers in Tanzania, Ghana and Nigeria and has mentored more than ten facilitators to run these newly developed centers.

Over one hundred laboratory personnel from the MoH system have been trained as malaria diagnostics QA officers and they are now offering malaria diagnostic QA to over 400 public health facilities throughout Kenya. Each QA officer conducted four monthly visits in assigned facilities using the re-modeled OTSS checklist adapted from the WHO malaria QA manual. Key elements addressed in the checklist included personnel training and competencies, availability of laboratory equipment, supplies and supply chain, availability of malaria reference materials, adherence to malaria microscopy and RDT procedures, smear preparation and quality of staining, laboratory safety practices, internal quality control practices, and participation in external quality assurance programmes.

Under the QA programme, QA officers crosschecked slides initially read by the lab technician at the facility and randomly picked 10 slides (5 negative and 5 weak positive) to be re-read by reference microscopists. All facilities showed improvements in many areas by the third and fourth visit. A total of 2060 slides were examined by both the QA officers and select reference microscopists with less than 5% discordance among readers.

Conduct of Regulated Clinical Trials, Testing Candidate Antimalarial Therapeutics and Vaccine Candidates (1995 to date)

The KEMRI/WRP's main mission has been fulfilled through studies that have resulted in the introduction into Kenya and sub-Saharan Africa of the artemether/lumefantrine (Coartem®) dispersible tablet for the treatment of malaria in children and through the availability of an intravenous artesunate manufactured under Good Manufacturing Practice (GMP) for use in the treatment of severe malaria in the United States. Following the successful completion of the artemether/lumefantrine trial and demonstration of efficacy, the drug was registered for use by regulatory authorities in several sub-Saharan countries including Kenya by the end of 2008[3].

Artemether/lumefantrine was included in the Kenya National Malaria Control Program in 2010. The main beneficiaries of this research conducted at the Kombewa Clinical Research Center and other African research sites are the general public through the Division of Malaria Control at the Ministry of Health[14]. The trials of a GMP intravenous artesunate led to its approval by the U.S. Food and Drug Administration (FDA) for investigational drug use (IND) and distribution by the US CDC for treatment of severe malaria in the United States[15]. The site has most recently participated in the successful Phase III RTS,S/AS01 malaria candidate vaccine trial which took place in 7 countries across sub-Saharan Africa.

The data on the RTS,S/AS01 vaccine candidate was submitted for evaluation to the European Medicines Agency (EMA) under article 58 and received positive decision. The WHO is now reviewing and recommendation for use are pending Should RTS,S/AS01 be licensed, it will be the first ever licensed vaccine against a parasitic disease in humans[16]. Given these developments, the research studies carried out at the KEMRI/WRP therefore have global health significance. The research lead to evidence based decision-making by policy makers in government and multilateral organizations such as the World Health Organization.

Malaria drug resistance laboratories (Monitoring Resistance Patterns to Antimalarial Compounds) 2008-to date

The research activities of the MDR laboratory focus on testing the susceptibility of malaria parasites isolated from samples collected throughout Kenya to antimalarials. The MDR has worked to validate markers of artemisinin resistance and to improve tools for tracking resistance to current and possible future antimalarial compounds[17]. Through this surveillance, molecular markers of atovaquone resistance were detected despite little exposure of the population to atovoquone/proguanil (Malarone)[18]; atovoquone has not been routinely used for treatment or prophylaxis in Kenya. Through collaboration with the Sanger Institute and thirteen other African countries in a consortium known as the Parasite Diversity Network Africa (PDNA), the MDR was able to validate the markers of artemisinin resistance in Kenya, which had been confirmed as markers of artemisinin resistance in SEA[17, 19]. The data revealed that none of the molecular markers described in SEA for artemisinin resistance had spread to African countries[17]. PDNA was recently described in *Science* and the artemisinin resistance markers were described in the *Journal of Infectious Diseases* [18]. Additionally, data suggesting that the response to artemisinin therapy is genetically determined in African malaria parasites have been submitted for publication[20]. This will be the first published report of a genetically determined response to artemisinin resistance in African malaria parasites.

The MDR also monitors the efficacy of non artemisinin antimalarials that are of public health significance such as sulfadoxine-pyrimethamine (SP). Surveillance of molecular markers associated with parasite resistance to SP were shared with the Kenyan Ministry of Health and the Division of Malaria Control; these are extremely important results as SP continues to be used in intermittent preventive treatment for malaria in pregnancy (IPTp)[21]. *In- vitro* and molecular analysis of quinine efficacy, (second line therapy for severe malaria in Kenya) suggests reduced susceptibility to quinine, indicating that malaria parasites in Kenya may be developing quinine resistance[22]. Conducting surveillance of emerging drug resistance to potential antimalarial compounds that are not fully deployed within a population is equally important in avoiding administration of a failing drug regimen such as atovaquone/proguanil (Malarone). Genotyping of molecular markers within the malaria parasite associated with atovaquone resistance revealed the presence of mutations critical for the survival of the parasite in the presence of atovaquone.

Basic Science Laboratory (2004 to date)

Studies conducted by the Basic Science Laboratory have included evaluation of how malaria parasites interfere with the wellbeing of blood cells that are essential for fighting bacterial infections. In this regard, BSL studies have shown that a blood molecule called MBL can bind to stages of malaria parasite and initiate complement activation. The programme has is also evaluating why malaria parasites infect only a small percentage of red blood cells; the hypothesis is that malaria parasites self-regulate parasite density in order to spare the host (and thereby also avoid killing themselves). In laboratory culture conditions, most malaria parasites die once parasite density reaches a certain threshold, thus supporting this hypothesis. The BSL lab has also been exploring resistance to antimalarials evolves and has found that that the change from a chloroquine-sensitive to chloroquine-resistant phenotype begins by change in population structure in the absence of genetic changes. The BSc programme also supports disease surveillance and outbreak investigation activities through an Acute Febrile Illness surveillance protocol. Data from this surveillance activity has demonstrated that malaria, Salmonella typhi and Q-fever continue to be the most commonly identified etiologies of febrile illness in Kenya. However, in more than half the people enrolled in the study pathogen causing the febrile illness was not identified.[10, 11].

Sources to Collaborate the Impact

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Disclaimer

The views expressed in this work are those of the authors and do not represent those of the Walter Reed Army Institute of Research, the U.S. Army Medical Department, the U.S. Department of the Army or Defense.

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