BUSITEMA UNIVERSITY

EXHIBITION 2021 MAY 8, 2021

COLLABORATIVE RESEARCH INITIATIVE FOR ADVANCING EVIDENCE BASED CLINICAL CARE

MBALE CLINICAL RESEARCH INSTITUTE
IN COLLABORATION WITH BUSITEMA UNIVERSITY







MBALE CLINICAL RESEARCH

Vision:

A centre of excellence in evidence based clinical research, training and innovation,

Mission:

To provide high quality evidence based clinical research and training for sustainable development

Values:

Integrity, Team work, Accuracy, Data Security









Vision:

A centre of academic and professional excellence in science, technology and innovation **Mission:**

To provide high standard training, engage in qual research and outreach for social-economic transformation and sustainable development

Values:

Professionalism, Respect for Diversity, Innovativeness, Internationalization, Team work





Professor Paul Waako, MB.Ch.B, MSc., PhD, FUNAS

Vice Chancellor Busitema University

Message from Vice Chancellor Busitema University

I am delighted to be Vice Chancellor at the time when research is spouting and advancing at Busitema University. At the Faculty of Health Sciences, collaboration with Mbale Clinical Research Institute (MCRI) is strategic for both research and capacity building.

The shared vision of being centre of excellence between the two institutions is better for common advancement.

It has been a unique experience to work with MCRI. For this initiative, one can safely comment that our research collaborations have been successful. These collaborations are not restricted to research. Capacity building through training, joint grants and joint curricular development are other core area of our collaborations.

This collaboration has a very rich treasure for the future of clinical research. The university is proud of its collaborations with MCRI and other similar initiatives.



Message from Executive Director, Mbale Clinical Research Institute

The Mbale Clinical Research Institute (MCRI) remains committed to progressive research collaborations with Busitema University. In the last 7 years, we have learnt and grown together in research at Mbale Campus.

If there is anything that an academician, research institute and University would be proud of, it is to make a humble contribution through asking key research questions whose answers directly advance the wellbeing of humanity and development. The MCRI and Busitema University research collaboration is just about that!

Professor Peter Olupot - Olupot, MB.Ch.B, MPH, PhD, SRF, FUNAS Executive Director MCRI

Through this collaboration we remain committed to relevant clinical research that brings solutions to the communities in Uganda, and where applicable beyond the boundaries. Together we stand to develop the relevant capacity in the various fields. Sharing of the resources to optimize outputs has also been a key aspect of our collaboration. Whereas there are some models of research collaborations to emulate from, our unique model that is driven by a common purpose and defined achievable milestones seems to work for us. This on itself has been a centre of learning and admiration by other institutions.

The pragmatic implementation of joint programmes remains a cordial value. Networking with other institutions and persons also bring value to our work and the future of research in Eastern Uganda. Our institutions are both indebted to Mbale Regional Referral & Teaching Hospital for being such an invaluable host.

To the physical and virtual participants at the 2021 University Exhibition, I thank you for taking your precious time and efforts to be with us.

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Message from the Operations Officer;



Egessa Michael

OPERATIONS OFFICER MCRI

Within a space of 5 years after inception as a platform for building International Research Capacity, Creating Collaborative research Networks and promoting Local Research. Mbale Clinical Research Institute (MCRI) is consistently and organically evolving with significant success. This has placed the institute at a level of excellence in evidence based clinical research, training and innovation.

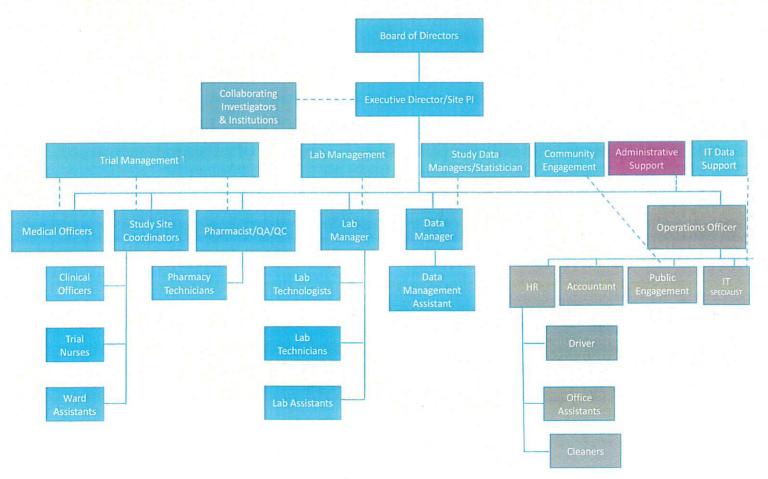
Operationally, the institute has developed efficient and aligned processes that establish it as a reliable organization to the research participants and all other internal and external stakeholders. MCRI has been assessed as conforming to

Good Financial Grant practices by African Academy of Sciences across a spectrum of policies, procedures and practices in financial management, human resources, procurement, Grant management and Compliance, Risk management and Governance.

