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In Search of Better Health

07 The perfect storm
How COVID-19 Ravaged
the Lives of the Adolescent

10 UNSEEN
Halting, Reversing the Silent
Epidemic of Cervical Cancer

14 KEMRI new Products
New Malaria & COVID-19
Diagnostic Kits

CONTENTS

04. VACCINATION: CRITICAL FOR THE CONTROL OF COVID-19 IN KENYA	18. KEMRI STAFF SHOWS A RARE SPIRIT OF PATRIOTISM AMID COVID -19 PANDEMIC	26. PICTURE SPEAK	38. HUNDREDS BENEFIT FROM KEMRI SPECIALIZED MEDICAL CAMP IN KIAMBU
07. THE PERFECT STORM: HOW COVID-19 RAVAGED THE LIVES OF THE ADOLESCENT.	20. DR. MONIQUE WASUNNA FETED FOR EXEMPLARY WORK IN NEGLECTED TROPICAL DISEASES (NTDS)	28. THE PROPOSED AMENDMENTS TO THE NHIF ACT ARE AN IDEA WHOSE TIME HAS COME	40. A GLEAM OF HOPE AS KEMRI LAUNCHES A STUDY ON CHILD BILHARZIA DRUG.
10. UNSEEN: HALTING, REVERSING THE SILENT EPIDEMIC OF CERVICAL CANCER	21. KEMRI HOSTS THE COVID-19 DRUG DEVELOPMENT CONSORTIUM	30. KEMRI STRENGTHENS REGIONAL LABORATORY CAPACITY IN AFRICA	44. WHO REPORT PROPOSE TOUGH MEASURE IN TOBACCO USE IN KENYA.
12. KEMRI'S CONTRIBUTION TO THE GROUND BREAKING RTS,S MALARIA VACCINE	22. NEW LINK BETWEEN MALARIA GENETICS AND SICKLE HAEMOGLOBIN IDENTIFIED	32. THE KENYA HEALTH & RESEARCH OBSERVATORY (KHRO) COMPANY	46. KEMRI'S NOVEL HERBAL FORMULATION AGAINST WORMS PROVES PROMISING.
14. KEMRI UNVEILS NEW MALARIA & COVID-19 DIAGNOSTIC KITS	24. TYPHOID CARRIAGE IN CHILDREN HIGHLIGHTS NEED FOR VACCINATION IN KENYA	34. THE INSTITUTE BESTOWED WITH A FOREST PROTECTION AWARD	48. LETTERS TO THE EDITOR Prayer and Healing - <i>Any Scientific Evidence?</i> National Scientific Conference on Miraa Made a case for Miraa Farmers
16. KEMRI LAUNCHED 4 COVID-19 RELATED PRODUCTS IN KENYA	25. AN OVERVIEW OF KEMRI'S KNOWLEDGE MANAGEMENT	36. MIRAA SCIENTIFIC CONFERENCE	52. KEMRI SCIENTISTS SCOOPS REGIONAL AWARDS



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VACCINATION: *Critical for the Control of COVID-19 in Kenya*

By Prof. Matilu Mwau

The Deltacron variant of coronavirus was first reported in Cyprus in late 2021 and widely considered a lab error. However, in the mid-February 2022, there were reports that the Deltacron variant had been detected in Britain, perhaps emerging independently in a patient who had been infected with both the Delta and the Omicron variants. It is unclear whether Deltacron is as infectious as Omicron or as deadly as Delta.

Seeing how lethal some variants have been, it is easy to despair on hearing this news. However, the fact that we have effective public health measures that protect us, and vaccines that are safe and effective even against variants of concern, should give us hope.

Modern man has been grappling with infectious diseases for at least 300,000 years. In fact, infectious diseases have been major actors in human history. The fact that germs can cause and spread disease was known at least 500 years before Christ. However, it was not until the 20th Century that sanitation, nutrition, and the widespread use of antibiotics and vaccines became major factors in the decreased incidence of numerous diseases and associated deaths.

Of these interventions, vaccination is considered the most powerful public health tool ever invented. Currently, at least 45 vaccines are available for up to 25 infectious agents. Even though they remain underutilised and undervalued, vaccines

prevent three million deaths annually. For each dollar used to vaccinate someone in Africa, 44 dollars are saved. In America, each dollar used saves 3 dollars.

In 1980, vaccination eradicated smallpox. Wild type polio and Hemophilus Influenza B have almost been eradicated in many regions. It is conceivable that vaccines will eradicate human papilloma virus, which causes cancer of the cervix, and malaria, which kills 11,000 Kenyans a year, in our lifetime.

Even though vaccines have been available for almost a century, they were not always accessible to those who needed them the most. Expanded programs on immunisation became commonplace only recently. Many of those born in the 1970's were not vaccinated. I myself was not, and bore the full brunt of measles, mumps, and chickenpox. USAID noticed my level of malnutrition and gave me Bulgur Wheat, Soy bean Oil, Powder Milk and Enriched Porridge Flour for a long time at Nazareth Hospital. I could have died, but I was lucky. Some of my playmates were not so lucky. Those who got polio were paralysed and those who got tuberculosis died.

One of the greatest achievements of modern man has been to design, test and bring COVID 19 vaccines into use within a year since the SARS CoV-2 pandemic began. The reasons for this are many, but chief amongst them is the fact that

“there are no plausible mechanisms by which COVID-19 vaccines can cause infertility or miscarriage”.

the immunology of SARS CoV-2 is “simple” to understand. Vaccine science has evolved rapidly due to the dogged pursuit of solutions for other disease that are quite complex including HIV, and Ebola, and this has helped accelerate the development of COVID-19 vaccines.

There are at least twenty-four available vaccines for COVID-19. As of Mid-February 2022, 56.1% of all humans had been fully vaccinated. And not just that: almost 3% of all humans had received a third dose. In contrast, 15.6% of all Kenyans had been vaccinated by mid-February 2022. This is only a third of the worldwide average. And all this is in spite of the fact that we know so much about COVID 19 Vaccine safety and effectiveness.

We know that it takes up to two weeks after full vaccination for the body to build sufficient immunity to SARS CoV-2. And this immunity is still good enough more than six months after vaccination. Data is beginning to flow in large quantities from all over the world showing just how effective some of these vaccines have been. For example, Argentina began to vaccinate its elderly residents and front-line workers in Buenos Aires in December 2020 with Sputnik V, ChAdOx1 or Sinopharm vaccines. In more than 663,000 vaccinated people, a 2-dose vaccination schedule reduced documented infection by 88.1% and COVID-19-related death by 98.3%. Even a single dose is very protective, reducing documented infection by 47.2% and COVID-19-related deaths by 74.5%. Our own scientists have shown that COVID-19 vaccines have been

very effective in preventing illness and death in vaccinated Kenyans.

COVID vaccines prevent serious illness and death even when a vaccinated person gets infected. Breakthrough infections occur when antibody levels begin to decline, but serious illness and death is prevented by the cell mediated immune responses that the vaccines induce.

COVID-19 vaccines are very safe, even in children. None of the vaccines available today can cause COVID-19. The Ministry of Health keeps detailed records of side effects to COVID-19 vaccines. These records show that most people have no side effects from COVID-19 vaccines at all. Some people may get side effects that may affect their ability to function normally, but these disappear in a few hours to a few days. Side effects are normal signs that the body is building protection.

Reactions to COVID-19 vaccines that can lead to death are extremely rare. Blood clots are rare. In Thailand, not even one clot was seen after 1.7 million injections. In the United States, 54 clots were seen after injecting 16.4 million doses, and all were treated successfully. In contrast, clots are seen in 20% - 40% of all people who get COVID-19 disease itself, and they often cause death. In Kenya, it has been almost impossible to pinpoint a single death caused by COVID-19 vaccines amongst the almost seven million injections given so far.

There are numerous urban myths and rumours surrounding COVID-19 vaccines. First of all, there are no plausible



mechanisms by which COVID-19 vaccines can cause infertility or miscarriage. Thousands of pregnant women have been vaccinated worldwide without any ill effects. COVID-19 vaccines have been given to millions of breastfeeding mothers safely as well. The vaccines do not cause a reduction in libido. In fact, in men, COVID-19 diseases itself causes short term and long-term failure to erect.

Getting vaccinated has always been a big challenge for many people. Even for me, despite the fact that I am a doctor, I fear needles very much, and at least three strong men must hold me down for an injection to be given. I bite, kick and scratch. Equally I become quite sick when vaccinated with anything; it is just how my body works. I fully appreciate that most men are as afraid of needles as I am. As a scientist and infectious diseases specialist, I know that COVID has killed disproportionately more men, and rendered many others impotent. I am proud to say that I have received the full dose of Sputnik and two doses of Moderna.

It is highly likely that the vaccines that are available now will continue to be effective against future SARS CoV-2 variants of concern. Without widespread vaccination, Kenyans cannot avoid death or serious illness in the future. I strongly recommend that all Kenyans aged 15 and above get vaccinated.

Prof. Matilu Mwau explains how the Cobas 8800 automated testing machine works



Prof. Mwau is an infectious diseases researcher at the Kenya Medical Research Institute and a Visiting Professor, Nagasaki University.



The perfect storm:

How Covid-19 Ravaged the Lives of the Adolescent.

By. Dr. Maricianah Onono

Adolescence is a critical developmental stage where adolescents experience biological, cognitive, psychological, behavioral and social development. While the impact of Coronavirus (COVID-19) disease on global development agendas has been thoroughly debated, little light has been shed on the impact on this important age group. Beyond getting sick, many adolescents' social, emotional, physical, reproductive and mental well-being has been impacted by the COVID19 pandemic. It is likely that the indirect and direct effects of COVID-19 faced at this critical developmental stage may have long-term consequences across their lifespan. Over the last several years, I have had the privilege of working and conducting research with large cohorts of adolescent girls and thus had a front row seat into their lived experiences as well as that of their peers and families. This article draws from this experience during the pandemic period.

For most of us, when we think about COVID-19 and adolescents—we think about the high and almost immoral figures of teenage pregnancies reported, the conflation of parental and teacher roles for our sons and daughters brought on by the school closures and more recently the burning of schools and dormitories occasioned by the school re-opening. In this article I posit that through a mix of direct and indirect pathways, COVID-19 created a perfect storm for the illumination of the heretofore neglected sexual reproductive and mental health rights and needs of adolescents. Below I highlight some of the challenges experienced by adolescents during the COVID-19 pandemic and demonstrate how this created a perfect storm for increased teenage pregnancy and poor mental health.

Challenges experienced by adolescents during the COVID-19 pandemic

1. Change in routines: The lockdown and movement restriction implemented in March 2020 in Kenya resulted in changes in social routines. While social and physical distancing are good Non-Pharmaceutical Interventions (NPIs) to avoid being exposed or spreading the virus, the need to keep a physical distance conflicts with adolescents' natural desire to connect with friends and with other important people in their lives. This disconnection has been shown to deepen the loneliness that has already been documented among young people and especially adolescent girls. The change in routines also deprived adolescents of various kinds of support. These include tangible support with items such as food or medicines, sanitary towels, emotional support and guidance, and social protection provided by schools. For example, I found that because my name and phone number was on the research consent forms, I received calls and WhatsApp messages of girls just wanting to chat, asking

when we will reopen the clinic or visit them or simply asking if they could just drop by the clinic to say hello and see the world "kuona nje" or not to be forgotten. They just wanted to connect.

2. Interruptions in continuity of learning: COVID-19 created the largest disruption of education systems in history, affecting nearly 1.6 billion students in more than 190 countries. School closures due to COVID-19 meant that adolescents were grounded at home. While the government was quick to adopt online, television and radio platforms to provide alternative education routes for students, in many rural areas and among the urban poor, access to the required resources and gadgets such as electricity, Internet, computers, smartphones, television and radio was a challenge. Adolescent students in these rural and urban poor settings were therefore deprived of such interventions, resulting in their academic progress being left behind as learning stopped. On the flip side, even those able to join classes via zoom often complained of "zoom fatigue" and many parents just stopped requiring their children from attending these classes.

In addition school closures did not just result in interruptions of learning, but also impeded access to co-curricular and development activities such as music, drama, athletics and games. Given the centrality of these extra-curricular activities in the growth and development of adolescents, one can say that the pandemic indirectly impacted on the development of athletic or hands-on vocational skills, with potential impacts on their higher education and professional future.

Even when schools began to reopen, adolescents expressed anxiety about re-integration, and re-connecting with peers and teachers. There was anxiety about having been left behind by not participating in online classes and missing out on trends and world matters. In a survey by Population Council, only 89 percent of the adolescent students felt confident that they would return to school. The remaining were not able to return to school during the reopening of schools and post COVID-19 owing to the heightened poverty (not being able to afford fees or extra costs for things like exams, uniforms and transport) as well as the numerous hardship related teenage pregnancies that occurred in this period.

3. Break in continuity of health care:

COVID-19 extensively strained the global healthcare system through the cutting of funds, diversion of staff and conversion of facilities to provide COVID-19 treatment, isolation and quarantine services. In Kenya, hospitals saw a decrease in volume of patients seeking services. Parents may have avoided seeking

health care for their children (including adolescents) due to the movement restrictions as well as fear of getting sick with COVID-19. This includes important well-child visits, immunizations and oral health care or specialised services such as mental health and occupational health services. A good example would be the uptake of HPV vaccination in the country. Prior to the onset of the pandemic, the Ministry of Health had just rolled out facility based HPV vaccination for girls aged 10 years. Across board, there were reductions in girls receiving this important vaccination. Similarly an analysis of data for the first four months (March-June) of the pandemic and the equivalent period in 2019 demonstrated rising teenage pregnancy rates with a rising adolescent maternal mortality rates but decreased maternal mortality amongst women aged 20 years and above. This high teenage pregnancy overlapped with the de-prioritization of reproductive health services including stock outs of contraceptives. In fact during this period, many effective long acting reversible contraceptives were not available resulting in the use of short acting and user dependent methods such as combined oral contraceptives.

4. Loss of security and safety: Related to the movement restrictions, many households experienced job loss and lost wages that affected the household income. Many studies including those by KEMRI have demonstrated that financial insecurity is linked to adverse development, academic achievement and health (physical and mental) outcomes. Adolescents in households impoverished by COVID-19 NPI were also exposed to food insecurity, unsafe housing and violence (emotional, physical, sexual). For instance, media reports revealed a spike in gender



based violence and exploitation as well as abuse and neglect in Kenya during COVID-19 related emergency lockdowns, school closures and the concomitant isolation and quarantine. Finally, the increased online activity among adolescents with access also put them at increased risk for online harms, such as online sexual exploitation, cyber-bullying, online risk-taking behaviour, and exposure to potentially harmful content.

Impact on health: increased teenage pregnancies and poor mental well-being

Evidence from the ongoing COVID-19 pandemic as well as previous pandemics such as Ebola reveal possible critical negative mid and longterm impacts of COVID-19 on adolescents such as widened inequality gap in adolescent health, educational and psychological well being, and loss of social and human capital (potential protective health assets). Here, I discuss mental health and teenage pregnancies as exemplars of the impact of COVID-19 on adolescent health.

