The Eastern Africa Consortuim for clinical Research (EACCR2)

Annual Newsletter

July 2019- August 2020

EACCR2 is part of the EDCTP2 Programme supported by the European Union under grant agreement RegNet2015-1104-EACCR2

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Word from the Chief Editor

Richard Linga

Dear our Partners and esteemed readership. Welcome to our second Annual Newsletter- the EACCR2 Heights. In this issue, we highlights of outstanding research articles from node coordinators, their profiles, besides we recount the various capacity building projects and activities in which EACCR members and students were actively involved since September 2019 until August 2020. This comes out at the time of the Global COVID-19 pandemic in which partners and research sites have exhibited a lot of innovations virtually. It has been an honour to edit and review very exciting articles full of innovative ideas. I leanrt of what is happening at various EACCR2 sites. The Newsletter will serve to reinforce and allow increased awareness and visibility of EACCR2 project activities.

We thank our Steering committee members for the guidance in producing this Newsletter, Node coordinators, students, staff for the contribution of articles and the secretariat for investing their time in editing and making the newsletter a reality.

We hope you enjoy reading this issue and we are open to any ideas that will help us improve our newsletter. Please email your ideas/views to the Chief Editor: rlinga@uvri.go.ug .

Meet the editorial team

Prof Pontiano Kaleebu
Dr Benard Kikaire
Mr Richard Linga
Emily Nyanzi Kabuye
Dennis Ernest Ssesanga
Saidat Namuli Musoke
Janet Nanseko

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Foreword

Despite the uncernity and anxiety brought about by the global COVID-19 pandemic,the last half of the project year provided the EACCR2 Network with an opportunity to reflect on many ways of having project activities implemented. The partners in the Eastern Africa Consortium for Clinical Research (EACCR2) prioritized and engaged in capacity building activities and preparedness to conduct COVID-19 for clinical trials using creativity and innovation in partnership with research institutions in the region. We are hopeful that the trials will yield positive results to benefit the region and Africa as whole.

EACCR2 is part of 2 large ICH-GCP-compliant clinical trials on TB-HIV in Uganda and Tanzania. These include the EXIT-TB study which is a cluster randomized study on improving TB treatment outcomes; the PrEPVac vaccine efficacy clinical trial involving 600 volunteers from Europe and Africa. The HIV node partners were involved in the WELTEL study in Kenya which explored the use of short text phone messages to improve retention of mother-baby pairs in the prevention of mother to child transmission of HIV (PMTCT) programs in Kenya.

Prof. Pontiano Kaleebu is the Overall Project Coordinator EACCR2

The network trained 25 clinical research associates in the reciprocal monitoring scheme (RMS. Of the 25, 4 RMS monitors received accreditation from the Association of Clinical Research Professionals (ACRP). These monitors have monitored more than 30 clinical studies in the region.

This has not only improved the quality of the studies being conducted, but also lowered the cost of clinical study monitoring in the region.

EACCR2 has over 25 fully functional clinical laboratories accredited to GCLP international standards (https://slmta.org/accredited-labs). These laboratories can be used by the network or contracted by an external clinical trial sponsor to support clinical trials in the region. The network supported infrastructural upgrades for laboratories in Taveta, Kenya, Nsambya hospital in Uganda and Mwananyamala hospital in Tanzania among others.

Partners in EACCR2 successfully published 8 papers in peer reviewed journals and a number of draft manuscripts are awaiting publication. The partners all together leveraged on previous investsments and were able to win over 20 M Euros in additional funding from EDCTP and other agencies. The partners in Tanzania, Sudan and Uganda are part of 4 other research Consortia including African Coalition for Epidemic Response and Research (ALERRT), Pan African Network for Rapid Research , response and Preparedness for Infectious disease epidemic (PANDORA).

All these have been possible because to the leveraged strength between the northern and southern partners in the EACCR2.

I commend the entire EACCR team for believing in the work that we do and for utilizing the potential that exists in the networks of excellence. I acknowledge EDCTP for investing in the networks of excellence and for creating avenues for working together to solve problems affecting our communities in Africa.

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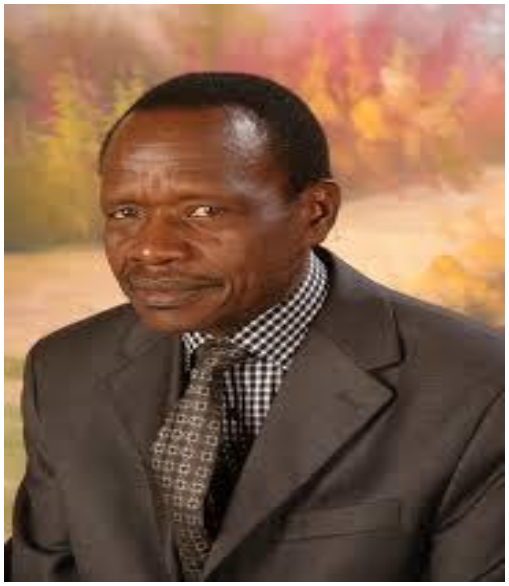
Remarks from the Chairman EACCR2-Steering Committee

I would like to congratulate all partners for the achievements this far despite the anguish, anxiety and uncertainties brought by COVID-19.
I thank the team working on Eastern Africa Consortium for Clinical Research (EACCR2) for prioritizing and continuing to engage in capacity building activities for clinical trials using virtual meetings, innovation and creativity to accomplish activities in the remaining part of the year.

I take the pleasure to remind of the vision of EACCR – which is'' to become a center of excellence in clinical trials with very good quality clinical trials that contribute evidence to policy, practice, and Knowledge to improve wellbeing of communities and fight the poverty related diseases. I applaud all partners for contributing to the attainment of this



Dr Samuel Okware- Chairman(Interim) EACCR2, Steering Committee-EACCR2

The success and visibility of EACCR2 as a capacity building Network funded by EDCTP in Eastern Africa depended much on the investments started by EDCTP 1 and impact created right from EACCR1 in 2009 to the achievements to date.

The idea of working with National Disease Programs in our home countries should be embraced if countries in Eastern Africa are to contribute research evidence for policy, practice and community well being in Eastern Africa. I cordially congratulate the node coordinators and the EACCR2 for the 2 years of project implementation well spent.

I further acknowledge EDCTP and appreciate the support and efforts of the node coordinators and Members of the Steering Committtee for the guidance

I am still hopeful that the partnerships and foundations created will help us realise more traction in the clinical research efforts directed towards social transformation.

