

KINTAMPO HEALTH RESEARCH CENTRE



2009 ANNUAL REPORT

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Mission and Vision Statements

Mission

To conduct public health research and develop health research capacity which will contribute to a reduction in ill-health and the achievement of the Millennium Development Goals (MDGs) in Africa's most disadvantaged communities.

Vision

To provide practical needs-based research of the highest quality which has a pro-poor and gender equity focus that is used to shape health policy and practice and build health research capacity of health and health related professionals so that they can effectively address Africa's health challenges.

Acknowledgment

The Kintampo Health Research Centre (KHRC) wishes to extend its profound gratitude to all the funders and collaborators for the work at KHRC over the years: of special mention are the London School of Hygiene and Tropical Medicine (LSHTM), the Department for International Development (DFID), the Malaria Vaccine Initiative (MVI), the Medicines for Malaria Ventures (MMV), the INDEPTH Network, the INDEPTH-Malaria Clinical Trials Alliance (INDEPTH-MCTA), the Bill & Melinda Gates Foundation, the National Institutes of Health (NIH), the World Health Organisation (WHO), the International Atomic Energy Agency (IAEA), the Newmont Ahafo Mining Area, the Wellcome Trust, the United Nations International Children Emergency Fund (UNICEF), and the African Malaria Network Trust (AMANET).

Others include the Ministry of Health, Ghana, the Ghana Health Service, the Municipal and District Health Management Teams (MDHMTs), the Ghana Atomic Energy Commission (GAEC), The Neonatal and Maternal Research Programme Consortium, the African Media and Malaria Research Network (AMMREN), GlaxoSmithKline (GSK), the School of Public Health, university of Ghana, the Noguchi Memorial Institute for Medical Research (NMIMR) and Contract Laboratory Services (CLS), South Africa.

We are also very thankful for the support we received from the Ghana Standards Board (GSB), the Food and Drugs Board (FDB), the Ghana Health Service Ethics Committee, our sister institutions – the Navrongo and Dodowa Health Research Centres as well as the Municipal and District Assemblies in our study areas.

Our sincere thanks also go to the chiefs and people of the communities in which we carry out our research activities.

We acknowledge the members of the editorial team, especially Dr. Kingsley Osei-Kwakye and Mr. Kabio Casimir Donlebo who were active in editing this year's annual report. We also wish to thank the staff who contributed reports on the various projects and departments.

-----Foreword-----



**Professor John Gyapong,
Director, HRU**

The Kintampo Health Research Centre (KHRC) is one of the health research institutions of the Ghana Health Service. It falls under the Research and Development Division of the Ghana Health Service. It has the mandate to conduct health research work with the aim of guiding decision-making and policy development within Ghana's health delivery system.

This report is a summary of the activities of the centre as well as the various research projects conducted in collaboration with its partners for the 2009 fiscal year. These projects seek to evaluate essential public health interventions and answer critical questions regarding micronutrient deficiencies, malaria, maternal reproductive health, neonatal/child health and mental health issues among others. This period experienced expansion in neonatal/child health activities including neonatal interventions trial.

The Kintampo Health Research Centre continues to make steady progress in her maternal and child health research activities and has positioned itself as a site of excellence in testing new and novel malaria drugs and vaccines – a status we are all proud to be associated with. It is evident with the 2008 Prince of Asturias Foundation award to the Kintampo Health Research Centre as one of the four award recipients in recognition of the Centre's contribution to malaria research, including research effort to develop a vaccine against malaria for better medical care in Ghana and sub-Saharan Africa.

I wish to congratulate the Director, Management and all the staff of the Kintampo Health Research Centre as well as their collaborating institutions for the excellent work being carried out in the central Ghana. Their good works speak volumes for themselves and are acknowledged by all.

Professor John Gyapong, Director, HRU

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Executive Summary:

From the Director

The Kintampo Health Research Centre (KHRC) continues to be strategic for its own continual existence as well as being a lot more relevant in its research activities, not only to Ghana as a country, but to the international community as a whole. The drive to build on new initiatives and the urge to sustain a centre of excellence took the best part of our focus in the year 2009 as reported in this document.

It is again gratifying to report that the year 2009 saw KHRC through the successful completion of our largest project – the ObaapaVita trial that enrolled over 200,000 women in childbearing age and followed them up over an eight year period within seven districts in the Brong Ahafo Region. This trial allowed us to assess the effects of regular doses of vitamin A on maternal mortality. Regular funding from the Department for International Development (DFID), UK, through the London School of Hygiene and Tropical Medicine (LSHTM) to us in KHRC resulted in the smooth running of the "ObaapaVita" trial. We also intervened on behalf of the newborn children of the mothers participating in the "ObaapaVita" trial by rolling out as a neonatal interventions trial (NEWHINTS).



**Dr. Seth Owusu-Agyei,
Director, KHRC.**

The centre has been progressing extremely well in other areas of research, having been established as a centre of excellence for malaria drugs and vaccines trials. Drug trials of Artemisinin Combination Therapy (ACT) anti-malarials have been carried out within this reporting period. The promising results generated from the clinically most advanced malaria vaccine, the GlaxoSmithKline (GSK) RTS,S malaria vaccine being tested under the sponsorship of the Malaria Vaccine Initiative (MVI) in collaboration with GSK has led to a pre-licensure trial of this vaccine that is currently ongoing and in collaboration with the London School of Hygiene and Tropical Medicine. The National Institute of Allergy & Infectious Diseases (NIAID) branch of the National Institutes of Health (NIH), USA has been supporting malaria research work over the next five years starting in 2006 as evident in a contract signed with the Noguchi Memorial Institute for Medical Research (NMIMR) and the Kintampo Health Research Centre (KHRC).

The role of Rapid Diagnostic Tests (RDTs) in the treatment of malaria using ACTs is being investigated. An effectiveness trial of the newly recommended ACT in Ghana is also being researched into. The results from these projects will provide useful feedback to the National Malaria Control Programme in Ghana and in other malaria endemic countries.

The Mental Health unit having completed a situational analysis in the whole country carried out a district level intervention. These include the Mental Health Multisectoral Forum which is made up of the various stakeholders in the Kintampo North Municipality; the provision of community level treatment, support and rehabilitation; the formation of four users' and carers' association; the collaboration between the traditional and faith healers in the two districts and the district level mental health information system.

The Health and Demographic Surveillance System (HDSS) within the Kintampo North Municipality and the Kintampo South district has expanded our scope of work in Population-Based Surveillance as the tracking of study participants and monitoring of the population dynamics have been enhanced further. A new HDSS has been started by KHRC in the Newmont Ahafo Mining area and this is expected to provide new research opportunities.

The mandate of KHRC to research into health problems pertaining to the middle belt to help inform policy within the Ghana Health Service/ Ministry of Health has been progressing very well. These goals can be achieved only through the unity and hard work among the rank and file of the staff. The business/strategic plan for KHRC is being followed stringently and has helped in charting our research agenda and keeping us on course. The major achievements include the creation of KHRC Advisory Board, increased collaborations, meeting targets on proposal submission and publications in peer reviewed journals among others.

I wish to thank all again, especially the traditional and political authorities, opinion leaders, and the community members within the areas that we work (Kintampo North Municipality and the Kintampo South district, Nkoranza North and South districts, Techiman, Wenchi and Tain districts), for their unflinching support, co-operation and interest in our activities.

My sincere thanks go to the staff of KHRC and the Director of the Research & Development Division of the Ghana Health Service. I wish to thank the Regional Director of the Brong-Ahafo Region, the District/Municipal Directors in KHRC's area of operations as well as the Medical Superintendents and all staff of the various health facilities for their cooperation and support over the period under review.

May I take the opportunity to thank our donors, funding agencies and collaborators, sister institutions and our sector ministry for the continued interest and support for our activities.

Dr. Seth Owusu-Agyei, Director, KHRC.

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PROJECT REPORTS

1. The Kintampo Health and Demographic Surveillance System (KHDSS) – A core resource for health research in the Kintampo Health Research Centre (KHRC)

Background

Surveillance activities were upgraded to cover the entire population of the Kintampo North Municipality and the Kintampo South District in November 2003. The surface area of both districts is 7,162 square kilometers which represents 18.1% of the total land area of the Brong Ahafo region. Its strategic location makes it the geographical centre of Ghana.

Field Operations

Updates for rounds nine (9) and ten (10) were conducted in 2009. In the round 9 and 10 updates, pregnancies, births, deaths, and migration were done. Also, activities on verbal autopsy and marriage continued. Furthermore, annual updates on education and immunisation were done during round 9 and 10 respectively. In addition, the access and costing component of the INESS study as well as the malaria and disability module which included the INESS fever question for all KHDSS households were introduced in round 10.

Meetings, Workshops and Training

From the 1st – 3rd June, 2009, Ernest Nettey attended an INDEPTH Network workshop on Mortality Clustering in Accra. The KHDSS has been part of the INDEPTH Network since June, 2004. In October 2009, Dr. Seth Owusu-Adjei, Charles Zandoh, and some senior staff of KHRC attended the 9th INDEPTH Network Annual General and Scientific meeting held in Pune, India. The INDEPTH Network awarded Mr. Abubakari Sulemana a scholarship to attend a short course in Population Studies at the Institute for Population and Social Research (IPSR), Mahidol University, Bangkok, Thailand from 9th September to 4th November, 2009.

Visitors

In March 2009, seven (7) people from different institutions in Ethiopia including Addis Ababa University, Mekelle University as well as Gondar University visited KHRC to understudy the KHDSS with the aim of gaining more experience for HDSS work in their respective institutions. Also, in June, 2009, five (5) people from various institutions in Zambia including the Ministry of Health, Central Statistical Office and Tropical Disease Research Centre (TDRC) visited KHRC for a similar purpose.

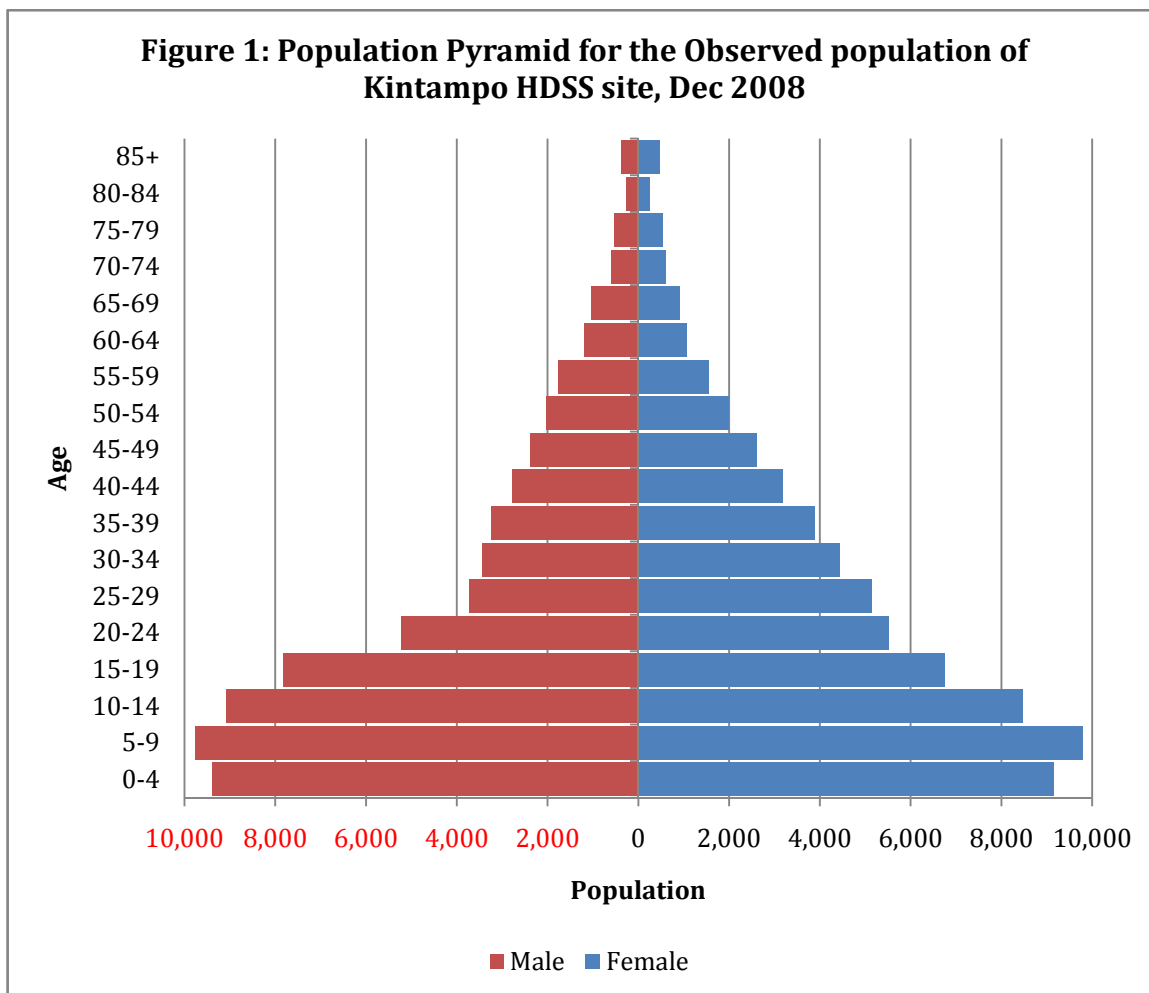
Outputs

As of 2007, the population of the Kintampo North Municipality and the Kintampo South district was 125,945, with a sex ratio of 97.0 males per 100 females. The population increased to 130,972 in 2008, although the sex ratio remained at 97.0 males per 100 females. Females constituted 50.7% (66,393) of the population with males making up to 49.3%, (64,579) which is consistent with the national average. The population pyramid for 2008 is presented in Figure 1.

Births and deaths

A total of 3,988 live births were recorded from January to December 2008. There was a slight increase in the attendance at ante-natal clinics during pregnancies from 81.8% in 2007 to 84.5% in 2008. Home delivery declined from 51.1% of all live births in 2007 to 44.9% in 2008. At the same time, births at

health facility and TBA houses increased from 34.4% in 2007 to 40.3% in 2008. There were 918 deaths registered during the period. Of these, 64.1% occurred in homes in 2008 compared to 70.5% in 2007. Institutional deaths registered increased from 26.4% in 2007 to 32.13% in 2008.



Household structure and characteristics

The number of compounds increased from 21,305 in 2007 to 21,729 in 2008. This means the KHDSS now covers 98% of the two districts. The number of households increased from 33,225 in 2007 to 37,090 in 2008. About a third of households in the KHDSS are in urban locations.