5. Poor Mental Health: A survey by the Population Council in Nairobi's informal settlement found that nearly half of the adolescents (46 percent) reported having felt down, depressed or hopeless at least once in the past two weeks. The vast majority of respondents (81 percent) said they felt threatened, concerned, scared or anxious because of COVID-19. Most respondents (87 percent) and in particular the younger adolescents also worried that they or their loved ones will be infected with COVID-19. For older adolescents the main reason influencing their current emotions was the economic situation. While this survey did not explicitly ask if the adolescents sought care, several other surveys done by UNICEF in other regions showed that less than half (46 percent) of adolescents experiencing adverse mental well being actually talked to someone about it. From a mental health perspective, one can posit that adolescents struggling with panic, stress, post traumatic stress disorder and extreme anxiety arising from their experience of the pandemic predisposes adolescents to deviant behaviour.

6. Teenage pregnancies: Similarly, this period showed an increase in teenage pregnancies. Experts projected that COVID-19 would result in over 15 million additional unintended pregnancies globally, many of which will occur among teenage girls. At the height of the pandemic, our local health facility in Kisumu was seeing 2-3 pregnant adolescent girls every day. During this period, I gained an unholy familiarity with the Police, Department of Child Services, Child Protection Services, rescue homes, shelters and FIDA. In reflecting on this issue, my mentor Prof. Elizabeth Bukusi (KEMRI-CMR) pointed out that these are social problems presenting as medical issues. And she is right!



Collectively, all the challenges listed above provided a perfect storm for unintended pregnancies. To put it into context, on one particular day, I was called by a health care worker to provide referral and linkage to a mother presenting to the sub-county hospital frantic---both her daughters (ages 14 and 17) were pregnant and of the same man, a relative who was housing them while the mother worked away from home. For these two girls, a combination of the lockdown, closure of schools, sexual violence, poverty, lack of family support and de-prioritization of sexual and reproductive health services and shortage of contraceptive commodities provided a perfect storm that resulted in unwanted teenage pregnancy.

Conclusion

For many adolescents, the direct COVID-19 health risks ranked behind the indirect but multiple complex and larger concerns of personal safety, economic and food insecurity, concerns of future planning and other health concerns such as mental health and access to reproductive health services. When put together, these effects may have deleterious lifecourse consequences for adulthood. Post-pandemic there is an urgent need for research and policies that offer social protection interventions targeting adolescents' social, economic and educational empowerment and that employ a life course approach.

Dr. Onono is a Reproductive Health Scientist working at the Centre for Microbiology Research (CMR) in KEMRI

UNSEEN: Halting, Reversing the Silent Epidemic of Cervical Cancer

The disconsolate Journey of Resilient KEMRI Scientists who beat all odds In Search of a Cervical Cancer Vaccine in Kenya

By Dr. Maricianah Onono

In the long rain season of 2008, I arrived in Muhuru bay as a medical officer and research scientist. I felt at home as I was no stranger to rural Kenya, having just come from Kapsowar in Marakwet. Unlike the lavish forest cover and red soils of Marakwet, Muhuru was dry, sandy and despite the rains, it was hot and heavenly -reminding me of Liter Valley in West Pokot where I had worked. It had been a two- and half-hour ride from Migori to Muhuru. For orientation, Muhuru Bay, is a small fishing village in the former Nyanza Province on the shores of Lake Victoria near the border of Tanzania.

I was young and energetic. I was here to conduct research on how HIV associated stigma affected utilization of maternal health services. As I donned my white coat and prepared to tackle the long line of waiting patients, a lady approached me and tagged me aside and whispered, "sister naomba unione leo?"

Even before I asked for her file, a sense of foreboding filled me. Every gynecologist or medic who has rotated in the gynecology wards would recognize the rotten meat smell. I asked the nurse to lead her to the only examination room at the facility. I wanted to "see" her. I asked for her file, I saw that she had been to the clinic every month without fail for her HIV care and was doing well. Despite repeatedly complaining about a mass in her genitalia, a foul-smelling discharge, bleeding when having sex... No-one had "seen" her i.e. done a pelvic exam. And when I did, there was a large fungating, bleeding lesion. In her own words she said, "vile umeniona, naona nimepona. Unfortunately for her, the disease was advanced and we had only one gynecologist in the former larger Migori. She could barely afford transport to the hospital and while colleagues and I raised money to get her to Migori District Hospital, she appeared to be all alone-no social support. She narrated how she could not stand the odor that accompanied the disease, so she had isolated herself from her children, her family, wanting to be alone. In fact after several

of her to weeks begging come to the gynecologist, we put her brought her alternated in Unfortunate this wife and mother of four died, alone. She was only 41 years of age. Even the HIV that had first brought her to hospital, had not been the final axe bearer.

When I think about this lady, I see all the barriers and delays that confluence to make cervical cancer such a lethal disease for women. I see so many missed opportunities that could have changed her trajectory. Cervical cancer is a leading cause of cancer-related death amongst women in sub-Saharan Africa. In Kenya, cervical cancer is the second most common cancer in women but the most common cause of cancer deaths. Current estimates indicate that every year 5,236 women are diagnosed with cervical cancer and 3,211 die from the disease. To put it into context, the equivalent of one *Nyauyenia* or *Easy Coach* or *Mombasa Raha* (insert your favorite bus) crashing and killing all its occupants every week for a year. *And yet there is no furor!*

The Human PapillomaVirus (HPV) is the main cause of cervical cancer. HPV is a common virus that is passed from one person to another during sex. Most sexually active people will have HPV at some point in their lives, but few women will get cervical cancer. Other factors that can increase the risk of cervical cancer are intimacy at an early age, multiple sexual partners, sexually transmitted diseases, HIV and cigarette smoking. **Cervical cancer is preventable and curable in early stages through primary, secondary and tertiary interventions involving vaccination, early diagnosis and treatment.** In developed countries, screening and immunization has led to a marked reduction in incidence and mortality from cervical cancer.



There are approved vaccinations in the market including multiple country programs. However, roll out among Low and Middle Income Countries (LMICs) has been poor, and even where it has been rolled out like in Kenya—the uptake has been poor. In LMICs, low vaccine coverage is due, in part, to the cost and logistics of reaching girls with standard multi-dose vaccine schedule; single-dose vaccination would halve vaccination costs, potentially increase coverage and simplify the logistics compared to multidose administration. Observational studies suggest that single-dose HPV vaccine effectiveness is equivalent to a two- or three-dose regimen; however, vaccination guidelines recommend multidose strategies and questions persist regarding single-dose efficacy.

Towards the end of 2018, an all-female team of investigators led by Prof Ruanne Barnabas, Prof Nelly Mugo (protocol chairs), Prof Elizabeth Bukusi, Dr. Betty Njoroge and myself begun conducting the single dose HPV study in Kisumu, Thika and Nairobi. In the trial, women 15 to 20 years old were randomly assigned a therapy and followed from December 2018 to June 2021:

- 760 received a bivalent vaccine that covered two strains of HPV (16/18), which represent 70% of cases;
- 758 received a nonvalent vaccine that covered seven strains of HPV (16/18/31/33/45/52/58), which represent 90% of cases;
- 757 received a vaccine that protects against meningococcal meningitis.

The majority of participants (57%) were between 15 and 17 years old and most reported one lifetime sexual partner (61%). To be eligible, participants needed to be sexually active, have no more than five lifetime partners, be HIV-negative, and have no history of HPV vaccination.

After 18 months, the bivalent vaccine was 97.5% effective against HPV 16/18 and the nonavalent vaccine was 97.5% effective against HPV 16/18. The nonavalent vaccine was 89% effective against HPV 16/18/31/33/45/52/58. Even if women tested positive for one strain of HPV, the vaccine protected them from other strains of the virus.

In the words of Prof Nelly Mugo a senior principal clinical research scientist with the Center for Clinical Research at KEMRI. "This trial brings new energy to the elimination of cervical cancer. It brings great hope to the women living in countries like Kenya, who have a high burden of the disease." Practically speaking, a single dose vaccine regime would 1) Simplify the logistics and costs of delivery of the HPV vaccine; 2) Expand the cohorts being provided for from just 9-14, to 15-20 -a multi age cohort approach can accelerate elimination of cervical cancer. Moreover, at the population level increasing vaccine coverage increases effectiveness; vaccination of multi-age adolescent cohorts (9-14 years) with catch-up vaccination (to age 26 years) would **doubly accelerate** the prevention of HPV-associated precancerous lesions

We are excited about these findings and the buzz and momentum that it brings towards accelerating prevention and elimination of cervical cancer. Already we are seeing momentum towards global policy change. Most recently, the Joint Committee on Vaccination and Immunization (JCVI), an expert scientific advisory committee which advises the UK government on matters relating to vaccination and

immunization, "agreed that there is now enough evidence to advise a change in the schedule from 2 doses of HPV vaccine to one dose in the routine adolescent programme for children aged up to (and including) 14 years of age." We are hopeful that our work will also catalyze similar policy changes in Kenya. In the interim we continue to follow up our cohort of girls to assess the single dose vaccine durability over a period of 5 years.

While the memory of the unseen Muhuru bay lady lingers in my mind, our goal is that her daughters and many other unseen daughters of Kenya do not develop cervical cancer, and if they do, that we catch the lesions early, link to care early and get good treatment outcomes. Indeed cervical cancer is a highly preventable and treatable type of cancer if all measures from screening programs, HPV vaccination to early and effective treatments are put in place. I hope and believe that I will see cervical cancer eliminated in my lifetime.

Dr. Onono is a qualified medical practitioner and research scientist with over ten years hands-on work experience in HIV and Sexual Reproductive clinical, program and research management.



KEMRI's Contribution to the Ground Breaking RTS,S Malaria Vaccine

By Dr. Samuel Akech and Dr. Simon Kariuki

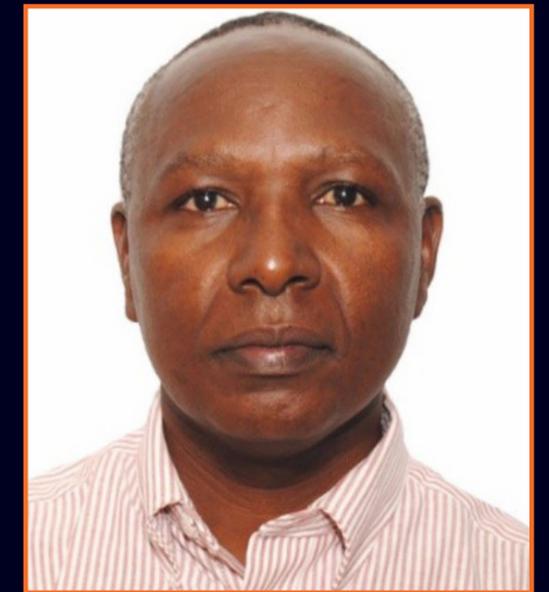
In a landmark announcement in October 2021, the World Health Organization (WHO) recommended widespread use of the RTS,S/AS01 (RTS,S) malaria vaccine among children in sub-Saharan Africa and in other regions with moderate to high malaria transmission. This recommendation was based on results from a pilot programme in Ghana, Kenya and Malawi that started in 2019. By October 2021, 800,000 children had been vaccinated in the pilot programme.

Data generated from the pilot programme showed that delivery of the vaccine within the routine childhood vaccination programme is feasible, there is high uptake and the vaccine helped to increase equity in access to malaria

prevention in vaccinating areas. The pilot findings also reaffirmed the vaccine's safety profile and substantially reduced incidence of clinical and severe malaria in areas where it was deployed.

Commenting on this historic moment, the WHO Director-General Dr Tedros Adhanom Ghebreyesus said, **"The long-awaited malaria vaccine for children is a breakthrough for science, child health and malaria control," "Using this vaccine on top of existing tools to prevent malaria could save tens of thousands of young lives each year."**

The development of the RTS,S malaria vaccine has a long and chequered history spanning



more than 30 years. It was created in 1987 by scientists at GlaxoSmithKline (GSK) laboratories. In early 2001, GSK and PATH Malaria Vaccine Initiative, supported by the Bill & Melinda Gates Foundation, entered into a partnership to develop the vaccine targeting infants and young children living in malaria endemic regions of sub-Saharan Africa. After evaluating the vaccine in several small clinical trials both in the US and Africa, the decisive moment came in 2005, when the RTS,S was shown to prevent malaria among children in Mozambique. Encouraged by these findings and the need to try the vaccine in areas with different malaria transmission settings, a large phase 3 trial was undertaken between May, 2009 and January, 2011 at 11 sites in 7 African countries-Kenya, Tanzania, Malawi, Mozambique, Gabon, Ghana and Burkina Faso. The trial enrolled 15,459 children in two age groups, 6-12 weeks and 5-17 months. Children were randomized 1:1:1 to receive either a control vaccine (C3C), three doses of RTS,S plus control vaccine at 18 months (R3C), or three doses of RTS,S plus a fourth dose of RTS,S at 18 months (R3R)- see figure below.

This pivotal phase 3 trial showed that, among the older children, in the 12 months following administration of the first 3 doses, vaccine efficacy against clinical malaria (uncomplicated and severe) was 51% and against severe malaria was 45%. Over a median of 46 months' follow-up after the third dose, in children who received a fourth dose 18 months after the third dose, vaccine efficacy against clinical malaria was 39% and 29% against severe malaria. Over the same period, the vaccine reduced

severe malarial anaemia by 61% and the need for blood transfusions by 29%.

Based on the phase 3 results, the vaccine received positive scientific opinion from the European Medicine Agency (EMA) in 2015. In 2016, WHO recommended that RTS,S be further evaluated through a pilot programme to address a number of key questions mainly on safety, feasibility and impact on preventing deaths in children. WHO recommends that the RTS,S malaria vaccine be used for the prevention of *P. falciparum* malaria in a schedule of 4 doses in children from the age of 5 years living in regions with moderate to high transmission in the context of comprehensive malaria control plans. The addition of RTS,S in the current arsenal of malaria control interventions could be a game changer in the fight against malaria.

Samuel Akech, MD, PhD and Simon Kariuki, PhD are Research Scientists based respectively at KEMRI- Kilifi and Kisumu Centres.

**L. Dr. Samuel Akech
R. Dr. Simon Kariuki**

KEMRI Unveils New Malaria & COVID-19 Diagnostic Kits

KEMRI recently launched two key diagnostic Kits against Malaria and COVID-19 adding to an array of locally manufactured reliable innovative kits by the Institute.

The kits, the KEMCoV-19 RT-PCR and the Plasmochek RTD were formerly launched during the 12th KASH pre-conference by Cabinet Assistant Secretary (CAS) Dr. Rashid Aman on behalf of the Cabinet Secretary, Hon. Mutahi Kagwe.

Four months into the pandemic, KEMRI launched 4 COVID related products during the familiarization visit to KEMRI- Kilifi by the Parliamentary Committee on Health on 18th June 2021. The products included the VTM, KEMrub Hand sanitizers, TBcide, KEMiZyme, Proficiency Testing kits among others (More details in a related article). Brief details of the new products are:



1. KEMCOV-19

The KEMCoV-19 kit is RT-PCR amplification kit that is intended for qualitative pathogen detection and characterization of SARS-CoV-2 RNA. The kit is designed to work with total nucleic acid isolated from nasopharyngeal and/or oral pharyngeal swab. The mode of action of this kit is through Reverse Transcription of the viral RNA into DNA which is then amplified through Real Time PCR. The detection of viral RNA is done through the positive amplification of part of the viral genome. The genes targeted by this kit include E gene, an envelope protein and ORF1ab gene. The reaction is controlled by a gene known as RnaseP which is expressed in the human genome.