Thanks to all members of the steering committee for supporting the vision

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Remarks from the Deputy Coordinator EACCR2

Inspite of the social distancing during COVID-19 pandemic, digital technology has enabled partners to actively work together to accomplish tasks including writing and submitting successful grant proposals in time!

The EACCR2 Training node developed a comprehensive training and mentorship plan for career development fellows, long and short term mentorship exchange programs. All together, 265 people have been trained in 10 different short courses across the network in this project year. Additionally, 4 post docs, 15 students (1 PhD and 14 MScs) are being supported by the consortium for long term training and there were 4 exchange visits for mentorships in laboratory skills in the Malaria node; participants from Ethiopia and Sudan visited laboratories in KEMRI-Wellcome Trust at Kilifi for more skilling

Among the courses offered in the network were the GCP training of trainers' course, and the GCLP training of trainers' course in which a total of 28 participants were trained. More than 50 individuals trained in ICH-GCP and GCLP across the network.

Prof. Blandina Mmbaga is Deputy Coordinator EACCR2

Other short courses offered where introduction to epidemiology and biostatistics, molecular diagnostics, malaria microscopy, research and finance management for project managers among others.

Additionally, the HIV node increased the data holding capacity at Uganda Virus Research Institute by buying additional space for the data servers at the institute and this space is being used by other studies at the institute and within the region.

The EACCR2 developed a data sharing plan and established a data managers' network which is aimed at improving data management across the region.

EACCR's strategic business and sustainability plan was developed with commitment from all partners.

This plan includes use of emails, telephones and other mechanisms of communication to improve the implementation of the project.

The network updated its website to an interactive site which includes social media accounts [@EACCR2]for Facebook and Twitter. These have continued to give EACCR2 vibility in the Eastern Africa region and beyond.

I applaud the entire EDCTP team upon the registered success and also gratefully thank EDCTP for its investment in the networks.

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Training

Building capacity to conduct clinical trials in Eastern Africa - Short- and Long-term training programs.

By Prof Reginald Kavishe-Coordinator Training

The EACCR2 trainig node is based at the Kilimanjaro clinical research institute (KCRI) in Moshi- Tanzania. Prof Reginald Kavishe is the training Node coordinator for the Eastern Africa Consortium for Clinical Research 2 (EACCR2). EACCR2's short and longterm training programmes are coordinated at the 4 Disease nodes [HIV node, Malaria node, TB node, Neglected Infectious Disease (NID) and the Training node].

The training node coordinates all short- and long-term training programs in the network. As the coordinator, my role is to conduct a needs assessment of the required training, identify experts and funding and coordinate the training. The trainings that take place include short courses that cut across the network and long-term training including Post-Doctoral, PhD and MSc training.

The objective of the trainings is to build capacity within the network to conduct ICH-GCP compliant clinical trials. Capacity building started during EACCR1 with some training at masters and PhD level. Most of the students trained at MSc in EACCR1 have moved on to do their PhDs at Universities in Europe with local supervisors and mentorship by professors in the North hence North- South collaboration.

EACCR2 has continued to build on the already existing foundation to maximize the capacity on clinical trials and increase the level of clinical research expertise within the network.

In EACCR1 and 2, capacity building was tailored to include different leading institutions with relatively more expertise in clinical research and less advanced sister sites/ institutions under the leading institutions such that the leading institutions provide expertise and mentorship, in addition to infrastructural upgrades, to elevate the capacity of the sister sites.

Such capacities include GCP and GCLP training, financial management, ethics, clinical research associates (CRA) training through theoretical courses and reciprocal monitoring practicum, cross-cutting laboratory skilling, epidemiology and biostatistics and several others.

Several masters training has been going on within other nodes like HIV, Malaria and NID where mentorship on skills related to specific diseases is emphasized. Also masters in vaccinology in collaboration with University of Lausanne, Switzerland is ongoing to strengthen vaccine development, testing and marketing expertise within the network.

Prof Kavishe was also taken through a case by case question and answering the following questions below:

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Prof. Reginald Kavishe

The vision of EACCR is to become a center of excellence in clinical trials with very good quality clinical trials that contribute evidence to policy, practice and Knowledge to improve wellbeing of communities and fight the poverty related diseases. There are several clinical sites involved in the conduct of clinical Trials were research capacities have been built through training and re-training in the use of new techniques and equipping of laboratories at research sites in the network and all of them have capacity built in over time.

The trainees are attached to sites with anticipation to learn from high quality clinical sites and institutions in every country like Uganda, Tanzania, Rwanda, Sudan, and Kenya. Many of the clinical trials may inform on clinical care to improve the liveliness of Africans because they give good information when it comes to decision making, clinical care to improved vaccines, improved medicines for the region and beyond.

Do you think there is enough research capacity in this region?

Research capacity is not yet enough because if one goes to research institutions and Universities in Europe, America and South Africa or the northern regions capacity is better compared to this. The Eastern Africa region is still lagging and there is need to catch up with the rest of the world through investing in human capital through training, investing in research infrastructure including upgrading and certifying laboratories.

What challenges are faced in research in the region?

Some of the major challenges are lack of research funding and prioritization by governments in Eastern Africa, lack of proper investment in training young upcoming scientists and over dependence on foreign funding for research.

Research in Eastern Africa is predominantly donor funded! This creates a problem of ownersip of the research findingsand translating reserrach into policy and practice;of prioritization of problems of African origin and no existing research agenda. For some of the areas like the trained clinical monitors for example, there is need to have them accredited and registered internationally with ISO and WHO, which is tedious and quite expensive so there is needed to also find funding to pay for their accreditation.

They must take on examinations to be registered. But when governments in Eastern Africa, The Research Commission and East African Community together with partner organizations like EDCTP come together to address such challenges, research in the region can be more beneficial and meaningful and can take us to another level towards realizing the SDGs.

