SEMI ANNUAL RESEARCH REPORT

January – June 2019

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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Please visit the AMPATH Research Program website to learn how our research programs are helping improve the health of the Kenyan people.

https://www.ampathkenya.org/research

Contents

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. A strategic planning meeting is scheduled for September 2019 to revisit the vision, mission, values and goals of the program. The revised outputs from the meeting will be available for the Semi Annual Report July – December 2019.

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 beginning of the New Year brought a change in leadership for the research program and AMPATH is pleased to announce Dr. Kara Wools-Kaloustian as the new co-director of research (North America). Wools-Kaloustian has dedicated her career to advancing global health and has been associated with AMPATH since 1991. Please see the Appendix B for AMPATH's announcement of Wools-Kaloustian's appointment.

The AMPATH Research Program Office conducted a SWOT analysis of 171 stakeholders in preparation to the 2019 Research Strategic Planning Meeting. Please find the detailed summary at the end of this report under 2019 AMPATH Research SWOT Analysis Survey Report

For the first half of 2019, the AMPATH Research Program's publication rate realized a record setting publication rate with articles published in journals around the world. AMPATH's research bibliography may be found at the end of this report.

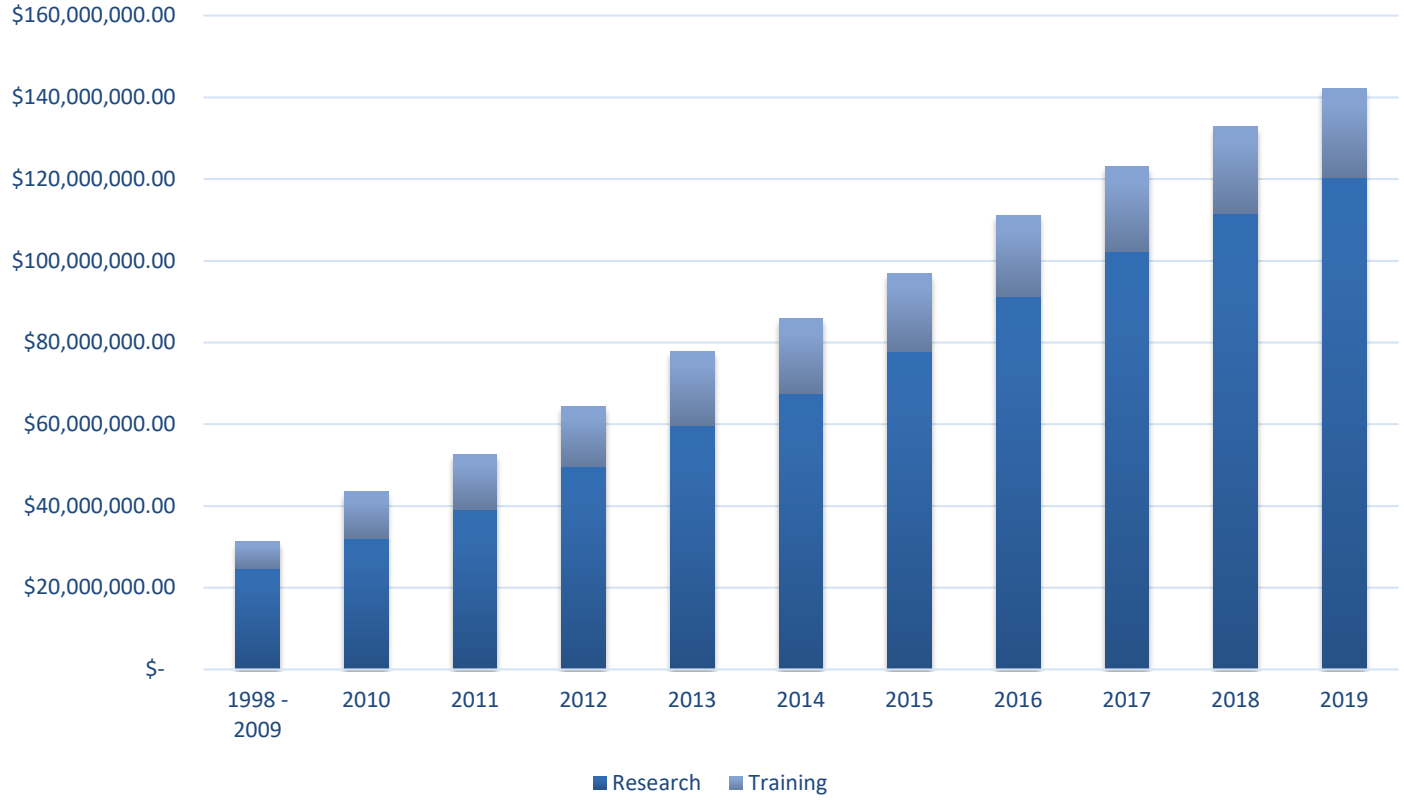
AMPATH investigators also received $6.1 million in new awards in the first six months of 2019. The new and existing awards pushed AMPATH's cumulative total of research and training awards to more than US$142 million.

The following report provides a snapshot of AMPATH's research activities from 1 January – 30 June 2019. It includes updates and progress from 56 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. Each report was provided by the project's Principal Investigator or their designee and, with the exception of formatting, are presented here largely unedited.

GRANTS

Investigators reported more than US$ 6.1 million in new awards in the first six months of 2019. This increased AMPATH's cumulative total of research and training awards to US$142.1 million since the start of the program in 1998 (See Figure 1).

Figure 1: Cumulative AMPATH Research & Training Grants Awarded by Year
($142.1 Million in Direct Costs in USD)



Pilot Awards

AMPATH collaborative research teams received $70,000 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 2019 (See Table 1). This year's awardees add to the five awardees from 2018, the six awardees from the 2017 competition, and the three studies awarded pilot grants for AMPATH related research in 2016.

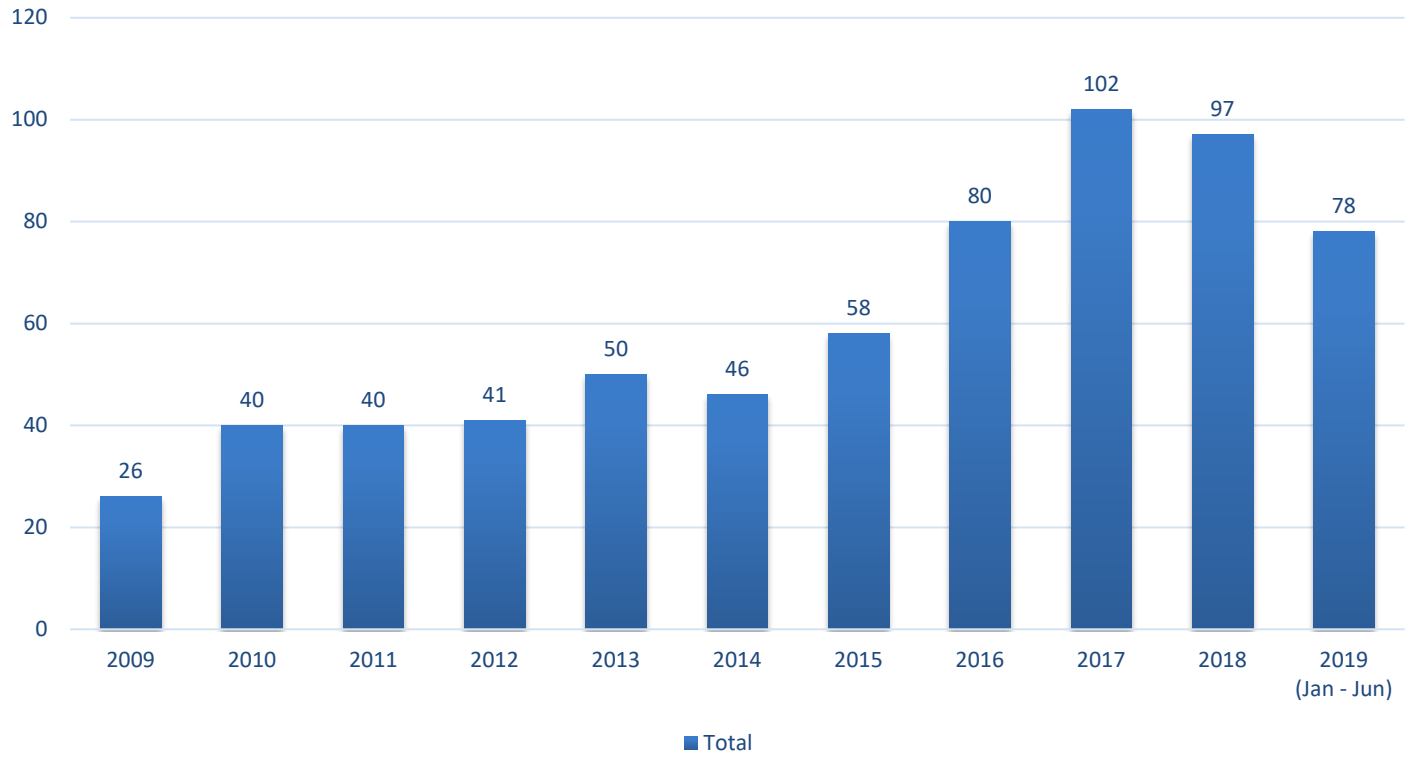
Table 1: 2019 CTSI Global Health Pilot Grant Awardees

Institution	Project Title	PI	Award
Purdue	Satiety response through delayed gastric emptying as related to dietary differences in the US and Kenya	B. Hamaker	$20,000
Indiana University	Chamas for Change: Adapting a Community-Based Peer Support and Health Education Model for Pregnant and Parenting Adolescents in Kenya	L. Ruhl	$50,000

Publications

AMPATH investigators published 78 articles in peer-reviewed journals since the start of 2019. The output during the first six months of 2019 nearly eclipses the record-setting year of 2016. A bibliography of all the publications produced from January – June 2019 is available at the end of this report.

Figure 2: AMPATH Research Publications per Year since 2009



STUDY REPORTS

The following reports were provided by AMPATH investigators and their study teams and cover the period of January – June 2019. 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	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.
Site(s)	Moi Teaching and Referral Hospital
Project Period	6/1/2018 - 5/30/2020
Funding Status	Funded - NIH - Fogarty International Center (FIC)

Direct Award (USD)	$261,673
Update	In the last six months we have hired and trained all study staff on the study protocol. In the past few months, we started phase one of the study which includes assembling and reviewing materials for our multimedia teacher training module. As part of this phase, we held a one-day curriculum workshop with the PI team and expert stakeholders including teachers and school administrators to revise the Teach HADITHI teacher training curriculum. The next part of phase one will be to enroll and interview key informants to finalize the training curriculum module. These key informants have been identified and interviews are ongoing with 19 interviews completed as of July 23rd 2019. We have also identified the schools that will be randomized to intervention and control for phase 2 testing of the intervention curriculum module.
Future Plans	In the next six months, we plan to: • Complete cognitive interviews with key informants to finalize the Teach HADITHI curriculum; • Hold 7 teacher workshops to deliver the Teach HADITHI intervention, which involves selecting sites and dates, consenting participants, and completing the baseline assessments with study participants. • Develop a RedCap database to house the quantitative data of the study. • Publish a systematic review from our phase one work on reviewing the literature on stigma interventions in schools.
Publication(s)	

Study Title	**A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector.**
Principal Investigator(s)	Jeremiah Laktabai, Moi University
Co-Investigator(s)	Diana Menya, Moi University
Working Group(s)	Public Health and Primary Care (PHPCWG)
Description	The ultimate goal of the proposed work is to improve antimalarial stewardship in the retail sector, which is responsible for distributing the majority of antimalarials in sub-Saharan Africa. Through a combination of diagnosis and treatment subsidies and provider-directed incentives, our approach will align provider and customer incentives with appropriate case management and thereby improve health outcomes. Specific Aim 1: Identify the combination of testing subsidies and conditional ACT subsidies that maximizes uptake of testing within specific budget constraints. Several studies, including our own, have shown that uptake of testing and ACT treatment are both sensitive to price. However, very little is known about how these prices should be related in order to maximize appropriate behavior and what effect conditional subsidies will have on treatment decisions. We will use an individually-randomized experiment to determine how different combinations of subsides, allocated between testing and treatment, affect the decision to be tested for malaria before treatment among clients seeking care in the retail sector. The objective of this experiment is to identify the combination of RDT and conditional (diagnosis-dependent) ACT subsidies that maximize the percent of clients receiving an RDT. We will test two different RDT price levels and two discounted ACT

	price levels in a factorial design. ACT discounts are conditional on a positive RDT result. The primary outcome measure is the decision to purchase an RDT before purchasing a drug. Secondary outcome measures are: 1). Decision to purchase an ACT stratified by testing status; a)Positive mRDT, b) Negative mRDT and c)No malaria test. All outcomes will be measured by interviewing the participant after they make their decision about whether to be tested and which medicines to purchase. Specific Aim 2: Test the impact of the subsidy package on targeting of ACTs in the retail sector. We will test the combination of subsidies (selected from Aim 1) in a cluster-randomized controlled trial to evaluate their impact on the proportion of ACTs sold to individuals with parasitologically-confirmed malaria among those seeking care in the retail sector.
Site(s)	Webuye District Hospital
Project Period	9/14/2018 - 8/31/2019
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	Not Reported
Update	For Aim 1, we have received protocol approval from both Duke and Moi IRBs. Conducted a protocol training for the research team on 22nd March 2019. We identified and enrolled 11 participating medicine outlets and we were able to launch Aim 1 of the study on 28th and 29th March 2019. We have so far enrolled 333 participants across all outlets.
Future Plans	Aim 2 is planned to begin in Spring 2020. We are currently developing the protocol and data collection tools, which we expect to submit for IRB review this fall.
Publication(s)	

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
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	The last participant was transitioned to primary care provider in April 2019. The study is now closed to follow up. Data cleaning and analysis is ongoing.
Future Plans	The protocol team is to continue with data analysis.
Publication(s)	

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)	
Working Group(s)	None
Description	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
Site(s)	Moi Teaching and Referral Hospital
Project Period	12/18/2013 - 12/31/2015
Funding Status	Funded - NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	The study is closed to follow up and data analysis is ongoing.
Future Plans	The protocol team to continue with data analysis and possible publication.

Publication(s)	
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	In the past 6 months, the site has been able to follow up all active participants and those who needed standard of care treatment were referred accordingly. No major challenges to report.
Future Plans	Continue with follow up of participants as per protocol schedule.
Publication(s)	
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, 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	Enrollment began in the fall of 2015. A total of 223 women have been recruited into the study (2 enrollees had inadequate specimens and one had unknown HIV status and therefore all 3 were excluded from analysis). Of the 220 evaluable subjects, 115 were HIV-infected with median age of 36 years, and 105 were HIV-uninfected with median age 33 years (p-value = 0.0009). This enrollment represents 100% of our planned total of 220 Kenyan women. Women have begun returning for follow-up quarterly visits as well. Results: 1. Among HIV-infected women, 86.8% were receiving ART; median duration between HIV diagnosis and enrollment was 7.2 years (IQR 4.1-10.3); median CD4 count was 471 (IQR 310-612). 2. Fewer HIV-infected women (35.7%) were married than HIV-uninfected women (67.3%) (p<.001). 3. The percentage of participants who reported using a condom less than 25% of the time was significantly lower for HIV-infected participants (27.8%) compared to HIV-uninfected women (73.3%) (p<.0001). 4. HIV-infected women had a median of 4 lifetime sexual partners (IQR 3-8) compared to HIV-uninfected women (median 3, IQR 1.5-4), p=.0001. 5. HPV of any type, all HR-HPV, and HPV 16 were detected significantly more often in HIV-infected women than in HIV-uninfected women in spite of ART use by most HIV-infected women (Table 1 and Figure 2). 6. Low risk HPV types were detected in 32.2% of HIV-infected women and 17.3% of HIV-uninfected women (p=.0113) 7. Of 223 patients followed in year 1, there were 15 positive STDs noted in 8 individuals, of which 10 received treatment and 2 are still awaiting treatment. In the second year, 11 women had 19 positive STDs results. All

patients on study were treated with antibiotics based on syndromic presentations. Conclusions: This study was initiated in Kenya to study HPV and cervical cancer epidemiology and treatment response. Several behavioral variables differed between HIV-infected and HIV-uninfected women. All HPV, all HR-HPV, and HPV 16 were detected significantly more often in HIV-infected women than in HIV-uninfected women, in spite of the use of ART. 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. Project 2 Summary: In project 2, 175 0f 180 planned clients have been recruited into the study across 3 study sites (i.e. MTRH, Webuye, and Chulambo). This accrual was lower than expected and completed near enrollment after opening a third clinic to increase opportunities for enrollment. Of these 175 clients, 85 underwent cryotherapy and 90 underwent LEEP (83 were HIV-infected and 91 were HIV-uninfected). Four patients have died (three HIV-infected; and one HIV-uninfected). All specimens from these women on this projects are banked at present and awaiting transport to the KEMRI laboratory for HPV analysis. Translational Biology Core Summary: Specific Aim 1: The Biobank has been established in the newly built Chandaria Chronic Disease and Cancer Building located on the campus of MUSOM and AMPATH. Its purpose is to store cervical cancer specimens, but also to store blood, biopsies and other tissue obtained from the U54. It is currently being managed by members of the U54 program working in Kenya, and has support from MUSOM and AMPATH as well. The Biobank now has freezers and space dedicated to specimen handling and processing. Eventually, this facility will be used to store specimens from all cancers obtained within the AMPATH network. Specific Aim 2 (Process and test samples from vaginal swabs, and cervical biopsies for Neisseria gonorrhea (NG), Chlamydia trachomatis (CT), HPV, and determining HPV types). Results: 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. As our participants return for their subsequent annual visits, their samples will continue to be tested for CT and NG. 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. 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. All HPV DNA testing has been performed in KEMRI in the laboratory of Drs. John Michael Ong'echa and Ann Moorman. Specific Aim 3. (Expand the capabilities and expertise of the current laboratories in Kenya (AMPATH and KEMRI), and provide mentoring to young investigators, students and technicians). Results: The TBC has provided data that has been utilized by the mentees funded under the auspices of the U54 to publish and present at inter-U54 conferences and international conferences. The TBC has also created an environment where graduate students and technicians have been able to learn new techniques and where mentees have been able to work and generate data for their own projects. Biostatistics and Data Management Core Summary: Accomplishments include: 1) Maintenance and modification of RedCap databases for Project 1 and 2; 2) Entry of clinical, lab and HPV testing data for 223 enrolled participants with data examination and quality control of all data entered in the RedCap databases and HPV testing data from KEMRI lab at Kisumu Kenya; 3) Merged and

	analyzed demographical, clinical, behavioral and HPV testing enrollment data with descriptive analysis including comparisons of the demographics, clinical factors, behavioral characteristics, and HPV testing results between HIV-uninfected and HIV-infected participants; and 4) Created and maintain an IU BOX folder for the U54 project to store all the project 1 and project 2 related raw data, statistical programs, cleaned analytical datasets, and analysis results, which also allows sharing of the data among all members in the U54 study team.
Future Plans	An extension proposal was submitted to continue the operations of this grant to include the follow up of participants currently enrolled.
Publication(s)	

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 IeDEA 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, Moi Teaching and Referral Hospital, FACES, Lumumba
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	Over the last six months, participant enrolment has begun in all the three IeDEA ACE study sites-Moi Teaching and Referral AMPATH, Kitale AMPATH, and FACES, Lumumba site. We have enrolled a total of 182 (165 Engaged in care and 17 Lost To Program) from MTRH (n=82), Kitale (n=53) and FACES Lumumba (n=47) for assessments at enrollment using a battery of questionnaires and blood samples taken for Viral Load and CD4 testing at AMPATH Reference lab and a later Resistance testing at Kantor's lab in the USA. Four participants (3 at FACES and 1 at MTRH) has been identified as Lost To Follow up (LTF) after unsuccessful tracing.We have received Viral Load and CD4 results for the tests done. RedCap database set up and testing was completed and data entry for the quantitative portion of the study is ongoing. We also completed qualitative part of the study by conducting Verbal Autopsy preparatory interviews with a total of 30 participants (15 Caregivers and 15 health care providers).Transcription and translation of these interviews are ongoing. Analysis of the qualitative data from the previously done Focus Group Discussions (FGD) with adolescents to develop a Discrete Choice Experiment (DCE) tool to measure adolescent clinic preferences has begun and hope to be completed soon.
Future Plans	In the next six months, we will: • Complete analysis of the qualitative data from FGDs and design the DCE tool that will be used in patient assessments. • Complete transcription and begin analysis of the qualitative data from Verbal autopsy preparatory interviews and start the actual VA autopsy interviews. • Begin data verification in RedCap database. • Shipment of specimen from the AMPATH Reference lab to Kantor's Lab in the USA for resistance testing. • Continue study enrolment and patient assessments at all sites. • Prepare abstracts and manuscripts for publications on our findings.
Publication(s)	

Study Title	**Bridging Income Generation with Group Interated Care(BIGPIC)**
Principal Investigator(s)	Rajesh Vedanthan, New York University
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)	Busia District Hospital, Uasin Gishu District Hospital, Trans-Nzoia and Kisumu West
Project Period	4/1/2015 - 1/1/2020
Funding Status	Funded
Direct Award (USD)	Not reported
Update	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 at NYU hired: Program Manager - NIH R01 grant successfully transferred from the Icahn School of Medicine at Mount Sinai to the New York University School of Medicine Aim 1: Barriers/facilitators/contextual factors - Manuscript writing ongoing Aim 1.1 (Barriers, Facilitators, & Contextual Model): - Data analysis and manuscript writing ongoing Aim 2 (Cluster RCT): - Logistics of trial Roll Out: o Rollout by health facility is complete - 24 facilities have been rolled out (6-GMV, 6-GMV-MF, 6-UC, 6-MF) oEnrollment has been completed A total of 2928 participants (Male=897, Female=2031) have been enrolled. o 3-month follow-ups have been completed. Total participants: 2682 (92%) o 12 month follow-ups are ongoing. A total of 1624 participants have completed 12-month follow ups thus far o Training of community health workers (CHWs) in group facilitation and microfinance process completed - Data collection, entry, & management: o Data collection instruments have been programmed in REDCap. Continuous testing and feedback is occurring throughout project implementation. o Real-time data entry occurring with REDCap on mobile devices Syncing of entered data also occurring when real-time network access is not available o Data analysis ongoing - Process evaluation: o Process evaluation implementation is ongoing o Qualitative data collection completed o Qualitative data analysis ongoing Aim 2.1(Mediation & Moderation Analysis): - Social network survey (SNS): o SNS currently being administered to all participants at baseline and 3-month f/u o Analysis ongoing Aim 3 (Cost Effectiveness Analysis): - Costing questionnaire survey (CQS): o CQS currently being administered to study participants.
Future Plans	Aim 1: - Manuscript preparation Aim 1.1 - Manuscript preparation Aim 2: - Complete 12-month follow-up assessments at appropriate time periods - Continue training and mentorship of rural clinicians, community health workers, and research staff who continue to be involved in the group medical visit-microfinance intervention - Continue and finalize implementation of process evaluation activities - Complete data analysis of baseline data - Initiate data analysis of outcome data - Carry out study dissemination activities at appropriate stages Aim 2.1: - Complete administering of social network survey to study participants at appropriate time period - Continue data analysis - Manuscript preparation Aim 3: - Complete administering of costing

	survey to study participants at appropriate time period - of intervention cost tracking data throughout intervention	Complete the collection implementation period
Publication(s)		

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	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 25% 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.
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/20/2015 - 8/31/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	Over the past 6 months, an analyst was identified to conduct longitudinal analysis. Measures are currently underway to facilitate this process.

