

SEMI ANNUAL RESEARCH REPORT

July – December 2018



Acknowledgements

The AMPATH Research Program Office is grateful to our sponsors and research partners who contribute to the success of our research program. Thank you to everyone who contributed to this report and our efforts to improve the health of people in Kenya and resource limited settings around the world.

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<https://www.ampathkenya.org/research>

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ABBREVIATIONS

ADAT	AMPATH Data Analysis Team
AMPATH	Academic Model Providing Access to Healthcare
AMWG	Adult Medicine Research Working Group
BSWG	Basic Science Research Working Group
CVMD	Cardiovascular and Metabolic Disease Research Working Group
IREC	Institutional Review and Ethics Committee
MTRH	Moi Teaching and Referral Hospital
MUCHS	Moi University College of Health Sciences
NCDs	Non-Communicable Diseases
ORWG	Oncology Research Working Group
PCWG	Pharmaceutical Care Research Working Group
PHPCWG	Public Health and Primary Care Research Working Group
PRWG	Pediatric Research Working Group
RHWG	Reproductive Health Research Working Group
RPO	Research Program Office
RSPO	Research and Sponsored Projects Office
SSRN	Behavioral and Social Science Research Working Group
TBWG	Tuberculosis Research Working Group

VISION, MISSION, & VALUES

VISION

We envision a **vibrant, world-class, Kenyan-led community of international researchers** in health and health care.

MISSION

Our mission is to **improve the health of people in resource-limited settings**, through the **identification**, development and **dissemination** of relevant and timely **information** on health and health care systems **for use by decision-makers** in medical care, public health, and public policy in Kenya and elsewhere in resource-limited settings.

VALUES

In our work we embrace:

- Service with **humility**
- A spirit of **collaboration** and **partnership**
- **Integrity** in relationships
- **Mutual respect** and **mutual benefit** in organizational partnerships
- A focus on **vulnerable populations**
- Efforts to **eliminate health disparities**

STRATEGIC PRIORITIES

In October 2015, the AMPATH Research Program held a strategic planning retreat to evaluate its performance and set strategic priorities to guide the development of the program. The following strategic goals were set by the program leaders and stakeholders who contributed to this planning process.

Over the next three years, the AMPATH Research Program will develop:

1. Stable, **resourced infrastructure for research** that enables the efficient conduct of high-quality, high-priority research
2. Successful **independent investigators** working in collaborative, interdisciplinary research teams to improve global health
3. Supportive, global health **research-intensive cultures** within the schools and departments of all AMPATH partners
4. Growth in key, high-yield, **research-related initiatives relevant to population health, policy-makers' questions, and healthcare delivery systems** and contextualized to resource-limited settings, including Basic and Translational Sciences Research, Biobanking, Oncology and NCDs, Population-focused Health, Informatics and Decision Support Systems, and Implementation Research dissemination.

OVERVIEW

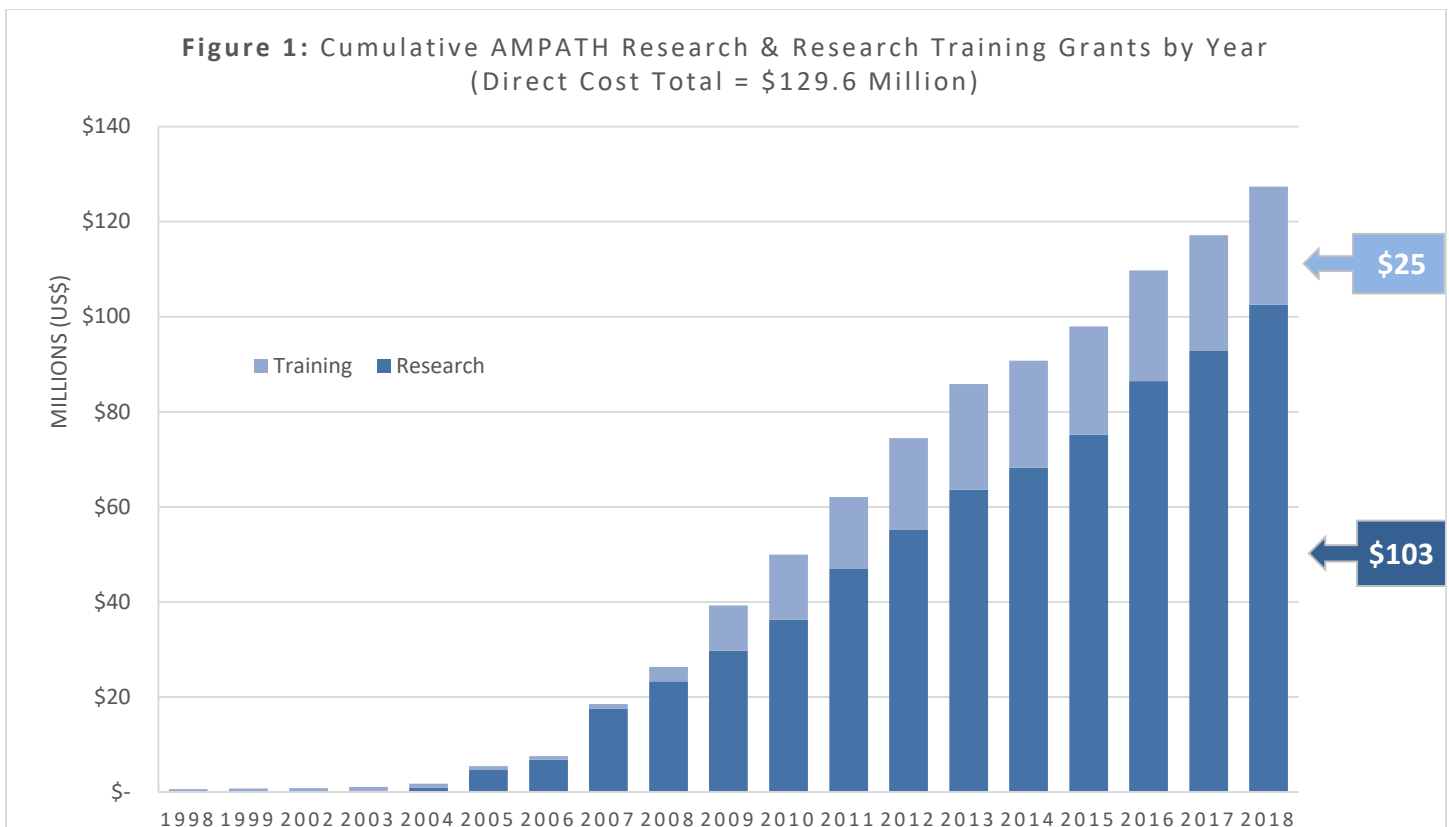
The AMPATH Research Program ended 2018 on a strong note. Our affiliated investigators produced 92 manuscripts in peer reviewed journals, received over US\$10 million in new research awards, and participated in major academic conferences and meetings around the world.

The program added new research infrastructure including the formation of a new Qualitative Research Core that will provide qualitative research support services and training to AMPATH researchers. Progress was made toward the creation of a new consolidated biorepository in the Chandaria Centre that will support future biobanking efforts and ongoing research. The program supported quality improvement assessments of key research infrastructure including the Research and Sponsored Projects Office and conducted a readiness assessment to develop a roadmap for AHRRP accreditation of IREC.

The following report provides a snapshot of AMPATH’s research activities from 1 July – 31 December 2018. It includes updates and progress from 57 research projects that were active during this period. Each update includes a summary abstract of the project’s aims, an update on progress made during the reporting period, and the project’s objectives for the next 6 months. The reports were provided by the project’s Principal Investigator or their designee and with the exception of formatting are presented here largely unedited.

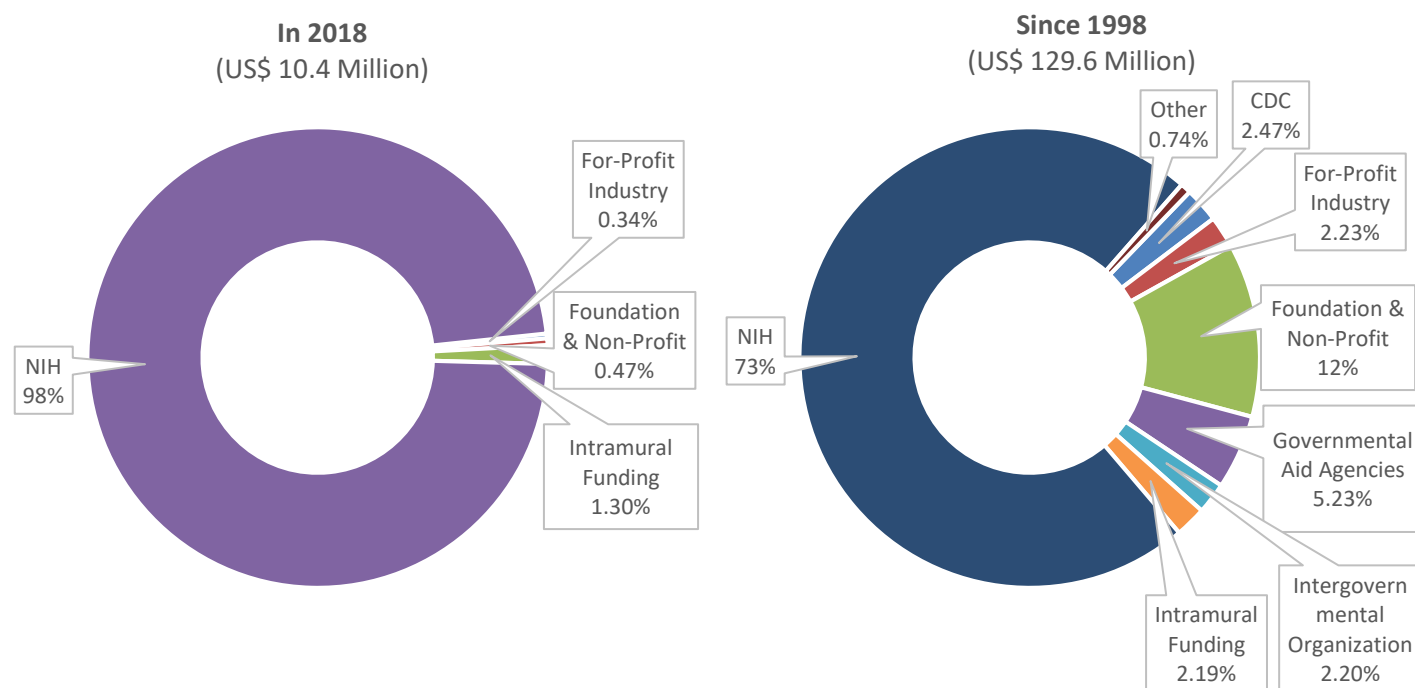
GRANTS

Investigators reported US\$10.4 million in new awards in calendar year 2018. This increased AMPATH’s cumulative total of research and training awards to over US\$129.6 million since the start of the program in 1998 (See Figure 1). Nearly a quarter of these awards provide training to develop new Kenyan investigators and their partners from North America including Fogarty supported training for clinical research and biostats and data management.



Since 1998, 73 percent of the awards AMPATH researchers were awarded came from the NIH. In 2018, 98 percent of the new awards researchers received were from the NIH – a much higher level than our average over the last 20 years (See Figure 2).

Figure 2: AMPATH Research Support by Sponsor Type in 2018 (YTD) and from 1998



Pilot Awards

AMPATH collaborative research teams received \$100,000 in pilot grants from the Indiana Clinical and Translational Sciences Institute (Indiana CTSI) and Indiana University Center for Global Health Global Health Research Pilot Grant Competition in 2018. The proposed projects will support pilot work to improve the delivery of complex care to HIV positive patients using the ECHO platform, address barriers to adolescent PrEP, provide urine pregnancy tests, and a variety of other topics (See Table 1). The six awardees for the 2017 competition add to the three studies awarded pilot grants for AMPATH related research in 2016.

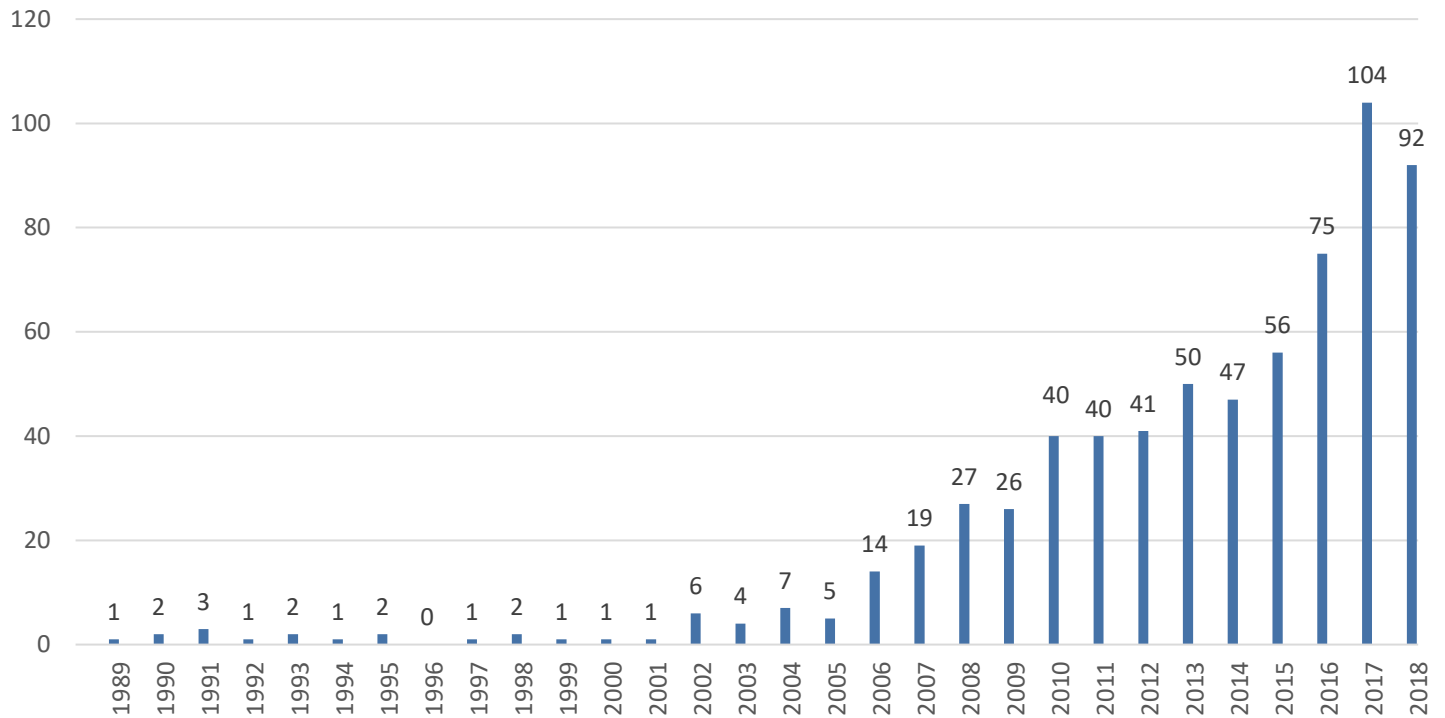
Table 1: 2018 CTSI Global Health Pilot Grant Awardees

Proposal Title	Co-PIs	Award
Improving the Delivery of Complex Care to HIV Positive Patients through Guided Practice using the HIV AMPATH Tele-ECHO Platform	Adrian Gardner (IU) Ali Shamim (MUCHS)	\$20,000
Addressing Barriers to Adolescent PrEP in Western Kenya Using an Implementation Sciences Approach	Mary Ott (IU) Edith Ogalo (MUCHS)	\$20,000
Community-based provision of urine pregnancy tests as linkage to reproductive health services	Caitlin Bernard (IU) Violet Naanyu (MUCHS)	\$20,000
Caregiver-focused intervention for neurodevelopmental delays in young children in western Kenya	Megan McHenry Eren Oyungu (MTRH)	\$20,000
Microfinance and Investments in Health in Rural Kenya	Molly Rosenberg (IU) James Akiruga (MUCHS)	\$20,000

PUBLICATIONS

AMPATH ended 2018 with 92 manuscripts published in peer reviewed journals. This rate continues trends from previous years and is an important indicator of productivity for AMPATH's research community. A bibliography of all the publications produced in 2018 is available at the end of this report.

Figure 3: Number of AMPATH Research Publications since 1989 (n=671)



STUDY REPORTS

The following reports were provided by AMPATH investigators and their study teams and cover the period of January – December 2018. The views expressed in these reports do not necessarily reflect the views of the AMPATH Research Program, its partners, or sponsors.

Study Title	A cluster randomized trial of 'Teach HADITHI' teacher training intervention to reduce classroom HIV-related stigma in Kenya'
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)
Description	<p>The objective of this study is to evaluate an innovative film-based, curricular intervention to reduce H/A stigma in school contexts and thereby reduce H/A stigma learned, perceived or experienced by youth. We will assess whether the intervention reduces the H/A stigma in their teaching and classrooms as experienced by HIV-infected youth enrolled in AMPATH. Our primary endpoint will be decreased teacher self-reports of stigmatizing knowledge, attitudes, and beliefs (K/A/B) about HIV six months after undergoing the Teach HADITHI teacher training. Secondary endpoints include reported H/A stigma and clinical outcomes among HIV-infected youth whose teachers have or have not gone through the training. The central hypothesis is that that introducing culturally relevant media and interactions that increase knowledge about HIV, its treatment, and living with HIV, while also engaging empathy and emotional connections, will alter both teachers' K/A/B about HIV, as well as the H/A stigma within their classrooms hence creating an environment that supports positive living with HIV. The specific aims are: Aim 1: Assemble a multimedia teacher training module, focused on HIV and H/A stigma and adapted for maximum cultural relevance, curricular cohesion, and impact among Kenyan primary and secondary school teachers. Aim 2: Assess the impact of the Teach HADITHI intervention on Kenyan teachers' attitudes, beliefs, and knowledge about HIV and the level of HIV-related stigma among teachers. Exploratory Aim 3: Examine whether HIV-infected children and adolescents in classrooms with teachers who have received the Teach HADITHI intervention report less perceived, enacted, or internalized stigma compared to those in classrooms with teachers who have not. We will take a phased approach to study activities. In Phase One (PHASE ONE: QUALITATIVE INQUIRY AND INTERVENTION DEVELOPMENT) we will conduct qualitative inquiry and intervention development to achieve Aim 1 to revise the HADITHI stigma module and materials. In Phase Two (PHASE TWO: RANDOMIZED TRIAL OF INTERVENTION), the 'Teach HADITHI' modular package developed in Aim 1, will be evaluated with a pre- and post-intervention design that compares teachers who complete the training with those at control schools in second sub-county who do not. Phase 2 will include testing the objectives of Aim 2 and the exploratory Aim 3.</p>
Site(s)	Matayos Health Centre Moi's Bridge Health Centre FACES Lumumba
Project Period	6/1/2018 - 5/30/2020
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)

Direct Award (USD)	\$259,480
Update	The study 'Teach HADITHI' teacher training intervention to reduce classroom HIV-related stigma in Kenya' has received approvals from MTRH/Moi University Institutional Research Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB) and the National Commission for Science, Technology and Innovation (NACOSTI). In preparation for the launch of study activities, the study team met with the County Director of Education and a representative for the Teacher Service Commission in Uasin Gishu County. Hiring of staff completed.
Future Plans	In the next six months, we plan to: <ul style="list-style-type: none"> • Training of all study staff on the study protocol. • Hold a one-day curriculum workshop with the PI team and expert stakeholders to create the Teach HADITHI teacher training curriculum; • Enroll and complete cognitive interviews with key informants to inform revision of the Teach HADITHI curriculum; • Begin planning activities to hold teacher workshops to deliver the Teach HADITHI intervention, which involves selecting sites and dates, consenting participants, and completing the baseline assessments with study participants.
Publication(s)	No



Study Title	A5263 'A Randomized Comparison of Three Regimens of Chemotherapy with Compatible Antiretroviral Therapy for Treatment of Advanced AIDS-KS in Resource-Limited Settings'
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Naftali Busakhala, Moi University
Working Group(s)	None
Description	This is an ACTG prospective, randomized, active-controlled clinical trial in which participants will be randomized 1:1:1 to oral etoposide (ET) plus antiretroviral therapy (ART), bleomycin and vincristine (BV) plus ART, or paclitaxel (PTX) plus ART. The primary objective will be to compare the clinical efficacy of two regimens, oral ET plus ART and BV plus ART, to PTX plus ART for initial treatment of advanced stage AIDS-KS.
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	4/1/2014 - 2/28/2021
Funding Status	Funded - NIH - AIDS Clinical Trials Group (ACTG) NIH - National Cancer Institute (NCI)NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	Not Reported

Update	<p>The NIAID DAIDS Co-Infections and Complications Data and Safety Monitoring Board (DSMB) met on March 13, 2018 to review safety and efficacy data from the A5263/AMC066 study. The DSMB recommended that A5263 be stopped because the bleomycin/vincristine arm was inferior to the paclitaxel arm when the primary composite endpoint was evaluated. No safety concerns were identified. The DSMB made the following recommendations: 1. The DSMB recommends stopping the study. The information at this interim analysis show that conclusions that can be made from this study at the current time will change little even if the study were continued to the end. The current statements that can be made about the two treatment arms are scientifically solid and important, and it is important to disseminate the results as soon as possible. 2. The study team should develop a plan to offer paclitaxel to patients who are currently on the study. To achieve recommendation #2, the team has developed a table that describes options for participants currently on study treatment in A5263/AMC066 and a Letter of Amendment (LOA) #2 was issued in June 2018. The LOA has been approved by both IREC and Pharmacy and Poisons Boards Expert Committee on Clinical Trials (ECCT) and was implemented at the site. Following this LOA, study participants have been transitioned to primary care provider, AMPATH and there are only 2 still on follow up since they require paclitaxel.</p>
Future Plans	Continue follow up of the two participants as per the protocol.
Publication(s)	Yes
Study Title	A5288 'Management Using the Latest Technologies in Resource-limited Settings to Optimize Combination Therapy After Viral Failure (MULTI-OCTAVE)'
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Priscilla Cheruiyot, Moi University
Working Group(s)	None
Description	<p>A5288 is an open-label phase IV, prospective interventional, strategy study in resource-limited settings (RLS) for HIV-infected participants with triple-class experience or resistance to [nucleoside reverse transcriptase inhibitors (NRTIs), non-NRTIs (NNRTIs), and protease inhibitors (PIs)] and who are failing their current regimen. The use of novel agents and contemporary management tools that include standard genotyping, plasma viral load (VL) monitoring will be evaluated. The screening genotype results and antiretroviral (ARV) history will be used to allocate potential participants to one of the four cohorts and for selection of ARV regimen for each potential participant. At sites where feasible and relevant(including MTRH) the study will also conduct an adherence study. This will be a randomized comparison of cell phone-based adherence intervention plus local standard-of-care adherence procedures (CPI+SOC) versus the SOC adherence procedures. The primary objective of the study is to use novel agents and contemporary management tools, including standard genotyping to select an appropriate third-line regimen, interventions to improve adherence and plasma viral load (VL) monitoring, in order to achieve a ? 65% rate of virologic control at 48 weeks of follow-up</p>
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)

