SEMI-ANNUAL RESEARCH REPORT

January – June 2013

Acknowledgements

We would like to extend our gratitude to all of the AMPATH investigators and project teams who contributed updates for this report as well as their project sponsors who help support our research programs. We would also like to acknowledge the contributions and support of AMPATH's co-directors of research, Professors Winstone Nyandiko and Tom Inui, whose support and guidance have helped strengthen this report.

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

www.medicine.iu.edu/ampathresearch

Contents

Overview

Every six months the AMPATH Research Program compiles reports from investigators involved in more than 110 open research studies at AMPATH in Western Kenya. The following report represents our collective progress from January to June 2013 and highlights the collaborative efforts of investigators from 15 academic institutions in North America and Kenya. These studies provide critical clinical research and bioethics training opportunities for Kenyan students, increase understanding of persistant health challenges like drug resistant HIV, TB, and malaria, and help improve clinical care for chronic diseases like cancer, diabetes, and heart disease.

This report describes a research program that has grown rapidly over the last decade. It is intended to showcase our program's progress and help investigators identify opportunities to develop additional research. Updates were collected from project teams using an online survey and include a list of project team members, AMPATH project sites, sponsors and awards, a general project overview, and a brief description of progress made since January 2013. The report concludes with a bibliography of AMPATH research publications.

We hope you will visit the Research Program Website, www.medicine.iu.edu/ampathresearch, to find previous semiannual reports and additional information on how AMPATH's research programs are helping improve the health of the Kenyan people.

Research Project Updates

Project Name:	A5225/HiFLAC Protocol – A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated Cryptococcal Meningitis		
Investigator(s):	Sidle, J. Siika, S. Lagat, D.		
Start Date:	5/18/2011	**End Date:**	12/31/2013
Source of Funds:	National Institute of Allergy and Infectious Diseases	**Direct Cost (USD):**	Not Reported
Site(s):	Moi Teaching and Referral Hospital (MTRH) (Modules 1-4)		
Project Description:	A5225/HiFLAC is a phase I/II dose escalation and validation study of the safety, tolerability, and therapeutic effect of an induction-consolidation strategy of high-dose fluconazole alone for the treatment of cryptococcal meningitis (CM) in HIV-infected participants. The study will proceed in two stages. In Stage 1, Dose Escalation, up to three induction doses of fluconazole will be tested in sequentially enrolled cohorts. Stage 2, Dose Validation, will not open until the maximum tolerated dose (MTD) of fluconazole has been identified in Stage 1. In Stage 2, induction doses of fluconazole that are found to be safe in Stage 1 will be tested in simultaneously enrolled cohorts. In each stage, participants will be randomized at entry into Step 1. Over the course of the study, participants will register to subsequents steps (Steps 2-4) based on their initial randomization and/or their response to treatment. The study steps are: • Step 1: Induction therapy with either high dose fluconazole or ampho B • Step 2: Induction following early ampho B intolerance (only for participants randomized to ampho B treatment in Step 1) (fluconazole at 400-800 mg daily) • Step 3: Consolidation therapy (fluconazole 400 mg daily) • Step 4: Maintenance therapy (fluconazole 200 mg daily)		
Update: (Last updated: 7/12/2013)	A total of 16 participants have been enrolled. 14 were enrolled into cohorts 1 and 2 and all completed study follow-up. Two participants have been enrolled in the third cohort (those randomized to fluconazole arm to receive 2000mg OD), both are active on study and are doing well.		
Project Name:	A Population-wide Home-Based Study of Hypertension Prevalence in Western Kenya		
Investigator(s):	Velazquez, E. Kimaiyo, S. Akwanalo, C. Bloomfield, J. Hogan, J. Maghasi, M. Anstrom, K.,		