Future Plans	Over the next 6 months, we still plan to do a longitudinal analysis of 6 & 12-month data. We also aim to do an overall analysis of all available data to evaluate whether our primary objective of increasing use of long term methods of family planning was achieved on the overall.
Publication(s)	

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	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 4 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. 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 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 effectives 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 ≥9% of participants being willing to be randomized to either the intervention or the control group; ≥ 8% attending all 1 biweekly caregiver meetings; ≥8% of children returning for their 6 month follow-up; and ≥8% 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,1 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 4% 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
Project Period	7/9/2018 - 7/1/2019
Funding Status	Funded - Indiana CTSI, Thrasher Early Investigator Award
Direct Award (USD)	$45,000
Update	We did month 6 follow up and evaluations of the 31enrolled cohort of children that we are following for a period of one year since enrolment to participate in the study. The study participants had two groups (Intervention and Control). We performed month 6 BSID-III assessments and obtained caregiver questionnaires on all participants, with the. We then swapped the two groups ones who were getting intervention became our control group and the control group became our intervention group. We started the CCDI program on the second intervention group with biweekly caregiver groups for the intervention group for a total of 10 sessions we are at session 9 for the group, while the Sequence control group were invited to return to access the child resource room for background exposures and other potential benefits of visiting the health center. We 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 headed to 12 month follow-up reassessing all the study participants using the BSID-III and caregiver questionnaires. Conduct semi structured interviews, home visits and caregiver focussed group discussions as we wind up the study follow up.
Publication(s)	

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), Pediatric (PRWG)
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, 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	Manuscript is still being finalized.
Future Plans	Complete and submit the manuscript.
Publication(s)	

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, 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 - NIH
Direct Award (USD)	$22,624 (USD) - For the first year
Update	We continued our qualitative work towards refining a conceptual model for adolescent retention and disengagement in HIV care. We completed key informant interviews with healthcare workers (HCWs) in the remaining AMPATH sites stipulated in the CARE protocol (Turbo, Kitale, Webuye and Chulaimbo). We conducted thirteen (6 females, 7 males) more interviews with HCWs, bringing their total to 28 (18 females, 10 males) participants. We also began recruitment of disengaged adolescents and their caregivers who are traced in the adolescent sentinel cohort study (ACE Study). During this period, we enrolled a total of 8 adolescents (5 female, 3 male) and 5 caregivers (all female). Two (2) of the adolescents and one (1) caregiver were enrolled from the Kitale AMPATH Clinic, whereas four (4) caregivers and six (6) adolescents were enrolled in RAFIKI Center - MTRH. We conducted key informant interviews with this group to investigate reasons for their disengagement from care. We are also carrying out a systematic review to evaluate the current literature regarding factors contributing to adolescents' disengagement from HIV care.
Future Plans	In the next reporting period, we hope to complete enrollment and in-depth interviews with the disengaged adolescents and their caregivers, as well as perform a qualitative analysis of the HCWs, adolescent and caregiver interviews; and synthesize the findings with existing literature, quantitative findings from the ACE study, and our previous qualitative work on barriers and facilitators to retention in care among adolescents. The emerging key factors that influence retention will be incorporated in the development of a tool to assess risk for disengagement from care among HIV infected adolescents.
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	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. SPECIFIC AIMS 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. 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. AIM 3: Elucidate ideas concerning appropriate service delivery and care for street-connected youth in Eldoret, Kenya from community members across different social strata 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.
Site(s)	Moi Teaching and Referral Hospital, Other community-based sites in Eldoret
Project Period	9/5/2016 - 12/31/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	We are still in the process of drafting manuscripts for submission. In total, we have 5 manuscripts drafted and are working on completing final drafts for submissions to various journals.
Future Plans	In the next six months, we hope to ensure all of the manuscripts are under review.

Publication(s)	
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 Yego, 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	The 30 CHVs recruited 308 women of reproductive age from both Turbo and Bunyala sub counties. These women were in need of urine pregnancy testing. To obtain information about the women, the results of their testing, and services for which they were counseled and referred. These same women were followed-up within a few

	months to determine whether they received services, their pregnancy status, use of family planning, and their satisfaction with the services from the CHV. We are now finished recruiting women for our study. We have been able to follow-up most women, but are still working with CHVs to complete follow-up of all women recruited. More than one third of the UPTs performed were positive, while two-thirds were negative. Women received counseling on ANC, FP and condom use, HIV/STI testing, and many more important areas of reproductive health education. In addition, many women sought care at ANC clinics and FP clinics on the advise of the CHVs. All women reported being very satisfied with the services of the CHVs providing UPTs with counseling and referral.
Future Plans	The final phase of the study is to hold focus group discussions with 30 CHVs from Turbo and Bunyala sub counties and members sub county health management team, including CHEWs and public health officer, to receive their feedback about the study. One such FGD was carried out in Bunyala sub county, we plan to carry out another FGD in Turbo sub county within the month of July. We plan to fully analyze both quantitative and qualitative components of the study following complete follow-up of the remaining participants, after which we will hold community knowledge dissemination forums and begin drafts for manuscripts.
Publication(s)	

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 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
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/31/2017 - 8/31/2020
Funding Status	Unfunded
Direct Award (USD)	
Update	The following is the summary progress from January to June 2019 1. Kenya National Research Misconduct Workshop Organized and held the National Research Misconduct workshop at KCB Leadership Centre, Nairobi between 28th February and 1st March 2019. We hosted 73 delegates from different institutions across Kenya, Africa and the world. A formal dissemination of study results was conducted during the workshop and an institutional Framework for preventing and managing Research Misconduct was also developed through a participatory approach. The workshop provided a great opportunity for the participants to learn about Research Misconduct and exchange ideas. 2. Data analysis and publications Data analysis was done and summary of the findings were presented in the workshop in February 2019. Two (2) abstracts were submitted and presented in the just concluded 6th World Conference on Research Integrity held in Hong Kong between 2nd and 5th June 2019. The team is in the process of preparing the publications. 3. Trainings on Responsible conduct of Research The project team is currently organizing the upcoming series of trainings on Responsible Conduct of Research which are scheduled to commence in July 2019. The activities include identification of trainers and preparation of training materials. So far training materials have been sourced and are being reviewed for use during the first training.
Future Plans	1. Conduct trainings on Responsible conduct of Research 2. Data Analysis and manuscript writing 3. Participate in setting up Moi University Research Integrity Oversight Office
Publication(s)	

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)	
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, 213 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, 213. 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, 213. The data for this study is collected using a comprehensive 1-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
Project Period	1/12/2015 - 12/31/2015
Funding Status	Unfunded
Direct Award (USD)	
Update	Manuscript writing and we recently submitted irec continue approval.
Future Plans	We are currently writing a manuscript, this will be submitted to Journal once it's ready, we hope to complete writing a manuscript by the end of August. Our continuing approval is under review at Irec.
Publication(s)	

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)	Pediatric (PRWG), Public Health and Primary Care (PHPCWG)
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 1 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	Amended the protocol to version 6.0 to include the NIH/NHLBI DSMB suggested changes after the study pause. The protocol was approved by IREC and we were able to resume enrollment on in April 2019. As at 18th July 2019 the study had enrolled a total of 138 participants (cumulative in all treatment groups).
Future Plans	We are continuing with enrollment as planned. Planning for the 4th study monitoring visit by an independent monitor. 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. The study team continues with weekly calls throughout the year.
Publication(s)	

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	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, depomedroxyprosterone acetate (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 nd/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 AMPATH Sites
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 been refining our analyses, and hope to have our first draft of the publication for primary outcome in the next 6 months.
Future Plans	In the next 6 months, we hope to have a first draft of the publication for 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 4 women who are <2wks gestation attending antenatal clinic at different project sites.
Site(s)	Huruma Sub-District Hospital, Moi Teaching and Referral Hospital, 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)	$564,629
Update	Over the past six months, all the blood test visits were done and completed with data entry done for these participants. Post-delivery follow-up calls were also conducted as well as data entry of completed forms. Preliminary analysis of the 2149 mothers screened indicates a 3.02% prevalence of GDM with 65 positive cases. Identified risk factors contributing to positive diagnosis include a previous history of GDM, family history of GDM or Diabetes, high social-economic status, high BMI, and age. In all these, a major challenge has been the loss to follow up of participants in subsequent visits.
Future Plans	In the next 6 months, post-delivery follow-up calls will be completed and data entry will be done. Upon completion of these, final data cleaning will also be conducted. A data analysis plan is to be put in place and drafted by the statistician to guide in the data analysis of the available data. Once the analysis is done, a manuscript will be drafted for publication.
Publication(s)	

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 unsurpressed 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
Project Period	9/12/2017 - 12/31/2018
Funding Status	Funded - OtherInternational AIDS Society, NIH - Fogarty International Center (FIC)
Direct Award (USD)	$136,199
Update	During the current reporting interval, we have completed a draft of the manuscript and is currently under review by coauthors. Secondly, we are currently completing laboratory testing as planned this month, concluding the active phase of this project.
Future Plans	Complete and submit the 2 primary manuscripts for this project concluding this initial phase of the project.
Publication(s)	

Study Title	**Evaluating reproductive and HIV outcomes and decision making among HIV-positive women on dolutegravir: A prospective, observational cohort at AMPATH, Kenya**
Principal Investigator(s)	Mercy Maina, Moi Teaching and Referral Hospital
Co-Investigator(s)	Caitlin Bernard, Indiana University
Working Group(s)	Reproductive Health (RHWG)
Description	This is a prospective ,observational cohort study that aims to evaluate reproductive health outcomes and decision-making among women exposed to dolutegravir. Specific aims include: To evaluate key reproductive health and HIV outcomes among women initially on DTG-containing ART. Specifically, we will determine the proportion of women continuing to use DTG vs. switching to EFV We will also determine contraceptive outcomes (uptake, method choice, and continuation rates and HIV outcomes (viral suppression rates) among these women. To investigate factors facilitating provider and patient decision-making for HIV-infected women choosing between ART and contraceptive choices.

Site(s)	Chulaimbo Sub-District Hospital, Moi Teaching and Referral Hospital, Saboti Sub-District Hospital
Project Period	4/17/2019 - 11/29/2019
Funding Status	Funded - University of Washington
Direct Award (USD)	$13,869.00
Update	Ethics approval was received on 19th march, 2019. Redcap data collection tool was pilot tested and 12 participants were called and the database readjusted. In-depth interviews are currently ongoing and 9 clinical providers form MTRH have been interviewed.
Future Plans	We intend to conduct in depth interviews with 9 health care providers from Chulaimbo as well as with women of reproductive ages (15-49) from both Chulaimbo and MTRH. Brief telephone interviews will be conducted with approximately 400 women to verify data collected through AMRS/POC EMR. We hope to fully analyze the quantitative and qualitative aspects of the study and plan for dissemination of the findings
Publication(s)	

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)	Aileen Chang, University of California San Francisco
Co-Investigator(s)	Sonak Pastakia, Purdue University
Working Group(s)	Adult Medicine (AMWG)
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)	Chulaimbo Sub-District Hospital
Project Period	2/1/2018 - 2/3/2020
Funding Status	Unfunded
Direct Award (USD)	
Update	During the last 6 months, we have transitioned the primary study coordinator role to Mr. Phelix Were. We continue to work with Mr. Philip Haji Odhiambo as our research assistant recruiting KS patients in Chulaimbo. Between January 1st 2019 to June 30th 2019, our study details are as follows: Number of patients recruited: 22 Number of patients enrolled: 9 Number of patients active: 7 Number of patients completed: 0 Number of patients withdrawn: 2 This period has quite a high number of patients who were not enrolled in the study despite their recruitment. The reasons for which they were not enrolled were as below: Leg lymph edema consistent with Campisi clinical stage 1A: 3 Pregnant female: 1 Currently taking medication known to cause edema (specifically nifedipine in this case): 1 Declined consent: 8 Those who declined consent mainly cited reasons of long distance and high transport fare that would not be covered by the transport subsidy that the study offers. Thus, a major challenge to recruitment has been the long distance that patients travel from various lake counties to be seen at Chulaimbo.
Future Plans	We will conduct our retrospective chart review of wound care patients seen at Turbo Health Center and MTRH between September 2016 and May 2019 (Aim 1). - We hope

	to add MTRH as a site of recruitment for Aim 2, given the challenges we are facing at Chulaimbo.
Publication(s)	
Study Title	**Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups in Kenya**
Principal Investigator(s)	Omar Galarraga, Brown University
Co-Investigator(s)	Becky Lynn Genberg, Johns Hopkins University
Working Group(s)	
Description	Sustained viral suppression (VS) continues to present major challenges to HIV treatment and prevention. Retention in care is a particularly challenging issue for persons living with HIV (PLHIV) because of lack of convenient access and issues related to economic stability. Our long-term goal is to help achieve the 90-90-90 goals through improved care delivery based on rigorous implementation research. The objective of this project is to demonstrate the effectiveness and longer-term sustainability of a differentiated care delivery model for improving HIV treatment outcomes. The central hypothesis is that the integration of HIV care delivery and community-based primary care with group-based microfinance will improve retention and rates of VS among PLHIV in Kenya via two mechanisms: improved household economic status and easier access to care. Thus, the specific aims are as follows: (1) To evaluate the extent to which integrated community-based HIV care with group microfinance affects retention in care and VS among PLHIV in rural western Kenya using a cluster randomized intervention design of existing (fully HIV+) microfinance groups to receive either: (A) integrated community-based HIV care, or (B) standard care. We will also augment trial data with a matched contemporaneous control group of patients in standard care (group C) comparing outcomes in groups A, B and C; (2) To identify specific mechanisms through which microfinance and integrated community-based care impact VS: Using a mixed methods approach, we will characterize the mechanisms of effect on patient outcomes. We will conduct quantitative mediation analysis to examine two main mediating pathways (household economic conditions and easier access to care), as well as exploratory mechanisms (food security, social support, HIVrelated stigma). We will also use qualitative methods and multi-stakeholder panels to contextualize the implementation of the intervention; and (3) To assess the cost-effectiveness of microfinance and integrated community-based care delivery to maximize future policy and practice relevance of this promising intervention strategy. Our working hypothesis is that the differentiated model will be cost-effective in terms of cost per HIV suppressed person-time, cost per patient retained in care, and cost per disability-adjusted life year saved. This project is part of the Academic Model Providing Access to Healthcare (AMPATH) program in western Kenya which cares for more than 150,000 PLHIV at over 500 sites in western Kenya since 2001. The main expected outcomes will be rigorous evidence of effectiveness, mechanisms and cost-effectiveness of a differentiated model for achieving the last key step in the HIV care continuum. These results are expected to have an important positive impact in terms of improved, high-quality services that

	address known individual and structural barriers to care and promote long-term sustainability of care for PLHIV in rural settings with high HIV prevalence.
Site(s)	Burnt Forest Sub-District Hospital, Busia District Hospital, Cherangany Health Centre, Chulaimbo Sub-District Hospital, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mois Bridge Health Centre, Mosoriot Rural
Project Period	Not Reported
Funding Status	Unfunded
Direct Award (USD)	
Update	Not Reported
Future Plans	
Publication(s)	

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	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. Alarmingly, 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 In-formatics 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.
Site(s)	Moi University, Makerere University, University of Bergen
Project Period	12/5/2013 - 6/30/2019
Funding Status	Funded - NORAD - Norwegian Agency for Development Cooperation
Direct Award (USD)	$2,757,830
Update	Not Reported
Future Plans	
Publication(s)	

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 IeDEA 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 216 to 217 (n ? 1, 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
Project Period	3/5/2018 - 6/1/2019
Funding Status	Unfunded
Direct Award (USD)	
Update	We completed retrospective data entry of all of the files in the antenatal and postnatal clinics into AMRS. POC has since been rolled out in these clinics for HIV+ patients, so data entry is now continuing in real time. The research assistant has since moved to Huruma Sub-District Hospital to complete data entry there and is expected to completely update the files as of the end of July 2019. He will then transition to Kitale District Hospital where he will begin data entry there. An abstract of the data from 2015-Feb 2019 was presented at the International Workshop of HIV and Hepatitis Observational Databases in March 2019.
Future Plans	Complete data entry at Huruma and Kitale; complete analysis of data from 2015-2019 and submit manuscript for publication.
Publication(s)	

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	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 1-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 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	All study follow-up and data collection is 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 (MEMS) 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: MEMS dichotomized adherence (90% of doses taken vs. <90%), 48-hour MEMS 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 MEMS and viral suppression outcomes. Odds ratios (OR) and 95% confidence intervals (95%CI) were calculated. In the last six months, we finished our analysis and found evidence that the adherence questionnaire 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 MEMS 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 MEMS 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, MEMS 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 non-adherence to ART in this international cohort of children, while demonstrating the validity of a short questionnaire to screen for non-adherence across diverse global settings. The results of this study were recently publishd in an article in the Journal of the International AIDS Society. Citation: Vreeman RC, Scanlon ML, Tu W, Slaven JE, McAteer CI, Kerr SJ, Bunupuradah T, Chanthaburanum S, Technau KG, Nyandiko WM. 2019. Validation of a self-report adherence measurement tool among a multinational cohort of children living with HIV in Kenya, South Africa, and Thailand.
Future Plans	We have completed data analysis. No additional analysis plans are currently in place.
Publication(s)	

Study Title	**Impact of malaria on shaping immunity to EBV and endemic Burkitt lymphoma**
Principal Investigator(s)	Ann Moormann, University of Massachusetts
Co-Investigator(s)	Festus Njuguna, Moi Teaching and Referral Hospital
Working Group(s)	Oncology (ORWG), Pediatric (PRWG)
Description	Endemic Burkitt lymphoma (eBL) remains the most prevalent pediatric cancer in equatorial Africa with an annual incidence of 2-5 per 100,000 children in western Kenya. Three hallmarks of eBL etiology are well-documented: primary Epstein-Barr virus (EBV) infection early in life, holoendemic Plasmodium falciparum (Pf) malaria exposure, and a characteristic chromosomal translocation resulting in over-expression of the c-myc oncogene. The peak age-incidence for eBL diagnosis is between 5-9 years of age, well after primary EBV infections (which occur before the age of 3 years in nearly 100% of these children) and after the high morbidity and mortality associated with malaria infections. Timing of co-infections prior to peak age-related incidence of eBL suggests a cumulative interaction that results in the deterioration of immune control over EBV. However, the sequence of events that result in impaired immune surveillance and high EBV load, thereby setting the stage for eBL, have not been determined. The goal of this proposal is to determine the immune regulatory mechanisms responsible for loss of immune control over EBV in children and to understand the mechanisms that inhibit anti-tumor immunity in children who subsequently go on to develop eBL. This knowledge will have implications for targeting malaria chemoprophylaxis as well as immuno-therapies to prevent or ameliorate eBL.
Site(s)	Chulaimbo Sub-District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre

Project Period	7/10/2014 - 5/31/2020
Funding Status	Funded - NIH - National Cancer Institute (NCI), Thrasher Research Fund
Direct Award (USD)	Not Reported
Update	Not Reported
Future Plans	
Publication(s)	

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	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 4 confirmed BL patients are needed, and up to 5 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.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/1/2016 - 8/31/2018
Funding Status	Funded - NIH - National Cancer Institute (NCI)
Direct Award (USD)	$225,072
Update	We have presented our trial data at the ASCO annual meeting in Chicago this spring. We have abstracts submitted and accepted to the College of American Pathologists and the International Society of Pediatric Oncology (SIOP) on our genetic and flow cytometry data this fall. All children have been enrolled in the trial and have completed therapy. Ongoing follow-up data is being finalized.
Future Plans	We hope to submit 2 or 3 manuscripts on our results and apply for further funding to advance our findings. We are in a no-cost extension of our grant and have no budget documents to report.
Publication(s)	

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 (PHPCWG)
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
Project Period	5/26/2017 - 5/26/2018
Funding Status	Funded - Abbvie Foundation
Direct Award (USD)	$20,860

Update	In the past 6 months, a drafted manuscript was revised by the investigators and is pending a final revision. We have worked with the TIMBY developers to access more media on the dashboard as well as worked on a blog post about our project. Publication of this is yet to be done.
Future Plans	Over the next 6 months, we aim to have a final manuscript ready for submission to a journal for publication. We plan to continue verifying any new reports and compile more stories from these as we look to do an in-depth analysis to identify any new arising themes that might inform a second manuscript.
Publication(s)	

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 Sciences (SSRN), Public Health and Primary Care (PHPCWG)
Description	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 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 Foundation, NIH
Direct Award (USD)	$152,806
Update	We have a preliminary draft of the qualitative analysis examining barriers and facilitators to linkage among those who tested positive during HCT and did/did not link to care following diagnosis. The barriers elucidated in the data are a combination of structural (social, contextual, healthcare environment factors) and individual (psychosocial, clinical, demographic, health beliefs). Not surprisingly, the results suggest that in an era of test-and-treat, additional counseling may be required for some patients who struggle with acceptance of their diagnosis, disclosure issues with respect to family, and perceived need for care given a lack of symptoms. At the same time, structural barriers such as stigma, poverty, and a lack of transportation prevent potential enabling factors from prompting action even in the face of challenging individual psychosocial concerns.
Future Plans	While our funding has now expired, we expect to continue working on this draft and will submit it for publication prior to the end of the year (December 2019).
Publication(s)	

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, Webuye District Hospital
Project Period	10/1/2016 - 6/30/2019
Funding Status	Funded - Thrasher Research Fund, Indiana University - Center for AIDS Research, Indiana CTSI, IU Center for Global Health
Direct Award (USD)	$57,500
Update	During this reporting period, we enrolled two additional peer mentors (1 female, 1 male) to further explore on their roles in supporting care for HIV infected adolescents. These were peer mentors working with street connected adolescents and they provided key narratives on barriers and facilitators to retention in HIV care among street connected adolescents. We also continued with the qualitative analysis of previously done key informant interviews with peer mentors, as well as focus group discussions involving the adolescents in HIV care and peer mentors. We had three abstracts accepted at the 11th International Workshop on HIV & Pediatrics, and one abstract accepted at the International AIDS Society Meeting, in July 2019, Mexico City. One manuscript has been submitted for publication and is currently under review after requested revisions.
Future Plans	We hope to complete qualitative analysis for the MaISHA project and draft multiple papers for publication in peer reviewed journals.
Publication(s)	

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, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	9/26/2016 - 9/26/2017
Funding Status	Unfunded
Direct Award (USD)	
Update	Results from this study were included within the thesis of Emory University Masters in Public Health graduate, Andrew Deathe, in 2018. His thesis can be seen here: https://etd.library.emory.edu/concern/etds/4m90dv63t?locale=zh The abstract has been under reviews by the International Journal for Equity in Health Manuscript of the same has also been under reviews
Future Plans	The abstract is under reviews by the International Journal for Equity in Health Manuscript of the same has also been under reviews
Publication(s)	