Project Period	12/18/2013 - 12/31/2015
Funding Status	Funded - NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	All the 8 participants who were on follow up in step 3 (an optional additional 96 weeks of follow-up beginning 48 weeks after the final participant is enrolled into Step 1, restricted to participants whose current study regimen includes study-provided RAL, DRV, or ETR) of the study were transitioned to the AMPATH resistance clinic. The study is closed to follow up.
Future Plans	Data cleaning and analysis is expected to be done centrally by the protocol team.
Publication(s)	No



Study Title	A5349/TBTC S31 Rifapentine-containing treatment shortening regimens for pulmonary tuberculosis: A randomized, open-label, controlled phase 3 clinical trial
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	David Lagat, Moi University
Working Group(s)	None
Description	This will be an international, multicenter, randomized, controlled, open-label, 3-arm, phase 3 non-inferiority trial. The primary objectives are: 1. To evaluate the efficacy of a rifapentine-containing regimen to determine whether the single substitution of rifapentine for rifampin makes it possible to reduce to seventeen weeks the duration of treatment for drug-susceptible pulmonary tuberculosis 2. To evaluate the efficacy of a rifapentine-containing regimen that in addition substitutes moxifloxacin for ethambutol and continues moxifloxacin during the continuation phase to determine whether it is possible to reduce to seventeen weeks the duration of treatment for drug-susceptible pulmonary tuberculosis
Site(s)	
Project Period	10/12/2017 - 1/31/2021
Funding Status	Unfunded
Direct Award (USD)	
Update	The protocol , being multi-center with 25 ACTG sites and 10 TBTC sites open for enrollment, was closed to accrual on 30/October/2018 having attained the protocol sample size of 2500 participants. Out of this 1615/1600 participants were enrolled at the

	ACTG sites. At the Eldoret site, 29 participants were enrolled and they are all on follow up.
Future Plans	The site will continue to follow up participants over the next 6 months.
Publication(s)	No
Study Title	AMPATH - Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS
Principal Investigator(s)	Patrick Loehrer, Indiana University - Purdue University in Indianapolis (IUPUI)
Co-Investigator(s)	Darron Brown, Indiana University - Purdue University in Indianapolis (IUPUI)
Working Group(s)	Oncology (ORWG)
Description	The core objective of this project is to better understand the natural history of oncogenic HPV infections in HIV-infected Kenyan women, and to identify potentially modifiable (and non-modifiable) factors that are associated with progression of oncogenic HPV infection to clinical disease, including cervical cancer. Our central hypothesis is that the incidence, persistence, and spectrum of HPV are all substantially greater in HIV-infected versus non-HIV-infected Kenyan women, and that this explains a higher incidence of cervical neoplasia in HIV-infected populations. We further hypothesize that these and other modifiable factors (such as concurrent STIs, sexual behaviors, nutrition, and environment) disproportionately and adversely impact outcomes of local therapies such as cryotherapy and Loop Electrosurgical Excision Procedure (LEEP) in HIV-infected women. The specific aims of this AMPATH-Oncology Institute are to: 1. Expand the capabilities and expertise of the current laboratories and biobanking capabilities in Kenya through AMPATH and the Kenya Medical Research Institute (KEMRI) 2. Identify potentially modifiable behavioral and biological factors that are associated with the duration of infection with oncogenic HPV and cervical dysplasia in HIV-infected and non-HIV-infected women from western Kenya 3. Assess the risk factors associated with the short and long term results of cryotherapy and LEEP in VIA- positive (including LEEP-eligible) HIV-infected and non-HIV-infected women in western Kenya. 4. Provide biostatistical and data management support for proposed projects in this application and for future pilot projects, and 5. To establish a sustainable, multi-institutional and transdisciplinary mentoring program fostering the development of new cancer researchers in Kenya
Site(s)	Moi Teaching and Referral Hospital (modules 1-4) Center for Global Health Research - KEMRI at Kisumu City, Kenya
Project Period	9/19/2014 - 8/31/2019
Funding Status	Funded - NIH - National Cancer Institute (NCI)
Direct Award (USD)	\$2,132,402

Update	The project has been run well with respective cores achieving their objectives. Total accrual goals have been reached for Project 1 and with modifications in the goals, 100% of the desired accrual for Project 2. The samples obtained at enrollment for Project 1 have been tested for NG and CT. The NG and CT testing of the samples collected at the second annual visit are nearly complete. Any participants who have tested positive, have been located and treated. All testing has been performed in the AMPATH research lab in Eldoret, Kenya. HPV DNA testing using the Roche Linear Array has been successfully performed on specimens collected from participants at enrollment for Projects 1 and 2. All HPV DNA testing has been performed in KEMRI in the laboratory of Drs. John Michael Ong'echa and Ann Moorman.
Future Plans	This study will continue to follow women on a quarterly basis, collecting a wealth of behavioral and clinical samples for the purpose of better understanding cervical cancer in HIV-infected and HIV-uninfected Kenyan women. As our participants return for their subsequent annual visits, their samples will continue to be tested for CT and NG. Specimens collected during the second annual visits for Project 1 are now being tested, and specimens from subsequent visits in Project 2 will be tested.
Publication(s)	No

Study Title	Analyzing the Adolescent HIV Care Cascade in East Africa Through the International Epidemiologic Databases Evaluating AIDS' (ACE STUDY)
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Edith Apondi, Moi University
Working Group(s)	Pediatric (PRWG)
Description	The objective of this study is to refine estimates of key outcomes and associated correlates among a subset of PIA in the East Africa leDEA cohort. We will use in-depth assessment and prospective tracing of adolescents to create an Adolescent Sentinel Cohort in order to address the following specific aims: Aim 1: Describe the engagement status (engaged, LTP with care disengagement, LTP with re-engagement, or LTFU), virologic suppression status (viral suppression or viral non-suppression), and vital status (alive, dead, or LTFU) for PIA. Aim 1.a (Exploratory): Among PIA who are dead, assess the feasibility of implementing a modified verbal autopsy tool to assess cause of death. Aim 2: Provide in-depth characterization of the populations of PIA engaged in and disengaged from care, including describing current HIV care-related characteristics (ART regimen, adherence to treatment, experiences of HIV-related stigma, HIV care preferences); virologic outcomes (viral suppression, viral failure, and drug resistance patterns); pregnancy status; and mental and behavioral health characteristics (depression, substance use). Aim 3: Describe virologic, mental and behavioral health outcomes and HIV care preferences by HIV care status (engaged, LTP with care disengagement, LTP with re-engagement, or LTFU). Aim 4: Identify patient-level factors (including clinical characteristics, mental and behavioral characteristics, and HIV care preferences) associated with HIV care status (engaged, LTP with care disengagement, or LTP with re-engagement), viral suppression, and death.

Site(s)	Kitale District Hospital, FACES Lumumba, Moi Teaching and Referral Hospital (MTRH)
Project Period	8/1/2018 - 7/31/2019
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	\$259,480
Update	The study 'Analyzing the Adolescent HIV Care Cascade in East Africa Through the International Epidemiologic Databases Evaluating AIDS' has received approvals from MTRH/Moi University Institutional Research Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB) and National Commission for Science, Technology and Innovation (NACOSTI). Study staff have been hired and trained on the study protocols. We completed the qualitative part of this study, which included four focus group discussions (FGD) with adolescents to develop a Discrete Choice Experiment (DCE) tool to measure adolescent clinic preferences. A total of 26 participants were enrolled and participated in FGDs (12 males and 14 females), with separate groups held for ages 10-14 and 15-19 years. The translation and transcription of the FGD recordings is complete and analysis will begin shortly. A REDCap database has been set up to house data for the quantitative portion of the study whereby we enroll adolescents for assessments using a battery of questionnaires.
Future Plans	In the next six months, we will: <ul style="list-style-type: none"> Complete analysis of the qualitative data from FGDs and design the DCE tool that will be used in patient assessments; Complete database testing and make any necessary changes to the REDCap database; Train laboratory personnel on study lab procedures at the CIS lab, which will serve as the study lab for study activities done at Lumumba clinic in Kisumu; Begin study enrolment and patient assessments at MTRH first, then roll the project out to Kitale and Lumumba in Kisumu.
Publication(s)	No
Study Title	Bridging Income Generation with Group Interated Care(BIGPIC)
Principal Investigator(s)	Rajesh Vedanthan, Mount Sinai School of Medicine
Co-Investigator(s)	Jemima Kamano, Moi Teaching and Referral Hospital
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)
Description	The objective of this proposal is to utilize a trans disciplinary implementation research approach to address the challenge of reducing CVD risk in low-resource settings. The research aims at integration of group medical visits and microfinance with the additional social network characteristics. Aim 1: Identify the contextual factors, facilitators, and barriers that may impact integration of group medical visits and microfinance for CVD risk reduction, using a combination of qualitative research methods: 1) baraza; and 2) focus group discussions among individuals with diabetes or at increased risk for diabetes, microfinance group members, and rural health workers. Then develop a contextually and

	culturally appropriate integrated group medical visit-microfinance model. Aim 2: Evaluate the effectiveness of group medical visits and microfinance groups for CVD risk reduction among individuals with diabetes or at increased risk for diabetes, by conducting a four-arm cluster randomized trial comparing: 1) usual clinical care; 2) usual clinical care plus microfinance groups only; 3) group medical visits only (no microfinance); and 4) group medical visits integrated into microfinance groups. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the trial.
Site(s)	Bumala A Health Centre Bumala B Health Centre Chulaimbo Sub-District Hospital Endebess Sub-District Hospital Kapsara District Hospital Khunyangu Sub-District Hospital Matayos Health Centre Moi's Bridge Health Centre Saboti Sub-District Hospital Angurai, Moding, Akichelesit, Malaba, Aboloi, Kamolo, Changara, Ziwa, Kipkabus, Chepngoror
Project Period	4/1/2015 - 4/1/2015
Funding Status	Unfunded
Direct Award (USD)	
Update	<p>Administrative - Capacity building of the study personnel with specialized and targeted training ongoing - Procurement of necessary supplies for point of care testing and stationery proceeding - Additional staff in Kenya hired: Biostatistician - NYU School of Medicine IRB approval received - Transfer application submitted in order to transfer grant from the Icahn School of Medicine at Mount Sinai to the New York University School of Medicine</p> <p>Aim 1: Barriers/facilitators/contextual factors - Manuscript writing ongoing - Abstract presented at the American Heart Association 2018 Scientific Sessions</p> <p>Aim 1.1 (Barriers, Facilitators, & Contextual Model):</p> <ul style="list-style-type: none"> - Data analysis and manuscript writing ongoing <p>Aim 2 (Cluster RCT):</p> <ul style="list-style-type: none"> - Logistics of trial Roll Out: <ul style="list-style-type: none"> o Rollout by health facility is complete - 24 facilities have been rolled out (6-GMV, 6-GMV-MF, 6-UC, 6- MF) o Enrollment has been completed o A total of 2928 participants (Male=897, Female=2031) have been enrolled. o 3-month and 12-month follow-ups are ongoing o A total of 1864 participants (Male= 572, Female=1292) have completed 3-month follow ups o A total of 871 participants (Male= 282, Female=589) have completed 12-month follow ups o Training of community health workers (CHWs) in group facilitation and microfinance process completed <p>Data collection, entry, & management:</p> <ul style="list-style-type: none"> o Data collection instruments have been programmed in REDCap o Continuous testing and feedback is occurring throughout project implementation. o Real-time data entry occurring with REDCap on mobile devices o Syncing of entered data also occurring when real-time network access is not available o Data analysis ongoing <p>Process evaluation:</p> <ul style="list-style-type: none"> o Process evaluation implementation is ongoing <p>Aim 2.1(Mediation & Moderation Analysis):</p> <ul style="list-style-type: none"> o Social network survey (SNS): o SNS currently being administered to all participants at baseline and 3-month f/u <p>Aim 3 (Cost Effectiveness Analysis):</p> <ul style="list-style-type: none"> - Costing questionnaire survey (CQS): o CQS currently being administered to study participants
Future Plans	<p>Aim 1:</p> <ul style="list-style-type: none"> o Manuscript preparation <p>Aim 1.1</p> <ul style="list-style-type: none"> o Manuscript preparation <p>Aim 2:</p> <ul style="list-style-type: none"> o Continue with process evaluation activities o Complete 3-month and 12-month follow-up assessments at appropriate time periods o Continue training and mentorship of rural clinicians, community health workers, and research staff who will be involved in the group medical visit-microfinance intervention o Continue and

	finalize implementation of process evaluation activities baseline data dissemination activities at appropriate stages social network survey to study participants at appropriate time period data analysis costing survey to study participants at appropriate time period cost tracking data throughout intervention implementation period	o Conduct data analysis of outcome data o Carry out study Aim 2.1: o Continue to administer o Continue Aim 3: o Continue to administer o Collect intervention
Publication(s)	Yes	



Study Title	Can integration of effective family planning services into Anticoagulation Management Services (AMS) improve uptake?	
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto	
Co-Investigator(s)	Imran Manji, Moi Teaching and Referral Hospital	
Working Group(s)	Reproductive Health (RHWG)	
Description	<p>The purpose of the study is to evaluate whether integration of family planning education and free, on-site provision of all reversible family planning methods in Anticoagulation Monitoring Service (AMS) Clinic can improve uptake of long-acting reversible contraception (LARC; specifically intrauterine contraceptive devices (IUCDs) and contraceptive implants) in this high-risk population. Our hypothesis is that implementation of an educational intervention emphasizing long-acting reversible contraception (LARC) combined with free on-site provision of LARC within Anticoagulation Monitoring Service (AMS) can improve uptake of these methods by 250% in this population. Our objectives are to: 1) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) is feasible. 2) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) can improve uptake of long-acting reversible contraceptive methods (IUCDs and contraceptive implants). 3) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within an Anticoagulation Monitoring Services (AMS) Clinic can prevent unplanned pregnancies. In order to evaluate these objectives we will provide the intervention and follow the participants for the following 1 year time period. At 3-month, 6-month, and 12-month follow-up we will evaluate whether they are using any method of family planning and whether they have experienced subsequent unplanned pregnancies. This data will be compared to the same group of women prior to implementation of the education intervention and free, on-site provision of all reversible contraceptive methods.</p>	
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)	
Project Period	4/20/2015 - 8/31/2016	
Funding Status	Unfunded	

Direct Award (USD)	
Update	In the last 6 months, a manuscript was submitted to and accepted for publication in the Contraception journal. Additionally, we presented on our study and the findings at the 2018 International Conference on Family Planning held in Rwanda after an abstract was accepted for an oral presentation. Longitudinal data analysis was put on hold pending availability of an analyst.
Future Plans	Over the next 6 months, we plan to do longitudinal analysis of 6 & 12 month data and also do an overall analysis of all the data available to evaluate whether our primary objective of increasing use of long term methods of family planning was achieved on the overall.
Publication(s)	Yes



Study Title	Caregiver Interventions for Developmental Delays in Young Kenyan Children
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi Teaching and Referral Hospital
Working Group(s)	Pediatric (PRWG)
Description	<p>PROBLEM STATEMENT: One promising intervention for neurodevelopmental delays in resource-limited settings is the Care for Child Development Intervention (CCDI) Program developed by UNICEF, in partnership with the World Health Organization.^{6,7} In the CCDI program, trained providers support families by promoting sensitive and responsive caregiver-child interactions and teaching them about cognitive stimulation and social support.⁶ The program is adaptable cross-culturally and has been used in over 40 countries.^{6,8} While few published evaluation studies look at the outcomes of implementing the CCDI program, one study performed in Pakistan showed that the program improved cognitive, language, and motor neurodevelopmental outcomes at 12 and 24 months of age, compared with a control group.⁹ In resource-limited settings, like Kenya, implementation of a neurodevelopmental intervention for neurologically typical children may divert significant resources from a smaller population who may gain greater benefits from the intervention. Additionally, most of the preventative services, such as weight checks and immunizations, are performed within the Maternal-Child Health clinics, and community health workers do not have the reach necessary to promote child health promotion on a large scale. There are reports indicating that care for child development has been implemented in some parts of Kenya as part of on-going child survival or nutrition programs. However, there hasn't been any evaluation of the intervention to produce data that could guide further implementation and escalation.</p> <p>JUSTIFICATION: Neurodevelopmental interventions are most effective if administered early, when the brain is growing rapidly and has the greatest plasticity.⁵ However, due to the overwhelmed healthcare systems in resource-limited settings, new interventions are often challenging to introduce and must be carefully evaluated to determine their benefits. Effective, sustainable interventions that can be integrated into the current models of care in resource-limited settings are critically needed to improve the neurodevelopmental outcomes of young children in these settings. Without such interventions, millions of children will be unable to reach their full developmental</p>

potential. In our study, we will only administer the intervention to children known to have neurodevelopmental delays. By focusing on adapting the intervention to be only a clinic-based treatment, a small number of community members could be trained to administer the program and increase the potential for sustainability. If the clinic-based group sessions prove to be effective for young children with neurodevelopmental delays, this would help inform the key areas of fidelity needed to maintain effectiveness of the intervention. This study is a critical first step to evaluating the CCDI program's potential as a cross-cultural intervention that is sustainable and effective for the children at highest risk for neurodevelopmental delay. These results will have significant impacts in improving early childhood neuro development both in Kenya and worldwide.

OBJECTIVES The Broad objective of this proposal is to pilot the CCDI program as an intervention to treat neurodevelopmental delays among 56 young children in Kenya

SPECIFIC AIMS Aim 1: Determine the feasibility of a randomized controlled trial protocol to examine the effectiveness of the CCDI Program for Kenyan children with neurodevelopmental delays aged 18-24 months within a public Maternal-Child Health (MCH) clinic setting. Hypothesis: The CCDI Program will be feasible, as measured by 90% of participants being willing to be randomized to either the intervention or the control group; 80% attending all 10 biweekly caregiver meetings; 80% of children returning for their 6 month follow-up; and 80% returning for 12 month follow-up. Aim 2: Determine the acceptability, facilitators, and barriers of the CCDI Program for use in eligible children. Hypothesis: The CCDI Program will be acceptable, as determined by an analysis of prospective, concurrent, and retrospective acceptability,¹⁰ and specific facilitators and barriers to the program will be identified. Using focus group discussions and semi-structured interviews with caregivers, clinical providers, and community leaders, we will determine aspects of the program are acceptable, facilitators, and barriers to improved neurodevelopmental care and allow the CCDI program to function optimally in this setting. Aim 3: Estimate the effect size of the CCDI Program to reduce neurodevelopmental delays in young Kenyan children. Hypothesis: We can demonstrate a 40% decrease in the number of children with neurodevelopmental delays, as determined by a culturally adapted Bayley Scales of Infant and Toddler Development, 3rd edition (BSID-III),^{11,12} standardized score with implementation of the CCDI Program. This data will inform sample size justification for a future intervention study.

Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	7/9/2018 - 7/1/2019
Funding Status	Funded - Indiana CTSI, Thrasher Early Investigator Award
Direct Award (USD)	\$45,000

Update We recruited 31 eligible children from the NEURODEV study into the study at baseline. We did subject-level randomization of the enrolled study participants into two groups (Intervention and Control). We performed baseline BSID-III assessments and obtained caregiver questionnaires on all participants, with the assessor being blinded to the treatment group. We started the CCDI program with biweekly caregiver groups for the intervention group for a total of 10 sessions, while the Sequence control groups were invited to return to access the child resource room for background exposures and other potential benefits of visiting the health center. We also conducted semi-structured interviews gathering qualitative data from caregivers, clinical providers, and community leaders, using the Health Belief Model (HBM) as a framework to understand concepts that

	predict why people may take action to prevent, screen for, or treat a particular medical conditions.
Future Plans	We are at 6 month follow-up reassessing all the study participants using the BSID-III and caregiver questionnaires. The intervention group will be discontinued to the CCDI program and be invited to return to access the child resource room, while the control group initiated to the CCDI program and followed up for six months.
Publication(s)	No

Study Title	Childhood Leukemia in Kenya Identified Through Malaria Slide Review
Principal Investigator(s)	Terry Vik, Indiana University
Co-Investigator(s)	F. Njuguna, Moi University
Working Group(s)	Oncology (ORWG)
Description	The aim of this study is to improve the case detection rate of leukemia by retrospectively reviewing blood smears done for malaria screening to identify children with leukemia in defined population cohorts. If the case detection rate can be improved by utilizing a common and well established procedure, then there is potential to identify children, refer them earlier for treatment and save lives.
Site(s)	Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Turbo Health Centre
Project Period	7/1/2012 - 6/30/2015
Funding Status	Funded - Alex's Lemonade Stand Foundation
Direct Award (USD)	\$200,000
Update	Presparing abstract to submit to ASCO conference for June 2019. Manuscript awaiting revisions from co-authors.
Future Plans	Present abstract and complete manuscript.
Publication(s)	No

Study Title	Clinical Assessment for Retention and Engagement (CARE)
Principal Investigator(s)	Leslie Enane, Indiana University
Co-Investigator(s)	Edith Ogalo, Moi Teaching and Referral Hospital

Working Group(s)	Pediatric (PRWG)
Description	HIV is a leading cause of death among adolescents globally, due to challenges that result in poor outcomes in the care cascade, including poor rates of retention. There is an urgent need to identify adolescents at high risk for disengagement from HIV care, and to intervene early to retain these adolescents. The objectives of this project are 1) to use a mixed-methods approach to investigate factors underlying disengagement among adolescents with HIV in East Africa, and 2) to develop an instrument to identify adolescents at risk for disengagement, for whom proactive interventions may support retention. This project will utilize the infrastructure of the NIH-funded International Epidemiologic Database to Evaluate AIDS East Africa Consortium (IeDEA-EA). We will first refine a conceptual model for adolescent disengagement from HIV care. This will be achieved through systematic literature review, qualitative inquiry, and synthesis of these findings with quantitative work in IeDEA-EA. We will work from this model to develop and pilot a reliable, developmentally- and culturally-relevant instrument to assess adolescent risk for disengagement from HIV care, the Clinical Assessment for Retention and Engagement (CARE). CARE will be designed for utility in clinical settings, to identify adolescents at risk for disengagement, for whom early interventions should be implemented. We will then develop an evidence-based algorithm to support intervention for vulnerable adolescents. Findings will support a future proposal to study CARE as part of an intervention package to improve retention and HIV outcomes for adolescents.
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital (MTRH), Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital, Lumumba Health Center, Kisumu
Project Period	3/1/2017 - 6/30/2018
Funding Status	Funded
Direct Award (USD)	NIH - \$22,624 (USD) - For the first year
Update	The CARE grant was launched during this reporting period and study activities commenced. Toward the objective of refining a conceptual model for adolescent retention and disengagement, we began our qualitative work with healthcare workers, as well as a systematic literature review. An interview guide for key informant interviews with healthcare workers was developed along with a short tool to capture their socio-demographic data. We recruited and consented 15 healthcare workers of different cadres; Clinical officers (7), Nurses (3), Outreach workers (4), and a Psychologist (1). The providers were drawn from AMPATH clinics including Rafiki (which provides HIV care and sexual and reproductive health services dedicated exclusively to adolescents and youth); MTRH Module 4 clinic (which provides HIV care to children up to approximately 14 years of age) and MTRH Modules 2 and 4, Burnt Forest and Turbo clinics (which provide HIV care to a mixed population including adolescents and youth). In Module 3 clinic, the providers interviewed have expertise treating patients with viral resistance. Interviews explored healthcare worker perspectives of multi-level factors underlying adolescents' disengagement from HIV care, as well as facilitators that support retention. Interviews also ascertained healthcare worker perspectives on implementation of a clinical assessment to identify adolescents at risk for disengagement.

Future Plans	In the next reporting period, we will enroll traced lost-to-follow-up adolescents and their caregivers for key informant interviews to evaluate factors underlying disengagement from HIV care. We will perform qualitative analysis of this work, and synthesis of findings with literature review and with previous research conducted by our study team. We will evaluate the domains influencing retention that will be incorporated in development of the CARE tool to assess risk for care disengagement.
Publication(s)	
Study Title	Community perceptions and perceived needs of street-connected children and youth in Eldoret Kenya: a qualitative investigation
Principal Investigator(s)	Lonnie Embleton, University of Toronto
Co-Investigator(s)	David Ayuku, Moi University
Working Group(s)	Pediatric (PRWG)
Description	<p>Very little research exists that explores public perceptions and reactions to street-connected children and youth in low- and middle-income settings and how this impacts the care and services they receive; and no one has explored this topic to date in our setting. Moreover, no one has investigated street-connected youth's opinions and perceptions of their treatment by the public and their needs in relation to the provision of healthcare and services in Eldoret. Gathering youth's opinions and perspectives on their treatment and care will assist with the design and development of services and interventions for this vulnerable population. When youth are involved in the design and development of programs they are more likely to uptake services and seek care that is responsive to their needs. Similarly, exploring the opinions and perspectives of local policymakers, community members, and healthcare providers concerning street-connected children and youth, which influence their decision-making (ethical or unethical) in regards to the provision of programs, services, treatment, support, and care for this population is vital to reduce the harms associated with street-involvement. Gathering this data represents the first step in designing and developing effective evidenced-based interventions and policies, in a community-based participatory manner, which are responsive to the perspectives of street-connected children and youth and community members within the local social-cultural context.</p> <p>SPECIFIC AIMS</p> <p>AIM 1: Explore and describe the perceptions of community members across different social strata about the causes, characters, and needs of street-connected youth in Eldoret, Kenya.</p> <p>AIM 2: Describe the experiences of street-connected youth in Eldoret, Kenya, aged 15-24, with stigma and discrimination on the streets and when accessing services and healthcare.</p> <p>AIM 3: Elucidate ideas concerning appropriate service delivery and care for street-connected youth in Eldoret, Kenya from community members across different social strata</p> <p>3.1) Identify street-connected youth's opinions on what will assist or facilitate access to healthcare and specifically explore their needs in relation to HIV prevention.</p>
Site(s)	Moi Teaching and Referral Hospital (modules 1-4) Other community-based sites in Eldoret
Project Period	9/5/2016 - 12/31/2016

Funding Status	
Direct Award (USD)	
Update	The past six months we have conducted extensive analytic meetings. We are now in the process of writing four manuscripts as a result of these analytic meetings to disseminate the study findings.
Future Plans	In the next 6 months we hope to have four manuscripts under review.
Publication(s)	No



Study Title	Community-based provision of urine pregnancy tests as linkage to reproductive health services
Principal Investigator(s)	Faith Yego, Moi University
Co-Investigator(s)	Caitlin Bernard, Indiana University
Working Group(s)	Reproductive Health (RHWG)
Description	Kenyan families experience persistently high rates of maternal and neonatal mortality, which disproportionately affects women with low income and education and those who live far from health services. Key proven interventions include prevention of pregnancy and birth spacing, early entry to antenatal care, and facility delivery. However, creative, cost-effective interventions are urgently needed to link particularly vulnerable populations with these important health services. Previous research has shown that equipping community health volunteers (CHVs) with a tool as simple as a urine pregnancy test and training to provide post-test counseling is effective in improving linkages to antenatal care and family planning services. Our proposal includes a multi-phase process to collect qualitative data through a needs assessment (Phase 1), use community input to develop (Phase 2) and implement a pilot intervention study (Phase 3) assessing the ability of CHV-based provision of urine pregnancy tests with CHV-provided and phone-based post-test counseling to link women with antenatal care and family planning services, and collect qualitative program evaluation data (Phase 4). This will provide much-needed information for how to effectively utilize and strengthen CHVs as part of a sustainable reproductive health care delivery system to improve maternal and neonatal mortality. Our broad objectives are to determine whether the use of community-based provision of urine pregnancy tests with post-test counseling and referral to care is acceptable to community health volunteers (CHVs) and participants and to determine which method of post-test counseling and referral to care, CHV-provided or phone-based, is more acceptable and more effective. Participant outcomes, including the primary outcome of utilization of ANC or family planning care, will be measured by telephone questionnaires one to three months post-enrollment. CHV outcomes will be determined by telephone questionnaires as well as review of CHV log books.
Site(s)	Port Victoria Sub-District Hospital Turbo Health Centre

Project Period	4/2/2018 - 4/2/2020
Funding Status	Funded - Indiana CTSI
Direct Award (USD)	\$14,139
Update	Between the months of July and September 32 CHVs and 32 women participated in 4 FGDs in Turbo and Bunyala subcounties. The participating women were between the ages of 20-51 years, mostly married (78%), with at least one child (97%), and at least a primary school education (91%). CHVs included 26 women and 6 men, age 28-85 years. There was congruence in themes between the two groups. Both groups reported that CHV-provided UPTs would save women time and money and would facilitate linkages to care. This program was seen as a means to prevent abortion by diverting women considering abortion to further counselling and ANC. Both groups identified that significant stigma exists for specific groups of pregnant women, especially adolescents. Both groups saw a CHV-provided UPT as an opportunity for male engagement, but also with potential negative relationship implications. Women expressed interest in counselling from CHVs due to their familiarity, as well as phone-based counselling due to concerns around confidentiality. A further 2 FGDs were conducted with 29 males in the same subcounties following early qualitative analysis of the transcripts from the CHVs and women. The appropriate IREC amendment was submitted and approval obtained. The analysis of these transcripts is ongoing. A participatory design process was held in November where 18 stakeholders participated to help design the intervention. Thirty CHVs were then trained (15 in Turbo and 15 in Busia subcounties) and they are currently rolling out the intervention. To date, 158 women are enrolled in the study.
Future Plans	Over the next 6 months we anticipate completing enrolment of 300 study participants. Within this timeframe all participants will receive follow up phone calls at 1-3 months following participation in the intervention. We expect to fully analyze both the quantitative and qualitative components of the study. We will plan a community knowledge dissemination forum as well as begin drafts for manuscripts.
Publication(s)	Yes

Study Title	Developing Capacity of Moi Teaching and Referral Hospital / Moi University Institutional Research Ethics Committee (MTRH/MU IREC), Kenya to Prevent and Manage Research Misconduct.
Principal Investigator(s)	Edwin Were, Moi University
Co-Investigator(s)	Jepchirchir Kiplagat, Moi University
Working Group(s)	None
Description	Research Integrity and Oversight (RIO) is a 3-year project whose overall goal is to increase the capacity of Moi Teaching and Referral Hospital / Moi University Institutional Research and Ethics Committee (MTRH/MU IREC) to prevent, detect and manage research misconduct in Moi University College of Health Sciences, Kenya by developing and implementing a scalable modular institutional framework for preventing, detecting and

	<p>managing research misconduct. The aims of the project are to: 1. To estimate the prevalence of research misconduct in recent HIV research and document perceptions on occurrence of the research misconduct 2. To document perceptions on the current capacity to prevent, detect and manage research and the characteristics of a model institutional framework to manage research misconduct 3. To identify and document international best practices through broad literature review and benchmarking visits to United States and sub-Saharan Africa institutions where such capacity exists and is functional and utilize the body of knowledge gathered and involve local research stakeholders and international bioethics experts, to adapt the international best practices to the local setting and formulate a scalable modular institutional framework for prevention, detection and management of RM in Kenya 4. Implement, on a pilot basis, the model institutional framework in MTRH/MU IREC specifically and Moi University, broadly, and document the lessons learned</p>
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	8/31/2017 - 8/31/2020
Funding Status	
Direct Award (USD)	
Update	<p>The following details the list of tasks that we accomplished between July and December 2018</p> <ol style="list-style-type: none"> 1. Bench marking exercise at the University of South Africa (UNISA): A 3-member team travelled to South Africa to conduct a bench marking activity at UNISA between 1st and 7th July 2018 and reported a successful visit. 2. Research Misconduct Workshop: We have been planning for the workshop which will be held from 27th February to 1st March 2019 at KCB Leadership Centre in Karen, Nairobi. We are planning to host 80 delegates in the workshop including representatives from all accredited Research and ethics committees in Kenya, medical universities, NACOSTI, PPB, National Bioethics Committee and Bioethics Society of Kenya, all the MTRH/MU IREC members and Technical Advisory Committee members. An 8 member steering committee was formed in July 2018 to oversee the planning of the upcoming workshop. The committee has held 4 meetings so far and is making great progress. A workshop concept note was written and finalized and 4 expert Speakers have been identified and invited to speak during the workshop. A draft of the workshop program has also been developed. 3. FGDs and IDIs with investigators and REC leaders: This exercise was concluded in December 2018 with 36 in depth interviews and 2 focus group discussions conducted. Transcription and coding has been done. 4. Request for research permit from NACOSTI: We requested for a research permit from NACOSTI in addition to the MU/MTRH IREC approval. The permit was granted in August 2018 and that enabled data collection in the various sites across the Country. We also submitted request for IREC continuing review and this was granted. 5. Data analysis and publications: The process is ongoing. Two abstracts were submitted for consideration in the conference on Research integrity in June 2019 in Hong Kong. Both quantitative and qualitative data is being prepared and summary of the findings will be presented during the workshop in February 2019. 6. TAC Meetings: We held the 4th and 5th Technical Advisory Committee meetings on 24th July 2018 and 22nd November 2018 respectively.
Future Plans	The planned tasks over the next 6 months include the following: 1. Hold the Research Misconduct workshop between 27th February and 1st March 2019 in Nairobi -

	Kenya 2. Conduct data Analysis and manuscript writing 3. Hold 6th Technical Advisory Committee meeting. 4. Conduct the 1st Responsible conduct of Research training workshop
Publication(s)	No
Study Title	Effect of free maternity care on maternal and fetal outcomes of preeclampsia/eclampsia at a teaching hospital in Western Kenya: A retrospective chart review.
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Co-Investigator(s)	
Working Group(s)	Pediatric (PRWG), Reproductive Health (RHWG)
Description	The aim of this study is to determine the incidence of diagnosis and treatment of pre-eclampsia and eclampsia at MTRH. We will measure the maternal and neonatal outcomes in women with these diagnoses. We will evaluate the data in order to determine areas for improvement in our diagnosis and management of pre-eclampsia/eclampsia in order to decrease maternal and neonatal morbidity and mortality at MTRH. Finally, we would like to evaluate the effect free maternal care has played in the measured incidence and outcomes of pre-eclampsia and eclampsia at our institution. Specifically, we will: 1. Determine and compare the incidences of pre-eclampsia within our institution in the year before and the year after the initiation of free maternal care in June, 2013 2. Evaluate the maternal and neonatal outcomes, including major causes of morbidity and mortality in each group. Again we will compare these before and after the initiation of free maternal care in June, 2013. 3. Evaluate the risk factors for adverse maternal and neonatal outcomes 4. Evaluate the adherence of treatment in our facility in accordance with World Health Organization standards, again comparing treatment before and after the initiation of free maternity care in June, 2013. The data for this study is collected using a comprehensive 100-item data collection form, including patient demographics, symptomatology, documented clinical signs and laboratory results, delivery details, and maternal and neonatal outcomes
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	1/12/2015 - 12/31/2015
Funding Status	
Direct Award (USD)	
Update	Proposal write up for an expedited review to apply data collected to an existing prediction model for mortality from pre-eclampsia as external validation is ongoing. This will be submitted to Irec once the proposal is ready.

Future Plans	we will be submitting a new IREC proposal for expedited review to apply the data collected to an existing prediction model for mortality from preeclampsia as external validation.
Publication(s)	No
Study Title	Enhancing Preventive Therapy of Malaria In children with Sickle cell anemia in East Africa (EPiTOMISE)
Principal Investigator(s)	Festus Njuguna, Moi University
Co-Investigator(s)	Steve Taylor, Duke University
Working Group(s)	Public Health and Primary Care (PHPC)
Description	Children with SCA are particularly vulnerable to infectious diseases and in malaria endemic areas, malaria is one of the leading causes of hospitalization and death among children with SCA. The current recommendation is chemoprevention with daily proguanil. However, this regimen suffers from suspected low adherence rates and probable reduced efficacy due to parasite resistance to antifolate drugs. We are conducting a randomized, three-arm, open-label, clinical trial of malaria chemoprevention in children with sickle-cell anemia at a single site in Homa Bay, Kenya in order to identify more effective chemotherapy regimens for malaria in children with SCA. Our primary objective is to compare the efficacy of daily proguanil with monthly sulfadoxine/pyrimethanine-amodiaquine (SP-AQ) and with monthly dihydroartemisinin-piperaquine (DP) on the incidence of falciparum malaria in children with SCA. The secondary objective is to compare the efficacy of these malaria chemoprevention strategies on the incidence of major complications of SCA. We will enroll 246 children of both genders between 1 and 10 years of age with laboratory-confirmed SCA living in malaria-endemic portions of Homa Bay or Migori Counties, randomize to one of three (1:1:1) malaria chemoprevention regimens, and followed up monthly for 12 months in order to record clinical episodes of malaria or SCA-related morbidity. Analyses will compare the efficacy of each regimen to prevent malaria and SCA morbidity. Blood samples will be taken every three months (5 time points - baseline, 3, 6, 9, 12 months) for laboratory testing and dried bloodspots will also be collected. Participants will also receive a malaria rapid diagnostic test using a finger-prick blood sample when they are ill.
Site(s)	Homabay County Hospital
Project Period	6/1/2016 - 2/28/2017
Funding Status	Funded - NIH
Direct Award (USD)	\$621,633
Update	As of December 2018, we had enrolled 110 participants into the study. NIH paused the study in October 2018, due to the deaths of four participants who were all in the same arm of study (SP-AQ arm). These have been reported to NIH/NHLBI and both Duke and Moi IRBs. In the study pause notice, NIH recommended for an establishment of a newly reconstituted DSMB to review the cause of death of the four participants in SPAQ arm.

	<p>The DSMB convened an adhoc meeting on 30 October to discuss participant deaths and recommended that the study continue. After this meeting, NIH/NHLBI dissolved this DSMB and requested that the study pause enrollment and pause distribution of SP-AQ as of 31 October; the sponsor convened a new DSMB on 19 November, who reviewed event data and requested changes to the protocol. At the subsequent DSMB meeting on 2 January 2019, these changes were accepted by DSMB and recommended for review and implementation, and as of this submission the team is awaiting approvals for these changes from Moi IREC, Duke IRB, and Kenya PPB. We have had one monitoring visit in November 27-30, 2018 conducted by an independent clinical research associate (CRA), and will continue these visits on a quarterly basis. During this reporting period we have amended the protocol (Amendment #5) in June 2018 which was approved by both Moi and Duke Institutional Review Boards (IRB).</p>
Future Plans	<p>It is expected that enrollment will be re-opened as soon as NIH receives the revised protocol that has incorporated all the DSMB recommendations and has been approved by both Duke and Moi IRBs. Final data cleaning and analysis is still expected to take place in the first half of 2021, with a manuscript planned for submission and the final report submitted to NHLBI by the end of 2021.</p>
Publication(s)	No
Study Title	Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy
Principal Investigator(s)	Rena Patel, University of Washington
Co-Investigator(s)	
Working Group(s)	Reproductive Health (RHWG)
Description	<p>ABSTRACT The use of effective hormonal contraceptives among HIV-positive women on antiretroviral therapy (ART) to prevent unwanted pregnancies in resource-limited settings can significantly reduce maternal-to-child HIV transmission as well as improve the woman's overall health. However, there is concern that potential drug-drug interactions between hormonal contraceptives and antiretrovirals (ARVs), particularly between Levonorgestrel-based (LNG) implants and efavirenz-based ART, may compromise the contraceptive's efficacy. To address this uncertainty, evidence from analysis of participant charts in Academic Model Providing Access to Healthcare (AMPATH), a large HIV treatment and care program, will help guide policy changes. We have conducted an initial data analysis with AMPATH electronic medical record system (AMRS) and charts from nearly 800 women; however, we lack key information, such as implant initiation and removal dates, and need to conduct further file reviews and brief phone interviews to obtain such information. Objectives: To help develop the evidence base for the relative effectiveness of LNG implants with concomitant efavirenz-based ART by conducting a data validation process among a random subsample of HIV-positive women attending AMPATH-supported HIV treatment facilities. Methods: We will conduct a rigorous data validation process by randomly sampling approximately 10% of HIV-positive women of reproductive age (15-45 years) attending AMPATH-supported HIV treatment facilities using hormonal contraceptives including implants, depomedroxyprogesterone acetate</p>

	(DMPA), and oral contraceptives, or no contraceptives and on nevirapine-, efavirenz-, and lopinavir/ritonavir-based ART regimens or no ART (16 exposure categories with approximately total n=6,000 women. Based on our findings from this subsample, we will use inverse probability weights to adjust our estimates for incident pregnancies for the overall cohort. The data validation process will include two steps: 1) thorough file reviews including, but not limited to, HIV clinic charts, family planning (FP) registers from both the HIV treatment and/or antenatal facilities, and pharmacy records, and 2) brief phone interviews with the female participants to confirm the findings of the file reviews. The goal of this data validation process is to determine the initiation, continuation, and discontinuation dates for the contraceptive methods, ART regimens, and likely date of conception for those women becoming pregnant. Anticipated Results: Based on this data validation process, we will be able to calculate point estimates for incident pregnancies for the 16 combination exposure groups in our random subsample, and then use these validated point estimates to refine our point estimates for the overall cohort data from AMPATH.
Site(s)	All
Project Period	5/1/2016 - 1/25/2021
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	\$194,981
Update	We have started data cleaning and analysis in the last six months.
Future Plans	In the next six months, we hope to make marked progress in analysis, to the point of moving onto the publication of the primary outcome.
Publication(s)	



Study Title	Ethnic Specific Risk Stratification in Early Pregnancy for Identifying Mothers at Risk of Gestational Diabetes Mellitus in Eldoret, Kenya
Principal Investigator(s)	Wycliffe Kosgei, Moi Teaching and Referral Hospital
Co-Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Working Group(s)	Reproductive Health (RHWG)
Description	Gestational diabetes mellitus (GDM) is a form of diabetes that develops in pregnancy and can lead to adverse maternal and fetal outcomes. There is not currently a screening program to identify women with GDM in Kenya and other low and middle income countries. The aim of the study is to determine the prevalence of GDM in a rural and urban Kenyan population, develop an accurate score based on easily obtainable risk factors to stratify women at risk of GDM in this population, and determine if a selective screening strategy would be cost-effective in Kenya. This is a prospective cohort study

	aiming to recruit 4000 women who are <20wks gestation attending antenatal clinic at different project sites.
Site(s)	Huruma Sub-District Hospital Moi Teaching and Referral Hospital (modules 1-4) Uasin Gishu District Hospital Reale Hospital, Langas Hospital,
Project Period	7/14/2015 - 7/13/2018
Funding Status	Funded - Medical Research Council
Direct Award (USD)	\$722,569
Update	In the last 6 months, we continued with enrollment of participants into the study for a few more months after a request for no cost extension was approved. On 30th October, enrollment of participants into the study was halted at a total enrollment of 4178. Of these, 3419 completed Visit 2, while those who have done V3 (OGTT test) are 2139. Follow up calls were done for those who have delivered with a total of 2011 forms completed. Data entry was done for all the visit 1, 2, 3, 4 & 5 that were pending while data cleaning was continued for all the visits.
Future Plans	In the next 6 months, we aim to complete the OGTT test for about 250 participants that are still eligible for the test. This is scheduled to be done and completed in the month of February. Data entry will be completed for these participants. We also aim to make follow up calls for the post-partum visit and have these data entered into the database as well complete the post-partum OGTT for those with a GDM+ diagnosis. Data cleaning will be done and completed in the next 6 months. A data analysis plan is planned to be drafted by the statistician to guide the analysis of available data. Once analysis is done, we plan to start writing drafts of manuscripts for publication.
Publication(s)	No