Participant receives award certificate from the Project Coordinator

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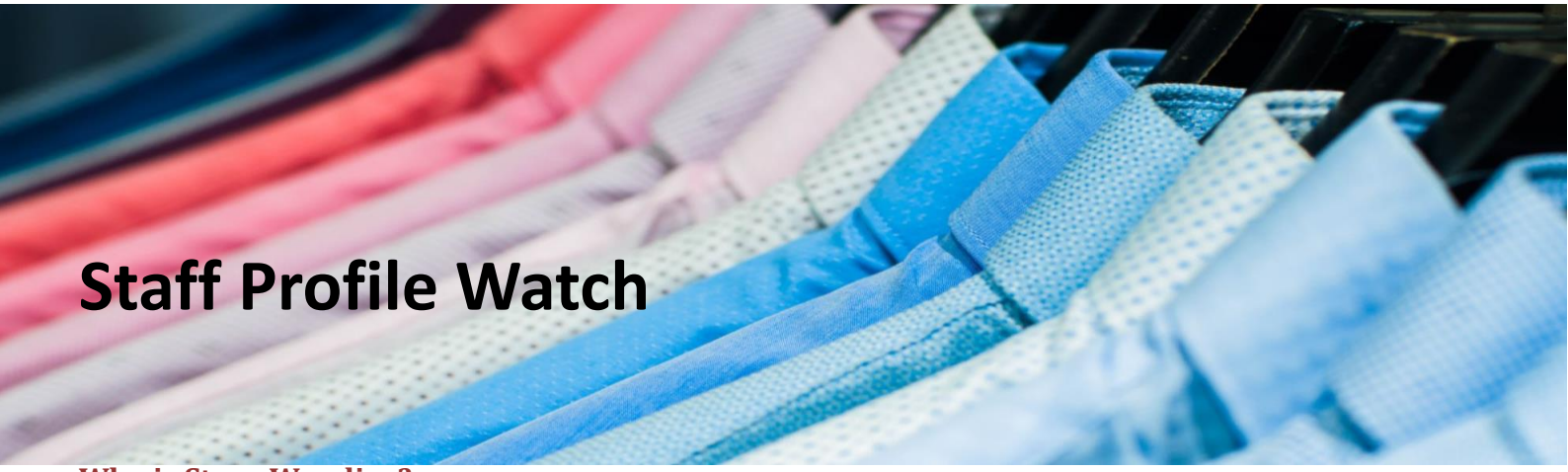


Staff Profile Watch

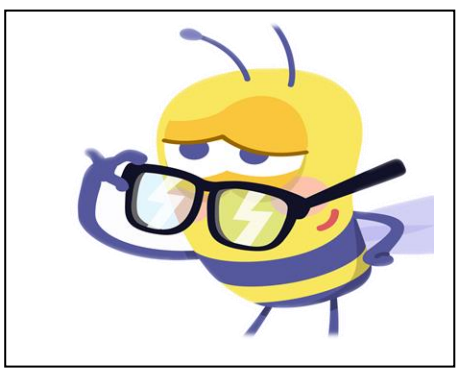
Who is Steve Wandiga?

Dr. Steve Wandiga is now the Acting Director of the Kenya Medical Research Institute (KEMRI) based at the Center for Global Health Research (KEMRI-CGHR) in Kisumu, Kenya He is one of the Senior Research Scientist at KEMRI-CGHR. He holds a PhD in Medical Research (International Health) from Ludwig Maximilian University of Munich, Germany.

Dr Wandiga serves on the TB Node of the Eastern Africa Consortium for Clinical Research, co-chairs the TB Stakeholder Community Engagement Working Group, and is a member of the TB Clinical Trials Infrastructure Working Group. He has also coordinated the East Africa Healthy Pregnancy, Birth, Growth, and Development Knowledge Initiative.

KEMRI-CGHR is one of the partners in EACCR2 and involved in TB, Malaria, NID, Training and HIV node activities. KEMRI-CGHR is part of the reciprocal monitoring scheme. Dr Wandiga joined KEMRI-CGHR in 2007 as part of the team of researchers prepared at the time to prepare staff to conduct TB vaccine trials through epidemiological studies in adolescents and infants.

Currently, he is the Head of Tuberculosis Research at KEMRI-CGHR.



He is also involved as one of the investigators in a multi-site and multi-country study looking at screening for TB actively in selected health facilities where Siaya County is the Kenyan site. Prior to this, he was the Professional Development Program Manager overseeing the preparedness of KEMRI-CGHR as a site for TB vaccine trials.

About his early work on TB at KEMRI-CHHR, Dr Wandiga was tasked with coming up with research modules to train research teams to prepare for TB epidemiology studies. He worked with the team to mimic the clinical trial environment and later moved to the TB vaccine trials under EDCTP framework. This was followed with TB drug trials and operation research as a way of strengthening TB program work within the western region of Kenya.

"Mentoring is very key in the research world, and mentees need to be more proactive in their engagements with mentors to have better outcomes. Mentees need to be inquisitive, self-driven, resilient and keep learning how to receive feedback especially negative." -Dr Steve Wandiga-

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Student Profile Watch

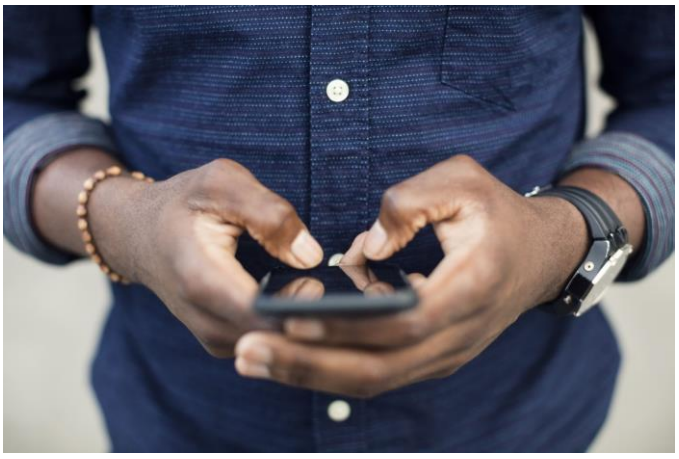
Meet Kennedy Micheal Ngowi

Kennedy is a PHD student from Kilimanjaro Clinical Research Institute. He is pursuing this PhD program at Amsterdam clinical centre on a Carrier Development Fellowship (CDF) funded by EDCTP. The focus of this PHD program is to explore the use of mobile technology (M-Health) health to improve adherence for people taking anti-retroviral treatment.

The study is in Kilimanjaro region in Tanzania and is exploring two interventions which are comparing with the standard of care for HIV treatment. The GHR.

The first intervention is the use of short message service (SMS) text reminders to people living with HIV in Kilimanjaro, Tanzania. The objective was to investigate technical feasibility of sending SMS reminders.