Water and Sanitation

About a third (32.9%) of households used water from streams and rivers in 2008 compared to 31.1% in 2007. Also, 23.0% had access to water from hand-pumps in 2008, compared to 23.4% in 2007 and another 25.1% from closed wells in 2008 comparable to the 25.3% recorded in 2007.

The use of WC remained available to only a small proportion (3.1%) of the population in 2008 compared to 2.7% in 2007. Over 90% of the overall usage of WC was in urban areas. The use of open fields remained at 37.1% from 2007 to 2008. Pit latrines were still the main toilet facility in the study area, with usage at close to three in five persons (59.1%) in 2008 from 59.6% in 2007. The use of

'bucket latrine' for the transfer of liquid waste from houses for disposal declined from 0.6% in 2007 to 0.01% in 2008.

Use of KHDSS data

In 2009, data from the KHDSS database was used by individuals and projects from within and outside KHRC. Notably among them were graduate students from the School of Public Health, University of Ghana as well as the Kintampo Municipal Assembly for their five-year medium term development plan.



A cross-section of KHDSS Staff

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2. MALARIA STUDIES

2.1 MAL 055

A phase III double blind (observer-blind), randomised, controlled multi-centre study to evaluate in infants and children, the efficacy of the RTS,S/AS01E candidate vaccine against malaria disease caused by *P. falciparum* infection, across diverse malaria transmission settings in Africa.

Trial management team:

KHRC: Kwaku Poku Asante, Ruth Owusu, Owusu Boahen, Kingsley Osei-Kwakye, David Dosoo, Evans Kwara, Samuel Ayamba, Philemon Amooba, George Adjei, Samuel Agra, Daniel Chandramohan, Brian Greenwood, Seth Owusu-Agyei

About the Phase III trial

The Kintampo Health Research Centre (KHRC) has been involved in the evaluation of the safety, rectogenicity and efficacy of the RTS, S malaria vaccine since 2005. Data from the studies have shown positive results. This has paved the way for the third phase of the vaccine study.

The RTS,S Phase III trial seeks to demonstrate the vaccine's efficacy in two groups of children – one aged 6-12 weeks and a second aged 5-17 months in different transmission settings across a wide geographic region. In all, the study is being conducted in 11 sites in seven African countries. The trial has been designed in consultation with appropriate regulatory authorities in Africa, including the Ghana Health Service, the Ghana Food and Drugs Board, and other northern institutions such as the European Union, the United States of America, and the World Health Organisation.

In Kintampo, a total of 1,000 children aged 5-17 months are expected to be recruited from the study area over a 6 month period. This will be followed by recruiting 200 infants aged 6-12 weeks.

Rationale

The trial has been designed to address the key safety and efficacy information required for licensure of the vaccine. Other disease endpoints that allow the evaluation of the public health impact and cost and cost effectiveness of vaccine implementation have been included in the study design.

Partners in this trial.

The Ghana Health Service (GHS) is a partner that ensures the implementation and successful completion of the trial. GlaxoSmithKline (GSK) Biologicals, Belgium provides the vaccines used in this trial. They also provide monitoring support during the conduct of the study. The Malaria Vaccine Initiative (MVI) of the Program for Appropriate Technology in Health (PATH), USA is paying for the conduct of this study. The Malaria Clinical Trial Alliance – INDEPTH Network has supported the trial with infrastructure and training of study staff.

Approvals

As per International Conference of Harmonisation (ICH) Regulations, the plans and conduct of the trial were reviewed and authorised by the following Institutional Review Boards prior to the beginning of the trial:

- Ghana Health Service Ethical Review Committee

- Food and Drug Board of Ghana
- Kintampo Health Research Centre Institutional Ethics Committee
- Kintampo Health Research Centre Scientific Review Committee
- Western Institutional Review Board in the USA
- Ethics Committee of the London School of Hygiene and Tropical Medicine

Staff recruitment and training

Recruitment of study staff started in March 2009 with key personnel with specialised skills such as laboratory personnel, fieldworkers and supervisors. All staff had Good Clinical Training (GCP) training from 22nd - 23rd June, 2009 and were also trained on the study protocol on 25th June, 2009. Local media men were invited to the Centre and briefed on the trial.

Community sensitisation

Community durbars and meetings with all stakeholders such as the district health administrations in the study area were held before the trial was initiated. All stakeholders assured the study team of their support and cooperation in the trial. The study was subsequently launched on 1st September, 2009 with both local and national media coverage.

Resources

The Malaria Clinical Trial Alliance (MCTA) sponsored the construction of three (3) clinical trial facilities at the local health centres in three (3) of the communities in the study area. The clinical trial facilities are used when clinics are held for study participants in the community. The facilities are also used by the local health centres for their antenatal and routine child welfare activities.

Laboratory facilities

Microbiology equipment (Bactec, incubator etc) have also been provided at the Centre's laboratory. This is supplementing the microbiology services at the Kintampo Municipal Hospital. The laboratory has the potential to be a reference laboratory for the middle belt of Ghana if adequately resourced.

Trial initiation

The trial was initiated by Quintiles South Africa from 19th to 21st August, 2009 and it involved all study staff and investigators.

Screening for enrolment

Screening for enrolment of the study participants started on 26th August, 2009.

Ensuring safety of trial participants

The study subjects are being monitored closely to detect any possible adverse effects from the vaccine. The investigators are ensuring safety in the trial through close observation of the study participants.



Picture of chiefs and invited guests at the launch of the Mal 055 trial on 1st September, 2009.

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2.2 Malaria Vaccines: Clinical Research and Trial Sites in Endemic Areas

The objective of this collaboration between the Kintampo Health Research Centre (KHRC) and the Noguchi Memorial Institute for Medical Research (NMIMR) is to implement clinical and field based research on malaria with the aim of evaluating new malaria vaccines and interventions in the middle belt of Ghana. Three field based epidemiological studies are currently being conducted. These include:

1. Determination of Baseline Malaria Epidemiology among a Birth Cohort of children in the Middle Belt of Ghana for Malaria Interventions (Malaria Birth Cohort Study)
2. Assessment of severe malaria in children in the Kintampo districts of Ghana (Severe Malaria Study)
3. Establishment of Laboratory Reference Values for the Population of the Kintampo North Municipality and the Kintampo South District in the Middle Belt of Ghana

All the study protocols were submitted to the GHS Ethical Review Committee, the KHRC Institutional Ethics Committee and Noguchi Memorial Institute for Medical Research Human Subjects Protection Board. Approvals had been received prior to the start of the studies.

Community meetings were held to brief various stakeholders about the study in September 2008. Participants at the meetings included community chiefs, queen mothers, opinion leaders, religious leaders, traditional Birth Attendants, health personnel and community members. Concerns and questions raised at these community meetings were addressed by the study team.

2.2.1 Determination of Baseline Malaria Epidemiology among a Birth Cohort of children in the Middle Belt of Ghana for Malaria Interventions (Malaria Birth Cohort Study).

Investigators:

KHRC: Kwaku Poku Asante, Justice Ajaari, Stephen Apanga, Samuel Newton, Owusu Boahen, Sulemana Abubakari, David Dosoo, Seth Owusu-Agyei.

Introduction

The objectives of this cohort study are to determine the incidence of clinical malaria in the first two years of life, attributable fraction of fevers due to malaria in the birth cohort, the effects of maternal malaria on the risk of malaria during infancy and immunological correlates of clinical immunity to malaria in children aged 0-2 years. Others are hemoglobin levels and pattern of change in the hemoglobin levels among the cohort of young children, host genetic factors associated with resistance or susceptibility to severe malaria and immunological correlates of clinical immunity to malaria in children aged 0-2 years. A total of 810 pregnant women will be recruited.

Current Status of the Study

As of 1st December, 2009, a total of 1,617 pregnant women had been enrolled out of the expected sample size of 2,000. A total of 1,054 live infants have been born into the cohort. There are 577 males and 477 females. Less than 5% of the participants have so far refused to continue participation. A total of 859 placental tissues have been collected and are being processed.

Preliminary analysis

Placental malaria infection is high (about 57%). The mean maternal age is similar among participants with placental malaria compared with those without placental malaria (Table 1).

N (%)	Positive	Negative	P – value
	57 (57)	43 (43)	
Mean maternal age	26.2 (95% CI 24.7 - 28.1)	28.5 (95% CI 26.7-30.3)	-
No education (%)	43.9	48.8	0.62
ITN use (%)	49.1	41.9	0.47
Low birth weight (%)	8.0	4.9	0.55

Table 1: Characteristics of mothers with placental malaria (N= 100)

Majority of respondents delivered in public health facilities (Figure 2) which is encouraging.

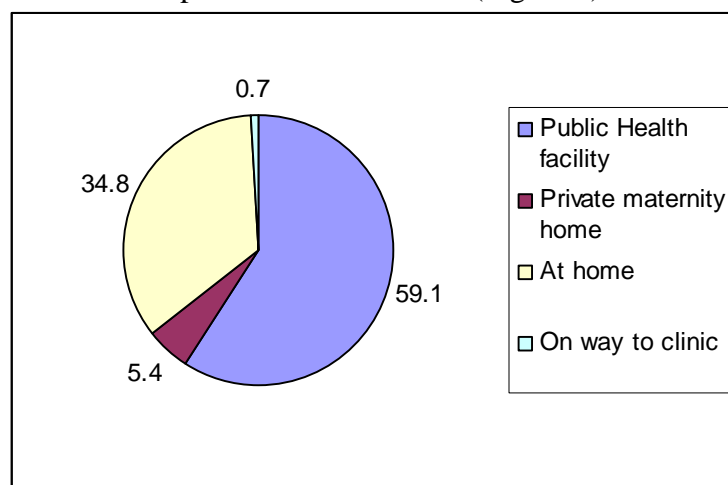


Figure 2: Place of birth

The presence of malaria parasitemia was found in 1.3% of infants by 2 months of age and peaks at 5 months to 15.6 % (Figure 3). Decrease in parasitemia may be because of treatment with antimalarial if the children had clinical malaria detected during the passive follow ups.

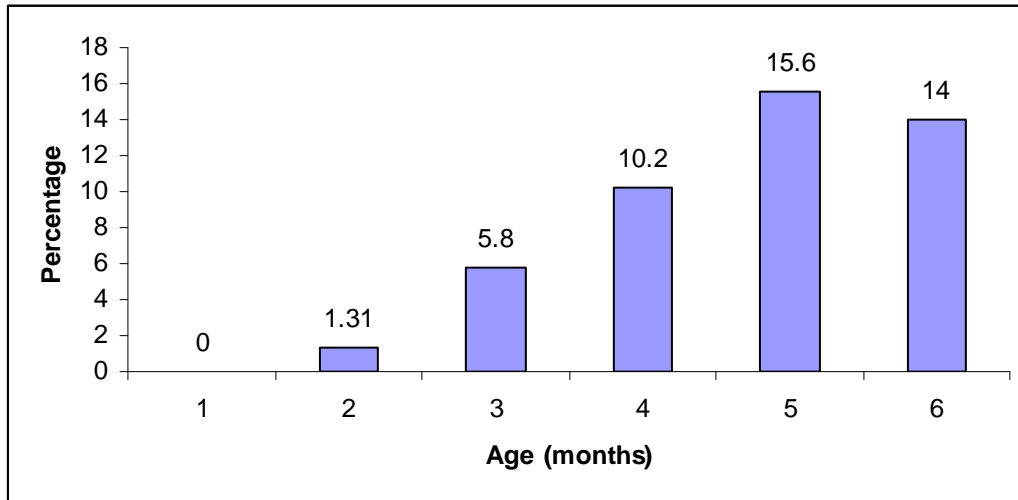


Figure 3: Proportion of children with malaria parasitemia by age (N=640)

The proportion of ITN use is constant throughout the year (Figure 4).

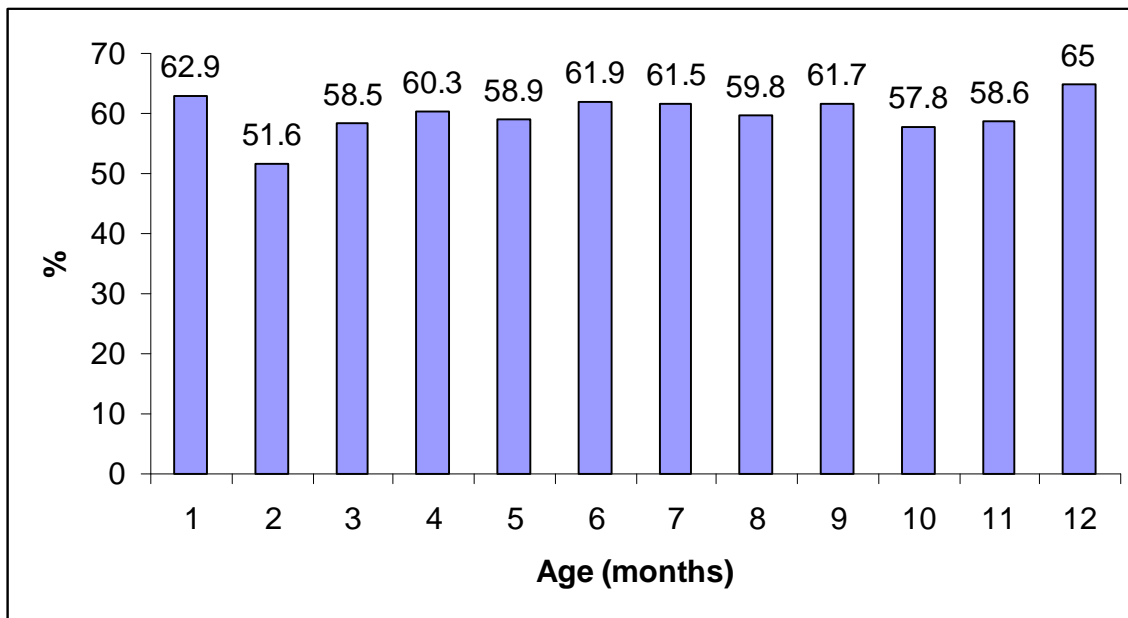


Figure 4: ITN Usage among infants by age (N= 896)

The proportion of infants with anemia at one month of age is high (36.2%) and this worsens as the cohort ages (figure 5).