Study Title	Evaluating Indicators of Poor Cardiac Function in Children and Adolescents Living with HIV in Western Kenya
Principal Investigator(s)	Andrew McCrary, Duke University
Co-Investigator(s)	Winstone Nyandiko, Moi Teaching and Referral Hospital
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)Pediatric (PRWG)
Description	The Ped HIV - Echo Study (PHES) seeks to define predictors of poor cardiac function in children and adolescents living with HIV. PHES has several core components that hold significant potential for defining the prevalence of cardiac dysfunction in this population, elucidating predictors of poor cardiac function, and begin to illuminate etiologies of cardiac dysfunction. Our central hypothesis is that echocardiographic evidence of early cardiac dysfunction is present in children and adolescents living with HIV and the dysfunction can be defined in terms of patient's immune status, HIV history, and same day biomarker levels. The specific aims for the PHES project are to: 1) Define the prevalence of early cardiac dysfunction using strain imaging compared in a large cohort

	of children and adolescents living with HIV, and compare with traditional echocardiographic measures of function. 2) Determine the impact of concurrent HIV viral load level on strain values. Additionally, we will model the impact of time with unsuppressed viral replication as the study population were almost entirely perinatally infected. 3) Measure the correlation between cardiac dysfunction (defined by strain) and inflammatory (IL-6 and tnf-?) and cardiovascular (pro-BNP) biomarkers.
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	9/12/2017 - 12/31/2018
Funding Status	Funded - Other International AIDS SocietyNIH - Fogarty International Center (FIC)
Direct Award (USD)	\$136,199
Update	Primary analysis is now complete. An abstract will be presented at CROI 2019. We have engaged KEMRI for additional viral testing not currently offered at AMPATH reference laboratory. The specimens have now been transferred to KEMRI and are currently undergoing testing.
Future Plans	Over the next 6 months, we will complete the viral testing at KEMRI and complete the secondary analysis.
Publication(s)	Yes

Study Title	Evaluation of locally-sourced compression therapy for treatment of chronic leg ulcers and management of Kaposi sarcoma leg lymphedema in western Kenya
Principal Investigator(s)	Sonak Pastakia, Purdue University
Co-Investigator(s)	Aileen Chang, University of California San Francisco
Working Group(s)	
Description	Compression therapy is a well-established cornerstone therapy and part of routine clinical care for chronic leg ulcers from venous disease and lymphedema, including Kaposi sarcoma (KS)-associated lymphedema. Chronic leg ulcers, from trauma or chronic venous disease, and lymphedema have a significant impact on quality of life, driven by pain, foul odor, and restricted mobility. The provision of compression therapy in resource-limited settings, as in western Kenya and other regions of East Africa, is a major challenge. In western Kenya, locally available elastic stockings are priced at 10-15 USD (1000-1500 kshs) per pair. Pre-packaged brand name kits are not locally available or affordable for patients, as imported kits costs 7-20 USD (700-2000 kshs) per package. However, materials used routinely in wound care, namely elastic crepe, gauze, and zinc oxide, are readily available and affordable for patients. Supplies required to dress one affected leg for a week cost 2 USD (200 kshs). The use of locally-sourced routine wound care supplies for compression therapy is poised to have significant impact on reducing morbidity, social stigma, and economic loss associated with chronic leg ulcers and Kaposi sarcoma-associated lymphedema. Demonstration of its feasibility and efficacy in treating chronic leg ulcers

and Kaposi sarcoma-associated lymphedema in western Kenya could have far-reaching implications for the treatment of these prevalent conditions across East Africa and sub-Saharan Africa. This project will utilize a 1) retrospective study design to evaluate the efficacy of compression therapy for the treatment of chronic leg ulcer patients seen at Turbo Health Center, one of the Academic Model for Providing Access to Healthcare (AMPATH) sites and 2) randomized controlled trial to evaluate the efficacy of compression therapy in the management of Kaposi sarcoma leg lymphedema patients seen at AMPATH/MTRH oncology clinics. If the outcomes of this project support the use of locally-sourced compression therapy in the treatment of chronic leg ulcers and Kaposi sarcoma-associated lymphedema, future studies for chronic leg ulcers will focus on scaling up use of locally-sourced compression therapy at other AMPATH clinics and exploring feasibility of community-based care. Future studies for Kaposi sarcoma lymphedema will focus on exploring feasibility of community or home-based lymphedema care. Specific Aim 1: Evaluate the efficacy of compression therapy for the treatment of chronic leg ulcer patients in western Kenya. We will conduct a retrospective study to evaluate the efficacy of paste bandage compression therapy for chronic leg ulcers, from trauma or chronic venous disease, with the use of locally available supplies routinely used in wound care. We will compare our primary outcome measure to a population mean. Specific Aim 2: Evaluate the efficacy of compression therapy in the management of KS leg lymphedema patients in western Kenya. We will conduct a randomized trial of immediate vs. delayed compression therapy to explore the impact of paste bandage compression therapy for management of KS lymphedema with the use of locally available supplies routinely used in lymphedema care. We will compare the change in our primary outcome measure before and after compression therapy between the immediate vs. delayed compression arms.

Site(s)

Project Period

2/1/2018 - 2/3/2020

Funding Status

Direct Award (USD)

Update

Aim1: Data collection will soon begin for the retrospective component with a member from the research team traveling to Turbo in the coming weeks to collect forms. Aim 2: Research assistant has been hired and trained and study began enrolling patients in Spring 2018. There are 18 enrolled patients. Patient recruitment has been somewhat slower than expected. We are currently uploading preliminary data to assess preliminary findings.

Future Plans

Aim 1: We hope to begin and complete data collection for this component of the project, as well as perform an analysis within the next 6 months. Aim 2: We hope to continue enrollment toward the goal of at least 50 patients and complete an interim analysis of the current data.

Publication(s)

Yes

Study Title

FLTR Evaluation

Principal Investigator(s)	Paula Braitstein, University of Toronto
Co-Investigator(s)	Sylvester Kimaiyo, Moi University
Working Group(s)	Adult Medicine (AMWG)
Description	The FLTR evaluation aims to evaluate the core aspects of the HIV prevention-care continuum, using a combination of quantitative and qualitative methods. We investigate issues related to Finding, Linking, Treating, and Retaining people living with HIV in AMPATH catchments, involving behavioral scientists, biostatisticians, epidemiologists, among others.
Site(s)	
Project Period	7/1/2014 - 7/31/2017
Funding Status	Funded - Eli Lilly Foundation
Direct Award (USD)	\$300,000
Update	Five papers have so far been published for this study, these are: 1. Olney JJ, Eaton JW, Braitstein P, Hogan JW, Hallett TB. Optimal timing of HIV home-based counselling and testing rounds in Western Kenya. <i>J Int AIDS Soc</i> 2018; 21(6): e25142. 2. Genberg BL, Shangani S, Sabatino K, et al. Improving Engagement in the HIV Care Cascade: A Systematic Review of Interventions Involving People Living with HIV/AIDS as Peers. <i>AIDS Behav</i> 2016; 20(10): 2452-63. 3. Shah P, Kibel M, Ayuku D, et al. A pilot study of 'Peer Navigators' to increase uptake of HIV testing, care and treatment among street-connected children and youth in Eldoret, Kenya. <i>AIDS & Behavior</i> 2018. 4. Genberg BL, Lee H, Hogan JW, et al. Point of diagnosis and patient retention in HIV care in western Kenya. <i>Journal of acquired immune deficiency syndromes (1999)</i> 2018. 5. Lee H, Hogan JW, Genberg BL, et al. A state transition framework for patient-level modeling of engagement and retention in HIV care using longitudinal cohort data. <i>Stat Med</i> 2018; 37(2): 302-19.
Future Plans	In the next six months, the study team expects to publish additional 8 papers that are currently at different stages of development; 2 (analysis pending), 1 (analysis in progress), 2 (manuscript in development), 2 (manuscript almost ready for submission) and 1 (manuscript about to be resubmitted).
Publication(s)	Yes

Study Title	HI-Train: Health Informatics Training and Research in East Africa for Improved Health Care
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Martin Were, Other

Working Group(s)	
Description	<p>With increased deployment of eHealth systems, comes the need for an appropriate health information technology workforce. This workforce includes: (a) Local level: Health IT professionals, eHealth specialized programmers, data managers, implementation managers, support specialists and reporting personnel; (b) Institutional level: chief medical information officers; and health information management specialists, (c) administrative: regional and national eHealth coordinators and eHealth monitoring and evaluation specialists, and (d) Other: health information privacy and security specialists and HI researchers. End users, institutional managers and policy makers also need to be appropriately trained on the relevant eHealth systems. Alarming, most sub-Saharan countries remain woefully unprepared to systematically train an adequate workforce to support the eHealth systems already being deployed. Countries like Uganda and Kenya recognize an emergent need for national strategies to build health informatics human capacity. These countries have appropriately developed national eHealth capacity-building strategies. Implementing the strategies however requires direct leadership by Higher Education Institutions in the relevant countries. The urgency for sustainable mechanisms to increase HI workforce and research capacity in developing countries is self-evident. This goal can only be realized by having enough faculty members from developing countries fully trained in Health Informatics. These staff faculty can then be part of a well-functioning and high quality HI program moving forward. Recognizing this need, and the multidisciplinary competencies needed for HI training and research, our team identified partner institutions with complementary capabilities to support advanced Health Informatics training in East Africa for our project. Aims 1) Provide post-graduate (Masters and PhD) level training in Health Informatics and research. The focus will be on post-graduate training for health professionals and computer science personnel to help them become HI faculty at their institutions. 2) Increase number of women and marginalized populations in faculty-level training in Health Informatics and research at the LMIC higher education institutions. 3) Improve the quality and quantity of Health Informatics research conducted primarily by re-searchers based in the LMIC countries in collaboration with our Northern partners. 4) Provide model curricula, educational programs and approaches for faculty-level health informatics training that can be emulated by regional higher education institutions.</p>
Site(s)	Moi University, Makerere University, University of Bergen
Project Period	12/5/2013 - 6/30/2019
Funding Status	Funded - Other NORAD - Norwegian Agency for Development Cooperation
Direct Award (USD)	\$2,757,830
Update	<p>The MSc. HI Cohort 1 successfully had a mock defense which led to 6 of our students submitting their Thesis report for marking. A final Defense is set for February, 2019 roadmap to Graduation. Most of Cohort 2 are now due for data collection and one is finalizing the proposal for IREC approval. Cohort 3 are winding up their second semester and are fine tuning their Abstracts. A new intake 2018/2019 are reporting on 28th February, 2019. To NOTE double effort by the Supervisors where one on one meetings have been continuously conducted between the supervisors MSc. and PhD students and this has had a positive impact in the Research progress. In August 2018 our system developers visited one of our sites at Mbita, Homabay as a followup on the Biometric</p>

	Implementation. The HI-Train Annual meeting with NORAD was held in Uganda last November 2018 that brought together partners who were able to discuss the progress of the Project. The PhD students were able to show case their research by presenting to the committee. And the end of the year December, 2019 the HI-Train System developers attended the OpenMRS implementation conference where they did a demo of the mUzima application. One of our PhD student was able to present a Poster during the conference.
Future Plans	1. Java Training-Our system developers will conduct a Java Training in collaboration with one of our Partners in February 2019 in Nairobi which will attract participants from all over the country.2. Our Phd students will have their mid-term evaluation in Norway one at the end of January and one early February, 2019. 3. Annual HI-Train Leadership meeting will be held in March 2019 in Kampala combined with Gender mentoring meeting.4. MSc. HI New Students Orientation in Nairobi for the new intake in February, 2019 and an MSc. Curriculum Evaluation is on going.
Publication(s)	Yes



Study Title	HIV-related Outcomes After Integration of HIV and Maternal and Child Health Services at Moi Teaching and Referral Hospital in Kenya (HAMMoCK)
Principal Investigator(s)	John Humphrey, Indiana University
Co-Investigator(s)	Julia Songok, Moi University
Working Group(s)	Pediatric (PRWG)
Description	The integration of HIV services within maternal and child health (MCH) services is a recently implemented strategy to improve outcomes for pregnant and postpartum women and their HIV-exposed infants (HEI) in Kenya. However, there are significant evidence gaps concerning the outcomes of HIV-infected pregnant and postpartum women and their HEIs who receive integrated HIV-MCH services. The overall objective of this study is to understand the outcomes of HIV-infected pregnant and postpartum women and their HEIs who receive integrated HIV-MCH services at Moi Teaching and Referral Hospital. Our specific aims are: 1) Describe HIV-infected women's engagement in the HIV care (time to ART initiation, adherence to clinic visits, retention, linkage of infant into care, retention of infant to post-breastfeeding HIV testing) cascade during pregnancy and the subsequent 2 years; 2) Determine the viral suppression rates for HIV-infected pregnant and postpartum women attending integrated HIV-MCH clinics at MTRH; 3) Determine the MTCT rate for infants of HIV-infected women enrolled in integrated HIV-MCH clinics at MTRH at 2 months, 12 months, and 18 months post-delivery, and following cessation of breastfeeding. To accomplish these aims, we will utilize leDEA infrastructure to review the AMPATH electronic medical record to identify all HIV-infected pregnant and postpartum women and their HEIs who have received care at an MCH clinic at MTRH from 2016 to 2017 (n ? 1,000 mother-infant dyads). This research is significant because it will inform strategies for optimal service delivery in the era of Option B+/universal ART eligibility and integrated HIV-MCH services.
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)

Project Period	3/5/2018 - 6/1/2019
Funding Status	
Direct Award (USD)	
Update	We have begun the analysis.
Future Plans	Complete the analysis and submit for publication.
Publication(s)	No



Study Title	IeDEA Comprehensive Adherence Measure for Pediatrics (ICAMP)
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)
Description	<p>The primary objective of the proposed study is to validate an adherence questionnaire for pediatric and adolescent patients at 3 IeDEA sites using electronic dose monitors (Medication Event Monitoring Systems, or 'MEMS', MWV/AARDEX, Switzerland) as external criterion for adherence. While the adherence questionnaire (known as the Comprehensive Adherence Measure for Pediatrics - Short Form, or 'CAMP-SF') has been previously validated in a large, urban referral site at AMPATH in the East Africa IeDEA region, re-validation is warranted to ensure external and internal validity is upheld across resource-limited sites. In conducting this validation study, we will also collect valuable, detailed prospective data on adherence to ART among this sample of HIV-infected children and adolescents using electronic dose monitoring. The study has the following specific aims and hypotheses: Specific Aim 1: Validate a 10-item adherence questionnaire for routine use as an adherence measurement tool in resource-limited settings. Hypothesis 1a: Adherence estimates from the CAMP-SF will be reliable and valid across 3 IeDEA sites in East Africa, Southern Africa and Asia-Pacific when compared with MEMS electronic dosing data. Specific Aim 2: Describe pediatric adherence to ART prospectively over 6 months using electronic dose monitoring (i.e., MEMS) and the CAMP-SF among a sample of HIV-infected children and adolescents at 3 IeDEA sites. Hypothesis 2a: Rates of adherence to ART will be similar for children across different IeDEA sites. Hypothesis 2b: More pediatric non-adherence will be reported during prospective evaluation using the CAMP-SF than in existing rates reported in IeDEA datasets for children. Specific Aim 3: Evaluate factors associated with adherence among a sample of HIV-infected children and adolescents at 3 IeDEA sites. Hypothesis 3a: Risk of medication non-adherence is increased among older children, children with lower disease stages, children with higher CD4 counts, children with a higher medication burden, and orphaned children. Hypothesis 3b: Sites will differ in factors that may influence adherence, including number of children initiating ART; availability of nutritional support, adherence support, disclosure support, and pediatric formulations; and routine use of standardized adherence measures. Specific Aim 4: Assess evidence of the impact of ART</p>

	non-adherence on clinical outcomes such as treatment failure and mortality, and programmatic factors such as loss-to-follow up. Hypothesis 4a: Medication non-adherence by MEMS is associated with increased risk of changing to second-line antiretroviral medications. Hypothesis 4b: Medication non-adherence by MEMS is associated with increased risk of mortality. Hypothesis 4c: Medication non-adherence by MEMS is associated with high risk of loss to follow-up.
Site(s)	Busia District Hospital HIV-NAT Clinic, Bangkok, Thailand; Rahima Moosa Mother and Child Hospital, Johannesburg, South Africa
Project Period	8/1/2014 - 7/31/2016
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	\$171,257
Update	<p>All study follow-up and data collection is now complete at all three IeDEA study sites - Busia clinic at AMPATH (Busia, Kenya), HIV-NAT clinic (Bangkok, Thailand) and Rahima Moosa Mother Child Hospital (Johannesburg, South Africa). We enrolled a total of 319 children aged 0 to 16 on ART from Kenya (n=110), South Africa (n=109), or Thailand (n=100). Children were followed for 6 months of adherence monitoring using Medication Event Monitoring Systems (MEMSif[®]) with at least one viral load measure. At month 3 and 6, children or their caregivers were administered a 10-item adherence questionnaire. Repeated measures analyses were used to compare responses on questionnaire items to: MEMSif[®] dichotomized adherence (i.e., ≥90% of doses taken vs. <90%), 48-hour MEMSif[®] treatment interruptions, and viral suppression (<1,000 copies/mL). Items associated with outcomes (p<.10) were coefficient-weighted to calculate a total adherence score, which was tested in multivariate regression against MEMSif[®] and viral suppression outcomes. Odds ratios (OR) and 95% confidence intervals (95%CI) were calculated. In the last six months, we have been analyzing the patient and adherence MEMS data from all sites. We have completed preliminary analyses and found evidence that the questionnaire we were testing performed well across sites but that non-adherence was still a major concern for children enrolled in this study, particularly for children in the Kenyan and South African sites. We identified some differences among the different international cohorts: Children from Thailand (mean 12.5 years) were significantly older compared to Kenya (9.5 years) and South Africa (9.3 years). Mean MEMSif[®] adherence was highest in Thailand (80% of doses taken) and slightly lower in South Africa (78%) and Kenya (75%). Child-reported adherence and caregiver-reported adherence using the questionnaire were consistent with external adherence criteria. Child-reported adherence was significantly associated with dichotomized MEMSif[®] adherence (OR 1.8, 95%CI 1.4-2.4), 48-hour treatment interruptions (OR 0.41, 95%CI 0.3-0.6), and viral suppression (OR 3.4, 95%CI 1.7-6.7). The questionnaire performed well across sites; however, different cut-points may be appropriate. For example, MEMSif[®] non-adherent children in Kenya had a lower adherence score (0.98) compared to South Africa (1.77) or Thailand (1.58). In conclusion, we found high levels of nonadherence to ART in this international cohort of children, while demonstrating the validity of a short questionnaire to screen for nonadherence across diverse global settings. A manuscript detailing the findings above was submitted and currently under review at the Journal of the International AIDS Society.</p>

Future Plans	Over the next 6 months, we plan to: Prepare additional manuscripts for publication with our partner sites that further explore adherence patterns in this multinational cohort of children and adolescents living with HIV.
Publication(s)	Yes



Study Title	Improvements of diagnosis, staging, and support of children with Burkitt Lymphoma
Principal Investigator(s)	Terry Vik, Indiana University
Co-Investigator(s)	Festus Njuguna, Moi University
Working Group(s)	Oncology (ORWG)Pediatric (PRWG)
Description	<p>The first objective and aim of this administrative supplement is to improve diagnostic testing including flow cytometry and genetic analysis by Fluorescence in situ Hybridization (FISH), to increase the speed and accuracy of diagnosing Burkitt Lymphoma (BL) in children in Kenya. A second objective and aim will be to use financial interventions that have been shown to decrease the rate of abandonment in other cohorts of patients with BL in Africa to test feasibility to decrease the high abandonment rate at our hospital, MTRH, based on our historical control group. The pilot project to be supported by this supplement will improve infrastructure and train clinical staff in the methods of clinical trial management of children with BL in western Kenya. The research support team for the project will ensure collection of diagnostic and staging information, and coordinate follow-up of patients enrolled on the study. The study will be extended to a second hospital, JOORTH, through collaborators in Kisumu. The study pathologists will coordinate the performance of diagnostic tests including immunohistochemistry, flow cytometry, and eventually FISH studies. Dr. Vance will train the research staff in FISH techniques at the primary performance site, and transfer the technology back to Kenya. The numbers of patients available for study at both the hospitals, MTRH and JOORTH, should make completion of this project feasible, as only 40 confirmed BL patients are needed, and up to 50 patients are diagnosed annually at the combined sites. AMPATH and MTRH will provide infrastructure for the clinical testing and care of patients. The parent cancer center clinical research staff will aid in the auditing of patient charts of children enrolled on the study. Study data will be audited periodically throughout the study to ensure accuracy, completeness of data and compliance with research ethics. The main outcomes to be monitored include: percent of required observations completed, number of patients confirmed to be eligible for the trial, Number confirmed to have a diagnosis of BL by each of the three tests of immunohistochemistry, flow cytometry, or FISH, and number of patients with complete staging by Murphy staging criteria. Additionally, number of patients who abandon treatment will be tracked, along with the time point that they abandon. Finally, overall one-year survival points will also be captured. The aim to improve diagnosis and decrease abandonment by comparing results at the end of the study to historical rates will measure the success of this project. Assuming the success of this project, next steps will be to partner with other sites in the region to propose a larger trial with a potential treatment outcome that can be measured and validated across multiple countries and treatment centers, ultimately improving the outcome for children with BL.</p>

Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	9/1/2016 - 8/31/2018
Funding Status	Funded - NIH - National Cancer Institute (NCI)
Direct Award (USD)	\$225,072
Update	We have completed enrollment for the study. Subjects continue to be followed in clinic for outcome measures. FISH genetic testing has started and samples are available to complete that testing are available. The microscope camera was repaired in January 2019 and now samples are being reported. Plans are to have all the FISH testing done in 1-2 months and have the testing validated in Indiana to show it works.
Future Plans	We are preparing an Abstract to be submitted to ASCO describing our clinical trial outcomes. A Kenyan graduate student will be first author on the manuscript for the trial, to be drafted this year. The FISH testing will be submitted as an abstract to the SIOP meeting for international paediatric oncology, for presentation in October.
Publication(s)	No