Start Date:	2/1/2012	**End Date:**	12/31/2013
Source of Funds:	NIH/NHLBI	**Direct Cost (USD):**	$20,000
Site(s):	Mosoriot		
Project Description:	Hypertension is one of the increasingly important health challenges facing the African continent and yet data on true community prevalence of hypertension in sub-Saharan Africa (SSA) is limited. The prevalence of hypertension in truly rural populations was said to be a rarity but this must have changed because of adoption of Western lifestyle. Recent studies indicate that the prevalence of hypertension and its clinically important outcomes is steadily increasing in SSA, more in the urban compared to semi urban and rural communities. The study will be conducted in two phases. Phase one of the study will be a cross sectional study which will be conducted on persons aged 18yrs or older from Mutwot location, Kosirai division, to assess for hypertension and diabetes mellitus. Diagnosis of hypertension and diabetes will be based on the JNC 7 and American diabetes association criteria. In the second phase of the study those individuals who are newly diagnosed with hypertension (at least 193 cases) will be assessed for target organ damage and compared to controls (386) in a 1 to 2 ratio. Target organ damage will be defined as the detection of electrocardiogram-left ventricular hypertrophy (ECG-LVH), micro albuminuria, or history of a stroke.		
Update: (Last updated: 12/31/2012)	We obtained IREC approval in August 2011 and NHLBI approval in December 2011. Training of counselors and research assistants on Diabetes and Hypertension screening and use of phone technology in data entry was completed in 2011 and included the online CITI Human Subjects Protection course. Since recruitment and screening for this study began in February 2012,the team has screened 1,586 patients in the Kosirai Division. Of these, 230 patients were referred to the clinic for confirmation of high blood pressure and 119 of referred patients have presented to the clinic. A total of 114 patients have been diagnosed with Hypertension and 5 with diabetes. We are currently awaiting IREC approval to begin a community outreach effort with the goal of tracing the participants who have not presented to the clinic. The following challenges have been identified thus far: • Screened patients do not report to designated health facilities due to lack of transport • Stigma related to HIV since HIV testing is being performed at the same time as blood pressure and diabetes testing.		
Project Name:	A Retrospective Analysis of Pregnancy Outcomes of HIV-Infected Women Enrolled in the AMPATH Program		
Investigator(s):	Bell, A. Were, E. Musick, B. Lane, K. Washington, S.		

	Shen, C. Akhaabi, P. Hogan, J. Wools-Kaloustain, K.		
Start Date:	3/1/2006	**End Date:**	5/31/2013
Source of Funds:	Not Reported	**Direct Cost (USD):**	Not Reported
Site(s):	All Sites		
Project Description:	This is a retrospective analysis of pregnancy outcomes of HIV-infected women enrolled in the AMPATH program from January 2006 to March 2009. Per protocol, pregnant women with CD4 < 200 begin cART immediately and those with a CD4 ≥ 200 start at 28 weeks gestation. The pregnancy outcomes are being compared between women pregnant at program enrollment (BE) and those who became pregnant after enrollment (AE). The specific hypotheses include: • Women who are already enrolled in the AMPATH program at the time of pregnancy diagnosis are more likely to initiate ART sooner (at a lower gestational age) than those who are not in the program prior to pregnancy diagnosis. • Women who are already enrolled in AMPATH at the time of pregnancy diagnosis are less likely to give birth to an HIV-infected baby than those who are not enrolled in the program prior to pregnancy diagnosis. • Women who are already enrolled in AMPATH at the time of pregnancy diagnosis will have better retention and adherence rates than those who are not enrolled in the program prior to pregnancy diagnosis. • Women who are already enrolled in the AMPATH program will have a lower rate of stillbirth and infant loss than those who are not enrolled in the program prior to pregnancy diagnosis.		
Update: (Last updated: 12/31/2012)	The preliminary findings were presented on January 10, 2012 at the 2nd International Conference on HIV and Women in Bethesda, Maryland. Feedback from the conferees was incorporated into the analysis plan. The dataset has been revised significantly. The analysis is underway. We expect to submit the manuscript for publication during the next quarter.		
Project Name:	A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI)		
Investigator(s):	Papas, R. Gakinya, B. Maisto, S. Martino, S. Baliddawa, J. Sidle, J. Hogan, J. Carroll, K.		
Start Date:	11/1/2011	**End Date:**	8/31/2016
Source of Funds:	NIAAA	**Direct Cost (USD):**	$2,268,832

