SEMI ANNUAL RESEARCH REPORT

July - December 2017

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 setting 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.

www.medicine.iu.edu/ampathresearch

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ABBREVIATIONS

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

VISION, MISSION, & VALUES

VISION

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

MISSION

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

VALUES

In our work we embrace:

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

STRATEGIC PRIORITIES

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

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

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

OVERVIEW

The last year was filled with opportunity and new developments for the AMPATH Research Program. Moi University College of Health Sciences (MUCHS) held an inaugural Research Symposium featuring research and abstracts from nearly 40 research projects led by MUCHS faculty. We held our very first NIH Mock Study Section to give investigators the opportunity to observe how a real NIH study section works and receive feedback on draft proposals and applications. In October, we convened an open house and poster presentation as part of the AMPATH Research Forum at the IU Center for Global Health and Regenstrief Institute in Indianapolis. These events were held in conjunction with AMPATH's Reunion celebrations and included participants from across the AMPATH consortium.

The AMPATH Research Program continued its strong record of growth publishing more than 100 articles in peer reviewed journals – a new record and a 28 percent increase from 2016. More than US$5 million in new research and training awards were reported by the end of 2017 ending our year with a cumulative total of more than US$116 million dollars in funded research and training.

The following report provides a snapshot of AMPATH's research activities from 1 July – 31 December 2017. It includes updates and progress from 62 research projects that were active during this period. Each update includes a summary abstract of the project's aims, an update on progress made during the reporting period, and the project's objectives for the next 6 months. The reports were provided by the project's Principal Investigator or their designee and with the exception of formatting are presented here largely unedited.

MOI RESEARCH SYMPOSIUM

In July 2017, the MUCHS organized an inaugural Research Symposium. Researchers from the Schools of Medicine, Nursing, and Public Health submitted more than 40 posters and abstracts to the symposium. The program included nearly 20 invited presenters focusing on topics ranging palliative use of Cisplatinum for advanced cervical cancer to an examination of the use of chaplaincy programs at Riley Mother and Baby Hospital in Eldoret (See Appendix B for the Program).

NIH MOCK STUDY SECTION

In cooperation with the CITE Fellowship Training Project, an NIH funded training program for research fellows (D43 TW 009105), the AMPATH Research Program hosted an NIH Mock Study Section to provide investigators an opportunity to see how NIH study sections review and evaluate grant applications. The study section reviewed 4 proposals submitted by investigators from MUCHS and MTRH following the NIH process for study sections. The review sessions were open to anyone interested in seeing the process. The study section members included senior faculty from IU and Moi who have participated on grant review committees and NIH study sections. Following the review the study section members fielded questions from the audience about the NIH review process and requirements. Investigators who submitted proposals for review were provided constructive feedback about how to improve their applications for submission to external sponsors.

Members of the NIH Mock Study Section respond to audience questions about the NIH review process.

The IU Center for Global Health organized a poster presentation as part of the 2017 AMPATH Research Forum held in Indianapolis.

Research Forum & Open House

Researchers from across the AMPATH Consortium converged on Indianapolis for AMPATH's triennial reunion celebration in October 2017. As part of the weekend's festivities, the IU Center for Global Health organized a series of events as part of the 2017 AMPATH Research Forum. Nearly 100 people participated in the weekend's research events that included an open house and poster presentation with more than 30 posters representing AMPATH's care, education, and research programs, a keynote speech by Professor Winstone Nyandiko, and a working group session where investigators from across the consortium met to discuss the strategic direction of the AMPATH Research Program.

Grants

Investigators reported nearly US$ 5 million in new awards in 2017. This increased AMPATH's cumulative total of research and training awards to more than US$116.5 million since the start of the program in 1998 (See Figure 1). Nearly a quarter of these awards provide training to develop new Kenyan investigators and their partners from North America including Fogarty supported training for clinical research and biostats and data management.

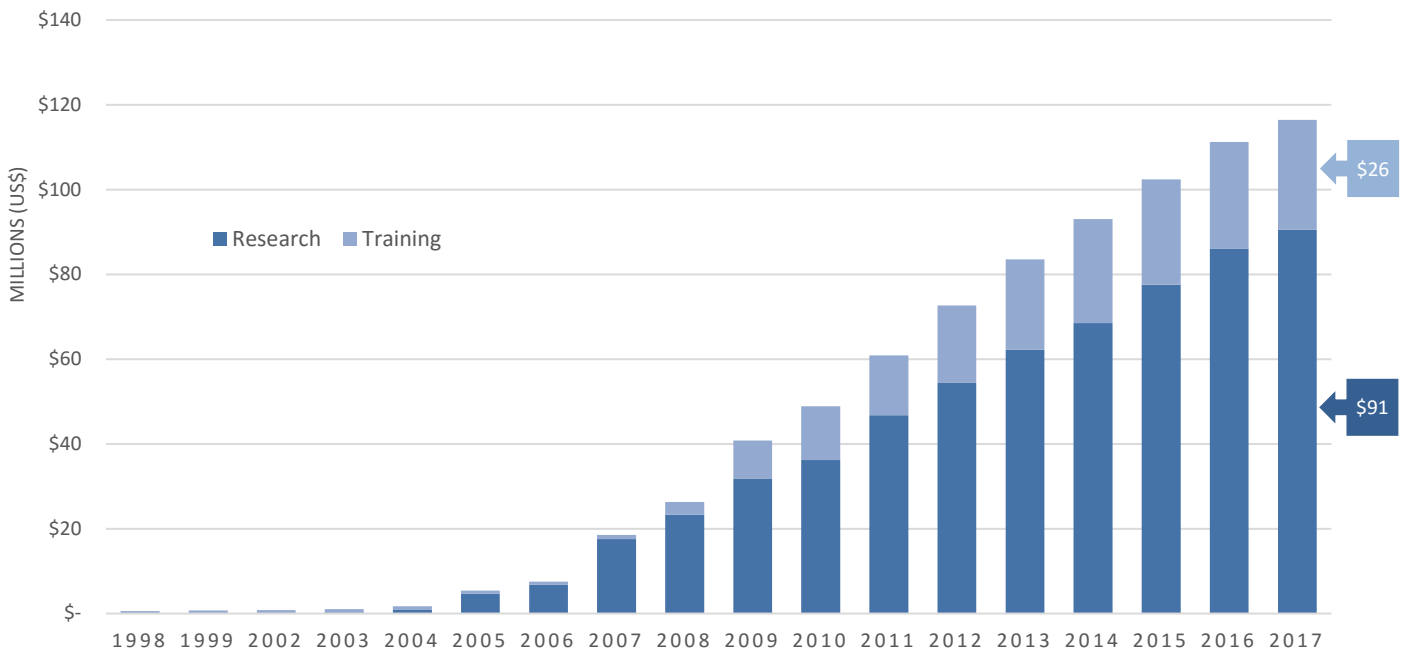
Pilot Awards

AMPATH collaborative research teams received $120,000 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 2017. The proposed projects will support pilot work to assess interventions providing home hospice care through mobile and telemedicine platforms along with compression therapy for chronic venous leg ulcers and a variety of other topics (See Table 1). The six awardees for the 2017 competition add to the three studies awarded pilot grants for AMPATH related research in 2016.

Table 1: 2017 CTSI Global Health Pilot Grant Awardees

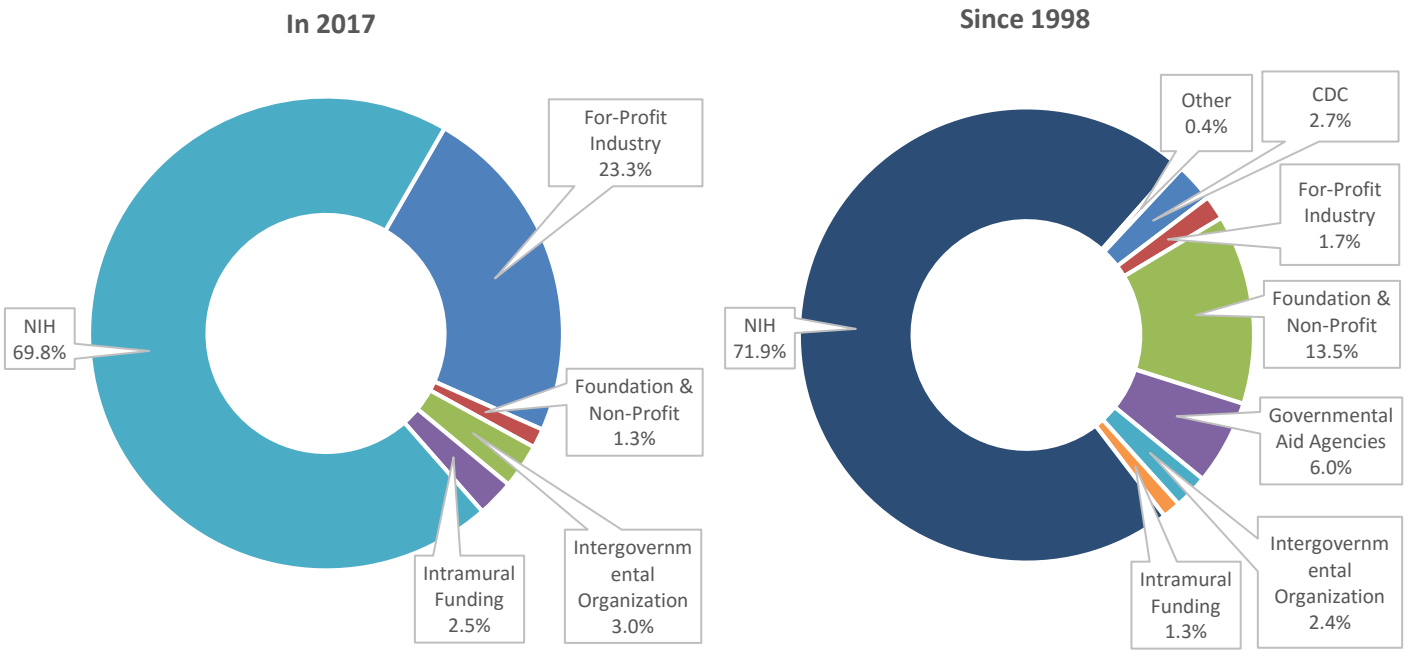
Proposal Title	PI	Institution	**Award**
1. Phylogenetic Inference of Vertical versus Horizontal HIV Transmission among Adolescents in Western Kenya	John Humphrey	IU School of Medicine	$20,000
2. Evaluation of locally-sourced compression therapy for treatment of chronic venous leg ulcers and management of Kaposi sarcoma leg lymphedema in western Kenya	Sonak Pastakia	Purdue	$20,000
3. The Epidemiology of Trauma and Trauma-Related Resources at a National Referral Hospital in Western Kenya	Connie H Keung	IU School of Medicine	$20,000
4. Facilitating Home Hospice Care Via Telecommunication in Kenya	Kenneth Cornetta	IU School of Medicine	$20,000
5. Strengthening the Adolescent HIV Care Cascade in Western Kenya: A qualitative study investigating critical gaps in care and potential interventions	Leslie Anne Enane	IU School of Medicine	$20,000
6. Pan African DrPH Strategic Leadership Training Needs Assessment: Kenya and Nigeria	Suzanne Babich	IUPUI	$20,000

Figure 1: Cumulative AMPATH Research & Research Training Grants By Year
(Direct Cost Total = $116.5 Million)



Since 1998, 72 percent of the awards AMPATH researchers were awarded came from the NIH. This trend continued in 2017 with percent of new awards came from the NIH. (See Figure 2).

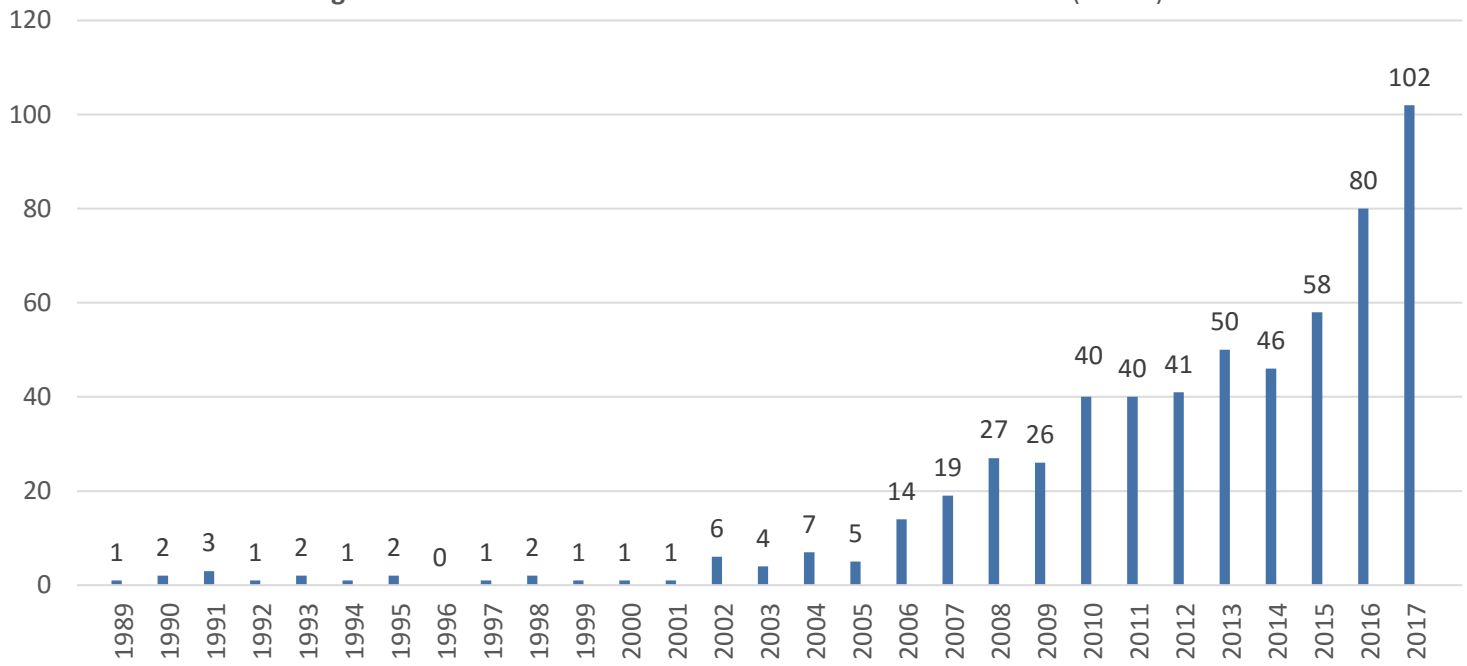
Figure 2: AMPATH Research Support by Sponsor Type in 2017 and since 1998



PUBLICATIONS

AMPATH investigators published 102 articles in peer-reviewed journals in 2017 – breaking the record for the number of publications produced in a single year for the third consecutive year. Investigators reported 46 new publications since our last reporting period putting us on track to surpass 600 publications by the end of the first quarter of 2018. A bibliography of all the publications produced from July – December of 2017 is available at the end of this report.

Figure 3: Number of AMPATH Research Publications since 1989 (n=583)



STUDY REPORTS

The following reports were provided by AMPATH investigators and their study teams and cover the period of July 1 – December 31, 2017. The views expressed in these reports do not necessarily reflect the views of the AMPATH Research Program, its partners, or sponsors.