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 (tele-therapy 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	Over the last six months adherence data retrieved from electronic dose monitors (MEMS caps) were cleaned and ready for analysis. Quantitative data analysis is ongoing. Twenty-nine ALWH completed the study (1 relocated). Mean age was 15.5 years and 17 (59%) were female. In pre-intervention interviews with 25 participants, ALWH identified important topics to address in the WhatsApp© groups: issues related to "stress" and "anxiety," myths and misconceptions of HIV, confidentiality, and disclosure of HIV status to friends, partners, and others in the community. In post-intervention interviews with 15 ALWH, participants expressed a number of benefits. First, participants used the platform to communicate and build relationships with other ALWH. Second, participants liked having access to a counselor, either through the group chat or one-on-one, to ask HIV-related and general health-related questions. They reported feeling uncomfortable asking their regular health provider these questions. There were several challenges to feasibility and acceptability, including network and power issues with phones, scheduling conflicts for regular chats, and parents not feeling comfortable with the ALWH having access to a phone. Parents' concerns prompted the counselor on several occasions to open up productive communication channels at the family level, that were ultimately deemed helpful to understand the home environment for ALWH. Finally, the younger age group was much less active on the WhatsApp© platform compared to the older group, suggesting that older ALWH may be a more appropriate target for this type of intervention. Preliminary analysis of the qualitative data collected during pre- and post-intervention interviews are described in an abstract entitled "A pilot study of the acceptability and feasibility of a mobile application for peer and counseling support among adolescents living with HIV in Kenya." This was submitted to the 2nd Annual HIV Adolescence Workshop in Nairobi in June 2019 and is under review.
Future Plans	In the next six months, we plan to complete the 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 more abstracts to conferences 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)	

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	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.Aim3 : 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.
Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital, 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 186 study participants against the target study population of 225 children, and administered the BSID-III to a total of 186 children. We have completed the

	recruitment targets for the HIV-exposed uninfected children and HIV-unexposed children 75 from each category respectively
Future Plans	Ongoing with recruitment of children within the HIV-infected group. We have so far enrolled 186 study participants against the target study population of 225 children, and administered the BSID-III to a total of 186 children, the enrollment phase is expected to be on-gong for the next 1-4 months. To further explain developmental delays among these children, we have documented psychosocial factors related to developmental delays based on the results of previous results. All the recruited children have also provided blood for determination of biological factors associated with developmental delays. We plan to ship the existing samples to the U.S. for further testing of immunological and inflammatory factors associated with development delays in this population.
Publication(s)	

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	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 Afri-ca. This is a critical missed opportunity for the >1 million children born to HIV-infected mothers annually. In-tegrating 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 chil-dren 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 psy-chometric 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 pi-lot, the following implementation outcomes will be measured: acceptability, feasibility, fidelity, implementa-tion 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 ther-apy and 2) creating a research platform to support the evaluation of innovative interventions and track longi-tudinal 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 pro-gram will identify and treat children with ND delays and create a research platform to evaluate future inter-ventions for ND delays.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/21/2018 - 8/31/2022
Funding Status	Funded - NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	$723,254 (total over 4 years)
Update	We have done cultural adaptation of the instruments (screening DSQ, PEDS:DM; Assessment: RNDA and MDAT) to determine and compare the reliability and validity of the neurodevelopmental instruments. This included translation, cognitive interviewing and brief pilot evaluations. Twenty caregivers of young children were recruited for cognitive interviews regarding questions and activities for all instruments. Two neurodevelopmental assessments (Rapid Neurodevelopmental Assessment(RNDA) and Malawi Developmental Assessment Tool (MDAT)) were performed on children aged 18-36 months to determine which items needed to be culturally adapted. While the screening instruments, Developmental Screening Questionnaire (DSQ) and Parent Evaluations of Developmental Status-Developmental Milestones (PEDS; DM), underwent appropriate translations and cognitive interviews.
Future Plans	We aim to recruit and enroll 240 young children between the ages of 18-36 months from the HIV-infected, HIV-exposed but uninfected children and Non-exposed children. 120 from MTRH MCH clinic, 60 from Turbo and Burnt Forest MCH clinics respectively. At enrollment we will collect anthropometric and demographic data ,maternal education (using the WAMI index40) and cognitive stimulation (using sections of the UNICEF multiple indicator cluster survey41) We will administer the DSQ, PEDS: DM, MDAT, RDNA, and BSID-III to each of the 240 children. With BSID-III being the goal reference standard of the two assessments (MDAT and RNDA).
Publication(s)	
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)	Cardiovascular and Metabolic Disease (CVMD)
Description	In the recent years there have been significant insights into the complex etiologies of neuropsychatric brain disorders. For example, neuropsychiatric genetics has achieved success with the identification of 18 loci for schizophrenia according t the Schizophrenia Working Group 214. 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 Africa 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. Specific Aims 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. The Moi site will recruit a total of 4 participants over 4 years, consisting of 2 cases and 2 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 fro insights from the genetic research.
Site(s)	Iten District Hospital, Kapenguria District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Webuye District Hospital, Kakamega and Kapsabet
Project Period	2/28/2017 - 3/1/2022
Funding Status	Funded - Broad Institute of MIT and Harvard
Direct Award (USD)	$252,150
Update	Accomplishment 1. 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. 2. successful data collection, extraction and shipment. 4. Recruitment break down-Total enrolled is 1715 participants, controls are 870 and Cases are 845. Challenges. 1. Delayed saliva kits because of customs check 2. Unstable network making it sometimes difficult to send data to server 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	1. Scaling up recruitment. 2. Recruitment moving to other NeuroGAP sites 3. Continue matching cases and controls
Publication(s)	

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)	Laura Ruhl, Indiana University
Working Group(s)	Pediatric (PRWG)
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 42 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
Project Period	4/24/2019 - 2/20/2020
Funding Status	Funded - James Lemon-Philanthropic Funding, MTRH Intramura Research Grant
Direct Award (USD)	$12,155
Update	The study request for continuing review to IREC was received on 21st of February. Upon this, the data collection tool was piloted and the database finalized. A CME conducted with care providers at the NBU unit. Enrolment of neonates was initiated on the 24th of April. So far, 151 participants have been recruited. Of these, 105 cases have been discharged with 12 occurrences of death. The 1st follow up at the outpatient pediatrics clinic is scheduled for the month of August.
Future Plans	Over the next 6 months, we aim to continue with enrolment with a target of 420 neonates enrolled. Data cleaning will also be done as well as preliminary baseline data analysis upon conclusion of enrolment. Enrolled participants will be followed up by the study team at the outpatient clinic for subsequent appointed hospital visits in addition to a developmental assessment done at 6,9 and 12 months. At the 1 yr mark, follow up will be stopped. At this point, plans for the manuscript will be initiated.
Publication(s)	

Study Title	**Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK)**
Principal Investigator(s)	Valentin Fuster, Mount Sinai School of Medicine

Co-Investigator(s)	Jemima Kamano, Moi University
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)
Description	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 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 QRISK2-211 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	4/1/2012 - 3/31/2019
Funding Status	Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	$2,104,519
Update	Aim 1 (barriers & Facilitators to Linkage/Retention 1. Aim 1: data collection and analysis are complete a) Primary qualitative analysis completed and manuscript "Barriers Influencing Linkage to Hypertension Care in Kenya: Qualitative Analysis from the LARK Hypertension Study": published in the Journal of General Internal Medicine b) Secondary qualitative manuscript nearly finalized. Subsidiary Aim 1.1 (Behavioral Assessment and Communication Strategy) 1. Manuscript in preparation Subsidiary Aim 1.2 (Smart-phone-based tool) 1. Manuscript in preparation Aim 2 (Cluster RCT) 1. Data analysis ongoing 2. Final outcomes analysis a) Final outcomes accepted as abstract to be presented as an oral presentation at European Society of Cardiology 2019 b) Final outcomes manuscript currently under review at JACC 3. Process evaluation manuscript in preparation Aim 3 (Cost Effectiveness Analysis) 1. Data analysis ongoing 2. Manuscript to be considered
Future Plans	1. Preparation and finalization of manuscripts
Publication(s)	

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, 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 1-15 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.
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	9/1/2012 - 9/1/2016
Funding Status	Funded - NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	$1,886,804
Update	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. All study intervention and follow-up of patients is complete and preliminary analyses of the data is ongoing. In total, we followed 285 child-caregiver dyads (children ages 10-14) attending eight AMPATH clinics (randomized to intervention or control) in western Kenya. Participants at intervention clinics received intensive counseling with trained disclosure counselors and culturally-tailored materials, compared to control clinics with standard care. Disclosure was treated as a time-to-event outcome, measured on a discrete time scale, with assessments at 0, 6, 12, 18, and 24 months. Quality of life, mental health and behavioral outcomes were assessed using standardized questionnaires and adherence to ART was monitored using electronic dose monitors (MEMS caps). Mean age was 12.3 years (standard deviation [SD] 1.5) and 52% were female with an average time-on-treatment of 4.5 years (SD 2.4). Between 0 and 6 months, disclosure prevalence increased from 47% to 58% in the control group and from 50% to 70% in the intervention group. Differences in disclosure were not sustained over the following 18 months. The prevalence of depression symptoms was significantly higher in the intervention compared to the control group at 6 months (odds ratio 2.07, 95%CI 1.01, 4.25); however, there was no evidence that these differences were sustained after 6 months. The clinic-based intervention increased disclosure of HIV status to children living with HIV in the short-term, resulting in earlier disclosures, but had less clear impacts longer-term. Though well-tailored interventions may support disclosure, children may still experience increased levels of depression symptoms immediately following disclosure. A manuscript detailing these findings was published in a special issue of the journal AIDS Vreeman RC, Nyandiko WM, Marete I, Mwangi A, McAteer C, Keter A, Scanlon ML, Ayaya SO, Aluoch J, Hogan J. (2019) "Evaluating a patient-centered intervention to increase disclosure and promote resilience for children living with HIV in Kenya," AIDS, 33:S93-S101.

Future Plans	Over the next 6 months, we plan to: • Complete data analyses for all study objectives, including the impact of the disclosure intervention on ART adherence recorded using electronic dose monitors. • 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)	

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)	
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, 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)	Khunyangu Sub-District Hospital, Moi Teaching and Referral Hospital
Project Period	10/1/2012 - 12/31/2013
Funding Status	Funded - World Health Organization (WHO)
Direct Award (USD)	$162,000
Update	We are analyzing the data within Redcap.

Future Plans	We hope to have a summary of the analyzed data and initial draft of a manuscript.
Publication(s)	
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	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 1-19 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 2 HIV-infected adolescent-mother dyads in whom the mode of infection is uncertain and 1 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 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
Project Period	5/1/2017 - 4/30/2018
Funding Status	Funded - Indiana CTSI
Direct Award (USD)	$20,000
Update	The study is still recruiting subjects. Thus far 85% of enrollment target has been achieved.
Future Plans	We anticipate completing enrollment and beginning the blood sample analysis by December 2019.
Publication(s)	

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 6 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 attemting 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
Project Period	2/5/2018 - 2/5/2019
Funding Status	Funded - Mt. Sinai Hospital
Direct Award (USD)	$3,422
Update	Data analysis was completed and a manuscript prepared. Some of the key findings included; The average age of participants was 26.6 years and enrolled women were at an average gestation of 25 weeks. 4.5% of the women enrolled had a previously identified history of cardiac disease although none of them could characterise the disease. Three women had echo-cardiographic evidence of RHD for an overall point prevalence of 5 per 1,000. When considering all clinically significant lesions, the point prevalence was 27.1 per 1,000. Pulmonary hypertension, right ventricular systolic dysfunction and pericardial effusion were only identified in RHD associated cases.

	History of mid-trimester loss (20 - 28 weeks) and vital signs parameters were not statistically different between women with and without a cardiac lesion. The average time it took to perform a screening ECHO for women without cardiac disease was 7 min as compared to 13 min for women with a significant cardiac lesion. A manuscript had been developed and was submitted to the Lancet and Heart for peer review. However, both attempts were not successful. We did get comments from reviews and we are editing the manuscript to fit their recommendations.
Future Plans	We hope to re-submit the manuscript for peer review.
Publication(s)	

Study Title	**Prospective study of Lopinavir based ART for HIV Infected childreN Globally (LIVING study)**
Principal Investigator(s)	Prof. Winstone Nyandiko, Moi University
Co-Investigator(s)	Prof. Samuel Ayaya, Moi University
Working Group(s)	Pediatric (PRWG)
Description	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/rtv) 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/rtv 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. 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. 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.)
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu District Hospital
Project Period	6/1/2016 - 12/31/2018
Funding Status	Funded - Drugs for Neglected diseases initiative - Geneva
Direct Award (USD)	$225,180

Update	Key accomplishments done in the last six months has been to finalize on collecting all the required patient study-related data and uploading of all the case reporting files to the database pool. We have also been able to respond to all the data queries that have been generated. There have been no major challenges experienced with this process since we had all the required resources to do the work available. Data cleaning is not yet complete, therefore we do not have any preliminary findings
Future Plans	It is our hope that in the next six months, that data will have been cleaned, analyzed and study findings shared with the study team.
Publication(s)	

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
Project Period	9/1/2015 - 8/31/2018
Funding Status	Funded -
Direct Award (USD)	$75,000
Update	The study has been closed for enrollment at our site and we have also completed following up the enrolled study participants.
Future Plans	We expect to complete the analysis of the data collected.
Publication(s)	

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, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, 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	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 questions related to: • 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 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. A manuscript describing the results of this study is currently under review at the Journal of the International Association of Providers of AIDS Care.
Future Plans	Over the next six months, we hope to complete additional data analyses and disseminate our findings through published manuscripts.
Publication(s)	

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 (PHPCWG)
Description	Malaria is a major public health problem, with an estimated 198 million cases occurring world-wide in 213. Effective strategies to reduce malaria transmission and disease have been highly successful leading to a 4% reduction in malaria cases in sub-Saharan Africa since 2. 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 hotpsot. 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 8 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.
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. The Final RPPR for this R21 was submitted to NIH in May 2019. In July we received additional funding to expand the cohort and continue activities for 5 years.
Future Plans	Household visits for weekly for entomology collections and monthly for survey and DBS collections continue and we will expand activities to 2 additional villages. Aim 2

	mosquito and DBS processing and matching of parasite haplotypes in mosquito and human samples collected is ongoing. We will also conduct preliminary analyses and draft manuscripts of the main outcomes in the coming year.
Publication(s)	

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 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.
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/1/2018 - 7/31/2020
Funding Status	Funded – Sick Kids, Toronto
Direct Award (USD)	$20,000
Update	We have developed an adolescent sexual and reproductive health curriculum in response to some of the needs identified in the design process. This was for program development at Rafiki and surrounding communities. However we are now delighted to proceed with an approved amendment to adapt the Chamas for Change program for adolescents; this curriculum will be included as a part of this. In addition, retrospective data from the MOH registers for 2017 and 2018 have been collected to understand the baseline adolescent data in greater accuracy at MTRH. We are preparing an amendment to adjust the protocol to allow for a retrospective data review instead of a prospective cohort; this will be submitted shortly. It is for practical reasons that we needed to change. In addition to its use for M&E with the department we hope to

	conduct a comparative analysis in 2021 or 2022 to observe for changes following the implementation of YFS. Following our Human-centred design thinking workshop, an idea to do a healthcare provider empathy training was born. We have developed training manuals and handbooks with aid from various facilitators with different expertise in preparation for the training. And in doing so, we have held a number of meetings with both our facilitators from the hospital and the county so as to review and compare our curriculum and the national guidelines and see how to merge them for a comprehensive output that can be adopted. We are preparing an IREC to study the implementation and evaluation of this training, also to be submitted shortly. Lastly, we have attended two conferences; 43rd annual KOGS (Kenya Obstetrical and Gynaecological Society) and the 3rd annual RHNK (Reproductive Health Network Kenya) where we have disseminated our results and way forward as a program.
Future Plans	Over the next 6 months, we intend to facilitate the Uasin Gishu county healthcare providers training on the provision of youth-friendly services and empathy training with collaboration with USAID-RMNCAH. This is as a program implementation. We are also looking at further pursuing this empathy training with research metrics in at least 2 other counties not under the USAID RMNCAH umbrella. As mentioned, we now have approval to adapt Chamas for Change for adolescents. The curriculum content we have developed will be included in this adaptation; our data from the design process will contribute to the adaptation process. As mentioned, an amendment to do a retrospective analysis of register data from 2017 and 2018, and then again 2021 and 2022 after YFS programs have been implemented, is forthcoming. Finally, we are moving forward in translating the Design Process data into clinical care changes in MCH and Rafiki clinics, including a targetted adolescent pregnancy care day and peer support groups. This is with full support from the paediatrics and reproductive health departments. As you can see we are moving forward with both research and care efforts, which are intimately related here. We will continue to engage stakeholders as we move forward.
Publication(s)	

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	Hypertension is a major risk factor for cardiovascular disease (CVD), and 8% 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 214-218 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 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.

Site(s)	Burnt Forest Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	6/1/2018 - 5/1/2019
Funding Status	Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	$268,469
Update	• Analysis of Aim 1 data • Human centered design team meetings • Hiring and training of peers • Development of health IT tool • Preparation of DSMB packet • Conduct pilot trial, including weekly and peer staff debriefs from pilot activities • Site clinician training on referral algorithms • Analysis of Aim 1 data • Development of health IT tool • Constitution of the DSMB and review of DSMB packet
Future Plans	1. Set up and hold the first DSMB meeting to initiate Aim 2 of the study, the cluster randomized RCT. This will include submission of any suggested DSMB changes to the trial protocol or trial documents to the institutional review board. 2. Begin enrollment of participants in the cluster randomized controlled trial (RCT) 3. Finalize analysis of Aim 1 data (referral network analysis, baseline observational process mapping, focus group discussions, mabaraza and key informant interviews) 4. Hiring and training of the peer navigators for the intervention sites. 5. Compete training of providers in the remaining two clusters. 6. Complete our pilot activities
Publication(s)	

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 July 2019, the Study managed to see 677 encounters of which 184 Cases have been enrolled. 121 participants are currently in active follow-up, while 63 are deceased. All Deaths have been documented. We have so far done 493 total follow-ups. The study has also enrolled 89 Controls matched to 15 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)	

Study Title	**Syndemics**
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Suzanne Goodrich, Indiana University
Working Group(s)	Adult Medicine (AMWG)
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 IeDEA 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 Teaching and Referral Hospital
Project Period	12/17/2018 - 12/17/2020
Funding Status	Unfunded
Direct Award (USD)	

Update	PSA 1 Progress: Data collection and entry has been completed at all sites for PSA1. A concept sheet will be developed for this analysis in 2019. PSA2 and PSA3 have been transitioned into PSA 3 below. PSA 2 Progress: Enrollment has begun at all sites. All qualitative interviews have been completed at all three sites and all but 3 interviews have been transcribed. Validation of the first 30 RA assessments with Psychiatric review has been completed at AMPATH and Mbarara. At AMPATH there is a strong correlation between RA diagnoses, based on screening assessments, with the Psychiatrists assessment. This validation from Mbarara is pending. FACES needs to complete another 12 assessments before a comparison between the RA and Psychiatric assessments can be undertaken. Activity AMPATH FACES Mbarara Qualitative Interviews (15) 15 15 16 Syndemics Cohort Enrollment 141 38 47 Validation of 30 Interviews by Psych. 30 18 30
Future Plans	PSA 1 completion coding and analysis of qualitative interviews PSA 2 complete enrollment and data cleaning PSA 3 Interviews to begin Jan 2020
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)	
Working Group(s)	Oncology (ORWG)
Description	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 1% 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 198'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.

Site(s)	
Project Period	10/1/2015 - 9/30/2018
Funding Status	Funded - NIH
Direct Award (USD)	$158,406
Update	The study is closed for enrollment; we have managed to enroll 59 study participants. We have been able to successfully ship all KS biopsy samples to Infectious Disease Institute Labs in Kampala, Uganda for analysis of the PDL1; and all the samples shipped have been analyzed.
Future Plans	We hope complete data entry and analyze the data.
Publication(s)	

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
Project Period	4/1/2017 - 4/30/2018
Funding Status	Not Reported
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 is currently going on and using 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)	

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)	Pediatric (PRWG), Public Health and Primary Care (PHPCWG), Reproductive Health (RHWG)
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 CentreSaboti, 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 (intervention) in TransNzoia were rolled out in 4 sub counties in March 2018 and have gained stability. We have 49 groups in the 37 intervention community units which are in our intervention arm and no groups in the 40 community units (clusters). The groups/chamas have had at least 28 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 574 women that have attended at least one Chama meeting and out of these, 190 women have attended 25% (1-6 sessions) of the meetings, 106 women have attended 50% (7-12 sessions) of the meetings and 278 women have attended more than 75% (13-24 sessions) of the meetings. We are also working with 92 Community Health Volunteers (CHVs) and 66 Community Health Extension Workers (CHEWs). Each Chama group has 3 officials 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 four times to ensure they are maintaining the standard MOH care as required. The main focus for the first half of this year was to finalize on implementation for Cycle 1(year I) and carrying out end line data collection. We collected end line data on 1528 women, out of which 728 women (control arm) and 800 women (intervention arm). Data collection has been done all parameters that we were focusing on except microfinance where we are intend to finalize as the groups share out. So far we had eight 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. Chamas are stable and we have been able to form three male groups called BabaToto.
Future Plans	We are in the process of doing preliminary data analysis for the project and present to the funders in preparation of scale up funding application. We also intend to publish the results of the study and share with the science community. To continue providing care, we plan to retain our cohort; both control and intervention arms and to recruit more women to join our Cycle 2 (year 2) group. The inclusion criteria for the women is that they should have children below 2 years to match with our intervention and are willing to join and participate actively in Chamas. We also plan to meet CHVs from our control arm so as to provide feedback on data collected and discuss our next implementation plan over the next 2 years. We will also recruit pregnant women to form our new Cycle (year 1) for the intervention community units. We will continue with bi-weekly Chama sessions and also review our curriculum. We also intend to complete our financial data collection and submit a comprehensive report once the analysis is done by end of the year. As a program we are committed to strengthening our partnership with the Ministry of Health officials at county level therefore we plan to have a dissemination meeting on the findings of our study
Publication(s)	
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 215 to December 216. 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	The study was published in the Journal of the International AIDS Society in April 2019 (doi: 10.1002/jia2.25272). The paper will be presented as an oral abstract at the International AIDS Society meeting in Mexico City in July 2019.
Future Plans	The study is completed.
Publication(s)	

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	This study will involve retrospective and prospective analysis of blood sampling from patients enrolled in a previous NIH-funded (Vreeman, 1K23MH87225) 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 21 and October 213. 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: 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.
Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital, Webuye District Hospital
Project Period	8/2/2016 - 7/31/2020
Funding Status	Funded - NIH
Direct Award (USD)	$613,511
Update	Over the last six months we completed cleaning all study data, including retrospective data from AMRS and study databases, prospective data, and electronic MEMS adherence data. These data are stored on a Brown University server and analyses are being led by a team of data managers and statisticians at Brown and AMPATH. Analyses of viral suppression, adherence, and drug resistance is ongoing. The final blood samples are being shipped to Rami Kantor's lab at Brown University for resistance testing. In preliminary analyses among 227 children enrolled in the study, mean age was 8.4 years and 45% were female with an average time on ART of 2.0 years. Mean CD4% was 26%. At time point 1 (1-3 months of follow up), 37% of children had therapeutic drug levels of NVP or EFV, while 49% reported >90% adherence by caregivers, and 68% were virally suppressed (defined as a viral load <1,000 copies/mL). At time point 3 (4-6 months of follow up), only 25% of children had therapeutic drug levels, 46% were adherent by caregiver report, and 81% were virally suppressed. Fourteen percent of children had viral failure at both time points. Among those with viral failure (>1,000 copies/mL), 94% had evidence of drug resistance mutations at time point 1 to an NNRTI or NRTI, and 90% had resistance at time point 2. Viral failure at time point 1 was significantly associated with younger age, lower CD4%, and longer time on ART, while viral failure at time point 2 was only associated with lower CD4%. Those with sub-therapeutic drug levels at time point 1 were 10.5 times more likely to accumulate drug resistance mutations. These preliminary findings are described in two upcoming abstract presentations (see presentations section).
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; •