In this intervention we send SMSs three times a week randomly to remind HIV patients to take their medication.



The other intervention is the use of the wise pills devise, where we provide the pill box to the participants. When a participant picks a pill from the box, it sends a signal to us to confirm the participant has taken the medication.

Through these randomised interventions, our focus is to assess whether the real time taking of medication potential to improve adherence to treatment.

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Overview of TB Research in Kenya

EACCR2-TB Node. A case of Western Kenya

By Dr STEVE WANDIGA

In 2018, an estimated 10 million people fell ill with tuberculosis (TB) worldwide and a total of 1.5 million people died from the disease (including 251 000 people with HIV) according to the World Health Organization (WHO 2018). TB is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS). Kenya is one of the 10 high burden Tuberculosis (TB) countries that contribute 80% of the global TB burden. Tuberculosis remains a major cause of morbidity and mortality in Kenya. It affects all age groups but has its greatest toll in the most productive age group of 15 to 44 years. The major factor responsible for the large TB disease burden in Kenya is the concurrent HIV epidemic. In the western part of Kenya, there are factors such HIV and diabetes that are on the rise and that contribute to driving the TB epidemic. For example, there are about 41% of TB-HIV co-infection country-wide but in western Kenya, TB-HIV coinfection ranges between 60-65%. A lot of TB cases are notified in the Western part of the country. Siaya county is among the top 10 counties out of 47 counties in the country with high TB infection rate. The world is grappling with a disease that requires attention so that we combat it from an informed point pf view by conducting research.

What are the likely causes of the high TB burden in the E.A region

The areas around Kisumu lake region has high incidence of HIV; so we know that there is tendency among fishermen to engage in unprotected sexual behavior and reckless alcohol drinking under the background that the following day they will be back to the lake to catch more fish and make more money. The uptake of message that is given by public health and practitioners and communities is low. This contributes to the drive on TB because of the underlying HIV infections.

There is also the epidemiological transition, where we are shifting to non-communicable diseases such as diabetes.

Diabetes is one of the new diseases driving TB infections. Literature shows that diabetic patients are three times likely to contract TB whereas people living with HIV are twenty times more likely to contract TB and therefore some interventions are needed such as prophylaxis (isoniazid) to help prevent to contracting TB. But some programmatic discussions are ongoing on sustainability and issues around resistance that can be developed.

What are the current On-going specific interventions against TB and HIV?

There are 3 million missing TB cases globally, which is an annual figure that keeps piling up and compounding itself so there is need to continuously perform TB symptom screening which is called active case finding. Being part of the team that looked at active case finding within the hospital set up and at the same time looking at what can be done in the community so there arms that are comparing where there high burden of TB. It is found that there is a high rate of TB within the hospitals but there is a strategy where you can trace the contracts of those with TB disease using a list provided by index TB patient of the people they stay around with because it is known that, "TB anywhere is TB everywhere", but because we start from the house and see whether it's possible for the people to get screened on the symptoms and then they provide sputum if symptomatic and so a laboratory evaluation rules out or rule in TB.

Secondly, there is a study taking place in Uganda and the idea is to see how we can be able to put people on Isoniazid Preventive Therapy (IPT), but the idea is not to give it to everyone. It is supposed to be targeted and prioritised for the populations that are more at risk of HIV as beneficiaries so that this can contribute to reducing incidents of TB.

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This is also another regional study within Uganda that will involve screening for TB infection through the blood so that we are able to identify those who are positive for TB infection because these are likely to move from infection to disease, so we want to intervene so that this does not take place. In Kenya we are also planning to have a similar study within one of the counties as pilot but discussions are ongoing within the TB program to see how it is going to be rolled out.

Who are the partners onboard to address the TB Problem?

Being an advocate of networking under the phrase, **"you either network or not work"**. I am a proponent of cross pollination between each other i.e., south to south more so because it is known that boarders are shared and since we are neighbouring countries. There is a study that is going on called "Exit TB", here screening literally is done within the health facility targeting female clients to try to understand whether more screening would highlight more TB that is traditionally associated with males as bearing the brunt of TB epidemic.

So, this is done at the outpatient, maternal child health department, the comprehensive care centers, diabetic clinics, inpatient wards and same time tracing contracts from home and including children such that if they are suspects based on the symptom screening the study seeks stool samples for testing on GeneXpert MTB/RIF to see the yield of TB. The Exit TB study is within East Africa and incorporates 35 study sites in Kenya, Tanzania, Uganda, Ethiopia and Sudan.

There are also the Northern partners who we work closely with in western Kenya such as the US Centers for Disease Control and Prevention (CDC) which supports Ministry of Health and National TB Program retreatment specimen processing within the TB laboratory.

We work collaboratively with other US universities such as Stanford University, Rutgers University, Emory University in very specific TB and TB/HIV research activities. We also conduct some studies together such as clinical trials such as AIDS Clinical Trials Group (ACTG), there some collaborative projects done in the TB-HIV co-infected patients since the two are related and other studies are conducted in terms of understanding the epidemiology of NCDs and infectious diseases jointly.

Prof. Sayoki Mfinanga-TB Node Coordinator

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The interventions taking place to address gaps in research capacity

The research capacity is not where it is supposed to be, that is why there is need for more south to south collaboration even as we seek more northern partners for better networking within research. We need to assess and maintain an inventory of technology in Africa to enhance cooperation and collaboration as we sharpen each other in the continent. Our South-to-South collaboration should be such that whatever is in Uganda, Tanzania, Ethiopia and is not in Kenya, it is made sure that the gap and capacity is bridged so that there is no need of shipping samples to US, yet they can be taken to Dar es Salaam, Moshi or Entebbe or Makerere and it will just be a courier overnight and the samples are worked on. We have seen innovations coming up like placing an equipment for free instead of purchasing but the contract is written such that the cost drivers are purchases of the reagents, equipment calibration and maintenance. As opposed to trying to raise a million dollars for an equipment that is not going to be possible in the environment where we are seeing decreased research funding.

We need to track our needs within South-South axis to know when to raise funds for leasing specific equipment that we direly need.

Where do you see the fight against TB in the next 5-10 years?

There is an urgent need to close-in on missing TB cases, so that would-be transmitters are initiated onto anti-TB treatment. There is an epidemiologic transition where people do not know that they are diabetic because they have not screened, so the health seeking behaviour is still a problem thus men traditionally known to have poor health-seeking behaviour compared to women need to be screened early for TB. Innovative active case finding activities will shape the finding of missed TB cases.