Our human resources strategy is driven by attraction and retention of the right people in the right positions at the right time, continuous improvement of staff through cost effective staff development, effective and progressive performance management, equal opportunity and healthy working environment.

We also aim to have the best and most reliable IT platforms supporting research procedures and compliance to Good Clinical Practices. I would like to take this opportunity to express enthusiasm towards all the MCRI Collaborations and Partnerships that will foster thriving research, training and innovations.

MCRI MANAGEMENT STRUCTURE



EDCTP Supported Work











EDCTP

Malaria Research

Senior Fellow: Professor Peter Olupot-Olupot, MB.Ch.B, MPH, PhD, SRF, FUNAS

Title

Strengthening Malaria Epidemiological, Pathophysiological and Intervention Studies in Highly Endemic Eastern Uganda (MEPIE)

Objectives

 To conduct epidemiological studies on acute kidney injury in childhood severe malaria at Mbale Regional Referral Hospital to characterise the disease over a period of 48months.

2. To describe the pathophysiology of haemoglobinuric malaria at Mbale Regional

Referral Hospital to understanding the disease process.

3. To study safety and early efficacy of paracetamol in ameliorating acute kidney injury (AKI) in children with severe malaria.

4. To explore the dose and effect of paracetamol in treatment of renal impairment in

children with haemoglobinuric malaria.

5. To train two junior researchers in malaria research including clinical trials.

Study Design

Prospective cross sectional studies are being conducted for malaria epidemiological and pathophysiological studies. Phase I/II randomised clinical trial will be conducted for evaluation of feasibility, safety and early effectiveness of paracetamol for treatment of AKI

Progress

- Objective 1: Work is ongoing. Over 500 study participants have been recruited.
- Objective 2: Work is ongoing and detailed descriptions of the pathophysiology of haemoglobinuric malaria in Eastern Uganda is underway.
- Objective 3: This Phase I/II trial has been registered with <u>www.clinicaltrials.gov</u>, the study will commence as soon as final regulatory clearance from National Drug Authority is secured.
- Objective 4: Dependent on the roll out of objective 3 above.
- Objective 5: Two Masters Fellows are being supported through this project. One has completed MPH, the other in final year of MMed Pediatrics.

Funding Information:

This project is part of the EDCTP2 programme supported by the European Union (grant number TMA2016 SF1514 MEPIE Study) to Busitema University.











Strengthening of Ethics Capacity in Uganda

Scaling up of Capacity of Research Ethics Committees in Uganda (SCRECU)

The Uganda National Council of Science and Technology (UNCST), Busitema University and Mbale Regional Referral Hospital are in a consortium aimed at Scaling up of Capacity of Research Ethics Committees in Uganda (SCRECU). The project has a number of components including:

- I. Training
- II. Capacity building
- III. Equipping the Research Ethics Committees (RECs)
- IV. Research

Progress

- Training Training of RECs has happened. This has resulted into the implementation of the NRIMS. The NRIMS is a UNCST's national online platform setup to facilitate research review processes online, national registration of research, communication with researchers, facilitate the study approval process, enabling multiple research ethics committee (REC) review if needed and monitoring of approved research in Uganda.
- Capacity building This was initiated and is ongoing. The REC Administrators have been specifically trained on aspects of NRIMS.
- Equipping the Research Ethics Committees (RECs) Equipment has been provided for each accredited REC in Uganda. These include laptops for the REC offices and electronic tablets for the REC Members. The latter is meant to improve review process, reduce the turn round time for the review process and to minimize on paperwork.
- The research is on Feasibility and Effectiveness of the National Research Information Management System (NRIMS) in Uganda, which is nested within the SCRECU project.

Funding Information:

This project is part of the EDCTP2 programme supported by the European Union (grant number CSA2018ERC-2315), to Uganda National Council for Science and Technology (UNCST).

MCRI PROFILE

Mbale Clinical Research Institute (MCRI) advances Clinical Research in pursuit of a vision "Center for Excellence in Evidence based Clinical Research, Training and Innovation" within Uganda and internationally.

Over the years, MCRI's portfolio has gradually expanded in Research, Funding and Staff compliment. Clinical research revolves on paediatric diseases including Severe Anaemia, Severe Pneumonia, Malnutrition, SCA, Malaria, alongside many other major studies.

Guided by the strategic focus, MCRI aims at:

- Supporting recruitment to large multi-center Clinical Trials
- Providing a platform for clinical research capacity building and Training
- Equipping of a research Laboratory to facilitate processing of Clinical specimens across a broad spectrum of assays to storage in the Biobank for epidemiological profile including Hematology, Microbiology, Parasite culture, Immunology and Molecular sections
- Enabling infrastructure to conduct internationally competitive research
- Attracting, Recruiting and motivating professionally competent core staff

MCRI is grateful to its supportive funders including Wellcome Trust, Imperial College London, MRC, Oxford University, EDCTP, KEMRI and Consortium partners Mbale Regional Referral Hospital and Busitema University Faculty of Health Sciences.