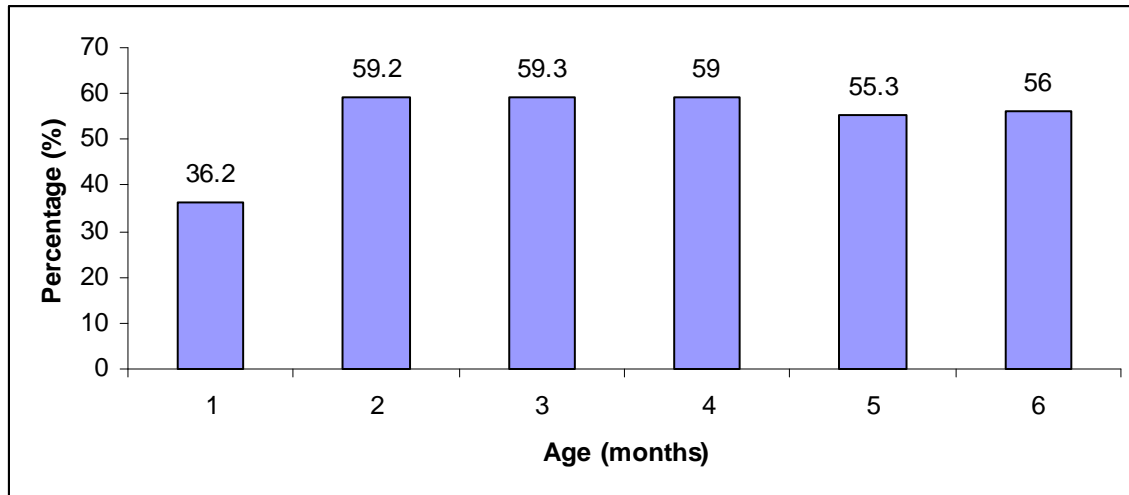


Figure 5: Proportion of infants with anemia by age (N= 755)

2.2.2 Passive case detection of malaria among children under five in health facilities in the Kintampo North Municipality: any implications for current practices?

Investigators: Kingsley Osei-Kwakye, Seth Owusu-Agyei, Stephen Apanga, Ruth Owusu, Evans Kwara, David Dosoo, Stephen Amenga-Etego, Kwaku Poku Asante.

Collaborator: Damien Punguyire, Medical Superintendent, Kintampo Municipal Hospital.

In spite of various efforts being implemented to control malaria which is said to be the leading cause of morbidity and mortality in children under five in Ghana, it continues to exert a significant toll on the socio-economic development of developing countries especially in those of sub-Saharan Africa.

Results from some studies have shown that the disease is also over-diagnosed in many health facilities in sub-Saharan Africa. It is therefore possible that a lot of the treatment that is prescribed for malaria to children who report with fever to health facilities in Ghana may not be needed. Since the usual method of confirming the disease is by laboratory methods i.e. microscopy and in recent times the Rapid Diagnostic Test (RDT), accurate diagnosis of the disease could significantly be enhanced by using these methods as the sole means of diagnosis.

The main objective of the Passive Case Detection (PCD) of malaria study is to determine if there is any benefit in basing the management of suspected cases of malaria only on laboratory confirmation of the infection as compared to presumptive treatment in children under five years reporting to the Kintampo Municipal Hospital (KMH). Another objective of the study is to determine the sensitivity and the specificity of the “PARASCREEN” malaria Rapid Diagnostic Test (RDT) kit that is being used in the study.

The study began on 9th October, 2008 at the Out-Patient’s Department (OPD) of the Kintampo Municipal Hospital. Recruitment into the study has ended and currently the remaining data is being

entered for analysis. One thousand one hundred and forty three (1,143) children were enrolled into the study.

2. 2.3 Severe malaria in children in the Kintampo districts of Ghana.

Investigators:

Kintampo Health Research Centre:

Ruth Owusu, Kingsley Osei-Kwakye, Evans Kwara, Livesy Abokyi, Owusu Boahen, Abubakari Sulemana, Kingsley Kayan, Samuel Danso, George Adjei, Seth Owusu-Agyei

Noguchi Memorial Institute for Medical Research:

Kwadwo A Koram, Josephine C Ocran, Susan Adu-Amankwah, Ben Gyan, Daniel Dodoo, Francis Nkrumah, Kwesi Addo, Michael Wilson

Collaborator:

Kintampo Municipal Hospital: Damien Punguyire

Severe malaria is a major cause of morbidity and mortality in children less than five years in sub-Saharan Africa. Several studies which have been done elsewhere to characterise severe malaria have shown that the pattern of severe malaria disease differs in different places hence the need to have relevant local data on severe malaria in the study area of KHRC.

Not all children under five develop severe malaria and this is because there are various factors which may make some children more susceptible or resistant to developing severe malaria. These risk factors may include socio-demographic factors, nutritional host genetic and immunological and parasite genetic factors. The study hopes to identify risk factors for severe malaria in children living in the study area and to help improve clinical management of acutely ill children in health facilities in the study area.

Since one of the aims of KHRC is to be a site for future malaria vaccine trials, it is important to characterise severe malaria in the study area and this study will be of benefit to vaccine trials which intend to use severe malaria as an endpoint.

Objective:

To describe severe malaria and common bacterial co-infections and identify possible host and parasite factors which predispose children to severe malaria disease and identify prognostic factors for fatality in children.

Study design:

The study is a descriptive study of severe malaria and other severe infections in children and a case-control study to determine risk factors for the development of severe malaria with cases being children who satisfy the protocol primary definition of severe malaria disease.

All children aged 0 to 59 months admitted with an acute medical illness who satisfy inclusion/exclusion criteria are enrolled and evaluated as potential severe malaria disease patients. Their clinical and laboratory presentation and course of illness are documented until day 14.

Two sets of controls (age, sex and location-matched controls) are selected for each case:
 OPD controls: Two children with uncomplicated malaria recruited from the Out-patient department of the hospital and from the communities.

Community controls:

Two healthy asymptomatic children recruited from the community.
 In all, 320 severe malaria cases are required with 640 each of OPD and Community controls.

Current status:

The study began in October, 2008 and so far 393 admitted children have been enrolled. Out of these, 104 met the primary case definition of severe malaria. The number of OPD and Community controls for the enrolled cases so far are 136 and 141 respectively.

Timelines:

Enrolment for the study is expected to take two years. Total duration for the study is expected to be three years.

374 admitted children (50% males and 50% females) have been recruited as at 1st December 2009. 98 of these (50% females and 50% males) satisfy the strict primary case definition for severe malaria. 139 children (45% (63) females and 55% (76) males) have also been recruited as healthy controls for study participants meeting the primary definition of severe malaria. 115 children (47% (54) females and 53% (61) males) have also been recruited as controls with uncomplicated malaria.

Preliminary analysis for first 170 participants

Mean age is similar among the disease categories. Majority of care-givers are uneducated (Table 2).

n	Severe Malaria	Malaria and non malaria disease	Other non malaria disease
	56	39	75
Mean age (months)	19.4 (16.7 – 22.1)	19.5 (15.4 -23.5)	17.2 (14.7 – 19.8)
Sex n(%)			
Male	30 (53.6)	22 (56.4)	36 (48.0)
Female	26 (46.4)	17 (43.6)	39 (52.0)
Care-giver Education			
No education	39 (69.6)	28 (71.8)	49 (65.3)
Some education	17 (30.4)	11 (28.2)	26 (34.7)

Table 2: Characteristics of children (N= 170)

Moderate anemia (hb 6-10.9 g/dL) is commoner among participants admitted for severe malaria compared to those admitted for other diseases (Figure 6).

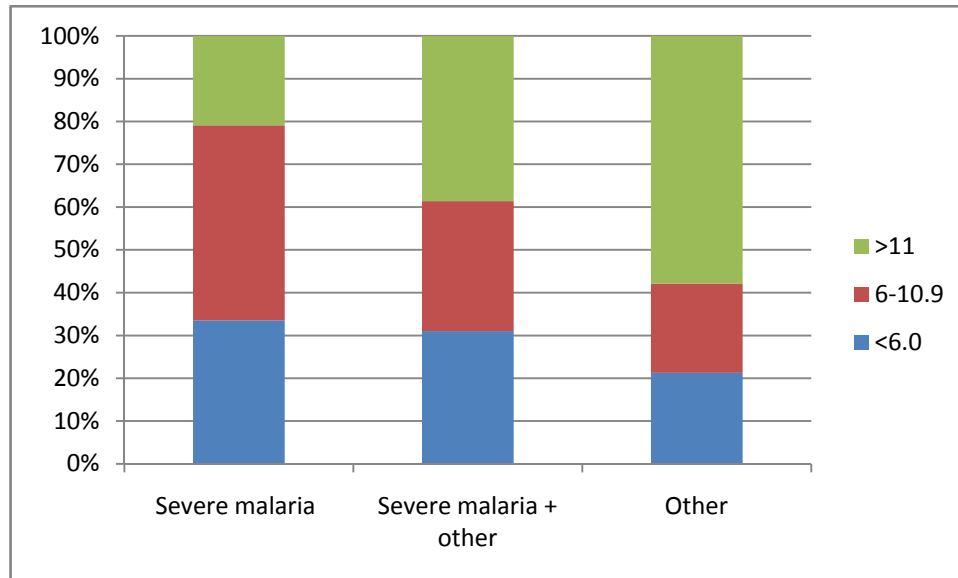


Figure 6: Graph of hemoglobin levels (g/dL) against category of diagnosis (severe malaria [56], malaria + other disease [39], other diseases [75]).

Geometric Mean Parasite Densities of Severe malaria alone and severe malaria and other diseases
 The geometric mean parasite density is higher among participants with severe malaria alone compared to those with co-morbidity (Figure 7)

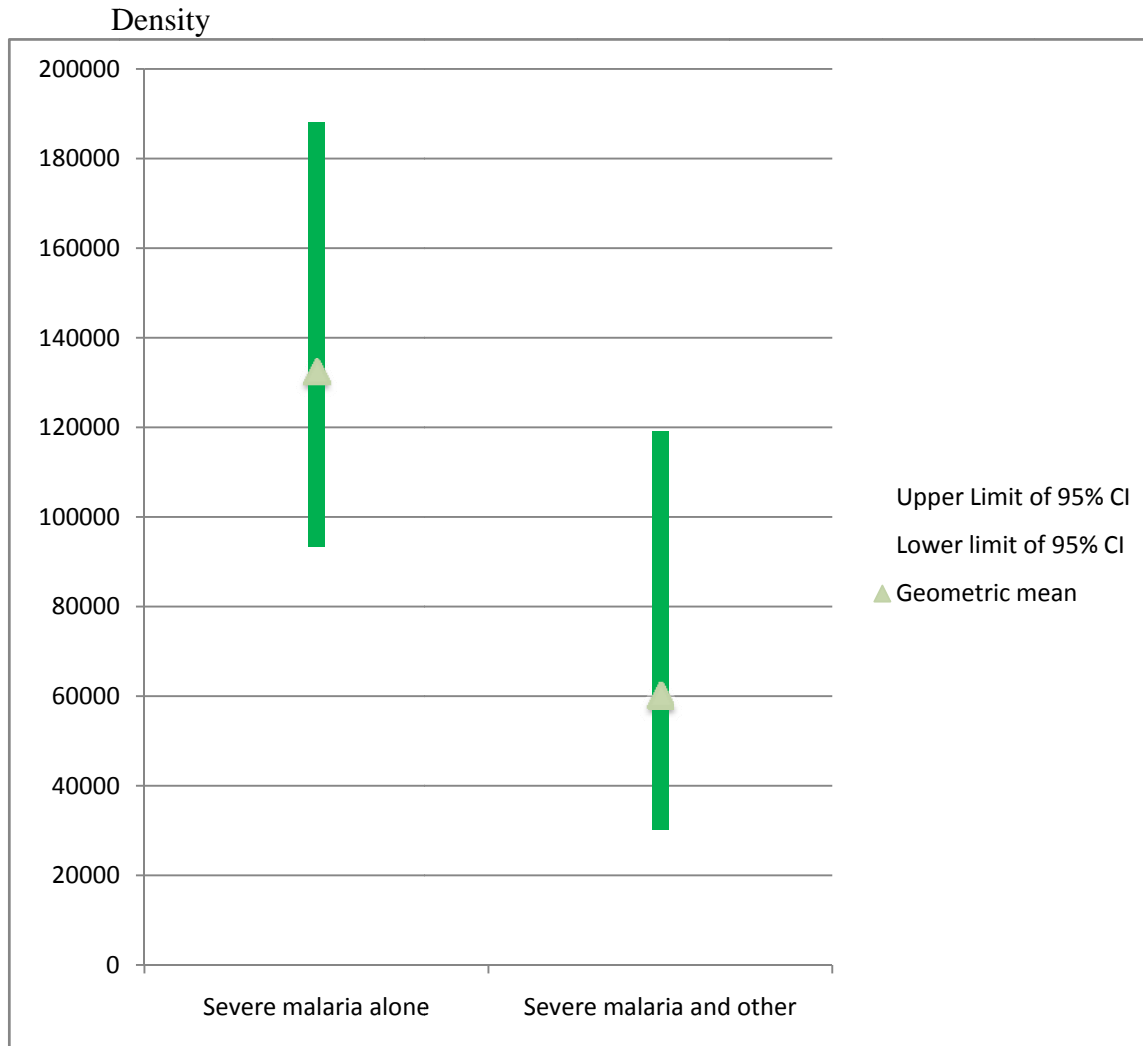


Figure 7: Geometric Mean Parasite

Sponsor

The study is sponsored by the National Institute of Allergy and Infectious Diseases, a branch of the National Institutes of Health (NIH) of the United States of America.

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2.2.4 Establishment of Laboratory Reference Values for the Population of the Kintampo North Municipality and the Kintampo South District in the Middle Belt of Ghana

Investigators:

Kintampo Health Research Centre:

David Kwame Dosoo, Kingsley Osei-Kwakye, Charles Zandoh, Kofi Tchum, Seeba Amenga-Eteego, Seth Owusu-Agyei

Noguchi Memorial Institute for Medical Research

Laboratory results, used in combination with clinical examination, provide useful information in screening, diagnosing and monitoring of diseases. Interpretation of laboratory results depends on reference values obtained from apparently healthy individuals from the population they are intended to serve. Reference values are affected by factors such as gender, age and race.

This study is aimed at establishing age and gender-specific biochemical and haematological reference values for the Kintampo North Municipality and the Kintampo South District. The reference values obtained in this study will be used for determining eligibility and assessing the safety of subjects participating in drug and vaccine studies. The study has a sample size of at least 2,340 subjects stratified into different age and gender groups. The study commenced on 29th September, 2008 and enrolled 2,440 out of 2,720 screened by the end of December 2009, as shown below in table 3.