	Continue with analysis and draft additional manuscripts for publications on our findings.
Publication(s)	

Study Title	**WEZESHA (Neurodevelopmental Screening in Children Born to HIV-Infected Mothers in Kenya)**
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi University
Working Group(s)	Pediatric (PRWG)
Description	Goal: implement an effective neurodevelopmental (ND) screening and intervention program to combat neurodevelopmental delays in children born to HIV-infected mothers in resource limited settings. Specific objectives: 1. Identify appropriate Neurodevelopmental instruments for use in HIV-exposed Kenyan children. 2. Evaluate an integrated Neurodevelopmental screening program within the existing care system. This will be done in three study sites: MTRH Maternal Child Health clinic, Turbo and Burnt Forest Maternal Child Health Clinics respectively. Study Aims: 1. Determine and compare the reliability and validity of neurodevelopmental screening tools and assessments for use among children aged 18-36 months in Kenya- by identifying an optimal screening tool and assessment for use in Kenya, conducting cross-cultural adaptation, comparing the psychometric properties of two Neurodevelopmental screening tools (DSQ; PEDS:DM) and two assessments (RNDA; MDAT) among 240 Kenyan children, using BSID-III as a reference standard. The findings from this aim will provide validated tools for implementation. 2. Evaluate neurodevelopmental screening implementation in an existing healthcare system in Kenya. â€¢ Develop a contextualized implementation plan: engaging with the community and key stakeholders to create an implementation plan for Neurodevelopmental screening and referral for assessments in local MCH clinics. â€¢ Pilot a Neurodevelopmental screening program at one MCH clinic in Kenya: perform a pilot evaluation of a neurodevelopmental screening tool within a routine clinical setting. We will measure implementation outcomes, including acceptability, feasibility, fidelity, implementation cost, and sustainability. In addition, we will assess effectiveness of neurodevelopmental screening, as determined by sensitivity; specificity; and positive and negative predictive values. 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 approvals for the aims.
Site(s)	Burnt Forest Sub-District Hospital, Moi Teaching and Referral Hospital, Turbo Health Centre
Project Period	9/21/2018 - 9/21/2022
Funding Status	Funded - NIH
Direct Award (USD)	$46,055 year 1 budget

Update	We have done cultural adaptation of the instruments (screening DSQ, PEDS:DM; Assessment: RNDA and MDAT) to determine and compare the reliability and validity of the neurodevelopmental instruments. This included translation, cognitive interviewing and brief pilot evaluations. Twenty caregivers of young children were recruited for cognitive interviews regarding questions and activities for all instruments. Two neurodevelopmental assessments (Rapid Neurodevelopmental Assessment(RNDA) and Malawi Developmental Assessment Tool (MDAT) were performed on children aged 18-36 months to determine which items needed to be culturally adapted. While the screening instruments, Developmental Screening Questionnaire (DSQ) and Parent Evaluations of Developmental Status-Developmental Milestones (PEDS; DM), underwent appropriate translations and cognitive interviews.
Future Plans	We aim to recruit and enroll 240 young children between the ages of 18-36 months from the HIV-infected, HIV-exposed but uninfected children and Non-exposed children. 120 from MTRH MCH clinic, 60 from Turbo and Burnt Forest MCH clinics respectively. At enrollment we will collect anthropometric and demographic data ,maternal education (using the WAMI index40) and cognitive stimulation (using sections of the UNICEF multiple indicator cluster survey41) We will administer the DSQ, PEDS: DM, MDAT, RDNA, and BSID-III to each of the 240 children. With BSID-III being the goal reference standard of the two assessments (MDAT and RNDA).
Publication(s)	

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Appendix A: Bibliography

The following bibliography includes AMPATH research publications that were published between January 1, and June 30, 2019. 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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Appendix B: Wools-Kaloustian Article

Wools-Kaloustian Named AMPATH North American Co-Director of Research

NEWS · SEPTEMBER 20, 2019

Kara Wools-Kaloustian, MD, MS, has been named co-director of research (North America) for the AMPATH partnership and director of research for the Indiana University Center for Global Health (IUCGH). Wools-Kaloustian was in the first IU School of Medicine residency class to complete rotations at Moi University and Moi Teaching and Referral Hospital in Kenya in 1991 and the first fellow to conduct research as part of the partnership in 1992.

These early global health experiences shaped Wools-Kaloustian's entire career. "I had been committed to providing health care to marginalized populations from the time that I entered medical school, but what I learned during my first residence rotation in Kenya was that I really enjoyed participating in improving health systems and creating systems where they did not previously exist," she said.

Wools-Kaloustian was one of AMPATH's earliest team leaders.

Professor Winstone Nyandiko and Dr. Kara Wools-Kaloustian are AMPATH's directors or research.

She served as one of the earliest medicine team leaders from 1993-94 and, with support from the World AIDS Foundation, she established both an educational program about sexually transmitted infections (STIs) and HIV for health care providers, and an STI diagnostic laboratory in collaboration with the Faculty of Health Sciences at Moi University. Her work in Kenya commenced again in 2003 when she became one of the founding co-directors of field research.

In her new role, Wools-Kaloustian collaborates with Professor Winstone Nyandiko, AMPATH's co-director of research (Kenya) and associate professor of child health and pediatrics at Moi University. Prof. Nyandiko is one of the pioneer pediatric HIV specialists in Kenya and has been integral to the development of the AMPATH research program as well the Kenyan National guidelines and curricula on HIV care, treatment and prevention. He has contributed to the treatment of thousands of children and his research has led to policy changes as well.

American colleagues she has conducted HIV research related to adults, children, complications and prevention of mother-to-child transmission that has improved the treatment and care of patients around the world.

“I entered medical school the year that HIV was discovered to be the virus that causes AIDS. By the time I started my clinical rotations in 1986, there was a test for HIV, but no treatment, and the life expectancy from diagnosis to death was about a year,” said Wools-Kaloustian. “As I progressed through my training, even though it was clear that HIV could not be spread by casual contact, my patients’ trays were left outside their rooms where they couldn’t get to them, some people would gown and glove just to enter a patient room, and very few people would touch patients that had HIV,” she continued. “Ultimately I felt that people with HIV needed a voice, someone who was willing to care for them and touch them without fear.”

Wools-Kaloustian is also the principal investigator for the East Africa IeDEA (EA-IeDEA) consortium, one of seven regional data centers funded by the National Institutes of Health to provide global HIV/AIDS data. The IeDEA regional data centers have the capacity to merge, share and analyze data for more than 1.7 million HIV patients worldwide.

PREVIOUS
Kenyan Students Spend Rotation at AMPATH's North American Partners

NEXT
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The AMPATH Habari is a recap of our latest programs, new programs, new priorities, and new ways to help.

Appendix C: 2019 AMPATH Research SWOT Analysis Survey Report

2019 SWOT Analysis Survey Report

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Please visit the AMPATH Research Program website to learn how our research programs are helping improve the health of the Kenyan people.

www.ampathkenya.org/research

CONTENTS

EXECUTIVE SUMMARY

In preparation for the AMPATH Research Program's 2019 Strategic Planning Retreat, the AMPATH Research Program conducted a SWOT analysis survey of 171 internal and external stakeholders. The purpose of this survey was to evaluate how well AMPATH Research Program is doing in meeting its vision, mission, and 2019 Strategic Objectives, identify internal strengths and weaknesses as well as external opportunities and threats, and gauge the performance of core administrative supports for research. The information from this survey is intended to assist stakeholders in the development of a new strategic agenda for the AMPATH research program.

The following report provides a detailed analysis of the findings of the 2019 AMPATH Research SWOT Analysis Survey. It begins with an executive summary that briefly describes the survey methodology, response rate, and key findings. Next if provides a more detailed description of the stakeholders who responded to the survey along with an evaluation of the program's performance towards meeting its 2015 strategic objectives. It then summarizes findings from performance evaluations conducted for the Research and Sponsored Projects Office (RSPO), the Research Program Office (RPO), and the Institutional Review and Ethics Committee (IREC). Finally, it concludes with descriptions of the common Strengths, Weaknesses, Opportunities, and Threats identified by stakeholders along with sample responses for each section. A full listing of stakeholder responses is included as appendices to this report.

Survey Methodology

The 2019 SWOT Analysis Survey was conducted over a period of four weeks from July 8, to August 2, 2019, using an online REDCap survey. It was sent by e-mail to 171 key stakeholders identified by the Research Program Office. These stakeholders included 130 internal stakeholders and 41 external stakeholders. Two separate questionnaires were used for internal and external stakeholders with questions tailored to those respondent groups. Dynamic branching was used to further tailor survey questionnaires to individual respondents based on individual responses. Copies of both questionnaires are included in Appendices F & G of this report.

Response Rate & Respondent Demographics

In total, 41 percent of the internal stakeholders and 22 percent of external stakeholders invited to complete the survey submitted responses with an overall response rate of 36 percent. Around 55 percent of the respondents were affiliated with institutions in North America while 45 percent were affiliated with institutions in Kenya. 55 percent of the internal stakeholders identified themselves as principal investigators or co-investigators on a research project. About half of the external stakeholders represented county governments and another half represented academic departments within Moi that have not traditionally engaged in AMPATH research programs. Open ended responses were categorized into standard categories to help identify common themes. Sample responses are provided in each section and de-identified responses are listed in full in Appendices A-E.

Key Findings

Perceptions of Research Vision & Mission

- Overwhelmingly, internal stakeholders strongly agreed (38 Percent) or agreed (48 Percent) that the current AMPATH Research Vision Statement fully captures where we should be going as a research program.
- However, nearly a third (28 percent) indicated that the vision statement needed some revision.
- Of the external stakeholders who were familiar with AMPATH's research mission, 57 percent believed that AMPATH was fully achieving its research mission.

Perceptions of Performance on 2015 Strategic Priority Goals

- Overall, the majority of internal stakeholders felt that the program was doing better today on each of the 4 strategic objectives then where the program was at in 2015.
- 50 percent felt the program was doing somewhat better on creating a stable, resourced infrastructure for research that enables the efficient conduct of high-quality, high-priority research (Objective 1).
- Nearly half of internal stakeholders felt that the program was doing much better or somewhat better in supporting successful independent investigators working in collaborative, interdisciplinary research teams to improve global health (Objective 2) though nearly a third noted no change from 2015.
- A third of respondents indicated that the program was doing somewhat better in terms of strengthening a supportive, global health research-intensive cultures within the schools and departments of all AMPATH partners (Objective 3).
- In terms of promoting 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 (Objective 4), .

Internal Strengths & Weaknesses

- Various aspects of the research program's organizational structure or core infrastructure was the most common strength identified by internal stakeholders (42 percent).
- The strength of our research partnerships (25 percent), clarity of research policies and procedures (21 percent), support provided by the Research Program Office (15 percent), and the research program leadership (15 percent) were among the top 5 most common strengths identified by internal stakeholders.
- 20 percent of internal stakeholders reported weaknesses related to working with RSPO to implement research projects. These included concerns over procurement, issues related to transparency and consistency in process, and lack of adequate resources.
- Second to concerns related to RSPO processes were issues related to a lack of mentorship for junior Kenyan faculty (20 percent) and the number of trained Kenyan faculty available to engage in research collaborations (14 percent).
- Connected with these issues were concerns related to a lack of career path for junior Kenyan researchers (8 percent) and gaps in training opportunities for Kenyan researchers (14 percent).

External Opportunities & Threats

- 17 percent of internal stakeholders noted that AMPATH's external reputation and support for the AMPATH model from donors as a key opportunity.
- Additionally, 13 percent of internal stakeholders felt that AMPATH's population health expansion offered new opportunities to expand AMAPTH's research program.
- Among the most common external threat noted by internal stakeholders dealt with changes in donor funding priorities (42 percent)
- Devolution (9 percent), growing competition with private academic institutions for resources (7 percent), weakening of core partnerships (7 percent), and a lack of technology (4 percent) were among the top five most commonly reported external threats.

Perceptions of Working Group & Core Structure

- Nearly 65 percent of internal stakeholders strongly agreed (29 percent) or agreed (35 percent) that AMPATH's structure of research working groups and cores successfully supports our mission, vision, and values.
- However, nearly a quarter did not agree that the working groups and cores achieved this goal.
- 74 percent strongly agreed or agreed that the working groups and cores served to catalyze new research.
- Similarly 76 percent of internal stakeholders strongly agreed or agreed that the working groups and cores provided useful peer review.
- Conversely, almost a quarter viewed the working groups and cores as an unnecessary barrier to research.

Perceptions of RSPO Performance

- While RSPO was consistently cited as an internal weakness in the SWOT analysis, internal stakeholders who accessed specific RSPO services felt generally positive about the service they received.
- Internal stakeholders were most satisfied with the pre-award budget preparation & development (32 percent extremely satisfied) and post-award contracting (23 percent extremely satisfied) services they received from RSPO
- Internal stakeholders were least satisfied with the human resources (hiring, staff training & development, payroll, performance appraisal) (27 percent dissatisfied) and procurement & supply chain (48 percent extremely dissatisfied or dissatisfied) services provided by RSPO
- Despite higher levels of dissatisfaction with some RSPO services, nearly 65 percent of respondents agreed or strongly agreed that RSPO provides the right set of services and supports to achieve AMPATH's research mission, vision, and strategic priorities.

Perceptions of Research Program Office Performance

- Overall, internal stakeholders were largely satisfied or extremely satisfied with the services they received from the AMPATH Research Program Office.
- Internal stakeholders were most satisfied with the meeting and conference call support they received (48 percent extremely satisfied) and the operational support and advice provided by RPO staff (42 percent extremely satisfied)

- Nearly all (92 Percent) of the internal stakeholders who used RPO support services agreed or strongly agreed that the RPO The Research Program Office provides the right set of services and supports to achieve AMPATH's research mission, vision, and strategic priorities.

Perceptions of IREC Performance

- 53 percent of internal stakeholders reported being satisfied with the services they received from IREC
- However, three quarters of the internal stakeholders noted that the time for reviews was too long and needed improvement.
- Nearly a quarter noted concerns with the quality of the peer review process and comments returned by reviewers.

External Priorities for AMPATH Research

- The 5 most frequently priorities for AMPATH research reported by external stakeholders were Food & Nutrition Security (78 percent), Training and Professional Development for medical personnel (67 percent), Oral Health (56 percent), Preventative Medicine (44 percent), and Cancer Treatment (44 percent)

Respondent Overview

In total, 171 internal and external stakeholders from the AMPATH research community were invited to complete the 2019 AMPATH Research SWOT Survey. Overall, 36 percent of respondents completed the survey. Internal stakeholders, which included principal investigators, research working group and core co-chairs, field co-directors, program managers, and other research staff or affiliated leaders, completed the survey at a higher rate (41 percent v. 22 percent) than external stakeholders, which included county health leaders and leaders from academic departments not traditionally engaged in the program. Of the 53 internal stakeholders providing complete responses, 60 percent had primary institutional affiliations with a school or department in the Moi University College of Health Sciences or Moi Teaching and Referral Hospital (See Figure 1.2) and 40 percent had primary institutional affiliations with institutions in North America. Around 55 percent of respondents reported being an investigator or principal investigator for an AMPATH related research project (See Figure 1.2).

Figure 1.1 Respondent's Primary Institutional Affiliation (n=53)

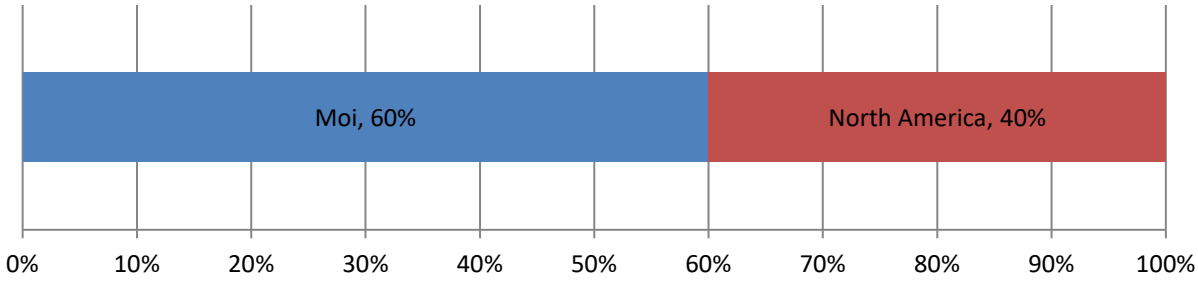
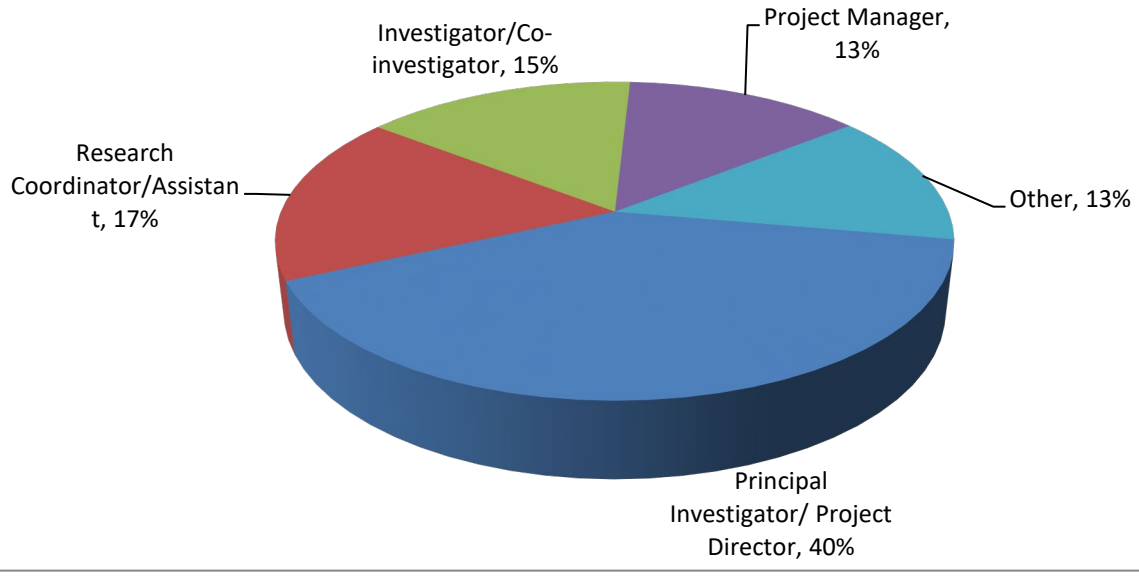


Figure 1.2 Respondent Roles (n=53)



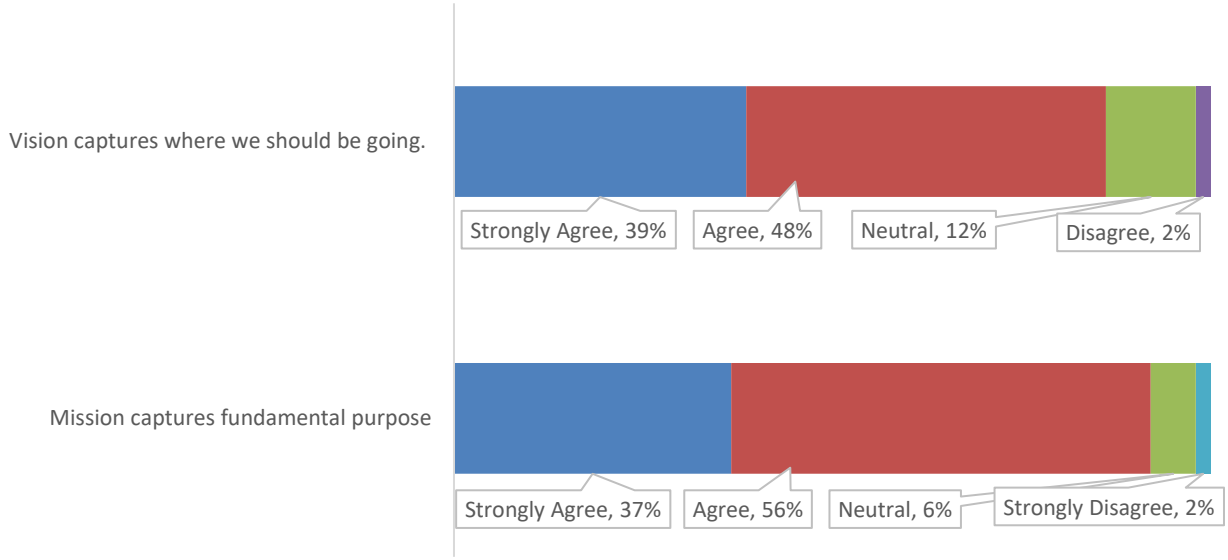
INTERNAL PERCEPTIONS OF RESEARCH PROGRAM VISION & MISSION STATEMENTS

Vision: Our vision is to create 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

Overall, internal stakeholders felt that the current AMPATH Research Program Vision & Mission Statements captured where the program should be going and its fundamental and unique purpose. Nearly 40 percent of internal stakeholders strongly agreed with the statement that, "The vision statement fully captures where we should be going as a program," and another 48 percent agreed with this statement (Figure 1.1). In terms of the program's mission statement, 37 percent of internal stakeholders agreed with the statement, "The mission statement captures our research program's fundamental and unique purpose," and another 56 percent agreed with this statement (Figure 1.1).

Figure 1.1: Internal Stakeholder Perceptions of Mission & Vision



Despite the general perception among internal stakeholders that the AMPATH Research Program's Vision and Mission statement captured where the program should be going as well as its fundamental and unique purpose, 28 percent indicated that some revision was needed of the vision statement and 21 percent indicated some revision was needed of the mission statement. Table 1.1 presents a sampling of unedited changes to the vision and mission statements proposed by internal stakeholders.

