

# HEARTBEAT

MRC | MRC/UVRI Uganda  
Research Unit on AIDS



UGANDA VIRUS RESEARCH INSTITUTE

The Quarterly Newsletter for the MRC/UVRI Uganda Research Unit on AIDS

VOL 4, ISSUE 1 — October 2016



Prof. Eugene Kinyanda  
Head— Mental Health Project

## Prof. Kinyanda Awarded GBP 2M for Mental Health Project

**P**rof. Eugene Kinyanda, the Head of the Mental Health Project at the MRC Uganda Unit has received the prestigious Wellcome Trust Senior Research Fellowship in Public Health and Tropical Medicine.

Prof. Kinyanda is the first Ugandan to receive the Award.

The GBP 2.02m Award will be used for work on “Integrating the management of depression into routine HIV care in Uganda (the HIV+D trial). Specifically, the funding will go towards developing a mental health integration model using theory

of change based approaches and will involve lay health workers (members of the village health teams, expert patients); members of the HIV care team (at public health care facilities) and specialist mental health workers (psychiatric clinical officers at district and regional referral hospitals).

The study will be undertaken in partnership with the Ministry of Health, district health services and NGOs involved in HIV and mental health care.

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*Pamela N. Wairagala  
Communications & Public Engagement Officer*

## Dear Reader,

Happy New Year and welcome to this edition of the Heartbeat.

Protocol deviations are a common occurrence in a research setting, in spite of all the care that is taken to ensure that they are minimised. In this edition, we bring you an overview of why they happen, what to do once they happen and how to minimise their occurrence.

Bio-risk is an ever present threat especially for staff that deal with infectious agents and toxins in laboratories. The Unit has undertaken a number of measures to ensure that staff are safe. Read about the new recipe for improving biosafety and risk management in our Health and safety section.

In this edition, we bring you articles on achievements by various Unit staff. Do not miss reading about Prof. Eugene Kinyanda and the Wellcome Trust Senior Fellowship that he recently received. If you are planning to apply for a grant anytime soon, this is a must read article about the dos and don'ts of grant application. Also, do not miss the article about Dr. Paula Munderi's recognition among the IAPAC 150 for her role in influencing the mission, vision, and programs of the International Association of Providers of AIDS Care (IAPAC) over the association's three-decade history.

Also in this edition are profiles of Ms. Suzanne Rupp and Prof. Moffat Nyirenda who have joined the Unit as Chief Operations Officer and theme Leader Non Communicable Diseases respectively. Also, do not miss the staff and research updates.

As always, we do appreciate and look forward to your feedback. We also welcome you to share with us your work by sharing an article or photo.

Happy reading and God bless you.

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# DIRECTOR'S NOTES



Prof. Pontiano Kaleebu  
Director MRC/UVRI

## Happy New Year and welcome to this edition of the Newsletter.

I am glad to inform you that after an extensive review process, the MRC UK Infection and Immunity Board approved funding the Unit's work. During the next 5-year funding cycle which starts April 2017, the Unit's future research activities will be conducted within three key priority thematic areas, namely: Re-search on the changing HIV/AIDS Epidemic (ROCHAE); Endemic, Neglected, Emerging and Re-emerging Infections (ENERI); and Non-Communicable Disease (NCD). Also as part of the transition, the Unit name will change and consequently the brand identity. The process to determine the respective areas started in 2014 with a high level strategic review of future health priorities of the East Africa region. I take this opportunity to convey my gratitude to all the Unit staff that participated in the review process and preparation for the quinquennial review process. We now await the final step of approval from the MRC Management Board which we are hopeful will also be smooth.

Congratulations to Prof. Eugene Kinyanda upon winning the Wellcome Trust Senior Research Fellowship in Public Health and Tropical Medicine valued at more than GBP 2Million. This is a highly competitive Award and is of great importance not only to Prof. Kinyanda, who is the first Ugandan to win this Award, but the Unit as well. The work that will be undertaken with this funding will not only consolidate our achievements in HIV related research as a Unit but we hope will also contribute

towards development of a much needed model that incorporates mental health into HIV Care, an area that is currently not provided for. Congratulations also go to Dr. Deogratius Ssemwanga upon winning the EDCTP Career Development fellowship. Such awards contribute towards the Unit's capacity building programme and also contribute towards in-creasing the much needed numbers of Researchers not only at the Unit but in the country and the region as a whole.

Congratulation to Dr. Maggie Nampijja for on getting the Saving Brains seed grant from Grand Challenges Canada (GCC). The funding will provide \$250,000 CAD over 24 months to conduct a RCT of the ABAaNA early intervention programme for children with neurodisability after new-born brain injury. We also had new funding from EDCTP to participate in HIV vaccine studies led by Prof Thomas Hanke in Ox-ford.

I also congratulate Dr. Paula Munderi upon being honored among the 'IAAPAC 150', a diverse group of global health leaders, clinicians and researchers, public health specialists, and people living with HIV/AIDS and their advocates from within affected communities. This recognition is a true testimony to her tremendous efforts in the HIV/AIDS fight as a physician and researcher as well as her contribution towards policy formulation, not only locally but globally.