Site(s):	Iten District Hospital Moi Teaching and Referral Hospital (modules 1-4) Turbo Health Centre Webuye District Hospital		
Project 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.		
Update: (Last updated: 7/12/2013)	Recruitment for the trial began in July 2012. We have since completed recruitment and randomization of 6 intervention cohorts, for a total of 197 participants. Participants have completed a 6-week group cognitive behavioral therapy or health education intervention delivered by paraprofessional counselors. Follow ups for participants who have completed the intervention stage began in October 2012 and are ongoing. One cohort has completed all follow ups. Target goals for recruitment and retention have been met.		
Project Name:	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)		
Investigator(s):	Siika, A. Busakhala, N. Njiru, E.		
Start Date:	11/28/2012	**End Date:**	Not Reported
Source of Funds:	The National Institute of Allergy and Infectious Diseases (NIAID) National Cancer Institute (NCI) National Institute of Dental Craniofacial Research (NIDCR)	**Direct Cost (USD):**	Not Reported
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project 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 naïve HIV-1 infected participants who are currently not receiving ART		
Update: (Last updated: 7/12/2013)	Accrual is ongoing and a total of 6 participants have been enrolled at Eldoret site. Accrual is slow since majority of the patients have advanced stage Kaposi's Sarcoma.		
Project Name:	A5265 – A Phase III, Open-Label, Randomized, Assessment-Blinded Clinical Trial to Compare the Safety and Efficacy of Topical Gentian Violet to that of Nystatin Oral Suspension for the Treatment		

	of Oropharyngeal Candidiasis in HIV-1 Infected Participants in Non-U.S. Settings		
Investigator(s):	Siika, A. Lagat, D.		
Start Date:	2/1/2012	**End Date:**	12/31/2012
Source of Funds:	The National Institute of Allergy and Infectious Diseases (NIAID) and The National Institute of Dental and Craniofacial Research (NIDCR)	**Direct Cost (USD):**	Not Reported
Site(s):	Moi Teaching and Referral Hospital (modules 1-4)		
Project Description:	A5265 is a phase III, open-label, randomized, assessment-blinded clinical trial in non-U.S. sites to compare the safety and efficacy of topical gentian violet (GV) to that of oral nystatin.Therapy will be considered as failed if participants have no clinical improvement (assessed by severity and extent of pseudomembranous candidiasis) during either treatment regimen. Evaluation of signs and symptoms of oral candidiasis (OC) will be done by an evaluator who is blinded to treatment assignment. Quantification of colony forming units (CFUs) of Candida species (spp.) and assessment of the emergence of resistance will be performed using an oropharyngeal swab and a second specimen from oral rinse/throat wash will be collected and stored for future testing		
Update: (Last updated: 7/12/2013)	Waiting for a new protocol version incorporating Data Safety and Monitoring Board (DSMB) recommendations.		
Project Name:	Addressing the Fourth Delay: Improving Communitybased Accountability for Maternal and Newborn Health		
Investigator(s):	Christoffersen-Deb, A. Songok, J. Ruhl, L. Fazen, L.		
Start Date:	12/1/2011	**End Date:**	12/1/2013
Source of Funds:	Grand Challenges Canada	**Direct Cost (USD):**	$248,000
Site(s):	Mosoriot Rural Health Training Centre Port Victoria Sub-District Hospital Teso District Hospital		
Project Description:	This project seeks to address a critical fourth delay that sustains high rates of maternal and neonatal mortality in western Kenya: the delay in a community's accountability to its mothers and infants. An innovative information technology platform that fosters rapid communication and feedback between mothers, their communities, and their healthcare providers called the Mother-Baby Health Network will be developed. This information platform will accomplish three primary objectives: (1) Facilitate home and group-based care through Community Health Workers (CHWs) to improve collective advocacy; (2) Provide communities with the capabilities to activate an emergency alert system; and (3) Foster		