Study Title	**A Formative Study to Develop Culturally Valid Psychosocial Assessment Tools and Interventions to Promote Family Well-Being in Kenya**
Principal Investigator(s)	Eve Puffer, Duke University David Ayuku, Moi University
Co-Investigator(s)	
Working Group(s)	PRWG, SSRN
Description	This study aims to contribute to the evidence base related to effective interventions for families in low-resource settings who are experiencing conflict and difficulties in relationships that affect child and caregiver wellbeing alike. Results of this study will (a) inform whether a family therapy approach is feasible and promising in communities in and surrounding Eldoret, Kenya and (b) inform how family wellbeing and mental health can be measured in culturally-valid ways in this context. Our long-term research goal is to establish an evidence-based and culturally-anchored family therapy intervention for very low-resource settings to improve family functioning, thereby preventing negative outcomes including mental health problems and HIV risk. Our objectives in this study are to create a new measure of family functioning and to develop and pilot a family therapy intervention. We will first develop a measure of family functioning that includes both survey and direct observation to complement self-report. We will then use a community-based participatory research process to develop a family therapy intervention that integrates evidence-based family therapy strategies with existing community solutions. Specific Aim #1: Develop new measures of family functioning including both survey measures and direct observation of family interactions. Specific Aim #2: Develop a family therapy intervention that integrates evidence-based family therapy strategies with existing community-based strategies for solving family problems. Specific Aim #3: Conduct a pilot study of the intervention with families to test feasibility and acceptability.
Site(s)	Moi Teaching and Referral Hospital
Project Period	5/28/2013 - 12/31/2018
Funding Status	Funded - Grand Challenges Canada & Johnson and Johnson
Direct Award (USD)	$129,000
Update	The measures validation study has concluded with publications in progress. For our intervention evaluation component, the single-subject case series design study (which is our second pilot round) is underway. We are collaborating with four religious congregations on this study and have begun providing the treatment to families. Due to

	the elections, the study did not begin when expected. The new expected completion date is July 2018.
Future Plans	We plan to collaborate with co-PI David Ayuku to publish results from our first pilot study and to complete this second pilot study described above. We are also submitting a grant to the NIH for further funding to conduct a larger study.
Publication(s)	

Study Title	**A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI)**
Principal Investigator(s)	Rebecca Papas, Brown University B. Gakinya, Moi University
Co-Investigator(s)	Michael Mwaniki, Maisto, S. Martino, S. Baliddawa, J. Sidle, J. Hogan, J. Carroll, K.
Working Group(s)	AMWG, SSRN
Description	This study will determine whether a group cognitive-behavioral therapy intervention that demonstrates preliminary evidence of reducing alcohol use among HIV-infected outpatients in western Kenya is effective when compared against a group health education intervention in a large sample over a longer period of time. It will be delivered by paraprofessionals, individuals with limited professional training. This approach is consistent with successful cost-effective models of service delivery in resource-limited settings in which paraprofessionals (e.g. clinical officers, traditional birth attendants and peer counselors) are trained.
Site(s)	Iten District Hospital, Moi Teaching and Referral Hospital , Turbo Health Centre, Webuye District Hospital
Project Period	11/1/2011 - 8/31/2016
Funding Status	Funded – National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Direct Award (USD)	$2,268,832
Update	Data analysis has continued over the last six months. One manuscript on 'Association with unprotected sexual behavior among HIV-infected outpatient drinkers in Western Kenya' as resulted from the ongoing analysis.
Future Plans	We plan to continue with data analysis and produce more publications

Publication(s)	Association with unprotected sexual behavior among HIV-infected outpatient drinkers in Western Kenya
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 Naftali Busakhala, Moi University
Co-Investigator(s)	
Working Group(s)	AMWG, ORWG
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)
Direct Award (USD)	Not Reported
Update	Enrollment into the protocol is ongoing. The site was able to enroll 5 participants during the second half of the year. These participants have benefited from closer attention to care, free chemotherapy and lab tests. On October 12, 2017, the ACTG Scientific Agenda Steering Committee reviewed and approved the protocol team request to continue with accrual beyond November 2017.
Future Plans	We plan to continue with recruitment efforts and enroll at least 8 participants in the next 6 months.
Publication(s)	

Study Title	**A5264/AMC067 A Randomized Evaluation of Antiretroviral Therapy Alone or with Delayed Chemotherapy versus Antiretroviral Therapy with Immediate Adjunctive Chemotherapy for Treatment of Limited Stage AIDS-KS in Resource-Limited Settings (REACT-KS)**
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	
Working Group(s)	AMWG, SSRN, ORWG
Description	A5264/AMC 067 is a phase III, open-label, prospective, randomized study stratified by CD4+ lymphocyte cell count and antiretroviral therapy (ART) history. The study will compare the KS tumor outcomes of ART alone or with delayed Etoposide (ET) to ART with immediate ET, for initial treatment of limited stage AIDS-KS in chemotherapy and radiation treatment na- HIV-1 infected participants who are currently not receiving ART
Site(s)	Moi Teaching and Referral Hospital
Project Period	11/28/2012 - 6/30/2014
Funding Status	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID) NIH - National Cancer Institute (NCI) NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	Not Reported
Update	All participants enrolled at Eldoret site completed follow-up.
Future Plans	The protocol team will continue with data analysis.
Publication(s)	

Study Title	**A5274/REMEMBER Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens '**
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Priscilla Cheruiyot, David K Lagat
Working Group(s)	AMWG, SSRN, TBWG
Description	In this randomized, open-label, phase IV strategy trial, participants from resource-limited settings (RLS) who present with advanced HIV disease and no probable or confirmed tuberculosis (TB), as defined in the current ACTG diagnosis appendix, and who are initiating antiretroviral treatment (ART) will be randomized to one of two strategy arms:

	immediate, empiric TB treatment (public health approach) or local standard of care TB treatment (individualized approach). The primary endpoint is survival status in the two arms 24 weeks after randomization. AIDS progression (any new WHO Stage 3 or 4 condition), virologic and CD4+ cell response, HIV and TB drug resistance, AND safety and tolerability of, and adherence to HIV and TB drugs will be evaluated, as will the cost-effectiveness of the two strategies. The primary objective is to compare survival probabilities between the two study arms 24 weeks after randomization.
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/10/2012 - 12/31/2016
Funding Status	Funded - NIH – AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	The last participant completed follow up on April 22, 2016. The study closed to follow up on May 3, 2016 and secondary data analysis is ongoing.
Future Plans	We expect secondary data analysis to continue.
Publication(s)	AIDS. 2017 Oct 23;31(16):2217-2225. doi: 10.1097/QAD.0000000000001606. Risk factors for early mortality on antiretroviral therapy in advanced HIV-infected adults. Bisson GP1, Ramchandani R, Miyahara S, Mngqibisa R, Matoga M, Ngongondo M, Samaneka W, Koech L, Naidoo K, Rassool M, Kirui F, Banda P, Mave V, Kadam D, Leger P, Henestroza G, Manabe YC, Bao J, Kumwenda J, Gupta A, Hosseinipour MC; Adult AIDS Clinical Trials Group A5274 (REMEMBER) Study Team.
Study Title	**A5288 'Management Using the Latest Technologies in Resource-limited Settings to Optimize Combination Therapy After Viral Failure (MULTI-OCTAVE)'**
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Priscilla Cheruiyot, Beatrice Wangari Ndege
Working Group(s)	AMWG, SSRN
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	Of the 23 participants enrolled at the Eldoret site, 15 have completed study follow up while 8 are still on follow up as they were enrolled to step 3 of the protocol. The 8 participants continue to receive closer attention to care, medication that would not otherwise be available in standard of care and more frequent labs at no cost.
Future Plans	Continue with follow up of the 8 participants on study.
Publication(s)	

Study Title	**A5290 A Randomized, Phase 2b Study of a Double-Dose Lopinavir/Ritonavir-Based Antiretroviral Regimen with Rifampin-Based Tuberculosis Treatment versus a Standard-Dose Lopinavir/Ritonavir-Based Antiretroviral Regimen with Rifabutin-Based Tuberculosis Treatment with or without Raltegravir in HIV-1-Infected Persons Requiring Treatment for Active TB and HIV**
Principal Investigator(s)	Abraham Siika, Moi University Fatuma Some, Moi University
Co-Investigator(s)	Priscilla Cheruiyot
Working Group(s)	TBWG
Description	A5290 is a prospective, randomized (1:1:1), open-label, phase 2b study comparing three lopinavir/ritonavir (LPV/r)-based antiretroviral (ARV) regimens among participants in high tuberculosis (TB) endemic resource-constrained settings undergoing treatment for confirmed or probable TB and requiring protease inhibitor (PI)-based antiretroviral therapy (ART). A two accrual period design will be used, including a full pharmacokinetic (PK) and safety evaluation to be conducted when 54-60 participants enrolled during the accrual period 1 have completed 28 days of ARV treatment and day 12 2 (after initiation of ART) drug levels are available (an early interim PK and safety evaluation will also be

	completed when 10-12 participants per arm have completed 28 days of ARV treatment and day 12 2 drug levels are available). Primary Objective: To compare rates of virologic suppression to < 400 copies/mL at 48 weeks for the two standard dose LPV/r and RBT arms versus the double-dose LPV/r and RIF arm.
Site(s)	
Project Period	5/13/2015 - 11/30/2018
Funding Status	Funded – NIH – AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	All study participants completed study follow up. The study was closed to follow up across all participating site on July 6, 2017.
Future Plans	There will be no further study activities for this protocol at the Eldoret site. The protocol team to continue with data analysis.
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 David Lagat, Moi University
Co-Investigator(s)	
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)	All Sites
Project Period	10/12/2017 - 1/31/2021

Funding Status	Unfunded -
Direct Award (USD)	
Update	The first participant was screened on 12/October/2017. By end of December 2017, a total of 7 participants had been screened and 5 enrolled into the study. Follow up is ongoing and there are no major challenges so far.
Future Plans	In the next 6 months, the site plans to ramp up recruitment and enroll as many participants as possible into the study before the protocol sample size is attained in this multi center trial.
Publication(s)	
Study Title	**Adapting, piloting, and evaluating an innovative HIV prevention intervention integrated with group-led matched-savings for street-connected young people in western Kenya**
Principal Investigator(s)	Lonnie Embleton, University of Toronto Paula Braitstein, University of Toronto
Co-Investigator(s)	
Working Group(s)	PHARMCRWG
Description	SUMMARY STATEMENT: The purpose of this two-phase concurrent mixed methods study is to adapt, pilot, and evaluate an HIV prevention intervention for street-connected young people aged 16-24 in Eldoret, Kenya. In the first phase, Stepping Stones, Creating Futures, and matched-savings GISE groups will be adapted using community-based participatory methods, including focus group discussions (FGDs), followed by small working groups, to adapt the combined program to the local social, cultural, and economic context of street-connected young people in Kenya. In the second phase, the HIV prevention intervention will be piloted using a pre-post research design and a baseline and endline survey will be used to quantitatively measure changes in HIV knowledge and gender equity. At the same time, the acceptability, appropriateness, impact, and unintended consequences of the intervention will be explored using participant observation, meeting documentation, attendance records, FGDs, and in-depth interview data collected over the course of the study. The rationale for using qualitative and quantitative data is that together these methods will be best to explain and explore how and why the intervention functioned and the impacts it had on participants. RESEARCH QUESTIONS: This proposal asks the following questions by objectives: Adaptation Objective: To adapt Stepping Stones combined with a livelihood-strengthening program to form a 16-week HIV prevention program for street-connected young people aged 16-24. 1. What program components from Stepping Stones, Creating Futures, and matched-savings GISE groups are acceptable and appropriate, and what components are not, for street-connected young people in Eldoret, Kenya? And why are they or why are they not acceptable and

	appropriate? 2.How were the program components adapted and integrated together into an HIV prevention intervention for street-connected young people in the context of Eldoret, Kenya? Pilot Objective: To quantitatively and qualitatively evaluate the impact of the intervention on changing HIV knowledge (primary outcome), gender equity (primary outcome), condom use self-efficacy, economic resources, and sexual health practices. 1. What was the magnitude and direction of change in HIV knowledge and gender equity for participants after completing the HIV prevention intervention? 2.Does participants' age, sex, relationship status, time street-involved, living circumstances, education and orphan status, impact changes in HIV knowledge and gender equity for participants completing the HIV prevention intervention? 3. Do participants' attendance rates impact changes in HIV knowledge and gender equity for participants completing the HIV prevention intervention? 4. How did participation in the HIV prevention intervention change street-connected young people's sexual health practices, HIV knowledge, gender equitable attitudes, and economic status? Evaluation Objective: To qualitatively evaluate the acceptability, appropriateness, nature of participation, and unintended consequences of the HIV prevention intervention on street-connected young people, PNs and young-adult facilitators (YAFs). 1. How do street-connected young people, PNs, and YAFs describe their experiences participating in the HIV prevention intervention? 2. How did participation in the HIV prevention intervention change street-connected young peoples, PNs, and YAFs lives? 3. What components of the adapted HIV prevention intervention were acceptable and appropriate, and what components were not, for street-connected young people, PNs and YAFs? And why were they or why were they not acceptable and appropriate? 4.What unintended consequences arose from participating in the HIV prevention intervention for street-connected young people, PNs, and YAFs?
Site(s)	Angurai Health CentreMois Bridge Health CentreZiwa Sub-District HospitalRafiki Centre for Excellence in Adolescent Health
Project Period	5/7/2017 - 1/31/2018
Funding Status	Funded - International Development Research Centre of Canada
Direct Award (USD)	$9,187
Update	From May to August 2017 in Eldoret, Kenya, we adapted the Stepping Stones and Creating Futures HIV Prevention intervention drawing on a modified ADAPT-ITT model using the following 7-step process: 1. Assessment, 2. Decision, 3. Administration, 4. Production, 5. Topical Experts, 6. Integration, 7. Testing. We used community-based participatory methods with four Peer Facilitators, topical experts, and 24 SCY, aged 16 to 24 years, who participated in adapting the intervention for the new context. From August to December 2017 we piloted the adapted curriculum in Eldoret, Kenya at the Academic Model Providing Access to Healthcare using a pre- and post-test study design. We recruited 80 SCY, into age and sex stratified groups (16-19 years and 20-24 years), with 20 participants per group, of which 67 completed both baseline and endline surveys. Participants attended sessions twice per week, for a total of 24 sessions over 14 weeks, and contributed to a matched-savings program conditional on attendance. Additionally we

	conducted four FGDs post-intervention and four in-depth interviews with the Peer Facilitators to evaluate the program.
Future Plans	Over the next six months I hope to analyze the data and submit numerous abstracts as well as draft manuscripts.
Publication(s)	Adapting an evidenced-based HIV prevention intervention for street-connected young people in western Kenya Embleton, L, Di Ruggiero E, Ayuku, D, Odep Okal E, Ronga D, Naliaka S, Nafula W, & Braitstein P. Oral Presentation. January 2018. University of Nairobi HIV/AIDS Meeting.
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) Darron Brown, Indiana University - Purdue University in Indianapolis (IUPUI)
Co-Investigator(s)	
Working Group(s)	ORWG, RHWG
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 Referal Hospital

Project Period	9/19/2014 - 8/31/2019
Funding Status	Funded - NIH – National Cancer Institute (NCI)
Direct Award (USD)	$2,132,402
Update	Study enrollment is now complete. 223 women have been recruited to project 1 and 166 have been recruited to project 2. STI testing is complete on initial encounter samples for all women and follow up and treatment was provided. All HPV serotype tests have been performed for the first encounter for samples for project 1 with project 2 nearing completion. A call for pilot projects was made and 3 projects were submitted from U54 consortium partners. The internal advisory board meeting was rescheduled due to the elections to January of 2018.
Future Plans	The rescheduled internal advisory board meeting will be held in January of 2018. The patient trackers are in place and will continue to encourage patients to return for their regularly scheduled visits. No additional recruitment is planned. The group is preparing abstracts for several conferences with the data available from the initial test results.
Publication(s)	

Study Title	**Analysis of ICU Admissions and Outcomes at the Moi Teaching and Referral Hospital Intensive Care Unit**
Principal Investigator(s)	Peter Kussin, Duke University Wangari Waweru-Siika, Moi Teaching and Referral Hospital
Co-Investigator(s)	Lalani, Hussain; Mwogi, Thomas
Working Group(s)	AMWG
Description	This study aims to explore the outcomes and mortality of patients admitted to the intensive care unit (ICU) at Moi Teaching and Referral Hospital by conducting a retrospective chart review of all patients admitted during 2011 through 2015. We aim to describe the demographic and clinical characteristics of these patients, evaluate specific procedures performed while patients are admitted to the ICU, investigate microbiological lab data specifically surrounding sepsis, and to establish the general cost of a hospital stay at MTRH. The overall goal is to develop a strong foundational data set that can be used to evaluate future clinical interventions. Furthermore, we intend for the prospective arm of this study, which is completely tablet-based, to serve as one step closer to the first electronic medical record for inpatient care at MTRH.
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/26/2015 - 6/1/2016

Funding Status	Unfunded
Direct Award (USD)	
Update	We have submitted the general analysis for submission and are in the process of getting it accepted for publication. We have added team members to assist with future analysis and writing.
Future Plans	Publish the general analysis. Begin submitting additional manuscripts.
Publication(s)	

Study Title	**Assessment of Airway Disease in Western Kenya**
Principal Investigator(s)	Peter Kussin, Duke University David Lagat, Moi University
Co-Investigator(s)	Elcy Birgen, O'Chieng, Nancy
Working Group(s)	AMWG, PRWG
Description	The World Health Organization (WHO) has identified chronic respiratory diseases as the 3rd leading cause of death globally.1,2 Unfortunately, the prevalence of these diseases and their underlying biology in much of sub-Saharan Africa is unknown. To this end we propose to first describe the prevalence of obstructive respiratory disease in Uasin Gishu County, Kenya using medical histories, validated questionnaires, and pre-and post-bronchodilator spirometry. We will then classify obstructive airway disease phenotypes as either bronchodilator responsive (FEV1 or FVC >12% post-bronchodilator) or unresponsive.3 We will also examine risk factors associated with airway disease including occupational history, TB, HIV, and biomass fuel use. Finally, we will compare our phenotypes to novel exhaled gas signatures based on levels of exhaled carbon monoxide and nitric oxide as surrogates of air pollution and eosinophilic airway inflammation, respectively, providing insights into the underlying biology of chronic lung disease in our population as well as estimates of the impact of air pollution on lung health.
Site(s)	Community based research study across Uasin Gishu
Project Period	8/31/2016 - 12/31/2017
Funding Status	Funded - NIH - Fogarty International Center (FIC)
Direct Award (USD)	$91,873

Update	We completed enrollment and are in the process of cleaning data and writing our manuscripts. We do not yet have preliminary findings.
Future Plans	To complete data analysis and draft of a manuscript.
Publication(s)	

Study Title	**Biomarkers of Vincristine Toxicity in Kenyan Children**
Principal Investigator(s)	Jodi Skiles, Indiana University F. Njuguna, Moi University
Co-Investigator(s)	
Working Group(s)	ORWG, PRWG
Description	This study evaluates the presence of peripheral neuropathy induced by Vincristine in Kenyan children receiving chemotherapy. The main purpose is to assess whether the genetic makeup of each child (particular the genotype of CYP3A5) influences drug exposure and subsequent vincristine toxicity.
Site(s)	Moi Teaching and Referral Hospital
Project Period	6/23/2011 - 6/30/2014
Funding Status	Funded - NIH
Direct Award (USD)	$8,743
Update	Study is now closed and manuscript has been published.
Future Plans	No further analysis is planned
Publication(s)	Skiles JL, Li CH, Chiang C, Li C, Martin S, Smith EL, Olbara G, Jones DR, Vik TA, Mostert S, Abbink F, Kaspers GJ, Njuguna F, Sajdyk, TJ, Renbarger JL. CYP3A5 genotype and its impact on vincristine pharmacokinetics and development of neuropathy in Kenyan children with cancer. Pediatr Blood Cancer. 2017; e26854. DOI: 10.1002/pbc26854.