Please join me to welcome Ms. Suzanne Rupp who joined the Unit in October 2016. Suzanne joins the Unit at very critical time of the Unit's transition and we look forward to benefitting from her invaluable experience, having worked in various capacities including as Head of Commercial Operations at the MRC Head Office for the last 8 years.

On a similar note, I welcome Prof. Moffat Nyirenda who joined the Unit as theme leader Non-Communicable Diseases. Prof. Nyirenda is a LSHTM Professor of Medicine in Global Non-Communicable Diseases and has served as Director of the Malawi Epidemiology and Intervention Research Unit (MEIRU) in Lilongwe. He is a renowned diabetologist/endocrinologist.

I would like to take this opportunity to welcome staff that have joined the Unit during the course of the last quarter and also thank those that have worked with the Unit and have moved on during the same period. I wish them the best in their careers.



## 2GBP For Mental Health Project



### **Congratulations Professor! Tell us about the Wellcome Trust Award you just won.**

On the 5th of December 2016 I received communication that I had successfully won the Wellcome Trust Senior Research Fellowship in Public Health and Tropical Medicine. It is a 5 year grant totalling GBP 2.02 million. I am the first Ugandan to win this Award. The other person who has got this Award before is Prof. Alison Elliot, also of the MRC Uganda Unit.

The 5-year funding is to undertake research to develop and test in a trial a mental health integration model in adult HIV care services in Uganda.

### **This is a very competitive award, what motivated you to apply for it?**

Wellcome Trust is one of few funders who provide career development grants. That is one of their grant schemes that provide researchers with the opportunity for 5-year funding cycles that are renewable.

At the time I applied for this grant, I was at a point in my research career where I wanted stability and continuity; having previously won a number of one-off career development grants such the Senior EDCTP Fellowship (2011-2013) and the MRC/DFID African Leadership Award (2014-2016). A Wellcome Trust Senior Research Fellowship in Public Health and Tropical Medicine seemed to me to fit the bill.

### **What was the application procedure like?**

The total application period took me 9 months. I started by writing a concept proposal, after which I was invited to write a detailed proposal and finally was invited to London to undertake an oral interview at the beginning of December 2016. The detailed proposal stage was the most exhausting to me.

I missed the first deadline because my proposal was not yet ready. Apart from having a good research idea, you need to put together an international consortium of collaborators that will help you undertake the project. It involves asking very busy people to spare some time to read your proposal and give you constructive comments, which is not easy.



## Tell us about the work you plan to undertake in the next 5 years?

About 30% of adult patients with HIV suffer from significant depressive symptoms at any one point in time. The west has addressed this problem by integrating mental health care in routine HIV care services. Unfortunately, the majority of HIV care services on the African continent including in Uganda do not have mental health care services. In this study, we propose to develop a mental health integration model that will use theory of change based approach and will involve lay health workers (members of the village health teams, expert patients); members of the HIV care team (at public health care facilities) and specialist mental health workers (psychiatric clinical officers at district and regional referral hospitals). The study will be undertaken in partnership with the Ministry of Health, district health services and NGOs involved in HIV and mental health care. This will be done over 24 months.

Once the mental health integration model has been developed and piloted, we shall put it to trial (over 36 months) at 40 public health care facilities. This work will be undertaken in the districts of Mpigi, Wakiso, Kalungu and Masaka.

## Any insights for people applying for similar awards?

Research like any other exerting endeavour in life requires discipline (writing the proposals, carrying out research projects and publishing), plenty of hard work (often unrecognised) and you must have a passion and really enjoy research. It is the passion which will take you over the dry spells. For example in 2015 I spent 8 months writing a proposal to EDCTP and it was not funded. I had to pick up the pieces and try again in 2016 and this time was successful. Equally important is that you must be in supportive and nurturing environment. I have been fortunate that since I completed my PhD in 2006, I have been working in one of the most supportive research environments in this country, the Medical Research Council Unit in Uganda.

***It is the passion which will take you over the dry spells. For example in 2015, I spent 8 months writing a proposal to EDCTP and it was not funded.***



## MRC Uganda Unit's Dr. Munderi recognized among the "IAPAC 150"

**IAPAC 150" are a diverse group of global health leaders, clinicians and researchers, public health specialists, and people living with HIV/AIDS and their advocates from within affected communities**



*Dr. Paula Munderi  
Head of HIV Care Research Programme*

Dr. Paula Munderi, the Head of the HIV Care Research Programme at the MRC/UVRI Uganda Research Unit on AIDS was among 150 individuals honored for influencing the mission, vision, and programs of the International Association of Providers of AIDS Care (IAPAC) over the association's three-decade history.

The "IAPAC 150" are a diverse group of global health leaders, clinicians and researchers, public health specialists, and people living with HIV/AIDS and their advocates from within affected communities. Their selection by the IAPAC Board of Trustees was announced at the IAPAC 30th anniversary commemoration on October 13, 2016, in Geneva, Switzerland.

Speaking about the recognition, Dr. Munderi, one of four Ugandans recognized said: IAPAC represents more than 27,500 clinician and lay providers in over 150 countries. Its mission is to expand access to and improve the quality of testing, prevention, care, treatment, and support services provided to men, women, and children affected by and living with HIV

and comorbid conditions. I feel extremely privileged to be acknowledged by them".