Table 1.1: Unedited Stakeholder Proposed Changes to the AMPATH Research Program's Vision & Mission Statements

Proposed Vision Statement Changes	Proposed Mission Statement Changes
• a vibrant, world-class, collaborative community of international researchers in health and health care. • Although I agree with the spirit of "Kenyan led," in reality there are simply too few Moi U. investigators to lead everything. The requirement that most/all grants and projects have North Am. and Kenyan co-leaders has resulted in most Kenyan investigators being spread so thin as to have little to do with many of the projects they are supposedly co-leading. That makes them more figurehead than Co-PI, which is then demeaning. Unless and until Moi U. greatly increases its number of investigators, or other Kenyan universities get involved, "Kenyan led" will be, and should be, more aspirational than real. • AMPATH stands for Academic Model Providing Access to Healthcare. The vision statement gives the impression that the research community is limited to healthcare researchers. "...community of international researchers in health and health care". AMPATH includes other disciplines, that can support access to healthcare (economists, policy makers, agronomists, engineers, educators) but the vision projects a more narrow limits. It's semantics but if ever you want to grow to include other disciplines - again that can support the access to healthcare - you may want to consider revising the vision to mirror the acronym meaning. • Because AMPATH does not only empowers researches but also communities and an a lot of the work done has helped improve health outcomes, i would suggest that the statement also includes the roles we have in the communities we work in • I would make the vision statement broader at this point in time such as the following: AMPATH Research Program aims to perform world class research that is translated into policy and implementation for not only Kenya but beyond. Research that is not translated into policy and implementation does nothing to better the lives of patients. All research must be done in collaboration- that goes without saying in 2019. The "Kenya led" modifier implies a limited vision. When the program was first started several decades ago, it likely needed to be stated but should not need to be stated now, or there is a problem that in greater than two decades the	• "Resource limited settings" could mean places in Indianapolis. The AMPATH Research Program is a GLOBAL HEALTH research program focused mainly on enhancing health and health care in Kenya and elsewhere in East Africa. Its mission statement should say that. The RESULTS of its research can and should be relevant to resource-limited settings anywhere, but the actual research will almost entirely be in Kenya and East Africa, where almost all (but not all) of it has been. • Expand it to not only cover health and Healthcare research that informs policy, but to also include policy research. Also, the term resource limited is a misnoma since all settings have limited resources. • I would say the mission should capture more than information to refer to other research products and services. Then I would like to see local communities explicitly come among the direct consumers of AMPATH research products. Additionally, it would be helpful and respectful to consider local communities as co-producers of AMPATH research products. I know we need a short mission statement and I don't know how to put this in a few words so am throwing it out there. • instead of resource-limited, i would prefer underserved but not a big deal • It could be revised to include other academic disciplines. Again with the singular focus of improving health but highlighting the role that access to food, water, infrastructure, employment, etc. plays in health. • It does not capture strengthening of the health system - issues of governance and accountability to the community • It is too long hence u would have wished it is shortened • Overall I agree. I would like to see something about end use involvement in the research processes • Revise the resource-limited areas to have a global presence. 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 the world.

Proposed Vision Statement Changes	Proposed Mission Statement Changes
capacity to lead has not been built. In addition, it may lead to misunderstandings that multi center collaborations are not wanted to welcomed (ACTG, TBTC, other clinical trials, etc.) Isn't it that the program wants all Kenya based projects to be performed in collaboration with Kenyans). • It would be nice to also strive to produce research that provides direct benefit to the care of patients in western Kenya. • Might consider making it clearer that we have a broad definition of health and healthcare that includes social determinants of health • More global • Proposing a slight change in wording so as to capture population health and health care: To create a vibrant, world class community of Kenyan and international researchers in population health and health care. • Strengthen the emphasis for development of Responsible Conduct of Research. • The Kenyan led component of the statement feels a bit forced. I prefer that we emphasize collaboration. • There is a heavy emphasis on "creating" but given this the 20th year of AMPATH, perhaps there should be more focus on maintaining, nurturting, growing, etc. • To create a vibrant, credible, world-class, Kenyan-led community of international researchers in health and health care. • To include an aspect of having research output influence policy changes. • We don't need to say "Kenyan-led" • Well, on the one hand I think the vision is great. We do want world class Kenyan leaders in research. On the other hand I think AMPATH participates actively in growing leaders and researchers in global health; we have a lot of award winners and junior researchers seeking to establish themselves as researchers in their own right through their work in Kenya. So can we not build Kenyans and others in thoughtful, care-led, world class research?	• The mission statement should include development of capacity of researchers in resource limited settings through collaboration. • There is repetition of the word "in resource limited setting". Probably delete or re-word the last statement. • There needs to be some incorporation of translating that evidence into real-world practice. • to improve the health of people in resource-limited settings, through RELEVANT RESEARCH RESEARCH dissemination AND IMPLEMENTATION

External Perceptions of Research Program Vision & Mission Statements

More than half of the external stakeholders surveyed (55 percent) indicated that they were fully aware of the AMPATH Research Program's vision and mission statements. Of those external stakeholders who indicated awareness of the program's vision and mission, 57 percent felt the program was fully achieving its vision and mission while the rest felt that the program was partially fulfilling its vision and mission. None of the external stakeholders reported that they felt the program was not meeting its vision or mission for research.

Respondent Perceptions of Performance on 2015 Strategic Priority Goals

In 2015 AMPATH conducted a strategic planning process and reduced the 13 strategic objectives defined in 2011 to four primary objectives. The 2015 Strategic Objectives were:

1. Create a stable, resourced infrastructure for research that enables the efficient conduct of high-quality, high-priority research;
2. Support successful independent investigators working in collaborative, interdisciplinary research teams to improve global health;
3. Strengthen a supportive, global health research-intensive cultures within the schools and departments of all AMPATH partners; and
4. Promote 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.

Over the last 4 years, these objectives have provided direction for AMPATH's research program leadership, its working groups, cores, and administration. They have served as the foundation for the development of core infrastructure, helped direct funding priorities, and guided the overall management of the research program.

As part of the 2019 SWOT Analysis Survey, research program stakeholders were asked, "In your opinion, how much better or worse is the AMPATH Research Program doing on each of its strategic priorities compared to three years ago?" Overall, respondents felt the research program was doing better on each of its strategic objectives when compared to 2015. Of note, 62 percent of respondents felt the program was doing much better or better on creating a stable and resourced infrastructure, 55 percent the program was doing better or much better on supporting successful independent investigators, and 67 percent thought the program was doing better or much better on promoting growth in key, high-yield, research related initiatives relevant to population health. While the majority of respondents felt progress had been made on strengthening a supportive, global health research-intensive culture within the schools and departments, 43 percent thought things had stayed the same and or gotten slightly worse.

Figure 2.1: Performance on 2015 Strategic Objectives (n=53)

	Much Better	Somewhat Better	Stayed the same	Somewhat worse	Much Worse	Don't Know
1. Create a stable, resourced infrastructure for research that enables the efficient conduct of high-quality, high-priority research;	12%	**50%**	18%	15%	0%	5%
2. Support successful independent investigators working in collaborative, interdisciplinary research teams to improve global health;	17%	**38%**	28%	5%	3%	8%
3. Strengthen a supportive, global health research-intensive cultures within the schools and departments of all AMPATH partners; and	17%	29%	**32%**	12%	0%	10%
4. Promote 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.	20%	**47%**	18%	3%	2%	10%

STRENGTHS

Respondents were asked to identify areas of the research program they viewed as strengths. Strengths were defined as any, ". . . positive internal factors that improve the research program's ability to be successful." Open ended responses were coded to help identify the common themes shown in the above word cloud and Table 3.1 below.

Among the common themes emerged around the research program's organizational structure and research management infrastructure. This included a variety of aspects related to the research working groups and cores, the Research Program Office and other administrative supports at AMPATH, and peer review processes. In addition, respondents felt that the knowledge and expertise found in the AMPATH research network were among the program's greatest strengths.

To a lesser extent the respondents also identified AMPATH's internal policies and procedures and supportive research culture as common strengths.

Table 3.1 Frequency of coded responses describing common Strengths identified by respondents

Strength Response Category	Count	Percent
Research Infrastructure & Organization Structures	22	42.31%
Strength of Research Partnerships	13	25.00%
Clear Policies & Procedures	11	21.15%
Support & Responsiveness of the Research Program Office	8	15.38%
Leadership	8	15.38%
Skilled Researchers	7	13.46%
Website & Newsletter	5	9.62%
Working Group Peer Review Process	5	9.62%

Research Working Groups	5	9.62%
Access to Mentorship	4	7.69%
Access to Training	3	5.77%
Publications Review Process	2	3.85%
Multidsiciplinary Approach to Research	2	3.85%
Strong Relationships with Key Stakeholders	2	3.85%
Record of Success	2	3.85%

Table 3.2 Unedited Sample Strength Responses

- Clearly defined structures particularly peer review system.
- Established research infrastructure (RPO, RSPO) Group of committed academic researchers Strong leadership of research program Strong track record of success
- Strong organization structures, strong partnerships, clear processes, experienced researchers, strong relations with MOH
- 1.Strong committed partners 2. Good organization 3. SOP's supportive of engagement and conduct of research 4. Skilled researchers
- Responsiveness of the AMPATH research manager is high; the publications review process is clear and efficient. The new AMPATH website looks wonderful and makes it easier to explain and present the partnership.
- Clear SOPs that guide the processes at AMPATH Already developed Infrastructure that support research
- Collaborative approach, Support from research office, Compliance office and assistance on financials in preparing grants, Many fees that are not dependent on the use of the services (would be better just to have a percentage if the work is research)
- Strengths: Being in touch with current funding opportunities and being able to promptly circulate to researchers. : The online portal for submission of proposals and manuscripts has made submissions easier : Prompt response to comments and questions by the research office
- The program is well organized, the right people doing what they know to do best and there is great accountability. Working with the communities on the ground
- The research program has done really well in terms of access to resources for investigators. Additionally, the research program has been as inclusive as possible with major decisions that concern all projects with the AMPATH research program. There has been a tremendous improvement in the organisational structure and processes especially with regards to working group approvals and publications committee.
- The protocols that exist for conducting and publishing research (e.g. SOPs for publications and initiating new projects) are quite helpful. The REDCap for new study submissions to the working groups are also good additions. The CTSI global health pilot grants have helped many investigators to conduct research at AMPATH.

WEAKNESSES

Respondents were also asked to identify program weaknesses. Weaknesses were defined as any, "negative internal factors that lessen the Research Program's ability to be successful. The above word cloud shows some of the common themes to emerge from this analysis.

A diverse set of weaknesses were identified by respondents. Among the most common themes to emerge were focused on systems within RSPO and a lack of mentorship for junior Kenyan faculy. Closely following these themes were issues related inadequate career pipelines for Kenyan investigators and a lack of trained Kenyan investigators who could lead research projects.

Table 4.1 below shows the frequency of coded responses that emerged from this analysis and Table 4.2 provides some sample responses regarding program weaknesses.

Table 4.1 Frequency of coded responses describing common Weaknesses identified by respondents

Weakness Response Category	Count	Percent
RSPO	11	21.57%
Lack of Mentorship for Junior Kenyan Faculty	10	19.61%
Lack of Kenyan PIs	7	13.73%
Inadequate Training & Mentorship Opportunities	7	13.73%
No Career Path for Kenyan Faculty Researchers	4	7.84%
Procurement Process	4	7.84%
Limited Integration Outside School of Medicine	3	5.88%
Policies Don't Support Research	3	5.88%
Slow Processes	3	5.88%

Lab Financial Instability	3	5.88%
Lack of Transparency about Policies	3	5.88%
Lack of Leadership Support	3	5.88%
Approval Process Not Supportive of Research	2	3.92%
Lack of Grant Writers	2	3.92%
Lack of Local Funding	2	3.92%
Lack of Engagement by Certain Schools	1	1.96%
Low Working Group Attendance	1	1.96%
Inadequate Staffing in Core Administrative Units	1	1.96%
No Protected Time for Research	1	1.96%
Absentee North American Pis	1	1.96%
Lack of Integration into MTRH	1	1.96%

Table 4.2 Unedited Sample Weakness Responses

- RSPO and Procurement needs improvement
- Young talent is not cultivated and supported up the academic ladder. Young talent may be viewed as competing rather than complementing present senior faculty. The MMED programs should be "think tanks" for the overall program. Yet, how many of the MMED theses are actually moved to publication? How often are they celebrated by a research day? How often are they presented as an AMPATH wide WIP? How often do these projects move into policy at MTRH/MUSOM?
- RSPO, or the perceptions regarding RSPO Lack of strong leadership from the Principal Need for stronger leadership in Oncology from MUCHS
- Extremely limited number of Kenyan faculty able and willing to be co-PIs Lack of mentorship of junior Kenyan faculty and lack of protected time for research, especially for clinicians Reliance on public procurement systems Less than 100% support from MTRH, MU leadership Some leadership of working groups not serious Limited attendance at working group meetings
- Slow processes though these are clearly defined.
- Limited training opportunities, punitive policies especially on retainer. Lack of grants writers.
- RSPO, procurement, supply chain, grants and contracts administration and timely audits
- limited integration with the activities of the Kenyan schools. There are very few Kenyan led proposals submitted through the research program in part because of this limited integration.
- Still a perception that ARP is for persons in AMPATH clinical program and on HIV. More work needed to create awareness of the scope of ARP
- Non-optimal financial and human resource support from Kenyan institutions as specified in RSPO MOU 2. Poor local funding 3. Inefficient procurement system arising from rules and regulations 4. Historical remuneration inequities among staff affecting staff morale 5. Absentee PI's who still make huge decisions on grants 6. Poor rates of indirects on grants 7. Relatively busy Kenyan researchers due to lack of research track in Moi 8. Cyber attack threats on data 9. Strict government policies on partner researcher's taxation affect collaboration going forward

- Communication about procedures is inconsistent. For example, there was a new salary structure put in place for research staff, and I was not informed. I often have a hard time finding information on procedures quickly without writing to ask specific questions. It seems like there could be more streamlined online forms to do things like submit publications for review, submit protocols for review by working groups, etc. That would structure the process, and the online forms could also have check boxes, sections, etc. that would ensure that investigators include all of the needed information the first time without rounds of feedback that create delays. The required funding lines for grants do not seem to make practical sense across the board. For some projects, it is likely that the AMPATH fee actually translates into what the sample budget justification says, but not for other projects. Things like biostatistics support or data management also should not at all be standard for budgets, as projects vary so much in the ways that they get and pay for support. I feel like I'm double paying for things because AMPATH really only supplies RSPO services for me and very minimal research manager time to answer my questions and send out publications for review. Everything else is done by other staff and collaborators (at Moi and my home university) that I pay for separately -- or for things like supplies or space, which the AMPATH fee justification includes, I pay for completely separately. I do not think it is a good use of grant money. Funders are paying twice for the same thing that I am not obtaining through AMPATH.
- Lack of Kenyan faculty participation, difficult RSPO processes with inconsistency & poor communication, lack of assistance in finding funding/grant writing
- Not enough pathways for new Kenyan researchers to serve as PIs. Too many grants still PI'ed by same more senior leadership.
- Arduous approvals and protocol process, Unclear goals of research working groups, Lack of Kenyan investigator participation (lots of hoops to jump through so Kenyan researchers choosing to operate outside of AMPATH), Difficult RSPO timelines and lack of clarity in spending on grants, Needing an "approval" in the research working groups rather than just seeing it as a mentorship forum to improve the research
- Weaknesses: Lack of strong support of locals to participate in research particularly AMPATH research
- Some of the schools at the college of Health sciences do not fully participate in Amath activities
- I think more needs to be done to bring the MTRH administration into accepting and working with the research program. Getting buy-in from MTRH leadership is crucial to promote more research being carried out by MTRH staff. Moreover, the research activities that MTRH engages in e.g. through the MIRF should be incorporated into the AMPATH research program as opposed to being managed independently within MTRH.
- IREC may be considered an external factor but is hurting research efforts, RSPO transparency to investigators
- Organizational problems with grant management and inflexibility in problem-solving or troubleshooting issues around grant funds disbursement. RSPO has a difficult time if the problem does not fit in a pre-defined process so people or vendors who should be paid wait an unacceptable period of time for payment.
- It is so big, broad, and diverse that something is always broken. Although this is expected, people get pissed and think that a lot is broken, when in reality most of it works great. Some workgroup leaders aren't very good leaders. It is unethical and immoral that NIH only pays 8% indirects on

foreign subcontracts. This means that poor in-country universities and hospitals/health systems have to PAY the rich U.S. and NIH for the privilege of hosting their research.

- It is hard. I am still new. It is a strength to have built an IREC, but the reviews take long and the comments don't always make sense. And I love getting the thoughtful comments. RSPO gives us different financial reports so consistency is lacking. Clarity and transparency in communication is lacking in budget making. Staff go without pay because paperwork gets misplaced. I don't know who to turn to if I need mentorship in stats, analysis, paper writing, and everyone is so busy. We don't have enough Kenyan peers doing research to actually take on the work so while I love my research I feel like a ghost writer sometimes without meeting the vision.
- The working groups concept is great but implementation is poor. 2) There is not enough emphasis or guidance on disseminating research results within AMPATH (e.g. SOPs or pathways for disseminating research to program stakeholders and clinicians). This could include schedule meetings, ECHO sessions, internal research conferences for AMPATH staff and researchers, etc. 3) There are many innovative implementation projects ongoing at AMPATH but only a fraction of them are disseminated to the broader HIV and clinical community more globally. Perhaps having a structured framework for publishing/disseminating these projects would be helpful, in which the people involved in program implementation work more closely with those more heavily involved in research to conduct program evaluations and publish implementation assessments of interventions ongoing at AMPATH. Currently the researchers and program implementers are siloed.
- There is a need for more training and mentorship programs within the research office that will help young upcoming research individuals, provide a partnership for mentorship between experienced scientific writers with publishing skills The research opportunities advertised are targeted to a group of individuals; Principal Investigators majorly and do not reach out to people who are not from the USA or European consortium universities.

OPPORTUNITIES

The above word cloud illustrates some of the common themes to emerge from respondent descriptions of opportunities that might benefit the AMPATH Research Program. Opportunities were defined as any, ". . . positive external factors that will likely improve the Research Program's ability to be successful in the future."

The strength of donor support for AMPATH was the most commonly noted opportunity by stakeholders followed by AMPATH's expansion into population health.

Table 5.1 details the frequency of stakeholder responses around these themes and table 5.2 provides sample responses.

Table 5.1 Frequency of coded responses describing common Opportunities identified by respondents

Opportunities Response Category	Count	Percent
Donor Support	8	17.39%
Population Health Expansion	6	13.04%
New diagnostic tools	4	8.70%
External Reputation	3	6.52%
Partnerships	3	6.52%
New Funding Opportunities for International Faculty	3	6.52%
Emerging Biomedical Engineering Program	2	4.35%
Support for Multidisciplinary Research	2	4.35%
Access to Good Mentors	1	2.17%
Engagement with Pharma & Clinical Trials	1	2.17%

NHIF Expansion	1	2.17%
Local Funding	1	2.17%
Political Support	1	2.17%
Community Support	1	2.17%
High Demand for Evidence Based Policy	1	2.17%
New Post-Graduate Fellowships in Kenya	1	2.17%
New Research Trends	1	2.17%

Table 5.2 Unedited Sample Opportunities Responses

- Collaborations
- Good will from donors.
- Large number of willing and able mentors to assist in young talent development, presently underused.
- Pop Health/UHC growth presents good opportunities for expansion of research
- Continued support for global health care programs that create opportunities for research External reputation of AMPATH remains very good
- High demand for policy engaging research; global deliberateness in promotion of partnerships; and growing realization of the need for interdisciplinary and trans-disciplinary studies especially with SDGs
- Partnerships with surrounding private institutions, establishment of a grants writing office,
- technological advances and new post-graduate fellowship programs at the school of medicine and new research areas
- Continued partnerships
- Push for more implementation research, expanding research domains e.g. incoming of IBMI & increasing mHealth initiatives
- greater integration.
- Engaging the whole college research enterprise through directorate of research, Moi University.
- Great partners with wealth of research expertise 2. AMPATH researchers well reknown in research arena and able to compete for grants 3. Continued funding for care programs gives research an opportunity to answer new questions
- Availability of Research infrastructure
- NIH Career development awards for International young investigators Pilot grants from CTSI
- re-think the purpose of the research working group
- Increased collaboration across subspecialties
- Availability of researchable areas/topics 2. Increased funding availability especially for early career LMIC investigators
- Expansion of EMR beyond HIV - to oncology, population health, MNCH, etc
- Involve all the schools at the college. Continue with community engagement for sustainability
- AMPATH's expansion into newer counties present a good opportunity for the research program to expand its activities.

- The support of NHIF to cover advanced diagnostics for cancer, such as flow cytometry and immunohistochemistry could lead to the strengthening of the AMPATH reference lab. Just as coverage of CT scans improved access to that technology, I expect similar advances in access to diagnostics will occur if the government lends support. The controls for how they cover that technology, e.g. having certification of labs/ quality control standards and sufficient criteria for approving of lab services will make the services at AMPATH competitive. So ensuring the government puts controls in place as they expand coverage will allow AMPATH to be a leader in providing these diagnostic services (if we decide to commit to that).
- Look for foci beyond HIV/AIDS, especially in NCDs. Partnership with governments and for-profit companies can provide opportunities for win-win-win. AMPATH is recognized by NIH, CDC, USAID, and others as the BEST IN THE WORLD. So opportunities to help developing countries deal with the NCD tsunami that's coming abound.
- Engagement from other consortium schools; new leadership in research program; decreased funding from PEPFAR in the future presents an important opportunity to assess the sustainability and outcomes of the HIV care program in the future (this could also be a threat to the program)
- Good will from political and community fronts
- 1. Improve on the technologies available for projects 2. employ new research management programs and trends in global research
- Technological resources - Virtual/ online communities of practice Improved research structures in the counties for collaboration and sustainability
- Complimentary changes in sponsor funding priorities. Most funding agencies would like to engage institutions with greater potential to enroll participants and that are able to support in evaluations/assessments.
- Full support form Partners and donors

THREATS

Along with the opportunities identified by stakeholders, respondents also identified a number of critical external trends that could threaten the continued development of the AMPATH Research Program. By far, the biggest common threat identified by respondents was a concern over changing donor priorities and increased competition for resources and talent within Kenya. This included concerns over the impact of devolution on data ownership.

Table 6.1 Frequency of coded responses describing common Threats identified by respondents

Threats Response Category	Count	Percent
Changes in Donor Priorities	19	42.22%
Devolution	4	8.89%
Growing Competition with Private Institutions in Kenya	3	6.67%
Fracturing of Partnerships	3	6.67%
Inadequate Technology	2	4.44%
Strikes	2	4.44%
Collapsing Public Health System	1	2.22%
Growing NCD Disease Burden	1	2.22%
Community Fatigue	1	2.22%
Kenyan Regulatory Restrictions	1	2.22%
Brain Drain	1	2.22%
Economic Downturn	1	2.22%

Table 6.2 Unedited Sample Threats Responses

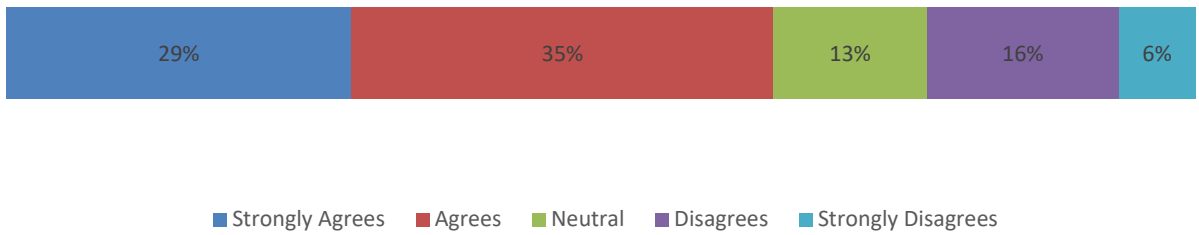
- Community and donor fatigue.
- Loss of promising young talent that moves to other programs. Poor communication from leadership in addressing identified problems or even acknowledging emails (acknowledging an email at times can be as supportive to the individual even if change cannot be enacted.). When communication is not even acknowledged, then the sender feels ignored and undervalued and is happy to leave- loss of talent and opportunity occurs.
- The fracturing relationships among county govt/MTRH/MU Inattentive or perhaps weak leadership at MUCHS Fragile informatics Fragile data management Persistent sub-optimal performance by RSPO Parallel grants management (e.g. Duke, ICI, AMPATH Plus grant)
- Emboldened county governments that increasingly feel ownership of "their data" Issues related to EMR rollout and uptake in various settings Establishment of a national data warehouse for HIV data
- Changes in research funding priorities; unequal and sometimes unfair international relations; Inadequate technology
- new guidelines and changes in funding agencies' priorities, President Trump's political agenda, and orientation.
- Lower available funding opportunities focused on local issues 2. Political changes in partner countries may affect funding streams 3. Payment inequities
- Sponsor funding priorities
- Changes in care funding that is likely to affect the research infrastructure
- Difficult & shifting bureaucracy/"politics" within AMPATH, increasing costs to do research
- Growth of other medical/health science schools in the region who can become alternative partners reducing role of MUCHS/MTRH
- Instability of devolved health units in Kenya, affecting quality care, testing and sustaining innovations
- Kenyans choosing to operate outside of AMPATH research program, individuals valuing the program on a whole, rising salaries cannibalizing grants
- Reduced support from MTRH administration, funding cuts from the US government.
- strikes
- Competition for research or philanthropic dollars could worsen as other organizations come in to compete is a real threat. Having successful programs to highlight AMPATH strengths and show the public the work we do will be critical to compete successfully in the coming years.
- NIH not caring enough about global health, and the CDC not caring much about treating NCDs. Success depends on leadership, and with a couple of high-level ineffectual leaders, if they happen, could kill it. Dealing with the GOK and Uasin Gishu could kill it.
- There is currently a small pool of Kenyan clinicians participating in research and these individuals are increasingly oversaturated with projects; healthcare worker strikes can have a significant effect on research both in terms of patient recruitment/follow-up as well as the Kenyan clinicians involved in research who get pulled away from research due to the need to cover clinical activities.
- Competing interests from private organizations such as the International Cancer Institute, poor lab infrastructure
- Competing programs from NGOs - national and local
- Lack of structural support when the program expands

- Donor community determining that AMPATH must become self-sustaining or that because of it's success it would be appropriate to reduce funding. Does AMPATH currently write letters to Congress - on behalf of donors who cannot lobby congress - to explain the impact that reduced funding will have on the program and results? Also is AMPATH working to identify how to make components of the program more self-sustaining, in anticipation of the donor community one day reducing contributions?