Study Title	**Bridging Income Generation with Gruop Interated Care(BIGPIC)**
Principal Investigator(s)	Rajesh Vedanthan, Mount Sinai School of Medicine Jemima Kamano, Moi Teaching and Referral Hospital
Co-Investigator(s)	Peninah Kiptoo
Working Group(s)	AMWG, CVMD
Description	The objective of this proposal is to utilize a trans disciplinary implementation research approach to address the challenge of reducing CVD risk in low-resource settings. The research aims at integration of group medical visits and microfinance with the additional social network characteristics.Aim 1: Identify the contextual factors, facilitators, and barriers that may impact integration of group medical visits and microfinance for CVD risk reduction, using a combination of qualitative research methods: 1) baraza; and 2) focus group discussions among individuals with diabetes or at increased risk for diabetes, microfinance group members, and rural health workers. Then develop a contextually and culturally appropriate integrated group medical visit-microfinance model. Aim 2:Evaluate the effectiveness of group medical visits and microfinance groups for CVD risk reduction among individuals with diabetes or at increased risk for diabetes, by conducting a four-arm cluster randomized trial comparing: 1) usual clinical care; 2) usual clinical care plus microfinance groups only; 3) group medical visits only (no microfinance); and 4) group medical visits integrated into microfinance groups. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the trial.
Site(s)	Bumala A Health CentreBumala B Health CentreChulaimbo Sub-District HospitalEndebess Sub-District HospitalAngurai, Moding,Akichelesit, Malaba, Aboloi, Kamolo, Changara, Ziwa, Kipkabus, Chepngoror
Project Period	4/1/2015 - 4/1/2015
Funding Status	Unfunded
Direct Award (USD)	
Update	Administrative - All-Investigator conference call held on September 5, 2017 - Positive feedback attained from participants on call - Procurement of necessary supplies both for point of care testing and stationery ongoing Aim 1: Barriers/facilitators/contextual factors - manuscript writing ongoing Aim 1.1 (Barriers, Facilitators, & Contextual Model): - Manuscript writing ongoing

Aim 2 (Cluster RCT):

- Logistics of trial Roll Out:
- Working with AMPATH's Chronic Disease Management (CDM) and Safety Net teams regarding logistics of trial rollout
- Intervention rollout is ongoing; thus far 18 facilities have been rolled out(4-GMV, 5-GMV-MF, 4-UC, 4-MF)
  - A total of 1414 participants (Male=485, Female=929) have been enrolled thus far.
  - A total of 543 participants(Male=183, Female=360) have completed 3-month follow ups
- CDSMP training of research staff and community health workers who will be involved in the group medical visit-microfinance intervention completed
- Group Facilitation Training of community health workers (CHWs) done on all facilities rolled out
- Operations manual completed
- Data collection, entry, & management: Data collection, entry, and management procedures ongoing.
- Process evaluation:
- Protocol for Process Evaluation completed, REDCap programming of data collection instruments completed, testing on going.
- Randomization completed
- Process evaluation activities have begun (3 Key Informant Interviews, Uasin Gishu CHV written test done)

Aim 2.1(Mediation & Moderation Analysis):

- Social network survey (SNS):
- SNS currently being administered to all participants at baseline and 3 month f/u
- Preparation underway to present abstract at upcoming ACC Conference

Aim 3 (Cost Effectiveness Analysis):

- Costing questionnaire survey (CQS):
- CQS currently administered to study participants
- Intervention cost tracking done, fourth quarter report nearly finalized

Future Plans

Aim 1:

- Manuscript preparation

Aim 1.1

- Manuscript preparation

Aim 2:

- Continue with and complete enrollment of individuals into the trial
- Finalize roll out of the remaining 6 facilities
- Continue with process evaluation activities
- Continue 3-month f/u assessments
- Initiate 12-month f/u assessments

	Aim 2.1: • Administer social network survey to study participants at appropriate assessment periods • Present abstract at 2018 ACC Conference in March Aim 3: • Administer survey to study participants at appropriate assessment periods
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 Imran Manji, Moi Teaching and Referral Hospital
Co-Investigator(s)	Christabell Umukagah
Working Group(s)	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 250% in this population. Our objectives are to: 1) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) is feasible. 2) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) can improve uptake of long-acting reversible contraceptive methods (IUCDs and contraceptive implants). 3) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within an Anticoagulation Monitoring Services (AMS) Clinic can prevent unplanned pregnancies. In order to evaluate these objectives we will provide the intervention and follow the participants for the following 1 year time period. At 3-month, 6-month, and 12-month follow-up we will evaluate whether they are using any method of family planning and whether they have experienced subsequent unplanned pregnancies. This data will be compared to the same group of women prior to implementation of the education intervention and free, on-site provision of all reversible contraceptive methods.
Site(s)	Moi Teaching and Referral Hospital

Project Period	4/20/2015 - 8/31/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	Over the last six months, data cleaning was done after completion of the 6&12 month follow up in preparation for continued data analysis. A review of the manuscript was done after receiving feedback from American Journal of Obstetrics and Gynecology (AJOG) and another submission done. Due to the strike in the health sector, the outreaches had to be suspended.
Future Plans	Over the next 6 months, we plan to do longitudinal analysis of 6 & 12 month data and also do an overall analysis of all the data available to evaluate whether our primary objective of increasing use of long term methods of family planning was achieved. Additionally, we will prepare another manuscript that will be submitted to a relevant journal for publication. We will also share our findings with the hospital administration with the aim of the integration strategy being adopted long-term.
Publication(s)	

Study Title	**Childhood Leukemia in Kenya Identified Through Malaria Slide Review**
Principal Investigator(s)	Terry Vik, Indiana University F. Njuguna, Moi University
Co-Investigator(s)	Priscilla Cheruiyot, Skiles, J., Moormann, A.
Working Group(s)	ORWG, 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
Project Period	7/1/2012 - 6/30/2015
Funding Status	Funded - Alex's Lemonade Stand Foundation
Direct Award (USD)	$200,000

Update	Continuing to revise manuscripts with collaborators for submission
Future Plans	Hope to submit manuscript.
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 David Ayuku, Moi University
Co-Investigator(s)	Braitstein Paula, Kamanda Allan, Wachira Juddy
Working Group(s)	PRWG, SSRN
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)	Other community-based sites in Eldoret

Project Period	9/5/2016 - 12/31/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	Over the past six months we finished data collection with the exception of 2 key informant interviews. Transcription and translation are underway and we expect to commence analysis in March 2018.
Future Plans	In the next 6 months we hope to complete analysis and draft manuscripts.
Publication(s)	

Study Title	**Developing and Assessing a Community-Based Model of Antiretroviral Care**
Principal Investigator(s)	Abraham Siika, Moi University Kara-Wools Kaloustian, Indiana University
Co-Investigator(s)	Naanyu Violet, PhD, Goodrich Suzanne, MD, Yiannoutsos Constantin, PhD, Mwangi Ann, PhD, Thirumurthy Harsha, PhD, Batenganya Moses, MD, Spira Thomas, MD, Nyunya Boaz
Working Group(s)	TBWG
Description	ART Co-ops study will develop and assess an alternative care model that is established on the platform of a HIV-infected peer-group (ART Co-op) and facilitated by community health workers (CHWs). This model of care is intended to decentralize ART services and bring them closer to the patients. Specifically, we will: 1. Develop an acceptable and sustainable model for extending HIV care and treatment into the community. 2. Perform a pilot study comparing the outcomes of patients enrolled in the ART Co-ops program to those receiving standard of care. 3. Determine the cost savings and cost effectiveness of ART Co-ops.
Site(s)	Kitale District Hospital
Project Period	2/9/2015 - 2/9/2017
Funding Status	Funded – Centers for Disease Control and Prevention
Direct Award (USD)	$924,042
Update	1. The study DSMB convened for the second meeting on the 11th of October 2017. The DSMB minutes for this meeting are yet to be released.

	2. The study had one (1) AE (death) on the 3rd of July 2017. The AE was reported to IREC,IRB & CDC. 3. Exiting of study patients who had completed 12 months of follow up started in November 2017. 4. The study was granted continuing review in October 2017, this will run up to October 2018.
Future Plans	1. Exiting of participants will continue up to early March 2018. 2. Data analysis will begin in March 2018 after the last participant has been exited 3. FGD's for post intervention perceptions will be completed in February 2018. 4. The study will close out in April 2018. 5. Final study report will be published in April/May 2018.
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 Jepchirchir Kiplagat, Moi University
Co-Investigator(s)	
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 (MTRH)
Project Period	8/31/2017 - 8/31/2020
Funding Status	Unfunded
Direct Award (USD)	
Update	We have made the following progress so far since the project commenced in August 2017 1. A Project Coordinator was hired in August 2017 2. Technical Advisory committee (TAC) Notification: The role of TAC is to provide project oversight to ensure the following that the project is implemented in line with the project proposal and is consistent with MUCHS/MTRH overall strategic plan and National Commission for Science, Technology and Innovation (NACOSTI) policies. Letters were sent to the Technical Advisory Committee notifying them that the grant application was successful and that their services will be required. 3. Data collection tools: The required interview guides for FGDs and In-depth Interviews were finalized in readiness for submission to the ethics committee. For the survey to measure the prevalence of scientific misconduct of research, we will use the Scientific Misconduct Questionnaire - Revised (SMQ-R) which is a validated instrument. 4. IREC review and approval The project was submitted for review and ethics approval and has been approved by MU/MTRH IREC. The next continuing review is due on 7th November 2018. 5. Survey preparation: Preparation to conduct the survey on prevalence of Scientific Misconduct (Aim 1-sub aim 1) is ongoing. We are in the process of developing the sampling frame [list of HIV related research protocols approved by MTRH, KNH & Moi IREC over the last 5 years and listed on NACC's Maisha Maarifa database. The REDCap online survey platform that will be used to capture the survey data is undergoing testing. 6. Abstract Presentation at the 2nd Bioethics Society of Kenya conference. An abstract was submitted to be considered for presentation at the 2nd BSK conference. The abstract was accepted and presentation done on 2nd Dec 2017. The presentation was well received and people are looking forward to progress reports. The slides are included as an attachment. 7. TAC Meeting

	The first Technical Advisory Meeting took place on 15th December 2017
Future Plans	The following activities are planned: • Conduct a survey on scientific misconduct • Interview and train Research Assistants • Conducting FGDs with investigators • Conducting IDIs with REC leaders • Conduct 2 bench marking visits (1 US based institution and 1 South African based Institution) • Continue to conduct Literature Review • Hold a Technical Advisory Committee meeting
Publication(s)	Developing Capacity of Moi Teaching and Referral Hospital / Moi University Institutional Research Ethics Committee (MTRH/MU IREC), Kenya to Prevent and Manage Research Misconduct. Corresponding Author: Dr. Edwin Were, e-mail: eowere@gmail.com Moi University, P.O. Box 4606-30100, Eldoret. Co- Author: Ms Jepchirchir Kiplagat. Presented at the 2nd Bioethics Society of Kenya Conference on 2nd December 2017
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)	Vincent Kibet, Parks caitlin Millar Heather Kosgey Wycliffe Thorne Julie Kipchumba Bett
Working Group(s)	RHWG
Description	The aim of this study is to determine the incidence of diagnosis and treatment of pre-eclampsia and eclampsia at MTRH. We will measure the maternal and neonatal outcomes in women with these diagnoses. We will evaluate the data in order to determine areas for improvement in our diagnosis and management of pre-eclampsia/eclampsia in order to decrease maternal and neonatal morbidity and mortality at MTRH. Finally, we would like to evaluate the effect free maternal care has played in the measured incidence and outcomes of pre-eclampsia and eclampsia at our institution. Specifically, we will: 1. Determine and compare the incidences of pre-eclampsia within our institution in the year before and the year after the initiation of free maternal care in June, 2013 2. Evaluate the maternal and neonatal outcomes, including major causes of morbidity and mortality in each group. Again we will compare these before and after the initiation of free maternal care in June, 2013. 3. Evaluate the risk factors for adverse maternal and neonatal outcomes 4. Evaluate the adherence of treatment in our facility in accordance with World Health Organization standards, again comparing treatment before and after the initiation of free maternity care in June, 2013. The data for this study is collected using a comprehensive 100-item data collection form, including patient demographics,

	symptomatology, documented clinical signs and laboratory results, delivery details, and maternal and neonatal outcomes
Site(s)	Moi Teaching and Referral Hospital, Saboti Sub-District Hospital
Project Period	1/12/2015 - 12/31/2015
Funding Status	Unfunded -
Direct Award (USD)	
Update	The results section of the manuscript - Effect of free maternal services on the maternal and neonatal outcomes of Pre-eclampsia/Eclampsia, was completed.
Future Plans	We hope to complete the manuscript - Effect of free maternity services on the maternal and neonatal outcomes of pre-eclampsia/eclampsia.
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 Steve Taylor, Duke University
Co-Investigator(s)	Joseph Kirui, Wendy P O'Meara PhD, Duke Global Health Institute, Chite Asirwa MD, Indiana University School of Medicine
Working Group(s)	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 10 years of age with laboratory-confirmed SCA living in malaria-endemic portions of Homa Bay or Migori Counties, randomize to one of three (1:1:1) malaria chemoprevention

	regimens, and followed up monthly for 12 months in order to record clinical episodes of malaria or SCA-related morbidity. Analyses will compare the efficacy of each regimen to prevent malaria and SCA morbidity. Blood samples will be taken every three months (5 time points - baseline, 3, 6, 9, 12 months) for laboratory testing and dried bloodspots will also be collected. Participants will also receive a malaria rapid diagnostic test using a finger-prick blood sample when they are ill.
Site(s)	Homabay County Hospital
Project Period	6/1/2016 - 2/28/2017
Funding Status	Funded - NIH
Direct Award (USD)	$621,633
Update	We managed to seek approval of the Kenya Pharmacy and Poisons Board (PPB) September 29th, 2017 and got assigned protocol ID number: ECCT/17/08/06 by PPB. We also registered the study with ClinicalTrials.gov (ID#: NCT03178643) and Pan African Clinical Trials Registry (ID#:PACTR201707002371165). We acquired the import permit from Kenya PPB to enable us to import one of the study drugs (SP-AQ) from Guilin Pharmaceuticals in China (the only WHO prequalified pharmacy with SP-AQ). For study data, we completed the development of the electronic database in REDCap and the hard copy CRFs. We acquired a dedicated research study space at Homa Bay County Referral Hospital. We established a DSMB with both US and Kenyan members, as well as members with expertise supportive of the study objectives. We hired study staff (nurses and clinical officers) on 5th July and conducted a site initiation training on 26th to 29th of September 2017. During this training, we invited the hospital staff for a half a day sensitization session about the study. We have managed to develop and finalize key study SOPs to guide the study operation. We had the Homa Bay site, activated on December 6, 2017, by DCRI. We started prescreening on December 6th, 2017 and actual screening on December 8th, 2017. We submitted a protocol amendment to both Duke and Moi University IREC on 27th October 2017 and was approved by both IRBs.
Future Plans	Moving forward we shall be proceeding with prescreening, screening and enrollment in February through to December 2018. Follow up visits will also be scheduled for the enrolled participants in each of the three arms. Consequently, we will begin to make significant progress towards answering the question in the primary objectives. We anticipate at least 50% of participants will be enrolled by the next reporting period. The DSMB will meet biannually to assess the study results, and on an ad hoc basis as necessary, as described in the DSMB charter. To ensure reliable and quality data for clinical decisions we have planned for bi-weekly data review meetings. We are in the process of establishing laboratory procedures for biobank samples as well as starting the shipping process. We also plan to set up a Community Advisory Board comprised of key representatives from the general public who will be meeting tentatively, on a quarterly basis to discuss any ethical issues concerning the study. We also anticipate the first site monitoring visit by an independent monitor after the first 5-10 participants have been enrolled.