The other Ugandans among the IAPAC 150 are Dr Alex Coutinho, Professor Elly Katabira and Professor Peter Mugenyi.

In recognizing the "IAPAC 150," IAPAC President/CEO José M. Zuniga said that while no such list is ever complete, "The 'IAPAC 150' honors individuals those still with us and those too-soon departed who have had a profound and positive impact on our association. We thank each one and express our gratitude, too, to the countless other people the world over with whom we are marching in solidarity on our journey to end AIDS as a public health threat by 2030."

Among the individuals honored posthumously was the late Jonathan Mann, MD, MPH, who was an IAPAC founding member and the first director of the United Nation's Global AIDS Program (the precursor to today's Joint United Nations Programme on HIV/AIDS [UNAIDS]).

## Dr. Ssemwanga wins €150,000 EDCTP Career Development Fellowship

**The Fellowship aims to address the severe shortage of training opportunities for mid-career scientists by supporting junior to midcareer researchers to train and develop clinical research skills**

Dr. Deogratius Ssemwanga, a Senior Scientist at the MRC/UVRI Uganda Unit has received a three year Career Development Fellowship from the European and Developing Countries Clinical Trials Partnership (EDCTP) worth €150,000. The Career Development Fellowship aims to address the severe shortage of training opportunities for mid-career scientists by supporting junior to mid-career researchers to train and develop clinical research skills and subsequently enable them to establish themselves as independent scientists in sub-Saharan Africa.

Funding from this award will go towards the 'Immunological Selection of Recombinants following HIV-1 Superinfection' (ISoReS) project. It is a Basic Sciences project that aims to investigate the role of immune responses among individuals with established HIV infection who subsequently acquire new HIV strains; a phenomenon known as HIV superinfection. The project also aims to describe how fast and which paths the virus follows to evade the immune response of the infected host, which, it is hoped will yield important information for vaccine development. Recombination is a successful strategy exploited by HIV and an attempt must be made to uncover weaknesses in the virus to hold it in its tracks. This study will generate results and some reagents that will be used to evaluate future vaccine candidates. Speaking about the award, Dr. Ssemwanga commended the conducive research environment at the Unit as being behind his successful application



*Dr. Deogratius Ssemwanga  
Senior Scientist*

and career plans. "The combination of the unique research environment at MRC/UVRI, the existing laboratory infrastructure, our local and international collaborations, the available mentors and the various study populations inspired me to apply for this award". "This fellowship therefore gives me the opportunity to train and develop clinical research skills to address our local HIV epidemic", he added.

He advised colleagues applying for similar awards to adequately put to use the resources at their disposal, noting that the research environment at the Unit is a good place for anyone to start. "The existing research environment at MRC/UVRI puts an applicant in a very good position to win such a grant. To submit a competitive application, one needs adequate time to prepare to address a relevant research question. Once a unique project is proposed, appropriate mentors, supervisors and collaborators must be identified to guide you in the application process. Your peers are equally important to advise you in the application process".

## Introducing Ms. Suzanne Rupp - Uganda Unit's Chief Operations Officer



*Ms. Suzanne Rupp  
Chief Operations Officer*

The MRC Uganda Unit has appointed Ms. Suzanne Rupp as the Unit's Chief Operations Officer (COO), replacing Mr. Simon Belcher, who served as Director of Operations until his departure from the Unit in April 2016. Suzanne is a Chartered Accountant and a member of the Chartered Institute of Bankers.

Ms. Rupp joined the Unit in October 2016 having formally worked as Head of Commercial Operations at the MRC Head Office in UK since joining MRC in 2008. In her former role, Suzanne was responsible for assisting the UK and African Units with contractual agreements, one off projects, procurement and process improvement, and change and commercial management.

Suzanne is a member of the MRC Operations Board and the UK Department for Business, Energy and

Industrial Strategy (BEIS - MRC's funding department) Procurement Board. Prior to joining MRC- UK, she worked in various commercial sector roles and more latterly headed up the Siemens Diagnostics division managing the business across Europe, Middle East and (French speaking) Africa.

Speaking about her new assignment, Suzanne expressed enthusiasm at the appointment and shared her plans for the Operations section "One of my objectives is to ensure that Operations work as closely as possible with science to ensure we support the scientific outputs. I firmly believe that every member of staff whatever their role has a part to play in helping achieve the Unit deliverables."



## Prof. Moffat Nyirenda joins Unit as Non Communicable Diseases Theme Leader

Prof. Moffat Nyirenda is a Diabetologist / Endocrinologist and Professor of Medicine (Global Non-Communicable Diseases) at the London School of Hygiene and Tropical Medicine (LSHTM).

Before joining MRC/UVRI Unit, Moffat was Director of Malawi Epidemiology and Intervention Research Unit (previously known as the Karonga Prevention Study). He holds a BSc in Immunology (University of London), MBBS ("hybrid" training between University of London and University of Malawi), and PhD in Molecular Medicine (University of Edinburgh).