The studies so far conducted at Mbale Clinical Research Institute include:

REACH

Realizing Effectiveness Across Continents with Hydroxyurea (REACH) is a prospective, phase I/II open-label dose escalation trial of hydroxyurea for children with confirmed Sudden Cardiac Arrest (SCA) between 12 months and 10 years.

TRACT

The Transfusion and Treatment of severe Anaemia in African Children (TRACT) is a randomized controlled Trial. TRACT is evaluating three different ways to reduce short and longer-term mortality and morbidity following admission to hospital with severe anaemia in African children.

PAC

The clinical trial mainly involves assessing the tolerability and safety of SLDPQ – Single Low Dose Primaquine in African Children with acute uncomplicated falciparum malaria and glucose 6 phosphate dehydrogenase deficiency.

TABS PKPD is clinical trial involving the investigation of Pharmacokinetics and Pharmacodynamics of Azithromycin in severe malaria and bacterial co-infection in African Children.

FLACSAM

FLACSAM stands for Firstline Antimicrobials in Children with Complicated Severe Acute Malnutrition. The study compares antibiotics used in managing infections in children. This is a clinical trial comparing effectiveness of antibiotics used to treat children with complicated severe acute malnutrition.

GASTROSAM

Gastroenteritis is a very common cause of diarrhea and vomiting. It is most likely to be caused by a bacterial or viral stomach infection and is particularly common in young children. This trial study is conducted at MCRI. In some cases, it can cause severe dehydration, a condition that requires immediate medical treatment.

NuTiP

This is an open, multicenter Randomized Controlled Trial of 840 participants, aged from 6months to 12 years, admitted with severe pneumonia, respiratory distress complicated by hypoxia (saturations<92%). This trial will investigate in these children whether supplementary feeding for 56 days (8weeks) using Ready to Use Therapeutic feeds (RUTAFA) in addition to the usual diet verses standard of care (usual diet alone) will improve primary and secondary outcomes at 90 days and 180 days. Children admitted to hospital with severe pneumonia and hypoxia are at risk of poor long term outcomes, where undernutrition is a risk factor. We aim to investigate whether nutritional support is an important adjunctive treatment for such children.

COCS

The Open Cohort Study (COCS), aims at refining COVID-19 case definitions, establish incidence of the pandemic and to characterize the clinical spectrum and outcomes of the disease among different populations.

COAST

The Children's Oxygen Administration Strategies Trial (COAST) was an open, multicenter fractional Randomized Control Trial (RCT) of 4200 participants aged between 28 days and 12 years, admitted to hospital with respiratory distress complicated by hypoxia. The COAST Trial was investigating what the best oxygen delivery strategies were, to reduce in – hospital mortality and mobility in African Children with respiratory distress complicated by Hypoxia.

This procedure was being done by evaluating two linked components of oxygen delivery to establish whether liberal oxygenation is superior to permissive hypoxia (current routine standard of care in hospitals not screening all admissions for Hypoxia) and to establish weather high flow oxygen delivery was better than low flow oxygen delivery (current routine standard of care in hospitals with no access to mechanical ventilation).

Planned studies

SMAART

The SMAART Study (Severe Malaria A Research and Trials consortium) is a prospective observational study that will recruit participants aged 3 months- 15 years for 36 months, admitted to hospital with *P. falciparum* malaria defined by a positive Paracheck rapid diagnostic test, history of fever or hypothermia and axillary temperature >37.5°C or <36°C.

The primary aim is to characterise the contemporary epidemiology (including features at presentation, diagnostic and treatment pathway) of severe malaria presenting to hospital for admission in children in Africa.

H-PRIME

H-PRIME (Hydroxyurea-Pragmatic Reduction In Mortality and Economic burden).

The Trial targets to recruit children diagnosed or suspected to have Sickle Cell Disease aged 1 to 10 years, a laboratory test to confirmed the diagnosis of SCD is mandetory prior to entry.

The trial will have 3 intervention strategies aimed at reducing mortality and morbidity in children with SCD. This include:

- R1: daily oral hydroxyurea vs placebo, dosing based on standard weight-bands and given with clinically driven (based on clinical signs/symptoms) rather than routine, scheduled laboratory monitoring
- R2: enhanced antimalarial prophylaxis with weekly dihydroartemisinin-piperaquine (DHA-PQP) vs standard of care (SOC) (monthly sulphadoxine-pyrimethamine, SP).
- R3: antimicrobial prophylaxis with daily co-trimoxazole (CTX) throughout childhood/adolescence vs SOC (twice-daily penicillin V until the age of 5 years).

The results of the Trial will help better up the management of SCD, a growing burden in low developed countries where intensive tests for the management of SCD patients who are on Hydroxyurea are not routinely perform. The data collected shall be kept confidential in line with ICH-GCP guidelines.

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Profile of Collaborative training initiatives between Busitema University and Mbale Clinical Research Institute

- 1. Curriculum Development
 - i. IDEA Fellowship Program
 - ii. Implementation Research Curriculum within MPH Training programme.

2. Workshops



3. Research Pharmacy



MBALE CLINICAL RESEARCH INSTITUTE LABORATORY AND BIOBANK BUILDING.