Publication(s)	

Study Title	**Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy.**
Principal Investigator(s)	Beatrice Jakait, Moi Teaching and Referral Hospital Rena Patel, University of Washington
Co-Investigator(s)	Caroline Kerich
Working Group(s)	RHWG
Description	This project aims to study the effect of antiretroviral medications (particularly Efavirenz) on the effectiveness of hormonal contraceptives. The main output to help develop the evidence base for the relative effectiveness of implants with concomitant efavirenz-based ART among HIV positive women in western Kenya
Site(s)	All
Project Period	5/23/2016 - 2/28/2017
Funding Status	Funded - NIH
Direct Award (USD)	$12,727
Update	Since Dr. Patel has been on maternity leave since August 2017, no major progress in data analysis has been made. These activities will resume when she resumes work again in March 2018.
Future Plans	Our goal is to complete the started main data analyses and prepare the main/primary publication.
Publication(s)	

Study Title	**ESYHI study - Identification, adaptation and piloting of innovative interventions to engage street-connected children and youth in the HIV prevention-care continuum in a resource-constrained setting**
Principal Investigator(s)	Paula Braitstein, University of Toronto David Ayuku, Moi University
Co-Investigator(s)	Pooja Shah, Milllar, Heather Wachira, Judy Lobun, Regina Apondi, Edith Gayapersad, Allison Embleton, Lonnie MacDonald, Katherine

Working Group(s)	PRWG
Description	This is an 18-month project funded by the Canadian Institutes for Health Research (CIHR) aiming to identify, adapt, and pilot interventions to engage street-connected children and youth (SCY) into HIV prevention, care and treatment. The first stage requires a comprehensive literature review identifying potential interventions from the literature; the second stage requires narrowing down the possible selection of interventions by their feasibility, cost, ethics, and potential effectiveness; and the third stage is to pilot and evaluate 2-3 interventions.
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/1/2016 - 9/30/2017
Funding Status	Funded - Canadian Institute of Health Research
Direct Award (USD)	$564,629
Update	We successfully completed a comprehensive training for clinicians at Rafiki and OSCAR over a two-day period. The aim of the training was to learn about effective family planning provision, STI diagnosis and treatment, VMMC provision, etc. as well as to familiarise staff with the particular challenges facing the SCY community and how to best be able to provide these services in this population. We carried out 4 focus groups with girls and young women who live on the street as a means of gaining their opinions and ideas on developing an HIV intervention specifically for the girls as an alternate coming of age ceremony that includes education on HIV and parenting, and teaching life skills. 2 groups were girls over the age of 18, and two groups were girls under 18. We have translated and transcribed the transcripts. We have developed a manuscript titled 'A pilot study of 'Peer Navigators' to increase uptake of HIV testing, care and treatment among street-connected children and youth in Eldoret, Kenya'. This paper has been reviewed by the publications committee and is currently under review at JAIDS. We updated the data for this paper in the past 3 months to include all data collected up to the end of October 2017 rather than April 2017. We have also written two papers on the data collected from the VMMC intervention: 'Acceptability of a pilot intervention of Voluntary Medical Male Circumcision and HIV education program for adolescent street youth in western Kenya' and 'Outcomes of a pilot intervention of Voluntary Medical Male Circumcision and HIV education program for adolescent street youth in western Kenya'. These papers are in the process of being finalized before being sent to the publications committee for review. Through analysis of data collected by peer navigators, it is clear that there is a need to improve ART adherence and retention in care for SCY who are HIV-positive. As a result, we have developed an intervention that uses modified Directly Observed Therapy (mDOT). Individuals will be provided with a small meal a day, during which a clinician will administer ART and directly observe ingestion to enhance adherence. An amendment has been made to the protocol, and we are currently awaiting approval from IREC for this intervention.
Future Plans	As soon as we receive approval from IREC for the mDOT intervention, we will begin procurement of the supplies needed and begin recruitment for the intervention. We are

	aiming to submit the VMMC papers to journals as soon as possible, and hopefully get all three manuscripts published in the upcoming months. We will also aim to disseminate findings from ESYHI interventions at conferences and symposiums as relevant.
Publication(s)	Shah P, Ayuku D, Makori D, Kamaara E, Choge E, Nyairo J, Abuya P, Wahome M, Wachira J, Braitstein P. Acceptability and uptake of voluntary medical male circumcision and educational modules as part of a coming-of-age retreat - an HIV prevention intervention for adolescent street youth in Western Kenya. Poster presented at: The International Association for Adolescent Health 11th World Congress on Adolescent Health (IAAH 2017); 2017 October 27-29; New Delhi, India.

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 Astrid Christoffersen-Deb, University of Toronto
Co-Investigator(s)	Pastakia Sonak
Working Group(s)	RHWG
Description	Gestational diabetes mellitus (GDM) is a form of diabetes that develops in pregnancy and can lead to adverse maternal and fetal outcomes. There is not currently a screening program to identify women with GDM in Kenya and other low and middle income countries. The aim of the study is to determine the prevalence of GDM in a rural and urban Kenyan population, develop an accurate score based on easily obtainable risk factors to stratify women at risk of GDM in this population, and determine if a selective screening strategy would be cost-effective in Kenya. This is a prospective cohort study aiming to recruit 4000 women who are <20wks gestation attending antenatal clinic at different project sites.
Site(s)	Huruma Sub-District HospitalMoi Teaching and Referral Hospital (MTRH)Uasin Gishu District HospitalReale Hospital, Langas Hospital,
Project Period	7/14/2015 - 7/13/2018
Funding Status	Funded - Medical Research Council
Direct Award (USD)	$564,629
Update	A total of 1652 pregnant women have been recruited into the study with 1152 having completed Visit 2 (Fasting/Random sugar before 20 weeks) and 554 having done Visit 3 (OGTT at 24-32 weeks). We are also working in data entry into our database Challenges: Despite the follow ups, education and transport reimbursement being offered to the mothers, only about 34% of the total enrolled participants have completed the oral

	glucose tolerance test. Among the reasons for this is inadequate transport reimbursement and lack of partner support.
Future Plans	We hope recruit more women, improve on the update of the OGTT visit and to this end have increased transport reimbursement and offering information to willing partners about the study.
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 Winstone Nyandiko, Moi University
Co-Investigator(s)	Bloomfield, Gerald; Barker, Piers
Working Group(s)	CVMD, 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 (MTRH)
Project Period	9/12/2017 - 12/31/2018
Funding Status	Funded - International AIDS Society

Direct Award (USD)	$136,199
Update	Enrollment began on September 12th, 2017. To date, we have enrolled 384 participants from Module 4 Pediatric and Rafiki Adolescent clinics. Participants have undergone echocardiograms, viral load testing, and plasma sample storage.
Future Plans	We will conclude enrollment in the study at the end of April. Following active recruitment, we will continue laboratory analysis of the stored samples, targeting inflammatory and cardiac biomarkers.
Publication(s)	

Study Title	**FLTR Evaluation**
Principal Investigator(s)	Paula Braitstein, University of Toronto Sylvester Kimaiyo, Moi University
Co-Investigator(s)	
Working Group(s)	AMWG
Description	The FLTR evaluation aims to evaluate the core aspects of the HIV prevention-care continuum, using a combination of quantitative and qualitative methods. We investigate issues related to Finding, Linking, Treating, and Retaining people living with HIV in AMPATH catchments, involving behavioral scientists, biostatisticians, epidemiologists, among others.
Site(s)	Bunyala, Chulaimbo, Teso
Project Period	7/1/2014 - 7/31/2017
Funding Status	Funded – Eli Lilly Foundation
Direct Award (USD)	$300,000
Update	We have continued to partly support the two Data Managers and the Biostatistician who have continued to work on data management and analysis respectively. IREC approval was received to further expand FLTR Evaluation activities and a further approval to carry out FLTR research activities within Moi Teaching and Referral Hospital.
Future Plans	Over the next 6 months, we will continue carrying out research activities related to FLTR evaluation in select AMPATH catchments.
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 Martin Were, Vanderbilt University
Co-Investigator(s)	Eileen Immaculate, Ayuo, Paul Nabukenya, Josephine Mughal, Khalid Tylleskar, Thorkild
Working Group(s)	TBWG
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	The MSc. Programme has been approved to move to Nairobi Campus meaning the next intake 2017-2018 has been effected to start February, 2018. A total of 16 applicants have been accepted with three from Marginalised areas and three have been awarded Scholarship. The MSc. curriculum was reviewed this month january, 2018. The HI-Train Annual Meeting will take place in Nairobi to be held on 4th&5th April, 2018 which will bring all the students together to view and show cause their project progress. The HI-Train Annual Meeting with Nohred was held in November 2017 at Norway where all the partners met to share the progress of the project and students. The First Cohort are finalizing their projects.
Future Plans	The project anticipates to have another MSc. intake in September, 2018 in Nairobi Campus. To Review the Ph.D curriculum before June 2018. To hold a Mobile Application workshop that will bring together students from various universities. To conduct three Gender mainstreaming workshops that will involve mentoring our female candidates and sharing experiences in making sure that the goals for HI-Train are accomplished.
Publication(s)	There was a presentation/demo for mUzima at the OpenMRS in Malawi by our System developer Simon Savai and three of our MSc. students. Another mUzima demonstration at Kemri in Kisumu by Sam Mbugua-System developer in December, 2018.

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 Julia Songok, Moi University
Co-Investigator(s)	Bett Kipchumba, Solomon Omarimba, Wycliffe Kosgei, Winfred Mwangi, Felix Chumba, Megan McHenry, Beverly Musick, Constantin Yiannoutsos, Kara Wools-Kaloustian
Working Group(s)	PRWG, RHWG
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 2016 to 2017 (n ? 1,000 mother-infant dyads). This research is significant because it will inform strategies for optimal service delivery in the era of Option B+/universal ART eligibility and integrated HIV-MCH services.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	3/5/2018 - 6/1/2019
Funding Status	Unfunded
Direct Award (USD)	
Update	The project is currently awaiting regulatory approval.
Future Plans	Data extraction and cleaning from AMRS; data analysis.
Publication(s)	

Study Title	**IeDEA Comprehensive Adherence Measure for Pediatrics (ICAMP)**
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Silas Wakoli, Samuel Ayaya, MBChB, MMED Department of Child Health and Paediatrics Moi University School of Medicine Annette Sohn, MD Director TREAT Asia/amfAR Mary-Ann Davies, MB ChB School of Public Health
Working Group(s)	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 10-item adherence questionnaire for routine use as an adherence measurement tool in resource-limited settings. Hypothesis 1a: Adherence estimates from the CAMP-SF will be reliable and valid across 3 IeDEA sites in East Africa, Southern Africa and Asia-Pacific when compared with MEMS electronic dosing data. Specific Aim 2: Describe pediatric adherence to ART prospectively over 6 months using electronic dose monitoring (i.e., MEMS) and the CAMP-SF among a sample of HIV-infected children and adolescents at 3 IeDEA sites. Hypothesis 2a: Rates of adherence to ART will be similar for children across different IeDEA sites. Hypothesis 2b: More pediatric non-adherence will be reported during prospective evaluation using the CAMP-SF than in existing rates reported in IeDEA datasets for children. Specific Aim 3: Evaluate factors associated with adherence among a sample of HIV-infected children and adolescents at 3 IeDEA sites. Hypothesis 3a: Risk of medication non-adherence is increased among older children, children with lower disease stages, children with higher CD4 counts, children with a higher medication burden, and orphaned children. Hypothesis 3b: Sites will differ in factors that may influence adherence, including number of children initiating ART; availability of nutritional support, adherence support, disclosure support, and pediatric formulations; and routine use of standardized adherence measures. Specific Aim 4: Assess evidence of the impact of ART 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	In the last six months, we have been in a phase of data cleaning and preparation for analysis. The MEMS data have been collected from Thailand, Kenya, and South Africa sites and have been sent to the IU biostats team for further cleaning and preparation for analysis. Analyses for individual sites has been undertaken, and the combined final analysis is currently underway.
Future Plans	Over the next 6 months, we plan to: • We expect to complete data cleaning and data analysis. • Prepare manuscripts for publication with our partner sites and conference presentations
Publication(s)	

Study Title	**Improvements of diagnosis, staging, and support of children with Burkitt Lymphoma**
Principal Investigator(s)	Terry Vik, Indiana University Festus Njuguna, Moi University
Co-Investigator(s)	
Working Group(s)	CVMD, ORWG, 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 40 confirmed BL patients are needed, and up to 50 patients are diagnosed annually at the combined sites. AMPATH and MTRH will provide infrastructure for the clinical testing and care of patients. The parent cancer center clinical research staff will aid in the auditing of patient charts of children enrolled on the study. Study data will be audited periodically throughout the study to ensure accuracy, completeness of data and compliance with research ethics. The main outcomes to be monitored include: percent of required observations completed, number of patients confirmed to be eligible for the trial, Number confirmed to have a diagnosis of BL by each of the three tests of immunohistochemistry, flow cytometry, or FISH, and number of patients with complete staging by Murphy staging criteria. Additionally, number of patients who abandon treatment will be tracked, along with the time point that they abandon. Finally, overall one-year survival points will also be captured. The aim to improve diagnosis and decrease abandonment by comparing results at the end of the study to historical rates will measure the success of this project. Assuming the success of this project, next steps will be to partner with other sites in the region to propose a larger trial with a potential treatment outcome that can be measured and validated across multiple countries and treatment centers, ultimately improving the outcome for children with BL.
Site(s)	Moi Teaching and Referral Hospital (MTRH)

Project Period	9/1/2016 - 8/31/2018
Funding Status	Funded - NIH - National Cancer Institute (NCI)
Direct Award (USD)	$225,072
Update	Since the project start, 55 children have been enrolled on the diagnostics portion of the study and 30 patients have been confirmed to have Burkitt Lymphoma. We have enrolled 75% of subjects. All subjects have flow cytometry data, and have material for FISH and IHC analysis, once the logistic difficulties of testing have been overcome.
Future Plans	We should complete enrolled on part 2 of the study with 40 confirmed patients on clinical trial. We hope to acquire the missing chemicals and supplies to begin testing samples via Fluorescent in situ Hybridization (FISH).
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 Faith Kosgei, Moi University
Co-Investigator(s)	Vincent Kibet, Bernard Caitlin Omukagah Christabell Hodgett Mary
Working Group(s)	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)	Mois Bridge Health Centre
Project Period	5/26/2017 - 5/26/2018
Funding Status	Funded - Other
Direct Award (USD)	$20,860
Update	In the past six months, trained timby reporters have managed to conduct interviews and sent in 120 reports to the dashboard. The topics of the reports have ranged from sex education, abortion, communicable and non-communicable diseases, family planning, the

	strike in the healthcare system, maternal mortality among others. From the verified reports, we have written 9 stories that have been published on the her timby website and on AMPATHS' Facebook page too. We have continued conducting training sessions with old reporters in addition to the new ones who have joined overtime. We identified a mainstream journalist interested in working with the project. To this end, the journalist conducted a training with the reporters on ethics of reporting and shared more insight on the same.
Future Plans	Over the next 6 months, we will keep working with the reporters to get more stories on various topics that have not been covered yet with a focus on population health strategic objectives. Additionally, we will be working closely with the journalist on certain topics to generate reports/stories that will hopefully then be published on print media and shared in other platforms. Mentorship and training will continue being held for 12 reporters that have shown commitment and consistency in reporting and for any new reporter who will join in. Analysis of our data will also be done to assess common and recurrent themes in the reports. We aim to start writing a manuscript once initial analysis is done.
Publication(s)	