Having trained/worked in Edinburgh for over 15 years (where he was supported by a prestigious MRC Clinician Scientist Fellowship), in 2010 Moffat returned to Malawi to take up the position of Professor of Research at the College of Medicine and Associate Director of Malawi-Liverpool-Wellcome Trust Clinical Research Programme. Moffat's research interests lie in mechanistic understanding (clinical and laboratory phenotyping) of the aetiology of chronic non-communicable diseases (NCDs), including i) investigating the association between early environmental insults and the risk of obesity, diabetes and hypertension in adulthood; ii)

using cross-cutting approaches to examine the interactions between infection and NCDs; iii) contributing to genomics studies of NCDs in sub-Saharan Africa.

Moffat has particular interest in research capacity building in Africa, and was Director of the Southern Africa Consortium for Research Excellence (SACORE), funded through the Wellcome Trust's African Institutions Initiative. He serves on a number of committees, including being chair-man of Scientific Advisory Board for GSK Africa NCD Open Lab, member of the Wellcome Trust Public Health and Tropical Medicine Interview Committee, member of MRC Global Health NCD Working Group, member of Awards Assessment Panel for Africa Research Excellence (AREF), member of WHO Working Group on integration of NCDs in other programmatic areas, member of the Lancet Commission on Diabetes in Africa, and member of the Non-Communicable Disease Technical Advisory Committee to Malawi Minister of Health.



*Prof. Moffat Nyirenda  
Theme Leader Non-Communicable Diseases  
(NCDs)*

## Risk Management - whose responsibility is it?



*Ms. Anya Bek  
Risk & Assurance Manager MRC – UK*

**The Unit is in the process of setting up a risk management team and in 2016, some staff attended training sessions in Entebbe in risk management theory and practice. Below are excerpts from an interview with Ms. Anya Bek - Risk & Assurance Manager at MRC Head Office who conducted the training.**

## **What is Risk Management and why is it important?**

Risk Management helps us meet the challenges that our organisation faces; by systematically assessing risk and their consequences, we can minimize their impact, or maybe prevent them from happening in the first place.

A risk something that may or may not happen, but if it does it will affect the Unit in meeting its objectives, so by managing our risks we are helping target our resources more effectively.

## **What are some of the key issues about risk management that Unit staff ought to know?**

Risk management is all about taking well managed decisions and not about stopping us from doing what we need to do. It does take a little effort to identify and assess risks, but the benefits are that we are aware of where the risks lie and that we are managing them appropriately. When we do this we can be more confident that we will meet our Unit objectives.

At its very simplest risk management is designed to help us talk about those things that “keeps us up at night ” and help with identifying a solution. Despite our best efforts things may still go wrong, but by thinking about risks in advance we will be quicker to put them right.

## **Whose role is it to manage risk in a setting such as that of the MRC/UVRI Unit?**

The MRC/UVRI Unit Director and Senior Management team are responsible for ensuring that risks are managed. However, we all have a part to play to raise risks, concerns and challenges to our line managers. We are the ones who probably notice when things aren't working properly and by raising these potential risks, we have a hand in helping the Unit manage them more effectively.

What areas were covered during the training that you conducted for Unit Management and staff? I ran two different sessions, one was about risk management theory. Looking at the 4 step risk cycle, Identify, Assess, Mitigate and Monitor risk. Staff had a go at identifying and scoring risks using the MRC risk scoring matrix and coming up with ways we can manage the risks. We used my favorite risk analysis tool, the bow tie method.

The second session covered the use of EasyRisk which is the MRC's risk management database tool in which all MRC head office and Unit risks are kept.

What are the future plans for the Unit, following the training? The Senior Management team will be setting up a risk committee who will be leading on the risk management in the unit. The team is currently deciding the most effective way of rolling out management of risks including who will need to use EasyRisk.



## Protocol Deviations; why do they keep happening?



*Dr. Ivan Namakola  
Clinical Trialist*

The most frequently cited violation in clinical research by far is “failure to conduct research in accordance with the investigational plan.” In fact, deviating from the protocol has been the most common observation worldwide yearly for the last decade.

### Why does this keep happening?

#### How protocols are written;

It comes as no surprise that not all protocols are well written. Important procedures tend to

be hidden in the most obscure places. Charts and tables depicting time and events schedules are well known for carrying footnotes that are not anywhere else in the protocol, yet convey important study procedures. The failure to follow study procedures compromises subject safety and the integrity of the data.

#### Quality of protocols;

It is also not surprising that not all protocols are error-free. Information in the charts and tables may not match the narratives; procedures in one section may conflict with those in another. If a site monitor spots an inconsistency, the investigator could be asked which of the two procedures was followed and why. For example if one procedure was performed only because the researchers never noticed there was another, then it would be clear that they never read the protocol as well as they should have. This may raise concern as to whether or not the study execution differs from the sponsors’ intentions. This is not a concern you want to trigger.

Therefore it is imperative that study staff read and understand the protocol. They need to ask questions about anything they are not sure of, seek clarifications on protocol inconsistencies, and get satisfactory responses before starting on a study. A PowerPoint overview is not sufficient training.

#### Evolving nature of protocols;

Another bothersome attribute of protocols that makes them difficult to follow is that they change. The tendency for most sites is to allocate time and resources for initial protocol training but there’s rarely a plan for training staff on protocol amendments. The biggest number of protocol deviations occur in the amended procedures because more often than

not, staff have received insufficient training on the amendments. (And when you do train on protocol amendments, don't forget to document it.)

