2021

UNC
PROJECT
Lilongwe, Malawi

ANNUAL REPORT

Improving the health of Malawi through research, capacity building and care.

CONTENTS

LETTER FROM THE COUNTRY DIRECTOR

Esteemed colleagues,
It is that time of the year when we reflect on our mission as UNC Project, and most of all, look back at our achievements and challenges in 2021.

Throughout 2021, we continued to stand firmly on the foundation of our mission, which is to conduct health research that is responsive to the country's priorities. We also strived to support the Malawi Government through technical support, service provision, and capacity building. Although most of our research is for the prevention and treatment of infectious diseases mostly HIV, over the years we have built a good portfolio of implementation research that enhances service provision.

Just like before, in 2021, UNC Project continued its journey of empowering Malawian investigators to conduct independent research and take lead as first authors of papers in peer-reviewed journals. Faculty members based in Malawi and UNC-Chapel Hill, USA, continued to provide mentorship and coaching to Malawian junior investigators. This continues to be an enviable achievement locally and internationally. We are indebted to all who support research activities that have led to various publications with Malawians as first authors. Let us keep the fire burning.

The COVID-19 pandemic continued to affect our operations in various but thanks to all for making immeasurable sacrifices during the year that have helped to reduce the number of cases in Malawi. We attest to the wonders that COVID- 19 vaccines have made in the country. It is our hope that our operations will not be affected again as we have seen during the various waves of the pandemic.

The year 2021 has also seen the ending of various big studies within UNC Project like S4, HVTN, LIFE, Ambition, and Promote. We continue to go through a lean period which also means that we cannot take more employees on board. This calls for staff to be flexible and multi-task in order to adapt to new realities. Further, our investigators must be vigilant in looking for new opportunities.

Management of UNC Project and the Board of Directors would like to thank all staff for their resilience and strength during one of the toughest years of our lifetime.

Thank you all for the zeal and passion to improve healthcare service provision in Malawi. Your hard work has made UNC Project continue providing hope to all the communities that we serve.

Zikomo!

The year 2021 was a year that showcased UNC Project, Malawi's status as a key public health and academic partner as we joined the Malawi Ministry of Health (MOH) in its clinical and laboratory efforts to control COVID-19; in research highlighted by leading the global effort in proving the efficacy of long-acting Antiretroviral therapy (ART) to prevent HIV infection among at risk women; in training as we continue to provide high level training opportunities for both Malawi and US-based learners; and as the flagship global site for the UNC Institute for Global Health and Infectious Diseases as we continue to show with real action our wholistic approach as a locally-led, global academic center.

In this calendar year our 320 faculty and support staff conducted 35 fully funded **research projects** with nearly half in the area of HIV and cancer treatment and prevention. Highlights of this research include determining the interaction between ART and TB treatment; improving the treatment regimen for cryptococcal meningitis (these results changed WHO policy!); improving cervical cancer screening and prevention interventions; improving the treatment for Kaposi's Sarcoma; COVID-19 vaccine efficacy trial; phase II evaluation of an HIV vaccine candidate; improved treatment for HIV infants with severe pneumonia; the interaction among women on ART initiating a contraceptive implant; determining the feeding and growth factors that lead to poor outcomes among infants born with low birth weight or fail to thrive; evaluating the effect of the WHO/MOH role out of the first partially effective malaria vaccine; evaluating the introduction of the integration of mental health services for depression care; determining the biologic factors that will lead to a syphilis vaccine; following cohorts of lymphoma and breast cancer patients to determine best practices for treatment and prevention; determining the treatment outcomes for esophageal cancer; in collaboration with the MOH, establish the infrastructure and standard operating procedures and training for a One Health, national level antimicrobial resistance (AMR) program; determine methods to improve the blood supply; improve access to sexual and reproductive services for adolescents.

These (and past years) research findings resulted in 126 peer-reviewed, accepted manuscripts that were published in 2021, with **25 of these with Malawian's as first authors.**

Core services that support this research (and care) effort includes our WHO-4 star **Laboratory** that was severely effected by COVID-19 and its supply chain and maintenance and repair challenges. Despite these challenges the lab took a leading partnership role with the MOH in establishing and conducting COVID-19 PCR testing and established a gene sequencing capacity to support our AMR and etiologic identification efforts. The **Pharmacy** that provided investigational clinical trial drug services for 14 studies, in addition to leading the distribution and management of the COVID-19 PPE and supportive medications. The **Nursing** department that includes 46 nurses that support the implementation of all the research studies and collaborate in supportive research and training with the UNC School of Nursing and the Kamuzu College of Nursing. The **Data Department** that includes pre study form and data collection systems development, quality control, quality assurance and internal monitoring and **Regulatory** that manages all the IRB approvals for each study both in Malawi and in coordination with UNC approvals, a difficult task that requires daily communication with these ethics and regulatory boards. The **Community** department that includes staff that maintains our long-standing community advisory board (CAB) that meets monthly and provides crucial community level feedback about both proposed and on-going research. This department is also responsible for the recruitment and retention of research participants, with a stellar performance again of over 93% retention for all longitudinal studies. The **Information and Communication Technologies Department** and its 5 IT experts are responsible for the networking and connectivity for not only the 320 employees based in Malawi across a multitude of buildings, clinics and facilities, but for the smooth communication and data sharing necessary between the hundreds of faculty, staff and students based in the US and their Malawi counterparts.

UNC Project operates **5 clinical registries** in the areas of Pediatrics, Cancer, Trauma, STI and Sickle Cell. Each of these electronic data bases captures vital clinical data that is used to analyze trends and to identify areas of care that require interventions with the overall goal of improving the standard of care. As an example, data collected from the in-patient pediatric ward has facilitated the reduction in overall mortality in the past decade from 9% to 4 %.

UNC Project has robust activities in the areas of **Community Service and Philanthropy.** We continue our long-standing relationship with **Proctor and Gamble** in providing water sterilization packets, soap and closed water storage containers to post-natal families in 33 rural health facilities in Lilongwe District. On the KCH Pediatric Ward the **Robinson Family** provides medicines, salary support and other direct care for children with Burkitts Lymphoma and the **Peacock Family** provided resources to renovate the emergency and admission ward. Our community development work in the rural hamlet of **Dzama** continues into its 2nd decade, where we provide support for pre and primary school teachers, school supplies and a daily nutritious breakfast for 2000 students and a hard-boiled egg per day to 500 pre-schooler's in an effort to combat stunting. The **Charlie Scholars Program** (named and funded in memory of the late, great Professor Charlie van der Horst) takes the best and brightest graduating primary schoolers and finances them in private boarding schools where they focus on English and Writing for 3 years in preparation to attend a top secondary school. To date, 6 scholars are in this program with another 2 to be chosen this year. In addition to providing PPE and developing strategies to keep our UNC staff and research participants safe, our **COVID-19** response included providing primary and tertiary care for infected persons arriving at KCH; housing at our guesthouse for hospital personal in isolation; PCR testing in support of the government testing program; and the donation of PPE and oxygen cylinders to the hospital.

In the area of **Training**, our A**nalysis and Manuscript Unit (AMU)** continued to be the hub for all learners in Malawi. They conducted didactic courses in Epidemiology and Biostatistics; provided one on one mentorship especially for design, analysis and writing; provided platforms for the dissemination of findings; conducted weekly works in progress attended by all learners; and conducted a grant writing workshop. UNC Project is the home to 3 Fogarty training grants, focused on Malawi learners each offering Masters and PHD level degrees and mentored pilot research programs in the areas of HIV implementation science, cancer outcomes and mental health research; the Fogarty Global Health Fellows program where a mix of 7 US and Malawian advanced students conducted year-long research projects in Malawi; the Lineberger Comprehensive Cancer Center sponsored a mentored pilot grant program to 3 scholars and UNC Project hosted 2 UNC grad Research Interns taking a gap year or 2 before applying to medical school.

Since its inception, UNC Project, Malawi has always provided **direct clinical care** within the care structure of the Kamuzu Central Hospital referral hospital, Bwaila District hospital and select health centers. This care is provided by our specialists, medical officers, clinical officers, nurses, counselors and lab techs and always includes training for Malawian clinical students. We provide this care in many disciplines including general pediatrics, pediatric cancer and sickle cell disease, adult medicine including HIV primary care, STI, OB-GYN; surgery, oncology, radiology, general lab services including pathology and microbiology.

In our 22nd year, **human resource (HR) development and management** remains a key element to the success of UNC Project. Indeed among the 320 UNC Project, Malawi employees, 14 have had 20 or more years of service. With a robust pension plan and medical scheme our employee retention is high. However, among the employees we facilitate advanced training for, especially in the areas of lab, regulatory and finance, there is a rising attrition as advanced opportunities become available in Malawi.

We sponsor outside activities including physical fitness classes, volleyball and soccer league teams and a regionally accomplished ultimate frisbee team.

On a sad note, our beloved HR and Admin Manager of 22 years, Mr. George Bonomali passed away this year from COVID-19 complications. However, we have now found a fantastic manager, Mr. Andrew Machado, who will continue to not only be in charge of all HR services but is the point person for all global travel and visitors, procurement, security, maintenance of all 70,000 sq/ft of lab, clinical and management space, and the motor pool.

RESEARCH PROJECTS

HIV Prevention and Treatment	11
Cancer Prevention and treatment	7
Sexual and Reproductive Health	4
Pediatrics	3
STI Prevention and treatment	3
Covid-19	3
Malaria Prevention	1
Anti-microbial resistance	1
Cryptococcal meningitis	1
Blood Safety	1

PUBLISHED PAPERS

126

MALAWI FIRST AUTHOR PAPERS

25

STAFF MEMBERS

320

TRAINEES

22

MALAWI **10**

US **12**

BACKGROUND BRIEF

The University of North Carolina at Chapel Hill has been conducting HIV and STD research in Malawi since 1990 when it collaborated with the Malawi Ministry of Health (MOH) to provide technical assistance in the design of several clinical management guidelines for HIV and STDs.

In 1999, this relationship with the MOH was institutionalized when UNC's Malawi activities were consolidated into a center of excellence for HIV/STD research, care and Capacity building called UNC Project-Malawi. Located in the capital city of Lilongwe, UNC Project-Malawi is on the premises of Kamuzu Central Hospital (KCH), a 1,000-bed, public tertiary care hospital operated by the Ministry of Health

UNC has worked with the Malawi Ministry of Health and partners in designing programs to control the spread of HIV, STDs, tuberculosis, malaria, anti-microbial resistance, COVID-19, as well as strengthening capacity in surgical best practice, cancer prevention and treatment, and mental health for those with chronic healthconditions.

UNC Project has a strong and growing relationship with the Malawi College of Medicine (COM) in Blantyre and Lilongwe. Several UNC faculty members hold joint appointments at COM, and COM classes are taught at UNC Project in epidemiology, pediatrics and HIV care. The two institutions collaborate in training and strategic planning.

Since 1999, UNC Project-Malawi has served as a training site of the NIH Fogarty International Center's AIDS International Training and Research Program. Through this program, UNC Project offers short-, medium- and long-term training of personnel in Malawi.

SPONSORS

- National Institutes of Health (NIH)
- The United Nations Children's Fund (UNICEF)
- World Health Organization (WHO)
- U.S. Centers for Disease Control and Prevention
- United States Agency for International Development (USAID)
- Family Health International
- Bill and Melinda Gates Foundation
- Gilead Pharmaceuticals
- Proctor & Gamble Children's Safe Drinking Water Project
- PATH Malaria Vaccine Initiative and GlaxoSmithKline Biologicals
- European and Developing Countries Clinical Trials Partnership
- The Fleming Fund

INTERNATIONAL COLLABORATORS

- AIDS Clinical Trials Group Network (ACTG)
- International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)
- HIV Prevention Trials Network (HPTN)
- HIV Vaccine Trials Network (HVTN)
- Microbicide Trials Network (MTN)
- Baylor International Pediatric AIDS Initiative – Malawi
- Elizabeth Glaser Pediatric AIDS Foundation
- Johns Hopkins University

LOCAL COLLABORATORS

- Malawi Ministry of Health
- Kamuzu Central Hospital
- College of Medicine
- Kamuzu College of Nursing
- Malawi College of Health Sciences
- Public Health Institute of Malawi
- The Lighthouse
- National AIDS Commission
- Malawi Network of AIDS Service Organizations (MANASO)
- Malawi Business Coalition Against HIV/AIDS (MBCA)
- Malawi Adventist University – Malamulo College of Health Sciences
- Mzuzu University
- Lilongwe District Health Office

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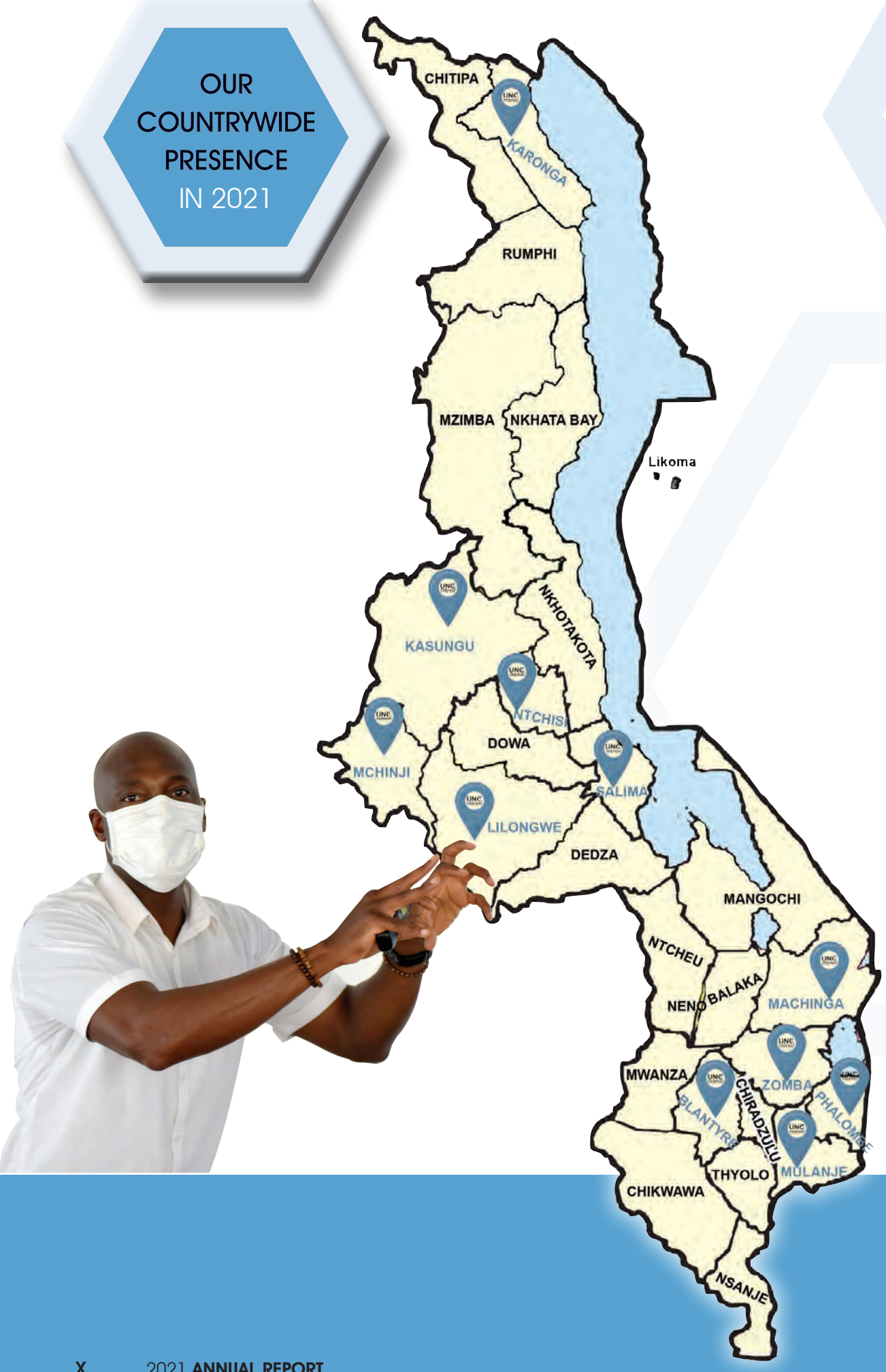
Tisungane Mvalo
PEDIATRICS
CO-CHAIR, FACULTY COMMITTEE

OUR COUNTRYWIDE PRESENCE IN 2021



RESEARCH

Distant view of Tidziwe and Annex buildings.

ACTG A5354 Effect of Antiretroviral Treatment Initiated during Acute HIV-1 Infection on measures of HIV-1 Persistence and on HIV-1- Specific Immune Responses

CONTEXT

The study design was phase II, prospective, open-label-two-step study to measure the effects of early antiretroviral therapy(ART) on the establishment of HIV-1 reservoir and HIV-1-specific immunity. Treatment-naïve participants with acute HIV-1 infection (AHI) will have an enrolment visit that will include the immediate initiation of ART.

The inclusion criteria;

- Participants transitioning directly from step 1 to step 2 as part of A5354 Version 2.0 OR
- Participants enrolling to step 2 after having previously completed the week 72 and who went off study under A5354 Version 1.0
- Most recent HIV-1 RNA< 50 copies m/L obtained within 90 days prior to step 2 entry
- Completed 72 weeks of follow-up on step 1
- Ability and willingness of candidate to provide written informed consent that includes step 2
- Ability and willingness to continue ART
- Women who are pregnant at the time of enrollment into step 2 and agree to use non-study provided ART and otherwise meet requirements are eligible.

AIMS

The study is being done to:

- Start ART early in those recently or acutely infected with HIV-1. Participants will receive antiretroviral therapy consisting of either one tablet of elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10mg (also known as EVG/COBI/FTC/TAF or Genvoya) by mouth daily or another medically appropriate antiretroviral therapy.
- See how starting ART as soon as the infection is found affects the amount of HIV-1 in blood and how well the body fights the HIV-1 infection
- Look at the amount of HIV-1 DNA (genetic material for HIV-1) seen in CD4+ T-cells (infection-fighting cells in blood) after 48 weeks of ART
- See how early treatment for HIV affects the numbers of HIV-1 infection fighting cells (CD4+ and CD8+ T-cells) in blood

Treatment-naïve participants with acute HIV-1 infection (AHI) will have an enrolment visit that will include the immediate initiation of ART.

OVERVIEW

Study PI: Mina Hosseinipour

Funding agency: National Institute of Allergy and Infectious Diseases

Project period: **na**

First screening: 13 March 2018

Expected last exit: Version 1 ended 28 Jul 2020 and version 2 started from 11 December 2020

STATUS Enrolling

Target accrual	5 Total enrolled in 2021	5 Total enrolled in entire study	20 Follow-up visits in 2021

PROGRESS & EVALUATION

During step 1 the sample size for the site was 25 and 11 pThe last participant enrolled into version 1 exited the study on the 28th July 2020. The study team released version 2 of the study which allows follow up of these participants for an addition 144 weeks in step 2 of version 2 and followed up every six months. Approvals for version 2 protocol obtained on 11 December 2020.

Version 1 enrolled 11 participants, three withdrew consent and 8 completed study. Out of 8 participants, we were able to trace back 6 participants. The two had moved out of Lilongwe. We screened the 6 participants and 5 were eligible and enrolled for version 2 of study.

Drug-Drug Interactions Between Rifapentine and Dolutegravir in HIV/ LTBI Co-Infected Individuals ACTG 5372

CONTEXT

This is an open-label, two-arm, multicenter pharmacokinetic (PK) study to investigate the potential interactions between dolutegravir (DTG) and steady state rifapentine (RPT) when RPT is given with isoniazid (INH) daily for 4 weeks (1HP) as part of treatment for latent TB infection (LTBI) in HIV-1 and LTBI co infected individuals.

The majority of participants will be on study for 6 weeks (a 4-week on-study treatment period and a 2-week follow-up period). The duration may be up to 8 weeks as participants will have up to 6 weeks from the time of study entry to complete 4 weeks of treatment.

Participants who are required to return for confirmation of virologic failure within 1 to 3 weeks after the follow-up visit may be on study for up to 11 weeks.

Sample size is maximum of 72 participants– 36 in Arm 1 and 36 in Arm 2, to yield at least 32 evaluable participants in each arm.

The study will begin enrollment with Arm 1. Opening of Arm 2 will depend on assessment of DTG PK data from participants in Arm 1.

Arm 1

- DTG 50 mg orally BID (~12 hours apart)
  - 1st dose: DTG 50 mg each morning from non-study ARV supply
  - 2nd dose: DTG 50 mg each evening from study supply
- 1HP: INH 300 mg + RPT 600 mg orally each morning for 4 weeks

Arm 2 (upon opening)

- DTG 50 mg orally each morning from non-study ARV supply
- 1HP: INH 300 mg + RPT 600 mg orally each morning for 4 weeks

All participants must also be on once-daily DTG-based ARV treatment with 2 NRTIs (excluding TAF) during the study.

All participants must receive pyridoxine (vitamin B6) 25 or 50 mg with each dose of INH based on the current local, national, or international dosing guidelines.

OVERVIEW

STATUS
Enrolling

Study PI: Cecilia Kanyama

Funding agency: National Institute of Allergy and Infectious Diseases

Project period: August 2020 - August 2022

First screening: 13 September 2021

Expected last exit: 30 August 2022

72 Target accrual	4 Total enrolled in 2021	4 Total enrolled in entire study	36 Follow-up visits in 2021

PROGRESS & EVALUATION

The study was open to accrual overall on 24 august 2020 and the first participant enrolled on 27 Feb 2021. Our site had the first enrolment on 20 September 2021 and completed follow up for first phase on 25 November 2021. The Arm 1 study is completed at all sites. Opening of Arm 2 will depend on assessment of DTG PK data from participants in Arm 1. If arm 2 opens, we will enroll seven participants. Our total target accrual is 10

ACTG 5381

Observational Cohort to Assess Therapeutic Efficacy and Emergence of HIV Drug Resistance Following Initiation of Tenofovir-Lamivudine-Dolutegravir (TLD) for First- or Second-Line ART or with Rifampicin-Containing TB Treatment

CONTEXT

With an HIV population of 36.7 million, the 90-90-90 targets and the ambitious target of ending the AIDS pandemic by 2030, there is an urgent need to identify and promote ART regimens and strategies that include drugs that can be co-formulated and have high potency, the high genetic barrier to resistance, proven safety, and no food or other restrictions. Integrase strand transfer inhibitor (INSTI)-based regimens, especially those including DTG, have emerged as highly attractive regimens for ART-naive and ART experienced patients. Nevertheless, the recent observation of a possible increase in the risk of neural tube defects (NTD) in children born to mothers exposed to DTG during conception underscores the need to carefully monitor DTG regimens that are rolled out, irrespective of strong attributes demonstrated in clinical trials. In clinical trials, DTG-containing first-line ART has been better tolerated, has higher virologic efficacy, fewer drug-drug interactions (DDIs), and less frequent emergence of HIV drug resistance than efavirenz (EFV)-containing ART.