The kit contains standardized master mix buffers, assay primer/probes that targets SARS-CoV-2 gene in the ORF1ab gene and E Gene, an internal control (IC) assay that targets the Human gene and positive Control. The sensitivity and specificity of the KEMCoV 19 RT-PCR assay has been evaluated for plasma procedures by testing 200 COVID-19 seronegative plasma specimens. The kits is local produced and is 100.0% sensitive and 100.0% specific.

2. PLASMOCHECK mRDT

Plasmochek is a Rapid test Kit intended for qualitative pathogen detection of the malaria causing parasites Plasmodium falciparum, P. vivax, P. ovale, and P. malariae.

The Plasmochek Malaria Pf/Pan Antigen Rapid Test utilizes antibodies specific to P. falciparum Histidine Rich Protein II (pHRP-II) and to P. Lactate Dehydrogenase (P-LDH) to simultaneously detect and differentiate infection with P. falciparum, P. vivax (Pv), P. ovale (Po), or P. malariae (Pm) antigen in human blood specimen. The test can be performed by untrained or minimally skilled personnel, without laboratory equipment. The kit contains a cassette, a buffer, an applicator stick and a pricker. The cassette contains a conjugate pad with a monoclonal anti-pHRP-II antibody conjugated with colloidal gold. The cassette also contains a nitrocellulose membrane strip containing two test lines (Pan and Pf lines) and a control line (C line). The kit is locally produced, cheaper than what is currently in the market and has 100% sensitivity and specificity.



KEMRI Launched 4 COVID-19 Related Products In Kenya

President Uhuru Kenyatta unveils the first locally developed Malaria Test Kit at the KEMRI

It was pomp and colour at KEMRI during the familiarization visit to KEMRI- Kilifi by the Parliamentary Committee on Health on 18th June 2021. KEMRI took the opportunity to launch four (4) COVID-19 related products that will for ever change the fight against the pandemic in this country and regionally. Some of the Products which were launched include the VTM, KEMrub Hand sanitizers, TBcide, KEMiZyme, Proficiency Testing kits among others.

The Committee in a session led by Hon. Martin Peters Owino, lauded and congratulated KEMRI for being in the forefront in the fight against the COVID-19 pandemic which has now been demonstrated through the launch of this very critical products that will boost the war against the pandemic. The product launch was witnessed by the Committee members notably, Hon. Dr. Eseli Simiyu, Hon. Capt. Ruweida Mohammed, the Chairman of the KEMRI Board of Directors, Dr. Daniel Mbinda and Director General KEMRI Prof. Sam Kariuki among other scientists and dignitaries.



Among the flagship products launched during the occasion was the KEMRI VTM which is a superior virus transport media used in safe transferring of COVID-19 virus as well as chlamydia and mycoplasma and has no inactivating agent added into it. The **KEMRI VTM** supported the COVID-19 diagnosis in the entire country as well as several countries in the Africa region. One of the flagship KEMRI product that played a critical role during the COVID-19 pandemic in Kenya is the **KEMRub** Hand Sanitizer that was also launched during a colorful ceremony in KEMRI-Kilifi. KEMRub is an alcohol-based hand sanitizer which has a WHO-recommended formulation with guarantee of 99% riddance of pathogens. This products' efficacy has been proven by peer reviewed studies comparing similar products in the market. This superior quality product is manufactured under very strict quality control guidelines using international quality control standards.

Another quality product that KEMRI launched was the **TBCide** a chlorine-based stabilized decontaminant (5-5.6% w/v). TBCide has a proven activity against Mycobacterium (spp) which is affordable and effective decontaminant for laboratories and hospitals complete with superior packaging. **KEMiZyme** is yet another product that was

also launched and will soon take the market by storm. This is a stable enzymatic cleaner with a combination of Lipase, Amylase and protease enzymes. It has been proven to remove organic/ biological residues in medical devices used in surgical or invasive medical procedures and a perfect product for laboratories and hospitals. Apart from being cost effective, non-corrosive and equipment friendly, KEMiZyme has shown quick cleaning efficacy with a stability guarantee of within 45 minutes of exposure.

In the KEMRI launch basket, is yet another product that played acritical role during the pandemic in especially offering solutions in discordancy of COVID-19 results from different laboratories in Kenya was the **KEMRI Proficiency Testing kit**. The kit which is accredited to offer external quality assessments for HIV antibody tests and COVID-19 Molecular diagnosis through PCR, supported the WHO Somalia in HIV PT for more than eight years. The kit is the 3rd facility to be accredited for COVID-19 molecular diagnosis proficiency testing regionally in both public and private laboratories. Other Products that will soon be launched in a few months time include the **KEMRivid Rapid Test** for COVID-19 and **KEMRI PCR Test Kit** for COVID-19.

Some of the Products which were launched include the VTM, KEMrub Hand sanitizers, TBcide, KEMiZyme, Proficiency Testing kits among others.



KEMRI staff Shows a rare spirit of Patriotism amid COVID -19 Pandemic

A pupil from Mbagathi Primary school sanitize their hands with KEMRI automated dispenser



Ms. Pauline Mueni prepares to swab hon. Dr. Naomi Shaban for COVID-19 during a CSR activity in Taita Taveta County



The Institute braved the anxieties and ravages of the COVID-19 pandemic to participate in a number of social action initiatives for the benefit of the deserving Kenyans.

Barely a few weeks after the dreaded pandemic was reported in the country, the Director General resolved to quickly take-up steps that would not only promote public health measures against the pandemic, but also mitigate its pangs on the society.

For instance, the Institute quickly repurposed its specialized laboratories throughout the country and began supporting the Ministry of Health with mass public COVID-19 testing. Indeed, three quarters of all tests carried out in the country were done by KEMRI in different facilities.

In addition, the Institute also donated thousands of litres of the KEM-rub hand sanitizers to hospitals, institutions like police and prison offices, schools, women and public Government Offices

Mbagathi Primary and High School was one of the beneficiaries of this charity. This public school neighbouring the Institute has an enrolment of at least 1,095 pupils and students, a majority from the sprawling Kibera slums. This school also has a special unit that accommodates the mentally and physically challenged children and has a perennial challenge of cleaning washing and drinking water.

The mounting of 10 automated dispensers

that is being regularly replenished with Kemrub sanitizers for the next one year free of charge at the cost of Ksh. 94,000 per year came in handy for Mbagathi primary school community in support of the COVID-19 mitigation and containment measures.

Our lady of Grace Children's Home which caters for orphans, semi-orphans, destitute and abandoned girls in Marimba Nkubu in Meru County is yet another institute that benefited.

It was all smiles for the 130 children of this Home when our team visited the centre towards the end of the year 2020 and donated Kemrub sanitizers and Tbcides valued at Ksh. 69,500, foodstuffs and toiletries among others.

Earlier, the KEMRI Football club that participated in the Nairobi West Branch regional league prior to COVID-19 pandemic disruption that adversely affected their sport and lives, were also fated with foodstuff, sanitation commodities, branded new kits and uniforms.

In addition 2021 the Institute joined other key stakeholders and organized medical camps targeting members of the public. The first one was a five-day event that coincided with the Africa Public Service Day held in collaboration with Kenya Medical Training College in Taita Taveta County from Monday 21st June, 2021.

The camp was also attended by area Member of Parliament, Dr. Naomi Shaban,



Part of KEMRI team (Sahara Adan, Martha Maina and Judy Nyagah) donates sanitizers to health workers from Taveta Sub-County Hospital.



Mr.Allan Mulera Team Manager and Mr.Evans Emily Team Coach receiving some of the items bought for the team from Dr.Evans Amukoye, Director Research and Development.

Students from Mbagathi secondary school looking on as the automated dispenser is being installed outside their classroom.



the then KEMRI boss, Prof. Michael Kiptoo, Head KEMRI, Taveta Station, Dr. Jimmy Hussein Kihara among others saw KEMRI Staff specialized medical attention and public awareness talks on different preventable diseases, communicable or non-communicable offered. Some of the services offered include health promotion talks, regular health check-ups and screening for diabetes, high blood pressure, breast, cervical and prostate cancers screenings among others.

During the World Hepatitis Day on 28th July 2021, a team from KEMRI and partners, celebrated the day at Marigat Sub-County Hospital where they conducted screening and public awareness campaign against Hepatitis disease.

Towards the end of September, on 25th 2021 in particular, the Institute teamed up with Kiambu County and the Christ is The Answer Ministries (CITAM) Church Kiambu road, and organized a Specialized Medical Camp for the local community. The Medical camp held at the church grounds along Kiambu Road benefited over 500 people. Some of the services offered during the medical camp included COVID-19 testing and vaccination, screening of life-style diseases among other things.



Dr. Monique Wasunna feted for exemplary work in (NTDs)

Dr. Monique Wasunna, Drugs for Neglected Diseases initiative (DNDi) Africa Regional Office Director has been decorated with the second highest award in France, the French National Merit award for her contribution in the Neglected Tropical Diseases (NTDs) in Africa.

Dr. Wasunna, a former Ag. Director KEMRI and a long serving former director of the KEMRI's Center for Clinical Research has been presented with the prestigious French National Order of Merit (Ordre national du Mérite) by the French government.

She was the only recipient of the award from the East African region in this cohort and received the honours on 23 September 2021 at the French Embassy in Nairobi. It was awarded by the Ambassador of France to Kenya and to Somalia, H. E. Mrs Aline Kuster-Menager.

"As founding partners of DNDi and longtime colleagues of Dr. Wasunna we are delighted and deeply honoured by this award which is a recognition of her exemplary work and passion in NTDs. This is not just a merit recognition, but a confirmation of Dr. Wasunna's passion, commitment and leadership in delivering workable solutions to health challenges facing millions of communities globally," said Prof. Sam Kariuki in his congratulatory message.

This particular presidential award recognizes distinguished services or acts of devotion, bravery, generosity, and commitment to the service of others, in the military or in the public and private sectors and is ranked as the second highest award in France after the Legion of Honour (Ordre national de la Légion d'honneur).

Dr. Wasunna's award was given in recognition of her exemplary contribution to research and development in Neglected Tropical Diseases (NTDs), advocating for, and delivering better treatments for neglected diseases in Africa, an area she has worked in for the last 30 years.

She has been a Principal Investigator in several clinical trials to find better treatment options for neglected diseases. She has spearheaded the building and strengthening of regional partnerships in research and development for NTDs in Eastern Africa to expand clinical trial capacities in the region. Her research interests primarily focus on visceral leishmaniasis, mycetoma, malaria, and HIV.

Her work has impacted the Research and Development (R&D) ecosystem in Africa for neglected diseases. She has led networking efforts with scientists working in NTDs through R&D platforms such as the Leishmaniasis East Africa Platform where young scientists and institutions have benefited from trainings and mentorship opportunities. She has also participated in efforts to ensure that patients have access to treatment for NTDs through close collaboration with National Ministries of health in the continent.



KEMRI HOSTS THE COVID-19 DRUG DEVELOPMENT CONSORTIUM

A new consortium targeting research and development of COVID-19 drugs in Kenya has been birthed. The nascent consortium that brings together five local Universities and KEMRI has received an initial seed funding of over Ksh. 50 million from the National Research Fund (NRF) for this task.

Members of the consortium who are also the Principal Investigators (PIs) include Prof. Isabel Wagara from Egerton University, Dr. Peter Kirira from Mount Kenya University, Dr. Meshack Onyambu from Kenyatta University, Dr. Martin Magu, of Multimedia University of Kenya, Dr. Joseph Mwafaida from Pwani University and Prof. Jennifer Orwa who is also the coordinator of the consortium from KEMRI.

The team held its inaugural two-days meeting on Monday 18th and Tuesday 19th October, 2021 at the KEMRI Headquarters and later announced that the consortium will be officially launched in November, 2021.

During the inaugural meeting, Prof. Walter Oyawa, Director General NACOSTI, congratulated the consortium for winning a grant on development of COVID-19 products totaling Ksh. 50,602,000.

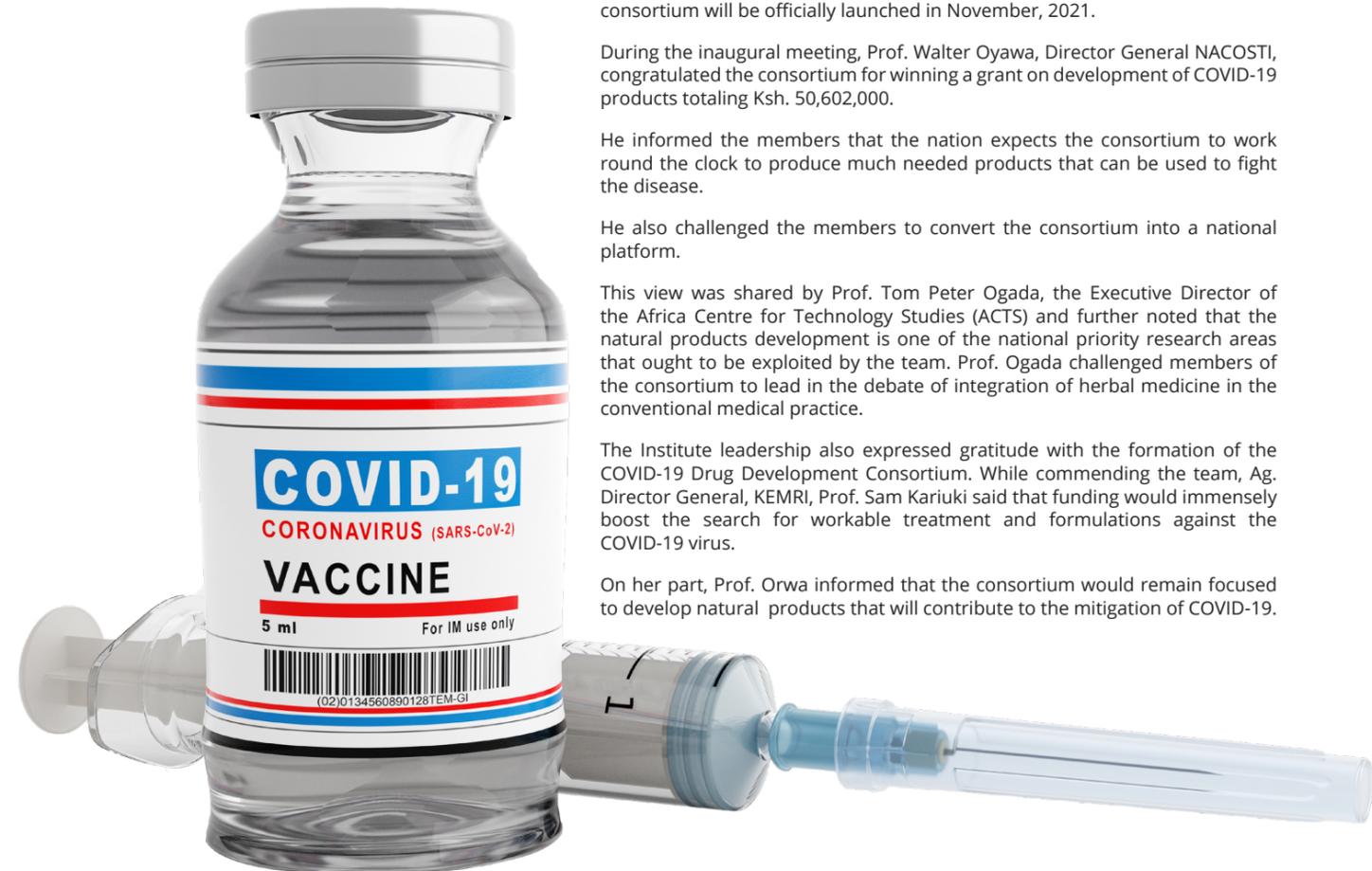
He informed the members that the nation expects the consortium to work round the clock to produce much needed products that can be used to fight the disease.