## And when they happen...

So you've thoroughly read the protocol, you've asked your questions and received the necessary clarifications, you've trained your staff on

the protocol and its amendments, and you do your best to follow them. Despite all your preparation and vigilance, protocol deviations happen. They just do. And when they do, here are two don'ts.

- (1) Don't panic.
- (2) Don't let the site monitor find them first.

## Document;

Take the time to fully document any protocol deviations. Be sure to record why they happened, how they were corrected, and what was submitted to the IRB.

IRBs have different requirements about what types of protocol deviations should be communicated. For example Out-of-window visits may be common and frequently considered too minor to report. But nothing's black and white. If the missed visit resulted in missed doses that would probably change the calculus. The PI needs to determine whether to notify the IRB, and if no submission is thought necessary, it's a good idea to document why not

## To avoid deviations

**JUST DON'T DO IT (OR FAIL TO DO IT).**  
When the deviation is an aspect/event outside

the protocol provisions (don't) or an omission of a protocol requirement (don't fail to fulfill requirements).

Study data that comes from a protocol-adherent clinical research site have a high level of compliance, thus of acceptability and utility. Data that is of high reliability come from the science of the study as much as the compliance. A sponsor is best off by far with both present.

A wellwritten protocol enhances smooth operations at a site, and the achievement of a high level of compliance.

A reputation for adhering to protocol and few deviations and violations make for a site that receives future participation invitations from sponsors.

As a member of the MRC/UVRI Uganda Unit, are you fulfilling your roles?

## Bio-risk Management - A New Recipe for Improving Biosafety and Biosecurity

Biorisk management is the effective management of risks posed by working with infectious agents and toxins in laboratories. It includes a range of practices and procedures to ensure the biosecurity, biosafety, and biocontainment of those infectious agents and toxins.

Biorisk management includes the full spectrum of safety and security measures for laboratories, from standard operating procedures to physical measures to individual practices in the laboratory.

Therefore, biosafety is the combination of practices, procedures, and equipment that protect laboratory workers, the public, and the environment from an intentional exposure to infectious agents and toxins used in the laboratory.

Some of the biosafety equipment used at MRC Uganda includes but not limited to personal protective equipment, biosafety cabinets, and other specially designed devices. In order to have a proper biosafety, there is always need to have a corresponding level of biocontainment. Biocontainment addresses the design of safety equipment and laboratories that will effectively contain infectious agents and toxins

**The anthrax attacks in the early 2000s proved how infectious agents and toxins can be misused to intentionally harm individuals or populations.**



and prevent an accidental and intentional release for harmful purposes.

However, biosecurity includes the measures taken to protect infectious agents and toxins from unauthorized intentional release, loss, theft and access for harmful purposes. In early 2000, the anthrax attacks proved how infectious agents and toxins can be misused to intentionally harm individuals or populations. Because there is the possibility of intentional misuse, infectious agents and toxins should be carefully guarded. Research some-times produces results that also could be mis-used, which is called dual use research of concern. In order to limit such misuse of infectious agents for harmful use, we use biosecurity measures which includes the physical barriers and other methods used to keep unauthorized personnel out of laboratories, such as fences and key coded locks on laboratory doors or refrigerators.

*Continued on page 19*



## Haemorrhagic and Ischemic stroke in urban Uganda: risk factors, outcomes, caregiver burden and experiences

Principal Investigator: [Dr. Gertrude Namale](#)

**Overall aim:** To assess the risk factors and outcomes for haemorrhagic and ischemic stroke and to document caregiver burden and experiences. These findings will be used to inform policy makers and scale up routine screening for and treatment of cardiovascular risk factors for stroke in Uganda.

**Approach:** This study will be a compilation of four sub-studies. The over-all study design uses a mixed-methods approach.

**SUB-STUDY I** is a systematic review to obtain information on risk factors for haemorrhagic and ischemic stroke in Sub-Saharan Africa.

**SUB-STUDY II** is a hospital based case control study to obtain baseline information on risk factors for haemorrhagic and ischemic stroke.

**SUB-STUDY III** is a prospective cohort study to obtain information on outcomes and associated factors of haemorrhagic and ischemic stroke. **SUB-STUDY IV** is a descriptive cross sectional study to obtain information on caregiver burden and experiences among caregivers attending to stroke patients.

The study is conducted in Nsambya hospital and recruitment of participants has started

## Increasing and Sustaining Usage of Future DPV/MPT rings by Engaging Young Women and their Influencers in South Africa and Uganda

Project Leads: [Rachel Regina](#), [Melanie Kahl](#), [Susan Kutalek](#), [Robert Fabricant \(DALBERG\)](#)

Project Leader : [Dr. Sylvia Kusemererwa \(MRC/UVRI\)](#)

This market assessment sponsored by USAID will use Human-Centered Design (HCD) methodologies with up to 150 participants from up to three different locations in KwaZulu - Natal, South Africa and Central Region, Uganda, including urban, peri-urban, and rural communities.

Participants will be recruited by local representatives from community-based organizations within each of the communities based on their willingness to participate in research activities including, individual interviews, creative workshops, and small group discussions, moderated by a local re-searcher.