Age	Gender	No. Enrolled
<6 months	M	75
<6 months	F	77
6-23 months	M	161
6-23 months	F	152
2-4 years	M	132
2-4 years	F	167
5-9 years	M	164
5-9 years	F	134
10-14 years	M	181
10-14 years	F	140
15-19 years	M	132
15-19 years	F	130
20-39 years	M	139
20-39 years	F	130
40-59 years	M	137
40-59 years	F	133
>59 years	M	127
>59 years	F	129

Table 3: Distribution of participants recruited by age and sex

Fieldwork for this study ended in December 2009.

A poster titled “The importance of characterising communities in terms of their haematological and biochemical parameters – the case of Kintampo in Central Ghana” was presented at the 58th Annual Meeting of the American Society for Tropical Medicine and Hygiene held from 18th to 22nd November, 2009 in Washington DC, USA.

Fieldwork for this study was completed in December 2009. Adenovirus sero-prevalence determination, G6PD and haemoglobin genotyping are planned to be done in 2010 using stored specimen.

Main challenges:

The main challenges anticipated to be faced are the laboratory analysis of large numbers of samples collected as shown below:

Birth Cohort study

A total of about 2,000 maternal blood and 5,000 infant blood samples have been collected so far in this study which will be analysed for immunological parameters while 1000 filter papers have also been collected for analysis of parasite and host genetic factors.

Severe Malaria study

Six hundred and fifty (650) serum samples have been collected for immunological analysis and an equal number has also been collected for analysis of parasite and host genetic factors.

All these specimens collected will be analysed in 2010 and study participant follow up will continue.

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2.3 Shifting from presumptive to confirmation-based management of malaria in Ghana

Kintampo ACT Study is moving into phase II

The ACT study is an operational research project designed to provide evidence to support the move by the Ghana National Malaria Control Program (GNMP) to rationalise the diagnosis of malaria, optimise the use of artemisinin-based combination therapy (ACT) and through these, facilitate appropriate management of non-malaria febrile illnesses. The study was initiated in the first quarter of 2009 to evaluate the Rapid Diagnostic Test (RDT) supplied by the GNMP in its pilot program, and to assess the implementability of test-based management of malaria using the integrated management of childhood illnesses as proxy indicator.

Enrolments in 2009

During the year under review, a total of 396 children were enrolled in the RDT evaluation and treatment outcome arm of the study. A preliminary evaluation report has been submitted to the Ghana Health Service Ethics Review Committee. Enrolment into this arm (component A) of the project is continuing at the Kintampo Municipal Hospital with the aim of getting 50 RDT negative study subjects enrolled within the first quarter of 2010. This will bring an end to this arm of the project and enable analysis to assess treatment outcome i.e. safety in restricting ACT to only RDT-positive children.

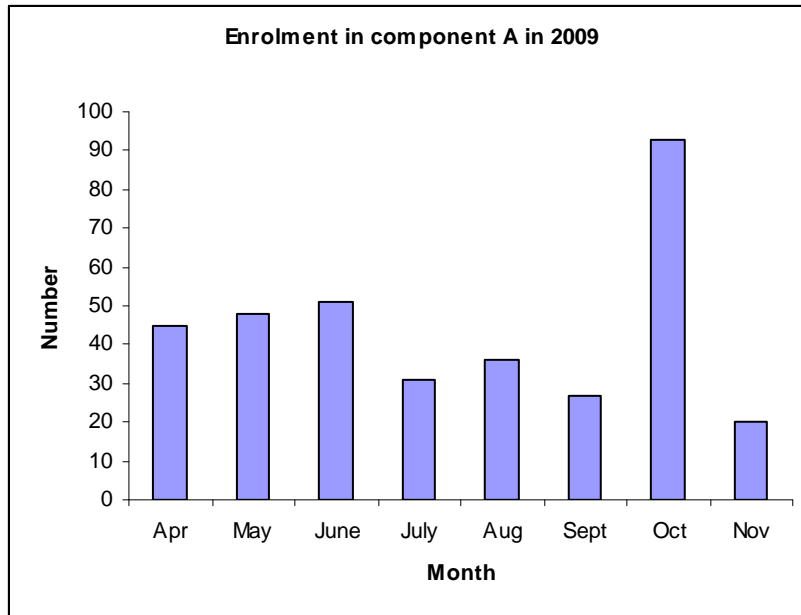


Figure 8: Enrolment in component A in 2009

The other aspect of this component of the study, which was implemented in various health centres and hospitals in five (5) districts of the Brong Ahafo Region aimed at evaluating current practices in the case management of febrile illnesses and to investigate related issues.

As at the end of 2009, the management of 1,898 cases of childhood febrile episodes had been systematically observed, with exit interviews and 10-14 day follow-ups conducted on 596 cases to determine treatment outcome. Inventory was also taken of available essential medicines and professional personnel. Preliminary findings of this “implementability” arm was presented at the December, 2009 review meeting of the malaria program in Accra and at the MIM conference in Nairobi, Kenya in November, 2009. The findings point to considerable over-diagnosis of malaria. It also suggested that beyond establishing the accuracy and safety of test-based malaria management, much will be required by way of targeted education to convince practitioners to shift from presumptive management. In-depth interviews are currently being conducted with clinicians and other health workers in the various facilities to gather qualitative data that would elucidate findings from the quantitative arm and further outline potential challenges as the program shifts from presumptive to test-management of malaria.



A study staff using a malaria rapid test kit on a study child.

Stage 2 of the Project

Concurrent with the above are preparations towards initiation of the major phase of the project in the second quarter of 2010. This stage will assess the long-term effect of test-based management. It will be conducted in 32 health centres in six districts of the region. It will be a cluster randomised control trials that will see half of the selected facilities fully resourced to implement test-based management, while the other half of facilities continue with the routine management. The hypothesis underpinning this stage of the project derives from the concern that a level of “herd” immunity will be removed with the restricted use of ACT, and that restricting ACT to RDT positive cases would lead to more frequent repeat febrile episodes and as a consequence anaemia in children. This effect could offset whatever short-term gains may be derived from the anticipated reduction in the wasteful use of ACTs. Whether this hypothesis is true will be determined in the next stage of the project.

The ACT project is funded by the ACT-Consortium and is being conducted in collaboration with the London School of Hygiene and Tropical Medicine.

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2.4 Indepth Phase IV Safety and Effectiveness Studies (INESS)

The main purpose of the study is to attempt to minimize the time gap between licensure and adoption of new anti-malarials by providing objective endemic country safety and effectiveness data that will help inform global and national policy and practice. This project will also enhance the capacity of Africa to monitor drug safety and local health systems in order to track costs, understand effective coverage, and demonstrate the effects of new or alternative post-registration antimalarial treatments.

General objective

To provide national, regional and international health decision makers with independent and objective evidence on the safety and effectiveness of new antimalarial drugs as a basis for malaria treatment policy in Africa.

Specific objectives

- i. To assess the effectiveness of new malaria treatments and its determinants in real life health systems.
- ii. To evaluate the safety of new malaria treatments through comprehensive pharmacovigilance in an African health systems context.

This project is carried out in 8 Health and Demographic Surveillance Systems (HDSS) sites in four (4) sub-Saharan African countries including Ghana, Tanzania, Burkina Faso and Mozambique over a 4-year period under the auspices of the INDEPTH network. In Ghana, the study is being conducted by the Dodowa, Kintampo and Navrongo Health Research Centres which are also HDSS sites in which the INESS study is carried out and their respective districts.

Ethical Approvals

The protocol has received approval from the Ghana Health Service Ethics Review Committee at the national level. It has also received approval from the Kintampo Health Research Centre Ethics Review Committee at the local level.

Sensitisation

A stakeholders' meeting was held on 15th July, 2009 at the site level. Participants included both public and private health practitioners within the Kintampo North Municipality and the Kintampo South District. Health professionals were also invited from the Regional Health Directorate. The district assemblies within the study area were also represented.

Community level sensitisation covering over one hundred and fifty (150) communities in the Kintampo North Municipality and the Kintampo South District started on 3rd August, 2009. Apart from community meetings, radio discussions were also held at the local FM station called Adars FM to create awareness of the study.

Training Workshops and Meetings

In January, 2009, an international stakeholders meeting was held to finalise the INESS protocol in Dar-es-Salaam, Tanzania. KHRC was represented by the Director, Dr. Seth Owusu-Agyei, Madam Livesy Abokyi and Mr. Samuel Danso.

At the national level in Ghana, another stakeholders' meeting was organised on the 18th and 19th June, 2009. At this meeting, the district chief executives and district directors of health in the study districts were present and they pledged their support for the INESS study. The National Malaria Control Programme manager and the Ghana Health Service Director in charge of Public Health were all present to lend their support.

Trainer of Trainees (TOT) meetings

Three TOT workshops that brought together representatives from the Kintampo, Navrongo and Dodowa Health Research Centres were held in Accra for different components of the study.

The first TOT took place from 20th to 24th July, 2009 and was on two modules:

1. Household access and costing
2. Patient Adherence

The second TOT that was held from 14th to 18th September, 2009 was on the following modules:

1. Targeting Accuracy
2. Provider Compliance
3. Cost and Cost Effectiveness
4. Community Acceptability (Qualitative) Module
5. Safety

The third meeting which was on the data linkage component of the INESS study was held from the 5th to 12th November, 2009.

Key staff working on the various modules attended these workshops.

Data collection has begun actively for three modules:

- Access together with some aspects of cost and cost effectiveness,
- Community and provider acceptability, and
- Safety.

1. Access module

Training of field staff has been done and data collection has commenced successfully. Data collection for all the Access module started in the last quarter of 2009.

The total number of household fever forms stood at 14,123 for this reporting period. All resident households in the KHDSS area are expected to be interviewed.

Eighty-nine (89) access and costing survey forms were completed out of an expected annual sample of 21,129 individuals in about 4,063 households.

For the population parasite prevalence survey component of the access module, a total of 162 blood samples have been collected for RDT and blood slides from 42 households. The annual sample size is 300 households.

2. Safety module

One of the objectives of the safety module is to strengthen the Spontaneous Adverse Event Reporting System (SAERS). A situational analysis on the SAERS has been carried out. Two district safety team meetings which brought together the District Directors of Health Services, hospital superintendents, pharmacists, a private representative, the chairman of the Kintampo Chemical Sellers' Association were held on the 7th October and 10th December, 2009.

Two safety training workshops on Adverse Drug Reaction (ADR) reporting have so far been organised for all the stakeholders within the Kintampo North Municipality and the Kintampo South District. This

was facilitated by an official from the Food and Drugs Board (FDB), Kumasi with the direct involvement of the District Health Management Teams (DHMTs).

Sensitisation and provision of forms to facilities for the take off of SAERS is planned for January 2010. The cohort event monitoring component of the safety study is planned to roll out when Coarsucam, a fixed dose artesunate-amodiaquine is introduced into the public health system.

3. Targeting accuracy and provider compliance modules (health facility surveys)

Familiarisation visits had been paid to all the health facilities in the sampling frame. Permission/notification letters had been sent to the health directorates in the module study area and approval had been given for the survey to be carried out.

Training of staff on study procedures and blood sample collection has been completed. Pre-testing of tools and study procedures by survey team has also been carried out. The actual data collection for the health facility survey is planned to begin on 8th January, 2010.

4. Community and provider acceptability

Four communities were selected based on the criteria in the Standard Operating Procedures (SOPs) for the qualitative work. The selected communities are Amoma (less than 5 kilometres from the Amoma health centre which is the reference facility), Ajina (greater than 5 kilometres from the Amoma health centre), New Longoro (less than 5 kilometres from the New Longoro health centre which is the reference facility) and Dwere (greater than 5 kilometres from the New Longoro health centre). The health facilities in the communities mentioned will serve as reference facilities for the study (the New Longoro health facility will also serve as the reference facility for the Dwere community).

Preparatory meetings have been held with the assembly members, unit committee members and other stakeholders from these communities to explain details of the INESS study, the objectives of the qualitative component and what their roles are and would be in the data collection process.

Training on the data collection tools has been organised for members of the qualitative team. Data collection started with the construction of seasonal calendars. Four seasonal calendars have been constructed for the dry season (low malaria transmission period. This was followed by Focus Group Discussions (FGDs) and six (6) have been conducted so far. In-depth Interviews (IDIs) and Illness Narrative Interviews (INIs) have also been conducted. Data collection for the low transmission period is expected to end in February, 2010.

6. Data linkage

At the meeting held in November, 2009 in Accra to train data linkage officers from the three sites in Ghana on the use of the software for the biometric data collection and health facility patient identification, some problems were identified with the software. These included:

1. The software was unable to recognise the fingerprint device.
2. The software could not be used to print the ID cards.

Efforts have been put in place to resolve these problems.

Training at the site level was organised for the core technical team in December, 2009. The aim of the meeting was to introduce to the team the software that had been developed, functionalities available and how technical problems could be resolved. The training on the data linkage was in two parts:

1. The biometric data collection aspect
2. The health facility patient identification aspects.

As part of the preparation to start the registration exercise early next year, the technical team is carrying out the following:

- Testing of software and accessories to assess the performance of the entire application in real life setting by producing ID cards for staff.
- Developing a spread sheet of communities and the number of days needed to conduct registration exercise. This will help in efficient planning of teams' schedules and logistics for the biometric data collection.
- Developing Standard Operating Procedures (SOPs) to standardise the operations of biometric data collection and processing of the entire data linkage activities.
-

Arrangements are being made to procure external webcams as this happens to be the main equipment left for the registration exercise to commence.

8. Patient adherence and other measures of effect and contextual determinants of malaria

Training and data collection on adherence is planned to start in January, 2010. A template is yet to be developed for the collection of data on other measures of effect and contextual determinants of malaria.

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3. MICRONUTRIENT INTERVENTIONS

3.1 Impact of Iron Fortification on Malaria Incidence in Ghanaian Children (Sprinkles Study)

Investigators (Ghana): Sam Newton, Irene Azindow, Hillary Abii Asiah, Seth Owusu-Agyei (PI),

Collaborators: (Canada) Hospital for Sick Children, University of Toronto, Ashley Aimone Stanley Zlotkin (PI).

Background:

Iron is a very important nutrient for growing infants because it helps to make red blood cells. When children do not get enough iron from their diet, they develop iron deficiency anaemia which has negative effects on physical and mental development, learning and school development achievement. Sprinkles, a micro encapsulated ferrous fumarate supplied in a powder form, has been shown to treat and prevent iron deficiency anaemia in Ghanaian infants and children. Sometimes, anaemia is also caused by parasitic infections such as malaria, a disease which contributes to many childhood deaths in Africa. It is therefore important to conduct a research to determine if Sprinkles is effective and a safer alternative to syrups and drops for providing iron to infants and children living in regions where the burden of malaria is high. The

study will determine whether Sprinkles will increase a child's risk of getting malaria or making the infection worse.