This will facilitate screening at the lowest levels of healthcare so that we identify the missed cases and rid the communities of TB. We look forward to battery driven diagnostic tools that will enable health facilities to also identify non-tuberculous mycobacteria to inform patient management. We look forward to validation of new TB diagnostic tools run against the gold standard of TB culture.

Finally, there has been a launch of new anti-TB drugs which is impressive though we need

to shorten the TB treatment period to less than 6 months to confer anti-TB treatment adherence benefits to the TB patients and possibly reduce multi-drug resistant TB (MDR-TB). We look forward to TB drug trials in this new decade.

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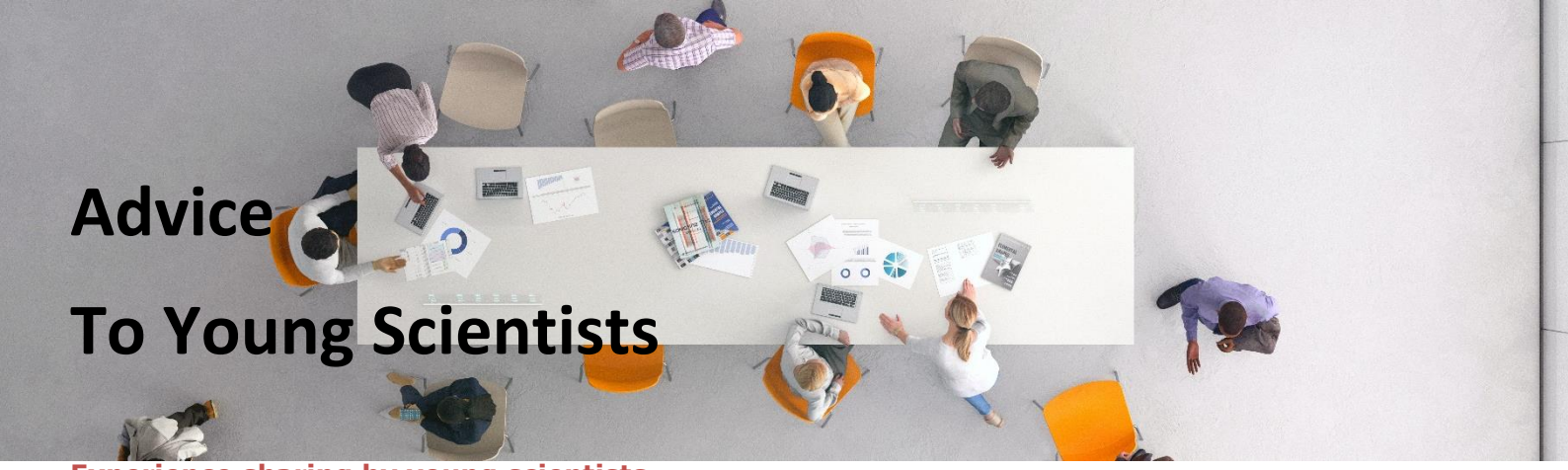

Advice To Young Scientists

Experience sharing by young scientists

Dr Senkoro Mbazi

Science is interesting and without science we could not be where we are for example the first research referred to is one in the Bible where Daniel and the boys were at the King's Palace and there was a comparative study where Daniel and his team were fed on vegetables whereas the other team fed on meat and delicacies.

It was found that the "vegetables group" performed better than the "meat and delicacies group". They were even brighter and had some additional traits that the other group did not have. I would plead with young scientists not to throw in the towel despite the challenges but to stay put as research is exciting and will enable them to contribute to knowledge that needs to be updated in the dynamic environments, we find ourselves living in.

Mentoring is very key in the research world, and mentees need to be more proactive in their engagements with mentors to have better outcomes. Mentees need to be inquisitive, self-driven, resilient and keep learning how to receive feedback especially negative. The ability to take up more tasks with expedient turnaround times positions mentees for greater roles and responsibilities in their career path. Mentors do not stay put in positions but look forward handing over to matured mentees in an elaborate succession planning agenda.

Mentees need to be inquisitive, self-driven, resilient and keep learning how to receive feedback especially negative. The ability to take up more tasks with expedient turnaround times positions mentees for greater roles and responsibilities in their career path.

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Improving Research Capacity : Quality Protocol Reviews

Improving quality conduct for ICH/GCP world class clinical Trials: Investing in quality Protocol Reviews Across the EDCTP NOEs.

By Emily Nyanzi, Mugisha D and Wangoda R

The European and Developing Countries Clinical Trial Partnership (EDCTP) conducted an independent mid-term evaluation of the Networks of Excellence (NoEs) in August 2019. The purpose was to assess the progress with the network objectives in line with the EDCTP strategic plan and the NOE call document of 2015. One of the objectives of EDCTP is to build capacity in conducting ICH/GCP world class clinical Trials and works with NOEs to attain this objective.

The independent consultants cited gaps in the methodologies and protocols for the on-going Clinical Trials in EACCR2 and recommended further capacity building in ethical review. The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)/Pan African Bio-Ethics Initiative (PABIN) scheduled a re-evaluation and training of the Research and Ethics Committees (REC) in Ethiopia- at the collage of health sciences at the Addis Ababa University (AAU) and Armauer Hansen Research Institute (AHRI) on 10th- 14th February 2020, respectively. The purpose of the trainings was to assist RECS (IRB-CHS-AAU and IRB- AHRI) and EDCTP NOE project managers to conduct quality review of research protocols.

The broad objective of the IRB trainings was to assist the board at AAU/AHRI to improve quality of review of research protocols using the five (5) SIDCER Assessment standards. The standards include but not limited to; the structure and composition of the IRB, adherence to international, national guidelines/regulations and specific policies (Standard Operating procedures), completeness of the new review process/quality review assessment, after the approval process and documentation and archiving

Specifically, the training and evaluation set out to facilitate and support procedures to assist the Ethical committees (ECs) towards QUALITY and TRANSPARENCY in ethical review. In addition, the training entailed mock hands-on independent evaluation of the EC and provided feedback on its practices and overall performance to ensure its compliance to international, national, and local standards. The availability of EC written Standard Operating Procedures (SOPs) and its adherence to its procedures was also assessed.