Study Title	**Innovative public-private partnership to target subsidized antimalarials in the retail sector**
Principal Investigator(s)	Wendy Prudhomme, Duke University Diana Menya, Moi University
Co-Investigator(s)	Joseph Kipkoech, Dr. Jeremiah Laktabai - Moi University
Working Group(s)	PHARMCRWG
Description	In most malaria-endemic countries, a large fraction of fevers are treated in the informal health sector where diagnostic testing is uncommon and effective drugs are expensive. For many families, particularly in rural areas, the first source of treatment for fevers are retail medicine outlets such as chemists, pharmacists and small, unregulated medicine shops.These retail outlets, also referred to as the 'informal health sector', are more accessible than formal health services, but effective drugs are expensive and most clients purchase cheaper, ineffective therapies to which high levels of resistance exist. The Global Fund piloted a drug subsidy called the Affordable Medicines Facility - malaria (AMFm) to reduce the prices of effective, high quality ACTs in the private sector. AMFm was launched in 2010 and provided quality-assured ACTs to wholesale markets at substantially reduced prices in seven pilot countries, including Kenya. $339 million dollars were earmarked for subsidies and 155.8 million doses were delivered in the first 18 months of the program (ICF International, 2012). Prices of subsidized ACTs in most pilot countries dropped below that of cheaper, ineffective drugs and substantial cost savings were seen by the end consumer. In Kenya, the retail market share of ACTs increased from 12% to 61% in the first 18 months of the program (Tougher et al., 2012). However, there is concern that dramatically lowering the price of ACTs opened the door to over-treatment and overuse

	of ACTs. The overall objective of this study is to evaluate the public health impact of targeted antimalarial subsidies through scale-up by determining the community-wide effects of targeting an antimalarial subsidy through a partnership between CHVs and the private retail sector. Cluster-randomized design was used to assign community units to either an intervention or control arm. The study is being be carried out in two sub-counties in Western Kenya (Bungoma East and Kiminini) with similar malaria burden but different access to health services. Community Units (CUs) in each sub-county were the clustered and randomized. There are 32 CUs in total across both sub-counties, 20 in Bungoma East and 12 in Kiminini. Half of the community units in each study area (10 in Bungoma East sub-county and 6 in Kiminini) were randomly allocated to the intervention and the remainder of the community units to the comparison arm. In the intervention arm a conditional subsidy is offered in the form of a voucher providing for the purchase of a WHO-qualified ACT at a reduced, fixed price to those with a positive malaria test that can be redeemed at a local drug retailer, while individuals in the comparison arm only receive standard community health volunteer (CHV) visits. Cross-sectional household surveying at pre-intervention, and 6 months, 12 months, and 18 months post-baseline will be used to determine any change in the percent of fevers that are tested for malaria and the effect of testing on subsequent drug purchasing decisions. The primary hypothesis to be tested is that offering a fixed-price voucher that reduces the cost for ACT purchase in the retail sector conditional on a positive malaria test (targeted subsidy) can improve uptake of testing for malaria and will increase the proportion of fevers tested for malaria before treatment. The primary outcome of this study is to compare the percent of fevers that receive a malaria test from any source between the intervention and control arms. The secondary outcomes of this study will also be measured and compared between intervention and control arms. The main secondary outcome is the percent of all ACTs used that were taken by people with a malaria positive test. Additional secondary outcomes are: the percent of all ACTs used that were taken by people without a test, the percent of those with a positive test who got an ACT, and the percent of those with a negative test who got an ACT.
Site(s)	Bungoma East Subcounty in Bungoma County and Kiminini Subcounty in Trans-Nzoia County
Project Period	1/1/2014 - 12/31/2018
Funding Status	Funded - NIH
Direct Award (USD)	$1,654,917
Update	In the last six months, the study team made significant progress completing Aim 2 data entry, analyses, and results dissemination. Process evaluation data entry and cleaning was completed for both CHW endpoint and discrete choice analysis data and shop focus group discussion data. The main longitudinal dataset for all Aim 2 Community-based survey data was finalized and is being used to generate results for key manuscripts. See below for a list of manuscripts completed and submitted for review. The primary Aim 2 main outcomes manuscript was completed and is currently being sent for review and publication at a high-impact, peer-reviewed, international medical journal. Small teams are currently drafting numerous other manuscripts on topics including cost of febrile

	illness and RDT, trust and beliefs about RDT, CHW motivation and satisfaction with the role, and polypharmacy for treatment of febrile illness. Other publications have been planned for the coming year, including a policy brief to be shared with key international stakeholders (e.g. WHO, UNITAID, etc.) and a cost-effectiveness analysis of the intervention to determine prospects for scale-up. In November 2017, six project team members presented abstracts and posters at the American Society of Tropical Medicine and Hygiene Meeting in Baltimore, MD. See below for a list of abstracts.
Future Plans	Analysis of Aim 2 data will continue throughout the upcoming project period with an emphasis on 1) primary and secondary study endpoints, determinants of high uptake and impact of the intervention, 2) process evaluation to describe the actual implementation vis a vis the intended implementation, and 4) projection of costs, scale-up feasibility, and sustainability of the public-private partnership compared to traditional subsidy approaches.
Publication(s)	Presented at ASTMH 2017 1) I. Saran, Does the experience of malaria testing increase trust in the test? Evidence from Western Kenya. 2) Diana Menya, Indrani Saran, Laktabai Jeremiah, Joseph Kirui, Wendy Prudhomme O'Meara. Malaria diagnostic testing is associated with significant increases in cost of care for families in rural western Kenya. 3) Jeremiah Laktabai, Matthew Boyce, Diana Menya, Lucy Abel, Indrani Saran, Joseph Kirui, Elizabeth Turner, Wendy Prudhomme O'Meara. Competence in RDT performance 121 months post training: Evaluation of malaria testing by CHWs. 4) W. Prudhomme O'Meara. A cluster-randomized trial to target subsidized artemisinin combination therapy (ACT) in the retail sector using a community-based testing and voucher scheme. 5) Paige Meier, Diana Menya, Joseph Kipkoech Kirui, Jeremiah Laktabai, Stephen Karuru, Wendy Prudhomme O'Meara, Indrani Saran. Households' perceptions and use of community health worker services in context of a malaria case management intervention trial. Submitted for peer-reviewed journal publication 1) W. Prudhomme O'Meara, D. Menya, J. Laktabai, A. Platt, I. Saran, E. Maffioli, J. Kirui, M. Mohanan, E. Turner. Effect of diagnosis-dependent subsidies on rational use of artemisinin combination therapy (ACT) for malaria: evidence from a cluster randomized controlled trial in western Kenya. 2) J. Laktabai, A. Platt, D. Menya, E.L. Turner, D. Aswa, S. Kinoti, W. Prudhomme O'Meara. A mobile health technology platform for quality assurance and quality improvement of malaria diagnosis by community health workers. 3) L. Winn, I. Saran, W. Prudhomme O'Meara. Motivation and satisfaction among community health workers administering rapid diagnostic tests for malaria in Western Kenya.

Study Title	**Linkage and Retention to Care in Western Kenya Following HIV Testing**
Principal Investigator(s)	Becky Genberg, Brown University Juddy Wachira, Moi University
Co-Investigator(s)	Paula Braitstein

Working Group(s)	AMWG, SSRN, 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 - National Institute of Mental Health (NIMH), NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	$152,806
Update	Over the last six months we have made progress on writing and analyzing our qualitative data and will continue to do so through the remainder of this calendar year.
Future Plans	We are in the writing phase of this project. We are working toward the final drafts of several papers from the second aim of this project which we expect to be submitted during the next six months.
Publication(s)	Lee H, Hogan JW, Genberg BL, Wu XK, Musick BS, Mwangi A, Braitstein P. A state transition framework for patient-level modeling of engagement and retention in HIV care using longitudinal cohort data. Statistics in Medicine 2017; 37(2): 302-319. Genberg BL,

	Wachira J, Kafu C, Wilson IB, Ware NC, Kamene-Owino R, Akinyi J, Koech B, Braitstein P. Provider perspectives on delivering HIV care in western Kenya: Results from a qualitative study. Poster presented at: The 9th IAS Conference on HIV Science, July 23-26, 2017, Paris, France. Abstract no. MOPED1082.
Study Title	**Making Inroads to Strengthen the Health of Adolescents (MaISHA)**
Principal Investigator(s)	Leslie Enane, Indiana University Edith Apondi, Moi Teaching and Referral Hospital
Co-Investigator(s)	Rachel Vreeman, Winstone Nyandiko, Elizabeth Lowenthal
Working Group(s)	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 (MTRH)Webuye District Hospital
Project Period	10/1/2016 - 6/30/2019
Funding Status	Funded - Thrasher Research Fund, Indiana University - Center for AIDS Research, IU Center for Global Health

Direct Award (USD)	$57,500
Update	The project was approved by the relevant Institutional Ethics boards in March 2017. We began recruitment in April 2017. We have recruited a total of 48 participants (caregiver-adolescent dyads) to date. A total of 16 were hospitalized adolescents at the MTRH hospital wards. We did interviews with 12 caregivers of these adolescents; five adolescents who were medically stable to participate were also interviewed. Information about their causes and outcomes of hospitalization were recorded. From the clinic cohort we have recruited 32 participants. Seventeen were non-disclosed adolescents. Of these, ten have been interviewed, two were not able to participate in interviews, while five will be doing their interviews when they come to the clinic for their return visit. Fifteen disclosed adolescents have been recruited and scheduled for a focus group discussion when they break from school for holidays. We have also had two focus group discussions with female caregivers of adolescents aged 10-19 years. Transcriptions and translations have been produced for the completed interviews and focus group discussions. Preliminary analysis of the transcripts has allowed for exploration of themes and refinement of the interview and focus group guides.
Future Plans	Over the next six months, we will continue recruitment and qualitative data collection until we have reached saturation of themes regarding barriers and facilitators to retention. We will then evaluate barriers along the cascade for hospitalized patients. We will continue to collect data on causes of hospitalization and mortality. We will begin recruitment of peer mentors for key informant interviews, as well as focus group discussions to consider areas of intervention to improve adolescent retention. We will perform data entry and verification. Clinical and demographic data will be analyzed by descriptive statistics. For the qualitative work, we will conduct first- and second-cycle coding of the data by multiple members of our team, and from these codes will establish a cohesive set of themes and concepts, as well as an overarching theoretical framework grounded in the data. We will prepare a meeting abstract and develop a manuscript.
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 Eren Oyungu, Moi University
Co-Investigator(s)	Roselyne Ananda
Working Group(s)	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)	Busia District Hospital, Matayos Health Centre, Mois Bridge Health Centre, Mt. Elgon District Hospital, Uasin Gishu District Hospital
Project Period	9/26/2016 - 9/26/2017
Funding Status	Unfunded
Direct Award (USD)	
Update	Data that was collected through oral interviews from the study participants 33 clinical staff and 78 caregivers that enabled us to learn what aspects of the Mother and Baby Booklet are typicaly completed at each visit, and what areas MCH clinical staff feel may need more attention, and how often caregivers are coming with their children to the MCH, if there are particular ages when caregivers ensure their children are seen at the MCH, and what pages in their book are typically completed when they come. Analysis of the data collected from the oral interviews to determine strategies to improve the preventative healthcare that MCH clinics provide, with a focus on child development.
Future Plans	Continue with data analysis
Publication(s)	The abstract has been under review by the African Journal for AIDS research.
Study Title	**Mental Health Screening and Phone-Based Counselling Support for Adolescents with HIV in Kenya**
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Bree Weaver, MD Department of Pediatrics, Indiana University School of Medicine. Edith Apondi, MBChB, MMED, Department of Child Health and Paediatrics, Moi University School of Medicine.
Working Group(s)	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	In September, we received IREC and IRB approval and trained the hired staff. In October, we introduced the study concept to the Turbo clinic to prepare for enrollment and data collection. As of December 31, 2017, 'The Mobile Mental Health Monitoring and support for Adolescents with HIV in Kenya' project has successfully enrolled 30 adolescents aged 10-19 years from Turbo clinic in western Kenya. Those participants enrolled who have not received a routine clinic blood draw and viral load testing within 6 months of enrollment in the study have consented and participated in a blood draw for viral load processing. Adolescents who have been recruited for the participation in the study have signed assent and have received consent from their caregivers. So far, the adolescents have participated in three peer support groups at Turbo clinic in early December. Participants have been assigned to a Whatsapp group, spearheaded by the counselor and have been interacting with the counselor through the Whatsapp platform, daily. The participants have also received Electronic Dose Timing caps (MEMS caps) to assess medication adherence during the study. Participants will be followed up for 6 months with monthly downloads of the MEMS cap adherence information and monthly individual counseling meetings with the counselor at Turbo clinic on their return-clinic day. The counselor is conducting both individual and group counseling via Whatsapp for the participants. The study follow up and conclusion will likely be in December 2018 after the periods of 6 month follow-up are complete and data are prepared for analysis.

Future Plans	In the next six months, we plan to continue with patient follow-up and conclude data collection after 6 months. We also plan to start data entry into the Redcap database, data cleaning and start quantitative and qualitative data analysis.
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 Eren Oyungu, Moi University
Co-Investigator(s)	
Working Group(s)	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)	Matayos Health Centre, Mois Bridge Health Centre, Uasin Gishu 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	Data that was collected through semi-structured interviews on 25 clinical staff and focus group discussions on 67 caregivers to understand the current knowledge and beliefs about Neurodevelopmental delays. For caregivers we generated information on collective views of neurodevelopment and for clinical staff it addressed several key questions specific to their individual training and experiences. We recruited 10 clinical officers for cognitive interviewing and asking screening questions to them to determine the feasibility of methods and measure reliability. These findings will be compared to potential gold-standard developmental assessments to determine validity by having a research staff perform the assessments on forty children. Also a research staff was trained to administer the Bayley Scales of Infant and Toddler Development (a neurodevelopmental assessment tool), which was culturally adapted for this study during the adaptive phase with 15 children, the tool was administered with modifications made by iterative process, under the guidance of a pediatric clinical psychologist, neuropsychologist, Kenyan pediatric neurologist, the adaptive phase aims to culturally adapt the Bayley Scales for use in our population of young children here in Kenya.
Future Plans	We are currently on the pilot phase aimed to recruit, enroll, and administer the BSID-III to a total of 225 children for utilization in children in western Kenya. Describe the biological and psychosocial factors associated with developmental delays. Assess the feasibility and acceptability of the adapted assessment tool and evaluate the reliability and validity of this screening tool used to examine neurodevelopmental delays and potential interventions among children with three different categories of HIV exposure: HIV-infected, HIV-exposed but uninfected, and HIV-unexposed.
Publication(s)	The abstract 'cultural Adaptation of the Bayley Scales of Infant and Toddler Development-III for Use in Kenyan Children Age 18-36 Months' was submitted to IDPAC 2017.

Study Title	**Nurse Management of Hypertension Care in Rural Western Kenya**
Principal Investigator(s)	Rajesh Vedanthan, Mount Sinai School of Medicine Sylvester Kimaiyo, Moi Teaching and Referral Hospital
Co-Investigator(s)	
Working Group(s)	AMWG, CVMD
Description	This project aims to evaluate barriers and facilitators to nurse management of hypertensive patients in rural western Kenya, using a qualitative research approach. The four specific aims for attaining this objective are: Aim 1: To evaluate facilitators and barriers to nurse-based management of hypertensive patients in rural western Kenya. This will be accomplished by conducting a rapid assessment procedure involving key

	informant interviews, focus group discussions, and field observations. Aim 2: To develop and evaluate an innovative smartphone-based DEcision Support and Integrated REcord-keeping (DESIRE) tool utilizing a participatory, iterative, human-centered design process, to assist nurses taking care of hypertensive patients. We will evaluate the usability and feasibility of the DESIRE tool using qualitative methods (e.g. think-aloud, mock patient encounters, semi-structured interviews, and focus groups). Aim 3: To conduct an impact evaluation of a pilot program for nurse-based management of hypertension to be implemented by AMPATH, by performing secondary analysis of routine clinical data collected by AMPATH. The primary outcome measure will be change in systolic blood pressure in hypertensive patients assigned to nurse-based management after one year. Aim 4: To estimate the nurse workforce requirements for stable, long-term treatment of hypertension throughout western Kenya, using a needs-based workforce estimation model.
Site(s)	Mosoriot Rural Health Training Centre, Turbo Health Centre
Project Period	9/17/2011 - 7/31/2017
Funding Status	Funded - NIH – Fogarty International Center (FIC)
Direct Award (USD)	$675,543
Update	Progress for this project over the last six months is delineated below. Aim 1: o No new updates Aim 2: o Secondary sub-aim: Patient perspectives on mHealth - Transcription/translation completed - Manuscript initiated Aim 3: o Manuscript in preparation, nearly complete Aim 4: o Manuscript in preparation
Future Plans	This project is closed. The only activity outstanding is manuscript completion and submission for Aims 2-4.
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)	Ruhl Laura Nyandiko Wiston Ng'etich Eric Christoffersen-Deb Astrid Browm Morgan Kunkel Melissa Alera Joy Kibet Vincent Bernard Christian Kosgei Faith
Working Group(s)	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 420 infants and follow them up until they are one year of age. Data will be collected on admission diagnosis, demographics, anthropometric measurements, treatment and follow-up and outcomes during admission and at one year of age. The objectives of the study are to determine the one year mortality rate of infants admitted to the NBU, determine the attrition and readmission rate, to determine the proportion of newborns with perinatal asphyxia or low birth weight and grade the severity and to determine the obstetric, medical and socio-economic factors associated with better short term and long term outcomes.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	10/23/2017 - 10/23/2019
Funding Status	Unfunded
Direct Award (USD)	
Update	Participant enrollment did not begin as planned. A review of the study protocol showed that there was a need to apply for funding for the project in order to achieve the intended goals.
Future Plans	We intend to submit an application for a grant that will aid in funding the study. A submission to IREC to amend the protocol in the event that the grant request is approved will also be done. Participant enrollment and follow up will also begin.
Publication(s)	

Study Title	**Optimizing Linkage and Retention to Hypertension Care in Rural Kenya**
Principal Investigator(s)	Rajesh Vendanthan, Mount Sinai School of Medicine Jemima Kamano, Moi University

Co-Investigator(s)	
Working Group(s)	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 QRISK2-2011 CVD risk calculator specific for Black African populations. This research will generate innovative and productive solutions to the expanding global problem of hypertension, and will add to existing knowledge on scalable and sustainable strategies for effectively managing hypertension and other chronic diseases in low- and middle-income countries.
Site(s)	Mosoriot Rural Health Training Centre, Turbo Health Centre
Project Period	5/4/2012 - 3/31/2017
Funding Status	Funded - NIH
Direct Award (USD)	$2,104,519
Update	Marked progress has been made on this project over the last six months. This progress is delineated below. Administrative • All-Investigator conference call held in 22 January 2018 • Faculty and study team visits to Eldoret, Kenya for the purposes of site monitoring, capacity building, and training are ongoing • Capacity building of the study personnel with specialized and targeted training in Biostatistics and implementation science. • Attended the Global Alliance for Chronic diseases Meeting in Argentina. • Personnel changes: • IT support left the study • Biostatistician shifted to Brown University with reduced time effort in order to pursue PHD • Prepared the staff for final closure of the study inclusive of employment implications. Aim 1 (Barriers & Facilitators to Linkage/Retention): • Secondary qualitative manuscript in preparation Subsidiary Aim 1.1 (Behavioral Assessment and Communication Strategy): • Content validity manuscript in preparation Subsidiary Aim 1.2 (Smart-phone-based tool): • Smartphone-based assessment tools and mUzima-based data collection tools (both linkage and retention) completed. Aim 2 (Cluster RCT): • Completed the data collection of Behavioral assessment tools done Community Health Workers (CHWs) across the three arms of the study. • Completed the data collection for 12 month follow-ups visits with a total of 1108 records.