	transparency in community and health system responsiveness to maternal and newborn health. CHWs will be equipped to use clinical decision-support on Android phones to correctly triage women and newborns for care. Integrated with SMS messaging, they will be capable of notifying healthcare providers, alerting nearby GPS-tracked Mother-Baby Taxis in an emergency transport system, and activating a personalized community of Mother-Baby Advocates to mobilize local resources. The Mother-Baby Health Network will strengthen dialogue between communities and facilities to create a sustainable, community-driven demand for accountable maternal and newborn care at all levels of care. Recognizing that 'it takes a village', the Mother-Baby Health Network will provide communities in western Kenya with the information and communication tools they need to ensure that every mother and child has access to essential care at time of delivery and within the first 48 hours of birth.
Update: (Last updated: 7/12/2013)	*Chama cha MamaToto* An evaluation of this program using a retrospective design with matched controls is underway. Although labour intensive, it is instrumental in providing the evidence necessary to validate this model of care. *AfyaJamii* A pre/post evaluation in facilities implementing the program is being conducted, and comparing these to facilities in the county that were not selected. Unfortunately, it has been necessary to adjust the evaluation design because of the recent announcement in June of free maternity services nationwide, thus making it all the more important to have a comparison set of facilities to assess impact. *Presentations* **April 16, 2013:** Julia Songok, Louis Fazen, Laura Ruhi, Astrid Christoffersen-Deb Site visit by US Ambassador, Robert Godec, and USAID Kenya Country Director, Karen Freeman **May 28, 2013:** Julia Songok, Astrid Christoffersen-Deb Site visit by USAID Kenya Head of Programs Mervyn Farroe and USAID Kenya MNCH Country Director, Sheila Macharia **June 20, 2013:** Julia Songok, Louis Fazen, Astrid Christoffersen-Deb Site visit by Head of Division of Community Health Services, Government of Kenya, Dr Mwitari **June 24-25, 2013:** Julia Songok, Astrid Christoffersen-Deb Site visit by leadership of AbbVie Foundation, Tracie Haas and Jeff Richardson **June 26, 2013:** Astrid Christoffersen-Deb Site visit by Abbott India representatives
Project Name:	Anticoagulation Project
Investigator(s):	Pastakia, S. Manji, I. Karwa, R. Akwanalo, C. Saina, C.

	Schellhase, E. Miller, M. Maina, M. Kanyi, J.		
Start Date:	12/1/2008	**End Date:**	12/31/2017
Source of Funds:	Purdue University College of Pharmacy; Indiana Hemophilia and Thrombosis Center; Celgene Corporation	**Direct Cost (USD):**	$100,000
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4) Webuye District Hospital		
Project Description:	A comprehensive pharmacist run anticoagulation care management system customized to a resource constrained setting has been created and implemented. The primary interventional element of this program is the creation of an organized system for INR monitoring of patients requiring anticoagulation with warfarin		
Update: (Last updated: 7/12/2013)	The patient volume in this clinic has grown significantly to over 350 active patients and over 700 patients ever enrolled. We are currently in the process of developing a medical records system that is linked to AMRS to ease the management of the large number of patient records.		
Project Name:	Assessment and Treatment of Pain in Hospitalized Patients at MTRH		
Investigator(s):	Vreeman, R. Owino, C. Gramelspacher, G. Huang, K. Njuguna, F. Hagembe, M. Strother, R. Monahan, P. Tabbey, R.		
Start Date:	3/28/2011	**End Date:**	6/30/2013
Source of Funds:	Indiana University Department of Medicine	**Direct Cost (USD):**	$1,000
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	Pain is often inadequately evaluated and treated in sub-Saharan Africa. The objectives of this study were to assess pain and pain treatment in 400 hospitalized patients at a national referral hospital in western Kenya, and to identify factors associated with pain and pain treatment. Using validated Kiswahili versions of two single-item pain assessment tools, the Numerical Rating Scale and the Faces Pain Scale-Revised, patients' pain levels were determined. Additional data collected included patient demographics, prescribed analgesics, and administered analgesics. Mean pain ratings and Pain Management Index (PMI) scores were calculated.		