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The four-day training involved the use of the SIDCER/PABIN framework including; an over view of international guidelines for quality research (WNA-Helsinki 1996, CIOMs 1982 and ICH-GCP 2016); National Guidelines like Uganda National Council guidelines (2016) for the case of Uganda; IRB SOPs and SIDCER Survey SOPs and IRB Meeting Minutes

Ugandan participants were exposed to the requirements of a quality review process and all particpants received training materials and SOPs, which can be tailored to serve IRBs in the different NOEs. This means that NOEs can conduct a peer review and evaluation of the IRBs in their networks. The participants also used the training to brain storm about challenges and solutions faced by sites during the implementation of the project activities across networks.

Participants who attended the re-evaluation and training of the Research and Ethics Committees (REC).

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HIV Node Research activities in Kenya

By Francis Angira

Francis Angira is a research officer based at Kenya Medical Research Institute (KEMRI) at the Centre for Global Research (CGHR) based in Kisumu. He speaks to us about his work as a lead of the HIV node activities in Kenya and as a study coordinator.

What does your work entail?

I work in the HIV research division of KEMRI-CGHR in HIV in Kisumu, Kenya. I am an investigator in a couple of trials and a study coordinator, but I also lead the HIV node activities for Eastern Africa Consortium for Clinical Research (EACCR2) in Kenya.

The main aim is to build capacity for clinical research among Kenyans and East Africans at large. Now I manage and coordinate clinic trials, comparing the use of oral HIV Pre Exposure prophylaxis verses Injectable drugs for HIV Pre Exposure prophylaxis to prevent HIV. I work through networks such as EACCR2 and the HIV Prevention Trails Network HPTN.

What challenges do you encounter in HIV work?

The first challenge is the workload. The workload is sometimes too high, but this depends on the seasons. Sometimes you are involved in many studies and must work 18 hours a day on operation work, work on protocols and manuscripts because they are important deliverables for our work.

The other challenge is working with colleagues in different levels. You have certain expectations that sometimes do not end up being met. You need to work hard to get a consensus and pull in one direction.

For example, when you work in clinical research, you have a coordinator who relies on data clerks, clinicians, nurses who also rely on people in the community to mobilize, to bring in what you need for the study. It is a whole chain but sometimes you do not get the best from certain areas, so it can be quite challenging to handle several things.

The other challenge is the area of funding for this kind of work. Basically, we are sustained by funding from donors. Often you have a researcher getting funding from different pots with other sponsors giving 50%, 20%, 10% and when one funding source dries up, you must work to get other sources of funding so that the work can continue. When I joined clinical research in 2002, there was so much funding.

These days the funding has gone down and those providing the funding are tagging it with a lot of deliverables, offering funds on milestone-based payments. For example, some funders give you provisional funds of like 10% or less to start the work and the rest of the money comes in later and this puts a lot of pressure on the researchers. However, some funders are quite flexible.

Do you see trends improving in the HIV fight?

I have worked in HIV for 17 years and there is a lot of improvement in some areas. For example, we have seen improvements programmatically and on the research side. When I joined the HIV world, the prevalence in Kenya was about 10%-11% but now it has come down to 5% nationally and in areas like Mother to Child HIV transmission, the levels have really gone down and we are tending towards elimination, although we have recently seen some little spike.

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When it comes to paediatric, adult care and treatment, we have many people who have been identified as HIV positive, put on care and treatment.
In terms of knowledge in the community, there is a lot of information about how to test and the fact that when one tests positive he/she will need treatment. Quite several people who are HIV positive are on treatment and stigma levels have also come down. HIV testing itself is a prevention, because when one has been tested negative and that individual has been engaging in risk behaviour, that person will tend to be more careful or desist from that behaviour. So, I think in terms of care and treatment in the programmatic world, there is a lot of improvement. This has in a way impacted on the clinical research area especially prevention trials because it is increasingly becoming difficult to find high risk individuals for serious HIV prevention trials. In many cases, even the people who consider themselves high risk individuals like the female sex workers, are aware about the risk of getting HIV and so they are using either of the tools, such as Pre-exposure prophylaxis (or PrEP) and they also get presumptive treatment for Sexually Transmitted Infections (STIs). Some areas which were traditionally favourable destination for HIV prevention clinical trials, are now being shunned because there are no numbers to warrant the studies.

EACCR support in building capacity for clinical research in Kenya

One of the key objectives of the EACCR2 is to identify gaps in terms of infrastructure and staff capacity for clinical trials. We are lucky that EACCR2 came in to support us in this area, for example EACCR2 has helped us come up with a standard tool to identify requirements that an ideal clinic would need to conduct clinical research.

We used the tool to assess two facilities, Jaramogi hospital and Thabitha clinic. At Jaramogi hospital, we were able enhance the staff capacity through clinical research trainings, secured equipment and internet access for the HIV clinic. At Thabilta we upgraded the laboratory to the Biosafety Level 3 (BSL3), and we are planning more trainings and equipment improvements. These interventions have contributed to developing the capacity for the facilities to conduct clinical trials

The next five years with EACCR collaborations within the region

As researchers within EACCR2 consortium, we have been able to come together within the six countries (Uganda, Kenya, Rwanda, Tanzania, Sudan, and Ethiopia) to do joint proposals to enhance clinical research capacity within the region.

I hope to see more south to south collaborations between the six countries because we now understand our research gaps and capabilities of every research site. With increased collaboration we can get multiple funding to expand clinical research within the region to address some of the health challenges.

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Mobile technology (M-Health) health

The use of mobile technology (M-Health) health to improve adherence for people taking anti-retroviral treatment.

By Kennedy Ngowi (PhD student)

How far have you progressed with the study?
The study on the use of Mobile phones to follow up treatment for patients on ART is a three years' study program, but we have completed two years of the study. We have so far enrolled 243 participants (adults) living with HIV who have not adhered to ART HIV and we have followed them up to one year. So far 40% of the people have finished their study visit and what we have observed is that of those receiving the SMS and those using the pill box devices, have shown a positive response to improved adherence to ARVs. This suggests that if we implement the intervention, this could improve the adherence.

What interested you in this kind of research?

I picked interest in this study because of the availability of simple infrastructure. For the SMS intervention, participants use simple phones that can receive the texts. With the use of simple mobile phones, we can cover a large group of participants because statistics show that majority of people who have access to mobile phones use simple phones.

" So far 40% of the people have finished their study visit and what we have observed is that of those receiving the SMS and those using the pill box devices, have shown a positive response to improved adherence to ARVs."