Primary Specific Objective:

The primary objective of this study is to determine the impact of providing encapsulated iron (as a powder added to complementary foods) on the incidence of malaria among infants and young children (6-35 months of age) living in an area where the prevalence of malaria is high.

Secondary Specific Objectives:

The secondary objective is to determine the impact of “point-of-use” iron fortification on the severity of clinical malaria by documenting parasite counts and hospital admission rates as well as differences in secondary complications of malaria infections, such as deaths, cerebral malaria, pneumonia, dehydration and diarrhoea.

Long term goal

The long term goal is to develop new evidence that will help in the development of policies and programs to prevent and treat iron deficiency disorders in malaria endemic regions

The study is a community based blinded randomised controlled trial in 1940 eligible children (6-35 months) spread over 80 communities in the Wenchi and Tain districts of the Brong Ahafo region of Ghana.

Preparatory activities for the study have started and recruitment is expected to begin in March 2010. The study will be carried out over six months.

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3.2 Obaapa Vitamin A trial: Ghana Vitamin A Supplementation and Maternal Mortality Trial

Project Title:

Randomised, Double-Blind, Placebo-Controlled Trial to Evaluate the Impact of Vitamin A Supplementation on Maternal Mortality in Ghana

Rationale:

Vitamin A deficiency is a nutritional problem in children in many developing countries, and it is known that vitamin A supplementation (VAS) reduces mortality in children. However, there is little empirical evidence of the effects of VAS in women. One randomised controlled trial in Nepal (the NNIPS-II trial) found that maternal mortality was around 40% lower for women in the VAS group compared to the placebo group. If this finding represents a real effect then vitamin A interventions should become an important component of maternal health initiatives. ObaapaVitA aimed to replicate this potentially important finding. The results from the trial will be important not only in identifying the potential role of vitamin A in Safe Motherhood Initiatives, but also in providing an explanation for the mechanisms through which an impact on mortality may be mediated.

Methodology:

The ObaapaVitA trial was a cluster-randomised double-blind placebo-controlled trial to evaluate the impact of low-dose weekly VAS to adult females on pregnancy-related and all-cause mortality in rural Ghana. Women aged 15 to 45 years were randomised to receive 25,000 IU (7,500µg) of vitamin A or placebo each week, and were followed up for a range of mortality and morbidity endpoints.

The trial had been conducted in seven contiguous districts in the Brong Ahafo region in the centre of Ghana (Kintampo North and South, Wenchi, Tain, Techiman and Nkoranza North and South). The districts fall within the forest-savannah transitional ecological zone, where vitamin A rich foods are less available than in the forest regions in the south.

ObaapaVitA started in December, 2000. Capsule distribution ended in October 2008. Field activities, including dissemination of final results continued until August, 2009.

Who is involved?

ObaapaVitA was a collaboration between the London School of Hygiene and Tropical Medicine (University of London) and the Kintampo Health Research Centre. The trial was funded by USAID and DFID. The total number of staff employed exceeded 400, and were distributed across the four sites in which the trial was conducted. While a large majority of the workforce carried out fieldwork (data collection and capsule distribution), dedicated sub-units functioned to provide information, education and communication (IE&C) inputs, data processing and logistics support. Specially trained supervisors were also involved in harnessing data from the four main hospitals in the study area, while a separate group undertook the completion of Verbal Post-Mortems (VPMs) in all deaths involving study participants and their off-spring below the age of one year. ObaapaVitA was one of the activities carried out at KHRC under the umbrella of the “Towards 4+5 Research Programme Consortium”.

Current status

In 2009, the surveillance for the ObaapaVitA trial was completed. First results were made available at the end of April, 2009. An intensive dissemination campaign was held from May until August, 2009. This included individual messages to all participating women and their families, the presentation of a policy brief at ministerial level, press releases for radio and written press, as well as meetings with all paramount chiefs of the seven districts to inform them about the main outcomes of the trial.

Excerpt from press release:

The study has answered a very important question for the survival of women and their babies in Ghana and in many other developing countries.

The ObaapaVitA study had tested whether or not weekly capsules of Vitamin A given to women of childbearing age prevent women dying in pregnancy & childbirth.

Although it is well-known that Vitamin A supplements are important for the health and survival of children, before this study there was no certainty if this was also true for women. For 8 years, Ghana’s Kintampo Health Research Centre (KHRC) and their partners – the London School of Hygiene and Tropical Medicine have worked with local communities and over 200,000 women, supported primarily by the UK Department for International Development.

By comparing women taking weekly capsules containing Vitamin A with women taking capsules without Vitamin A, the study showed beyond doubt that taking Vitamin A does not reduce the risk of

death in pregnancy or childbirth. This high quality study had also been able to confirm that there was no harm from taking Vitamin A.

The full press release is available at:

<http://www.kintampo-hrc.org/khrcnews/obaapavitaresults.html>

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3.3 Evaluation of effect of Vitamin A and zinc supplementation on Malaria Morbidity (AMANI STUDY)

Investigators (Ghana): Sam Newton, Lawrence Gyabaa, Martha Ali, Kwame Adjei, Kofi Tchum, Mohammed Adams, Seth Owusu-Agyei

Collaborators: International Atomic Energy Agency, Health Institutions in Burkina Faso, Mali and Cameroon

Background:

AMANI stands for African Malaria and Nutrition Initiative and the study was conducted jointly by the Kintampo Health Research Centre and the International Atomic Energy Commission to assess the effect of vitamin A and zinc supplementation on malaria morbidity in infants up to 3 years of age.

The study which started on 30th March, 2009 was a randomised controlled trial involving health institutions in Burkina Faso, Cameroon, Mali and the Kintampo Health Research Centre. The trial became necessary because malaria is a leading cause of death and ill health among young children and recent research suggests that combining daily zinc with a single large dose of vitamin A reduces the incidence of malaria episodes and delays malaria attacks.

Each eligible child was randomised to receive daily zinc and vitamin A every 6 months or daily zinc placebo and vitamin A every 6 months. All study participants received vitamin A supplements as part of the national programs and either zinc or a placebo for 6 months. All children aged less than 12 months received 100,000 IU vitamin A and those greater than or equal to 12 months received 200,000 IU vitamin A at the beginning of the study and every 6 months thereafter in accordance with national guidelines. The dose of zinc was 10 mg per day.

Weight and length/height measurements were carried out at the start and end of the study. Blood samples were collected to assess vitamin A status, haemoglobin, plasma zinc, and blood smears were taken for malaria detection. By the end of October 2009, field work had been completed.

Objectives:

Primary Specific Objective:

1. To determine the effect of vitamin A alone vs. vitamin A and zinc on the incidence of clinical malaria.

Secondary Specific Objectives:

1. To determine the effect of vitamin A alone vs. vitamin A and zinc on changes in anthropometric measurements (weight and length/height).
2. To assess the effect of the study interventions on the incidence of anaemia, diarrhea and pneumonia.
3. To assess the tolerability of these supplements.
4. To determine the change in zinc status as assessed by plasma zinc concentration using atomic absorption spectrometry during and at the end of the intervention.
5. To determine the change in vitamin A status as assessed by the modified relative dose response (MRDR) test during and at the end of the intervention.

The sample size for the study was 200 children per site. Out of the 200 children enrolled for the Ghana site, 182 completed the study and the serum samples which were collected are being analysed for zinc and retinol levels. Data analysis is also ongoing.

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3.4 A randomized home-based trial of the effects of fortified complementary foods on Vitamin A status and body pool Size in Ghanaian infants (VitA pool study)

Investigators (Ghana): Sam Newton, Martha Ali, Kwame Adjei, Kofi Tchum, Seth Owusu-Agyei,

Collaborator: International Atomic Energy Agency (IAEA)

Background:

The growth rate of breast fed infants in developing countries is comparable to infants in developed countries in the first 6 months of life. However, infants in developing countries deviate from this satisfactory pattern after this period. This has been attributed to the lack of nutrient dense complementary foods. This makes children in developing countries vulnerable to disease and death during the weaning period. Utilisation of home-based complementary foods using local weaning foods has several advantages because it does not require major changes in dietary practices and allows the child to obtain the full dose of micronutrients when it is mixed with a small quantity of food. This study is expected to contribute to our knowledge of home fortification and the use of stable isotopes in this age group.

Objectives:**Primary Specific Objective:**

To assess the efficacy of home fortified foods on vitamin A status and body pool size in children using stable $^{13}\text{C}_2$ retinol as a tracer and conventional techniques such as the modified relative dose response tests (MRDR) tests among those who receive sprinkles with or without vitamin A.

Secondary Specific Objectives:

1. To determine the degree of dilution in the vitamin A body pool using stable $^{13}\text{C}_2$ retinol as a tracer in children who are given sprinkles with or without vitamin A.

2. To assess the efficacy of home fortified foods in improving the vitamin A status using conventional techniques such as the modified relative dose response tests (MRDR) in children who are given sprinkles with or without vitamin A.

This study is a double blind study in which 94 infants between 7-9 months of age will be randomised to receive either sprinkles with vitamin A or sprinkles without Vitamin A daily for 5 months. Weight and length measurements will be carried out at the start of the study and at the end. Blood samples will be collected to assess vitamin A status at the start of the study using the modified relative dose response test and at the end using stable $^{13}\text{C}_2$ retinol as a tracer in children who are given sprinkles with or without vitamin A. The study started in January, 2010 and is expected to be completed by June, 2010.

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4. MATERNAL AND NEONATAL INTERVENTIONS

4.1 Newborn Home Intervention Study (NEWHINTS)

Project title:

Cluster randomised trial to evaluate the impact of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life on neonatal mortality in rural Ghana

Rationale:

Although the child survival revolution of the 1980s led to dramatic reductions in overall child mortality, it has had little impact on neonatal mortality – just under four million infants die each year before reaching one month of age and neonatal deaths now account for 38% of the 10.8 million deaths among children younger than 5 years of age, 98% of these in low- and medium-income countries. Tackling neonatal mortality is therefore essential if the millennium development goal to reduce by 2015 overall child mortality by two-thirds from its levels in 1990 is to be achieved.

In the 1970s, the average neonatal mortality rate in sub-Saharan Africa was 44 deaths/1,000 live births, and by the 1990s it had only decreased to 39/1,000 births. Furthermore, the projections on percentage of skilled attendance at delivery suggest that in sub-Saharan Africa this will remain static at just above 40% over the period to 2015. Complementary strategies, such as delivering community-based interventions, are urgently required.

Trained community workers are considered by many to be pivotal to newborn care in the community, as they can act as catalysts for community actions and also be providers of care. The feasibility and effectiveness of such an approach has not yet been evaluated in Africa.

NEWHINTS aims to develop a feasible and sustainable community-based approach to improve neonatal survival in rural Ghana. This is hoped to be achieved through routine home visits by Community Based Surveillance Volunteers (CBSVs) who will provide a package of essential newborn care interventions in the third trimester of pregnancy and first week of life.

Objectives

- To link with the District Health Management Teams (DHMTs) to develop a feasible and sustainable intervention to improve newborn care practices through routine home visits in pregnancy and the first week of life
- To evaluate the impact of these home visits on all cause neonatal mortality
- To evaluate their impact on newborn care practices
- To evaluate the cost-effectiveness of the intervention
- To assess the coverage and quality of the service provided and the family and community response to the service.
- To evaluate whether the impact of the intervention on neonatal mortality differs between home- and facility-based deliveries.
- To evaluate the impact of the intervention on age- and cause-specific neonatal mortality.

How is the research undertaken?

NEWHINTS is a cluster-randomised trial in which the current network of CBSVs are trained to identify pregnant women in the community and to conduct two home visits during pregnancy and three in the first week of life of the neonate to address essential maternal and neonatal care practices. It also involves developing a sustainable supervisory and remuneration structure for the CBSVs in accordance with the plans of the Ghana Health Service in order to make the eventual roll out of the intervention feasible.

The trial is being conducted in seven (7) districts in the Brong Ahafo Region: Kintampo North and South, Tain, Nkoranza North and South, Wenchi and Techiman Districts.

Approximately 18,000 pregnancies and 15,000 live births take place each year in the seven districts, and are under 4-weekly surveillance. NEWHINTS will be evaluated on the basis of process and outcome indicators. The data for the evaluation will be collected through the supervisory system (process indicators), and through the routine surveillance data collection.

Time line

NEWHINTS will span a period of three and a half years from 2006 to 2010 and is planned in 3 phases. The first phase which involved the intervention design – a series of formative research activities aimed at identifying gaps in knowledge and to improve the feasibility and optimality of the planned intervention were conducted in 2006 and 2007. The second phase consisted of piloting and start-up of the intervention (2007-2008) and the third phase (2009), is the full implementation of the intervention. The main results of the trial are expected in mid-2010.

Who is involved?

The NEWHINTS trial is a collaboration between GHS, KHRC and LSHTM. The funders are Saving Newborn Lives, WHO and DFID. The NEWHINTS intervention is being developed and implemented in close collaboration with the 7 District Health Management Teams (DHMTs), with input from relevant national programme coordinators.

NEWHINTS is one of the activities carried out at KHRC under the umbrella of the “Towards 4+5 Research Programme Consortium”.

Current status

In 2009, NEWHINTS was fully implemented in seven districts by 426 CBSVs. They were supervised on a monthly basis during home visits or in group meetings. Supervisors received several training workshops and were visited on-site. The volunteers identified and referred babies with any of a set of ten danger signs, the hospitals were visited by the NEWHINTS research team to update hospital staff about NEWHINTS and to inform them about the possible referrals by CBSVs. Training was offered to 35 new recruited CBSVs.

The intervention will be handed over to the DHMTs at the end of January 2010, when the research component of NEWHINTS will come to a close.

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4.2 TOWARDS 4+5 (MATERNAL AND NEONATAL RESEARCH PROGRAMME CONSORTIUM)

Background information:

Towards 4+5 is a five year Research Programme Consortium on maternal and newborn health. The goal of the consortium is to support evidence based policy and practice for maternal and newborn health to facilitate the achievement of the Millennium Development Goals 4 and 5. The programme is supporting research concentrated in five developing countries. These are Bangladesh, Burkina Faso, Ghana, Malawi and Nepal. It focuses on ways to improve mother and infant care at both the facility and community levels.

Key partners:

London School of Hygiene and Tropical Medicine (LSHTM); Institute of Child Health (ICH), UK; Kintampo Health Research Centre (KHRC) Ghana, Centre Muraz, Burkina Faso, DAB, Bangladesh, ICCDR-B, Bangladesh, MIRA, Nepal and Maimwana, Malawi.