	• Assessment tool: A total of 488 behavioral assessment tools have been administered by CHWs and all the entries done on the production server. • Data Management plan is ongoing • Data cleaning is ongoing; quarterly data freezes implemented Aim 3 (Cost Effectiveness Analysis): • Costing questionnaire survey (CQS): • Administration of 12 month follow-up costing questionnaires was completed. • Preliminary data analysis is ongoing • Cost tracking spreadsheet has been completed and intervention cost tracking procedures have been implemented
Future Plans	Administration: • Submission of 2nd No Cost Extension requests • Submission of final performance report. • Conduct a post project end review. • Closure of procurement and contracts • Release of assets and resources, including human resources. • Meet to complete the closure of the project and present on findings. • Final DSMB meeting Aim 1: • Complete and submit secondary qualitative analysis manuscript Aim 1.1 • Complete and submit content validity manuscript Aim 1.2 • Continue device management and mentorship of use of devices Aim 2: • Complete data cleaning and the analyses • Baseline manuscript Aim 3: • Complete tool (spreadsheet) for cost tracking analysis of intervention delivery and the analyses.
Publication(s)	The following manuscripts are in preparation: • Perceptions of the Role of Community Health Workers in Hypertension Management: A Qualitative Study from Rural Kenya • Development and Validation of a Behavioral Assessment Tool to Optimize Linkage and Retention to Hypertension Care in Kenya: LARK Hypertension Study • Process Evaluation • Sex differences in Health care utilization, costs, insurance, and poverty • Self-Linkage Analysis o • Implementation Challenges

	• Association between physical activity and severity of blood pressure among people with elevated blood pressure
Study Title	**Pathways to better health**
Principal Investigator(s)	Paula Braitstein, University of Toronto
Co-Investigator(s)	Monica Nyambura
Working Group(s)	AMWG
Description	The goal of this study is to merge together data from the home-based HIV counseling and testing program with HIV care and treatment data from the AMRS.
Site(s)	The catchments of Bunyala, Teso, and Chulaimbo
Project Period	1/4/2016 - 10/31/2016
Funding Status	Funded – Regenstrief Institute
Direct Award (USD)	$45,000
Update	This study is completed.
Future Plans	The study is completed.
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 W. Nyandiko, Moi University
Co-Investigator(s)	
Working Group(s)	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 10-15 years who are enrolled in HIV care within the eight selected AMPATH clinics in western Kenya will be eligible for study enrollment and have a comprehensive patient assessment every 6 months for 2 years.
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	9/1/2012 - 9/1/2016
Funding Status	Funded – NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	$1,886,804
Update	In the last 6 months, we have been focused on data analysis to address the HADITHI aims. The analyses for the primary outcome of disclosure have been completed. We found that disclosures in both control and intervention arms (no difference at baseline) increased over follow-up, but the intervention arm had significantly more disclosures, with more new disclosures between 18 to 24-month time points (hazard ratio 2.47, 95% CI: 1.01, 6.04). Across the study, children reported substantial depression, anxiety, behavioral and stigma-related concerns, but the impact of the intervention on mental health and psychosocial outcomes was varied. These findings have been submitted as a manuscript for a special issue of AIDS focused on HIV and resilience. Data analyses to assess additional results from this study are underway and will be continuing.
Future Plans	Over the next 6 months, we plan to: • Complete key data analyses for each of the study objectives. • Complete the evaluation of drug level concentrations on hair samples sent to UCSF to the laboratory of Dr. Monica Gandhi, as well as compile evaluations assessing the feasibility and validity of this type of testing in our population. • Submit manuscripts for publications
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

	B Jakait, Moi Teaching and Referral Hospital
Co-Investigator(s)	Mercy Maina, Pastakia S. Karwa R. Ngetich C. Inui T. Sidle J. Wools-Kaloustian, K. Nyandiko W. Pandit J. Olsson S. Maina M. Olwande C.
Working Group(s)	AMWG
Description	Little is known about the toxicity profile of combination antiretroviral treatment (cART) in African populations where genetic differences, co-morbidities, and malnutrition together may influence the adverse reactions of cART in this population. The purpose of this project is to evaluate the feasibility and effectiveness of five approaches to Targeted Spontaneous Reporting (TSR) for documenting SADR in the resource constrained clinical setting in western Kenya. The approaches include; TSR 1: The completion of the Kenya National Suspected Adverse Drug Reaction form for patients with a change or discontinuation in their cART. These forms are then forwarded on to the National pharmacovigilance (PV) office at the Pharmacy and Poisons Board (PPB) in Nairobi. TSR 2: Use of routinely-used clinical encounter forms that have been enhanced to specifically collect a relatively small amount of SADR data to be collected by the provider seeing the patient during the clinical visit. TSR 3 and TSR 4: Involve conducting in-depth interviews on 1,000 patients receiving cART treatment to prompt patients about SADR and their impact on patient adherence and quality of life. Patients undergoing interviews are randomly assigned to be interviewed by an HIV peer (TSR 3) or a pharmacy personnel (TSR 4) who will have received the same training for the project. The interviews will be conducted over 12 months or a maximum of 12 scheduled clinical visit (Whichever comes first). TSR 5: Use of data routinely captured in the pharmacy when clinicians substitute or change a patient's regimen, including documentation if such an event occurred on the prescription form and the cause of the event (i.e. toxicity, treatment failure, TB drug interaction, pregnancy, other).
Site(s)	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 received the final data analysis report and we are working on manuscript drafts for the paper.
Future Plans	We hope to have the first draft of the manuscript circulated to the investigators for comments.
Publication(s)	

Study Title	**Phylogenetic Inference of Vertical versus Horizontal HIV Transmission among Adolescents in Western Kenya**
Principal Investigator(s)	John Humphrey, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Kara Wools-Kaloustian, Joe Hogan, Rachel Vreeman, Rami Kantor
Working Group(s)	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 10-19 years of age via the following specific aims: 1) examine the feasibility of phylogenetic inference to determine HIV infection through vertical versus horizontal transmission in adolescents, and 2) compare demographic, clinical and laboratory characteristics of vertical and horizontal predicted-infection in HIV-infected adolescents and their mothers. This study will be conducted at the Academic Model Providing Access to Healthcare (AMPATH) Center, a large HIV treatment and research facility in western Kenya, in collaboration with Indiana University and Brown University. We will enroll 20 HIV-infected adolescent-mother dyads in whom the mode of infection is uncertain and 10 HIV-infected child-mother dyads in whom vertical infection is highly likely. HIV viral load testing and pol sequencing will be performed for all subjects, including those with undetectable viral load by archived DNA genotyping. The epidemiologic linkage and clustering of HIV sequences among adolescent-mother dyads will be inferred phylogenetically and compared to (i) phylogenetic clusters of child-mother dyads that likely represent vertical transmission; and (ii) non-phylogenetic prediction of mode of infection, based on demographic and clinical risk factors elicited through a chart review and epidemiologic survey. We hypothesize that phylogenetic inference will differentiate vertically and horizontally-acquired infections, and that characteristics will differ between horizontally and vertically infected adolescents. This study will also add insight into the natural history of perinatally infected individuals who are diagnosed as adolescents, as current estimates of survival and disease progression are limited by an inability to confirm vertical infection in these individuals. This proposal will employ an innovative phylogenetics approach to 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)	Mois Bridge Health Centre
Project Period	5/1/2017 - 4/30/2018

Funding Status	Funded - Indiana CTSI
Direct Award (USD)	$20,000
Update	We have received regulatory approvals. We anticipate initiating enrollment in January 2018.
Future Plans	We hope to complete enrollment and perform the analysis of the data.
Publication(s)	

Study Title	**Point in Time (PIT) Count of Street Children in Eldoret**
Principal Investigator(s)	Paula Braitstein, University of Toronto David Ayuku, Moi University
Co-Investigator(s)	
Working Group(s)	PRWG
Description	This is a one-time project funded by the Canadian Institutes for Health Research (CIHR) and aims at counting all the street children and youth in Eldoret Town and its Peri-urban areas namely; Langas, Huruma, Kapsoya, Town Bases; California, Juakali, Mangula, Asiz and Eastleigh. Counting will be facilitated using Fingerprint Scanners and related supplies, HIV and First Aid Services will be provided. The count will take place over a seven day period. The aims of the project are to determine whether counting street children in a low-income setting is feasible using PIT count techniques, used in homeless populations successfully in Canada and the United States, estimate the number of street-connected children and youth in Eldoret, and estimate HIV prevalence among them.
Site(s)	Moi Teaching and Referral Hospital
Project Period	5/1/2016 - 12/31/2016
Funding Status	Funded – Canadian Institutes of Health Research
Direct Award (USD)	$29,791
Update	This study was a one time project and implementation was completed in the September 2016. Publication process is on-going and a manuscript has been submitted to the Lancet Global Health for review.
Future Plans	The study team will continue writing papers for publication.

Publication(s)	
Study Title	**'Point of Care CD4 testing for people who fail to engage in care after testing HIV positive'.**
Principal Investigator(s)	Paula Braitstein, University of Toronto Samson Ndege, Moi University
Co-Investigator(s)	
Working Group(s)	AMWG
Description	This supplement responds to unique aspects of Specific Aim 1 of the East Africa-International epidemiological Databases to Evaluate AIDS (IeDEA) grant, which seeks to 'Determine the short and long-term outcomes of adults and children along the entire spectrum of HIV care.' Our broad aim is to inform and evaluate the implementation of AMPATH's HIV treatment and prevention work by fully characterizing the cascade of HIV care in population-based settings and identifying gaps and opportunities for improvement. The primary objective of this study is to characterize the outcomes of HIV-positive adults who did not engage with HIV care following the catchment-wide HBCT campaign held from Dec 2009-Feb 2011 in Bunyala.
Site(s)	Bunyala Sub-county
Project Period	2/2/2015 - 2/1/2016
Funding Status	Funded – NIH
Direct Award (USD)	$62,432
Update	A manuscript has been prepared. See the abstract below: Background. Data on engagement in HIV care following testing and diagnosis outside of healthcare facilities or research settings in programs such as home-based counseling and testing (HBCT) in sub-Saharan Africa are limited. The objective of this study was to use double-sampling methods to estimate linkage to and engagement in HIV care and mortality among adults newly diagnosed with HIV in three regions of western Kenya. Methods. HBCT was conducted door-to-door from 2010 to 2015 in three sub-Counties of western Kenya by AMPATH (Academic Model Providing Access to Healthcare). For those diagnosed with HIV, data were merged with electronic medical records to determine engagement with HIV care. A randomly-drawn follow-up sample of 120 adults newly diagnosed via HBCT who had not linked to care as of June 2015 in Bunyala sub-County were visited by trained fieldworkers to ascertain vital status and use of HIV care services. These 'double-sampled' data were used to generate, via multinomial regression, predicted probabilities of engagement in care and mortality among those whose status could not be ascertained by matching data in the AMRS. These were used to update engagement in HIV care and mortality estimates among newly diagnosed adults in all three catchment areas. Results.

	Additional information on vital status and engagement in HIV care following diagnosis was available for 69 randomly selected individuals who were located; ;the rest had moved away with no forwarding address. With manual record matching, estimates of linkage to care ranged from 28-36% across the three catchments. Incorporating information from the follow-up sample yielded estimates between 55 and 59%. Mortality estimates ranged from 10-13% of those who were newly diagnosed via HBCT. Conclusions. In settings without universal national identifiers, rates of linkage to care from community-based HIV testing may be subject to substantial underestimation. Follow-up samples of those with missing information can be used to partially correct this bias. There is a need for harmonized data systems across health systems and programs in low- and middle-income countries.
Future Plans	Submission of manuscripts to identified journals for publication.
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 Prof. Samuel Ayaya, Moi University
Co-Investigator(s)	Prof. Wamalwa Dalton Prof Obimbo Elizabeth Dr Bukusi Elizabeth Dr Otieno Godfrey Allan Prof Musoke Rachel Dr Oyaro Patrick Dr Mbuthia Joseph K Dr Koech Lucy
Working Group(s)	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 (MTRH)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	Since study commencement, the study has achieved great milestones in the last six months. One of the major accomplishment is enrollment of the expected 100 study participants has been completed. Follow up is still ongoing. So far 38 participants have completed 12 month of study follow up and 21 participant are close to complete their 24 month follow up period. We have had 7 withdrawals ; 2 participants succumbed to complications arising from the HIV infection, 2 children have been lost to follow up, 2 children have had consent withdrawn, while 1 child transferred to Nairobi.
Future Plans	We hope to complete the 24 month study follow up for some of the study participants, so we can get some preliminary analysis commence. Overall continue with working on towards improving the quality of care and data as we focus on follow up of children who have remained viremic in the study and understanding why this is so.
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 Evangeline Njiru, Moi Teaching and Referral Hospital
Co-Investigator(s)	
Working Group(s)	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)	All
Project Period	9/1/2015 - 8/31/2018
Funding Status	Funded - NIH
Direct Award (USD)	$75,000
Update	The study is open for enrollment, we have managed to enroll 3 study participants so far into study, but one was discontinued due to disease progression and 4 participants were screen failures. We have developed innovative methods for recruitment in order to ensure we are able recruit more study participants into the study.
Future Plans	The study hopes to continue to recruit more study participants into the study in next 6 months given two sites are open in Africa to enroll and hopefully all the other remaining study sites in Africa will be activated to enroll.
Publication(s)	

Study Title	**REALITY 'Reduction of EArly mortaLITY in HIV-infected adults and children starting antiretroviral therapy'**
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University Abraham Siika, Moi University
Co-Investigator(s)	Priscilla Cheruiyot, Prof. Winstone Nyandiko
Working Group(s)	AMWG, PRWG
Description	A 2x2x2 open-label factorial multi-centre trial, conducted in 9 centres in 4 countries (Kenya, Malawi, Uganda, Zimbawe). Study participants will be1800 HIV-infected patients including adults, adolescents and children aged 5 years or older with low CD4 counts about to initiate combination antiretroviral therapy (ART). There will be Three methods to reduce early mortality following ART initiation (i) increasing the potency of ART with a 12 week induction period using 4 antiretroviral drugs from 3 classes (ii) augmented prophylaxis against opportunistic/bacterial infections and helminths for 12 weeks (iii) macronutrient intervention using ready-to-use supplementary food for 12 weeks. Each intervention will be compared with standard of care, which in previously untreated patients presenting late with very low CD4 counts is to initiate ART with 3 drugs from 2

	classes, together with cotrimoxazole prophylaxis and macronutrient intervention only for those with low BMI (or low weight-for-height/mid-upper arm circumference in children). The primary objective of the trial is to identify effective, safe and acceptable interventions to reduce early mortality (all-cause) in HIV-infected adults, adolescents, and older children (5 years or more) initiating ART.
Site(s)	Kenya, Malawi, Uganda, Zimbawe
Project Period	8/1/2013 - 8/1/2017
Funding Status	Funded - Medical Research Council
Direct Award (USD)	Not Reported
Update	This protocol was closed to accrual in 2016. There have been no activities at the site in the past 6 months. However, data analysis has been ongoing.
Future Plans	No further activities at the site. Secondary data analysis is ongoing.
Publication(s)	1. Enhanced Prophylaxis plus Antiretroviral Therapy for Advanced HIV in Africa. Lancet NEJM July 20, 2017