Study Title	Innovative Community Sourcing Techniques to Investigate Reproductive Health Issues in a Population Aged 13-65 Years in Western Kenya
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Co-Investigator(s)	Faith Kosgei, Moi University
Working Group(s)	Public Health and Primary Care (PHPC)
Description	In this project, we will use innovative community-sourcing technologies (the TIMBY suite of tools) to generate a series of investigative stories to help answer arising questions on maternal and child health matters as well as surrounding and related issues. We aim to demonstrate feasibility of using TIMBY phone application to generate evidence on reproductive health matters as well as in developing targeted interventions and disseminate them to key stakeholders.
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	5/26/2017 - 5/26/2018
Funding Status	Funded - Other Abbvie Foundation
Direct Award (USD)	\$20,860
Update	Over the past 6 months, we submitted a grant application for funding to enable a scale-up of our project but we were unsuccessful. To increase depth, several field activities were carried to gather reports from Trans-Nzoia and Bunyala region in addition to reports being

	collected locally (Eldoret) and synced to the dashboard. These reports were verified. A draft of a manuscript was prepared.
Future Plans	In the next 6 months, we aim to finalize the manuscript and identify relevant journals in which it can be published. We plan to continue verifying any pending reports and compile more stories from these. We are also looking to apply for funding as opportunities arise. Once we have a good number of reports, we aim to do an in-depth analysis to identify any new arising themes that might inform a second manuscript.
Publication(s)	No



Study Title	Innovative public-private partnership to target subsidized antimalarials in the retail sector
Principal Investigator(s)	Wendy Prudhomme, Duke University
Co-Investigator(s)	Diana Menya, Moi University
Working Group(s)	Public Health and Primary Care (PHPC)
Description	<p>In most malaria-endemic countries, a large fraction of fevers are treated in the informal health sector where diagnostic testing is uncommon and effective drugs are expensive. For many families, particularly in rural areas, the first source of treatment for fevers are retail medicine outlets such as chemists, pharmacists and small, unregulated medicine shops. These retail outlets, also referred to as the 'informal health sector', are more accessible than formal health services, but effective drugs are expensive and most clients purchase cheaper, ineffective therapies to which high levels of resistance exist. The Global Fund piloted a drug subsidy called the Affordable Medicines Facility - malaria (AMFm) to reduce the prices of effective, high quality ACTs in the private sector. AMFm was launched in 2010 and provided quality-assured ACTs to wholesale markets at substantially reduced prices in seven pilot countries, including Kenya. \$339 million dollars were earmarked for subsidies and 155.8 million doses were delivered in the first 18 months of the program (ICF International, 2012). Prices of subsidized ACTs in most pilot countries dropped below that of cheaper, ineffective drugs and substantial cost savings were seen by the end consumer. In Kenya, the retail market share of ACTs increased from 12% to 61% in the first 18 months of the program (Tougher et al., 2012). However, there is concern that dramatically lowering the price of ACTs opened the door to over-treatment and overuse of ACTs. The overall objective of this study is to evaluate the public health impact of targeted antimalarial subsidies through scale-up by determining the community-wide effects of targeting an antimalarial subsidy through a partnership between CHVs and the private retail sector. Cluster-randomized design was used to assign community units to either an intervention or control arm. The study is being carried out in two sub-counties in Western Kenya (Bungoma East and Kiminini) with similar malaria burden but different access to health services. Community Units (CUs) in each sub-county were clustered and randomized. There are 32 CUs in total across both sub-counties, 20 in Bungoma East and 12 in Kiminini. Half of the community units in each study area (10 in Bungoma East sub-county and 6 in Kiminini) were randomly allocated to the intervention and the remainder of the community units to the comparison arm. In the intervention arm a conditional subsidy is offered in the form of a voucher providing for the purchase</p>

	<p>of a WHO-qualified ACT at a reduced, fixed price to those with a positive malaria test that can be redeemed at a local drug retailer, while individuals in the comparison arm only receive standard community health volunteer (CHV) visits. Cross-sectional household surveying at pre-intervention, and 6 months, 12 months, and 18 months post-baseline will be used to determine any change in the percent of fevers that are tested for malaria and the effect of testing on subsequent drug purchasing decisions. The primary hypothesis to be tested is that offering a fixed-price voucher that reduces the cost for ACT purchase in the retail sector conditional on a positive malaria test (targeted subsidy) can improve uptake of testing for malaria and will increase the proportion of fevers tested for malaria before treatment. The primary outcome of this study is to compare the percent of fevers that receive a malaria test from any source between the intervention and control arms. The secondary outcomes of this study will also be measured and compared between intervention and control arms. The main secondary outcome is the percent of all ACTs used that were taken by people with a malaria positive test. Additional secondary outcomes are: the percent of all ACTs used that were taken by people without a test, the percent of those with a positive test who got an ACT, and the percent of those with a negative test who got an ACT.</p>
Site(s)	
Project Period	1/1/2014 - 12/31/2018
Funding Status	Funded - NIH
Direct Award (USD)	\$1,654,917
Update	We also had an opportunity to do a presentation of the main study outcomes at the Kenya National Malaria Forum in Nairobi, on 18th September 2018. At the same forum, we shared a policy brief of the study and we still have plans to share the same brief with other organizations such as; World Health Organization (WHO), United, the Department for International Development UK (DFID), and the Global Fund to Fight AIDs, Tuberculosis, and Malaria (GFATM).
Future Plans	Targeted teams led by study investigators are currently drafting numerous other manuscripts on topics including the cost of febrile illness and RDT and polypharmacy for treatment of febrile illness. These are being finalized and are expected to be submitted for publication by before the end of 2019.
Publication(s)	Yes
Study Title	Linkage and Engagement in Care of HIV Positive Children and Adolescents
Principal Investigator(s)	Paula Braitstein, University of Toronto
Co-Investigator(s)	Samson Ndege, Moi University
Working Group(s)	Pediatric (PRWG)

Description	<p>The HIV care cascade is a model that outlines the sequential steps or stages of HIV treatment and care that people living with HIV go through from initial diagnosis to achieving the goal of viral suppression. Despite several advances in HIV diagnostics and therapeutics over the years, many infected children and adolescents (CA) are unable to experience these benefits due to non-entry, delayed entry or disengagement at various steps of the care continuum. There are limited data available for both adults and children to elucidate engagement in the HIV care cascade from population-based settings. Data from HBCT enable estimates of engagement in care among all those currently living with HIV in a given community. We have a large dataset containing data from two rounds of home-based counseling and testing (HBCT) and care and treatment data from the AMPATH Medical Records System. This study will make use of these existing data to conduct retrospective observational analyses of engagement in care and mortality among HIV-positive children and adolescents identified through HBCT for three high HIV burden catchments. In addition we prospectively traced a random sample of HIV-positive children and adolescents identified through HBCT who according to our data are not linked to care, for one catchment only. Our specific aims are: Aim 1: With existing data, determine the proportion of children and adolescents (age <18 years at HBCT) with known HIV infection through HBCT who have ever and are currently engaged with care and initiated/receiving ART in three catchments (Bunyala, Chulaimbo, Teso). Aim 2: With existing data, characterize the risk and protective factors for CA living with HIV failing to link to care as defined by having an initial clinical encounter and initiation of ART (Bunyala, Chulaimbo, Teso). Aim 3: Determine the outcomes of CA living with HIV who failed to link to care and initiate ART in one catchment (Bunyala). Using prospective ascertainment of participants who failed to link to care, we hypothesize that a high proportion of those who failed to link to care will have moved out of the area, or be deceased at the time of ascertainment. We will then revise our analyses and incorporate these data into our estimates of engagement in care and mortality among these populations.</p>
Site(s)	Bunyala, Teso and Kisumu West Sub-Counties
Project Period	2/1/2018 - 12/31/2019
Funding Status	Funded - NIH
Direct Award (USD)	\$121,141
Update	<p>Approval of amendment for the study was received on 2nd August 2018 from IREC and a list of staff working under the project was approved by IREC on 20th September 2018. The study team and staff were trained on the study protocol on 30th-31st August 2018 in Eldoret after which participant tracing commenced on 3rd September 2018. During a field supervisory visit, a protocol deviation was observed where written informed consents/assents were not obtained from participants after verbal consent to participate in the study was obtained from them. Prompt reporting was immediately done to IREC and acknowledgement has been received to implement the corrective measures outlined in the reporting form, these are:</p> <ul style="list-style-type: none"> • Undertake Refresher training for the counselors on the protocol, consenting processes and Standard Operating Procedures. • Revisit participant households by the counselors, apologize to the participants for not giving them consent/assent forms to sign earlier, then request the participants to sign the forms. • Seek consent from the participants to use data already collected from them. <p>Project supplies like bags for the counselors, gumboots, assorted stationery materials, printer/scanner, desk, chairs, cabinet and sugar for the participants have already been</p>

	procured and delivered for use to facilitate smooth implementation of the study. A few supplies though are still pending like the laptop and umbrellas. During the period under review, the counselors traced 97 participants out of 134 we are attempting to trace and their forms completed. The approved sample for the study is 167 but 33 participants were found ineligible to continue participation since they had already linked to care by the time the study commenced. The qualitative team have done 20 in-depth interviews out of 60.
Future Plans	The following activities are planned for the next 6 months: 1. Receive ethics continuing review approval for the study. 2. Undertake refresher training for the counselors. 3. Obtain written consents/assents from participants that were missed. 4. Complete tracing of the remaining 37 participants and their forms completed and data entered. 5. Begin data analysis and writing of manuscripts.
Publication(s)	No



Study Title	Linkage and Retention to Care in Western Kenya Following HIV Testing
Principal Investigator(s)	Becky Genberg, Brown University
Co-Investigator(s)	Juddy Wachira, Moi University
Working Group(s)	Adult Medicine (AMWG) Behavioral and Social Science (BSSWG) Public Health and Primary Care (PHPC)
Description	<p>This project is focused on identifying the individual, psychosocial, and structural barriers to timely linkage and retention. This project has three specific aims: 1. To comprehensively describe linkage and retention to HIV care following home-based counseling and testing by examining time from testing to linkage and the socioeconomic, demographic and structural determinants of linking to care. We will conduct retrospective and multilevel analyses using existing de-identified clinical and facility-level data collected within AMPATH, defining linkage to care as the completion of an initial HIV clinical encounter with a provider following testing. We will also examine factors that predict retention in HIV care over time. 2. To characterize the psychosocial and structural facilitators and barriers to linkage and retention to care following positive HIV diagnosis through HBCT and PITC. We will conduct a qualitative study to examine the psychosocial factors inhibiting or motivating linkage to care, experiences in accessing care, and factors that promote or interrupt retention among those who tested positive via HBCT or PITC. We will also collect data from clinicians and community health workers to examine how features of the healthcare system facilitate or constrain linkage and retention to care. 3. To develop and implement a feasibility study of a pilot psychosocial intervention aimed at increasing linkage to care among individuals testing positive for HIV. The content of this intervention pilot will be informed by the results of Aims 1 and 2. The first aim of this study involves secondary analysis of data collected during home-based counseling and testing linked to medical records data. This data will include information collected as part of routine testing procedures and care, for those who successfully linked to care. AIM 2 will employ qualitative approaches to identify barrier and facilitators to linkage and retention. AIM 3 will include information collected as part of routine care, for those who</p>

	successfully linked to care. Specifically, medical record reviews at baseline and post-intervention.
Site(s)	
Project Period	6/4/2012 - 12/20/2013
Funding Status	Funded - Eli Lilly Foundation Bill and Melinda Gates FoundationNIH
Direct Award (USD)	\$152,806
Update	We have completed the analysis of qualitative data from HIV care providers and published our results. Our analysis of qualitative data from people who did not link to care following HIV testing via HCT is ongoing.
Future Plans	We will continue to finish the analysis of qualitative data and expect to have a draft of a manuscript on this data submitted by June 2019.
Publication(s)	Yes

Study Title	Making Inroads to Strengthen the Health of Adolescents (MaISHA)
Principal Investigator(s)	Leslie Enane, Indiana University
Co-Investigator(s)	Edith Apondi, Moi Teaching and Referral Hospital
Working Group(s)	Pediatric (PRWG)
Description	The objective of this project is to investigate critical gaps in care for adolescents with HIV, and the underlying barriers complicating care for adolescents. The direct causes of severe illness among adolescents with HIV will also be explored. To achieve our project objective, we will pursue the following specific aims: Aim 1. To quantify missed opportunities along the HIV care cascade among adolescents prior to hospitalization in western Kenya, by examining timing and outcomes of HIV diagnosis, linkage to and retention in care, and viral suppression. This will be accomplished through a prospective study of hospitalized adolescents in western Kenya. Measures of engagement in HIV care prior to hospitalization will also be assessed. Secondary Aim: To determine the causes of hospitalization and mortality among adolescents with HIV in western Kenya. Hospital record data and consultation with care providers will be utilized to determine causes of hospitalization and mortality. Aim 2. To define critical barriers contributing to delays or failures in the care cascade, as well as facilitators to care, and to identify areas of potential intervention. Barriers and facilitators to the long-term retention of adolescents in care will be specifically explored. This will be accomplished through qualitative inquiry of youth with HIV and their caregivers. Phase I will be a prospective mixed-methods study of youth with HIV that will specifically investigate barriers and facilitators to long-term retention of adolescents in HIV care. This will include interviews with key informants: hospitalized youth and their caregivers, and peer mentors; and focus groups of youth engaged in HIV care and their caregivers. Phase II will be a prospective mixed-methods

	study of hospitalized adolescents that will determine outcomes along the care cascade, causes of hospitalization and mortality, and qualitative barriers and facilitators to care at each stage.
Site(s)	Chulaimbo Sub-District Hospital Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Webuye District Hospital
Project Period	10/1/2016 - 6/30/2019
Funding Status	Funded - Other Thrasher Research Fund Indiana University - Center for AIDS ResearchIndiana CTSI OtherIU Center for Global Health
Direct Award (USD)	\$57,500
Update	Recruitment of study participants and study activities continued during this reporting period. After obtaining IREC approval for a study amendment, we performed additional peer mentor interviews to fully ascertain narratives on the roles of peer mentors in supporting adolescents navigating the HIV care cascade. In total, 14 key informant interviews were completed during this reporting period. During the school holidays of August 2018, we conducted 8 focus group discussions (FGDs) with adolescents living with HIV, stratified by age and gender (two male and two female groups ages 10 - 14; and two male and two female groups ages 15 - 19). FGDs were co-facilitated by peer mentors, and sought to explore areas of intervention to improve retention of adolescents in HIV care. This work completed study activities for Phase I of the MaSHA study. Transcription for the peer mentor interviews and the FGDs were completed during this reporting period. Transcripts were uploaded. A code book was developed, and final coding and analysis is underway. Phase II activities were also completed during this reporting period. We enrolled 27 hospitalized adolescents and their caregivers for surveys and interviews regarding barriers and facilitators along the cascade of care. We also completed chart reviews and data abstraction regarding causes of hospitalization and mortality in this group. A manuscript reporting on previous qualitative work in the MaSHA study was submitted for publication, and abstracts of this work were presented at AIDS 2018 and at multiple local conferences.
Future Plans	Study enrollment has completed. We have completed much of the qualitative analysis and will finalize analysis from our work with peer mentors and hospitalized adolescents. We are performing quantitative analyses to describe this cohort and associations with measures of retention and disengagement. We will be submitting multiple publications from this project.
Publication(s)	Yes
Study Title	MCH STUDY (Evaluations at Infant and Child Visits a MCHs in western Kenya: A Needs Assessment)
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi University

Working Group(s)	Pediatric (PRWG)
Description	The specific aims for MCH study are : Aim 1: To identify the evaluations and preventative care performed at MCH clinics and identify additional preventative areas that MCH clinical staff are interested in investigating further. Aim 2 :To determine the frequency of visits for children attending MCH clinics and also identify at what ages a child is more likely to have visited the MCH. Aim 3.:To determine the scope to which child development is currently evaluated at the MCH clinics and documented in the Mother and Baby Booklets. The study took place in western Kenya at the following MCH clinics: MTRH, Turbo, Webuye, Mosoriot, Burnt Forest, and Kitale. During this study, we recruited two groups of study participants. The first was clinical staff working at each of the MCHs. The second group were caregivers who brought young children to the MCH. This study was reviewed and approved by the Indiana University School of Medicine Institutional Review Board and the Moi University Institutional Research and Ethics Committee.
Site(s)	Burnt Forest Sub-District Hospital Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Mosoriot Rural Health Training Centre Turbo Health Centre Webuye District Hospital
Project Period	9/26/2016 - 9/26/2017
Funding Status	
Direct Award (USD)	
Update	Ongoing with analysis and presentation of manuscripts for review by African Journal for AIDS research
Future Plans	Abstract and manuscript reviews by the African Journal for AIDS research.
Publication(s)	Yes

Study Title	Mental Health Screening and Phone-Based Counselling Support for Adolescents with HIV in Kenya
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)
Description	The objective of this pilot study is to explore options to provide mental health services and support to Kenyan youth living with HIV (YLWH) using a readily available potential tool-WhatsApp (WA) - and a counselor-guided WhatsApp group designed to provide education and counseling to YLWH. We will gather critical preliminary data related to the use of tele-therapy and tele-peer support for HIV-infected adolescents in Kenya to achieve the study aims. Throughout six months of follow-up, the enrolled group of adolescents will receive group and individual counseling via WhatsApp, with the option for peer group chatting related to key topics as well. In addition, they will receive adherence monitoring,

	testing for viral suppression, and mental health evaluations at baseline and at 6 months of follow-up. The specific aims are: Aim 1: Assess the feasibility, acceptability, and usability of a cell phone-based intervention to provide mental health services (teletherapy and tele-peer support) for HIV-infected adolescents in Kenya. Aim 2: Evaluate the user engagement with both the cell phone-based intervention and the clinical care system throughout the monitoring period using counselor reports, usage tracking, and clinical database evaluation. Aim 3: Describe key clinical, mental, and emotional health outcomes for this cohort during the monitoring period, including medication and clinic adherence, viral suppression, depression symptoms and other behavioral or emotional symptom reports, and engagement with support services such as peer support groups.
Site(s)	Turbo Health Centre
Project Period	1/1/2017 - 7/31/2018
Funding Status	Funded - Indiana University - Center for AIDS Research
Direct Award (USD)	\$10,000
Update	The study 'Mobile Mental Health Monitoring and support for Adolescents with HIV in Kenya' project successfully enrolled 30 adolescents aged 10-19 years from Turbo clinic in western Kenya and each were assigned a smartphone and a WhatsApp group for tele-counseling, in addition to in-person peer support groups at the clinic. The adolescent participants participated in two peer support groups at the Turbo clinic, totaling five peer support groups at Turbo clinic during the study period. Participants were also involved in monthly individual counseling meetings with the counselor at Turbo clinic on their return-clinic day. The six month follow up ended with 29 participants (one participant withdrew from the study) and study intervention activities are completed. Over the last six months, we completed data entry and verification of individual patient characteristics into a REDCap database, and preliminary quantitative data analysis is ongoing. We completed transcription and translation of the qualitative data collected through WhatsApp discussions and initial coding has begun. Finally, adherence data retrieved from electronic dose monitors (MEMS caps) were cleaned and are also ready for analysis.
Future Plans	In the next six months, we plan to complete qualitative and quantitative data analysis on the feasibility and acceptability of the pilot WhatsApp project to support mental health among this cohort of adolescents living with HIV. With these data, we hope to submit an abstract to a conference for presenting these analyses. These analyses will also be used to support the development of a larger research grant that incorporates WhatsApp technology as a novel telehealth intervention for mental health counseling among adolescents living with HIV.
Publication(s)	No
Study Title	NEURODEV (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study)
Principal Investigator(s)	Megan McHenry, Indiana University

Co-Investigator(s)	Eren Oyungu, Moi University
Working Group(s)	Pediatric (PRWG)
Description	<p>The specific aims for Neurodev (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study) are: Aim 1. To utilize qualitative methods to determine the perceived etiology, manifestations, and intervention options for child NDDs from the perspectives of clinical staff and caregivers of HIV-infected and HIV-exposed children in Kenya. Aim 2: To develop brief, candidate neurodevelopmental screening questions that are clinically relevant and culturally acceptable by utilizing developmental assessments validated in other settings and incorporating contextual caregiver and clinicians' perspectives. Aim 3: To evaluate the feasibility of implementing a validation study to examine NDD screening methods in a pilot sample of children under three years of age born to HIV-infected mothers. In Phase One, we utilized semi-structured interviews (SSIs) and focus group discussions (FGDs) with caregivers and clinicians to understand current knowledge and beliefs about NDDs. FGDs were chosen for caregivers to generate information on collective views of neurodevelopment and the meanings and implications that lie behind those views. SSIs were chosen for clinical staff to address several key questions specific to their individual training and experiences, while allowing both the interviewer and clinical staff to further pursue an idea or response in more detail. Phase Two will allow us to pilot key methods needed for future validation testing of these items. As we aim towards a large validation study to assess the reliability and validity of these screening questions in this setting, we will conduct prospective feasibility testing, piloting these questions during cognitive interviews with caregivers and clinical officers, in the clinical setting in Kenya and also piloting the implementation of the gold standard for developmental screenings - lengthy, comprehensive developmental assessments of young children. No modifications have been made to the specific aims as stated in the original proposal. We have ongoing Institutional Review Board and local ethics committee approval for the aims.</p>
Site(s)	Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Port Victoria Sub-District Hospital Turbo Health Centre Webuye District Hospital
Project Period	1/10/2016 - 9/30/2017
Funding Status	Funded - Indiana University - Center for AIDS Research
Direct Award (USD)	\$597,800
Update	The pilot phase of recruiting children within three different categories of HIV exposure: HIV-infected, HIV-exposed but uninfected, and HIV-unexposed is on-going. We have so far enrolled 135 study participants against the target study population of 225 children, and administered the BSID-III to a total of 135 children
Future Plans	The pilot phase of recruiting children within three different categories of HIV exposure: HIV-infected, HIV-exposed but uninfected, and HIV-unexposed is on-going. We have so far enrolled 135 study participants against the target study population of 225 children, and administered the BSID-III to a total of 135 children
Publication(s)	Yes