In August 2017, the decision was made to support rapid adoption of the single-tablet regimen of TLD as first-line and second-line ART for adults and adolescents in PEPFAR programs, with rollout starting in 2018. Countries are encouraged to include HIV-1 positive pregnant women, breastfeeding women, adolescents (from age 10 years and body weight >30 kg), and patients requiring treatment for TB (for whom an additional DTG 50 mg dose is used with RIF-based treatment) in their TLD transition planning. The primary objectives are (1) among participants still on TLD at 6 months of follow up, to estimate the proportion achieving virologic success (HIV-1 RNA ≤1000 copies/mL) and the proportion with new DTG resistance mutations and (2) among participants taking concomitant TLD (including an additional daily dose of DTG 50 mg) and RIFcontaining TB treatment (Group 3), to estimate the proportion achieving virologic success (HIV-1 RNA ≤1000 copies/mL) and the proportion with new DTG resistance mutations at the end of concomitant treatment.

AIMS

To better understand risks and benefits of Tenofovir-Lamivudine-Dolutegravir (TLD) roll out in programs done in low- and middle-income countries.

There will be no treatment provided through the study. Each participant will be followed for 36 months.

OVERVIEW

Study PI: Cecilia Kanyama

Funding agency: National Institute of Allergy and Infectious Diseases and United States President's Emergency Plan for AIDS Relief (PEPFAR)

Project period: **August 2019 - December 2023**

Expected last exit:

STATUS
Enrolling

200 Target accrual	24 Total enrolled	24 Total enrolled in entire study	400 Follow-up visits in 2021

PROGRESS & EVALUATION

SWe recruited participants in total less than expected. This is because of COVID 19 and the closure of all ACTG studies to enrolment from 19th March 2020 to August 2020. We resumed enrolment in July 2020. However, we still experienced drop-in recruitment due to COVID 19 restrictions. One of the study arms looking at patients transitioning from Efavirenz to Dolutegravir is also slow to recruit because most have already transitioned to the DTG based regimen during the period site was closed to accrual. We had expanded enrolment sites and targeted teen clubs to improve recruitment. But we were unable to find participants because they had switched regimens mainly during the COVID enrolment pause by ACTG.

Drug-Drug Interactions Between Rifapentine and Dolutegravir in HIV/ LTBI Co-Infected Individuals

AMBITION

CONTEXT

Cryptococcal meningitis is a leading cause of death in HIV-infected individuals in Africa. The current recommended treatment is a drug called amphotericin B deoxycholate (D-AmB). Current guidelines recommend treatment with amphotericin B deoxycholate which requires at least 7 days of intravenous infusions given in hospital, making it difficult and costly to administer. It also causes many side effects, including kidney impairment and anaemia, making close laboratory monitoring essential.

A modified form of amphotericin B is available called liposomal amphotericin B(Ambisome or L-AmB). This is considerably less toxic than standard amphotericin B deoxycholate, and is known to be efficacious in treatment of cryptococcal meningitis.

AMBITION has The African Meningitis Trials Network (AMNET) was established in October 2017, launched in Lilongwe in January 2018. The network brings together African and European Clinical Researchers whose main aim is to reduce the large number of deaths caused by meningitis in Africa through collaborative clinical trials. The objective of the Network is to build on existing experience, resources and infrastructure in order to enable other institutions and researchers to build on the AMBITION experience. The hope is that this will streamline the development of large, international randomized controlled trials in the future. This work continues with monthly conference calls and meetings held around major international conferences

AIM

This study aims to define a new easy to administer, effective, and cost-effective schedule for L-AmB use in the treatment of cryptococcal meningitis. A preliminary small study has shown that a single high dose of L-AmB is as effective at clearing cryptococcal infection from the cerebrospinal fluid (CSF) as 14-day courses. This study will determine whether a single high dose of L-AmB is as effective as the standard treatment in terms of preventing deaths from cryptococcal meningitis.

OVERVIEW

STATUS
Completed

Study PI: Cecilia Kanyama

Funding agency: National Institute of Allergy and Infectious Diseases

Project period: **November 2018- June 2021**

First screening: 21 November 2018

Last exit: June 2021

72 Target accrual

110 Total enrolled

48 Follow-up visits in 2021

PROGRESS & EVALUATION

The study completed enrolment on 2nd march 2021. Lilongwe site enrolled 110 participants, Overall the study enrolled 844 participants out of projected 850.However this was deemed sufficient by DSMB because study had no to follow up. The follow up phase continued to June 2021. The initial results were presented at IAS July 2021.
Following the successful dissemination at IAS, we had local dissemination on 20th August at Capital hotel, Lilongwe. This dissemination was organised in conjunction with Malawi Liverpool Welcome Trust who were doing a similar study. We had invited the press, MOH and other stakeholders. We had a follow up dissemination to KCH staff at Ufulu gardens on 29th Oct 2021.We continued to give radio and TV interviews disseminating information on cryptococcal meningitis and current evidence-based management.

Unfortunately, due to COVID, we saw very few patients in the medical ward. Therefore, the enrolment rate was slow but initial target of 110 was met. The final monitoring and data cleaning exercise was done virtually in June 2021. Data based was closed July 2021. All financial reconciliations will be done by end February 2022

A research dissemination to major stake holders was done on August 20th, 2021. We had a dissemination for KCH staff on October 29th 2021.

Representatives from Wellcome Trust, UNC Project together with Malawi Government officials and various partners

STUDY RESULT NEWS

AMBITION

Single high-dose liposomal amphotericin based regimen for treatment of HIV-associated Cryptococcal Meningitis is non-inferior to the WHO standard of care.

On 20 August 2021 study representatives for the Malawi sites namely Malawi-Liverpool-Wellcome Trust Clinical Research Programme and UNC Project jointly held a dissemination conference in Lilongwe where they shared results of the AMBITION-cm Randomised Trial.

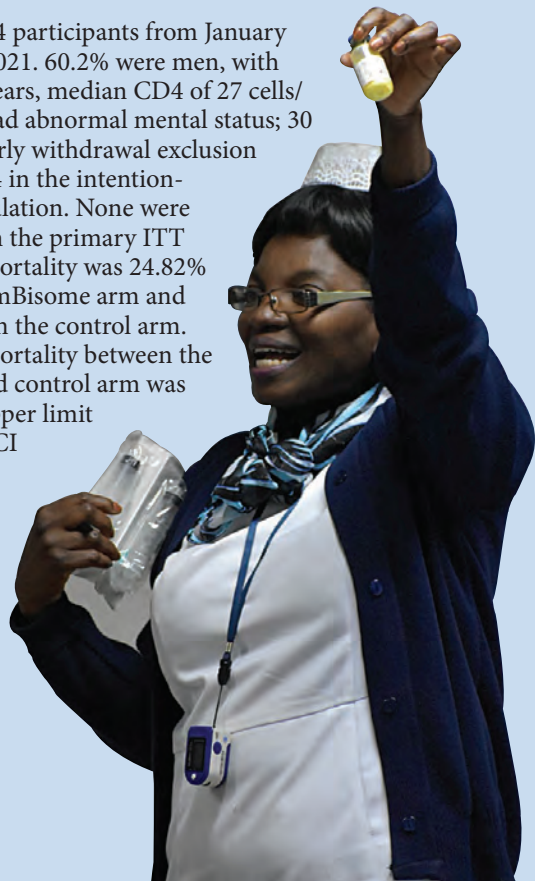
The results showed that 'a single high-dose AmBisome on a backbone of flucytosine and fluconazole was non-inferior to the current WHO recommended standard of care for HIV-associated cryptococcal meningitis'.

The trial was conducted in six large referral hospitals across five countries in sub-Saharan Africa of Botswana, South Africa, Zimbabwe, Malawi and Uganda.

BACKGROUND:
Cryptococcal meningitis (CM) is a leading cause of HIV-related mortality. Based on phase-II study data showing that a single high-dose of 10mg/kg liposomal amphotericin-B (AmBisome, Gilead Sciences Inc) was non-inferior to 14 days of standard dosing in clearing Cryptococcus from the cerebrospinal fluid we performed a phase-III randomised controlled non-inferiority trial to examine the impact of a single high-dose of AmBisome in averting all-cause mortality from CM.

METHODS:
HIV-positive adults with a first episode of CM in Botswana, Malawi, South Africa, Uganda and Zimbabwe were randomised to induction therapy of either (i) single, high-dose AmBisome (10mg/kg) given with 14 days of flucytosine 100mg/kg/day and fluconazole 1200mg/day (AmBisome) or (ii) 7 daily doses of amphotericin B deoxycholate (1mg/kg) plus 7 days of flucytosine 100mg/kg/day, followed by 7 days of fluconazole 1200mg/day (control). All participants received consolidation therapy of fluconazole 800mg/day for eight weeks. The primary endpoint was all-cause mortality at 10 weeks with the trial powered to show non-inferiority with a 10% margin.

RESULTS:
We randomised 844 participants from January 2018 to February 2021. 60.2% were men, with median age of 37 years, median CD4 of 27 cells/mm2, and 28.5% had abnormal mental status; 30 participants met early withdrawal exclusion criteria, leaving 814 in the intention-to-treat (ITT) population. None were lost to follow-up. In the primary ITT analysis 10-week mortality was 24.82% (101/407) in the AmBisome arm and 28.75% (117/407) in the control arm. The difference in mortality between the AmBisome arm and control arm was -3.93%, with the upper limit of the 1-sided 95%CI for the difference being 1.17%, well below the pre-specified 10% non-inferiority margin. The single high-dose AmBisome treatment was well tolerated.



A Randomized, Placebo-Controlled Trial of HPV Vaccination to Reduce Cervical High-Grade Squamous Intraepithelial Lesions among HIV-Infected Women Participating in an HPV Test-and-Treat Program (COVENANT)

AMC 099

CONTEXT

Cervical cancer is one of the top 4 commonest cancers in women worldwide and more than 85% of the global burden of this disease occurs in the developing world. In 2012, 266 000 deaths due to cervical cancer occurred. Almost 9 out of every 10 of these lived and died in low-to-middle income countries (LMICs). In contrast, 1 out of every 10 of these women, lived and died in high-income countries. Human papillomavirus is virtually responsible for all cases of cervical cancer. In Malawi, cervical cancer remains a public health problem. It is the most common cancer and a leading cause of cancer deaths among women in Malawi. It accounts for 40% of all cancer cases among women with an estimate of 3, 684 women developing cervical cancer and 2, 314 dying from the disease annually. HIV is closely linked to cervical cancer. HIV infected women are at higher risk of HPV infection with rates as high as 45-90%. Some studies showed that quadrivalent HPV vaccine reduced the risk by 46.2% of subsequent HPV disease and cervical HSIL by 64.9% when compared to placebo among HIV-uninfected women who were participating in clinical studies of the quadrivalent HPV vaccine and underwent cervical treatments.

OBJECTIVE

The primary objective is to determine if HPV vaccination reduces the occurrence of severe cervical dysplasia among HIV-infected women participating in an HPV test-and-treat strategy for cervical cancer prevention.

At screening, potential participants will be tested for cervical human papillomavirus (HPV) infection (GeneXpert hrHPV assay and HPV DNA PCR) and undergo cervical colposcopy to confirm the absence of cervical cancer. If eligible, the participant will be randomized to receive either the 9-valent HPV vaccine or saline placebo.

Participants will return 4 and 26 weeks later for the second dose of vaccine or placebo. At week 4, participants will have cervical colposcopy and undergo cryotherapy or loop electrosurgical excisional procedure (LEEP) as appropriate. Participants undergoing cervical cryotherapy will have cervical biopsies before the treatment. Participants will be followed with HPV testing (Gene Xpert and HPV DNA PCR) at weeks 26, 52, 78, and 104, and will have cervical cytology and colposcopy with biopsies at weeks 26, 52, and 104.

OVERVIEW

STATUS
Enrolling

Study PI:	Lameck Chinula
Funding agency:	AIDS Malignancy Consortium
Project period:	July 31, 2019 - January 2024
First enrollment:	2019
Expected last exit:	January 2024

120	Target accrual	15	Total enrolled	33	Total enrolled in entire study	31	Follow-up visits in 2021

AMC 100 A Phase II Multicenter Study of Pomalidomide Monotherapy in HIV-Positive Individuals With Kaposi Sarcoma (KS) in Sub-Saharan Africa (SSA)

BACKGROUND

This phase II clinical trial studies the side effects of pomalidomide and how well it works in treating patients with Kaposi sarcoma and human immunodeficiency virus (HIV) infection. Biological therapies, such as pomalidomide, may stimulate the immune system in different ways and stop tumor cells from growing and it may also block the growth of new blood vessels necessary for tumor growth.

OBJECTIVES

To determine if pomalidomide monotherapy induces a minimal level of antitumor efficacy to justify its further development for HIV-associated Kaposi sarcoma (KS) in sub-Saharan Africa and is safe and tolerable.

SECONDARY OBJECTIVES:

To evaluate the effects of pomalidomide monotherapy on standard measures of HIV control, i.e., CD4 counts and HIV viral loads, in this participant population.

TERTIARY OBJECTIVES:
To assess the effect of pomalidomide treatment on serum cytokine levels. II. To evaluate if changes in serum cytokine levels correlate with clinical response.

OUTLINE:

Patients receive pomalidomide orally (PO) once daily (QD) on days 1-21. Treatment repeats every 28 days for up to 12 courses in the absence of disease progression or unacceptable toxicity.

After completion of study treatment, patients are followed up every 12 weeks for 48 weeks.

OVERVIEW

Study PI: Lameck Chinula

Funding agency: Covid-19 Prention Trials Network

Project period: April 26, 2021 - October 30, 2023

Expected last exit: October 30, 2023

STATUS
Enrolling

10 Target accrual	7 Total enrolled	7 Total enrolled in entire study	7 Follow-up visits in 2021

An implementation science approach to monitoring women's engagement in HIV care. CONNECT

CONTEXT

An implementation science approach to monitoring women's engagement in HIV care. Its background, the scale up of antiretroviral treatment (ART) to all pregnant and breastfeeding women, known as Option B+, had been the potential to radically improve maternal health and end mother – to-child HIV transmission. However, lack of engagement in HIV care among peripartum women threatens to limit the anticipated advances of Option B+. In Malawi, women who initiate ART during pregnancy are 5 times likely to never return to HIV care after their initial visit, compared to non-pregnant women initiating ART. In order for the potential of Option B+ to be realized, women must be engaged and retained in HIV care and those who are lost to follow-up (LTFU) must be re-engaged in care. Few efforts to re-arrange women in HIV care exist. Routine HIV program monitoring was vital to track women's engagement in HIV care under Option B+, but was limited in its ability to accurately distinguish women who were LTFU from those who had transferred to another HIV CLINIC. Identifying women who are LTFU is essential for timely re-engagement in HIV care.

AIMS

To evaluate use of biometric fingerprint scanning as an implementation strategy to monitor women's engagement in HIV care across a network of HIV clinics and identify women who are LTFU during the perinatal period. The study sites were Bwaila Family Health Unit, Kawale, Area 18, Area 25 Health Centers and Likuni.

OVERVIEW

STATUS
Enrolling

Study PI:	Dr. Angela Bengtson and Wiza Kumwenda
Funding agency:	National Institute of Mental Health (NIMH)
Project period:	17 August 2017 - 31 July 2022
First screeening:	11 February 2020
Expected last exit:	30 June 20211

700 Target accrual

192 Total enrolled

520 Total enrolled in entire study

244 Follow-up visits in 2021

PROGRESS & EVALUATION

Its progress, the study was supposed to enroll 700 HIV positive pregnant women but due to Covid disruptions, the study enrolled 402 HIV positive pregnant women. Recruitment ended in February 2021. They were in follow up phase. They started exiting participants who had reached 9 months postpartum and so far, 214 of the 402 participants had exited. They were about to start running of month9 viral load samples for those who had exited the study for preliminary data analysis. 1 participant died though not related to the study. Retention was around 83% across the 5 study sites.

COLLABORATIONS

The study worked with Government HSAs, other partners to track participants in the communities although they were faced with the usual challenges like participant relocation, false locator information etc. They had intensified visit reminders through phone calls for those with working phone numbers.

Part of Area 25 Health Centre, one of the sites where the CONNECT study activities are taking place in Lilongwe.

CoVPN 3008

UBUNTU STUDY

A randomized efficacy study of a COVID-19 mRNA 2-dose Vaccine in African regions with SARS-CoV-2 variants of concern.

BACKGROUND

The study vaccine was developed by Moderna TX and is known as the Moderna COVID-19 mRNA vaccine. The study will enroll about 14,000 people at approximately 54 research clinics across Eastern and Southern Africa. Anyone interested in joining the study will go through an informed consent process to learn about it before being asked if they wish to participate.

The Moderna COVID-19 vaccine used in this study is under an Emergency Use Authorization in the United States.

This vaccine also has an Emergency Use License by the World Health Organization.

It has been given to more than 55 million people globally and has been shown to work against the original strain of SARS-CoV-2.

The vaccine is over 90% effective in preventing COVID-19 caused by the strains of the virus in the US and Europe. It has demonstrated an acceptable safety profile to date.

OBJECTIVES

- To test how well the Moderna COVID-19 mRNA vaccine made from the original strain of virus works against the new variants called Beta, Delta and possibly others circulating in our region (Africa).
- To know if this vaccine works in people over 18 years of age who are living with HIV or have risk factors for severe disease.

It is known that Moderna works in reducing the symptoms and severity of COVID-19 illness against the original strain of the virus. It is widely used in the United States and many other countries. People with abnormal immune systems may have worse Covid-19 symptoms and a higher death rate. All participants will receive at least 2 doses of the vaccine. A third dose of the vaccine will be given to half of the participants to see if they have an improved immune response and if this helps protect them against Covid-19 symptoms

OVERVIEW

Study PI: Mina Hosseinipour, Terence Tafatatha

Funding agency: Covid-19 Prention Trials Network

Project period: **November 2021 - March 2021**

First screening: na

Expected last exit: **March 2021**

STATUS
Pending

300 Target accrual	na Total enrolled	na Total enrolled in entire study	na Follow-up visits in 2021

PROGRESS

- All the approvals for the study (NHSRC, PMRA, US) available.
- Protocol specific training was conducted from 9-12 November 2021.
- All concerned departments have attended all the relevant specific trainings
- Had the dry run on December 15, 2021 coupled with the Lab clinic practical session.

The study was about to start enrolling towards the end of 2021

Staff during opening of the bulding to be used to COVID-19 studies at the George Joaki Research Centre at Area 18.

RESEARCH

A prospective study of acute immune responses to SARS-CoV-2 infection COVPN 5001

AIMS

The main purpose of this study is to learn more about SARS CoV-2 infection and how our bodies develop immune responses to it, this information will be used in the future to help develop better interventions like;

- Better tests for SARS CoV-2 infection
- Develop future vaccines
- Develop other preventive strategies and treatments.

OBJECTIVES

Primary objective 1:
To generate Uniform datasets describing the quality, degree, and kinetics of body immune responses to SARS-CoV-2 infection in asymptomatic participants and symptomatic participants (both hospitalized and non-hospitalized) experiencing a range of clinical outcomes in order to prepare for similar assessments during trials of immune-based preventive strategies.

Primary objective 2:
To characterize innate (inborn) and cellular immune responses to SARS-CoV-2 infection during infection with SARS-CoV-2 in asymptomatic and acutely symptomatic participants (both hospitalized and non-hospitalized).

The following are some of the inclusion criteria for the study:

- Age 18 years or older.
- Test result indicating presence of SARS-CoV-2 virus.
- Ability and willingness to provide informed consent.
- For the asymptomatic cohort of participants, they must have a positive SARS-CoV-2 RNA test within six days prior to enrollment and no current symptoms i.e. no symptoms consistent with COVID-19 within 2 weeks prior to positive test.
- For the symptomatic cohort of participants, they must have a positive SARS-CoV-2 RNA test within six days prior to enrollment and onset of mild symptoms consistent with COVID-19 within 6 days prior to enrollment.
- For symptomatic (hospitalized) participants, participant must be hospitalized for COVID-19 within 3 days prior to enrollment.

OVERVIEW

STATUS
Completed

Study PI:	Mina Hosseinipour, Terence Tafatatha
Funding agency:	National Institute of Allergy and Infectious Diseases
Project period:	March 2021 - September 2021
First screening:	23 April 2021
Last exit:	7 on September 22, 2021

20	Target accrual	18	Total enrolled	18	Total enrolled in entire study	na	Follow-up visits in 2021

PROGRESS & EVALUATION

- All visits were done successfully
- Total enrollments – 18 participants
- 1 refused further participation after enrolment
- 1 died after completing 3 visits.
- Retention – 90%

HVTN 405/HPTN 1901

A prospective cohort study of SARS-CoV-2 infection in participants with a history of SARS-CoV-2 infection

AIMS

This study was trying to understand the natural Body immune responses following infection with SARS-CoV-2 for recovered people to improve understanding of natural infection with SARS-CoV-2 in order to develop;

- Better tests for SARS CoV-2 infection
- Develop future vaccines
- Develop other preventive strategies and treatments.

OBJECTIVES

Primary objective 1:
To identify serologic reactivities that differentiate SARS-CoV-2 infection from vaccination.

Primary objective 2:
To develop and formally qualify a group of immunologic assays and reference reagents that permit detailed cross examination of the immune response to SARS-CoV-2 infection in preparation for similar assessments of vaccine-triggered immune responses and immunotherapeutic.

Primary objective 3:
To measure SARS-CoV-2-specific adaptive immune responses in order to identify immune markers of COVID-19 disease severity and duration in different demographic groups (e.g., age, gender) and in people with different medical histories, including pre-existing conditions, new acute or chronic medical conditions, and concomitant medications.

Primary objective 4:
To characterize (describe) presentations of SARS-CoV-2 infection, including the clinical course of COVID-19, among convalescent individuals.

OVERVIEW

Study PI:	Mina Hosseinipour, Terence Tafatatha
Funding agency:	National Institute of Allergy and Infectious Diseases (NIAID)
Project period:	September 2020 -
First screening:	24 September 2020
Last exit:	December 15, 2021

STATUS Enrolling, Followup, Analysis

20	Target accrual	13	Total enrolled	13	Total enrolled in entire study	26	Follow-up visits in 2021

PROGRESS

All the approvals for the study (NHSRC, PMRA, US)
Enrolment started on 24th of September 2020 and finished on October 14, 2020.

- A total of 13 participants were enrolled
- Out of 13 participants, 13 reported for visit 3.0 = 100 %
- Finished visit 2.0 on 4 January 2021,
- Visit 3.0 started on January 14, 2021 and finished on 17th March 2021 .
- Visit 4.0 started on September 21, 2021 and finished on December 15, 2021.
- 100% of all the visits have been done.