He also challenged the members to convert the consortium into a national platform.

This view was shared by Prof. Tom Peter Ogada, the Executive Director of the Africa Centre for Technology Studies (ACTS) and further noted that the natural products development is one of the national priority research areas that ought to be exploited by the team. Prof. Ogada challenged members of the consortium to lead in the debate of integration of herbal medicine in the conventional medical practice.

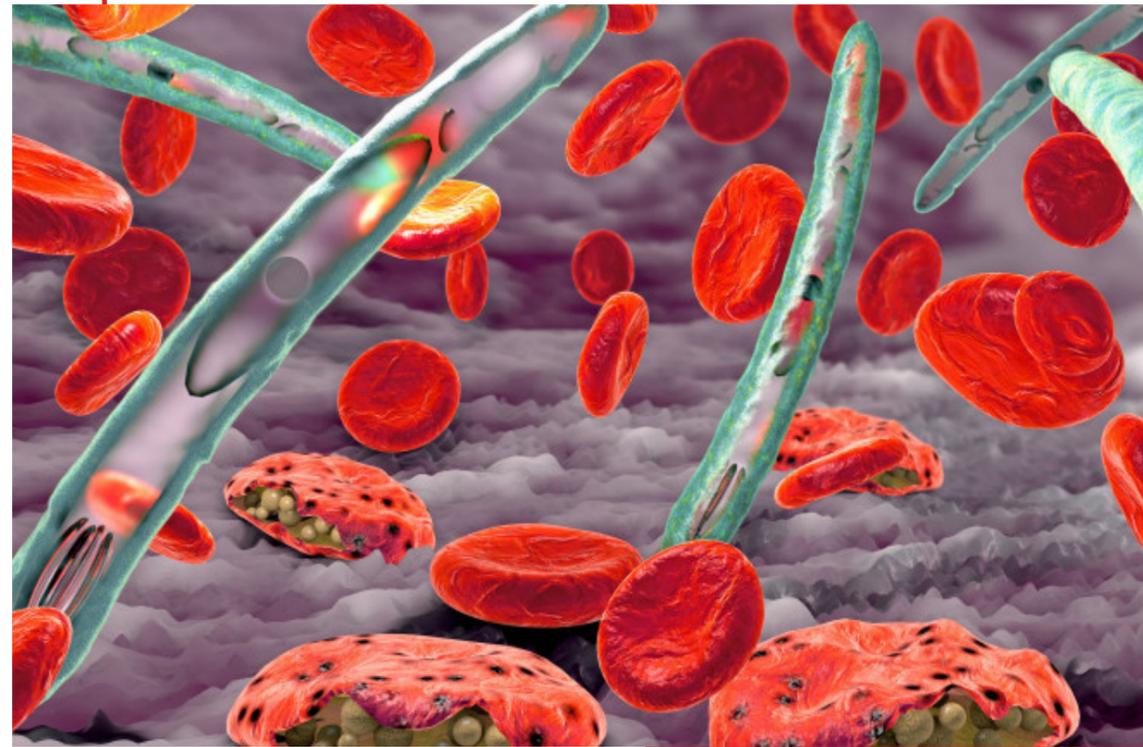
The Institute leadership also expressed gratitude with the formation of the COVID-19 Drug Development Consortium. While commending the team, Ag. Director General, KEMRI, Prof. Sam Kariuki said that funding would immensely boost the search for workable treatment and formulations against the COVID-19 virus.

On her part, Prof. Orwa informed that the consortium would remain focused to develop natural products that will contribute to the mitigation of COVID-19.



"As founding partners of DNDi and longtime colleagues of Dr. Wasunna we are delighted and deeply honoured by this award which is a recognition of her exemplary work and passion in NTDs. This is not just a merit recognition, but a confirmation of Dr. Wasunna's passion, commitment and leadership in delivering workable solutions to health challenges facing millions of communities globally," said Prof. Sam Kariuki in his congratulatory message

New Link Between Malaria Genetics and Sickle Haemoglobin Identified



For the first time, malaria genetic variants have been discovered to associate with the human sickle haemoglobin gene, suggesting these parasites may have adapted to overcome the protection offered by this well-known red blood cell human mutation.

The new research, by the KEMRI in collaboration with the Wellcome Sanger Institute, the University of Oxford and the MRC Unit the Gambia, along with collaborators from the U.S. and Mali, suggests that this group of malaria parasites may have evolved to be able to infect and cause serious disease in those who carry sickle haemoglobin. Further research is needed to understand the biological mechanisms behind this.

The study, published on 9th, December 2021 in Nature, identified three genetic variants in the parasite genome that are found unusually often in infections of individuals who carry at least one copy of the sickle haemoglobin gene, showing correlation between the two. Sickle haemoglobin, which causes sickle-cell anaemia when inherited in two copies, is commonly found in individuals from sub-Saharan Africa because one copy provides protection against malaria.

From this study, further research into the biological function of these parasite variants and the mechanisms by which they interact with sickle haemoglobin can be investigated. Understanding these key questions could lead to new ways to protect against and treat malaria.

Malaria is one of the world's most deadly infectious diseases, with an estimated 229 million cases and over 400,000 deaths by 2019, most of which were young children in sub-Saharan Africa. In this region, the disease is mainly caused by the parasite, *P. falciparum*, which has been shown to have different genetic profiles depending on which area it is found in. Tracking these parasite populations gives insight into how different groups of malaria parasites compete for survival and spread, and can help inform control measures.

In this new study, researchers sequenced the parasite genomes from over 3,000 infected children from Gambia and Kenya, all of whom had severe symptoms of malaria and compared their host and parasite genomes.

They found that infections of individuals with sickle haemoglobin tend to be caused by a certain type of parasite. Specifically, they tend to have particular

Some malaria parasites in sub-Saharan Africa have genetic variants that allow them to infect those with sickle haemoglobin, which is normally thought to give strong protection against the disease.

Publication:

[G. Band, et al. \(2021\) Malaria protection due to sickle haemoglobin depends on parasite genotype. Nature. DOI: 10.1038/s41586-021-04288-3](#)

mutations in three regions of the parasite genome, all of them appearing in genes whose function is currently unknown.

The researchers suggest that sickle haemoglobin in humans may have acted as a selective pressure on the parasite, driving it to adapt and leading to a population that can now infect people with sickle haemoglobin as well as those with normal haemoglobin. However, these sickle-associated parasites are not fully dominant across the African continent even though they seem to be able to infect the majority of humans compared to other strains, implying there may also be other factors impacting spread.

While this research implies that sickle haemoglobin in humans plays a role in shaping parasite genomes, further research is needed in larger populations and in those that are asymptomatic to shed light on the genetic interaction between the parasites and host genome.

Professor Tom Williams, author and Wellcome Trust Senior Fellow at the Kenyan Medical Research Institute (KEMRI), Kenya, said: "Malaria is a deadly disease, taking hundreds of thousands of lives every year. Previously, sickle haemoglobin was believed to have a protective effect against severe disease. However, this study highlights the importance of continually investigating this parasite so that we can be informed about how it adapts against selective pressures."

Dr. Gavin Band, first author and Statistician at the Wellcome Centre for Human Genetics, University of Oxford, said: "We have known for years that human genetic variants such as sickle haemoglobin can provide protection against malaria, but we wanted to understand if malaria parasites have evolved to overcome this. In our study, large scale genome sequencing allowed us to compare thousands of human and parasite genomes. For the first time, we were able to highlight a correlation between the human sickle haemoglobin mutation and three regions of the parasite genome, suggesting that the human genome is a selective pressure in the evolution of the parasite."

Professor David Conway, author and Professor of Biology at London School of Tropical Medicine, said: "Making the connection between the genetic variants of the parasite and its ability to infect those with sickle haemoglobin paves the way for research to dive deeper into the biological mechanisms behind this. Greater clarity on the ways that *P. falciparum* evades the human body's defences could lead to new opportunities for protecting against malaria and treating those living in the most affected areas."

Professor Dominic Kwiatkowski, senior author and Senior Group Leader at the Wellcome Sanger Institute and Director of the MRC Centre for Genomics and Global Health, said: "Ongoing genomic surveillance is incredibly important in identifying and tracking parasite variants to ensure that we are aware of how the disease is spreading and evolving. This study is the first time we have found a correlation between these genetic variants in parasites and their ability to infect people with sickle haemoglobin, making it an important group to monitor due to the implications for public health."



Typhoid Carriage in Children Highlights Need for Vaccination in Kenya

By Prof. Sam Kariuki

Drug-resistant typhoid is endemic to Kenya, with children younger than 16 years of age most heavily impacted. We have known this for years. What we didn't know was the prevalence of typhoid carriage—or chronic, asymptomatic infection—and the role it can play in spreading the disease and perpetuating new, more dangerous strains in a community. Our recent study found a high rate of carriage among children in the Mukuru settlement of Nairobi, Kenya. This finding has implications for the race against drug resistance.

Tracking drug-resistant typhoid in Kenya

For the last two decades, most cases of typhoid in Kenya have been multidrug-resistant (MDR), and reduced susceptibility to second-line fluoroquinolones rising in frequency.

Our team has been intensively studying typhoid and other diseases in the informal settlement of Mukuru. Approximately 150,000 people live in Mukuru. We know that the prevalence of typhoid among children in this population is high, with cases predominantly associated with contaminated water sources and lack of sanitation.

Our team conducted a five-year case-control typhoid surveillance study in Mukuru. The study included identifying both cases and asymptomatic carriage among children younger than 16, sequencing the genomes of typhoid found in both and utilizing geospatial mapping to characterize the population structure and transmission dynamics of *S. Typhi* in the community.

Uncovering the role of asymptomatic carriers

Our study found that symptomatic typhoid is common among all children in Mukuru, with the highest rate (4.3%) of positivity among school-aged children 7 to 16 years of age. The most surprising finding, however, is how

commonly children become typhoid carriers. We observed an asymptomatic typhoid carriage rate of 1.1% among all children under 16. The lowest rates were among infants and the highest rates were among school-aged children.

Importantly, the strains of typhoid (predominantly MDR strains) were similar between the acute cases and carriers, suggesting a common source of infection and transmission between the two groups. In other words, carriers may be serving as a reservoir for the community spread of drug-resistant typhoid in Mukuru.

Carriers may also accelerate the development of new drug resistance mutations. Because typhoid can live and replicate in the gut of carriers for long periods of time, it has more time to evolve. We did not find any difference in MDR prevalence between active cases and carriers. However, like previous studies, our study found typhoid isolates from carriers had more mutations than those from active cases.

Stopping drug resistance through community-wide vaccination, WASH, and surveillance

Our findings in Mukuru highlight the need for action. First, enhanced surveillance for drug resistance and genomic sequencing in Africa will be necessary to inform both treatment guidelines and control strategies. More information helps guidance keep pace with the local evolution and spread of resistance.

Most importantly, our study shows that intervention strategies to stop the spread of typhoid are urgently needed in Kenya. The introduction of typhoid conjugate vaccine (TCV) in the national immunization program would give every child protection from typhoid infections, asymptomatic and symptomatic alike. Improvements to water and sanitation and Hygiene (WASH) will also be necessary for long-term prevention, especially given current urbanization trends.

AN OVERVIEW OF KEMRI'S KNOWLEDGE MANAGEMENT

By: Lilian M Mayieka, RD&KM

Knowledge Management (KM) can be defined as an effort to make accessible and share not only explicit factual information but also the tacit knowledge that exists in an organization in order to advance the organization's mission.

KEMRI's mission is to improve human health and quality of life through Research, Capacity Building, Innovation and Service Delivery. Her role to human health is to conduct high quality research that informs evidence-based policy, translating research into best practices, capacity building and service delivery for human health.

Knowledge resides within the person, but when learning takes place in an institutional context, then others could benefit through shared knowledge. Although knowledge is a highly personal attribute embedded within the individual, it has also been thought of as an organizational asset with sustainable competitive advantage (Davenport & Prusak, 1998). Therefore, there is need to deploy a knowledge capture (retention) mechanisms so as to avoid loss of critical knowledge for national development.

In order for the knowledge to be shared, it must be in a form to which colleagues and stakeholders can easily access. Knowledge sharing can take place through conversations or interviews, written reports of "lessons learned," best practices documents, taped presentations and transcribed discussions. These can be presented as written or physical evidence which can be stored as knowledge artifacts for easy accessibility by the staff of the organization.

The research scientist in KEMRI produces hundreds of new scientific findings (evidence) annually and it may be of little value unless it is put into practice. This

can only be of benefit if it can be accessible and comprehensible.

Ensuring the use of research and evidence in policy, decision making and health systems management is an important challenge. The World Health Organization (WHO) defines Knowledge Translation (KT) as "the synthesis, exchange and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovation in strengthening health systems and improving people's health (WHO, 2012)." The Research Development and Knowledge Management (RD&KM) office undertook a KT related activities following request by the Ministry of Health, for evidence to inform COVID-19 pandemic national control strategies. Scientists from RD&KM were able to access previous peer reviewed research articles, conducted systematic reviews & meta-analysis, hosted a webinar presentation, undertook two online national surveys, synthesized emerging information and generated several policy and evidence briefs which were also presented to the Ministry of Health to inform decisions. A sample of the knowledge products are shown below; hence the need for knowledge translation.





Picture Speak



THE PROPOSED AMENDMENTS TO THE NHIF ACT: Ideas whose time has come

By Prof. Edwine Barasa

The proposed amendments to the NHIF act have elicited varying reactions with some stakeholders, notably the Central Organization of Trade Unions (COTU) and the Association of Kenyan Insurers (AKI), voicing their opposition. However, the proposed amendments are timely and, if well implemented, will offer immense benefits to Kenyans by promoting Universal Health Coverage (UHC). **First, the amendments will expand the range of healthcare service providers available for Kenyans to access services.** Currently, the NHIF Act only recognizes hospitals, and "hospital type" healthcare facilities (maternity/nursing homes and clinics), that offer inpatient and outpatient healthcare services.

The NHIF will not pay for services provided by a stand-alone laboratory or an individual doctors practice because these do not meet the definition of hospital prescribed in the current law. The proposed amendments broaden the definition of healthcare service providers to include duly registered healthcare professionals and those that offer diagnostic services, opening the door to private individual practices and standalone laboratory and diagnostic imaging services for instance. This is a win for the public since they will have wider options when seeking care. It is also a win for the healthcare professionals fraternity since it has widened the opportunity for their members in individual practice and those offering laboratory services to become service providers under the NHIF. It is only rational therefore that healthcare professional associations and their trade unions should support proposed amendments.

Second, the proposed amendments will expand the range of services that Kenyans have access to from a narrow focus on treatment to a broader focus on health prevention and promotion. It is a well-known fact that prevention is better than cure, and that preventive and promotive services including for



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instance immunization and family planning services are more cost-effective compared to treatment of diseases. However, the NHIF has historically ignored preventive and promotive services and instead prioritized treatment. The proposed amendments promise to right this wrong, to the benefit of Kenyans, by opening the door for a revision of the NHIF service package to include critical preventive and promotive services such as screening for cancer and modern contraceptive services.