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## The effect of helminth infection on insulin resistance and type 2 diabetes in rural and urban Uganda – A sub-study of the Lake Victoria Island Intervention Study on worms and Allergy-related diseases (LAVIISWA)

Principal Investigator: [Prof Alison Elliott](#)

Project Leader: [Dr. Richard Sanya](#)

The main objective of this study is to investigate the effect of helminth infection and its treatment on metabolic health in humans. The metabolic outcomes of interest are insulin resistance (as a primary outcome), fasting blood glucose, glycated haemoglobin, serum lipid levels, blood pressure, body mass index, waist and hip circumference (as secondary outcomes). This sub-study will be nested within two on-going studies; LAVIISWA, a cluster randomised trial of standard ver-sus intensive anthelmintic treatment in the rural Lake Victoria island communities of Koome sub-county and the Entebbe Urban Survey on Allergyrelated and Metabolic Outcomes, a cross-sectional study in Entebbe Municipality.

In LaVIISWA, 1950 participants will be sampled in a survey to investigate the effect of four years of anthelmintic intervention on metabolic health. Comparisons will be made between the metabolic outcomes in the rural island communities and the Entebbe Urban Survey (targeted sample size for the Urban Survey – 1600 participants). The role of inflammation in the associations (if any) between helminth infection and metabolic outcomes will also be explored by measurement of key mediators of inflammation.

This study will help in understanding whether helminth infections convey important benefits for insulin resistance in humans and, if so, to understand the mechanisms with a view to harnessing this knowledge for prevention and therapy of diabetes. The study awaits ethical approval to commence.

## Determinants and immune correlates of Kaposi's sarcoma associated herpesvirus (KSHV) suppression and transmission in Uganda

Principal Investigator: [Angela Nalwoga](#)

Co investigators: [Stephen Cose](#), [Robert Newton](#), [Denise Whitby](#)

This is a cross sectional study nested within two cohorts, the Entebbe Mother and Baby Study (EMaBS) and the General Population Cohort (GPC). The main objectives of this study are: (1) To investigate immune correlates of transmission of KSHV from mother-to-child within an urban birth cohort in Uganda; and (2) To investigate determinants and immune correlates of KSHV viral suppression across the life course within a rural Ugandan cohort. Both T cell and antibody KSHV specific immune responses will be determined. In addition other risk factors such as parasite infections and socio-demographic factors will be investigated in relation to KSHV viral suppression and transmission.

Data generated from this study will provide information on (1) the risk factors that facilitate KSHV transmission, and (2) the immune response needed to control the virus and prevent transmission. This information could be used to develop a KSHV vaccine and apply public health policies that can control transmission of the virus.

All regulatory approval has been obtained for this study.

## Increasing and Sustaining Usage of Future DPV/MPT rings

*Continued from page 15*

Data from these activities will be recorded in written notes and analyzed through debrief discussions between the project team and local researchers.

The interviews will take approximately 14 days. No follow up of participants will be done. The whole project is scheduled to take 8 months to conduct.

The study will be conducted in Masaka field station and awaits approval.



## Hormonal Contraception and Bacterial Vaginosis (HCBV): The effect of norethisterone enanthate on recurrent bacterial vaginosis among women at high risk for HIV infection in Kampala, Uganda

Chief Investigator: [Dr. Suzanna C Francis](#)

Principal Investigator: [Prof. Janet Seeley](#)

Co investigators: [Prof. Pontiano Kaleebu](#), [Dr. Yunia Mayanja](#), [Prof. Helen Weiss](#),  
[Prof. Janneke Van De Wijgert](#), [Prof. Robin Shattock](#)

The study will have both randomised and observational components. A total of 1026 participants will be recruited into the study; the study is anticipated to continue for 15 months.

The primary aim of the HCBV study is to investigate the effects of NET-EN and DMPA on the vaginal microbiota, BV and markers of inflammation among women at high risk for HIV in the Good Health for Women Project (GHWP) in Kampala, Uganda.

### The specific objectives will be to;

1. Compare the time to second BV diagnosis (i.e. recurrence) between: Women randomised to NET-EN plus condoms and condoms-only (primary comparison), and Women currently using DMPA plus condoms and condoms-only (secondary comparison)
2. Compare the composition, abundance and stability of the vaginal microbiota in same pair-wise comparisons as in 1
3. Compare markers of inflammation in the same pairwise comparisons as in 1
4. Assess the acceptability of, and adherence to, NET-EN among women initiating NET-EN and compare to women using DMPA
5. Store samples for future research on metagenomics, transcriptomics and markers of immune response

The primary outcomes will be differences in vaginal microbiota, time to recurrent BV, and inflammatory markers. Qualitative research will be carried out to assess the acceptability of, and adherence to, NET-EN. Safe and effective hormonal contraception may augment current or future (e.g. probiotic) treatment for women with recurrent BV, and results from our study may inform future clinical trials investigating BV and HIV prevention.

The study still awaits regulatory approval.

## An open label phase I clinical trial to evaluate the effect of late boost on HIV-uninfected vaccines from EV06 trial (EV07)

Principal Investigator: [Prof. Pontiano Kaleebu](#)

This is an open label, late boost follow-up study to EV06 trial.