An evaluation of efficacy, safety and tolerability of a heterologous HIV vaccine regimen for the prevention of HIV-1 infection in women in sub-Saharan Africa.

HVTN 705/ HPX2008

HVTN 705 is a multicenter, randomized, double-blind, placebo-controlled phase 2b efficacy clinical trial of a heterologous HIV vaccine regimen in preventing HIV-1 infection in women in sub-Saharan Africa. The study is multicenter meaning that it is being conducted in several countries namely Malawi, Zambia, Mozambique, Zimbabwe and South Africa. There are about 30 clinical research sites across the five countries. It is a randomized clinical trial, meaning that some participants will receive an experimental vaccine and some will receive a placebo. It is a double-blinded study meaning that both the investigators and participants will not know who is receiving a vaccine or placebo. It is a phase 2b study meaning that it is being done in a larger population of people.

OBJECTIVES

The objective of the study is to evaluate the efficacy, safety and tolerability of a heterologous HIV vaccine regimen for the prevention of HIV-1 infection in women in sub-Saharan Africa. The study will enroll 2600 women across all the clinical research sites. Half of the women will receive a vaccine and half will receive a placebo. UNC Project has been allocated 154 women to enroll into the study.

INVESTIGATIONAL PRODUCTS

There were two types of HIV vaccines in this study. One was called AD26 vaccine and the other is called a Protein vaccine. AD26 vaccine was developed from a virus which causes common cold (flu) called adenovirus type 26. The AD26 was made weak (attenuated like the TB vaccine), and HIV particles generated in the lab were put inside AD26 – making it the carrier of the HIV vaccine particle. This was also called the primer. The Protein Vaccine is a booster. It was developed in the lab to look like one of the proteins found on the membrane of the HIV virus called GP140. The AD26 would be administered at month 0 (enrollment) and month 3 month 6 and month 12 while the Protein vaccine would be administered at month 6 and 12. This means that participants received one vaccine (AD26) at months 0 and 3 and two vaccines (AD26 and Protein) at months 6 and 12.

OVERVIEW

STATUS
Discontinued and followups

Study PI: Mina Hosseinipour, Terence Tafatatha

Funding agency: Bill & Melinda Gates Foundation (BMGF) and the National Institute of Allergy and Infectious Diseases (NIAID)

Date of first screening: 05-04-2018

Expected last exit date : 05-31-2021

Project period:

First screening: 05-04-2018
Expected last exit: 05-31-2021

160 Target accrual	157 Total enrolled	157 Total enrolled in entire study	na Follow-up visits in 2021

PROGRESS

On 31 August 2021 Johnson & Johnson and partners announced that the study would discontinue the large-scale HIV vaccine trial. Initial results showed that the vaccine did not provide significant protection against HIV infection in young women in sub-Saharan Africa.

EMPIRICAL

A multicenter, open-label randomized controlled clinical trial for treatment against cytomegalovirus and tuberculosis in HIV infected infants with severe pneumonia

BACKGROUND

Pneumonia remained the main infectious cause of death in children in the post-neonatal, with 900,000 deaths globally each year and that the risk of death from severe pneumonia increased in HIV infected children and about 35% in children aged less than 1 year of life even if they had already commenced antiretroviral treatment and were treated with standard of care antibiotics.

Cytomegalovirus (CMV) and TB were other vital causes of death and were still heavily under-recognized. CMV and TB were also challenging to diagnose in children and hence possibly undertreated in this population.

The phase II-III, open-label randomized clinical trial and was being conducted in six countries, namely; Ivory Coast, Malawi, Mozambique, Uganda, Zambia and Zimbabwe.

The study population was HIV infected infants hospitalized due to pneumonia and that the accrued target over a period of 2 years would be 35 children from Kamuzu Central Hospital site and 624 across all sites in Africa.

Eenrolled patients would be followed up for a period of 1 year and that the initial study visit would be performed whilst hospitalized whilst other visits would occur on an outpatient basis at the study clinic based at KCH.

AIMS

To compare the impact on 15-day and 1-year mortality of combined systematic empirical treatment against TB and CMV plus standard of care (SoC) versus SoC in HIV-infected infants with severe pneumonia.

Study PI: Tisungane Mvalo

Funding agency: European and Developing Countries Clinical Trials Partnership (EDCTP)

Project period: 1 July 2021- 30 June 2024

First screening: 20 October 2021.

Expected last exit:

STATUS Enrolling

35	Target accrual	6	Enrolled in 2021	6	Total ever enrolled	na	Follow-up visits in 2021

PROGRESS

All ethics committee and regulatory approvals had been attained (NHSRC in April 2021, PMRA in August 2021 and UNC IRB in September 2021) and that the site initiation visit virtually performed on 30th August 2021 by CRO (study monitors). The protocol team provided Lilongwe site green light to commence study procedures on 5th October 2021 and the study dry and wet runs were performed on 27th September 2021 and 5th October 2021 respectively. The study screened 2 patients and enrolled 1 patient on the 20th of October 2021.

TONSE PAMODZI

OBJECTIVES

The Tonse Pamodzi 2 (TP2) study was a pilot study that was being conducted at Bwaila District Hospital. Recruitment started in March 2020. TP2 study was designed to assess the acceptability ,fidelity and clinical outcomes associated with a combination intervention for adherence support. Its overarching goal was to provide preliminary data to inform a larger, definitive trial of the combination adherence intervention.

The study comprised two parallel-randomized trials, enrolling HIV-positive pregnant women on antiretroviral therapy (Trial 1, n=100) and HIV-negative pregnant women wishing to initiate PrEP (Trial 2, n=200). Within each trial, participants are randomized 1:1 to either the intervention or the control arm. The Tonse Pamodzi adherence intervention comprises patient-centered counseling (adapted Integrated Next Step Counseling, or iNSC) and external adherence support tailored to the clinical context (i.e., for ART or PrEP). Participants randomly assigned to the control group receive standard counseling based on local HIV guidelines. Participants are followed for six months. To assess intervention acceptability, we employ a mixed method approach to describe participant engagement, satisfaction, and discussion content. We audited and score recorded counseling sessions to evaluate the implementation fidelity of iNSC sessions.

The study also assessed clinical outcomes at three and six months for both Trial 1 (retention in care, viral suppression of HIV) and Trial 2 (retention in care, plasma and intracellular tenofovir drug concentrations). Participants were followed up for 6 months

OVERVIEW

STATUS
Completed

Study PI:	Ben Chi , Wilbroad Mutale , Friday Saidi
Funding agency:	**US National Institutes of Health (R01 AI131060)**)
Date of first screening:	March 2020
Expected last exit date :	Dec 2021
Project period:	Jan 2020- Dec 2021

300	Target accrual	na	Enrolled in 2021	300	Total enrolled in entire study	662	Follow-up visits in 2021

PROGRESS

Enrolment of 300 participants was achieved per protocol and participants were followed up for 6 months. A six month retention of 84% and 86% achieved for trial 1 and trial 2 respectively.

Study participant follow up was finalized. Team was doing data cleaning and data analysis was planned to start in September 2021.

FP-ART

A prospective cohort evaluating the pregnancy rates and pharmacokinetic interactions among HIV-infected Malawian women on Efavirenz or Dolutegravir initiating the Levonorgestrel Implant or the Depot Medroxyprogesterone Acetate Injectable

CONTEXT

Sub-Saharan Africa (SSA) has high rates of unintended pregnancy, maternal mortality, and perinatal HIV. Increased use of effective contraception could reduce all three. The Levonorgestrel (LNG) implant is a highly-effective and reversible contraceptive that provides up to 5 years of protection and is not dependent upon external factors such as regular clinic attendance or breaks in the health system supply chain.

OBJECTIVES

Objective 1
To compare the typical-use pregnancy rates of the LNG implant versus the DMPA injectable in a prospective cohort of 1,420 HIV+ women on EFV or DTG (710 initiating the LNG implant and 710 initiating DMPA).

Objective 2
This is a sub-study of up to 60 women from the cohort in Objective 1 who initiated the LNG implant that will utilize a 2:1 nested case-control study to determine if higher EFV concentrations in hair (a biomarker for EFV exposure) are associated LNG implant contraceptive failure.

Objective 3
This is a sub-study of 25 women from the cohort in Objective 1 who initiated the LNG implant and 25 women from the cohort in Objective 1 who initiated DMPA that will evaluate the pharmacokinetic effect of switching from EFV to DTG on LNG, MPA, and SHBG concentrations and viral load (VL).

Objective 4
This is a sub-study of up to 1,000 women enrolled from the cohort in Objective 1 that will use already collected biologic specimens (blood and hair) to measure rates of viral suppression and ARV resistance before and after switching from EFV- to DTG-based ARV therapy, among women who made the switch during the study follow-up period.

OVERVIEW

Study PI:	Jennifer Tang
Funding agency:	National Institutes of Health/National Institute of Child Health and Human Development
Project period:	September 27, 2016 – June 30, 2022
First screening:	August 17, 2017
Expected last exit:	June 30, 2022

STATUS
Exiting

1,420 Target accrual

na Enrolled in 2021

1,371 Total enrolled in entire study

Follow-up visits in 2021

PROGRESS

The study was still exiting participants. So far 543 participants had been exited from Area 18 and Area 25 Health Centres. All sites were now terminating participants and the study had been given approval to conduct remote interviews for those that have relocated to other districts for final visits. The team was still tracing participants who had been missing their visits due to COVID 19.

Family planning unit of Area 25 Health, one of the FP-ART activity sites.

HPTN 084

A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women

The proposed HPTN 084 trial was designed as a superiority trial. The primary analysis is designed to show superiority of CAB/LA to TDF/FTC. If, contrary to expectations, adherence to TDF/FTC is substantially higher than expected, the study will provide a supportive non-inferiority analysis with an adherence-dependent margin

OBJECTIVES

• Efficacy: To evaluate the relative efficacy of oral CAB/CAB LA (oral run-in and injections, Steps 1 and 2) vs. daily oral TDF/FTC for HIV prevention (Steps 1 and 2).

• Safety: To evaluate the relative safety of oral CAB/CAB LA (oral run-in and injections, Steps 1 and 2) vs. daily oral TDF/FTC for HIV prevention (Steps 1 and 2).

Secondary Objectives:

• To compare HIV incidence among participants receiving oral CAB/CAB LA vs. daily oral TDF/FTC (Steps 1, 2 and 3).

• To evaluate relative efficacy of oral CAB/CAB LA vs. oral TDF/FTC in subgroups defined by the baseline factors of: age, herpes simplex virus-2 (HSV-2) serostatus, contraceptive method, and body mass index (BMI).

• To describe and model the relationship between HIV incidence and drug concentration, within each arm.

• To describe the distribution and correlates of drug concentration, within each arm.

• To compare the acceptability of and preferences for CAB LA vs. oral TDF/FTC.

The HPTN 084 team presenting initial research findings to the press in 2020

OVERVIEW

STATUS
Data analysis

Study PI: Mina Hosseinipour

Funding agency: U.S. Centers for Disease Control and Prevention and National Institute of Health

Date of first screening: 11-12-2018

Date of first enrolment: 11-23-2018

111 Total screened

111 Total ever enrolled

Follow-up visits in 2021

PROGRESS

The study was in follow-up phase. The study started screened on 12 Nov 2018, screened 153, enrolled 111 participants, screened and enrolled for the site as guided by the protocol team stopped on 24th October 2019. The study was in follow-up phase.

Results of the study revealed that long-acting injectable cabotegravir (CAB LA) as PrEP was highly effective in preventing HIV acquisition in women compared to oral Truvada. Following a letter of amendment number 4, participants were informed of the study results and were unblinded. They were currently being followed on their assigned arms.

CHALLENGES

The challenges that the study experienced were that some participants falsely indicated that they had relocated however, the community team was handling those issues. Participants were reluctant to use Long Acting Contraceptives

IMPAACT 2008

Phase I/II Multisite, Randomized, Controlled Study of Monoclonal Antibody VRC01 with Combination Antiretroviral Therapy to Promote Clearance of HIV-1-Infected Cells in Infants.

CONTEXT

HIV-1 transmission to infants is still ongoing despite progress over the past two decades in identifying strategies to reduce in utero, peripartum, and breastfeeding HIV-1 transmission. HIV-1 infection in infants face a lifetime of antiretroviral therapy (ART) due to almost immediate establishment of HIV-1 reservoirs that re-establish viremia when treatment is stopped. Therefore, novel treatments for infants that restrict HIV-1 reservoir establishment and have long acting antiviral activity are needed. Broadly neutralizing monoclonal antibodies (bNAbs) are an emerging class of HIV-1 therapeutics with direct antiviral properties, largely mediated through virus neutralization. However, bNAbs may also facilitate viral clearance through antibody dependent cellular cytotoxicity (ADCC), which promotes killing of HIV-1 infected cells. Combining ART with bNAbs offers a novel approach to HIV-1 therapeutics for infected infants that will perhaps result in faster clearance of plasma viremia and HIV-1-infected cells, thereby lowering viral reservoir size.

PURPOSE

To evaluate the safety and antiviral activity of VRC01 administered in addition to combination antiretroviral therapy (cART) to HIV-1-infected infants to promote clearance of HIV-1-infected cells.

STUDY POPULATION

HIV-1-infected infants initiating cART within 12 weeks of birth. Infants' mothers may optionally be enrolled in the study for one-time specimen collection for exploratory evaluations.

OVERVIEW

Study PI: Lameck Chinula

Funding agency: National Institute of Allergy and Infectious Diseases, EuniceKennedy Shriver National Institute of Child Health and Human Development National Institute of Mental Health

Date of first screening: 08-05-2019

Expected last exit date : 30-10-2021

STATUS Completing data collection and data analysis

18 Target accrual	na Enrolled in 2021	13 Total enrolled in entire study	4 Follow-up visits in 2021

PROGRESS

The study completed followups on 26th January 2021. We were conducting data cleaning pending data lock on 1 September 2021

Because of the data-base lock, there were monitors on site to resolve follow up issues during the last monitoring visit; and to verify entry of drug resistance results.

IMPAACT 2016

Evaluation of a group based intervention to improve mental health and ART adherence among youth living with HIV in low resource setting

CONTEXT

TIMPAACT 2016 is a study which will evaluate whether an Indigenous Leader Outreach Model (ILOM) of trauma informed cognitive behavioral therapy (TI-CBT) [referred to as TI-CBT delivered by Indigenous Youth Leaders (IYL)] is associated with improved mental health outcomes and ART adherence among youth living with HIV. This Trial is multi-site, two-arm randomized controlled trial of TI-CBT compared to Discussion Control groups.

Despite scale up efforts of effective ART, in the absence of evidence-based mental health interventions and the lack of resources to deliver effective programs, millions of adolescents living with HIV in low-income countries will remain disproportionately vulnerable to accelerated disease progression due to untreated mental health symptoms. The need for effective mental health interventions, especially those that can be administered by trained lay people in low resource settings, to reduce mental health problems among youth living with HIV is a public health emergency.

PURPOSE

To evaluate whether a TI-CBT Intervention is associated with improved depression, anxiety, and/or traumatic stress symptoms for youth living with HIV compared to a Discussion Control at six months.

POPULATION

This study will test the effects of the ILOM of TI-CBT on depression, anxiety, and trauma symptoms among youth 15 - 19 years old living with HIV in low-resource settings. The study will also evaluate the impact of the intervention on youth adherence to ART.

IMPAACT 2016 would be done in four phases as follows: 1 stakeholders' meeting, 2 Focus group discussions, 3 Pilot studies, 4 Main studies

OVERVIEW

STATUS
Enrolling pending

Study PI: Lameck Chinula

Funding agency: National Institute of Allergy and Infectious Diseases EuniceKennedy Shriver National Institute of Child Health and Human Development National Institute of Mental Health

Date of first screening: 08-05-20

Expected last exit date : 30-10-2021

50 Target accrual *50 participants and 50 caregivers*	na Enrolled in 2021	na Total enrolled in entire study	na Follow-up visits in 2021

PROGRESS

The team had worked on the protocol manuscript and finalised translations of study manuals, and also finalised the study recruitment and retention standard operating procedures. The team had been looking forward to working in this qualitative study which involves adolescents. However, the COVID-19 pandemic has greatly affected the progress.

IMPAACT 2026

Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs during Pregnancy and Postpartum

PURPOSE

To describe the pharmacokinetic (PK) properties of antiretroviral (ARV) and anti-tuberculosis (TB) drugs administered during pregnancy and Postpartum.

The study has 5 components, Lilongwe site will not do

- Component 1 because the arm will use 3rd line ARVs that are not currently available in Malawi
- Component 2 because of delays in approvals Component 2 is a follow up of babies born from mothers who had CABLA in pregnancy -HPTN 084 Participants. This components has been or will be added to the HPTN 084 STUDY
- Component 3: Pregnant WLHIV receiving ARVs and first-line TB treatment, and their infants
- Component 4: Pregnant WLHIV and HIV-uninfected women receiving second-line TB treatment, and their infants
- Component 5: Postpartum WLHIV breastfeeding while receiving oral ARVs, and their infants:

OVERVIEW

Study PI: Lameck Chinula

Funding agency: National Institute of Allergy and Infectious Diseases Eunice, Kennedy Shriver National Institute of Child Health and Human Development National Institute of Mental Health

Expected last exit date :

STATUS
Pending screening

	Target accrual	na	Follow-up visits in 2021
na	Enrolled in 2021	na	Unscheduled visits in 2021
na	Total enrolled in entire study		

PROGRESS

- Working on activation checklist
- IRB approvals done
- Waiting for clinical trial insurance
- DAIDS protocol registration.
- Lab training and approval

IMPAACT 2028

It is a multisite observational study of long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV

It is an observational study to characterize a cohort of children who may participate in future research related to HIV remission or cure.

Children who have previously received early or very early treatment for HIV in other IMPAACT studies

The study will include up to 250 children across all sites, Lilongwe site will enroll 20 children from IMPAACT 2008 and P1115.

PURPOSE

To characterize the long-term clinical, immunologic, and virologic profiles of children who received early treatment for perinatally-acquired HIV

OVERVIEW

STATUS
Pending screening

Study PI: Lameck Chinula

Funding agency: National Institute of Allergy and Infectious Diseases Eunice, Kennedy Shriver National Institute of Child Health and Human Development National Institute of Mental Health

Date of first screening:

Expected last exit date :

Target accrual	Enrolled in 2021	Total enrolled in entire study	Follow-up visits in 2021
50 participants and 50 caregivers	na	na	na

PROGRESS

- Received IRB approval
- Waiting for DAIDS protocol registration
- Working on activation checklist
- Waiting for LAB approval

AMP ATI (HVTN 805/HPTN 093)

An Antiretroviral analytical treatment interruption study (ATI)

CONTEXT

The study was going to assess immunologic and virologic responses in participants who initiated ART early in HIV infection after having received VRC01 or placebo in HVTN 703/HPTN 081 (AMP STUDY). The study was to enroll former AMP (HPTN 081) participants: These were participants who initiated ART soon after HIV diagnosis.

OBJECTIVES

Its primary objective was individuals who initiated ART early in HIV infection during AMP study would suppress plasma viremia and maintain CD4 count longer than others.

The study design was an exploratory study of participants living with HIV undergoing an analytical treatment interruption following HIV acquisition in AMP study after receiving VRC01 or placebo infusions

The study duration was potentially indefinite for a participant maintaining extended viral control during ATI. However, most participants were expected to be in the study for 13-18 months. The maximum anticipated duration for any participant was expected to be approximately 21/2 to 3 years.

INCLUSION CRITERIA

Participants in the study were to meet the following inclusion criteria:

- Should be a former AMP participant
- Estimated date of HIV-1 acquisition is within 8 weeks of (i.e, before or after) having received an HVTN 703/HPTN 081 infusion
- Initiated ART within 28 weeks of HVTN 703/HPTN 081 date of HIV-1 diagnosis
- Receiving continuous ART for at least 1 year
- Willingness to interrupt ART for up to 24 weeks or up to the time of meeting ART re-initiation criteria
- Willingness to use barrier protection (i.e, male or female condoms) for all sexual activity during the ATI and until confirmation of viral suppression following ART re-initiation.
- Willingness for CRS staff to contact primary HIV care provider to exchange information regarding HVTN 805/ HPTN 093 and participant medical history
- Generally, good health as evidenced by lab evaluations as stipulated by the protocol
- Not pregnant and breastfeeding

OVERVIEW

Study PI: Mina Hosseinipour

Funding agency: Division of AIDS (DAIDS)

Project period: **6 August 2021 - 2023**

First screening: 6 August 2021

Expected last exit: July 2023

STATUS
Enrolling

3 Target accrual	1 Enrolled in 2021	1 Total enrolled in entire study	na Follow-up visits in 2020

PROGRESS

The study team had screened 4 prospective participants. 1 was pregnant, 1 relocated to Blantyre, 1 stopped taking ARVs and 1 was screened on 06 August 2021, however her window closed on 1st October 2021 while they were waiting for 30 days to elapse from the time she got COVID-19 vaccine per protocol, as such they failed to enroll her during that time.

Low Birthweight Infant Feed Exploration

LIFE

CONTEXT

In 2011, the World Health Organization released Guidelines on Optimal Feeding for Low Birthweight Infants in Low- and Middle-Income Countries (LMICs). However, 70% of the guidelines are based on "low or very low" quality of evidence (WHO 2011), and the majority of research regarding mother's own milk (MOM) alternatives has been in high-income, hospital-based settings. There is a pressing lack of information about LBW infants in LMICs: existing feeding patterns; rates and causes of unsuccessful breastfeeding; and effective options for feeding, fortification, or supplementation with micronutrients. Forty global health organizations recently issued an urgent call to action to improve the evidence base, specifically for neonatal care units.

This study hopes to address these gaps. This is a mixed study design as there a 6 populations or settings from which data would be collected. The methods to be used include prospective cohort follow up, retrospective data collection from hospital patient files, qualitative design through focus group discussions (FGD) or in-depth interviews (IDI) and literature review exercise and data meta analyses. Three Objectives of the study (1) Understand the current practices and standard of care (SOC) for feeding LBW infants (2) Define and document the key outcomes (including growth, morbidity, and lack of success on MOM) for LBW infants under current practices (3) Assess the acceptability and feasibility of a system-level infant and young child feeding (IYCF) intervention and the proposed infant feeding options for LBW infants

OVERVIEW

Date of first screening: 21-10-2020
Date of first enrolment: 21-10-2020
Funding agency: Bill and Melinda Gates Foundation

Study PI: Katherine Elizabeth Amanda Semrau, Tisungane Mvalo
Thematic area: Nutrition
Study population: Mothers, Children, Hospital Inpatients, Adolescents

STATUS
Enrolling

167 Total enrolled in entire study

300 Mother-infant pairs enrolled in study

300 Follow ups in prospective cohort

Target accrual:
35 infant-mother pairs in patient, 300 infant-mother pairs follow up, 20-32 mothers focus group, 10-32 family members focus group, 10-32 religious leaders/ community leaders/trad. healers focus group, 24-60 clinical staff in depth interviews, 6-12 MOH/milk supply chain in depth interview, 2 facility context assesments, 150 mother-infant pairs for chart review.