Third, the proposal that private health insurers incur the first charge of medical bills before the NHIF will promote equity which is a foundation for UHC. Currently, private insurance companies require that the NHIF incurs the first charge of medical bills, with the private cover paying the balance. This practice is inequitable and amounts to robbing the poor to pay for the healthcare services of the rich for the following reason. Only about one percent of Kenyans have private health insurance. Those with private health insurance also happen to be the richer in

society given that private health insurance is expensive. About 20 percent of the Kenyan population is covered by the NHIF. The one percent that have private health insurance is part of the 20 percent that is covered by the NHIF but is clearly the minority, with most people covered by the NHIF not having private health insurance. Since NHIF contributions are pooled, the current practice results in contributions for NHIF members without private health insurance (the poorer member) being used to pay for healthcare bills of NHIF members with private health insurance (the richer members). The proposed amendment will achieve the opposite, with the rich in society paying for the less poor in society. This is more in line with the principles of equitable health systems. One would expect that a worker's union whose majority members do not have private health insurance would be supportive of such a move since it is clearly in the interest of the majority of its members.

Fourth, the amendments will strengthen the governance and accountability of the NHIF. The NHIF has faced perennial governance and accountability challenges including weak leadership, corruption and poor accountability to the public. The proposed amendments prescribe, for the first time, minimum qualifications and experience for the NHIF CEO. While this is not a silver bullet for NHIFs leadership problems, it ensures that at the very least, the person in charge of leading this very important institution has the competencies required to do so. The amendments also propose a strengthening of NHIFs accountability by requiring it to provide statements to its members. Further, the proposal to increase fines on individuals and healthcare facilities that commit fraud from a measly KES 500,000 to KES 10 million is likely to discourage and reduce cases of fraud that cost the NHIF millions if not billions of shillings annually. Healthcare facilities that commit fraud now face deletion from the register of contracted health care providers via Gazettement of this deletion.

Lastly, the proposal for employers to match employer contributions to the NHIF is a game changer that will boost resource mobilization and sustainability for UHC. The goal of using the NHIF as a vehicle for UHC by scaling up its membership to cover every Kenyan cannot be achieved by relying on member contributions alone. Such reliance is unsustainable and at odds with international best practice and evidence. Why? Over 83 percent of Kenyans in employment are in the informal sector, and 36 percent of Kenyans are poor. Reliance on contributions alone effectively excludes the poor and those in the informal sector and effectively buries Kenya's UHC dream. Employer matching of contributions will mobilize additional funds that can be used to scale NHIF coverage to the poor. Employer matching is not an outlandish idea. Established social health insurance schemes in Europe, including Austria, Belgium, France, Germany, Luxembourg, and the Netherlands, Asian countries such as Thailand, Indonesia and the Philippines, and closer home, Tanzania, Gabon, and Sudan all have social health insurance schemes whose employers match employee contributions. It is very surprising that trade unions that represent workers would be opposed to this especially because the amendment is in the interest of its members (workers) by mobilizing additional resources on behalf of the workers, from corporate resources rather than individual worker resources. It is about time that the NHIF is reformed to live up to its promise of delivering UHC to Kenyans. The proposed amendments are a step in the right direction and hope and call on stakeholders to be on the right side of history by supporting these legal reforms.

KEMRI STRENGTHENS REGIONAL LABORATORY CAPACITY IN AFRICA



At least seven regional countries of Djibouti, Ethiopia, Sudan, South Sudan, Uganda, Rwanda, and hosts Kenya participated in the KEMRI/JICA Third Country Training Programme (TCTP) held virtually from 4th October 2021 at KEMRI Headquarters.

The workshop which brought together 15 participants was officially opened by Acting Director General of KEMRI, Prof. Sam Kariuki and the JICA Chief Representative in Kenya, Mr. Iwama Hajime.

Prof. Kariuki reiterated when addressing the forum that JICA has continuously for more than four decades, worked with the institute in the area of capacity building that has contributed to making KEMRI what it is today, a premier Human Health Research Institute that caters for not just Kenya but the whole region as well. "TCTP is an important period for us & JICA especially, looking at the long-term collaboration we have had with the People and Government of Japan," he added.

Prof. Kariuki went to enumerate some of the benefits of the long historic relationship between the two organizations as thus, "the construction of the Central Laboratory Complex at the Headquarters in 1980 and the capacity building initiatives through the initial third country training programmes in blood safety between 2001-2005 and the now very popular school deworming programme between 2004-2008." He noted that so successful was the school deworming programmes that the government through

the Ministry of Health are keen to up-scale it in endemic counties in the country.

The other flagship projects of the KEMRI/JICA friendship was in the laboratory enhancement initiatives that saw the agency undertake the construction of the Level 3 Biosafety facility at the KEMRI Headquarters which has largely contributed the Institute's effective and efficient response to COVID-19 pandemic and other emerging and re-emerging infections in the region.

It is against this background that the current training programme was mooted four years ago. Like the other initiatives, this particular ones are aimed at building institutional and human capacity of over 100 medical personnel involved in emergencies in Eastern Africa countries through training, equipping and skills transfer, while strengthening the laboratory networks in the target region to better respond to emerging infectious diseases. "In this era of COVID-19 pandemic, it is timely to welcome you the participants drawn from national, regional and/or local health authorities and your respective countries that are involved in laboratory preparedness and response," Prof. Kariuki said adding that the training was timely given that they are frontline workers involved in the COVID-19 response activities.

On his part, the JICA Chief representative, Mr. Iwama Hajime intimated that the agency had deliberately taken steps to rebrand globally



Prof. Shingo Inue presents a certificate to one of the participants during the closing of the TCTP at KEMRI HQ



Dr. Kizito Lubano, Director Scientific Programmes, Partnership & Grants Management presents a gift to Prof. Shingo Inue from Nagasaki University



as agency that is keen "to strengthen our work in protecting people's lives is prevention, precaution & treatment in which we aim to support the campaign of Universal Health Coverage." He added, "this training program in my view fits very well in this initiative and we look forward to strengthen our activity and capacity preparedness and response across the regions."

He intimated that JICA was implementing partnership for building resilience against public health emergency through advanced research and education that has three major components including institutional capacity development, specialized human resource development and partnership with global and regional initiative.

The meeting was told that JICA's role in the East African region was to strengthen laboratory capacity so that countries are well prepared to respond to outbreaks, a capacity building need that has been demonstrated by the COVID-19 pandemic that it is lacking.

Mr. Hajime urged all participants to share their knowledge, experience, ideas, and innovation through this programme and build strong networks to formulate and implement strategies that will contribute to build systems plus UHC in Africa.

The Kenya Health & Research Observatory (KHRO) Company

By Safari Agure

The idea of an observatory dates back to the end of 17th century, as "a place or making observations of natural phenomena". The main disciplines that traditionally used observatories include Astronomy, Climatology/Meteorology, Oceanography and Volcanology; as a means for observing natural happenings such as terrestrial, marine, or celestial events.

It was not until the 19th century that observatories found use in health specifically to enhance and facilitate Evidence Based decision making and strengthening of health systems hence improving sector performance. In 1974, France gave us the first health focused observatory; the regional public health observatory. A growing need for reliable and up-to-date information for monitoring and evaluating of the impact of health programs and policies has seen the development of more Health Observatories.

Today, the World Health Organization (WHO) hosts the Global Health Observatory (GHO) which is a gateway to health-related statistics for its 194 Member States. In 2011, WHO established the African Health Observatory (AHO) aimed at facilitating collaboration and partnership in accessing and using information to strengthen national health systems for improvement of health outcomes. This development set in motion the activities towards the establishment of National Health Observatories (NHOs) by the 46 member states with



support from AHO after receiving the blessings from WHO Regional Committee for Africa during the 62nd Session of Health Ministers.

Nationally, the development of Kenya's NHO began with the Ministry of Health identifying the need to improve the availability and use of health information as one of the six priorities of the Kenya Health Data Collaborative of 2016. It is acknowledged that access to evidence remains one of the major barriers hindering policy-makers' use of evidence in their decision-making. In June 2017, with support of WHO and the World bank, several stakeholders including the Ministry of Health, University of Nairobi, the Kenya Medical Research Institute (KEMRI), World Bank, the United Nations Children's Fund (UNICEF), CDC,

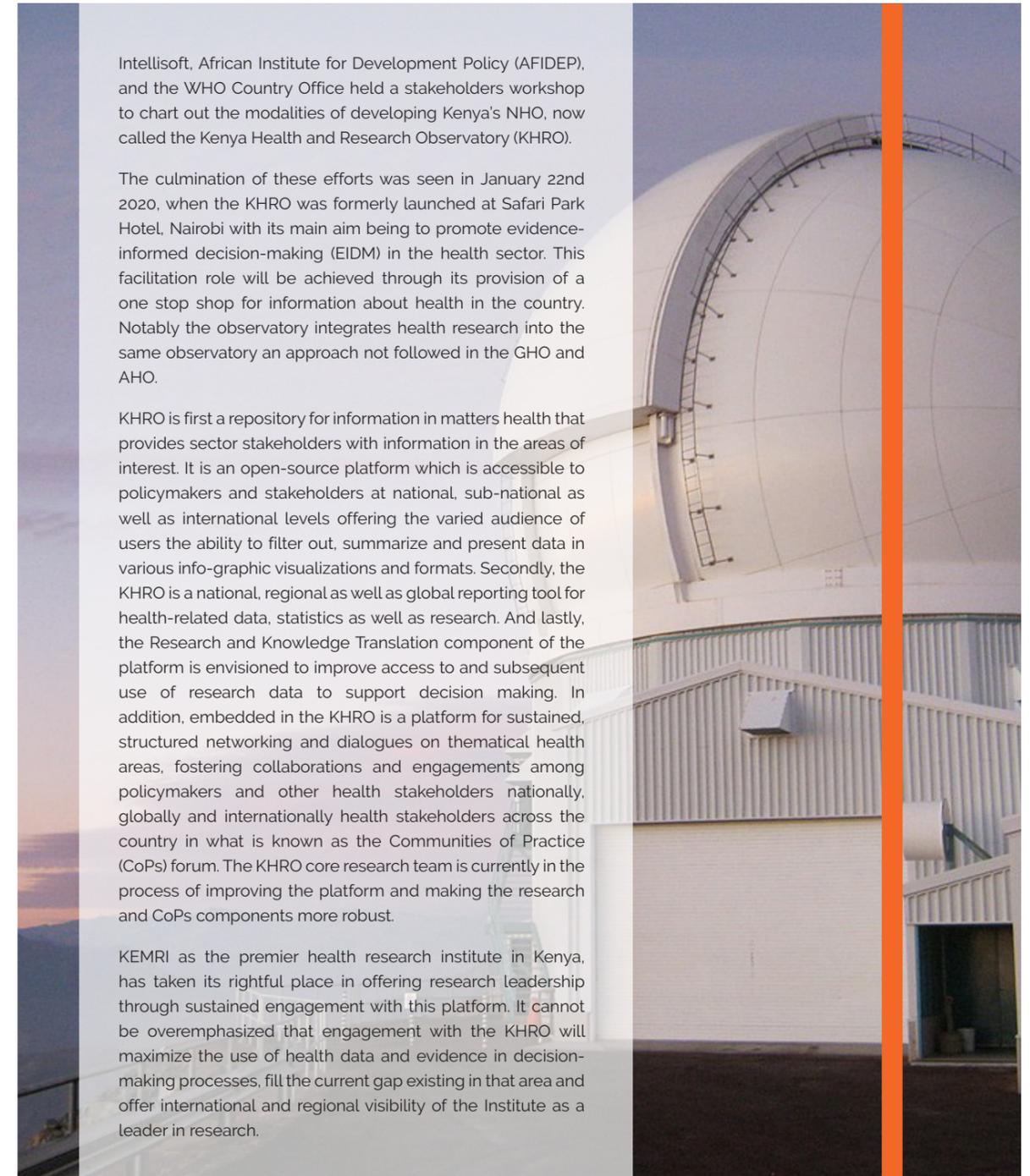
Intellisoft, African Institute for Development Policy (AFIDEP), and the WHO Country Office held a stakeholders workshop to chart out the modalities of developing Kenya's NHO, now called the Kenya Health and Research Observatory (KHRO).

The culmination of these efforts was seen in January 22nd 2020, when the KHRO was formally launched at Safari Park Hotel, Nairobi with its main aim being to promote evidence-informed decision-making (EIDM) in the health sector. This facilitation role will be achieved through its provision of a one stop shop for information about health in the country. Notably the observatory integrates health research into the same observatory an approach not followed in the GHO and AHO.

KHRO is first a repository for information in matters health that provides sector stakeholders with information in the areas of interest. It is an open-source platform which is accessible to policymakers and stakeholders at national, sub-national as well as international levels offering the varied audience of users the ability to filter out, summarize and present data in various info-graphic visualizations and formats. Secondly, the KHRO is a national, regional as well as global reporting tool for health-related data, statistics as well as research. And lastly, the Research and Knowledge Translation component of the platform is envisioned to improve access to and subsequent use of research data to support decision making. In addition, embedded in the KHRO is a platform for sustained, structured networking and dialogues on thematic health areas, fostering collaborations and engagements among policymakers and other health stakeholders nationally, globally and internationally health stakeholders across the country in what is known as the Communities of Practice (CoPs) forum. The KHRO core research team is currently in the process of improving the platform and making the research and CoPs components more robust.

KEMRI as the premier health research institute in Kenya, has taken its rightful place in offering research leadership through sustained engagement with this platform. It cannot be overemphasized that engagement with the KHRO will maximize the use of health data and evidence in decision-making processes, fill the current gap existing in that area and offer international and regional visibility of the Institute as a leader in research.

Agure is a Senior Research Scientist in KEMRI & a Technical Working Group (TWG) member of both KHRO and National Research.



THE INSTITUTE BESTOWED WITH A FOREST PROTECTION AWARD

KEMRI received a rare award - The **Stewardship Award** from very unlikely quarters - The East African Wildlife Society (EAWLS) during the forest challenge 2021, that was held at the Kereita Aberdare forest in Lari constituency, Kiambu County

But even as team KEMRI took to the stage to receive the unusual award, their first-ever participation in the Forest Challenge, it was all hats off to EAWLS in collaboration with Kijabe Environment Volunteers (KENVO) and Kenya Forest Service (KFS) for the initiative that seeks to protect the country's forest cover and the restoration of threatened water towers.

The event provide a unique opportunity for participants to interact with nature through competitive yet fun activities in Kereita Forest in furtherance of environmental conservation.

Specifically, the 2021 event was geared towards restoring key water catchments areas in Kenya that are essential to support livelihoods and the survival of wildlife ecosystems.

KEMRI was excited to be associated with this initiative that incidentally touches on the very core of its mission of improving human health and



quality of life through research, capacity building, innovation and service delivery. "This initiative is close to our hearts in particular in the context of One Health Approach," said Ag. Director General, Prof. Sam Kariuki in remarks read on his behalf, by Ms. Lucy Kanyara who lead a strong laboratory team in carrying out free COVID-19 tests, a pre-requirement confirmation for participants.