The consortium is directed by Professor Anthony Costello of ICH and Dr. Veronique Fillipi of LSHTM.

KHRC Investigators:

Charlotte Tawiah, Dr. Guus Ten Asbroek, Dr. Alexander Ansah Manu and Dr. Seth Owusu-Agyei

Partners at LSHTM:

Prof. Betty Kirkwood and Dr. Karen Edmond

Research themes

Towards 4+5 research is organised in four key themes:

- Levels and trends in maternal and newborn mortality and morbidity
- Improving maternal and newborn health services
- Working with communities to improve maternal and newborn health
- Evaluating the effectiveness of micronutrient interventions

The consortium is also working on two cross-cutting themes:

- The role of evidence-based policymaking in maternal and newborn health
- Integration issues concerning maternal, newborn and child health

Current research activities carried out by all the partners include:

- [Community-based participatory intervention to improve essential newborn care in rural Makwanpur, Nepal](#) (A. Costello, D. Manandhar, D. Osrin)
- [Community-based interventions for infant health in Dhanusha, Nepal](#) (A. Costello, D. Manandhar, D. Osrin)
- [Effectiveness of facility-based audits to improve the responsiveness of West African hospitals to obstetric emergencies: a three-country randomised controlled trial](#) (M. Borchert)
- Ethnography of policy making in maternal and neonatal health (D. Behague)
- [Evaluation of the impact of TBAs in rural Bangladesh, to prevent and manage birth asphyxia](#) (A. Costello, K. Azad, S. Barnett)
- Historical ethnography of safe motherhood research and policy (K. Storeng)
- [Improving Essential Maternal and Newborn Care in Poor Rural Communities in Malawi](#) (A. Costello, C. Mwansambo, P. Kazembe, D. Osrin)
- Research to determine the burden of maternal ill health and death and its programmatic implications in rural Bangladesh (C. Ronsmans, M. Koblinsky, V. Filippi)
- [Consequences of obstetric complications on women's health and lives in Burkina Faso](#) (V. Filippi, R. Ganaba, S. Murray)
- Schistosomiasis in pregnancy in Burkina Faso: implications for control - pilot study (H. Diallo, S. Cousens, N. Meda)
- Systematic review of the impact of multiple micronutrient supplements during pregnancy (B. Margetts, C. Ronsmans)
- [Use of community health workers to give antenatal and postnatal home visits in Ghana](#) (A. Manu, C. Tawiah-Agyemang)

Activities carried out in the year:

The Consortium held four (4) executive committee meetings in the year under review. These meetings were held at the ICH and LSHTM. KHRC and the other partners participated in all the meetings via telephone. The meetings helped the consortium to discuss the progress of work. In addition to that, quarterly reports about the consortium activities at KHRC were sent to LSHTM and ICH for onward submission to DFID, which is the main funder of the Consortium.

The Consortium supported Charlotte Tawiah to attend the Micronutrient Forum in Beijing, China in May 2009 where the results of the maternal mortality trial (ObaapaVitA study) were presented. Nelson Amanfo was also supported by the Consortium to undertake a one year MSc course at the Brunel University in the UK.

The website for the Towards 4+5 is: www.towards4and5.org.uk

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5. MENTAL HEALTH

5.1 Title: Ghana maternal depression study: Cohort study of the epidemiology of antenatal and postnatal depression in rural Ghana and its adverse infant and maternal health consequences (including mortality) - DON study.

Summary: This study ended during the year under review. Data is being cleaned and made ready for analysis to commence.

DON is the popular title for this study. The acronym 'DON' stands for 'Depression in ObaapaVitA and NEWHINTS'. Essentially, DON is interested in measuring depression in both ObaapaVitA and NEWHINTS trials that are currently on-going (these trials are designed to reduce mortality outcomes in pregnant, delivered women, newborns and infants). Given this rare opportunity made possible through the excellent collaboration between researchers on both trials and the mental health unit, DON aims to answer questions with significant impact on public health:

1. How much depression during pregnancy and after delivery are women faced with?
2. Could depression during pregnancy and after delivery affect the health of the neonate, infant and woman?
3. Could counseling on essential neonatal care practices delivered by community based surveillance volunteers (CBSV) to pregnant and delivered mothers reduce depression?

To be able to answer these, field workers have been trained on how to screen pregnant and delivered women for depression using the validated Patient Health Questionnaire (PHQ-9).

Why carry out the research?

The motivation for conducting this sub-study stems from interesting findings from two recent studies in Asia, linking depression during pregnancy to low birth weight infants (Patel and Prince, 2006; Rahman et al 2004b), and depression during the first few weeks after birth to infant malnutrition and stunting at 6 months (Patel et al 2004; Rahman et al 2004b). In addition to this, a recent validation study conducted at the centre revealed a likely prevalence of depression in 1 out of every 3 women during the period after birth (Weobong et al 2009).

Furthermore, the evaluation of home visits intervention on improving the mental health status of mothers during the perinatal period has not been studied in sub-Saharan Africa. Evidence from the West however exists to support the fact that structured home visits by para-professionals (lay visitors/peer support or community workers) improved maternal mental health and mother- child interaction following 2 years after the visits (Olds et al, 2004).

Given that low birth weight, infant malnutrition and stunting are significant causes of infant deaths, the effects of depression during pregnancy and after birth assumes high public health significance, especially in sub-Saharan Africa where quality of care during pregnancy and after birth is not very impressive. Positive findings from DON would therefore have far-reaching consequences for public health and for antenatal and postnatal services in the region, supporting the development of culturally

appropriate mental health interventions, to help reduce infant/maternal mortality in Sub-Saharan Africa and improve women's mental health. These would need to be integrated into existing programmes, including, potentially, micronutrient intervention programmes, such as ObaapaVitA, and neonatal care support programmes such as NEWHINTS.

How is the research undertaken?

DON was borne out of an excellent symbiotic arrangement between researchers on the ObaapaVitA and NEWHINTS trials and the mental health unit.

Field workers, supervisors and coordinators on the ObaapaVitA trial were trained on how to screen for depression using the depression module of the Patient Health Questionnaire (PHQ-9). The PHQ-9 has nine items and covers the nine criteria upon which the diagnosis of depressive disorders is based in the current edition of the Diagnostic and Statistical Manual - DSM-IV (American Psychiatric Association 2000). The PHQ-9 has been previously validated in a sample of postnatal women within the study area (under review-Journal of Affective Disorders), and found to be psychometrically robust.

The screening for depression were in two arms: (1) All women on the ObaapaVitA trial who were scheduled to receive their first pregnancy visit were screened for depression and (2) All women on the ObaapaVitA trial who were scheduled to receive their first postpartum visit were screened for depression. All eligible women were consented for their participation in the study. Concurrently, these women were visited and provided counselling on pregnancy and neonatal care by CBSVs.

Who is involved?

The DON study is a collaborative venture involving researchers on the ObaapaVitA and NewHints trials and the Institute of Psychiatry in the UK. The study is partly funded by a grant from the Psychiatric Research Trust (PRT), UK. The study is being led by Benedict Weobong.

What is the current status?

Active data collection ended in July, 2009. Depression data are available for 19,941 pregnant women and 21,579 recently delivered women; both are available for 17,110 of these women. Data cleaning and analysis is planned for the coming year.

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5.2 MHAPP

Introduction:

The mental health unit contributes to the unique position of KHRC as the only health research institution in Ghana and the West African sub-region that conducts population based multidisciplinary mental health research. On the international front, the unit plays various leadership roles in mental health research as in the INDEPTH mental health working group, led by Dr. Victor Doku.

Research activities:

Mental Health and Poverty Project:

Summary

The Mental Health and Poverty Project (MHaPP) is a five-year Research Programme Consortium (RPC) funded by the Department for International Development, UK. It aims at developing and evaluating national-level mental health policy interventions in poor countries in Africa. The research is based in four African countries: Ghana, South Africa, Uganda and Zambia. The MHaPP in Ghana has three broad interventions namely: the Mental Health Information System (MHIS) Intervention, the Legislation Intervention, and the District Demonstration Intervention all aimed at breaking the negative cycle of poverty and mental ill-health. The first two interventions are based at the national level (Accra) and the third intervention is based at the Kintampo Health Research Centre. This report focuses on the district demonstration intervention.

Why carry out the research?

The situational analysis of mental health policy and services in Ghana conducted for the first phase of the MhaPP revealed that only a small proportion of those with mental illness receive treatment, and that the quality of this care is often inadequate. While the mental health policy in Ghana states a commitment to decentralisation, community-based mental health care and the integration of mental health into primary care, in practice, progress on the implementation of this policy has been limited. In addition, while such strategies are widely advocated for improving mental health care delivery worldwide (WHO 2001, 2003), there is little research evidence on their effectiveness for treating people with mental disorders in low-income countries (Flisher *et al* 2007). The purpose of this study is to implement and evaluate models of best practice for the integration of mental health into the general health care of a rural district of central Ghana, Kintampo North Municipality.

How is the research undertaken?

In order to enhance the chances of influencing policy through research activities, this study employs participatory action research (PAR) in which interventions are designed, implemented and evaluated in collaboration with stakeholders in mental health. The intervention activities focus on four main areas: (1) to determine mechanisms and processes that are effective for setting up a district level multi-sectoral forum for mental health; (2) implement and evaluate best practices for providing community level treatment and support for people with serious mental disorders; (3) implement and evaluate effective methods of enhancing social inclusion and recovery for people with serious mental disorders; (4) implement and evaluate methods of collecting accurate and consistent longitudinal data on mental disorders at the district level which can be integrated into regional and national level health management information systems and the Kintampo Health and Demographic Surveillance System. The year 2009 saw the full roll out of all interventions activities.

Meeting

In November, 2009, the PI and research fellow also attended the RPC meeting in Zambia.

Who is involved?

The research programme consortium involves a number of international partners including the University of Cape Town, Makerere University, Uganda, WHO and the University of Leeds, UK.

The Ghana team comprises:

Dr. Victor Doku, Principal Investigator; Dr. Angela Ofori-Atta, Co-Principal Investigator; Dr. Akwasi Osei, Ministry of Health Representative; Edward Adiiboka, Research Fellow; Alex Ghartey, Research Officer; Solomon Nyame, Research officer; and Osei Assebey Okyere, Research Officer.

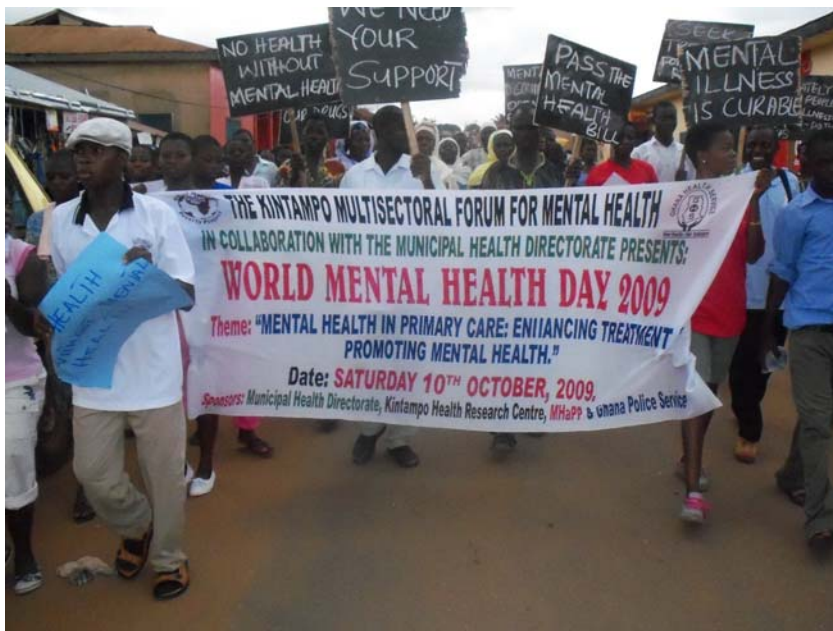
Ghana like the other four African countries has a multidisciplinary advisory Committee which meets quarterly to give expert advice and help steer the project.

Time lines:

The first phase of the project has ended (2005-2008), and the second phase commenced in August 2008 and will end in July 2010.

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World Mental Health Day celebration in Kintampo on 10th October, 2009.

6. PUBLIC ENGAGEMENT

6.1 Public Engagement in Research Activities (PERA)

Introduction

In 2008, the Kintampo Health Research Centre (KHRC) started the PERA project which was sponsored by the Wellcome Trust. This project sought to create awareness among stakeholders and to seek opinions about KHRC’s research activities and agenda in the Kintampo North Municipality and the Kintampo South District. This became necessary in that there was a gap in getting feedback from the community on KHRC’s research activities. The target audiences included various stakeholders such as community members, District Assemblies, the media and health professionals.

Objectives:

- To explain KHRC’s activities and research agenda in detail for target audiences.
- To seek, discuss and address respective audience’s perceptions, opinions and expectations of KHRC’s activities and research agenda.
- To strengthen KHRC’s communication unit to respond to community members and media questions with consistent messages regarding KHRC’s research activities and research agenda.
- To share experiences and lessons learnt with the local and international research community.

How the study was undertaken

Focus Group Discussions (FGDs) and In-depth Interviews (IDIs)

The project was mainly qualitative in terms of its design. The main qualitative methods used were Focus Group Discussions (FGDs) and In-depth Interviews (IDIs). A total number of about twenty four (24) FGDs were conducted among the various age groups or population units. These groups included: male and female adolescents, women with children under five, men whose children have or have not been involved in any study conducted by KHRC and women who are 45 years and above. These groups were selected based on the geographical location of the communities in the two districts. The ethnic backgrounds of these communities were also considered in the selection process to ensure ethnic diversity in responses. A total of twenty seven (27) in-depth interviews were conducted among some selected community opinion leaders in the two districts. These included: assembly members, unit committee members, chiefs, herbalists, catechists, heads of departments, officials from the Ghana Private Road Transport Union (GPRTU), health professionals, and chemical sellers.

Workshops

Separate workshops were held for each of the stakeholders. The attendance was good and this led to a fruitful discussion and feedback that is beneficial in moving forward the research agenda of KHRC. Leaflets which contain a summary of the completed and current projects undertaken by KHRC were distributed to these stakeholders at the workshops.

Video shows

Video shows were organised and about 51,909 people in the communities attended the video show on the research activities of KHRC. This was a way of conveying the research activities of KHRC to the community members in the form of a drama and to get feedback from them. This was done with the support of the Information Services Department (ISD).