PROGRESS

For the period, 01 Jan – 31 Dec 2021, the activities that were taking place taking place were Prospective Cohort and In-depth interviews.

In June 2021, the 0-6 months results of the LIFE Study were presented as a White paper to the study sponsors (Bill and Melinda Gates Foundation) and stakeholders.

Follow up of the last mother-infant pair in the prospective cohort was completed on 28 July 2021.

MVIP Malaria Vaccine Implementation Program

SAFETY HOSPITAL SURVEILLANCE

CONTEXT

Following the phase 3 RTS,S/ASO1 Malaria vaccine trial (MAL 055) which demonstrated that the malaria vaccine was partly effective, the World Health Organization (WHO) recommended that the RTS,S/ ASO1 vaccine be implemented as a pilot in 3 African countries which would include further evaluation of the vaccine in the real world.

OBJECTIVES

1. To investigate the impact of RTS,S on childhood mortality in the real world setting.
2. To investigate any safety concerns of the malaria vaccine via hospital surveillance system
3. To assess the feasibility of administering the malaria vaccine in children via a 5, 6, 7 and 22 months schedule.

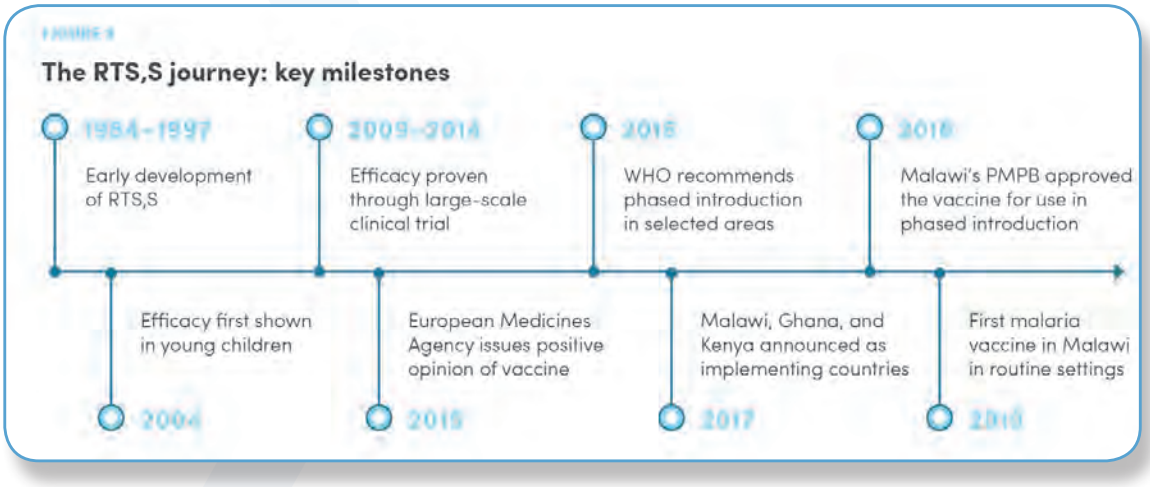
Countries involved in this pilot are Malawi, Ghana and Kenya. In these countries, vaccination is to be done by the Ministries of Health. The evaluation of the pilot is to be done by research institutions. In Malawi the evaluation institutions are the College of Medicine and UNC Project.

The evaluation is taking place in 9 districts namely; Nsanje, Chikhwawa, Phalombe, Machinga, Balaka, Mangochi, Lilongwe, Ntchisi and Mchinji.

UNCPM is responsible for Lilongwe, Ntchisi and Mchinji hospital surveillance and mortality assessment while providing overall oversight for hospital surveillance in the 4 sentinel district hospitals in Ntchisi, Mchinji, Balaka and Machinga.

The MVIP evaluation consortium in Malawi comprises of UNC project Malawi and the Kamuzu University of Health Sciences (KUHeS, formerly University of Malawi, College of Medicine). The KUHeS team is leads in the Impact and Feasibility objectives of the study, and the UNC team leads in the safety objectives of the study.

The MVIP evaluation consortium also works with the Expanded Programme on Immunizations (EPI) team under the Ministry of Health. The EPI team is responsible for delivering the vaccine to children, and all the associated logistics.



OVERVIEW

Study PI:	Dr. Tisungane Mvalo
Funding agency:	World Health Organization (WHO)
Project period:	December 2018 to April 2023
First enrolment:	26 April 2019
Expected last exit:	April 2023

STATUS
Enrolling

6965 Enrolled in 2021

17806 Total enrolled in entire study

na Follow-up visits in 2021

An MVIP evaluation assistant ready to go the field.

PROGRESS

Midway data analysis (on data for May 2019-April 2021) showed that the vaccine was safe to be given to children in Africa. The number of children with meningitis and cerebral Malaria was not different in communities where the vaccine is being given compared to communities where the vaccine is not being given. Refresher trainings on protocol and SOPs for all sentinel sites, currently awaiting decision from Government of Malawi on wider use of the vaccine in Malawi.

On 6 October 2021, WHO recommended the RTS,S/AS01 malaria vaccine for widespread use among children in sub-Saharan Africa and in other regions with moderate to high P. falciparum malaria transmission. Review of data from the midline (24 months) data analysis across all the 3 countries involved contributed to this decision by the WHO. The preliminary results showed a 30% reduction in severe malaria cases, and a favourable safety profile after 2.3 million doses were given to children in the 3 countries. The vaccine introduction was shown to be feasible, with high and equitable coverage even in the context of the covid-19 pandemic, despite having a different immunization schedule than the other routine vaccines. Modelling estimates also showed that the vaccine is cost effective in areas of moderate to high malaria transmission.

On sample size, the evaluation was occurring across 9 districts: Rural Lilongwe, Mchinji, Ntchisi, Machinga, Balaka, Chikwawa, Nsanje, Mangochi. UNCPM is performing the evaluation in the first 3 mentioned districts (Lilongwe, Mchinji and Ntchisi) whilst KUHES works in the other districts.

Data collection (mortality surveillance) was done by Evaluation Assistants and monitoring started on 5th July 2019 and was still on-going, also still conducting verbal autopsies
Since inception all the 9 districts since to 5 November 2021 had recorded 11,061 cases

- Facility cases 2,296
- Community cases 8,765

PEER

Prevention of cervical cancer through an HPV-based screen-and-treat strategy in Malawi: a cluster randomized trial

AIMS

The PEER Cervical Cancer team developed a cluster randomized trial that will integrate a novel cervical cancer screen-and-treat algorithm into voluntary family planning (VFP) services via two different models. Model 1 involves: 1) cervico-vaginal self-sampling for high-risk HPV (hr-HPV) while waiting for appointments at the VFP clinic or other clinics, 2) same-day VIA for those women found to be hr-HPV-positive by rapid GeneXpert HPV testing, and 3) same-day thermocoagulation treatment for HPV-positive women who are eligible for ablative therapy by VIA. Model 2 will offer women the same services as in Model 1, but they will also be given the option to perform cervico-vaginal self-sampling in their homes, via Heath Surveillance Assistants (HSAs) who will bring their HPV sample to the clinic and notify them to return to the clinic for VIA and possible same-day thermocoagulation if their hr-HPV test is positive.

This screen and treat demonstration project with HPV self-testing and thermocoagulation was taking place in Lilongwe and Zomba, Malawi.

Objective 1
To compare the proportion of eligible women who receive cervical cancer screening (CCS) and VFP services in the catchment areas of health facilities assigned to the two models.

Objective 2
To assess the acceptability, appropriateness, and feasibility of the two models among key stakeholders, including service providers and clients, during the early, midline, and final implementation phases of the project.

Objective 3
To estimate the cost and budget impact of each model compared to the standard-of-care (VIA and cryotherapy), using information collected for the previous objectives.

OVERVIEW

Study PI: Jennifer Tang, Lameck Chinula

Funding agency: National Academy of Sciences/ U.S. Agency for International Development

Project period: March 29, 2019 – March 31, 2022

Date of first screening: February 24, 2020

STATUS Enrolling

39000	5696	3929	677	332
Target accrual	HPV positive	Treated	Hospital referrals	Cancer suspects

Project staff and partners during one of the quartery review meetings held in Mangochi.

PROGRESS

The cumulative number screened through PEER up to November 2021 is **19,810** and cumulatively treated is 5696. We have had 2 quarterly review meetings and 6 local advisory board meetings. A manuscript on the PEER protocol was published in April 2021 in Pilot and Feasibility studies.

The COM continued to work with Dr. Agatha Bula from UNC Project to code and analyze the qualitative interviews from the Early Implementation Evaluations, which include Client In-Depth Interviews (IDIs), Focus Group Discussions (FGDs) with providers and HSAs, and IDIs with Clinic Managers and Coordinators.

They also had been able to provide facility support to participating facilities in terms of medical supplies and items of their choices according to the allocated funds available. The team had conducted an end line household survey to assess the acceptability and appropriateness of the study to targeted women the time they were reporting to staff.

Adaptation of the Friendship Bench Mental Health Intervention for HIV-infected Perinatal Women in Malawi

PERISCOPE

RATIONALE

- Option B+, has the potential to improve maternal health and end mother-to-child HIV transmission.
- Lack of engagement in HIV care among peripartum women threatens to limit the positive impact of Option B+ on HIV care outcomes.
- Many pregnant and postpartum women living with HIV experience feelings of sadness or depression
- Depression may adversely affect women's mental health and physical health, making it difficult to remain engaged in HIV care.
- Counseling, plus support to stay engaged in HIV care, may help to improve women's mental health and engagement in HIV care.

OBJECTIVES

The objective of this study was to adapt and enhance the Friendship Bench and assess its feasibility, fidelity of delivery, and acceptability in addressing PND and HIV care engagement among perinatal HIV-infected women.

Study population was supposed to have the following characteristics:

- women who engage in ANC
- 18 years or above
- at ≤34 weeks gestation
- who are living with HIV
- Established on ART, initiating or initiated ART during the current pregnancy or re-initiating ART and are identified with antenatal depression- SRQ score >8

One of the PERISCOPE study activity sites

OVERVIEW

STATUS
Enrolling

Study PI:	Brian Pence, Angela Bengtson
Funding agency:	NIMH
Local IRN submission:	07-12-2019
Local IRB approval:	10-04-2019
Date of first screening:	12-10-2019
Date of first enrollment:	12-10-2019
Expected last exit date :	04-30-2020
Study population:	Pregnant and HIV infected women

121 **Target accrual:** 708 Total screened 92 Total ever enrolled 56 Exited

PROGRESS

Counselling sessions were still in progress. Women would be followed from antenatal care through 6 months postpartum

Women were asked to complete a baseline study visit and a study visit at 6 months postpartum.

- At 6 months the study was to assess:
- Mental health status
- Engagement in HIV care status
- Viral load
- Infant HIV testing and health

Study Sites were

- Mitundu Rural Hospital
- Lumbadzi Health Center
- Nathenje Health Center
- Bwaila Hospital
- Area 18 Health Center

PROMOTE

Promise Ongoing Treatment Evaluation

PROMOTE is a multi-site, longitudinal, extended observational cohort study of mothers and infants that were enrolled in the Breastfeeding Version of PROMISE study. This study is being conducted in PROMISE high enrolling sites in the following African countries: Malawi, Zimbabwe, Uganda and South Africa.

AIMS

The study aims to generate important long-term scientific safety and effectiveness information that will advance global implementation of ART programs. It focuses on health outcomes of HIV-infected mothers and their HIV-exposed children as well as strengthening local capacity by training and mentoring of emerging African scientists.

The protocol was closed to accrual on 30 June 2017. However, new infants who are born during the study, are also enrolled, and will be followed up to the end of the study. 1987 mothers, as well as 2294 infants have been enrolled across all sites. Participants will be followed up, every 3 months in the first year of the study, and every 6 months, for the subsequent four years

We conducted month 24 follow up visits for non-pregnant mothers and their infants. Repeat pregnancy registration, 8 weekly follow ups of those repeat pregnancies, labour and delivery visits, as well as week 6, month 3, month 6, month 12, month 18, and month 24 post-delivery follow up visits of these mothers and their respective infants were also conducted during this period. We also had unscheduled visits which included adherence counselling sessions following high viral load results, further investigations, treatment and reporting on abnormal lab results, participants reporting due to illness, and also clinical follow up on treatment of ongoing illness as required.

Over 85% of the scheduled visits have been conducted. Some were yet to report as the windows for their visits were still open beyond June 30. However, some have missed their scheduled visits and will be traced for their next scheduled follow up visit.

2020 **OVERVIEW**

Study PI: Lameck Chinula

Date of first screening: 02-15-2017
Expected end date : 06-30-2022

Funding agency: President's Emergency Plan for AIDS Relief (PEPFAR)

STATUS
Data analysis

PROGRESS

In Malawi, this study is being conducted in Lilongwe by UNC Project Malawi, and in Blantyre by College of Medicine-John Hopkins University CRS.

Analysis for the longitudinal data is ongoing.

Some of the team members who have facilitated the study.

Global sequence and surface antigenic diversity of Treponema pallidum outer membrane proteins

SAVI

CONTEXT

Despite the wide availability of antibody (Ab)-based screening tests and effective antimicrobial therapy, syphilis control strategies have fallen short, particularly in resource-poor countries where proper diagnosis and partner services to reduce transmission are not always feasible or available. The inability of traditional public health prevention strategies to curtail the spread of venereal syphilis underscores the critical need to develop a safe and effective vaccine. However, to develop a syphilis vaccine based on protective antibodies, there is need to first identify *Treponema pallidum* (TPA) outer membrane antigenic targets.

AIM

The aim of the study is to understand and characterize the TPA genomic sequences and global repertoire of its outer membrane proteins. Knowledge on the different types of the syphilis would be used to develop a vaccine that can work against all or the most common types of syphilis.

The study population is approximately 1850 adults with untreated early (primary) secondary and tertiary syphilis across all sites. For Malawi, the study would enroll 120 participants with primary syphilis over a period of 5 years.

The study design is a prospective, cross-sectional study of patients with primary and secondary syphilis in Malawi. The study is being conducted at Bwaila District Hospital in Malawi, UNC Chapel Hill in USA, Southern Medical University Dermatology Hospital in China and CIDEIM in Columbia.

INCLUSTION CRITERIA

- ≥ 18 years male or female
- Presents with genital ulcer consistent with syphilis.
- Has a positive Darkfield microscopy test
- Stays within the UNC Lilongwe catchment area
- Willing to undergo finger prick for hemoglobin test
- Has not been prescribed antibiotics which may treat syphilis e.g. Doxycycline, Azithromycin in the last four weeks.

OVERVIEW

STATUS
Data analysis

Study PI:	Mitch Matoga, Irving Hoffman
Funding agency:	NIAID
Project period:	2019 - 2024
First screening:	9 January 2020
Expected last exit:	2024

582 Total screened

52 Total ever enrolled

PROGRESS

The study in terms of progress it started screening and enrolling on January 9, 2020 and 582 participants were screened, 39 enrolled and 113 refused.

CHALLENGES

The clinic had been seeing low turn up of patients during this cold weather and this has affected the screening numbers.

SHARP A Clinic-Randomized Trial of Strategies to Integrate Depression Care in Malawi

CONTEXT

The purpose of SHARP study is to evaluate the most effective strategies for integrating depression treatment into non-communicable Diseases (NCD care) in 10 district hospitals across Malawi i.e. 2 in the north, 4 in the central and southern region respectively. Implementation strategies that are compared are Basic i.e. identifying an internal coordinator and 2 deputies who are MoH staff, train them and let them to train, mentor and support their peers at the clinic; and enhanced ie combining the internal coordinator and deputy roles with an external quality assurance committee that visits the facilities on quarterly basis to audit activities at the facility and evaluate compliance with the depression treatment protocol as well as providing high-level support in implementing the treatment program through clinical expertise and limited on-site presence.

10 SHARP sites have been randomized 1:1 to receive either the basic or the enhanced implementation package. All clinics do implement depression treatment as part of standard care at their NCD clinics. All patients at each clinic receive that clinic's standard care.

Study activities take place at these clinics across Malawi: Bwaila Hospital,(Lilongwe District) Chilumba Rural Hospital, Karonga District Hospital, Kasungu District Hospital, Machinga District Hospital, Mchinji, Mulanje, Phalombe, Salima and Zomba Central Hospitals.

OBJECTIVE

SHARP study primary objective is to compare two different implementation strategies to facilitate ongoing Ministry of Health efforts to scale up evidence-based depression treatment within the non-communicable diseases (NCD) care.

OVERVIEW

Study PI: Brian Pence, PhD, MPH

Funding agency: National Institute of Mental Health (NIMH)

Project period: **01 November, 2017 – 30th June 2022**

First screening: 2 May, 2019

Expected last exit: June 30, 2022

STATUS Enrolling

279 Enrolled in 2021

960 Total enrolled in entire study

888 Follow-up visits in 2021

UNC project staff and partners during SHARP sustenance meeting held on November 22 2021

PROGRESS & EVALUATION

On 31 December, 2021, SHARP stopped enrolment and is continuing with follow up of already enrolled participants. Study staff also collected mid-term and end of term qualitative data through phone, zoom calls and face to face completing 45 one-on-one in-depth interviews (mid-term(and 40 interviews (end of study evaluation) respectively.

Qualitative patient-level data from SHARP's formative phase have been analysed, written into manuscript form, and published in BMC Psychiatry in early 2020. Qualitative provider-level data from the same formative phase have been analysed, written into manuscript form, and published in International Journal of Mental Health Systems in June 2021. A protocol of SHARP's capacity building activities was published in late 2019 in the Journal of International Mental Health Systems and another protocol of SHARP's trial activities was published in a special issue of Psychiatric Services alongside other study protocols from the same cohort of NIMH U-19 recipients in 2020.

Baseline data from main SHARP study have been used and published as well.

COLLABORATIONS

We remain engaged with the partner organizations outlined in our previous report: Malawi Epidemiology and Intervention Research Unit (MEIRU), the Malawi Ministry of Health, and The University of Malawi College of Medicine as key stakeholders as well as implementing partners.

NEXT STEPS

For half of 2022, SHARP will continue to follow up of study participants, do analysis and write up of manuscript as part of dissemination of the study results.


CANCER RESEARCH

LCCC 1905

A novel cervical cancer screen-and-treat demonstration project with HPV self-testing and thermocoagulation for women in Lilongwe, Malawi

Dr. Lameck Chinula displaying apparatus used during thermocoagulation

CONTEXT

Cervical cancer remains the common cause of cancer deaths among women in Malawi. Though visual inspection with acetic acid (VIA) has been implemented in Malawi since 2004, many women remain unscreened and few of those requiring treatment receive it.

The study uses the high-performance HPV testing, and combines testing of self-collected samples with same day testing using Xpert machine and treatment with battery powered thermocoagulator. The algorithm used in this study has not been rigorously evaluated among women, including those living with HIV, especially in settings like Malawi but is promising in ensuring screening of a large number of women.

PRIMARY OBJECTIVES

- To assess completion of a novel cervical cancer screen-and-treat strategy among women in Lilongwe, Malawi, using self-collected vaginal brush for HPV testing, followed by same-day VIA and thermocoagulation for HPV-positive and thermocoagulation -eligible women.
- To determine the 24-week efficacy of thermocoagulation among women with cervical pre-cancer, including those living with HIV.

OVERVIEW

Study PI:	Lameck Chinula
Funding agency:	NIH, UNC Lineberger Comprehensive Cancer Center Institute of Health
Local IRB submission:	03-01-2020
Local IRB approval:	08-09-2020
Date of first screening:	09-19-2017
Study population:	Females

STATUS
Enrolling

1250 **Target accrual**

1170 Total enrolled in entire study

na Follow-up visits in 2021

PROGRESS

The study is being conducted at UNC Project-Malawi Tidziwe Centre. The plan is to recruit 1250 participants in total, with 625 HIV positive and 625 HIV negative.

Women are followed up for approximately 6 months with at most 4 visits. Women are recruited from surrounding clinics and communities with many recruited through word of mouth from friends and health talks from community personnel.

- Enrolment of study participants began on 24 June 2020 and expected to finish enrollments in March 2022, with follow-up period to August 2022.
- 1,201 participants have been prescreened
- 1,061 have been enrolled, with HIV positives 487 and HIV negatives 574.
- For HPV status negatives are 648 and 413 HPV positives.

Developing a prospective lymphoma clinical cohort in Malawi LCCC 1229

This study is designed to address the severe deficit of prospective longitudinal data related to lymphoma in sub-Saharan Africa, and to serve as a foundation for developing optimal treatment strategies in this challenging environment.

OBJECTIVES

The primary objective of the study is to develop a prospective cohort/ registry of lymphoma patients in Malawi who are comprehensively and longitudinally characterized with respect to clinical, laboratory, and histopathologic features while receiving care according to local standards.

The secondary objectives are:

- To characterize non-lymphoma diagnoses among patients in Malawi referred for suspected lymphoma.
- To understand key genetic patterns in lymphoma specimens in Malawi, in order to gain insights into lymphomagenesis in this setting and identify therapeutic targets for optimized treatment.
- To examine correlations between clinical and laboratory findings among patients with suspected lymphoma and final histopathologic diagnoses, in order to develop optimal diagnostic algorithms in settings of limited diagnostic pathology.

The study duration is 5 years. In view of activities of the study, participants come for treatment every 14 days, 21 days and 28 days respectively for 6 to 8 months depending on the type of lymphoma and treatment protocol, after treatment these participants are then followed monthly and then every 3 months up to 2 years then every 6 months as a long term follow up for 5 years.

2020 OVERVIEW

STATUS
Enrolling

Study PI:	Yuri Fedoriw MD
Funding agency:	UNC Lineberger Comprehensive Cancer Center and NIH
Project period:	May 2013 - 2021
First screening:	May 30 2013
Expected last exit:	2021

1200 **Target accrual**

46 **Enrolled in 2021**

938 Total enrolled in entire study

na Follow-up visits in 2021

PROGRESS & EVALUATION

Since its inception the study has been actively recruiting participants, it has established the largest prospective longitudinal clinical cohort of lymphoma patients in Malawi and in the region of sub-Saharan Africa in general. The initial sample size was 200 participants, got amended to 400 participants then 800 and now the number has been increased further to 1200 participants following successful NHRSC approval. The study protocol anticipates that the enrolment target of 1200 participants will be reached within 10 years. With 875 participants enrolled to date, the study is on track to meet this target in May 2023.