Study Title	**SAFI (Stigma in AIDS Family Inventory) Validation Study**
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Irene Marete, Hai Liu, Violet Naanyu
Working Group(s)	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	In the last 6 months, we completed data cleaning for the questionnaire data collected through the SAFI study to provide a comprehensive and validated family HIV/AIDS-related stigma measure for assessing H/A stigma. Data cleaning for our adherence monitoring data collected through MEMS® monitors are ongoing. The analyses to assess the validity of the measures of stigma were completed, the manuscript drafted, and it was recently submitted to the Journal of AIDS Patient Care and STDs. 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. In addition, we launched a community-based assessment of the impact of the stigma-related adolescent films that were created through this project.
Future Plans	Data from the MEMS® adherence monitoring for these patients was not incorporated into the initial validation analyses, and so we will conduct additional analyses looking at the interaction of ART adherence and measured stigma in the next 6 months. An abstract will also be prepared and submitted to the IAS AIDS 2018 meeting in Amsterdam.
Publication(s)	

Study Title	**Spatial scales of Plasmodium falciparum generations; implications for elimination**
Principal Investigator(s)	Andrew Obala, Moi University Wendy O'meara, Duke University
Co-Investigator(s)	Joseph Kirui, Judy Mangeni
Working Group(s)	PHPCWG

Description	Malaria is a major public health problem, with an estimated 198 million cases occurring world-wide in 2013. Effective strategies to reduce malaria transmission and disease have been highly successful leading to a 40% reduction in malaria cases in sub-Saharan Africa since 2000. It has been observed that infections cluster geographically and such clustering becomes more pronounced as transmission declines. The science of identifying 'hotspots' of infection or foci of transmission is a growing area that promises to help target interventions more effectively. However, it has not been shown whether infected individuals in close physical proximity (i.e. in the same household) are jointly infected due to simply living in a risky place, or because an infected household member is a risk factor for nearby susceptible individuals. If the former, then targeting hotspots should focus on reducing environmental risk factors in the area around a 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 80 villages) will be sequenced at a moderately polymorphic gene using deep sequencing techniques. This will provide evidence for local, focal transmission if nearby infections are more closely related or will point to mixed transmission whereby infections only begin to differ as you reach the distance of mosquito flying ranges. Our second objective is to trap malaria mosquito vectors and identify infected mosquitoes. We will determine the source of the mosquito's infection by sequencing parasites in the mosquito salivary glands and comparing to parasite genotypes in humans. By doing so, we can find out whether infections are being transmitted at a household scale or transmission is 'well mixed' geographically and only limited by the range of the mosquito. If successful, this will be the first report of linking individual infections in mosquitoes to their human source. The ability to track infections from human to mosquito and back again would allow us to understand the dynamics and scale of transmission in a way that has not previously been possible. We expect to scale up this approach to larger populations in subsequent studies. These results will provide insight into the expected impact of interventions designed to target hotspots.
Site(s)	Ziwa Sub-District Hospital
Project Period	2/15/2017 - 1/31/2019
Funding Status	Funded - NIH
Direct Award (USD)	Not Reported
Update	Processing of Aim 1 DBS and mosquito samples is ongoing at the Taylor Lab at Duke University. All RDT-positive participants have been identified and P. falciparum infection has been confirmed and typed using a species-specific real-time PCR assay. The study team also continues to optimize and update high-throughput parasite genotyping and

	multiplex sequencing protocols. 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 bednets 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. Two shipments of mosquito and DBS samples were sent from Eldoret, Kenya to the Taylor Lab for processing in October 2017 and January 2018.
Future Plans	Study households will be visited weekly for entomology collections and monthly for survey and DBS collections through December 2018. Our focus during the next project will be to complete all Aim 2 mosquito and DBS processing and matching of parasite haplotypes in mosquito and human samples. We will also begin to conduct preliminary analyses and draft manuscripts of main outcomes in the coming year.
Publication(s)	

Study Title	**Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS)**
Principal Investigator(s)	Constantine Akwanalo, Moi University Jemima Kamano, Moi University
Co-Investigator(s)	Violet Naanyu Ann Mwangi Benson Njuguna Tim Mercer Rajesh Vedanthan JJ Dick Sonak Pastakia
Working Group(s)	CVMD
Description	Hypertension is a major risk factor for cardiovascular disease (CVD), and 80% of global mortality due to CVD occurs in low- and middle-income countries (LMICs). In LMICs, lack of coordination between different levels of the health system threatens the ability to provide the care necessary to control hypertension and prevent CVD-related morbidity. Strong referral networks have improved health outcomes for chronic disease in a variety of settings. Health information technology (HIT) and peer-based support are two strategies that have improved care coordination and clinical outcomes. However, their effectiveness in strengthening referral networks to improve blood pressure (BP) control and reduce CVD risk in low-resource settings is not known. The Academic Model Providing Access to Healthcare (AMPATH) partners with the Kenya Ministry of Health (MOH) to provide care for non-communicable chronic diseases (NCDs), including hypertension and CVD, at all levels of the health system. The Kenya MOH Health Sector Referral Strategy 2014-2018 calls for improving the referral system at every level of the health system. AMPATH has piloted both HIT and peer support for NCDs, and both strategies are feasible in this setting. However, the impact of integrating HIT and peer

	support to strengthen referral networks for hypertension control is not known. The objective of this proposal is to utilize the PRECEDE-PROCEED framework to conduct transdisciplinary, translational implementation research focused on strengthening referral networks for hypertension control. The central hypothesis is that HIT integrated with peer support will be effective and cost-effective in strengthening referral networks, improving BP control, and reducing CVD risk among patients with hypertension in western Kenya. We hypothesize that HIT and peer support will synergistically address barriers to hypertension control at the patient, provider and health system levels. We further hypothesize that changes in referral network characteristics may mediate the impact of the intervention on the primary outcome, and that baseline referral network characteristics may moderate the impact of the intervention. To test these hypotheses and achieve the overall objective, we propose the following specific aims: Aim 1: Conduct a baseline needs and contextual assessment for implementing and integrating HIT and peer support to strengthen referral networks for hypertension control, using a mixed-methods approach, including: observational process mapping and gap assessment; baseline referral network analysis; and qualitative methods to identify facilitators, barriers, contextual factors, and readiness for change. Sub-Aim 1.1: Use data from the baseline needs and contextual assessment to develop a contextually and culturally appropriate intervention to strengthen referral networks for hypertension control using a participatory, iterative design process. Conduct pilot acceptability and feasibility testing of the intervention. Aim 2: Evaluate the effectiveness of HIT and peer support for hypertension control by conducting a two-arm cluster randomized trial comparing: 1) usual care vs. 2) referral networks strengthened with an integrated HIT and peer support 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 HospitalKitale District HospitalMoi Teaching and Referral Hospital (MTRH)Mosoriot Rural Health Training CentreTurbo Health CentreWebuye District Hospital
Project Period	9/1/2017 - 5/31/2018
Funding Status	Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	$268,469

Update	Administrative • Project start up meeting between investigators and RSPO held in October 2017 • Calls • All-Investigator conference calls held in November 2017 and January 2018 • Weekly calls held between available investigators to facilitate project start up • Positive feedback attained from participants on calls • Project protocol and participant consent forms approved by Moi/MTRH IREC • Process for sub-contracting Sinai(Vedanthan)/IU & Purdue(JJ & Pastakia)/UT Austin(Mercer) initiated • Interviews for research coordinator completed and top candidate picked, awaiting issuance of hiring letter • PI and three co-investigators attended inaugural NIH/NHLBI meeting for project • Office space and conference line acquired • Procurement plan done. Awaiting signing by University Aim 1: Barriers/facilitators/contextual factors/referral network analysis • Tools for conducting baseline process mapping, focus group discussions, mabaraza, and key informant interviews drafted, awaiting final PI approval before IREC submission as amendments • Survey for baseline referral network analysis tested and awaiting final approval by PI as above Aim 2 (Cluster RCT): • Point of care (POC) referral module design outline created for health IT tool
Future Plans	Aim 1: • Complete registration of trial in ClinicalTrials.gov • Get procurement plan approved to facilitate equipment and items purchase • Complete hiring and training of three research assistants • Start baseline process mapping • Start FGDs, KIIs and Mabaraza • Complete baseline referral network analysis Aim 2: • Complete hiring and training of research assistants • Test POC referral module Publications: • Submit project protocol paper to Implementation Science
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)	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)	Angurai Health Centre
Project Period	9/1/2015 - 8/31/2019
Funding Status	Funded - NIH
Direct Award (USD)	$750,186
Update	We have managed to enroll 188 cases into study and managed to follow up to the study participants. We have managed to enroll our cases from different AMPATH sites.
Future Plans	We will continue to enroll our cases into study and start the process of selection and recruitment of controls for the cases in the next 6 months. The study will continue to follow up the identified study participants as stipulated in the protocol.
Publication(s)	

Study Title	**The Production and Reproduction of Kinship in CCIs in Uasin Gishu County**
Principal Investigator(s)	Allison Gayapersad, University of Toronto
Co-Investigator(s)	Paula Braitstein, Caroline Ombok, Allan Kamanda
Working Group(s)	PRWG

Description	This is a qualitative social science project that seeks to explore how residents of Charitable Children's Institutions (CCIs; including orphanages) produce and understand kinship relations. Based on a structural-functionalist theoretical orientation, we hypothesize that when children move to CCIs, they will create new fictive kin relationships. We hope to map these relations and explore the directionality of things like authority and hierarchy, and to understand the sorts of privileges and obligations inherent in these relationships. We will conduct a series of open-ended, semi-structured interviews with current and former residents and staff of CCIs in Uasin Gishu county, Eldoret. Our survey instrument is designed to elicit information about the nature of kin networks at the CCI, and how traditional life milestones (such as marriage or coming of age) are manifest in these networks. We will also ask residents to draw kinship diagrams to better visualize their relationship networks. The data will be analyzed with an emphasis on functionalism and symbolic anthropology.
Site(s)	Uasin Gishu County Charitable Children's Insitutions
Project Period	8/1/2016 - 6/30/2018
Funding Status	Unfunded
Direct Award (USD)	
Update	Data analysis was completed and a manuscript has been prepared for publication. A final draft is being circulated to AMPATH publications committee for comments/feedback. The findings revealed that social interaction and other factors determine the ease or difficulty with which OSCAs adopted novel familial identities. CCIs created a family-like care environment resulting in OSCAs redefining the traditional concept of family based on consanguinity to one composed of non-kin providing care and support. Social interaction through family related activities reproduced novel familial identities and OSCAs felt they were part of a family. Being poor role models or not meeting expectations based on CCI regulations sometimes resulted in OSCAs being expelled. These factors in addition to being exited from the CCI at 18 years of age and the stigma of being an orphan in residential care resulted in the prominence of their orphan identity rather than a familial identity. While there are benefits to being in a CCI including building long-term family bonds the loss of OSCAs' tribal affiliation, culture, language, traditions, and tribal identity has implications for their self-image, general health, mental health, and social relations.
Future Plans	Complete final revisions to the manuscript and submit for publication.
Publication(s)	

Study Title	**The role of mPHRs in Western Kenya**
Principal Investigator(s)	Martin Were, Vanderbilt University Medical Center Jessica Ruff, Vanderbilt University Medical Center

Co-Investigator(s)	Naanyu, Violet Kirui, Nicholas
Working Group(s)	CVMD
Description	This study aims to identify patterns of cellphone use in Kenya and evaluate the role of mobile personal health records (mPHR) for patients with chronic diseases in LMICs. Working with key stakeholders, we will use a user-centered approach to inform the development of the mPHR application. The mPHR will be pilot-tested with patients who have hypertension and HIV in Kenya, and its acceptability and uptake will be evaluated. This work will be conducted in close collaboration with the local community, the Ministry of Health, the AMPATH care program, and the Institute of Biomedical Informatics at Moi University in Kenya. The specific aims of this study are as follows. Aim 1: Identify current smartphone usage patterns and barriers to its use for mPHR for chronic disease care in LMICs. Aim 2: Develop an acceptable model for implementing mPHR for chronic disease care in LMICs. Aim 3: Develop a modular mPHR application to support patients with chronic diseases in LMICs. Aim 4: Evaluate usability and feasibility of the mPHR solution among patients with hypertension/stroke or HIV/AIDS in Western Kenya.
Site(s)	Huruma Sub-District Hospital, Moi Teaching and Referral Hospital (MTRH)Turbo Health Centre
Project Period	9/1/2017 - 8/31/2019
Funding Status	Funded - NIH - National Institute of Neurological Disorders and Stroke (NINDS)
Direct Award (USD)	$13,000
Update	This project received CMVD Working Group approval.
Future Plans	Over the next six months we plan to obtain IREC approval from Moi University and IRB approval from Vanderbilt University; hire and train 2 research assistances; and begin participant enrollment and data collection for Aims 1 and 2.
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 Asirwa Chite, Indiana University
Co-Investigator(s)	Job Kisuya, Evangeline Njiru Toby Maurer Mike Rosenblum Stefanie Sowinski
Working Group(s)	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 10% of adult cancers. Although sub-Saharan Africa was already a hotbed for KS, the clinical manifestations and impact of the disease dramatically changed with the onset of the HIV epidemic in the 1980's when the incidence of KS and other HIV associated malignancies exploded. The advent of anti-retroviral therapy (ART) improved prognosis of HIV-associated KS, but survival remains unacceptably poor in low to middle income countries(LMIC). A recent Cochrane review on late stage KS showed that in 6 studies in which chemotherapy was added to HAART, no survival benefit was seen above that of ART therapy alone nor amongst the different types of chemotherapy. Endemic KS, while less likely to progress to visceral disease, leaves patients with profound functional disabilities often requiring treatment. Because this population is HIV negative, ART is not used. Research that leads to a better understanding of the biology of KS must be explored to provide alternative therapies to ART and standard chemotherapy. Based upon preliminary data from UCSF which supports the role of PD1 pathway and tissue micro-environment in KS, we propose to conduct a prospective analysis on two patient cohorts. Cohort 1: KS in HIV-infected subjects who have failed at least one KS-directed chemotherapeutic intervention; and Cohort 2: KS in HIV-negative patients (i.e. endemic KS) who have failed at least one KS-directed chemotherapeutic intervention.
Site(s)	
Project Period	10/1/2015 - 9/30/2018
Funding Status	Funded – NIH - National Cancer Institute (NCI)
Direct Award (USD)	$158,406
Update	The study is open for enrollment; we have managed to enroll 7 study participants so far into study.
Future Plans	Study hopes to continue to recruit more study participants into the study in next 6 months.
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 Winstone Nyandiko, Moi University
Co-Investigator(s)	McCoy Brittany,McAteer Carole,Aluoch Josephine

Working Group(s)	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. In addition, we will gather preliminary data on the films' efficacy at reducing HIV stigma. 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 (MTRH)
Project Period	4/1/2017 - 4/30/2018
Funding Status	Unfunded
Direct Award (USD)	
Update	IREC and IRB approvals for this study was secured. Recruiting participants began on 10th April 2017. Seven focus group discussions and questionnaires were done, with both caregivers of HIV-infected children and with HIV-infected children, which ended on 28th April 2017. Transcription/Translation of the focus group discussions has been completed. The second phase of assessments of the longer-term impact of the films, which was to be done three months after viewing, has begun and is ongoing.
Future Plans	Within the next month, the second phase of the study will be completed. The focus group discussions in phase 2 will be translated, transcribed and prepared for qualitative data analysis. The quantitative data will be entered into a REDCap database and cross-checked for preparation of data analysis. A manuscript describing the creation of the films is also underway.
Publication(s)	

Study Title	**Validating an Integrated Community Based Strategy of Peer Support in Pregnancy and Infancy**
Principal Investigator(s)	Julia Songok, Moi University Astrid Christoffersen-Deb, University of Toronto
Co-Investigator(s)	Laura Ruhl Justus Elung'at
Working Group(s)	PHPC, 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 Centre, Saboti, Kiminini, Cherangani and Kwanza Sub counties
Project Period	10/1/2017 - 10/1/2018
Funding Status	Funded - Grand Challenges Canada, ABBVIE
Direct Award (USD)	$197,510
Update	Nothing much has happened this reporting period due to Nurses' strike that began on 5th June. Considering nurses are the primary caregivers for antenatal, postnatal and child wellness clinics in Kenya, we had no referral centers that would have catered for Chama women. The program had to wait for strike to be called off before beginning any Chama related activities. The strike was finally called off on 3rd November, 2017 upon which the second round of recruitment was conducted. This is after refresher training for the enumerators which happened between 23rd and 25th November. During recruitment, a lot of activities were happening concurrently including regular supervision by our staff on the ground, quality checks, data entry and cleaning, among others. By 31st December, we had managed to recruit a total of 1004 women.
Future Plans	The next 6 months are going to be intensive for the program. As of now, recruitment is still ongoing as we aim to reach our target sample size of 1600 women. Based on the average numbers we are getting per week, we anticipate to conclude the baseline survey by 31st January. We are also having the data team pull out the list of women recruited which is forwarded to our implementation leads to be given to the CHVs for tracing; this is done every Friday. All activities mentioned earlier that are related to baseline data

	collection will still be ongoing. We are in the process of organizing a three-day refresher training for the 74 Community Health Volunteers (CHVs) who will facilitate Chamas in the 4 sub counties. We have planned this to be done by 31st January so that Chamas can start early February. This will involve 37 groups of approximately 20-25 pregnant women. We are aiming to complete 12 sessions. During this period, mothers will receive health, social and financial education and continue with Group Integrated Savings and Health Empowerment and GISHE. We plan to analyse the data collected by mid-march to obtain baseline information on our targeted maternal and child health indicators. Alongside implementing the program we will provide bi-weekly supervision of the Chama sessions. This entails having the implementation leads visit the Chama and listening to the CHVs during facilitation to ensure that they maintain program fidelity.
Publication(s)	