	Averaged between the NRS and FPS-R, 80.5 percent of patients endorsed pain and 30 percent of patients reported moderate to severe pain. Older patients, patients with HIV, and cancer patients had higher pain ratings. 66 percent of patients had been prescribed analgesics at some point during their hospitalization, the majority of which were non-opioids. A majority of patients (66 percent) had undertreated pain (negative scores on the PMI). In conclusion, this study shows that hospitalized patients in Kenya are experiencing pain and that this pain is often under-treated.		
Update: (Last updated: 7/12/2013)	Our final manuscript has been accepted for publication by the Journal of Palliative Medicine. We are now finished with the project.		
Project Name:	Awareness Of Breast Cancer, Among Men And Women In Western Kenya		
Investigator(s):	Chite, F. A. Busakhala, N. Inui, T.		
Start Date:	10/1/2011	**End Date:**	7/1/2014
Source of Funds:	Walther Cancer Foundation	**Direct Cost (USD):**	$1,200,000
Site(s):	Mosoriot Rural Health Training Centre Mt. Elgon District Hospital Turbo Health Centre		
Project Description:	This is a questionnaire based study to evaluate the awareness of breast cancer among men and women in western Kenya. This includes questions related to their knowledge of risks for breast cancer, signs and symptoms and health seeking behaviour		
Update: (Last updated: 7/12/2013)	Data entry has been completed and data analysis is on going for the study.		
Project Name:	Biomarkers of Vincristine Toxicity in Kenyan Children		
Investigator(s):	Renbarger, J. Njuguna, F. Skiles, J.		
Start Date:	6/23/2011	**End Date:**	6/30/2014
Source of Funds:	NIH	**Direct Cost (USD):**	$8,743
Site(s):	Moi Teaching and Referral Hospital (modules 1-4)		
Project 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.		

Update: (Last updated: 7/12/2013)	This project is going quite well to date. At present, 106 subjects have been enrolled in the study. Our IREC amendment to increase our sample size and diagnostically target our population (by changing from patients with any cancer for which vincristine is utilized in the therapy to only those patients with ALL or NHL) was approved and enrollment to the study continues without incident. This work has been presented at the ASCO 2012 National Meeting and 3 publications are underway to report our findings. Additionally, a new study protocol is being developed based on the data learned from this project. The new protocol has been submitted to the Research Office and will soon undergo IREC review.		
Project Name:	Building Competencies through Bilateral International Exchanges-Using Qualitative Methods to Measure the Impact on Pediatric Residents from Host and Visiting Countries in Professionalism, Communication and Systems-Based Care		
Investigator(s):	Litzelman, D. Ayaya, S. Umoren, R. Woodward, J. Vreeman, R. Palmer, M. Stelzner, S. Lorant, D. Riner, M.		
Start Date:	11/27/2007	**End Date:**	6/30/2014
Source of Funds:	IU Office of Research in Medical Education	**Direct Cost (USD):**	Not Reported
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	This study uses focus groups to assess the impact of resident exchange project on participating residents from Indiana University School of Medicine (IUSOM), Moi University School of Medicine (MUSM), and Universidad Autonoma del Estado de Hidalgo Health Sciences Campus (UAEH) particularly related competencies in professionalism, communication, systems based practice, and practice based learning and improvement.		
Update: (Last updated: 12/31/2012)	Will recruit additional Kenyan registrars from the 2011 and 2012 groups that have completed the IU elective once study has been reapproved by IREC.		
Project Name:	Causes of early mortality in HIV-infected Africans on antiretroviral therapy		
Investigator(s):	Siika, A. Chumba, D. Buziba, N. Ayikukwei, R. Tierney, W. Wools-Kaloustian, K. Carter, J. Yiannoutsos, C.		