During this reporting period, the role of study PI has transitioned from Dr. Satish Gopal to Dr.Yuri Fedoriw. The current COVID-19 pandemic has led to unanticipated challenges for the study during this reporting period. That being said many of the challenges do not have a significant impact on the operations of the study. Regardless of the risks of COVID-19, cancer treatment at KCH is still active and suspected lymphoma patients are still referred to KCH for diagnosis and treatment. Thus, continuing enrolment into the lymphoma cohort during the pandemic does not pose any additional risks for these patients as they are already presenting to KCH for standard of care. Adjustments have been made to patient follow-up methods to minimize the need for healthy patients to travel to KCH and to postpone unnecessary clinical visits during the pandemic.

Cancer Centre within Kamuzu Central Hospital where clients are also enrolled from.

LCCC 1611

Establishment of a novel breast cancer cohort in Malawi

Breast cancer is the establishment of a Novel Cohort at KCH in Malawi. The study enrolls patients with pathologically confirmed breast cancer.

Standardized clinical assessment tools are used to collect demographic and risk factor data, comorbidities, tumor stage, pathological findings, and outcomes including treatment –related toxicities and health- related quality of life.

AIMS

This study aims to establish a prospective cohort of breast cancer patients at Kamuzu Central Hospital (KCH) in Malawi. Breast cancer is one of the most common cancers among women in sub-Saharan Africa, but high-quality data are lacking regarding its presentation, treatment, and outcomes there. We will use active case finding at KCH, a national teaching hospital in Lilongwe, the capital of Malawi, to enroll consenting women with pathologically confirmed breast cancer into a clinical cohort.

The primary objective is to develop a prospective cohort of Malawian breast cancer patients, who are comprehensively characterized with respect to clinical, laboratory, and histopathologic features, while receiving care according to local standards. The secondary objectives are to assess if the clinical characteristics of breast cancer at KCH differ by HIV status; to assess the feasibility and acceptability of interviewing patients for risk factors and treatment outcomes; and to evaluate tumour blocks for histologic, molecular, and genomic characterization.

OVERVIEW

Study PI: Tamiwe Tomoka

Funding agency: NCI- UNC-Malawi Cancer Consortium (U54CA190152)

Project period: February 2017 to August 2019 (4 years enrolment, 96 weeks follow-up)

First screening: December 2016

End date: 18 December 2022

STATUS
Enrolling

200 **Target accrual**	32 **Enrolled in 2021**	32 Total enrolled in entire study	na Follow-up visits in 2021

PROGRESS

The cancer study resumed recruitment on the 22nd of June 2020 after receiving approval from the NHRSC and IRB to increase the sample size from 100 to 200 participants. The study transitioned from using a Microsoft access database to Redcap database for data collection.

Data from the first phase of the breast cancer cohort was analysed and used to produce two scientific manuscripts (listed in the publications section)

Since resuming enrolment the study has been steadily recruiting participants. Previous data monitoring, quality control issues and issues with the redcap survey instrument have been resolved. The study team including the principal investigator and pathologist (Dr.Tamiwe Tomoka), study nurses, data staff and cancer research coordinator have resumed regular meetings to discuss clinical, regulatory, data and other study related issues.

Regardless of the risks of COVID-19, cancer treatment at KCH is still active and suspected breast cancer patients are still referred to KCH for diagnosis and treatment. Thus, continuing enrolment into the breast cancer cohort during the pandemic did not pose any additional risks for these patients as they were already presenting to KCH for standard of care. Adjustments had been made to patient follow-up methods to minimize the need for healthy patients to travel to KCH and to postpone unnecessary clinical visits during the pandemic.

The study experienced some challenges with the transition from using a Microsoft access database to redcap database for data collection. These data monitoring and quality control issues were addressed by the study team and thus will be prevented with new enrolees.

Isothermal Acid Amplification System Device LCCC 1940

This is a multicentre study being conducted in sub-Saharan countries namely Malawi, Ghana, Botswana, Rwanda and Tanzania.

To address the need for new approaches of diagnosis of Kaposi Sarcoma, investigators developed a machine known as TINY. An assay based on nucleic acid measurement that has a potential to be delivered at point of care.

A total of 2000 participants will be enrolled across all sites. Lilongwe site will enrol 300 participants. Patients are screened and enrolled from Cancer Centre and Light House Trust

OBJECTIVES

The purpose of this study is to check the performance of tiny machine for the diagnosis of Kaposi Sarcoma in a clinical setting.

OVERVIEW

STATUS
Enrolling

Study PI: Bongani Kaimira

Funding agency: AIDS Malignancy Consortium (AMC)

Project period:

First screening:

Expected last exit: 2021

Screening and enrolment: 1 April, 2021

300 **Target accrual**	90 **Enrolled in 2021**	90 Total enrolled in entire study	na Follow-up visits in 2021

PROGRESS

Screening and enrolment started on 1st April, 2021

- Total number of patients screened: 52
- Enrolled:49
- Patient reported for results: 41
- Results pending: 06

LCCC 1950

Rituxmab for multicentric Castleman disease in Malawi, a single-arm phase ii safety/ efficacy trial

MCD is a disease caused by a virus that makes your lymph nodes swell causing fatigue, fevers, loss and anaemia among other symptoms. Many types of chemotherapy are effective at controlling MCD but when chemotherapy is stopped, MCD returns and is usually deadly.

AIMS

This is a research study to find out if a drug called rituximab is safe for the treatment of multicentre Castlemans disease in Malawi. However, rituximab has not been well studied in sub-Saharan Africa and this study aims to evaluate its safety in Malawi.

A total of approximately 27 people will take part in this study.

OVERVIEW

Study PI: Matthews Painsschab

Funding agency: AIDS Malignancy Consortium (AMC), Fogarty International Centre and National Cancer Institute

Project period: **2021-2024**

First screening: 23 June 2021

Expected last exit: 2024

Screening and enrolment:

3 Total enrolled in entire study

na Follow-up visits in 2021

27 **Target accrual**

3 **Enrolled in 2021**

Treatment Outcomes for Esophageal Cancer in Malawi - TOEC

This study is a prospective cohort design in which patients with oesophageal at KCH, Lilongwe, Malawi are followed to collect key clinical and treatment related data until deaths or loss to follow up.

Data collected includes information about patient's health, family, symptoms and treatment of the disease such as Chemotherapy, Radiation therapy, Chemo-radiotherapy, esophageal stenting, esophagectomy, palliative care alone, as well as any combined or sequential therapies.

OBJECTIVES

The goal is to evaluate the effects of different treatments for esophageal cancer on Quality of life and survival. The study commenced on 1st June 2021.

- Sample Size is 300,
- Duration of the study is 3 years
- 61 questions are asked during enrolment, including contact information and socio-demographics.
- 40 questions are asked at follow up intervals, post enrollment and Treatment that is 1month, 3month and every 3months until death of lost to follow up)

OVERVIEW

STATUS
Enrolling

Study PI:	Bongani Kaimila
Funding agency:	Lineberger Comprehensive Cancer Center
Project period:	**1 July 2021 - July 2021**
First screening:	1 June 2021
Expected last exit:	July 2024

300 **Target accrual**

40 **Enrolled in 2021**

40 Total enrolled in entire study

25 Follow-up visits in 2021

PROGRESS

The study has enrolled 24 participants since its commencement on 1st June 2021

Death- 9
Lost to follow up-1
Active follow up- 14

Staging sub study:

In a subset of patients in the main treatment outcomes study (TOEC), we will obtain x-ray and cross-sectional imaging to learn how to best evaluate the extent of disease in patients with oesophageal cancer in Malawi, in simple terms, patients are undergoing a set of imaging studies (CT scan of the chest and abdomen, chest x-ray, and abdominal ultrasound to determine if the cancer has spread to other parts of the body.

These imaging findings will be used to determine if there is any association between stage of the disease and quality of life outcomes.

Sample size -160

Update: 12 patients have been sent for imaging.

Stent registry

It is part of the TOEC study, which aims to establish a tracking system for use of the subsidized Boston Scientific Corporation of esophageal self-expanding metal stents (SEMS). The registry captures the following data for every Stent placement from participating sites: patient demographics, procedural information, serial numbers of SEMS, clinicopathologic data, immediate adverse events, postprocedural quality of life metrics, and 30-day outcomes.

Stent registry data is captured in the Redcap, a secure web-based database

Update: So far 11 Stents have been placed and registered.

CANCER SYMPOSIUM **NEWS**

Some of the delegates on the opening day of the symposium

'TOGETHER AGAINST CANCER'

UNC PROJECT MALAWI HOSTS 3RD CANCER SYMPOSIUM

The 3rd Malawi Cancer Symposium took place from 26 to 27 May 2021 in Lilongwe and drew together various physical and online participants from across Malawi and beyond.

Themed 'Together against cancer,' the symposium was organized by the UNC Project Cancer Program and was funded by the National Institutes of Health.

Kicking off the event, Malawi Minister of Health Khumbize Kandodo Chiponda said cancer was a serious issue which government was taking seriously. She said Malawi was having an increased number of cancer patients needing medical attention.

"It has been a challenge sending patients outside the country for treatment as it is expensive and the country cannot manage to send everyone. That is why we are working to have the National Cancer Centre in Lilongwe fully functional so that we can attend to more patients locally," she said.

The minister added that the country would soon start admissions for adults at the cancer centre, where during therecor time only children were receiving treatment.

National cancer control strategic plan

UNC Project Cancer programme co-director Dr. Tamiwe Tomoka said Malawi was moving forward in the implementation of its national cancer strategic plan despite various challenges.

She said the strategy had these main domains: prevention (screening), treatment, diagnosis and surveillance.

"For instance on the treatment domain we have the cancer treatment centre which was opened for some patients last year. However there is some infrastructure that we have to develop; for instance we don't have

radiotherapy and that is in our plan to have it. We do have some chemotherapy but that needs to be increased as well," she said.

She added that under the strategy there were also plans to include breast cancer screening in the prevailing infrastructure of cervical cancer screening. She also lauded the interest which government was showing in the implementation of the national cancer strategic plan.

Lack of infrastructure

Tomoka said lack of infrastructure was affecting care at so many levels.

She said: "It is difficult for a patient who has got cancer to get to the final stages of testing. People leave in hard to reach areas and knowledge is low. Some will have a swelling and they will not know it is cancer.

"For one to navigate from the hard-to-reach areas to where we give the services, it can be a challenge. We have limited pathology services; we only have three laboratories; one is private while the other two are public. The Lilongwe one alone serves the whole central region and the northern part of Malawi which is almost half of the country.

She also cited lack of oncologists in the country and equipment to enable the few available staff see a good number of patients.

"Efforts are there but we are not moving as fast as we would. What saddens me a lot is that we do have people from low socio-economic backgrounds who have nobody to voice out for them when they need referral cancer care outside Malawi. We have seen those who are privileged call for funds through friends on social media to facilitate their treatment. But what are doing for the other ones who don't have a voice? This is where we need to put our effort so that everybody has equal care. That's the direction we want to move in," she said.

Key stakeholders in the symposium presented on issues related to the national cancer strategy, care, advocacy and research in Malawi, including current challenges, future priorities and opportunities to work together across sections. The symposium also provided a platform for both local and international cancer research, care and advocacy stakeholders to exchange information, highlight strategic priorities and identify opportunities for collaboration and personal development.

Keynote speaker for the symposium was Dr. Jackson Orem, director of the Uganda Cancer Institute (UCI) who has played a key role in growing UCI into a national teaching and research institute under the Government of Uganda Ministry of Health affiliated with Makerere University.

Cancer Programme Co-director Kate Westmoreland

Principal Investigator Matthew Painschab

SYMPTOM TOOLKIT FOR ADOLESCENTS AND YOUNG ADULTS (AYAS) WITH LYMPHOMA

OVERVIEW

Palliative care is essential to alleviate suffering related to serious illnesses but is one of the most neglected disciplines in global health.

Reducing patient suffering is a crucial aspect of improving health, and palliative care has recently been prioritized in providing universal health coverage.

Implementation of palliative care globally has typically focused on older adults, neglecting children, adolescents, and young adults.

Adolescents and Young Adults (AYAs) with cancer are a particularly challenging group to support during their cancer experience.

Incorporating palliative care into cancer care for AYAs is important, as this group often has poorer emotional well-being and quality of life.

In Sub-Saharan Africa (SSA), lymphoma is the most common adolescent cancer, and survival rates are much lower in SSA than elsewhere. Poor outcomes in these settings are often due to treatment abandonment.

This study seeks to implement a symptom toolkit to assess its effectiveness in managing patient symptoms, with the goals of improving quality of life and successful treatment completion.

Would use patient-reported outcome (PRO) measures, PROMIS and PRO-CTCAE, to estimate disease and treatment effects on patients' mental, physical, and social health-related quality of life.

AIMS

To demonstrate the feasibility of a symptom management toolkit among AYA Lymphoma patients in Malawi.

Secondly to measure the impact of the symptom toolkit on health-related quality of life using the Chichewa Pediatric/AYA PROMIS-25 Profile and on symptom management using the Chichewa Pediatric/AYA PRO-CTCAE.

Thirdly to test the effectiveness of a toolkit that enables patients to self- manage moderate chemotherapy side effects. The toolkit includes medication, a journal to document symptoms and instruction and counselling on how and when to use medications.

OVERVIEW

Study PI:	Kate Westmoreland
Funding agency:	UNC IGHID Explorations Grant
Project period:	April 2021- April 2023
First screening:	April 2021
Expected last exit:	Following enrollment completion

50	**Target accrual**	27	**Enrolled in 2021**	27	Total enrolled in entire study	na	Follow-up visits in 2021

PROGRESS

Enrollment at initial chemotherapy visit; study would be explained to participants

The symptom toolkit would be equipped with medications that are used to symptomatically manage some of the most common symptoms experienced by patients with cancer.

Symptom toolkit would include medications labeled with symptom graphics and symptom toolkit journal

Patients would receive counseling on common symptoms and side effects of cancer and chemotherapy and instructed to take medications as is needed and indicate in journal how often they experienced symptoms or used medications

On return visits, Pediatric/AYA PROMIS and Pediatric/AYA PRO-CTCAE would be completed and additional counseling and medications will be given as is needed.

MEDICATIONS

Nausea/vomiting (promethazine), Constipation (Bisacodly) lactulose to be administered as needed, Oral mucositis (honey), Pain (paracetamol), oral morphine to be administered as needed, Insomnia (diphenhydramine), Gastritis (magnesium) Cimetidine to be administered as needed.

PEADIATRIC/AYA PRO-CTCAE

The Pediatric/AYA Patient-Reported Outcomes Measurement Information System 25-item pediatric short form (PROMIS-25) assesses six health-related quality of life domains:

- Mobility, Anxiety, Depression, Fatigue, Peer relationships
- Pain interference

PEADIATRIC /AYA/PROMISE

The Pediatric/AYA Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) assesses 15 core symptom domains: Abdominal pain, Constipation, Diarrhea, Oral mucositis, Nausea, Vomiting, Fatigue, Pain, Anorexia, Headache, Peripheral sensory neuropathy, Anxiety, Depression, Insomnia, Cough

PROJECT ACTIVITIES

Activities completed in 2021 included:

- Support for meetings of the Malawi AMR Technical Working Group.
- Renovattion of office and conference facility for the AMR National Coordinating Committee (AMRNCC).
- Support to the World Antibiotic Awareness Week activities at Kamuzu Central Hospital.
- Support towards the Malawi Standard Treatment Guidelines review meeting.
- Facilitation of the National Microbiology Reference Laboratory (NMRL) application for Southern African Development Community Accreditation Services (SADCAS) accreditation. Initial assessment was conducted in December 2021.
- Launching of the AMR data repository for AMR, based with the AMRNCC.
- Support for the AMR/AMU data analysis through training workshops.
- Training of clinicians and nurses at 7 human health facilities across Malawi on proper specimen collection and transport techniques.
- Renovation of the NMRL, plus 7 human health [HH] (Kamuzu Central Hospital, Mzuzu Central Hospital,

CLOVE

AIMS

The aim of the study is to provide epidemiologic evidence and guidance to inform and improve the district-wide public health HIV prevention response in Blantyre, Malawi.

The study will assess whether adding acute HIV testing at MOH testing sites and STI clinics and extending testing outreach to social venues could lead to improve strategies for HIV prevention and treatment.

OBJECTIVES

- To compare the population size and characteristics of clinic-based populations vs the venue-based populations among people with acute, recent, or chronic uncontrolled HIV infection.
- To compare the population size and characteristics of clinic-based populations vs the venue-based populations among people at high risk of acquiring HIV who are not currently reached by HIV prevention programs.
- To identify geographic clusters of unknown infection or prevention need in Blantyre district.

OVERALL IMPACT

- The study will support a district-wide HIV prevention project in Blantyre (BPS).
- Initial recruitment period is from October, 2021 – December,17, 2021
- Recruitment sites include 13 Health facilities within Blantyre district and Social Venues within Blantyre City.

EXPECTED OUTCOMES

- Create behavioral and HIV profiles (acute, chronic, recent, virally suppressed, not infected) of the clinic-based and venue-based populations, as well as their engagement with HIV prevention and treatment programs.
- Identify sub-groups missed by clinic-based testing strategies in order to assess whether venue-based outreach fills an important gap missed by clinic-based approaches.
- Generate descriptions of the geographic pockets in Blantyre associated with high prevalence of acute, recent, or undiagnosed/unsuppressed HIV that could be used to prioritize HIV prevention activities.
- Identify key-population specific findings including size estimates of interest to NGOs and others engaged in key-population prevention work.

Target enrollment
- 3,200 clinic-based patients age 15+;
- 400 community informants age 18+;
- 800 venue informants age 18+;
- 3,200 men and women at venues age 15+;
- 10-30 persons with acute infection and their partners.

OVERVIEW

Study PI:	Sharon Weir, Emmanuel Singogo
Funding agency:	London School of Hygiene and Tropical Medicine
Project period:	January 2020 to December 2022

PROGRESS

- An exercise to identify prevention priority areas (PPA's) was done and 35 prevention priority areas were identified.
- Sampling for the targeted health facilities was done and we will target 13 health facilities.
- The study was approved by UNC IRB and NHSRC
- The plan was to start the first phase of the study which involved venue identification early October 2021 and research assistand were recruited.
- Planning was also done for a qualitative sub study that will look at understanding methods of voluntary assisted partner notification among people testing positive with acute HIV infection in the CLOVE study.
- Planning was done to have debriefing meeting with the 13 health facilities that are being targeted.
- Preparations were done to have lab supplies and necessary equipment for phase three of the study.

Facilitators and research assistants during training in Blantyre in 2021.

Facilitators and participants during training in Salima on 27 September 2021.

A collaboration with MBTS, KUHeS/COM aimed at addressing blood supplies

BLOODSAFE

This is a collaboration with MBTS, KUHeS/COM aimed at addressing blood supplies. It is being implemented in 2 phases: pilot- Year 1 & 2 & clinical trial phase- Year 3-6

- DCC at UMN and DSMB

PROTOCOLS

Protocol 1:
Improving epidemiological surveillance of transfusion transmissible infections in Malawi, PI: Emmanuel Singogo, MSc, PhD

Protocol 2:
Exploring facilitators and barriers to blood collection and repeat donations in high and low performing districts/ programs in Malawi, PI: Dr Effie Chipeta KUHeS.

OVERVIEW

Study PI:	Mina Hosseinipour, Bridon Mbaya
Funding agency:	National Institutes of Health/NHLBI
Project period:	Phase: 1 July 2020 to June 2022 Phase: 1 July 2022 to June 2026

PROGRESS

Year 1 Progress updates

- Active participation in the Steering Committee (SC) and its subcommittees
- Ethics approval for the 2 study protocols
- Collaboration with the Data Coordinating Center (DCC)
- Developed key Partnerships with Ministry of Health and Ghana and Kenya teams.
- Participation in Technical Working Groups- discussing transfusion issues in Malawi
- Blood donation stakeholders' meetings
- Conducted 3 regional meetings

Year 2 Progress updates

- Data cleaning was conducted in June 2021
- Data cleaning exercise done
- Data analysis preparations in progress
- Auditing Hospital blood banks
- **Data quality improvement projects**
  - Baseline QI assessment happening week of September 20, 2021- Nsanje, Balaka, KCH and MCH
  - QI training planned for week of September 27, 2021 in Salima- targeting lab, Paeds, maternity, transfusion focal persons.

- **Systematic reviews**
  - *Aim 1*: A systematic review of prevalence, risk factors of transfusion transmissible infections among blood donors and blood safety interventions in Southern Africa.

  -*Aim 2:* A systematic review of barriers and facilitators to maintain repeat blood donors in Southern Africa.

MPHAMVU

AIMS

The main objectives of Mphamvu project:

- To determine the number and frequency at which adolescent girls and young women (AGYW) and adolescent boys and young men (ABYM) receive one or multiple sexual and reproductive health services (SRH).
- To estimate the number and percentage of AGYW/ ABYM who are newly diagnosed with HIV infection and are linked to HIV care and treatment,
- To assess trends in uptake of HIV and SRH services among AGYW/ABYM, at the project sites.
- To prevent HIV mother to child transmission in pregnant and breastfeeding AGYW.

PROGRESS

2021 has been another successful year for Mphamvu project, we saw a total of 15090 young people take at least one or more services at our clinics at Kawale and Kabudula. An average of 600 clients were seen every month. Of the 15090 clients that took services at our clinics 945 were adolescent boys and young men (ABYM) representing 6.3% and 14144 were adolescent girls and young women (AGYW) presenting 93.7% of the total clients seen this year.

In addition, 8792 of these were new clients representing 58.3% of the total clients seen this year. This proves that our project is reaching new young people who need sexual and reproductive services (SRH) each month. Close to half of these were revisits I.e. clients that have come for more than one visit. This also proves we are able to retain our clients on the projects.

Furthermore, 2021 has been the year where we bounced back from the effects of Covid 19 pandemic. In 2020 we experienced a significant drop in service uptake at our clinics due to covid 19 challenges. In 2020 we only had a total of 6612 clients at Kawale and Kabudula clinics combined. However, in 2021 we have more than doubled that figure. The number of clients we have seen in 2021 proves that we have grown and reached more young people that need SRH services in Lilongwe.