Study Title	**Validation of Spirometry Prediction Equations in Western Kenya**
Principal Investigator(s)	Peter Kussin, Duke University David Lagat, Moi University
Co-Investigator(s)	
Working Group(s)	AMWG
Description	This is a cross-sectional study of healthy adult Kenyans living in and around Eldoret. The purpose of the study is to validate a set of spirometry prediction equations for the local population. Adults age 18 years and older who are HIV negative, with no history of chronic cardiac or pulmonary disease and with <5 pack year smoking history are eligible for participation. Specific Aim: Determine pulmonary function reference equations that can accurately predict normal spirometric values in a Kenyan population. 1A: Statistically compare phenotypically normal Kenyan spirometric profiles with values obtained from published pulmonary function reference equations to determine the most accurate equation set. 1B: If published reference equations do not accurately reflect normal Kenyan lung function profiles, develop new reference equations.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	1/1/2015 - 3/1/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	We published a manuscript

Future Plans	Study is closed
Publication(s)	Int J Tuberc Lung Dis. 2018 Jan 1;22(1):112-118. doi: 10.5588/ijtld.17.0005. Validation of spirometry prediction equations in western Kenya. Paul DW1, Lagat DK2, MacIntyre N3, Egger JR4, Murdoch DM3, Que LG3, Kussin PS5.
Study Title	**Vincristine Optimization in Kenyan Children with Cancer**
Principal Investigator(s)	Jodi Skiles, Indiana University - Purdue University in Indianapolis (IUPUI) Festus Njuguna, Moi University
Co-Investigator(s)	Moi Teaching and Referral Hospital (MTRH)
Working Group(s)	ORWG, PRWG
Description	In resource-limited settings, access to chemotherapeutic agents is confined to a few therapies. Vincristine (VCR) is a mainstay in such settings due to its low cost and lack of myelosuppression, however, little is known regarding its disposition and true optimal dosing, especially in the pediatric population. Negative clinical outcomes, such as serious side effects due to drug overdosing or lack of efficacy due to sub-therapeutic dosing, may result. VCR is associated with highly variable cumulative dose-dependent peripheral neuropathy (VIPN). While pediatric oncology patients in the U.S. who receive VCR experience significant VIPN and excellent disease outcomes, Kenyan children with cancer who receive VCR experience little to no VIPN, highlighting the opportunity for optimization of VCR in this population. While there are clearly multiple factors that contribute to poor disease outcomes in Kenya, suboptimal dosing of VCR is the piece we aim to address in this study. The biological basis for the minimal VIPN we have observed in Kenyan children is uncertain but includes such things as genetic differences in VCR pharmacologic pathways as well as genetic variability in susceptibility to neuropathy. This gap in knowledge provides a clear opportunity to optimize use of this medication in Kenyan children with cancer and evaluate genetic associations with VIPN in order to personalize this medication for individual children once VCR dosing is augmented. Preliminary data has shown that Kenyan children with cancer (n=100) experience minimal VIPN. Despite the negligible neuropathy observed, subclinical VIPN can be detected using a very detailed, non-invasive assessment tool that we developed for detecting even very minor toxicity. Utilization of this tool in Kenyan children allowed us to identify an association between VIPN severity, CYP3A5 genetic polymorphisms, and an individual's ability to metabolize VCR, such that children with an allelic variant of CYP3A5 that results in a high VCR metabolizer phenotype experience less VIPN. Variability in VCR response and toxicity may be particularly significant within Africa, where human genetic variability is greatest, and where ~90% of Kenyans patients were fast VCR metabolizers. In one recent study, pharmacokinetic (PK) variability was linked to overall survival in children with acute lymphoblastic leukemia (ALL), such that children with faster VCR clearance had a greater chance of relapse. If VCR disposition, response, and neurotoxicity are linked, it may be possible to optimize dosing based on easily obtained knowledge of genetic

	polymorphisms responsible for disposition and subsequent neurotoxicity variability. This research is of particular importance in Africa, where VCR is one of few available anticancer drugs and is used in the treatment of over half of all cancer patients. Furthermore, given that most Kenyan children are CYP3A5 high expressers and thus VCR fast metabolizers, they may tolerate and benefit from higher doses of vincristine than are conventionally used in the U.S. and Africa. This proposed prospective study will be conducted in two parts, which will both enroll pediatric patients age 1-18 years with newly diagnosed acute lymphoblastic leukemia or nephroblastoma. Part I will be a VCR dose escalation phase (in combination with routine multi-agent chemotherapy) to determine the maximum tolerated dose of VCR in a population of Kenyan children with cancer. Part II will be utilize the maximum tolerated dose of vincristine determined from Part I in place of the standard dose of VCR in combination with routine multi-agent chemotherapeutic protocols. DNA and pharmacokinetic samples will be collected on all subjects to allow determination of biomarkers of development of VIPN. Subjects will be monitored closely for development of toxicity with laboratory assessments as well as detailed neuropathy assessments. The specific aims (SA) for this proposal are as follows: SA1: To determine the maximum tolerated dose (MTD) of VCR administered in conjunction with conventional chemotherapy in cohorts of Kenyan children with ALL or Wilms tumor receiving VCR as part of their anti-cancer treatment. SA2: To validate our pilot study findings and to further evaluate the association between common or functional variants in genes in the vinca alkaloid pharmacologic pathway and across the human genome with VCR PK, VIPN, and disease response in the same populations as SA1. SA3: To further develop our pharmacologic prediction model of VIPN describing associations between pharmacogenetic, pharmacokinetic, and clinical biomarkers and carefully characterized VIPN in the same population of patients as SA1. SA4: To evaluate the validity and reliability of several chemotherapy-induced peripheral neuropathy (CIPN) measurement approaches when used to quantify neuropathy and associated neuropathic pain in Kenyan children receiving vincristine.
Site(s)	
Project Period	2/3/2014 - 1/31/2018
Funding Status	Funded – NIH- National Cancer Institute (NCI), NIH – Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Direct Award (USD)	$103,254
Update	Recruitment to this study began in February 2014. In September 2015, we observed our first dose-limiting toxicity at Dose Level 3 manifesting in the form of cranial nerve neuropathy presenting as diplopia. An additional 3 subjects were enrolled at Dose Level 3 in accordance with the protocol. Unfortunately, it was noted that patients in Dose level 3 had a statistically significantly higher rate of death compared to historical controls. While it is not clear whether the cause of the increased rate of death is related to the VCR dose escalation, out of concern for patient safety, enrollment to Dose Level 3 was suspended and a prompt report was submitted to the IRB and IREC. All patients who were previously receiving dose level 3 were dose-reduced to Dose Level 2. In accordance with the protocol, an additional 3 subjects were enrolled on Dose level 2 to ultimately define

	Dose level 2 as our MTD. No further dose-limiting toxicities have been observed since that time. The last enrolled subject completed therapy in December 2017. Final biospecimens are anticipated to arrive to the US in late Jan 2018 with data analysis to commence shortly thereafter.
Future Plans	Data analysis and manuscript draft
Publication(s)	

Study Title	**Viral Suppression among HIV-infected Children and Caregivers in Western Kenya**
Principal Investigator(s)	John Humphrey, Indiana University Edith Apondi, Moi University
Co-Investigator(s)	Becky Genberg, Adrian Gardner, Joseph Hogan, Kara Wools-Kaloustian
Working Group(s)	PRWG
Description	The suppression of HIV viral load through administration of antiretroviral therapy is a key objective for all HIV-infected patients. However, optimal approaches to family-centered HIV management are not well known, particularly when children and their caregivers are both in need of HIV treatment. In order to better understand viral suppression among HIV-infected children who also have HIV-infected parents or caregivers, we will conduct a retrospective review of all HIV-infected child-caregiver dyads receiving HIV care at the AMPATH program in western Kenya from January 2015 to December 2016. We will achieve the following specific aims: (1) Characterize viral suppression in HIV-infected children and in their HIV-infected caregivers; (2) Estimate the association between viral non-suppression in children and their HIV-infected caregivers; (3) Identify factors associated with viral non-suppression among HIV-infected child-caregiver dyads. The knowledge gained from this study will inform our understanding of the management of HIV in HIV-affected families. This may lead to better strategies to improve the delivery and monitoring of antiretroviral therapy in these families in the future.
Site(s)	Angurai Health Centre
Project Period	1/1/2017 - 12/31/2017
Funding Status	Funded - Indiana University - Center for AIDS Research
Direct Award (USD)	$12,500
Update	We completed the preliminary analysis and submitted an abstract that was accepted as a poster presentation in March at CROI 2018 in Boston, MA. In our preliminary results of 2,154 caregiver-child dyads who met the inclusion criteria, dyad viral suppression was:

	both suppressed (56%), caregiver suppressed and child unsuppressed (23%), caregiver unsuppressed and child suppressed (10%), and both unsuppressed (11%). Children with unsuppressed caregivers were 3 times more likely (OR=2.8, 95% CI: 2.3-3.5) than children with suppressed caregivers to have unsuppressed viral loads.
Future Plans	We hope to complete the analysis and manuscript and submit for publication.
Publication(s)	

Study Title	**Virologic Treatment Failure and Drug Resistance in HIV-Infected Kenyan Children (RESPECT) study.**
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Josephine Aluoch, Rami Kantor, MD Department of Medicine Brown University School of Medicine rkantor@brown.edu Samuel Ayaya, MBChB, MMED Department of Child Health and Paediatrics, Moi University School of Medicine ayaya.samuelaluanga@gmail.co Joe Hogan, PhD
Working Group(s)	PRWG
Description	This study will involve retrospective and prospective analysis of blood sampling from patients enrolled in a previous NIH-funded (Vreeman, 1K23MH087225) randomized controlled trial titled, 'Evaluation of a Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy' or the 'CAMP study.' That was conducted between May 2010 and October 2013. This particular cohort provides an unprecedented and timely opportunity to characterize longitudinal processes that lead to treatment failure and drug resistance development among HIV-infected children in a sub-Saharan African setting, and its translation into evidence-based interventions. The specific aims of this study are: 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)	Matayos Health CentreMois Bridge Health CentreUasin Gishu District HospitalChecked
Project Period	8/2/2016 - 7/31/2020

Funding Status	Funded - NIH
Direct Award (USD)	$613,511
Update	Over the last six months we have continued with participants' recruitment and follow up. We have enrolled a total of 403 for the prospective assessments of participants that include blood draws for viral load levels, CD4 counts, drug levels and resistance testing. A total of 89 specimens have been shipped to the Dr. Rami Kantor's laboratory at Brown University for resistance testing. Three-month follow-up with MEMS adherence monitoring is now ongoing for a subset of about 28% of the enrolled participants, with 93 out of 114 participants enrolled having completed this additional monitoring. We have done one verbal autopsy. Over the last six months data entry in the REDCap database has been ongoing with weekly data quality checks by the data management team.
Future Plans	We plan to complete participants' enrollment and follow-up to evaluate the participants' immunologic, virologic and drug resistance outcomes. We plan to continue administering the verbal autopsy forms to assess participants found to have died since the original study enrollment. In the next 6 months, we will complete data entry and cross-checking in the REDCap database, as well as to determine current viral load and CD4 count levels and send the remaining blood samples for all participants to Brown University for phenotyping and resistance testing.
Publication(s)	• The initial viral resistance findings were presented as an oral presentation, entitled 'HIV-1 Treatment Failure and Extensive Drug Resistance in Perinatally-Infected Children Failing 1st-Line Antiretroviral Therapy in Western Kenya', at the 17th International Workshop on HIV Drug Resistance and Treatment Strategies in Johannesburg, South Africa. • An abstract entitled 'Characterizing adherence and drug level effects on viral outcomes in HIV-infected Kenyan children' was submitted to the CROI 2018 conference in Boston, USA.

Appendix A: Bibliography

The following bibliography includes AMPATH research publications that were published between July 1, and December 31, 2017. 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, www.medicine.iu.edu/ampathresearch/member-access.

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APPENDIX B: MUCHS RESEARCH SYMPOSIUM PROGRAM

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COLLEGE OF HEALTH SCIENCES
Office of the Principal

Medical Education Centre Building
Nandi Road, Opp. MTRH
P O Box 4606, 30100
Eldoret, KENYA

Moi University College of Health Sciences Symposium
Date: Thursday, July 17, 2017
Venue: PDN Building

Time	Session	Speaker	Facilitator(s)
8.00-8.30am	Arrival and Registration		N. Mueni J. Kiplagat
8.30am-8.35am	Opening Prayer	Rev. Katwa	Prof. W. Nyandiko
8.35am-8.40am	Introduction	Prof. Nyandiko	
8.40am-9.30am	Opening Remarks	Dean SOM Dean SON Dean SPH Dean SOD Principal CHS DVC Research	
9.30am-10.30pm	Session 1: Oncology (*Each presenter – 12 Minutes; Q&A – All presenters – 15 minutes*)		Dr. P. Tonui & Dr. Lukandu
	Post-Leep follow-up by VIA and PAP smear in HIV positive and HIV-negative women in western Kenya	Dr. Omenge	
	Challenges of setting uo flow cytometry for diagnosis of Leukemia and lymphoma at MTRH, Eldoret, Kenya	Dr. T. Lotodo	
	The use of Palliative Cisplatinum for advanced cervical cancer : A case of MTRH	Dr. P. Itsura	
	Is the Biology of Breast Cancer in Africa changing?	Dr. K. Patel	
10.30am – 11.00am	**TEA BREAK and POSTER VIEWING**		
11.00am-11.30pm	Guest Speaker		Prof. P. Ayuo
11.30pm-12.15pm	Session 2: HIV *Each presenter – 12 Minutes; Q&A – All presenters – 9 minutes*)		Prof. V. Naanyu & Dr. P. Chege
	Dynamics of TH1 and TH2 Type of Cytokines in Conjoint Cases of Human Immunodefeciency Virus and Pregnancy: A Longtidunal Study in Western Kenya.	S. Musyoki	
	A Chance to Live": Perspectives from Community on Home Based Counseling and Testing (HBCT) for HIV, Western Kenya	J. Sitienei	
	CCR5 Co-Receptor Expression on Circulating CD4+ Lymphocytes in HIV-1 Patients on HAART at MTRH, Eldoret-Kenya	B. Simiyu	

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12.15pm-1.00pm	Session 3: Cross Cutting *Each presenter – 12 Minutes; Q&A – All presenters – 9 minutes*)		
	Q fever, scrub typhus and rickettsial diseases are common causes of fevers of unknown origin among pediatric patients in western Kenya	Dr. J. Laktabai	Dr. Kinyanjui & Dr. K. Patel
	Quality of ANC Care Offered in Nambale Sub-County, Busia County	Dr. D. Muyodi	
	A Situational Analysis of Spiritual Care Provision at the Riley Mother and Baby Hospital (RMBH) MTRH, Eldoret, Kenya	Dr. P. Nyongesa	
1.00pm-2.00pm	**LUNCH BREAK and POSTER VIEWING**		
2.00pm-2.30pm	Special Session *Each presenter – 15 Minutes* Moi University Clinical Trial Unit and Laboratory Capacity Highlight from the Chronic Disease Management	 Prof. A. Siika Dr. J. Kamano	Prof. L. Diero
2.30pm-3.30pm	Session 4: Community Based Education Services (COBES) and Education Systems *Each presenter – 12 Minutes; Q&A – All presenters – 15 minutes*)		
	Students' Perception and Preference of SPICES Model at School of Medicine, College Of Health Sciences, Moi University, Eldoret, Kenya	J. Katwa	Prof. E. Were & B. Milimo
	How Community Based Education And Services Removes Silos and improves Global Health at Moi University College of Health Sciences, Eldoret, Kenya	Dr. J. Baliddawa	
	Assessment of Dietary habits of undergraduate medical students and College of Health Sciences , Moi University	COBES IV	
	The level of job satisfaction among Doctors and Nurses at Webuye County Hospital in the immediate post devolution era.	M. A. Gitonga	
3.30pm-4.15pm	Session 5: Cross cutting *Each presenter – 12 Minutes; Q&A – All presenters – 9 minutes*)		
	Voiding dysfunction among female patients with Diabetes mellitus at MTRH	Dr. E. Mugalo	Dr. R. Tonui & Dr. F. Yego
	R2E Project: Re-Engineered Enhanced Discharge Instructions at the Moi Teaching and Referral Hospital. A Block Randomized Patient Safety Trial	B. Rono	
	Hearts to Hearts: A Multi-professional advocacy for Rheumatic Heart Disease Prevention and Management in Uasin Gishu County.	D. Nyariki	
4.15pm – 4.30pm	Closing Remarks	Prof. S. Mining CEO, MTRH	Prof. W. Nyandiko
4.30pm-5.00pm	**TEA BREAK and POSTER VIEWING**		

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