Start Date:	7/1/2009	**End Date:**	8/31/2013
Source of Funds:	NIH-NIAID	**Direct Cost (USD):**	$448,880
Site(s):	Moi Teaching and Referral Hospital (Modules 1-3)		
Project Description:	The autopsy study aims to determine the causes of early mortality in AMPATH -enrolled HIV-infected African patients on ART. The central hypothesis in this study is that the vast majority of early deaths in HIV infected African patients on ART are caused by treatable infectious complications. The rationale behind this research study is that interventions to interrupt early death in HIV-infected patients on ART are more likely to succeed if they target cause-specific mortality. Further, solutions to HIV care and treatment challenges in sub-Saharan Africa are more likely to be found if the research conducted addresses the region's specific healthcare needs and the results of such research can be translated into local practice. The study has two specific aims: 1. 1. To establish the causes of death by performing detailed pathological autopsies in patients who die in the first 12 months of ART. 2. 2. To develop a verbal autopsy questionnaire that is accurate, specific to HIV infection, and appropriate for identifying causes of death in resource constrained settings.		
Update: (Last updated: 7/12/2013)	The study closed enrollment in April 2013 after enrolling 350 participants. Study close-out process has been initiated and data cleaning is on-going.		
Project Name:	Cervical Cancer See and Treat: How Best to Follow-up		
Investigator(s):	Cu-Uvin, S. Omenge, E. Mabeya, H. Washington, S. Itsura, P.		
Start Date:	9/1/2011	**End Date:**	6/30/2013
Source of Funds:	Not Reported	**Direct Cost (USD):**	Not Reported
Site(s):	Chulaimbo Sub-District Hospital Moi Teaching and Referral Hospital (modules 1-4) Mosoriot Rural Health Training Centre Turbo Health Centre		
Project Description:	This is a cross sectional study involving 660 HIV-infected women attending 4 AMPATH-CCSPP (Cervical cancer Screening and Prevention Program) sites who have undergone VIA and cryotherapy >6 months for cervical dysplasia. Demographic information as well as a full medical history will be obtained. They will undergo a gynecologic examination. Women with suspected frank cervical cancer or current genital tract infection will not be enrolled and will be referred for standard of care. Women with genital tract infection will undergo syndromic treatment and will be eligible to be enrolled 3 weeks after treatment if they have cleared the infection. During the gyn		

	exam, the following will be done for all study participants: VIA, conventional Pap smear, endocervical cytobrush for HPV typing. All women with positive VIA result will undergo colposcopy and biopsy at the next available colpo/biopsy clinic day. Those with negative VIA result will return in 4-6 weeks to receive the results of their Pap smear and HPV typing. If either the Pap smear or HPV typing is abnormal, they will undergo colposcopy with biopsy on the next available colpo/biopsy clinic day. Women with negative VIA, PAP smear and HPV will follow standard of care that is annual screening with VIA. Histological diagnosis will be the gold standard. Women will be asked several questions regarding their experience.		
Update: (Last updated: 12/31/2012)	Not Reported		
Project Name:	CDC Records Study		
Investigator(s):	Tierney, W. Diero, L. Sidle, J. Wools-Kaloustian, K. Caloia, D. Spitzer, R. Ayaya, S. Songok, J. Chemwolo, B. Bell, A. Kiplagat, J. Were, M.		
Start Date:	10/1/2007	**End Date:**	12/31/2012
Source of Funds:	CDC	**Direct Cost (USD):**	$1,131,288
Site(s):	Burnt Forest Sub-District Hospital Moi Teaching and Referral Hospital (modules 1-4) Mosoriot Rural Health Training Centre Turbo Health Centre		
Project Description:	Develop a primary care module for the AMPATH rural health centers and for MTRH's TB, ANC, and Sick Child clinics. To use this module to help coordinate care among patients whose care is shared by both the primary care providers and AMPATH by adding the primary care data to the AMRS and then producing visit summaries with preventive care reminders.		
Update: (Last updated: 7/12/2013)	Study has completed and the final report has been submitted. Two papers were accepted as posters for Medinfo 2013 in Copenhagen (Aug 20-23) and a paper was published in *Pediatrics* on pediatric reminders. No further updates will be provided on this study.		
Project Name:	Childhood Leukemia in Kenya Identified Through Malaria Slide Review		
Investigator(s):	Vik, T. Njuguna, F.		