SERVICES IN 2021

1. HIV testing and counselling
2. Sexually Transmitted infections (STI) screening and treatment
3. Condom use
4. Family planning
5. Prevention of mother to child transmission (PMTCT)
6. Post- natal care (PNC)
7. Early Infant Diagnosis (EID)
8. Gender based violence (GBV) screening and treatment

A sensitisation meeting at Kabudula in 2021

ACHIEVEMENTS

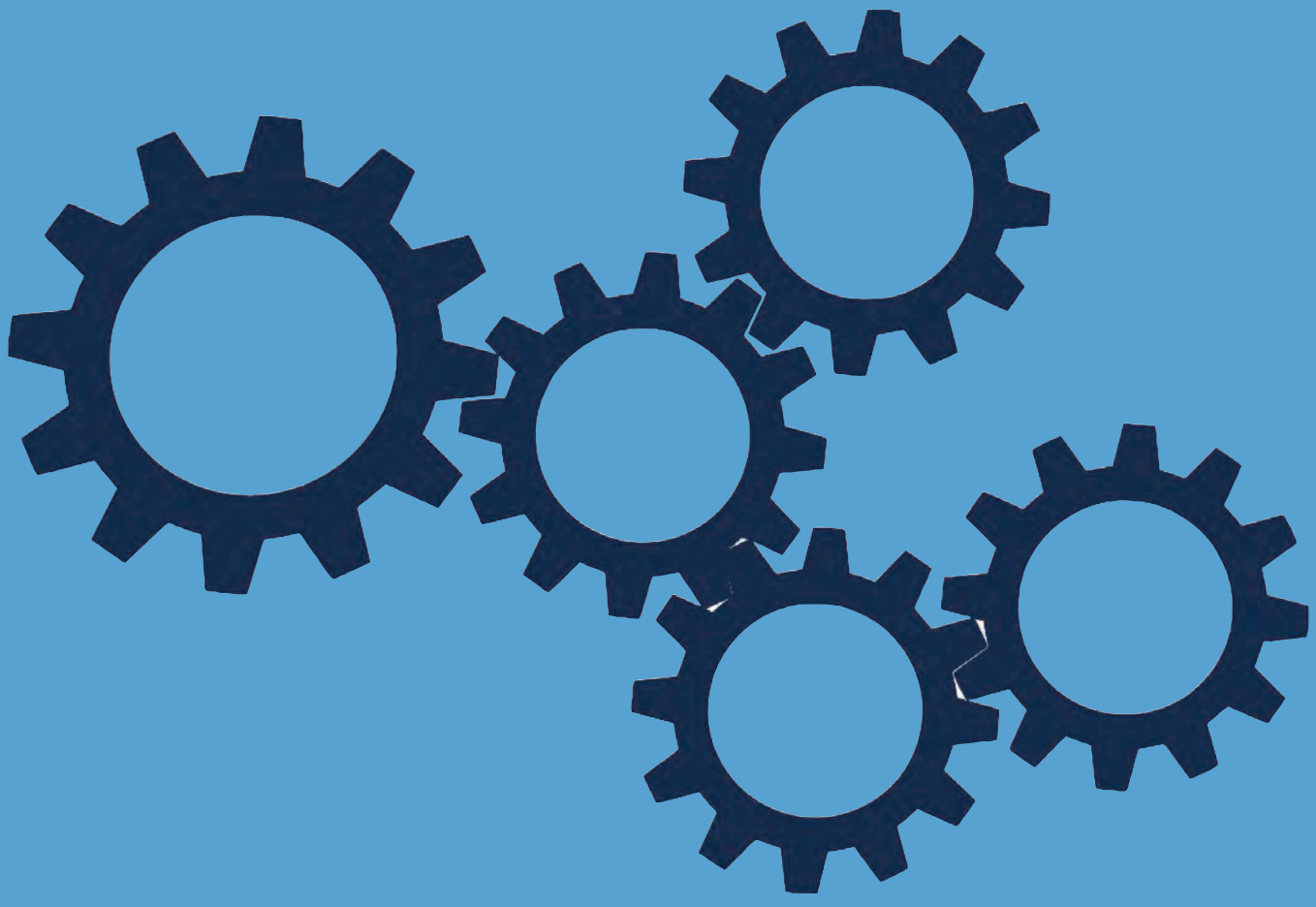
We are celebrating three main achievements of 2021:

1. Introducing PrEP at Mphamvu clinics:
We expanded our HIV services to include PrEP. When government rolled our PrEP in Malawian clinics we were one of the first sites to be given PrEP. We were also allowed to dispense PrEP from the youth clinic. We were given PrEP registers where we document PrEP dispensed and at the end of each month we give a report on the prep dispensed from the youth clinic.

2. Community clinics:
We have always worked closely with the communities around our catchment areas. Once every fortnight we go into the community (bars, schools, colleges, markets, villages etc.) to mobilize the youth to come to our clinics for services. However, in 2021 we added another layer where we took the clinics to the community. This was done to reach young people that live in hard to reach areas who would not ordinarily come to our clinics for HIV/SRH services. We managed to do two community clinics in the last quarter of 2021. We employed services of clinicians/ nurses, HTS counsellors, peer educators on locum to offer the services in the community. These community clinics pulled huge crowds because we combined music, dance, drama and HIV services.

3. Client satisfaction questionnaire:
In order to improve our accountability to our target population (AGYW) we introduced the client satisfaction questionnaire where we ask the clients how they feel about the services offered at our clinics, what they like and don't like and what we can do in order to improve on our weakness. We feel this data will give us real time feedback from our clients and that will help us modify the project to suit their needs.

CORE SERVICES



LABORATORIES

GENERAL UPDATES

The UNC Project Laboratory in 2021 continued to be impacted by COVID-19 and as such the workload had further diminished. Laboratory staff have adapted through scheduled rotations to minimize exposure and assure functioning of the departments.

The Pathology Department reached ten years of full operation since 2011. After a steady annual rise in the number of histology samples processed, the total has plateaued since 2019. Cytology cases rose in 2021 due in part to increased national cervical cancer screening managed by several external clients such Lighthouse, Partners in Hope and Malscot-Nkhoma Project. The UNC Project Pathology Department is responsible for the bulk of all pathology processing in Malawi.

The laboratory hosted the annual DAIDS audit onsite between October 5-8, 2021.

The laboratory received support with appreciation to CFAR towards funding to purchase a second Leica TP-1020 Tissue Processor as well funding to cover refurbishment of the Leica Bond Max (donated by UNC-Pembroke) which will automate immunohistochemistry (IHC) staining procedures.

The laboratory has struggled with repair service needed for the water distillation units that are coupled with the cobas c311 chemistry analyzers, the systems have been out of service for months. The latest variant has hampered engineers traveling from South Africa as well as turnover in customer support services by Roche.

Global supply chain issues negatively impacted the laboratory leading to suspension of testing by DCLOT as both UNC Project and JHU Blantyre laboratories lacked supply of hematology controls.

The laboratory continued supporting Malawi MOH with COVID-19 testing to the general community at no fee using reagents supplied by MOH and other partners.

Some staff from the pathology lab.

PHARMACY

The pharmacy department has Seven dedicated members of staff (2 pharmacists and 4 pharmacy technicians and 1 pharmacy assistant) who works tirelessly for the betterment of the project. The staff members are not just effective but also efficient in their line of work. The teamwork sprit makes the department stronger each passing year. The UNC pharmacy has three main dispensaries located at Tidziwe down stairs, George Joaki Centre and Bwaila Hospital. We also have a chemotherapy compounding area at KCH.

OBJETIVES

- To dispense drugs to participants in doses that meets their clinical requirements.
- To store drugs at recommended temperature as directed by manufacturers.
- To ensure availability of all study drugs, non-study drugs and medical supplies at all times

ACTIVITIES

Network and non-network studies
In 2021, the pharmacy has supported both the network and non-network studies with investigational pharmaceutical product. In total, the pharmacy staff supports over 14 ongoing active studies within the project. The pharmacy consistently meets network standards for monitoring and auditing with no major findings. On the other hand the pharmacy has managed to start working as a recharge center that will ease the study charging challenges that were there before.

Covid-19 support
The pharmacy department continued playing a crucial role in the fight against the covid19 pandemic at the project. Since the pandemic started, the pharmacy has been the center in procuring and distribution of PPE and supportive medication including oxygen. The pharmacy staff volunteered themselves to work even during odd hours just to make sure that the affected staff are getting the timely assistance.

Direct Relief donations
The pharmacy department also work in collaboration with Direct Relief International (DRI) from the United States that provides pharmaceutical support to the project free. In the year 2021, the pharmacy has been receiving various shipments from them that include; medications, PPE and equipments. Some of the donated items have been distributed to Kamuzu Central Hospital, Bwaila Hospital, Nkhoma Hospital and Area 18 heath center

Pharmacy Research
With the NCD BRITE grant, the pharmacists are conducting a research in diabetes and hypertension at Kamuzu Central Hospital. They are also taking opportunities of applying for the different available advertised grants.

Some of the drugs and items from Direct Relief International

NURSING

UNC Project-Malawi-Nursing Department is responsible for collecting research data and providing nursing care to all study participants taking place at UNC project. The nurses are also key in the development of study Standard operating procedures and some work as team leaders and study coordinators for different studies. The nurses have also been involved in the screening for Covid-19 to UNC staff and people from the public at Tidziwe centre since the first wave in 2020. The department has a total number of 46 nurses distributed across all studies. Of these, 28 are nurses and midwife technicians and 16 are state registered nurses. Of the RNs, -10 have a Diploma in nursing, 3 have bachelor's degrees, 3 has MSc and 2 have PhDs.

COLLABORATIONS

The department has been collaborating with UNC Chapel hill, School of Nursing (SON), Kamuzu college of Nursing and Kamuzu Central Hospital (oncology department) to develop an educational program for oncology nurses and those interested in oncology nursing since 2018. Since 2019, the team from UNC Chapel Hill, school of Nursing (The Dean Nena Peragallo Montano, Dr. Ashley Bryant, Dr. Lixin Song, Jane Haley) in collaboration with the UNC Project Malawi nurses (Drs. Agatha Bula and Chifundo Zimba)-both adjunct faculty members at UNC Chapel Hill, School of Nursing and KCH Oncology specialized nurses (Samuel Bingo and Tikondwe Sichinga) have jointly been conducting two studies both focusing on Oncology nursing in Malawi with funding from Lineberger Comprehensive Cancer Centre (LCCC). The first study evaluates Pre-Test and Post-Test Knowledge after Cancer Education in Malawian Nurses through Webinars sponsored by the UNC School of Nursing. In this study, the team have been conducting 1-2 hours virtual cancer sessions (8 sessions so far completed) to KCH and UNC nurses and faculty members from Kamuzu college of Nursing. The second study aims to understand perceptions of oncology clinicians, patients and guardians in Malawi about cancer care in Malawi. A total of 35 participants including Nurses, clinicians, patients and guardians have been interviewed. Currently we are coding and analyzing the data.

The team also jointly conducted systematic review to understand supportive and psychosocial care in adults with Cancer in sub-Saharan Africa. So far 2 papers have been submitted for publications. The first paper titled: Quality of life among patients with cancer and their family caregivers in the Sub-Saharan Region: a systematic review of quantitative studies has been accepted for publication at PLOS Global public Health journal. The second paper titles: Systematic Review of Psychosocial Interventions for Adult Cancer Patients and Their Family Caregivers in Sub-Saharan Africa was submitted to the Journal of Global Oncology. The team is currently finalizing the last qualitative paper from the same systematic review.

The UNC Project nursing team will continue collaborating with UNC School of Nursing, KCH and KCN in professional development and grant writing.

DATA

INTRODUCTION

The mission of data department is to ensure that research conducted at UNC Project generates high quality, reliable and statistically sound data. The department has three sections: Data and Quality Control (QC) section, Quality Assurance (QA)/Internal Monitoring section, and Regulatory Section.
The department provides technical leadership, mentorship/training, development and implementation of data management systems, quality assurance and control systems, research ethics, monitoring and evaluation, and data storage/archive systems. This report covers the activities undertaken by QA and Data/QC section between January and December 2021.

KEY HIGHLIGHTS

Data management performance across network studies (HPTN, HVTN, IMPAACT, ACTG, and COVPN) has been outstanding averaging 95% in terms of timeliness to data entry, transmission, query resolution and responsiveness. The site has received two awards for outstanding data management performance in HPTN 084 and PROMOTE study.

Monitoring/audit visits: the team were able to manage remote and hybrid visits successfully. The internal monitoring team assisted teams to prepare for the visits. The team were able to record QA findings on the internal QC tool but not consistently on the chart review tool thus deviating from clinical quality management plan.

Utilization of the internal QC database across non-network studies has increased from 40% to 60% and all network studies have consistently use the database system. The remaining 40% of the studies that are not utilizing the internal QC database are somewhat programmatic in nature like blood safe, FP-ART, CONNECT, MSI, PACHIMAKE, COVID and Cancer registries. However, they were able to do quality control checks. The departmental leadership is brainstorming on the best way to accommodate these type of studies into the internal QC database system.

The monitoring reports were good as they did not find the site as inadequate across all visits but had some major findings on informed consent process in some of the visits. One particular finding was use of unapproved assessment of understanding/comprehension checklist. Other findings that were picked by monitors and our internal QC system picked were staff not signing delegation log of responsibility, inconsistent time of consent.

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Staffing issues: regulatory office needs to add a regulatory associate to assist with logistical work of the office. The regulatory office is often had high workload which affects the office ability to comply with the CQMP stipulations especially non-network studies like performing quarterly/biannual QA reviews consistently. There is need for a data archivist to manage the four data warehouses.

The department reviewed approximately 2469 visits of which 1138 (46%) visits were for network studies and 1331 (54%) visits were for non-network studies. A total of 1762 (71%) visits were without errors and a total of 988 errors were identified. The common errors/queries identified through quality control check were inadequate or discrepant source documentation. The root cause was failure to perform self-QC by data collectors or data entry persons.

Frequent issues: regulatory office: delay payments from accounts to ethics, delayed submission by PIs of ethical applications, lapses in submission of GCP/HSP. Data office: poor maintenance of heavy duty printers' thus high downtime and delayed maintenances, delay response to internal queries due to "I will do it later attitude". QA office: an air conditioner is required and delayed response to queries by teams.

UNC PROJECT
IN THE COMMUNITY

Despite three COVID-19 waves in 2021, the team adapted and multitasked to ensure that they rendered necessary support to meet the protocol set accrual and retention goals for various studies. The team had a really hard year with limited and at times suspended community engagement activities due to the surge of COVID-19. However they had to be innovative in to reach out to participants during this period.

WORLD AIDS DAY 2021

UNC Project was invited to present at Lilongwe City Council World AIDS day commemorations which took place on 18 December 2021. At this event the Project showcased activities on HIV prevention like vaccines and other preventive measures, and treatment. They also talked about on-going COVID -19. During this colorful event, the team opportunity to interact with numerous stakeholders and communities and discuss their activities.

RECRUITMENT AND RETENTION

In 2021 the team has been working on recruitment of the participants into the COVID-19 trials. This being a very new area of work, it involved identifying new stakeholders and partnering to get participants on board. Despite all the misconceptions and challenges around COVID-19, the team was able to develop and implement strategies that resulted in meeting accrual goals for studies.

Retention activities all centered on counseling participants when they came for their visits on site and spending some time discussing issues that might hinder them from coming during the epidemic. There was a shift to the majority of contact with participants being done via phone so us to reduce the risk of contracting COVID-19 in the communities.

COMMUNITY ADVISORY BOARD (CAB)

The Board was affected by the COVID-19 epidemic, meetings were called off when the infection rates were at their peak. Despite challenges faced during the year, 4 new members were enlisted to focus and give insight on sickle cell disease and its challenges in the communities.

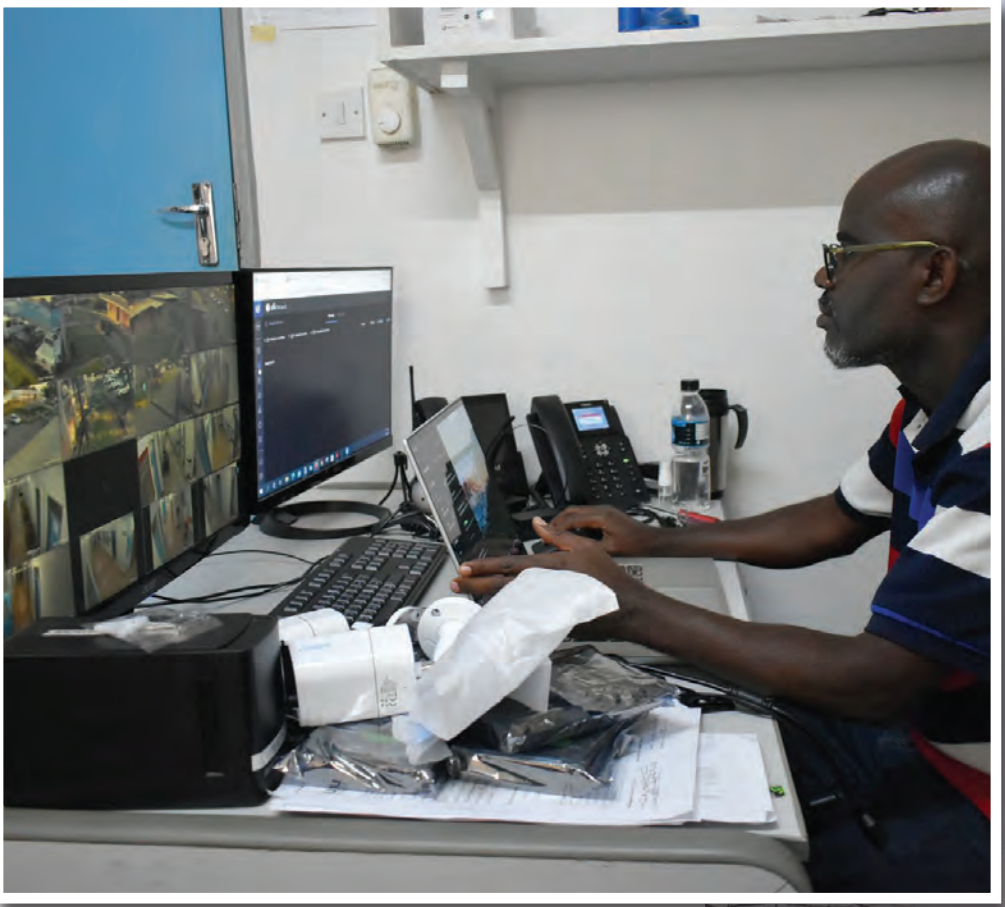
For the first time since its inception, the youth in the CAB organized a youth interface at Kawale Health Center on 1st December 2021. This brought together youths from the surrounding communities to discuss issues of HIV prevention and COVID 19 vaccines. The Community team also presented on the HIV prevention work that they had been doing throughout its inception and the impact it had on the HIV prevention spectrum.

PROTOCOL REVIEW

The protocol review subcommittee was also involved in the reviewing ACTG protocols throughout the year, sharing their views on upcoming studies so that views of local Malawian communities were incorporated.

2021 ended on a high note as Ms. Maureen Phiri (Youth CAB) was selected to represent the site in the Community Scientific Subcommittee (CSS) of the ACTG. She becomes the second representative for the site in the committee.

ICT DEVELOPMENT



In 2021, the ICT department began process for acquisition and deployment of Premier HR, which is a human resources management information system – January 2022.

Among benefits of this acquisition is the transformation of the traditional paper-based employee file to an electronic file with all necessary attached documents; creating electronic job descriptions; easy access to employee records for performance appraisals and personal development plans and planning training interventions for employees.

Apart from human resource management, the requisition has strategically aligned the human resource system with payroll system making it a one-stop solution for adding new employees, job titles, personal details and position analysis changes.

In the year the ICT department was also started the implementation process of a new enterprise resource planning system called NETSUITE. This is a single integrated suite of applications for managing accounting, order processing, inventory management, production, supply chain and

warehouse operations.

Netsuite will cover areas of online requisitions, purchase requests and related approvals, as well as financial reporting. This online system will help in making the whole approval process and reporting quicker and easier than before, since employees will no longer be required to go in different offices to seek approvals.

Prior to this, UNC Project has been having different software for various departments and it has been hard to get all the main operations of these software into one main system. We have hope that in 2022 the new system will be operational as soon as configuration and testing is done.

Some of the ICT whoa have been behind the developments

CLINICAL SERVICES & REGISTRIES

PACHIMAKE

This is a cross-sectional, prospective, observational study of all children aged 2 weeks to 5 years presenting urgently for care and admitted to the KCH Pediatric ward that began in October 2017 and is ongoing.

The main objective of this study is to obtain vital and comprehensive information about the burden of disease in the pediatric population admitted emergently to Kamuzu Central Hospital Pediatric Department, to describe components of the care patients received, and to record their outcomes.

BACKGROUND

Kamuzu Central Hospital (KCH) is the national referral hospital in the capital city of Lilongwe serving the central region of Malawi. The pediatric ward admits more than 27,000 patients per year and manages all medical emergencies. Multiple institutions (US based medical institutions and private organizations) have been independently supporting pediatric care in various capacities since 2005. This uncoordinated presence has already resulted in a decrease in pediatric inpatient mortality from approximately 9-10% between 2009 and 2011 to the current estimated rate of 4%.

NEED

Despite the progress made thus far, critical gaps exist in pediatric care at KCH. The primary gaps identified include lack of communication and coordination between KCH and institutions sponsoring rotating consultants and trainees, lack of adequate staff in number and skill set, lack of reliable systematic data collection, lack of standardization of clinical care, and lack of multi-faceted funding sources and support infrastructure.

Working collaboratively with KCH staff, this consortium prioritizes and addresses these gaps to improve pediatric outcomes. We anticipate this consortium can serve as a model of collaboration for institutions striving to improve pediatric healthcare systems in other Low- and Middle-Income Countries (LMICs).

Institutional Partners: KCH Department of Paediatrics, Malawi College of Medicine, BCM Children's Foundation and Center of Excellence, Texas Children's Hospital / Baylor College of Medicine (BCM), Cincinnati Children's Hospital Medical Center (CCHMC), University of North Carolina (UNC) Chapel Hill / Project Malawi, University of Utah / Primary Children's Hospital.

OVERALL MISSION

Through a sustainable, bi-directional collaboration, to improve the care of acutely ill children at Kamuzu Central Hospital (KCH) through implementation of effective, coordinated, high-quality clinical, educational, quality improvement and research initiatives.

Specific Objectives:

1. To describe the patient population (demographics and initial clinical presentation) of all children aged 2 weeks to 5 years acutely admitted to KCH Department of Pediatrics.
2. To describe the initial testing and interventions provided to patients upon admission.
3. To identify modifiable gaps in the provision of standard care to acutely ill pediatric patients by identifying delays in labs, studies, and consults.
4. To report data outcomes for this cohort of patients, including discharge diagnoses, medications prescribed, and patient education provided.

MONTH/YEAR	2018	2019	2020	2021
JANUARY	504	1019	1561	1
FEBRUARY	659	1520	1730	57
MARCH	1027	1018	1426	80
APRIL	780	932	668	75
MAY	746	938	643	54
JUNE	681	732	622	49
JULY	416	596	433	446
AUGUST	387	561	431	459
SEPTEMBER	375	591	466	451
OCTOBER	415	838	668	548
NOVEMBER	430	783	751	792
DECEMBER	462	869	466	577
TOTAL	**6882**	**10397**	**9865**	**3589**

CANCER REGISTRY

Some of the oncology nurses at Kamuzu Central Hospital old cancer wards.