What advice would give to young scientists joining this kind of research?
There is still high potential to explore through working with networks like EACCR. I have seen a lot of advantages because through the networks, for example when I present my work, I receive a lot of support and feedback which helps me improve. As a benefactor of networks, I would urge young researchers planning to conduct studies, to consider working under networks so that they can get the necessary assistance. Mentorship and supervision of students by experienced reserachers in different research institutions and universities in Eastern Africa and Europe

Where do you see yourself after completing your PhD program?

I see myself as an experienced Junior research after this study and research. I have also enrolled at Amsterdam Medical Centre which is one of the advanced universities, so to me this opportunity has presented me with advanced training, improved my research skills and I have also been exposed to world class researchers. I hope that when I finalise my strides, I can share the knowledge and experiences in research management training and scientific writing as well as inspire young scientist in our local institutions.

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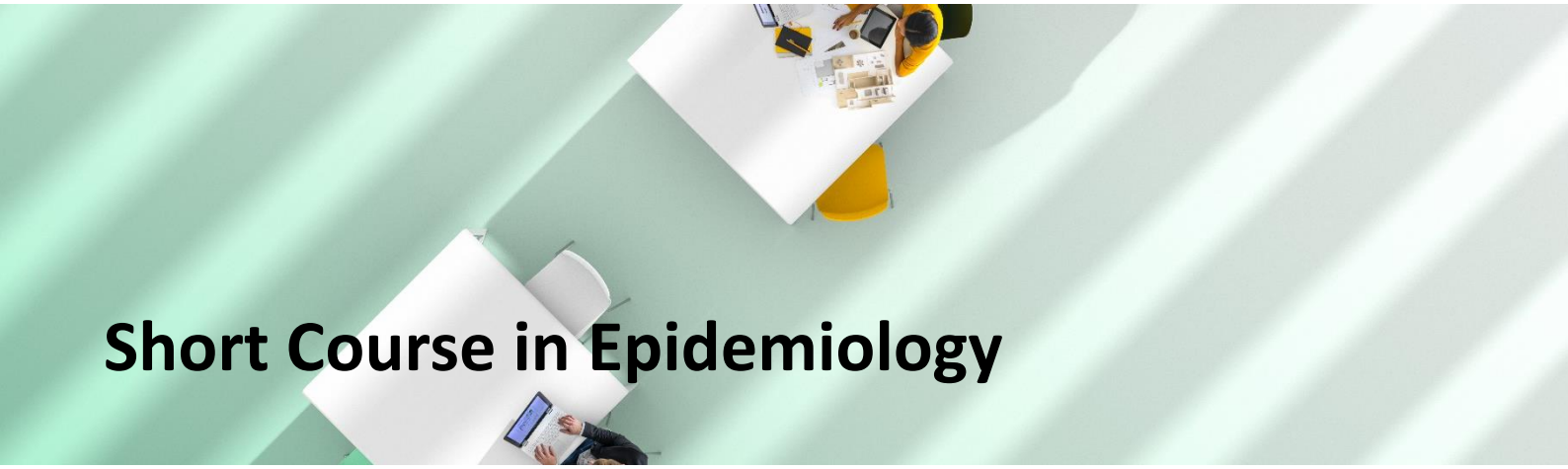

Short Course in Epidemiology

The Eastern Africa Consortium for Clinical Research-2 Epidemiology and Biostatistics January 2020.

By Namuli.S, Mbata .E, Kikaire B, Mudhune. V, Khagayi. S and Wadinga. S

On 27th -31st January 2020**,** the Eastern Africa Consortium for Clinical Research-2 (EACCR-2) conducted a short course in Epidemiology and Biostatistics at the KEMRI Centre for Global Health Research in Kisumu- Kenya.

The course attracted 25 participants from 5 of the 6 EACCR2 member countries: Ethiopia, Kenya, Sudan, Tanzania and Uganda. The course targeted young researchers, Medical doctors, laboratory technologists, Masters' and Ph.D. students who needed the skills in basic epidemiology and biostatistics who had ready data sets.

The purpose of the training was to equip research scientists and students with skills to design studies; calculate sample size, analyze study data and publish scientific papers. The course consisted of intensive learning sessions and hands on practical sessions in Epidemiology delivered by some of the leading Epidemiologists and Biostatistician in the region.

The objectives of the course were; to introduce researchers and students to the theory of Epidemiology and Biostatistics, to provide knowledge and practical skills to design experiments in Epidemiology and Biostatistics research including vaccine research studies, to equip researchers and students with skills to design studies, calculate sample size, analyse study data and publish scientific papers. Seven facilitators delivered the training from KEMRI Centre for Global Health Research in Kisumu Kenya and Uganda Virus Research Institute delivered the course.

The course provided participants with a chance to know one another and the research area they are involved in. Students got a chance to meet experts in data analysis and they were paired up for further assistance.

Participant receiving certificate from the Prof Pontiano Kaleebu

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Research Publications: 1

Clinical Outcomes of New Algorithm for Diagnosis and Treatment of Tuberculosis Sepsis in HIV Patients

Kenneth Byashalira[1,2], Peter Mbelele[2], Hadija Semvua[1,3], Jaffu Chilongola[1,3], Seleman Semvua[1], Alphonce Liyoyo[2], Blandina Mmbaga[1,3], Sayoki Mfinanga[4], Christopher Moore[5], Scott Heysell[5], Stellah Mpagama[1,2]

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Background: Despite effort to diagnose tuberculosis (TB) in the Human Immunodeficiency Virus (HIV) infected population, 45% of adults with HIV that had a previously unknown reason for death, demonstrated TB was the cause by autopsy examination. We aimed to assess the clinical outcomes of implementation a new algorithm for diagnosis and treatment of tuberculosis (TB) related sepsis among PLHIV presenting with life-threatening illness.

Methods: This study is a prospective cohort conducted in three-referral hospitals in Kilimanjaro, recruited 97 PLHIV from February through June 2018. Patients provided urine and sputum samples for testing lateral flow – lipoarabinomannan (LF-LAM) and Xpert Mycobacterium tuberculosis (MTB)/rifampicin (RIF) assays, respectively. Anti-TB was prescribed to patients with positive LF-LAM or Xpert MTB/RIF or received broad-spectrum antibiotics but deteriorated.