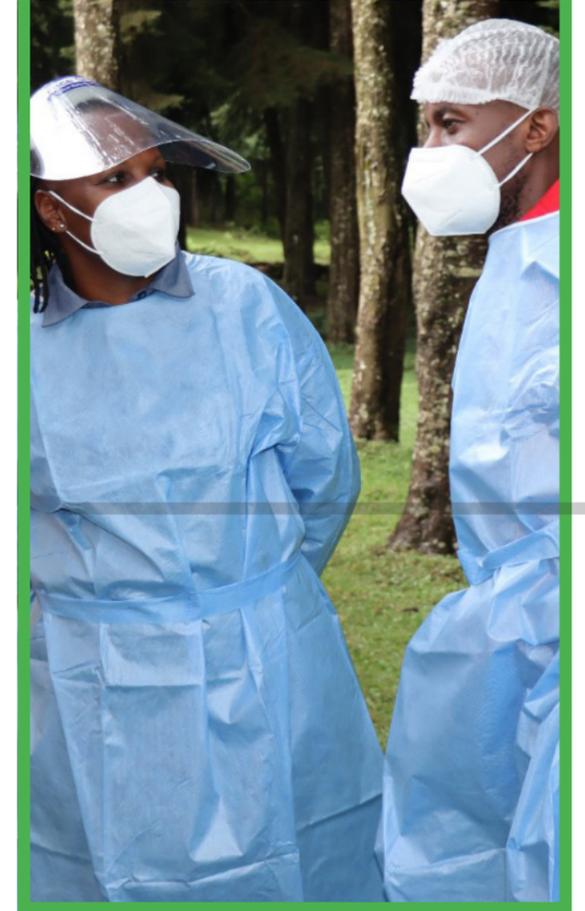
One Health is one among eight research programmes in KEMRI



that looks at the nexus between, the health of animals, humans, and the environment. It is a collaborative, multisectoral, and trans-disciplinary approach with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment. "The Forest is part of our environment that contributes to our own health because it affects the animals, the people and the plants," he said adding, "therefore, by conserving the Forest through such initiatives will in-turn lead to good health which is in consistent with our motto of In Search of Better Health."

It's for this reason that the event's theme apt as "Reforest to Replenish the environment" with the vision of restoration of key water catchments areas in Kenya being essential to support livelihoods and the survival of wildlife ecosystems. The event is meant to give participants an excellent and unique opportunity to interact with nature by taking part in competitive yet fun activities in Kereita-Aberdare Forest.

The Forest is part of our environment that contributes to our own health because it affects the animals, the people and the plants," he said adding, "therefore, by conserving the Forest through such initiatives will in-turn lead to good health which is in consistent with our motto of In Search of Better Health."





Meru Governor HE. Kiraitu Murungi and Deputy Governor Titus Ntuchiu receiving miraa wine and miraa juice during the first ever Miraa Conference held at the University of Nairobi Chandaria Hall



MIRAA SCIENTIFIC CONFERENCE 2021

As the curtains came down on the first Miraa Scientific Conference held at the University of Nairobi, Chandaria Hall, delegates at the 2-day historic conference sponsored by County Government of Meru, in collaboration with KEMRI, pleaded with the world to give miraa a chance

The County Government of Meru promised all the stakeholders in the miraa business from farmers to transportation and distributors, that they will work hand in hand to see the green gold (khat) of Meru County achieve value addition by unlocking opportunities that are available to access the market both international and local.

On the final day of the National Scientific Miraa Conference, various government agencies that have limited the value addition of the crop, brought on Board National Authority for the Campaign Against Alcohol and Drug Abuse (NACADA) chairlady, Prof. Mabel Imbuga and Kenya Bureau of Standards (KEBS) Director General, Bernard Njiraini, with the two bodies being taken to task by speakers why scientifically proven dangerous drugs like Nicotine and alcohol are given lee way to manufacture their products, but have continuously given legal bottle-necks to the Miraa sector based on technicalities.

However, HE. Governor Kiraitu Murungi admitted there is need of a legislative agenda to amend all the Parliamentary acts that have been used by the two agencies to limit the value addition of the crop classifying it as a drug. Even as the legislation is being amended, Governor Kiraitu called for agencies to avoid punitive enforcement of the law that can ride people to poverty, asking them to assess the social-economic effect of any law before implementation. Governor Kiraitu gave 5 acres of the county's land to KEBS, to build a regional office in Meru.

Ambassador Peter Kaberia, Industrialization-Principal Secretary promised to push for the regional KEBS office in two months' time, to encourage more value addition ventures and promote entrepreneurship in the County



In Search of Better Health



CHRIST IS THE ANSWER MINISTRIES [CITAM]

Hundreds Benefit from KEMRI Specialized Medical Camp in Kiambu

At least three hundred residents of Kiambu County benefitted from the first-ever specialized medical camp mounted on Saturday, 25th, September 2021 by the Kenya Medical Research Institute in partnership with Christ is the Answer Ministries (CITAM) Church Kiambu and Kiambu County Government at the CITAM Church in Kiambu grounds.

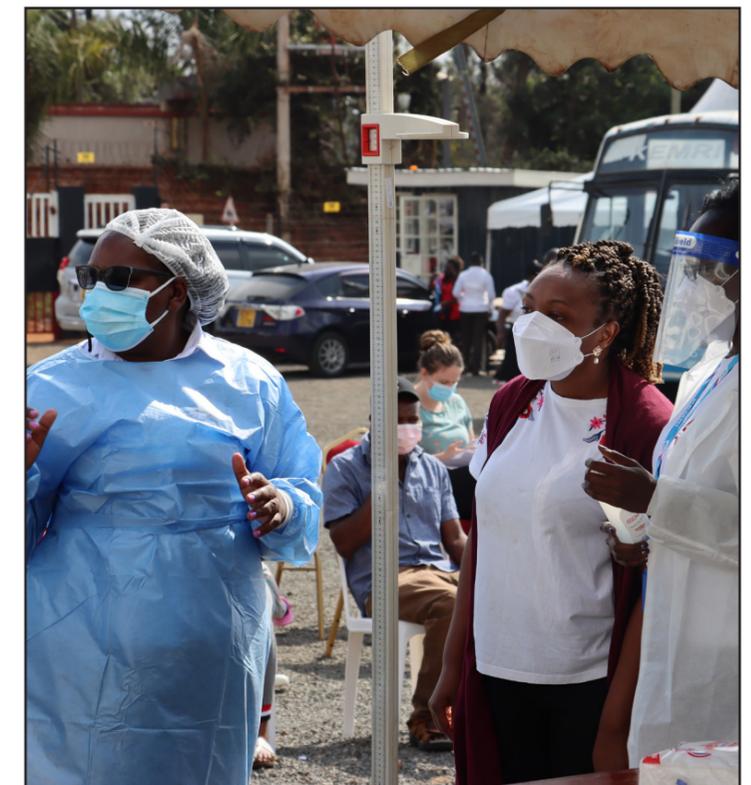
During the medical camp, at least 255 residents took advantage to receive their COVID-19 vaccination, which was part of the services on offer, while others not only received a rapid COVID-19 tests, but were also screened against life-style diseases and other health challenges.

Presiding minister at the CITAM-Kiambu Church, Senior Pastor Rev. Charles Thuku was full of praise for the dedication to service offered by the KEMRI Staff that mounted a successful medical camp to the benefit of hundreds of the Kiambu community.

"We are extremely gratified by the work that has been done today by KEMRI, we are particularly impressed and humbled by the dedication to service of all of you and for giving your all towards making this a success," said Rev. Thuku.

His view was shared by Director General Prof. Sam Kariuki who braved the early chilly morning to join the team for the better part of the event. "Indeed, you have done well in line with our motto In Search of Better Health for all our clients". Prof. Kariuki Stated

Other than the COVID-19 vaccination, other services offered during the camp included testing for lifestyle diseases like; blood pressure (BP), Body Mass Index (BMI) and blood sugar. KEMRI team led by doctors and nurses also offered counselling services to people who needed further medical attention. Above all the CITAM team offered counselling services and spiritual nourishment to the residents of Kiambu.





A GLEAM OF HOPE AS KEMRI LAUNCHES A STUDY ON CHILD BILHARZIA DRUG.

By Dr. Maurice R. Odiere



Q: What is Schistosomiasis (Bilharzia)?

A: Schistosomiasis (Bilharzia), one of the neglected tropical diseases (NTDs) is an acute and chronic parasitic disease caused by blood flukes (trematode worms) of the genus *Schistosoma*. It affects over 240 million people globally and in 78 countries where the disease is endemic. In Kenya, six million people are infected with 70 percent believed to be school-age children and approximately 17.4 million people are at risk of schistosomiasis. Globally, the disease affects at least 25 million preschool-age children, and in these very young children, prevalence of infection may exceed 60 percent. In Kenya, it is estimated that between 130,000 to 250,000 young children under the age of five years are infected. Prevalence rates among preschool-age children are estimated to be 5.5 percent around Central Kenya and between 20-35 percent at the Coastal region and on the shores of Lake Victoria in western Kenya regions.

Q: What is the mode of Infection and transmission?

A: People become infected when larval forms of the parasite – released by freshwater snails – penetrate the skin during contact with infested water. Transmission occurs when people suffering from schistosomiasis contaminate freshwater sources with their excreta containing parasite eggs, which hatch in water. In the body, the larvae develop into adult schistosomes. Adult worms live in the blood vessels where the females release eggs. Some

of the eggs are passed out of the body in the faeces or urine to continue the parasite's lifecycle. Others become trapped in body tissues, causing immune reactions and progressive damage to organs.

Q: Please explain the disease epidemiology?

A: Schistosomiasis is prevalent in tropical and subtropical areas, especially in poor communities without access to safe drinking water and adequate sanitation. It is estimated that at least 90 percent of those requiring treatment for schistosomiasis live in Africa. There are two major forms of schistosomiasis – intestinal and urogenital – caused by five main species of blood fluke (*Schistosoma mansoni*, *S. japonicum*, *S. mekongi*, *S. guineensis* and related *S. intercalatum*, and *S. haematobium*).

Q: What are some of the disease symptoms?

A: Symptoms are caused by the body's reaction to the worms' eggs. Intestinal schistosomiasis can result in abdominal pain, diarrhoea, and blood in the stool. Liver enlargement is common in advanced cases and is frequently associated with an accumulation of fluid in the peritoneal cavity and hypertension of the abdominal blood vessels. In such cases there may also be enlargement of the spleen.

The classic sign of urogenital schistosomiasis is haematuria (blood in urine). Fibrosis of the bladder and ureter, and kidney damage are sometimes diagnosed in advanced cases. Bladder cancer is another possible complication in the later stages.

Q: What are some of the economic and health effects of Schistosomiasis?

A: The economic and health effects of schistosomiasis are considerable, and the disease disables more than it kills. In children, the disease can cause anaemia, stunting and a reduced ability to learn. Chronic schistosomiasis may affect people's ability to work and in some cases can result in death. The number of deaths due to schistosomiasis is often difficult to estimate because of hidden pathologies such as liver and kidney failure, bladder cancer and ectopic pregnancies due to female genital schistosomiasis. The death estimates varies between 24,000 and 200, 000 globally per year. When left untreated, schistosomiasis can cause a range of harmful and sometimes irreversible health effects while perpetuating cycles of reinfection and poverty within communities. Infected children can experience a range of signs and symptoms, including decreased school performance, stunted growth, and a reduction in the quality of life. These detrimental health outcomes place a large burden on families, communities, and national health systems and economies because of out-of-pocket costs for accessing health care and lost productivity.

Q: What is the diagnosis?

A: Through the detection of parasite eggs in stool or urine specimens. Antibodies and/or antigens detected in blood or urine samples are also indications of infection.

Q: Any available treatment?

A: The existing drug of choice for the treatment of schistosomiasis is praziquantel, which was developed in the 1970s.

Q: What is the problem with the current existing drug in treating schistosomiasis in young children?

A: WHO-recommended global strategy to control schistosomiasis already exists; preventive chemotherapy involves yearly administration of praziquantel to entire populations at risk. Tablets (usually 600 mg) are given as single oral doses, but the prophylactic treatment is suitable only for school-age children and adults. Younger children usually cannot swallow the existing tablets because of their large size and bitter taste.

Q: How big is the challenge presented by schistosomiasis in Kenya?

A: The *Schistosoma* parasite is endemic in 62 of the 290 sub-counties in Kenya. Around six million people are infected, though this is likely a conservative estimate, the number might be as high as nine million. But 70 percent of those infected are believed to be in the five to 14 age group. There are three major endemic areas – the Coastal region (mainly *Schistosoma haematobium*), parts of Central and Lower Eastern areas (both *S. haematobium* & *S. mansoni*) and the Lake Victoria basin (mainly *S. mansoni*) with few pockets of *S. haematobium* further inland. Transmission is still commonplace in many areas, with people infected during a wide range of activities – domestic, agricultural and commercial. Exposure to the worm can happen while car washing, sand harvesting, and fishing, and during recreation such as swimming.

Q: What has been done to address the disease up to this point?

A: KEMRI is a key partner in the National School-based Deworming (NSBDP) program, working with the Ministries of Health and Education and other partners. Our own work at the KEMRI NTD Unit (at the Centre for Global Health Research in western Kenya) has focused on understanding disease transmission dynamics, burden and morbidity, and immunity/resistance to infection. We also explore operational research on

controlling schistosomiasis, and we evaluate new diagnostic tools for potential use by control program. Kenya's second National Strategic Plan for Control of NTDs 2016-2020 is currently underway, with a focus on reducing disease through periodic, targeted treatment using praziquantel (PZQ) for large-scale preventive chemotherapy (PC). In addition, there is the Kenya National Breaking Transmission Strategy (BTS) (2019-2023) that is targeting four neglected tropical diseases (schistosomiasis, intestinal worms, trachoma and lymphatic filariasis) that are amenable to PC.

Q: What is the impact of schistosomiasis in pre-school children?

A: Sensitive diagnostic approaches such as using multiple stool samples or serologic assays show that sizeable proportions of young children are infected early in life, confirming the urgent and acknowledged need for a formulation of PZQ for infants. At present, preschool-age children are left untreated in public health programs due to lack of confirmatory clinical data and a missing appropriate child-friendly formulation of the drug praziquantel. Young children currently have to wait for treatment until they are five years. This systematic exclusion of young children from receiving treatment through mass drug administration campaigns that target mainly school-age children is a problem for two reasons. First, ultrasound shows that by that age of five years, there is already evidence of significant morbidity to the liver, so infection is not free of harm. Second, it is not possible to interrupt transmission while a reservoir of infection remains, and this impedes our elimination targets. Therefore, this age group of preschool-age children is strategically important because an active infection acquired at an early age might aggravate the clinical significance of schistosomiasis in later-life, and they play an important role in local disease transmission. By not receiving treatment, health inequities among this age group will be further exacerbated.

Q: What is the Pediatric Praziquantel Consortium (PPC)?

A: The Pediatric Praziquantel Consortium (PPC) is an international Public-Private not-for-profit partnership that aims to reduce the global disease burden of schistosomiasis by addressing the medical need of infected preschool-age children. The Consortium was established in July 2012 by Merck (Merck), Astellas Pharma Inc. (Astellas), Swiss Tropical and Public Health Institute (Swiss TPH) and Lygature. The Consortium operates through an innovative approach that engages new partners as needed:

- at the beginning of 2014, Farmanguinhos and Simcyp, a Certara company, joined the Consortium as full partners (Simcyp retired in 2017)
- in the summer of 2016, the SCI Foundation (SCI; until 2019 part of Imperial College London), joined

- at the beginning of 2018, Kenya Medical Research Institute (KEMRI) and Université Félix Houphouët-Boigny (UFHB) became full partners.