Radio discussions

Seven (7) interactive radio discussions with phone-in questions and answers were held on the local radio station (Adars FM). The discussions were done in the two main languages spoken in the study area – Akan and Mo. The project team explained to the general public the research activities of KHRC and people called in to ask questions and to make contributions to the discussion. A panel comprising radio presenters and other media personnel had a session to discuss the content of the messages that were discussed.

Achievements

The main achievement of this project was the creation of awareness about KHRC's activities among community members and key stakeholders. Appropriate key messages and communication policies have been developed to better engage the community and other stakeholders. These activities and resources from this project had strengthened KHRC's communication unit.

Furthermore, the community members came to understand that KHRC is not a Non Governmental Organisation (NGO) as many perceived it to be. From this study, community members who used to perceive KHRC as a philanthropic organisation have now come to terms with the fact that it is a health research institution under the Ghana Health Service which conducts research into various areas of health. This was important in dispelling the unduly high expectations of many community members that the centre should help provide them with some amenities like school buildings.

In one of the post interviews held for the stakeholders, an assembly member had this to say *“This has been a big eye opener and has led to the doing away of the perception that KHRC is an NGO. I now know that you are part of the Ghana Health service and you work closely with them. My take is that you extend your areas of operation. What we are saying is that you should extend your area of operation. For me and my people your activities help a lot”*.

In addition, it was clear from the evaluations that people living in the communities now know that apart from malaria and vitamin A trial, the centre conducts research into other areas such as mental health, newborn health and other studies. This has been an important achievement in that people have now understood that the centre is diverse in its research activities and its findings contribute to the formulation of health policies in the country.

Community members also provided useful suggestions to enhance the interaction between the centre and various communities in the Centre's study areas. One of them was that the centre should take advantage of the quarterly and yearly meetings as well as the open days of the district assemblies to brief them or give updates on the ongoing research activities at the centre.

Key findings

Knowledge of KHRC as an institution was widespread and this was because community members were always engaged at preparatory stages of KHRC's research activities. However, it was felt that the Centre's activities were skewed towards malaria research studies. New research areas recommended for KHRC's research activities included investigation into HIV/AIDS, guinea worm infestations, skin diseases, elephantiasis, breast cancer, malnutrition (Kwashiorkor) and many more.

Even though community members were able to mention the names of some projects that were ongoing, they were however unable to identify the core activity of KHRC. Community members were of the view that KHRC's mandate is to administer drugs, give vaccines and advise on the outcome of these drugs and injections.

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7. OTHER PROJECTS

7.1 Determining the effect of prophylactic administration of Oxytocin in Uniject™ by a Community Health Officer on postpartum haemorrhage at home births in the Kintampo North and South districts of Ghana (Oxytocin Study)

Investigators (Ghana): Sam Newton, Seth Owusu-Agyei, John Gyapong

Collaborators: Johns Hopkins Bloomberg School of Public Health, Cynthia Stanton
& PATH Washington DC

Background:

This study is designed to test the hypothesis that the intramuscular administration of 10 IU of oxytocin in Uniject™ during the third stage of labour by a Community Health Officer (CHO) at home births will reduce the risk of postpartum hemorrhage by 50% relative to home births attended by the same type of provider who does not provide a uterotonic drug.

Primary Specific Objective:

To determine if administration of 10 IU of Oxytocin in Uniject™ during the third stage of labour by Community Health Officers in Ghana will reduce the risk of postpartum haemorrhage, defined as blood loss of 500ml or more, by 50% relative to deliveries attended by the same type of provider who does not provide a uterotonic drug.

Secondary Specific Objectives:

1. To document the frequency of appropriate and inappropriate use of Oxytocin by Community Health Officers (CHO) in Ghana, with appropriate use defined as use and correct dosage administered immediately following the birth of the baby (and/or for treatment of postpartum haemorrhage) and inappropriate use defined as the administration of Oxytocin prior to the delivery of the baby.
2. To document the occurrence of adverse maternal and foetal outcomes which are associated with inappropriate use of Oxytocin by Community Health Officers in Ghana.
3. To document the success rate of CHOs to arrive in a timely manner to intervene once they have been contacted by a pregnant woman in labour.
4. To document logistical issues that must be addressed to assure expanded coverage of Oxytocin for postpartum haemorrhage prevention, including community acceptance of the practice to call a CHO at the time of delivery, sufficient supply, adequate storage and appropriate disposal of Oxytocin in Uniject™ and changes over time in CHO practice.
5. To assess the reliability of women's self-report on medical and traditional care received during labour and delivery.

The study will be a cluster randomized, community-based trial in which 1128 pregnant women in the Kintampo North and South Districts will be either assigned to receive either Oxytocin or no Oxytocin to test the effectiveness of home-based prophylactic administration of Oxytocin in Uniject™ by Community Health Officers (CHOs) to reduce the risk of postpartum haemorrhage.

Preparatory activities for the study have started and recruitment is expected to begin in May 2010. The study is expected to be completed in one year.

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DEPARTMENTAL/INSTITUTIONAL REPORTS

1. ADMINISTRATION

Introduction

The Kintampo Health Research Centre (KHRC) continues to maintain its collaborations with institutions such as the London School of Hygiene and Tropical Medicine (LSHTM), Hospital for sick children in Toronto, Noguchi Memorial Institute of Medical Research (NMIMR) and the Institute of Psychiatry-UK. KHRC continues to attract funding from the World Health Organisation (WHO), Department for International Development (DFID), the Wellcome Trust, Malaria Vaccine Initiative (MVI) and Malaria Vaccine Partnership among others.

Staff

KHRC had a total of staff strength of 640 as at January 2009 and this shrank to 411 at the close of August in the same year. The reduction in staff was largely due to the end of the Obaapa vitamin A project which started in 2000. It is the hope of the centre to call back most of these staff when new projects start. Various projects were carried out under year of review namely:

- ❖ Obaapa Maternal Vitamin A project
- ❖ Neonatal and Maternal Research Programme Consortium
- ❖ Mental Research Programme Consortium (MRPC)
- ❖ Mal 055 vaccine trial
- ❖ Indepth Phase IV Safety and Effectiveness Studies (INESS)
- ❖ Artemisinin Combination Therapy (ACT) study
- ❖ Depression in Obaapa & NEWHINTS (DON) Study
- ❖ Newborn Home Intervention Trial (NEWHINTS)
- ❖ Malaria Clinical Trial Alliance (MCTA)
- ❖ Biomass Study

- ❖ National Institutes of Health malaria epidemiological studies (NIH)
 - Severe malaria study.
 - Passive case detection study
 - Birth Cohort study
 - Reference Value study
- ❖ African Malaria and Nutrition Initiative (AMANI)
- ❖ Public Engagement in Research Activities (PERA)

The Centre continued to carry out the Kintampo Health and Demographic Surveillance System (KHDSS). This core activity offers support to all projects at the Centre, and again provides a demographic database that informs prospective collaborators in making informed decisions about work. The KHDSS currently has about fifty one (51) staff working and this figure includes one National Service personnel who will be completing her service in August, 2010. Talks have also started with Newmont Ghana Gold Limited to start a new Health and Demographic Surveillance System (HDSS) in the Newmont mining area.

Junior staff in the Centre usually have higher turnover compared to the senior staff. For lack of space, mention will be made of the senior staff only. During the year under review, the Centre recorded some number of resignations at the senior level. They included Dr. Stephen Apanga and Dr. Ruth Owusu who both worked on the Mal 055 project. Mr. Danso Yeboah also resigned from the IE&C wing of the Obaapa vitamin A project.

The Centre also took on Mr. Seworno Sovoe Anane as the person in charge of logistics. It is also worth noting that the Centre regularised the status of all National Service personnel from 2008 into full time staff. Mr. Isaac Asante and Dr. Frank Baiden also joined the Centre as pharmacist and Project Investigator (ACT study) respectively.

The Centre continued to upgrade staff at both junior and senior levels. At the junior level, four people were sponsored to undertake the Community Health Nursing Programme. At the senior level, Mr. Emmanuel Mahama was sponsored to do his Masters' degree in medical statistics at the LSHTM; Mr. Nelson Amanfo also had the opportunity to do his Masters' degree in Anthropology in the UK while Dr. Alexander Ansah Manu and Dr. Kwaku Poku Asante started their PhD courses at the LSHTM. The following staff are also expected back in the Centre after their Masters courses: Messrs Lawrence Gyabaa, Nicholas Amoako, Matthew Sangber Dery, Kenneth Asaya and Ms. Akua Budu. Mr. Azumah Sylvanus Illedi and Ms. Pearl Nii Boi are still in school pursuing Executive Masters in Business Administration and ACCA respectively.

The Centre engaged the services of eight (8) National Service personnel in 2009 at various departments.

Study Areas

The Centre continues to operate in the six (6) contiguous districts of the Brong Ahafo region namely Kintampo North and South, Nkoranza, Wenchi, Techiman and Tain with Kintampo North as the Headquarters. Links with Afrancho, Akumadan and Nkenkensu communities are still being maintained for future work.

Transport

The Centre under the year of review had six pick ups, one KIA truck, one Nissan primera and thirteen Toyota land cruisers station wagons. The total number of motorbikes stood at 77.

Building construction

The centre completed the construction of an archive in the year under review. The archive had become very necessary in view of the large amount of paper data required to be stored. The archive, besides storing data from projects will also have sections for the storage of documents from the clinical laboratory and the accounts department. The management of the Centre has planned to engage the National Archive to train some staff to man the place.



KHRC Archive

The Centre also completed the building of a sports complex. The sports complex has the following facilities: Volley ball court, lawn tennis court and a gymnasium

The purpose of the facility is to enable staff exercise to maintain good health. It must be noted that the gym was built with funding KHRC got from the Prince of Asturias Award in Spain.



KHRC Sports Complex

Guest House

The KHRC guest house is still in operation and it received 214 visitors within the period under consideration.

Advisory Board meeting

The Centre also hosted its second Advisory Board meeting in August 2009. The following distinguished people attended:

Prof. Fred Binka

Prof. John Gyapong

Prof. Betty Kirkwood

Dr. Cheikh Mbacke

Dr. Aaron Offei and members of KHRC management committee.



Advisory Board members of KHRC

Visitors

The Centre was privileged to host about 220 personalities during the period under review. Due to constraint of space, just a few will be mentioned. They include:

- Dr. Aaron Offei
- Prof. Daniel Chandramohan
- Dr. Wurapa
- Dr. Zelee Hill
- Dr. Moses Adibo
- Prof. Wendy Graham
- Dr. Oona Campbell
- Dr. Charles Brown
- Dr. Rajiv Bahl
- Dr. Bernhard Ogutu
- Prof. K.A Koram
- Dr. Steve Rosenthal
- Dr. Cheikh Mbacke
- Prof. John Gyapong
- Prof. Brian Greenwood
- Dr. Jane Bruce
- Prof. Stanley Zlotkin

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2. SCIENTIFIC REVIEW COMMITTEE (SRC)

Core responsibility

The Scientific Review Committee (SRC) is charged with the responsibility of reviewing the scientific merit of all protocols before the studies are conducted in the Centre.

Schedule of meetings

The SRC meets routinely on the first Monday of every month. The Chairman can also convene a meeting outside this schedule whenever it becomes necessary.

The review process

Protocols to be reviewed are submitted at least two weeks before the date of review, and soft copies are distributed to members to study and note their comments prior to the meeting.

The review process is robust, transparent and democratic. The Principal Investigator of the proposed study gives a brief summary of the protocol after which three principal reviewers, selected prior to the meeting give their independent comments. The floor is then opened for the comments of other reviewers. After that, the team of research investigators on the protocol move out of the meeting for a decision to be taken. Most of the time, the protocol is given conditional approval and the investigators are required to address the main concerns of the reviewers before the protocol is given full approval for the study to be conducted.

The SRC continues to maintain a critical attitude during reviews, and all legitimate concerns are taken on board by the research team and addressed. Being a multidisciplinary committee, members look at the protocols from diverse perspectives, and this helps to shape the protocols and strengthen their scientific merit.

During the year 2009, 12 protocols were reviewed, covering areas as diverse as malaria treatment, malaria vaccine trials, drug effectiveness and mental health.

Membership and office holders

The SRC membership consists of senior staff from research Fellow and above. The current membership is 40. In July 2009, a convention was adopted, allowing senior staff below level 13 to sit in as “aspiring members”.

The current office holders include

1. Dr. Seth Owusu-Agyei (Director of the Centre)	Chairman
2. Dr. Samuel Newton	Deputy Chairman
3. Bright Akpalu	Secretary
4. George Adjei	Deputy Secretary

The membership of the SRC is dynamic, as people move into this category as a result of promotion and higher degrees.

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3. INSTITUTIONAL ETHICS COMMITTEE (KHRC IEC)

The year under review witnessed the implementation of most of the activities planned by the Kintampo Health Research Centre Institutional Ethics Committee (KHRC-IEC). Members exhibited immense commitment towards the activities of the committee which explains the success story reported herein. However, the secretariat acknowledges some set backs which would be urgently addressed by the committee in its 2010 activity plan. This report covers the following broad areas: (1) Current membership, (2) Accomplished activities, (3) Public education/capacity building (4) Future plans/conclusion and (5) Protocol submission requirement(s).

Current membership

The committee is diverse in composition – seasoned researchers, academia, traditional authority, civic educationist and as well gender sensitive. As such, protocols brought before the house are reviewed thoroughly cognizance of local context, gender issues and as much as possible in tandem with pertinent research agenda in Ghana and the world at large. There are nine (9) voting members and three (3) non-voting members. A quorum of five (5) voting members present qualifies a review meeting to be convened.

1. Rev. Dr. Joe Eyison (Chair/voting member)
2. Dr. Samuel Newton (Vice Chair/voting member)
3. Mrs. Charlotte Tawiah (voting member)
4. Mr. Jeremiah Tiimob (voting member)
5. Nana Franklin K. Fei (voting member)
6. Dr. Ruth Owusu (voting member)
7. Mr. Emmanuel Ofori (voting member)
8. Ms. Cecilia Addae (voting member)
9. Dr. Adenuga Yusuf Bayo (voting member)
10. Dr. Seth Owusu-Agyei (non-voting member)
11. Mr. Benedict Weobong (non-voting member)- Administrator
12. Mr. Dominic Dery (non-voting member)- Assistant Administrator

Accomplished activities

SOP review

The committee review process was challenged in the previous year due to the complex nature of protocols brought before it – multi-centre studies, vaccine/drug trials, students’ dissertation field studies and external studies outside KHRC domain but within Kintampo. As such, the committee decided to review its SOPs to reflect current trends in KHRC. This activity had tremendous input from committee members. Five (5) major SOPs were successfully reviewed and four (4) new ones added to meet current trends in the committee review process.