Study Title	Neurodevelopmental Screening in Children Born to HIV-infected Mothers
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi University
Working Group(s)	Pediatric (PRWG)
Description	<p>PROJECT SUMMARY Children born to HIV-infected mothers are more likely to have neurodevelopmental (ND) delays than HIV-unexposed children. Early identification and referral to intervention services is critical to improve the lives of children with ND delays, but it is not routinely performed in HIV-prevalent areas, such as sub-Saharan Africa. This is a critical missed opportunity for the >1 million children born to HIV-infected mothers annually. Integrating sustainable ND evaluation programs, with screening, assessment, and intervention services, is critically needed within clinical systems caring for children born to HIV-infected mothers. The long-term goal is to implement an effective ND screening and intervention program to combat ND delays in children born to HIV-infected mothers in resource-limited settings. The overall objectives of this application are: (1) to identify appropriate ND instruments for use in HIV-exposed Kenyan children and (2) to pilot an integrated ND screening program within the existing care system. The central hypothesis is that the integration of a ND evaluation program using appropriate tools will be feasible and effective at identifying HIV-exposed children with ND delays in Kenya. These objectives will be achieved by pursuing the following specific aims: 1) Determine and compare the reliability and validity of ND screening tools and assessments for use among children aged 18-36 months in Kenya and 2) Evaluate ND screening implementation in an existing health care system in Kenya. Under the first aim, a rigorous cross-cultural adaptation will be performed, and psychometric properties of two ND screening tools and two assessments will be evaluated among 240 Kenyan children. This will identify an optimal screening tool and assessment for the setting. Under the second aim, an implementation plan will be developed using principles of community-based participatory research and implementation science. An ND screening program will then be piloted at one clinic in Kenya. Within this pilot, the following implementation outcomes will be measured: acceptability, feasibility, fidelity, implementation cost, and sustainability. The diagnostic accuracy of ND screening at identifying ND delays will also be determined. This study is significant because of its potential to sustainably improve the neurodevelopment of HIV-exposed children by: 1) identifying HIV-exposed children with ND delays and referring them to therapy and 2) creating a research platform to support the evaluation of innovative interventions and track longitudinal outcomes. The proposed research is innovative because a sustainable ND screening program will be created and integrated within the current model of care. This will provide preliminary data for a cost-effectiveness analysis of a larger scale-up of implementation. An integrated, sustainable ND screening program will identify and treat children with ND delays and create a research platform to evaluate future interventions for ND delays.</p>
Site(s)	Moi's Bridge Health Centre
Project Period	9/21/2018 - 8/31/2022

Funding Status	Funded - NIH – National Institutes of Mental Health (NIMH)
Direct Award (USD)	\$723,254 (total over 4 years)
Update	Starting study now.
Future Plans	Training on assessments used in study, cultural adaptation and enrollment of participants for adaptation phase. Initiation of validation phase of Aim 1
Publication(s)	No

Study Title	Neuropsychiatric Genetics of African Population-P
Principal Investigator(s)	Prof. Lukoye Atwoli, Moi University
Co-Investigator(s)	Dr. Edith Kwobah, Moi University
Working Group(s)	Behavioral and Social Science (BSSWG)
Description	<p>In the recent years there have been significant insights into the complex etiologies of neuropsychiatric brain disorders. For example, neuropsychiatric genetics has achieved success with the identification of 108 loci for schizophrenia according to the Schizophrenia Working Group 2014. Furthermore, meta-analyses of genome-wide association study results encompassing thousands of samples have been completed for other psychiatric disorders including attention-deficit disorders, bipolar disorder, autism spectrum disorder, and major depressive disorder. However, published results on neuropsychiatric disorders have often not included samples of African ancestry. The study takes a case-control design. Cases will be individuals with schizophrenia or Bipolar disorder and Controls will be age, sex and ancestry matched individuals from the same geographic locations.</p> <p>Specific Aims</p> <ol style="list-style-type: none"> 1. To determine the phenotypic presentation of psychotic disorders in African population. 2. To describe the genetic variation between patients with psychotic disorders and those without in African population. 3. To examine the association between genetic variation and risk for schizophrenia and Bipolar disorder in African populations. 4. To provide opportunities for training of African scientists in neuropsychiatric genetics research. <p>The Moi site will recruit a total of 4000 participants over 4 years, consisting of 2000 cases and 2000 controls. The study is an opportunity for Kenya to be involved in neuropsychiatric genetic research and therefore contribute to subsequent treatment innovations that may arise from insights from the genetic research.</p>
Site(s)	
Project Period	2/28/2017 - 3/1/2022
Funding Status	Funded - Other Broad Institute of MIT and Harvard
Direct Award (USD)	\$252,150

Update	PROGRESS We have recruited 648 participants the last 6 months. Total participants enrolled so far are 951 (522 controls and 429 cases). We have had regular meetings and training of continuing and new staff on the project requirements as per the protocol, which has enabled us get quality data. CHALLENGES We had a public transport strike which made it difficult for participants to reach facility for recruitment. PRELIMINARY FINDINGS We have submitted a manuscript on our study protocol to BMJ Open, and this has been accepted for publication. Preliminary findings from 192 samples analysed so far show that self-reported linguistic group so far matches very closely the known genetic clusters in the East African Region. Analyses based on our study objectives will commence once we have reached our data collection targets.
Future Plans	We plan to continue scaling up recruitment to help us achieve our targets of the second year. Additionally, we expect to begin data collection at the non-MTRH sites this year.
Publication(s)	Yes



Study Title	One Year Morbidity and Mortality of Infants Diagnosed with Perinatal Asphyxia or Low Birth Weight Admitted to The New Born Unit at Moi Teaching and Referral Hospital.
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	
Working Group(s)	Pediatric (PRWG) Reproductive Health (RHWG)
Description	A prospective cross-sectional study looking at the one year morbidity and mortality of infants with low birth weight (LBW) and perinatal asphyxia admitted to the new born unit (NBU) at Moi Teaching and Referral Hospital (MTRH). We hope to enroll 420 infants and follow them up until they are one year of age. Data will be collected on admission diagnosis, demographics, anthropometric measurements, treatment and follow-up and outcomes during admission and at one year of age. The objectives of the study are to determine the one year mortality rate of infants admitted to the NBU, determine the attrition and readmission rate, to determine the proportion of newborns with perinatal asphyxia or low birth weight and grade the severity and to determine the obstetric, medical and socio-economic factors associated with better short term and long term outcomes.
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	10/23/2017 - 10/23/2019
Funding Status	
Direct Award (USD)	
Update	A submission to IREC to amend the study period was approved. Database for data collection was developed.

Future Plans	We intend to start participant enrollment in the next few weeks. A submission to IREC to request for a continue renewal has been submitted.
Publication(s)	No
Study Title	Optimizing Linkage and Retention to Hypertension Care in Rural Kenya
Principal Investigator(s)	Rajesh Vendanthan, Mount Sinai School of Medicine
Co-Investigator(s)	Jemima Kamano, Moi University
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)
Description	<p>Hypertension awareness, treatment, and control rates are low in most regions of the world. A critical component of hypertension management is to facilitate sustained access of affected individuals to effective clinical services. In partnership with the Government of Kenya, the Academic Model Providing Access to Healthcare (AMPATH) Partnership is expanding its clinical scope of work in rural western Kenya to include hypertension and other chronic diseases. However, linking and retaining individuals with elevated blood pressure to the clinical care program has been difficult. To address this challenge, we propose to develop and evaluate innovative community-based strategies and initiatives supported by mobile technology. The objective of this project is to utilize a multi-disciplinary implementation research approach to address the challenge of linking and retaining hypertensive individuals to a hypertension management program. The central hypothesis is: community health workers (CHWs), equipped with a tailored behavioral communication strategy and a smartphone-based tool linked to an electronic health record, can increase linkage and retention of hypertensive individuals to a hypertension care program and thereby significantly reduce blood pressure among these patients. We further hypothesize that these interventions will be cost-effective. To test these hypotheses and achieve the overall objectives, we will pursue the following specific aims: Aim 1: Identify the facilitators and barriers to linking and retaining individuals with high blood pressure to a hypertension care delivery program, using a combination of qualitative research methods: 1) baraza (traditional community gathering) form of inquiry; 2) focus group discussions among individuals with elevated blood pressure during home-based testing; and 3) focus group discussions among CHWs. Subsidiary Aim 1.1: Using identified facilitators and barriers, develop a tailored behavioral communication strategy guided by the Health Belief Model modified by incorporating emotional elements for the CHWs to use with hypertensive patients, focusing on regular and timely attendance at hypertension clinic. We will test the communication strategy for face and content validity using focus group discussions with CHWs and individuals with elevated blood pressure. Subsidiary Aim 1.2: Using identified facilitators and barriers, develop a smartphone-based tool linked to the AMPATH Medical Record System (AMRS) to be used by CHWs to optimize linkage and retention of hypertensive patients to the care program, and evaluate the usability and feasibility of this tool using think-aloud technique, mock patient encounters, focus group discussions, and participant observation. Aim 2: Evaluate the effectiveness of CHWs equipped with a tailored behavioral communication strategy and a smartphone-based tool in improving linkage and reducing blood pressure among hypertensive patients, by conducting a cluster randomized trial comparing: 1) usual care (CHWs with standard training on recruitment of individuals with any chronic</p>

	condition); 2) CHWs with an additional tailored behavioral communication strategy; and 3) CHWs with a tailored behavioral communication strategy an also equipped with smartphone-based tool linked to the AMRS. The co-primary outcome measures will be: 1) documented linkage to care following home-based testing, and 2) one year change in systolic blood pressure among hypertensive individuals. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial. Cost effectiveness will be presented both in terms of costs per unit decrease in blood pressure and in terms of costs per reductions in cardiovascular disease (CVD) risk by extrapolating one-year blood pressure reductions to CVD risk reductions based on the QRISK2-2011 CVD risk calculator specific for Black African populations. This research will generate innovative and productive solutions to the expanding global problem of hypertension, and will add to existing knowledge on scalable and sustainable strategies for effectively managing hypertension and other chronic diseases in low- and middle-income countries.
Site(s)	Mosoriot Rural Health Training Centre Turbo Health Centre
Project Period	5/4/2012 - 3/31/2017
Funding Status	Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	\$2,104,519
Update	Marked progress has been made on this project over the last six months. This progress is delineated below. Aim 1 (barriers & Facilitators to Linkage/Retention o Secondary qualitative manuscript nearly finalized Subsidiary Aim 1.1 (Behavioral Assessment and Communication Strategy) o Content validity manuscript in preparation Subsidiary Aim 1.2 (Smart-phone-based tool) o Content validity manuscript in preparation Aim 2 (Cluster RCT) o Data analysis ongoing o Outcomes manuscript in preparation Aim 3 (Cost Effectiveness Analysis) o Manuscript in preparation
Future Plans	o Complete data analysis o Manuscript preparation and finalization
Publication(s)	No

Study Title	Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	W. Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)
Description	The purpose of this study is to assess the effect of a patient- and family-centered intervention guiding disclosure to HIV-infected Kenyan children using a randomized trial comparing the intervention to routine care. The primary endpoint will be probability of disclosure among children, with secondary endpoints of adherence, clinical outcomes,

	<p>psychological distress and social outcomes. Phase One, which will last 6 months, focuses on cultural adaptation of the intervention materials through intensive patient participation, including focus groups and cognitive interviewing; selecting narrative components; and training dedicated disclosure counselors. Phase Two consists of a randomized design to examine whether the culturally adapted, multi-component HADITHI intervention increases the prevalence of disclosure to HIV-infected children in western Kenya compared to children receiving usual care. HIV-infected children ages 10-15 years who are enrolled in HIV care within the eight selected AMPATH clinics in western Kenya will be eligible for study enrollment and have a comprehensive patient assessment every 6 months for 2 years.</p>
Site(s)	<p>Burnt Forest Sub-District Hospital Chulaimbo Sub-District Hospital Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Mosoriot Rural Health Training Centre Turbo Health Centre Webuye District Hospital</p>
Project Period	<p>9/1/2012 - 9/1/2016</p>
Funding Status	<p>Funded - NIH - National Institute of Mental Health (NIMH)</p>
Direct Award (USD)	<p>\$1,886,804</p>
Update	<p>This was a cluster-randomized trial of a counseling intervention that consisted of a curriculum for disclosure and adherence counseling (video-taped narratives and animated, tablet-based educational modules), dedicated counselors to provide family and one-on-one, facilitated peer support groups, and additional materials including pamphlets, FAQ summaries, written narratives for discussion. The primary outcome was disclosure status, treated as a time-to-event outcome, measured on a discrete time scale. All study intervention and follow-up of patients is complete. Over the last six months, we have been conducting preliminary analyses of the data. 285 children and their caregivers were followed. Their mean age was 12.3 years, 52% were female. Their average time-on-treatment was 4.4 years, mean CD4% of 28%, with 95% on first-line ART. At baseline, 32% of children reported knowing their HIV status already (no difference between control and intervention groups.) Disclosures in both control and intervention arms increased over follow-up, but the intervention arm had significantly more disclosures. Using child-reported disclosure, the prevalence of disclosure increased significantly between baseline and 24 months of follow-up from 29.2% to 58.5% in control arm and 33.2% to 74.0% in intervention arm. This was a significant difference in disclosure prevalence for the intervention group at 24 months (difference of 15.5%, 95% confidence interval: 3.7, 27.3). Thus, the intervention group had both more disclosures and earlier disclosures, with the largest increase in disclosures at 6 months. The secondary mental and behavioral health outcomes are still under analysis, but overall, there were not significant differences in mental and behavioral health outcomes at the end of the two years. However, trends suggested mental and behavioral distress increased at month 6 in intervention group as disclosures increased, and then decreased compared to controls thereafter. Viral load measures were drawn at 24 months, and 118 of 250 participants (47%) had detectable viral load at the level of >40 copies/mL. Individuals in intervention group had lower odds of having detectable viral load (odds ratio = 0.80, 95% CI: 0.22-2.84) and higher odds of achieving viral suppression (2.29, 95% CI: 0.89-5.39) although neither was statistically significant. A manuscript detailing these findings from our initial analyses was invited for submission to a special issue of the journal AIDS on resilience among people living with HIV. The manuscript, entitled 'Resilience through knowing? Evaluating a patient-centered</p>

	disclosure intervention for children living with HIV in Kenya,' is still under review and will hopefully be published in 2019.
Future Plans	Over the next 6 months, we plan to: <ul style="list-style-type: none"> Complete data analyses for all study objectives. Complete analyses of drug level concentrations on hair samples to assess drug adherence that were sent to University of California San Francisco. Draft additional manuscripts for publications on our findings.
Publication(s)	Yes



Study Title	Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretroviral Treatment
Principal Investigator(s)	Paula Braitstein, University of Toronto
Co-Investigator(s)	B Jakait, Moi Teaching and Referral Hospital
Working Group(s)	None
Description	Little is known about the toxicity profile of combination antiretroviral treatment (cART) in African populations where genetic differences, co-morbidities, and malnutrition together may influence the adverse reactions of cART in this population. The purpose of this project is to evaluate the feasibility and effectiveness of five approaches to Targeted Spontaneous Reporting (TSR) for documenting SADR in the resource constrained clinical setting in western Kenya. The approaches include; TSR 1: The completion of the Kenya National Suspected Adverse Drug Reaction form for patients with a change or discontinuation in their cART. These forms are then forwarded on to the National pharmacovigilance (PV) office at the Pharmacy and Poisons Board (PPB) in Nairobi. TSR 2: Use of routinely-used clinical encounter forms that have been enhanced to specifically collect a relatively small amount of SADR data to be collected by the provider seeing the patient during the clinical visit. TSR 3 and TSR 4: Involve conducting in-depth interviews on 1,000 patients receiving cART treatment to prompt patients about SADR and their impact on patient adherence and quality of life. Patients undergoing interviews are randomly assigned to be interviewed by an HIV peer (TSR 3) or a pharmacy personnel (TSR 4) who will have received the same training for the project. The interviews will be conducted over 12 months or a maximum of 12 scheduled clinical visit (Whichever comes first). TSR 5: Use of data routinely captured in the pharmacy when clinicians substitute or change a patient's regimen, including documentation if such an event occurred on the prescription form and the cause of the event (i.e. toxicity, treatment failure, TB drug interaction, pregnancy, other).
Site(s)	Khunyang Sub-District Hospital Moi Teaching and Referral Hospital (modules 1-4)
Project Period	10/1/2012 - 12/31/2013
Funding Status	Funded - World Health Organization (WHO)

Direct Award (USD)	\$162,000
Update	The data is being analyzed.
Future Plans	We hope to have the summarized data and an initial draft of a publication on the project within the six months.
Publication(s)	Yes



Study Title	Phylogenetic Inference of Vertical versus Horizontal HIV Transmission among Adolescents in Western Kenya
Principal Investigator(s)	John Humphrey, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)
Description	<p>HIV is the leading cause of death among adolescents in sub-Saharan Africa. However, the identification and epidemiologic impact of different modes of HIV transmission within the adolescent population remain unclear. For adolescents newly diagnosed with HIV who also have an HIV-positive mother, it can be unclear whether the adolescent's infection occurred through vertical (i.e. mother-to-child) or horizontal (e.g. unprotected sex) transmission. Characterizing the contributions of vertical and horizontal transmission among adolescents in sub-Saharan Africa is important, as it can enhance understanding of the epidemiologic drivers of HIV infections and inform the implementation of tailored prevention and treatment strategies. The objective of this proposed pilot study is to identify methods to distinguish modes of HIV infections among Kenyan adolescents 10-19 years of age via the following specific aims: 1) examine the feasibility of phylogenetic inference to determine HIV infection through vertical versus horizontal transmission in adolescents, and 2) compare demographic, clinical and laboratory characteristics of vertical and horizontal predicted-infection in HIV-infected adolescents and their mothers. This study will be conducted at the Academic Model Providing Access to Healthcare (AMPATH) Center, a large HIV treatment and research facility in western Kenya, in collaboration with Indiana University and Brown University. We will enroll 20 HIV-infected adolescent-mother dyads in whom the mode of infection is uncertain and 10 HIV-infected child-mother dyads in whom vertical infection is highly likely. HIV viral load testing and pol sequencing will be performed for all subjects, including those with undetectable viral load by archived DNA genotyping. The epidemiologic linkage and clustering of HIV sequences among adolescent-mother dyads will be inferred phylogenetically and compared to (i) phylogenetic clusters of child-mother dyads that likely represent vertical transmission; and (ii) non-phylogenetic prediction of mode of infection, based on demographic and clinical risk factors elicited through a chart review and epidemiologic survey. We hypothesize that phylogenetic inference will differentiate vertically and horizontally-acquired infections, and that characteristics will differ between horizontally and vertically infected adolescents. This study will also add insight into the natural history of perinatally infected individuals who are diagnosed as adolescents, as current estimates of survival and disease progression are limited by an inability to confirm vertical infection in these individuals. This proposal will employ an innovative phylogenetics approach to</p>

	address a key priority for HIV research in sub-Saharan Africa, namely, the uncertain impact of vertical and horizontal transmission among adolescents living in HIV-affected families.
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	5/1/2017 - 4/30/2018
Funding Status	Funded - Indiana CTSI
Direct Award (USD)	\$20,000
Update	We have initiated recruitment.
Future Plans	Finish recruitment and begin the analysis.
Publication(s)	No



Study Title	'Point of Care CD4 testing for people who fail to engage in care after testing HIV positive'.
Principal Investigator(s)	Paula Braitstein, University of Toronto
Co-Investigator(s)	Samson Ndege, Moi University
Working Group(s)	Adult Medicine (AMWG)
Description	This supplement responds to unique aspects of Specific Aim 1 of the East Africa-International epidemiological Databases to Evaluate AIDS (IeDEA) grant, which seeks to 'Determine the short and long-term outcomes of adults and children along the entire spectrum of HIV care.' Our broad aim is to inform and evaluate the implementation of AMPATH's HIV treatment and prevention work by fully characterizing the cascade of HIV care in population-based settings and identifying gaps and opportunities for improvement. The primary objective of this study is to characterize the outcomes of HIV-positive adults who did not engage with HIV care following the catchment-wide HBCT campaign held from Dec 2009-Feb 2011 in Bunyala.
Site(s)	Bunyala Sub-county, could be others as well
Project Period	2/2/2015 - 2/1/2016
Funding Status	Funded - NIH
Direct Award (USD)	\$62,432
Update	The manuscript earlier developed was submitted and came back with comments from the reviewers. The comments are currently being addressed and is about to be resubmitted.