Results: Of 97 patients, 84 (87%) provided urine and sputa, and 13 (13%) provided only urine. The mean age (95% confidence interval) was 40 (38–43) years and 52 (54%) were female. In 84 patients,LF-LAM increased TB detection from 26 (31%) by Xpert MTB/RIF to 41 (55%) by both tests. Of 97 patients, 69 (71%) prescribed anti-TB, 67% (46/69) and 33% (23/69) had definitive and probable TB respectively. Sixteen (16.5%) patients died, of which one died before treatment, 73% (11/15) died within 7 days of admission. The 30-day survival was similar in both treatment groups (log rank = 0.1574). Mortality was significantly higher among hospitalized patients compared to outpatients ($P \leq 0.027$).

Conclusion: Implementation of new algorithm increased TB case detection in patients that could have been missed by Xpert MTB/RIF assay. Survival of PLHIV with confirmed or probable TB was comparable to those of PLHIV that were treated with broad-spectrum antibiotics alone. Further work should focus on the optimal timing and content of the immediate antimicrobial regimen for sepsis among PLHIV in TB-endemic settings.

Keywords: Lateral flow, lipoarabinomannan, PLHIV- danger signs, tuberculosis

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Research Publications: 2

Technical and Psychosocial Challenges of mHealth Usage for Antiretroviral Therapy Adherence Among People Living With HIV in a Resource-Limited Setting: Case Series

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Background: Mobile communication has been found to improve antiretroviral therapy (ART) adherence among people living with HIV. In an ongoing randomized clinical trial, 2 mobile communication strategies (ie, sending SMS text messages and real-time medication monitoring [RTMM]) were used to improve adherence to ART among people living with HIV in Tanzania. We noticed remarkable discrepancies between self-reported adherence and adherence recorded by SMS text messaging or RTMM among some of the first trial participants.

Objective: Our objective was to describe these cases and the observed discrepancies in more detail, to serve as a useful illustration of some of the challenges in using mobile health in resource-limited settings.

Methods: In an ongoing randomized trial, adults living with HIV from two HIV treatment centers in Tanzania who were suspected of low levels of adherence were randomly assigned in a 1:1:1 ratio to receive (1) SMS text message reminders, (2) an RTMM device, or (3) no additional intervention to standard HIV care. During bimonthly study visits, the participants self-reported their level of adherence, received feedback about their level of adherence based on SMS text messaging or RTMM, and discussed strategies to overcome adherence problems with nurses providing HIV care. For the purpose of this report, we selected people living with HIV who had completed 5 follow-up visits and consistently reported more than 95% adherence, while SMS text messaging or RTMM recorded lower than 75% adherence. The participants were invited for a short, face-to-face in-depth interview to explore reasons for this discrepancy.

Results: At the time of this analysis, 26 participants had completed follow-up. Six of these evidenced the above-mentioned discrepancies, with an average adherence of 46% based on SMS text messaging or RTMM, while self-reported adherence was 98%. Five of these 6 participants insisted that their adherence to ART was good, with 4 reporting that their adherence to properly using the monitoring device was low. Three participants mentioned concerns about involuntary disclosure of HIV status as a main reason for low adherence to using the device. Two participants were still depending on other reminder cues despite receiving SMS text message or RTMM reminders. Poor network coverage caused low adherence in 1 participant.

Conclusions: Psychosocial barriers were reported as importantly contributing to low adherence, both with respect to use of ART and proper use of the adherence-monitoring device. This case series illustrates that when introducing new digital adherence monitoring technology, researchers should consider psychosocial barriers and distinguish between adherence to device use and adherence to treatment.

Trial Registration: Pan African Clinical Trials Registry PACTR201712002844286; https://tinyurl.com/y98q4p3l ***(JMIR Form Res 2020;4(6):e14649)*** doi: 10.2196/14649

KEYWORDS: mHealth; case series; adherence; HIV; real-time medication monitoring; SMS; antiretroviral therapy

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Research Publications: 3

Social concerns related to HIV status disclosure and participation in the prevention of mother-to-child transmission of HIV care among pregnant women in Kenya.

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Background: Social concerns about unintentional HIV status disclosure and HIV-related stigma are barriers to pregnant women's access to prevention of mother-to-child transmission of HIV (PMTCT) care. There is limited quantitative evidence of women's social and emotional barriers to PMTCT care and HIV disclosure. We aimed to investigate how social concerns related to participation in PMTCT care are associated with HIV status disclosure to partners and relatives among pregnant women living with HIV in western Kenya.

Methods: A cross-sectional study, including 437 pregnant women living with HIV, was carried out at enrolment in a multicentre mobile phone intervention trial (WelTel PMTCT) in western Kenya. Women diagnosed with HIV on the day of enrolment were excluded. To investigate social concerns and their association with HIV disclosure we used multivariable- adjusted logistic regression, adjusted for sociodemographic and HIV-related characteristics, to estimate odds ratios (OR) and 95% confidence intervals (CI).

Results: The majority (80%) had disclosed their HIV status to a current partner and 46% to a relative. Older women (35– 44 years) had lower odds of disclosure to a partner (OR = 0.15; 95% CI: 0.05–0.44) compared to women 18–24 years.

The most common social concern was involuntary HIV status disclosure (reported by 21%). Concern about isolation or lack of support from family or friends was reported by 9%, and was associated with lower odds of disclosure to partners (OR = 0.33; 95% CI: 0.12–0.85) and relatives (OR = 0.37; 95% CI: 0.16–0.85). Concern about separation (reported by 5%; OR = 0.17; 95% CI: 0.05–0.57), and concern about conflict with a partner (reported by 5%; OR = 0.18; 95% CI: 0.05–0.67), was associated with lower odds of disclosure to a partner.

Conclusions: Compared to previous reports from Kenya, our estimated disclosure rate to a partner is higher, suggesting a possible improvement over time in disclosure. Younger pregnant women appear to be more likely to disclose, suggesting a possible decreased stigma and more openness about HIV among younger couples. Healthcare providers and future interventional studies seeking to increase partner disclosure should consider supporting women regarding their concerns about isolation, lack of support, separation, and conflict with a partner. PMTCT care should be organized to ensure women's privacy and confidentiality.

Keywords: HIV, Concerns, Disclosure, Pregnant women, PMTCT, Kenya

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Nordberg *et al. BMC Pregnancy and Childbirth* (2020) 20:225 https://doi.org/10.1186/s12884-020-02907-x

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The Project Year 2019/20 in Photos








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