The purpose of the cancer registry is to help investigators and clinicians to have the capacity to determine the number of cancer patients seen at the hospital, what type of cancer they have and how it's treated. The data provided by this registry is used for reaching the effects of HIV and other infectious diseases on cancer prevention, cancer epidemiology, support future clinical trial design, and provide preliminary data for grant applications. In addition, this registry's data is used by individual clinicians, departments, the KCH hospital administration and the Ministry of Health to allocate resources for treatment of cancer patients.

Furthermore the registry's data is compatible to the World Health Organization's cancer registry contributing to the tracking of cancer trends worldwide. The registry also allows to determine the outcomes of patients treated for cancer, and finally this registry allows to follow patients clinically.

OBJECTIVES OF THE REGISTRY

The objective of the registry is to characterize the demographics, history, physical exam, laboratory assays, imaging studies, histopathology, HIV status and outcomes of patients who present to Kamuzu Central Hospital (KCH) with a known or suspected cancer. Through these efforts, it is aimed to identify ways to improve diagnosis, medical, and surgical treatment of cancers.

STI REGISTRY

UNC Project still provided STI management and treatment services to patients presenting to the STI clinic at Bwaila District Hospital in conjunction with its ongoing and diverse STI research projects. In addition to conducting operations research for the Malawi Ministry of Health, UNC Project also monitors gonococcal resistance patterns and continues to evaluate algorithms for the syndromic management of STIs under the leadership of Mitch Matoga.

Total individuals recruited into the registry since inception = **31250**
Total recruitment for 2021 = **8928**

TRAUMA REGISTRY

This is an ongoing collection of trauma surveillance data for all trauma patients presenting to KCH.

Through a collaboration between the Department of Surgery and the UNC Injury Prevention Research Center, we designed and implemented a hospital based trauma surveillance registry at KCH utilizing an expanded minimal data set, in which trained personnel use a 1-page registry form capturing demographic characteristics, injury causation, treatment and outcome. We have demonstrated the feasibility of establishing an effective trauma registry using limited resources and without a sophisticated software package. Analysis of our data collection is ongoing With these data, we can implement focused injury prevention strategies and programs based on epidemiology, geography and injury prevalence and patterns, thereby extending our surveillance program to other central and district hospitals.

Road accidents are common on Malawi roads resulting in deaths and hospitalizations.

COMMUNITY SERVICES & PHILANTHROPY

P&G (Pure water)

The Procter & Gamble (Pure water) program started in December 2008 at Area 18 and Area 25 health centers. Later on, the program scaled up to 35 health facilities in Lilongwe district with the aim of improving nutrition and reducing diarrhea disease amongst exposed babies and their families. Currently we have 33 facilities.

Babies enrolled in this program are born from HIV positive mothers and some are screened from under five clinics, OPD and ART.

Routine under-five clinic care is done to all babies, nutritional counselling and dispensing of ART therapy to both infected mothers and exposed infants and checking status of exposed babies. In terms of illness, babies are referred to clinicians for proper management and treatment. P & G water packets are also dispensed to families and pregnant women up to 2 years of the babies' age. Other infected babies beyond this age are also given P&G water packets on clinicians' discretion in collaboration with MOH staff.

DISTRIBUTION OF P&G WATER TREATMENT

- P&G sachets are distributed in 33 health facilities within Lilongwe district on monthly basis. The quantity is determined according to number of HIV pregnant mothers and exposed infants up to 2 years after birth.
- Distribution of P&G water packets is done by the project vehicle from the warehouse to the facilities in Lilongwe.

MAIN ACTIVITIES OF THE PROGRAM

- Monthly distribution of P&G water packets in 33 facilities.
- Monthly data collection and to be submitted to the director quarterly.
- Continuous mentorship during P&G distribution as one way of making sure that the program is on track.
- Ordering of new stock if the levels are going down.
- Debriefing sessions to staff on P&G activities yearly.

CHALLENGES OF THE PROGRAM

- Documentation in the registers is a main challenge despite being mentored on monthly basis.
- Change of staff in the health facilities makes it difficulty in distribution of P&G Sachets to clients since others are not oriented.
- Some staff just distribute P&G without any documentation on distribution forms.

Beneficiaries of the P&G water treatment packs at Nathenje Health Centre.

The Robinson Malawi Fund

A mother supporting her child in the paediatric cancer ward at Kamuzu Central Hospital.

This charity was established to support Burkitt's lymphoma direct patient care in Malawi including buying chemotherapy and supportive medications, nutritional support, transport reimbursements.
It started as one event. Porter Robinson a famous musician whose brother, Mark Robinson had also suffered Burkitt's lymphoma cancer established the fund. Mark was treated by Dr. Kate Westmoreland at the University of North Carolina Hospital. Dr. Kate has also for a long time treated children in a similar fate at Kamuzu Central Hospital in Lilongwe, Malawi. After the successful first 'Second Sky Festival' in 2019, another festival was held from 18-19 September 2021, Oakland Arena, CA. All the two festivals have been done to help improve plight of the cancer children at Lilongwe.

The first 'Second Sky' Festival raised over $155,000 while the second one managed to raise. The majority of these funds went towards the purchase of the actual chemotherapy medicine used to fight cancer and supportive care costs (such as painkillers, anti-nausea medication, antibiotics, and nutritional support) to support a patient undergoing cancer treatment. Some funds were used to purchase personal protective equipment for the staff at Kamuzu Central Hospital, where patients are treated, during the COVID-19 pandemic. Some funds have also supported laboratory and radiology tests that patients need to treat their cancer. We also used funds to support a portion of the salary for both a Malawian doctor and nurse providing direct patient care for pediatric Burkitt's lymphoma patients at Kamuzu Central Hospital.

In the second 'Second Sky' Festival was also aimed at raising over $155,000 to continue to support direct patient care AND do more!

The Fund also has a long-term goal of building a pediatric and adolescent "guardian shelter" which will be a 'home away from home' for families. Construction of the guardian shelter/hostel at Kamuzu Central Hospital, next to the pediatric cancer ward, would allow patients and their guardians to comfortably stay during the duration of treatment. They will have rooms to sleep in, a kitchen to cook meals together, play area, school classroom, a place to socialize and support one another through the cancer treatment.

DZAMA EDUCATION DEVELOPMENT PROGRAM

INTRODUCTION

Dzama Education Development Program was established in 2004, its main aim centered at helping orphans whose parents had died of HIV/AIDS. It started as a pre-school orphanage in a small makeshift church and had only 36 children. In the same year, UNC Project started providing technical and financial support. Since its inception, the program has significantly helped in many aspects such as Nutrition, Education, Infrastructures and Agriculture just to list a few. In 2014, Ministry of Education (MoE) upgraded the pre-school into a junior primary school. UNC Project through this initiative has also managed to construct other School blocks due to the rapid population growth in Dzama village and now the School has a Nursery and a Primary School.

OBJECTIVES

- To promote right to education through access to quality education.
- To address social-economic constraints affecting quality education.
- Creating a child-enabling environment for quality education.
- To enhance safety, early childhood development and promoting the culture of peace through. community empowerment and participation

FEEDING PROGRAM

Despite the impact of the COVID-19 pandemic in our communities, UNC Project has sustained its operations in terms of food distribution. Approximately 500 kids receive food portions; 2kg of Likuni Phala, and 3 eggs every fortnight. In normal circumstances, when schools are not closed following government restrictions, both Nursery and Primary school pupils receive Likuni Phala. About 1,500 pupils eat porridge every day.

MAINTENANCE WORKS

To make a good learning environment, two class rooms have been renovated, three rooms with chipped floors were maintained and the drainage was also rehabilitated.

CHARLIE SCHOLARSHIP.

Six outstanding students were granted full scholarships to continue their primary education at Victoria Gardens Academy for Boys and Nazarene Primary school for the girls. The names of these pupils are Evidence Elemiya, Harrison Davison, Chimwemwe Madalitso, Ethel Mayimba, Prisca Kanyama and Liviness Magombo. All necessities are provided to the children including transport to and from the school. Two (Evidence Elemiah and Chimwemwe Madalitso) are in class seven the rest are in class 8 where they will be writing MANEB exams.

This has boosted the school moral and there is increase in number of kids attending classes which was not the case previously because most of children were busy with cultural activities which was hindering them from going to school.

CHRISTMAS PARTY

As per tradition, at the end of every year a Christmas Party is thrown for the Nursery School pupils. 2021 year's party was held on 19 November 2021; approximately 390 pupils received Christmas presents.

Some of the key members of the UNC Project's evaluation team who are diagnosing and treating fellow staff members.

When the first case of COVID-19 was confirmed in Malawi in April 2020, UNC Project had in place measure to control spread of the virus and to help staff who in case of infections. Additional personal hygiene measures were advised which included mandatory wearing of masks for all staff members. Handwashing facilities were also provided in all entrances.

Also in the wake of the pandemic most sponsors advised that enrollment had to be put on hold. Those with pre-existing conditions were also advised to work from home upon consideration from management.

A clinical team comprising Drs. Kanyama, Hosseinipour, Westmoreland and Munyanga was instituted to be in the frontline helping staff and also participating in the KCH initiative. The nursing leadership led by Dr. Bula, Mary Kadiwa and Nelecy Chome are part of our frontline nursing team.

Gowning rooms at Tidziwe and Annex for overnight UV decontamination of gowns and N95 respirators were also installed. This was also extended to George Joaki Centre (Area 18) and Bwaila. These were to be used by staff who were seeing patients and participants at unscreened facilities (Kamuzu Central Hospital and National Cancer Centre wards) and those clinicians attended participants who screened positive at our screening points.

COVID – 19 Taskforce was responsible for the evaluation of significant exposures and isolations, give supportive care and follow up of infected cases to ensure a safe environment for staff, study participants, visitors and staff relatives regarding COVID – 19 and that its mission was to have a UNC Project with zero cases and zero contacts of COVID.

Staff were being encouraged to contact the COVID-19 Taskforce us directly as the vaccination status helps to understand the immunity distribution and propagates the infection prevention strategy to be implemented. Key messege was: "Protect yourself, Protect Others and Protect the environment.

In 2021 management and staff took the COVID-19 shots to enhance self protection.

UNC HEALTH FOUNDATION POST GRADUATE CLINICAL TRAINING

BENEFICIARY **PROFILE**

DR. SHIRAZ KHAN

He is a Malawian medical school graduate currently in residency training in anatomical pathology at the University of Kwa-Zulu Natal, in Durban, South Africa. Currently in his third year of training, he is scheduled to complete the residency program in December 2022.

He is being sponsored by the UNC Health Foundation post graduate clinical training

Dr. Khan's interest in anatomical pathology began during his internship at Kamuzu Central Hospital in Lilongwe, Malawi. The KCH serves the entire central region of Malawi, mostly rural patients who travel long distances to their district hospitals and then have their pathology samples sent to the KCH/University of North Carolina (UNC) pathology lab, which is approximately 300 miles away from the district hospitals.

Prior to UNC Project involvement, patients often did not receive their test results in a timely manner. Sometimes could come out after six months or even a year. For many, it meant the difference between life and death. However, now, the results are received within 2 weeks and this early diagnosis means that doctors can intervene accurately with surgery, chemotherapy, and radiotherapy, and save lives.

Currently there are only 5 working pathologists in Malawi, a country of nearly 20 million. This lack of specialist support in the cancer arena motivated Dr. Khan to become a pathologist.

"I knew if I acquired the skills of anatomical pathology I could directly reduce people's pain and suffering, and support my colleagues in different disciplines of cancer care by providing them with answers they needed to make informed decisions," he says.

His interest in research, coupled with the dedication he observed at UNC Project Malawi in providing training to local doctors over the years in various clinical and public health disciplines, drew him to join the organization in September 2011. It was in the same year that a collaboration between the Malawi Ministry of Health (MoH) and University of North Carolina (UNC) established pathology laboratory at Kamuzu Central Hospital; the only functional pathology laboratory to date within the central and

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northern regions of Malawi with a population of 12 million.

Before hits current training University of Kwa-Zulu Natal, he worked at UNC Project Malawi for six years during which time he gained enormous experience in various aspects of research.

Dr. Khan has many plans to carry out when he completes his studies. Firstly, upon finishing his studies he would like to re-join UNC Project Malawi and work with their team of Malawian pathologists. He would also like to work with two other central teaching hospitals in Malawi that do not have pathology laboratories so that, in conjunction with UNC Project Malawi, he can help establish labs there, thereby reducing turnaround times for tests and resulting in better patient care.

Thirdly, he also aspires to help establish a Malawian postgraduate training program in pathology. The creation of such a program would enable more pathologists to be trained in a shorter period of time and improve patient care..

Dr. Khan sees many ways in which I can improve patient care here in Malawi.

BENEFICIARY **PROFILE**

DR. TAKONDWA ZUZE

She is a highly motivated young Malawian medical officer who has worked in internal medicine for 4 years, three of which have been spent in oncology where she developed a keen interest in hematological oncology and gained valuable knowledge and experience in medical oncology.

During my childhood, I suffered from severe headaches, which my doctor blamed on 'eye problems'. While the headaches didn't bother me too much, I hated waiting for hours to be treated. Since then, I realized that I must become a health care provider so someday people don't have to wait in line for long hours like I did.

"I attended one of the best catholic girls secondary schools in Malawi; Providence secondary school where I was selected to study medicine at the College of Medicine of Malawi (COM) in 2009. Later, she earned a Bachelor of Medicine, Bachelor of Surgery (MBBS) in 2014.

During her internship at Queen Elizabeth Central Hospital (QECH), a busy public referral center for Southern Malawi located in Blantyre, Malawi's second largest city, she became interested in medical oncology. She was shocked to learn that QECH had only one oncologist who cared for half of Malawi's cancer patients. The huge burden of complicated, frequently comorbid cancer patients helped her realize how necessary more oncologists were to help

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best serve patients.

Following her internship at QECH, she joined UNC Project Malawi. Under mentorship of Dr. Satish Gopal, she had the privilege to work as lead medical officer for the Cancer Program at Kamuzu Central Hospital. She assumed increasing responsibility as a study coordinator and investigator for NIH-funded cancer studies and Aids Malignancy Consortium (AMC) network studies. Through her roles developed essential skills for implementing and coordinating clinical trials and study-related activities.

In 2019, she applied for an internal medicine fellowship program at the University of Cape Town (UCT) after which she plans to pursue her dream of becoming a medical oncologist. The excellent medical training and research opportunities at UCT sparked her interest to apply for admission into their program. She believes this is an exceptional opportunity to further my medical career and empower me to become a regional leader on cancer care and research in sub-Saharan Africa (SSA).

To prepare for my internal medicine fellowship, she began working in the adult internal medicine department at KCH under the mentorship of Dr. Cecilia Kanyama, a Malawian physician. The department is extremely understaffed—there are only 3 Malawian internal medicine physicians who serve approximately 7 million people. Consequently, most patients receive suboptimal management before meeting with the specialists, if they get a chance at all.

Through both clinical care and research, her work at KCH and UNC has given her the privilege to address the immense consequences of Malawi's limited healthcare resources and realize that patient care requires more than just one-on-one clinical encounters. She has learned the importance of having an internist on a team and how critical research is to improve patients' access to novel treatment, quality of care, and our ability to implement policies to improve mortality in low-income SSA settings.

Cancer is a growing concern worldwide and most deaths occur in low- and middle-income countries due to lack of human and material resources. I firmly believe increasing human capacity to deal with cancer is critical to decrease this morbidity and mortality. I would like to be one of the cancer pioneers in my country. I am excited to continue my growth as a medical oncology specialist and academic researcher.

The internal medicine program at UCT offers the best opportunity and environment to train with fellow SSA physicians, challenge herself, and eventually address healthcare issues in Malawi. Following the internal medicine fellowship, her goal is to receive oncology training, return to Malawi and re-join UNC Project-Malawi and become a leader in efforts to improve cancer clinical care in SSA.

TRAINING

ANALYSIS AND MANUSCRIPT UNIT (AMU)

Over the years, UNC Project-Malawi has grown into an internationally recognized research institution. Despite the growth in quality of research work being conducted at UNC Project-Malawi, few Malawians could participate in manuscript preparation, let alone lead a manuscript as first-author. On-site Malawian investigators had limited capacity and potential to gain independence and conduct and publish their own research. As a result, most of the data analysis and dissemination were developed off-site. The AMU was therefore established to bridge the gap in local analytic and writing skills within UNC Project.

To achieve this mission, the AMU conducts didactic courses and workshops, one-on-one consultations with Malawian and on-site investigators, analysis of UNC Project and other Malawian data sources, and coordinates dissemination of findings. The courses that AMU conducts include Introduction to Clinical Epidemiology, Introduction to Biostatistics using Stata, Introduction to Data Management using Stata, Manuscript writing, and Grant Writing. The AMU also coordinates the weekly Work-in-Progress (WIP) meetings – a forum for practicing a range of scientific skills including presenting research design or findings, facilitating discussions, and peer reviewing.

All activities training activities are coordinated by two people, the Director (Dr. Maganizo Chagomerana) and Data analyst (Evaristar Kudowa). The AMU is now collaborating with the Malawi HIV Implementation Research Training (MHIRST) program coordinator at Kamuzu University of Health Sciences to ensure that all MHIRST students, fellows, and investigators participate in and benefit from the AMU activities.

Dr. Maganizo Chagomerana

In 2021, the AMU conducted a one-week grant-writing workshop that targeted researchers who were ready to submit grant applications for the UJMT Fogarty Global Health Fellowship. The unit also led 29 WIP sessions with an average attendance of 22 people. A total of 126 manuscripts were published in international peer reviewed journals; of these 24 were led by Malawian first- authors.

MHIRST SCHOLARS

MHIRST 2021 Scientific Priorities Workshop from April 26 to April 28 2021 in Lilongwe.

MHIRST 2021 from November 29 to December 1 2021 in Salima.

MHIRST MASTERS FELLOW

MITCH MATOGA

MSC: Improving STI/HIV passive partner notification using quality improvement methods (Transition from MSC to PHD)

Paper 1: Implementation of a multi-faceted intervention for scale-up of uptake of VMMC in Malawi

Paper 2: Uptake of and factors affecting uptake of VMMC in Africa/Malawi -

MHIRST PhD FELLOWS

MITCH MATOGA

Uptake of Voluntary Medical Male Circumcision among Men attending a Sexually Transmitted Infections Clinic in Lilongwe Malawi

Paper 1: Implementation of a multi-faceted intervention for scale-up of uptake of VMMC in Malawi

Paper 2: Uptake of and factors affecting uptake of VMMC in Africa/Malawi

Paper 3: Effects of HIV VMMC programs on sexually transmitted infections Published- Current Opinion in infectious diseases.

WIZA KUMWENDA

Evaluation of process mapping and quality improvement (PROMAQI) as an implementation strategy to enhance monitoring of women's engagement in Option B+ across six health facilities.

MCNEIL MNGONGONDO

Discontinuation of Tenofovir Disoproxil Fumuate due to renal adverse events in initial AT regimens: A secondary analysis of data from four multi-country clinical trials

Dr. Mitch Matoga making a presentation on implementation science.

More cross sectional views of the MHIRST meeting in April 2021.

MHIRST SENIOR RESEARCH FELLOWS

FRIDAY SAIDI

Evaluating the Implementation fidelity of the integrated next step counselling to improve antiretroviral adherence amongst pregnant and breastfeeding women.

PAPER 1: *IA combination adherence strategy to support HIV antiretroviral therapy and pre-exposure prophylaxis adherence during pregnancy and breastfeeding: protocol for a pair of pilot randomized trials.*

Paper 2: *Evaluating the implementation fidelity of the integrated next step counseling to improve antiretroviral adherence amongst pregnant and breastfeeding women.*

MAGANIZO CHAGOMERANA

Assessing male partner engagement in HIV testing using partner notification slip plus oral hiv self-testing kit among male partners of HIV negative pregnant women with syphillis

CECILIA KANYAMA

Feasibility and clinical impact of integrating point of care testing in a tertiary hospital in Lilongwe, Malawi 2016-2017

MHIRST INTERNS

EDWARD NGWEMBA

Uptake of Voluntary Medical Male Circumcision among Men attending a Sexually Transmitted Infections Clinic in Lilongwe Malawi

CONFIDENCE BANDA

Evaluation of the HIV 3-test HIV algorithm and the Scan Form Technology: Joint Qualitative Study.
Factors affecting viral load turn around time.

FOGARTY GLOBAL HEALTH FELLOWS

MELISSA REIMER-MCATEE, MD

An Internal Medicine/Infectious Diseases physician who is studying the role of parasitic infection on immune activation among people living with HIV on suppressive Antiretroviral Treatment.

MAGGIE NYIRENDA NYANG'WA

A pediatrician and PhD student who is evaluating the performance of the SARS-CoV-2 lamp assay as a diagnostic test.

ESTHER KIP, PHD

Is conducting an implementation science study Adopting the HEADSS approach for engagement of adolescents living with HIV as a part of holistic care including mental health.

MELISSA STOCKTON, PHD

A former Fogarty Global Health Fellow and Fogarty Fulbright, returned to Malawi to complete her activities after COVID had disrupted her original program. Her research is focused on integration of mental health services into routine care and the intersection of HIV and mental health stigma. She recently submitted a Fogarty K01 career development award that was favorably reviewed.

JENNIFER MORGAN

Dr. Morgan was a Fogarty fellow 2020-2021 and is an AIDS Malignancy Consortium fellow and Global Oncology fellow (for the M-CORP D43) this year. Her primary project is focused on studying the barriers to optimal breast cancer treatment among patients and providers in Malawi. She also has funding from an American Society of Clinical Oncology Young Investigator Award to study a pilot program of integration of breast cancer screening with cervical cancer screening in community campaigns.

KAUSHIK PURANAM

Kaushik is a Fulbright / Fogarty scholar with UNC Project 2021-2022. He graduated from UNC Chapel Hill undergraduate before attending medical school at Georgetown University in Washington, D.C.. As a Fulbright/Fogarty Scholar he is taking a one year break from medical school while receiving research training and experience at UNC Project Malawi. He is studying clinical and genetic prognostic factors in diffuse large B cell lymphoma, the most common lymphoma subtype. DLBCL is much more common in people living with HIV and makes up the majority of the lymphomas that we treat in Malawi.

APRIL EVANS

Dr. April Evans is a pediatric hematology oncology fellow at UNC and spending the year (2021-2022) here at UNC Project Malawi as a Fogarty Global Health Fellow. Her primary project is to validate and implement patient reported outcomes tool (PRO-CTCAE) to measure symptomatic adverse events among pediatric lymphoma patients at Kamuzu Central Hospital. She was recently accepted to UNC Transfusion Medicine fellowship after she completes her pediatric hematology oncology fellowship training and will ultimately be dual certified. Therefore, she is working on two secondary transfusion-related projects: first a RBC alloimmunization study in pediatric sickle cell patients and second a QI project looking at blood transfusion availability and turn-around times for Kamuzu Central Hospital pediatric department.