Future Plans	Over the next six months, the study team hope to resubmit the manuscript and hopefully be published.
Publication(s)	No

Study Title	Prevalence of cardiac disease in pregnancy among a population of antenatal patients at a tertiary care institution in western Kenya
Principal Investigator(s)	Dr. Bett Kipchumba, Moi Teaching and Referral Hospital
Co-Investigator(s)	Dr. Felix Barasa, Moi Teaching and Referral Hospital
Working Group(s)	Reproductive Health (RHWG)
Description	This is a cross-sectional study that seeks to determine the point prevalence of cardiac disease among 600 pregnant women receiving antenatal care at the Moi Teaching and Referral antenatal care clinic. The main objectives of the study will be to 1. Use focused echocardiography to as a screening tool evaluate cardiac structure and function; 2. Use focused echocardiography as a screening tool to determine the prevalence of cardiac disease among pregnant women attempting MTRH antenatal clinic; 3.Determine the proportion of pregnant women with cardiac disease who endorse clinical symptoms as a potential means to develop a screening tool; 4. Promote a case-finding culture for cardiac disease in pregnancy
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	2/5/2018 - 2/5/2019
Funding Status	Funded - Other Mt. Sinai Hospital
Direct Award (USD)	\$3,422
Update	A total of 601 participants were enrolled into the study. All participants had detailed medical and obstetric history data collected and a focused cardiac ECHO was performed. 15 participants were noted to have a cardiac lesion. Three participants who had severe lesions were referred for a joint review by a cardiologist and reproductive health consultant. The other participants were all referred to the cardiology clinic for continued review.
Future Plans	We hope to complete data analysis of the data collected and prepare the draft manuscript for review.
Publication(s)	No

Study Title	Prospective study of Lopinavir based ART for HIV Infected children Globally (LIVING study)
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Principal Investigator(s)	Prof. Winstone Nyandiko, Moi University
Co-Investigator(s)	Prof. Samuel Ayaya, Moi University
Working Group(s)	Pediatric (PRWG)
Description	<p>The study entitled Prospective study of Lopinavir based ART for HIV Infected children Globally (LIVING study) is an open-label, prospective, non-randomized, multi-centre, single arm phase IIIb clinical study. It is looking at a new formulation of lopinavir/ritonavir (LPV/r) that has been developed as pellets (very small tablets) that do not require refrigeration, do not contain alcohol and are expected to be more acceptable than LPV/r liquid for infants and young children. This implementation study is being carried out to provide supportive clinical data on the feasibility, effectiveness, safety, and tolerance, pharmacokinetics and acceptability of LPV based therapies in routine treatment setting.</p> <p>Primary objective: • Evaluate the effectiveness of LPV/r pellets in addition to AZT/3TC (or ABC/3TC) paediatric fixed dose combination (FDCs) tablet under routine treatment conditions in HIV infected infants and young children who cannot swallow tablets.</p> <p>Secondary objectives: • Document the safety of LPV/r pellets and AZT/3TC or ABC/3TC • Assess the population pharmacokinetics of LPV/r and NRTIs when administered as LPV/r pellets plus AZT/3TC or ABC/3TC • Measure adherence to the new formulation • Evaluate children acceptability of the LPV/r pellets and associated dual NRTIs as well as ease of use by the caregiver. (It has to be noted that this study is not intended to compare the treatment modalities, but rather to evaluate in field/programmatic conditions their individual effectiveness and safety in different settings of some of the most affected endemic countries.)</p>
Site(s)	Moi Teaching and Referral Hospital (modules 1-4) Uasin Gishu District Hospital
Project Period	6/1/2016 - 12/31/2018
Funding Status	Funded - Other Drugs for Neglected diseases initiative - Geneva
Direct Award (USD)	\$225,180
Update	Key accomplishments done over the past six months in the study, has been successful completion of study follow up for all the enrolled participants. We have managed to have all the exited patients transitioned back to the normal routine care in the program and all the required data has been uploaded in the database. Data cleaning is in progress and final analysis and findings are anticipated in this first quarter of the year 2019.
Future Plans	To finish cleaning the data and have the study findings completed and published. We hope to disseminate the findings back to the program.
Publication(s)	No
Study Title	Randomized, Phase II Trial of CHOP vs. Oral Chemotherapy with Concomitant Antiretroviral Therapy in Patients with HIV-associated Lymphoma in Sub-Saharan Africa

Principal Investigator(s)	Naftali Busakhala, Moi University
Co-Investigator(s)	Evangeline Njiru, Moi Teaching and Referral Hospital
Working Group(s)	Oncology (ORWG)
Description	Patients will be randomized to one of two treatment arms: either standard, intravenously delivered CHOP, delivered over six 3-week cycles or oral chemotherapy delivered over three 6-week cycles. Formal assessment of objective response (complete response [CR]/partial response [PR]/stable disease [SD]) will be performed following cycle 6 for CHOP and following cycle three for the oral regimen, and the patient will then be followed for relapse and survival. Patients found to have progressive disease (PD) at any time will come off study and receive the local standard of care treatment for their disease.
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	9/1/2015 - 8/31/2018
Funding Status	Funded
Direct Award (USD)	\$75,000
Update	The study has been closed due poor accrual.
Future Plans	We will continue with follow-up of the enrolled study participant.
Publication(s)	No



Study Title	SAFI (Stigma in AIDS Family Inventory) Validation Study
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)
Description	For families raising HIV-infected children in resource-limited settings, HIV/AIDS-related stigma shapes every aspect of the children's HIV management, from daily adherence to medication to decisions about pediatric HIV disclosure. We do not know the most effective strategies to reduce stigma for HIV-infected children and their families in resource-limited settings nor how to measure its effects on physical, emotional, or social outcomes. We want to learn more about how stigma affects families. As part of the HADITHI study, SAFI aims to develop and test a reliable, valid instrument to measure HIV/AIDS stigma as perceived, enacted, and internalized by Kenyan families with HIV-infected children. The specific aims for the SAFI validation study are to: Aim 1: Identify and modify H/A stigma questionnaire items for maximum reliability and content validity to measure perceived, enacted and internalized H/A stigma among Kenyan families with HIV-infected children. Aim 2: Assess the validity of the measures of perceived, enacted

	and internalized H/A stigma compared to independent construct measures including pediatric adherence to therapy and children's physical, psychological and social outcomes. Aim 3: Examine whether disclosure of a child's HIV status to the child reduces perceived, enacted, or internalized stigma for families with disclosed children compared to families with non-disclosed children. We thus propose assembling, adapting, and then validating measurement items for assessing the relevant domains of H/A stigma experienced by HIV-infected children and their caregivers in sub-Saharan Africa.
Site(s)	Burnt Forest Sub-District Hospital Chulaimbo Sub-District Hospital Khunyang Sub-District Hospital Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Mosoriot Rural Health Training Centre Turbo Health Centre Webuye District Hospital
Project Period	12/17/2013 - 11/30/2015
Funding Status	Funded - NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	\$567,828
Update	<p>We completed preliminary analyses for validating this stigma measurement questionnaire among children and their caregivers. These preliminary analyses were presented in a poster presentation at the AIDS meeting in July 2018 in Amsterdam, which was titled, 'Validation of an HIV/AIDS stigma measure for children living with HIV and their families.' In these analyses, we found that our stigma evaluations revealed a significant degree of HIV-related stigma with which families in western Kenya are coping. Among our cohort of 285 children and their caregivers, almost half of children reported that it was important to keep HIV status secret. About 10% reported delays taking their medicines so that others would not see. Between 7%-14% of children and caregivers reported feeling stress, anxiety, depression, and sadness due to child's HIV status. The stigma instrument showed high validity compared to emotional and behavioral outcomes, and our study adds to the limited literature on the reliability and validity of stigma measures for children living with HIV in sub-Saharan Africa. Test-retest reliability was high; responses by both children and caregivers were consistent from month 18 to 24. Both child and caregivers' stigma questionnaire item responses showed high construct validity with the Strengths and Difficulties Questionnaire (SDQ), while several caregiver stigma items also showed construct validity with the GHAC General Health domain, MEMS [®] adherence, and viral loads. The stigma measurement items showing the highest construct validity were:</p> <ul style="list-style-type: none"> • Experiencing discrimination • Feeling stressed and/or anxious due to HIV stigma • Feeling depressed and/or sad due to HIV stigma • Hopes for future changing negatively due to HIV <p>Thus, this initial study of the SAFI questionnaire reveals that HIV-infected children and their caregivers in this Kenyan cohort reported fearing or experiencing HIV stigma, with caregivers generally reporting higher levels of stigma. The SAFI instrument has utility for screening for HIV-related stigma among children and their families, as demonstrated by construct validity with primary criterion constructs. Utility may be improved by testing to reduce number of items for a short-form questionnaire, which will be some of the additional analysis work to follow. Screening for HIV stigma with a validated instrument may be an important clinical strategy to identify families who would benefit from counseling or other support services.</p>
Future Plans	Over the next six months, we hope to complete additional data analyses and disseminate our findings through published manuscripts. We currently have one manuscript, titled

	'Validation of an HIV/AIDS stigma measure for children living with HIV and their families,' submitted and under review at the journal AIDS and Behavior.
Publication(s)	Yes
Study Title	Spatial scales of Plasmodium falciparum generations; implications for elimination
Principal Investigator(s)	Andrew Obala, Moi University
Co-Investigator(s)	Wendy O'meara, Duke University
Working Group(s)	Public Health and Primary Care (PHPC)
Description	<p>Malaria is a major public health problem, with an estimated 198 million cases occurring world-wide in 2013. Effective strategies to reduce malaria transmission and disease have been highly successful leading to a 40% reduction in malaria cases in sub-Saharan Africa since 2000. It has been observed that infections cluster geographically and such clustering becomes more pronounced as transmission declines. The science of identifying 'hotspots' of infection or foci of transmission is a growing area that promises to help target interventions more effectively. However, it has not been shown whether infected individuals in close physical proximity (i.e. in the same household) are jointly infected due to simply living in a risky place, or because an infected household member is a risk factor for nearby susceptible individuals. If the former, then targeting hotspots should focus on reducing environmental risk factors in the area around a hotspot. If the latter, then interventions to identify and treat 'transmitters' will reduce transmission and reduce the incidence of new cases. Therefore, we need to understand the spatial scale of malaria transmission to predict the impact of community case detection and hotspot targeting. To shed light on this important issue, we propose two scientific objectives. First, we will measure the genetic relatedness of infections within the same household compared to the relatedness of infections at further distances. We will determine whether this relationship differs in fever 'hotspots' (geographic clusters of high fever incidence) and fever 'coldspots'. Parasite DNA from dried blood spots collected from a moderate endemic study area in western Kenya (approximately 15 km by 28 km encompassing more than 80 villages) will be sequenced at a moderately polymorphic gene using deep sequencing techniques. This will provide evidence for local, focal transmission if nearby infections are more closely related or will point to mixed transmission whereby infections only begin to differ as you reach the distance of mosquito flying ranges. Our second objective is to trap malaria mosquito vectors and identify infected mosquitoes. We will determine the source of the mosquito's infection by sequencing parasites in the mosquito salivary glands and comparing to parasite genotypes in humans. By doing so, we can find out whether infections are being transmitted at a household scale or transmission is 'well mixed' geographically and only limited by the range of the mosquito. If successful, this will be the first report of linking individual infections in mosquitoes to their human source. The ability to track infections from human to mosquito and back again would allow us to understand the dynamics and scale of transmission in a way that has not previously been possible. We expect to scale up this approach to larger populations in subsequent studies. These results will provide insight into the expected impact of interventions designed to target hotspots.</p>

Site(s)	Webuye District Hospital
Project Period	2/15/2017 - 1/31/2019
Funding Status	Funded - NIH
Direct Award (USD)	Not Reported
Update	As reported in the previous semiannual update, data and sample collection is ongoing. The Aim 2 field research team continues to visit enrolled households monthly to collect basic demographic and behavioral information including who slept in the home, how frequently bed nets were used, and to collect dried blood spot samples from each eligible member. On demand malaria diagnostic testing is also provided to household members with suspected malaria illness. Six private medicine outlets continue to provide free antimalarials to patients with confirmed malaria illness. Weekly mosquito collection at each enrolled household is also ongoing and mosquitoes collected from household continue to be sorted by genus and archived for dissection to identify infection in the salivary glands and abdomen. We shipped mosquito and DBS samples Taylor Lab in Duke for processing in August 2018. We received an amendment approval from IREC in December 2018. The protocol was amended to extend the period of observation to 24 months rather than 18 months, as it has been initially planned. We are extending the timeframe to continue to collect data on more malaria cases because malaria incidence was lower than anticipated in the study area over the past year. We also updated the actual number of active subjects to 286 in 36 households.
Future Plans	Study households will be visited weekly for entomology collections and monthly for survey and DBS collections through May 2018. Our focus during the next project period will be to complete all Aim 2 mosquito and DBS processing and matching of parasite haplotypes in mosquito and human samples collected during spring and summer 2018. We will also conduct preliminary analyses and draft manuscripts of main outcomes in the coming year. In fall 2018 we submitted new proposals for funding that would allow us to expand this work and cohort and we expect those proposals to be reviewed in the next few months.
Publication(s)	No



Study Title	Starting at the Roots: Using Human-Centered Design to Develop an Adolescent Pregnancy Program in Eldoret, Kenya
Principal Investigator(s)	EDITH APONDI, Moi Teaching and Referral Hospital
Co-Investigator(s)	Heather Millar, University of Toronto
Working Group(s)	Pediatric (PRWG), Reproductive Health (RHWG)
Description	Our proposed project involves using a participatory design process (human centred design) to create an adolescent-friendly antenatal care clinic in line with Kenya's National Adolescent Sexual and Reproductive Health Policy. The organizations coming together are AMPATH and IDEA Couture from Toronto, Canada. We are proposing to improve

	<p>adolescent pregnancy services in Uasin Gishu County with two objectives: Objective 1: Develop an adolescent pregnancy care intervention to improve maternal, newborn and child health care using a human-centered, participatory, iterative design process. Objective 2: Evaluate the impact of this adolescent pregnancy care program on uptake of services and pregnancy outcomes. By employing a human-centered design strategy, local participation in and ownership of the design outcome will enable a more effective and sustainable approach to the development of a care program for pregnant adolescents. This program will address current barriers to care utilization and outcomes as they relate to the experience of pregnancy at the patient and provider level. In doing so, this approach will lead to overall improvements in antenatal care attendance, facility delivery, maternal and neonatal outcomes, postnatal care attendance, exclusive breastfeeding, and family planning uptake.</p>
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	8/1/2018 - 7/31/2020
Funding Status	Funded - Other SICK KIDS, TORONTO
Direct Award (USD)	\$20,000
Update	<p>Between 24th Sept - 5th Oct 2018 we carried out the Human Centred Design (HCD) thinking workshop with a design team made up of 8 members. This workshop, which constituted Phases 1 and 2 of the study, was facilitated by a representative from IDEA Couture, Canada. The workshop provided insights and knowledge on how to develop an adolescent friendly ANC clinic that is user initiated. This includes a Journey Map describing the journey of an adolescent from conception to 2 years postpartum, an intense picture of her social and economic struggles, including from school, her parents, her peers, and her neighbours. Healthcare provision is often perceived as rough and unfriendly. Several general ideas were generated, including a healthcare provider Empathy Training Program, peer support and mentor mother groups, community outreach, skills building sessions, and interior design for the clinic. The protocol for these is being prepared so as to submit an amendment. Phase 3 was the two prospective cohort studies. Enrolment began at MTRH on October 25th, but it has been slow. In spite of 90 teens presenting to clinic only 19 have consented to participate. We are thus re-considering our qualitative data source and may review the existing registers instead.</p>
Future Plans	<p>Over the next 6 months, we intend to - submit an IREC amendment (first order of business in order to research and evaluate clinical care innovations) - create information booklets, pamphlets, and flipcharts for healthchare providers and teens for use in the clinic - pilot/pitch the information sources to groups of teens - create an empathy training protocol - create an adolescent clinic care flow diagram and protocol - create a peer support implementation strategy and include this in routine adolescent care - plan a skills building workshop in April when the teens are not in school - pitch the suggested clinical care program changes to the care staff for input and further planning - build an adolescent register that is reportable to the DHIS - work with POC to bring the MCH registers online - conduct further surveys and interviews with adolescents to understand their experiences - establish a baseline data set to compare adolescent outcomes before and after the care program is developed - introduced acceptability and feasibility tools to the study plan</p>

Publication(s)	Yes
Study Title	Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS)
Principal Investigator(s)	Constantine Akwanalo, Moi University
Co-Investigator(s)	Jemima Kamano, Moi University
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)
Description	<p>Hypertension is a major risk factor for cardiovascular disease (CVD), and 80% of global mortality due to CVD occurs in low- and middle-income countries (LMICs). In LMICs, lack of coordination between different levels of the health system threatens the ability to provide the care necessary to control hypertension and prevent CVD-related morbidity. Strong referral networks have improved health outcomes for chronic disease in a variety of settings. Health information technology (HIT) and peer-based support are two strategies that have improved care coordination and clinical outcomes. However, their effectiveness in strengthening referral networks to improve blood pressure (BP) control and reduce CVD risk in low-resource settings is not known. The Academic Model Providing Access to Healthcare (AMPATH) partners with the Kenya Ministry of Health (MOH) to provide care for non-communicable chronic diseases (NCDs), including hypertension and CVD, at all levels of the health system. The Kenya MOH Health Sector Referral Strategy 2014-2018 calls for improving the referral system at every level of the health system. AMPATH has piloted both HIT and peer support for NCDs, and both strategies are feasible in this setting. However, the impact of integrating HIT and peer support to strengthen referral networks for hypertension control is not known. The objective of this proposal is to utilize the PRECEDE-PROCEED framework to conduct transdisciplinary, translational implementation research focused on strengthening referral networks for hypertension control. The central hypothesis is that HIT integrated with peer support will be effective and cost-effective in strengthening referral networks, improving BP control, and reducing CVD risk among patients with hypertension in western Kenya. We hypothesize that HIT and peer support will synergistically address barriers to hypertension control at the patient, provider and health system levels. We further hypothesize that changes in referral network characteristics may mediate the impact of the intervention on the primary outcome, and that baseline referral network characteristics may moderate the impact of the intervention. To test these hypotheses and achieve the overall objective, we propose the following specific aims: Aim 1: Conduct a baseline needs and contextual assessment for implementing and integrating HIT and peer support to strengthen referral networks for hypertension control, using a mixed-methods approach, including: observational process mapping and gap assessment; baseline referral network analysis; and qualitative methods to identify facilitators, barriers, contextual factors, and readiness for change. Sub-Aim 1.1: Use data from the baseline needs and contextual assessment to develop a contextually and culturally appropriate intervention to strengthen referral networks for hypertension control using a participatory, iterative design process. Conduct pilot acceptability and feasibility testing of the intervention. Aim 2: Evaluate the effectiveness of HIT and peer support for hypertension control by conducting a two-arm cluster randomized trial comparing: 1) usual care vs. 2) referral networks strengthened with an integrated HIT and peer support</p>

	<p>intervention. The primary outcome will be one-year change in systolic blood pressure (SBP) and a key secondary outcome will be CVD risk reduction. Sub-Aim 2.1: Conduct mediation analysis to evaluate the influence of changes in referral network characteristics on intervention outcomes, and a moderation analysis to evaluate the influence of baseline referral network characteristics on the effectiveness of the intervention. Sub-Aim 2.2: Conduct a process evaluation using the Saunders framework, evaluating key implementation measures related to fidelity, dose delivered, dose received, recruitment, reach, and context. Aim 3: Evaluate the incremental cost-effectiveness of the intervention, in terms of costs per unit decrease in SBP, per percent change in CVD risk score, and per disability-adjusted life year (DALY) saved. This research project will add to the existing knowledge base on innovative and scalable strategies for strengthening referral networks to improve control of NCDs in lower-MICs. If proven to be effective, it has the potential to be a scalable model for other low-resource settings globally.</p>
Site(s)	Burnt Forest Sub-District Hospital Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Mosoriot Rural Health Training Centre Turbo Health Centre Webuye District Hospital
Project Period	9/1/2017 - 5/31/2018
Funding Status	Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	\$268,469
Update	<p>We have continued to have all Investigator conference calls which are being held monthly thus the last Tuesday of the month and weekly calls which are held every Tuesday. In regards to personell, we hired Programmer to assist in the development of our Health Information Technology Tool and an administrative intern to assist with coordinating DSMB activities. Our team Completed the training for Human centered design approach for social innovation as preparation to design the study's intervention. With regards to ethical approvals, we recieved our NACOSTI approval and IREC continuing review for the year 2019. Our final Informed consent(s) and assent forms: English and Swahili consent forms for KIIs, Mabaraza, FGDs, Survey and Trial approved by IREC that were used for data collection of aim one activities. We also recieved approval from IREC to have our Research Assistants added to the study team for data collection. Before we started our aim one activities, we conducted pilot testing for aim one activities to access feasibility and usability of the tools.This was then followed by data collection for aim one activities; observation process mapping, Referral network analysis- 128 participants , Focus Group discussion 75 participants both patients and clinicians, Mabaraza 186 participants, Key Informant Interviews 32 participants and Observation process mapping 16 participants which is now complete. We had a total of 436 Participants who were enrolled in the study for our aim one activities. Currently we are ongoing with data analysis. In preparation for aim two we have put together a team of experienced patients, providers, and other clinic staff who will participate in a human-centered design process to create a basic model for the program intervention which will be evaluated by the trial. We submitted our draft protocol to NHLBI/CTRIS for review and the list of proposed DSMB members and waiting for feedback. We had two of our investigators attend the TREIN/Hy-TREC consortium meeting in Nepal in September. In addition we send our project coordinator to participate in the 1st Implementation Science School in Brazil as a way of capacity buiding our team</p>

Future Plans	<p>if¼ Plan for annual all investigators meeting and Translation Research Capacity Building Initiatives in Lower Middle Income Counties /Hypertension Outcomes for T4 REsearch within Lower Middle-Income Countries (TREIN/Hy-TREC) together with NHLBI to be held on 14th-16th March 2018 and 18th-20th March respectively. if¼ Finalize Protocol after Comments/input from NHLBI/CTRIS provided and prepare amendments submission to institutional ethical review. if¼ Continue with the development of our papers and publications i.e STRENGTHS Methods paper, Referral Networks Systematic review and Stakeholder engagement paper. if¼ Complete creation of a basic model for the program intervention through human-centered design process and manual of operating procedures for the study. if¼ Have the DSMB constituted, and DSMB Charter approved. if¼ Submit our Protocol to DSMB for review and have feedback. If there are required changes, review made and re submit, and wait for approval before it's sent for approval to IRB and IREC. if¼ Hiring and training of peer navigators and also clinicians in study sites trained on referral activities if¼ Complete transcriptions coding and analysis of all the qualitative portions of the study which include: Observational process mapping and gap assessment, FGDs, KIIs and Mabaraza and referral network survey. if¼ Complete data collection for our Sub aim 1.1 and analysis. if¼ Conduct pilot testing to assess for feasibility and acceptability which will see the roll out the study's intervention.</p>
Publication(s)	Yes