The Consortium builds a sustainable partnership by working with credible and experienced partners, using an R&D operating model that allows new partners to join as needed and performing a regular gap analysis to identify the need for additional expertise, resources and/or funding and proactively identify future partners or funding opportunities.

The consortium's mission is to develop, register and provide access to a suitable pediatric praziquantel formulation for treating schistosomiasis in preschool-age children. In order to achieve this, the consortium established a pediatric drug development program, divided into four major steps: preclinical development, clinical development, registration and access.

Q: What is in the Phase III clinical trial of Pediatric Praziquantel (PZQ)?

A: The Phase III clinical trial of Pediatric Praziquantel (PZQ) currently being conducted in Homabay, Kenya and Mann, Cote D'Ivoire is part of the Clinical development step. The trial is hosted at the Homabay Teaching and Referral Hospital (HTRH). The study is an open-label, efficacy and safety trial of Levo-Praziquantel 150mg in Schistosoma-infected children three months to six years of age, including a 2:1 randomized, controlled cohort of Schistosoma mansoni-infected children four to six years of age treated with L-PZQ Orodispersible tablets (ODT) or commercial praziquantel.

The new medicine, set to come to market in 2023, is a small, orally dissolvable tablet that can withstand the heat of tropical climates and has an acceptable taste that will make it tolerable to young children and enhance its pharmacological effectiveness in treating schistosomiasis.

The development and introduction of this new pediatric medicine is indeed an unprecedented opportunity to close the treatment gap and break the transmission of schistosomiasis in Kenya.

Q: What is KEMRI's role in the Pediatric Praziquantel Consortium?

A: KEMRI provides expertise on local disease epidemiology, expertise on conducting clinical trials and clinical care and is responsible for conducting the trial in Kenya according to ICH-Good Clinical Practice and National and local regulatory and ethics standards. KEMRI also provides the necessary infrastructure and brings on board significant experience:

- in conducting studies in young children living in remote areas in extreme poverty and carrying chronic and debilitating parasitic infections such as schistosomiasis.

- In mobilizing communities in endemic regions for participation in the research.
- In conducting clinical studies on schistosomiasis in general
- KEMRI is very committed together with other partners to confirming the potential of the new pediatric PZQ formulation.

Q: Is praziquantel (PZQ) the only solution to schistosomiasis?

A: PZQ is extremely important, but drugs cannot meet the challenge on their own. A more comprehensive approach includes provision of potable water, adequate sanitation, behaviour change and snail control. At the KEMRI NTD Unit, we have conducted social and behavioral studies, to identify activities that contribute to transmission. Long-term success depends on engaging properly with affected communities, rather than relying on a top-down 'treat and leave' approach. Some communities have taken part in Community-Directed Intervention (CDI) approaches, where the community is empowered to take charge and ensure that interventions are sustained. This helps to address systematic non-compliance and areas that are difficult to reach.

Q: What comes next after the Phase III trial?

A: The new child-friendly medicine for treating schistosomiasis—pediatric praziquantel—

will likely be available starting in 2023. The availability of this new medicine represents an unprecedented opportunity to improve the health and wellbeing of children and communities as a whole while advancing Kenya's progress towards universal health coverage and the Sustainable Development Goals. Once approved, the paediatric formulation will be made available on a not-for-profit basis. Together with relevant stakeholders, the Consortium is exploring new procurement and business models, including local manufacturing, to ensure that the product is available free of charge to the young patients in need. As part of its overall Access strategy, the Consortium is planning a pilot and implementation program in the first African priority countries.

Q: What else are we working on at KEMRI?

A: Apart from the clinical trial, and jointly with the National NTD program, we are exploring how to tailor interventions to specific settings, such as western Kenya where transmission is high (where a focus on morbidity control is appropriate), and areas with low transmission, where elimination is a realistic goal. Education is key – for populations and for frontline health care workers. We are also engaging with other health

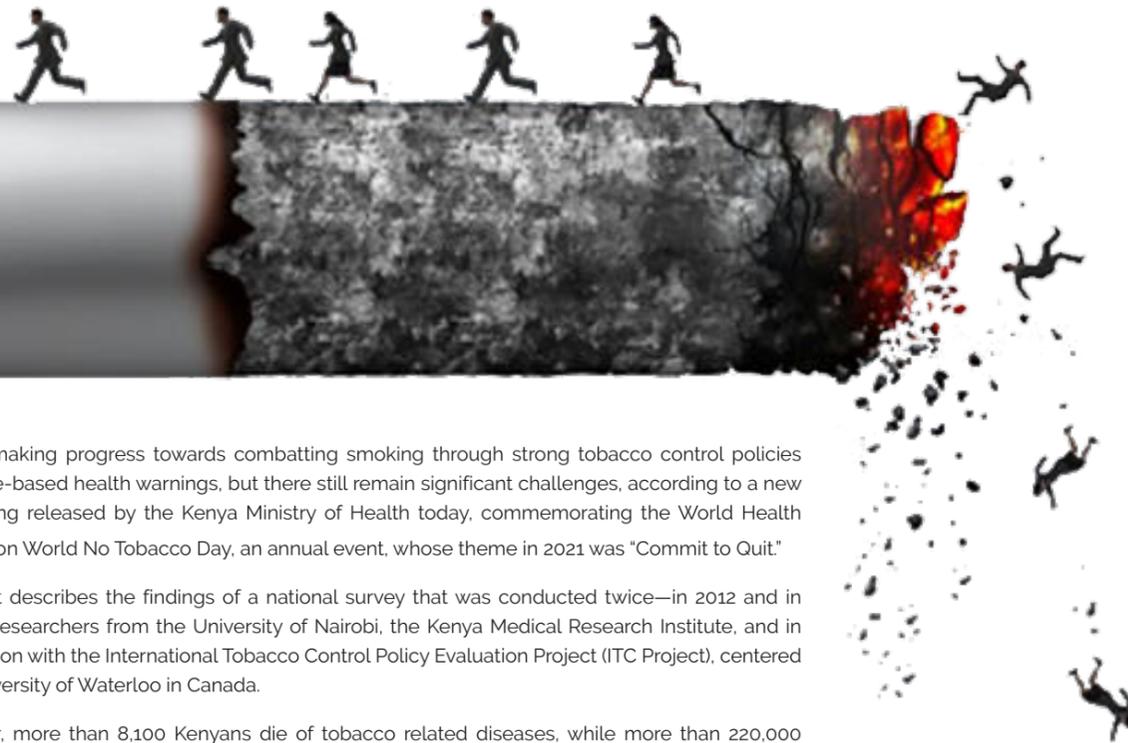
partners to capture data that needs to be shared more widely. Operational research remains an important ongoing element, giving operational managers new strategies and tools that can be layered onto existing activities. We are looking at persistent hotspots – villages that resist elimination of the parasite – and we have seen that mass drug administration can be less effective in such hotspots compared with other villages. Finding ways to identify hotspots is important, because it informs the design of our intervention strategies so that they are tailored to local conditions. The area of better diagnostics is at the heart of our research activities where we continue to evaluate several better/more sensitive alternatives diagnostic tools to the ones currently available.

A snapshot of schistosomiasis in Kenya

- Endemic in 62 of the 290 sub-counties
- Affects 6 million people (over 4 million aged 5-14 years)
- Schistosoma mansoni and Schistosoma haematobium species are present
- A National Strategic Plan for Control of NTDs 2016-2020 is currently underway. In addition, there is the Kenya National Breaking Transmission Strategy (BTS) (2019-2023) that is targeting four neglected tropical diseases (schistosomiasis, intestinal worms, trachoma and lymphatic filariasis) that are amenable to preventive chemotherapy.
- Large-scale treatment is delivered to affected populations through various platforms including schools and also community.
- Research on schistosomiasis at KEMRI includes understanding of disease distribution, diagnostics, basic organism biology, operational research, and social/behavioural research
- The country is taking part in the Consortium's Phase III trial to demonstrate the efficacy and safety of a single dose of the new PZQ orally disintegrating tablets (ODT) in children aged 2 to 6 years and infants & toddlers aged 3 to 24 months.

Dr. Odiere is the Head of the Neglected Tropical Diseases Unit at KEMRI's Centre for Global Health Research in Kisumu. He is also the PI of the Pediatric Praziquantel Study which he recently unpacked in this interview.

WHO Report Propose Tough Measures in Tobacco Use in Kenya.



Kenya is making progress towards combatting smoking through strong tobacco control policies like picture-based health warnings, but there still remain significant challenges, according to a new report being released by the Kenya Ministry of Health today, commemorating the World Health Organization World No Tobacco Day, an annual event, whose theme in 2021 was "Commit to Quit."

The report describes the findings of a national survey that was conducted twice—in 2012 and in 2018—by researchers from the University of Nairobi, the Kenya Medical Research Institute, and in collaboration with the International Tobacco Control Policy Evaluation Project (ITC Project), centered at the University of Waterloo in Canada.

Every year, more than 8,100 Kenyans die of tobacco related diseases, while more than 220,000 children and more than 2,737,000 adults continue to use tobacco each day. Thus, prevention and cessation services are important to save the lives of Kenyans.

The ITC Kenya Project team conducted their surveys among 1,500 tobacco users and 600 non-tobacco users. The survey is part of the 29-country ITC Project, which since 2002, has evaluated policies of the WHO Framework Convention on Tobacco Control (FCTC), a global health treaty which Kenya ratified in 2004. As a Party to the FCTC, Kenya is obligated to implement strong national policies to reduce tobacco use, including large pictorial health warnings, bans on smoking in public places, bans on tobacco advertising, promotion and sponsorship, and increases in tobacco taxes and prices.



Kenya introduced three picture-based health warnings on cigarette packages in 2016, following the unsuccessful challenge by British American Tobacco (BAT). The ITC Kenya Surveys found that introduction of picture warnings significantly increased the effectiveness of warnings. Awareness of the warnings increased from 64 percent to 72 percent of smokers; thinking about the health risks of smoking increased from 28 percent to 43 percent of smokers; and smokers who said that health warnings made them "a lot" more likely to quit increased from 24 percent to 38 percent. Knowledge of many of the health effects caused by smoking increased between 2012 and 2018.

However, the report also identified the need for the Government of Kenya to strengthen tobacco control efforts. Smokeless tobacco is the primary form of tobacco used by Kenyan women. The survey found that only 12 percent of smokeless tobacco users reported noticing health warnings "often" on smokeless tobacco. KEMRI researchers including Dr. Jane Rahedi Ong'ang'o were actively involved in this survey. Others are Prof. Lawrence Ikamari (University of Nairobi), Prof. Geoffrey T. Fong (University of Waterloo, Canada) and Ministry of Health's Ms. Anne Kendagor.

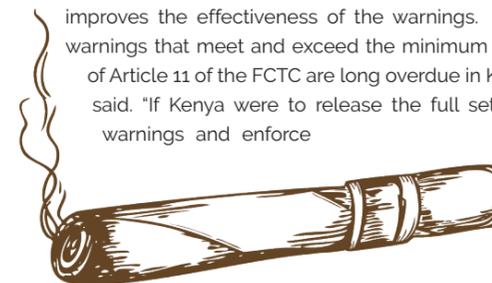
Although the 2014 tobacco control regulations approved 15 new pictorial warnings for both smoked and smokeless products, at the time of the 2018 survey only 3 warnings had been implemented, and the warnings on smokeless tobacco had not been uniformly introduced.

Because most smokeless tobacco is sold in loose form instead of packaged, most smokeless tobacco users are not exposed to health warnings at all. Thus, educating the public about the harms of tobacco products through health warnings on packaging is rarely effective for smokeless tobacco users, including young people who may be starting to use those products.

The report described a challenge to reducing tobacco use is the high rate of single cigarettes. The 2018 survey found that 82 percent of smokers reported last purchasing single cigarettes rather than a pack, about the same as in 2012. There is a need for Kenya's existing ban on packs containing fewer than 12 cigarettes to be more strongly enforced.

There is also a need for Kenya to increase the size of their health warnings, from their current 30 percent to at least 50 percent, which is the required size of warnings under the FCTC.

Professor Geoffrey T. Fong of the University of Waterloo in Canada, Chief Principal Investigator of the ITC Project, said "ITC evaluation studies in countries throughout the world show that increasing the size of pictorial health warnings significantly improves the effectiveness of the warnings. Large pictorial warnings that meet and exceed the minimum size guidelines of Article 11 of the FCTC are long overdue in Kenya", Dr. Fong said. "If Kenya were to release the full set of 15 rotating warnings and enforce



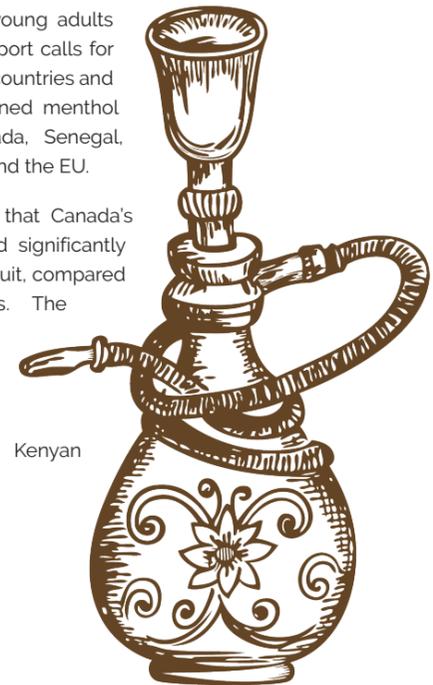
cigarettes, there would be significant benefits in motivating smokers to quit and reducing the number of young people who start smoking."

The survey also found that even smokers support stronger health warnings and other tobacco control policies. 73 percent of smokers are in favor of more health information on cigarette health warnings and 84 percent are in favour of more health information on smokeless tobacco warnings.

Finally, the ITC survey highlighted the threat from menthol cigarettes, which are particularly popular in Kenya: about 1 in 5 smokers in Kenya who have a regular brand of cigarettes smoked menthols, higher than in most high-income countries. Over two-thirds of Kenyan smokers incorrectly believe that menthols are less harmful than cigarettes.

Canada and the European Union have banned menthol cigarettes because menthol reduces the harshness of tobacco smoke, which makes it easier for children and young adults to take up smoking. The report calls for Kenya to join more than 30 countries and jurisdictions that have banned menthol cigarettes, including Canada, Senegal, Nigeria, Uganda, Ethiopia, and the EU.

A recent ITC study found that Canada's menthol cigarette bans led significantly more menthol smokers to quit, compared to non-menthol smokers. The results of the Canadian menthol ban suggest that if Kenya were to ban menthol cigarettes, this would lead 29,000 more Kenyan smokers to quit.





KEMRI's Novel Herbal Formulation Against Worms: Promising.



Prof. Elijah Songok

The Kenya Medical Research Institute (KEMRI) has started a third clinical trial of Ujplus, a fortified herbal formulation among children infected with schistosomiasis in Mbita, Homa Bay County in an efforts to boost the elimination of roundworms and hookworms in children.

The on-going study involves targets school going children infected with schistosomiasis in Mbita Division along the shores of Lake Victoria in Homa Bay County. The team headed by Prof. Maritim Songok, shared their experiences with the media on the effects of this KEMRI's new homegrown local herbal innovation with potential to change the approach to child deworming in Africa.