EV06 trial has shown that the vaccine regimen is safe and well tolerated. Preliminary antibody immunogenicity analysis has demonstrated that the DNA/gp120 protein vaccine regimen induced strong gp120, gp140 and V1V2 region-focused binding IgG and neutralizing antibody responses, with this high immunogenicity, a study with an additional boost with DNA-HIV-PT123 and AIDSVAX®B/E (Late Boost) is warranted in order to better investigate and understand the effects of the late boost on the response rate, magnitude and durability of vaccine induced immune responses.

A total of up to 54 volunteers who received three active vaccines during the EV06 trial and are HIV negative, eligible and willing to participate will be enrolled into the study at two MRC/UVRI sites in Masaka and Entebbe. The study will take approximately nine months.

## Biorisk Management

*Continued from page 14*

It also entails ensuring that all workers allowed access to high containment biological laboratories are trustworthy and reliable. Assessments of personnel reliability have evolved to focus on the whole person, not just a resume or a simple background check but also during hiring of such personnel into our Unit.

In order to incorporate Biorisk Management as a new recipe for improving biosafety and biosecurity at MRC/UVRI Uganda Unit, the Health and Safety Security office embarked on training all our laboratory workers, clinicians, support staff and administrators in Biorisk management. The primary goal of the training was to build capacity of the participants to identify, characterize, evaluate and mitigate biosafety and biosecurity risks in our laboratories and at our stations. The training also empowered the participants to execute Biorisk assessment in their various sections and hence enable the identification of pertinent Biorisk mitigation strategies in their sections.

## A Follow-On, Open-Label Trial to Assess Continued Safety of and Adherence to the Dapivirine (25 Mg) Vaginal Ring-004 in Healthy, HIV-Negative Women (Phase IIIb)- DREAM Study (IPM032)

(DREAM: Dapivirine Ring Extended Access and Monitoring)

Principal Investigator: [Dr. Sylvia Kusemererwa](#)

Co Investigators: [Dr. Martin Onyango](#), [Dr. Anita Kabarambi](#), [Dr. Freddie Mukasa Kibengo](#)  
[Dr. Sylvia Nanono](#)

IPM 032 is a Phase IIIb follow-on trial to IPM 027. It has been designed as an open-label clinical trial to collect additional safety data and establish adherence to ring use of the Dapivirine (25 mg) Vaginal Ring-004 in healthy, HIV-negative women with monthly (at least one to a maximum of three months) followed by 3-monthly research centre follow-up visits over 12 months. Approximately 1400 participants will be enrolled.

### The Primary Trial Objectives are:

To assess the safety profile of the 25 mg Dapivirine Vaginal Ring-004, when inserted at monthly intervals, in an open-label trial

To assess adherence to the use of the 25 mg Dapivirine Vaginal Ring-004 inserted at monthly intervals, in an open label trial

### The Secondary Trial Objectives are:

1. To assess the incidence of HIV-1 sero- conversion
2. To assess the frequency of HIV-1 drug resistance in women who acquire HIV-1 infection

### The Exploratory Trial Objectives are:

1. To assess the feasibility of 3-monthly follow-up visits, as a possible schedule for post-licensure vaginal ring clinical follow-up
2. To explore the correlation between drug concentrations and results from the visual inspection of the returned vaginal rings by research staff between the monthly and 3-monthly research centre follow-up schedules
3. To determine the proportion of participants electing to undergo HIV rapid tests at the research centres between scheduled 3- monthly visits . Women will be in the study for 12 months, it is anticipated that the study will continue for approximately 18months.

This study will be conducted at Masaka site. All regulatory approvals are in place and team is ready to start recruitment

## IT Help Desk Support



Andrew Mairu  
IT Section Entebbe

Like any successful organization, the Unit's research activities heavily rely on IT Support for their success. IT Help Desk service support plays a big role in daily operations of Organizations.

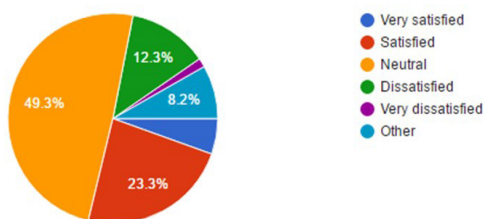
The Unit IT Help Desk service support plays a significant role in the Organization in a number of ways; housing of Databases for different studies especially from the Statistics and Laboratory sections; management of Medical Research Council Network infrastructure i.e. Internet connectivity, Email access, connectivity to servers that contain most of the resources for daily activities e.g. Staff documents, staff personal folders, procurement folders and different Laboratory file shares such as Cisp, hematology, wireless connectivity, Ethernet Cable connection to internet and resources internally in the organization.

The Unit IT department also manages Security systems in the organization such as cameras, Bio-metric thumb and Reader Card Access systems. The department facilitates comfortable working conditions for employees by availing help desk assistance which is accessible by IT Phone help lines (Ext.124), email (IT-HelpDesk@mrcuganda.org) and face to face interactions.