Internal Stakeholder Perceptions of Working Groups & Cores

Internal stakeholders largely view AMPATH's Working Groups and Cores as a program strength. Of the 30 internal stakeholder who responded to questions regarding the working groups and cores, 64 percent agreed or strongly agreed that AMPATH's structure of research working groups and cores successfully supports our mission, vision, and values (Figure 7.1). Internal stakeholders largely agreed that the working groups and cores successfully supported the development of new North American researchers at AMPATH affiliated institutions (33 percent Strongly Agreed and 23 percent Agreed). In addition, 43 percent felt the groups provided useful peer review for the development of research projects in Kenya and 50 percent believed the current structure was the right structure for the growth of the research program over the next 5 years (Table 7.1).

Figure 7.1: Stakeholder Agreement that AMPATH's structure of research working groups and cores successfully supports our mission, vision, and values (n=30)



However, nearly a quarter viewed the working groups and cores as an unnecessary barrier to research. 30 percent disagreed or strongly disagreed with the statement that working groups are viewed as an easily accessible resource by researchers (Table 7.1).

Table 7.1: Internal Stakeholder Perceptions of Working Group & Cores (n=30)

AMPATH's current structure of research working groups and cores:	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't Know
Fosters Kenyan leadership of research.	23%	**33%**	30%	3%	7%	3%
Supports the development of new Kenyan researchers at Moi University and MTRH.	23%	13%	**30%**	17%	7%	10%
Supports the development of new North American researchers at AMPATH affiliated institutions.	**33%**	23%	30%	7%	0%	7%
Catalyzes new research collaborations and projects based in Kenya.	17%	**57%**	13%	7%	3%	3%

Removes obstacles to conducting research in Kenya.	3%	27%	**43%**	10%	10%	7%
Mitigates conflict in research.	0%	37%	**40%**	13%	0%	10%
Provides useful peer review for the development of research projects in Kenya.	33%	**43%**	7%	10%	3%	3%
Is seen as an easily accessible resource for researchers.	17%	**30%**	20%	20%	10%	3%
Is an unnecessary barrier to research at AMPATH.	7%	17%	10%	**37%**	23%	7%
Is the right structure for the growth of the research program over the next 5 years.	**30%**	20%	23%	10%	7%	10%

Working Group & Core Strengths

30 percent of internal stakeholders noted an aspect of the peer review process within the working group and core as a strength. An additional 17 percent described the groups' roles in mentorship of new investigators as a key strength as well as 10 percent who noted the role of the groups in providing peer support for ongoing projects (Table 7.2). Sample responses to working group and core strengths are provided in Table 7.3.

Table 7.2 Frequency of coded responses describing common Working Group and Core Strengths identified by respondents

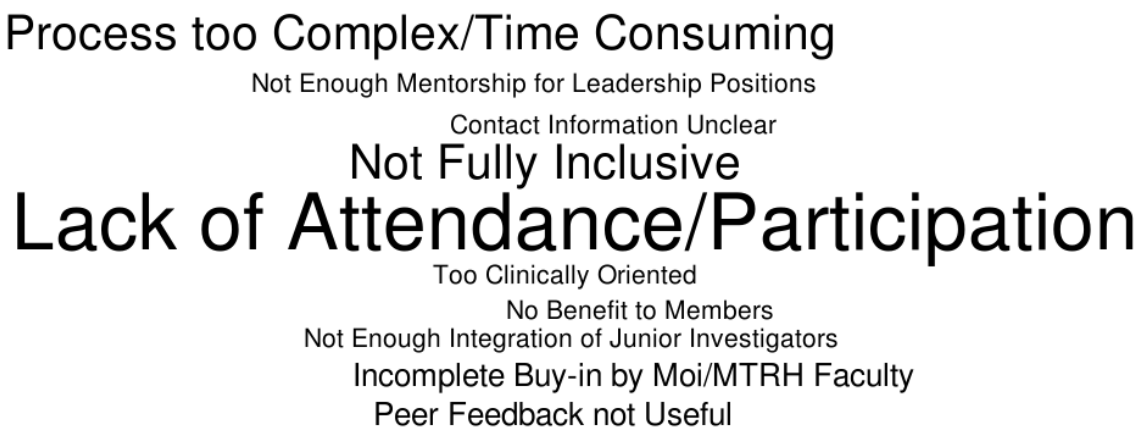
Working Group Strengths Category	Count	Percent
Peer Review Strengthens Proposals	9	30%
Provides Mentorship Opportunities	5	17%
Facilitates Partnership Identification	3	10%
Forum for Communication with Care, Education, & Research	2	7%
Consistent Communication	2	7%

Peer Support for Ongoing Projects	3	10%
Leadership	2	7%
Prevents Micromanagement of Projects	1	3%
Efficient Structure to Organize Research Priorities	3	10%
Fosters Colllaboration	2	7%

Table 7.3 Unedited Sample Strengths Responses

- 1. Peer review strengthens proposals 2. Mentorship encouraged 3. Pairing of partner collaborators 4. Discuss not only research but also education and care programs
- 1. Specialized reviews and able to give more technical support to researchers
- A number of key areas are well defined and functional
- consistent communication and participation
- Continued support of ongoing projects.
- dual collaboration and coverage by multiple leaders of each area
- Encourages Mentorship and Peer reviews
- Having leads from Kenya and North America Primary and secondary review from 2 different working groups adds tremendous value to research proposals
- It a friendly accessible space where any investigator can find support
- It is comprehensive in groups and boxes that are in the flow chart
- Leaderships
- organized and fairly comprehensive structure that is easy to follow; competent and respected leaders
- Partnering N. American and Kenyan leadership, and providing opportunities for young and mid-level investigators to gain leadership experience. Relying on the Working Groups and Cores helps prevent paralyzing micromanagement by high-level leaders in AMPATH and its Research Program.
- Peer review of research proposals Collaborations with other partners
- Peer review processes.
- People contribute to the research areas of interest. There are a good number of working groups so all specialities are catered for
- provides a structured way of providing support to researchers and encouraging research culture in AMPATH
- Specialization of the cores as per research areas Healthy mix of expertise Predictable meeting schedules
- The collaborative spirit
- The cores can provide support to teams where they are lacking certain expertise. New leadership is focusing on how to restructure the program to fit the needs of those on the ground.

Working Group & Core Weaknesses



The most frequent weakness reported by internal stakeholders related to the working groups and cores was the lack of attendance and participation in the working groups (37 Percent). 17 percent of stakeholders reported some perception of the groups as not being fully inclusive or viewed externally as not welcoming to outsiders. Another 17 percent thought the process for seeking working group review and approval was too complex and time consuming creating a barrier to research and the development of new investigators (Table 7.4). Sample weaknesses responses are provide in Table 7.5.

Table 7.4 Frequency of coded responses describing common Working Group and Core Weaknesses identified by respondents

Working Group Weaknesses Category	Count	Percent
Lack of Attendance/Participation	11	37%
Not Fully Inclusive	5	17%
Process too Complex/Time Consuming	5	17%
Incomplete Buy-in by Moi/MTRH Faculty	2	7%
Peer Feedback not Useful	2	7%
Too Clinically Oriented	1	3%
No Benefit to Members	1	3%
Not Enough Integration of Junior Investigators	1	3%
Not Enough Mentorship for Leadership Positions	1	3%
Contact Information Unclear	1	3%

Table 7.5 Unedited Sample Weaknesses Responses

- 1. Basic science working group is too diverse to be fully functional 2. The working groups are still not fully inclusive 3. Working groups are very clinical oriented
- 1. luck of quorum for meetings 2. No added advanatge for RWG leads
- I don't think that the structure of the cores and leadership is well known to researchers at AMPATH (e.g. who to contact for a specific issue); the semi-annual research compendium that logs all active projects and their status is helpful but quite lengthy and the format makes it

difficult to get a sense of the different active projects at AMPATH and build cross-collaborations with. A dashboard or summary table could be helpful.

- integration of young Kenyan investigators and mentoring for leadership positions
- Knowing who to contact and who to include in discussions is always a difficult task.
- lack of attendance and buy in not fully supported by MU and MTRH (other mechanisms for pursuing research that don't require use of the working groups)
- Lack of participation of individuals within them--but I do not have a good sense of the root cause of that lack of participation
- Monthly meeting and activities not well attended Quorum hitches for meetings Activities not well planned to maximize opportunity for local and international partners
- Not all members required to review do usually review.
- Not all the groups have counterparts. Our working group has nothing to do with research and 1.5 people who give feedback on research projects.
- Not everyone participates in the cores and research working groups as they should.
- Often the requirement for review by working groups delays things unnecessarily and the suggestions reflect a lack of attention to the proposal details. The added requirements of a secondary review group also creates delays, and the secondary group is even less likely to have the background and time to give a careful review. Calls are not well-attended, and a lot of time is spent waiting. They are scheduled around the work hours in Kenya, which is fine, but it It does not seem to be convenient for Kenyan colleagues either, as attendance is remarkably low. It also is not family friendly to people in other countries for whom the calls are very early in the morning. Proposal reviews should only be required in writing -- not to be discussed on calls -- and there should be brief online forms to gather the essential information so that the working group can quickly login, see the important details, and focus their feedback -- also given within an online form rather than a long chain of emails that is hard for people to follow on their phones.
- Participation of Kenyan researchers is meager
- People get too busy to attend meetings
- Some of the groups lack motivation. Perhaps there is need to think of how to motivates groups to keep working - otherwise over time people become fatigued.
- Sometimes, feedback from the working groups may take time. Also, some researchers within MTRH and MU do not recognise the AMPATH research working groups, perhaps because their research is not directly related to AMPATH. Yet, we know that there is immense benefit in researchers routing their proposals through the working groups.
- The bureaucracy may be discouraging to new faculty
- The groups have left out Kenyan investigators especially the younger ones.
- The research working groups are not effective and not worth attending. Many of them have a very bad culture that does not encourage new researchers but rather cause them to look for ways to avoid presenting their work because they are worried they won't "get approved" or will be humiliated due to the culture.
- the review process is slow and can result in uninformative feedback
- unclear where engineering, education, and other new areas would fit
- very few people in the structure are full time on these duties

Proposed Changes to Working Group & Core Structure

Internal stakeholders had a variety of suggestions for improving the working groups and cores. 13 percent suggested additional funding or other resources like staff support to assist in the working group and core operations. Another 13 percent suggested that more was needed to integrate the working groups into the department and care programs. More accountability and performance metrics to help groups ensure they were meeting their objectives were suggested by 10 percent of the respondents (Table 7.6). Table 7.7 provides samples of the suggestions made by respondents to improve the working groups.

Table 7.6 Frequency of coded responses describing proposed changes to the working group and core structures identified by respondents

Working Group Weaknesses Category	Count	Percent
More Funding/Resources for Working Groups	4	13%
Better Integration with Departments & Care Programs	4	13%
Greater Accountability & Performance Measurement	3	10%
Add Formalized Mentorship Component	3	10%
Rotate Group Leadership	2	7%
Reorganize Low Functioning Working Groups	2	7%
More Community Engagement	1	3%
Expand Groups to include Emergent Fields	1	3%
Improve Collaboration Between Leaders	1	3%
Better Orientation for New Investigators	1	3%

Table 7.7 Unedited Sample Changes Responses

- 1. Avail more funding for RWG activities that should include grant writing and seed funding 2. Rotation of RWG leads to allow new ideas and leadership development 3. Purpose to be involved in care activities and programs. 4. Better community engagement
- Basic science working group should be broken up and the other working groups reworked to include both clinical and lab components in each.
- expand areas for emergent fields (e.g., working group for "interdisciplinary" or other); specific clear area for engineering and education initiatives
- facilitating more interaction between Kenyan and NA leaders
- I want to say the operations core seems great and I wish I had been oriented to these systems better earlier. They certainly know how to make linkages and I feel like they are higher up in the hierarchy. I am not sure what to do with the WGs. We are so short on time as a group. I think we are starting to develop nuclei that should allow for sub-cores but part of it is just that the department at MTRH does not see itself as an academic department with a shared goal of research, even if individuals do it, and there is not the same portfolio building and tracking structure that I see in NA institutions. Maybe we need profile pages for the Lecturers and visiting lecturers online
- I would suggest better accountability for the groups.
- Introduce open days for the groups to market themselves to faculty.
- Mentoring component could be added
- More support for Kenyans to participate in the research
- Performance metrics may need to be developed for self reflection as well as measure progress
- perhaps a working group that is more closely connected to Ampath's programmatic activities (e.g. population health) would help support more rigorous research in this area and dissemination of the interventions implemented by the program.
- Probably combine others to make good numbers.
- resource it better, increase number of staff and introduce new support eg finalize recruitment of new grant writer, run writing "boot camps" etc
- Strengthen Lab support especially histology
- The protocols need to be simplified and be less dictatorial. They should be about mentoring and encouraging colleagues rather than providing "oversight".
- There is a need to incorporate researchers who are part of MTRH and MU but are doing research that is not directly related to AMPATH. This may need working with the administrations of the partner organisations to engage these researchers somehow.
- There needs to be a re-commitment of Kenyan and North American faculty if they are actually going to function effectively More administrative support with a culture of minute taking and accountability
- Timing of meetings to incorporate schools of medicine/ density and public health staff Improve activities to promote research growth locally Include activities that will benefit postgraduate students Change the chairs/ co-chairs to incorporate new people with new ideas
- Working groups need to be motivated - I don't know how but I know it is necessary.

PERCEPTIONS OF RSPO PERFORMANCE

Nearly 90 percent of the respondents (n=48) reported using one of RSPO's services in the last 12 months. Of these respondents, nearly 65 percent agreed or strongly agreed that RSPO provides the RSPO provides the right set of services and supports to achieve AMPATH's research mission, vision, and strategic priorities. However, 48 percent of respondents who had used RSPO's procurement services in the last 12 months were dissatisfied or extremely dissatisfied. Similarly, 35 percent were dissatisfied or extremely dissatisfied with the support they received from RSPO's HR department in the last 12 months and 29 percent were dissatisfied with the financial management services they received (Table 8.1).

Table 8.1: Stakeholder Satisfaction with RSPO services accessed in the last 12 months

	n	Extremely Satisfied	Satisfied	Neutral	Dissatisfied	Extremely Dissatisfied
Pre-award budget preparation &development	28	32%	**57%**	4%	4%	4%
Post-award contracting	26	23%	**46%**	15%	12%	4%
Financial management services (award management, status of funds, invoicing, audit)	39	8%	**34%**	29%	24%	5%
Human resources (hiring, staff training & development, payroll, performance appraisal)	37	5%	**32%**	27%	27%	8%
Procurement & supply chain	40	3%	**28%**	23%	**28%**	20%
Other (not listed)	5	**60%**	20%	20%	0%	0%

Table 8.2 Unedited Changes to RSPO Proposed by Stakeholders

- need to have alternative procurement processes for large purchases. HR department needs an overhaul and should be more independent from partner institution interference.
- 1. More support form parent partner institutions or complete move to have contract staff 2. Equity in all RSPO salaries- same pay for same job 3. Continued training
- 1. Project specific guidelines be applied and followed as project uniqueness is occasionally ignored .
- 1. Research projects have predetermined budgets: RSPO rates for RAs and research support staff way too exorbitant and stymie research with small funding. 2. Procurement too laborious and lengthy. Delays project work and defeats the purpose of the very reason for

RSPO's existence 3. Imprest accounting is too petty and and expect receipts for every little thing. Some local running imprests can be based on research and policy embedded rates just like per diem rates that should not be accountable by receipts.

- Employment of more staff...go for very qualified type/ willing to grow & learn
- HR needs to be standardized and salaries revised so they are affordable to researchers. Procurement needs to be completely re-organized and be able to provide requests within 1-2 months. Accounting needs more staff and better skill level in order to provide ACCURATE and MONTHLY invoices.
- I think a better system to speed the process from request from the PI to the actual procurement of goods, services, or subcontracts is critical. Many of the services provided on a recent grant were never paid for and left us with unpaid vendors long after the grant fund year had run out. The inefficiency of RSPO in unacceptable even as the structure is fine and should be able to handle requests.
- Improve accessibility to staff
- Improve on communication, increase the number of staff.
- improve the procurement system Too many control points which delay the process Improve accountability to the client
- Increase capacity for personnel and assign specific persons to specific grants for easier follow up of activities.
- Increase staffing levels and training. Reduce administrative hurdles
- Increase the work force
- Make it lean and efficient in terms of the processes by employing ERP enterprise resource planning thus automating all the processes such as to sustainable from the funds allocated. Both MTRH and Moi University to have provide proportionate qualified staff on a permanent and rotational basis of defined duration.
- Moi and MTRH should re-design how RSPO staff are managed to reduce the high turn over
- more clear guidance/training and documentation
- More staff to adequately respond to each project's needs More training for project staff so as to understand RSPO requirements/operations
- More transparency about SOP/policies/actions, improved communication about invoicing/costs (e.g. they increased my RA salary without notifying me why or that they were doing it, throwing off my whole budget), speedier & more fair procurement procedures (e.g. rejecting requests for no clear reason, taking 3 months just to get toilet paper, etc). They did help me with quick turnaround for signing a statement of work & Abraham Onchere is always great.
- Resource it better
- Support with more staff Re-look at policies and make them more facilitative Regular (quarterly) researchers and RSPO feedback sessions
- The ATP systems needs to be well protected and made reliable in generating timely reports.
- The information about salaries for research staff seems to be very vague and somewhat hidden. Sometimes questions have to be asked repeatedly. When I've asked several questions, only a subset are answered, leading to long exchanges. Usually the questions hardest to get answers to are related to suggested salaries. I'm not sure why this is, but I think there should just be a table that everyone tries to follow.

- The partners in RSPO are very nice people. Certain employees aren't as accurate or don't provide service as timely as others.
- The PI should be able to track the financial expenditure real time
- The processes are quite slow and approval flows do not have specific timelimes. There is need to align services and facilitate faster approval flows especially for items required for patient care e.g. drugs
- The RSPO, should be neutral, in-terms of staff, and follow clear policies on HR, and Finance to support procurement to deliver best services by facilitating the payments on time.
- The systems of communication are very poor; invoices are delivered far too late; the majority of the time we request RSPO to help us produce an accurate accounting of the money we've spent on a project they are unable to do so for various reasons (e.g. the system has not yet processed all requests, etc.). The pre-award process is transparent but the post-award process is problematic. Procurement takes far too long to procure supplies and there are too many restrictions on what can/cannot be purchased (e.g. if I see a supply available at a local store that I want for the project there should be no reason why it should take 1-2 months to procure it from RSPO)
- There have been great improvements in RSPO over the last 2-3 years. However, I do feel like the efficiency in HR and payroll needs to be improved.Additionally, procurement, while much better than it used to be before, can still be improved in terms of efficiency of staff, attitudes towards other project staff and timeliness of response to queries.
- There needs to be more commitment from the home institutions and Kenyan government for research infrastructure support The ERP changes need to be effected in a way that actually improves efficiency Less conflict between AMPATH Plus and RSPO main
- they need to be more responsive to the needs of the various programs they manage. They sometimes introduce arbitrary rules and impede the progress of certain activities

PERCEPTIONS OF RESEARCH PROGRAM OFFICE PERFORMANCE

Nearly 70 percent of the respondents (n=36) reported using one of the Research Program Office's services in the last 12 months. Of these respondents, nearly 92 percent agreed or strongly agreed that RPO provides the right set of services and supports to achieve AMPATH's research mission, vision, and strategic priorities. Respondents appeared most satisfied with the meeting or teleconferencing support they received followed by the operational support and advising they received from RPO staff (Table 9.1).

Table 9.1: Stakeholder Satisfaction with RPO services accessed in the last 12 months

	n	Extremely Satisfied	Satisfied	Neutral	Dissatisfied	Extremely Dissatisfied
Meeting or teleconference scheduling	29	48%	52%			
Project space rental	15	40%	53%		7%	
Operational support or advising	24	42%	50%	8%		

Publications review	15	20%	60%	13%		7%
Training	8	13%	75%	13%		
Other	4	75%	25%			

Table 9.2 Unedited Changes to RPO Proposed by Stakeholders

- 1. Include grant writer in RPO 2. Better support in transport activities
- ARPO should take a more active role in IRB processes especially intervening where the researcher and IREC are not in agreement over a matter.
- Both Moi and MTRH to provide qualified trained staff hired by the institutions and provided with incentive and responsibility allowances.
- Doing a fairly good job but could do better with awareness creation for non AMPATH affiliated faculty.
- I still have difficulty knowing who to talk to, or what steps I need to take to process a request or proposal. The process is improving, but more flexibility needs to be incorporated to assist PIs as they seek funds for research that ultimately supports the whole program.
- Improve the training capacity.
- It seems the amount each project must provide to this office does not really reflect how much the project will use the office.
- Keep up on being efficient.
- mentorship of new staff so we don't fall apart when Chiri leaves
- More orientation for new investigators; emphasis on dissemination of research findings within AMPATH and more broadly (and ARPO can help direct investigators towards those channels by working with AMPATH leadership and researchers)
- More staff to ensure availability of its services to all current and potential investigators More effort to make AMPATH Research more open to all potential investigators
- More staffing
- Need to expand and support publications for junior investigators who are doing research towards AMPATH vision and goals.
- The officers should be on the look out for and share opportunities through which junior research staff can be empowered.
- The publications office should either be dismantled or re organised. They dont give feedback especially for Kenyans.
- The publications review request should be sent to all co-authors on a paper. Again, an online form that allows for this to be uploaded into a system and then feedback to be given within that system would save time and confusion from so much email back and forth with so many people involved.
- The RPO is doing well in general. I have no further changes to suggest.
- The systems are in place but the timeliness of the service should be improved
- Their role should be made clear to investigators.
- Would love more help with finding funding & grant writing

PERCEPTIONS OF IREC PERFORMANCE

Nearly 74 percent of respondents (n=39) accessed services through IREC in the last 12 months. 58 percent of internal stakeholders reported being satisfied or extremely satisfied with the service they received from IREC. However, 24 percent were dissatisfied or extremely dissatisfied with the support they received from IREC. Stakeholders proposed a variety of changes to improve IREC support and a sample of those responses are provided in Table 10.1.