Field monitoring visits

Field monitoring visits (announced and un-announced) of studies approved by the committee is a core function of the ethics committee. As such, the committee embarked on three important field visits of studies approved by the committee. In doing so, the committee is able to unearth protocol violations and ethical breaches. Though this activity had setbacks due to the unavailability of members at the proposed time of visits because of their tight official schedules, three of the scheduled four were accomplished.

Progress reports and final reports of studies

In total, seventeen (17) studies/projects approved by the committee are ongoing (OPENED), but at different stages/timelines. For the year under review, four (4) final reports of completed studies and two (2) progress reports of studies still running have been submitted by PIs to the committee. With the installation of PRO-IRB software (courtesy AMANET grant), studies due for progress or final report submissions are flagged at the secretariat desk for administrator(s) to accordingly notify PIs of submissions which has tremendously improved communications between PIs and the committee.

Protocols reviewed

For the year under review, eleven (11) protocols/studies came before the committee for review. Of these, six (6) got straight approvals, five (5) received conditional approvals pending minor modifications and were subsequently granted full approval after PIs satisfied concerns of the committee. It is gratifying to note that upon revisions of SOPs, the review process has become thorough and stringent and this therefore enables PIs to commit less protocol/ethical violations. The PRO-IRB database has tremendously improved the tracking measures of the secretariat to curb violations.

Public Education and capacity building

Three major activities planned by the committee came to fruition (courtesy AMANET grant). The first was a “Learn how we operate” presentation organized for staff of KHRC, health personnel at the district hospital and the Rural Health Training school. The second activity was a bioethics workshop organized for researchers, lecturers and civic society on ethics in research. This comprised presentations, case studies and open discussions. The third activity was a radio discussion on the operations of the ethics committee to the general populace in Kintampo which was broadcast live on the local FM station (ADARS FM). These three activities put a spotlight on the existence of the committee, its activities and the relevance of it in a research committee like Kintampo. In respect of building the capacity of members, IT training for committee members started with two members and it is to be conducted for the entire house at an advanced level.

Future plans/conclusion

The future plans of the committee include but are not limited to the following:

1. Embark on visit(s) to sister institutions with ethics committees for knowledge sharing and skills transfer.
2. Conduct community meetings within areas of active field research and those with completed research aimed at creating awareness, assuring and building confidence in research communities.
3. Deliver lecture(s) to middle level health personnel (Technical Officers and Field Technicians) undergoing training at the Rural Health Training School in Kintampo.

In conclusion, the committee is poised to take research ethics (bioethics) to higher grounds in the interest of research participants in Kintampo, Africa and the world. More importantly, the committee envisages a fruitful and fulfilling coming year (2010) and renewed energy and commitments to protect research participants in the course of reviewing research protocols.

Protocol Submission Requirement(s)

1. Scientific Approval from KHRC scientific review committee
2. Covering / submission letter from PI – addressed to chairman

3. Complete protocol
 - ✓ Summary + detail protocol/study
 - ✓ Data collection tools
 - i. Enrollment forms
 - ii. Questionnaires/FGDs/IDIs guides
 - iii. Study information/consent forms
 - ✓ Timelines and Budget
 - ✓ CV of Investigators

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4. CLINICAL LABORATORY

The clinical laboratory of the Kintampo Health Research Centre provides laboratory support for studies being carried out by the Centre and the Municipal Hospital. Studies supported during this period included the Malaria Vaccine Studies (Mal 050, Pre-Mal 055 and Mal 055), Birth Cohort, Severe Malaria, Reference Value, Passive Case Detection, ACT and the African Malaria and Nutrition Initiative (AMANI).

The staff strength of this department currently stands at 34. This is made up of 6 biomedical scientists, 1 research clinical microbiologist, 1 entomologist, 1 principal laboratory technician, 10 research officers, 11 laboratory assistants, 2 National Service persons and 2 biomedical engineers. Staff have received training in Good Clinical Laboratory Practice (GCLP) and Good Clinical Practice (GCP).

The clinical laboratory currently consists of the following units: Haematology, Clinical Chemistry, Parasitology, Bacteriology, Entomology, Molecular Biology, Micronutrients, Immunology and Virology.

Haematology unit

Two Horiba-ABX Micros 60 haematology analyzers are available in this unit for performing Complete Blood Counts (with 3-part differential counts). Other tests performed in this unit include screening for sickle cells and Glucose-6-phosphate dehydrogenase (G6PD) deficiency. The unit participates in the United Kingdom National External Quality Assessment Scheme (UK NEQAS) to monitor the quality of tests performed.

Clinical chemistry unit

This section is equipped with two Vitalab Selectra Clinical Chemistry autoanalysers and two electrolyte (sodium, potassium and chloride) analysers. Tests performed in this unit include liver and kidney function tests, blood lipids and glucose.

Parasitology unit

The unit at the end of the year produced 10 Expert and 5 Reference malaria microscopists (according to the World Health Organisation criteria for grading microscopists). All blood slides are examined by two independent microscopists and slides with discordant results are examined by a third microscopist.

Discordant rate among microscopists is less than 5%. The unit is registered with the External Quality Assessment Scheme organised by GlaxoSmithKline Biologicals and the National Institute for Communicable Diseases, South Africa (GSK/NICD).

Bacteriology unit

This unit is equipped with 2 Bactec 9050 machines for performing blood cultures. Other specimen processed include cerebrospinal fluid, urine, swabs (wound, ear and eye). Work is carried out in a Class II Biological Safety Cabinet and cultures done in carbon dioxide incubators. Selection, processing and reporting of susceptibility of antibiotics are done using the Clinical and Laboratory Standard Institute (CLSI) guidelines. American Type Culture Collection (ATCC) strains are used for quality control of reagents, media and antibiotics. The unit participates in EQA scheme organised by GSK/NICD.

Entomology unit

The entomology unit was not active for the year under review. Nonetheless, the unit focused mainly in writing manuscripts from past research data for publications. Notably, one paper was published and two are in press. The unit has extensive experience in general entomology (medical entomology) but specifically specialises in malaria entomology to complement malaria studies in KHRC. The unit has three experienced personnel who support in other laboratory duties specifically parasitology and therefore enjoys reputable recognition. The unit also collates continuous monthly rainfall and temperature data to support data analysis in KHRC. The unit employs CDC light traps to catch mosquitoes from the field for determination of circumsporozoite antigens in *Anopheles* mosquitoes to estimate EIRs. In building the platform for malaria studies, the unit created field sentinel communities with well mapped data or entomology indices; vector abundance, speciation, *kdr* genotypes and distribution of molecular forms.

Currently, there is preparatory work to undertake three studies; a Malaria Transmission Intensity trial, an EIR cross-sectional survey and WHO commissioned vector control trial.

The unit is currently equipped with the following equipment: an ELISA plate reader (DYNEX®) with Revelation 4.2 software; an automated ASYS Atlantis plate washer and CDC light traps and accessories

Immunology unit

The unit had been processing samples for Cell Mediated Immunity (CMI) and shipping the cells abroad for processing. The laboratory would soon be equipped with the necessary equipment such as flow cytometer, laminar flow, incubators and also build capacity locally to be able to support clinical trials without having to ship samples abroad.

Micronutrient unit

The micronutrient unit is equipped with a Scanning Spectrophotometer a High Performance Liquid Chromatography (HPLC) analyser for measuring micronutrients such as vitamins. Both machines were donated by the International Atomic Energy Agency (IAEA), which has also trained 2 scientists on HPLC techniques in the USA.

Biomedical engineering unit

The laboratory has a biomedical engineer and an assistant who perform in-house routine servicing and repairs of laboratory equipment. This has enhanced the continuous flow of work.

Cold rooms

The clinical laboratory maintains cold rooms for the storage of reagents, samples and vaccines. All refrigerators and freezers are monitored twice daily. All sensitive equipment in the laboratory are hooked on to a 10kVA UPS, in addition to the backup generators.

Staff development

Three laboratory staff are currently pursuing MSc programmes in Biomedical Sciences and Infectious Diseases with institutions based in the United Kingdom. One staff is also pursuing a BSc Medical Laboratory Science course at the College of Health Sciences of the University of Ghana.

Laboratory assessment and support

The clinical laboratory received assessors from the Contract Laboratory Services (CLS)/GSK Biologicals and the National Institutes of Health, USA. These assessments helped the clinical laboratory maintain a high standard in its quality management systems.



A UV-1800 spectrophotometer



Zinc Protoporphyrin analyser

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MALARIA DIAGNOSTIC CENTRE OF EXCELLENCE (MDCoE)

Microscopy is the gold standard method for the detection and quantification of malaria parasites during clinical trials. The need to have laboratory scientists adequately trained for this purpose cannot be overemphasised. It is for this reason that the Malaria Diagnostic Centre of Excellence (MDCoE) was set up at KHRC with support from the MDCoE (Kisumu, Kenya) and the Malaria Clinical Trial Alliance (MCTA).

The main objectives of the training at the MDCoE include:

1. Ensuring valid malaria microscopy in clinical trials through:
 - a. Standardised training and methods

- b. Providing quality training materials, including malaria smears, pictures, written materials and Powerpoint presentations
 - c. Certification of microscopists
2. Transferring skills to other sites to harmonise procedures for malaria diagnosis.

The curriculum for the 2-week basic training currently includes the following:

- Overview of trials and tribulations of microscopy
- Development of Standard Operating Procedures (SOPs)
- Qualities of a good microscopist
- Malaria Quality Control (QC) and Quality Assurance (QA)
- Microscope maintenance
- Life cycle of the malaria parasite
- Identification of malaria species
- Approach to mixed malaria infection
- Artifacts, pseudo-parasites and the reality of false positives
- Counting techniques
- Approach to low density malaria infections
- Preparation of standard malaria blood smears

During the period under review, the MDCoE had the following sessions:

1. An in-house training for staff of the KHRC clinical laboratory. This training led to an increase in the number of certified microscopists from 10 in 2008 to 15 in 2009.
2. A Newmont Ghana-sponsored training for 5 laboratory personnel working in health centres of the mining area was held from 28th September to 10th October, 2009. One laboratory staff each from the Holy Family Hospital (Techiman), St. Theresa's Hospital (Nkoranza) and the Methodist Hospital (Wenchi) were sponsored by KHRC to join this training. This was in line with KHRC's vision of training microscopists within the Brong Ahafo Region. One laboratory technologist each from the Kintampo North and Kintampo South Hospitals had been trained in previous years.

It is hoped that other blood parasites, such as microfilaria, *Trypanosoma*, *Borrelia*, *Leishmania*, and *Babesia* species would be included in future trainings as these are also found in the blood and are included in test specimens provided by some External Quality Assessment (EQA) providers.

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5. COMPUTER CENTRE

Introduction

The computer centre management team had a very difficult year. From the beginning of the year, the need had arisen to scale down at a point because the ObaapaVitA project was winding up. Nobody

wanted to be laid off and for this reason, work performance was at its best. Annual appraisals had to be done in the third quarter of the year and the ranking of staff in the same category, by order of merit was extremely difficult. However, this exercise was carried out and nine (9) data entry clerks (DECs) were laid off. The computer centre organised a mega “serve-yourself” party in honour of those who had been laid off.

Data Processing and Management

Data processing and management is done using Microsoft Visual FoxPro, Access and Epi-Data. The centre has invested so much time and expertise in developing data management systems using FoxPro but it is currently not being supported by Microsoft. A decision was therefore taken to migrate to SQL Server while keeping Access and Epi-data. This migration requires training for all staff of the computer centre and this is hoped to be achieved in 2010. But the most disturbing question to resolve has been “what to do with the data management system of the Health and Demographic Surveillance System (KHDSS), currently running on FoxPro?” Migrating to SQL as well is being considered.

The Internet Service

In order to reduce cost and achieve a reliable internet service, the Centre had taken a decision to host its own mails. Over 70% of the mails originate from the Centre hence are delivered internally and does not affect the traffic on the bandwidth. However, the target of achieving reasonably fast internet connectivity 24/7 is still something yet to be achieved. There have been times staff are unable to access other web mails such as Yahoo, Hotmail, G-mail etc during working hours most likely due to the traffic in the system.

The centre is currently in the process of replacing old 10/100 switches with intelligent 10/100/1000 switches to enhance the performance of the internet.

NComputing Technology

One of the biggest problems the centre has had in the past year is maintenance costs. Computers frequently breakdown after they are being used for 3 years. Consequently, all computers have to be on UPSs which also breakdown quite frequently due to power surges and fluctuations. Plans are therefore far advanced to move onto NComputing technology where data processing staff would have access to terminals from a server equipped with an efficient redundancy system. This would greatly cut down on all the problems enumerated in the main data entry room.

IT Committee

For the kind of research work that is carried out by KHRC, IT has become the environment without which such work would be almost impossible to do. This committee would formulate the IT policy for the centre including spelling out restricted websites, coming out with recommendations for anti-virus software(s), software(s) upgrades, internet connectivity, maintenance routines, life span of a computer etc.

Battery Power Backup System

A second battery power backup system has been installed to complement the existing malfunctioning system and in anticipation of the acquisition of a new server for the NComputing technology.

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6. STAFF WELFARE ASSOCIATION

Projects

One of the planned activities of the association for the year under review was the procurement of “Friday cloths”, T-shirts and caps and achieving this was made possible with financial assistance from management of KHRC.

A gym has been put up for use by staff and it was opened in December 2009.

The leadership of the association has not been able to tackle the issue about staff bus. It is expected that the next batch of executives would endeavour to achieve this.

Audit

Article 4 Section 1 of the association’s constitution states that “The Association’s accounts shall be audited annually by internal auditors. The audit report shall be published (on the notice boards) one week to the last quarter general meeting of the year and tenure of office of the executive body. The report shall finally be read in a general meeting.”

The executives of the committee are therefore fervently preparing the books for auditing. Fresh elections will be held after the audit report has been published.

In Transition

The centre lost Duut Jabong (JL) in a motor traffic accident on the 18th of September, 2009. He was an officer in the accounts unit. Then on 27th December, 2009 information reached the centre that Olivia Minyila (MN) had also passed away after a short illness. We wish JL and MN eternal rest until we meet again.

Conclusion

In conclusion, the executive board of the association is appealing to senior staff to get involved in the welfare business. It is time consuming but there is a lot to learn from serving on the welfare executive board. For very good reasons, the junior members are very vulnerable and so might have difficulties leading the association. Remember, “if a good leader refuses to lead, then he/she has to be content with bad leadership from those willing to do so”.

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