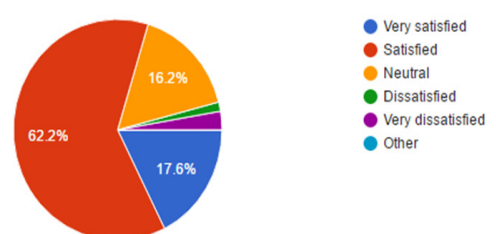
The above Help-Desk services are available at all the Unit field stations; Mengo, Masaka and Kyamulibwa.

A survey conducted towards the close of 2016 gave an indication of user perception of the IT department. The following is a summary of the survey findings;

Overall quality of off-site support? (73 responses)



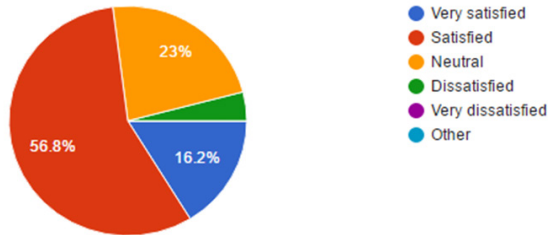
The ability of help desk to diagnose your problem? (74 responses)



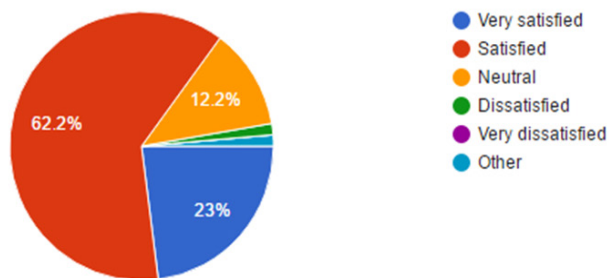


# RESEARCH UPDATES

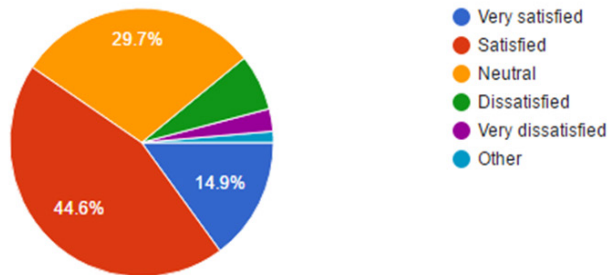
Availability of all IT Services (Email, Internet, Databases and others)  
(74 responses)



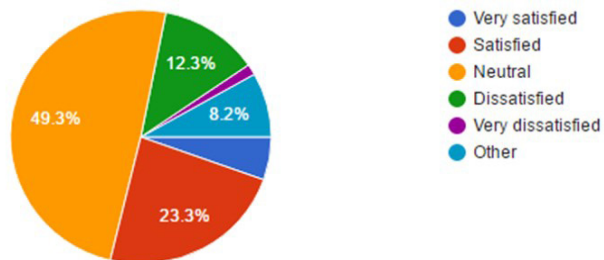
Knowledge and professionalism of the help desk support staff?



Communication and follow-up on problem resolution? (74 responses)



Overall quality of off-site support? (73 responses)



On behalf of MRC IT Help Desk , I would like to thank you for your continued support towards excellence of Medical research Council Uganda IT Department.

# STAFF UPDATES



## ARRIVALS

The following staff joined the unit in the last quarter;

NAME	TITLE	STATION
Edith Muhumuza	Accounts Officer	Entebbe
Jacob Ochola	Data Manager	Entebbe
Pius Tumwesige	Clinical Officer	Entebbe
John Obi Ahisibwe	Clinical Officer	Kyamulibwa
Ivan Ssali	Laboratory Technologist	Entebbe
Samuel Jefferson Mutyaba	Data Manager	Entebbe
Juliet Nakityo	Administrative Assistant	Masaka
Kevin Nakuya	Study Clerk	Kampala
Innocent Erone Lino	Data Manager	Kyamulibwa
Clare Athieno	Accountant	Entebbe



## DEPARTURES

The following staff left the unit in the last quarter;

NAME	TITLE	STATION
Michael B Ssabayinda	Field Worker	Mengo
Allen Asiimwe	Field Worker	Kyamulibwa
Judith Nalwadda	Field Worker	Kyamulibwa
Josephine Wanyenze	Clinical Officer	Kyamulibwa
Monica Kuteesa	Senior Scientist	Mengo
Joseph Kirangwa	Laboratory Technologist	Entebbe
Grace Nabakooza	Laboratory Technologist	Entebbe
Beatrice Nassanga	Laboratory Technologist	Entebbe
Herbert Mulindwa	Senior Data Programmer	Entebbe
Josephine Wanyenze	Clinical Officer	Kyamulibwa
Racheal Abuine	Lab technologist	Entebbe
Doreen Nambuba	Sen Data Management Assistant	Entebbe
Anne Wajja	Senior Scientist	Entebbe
Dennison Kizito	Lab Manager	Entebbe
Angella Nakazzi	Counsellor	Kampala
Henry Kyambadde	Office Attendant	Kyamulibwa
Remy Hoek Spaans	Scientist B	Entebbe

# HEARTBEAT

**The Heartbeat is an official publication of;**

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**Masaka**

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**Kyamulibwa**

Gomba Road– Kyamulibwa Town Council  
Next to the Sub-County Offices  
Kalungu District  
Tel: 0392-720042