Table 10.1 Unedited Changes to RPO Proposed by Stakeholders

- 1. Faster review of proposals 2. Notification of reviewers before routing proposals to ensure presence/absence
- 1. Reduce time to approval 2. Work towards single IRB review to speed up study initiation time
- A single IRB between IU and IREC should be a high priority. Currently the process of receiving IREC approval followed by IU IRB review inhibits research unnecessarily. After obtaining IREC approval, investigators must seek IU IRB approval. The IU IRB inevitably requests changes be made to the consent form or other documents. These changes require translation to Swahili and resubmission to IREC as an amendment, and once IREC approval of the amendment is obtained, resubmission to IU IRB for final approval. This process takes months and is often frustrating. Additionally, the IREC comments on proposals are often irrelevant to the protection of human subjects (e.g. "change the title" or "explain how this a pilot study and not a full study", etc.) These comments also require addressing, and with the IREC panel meeting once monthly, they also cause a significant delay in processing of proposals.
- Add more reviewers
- Better timeliness in processing proposals and other requests Standardization of applicable rules and regulations
- comments are not usually related to the science or ethics and often focus on irrelevant issues. they should stick to the mandate of IREC.
- Fast tracking review of protocols presented.
- I am fine with the IREC process because I have good support from my Kenyan colleagues and I know what IREC needs to accept my proposals.
- It should focus on ethics and not methodology. I have been forced to change my methodology because the reviewer deemed there was a "better" method without considering the available budget. There was no ethical problem at issue.
- It's ok
- Make review and approval process faster
- Meetings seem to be cancelled often. The proposals go into a black hole, and you have to continually follow up to find out. It's unnecessarily suspenseful and disorganized. Each time there is feedback from someone, I get it in a different way -- usually my co-I somehow tracks it down. Then I have to give feedback and wait for another meeting. It's a waste of everyone's time. Often the feedback includes questions about things that were clearly already in the proposal (such as a sample size or asking what compensation will be), so I have to find a polite way to point them to it. For the large amount of money it costs, the process could be more professional and streamlined. Again, if a possibility of a streamlined online process that includes status updates, this would be so much more helpful.

- More diligence in the review of their work and to offer training opportunities in light of the growing Ethics need, with the advancement of technology and upcoming research
- More use of technology
- Needs to be a bit more efficient. Some of the reviewers who make relatively meaningless comments/suggestions should be replaced
- projects are often delayed due to getting feedback from irec, adding investigators or research personnel has gotten more difficult, when there are strikes it takes even longer to get feedback
- Quicker turnaround, less unhelpful/unnecessary comments (sometimes it appears they have not completely reviewed the submission).
- Should improve efficiency, and train reviewers so that reviews are useful.
- Stop continuing review - use study period Use online platform Use expedited & exempt review options more
- Student proposals take as long as 9 months Reviewers should be vetted - some make remarks which are not helpful and are at time personal - should do an audit on reviewer comments IREC should carry out a client satisfaction survey as an institution
- The online application system will go a long way. Track and share reminders with investigators when continuing reviews and annual reports are due
- The time required for reviewing the proposals should be shorten
- There should be better organization at IREC including timelines, processes and directions on how to go about certain processes.
- they have a total disregard to the input of co-PI in writing of clinical protocols, and a limited understanding of the ethical issues involved with review, they are unprofessional
- They should be trained on implementation science research
- time for reviews and clear feedback
- Timing and the owners of the proposals should be communicated to very well without assuming everyone knows the process.
- To be fully online on the review and tracking process.
- Turnaround time needs to be improved significantly. Waiting 2-3 months for feedback on a proposal is not fair to the investigators Furthermore, the process of submission needs to be better. With so much technological advancement, we cannot be submitting 4 paper copies and a CD! It's such a waste of paper. Plus most laptops don't even have CD drives these days. The CD was defunct 5 years ago. My suggestion is to have an online submission system similar to the working group submission or other IRBs. They also need to add more options of payment of IREC fees e.g. M-pesa, credit card etc. in addition to depositing into the bank account, which can be really tedious.
- The turn-around time for review of protocols to be improved.

External Stakeholder Priorities for AMPATH's Research Program

Of the 41 external stakeholders who were invited to complete the survey, 22% (n=9) responded to the survey. 56 percent of external stakeholders responding identified themselves as University/Higher Education Partners. This included department chairs for departments who have not traditionally engaged in AMPATH research activities. The remaining external respondents represented national and local government partners (11 percent), community partners (11 percent), and health care provider partners (22 percent). This small sample size provides a limited insight into how external partners view AMPATH's research program and a larger sampling would be needed to provide a more complete view of external stakeholder priorities. However, this small sample revealed a general picture of priorities.

The external partners were asked to rank their top 5 priorities for research. Table 11.1 illustrates their coded responses. Stakeholder responses were variable in their priority. However, the 5 most frequently cited priorities to emerge were Food & Nutrition Security (78 percent), Training and Professional Development for medical personnel (67 percent), Oral Health (56 percent), Preventative Medicine (44 percent), and Cancer Treatment (44 percent).

Table 11.1: External Stakeholder Priorities for AMPATH Research (n=9)

	First Priority	Second Priority	Third Priority	Fourth Priority	Fifth Priority	Total Count	Overall Frequency
Food & Nutrition Security	11%	11%	11%	11%	33%	7	78%
Training & Professional development	0%	11%	22%	11%	22%	6	67%
Oral Health Care	11%	11%	11%	11%	11%	5	56%
Preventive Medicine	11%	11%	0%	11%	11%	4	44%
Cancer Treatment	0%	11%	11%	11%	11%	4	44%
Communicable Diseases (HIV, Malaria)	22%	0%	11%	0%	0%	3	33%
New Diagnostic Tools (Ultrasound Scanning, CT Scanning)	11%	11%	0%	11%	0%	3	33%
Social & Behavioral Change	0%	0%	22%	11%	0%	3	33%
Health Systems Strengthening	11%	0%	0%	11%	0%	2	22%
Diabetes	0%	0%	0%	11%	11%	2	22%
Environmental Health	0%	0%	0%	11%	11%	2	22%
Laboratories for Cancer Diagnosis	11%	0%	0%	0%	0%	1	11%
Clinical Trials	0%	11%	0%	0%	0%	1	11%
Population Health	0%	0%	11%	0%	0%	1	11%
Maternal & Child Health	0%	0%	0%	11%	0%	1	11

APPENDIX A: STRENGTHS RESPONSES

- Research groups
- Clearly defined structures particularly peer review system.
- Availability of American co_investigators
- reasonably good infrastructure.
- David Plater's leadership Wools-Kaloustian has strong leadership capacity and has demonstrated capacity for collaboration
- Established research infrastructure (RPO, RSPO) Group of committed academic researchers Strong leadership of research program Strong track record of success
- strong human resource capacity for research; strong multi and interdisciplinary research teams, and access to training and mentorship.
- Strong organization structures, strong partnerships, clear processes, experienced researchers, strong relations with MOH
- clear defined processes and institutional support
- The partnerships and inviduals dedicated to AMPATH
- Organisational structure, infrastructure
- Strong organizational structures, mentorship
- the talent that we have attracted over the years is quite good and is spurring continued success with grantsmanship
- Collaborative research Peer review process for research proposal and publication
- 1.Strong committed partners 2. Good organization 3. SOP's supportive of engagement and conduct of research 4. Skilled researchers
- Collaborations Move from HIV to NCDs
- Responsiveness of the AMPATH research manager is high; the publications review process is clear and efficient. The new AMPATH website looks wonderful and makes it easier to explain and present the partnership.
- Clear SOPs that guide the processes at AMPATH Already developed Infrastructure that support research
- faculty with research expertise
- Highly motivated people, strong support systems for navigating the systems
- 1. Multiple partners 2. Strong discipline/team leaders 3. Strong RSPO/RPO
- Research working groups' quality inputs Availability of clear SOPs
- Collaborative approach, Support from research office, Compliance office and assistance on financials in preparing grants, Many fees that are not dependent on the use of the services (would be better just to have a percentage if the work is research)
- Strengths: Being in touch with current funding opportunities and being able to promptly circulate to researchers. : The online portal for submission of proposals and manuscripts has made submissions easier : Prompt response to comments and questions by the research office
- The program is well organized, the right people doing what they know to do best and there is great accountability. Working with the communities on the ground

- The research program has done really well in terms of access to resources for investigators. Additionally, the research program has been as inclusive as possible with major decisions that concern all projects with the AMPATH research program. There has been a tremendous improvement in the organisational structure and processes especially with regards to working group approvals and publications committee.
- dedicated AMPATH members
- Working groups
- Committed Kenyans who want to make the research programs and infrastructure stronger are the greatest asset of AMPATH.
- The structure and organization.
- It is based in implementation science and hence tightly tied to the clinical and other health-related operations of AMPATH. It has a wonderful structure of Workgroups and Cores that divide the work up into manageable pieces and provide lots of opportunities for growing leaders. It has the AMRS, which is unparalleled as a research resource. The Research Offices in Indianapolis and Eldoret are terrific with terrific people. Same for the RSPO in Eldoret. It has had strong, unflagging support from Moi University. It has well-though-out SOPs. It is financially stable.
- The emails on a weekly basis are actually great and highly informative.
- Kenyan leadership; diversity of initiatives
- The protocols that exist for conducting and publishing research (e.g. SOPs for publications and initiating new projects) are quite helpful. The REDCap for new study submissions to the working groups are also good additions. The CTSI global health pilot grants have helped many investigators to conduct research at AMPATH.
- Wealth of Expertise in the various fields
- Access to training and mentorship
- 1. Structures are clearly developed and followed . 2. Quality infrastructural developments that lead to efficiency in research work
- Strong collaboration, efficient systems and strong organisational culture
- Partnerships
- They announce research opportunities and share the current research undertakings that are getting published.
- Strong and dedicated leadership
- Strong organizational Structure
- Strong organizational structures eg good reporting systems -Clearly defined processes eg protocol review systems by specific research working groups as per discipline -Well organized dissemination of findings
- Internal communication on research program
- Strong institutional structures and collaboration that can attract funding.
- Availability of infrastructure, supportive staff, clear structures,
- Good research infrastructure and great support to researchers
- The program is well coordinated and supportive of study implementation activities.
- training and mentor-ship of the staff
- Improved community engagement, Improvements in the avaialbility of
- Relationships and the common vision, leadership and organizational structure
- Requirement to collaborate with Kenyan partners.

APPENDIX B: WEAKNESSES RESPONSES

- RSPO and Procurement needs improvement
- Most Kenyan investigators are subcontracted - the number of Kenya PI has not improved.
- Lack of local financial support.
- Young talent is not cultivated and supported up the academic ladder. Young talent may be viewed as competing rather than complementing present senior faculty. The MMED programs should be "think tanks" for the overall program. Yet, how many of the MMED theses are actually moved to publication? How often are they celebrated by a research day? How often are they presented as an AMPATH wide WIP? How often do these projects move into policy at MTRH/MUSOM?
- RSPO, or the perceptions regarding RSPO Lack of strong leadership from the Principal Need for stronger leadership in Oncology from MUCHS
- Extremely limited number of Kenyan faculty able and willing to be co-PIs Lack of mentorship of junior Kenyan faculty and lack of protected time for research, especially for clinicians Reliance on public procurement systems Less than 100% support from MTRH, MU leadership Some leadership of working groups not serious Limited attendance at working group meetings
- Slow processes though these are clearly defined.
- Limited training opportunities, punitive policies especially on retainer. Lack of grants writers.
- inadequate access to training and mentorship, still predominantly clinical departments and researchers participating.
- RSPO, procurement, supply chain, grants and contracts administration and timely audits
- Systems such procurement, lack of mentorship
- Poorly defined processes, limited RSPO staff
- limited integration with the activities of the Kenyan schools. There are very few Kenyan led proposals submitted through the research program in part because of this limited integration.
- Still a perception that ARP is for persons in AMPATH clinical program and on HIV. More work needed to create awareness of the scope of ARP
- 1. Non-optimal financial and human resource support from Kenyan institutions as specified in RSPO MOU 2. Poor local funding 3. Inefficient procurement system arising from rules and regulations 4. Historical remuneration inequities among staff affecting staff morale 5. Absentee PI's who still make huge decisions on grants 6. Poor rates of indirects on grants 7. Relatively busy Kenyan researchers due to lack of research track in Moi 8. Cyber attack threats on data 9. Strict government policies on partner researcher's taxation affect collaboration going forward
- Publicity Openness
- Communication about procedures is inconsistent. For example, there was a new salary structure put in place for research staff, and I was not informed. I often have a hard time finding information on procedures quickly without writing to ask specific questions. It seems like there could be more streamlined online forms to do things like submit publications for review, submit protocols for review by working groups, etc. That would structure the process, and the online forms could also have check boxes, sections, etc. that would ensure that investigators include all of the needed information the first time without rounds of feedback that create delays. The required funding lines for grants do not seem to make practical sense across the board. For some projects, it is likely that the AMPATH fee actually translates into what the sample budget

justification says, but not for other projects. Things like biostatistics support or data management also should not at all be standard for budgets, as projects vary so much in the ways that they get and pay for support. I feel like I'm double paying for things because AMPATH really only supplies RSPO services for me and very minimal research manager time to answer my questions and send out publications for review. Everything else is done by other staff and collaborators (at Moi and my home university) that I pay for separately -- or for things like supplies or space, which the AMPATH fee justification includes, I pay for completely separately. I do not think it is a good use of grant money. Funders are paying twice for the same thing that I am not obtaining through AMPATH.

- Division in RSPO that leads to negative competition
- 1. rules are taken as a formality - ie. research working groups 2. people are often more political and less collaborative in their participation in research 3. costs for personnel make rolling out research activities prohibitive
- Lack of Kenyan faculty participation, difficult RSPO processes with inconsistency & poor communication, lack of assistance in finding funding/grant writing
- Not enough pathways for new Kenyan researchers to serve as PIs. Too many grants still PI'ed by same more senior leadership.
- 1. Lab financial instability 2. Weak basic science component
- Challenges with the reference lab Support systems eg procurement/IRB
- Arduous approvals and protocol process, Unclear goals of research working groups, Lack of Kenyan investigator participation (lots of hoops to jump through so Kenyan researchers choosing to operate outside of AMPATH), Difficult RSPO timelines and lack of clarity in spending on grants, Needing an "approval" in the research working groups rather than just seeing it as a mentorship forum to improve the research
- Weaknesses: Lack of strong support of locals to participate in research particularly AMPATH research
- Some of the schools at the college of Health sciences do not fully participate in Amath activities
- I think more needs to be done to bring the MTRH administration into accepting and working with the research program. Getting buy-in from MTRH leadership is crucial to promote more research being carried out by MTRH staff. Moreover, the research activities that MTRH engages in e.g. through the MIRF should be incorporated into the AMPATH research program as opposed to being managed independently within MTRH.
- IREC may be considered an external factor but is hurting research efforts, RSPO transparency to investigators
- Inadequate staffing of RPO
- Organizational problems with grant management and inflexibility in problem-solving or troubleshooting issues around grant funds disbursement. RSPO has a difficult time if the problem does not fit in a pre-defined process so people or vendors who should be paid wait an unacceptable period of time for payment.
- The accountability for those that don't follow the rules.
- It is so big, broad, and diverse that something is always broken. Although this is expected, people get pissed and think that a lot is broken, when in reality most of it works great. Some workgroup leaders aren't very good leaders. It is unethical and immoral that NIH only pays 8% indirects on foreign subcontracts. This means that poor in-country universities and

hospitals/health systems have to PAY the rich U.S. and NIH for the privilege of hosting their research.

- It is hard. I am still new. It is a strength to have built an IREC, but the reviews take long and the comments don't always make sense. And I love getting the thoughtful comments. RSPO gives us different financial reports so consistency is lacking. Clarity and transparency in communication is lacking in budget making. Staff go without pay because paperwork gets misplaced. I don't know who to turn to if I need mentorship in stats, analysis, paper writing, and everyone is so busy. We don't have enough Kenyan peers doing research to actually take on the work so while I love my research I feel like a ghost writer sometimes without meeting the vision.
- occasional ambiguity of responsibility, scope between different areas of work
- research administration and compliance
- 1) The working groups concept is great but implementation is poor. 2) There is not enough emphasis or guidance on disseminating research results within AMPATH (e.g. SOPs or pathways for disseminating research to program stakeholders and clinicians). This could include schedule meetings, ECHO sessions, internal research conferences for AMPATH staff and researchers, etc. 3) There are many innovative implementation projects ongoing at AMPATH but only a fraction of them are disseminated to the broader HIV and clinical community more globally. Perhaps having a structured framework for publishing/disseminating these projects would be helpful, in which the people involved in program implementation work more closely with those more heavily involved in research to conduct program evaluations and publish implementation assessments of interventions ongoing at AMPATH. Currently the researchers and program implementers are siloed.
- Weak management systems
- Poorly defined processes
- 1. Better well planned training and mentor ship programmes should be developed 2. Avoid duplication of processes to reduce wastage of time and resources
- Poor infrastructure in lab structures, poor motivation of staff at the sites
- Not expanding quickly enough to meet local needs
- There is a need for more training and mentorship programs within the research office that will help young upcoming research individuals, provide a partnership for mentorship between experienced scientific writers with publishing skills The research opportunities advertised are targeted to a group of individuals; Principal Investigators majorly and do not reach out to people who are not from the USA or European consortium universities.
- Lack of capacity enhancement
- little access to training and mentorship
- Little access to training and mentorship
- Weak structures for addressing concerns No round table discussions among stakeholders every quarter Weak link with counties to remove duplication of effort among partners
- Limited access to mentorship.
- Little training's and mentorship for upcoming researchers.
- Minimal access to training and mentor-ship of junior staff. The program focuses more on senior researchers at the doctoral level.
- little access to training and mentorship
- I don't know if this is a weakness but it would be imperative to make sure research/problem statements are identified and developed by Kenyan stakeholders. Research is universally

conducted through a western lens/perspective. It is critical to ensure that Kenyan's are identifying and defining the research parameters and challenges they want to investigate, applying their own perspectives to posing and answering those research questions.

APPENDIX C: OPPORTUNITIES RESPONSES

- Collaborations
- Good will from donors.
- Large number of willing and able mentors to assist in young talent development, presently underused.
- Pop Health/UHC growth presents good opportunities for expansion of research
- Continued support for global health care programs that create opportunities for research External reputation of AMPATH remains very good
- High demand for policy engaging research; global deliberateness in promotion of partnerships; and growing realization of the need for interdisciplinary and trans-disciplinary studies especially with SDGs
- Partnerships with surrounding private institutions, establishment of a grants writing office,
- technological advances and new post-graduate fellowship programs at the school of medicine and new research areas
- Continued partnerships
- Push for more implementation research, expanding research domains e.g. incoming of IBMI & increasing mHealth initiatives
- greater integration.
- Engaging the whole college research enterprise through directorate of research, Moi University.
- 1. Great partners with wealth of research expertise 2. AMPATH researchers well reknown in research arena and able to compete for grants 3. Continued funding for care programs gives research an opportunity to answer new questions
- Availability of Research infrastructure
- NIH Career development awards for International young investigators Pilot grants from CTSI
- re-think the purpose of the research working group
- Increased collaboration across subspecialties
- 1. Availability of researchable areas/topics 2. Increased funding availability especially for early career LMIC investigators
- Expansion of EMR beyond HIV - to oncology, population health, MNCH, etc
- Improving Kenyan bench strength, improving interest in research team helping to answer questions on the care program (implementation science)
- 1. Forming of collaborations for research training opportunities eg fellowships and phDs 2. Stronger linkage with other local research funding opportunities
- Involve all the schools at the college. Continue with community engagement for sustainability
- AMPATH's expansion into newer counties present a good opportunity for the research program to expand its activities.
- Ability to charge RPO expenses directly to grants can resource RPO better
- The support of NHIF to cover advanced diagnostics for cancer, such as flow cytometry and immunohistochemistry could lead to the strengthening of the AMPATH reference lab. Just as coverage of CT scans improved access to that technology, I expect similar advances in access to diagnostics will occur if the government lends support. The controls for how they cover that technology, e.g. having certification of labs/ quality control standards and sufficient criteria for

approving of lab services will make the services at AMPATH competitive. So ensuring the government puts controls in place as they expand coverage will allow AMPATH to be a leader in providing these diagnostic services (if we decide to commit to that).