Ujplus is a herbal formulation designed to be taken as a school meal snack for both nutrition and deworming purpose. Other earlier clinical trials among school children were done in Nandi and Kirinyaga County and showed that Ujplus was not only very effective in deworming school children and increasing their nutritional indicators (weight, Hb etc) but also cleared ringworms, a common malady among Kenya's children.

Below: Pupils of Nyamanga Primary School queuing to receive Uji Plus during the launch of the Third Trial at Mbita

Schistosomiasis or birlhazia and intestinal worms (helminths) are of major public health problem in Kenya and Africa. Their highest burden is among school-aged children causing malnutrition, anemia and retarded growth. In 2001, the World Health Organization (WHO) passed a resolution for large-scale mass deworming of school children using the drug albendazole for helminths and praziquantal for schistosomiasis. Africa countries, including Kenya has taken the schools deworming call in earnest. By 2019, more than 10 million Kenyan children were being dewormed annually with the drugs through school based deworming programs.

The schools deworming program has largely been successful. There is however an underlying gap. Children six years and below, who are the most at risk are left out of the schistosomiasis deworming campaign because there is no currently acceptable child formulation of praziquantal (the current available formulation is toxic to children), although another KEMRI study is working towards this end. For albendazole, it is not recommended for children under two years.

In addition, the current school deworming programs has little direct focus on child malnutrition, a very common malady among Kenya's rural school children. If anything, it is often recommended that the deworming drugs should be taken with meals. It is for this reason that Ujplus comes to addresses the urgent need for child deworming alternatives that are not only effective, safe, affordable, and inclusive but also directly enhances child nutrition status.



LETTERS TO THE EDITOR

- **Prayer and Healing – Any Scientific Evidence?**
- **National Scientific Conference on Miraa Made a Case for Miraa Farmers**



PRAYER AND HEALING – ANY SCIENTIFIC EVIDENCE?

By Dr. Amos Lewa Mwavita



The world of scientists is in misperception for scientific evidence of healing through prayer, some doubt whether prayer can in any way produce healing. This ideology requires more psychosocial and medic logical studies to explain the scientific evidence of organized prayer for physiological changes that normalize body systems what we call healing. Disorders are what we describe as infirmities.

The human body is an organized physiological organ, electrified by neurones or nerve cells, the brain is the centre of the nerves serving the peripheral nerve system. There are also body chemicals; Signal transduction/cellular communication, molecular diagnostics, interactions, Toxicology, chemical biology, affecting the body chemistry. Nerve transmission chemicals (Acetyl choline) and hormonal components triggered from the nerve centres to the different body organs, affecting the general or wholesome human physiology. In their normal phase the body is wholesome or healthy. Any negative stimulant affecting this normalcy results into nerve transmissions, biochemical changes and physiological changes to the peripheral systems, this is an ailment, a disease or a sickness.

Leprosy is a bacterial organism (*Mycobacterium leprae*) affecting the body tissues; it relates with the nerve system affecting sensations. Cancer is a gene malformation proliferating tumours sourced from radical or disorganized cells, triggered by either viral stimulants or autoimmune stimulants. A single mutation in microbial or tumour DNA will lead to drug resistance and treatment failure, it is a gene and physiological disorder. Many Skin disorders are linked to liver physiological dysfunctions, other

superimposed infectious agents. Gynaecological malignancies are hormonal based from physiological changes which relate with brain stimuli, the nerve centre. All these are maintained at energy levels of the body and grounded on immunity.

Prayer is a wavelength, an energy with pharmacodynamics potential. Prayer is able to pharmacodynamically enter into nerve cells and create a stimulus. There are two distinct sources of energy that provide pharmacodynamics. As tools of energy sources can either be negative resulting to infirmity, or Positive energy organized to bring therapy. Demons are medieval spirits or parapsychological beings that can inhabit the nerve system and the brain centres. These are spiritual beings able to course infirmities, sicknesses and ailments affecting human physiology. Demons can disrupt the cytoplasmic membrane or electron transport chain, are more likely to cause toxicity problems. They are spirit beings of medieval energy sources which are disorderly and able to provide negative dynamism; a parapsychological invasion with ultra-forces of energy but specialize in bringing disorders to the human body. They cause infirmities, ailments and diseases especially by night, the early hours of the morning when the body is asleep and most receptive to either bacterial, viral or autoimmune disorders, sources including physiological changes affecting biochemical or hormonal sources that contribute to malignancies and tumours. There is another higher energy source that is some highly organized wavelength, an ultra-parapsychological energy with orderly waves. This is Gods source of Pharmacodynamics. It is a para dynamic energy source, and tapping or executing this organized energy for pharmacological mechanisms energy is described as PRAYER. This energy is acquired through worship, prayer and fasting when the body is most physiologically receptive, in a fasting mood, or during the hours of the night or the silent hours of the morning, this results to effective or dynamic prayer. This energy can dislodge tumours including cancers similar to radioactive energy used in radiography, agitate hormonal changes and normalize body biochemistry. This energy changes human physiology affecting the entire body. This brings wholesome normalcy. The human body can be described as totally cured. To obtain this evidence requires a pre and post analysis of the features that were transformed by this energy applications. Are the tumours gone? Is the cancer healed? Is the cough gone? Is the gynaecological malignancy normalized? Can those in Science tap this energy? Parapsychology is a current concept study used in engineering for bridge constructions and warfare by advanced countries, they at times tap these energise from medieval levels.

We in Africa can employ the Prayer industry to tap this energy through faith in God to formulate curative medicines or supplements for healing purposes, to compose scientific tools and provide directions for management of activities. I conclude that Prayer is an energy, a wavelength, a par dynamic tool that can provide physiological changes evidenced scientifically.

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Dr. Mwavita is a Microbiologist of infectious diseases working at KEMRI Cennter for Microbiology at Kwale. I also serve as the Executive Scientist of Pwani Herbs & Laboratories at Kilifi a pharmacognosy manufacturing and production organisation.

National Scientific Conference on Miraa Made a case for Miraa Farmers

By Dr. Sospeter Ngoci Njeru



The Ameru nation, in a quest to set records straight on where miraa (*Catha edulis*) stands in science, opted for evidence driven defense of their "green gold". Whereas there was politics, high voltage show of government support and lobbying, let me only venture into my domain and highlight some of the scientific findings presented on the health benefits and chemical composition of miraa also called Khat. Whereas, some in the meeting were quick to assume there is "that scientific imagination" to tarnish the good name of the "green gold," one of the honorable Ameru leaders was quick to argue in favor of science, "as the indisputable evidence."

As one of the co-Rapporteur of the conference, I followed the deliberations with keen interest. And so, the science flowed in the first session of the conference, and fortunately for the Ameru nation, a lot was in support of the health benefit of miraa.

Two independent studies did demonstrate that miraa extracts have capacity to kill germs associated with common sicknesses affecting our stomachs, skin, breathing system and even our reproductive system. What this means is that miraa can potentially be harnessed to produce products to treat skin, stomach, and genital infections, as a microbicide. Whereas, this can be counter-argued as a potential disaster in the era of antimicrobial resistance, a case for potential miraa-derived microbicide will be the fact plant product have the least pressure to fuel resistance.

Tagged on this finding was even a more interesting finding that, miraa extract could specifically kill cancer cells outside the body, while sparing the normal non-cancerous cells. This is like a double-edged sword in that, it argues on safety of miraa, while acting like a magic bullet toward cancerous cells. This is definitely a finding with a great promise and should be taken further. However, there is a need to reconcile these findings in the context of high incidences of cancer in Meru county, and whether we can derive any association between miraa consumption and reduced cancer incidences.

It is important to note that, these studies were undertaken using "crude extracts" which contained a mixture of miraa constituents. It is possible that, if the specific active ingredients are purified, they are likely to give higher and better germs killing or cancer killing effects, thus opening medical value addition avenues for miraa.

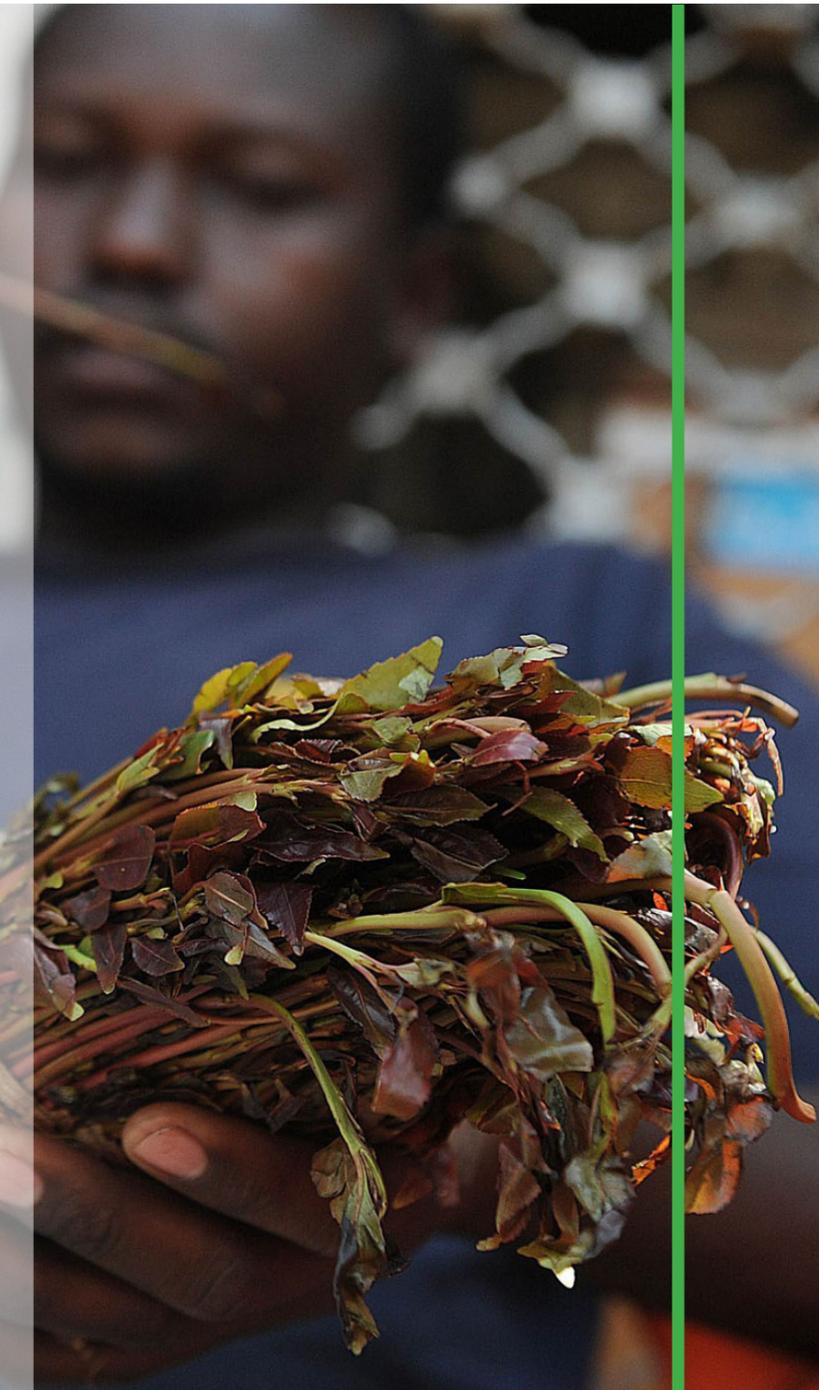
Talking of miraa ingredients, a chemist alluded to a "community bias" on what miraa contains. It is almost thought that khat has only the "handas-inducing" cathinone, and the lesser problematic cathine. However, miraa has a number of other constituents ranging from vitamins, minerals, flavoring compounds, with antioxidants activities.

The fact that miraa has very high antioxidant activity alludes to possibilities of being tapped to deal with degenerative conditions associated with "reactive oxygen species". This is a point that was strongly brought out by the Cabinet Secretary of Agriculture, Mr. Peter Munya and affirmed by the science of the day. Further, the chemistry argued that the bad guy in miraa is the cathinone. However, he gave some hope backed with data, that, during drying, the bad guy "disappears" by turning into the less problematic cathine. As to whether, this means we need to shift from the green twigs to dry twigs and how this will affect the much needed handas, still need serious consideration.

On a rather negative note, for athletes if you chew miraa, you are likely to get into trouble with anti-doping authorities. This is because the bad guy in miraa (cathinone) has effects and "looks" almost related to those of amphetamine, a banned substance in sport work. All in all, the chemists' reports cracked the window and we could appreciate the many chemicals miraa contains. One possibility propounded was to purify those chemicals and take them through scientific modification into useful medical products.

To cap it all, the Ameru were asked on how they traditionally used miraa in medicine. Some of the uses agreed with the reported findings such as in treating and/or managing coughs and diarrhea which can be explained by the presented microbicidal potential of miraa. However, there are still several traditionally acclaimed health benefit that need scientific validation such as in treatment of asthma, heart-burn, weight loss, increase or decrease in libido among others. Whereas data may exist on these aspect, there was strong case for targeted research. It was strongly pointed out that as a nation we heavily depend on scientific information from foreign laboratories. There is a need to shift from this foreign dependence and domesticate miraa research to offer scientific justification in our own context.

Dr. Ngoci Njeru is a Research Scientist at the Centre for Traditional Medicine and Drug Research (CTMDR) in KEMRI. His article was first published by the Standard Newspaper in December 2021.



CONGRATULATIONS

KEMRI Scientists Scoop Regional Awards

Two of KEMRI's scientists were named Africa Evidence Leadership Award (AELA) 2022 Runners-up by the Africa Evidence Network.

The two, Prof. Jennifer Orwa, Deputy Director, Resource Development and Knowledge Management and Prof. Eleanor Ochodo-Opondo, Research Scientists based at KEMRI's Centre for Global Health Research (CGHR) were among many African scientists nominated from various institutions and organizations in Africa based on their contribution in the evidence ecosystem. The two emerged runners-up in the Evidence Intermediaries and Evidence Producer categories respectively.

Prof. Orwa is celebrated for her significant contribution to evidence intermediary work in the Africa evidence ecosystem. She also spearheads the provision of institutional mechanism for sustained evidence reviews and synthesis to support the ministry of Health and County Level decisions in health through capacity building in knowledge translation and management for enhanced innovation. She is also the current Director of Cochrane Kenya, an affiliate of Cochrane collaboration hosted by KEMRI.

Equally, Prof. Ochodo was awarded for her contribution as an evidence champion whose work in evidence production has made significant contributions to the Africa evidence ecosystem also wears many hats in matters science. She is an academic editor for the Cochrane infectious diseases group where she offers editorial and peer review for systematic reviews of infectious diseases. She is equally part of the Cochrane Africa Steering committee and a fellow of the African Science Leadership Programme. Prof. Ochodo was named as one of the Youngest Promising Researchers in 2018 by the National Research Foundation of South Africa and the top forty-career scientists in Africa by the African Academy of Sciences 2021.

The Africa Evidence Network works with various entities in Africa to contribute to the increase of the use of evidence in decision making (EIDM) and KEMRI's scientists are among the Pan African participants for this forum whose main goal is making use of the best available evidence for the decision at hand. KEMRI celebrates these scientists for their impeccable work in putting the Institution in the Global map as far as research is concerned. Congratulations.



Prof. Jennifer Orwa



Prof. Eleanor Ochodo-Opondo





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