MENTORED PILOT GRANT PROGRAM

FUNDED BY THE UNC LINEBERGER COMPREHENSIVE CANCER CENTER (LCCC)

JOHN CHAPOLA

Women's perceptions and attitudes towards mobile phone text messaging as a model of communication to receive HPV results and remind women to report for cervical cancer treatment in Malawi.

This study will be one of the first qualitative studies to provide this level of insight on practical utility of text messaging as an intervention in a cervical cancer screening project.

GERALD TEGHA

Prevalence and molecular characterization of antibiotic resistant bacteria isolated from patients with neutropenic fever in Lilongwe.

The results will be among the first on the mechanisms of AMR amongst cancer patients in sub-Saharan Africa.

MAGANIZO CHAGOMERANA

Estimating population-based cancer incidence and trends in Malawi.

The study has the potential to serve as a model for cancer registry utilization in the sub-Saharan Africa region.

M-CORP

Malawi Cancer Outcomes Research Program (M-CORP) is a program that aims to address gaps in cancer research capacity in Malawi and provide focused strategic investment to increase the cadre of trained investigators who can pursue independent research careers and improve cancer outcomes in Malawi.

This is to be achieved by:

- establishing a robust curriculum and training opportunities across the continuum of cancer outcomes research specific to the Malawian environment and research priorities

- supporting advanced degrees

- overcoming obstacles to research independence by providing postdoctoral opportunities including mentored pilot grants

MCORP involves a collaborative leadership strategy based at UNC-Chapel Hill, UNC Project-Malawi, and Kamuzu University of Health Sciences that optimizes our strengths across the spectrum of cancer outcomes research. An exceptional pool of multidisciplinary mentors, a detailed plan for program evaluation, and robust, broad-based partnerships between UNC and Malawian institutions ensure that M-CORP objectives will be met and will establish Malawi as an internationally recognized center of excellence for cancer outcomes research.

M-CORP provides a one-year mentored research training opportunity in cancer outcomes research for UNC postdoctoral fellows.

M-CORP provides a scholarship for two PhD trainees at one of two institutions associated with this training program: U.S.: UNC GIllings School of Global Public Health, Department of Health Policy and Management. Malawi: Kamuzu University of Health Sciences (KUHeS), Department of Bioinformatics

The program is directed by Dr. Yuri Fedoriw.

WARMHEART

WARMHEART: Malawian Program for Mental Health Research Training

The program strategized to employ a model to accelerate mental health research capacity across the lifespan in Malawi that emphasizes three complementary dimensions: depth, breadth, and reach. This initiative builds on the strong training track records of and successful collaborations between UNC-Chapel Hill, Kamuzu University of Health Sciences, the Malawi Ministry of Health, and many other partners.

Specifically, the program aims to:

1. train 4 clinical psychiatry researchers and 5 postdoctoral mental health research fellows who will participate in leadership training, short courses, mentored research projects, writing workshops, and conference attendance, (depth);

2. hold broad initial stakeholder meetings to prioritize research and policy questions, require cross-specialty collaboration in mentored research projects, co-sponsor an Annual Mental Health conference, enhance mentorship skills among in-country faculty, and sponsor regular mental health journal clubs for a broad audience (breadth);

3. extend the impact of these researchers through leadership and policy translation training, require collaboration with a policymaker in mentored research projects, and hold a policy translation meeting at the end of the project period (reach).

The Malawian Program for Mental Health Research Training (WARMHEART) will create an expert pool of mental health researchers trained as leaders and able to collaborate with other disciplines and policymakers to address the role of psychiatric illness across the lifespan.

Principal investigator for the program are: Prof. Bradley Gaynes, MD, MPH, UNC Department of Psychiatry; Division Head, Global Mental Health and Dr. Kazione Kulisewa, MBBS, MMed, Head of Department of Mental Health, Kamuzu University of Health Sciences.

2021 INTERNS FROM CHAPELHILL

SYDNEY PUERTO-MEREDITH
HIV Group Research intern.

MORGAN DEWEY
UNC Project Cancer Programme

CARE

Dr. Kate Westmoreland checking on paediatric cancer patient in the Cancer Centre ward.

Each UNC Project clinician devotes minimum of 20% of her or his time to providing service somewhere in the hospital complex.

PEDIATRICS

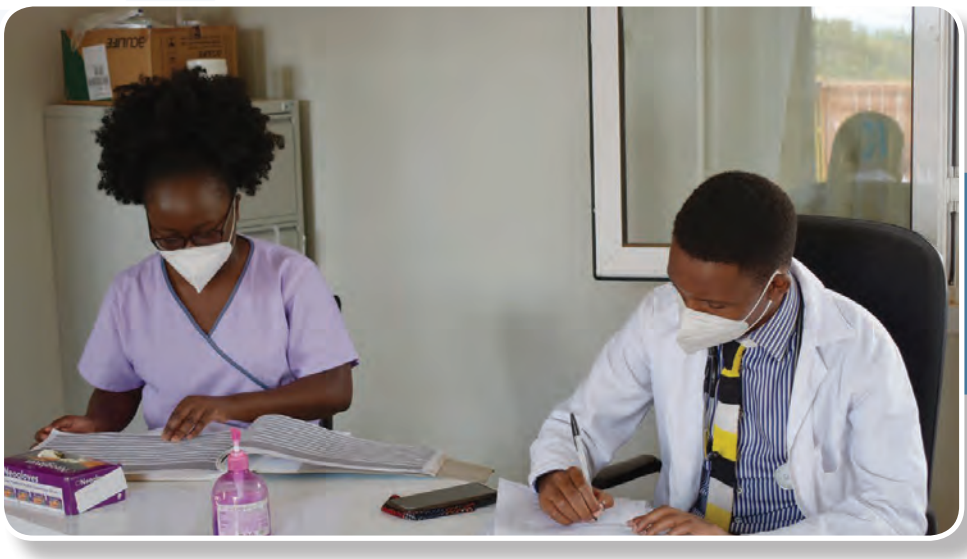
After successful development of a Pediatric Acute Care Lab in 2020, with funds from the Malawi Children's Initiative, in 2021 there was the reconstruction of a pay wing within the paediatric wards of the Kamuzu Central Hospital. There is also a new partnership between Rad-AID, UNC Radiology, UNC Pediatrics to sponsor and support a dedicated pediatric ultrasonographer, funded by Malawi Children's Initiative.
PACHIMAKE, a novel consortium that was created in 2016 but formalized in 2018, continued to help in improving care of acutely-ill pediatric patients at Kamuzu Central Hospital.

GENERAL CLINICAL CARE SERVICES

Selected UNC physician faculty members continued to attend at KCH and make rounds in the medical ward. In addition, other UNC clinicians attend to the inpatients on a daily basis. UNC Project nurses continued to operate on daily schedules to provide care in the medical ward, cancer clinic and the antenatal and labour wards.

SICKLE CELL UNIT

In 2015, Kamuzu Central Hospital opened a dedicated sickle cell disease clinic in collaboration with UNC Project-Malawi. The clinic now serves a cohort of 550 children. Goals for the new program include providing a clinical standard of care that approaches the level of care in the U.S In 2020 team of researchers led by Dr. Kate Westmoreland has received a one-year, $500,000 grant to build clinical



UNC Project staff working in the Sickle Cell Unit.

and research capacity in Malawi to better diagnose and treat children with sickle cell disease. The funding is a joint award from the NIH's National Heart, Lung, and Blood Institute and National Institute of Allergy and Infectious Diseases.

STI PRIMARY CARE SERVICES

In conjunction with ongoing and varied sexually transmitted diseases (STI) research projects, UNC Project still provided STI management and treatment services to patients presenting to the STI clinic at Bwaila District Hospital. Under the leadership of Mitch Matoga who is Director of STI Research and Clinical Service, UNC Project also performs operations research for the Malawi Ministry of Health, including monitoring of gonococcal resistance patterns and continued evaluations of the algorithms for the syndromic management of STIs.

OBSTETRICS& GYNECOLOGY

In 2021, UNC Project obstetricians and gynecologists dedicated their time at KCH and Bwaila Maternity hospital and make rounds in obstetrical and gynecological wards in addition to taking consultant calls at both hospitals. Our specialists Dr. Lameck Chinula and Dr. Friday Saidi were also involved in conducting high-risk surgeries and offered antenatal clinics.

SURGERY

Dr. Anthony Charles, director of global surgery at the Institute of Global Health and Infectious Diseases at the UNC School of Medicine, still focused on improving surgical quality in low and medium-income countries. There were few surgeons when he came to Kamuzu Central Hospital in 2008. At the end of 2021, thanks to Charles and his team, the number of certified surgeons increased to 16 and is likely to grow in the years to come. The Malawian Surgical Initiative that Charles has built was designed to be self-sustainable, in which the surgeons trained by Charles will continue to train future surgeons.

ONCOLOGY

Despite limited resources, a remarkable network for cancer care and research exists in Malawi.
Cancer care is currently centralized in Lilongwe for the central and northern provinces on the country. In 2021 UNC Project medical doctors, clinicians and nurses continued to provide care to cancer patients at the nearby cancer centre, which was partially opened last year within the Kamuzu Central Hospital campus.

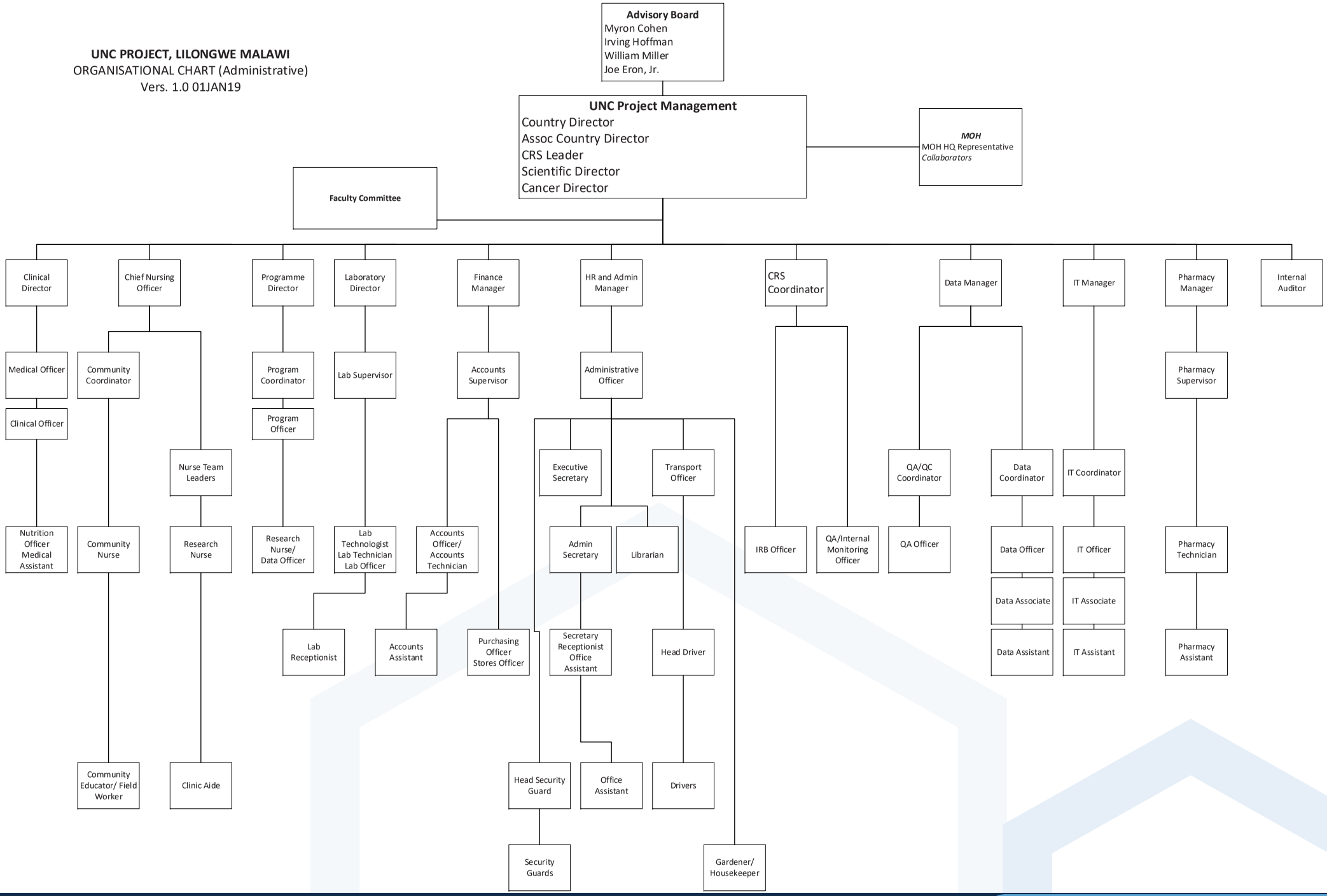
LABORATORY

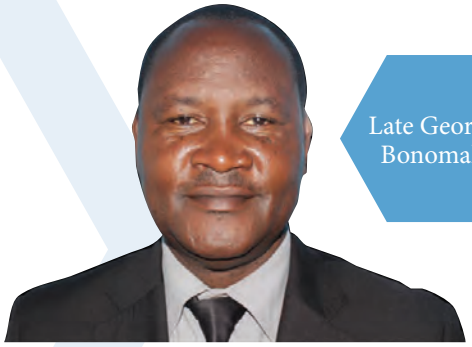
In 2021 our laboratories at the Tidziwe and Annex building continued to provide diagnostic assistance to Kamuzu Central Hospital and various health facilities in the central and northern regions of Malawi. Key among these are pathology services. Further, UNC Project continued to provide salary supplement a Ministry of Health pathologist.

Project staff sorting slides in the pathology laboratory.

OPERATIONS

UNC PROJECT, LILONGWE MALAWI
ORGANISATIONAL CHART (Administrative)
Vers. 1.0 01JAN19





Late George Bonomali

2021 started on a sad note with the passing of the then Human Resources and Administration Manager, George Bonomali. George joined the UNC Project on 1st March, 1999 and passed away on 21st January 2021, having worked with the organization for almost twenty-two years. His enormous contribution to the Project while leading the HR/Admin team is greatly appreciated. May his soul rest in peace.

Two staff who led the HR and Admin team, Baxter Givens and Patrick Chitsime left the organization by June 30, 2021, replaced by Priscilla Bandawe who joined end June, 2021 and Andrew Machado who joined early July, 2021.

MAIN ROLES

HR and Administration Department handled a number of roles in 2021, including the following:

Recruitment and separation processes for staff

MONTH	NEW STAFF	SEPARATIONS
July	10	6
August	1	2
September	2	5
October	5	5
November	6	
December	2	23
TOTAL	**26**	**41**

Monthly recruitment and separation with staff from July 2021

Monitoring contractual agreements for Consultants,
Temporary Staff, Interns and Research Assistants
HR maintains a register that tracks contractual agreements for Consultants, temporary staff, Interns and Research Assistants.

Collaboration with Accounts on payroll management
Payroll updates were shared with Finance on a monthly basis, highlighting new recruits and rates of pay, separations, and effort allocations.

Coordinating on the end of year appraisal process
The end of year annual staff appraisal exercise for 2021 started towards end October and was finalized on November 12, 2021 with a few outstanding ones submitted in December, 2021.

Assisting with issuance of staff employment contracts
Employment contracts for new staff were issued at time of entry. Staff contracts commencing January 1, 2022 were issued in December 2021.

Leave management
Annual leave and sick leave days are monitored through a leave tracker

Work permits for expatriate staff and permits for US Interns
HR maintains a register that tracks permits of expatriate staff and Interns

Part of logistics on workshops/meetings
Administration helped with budgets, provision of meals, and arrangements for accommodation during trainings/ workshops

Staff Welfare
The Staff Welfare Committee, in collaboration with Administration coordinated sporting activities, provision of gifts to retired staff, payment of condolence cash and arrangement of gifts for staff weddings.

In August 2021, Staff Welfare Committee members went around to thank former staff, especially security guards, for their service to the Project.

Procurement
The Department assisted with some procurement of office items during the year such as furniture, printing of family planning registers, arranging for staff IDs

Pension
The Department linked up with Old Mutual to process benefits for staff retiring early, and also to get clarifications on any issues raised by staff regarding pension benefits.

DUTY/Tax waivers
The Department handled communications with MRA on duty/tax waivers on imported items, mostly laboratory supplies.

Fumigation services
Offices, warehouses and Guest houses (Tidziwe, Annex, Bwaila, Area 18 and Area 25) were fumigated against pests like mosquitos, bugs, spiders, cockroaches, ants etc. in June 2021 and December 2021.

Mail and filing
The Department helped in handling mail and filing of various documents/communications through the General Officer.

Medical Scheme Management
Admin reviewed invoices from Clinics before passing them over to Finance for payment. Admin also coordinated on processing of medical expense claims for staff.

Security management
UNC Project terminated services of about 43 staff who worked as Security Guards and engaged a private firm to manage security issues from 1st July, 2021

Management of utilities
Administration manages utility bills (phones, water and electricity) for the Project

Coordinating on maintenance activities
Maintenance activities managed by Administration included plumbing services, carpentry, painting, maintenance of office equipment, and rectifying water and electrical faults.

Insurance
The Department coordinated on arrangements for various insurance policies including insurance on loss/damage to equipment, workers' compensation, professional liability, fire, and theft of cash in transit/all risks.

Coordinating on General Staff Meetings and Supervisors' meetings
General staff meetings were conducted virtually as a COVID prevention measure, on a monthly basis and Supervisors' meetings took place once every two months.

PROMOTIONS

- Mrs Nelecy Chome, promoted to position of Chief Nursing Officer, effective 1st April 2021
- Ms Fanny Mtambo, promoted to position of Administrative Officer, effective January, 2021
- Ms Tiyamike Nthani, promoted to position of Senior Research Officer, effective 1st December 2021
- Dr. Mitch Matoga, promoted to position of Director of STI Research & Clinical Services effective 1st November, 2021

TRANSFERS

- John Chapola got transferred to move to Blantyre as Study Coordinator for MESH CLOVE Study
- Confidence Banda was transferred to Blantyre as Lab Liason Officer for MESH CLOVE Study

LONG-SERVICE

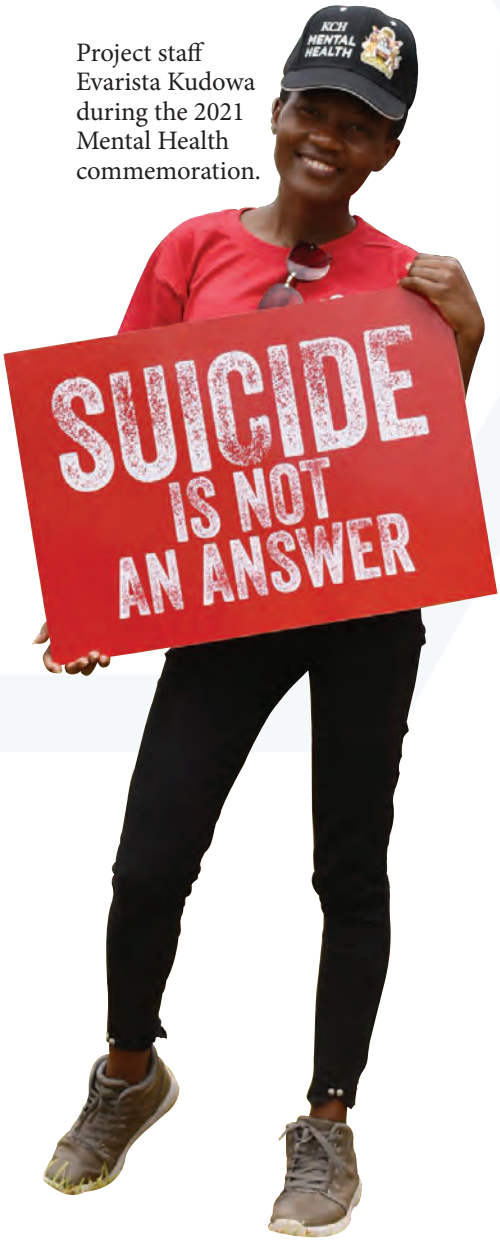
NAME	YEARS OF SERVICE
Michael Chizombe	22
Thom Kaunda	22
Yvonne Makala	22
Esnath Msowoya	22
Edward Jere	21
MacFelo Chisi	21
Tchangani Tembo	21
Joyce Mhone	20
Phaleda Kumwenda	20
Ellen Kapinga	20
Naomi Nyirenda	20
Tiwonge Kamvaunamwali	20
Olivia Kaliati	20
Pluxidia Kanduku	20

Pluxidia Kanduku, Senior Research Nurse Technician, went on retirement as at 31st December, 2021.

320 STAFF

As at 31st December, 2021, the Project had 319 staff, excluding the twenty-three staff who left in December, 2021.

AMBITION staff in a TV shooting focussing on the pneumococcal meningitis.



Project staff Evarista Kudowa during the 2021 Mental Health commemoration.

Project staff during a match to raise awareness on anti-mcirobial resistance

Community staff during Lilongwe city commemoration for the World Aids Day

Physical fitness activities went to a higher level in 2021.

Project staff and various partners during the World Diabetes Day commemorations.

Awarding nurse Ezylia Makina for her tireless service for over ten years under PROMISE and PROMOTE studies.

2021 **PUBLICATIONS LIST**

Hosseinipour, MC1–28 Chinula, L8,29–42 Kamthunzi, P43–48 Mvalo, T48–58 Kanyama, C1,16,20,21,59,60 Chagomerana, MB5,6,14,37,40,61,62 Saidi, F37,55,58,63–67 Ngongondo, M20 Tegha, G29,42,48,53,68–70 Rosenberg, NE29,64–66,71–77 Zimba, C9,11,28,29,64,76,78–84 Mofolo, I5,14,85 Tang, JH8,30–34,37,40,42 Hoffman, IF7,19,23,48 ,53,55,57,58,61,68,70,85,86 Kamanga, G61 Udedi, MM9,11,25,26,28 Bula, A23,30–34 "Aspire/MTN"39,78–80,83,87–90 Zuze, T91,92 Gopal, S8,33,91–94 Tomoka, T91 Painschab, M62,91–93 Charles, A95–122 Martinson F29,39,80,88,89,123 Mukuzunga, C124 Herce, ME5,14,15,125 Fitzgerald E54,126 Matoga, M7,19,20,40,60,61,68,86,127 Banda C128 Tsidya M129

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MALAWIAN FIRST AUTHORS

MALAWIAN FIRST AUTHOR – 2019

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1st AUTHOR PUBLICATION AWARDS

8 October 2021

Dr. Michael Udedi from the Malawi Ministry of Health

Dr. Chifundo Zimba

Awardees accompanied by counterparts.

Country Director Innocent Mofolo and Scientific Director Prof. Mina Hosseinipour award Dr. Cecilia Kanyama.

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NOTES


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