- A large opportunity that exists would be to more aggressively pursue clinical trials.
- Look for foci beyond HIV/AIDS, especially in NCDs. Partnership with governments and for-profit companies can provide opportunities for win-win-win. AMPATH is recognized by NIH, CDC, USAID, and others as the BEST IN THE WORLD. So opportunities to help developing countries deal with the NCD tsunami that's coming abound.
- I'd love to see departmental research days that also highlight registrar research and colleague research with other organizations or research groups. I think that would allow for celebration, stimulation, and networking. I'd also love to see more academic rounds in all departments With junior faculty often on the ground, if they are to build research capacity in themselves and their Kenyan colleagues then they need more mentorship and leadership building.
- look at boundaries where interdisciplinary research could emerge; with growing engineering program (and education interests) expand opportunities for engineering and its intersections with other research areas, and education and its intersections
- Engagement from other consortium schools; new leadership in research program; decreased funding from PEPFAR in the future presents an important opportunity to assess the sustainability and outcomes of the HIV care program in the future (this could also be a threat to the program)
- Good will from political and community fronts
- Improved access to training opportunities especially in grant writing and management Technological advancements
- 1. Improve on the technologies available for projects 2. employ new research management programs and trends in global research
- Employee motivation, annual refresher courses and team building
- Growth for junior researchers
- There is already growing infrastructure supporting research activities and the research office. The office is well recognized and may expand a little to support more activities.
- New research trends
- New research trends
- Existing settings to implement research
- Technological resources - Virtual/ online communities of practice Improved research structures in the counties for collaboration and sustainability
- Complimentary changes in sponsor funding priorities. Most funding agencies would like to engage institutions with greater potential to enroll participants and that are able to support in evaluations/assessments.
- Full support form Partners and donors
- Access to leading researchers who can help develop emerging researcher within the program
- Identify and share opportunities that can be of help to the growth of junior research staff.
- New research trend on population health such as the chronic diseases
- Engaging the engineering faculty across institutes

APPENDIX D: THREATS RESPONSES

- Community and donor fatigue.
- Strengthen lab capability.
- Loss of promising young talent that moves to other programs. Poor communication from leadership in addressing identified problems or even acknowledging emails (acknowledging an email at times can be as supportive to the individual even if change cannot be enacted.). When communication is not even acknowledged, then the sender feels ignored and undervalued and is happy to leave- loss of talent and opportunity occurs.
- The fracturing relationships among county govt/MTRH/MU Inattentive or perhaps weak leadership at MUCHS Fragile informatics Fragile data management Persistent sub-optimal performance by RSPO Parallel grants management (e.g. Duke, ICI, AMPATH Plus grant)
- Emboldened county governments that increasingly feel ownership of "their data" Issues related to EMR rollout and uptake in various settings Establishment of a national data warehouse for HIV data
- Changes in research funding priorities; unequal and sometimes unfair international relations; Inadequate technology
- Collapsing public health system,
- new guidelines and changes in funding agencies' priorities, President Trump's political agenda, and orientation.
- KRA and clearing donations
- Limitations at RSPO
- diminishing interest amongst Kenyan colleagues to collaborate on research activities.
- Fear of lengthy peer review process. So increase awareness of rest of College faculty
- Lower available funding opportunities focused on local issues 2. Political changes in partner countries may affect funding streams 3. Payment inequities
- Sponsor funding priorities
- Changes in care funding that is likely to affect the research infrastructure
- Difficult & shifting bureaucracy/"politics" within AMPATH, increasing costs to do research
- Growth of other medical/health science schools in the region who can become alternative partners reducing role of MUCHS/MTRH
- Instability of devolved health units in Kenya, affecting quality care, testing and sustaining innovations
- Kenyans choosing to operate outside of AMPATH research program, individuals valuing the program on a whole, rising salaries cannibalizing grants
- Lack of uniformity of support for locals compared to those from North America in accessing research opportunities, funds and data
- The global economic depression Emmagence of other burdens of diseases Dependency creation
- Reduced support from MTRH administration, funding cuts from the US government.
- strikes
- Inadequate numbers of new research investigators joining the current group of successful/experienced researchers

- Competition for research or philanthropic dollars could worsen as other organizations come in to compete is a real threat. Having successful programs to highlight AMPATH strengths and show the public the work we do will be critical to compete successfully in the coming years.
- Donald Trump
- NIH not caring enough about global health, and the CDC not caring much about treating NCDs. Success depends on leadership, and with a couple of high-level ineffectual leaders, if they happen, could kill it. Dealing with the GOK and Uasin Gishu could kill it.
- Unclear processes (eg needing to go through certain hierarchies to get permission to do research that aren't clear) Not enough new Kenyans collaborating to do research
- need to broaden expertise in engineering and education to achieve integration of those new disciplinary areas
- There is currently a small pool of Kenyan clinicians participating in research and these individuals are increasingly oversaturated with projects; healthcare worker strikes can have a significant effect on research both in terms of patient recruitment/follow-up as well as the Kenyan clinicians involved in research who get pulled away from research due to the need to cover clinical activities.
- Unstable donor funding
- minimal sponsor funding
- Use of old technologies
- Competing interests from private organizations such as the International Cancer Institute, poor lab infrastructure
- Mentorship and growth of local and junior researchers.
- Negative changes in sponsor funding may affect monetary resources to expand.
- Funding opportunities
- Changes in sponsor funding priorities may limit research to be undertaken
- Competing programs from NGOs - national and local
- New research trends which requires modern technologies
- Less or No Government involvement in supporting research
- Failure to retain already empowered and experienced research staff resulting from shortage of funds to continue or set up new research activities/studies.
- Inadequate fundings
- Lack of structural support when the program expands
- Donor community determining that AMPATH must become self-sustaining or that because of it's success it would be appropriate to reduce funding. Does AMPATH currently write letters to Congress - on behalf of donors who cannot lobby congress - to explain the impact that reduced funding will have on the program and results? Also is AMPATH working to identify how to make components of the program more self-sustaining, in anticipation of the donor community one day reducing contributions?

APPENDIX E: OTHER COMMENTS

- Work towards having a research/education tracks in university 2. More support needed form parent institutions 3. More infrastructure support needed- e,g laboratory
- capacity building trainings for coordinators on The various aspects of research will greatly Improve quality of research in The various disciplines.
- Conduct annual client satisfaction survey for each unit in order improve services
- continued availability of pilot grant opportunities are important to continue to stimulate research at AMPATH
- Embrace all the fields of health sciences research starting from the molecular level to population medicine, create tangible County Health responsive legal frameworks as health is a devolved function.
- Empower the research leadership, make it more independent to reduce interference from overall partner I stitutions, review the fte provisions
- Funds should be allocated to the research office to hold internal trainings for research staff on matters related to research practice such as Good Clinical Practice, fundamentals of research ethics, data collection and management skills, etc.
- Great work.
- i've provided them previously, earlier this year.
- Make sure the Indiana Director has sufficient discretionary funds to help catalyze important research and support investigators, especially early career and Kenyan investigators.
- Mentorship of other leadership in research management and restricted tenure of worker to bring out new leadership. It is health for all organizations.
- More support is needed for the support units including lab
- My area of interest was deemed "not to be of interest/priority at AMPATH;" therefore, I (sadly) have no longer been writing grants and utilizing these services at AMPATH and have taken my work elsewhere in Kenya to other NGOs- not because I wanted to do so but little other choice was available. I did write and visit several times to try to get things moving again but to no avail (written queries usually received no answer at all. In person meeting was venue for being told my area was not a priority.) Interested parties should be encouraged to engage, not discouraged. This represents a lost opportunity for the program and for collaborations, as when it is seen to happen, I am sure it spills over and results in loss than more than that one individual collaborator. Not clear to me how often this happens but anytime it happens this is not good for the overall program. I returned to survey to note- I used to spend up to 40% of my time on research at AMPATH- it is now at 0%. I was unable to place this information in the last question.
- Please give the group more authority to hold people accountable for not following the rules.
- Really pleased we are going through this process! Thank you for leading it. We will only come out stronger.
- Regular sharing of available resources and ongoing projects will be helpful. Continuous staff education on research will also be helpful
- Removing layers of approvals -- taking an inventory of all forms and communications to eliminate those that are redundant or inefficient might reveal opportunities for streamlining while not sacrificing any quality control.
- Support for care programs to conduct evaluations and implementation research

- There is need now as before to encourage Kenyan faculty specially those in biomedical sciences to join the working groups and participation.
- They are doing excellent work.
- To keep up with the good work but work on the weaknesses

APPENDIX F: 2019 SWOT SURVEY INSTRUMENT – INTERNAL STAKEHOLDERS

Confidential

2019 Strategic Planning Survey

OverviewEvery 3 years the Academic Model Providing Access to Healthcare's (AMPATH) Research Program engages program stakeholders in a strategic planning process to evaluate progress in meeting our strategic objectives from the last 3 years and identify key strategic priorities for research in the next 3 years. The Program will invite key stakeholders to participate in a strategic planning meeting on September 12-13, 2019, in Eldoret, Kenya.

As an important stakeholder in AMPATH's research program, we would like to invite you to take a brief survey on how the Research Program is doing and help us assess our strengths, weaknesses, opportunities to grow stronger, and potential threats to the program's future. Your responses will be used to help evaluate progress toward achieving the research program's current strategic priorities and help inform the development of a new strategic agenda for the future.

Survey OverviewThe following survey will ask you to provide responses to several open ended questions that should take no more than 15-30 minutes to complete. Your responses will be de-identified and compiled in a summary report that will be presented to the Research Program Leadership and may be used in the strategic planning process.

DeadlinePlease complete the survey by August 2, 2019.

Save & ReturnYou can save your responses and return to complete the form at any point by selecting the "Save & Return Later" button at the bottom of each page. If you select this option, you will be provided a unique access code that will allow you to return to the submission form. Please keep this code for future reference.

Form NavigationPlease do not navigate using browser arrows as this will cause you to exit the form and your previous information will be lost. We suggest saving the form frequently, noting your retrieval code and using the buttons at the bottom of the page to navigate through the form.

Questions?Please contact the AMPATH Research Program Office, research.manager@iukenya.org, with any questions or concerns.

Vision

The AMPATH Research Program Vision Statement is meant to describe what our program will look like in the future.

Our current vision is to create a vibrant, world-class, Kenyan-led community of international researchers in health and health care.
How strongly do you agree with the following statements?
The vision statement fully captures where we should be going as a program.

◯ Strongly Agree ◯ Agree ◯ Neutral ◯ Disagree ◯ Strongly Disagree

Vision

Do you feel the AMPATH Research Program's Vision Statement requires any revisions?

◯ Yes
◯ No

How would you you change the vision statement to better capture where we are going as a program?

Mission

The AMPATH Research Program's mission statement describes our fundamental and unique purpose and should describe how we will achieve our Vision.

The AMPATH Research Program's current 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.
How strongly do you agree with the following statement?
The AMPATH Research Program's Mission Statement captures our research program's fundamental and unique purpose.

◯ Strongly Agree ◯ Agree ◯ Neutral ◯ Disagree ◯ Strongly Disagree

Mission

Do you feel the AMPATH Research Program's Mission Statement requires any revisions?

◯ Yes
◯ No

How would you you change the mission statement to better capture our research program's fundamental and unique purpose?

Strategic Priorities

In 2015 the AMPATH Research Program convened a strategic planning meeting with program stakeholders and identified the following 4 strategic priorities for the AMPATH Research Program.

In your opinion, how much better or worse is the AMPATH Research Program doing on each of the following priorities compared to three years ago?

	Much better	Somewhat better	Stayed the same	Somewhat worse	Much worse	Don't Know
Creating a stable, resourced infrastructure for research that enables the efficient conduct of high-quality, high-priority research;	○	○	○	○	○	○
Supporting successful independent investigators working in collaborative, interdisciplinary research teams to improve global health;	○	○	○	○	○	○
Strengthening a supportive, global health research-intensive cultures within the schools and departments of all AMPATH partners;	○	○	○	○	○	○
Promoting 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.	○	○	○	○	○	○

Internal Strengths & Weaknesses

What areas of the research program do you see as strengths?

Strengths are defined as positive internal factors that improve the Research Program's ability to be successful.

(For example, strong organizational structures, clearly defined processes, high quality infrastructure, access to training & mentorship, etc.)

What areas of the research program do you feel are weaknesses?

Weaknesses are defined as negative internal factors that lessen the Research Program's ability to be successful.
(For example, weak organizational structures, poorly defined processes, poor quality infrastructure, little access to training & mentorship, etc.)

External Opportunities & Threats

What opportunities exist to strengthen and expand the research program?

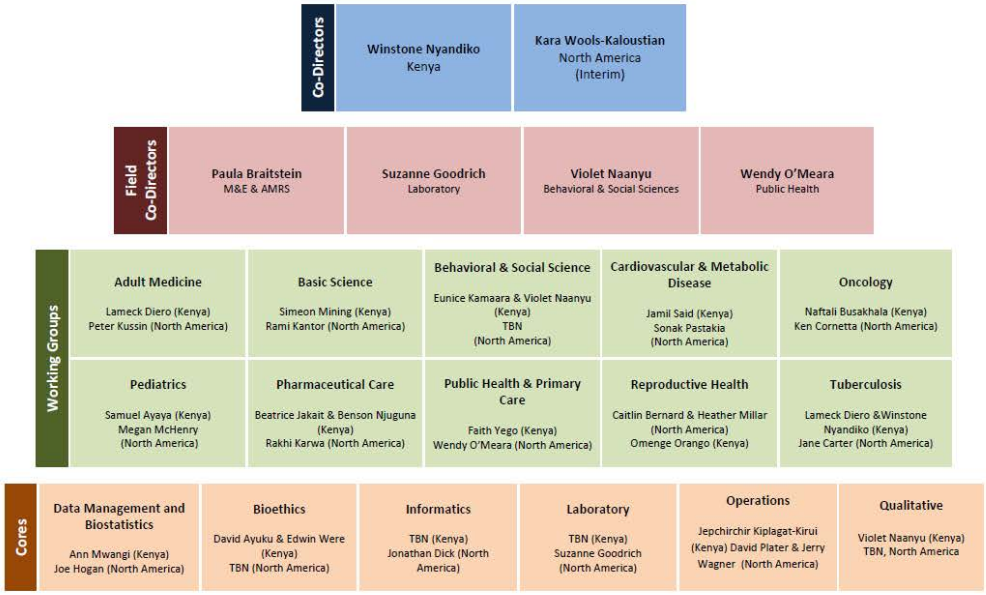
Opportunities are defined as positive external factors that will likely improve the Research Program's ability to be successful in the future.
(For example, new research trends, complimentary changes in sponsor funding priorities, technological advancements, etc.)

What threats exist to strengthening and expanding the research program?

Threats are defined as negative external factors that will likely lessen the Research Program's ability to be successful in the future.
(For example, new research trends that could hinder research, negative changes in sponsor funding priorities, inadequate technology, etc.)

Research Working Groups & Cores

The following structure of research working groups and cores was created to support AMPATH's research mission, vision, and values and facilitate collaborative research in Kenya.



Given your experience with AMPATH's research working groups and cores, how strongly do you agree with the following statement?

AMPATH's structure of research working groups and cores successfully supports our mission, vision, and values.

◯ Strongly Agree ◯ Agree ◯ Undecided ◯ Disagree ◯ Strongly Disagree

Research Working Groups & Cores

In your view, what are the greatest strengths of the current system of research working groups and cores?

In your view, what are the greatest weaknesses with the current system of research working groups and cores?

What changes, if any, do you think need to be made to the current system of research working groups and cores to better support AMPATH's research mission, vision, and values over the next 3 years?

How strongly do you agree with the following statements?

AMPATH's current structure of research working groups and cores:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't Know
Fosters Kenyan leadership of research.	○	○	○	○	○	○
Supports the development of new Kenyan researchers at Moi University and MTRH.	○	○	○	○	○	○
Supports the development of new North American researchers at AMPATH affiliated institutions.	○	○	○	○	○	○
Catalyzes new research collaborations and projects based in Kenya.	○	○	○	○	○	○
Removes obstacles to conducting research in Kenya.	○	○	○	○	○	○
Mitigates conflict in research.	○	○	○	○	○	○
Provides useful peer review for the development of research projects in Kenya.	○	○	○	○	○	○
Is seen as an easily accessible resource for researchers.	○	○	○	○	○	○
Is an unnecessarry barrier to research at AMPATH.	○	○	○	○	○	○
Is the right structure for the growth of the research program over the next 5 years.	○	○	○	○	○	○

Are there any alternative structures to the current system of working groups and cores you think AMPATH should consider?

◯ Yes
◯ No

Please describe any alternative approaches you believe would improve AMPATH's ability to fulfill its research mission.

AMPATH's Research and Sponsored Projects Office (RSPO) is the primary administrative support unit for sponsored projects and activities conducted through both the Moi University College of Health Sciences (MUCHS) and Moi Teaching and Referral Hospital (MTRH). RSPO has 5 departments (grants and contracts (pre- and post- award support), human resources, compliance, procurement, and finance). RSPO's staff is responsible for the processing and administration of sponsored awards and provides specialized support for grants and contracts, program analysis and reporting, human resource management, cash management, compliance oversight, and procurement.

Have you accessed any Research and Sponsored Projects Office (RSPO) services in the last 12 months?

◯ Yes
◯ No

Which of the following RSPO services have you accessed in the last 12 months?
(Please select all that apply.)

- ☐ Pre-award budget preparation &development
- ☐ Post-award contracting
- ☐ Financial management services (award management, status of funds, invoicing, audit)
- ☐ Human resources (hiring, staff training & development, payroll, performance appraisal)
- ☐ Procurement & supply chain
- ☐ Other (not listed)

Please describe the service you accessed?

How satisfied were you with the service you received from RSPO?

	Extremely Satisfied	Satisfied	Neutral	Dissatisfied	Extremely Dissatisfied
Pre-award budget preparation & development	○	○	○	○	○
Post-award contracting	○	○	○	○	○
Finanical management services (award management, status of funds, invoicing, audit)	○	○	○	○	○
Human resources (hiring, staff training & development, payroll, performance evaluation)	○	○	○	○	○
Procurement & supply chain	○	○	○	○	○
Other - [rspo_services_used_other]	○	○	○	○	○

How strongly do you agree or disagree with the following statement?

RSPO provides the right set of services and supports to achieve AMPATH's research mission, vision, and strategic priorities.

◯ Strongly Agree ◯ Agree ◯ Neutral ◯ Disagree ◯ Strongly Disagree

In your opinion, what should be changed about RSPO to ensure AMPATH achieves its research vision, mission, and strategic priorities?

The AMPATH Research Program Office (ARPO) provides specialized support to members of the AMPATH Research Network. Specifically, ARPO includes eight professional staff members who specialize in the development of international partnerships, program evaluation, research program management, and training. ARPO manages the core research infrastructure for bioethics, biostatistics, laboratory, biobanking, informatics, and qualitative research. It also oversees AMPATH's protocol review and development process and compliance with institutional policies and procedures for research. ARPO also administers research project space rental at the Chandaria Centre and meeting and teleconferencing support services.

Have you accessed any services provided by the Research Program Office in the last 12 months?

◯ Yes
◯ No

Which of the following ARPO provided services or supports have you accessed in the last 12 months?

- ☐ Meeting or teleconference scheduling
- ☐ Project space rental
- ☐ Operational support or advising
- ☐ Publications review
- ☐ Training
- ☐ Other

Please describe the service you accessed?

How satisfied were you with the service you received from the AMPATH Research Program Office?

	Extremely Satisfied	Satisfied	Neutral	Dissatisfied	Extremely Dissatisfied
Meeting or teleconference scheduling	○	○	○	○	○
Project space rental	○	○	○	○	○
Operational support or advising	○	○	○	○	○
Publications review	○	○	○	○	○
Training	○	○	○	○	○
Other - [arpo_services_used_other]	○	○	○	○	○

How strongly do you agree or disagree with the following statement?

The Research Program Office provides the right set of services and supports to achieve AMPATH's research mission, vision, and strategic priorities.

◯ Strongly Agree ◯ Agree ◯ Neutral ◯ Disagree ◯ Strongly Disagree

In your opinion, what should be changed about AMPATH Research Program Office to ensure AMPATH achieves its research vision, mission, and strategic priorities?

The Institutional Research and Ethics Committee (IREC) reviews research projects to evaluate the scientific and ethical merits of proposed research. IREC reviews projects to ensure they adhere to human subjects protections requirements and approves studies for implementation in Kenya.

Have you had a proposal reviewed by IREC in the last 12 months?

◯ Yes
◯ No

How satisfied were you with the service you received from IREC?

◯ Extremely Satisfied ◯ Satisfied ◯ Neutral ◯ Dissatisfied ◯ Extremely Dissatisfied

In your opinion, what should be changed about IREC to ensure AMPATH achieves its research vision, mission, and strategic priorities?

Do you have any additional comments or suggestions for strengthening the AMPATH Research Program?

Which of the following best describes your role within AMPATH research program?

- ◯ Principal Investigator/ Project Director
- ◯ Investigator/Co-investigator
- ◯ Project Manager
- ◯ Research Coordinator/Assistant
- ◯ Other

Please describe your role:

_____

What percentage of your full time effort is spent on AMPATH-related research activities?

0% 50% 100%

(Place a mark on the scale above)

APPENDIX G: 2019 SWOT SURVEY INSTRUMENT – EXTERNAL STAKEHOLDERS

Confidential

2019 Strategic Planning Survey

OverviewEvery 3 years the Academic Model Providing Access to Healthcare's (AMPATH) Research Program engages program stakeholders in a strategic planning process to evaluate progress in meeting our strategic objectives from the last 3 years and identify key strategic priorities for research in the next 3 years. The Program will invite key stakeholders to participate in a strategic planning meeting on September 12-13, 2019, in Eldoret, Kenya.

As an important stakeholder in AMPATH's research program, we would like to invite you to take a brief survey to help us identify future research priorities and assess our strengths, weaknesses, opportunities to grow stronger, and potential threats to the program's future. Your responses will be used to help evaluate progress toward achieving the research program's current strategic priorities and help inform the development of a new strategic agenda for the future.

Survey OverviewThe following survey will ask you to provide responses to several open ended questions that should take no more than 10-20 minutes to complete. Your responses will be de-identified and compiled in a summary report that will be presented to the Research Program Leadership and may be used in the strategic planning process.

DeadlinePlease complete the survey by August 2, 2019.

Save & ReturnYou can save your responses and return to complete the form at any point by selecting the "Save & Return Later" button at the bottom of each page. If you select this option, you will be provided a unique access code that will allow you to return to the submission form. Please keep this code for future reference.

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Questions?Please contact the AMPATH Research Program Office, research.manager@iukenya.org, with any questions or concerns.

AMPATH's envisions a vibrant, world-class, Kenyan-led community of international researchers in health and health care who work together 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.

Before today, how aware were you of AMPATH's research vision and mission?

◯ Fully Aware ◯ Somewhat Aware ◯ Somewhat Unaware ◯ Fully Unaware

AMPATH's envisions a vibrant, world-class, Kenyan-led community of international researchers in health and health care who work together 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.

How well does AMPATH achieve its research mission?

◯ Fully Achieves ◯ Partially Achieves ◯ Fails to Achieve ◯ Don't know

You indicated that AMPATH [mission_ex] its research mission.

In your opinion, what should AMPATH do differently to better achieve its research mission?

As part of the AMPATH Research Program's strategic planning process we would like to identify priority areas of focus that will have the greatest impact on improving the health of people in Kenya.

In order of priority (Most important to least important), please rank the top five priorities for health research in your [ex_org].

First Priority (Most Important) _____

Second Priority _____

Third Priority _____

Fourth Priority _____

Fifth Priority (Least Important) _____

What opportunities for research in your [ex_org] might benefit from or support collaborations with researchers from AMPATH?

Opportunities are defined as positive factors that will improve mutually beneficial research collaborations.
(For example, community interest in research, access to clinical facilities or other infrastructure, local funding for research, etc.)

What threats or issues might impact your [ex_org]'s desire or ability to collaborate with researchers from AMPATH?

Threats are defined as negative factors that will likely lessen the ability of AMPATH to collaborate with your [ex_org] to conduct mutually beneficial research.
(For example, lack of community interest in research, limited facilities, no local funding, etc.)

Do you have any additional comments or suggestions for making AMPATH's research program relevant to your [ex_org]?

Which of the following best describes your [ex_org]'s association with AMPATH?

- ◯ Community Partner
- ◯ NGO or Civil Society Partner
- ◯ County Government Partner
- ◯ National Government Partner
- ◯ Health Care Provider Partner
- ◯ University/Higher Education Partner
- ◯ Other

Other (Please describe):

How would you describe your role in your [ex_org] (e.g. chief executive, staff member, director)?

Has your [ex_org] worked with any AMPATH programs in the last 3 years (e.g. cancer screening & treatment, child health, chronic disease screening & treatment, economic empowerment, HIV/AIDS prevention & treatment, etc.)

- ◯ Yes
- ◯ No
- ◯ Don't Know

Which of the following AMPATH programs did your [ex_org] work with?
(Please select all that apply.)

- ☐ Cancer
- ☐ Child Health
- ☐ Chronic Diseases (diabetes, heart disease, mental health, etc.)
- ☐ Economic Empowerment & Agriculture
- ☐ HIV & AIDS
- ☐ Specialty Care (tuberculosis, malaria treatment, palliative care, etc.)
- ☐ Supportive Services (mobile radiology, pharmacy, legal advocacy, etc.)
- ☐ Surgery
- ☐ Women's Health (reproductive health and maternal care)
- ☐ Other

Other (Please describe):

What prevented your [ex_org] from working with AMPATH's programs?