Study Title	Study of Newly Diagnosed Kaposi's Sarcoma
Principal Investigator(s)	Dr. Naftali Busakhala, Moi University
Co-Investigator(s)	
Working Group(s)	Oncology (ORWG)
Description	To achieve our scientific objectives, we will identify a community-based sample of HIV-infected adults with newly diagnosed KS. We propose to use a rapid case ascertainment (RCA) approach to quickly evaluate patients suspected to have KS. RCA refers to the swift and thorough evaluation of a patient with a new disease diagnosis. We note that RCA does not refer to a new technique for making diagnoses of KS, but it instead refers to the process of rapidly assessing status and extent of disease once the diagnosis has been made. It is most useful for diseases that are potentially rapidly progressive and potentially fatal. It involves the establishment of a system whereby when a diagnosis is made, a central team is made aware, and the affected patient is rapidly evaluated. It has been mainly used in the cancer field to facilitate epidemiologic research for establishing population-level incidence and stage of cancer at time of diagnosis.
Site(s)	
Project Period	9/1/2015 - 8/31/2019
Funding Status	Funded - NIH

Direct Award (USD)	\$750,186
Update	As end of December 2018, the Study managed to see 309 encounters of which 153 Cases have been enrolled. 104 participants are currently in active follow-up, while 49 are deceased. All Deaths have been documented. We have so far done 330 total follow-ups. The study has also enrolled 83 Controls matched to 10 Cases.
Future Plans	The study continues to enroll cases and controls over the next several months. Follow-up of cases will also continue as stipulated in the protocol.
Publication(s)	No



Study Title	Syndemics
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Suzanne Goodrich, Indiana University
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)
Description	This project uses a syndemic (two or more linked epidemics that synergistically interact to effect outcomes) approach to understand how mental health disorders and substance use shape engagement and retention in care and clinical outcomes among HIV+ individuals enrolled in three leDEA clinics in Kenya (AMPATH, FACES) and Uganda (Mbarara). Despite the potential negative implications of mental health disorders and substance use on the HIV epidemic, little is known about the prevalence of these conditions among HIV+ clinic attendees in sub-Saharan Africa or the subsequent effect on their clinical outcomes. More information is needed to guide the development and delivery of care to keep these high risk individuals retained at every step of the HIV care cascade and to provide the quantitative data needed to prioritize further diagnostic and treatment interventions. Specific Objectives: AIM 1: Identify community and clinic-based services available for treatment of substance use and mental health disorders in the four research sites. AIM 2: Determine the prevalence of substance use (drug and alcohol) and mental health disorders in patients enrolling into care. AIM3: Assess the impact of substance use, mental health disorders and dual diagnoses on patient adherence and retention in the cascade AIM 4: Conduct qualitative interviews with a sub-sample of cohort patients to explore access, use, and experiences with substance use and mental health services.
Site(s)	Moi's Bridge Health Centre
Project Period	12/17/2018 - 12/17/2020
Funding Status	-
Direct Award (USD)	

Update	Enrollments for this study begun on 17th December 2018. Six participants were enrolled before Christmas break. There were no major challenges this week.
Future Plans	By the end of June this year, an enrollment target of 215 participants is expected to have been achieved.
Publication(s)	
Study Title	The Role of PD-1 Pathway and Tissue Microenvironment in HIV-Kaposi Sarcoma and Endemic Kaposi Sarcoma Cohort in Western Kenya
Principal Investigator(s)	Patrick Loehrer, Indiana University
Co-Investigator(s)	Asirwa Chite, Indiana University
Working Group(s)	Oncology (ORWG)
Description	<p>Even before the HIV pandemic, equatorial Africa had among of the highest KS incidences in the world. In this area, 'endemic KS' (the term given to the HIV-unassociated form of KS) was manifested primarily as indolent localized disease in men and represented 4 to 10% of adult cancers. Although sub-Saharan Africa was already a hotbed for KS, the clinical manifestations and impact of the disease dramatically changed with the onset of the HIV epidemic in the 1980's when the incidence of KS and other HIV associated malignancies exploded. The advent of anti-retroviral therapy (ART) improved prognosis of HIV-associated KS, but survival remains unacceptably poor in low to middle income countries(LMIC). A recent Cochrane review on late stage KS showed that in 6 studies in which chemotherapy was added to HAART, no survival benefit was seen above that of ART therapy alone nor amongst the different types of chemotherapy. Endemic KS, while less likely to progress to visceral disease, leaves patients with profound functional disabilities often requiring treatment. Because this population is HIV negative, ART is not used. Research that leads to a better understanding of the biology of KS must be explored to provide alternative therapies to ART and standard chemotherapy. Based upon preliminary data from UCSF which supports the role of PD1 pathway and tissue micro-environment in KS, we propose to conduct a prospective analysis on two patient cohorts. Cohort 1: KS in HIV-infected subjects who have failed at least one KS-directed chemotherapeutic intervention; and Cohort 2: KS in HIV-negative patients (i.e. endemic KS) who have failed at least one KS-directed chemotherapeutic intervention.</p>
Site(s)	
Project Period	10/1/2015 - 9/30/2018
Funding Status	Funded - NIH
Direct Award (USD)	\$158,406

Update	The study is open for enrollment; we have managed to enroll 57 study participants. We have been able to successfully ship KS biopsy samples to Infectious Disease Institute Labs in Kampala, Uganda for analysis of the PDL1; all the samples shipped have been analyzed.
Future Plans	We hope to complete the enrollment of the remaining study participants within the next 6 months.
Publication(s)	No

Study Title	Understanding Barriers And Facilitators Predicting Linkage To Group-Based Diabetes And Hypertension Care In Rural Western Kenya: A Mixed-Methods Study
Principal Investigator(s)	Dan (Tina) Tran, Purdue University
Co-Investigator(s)	Constantine Akwanalo, Moi Teaching and Referral Hospital
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)
Description	1. Aim 1: Identify patients who screen positive for diabetes and/or hypertension but do not link to group- based care 2. Aim 2: Evaluate characteristics predicting linkage to group-based care 3. Aim 3: Explore barriers and facilitators influencing linkage to group-based care Our study has completed recruitment (n=105). We have also completed aim 1 of the study. We are in the process of analyzing our data to achieve aim 2 (predictors for linkage to group-based care). Aim 3 activities are set to take place in August 2018. The study will complete by the end of August 2018.
Site(s)	Angurai Health Centre
Project Period	7/1/2017 - 8/31/2018
Funding Status	Funded - NIH - National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Direct Award (USD)	\$10,000
Update	Our team completed the proposed study on August 31, 2018. Quantitative data (for Aims 1 and 2) is undergoing analysis. We recently completed transcription and translation for our qualitative portion of the study (Aim 3), and qualitative data analysis has already taken place.
Future Plans	February 2019: complete qualitative data analysis (n=105) March 2019: complete quantitative data analysis (14 transcripts) April-June 2019: triangulate context, qualitative data and quantitative data to do a formal write-up and dissemination of the study results
Publication(s)	No

Study Title	Using Narrative Films to Combat HIV Stigma: Perspectives from HIV-Infected Adolescents and their Caregivers
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)
Description	The objective of this pilot study is to assess the cultural acceptability, credibility, and quality of narrative films created to illuminate the experiences of HIV-infected adolescents coping with HIV-related stigma, as well as to identify ideal viewing audiences and potential settings in which to show these films. The long-term goal of this study is to better understand how the HADITHI films can be implemented within communities in western Kenya in a culturally-appropriate and sensitive manner. The specific aims are: Aim 1: To explore the perspectives of HIV-infected adolescents and their caregivers on the cultural acceptability, quality, credibility, potential audiences, and potential settings for showing the four HADITHI narrative films addressing adolescents' experiences with HIV stigma in Kenya. Aim 2: To describe the impact of the HADITHI films on the attitudes, beliefs, and knowledge about HIV and HIV-related stigma held by HIV-infected adolescents and their caregivers. Aim 3: To evaluate whether viewing the HADITHI films alter experienced, perceived, or internalized stigma reported by HIV-infected adolescents and their caregivers.
Site(s)	Moi Teaching and Referral Hospital (modules 1-4)
Project Period	4/1/2017 - 4/30/2018
Funding Status	
Direct Award (USD)	
Update	Over the last six months, analysis for both quantitative and qualitative data has been going on. In preliminary analyses of the quantitative data, participants performed significantly worse on the Genberg Discrimination questions immediately after watching the films. This likely indicates that they more strongly recognize and identify the extent to which persons living with HIV in the community are experiencing stigma after being sensitized by the films. However, they show significant improvement from baseline in Discrimination, Equity, and Total Genberg scores at 3 month follow-up. When you look at adolescents and caregivers separately, it seems that the improvements at follow-up are primarily attributable to improvements in caregivers' scores. The mean differences in scores for adolescents at follow-up are smaller in magnitude and not statistically different. Given that caregivers' mean scores were lower at baseline, though, caregivers had a greater potential for improvement than adolescents. In addition, we used the preliminary results from this study to shape the implementation of our new R21 grant which will use the stigma films as part of a teacher training intervention to modify teachers' knowledge, attitudes, and beliefs about HIV through training sessions with primary and secondary school teachers in Uasin Gishu county.

Future Plans	Within the next six months, we plan to complete qualitative and quantitative data analyses and present our findings through abstracts and manuscripts.
Publication(s)	No
Study Title	Validating an Integrated Community Based Strategy of Peer Support in Pregnancy and Infancy
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Working Group(s)	
Description	This project seeks to address the inequities that drive maternal and infant mortality in sub-Saharan Africa by validating an intervention that builds community empowerment in MNCH and facilitates processes of accountability using CHV-led women's groups (Chamas). Chama cha MamaToto (chamas) is a peer-support model that groups together pregnant women in the same community. Central to our approach is the integration of health, social and financial literacy education with a savings/loans program. Chamas are designed to improve MNCH by generating positive peer support for women to advocate for themselves and account for the care they receive. We have combined best practices from women's health groups and microfinance programs to design an integrated service delivery platform that is low-cost, self-sustaining and self-managed. Its a randomized cluster trial to be implemented in 4 sub counties in Trans Nzoia county where a cluster is a community unit.
Site(s)	Cherangany Health Centre Saboti, Kiminini, Cherangani and Kwanza Sub counties
Project Period	10/1/2017 - 10/1/2018
Funding Status	Funded - Grand Challenges Canada, ABBVIE
Direct Award (USD)	\$197,510
Update	Chamas (groups) in TransNzoia were rolled out in 4 sub counties in March 2018 and have gained stability. We have 50 groups in the 37 intervention community units and have had at least 10 meetings per group. Our target was for the groups to have met at least 10 times before graduating into Cycle 2 (2nd Year) which has been achieved. Currently we have 860 women that have attended at least one Chama meeting and out of these, 623 women are consistent in attending Chamas. We are also working with 93 Community Health Volunteers (CHVs) and 77 Community Health Extension Workers (CHEWs) are involved. Each Chama group has an official for the Group Integrated Savings and Health for Empowerment (GISHE). These officials (n=108) received training on record keeping, money counting and group account management. We have been able to meet the control CHVs twice; the first meeting was to give them control names for tracing and the second meeting was for the feedback on tracing. They managed to trace 924 women and are engaging them as per the Ministry of Health community strategy so that we don't lose them. We have also had six review meetings with the Sub County Health Management

	Teams (SCHMTs) since launching Chamas to strengthen our partnerships and with the local NHIF team to ensure that our Chama women can access health services using Linda Mama cards. Officials from NHIF offices and our team have formed a strong coalition and we are working to ensure all Chama women have obtained this coverage. Chamas have now become stable and we have been able to form two male groups called BabaToto.
Future Plans	We hope to continue bi-weekly Chama sessions and hoping to complete the first Cycle in April 2019 and begin our end line data collection from May 2019 (Which was mistakenly indicated as end line assessment in the previous report. We also aim to start the data cleaning process within the next 6 months.
Publication(s)	Yes



Study Title	Vincristine Optimization In Kenyan Children With Cancer
Principal Investigator(s)	Jodi Skiles, Indiana University - Purdue University in Indianapolis (IUPUI)
Co-Investigator(s)	Festus Njuguna, Moi University
Working Group(s)	Oncology (ORWG), Pediatric (PRWG)
Description	In resource-limited settings, access to chemotherapeutic agents is confined to a few therapies. Vincristine (VCR) is a mainstay in such settings due to its low cost and lack of myelosuppression, however, little is known regarding its disposition and true optimal dosing, especially in the pediatric population. Negative clinical outcomes, such as serious side effects due to drug overdosing or lack of efficacy due to sub-therapeutic dosing, may result. VCR is associated with highly variable cumulative dose-dependent peripheral neuropathy (VIPN). While pediatric oncology patients in the U.S. who receive VCR experience significant VIPN and excellent disease outcomes, Kenyan children with cancer who receive VCR experience little to no VIPN, highlighting the opportunity for optimization of VCR in this population. While there are clearly multiple factors that contribute to poor disease outcomes in Kenya, suboptimal dosing of VCR is the piece we aim to address in this study. The biological basis for the minimal VIPN we have observed in Kenyan children is uncertain but includes such things as genetic differences in VCR pharmacologic pathways as well as genetic variability in susceptibility to neuropathy. This gap in knowledge provides a clear opportunity to optimize use of this medication in Kenyan children with cancer and evaluate genetic associations with VIPN in order to personalize this medication for individual children once VCR dosing is augmented. Preliminary data has shown that Kenyan children with cancer (n=100) experience minimal VIPN. Despite the negligible neuropathy observed, subclinical VIPN can be detected using a very detailed, non-invasive assessment tool that we developed for detecting even very minor toxicity. Utilization of this tool in Kenyan children allowed us to identify an association between VIPN severity, CYP3A5 genetic polymorphisms, and an individual's ability to metabolize VCR, such that children with an allelic variant of CYP3A5 that results in a high VCR metabolizer phenotype experience less VIPN. Variability in VCR response and toxicity may be particularly significant within Africa, where human genetic variability is greatest, and where ~90% of Kenyans patients were fast VCR metabolizers. In one recent study, pharmacokinetic (PK) variability was linked to overall survival in children

with acute lymphoblastic leukemia (ALL), such that children with faster VCR clearance had a greater chance of relapse. If VCR disposition, response, and neurotoxicity are linked, it may be possible to optimize dosing based on easily obtained knowledge of genetic polymorphisms responsible for disposition and subsequent neurotoxicity variability. This research is of particular importance in Africa, where VCR is one of few available anticancer drugs and is used in the treatment of over half of all cancer patients. Furthermore, given that most Kenyan children are CYP3A5 high expressers and thus VCR fast metabolizers, they may tolerate and benefit from higher doses of vincristine than are conventionally used in the U.S. and Africa. This proposed prospective study will be conducted in two parts, which will both enroll pediatric patients age 1-18 years with newly diagnosed acute lymphoblastic leukemia or nephroblastoma. Part I will be a VCR dose escalation phase (in combination with routine multi-agent chemotherapy) to determine the maximum tolerated dose of VCR in a population of Kenyan children with cancer. Part II will utilize the maximum tolerated dose of vincristine determined from Part I in place of the standard dose of VCR in combination with routine multi-agent chemotherapeutic protocols. DNA and pharmacokinetic samples will be collected on all subjects to allow determination of biomarkers of development of VIPN. Subjects will be monitored closely for development of toxicity with laboratory assessments as well as detailed neuropathy assessments. The specific aims (SA) for this proposal are as follows: SA1: To determine the maximum tolerated dose (MTD) of VCR administered in conjunction with conventional chemotherapy in cohorts of Kenyan children with ALL or Wilms tumor receiving VCR as part of their anti-cancer treatment. SA2: To validate our pilot study findings and to further evaluate the association between common or functional variants in genes in the vinca alkaloid pharmacologic pathway and across the human genome with VCR PK, VIPN, and disease response in the same populations as SA1. SA3: To further develop our pharmacologic prediction model of VIPN describing associations between pharmacogenetic, pharmacokinetic, and clinical biomarkers and carefully characterized VIPN in the same population of patients as SA1. SA4: To evaluate the validity and reliability of several chemotherapy-induced peripheral neuropathy (CIPN) measurement approaches when used to quantify neuropathy and associated neuropathic pain in Kenyan children receiving vincristine.

Site(s)

Moi Teaching and Referral Hospital (modules 1-4)

Project Period

2/3/2014 - 1/31/2018

Funding Status

Funded - NIH - National Cancer Institute (NCI) NIH - Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Direct Award (USD)

\$103,254

Update

Recruitment to this study began in February 2014. In September 2015, we observed our first dose-limiting toxicity at Dose Level 3 manifesting in the form of cranial nerve neuropathy presenting as diplopia. An additional 3 subjects were enrolled at Dose Level 3 in accordance with the protocol. Unfortunately, it was noted that patients in Dose level 3 had a statistically significantly higher rate of death compared to historical controls. While it is not clear whether the cause of the increased rate of death is related to the VCR dose escalation, out of concern for patient safety, enrollment to Dose Level 3 was suspended and a prompt report was submitted to the IRB and IREC. All patients who were previously receiving dose level 3 were dose-reduced to Dose Level 2. In accordance with the protocol, an additional 3 subjects were enrolled on Dose level 2 to ultimately define

	Dose level 2 as our MTD. No further dose-limiting toxicities have been observed since that time. The last enrolled subject completed therapy in December 2017. Biospecimens have been analyzed. Data analysis is complete. Manuscript is being drafted.
Future Plans	Publication of manuscript
Publication(s)	No



Study Title	Viral Suppression among HIV-infected Children and Caregivers in Western Kenya
Principal Investigator(s)	John Humphrey, Indiana University
Co-Investigator(s)	Edith Apondi, Moi University
Working Group(s)	Pediatric (PRWG)
Description	The suppression of HIV viral load through administration of antiretroviral therapy is a key objective for all HIV-infected patients. However, optimal approaches to family-centered HIV management are not well known, particularly when children and their caregivers are both in need of HIV treatment. In order to better understand viral suppression among HIV-infected children who also have HIV-infected parents or caregivers, we will conduct a retrospective review of all HIV-infected child-caregiver dyads receiving HIV care at the AMPATH program in western Kenya from January 2015 to December 2016. We will achieve the following specific aims: (1) Characterize viral suppression in HIV-infected children and in their HIV-infected caregivers; (2) Estimate the association between viral non-suppression in children and their HIV-infected caregivers; (3) Identify factors associated with viral non-suppression among HIV-infected child-caregiver dyads. The knowledge gained from this study will inform our understanding of the management of HIV in HIV-affected families. This may lead to better strategies to improve the delivery and monitoring of antiretroviral therapy in these families in the future.
Site(s)	
Project Period	1/1/2017 - 12/31/2017
Funding Status	Funded - Indiana University - Center for AIDS Research
Direct Award (USD)	\$12,500
Update	We have completed the analysis and submitted the paper to JIAS. The manuscript is under review.
Future Plans	Publish the manuscript.
Publication(s)	No



Study Title	Virologic Treatment Failure and Drug Resistance in HIV-Infected Kenyan Children (RESPECT) study.
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)
Description	<p>This study will involve retrospective and prospective analysis of blood sampling from patients enrolled in a previous NIH-funded (Vreeman, 1K23MH087225) randomized controlled trial titled, 'Evaluation of a Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy' or the 'CAMP study.' That was conducted between May 2010 and October 2013. This particular cohort provides an unprecedented and timely opportunity to characterize longitudinal processes that lead to treatment failure and drug resistance development among HIV-infected children in a sub-Saharan African setting, and its translation into evidence-based interventions. The specific aims of this study are:</p> <p>Specific Aim 1: Determine prevalence of viral failure and examine resistance mutations among a retrospective study cohort of 685 prenatally HIV-infected Kenyan children on 1st-line ART. Specific Aim 2: Investigate associations between specific adherence patterns, ART drug levels and other demographic and clinical factors, with viral failure and drug resistance. Specific Aim 3: Study long-term immunologic, virologic and drug resistance outcomes and their associations in prospectively re-enrolled study participants Specific Aim 4: Enhance analyses of viral failure, drug resistance accumulation and associated demographic and clinical factors by examining the longitudinal banked samples available for a subset of the study cohort (n=327). Specific Aim 5: Develop a data-driven intervention algorithm to identify children at risk for viral failure and resistance.</p>
Site(s)	Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Webuye District Hospital
Project Period	8/2/2016 - 7/31/2020
Funding Status	Funded - NIH
Direct Award (USD)	\$613,511
Update	<p>We have completed most of the drug resistance testing (DRT) of the stored samples for the cohort of children from the prior CAMP studies. Preliminary analyses of DRT data and their association with adherence data were presented in two abstracts at the AIDS meeting in July, 2018 in Amsterdam. This abstract described results from 207 children who were enrolled in CAMP Phase Two that followed children for six months in 2011-2012. Using caregiver reported adherence, MEMS electronic dose monitoring, and ART drug levels, we found significant adherence issues. While only 21% of caregivers reported their children missing doses in the past 30 days, 45% were <90% adherent on MEMS, 31% had treatment interruptions, and 33% experienced treatment failure. There was high viral resistance in this cohort, with 81% having intermediate-high resistance to >1 drug on genotyping and 75% having high resistance to potential second-line ART (including tenofovir, etravirine, and raltegravir.) In addition to presenting these preliminary results, over the last six months we completed participant recruitment and follow up. We enrolled a total of 506 for the prospective assessments of participants that include blood</p>

draws for viral load levels, CD4 counts, drug levels and resistance testing. A total of 1779 specimens have been shipped to Dr. Rami Kantor's laboratory at Brown University for drug resistance testing. Three-month follow-up with MEMS electronic dose monitoring was completed with a subset of 130 participants. These MEMS adherence data are in the process of being cleaned and prepared for analysis. We completed 7 verbal autopsies to assess cause of death among those found to have died since the original study enrollment. We have received all current viral load and CD4 count levels from AMRS and the Kantor lab to evaluate the participants' immunologic, virologic and drug resistance outcomes. Analyses of viral suppression, adherence, and drug resistance among this cohort is ongoing. We hope to include these in a number of upcoming abstracts and manuscripts in 2019. As analyses are ongoing, we continue to share drug resistance results with the AMPATH clinics and clinicians.

Future Plans

In the next 6 months, we plan to: Send the remaining blood samples for all participants to Brown University for phenotyping and resistance testing; Clean all study data, including retrospective data from AMRS and study databases, MEMS adherence data, and all follow-up data so that analyses can begin.

Publication(s)

Yes

Appendix A: Bibliography

The following bibliography includes AMPATH research publications that were published between January 1, and December 31, 2018. A complete bibliography of AMPATH research publications published since 1989 along with full text articles is available online through the AMPATH Research Member Access Portal.

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