	Skiles, J. Moormann, A.		
Start Date:	7/1/2012	**End Date:**	6/30/2014
Source of Funds:	Alex's Lemonade Stand Foundation for Childhood Cancer	**Direct Cost (USD):**	$200,000
Site(s):	Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Turbo Health Centre		
Project 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.		
Update: (Last updated: 7/12/2013)	No changes, the study is progressing as planned.		
Project Name:	Comparison of Protein Energy Malnutrition and Malaria Levels in AMPATH and Non-AMPATH COBESCentres in Western Kenya		
Investigator(s):	Taylor, K. Kwena, A. MacDowell, M. Mining, S. Wakhisi, J.		
Start Date:	8/1/2011	**End Date:**	8/1/2013
Source of Funds:	Moi University	**Direct Cost (USD):**	$7,600
Site(s):	Burnt Forest Sub-District Hospital Chulaimbo Sub-District Hospital Mosoriot Rural Health Training Centre Turbo Health Centre		
Project Description:	The main objective of the study is to determine the nutritional status of children in COBES AMPATH and non-AMPATH centres. In addition, this study seeks to ascertain if the presence of AMPATH has been beneficial in elevation of malnutrition in some centres.		
Update: (Last updated: 7/12/2013)	Analysis of malaria data in AMPATH and non-AMPATH sites is ongoing before the project comes to a conclusion.		
Project Name:	Computerized Counseling to Promote Positive Prevention and HIV Health in Kenya (CARE+ Kenya)		
Investigator(s):	Kurth, A.		

	Siika, A. Sidle, J. Ayuku, D. Baliddawa, J. Fortenberry, J. D. Wools-Kaloustian, K.		
Start Date:	8/14/2009	**End Date:**	6/30/2013
Source of Funds:	National Institutes of Health / NIMH	**Direct Cost (USD):**	$1,810,361
Site(s):	Burnt Forest Sub-District Hospital Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	The specific aims of this project are: 1. Adapt a theoretically driven computerized counseling intervention (CARE+ Kenya) for use in Western Kenya (1st 18 months). 2.1.A. Conduct interviews with up to 25 HIV-positive urban and up to 25 rural men and women patients from the Academic Model Providing Access to Healthcare (AMPATH) to understand HIV and computer training needs. Conduct two staff focus groups (n~16) to assess positive prevention and ART adherence support practices, beliefs about patient computer use and training needs. 2.1.B. Using above, modify intervention content,translate and record audio files into local Kiswahili, and adapt skill-building videos on 'positive health' (prevention, disclosure, ART adherence, reproductive health, etc.). 2.1.C. Conduct iterative software usability testing with 10 urban and 10 rural patients (n=20) and 8 staff. Perform three day test-retest reliability assessment to establish psychometric performance of measures. 2.2 RCT. Establish biological and behavioral efficacy of a longitudinal HIV computerized counseling intervention in Kenya ('CARE+Kenya') (Months 18-42). 2.2.A. Longitudinal RCT in an urban and a rural clinic. Randomly assign HIV-positive adults with missed ART doses on self-report, pharmacy refill or pill counts; or unprotected sex in last 6 months, >1 partner in last year, or sexually transmitted infection (STI) in last 3 years; to intervention (n=125) or risk-assessment control (n=125) for baseline, 3, 6, and 9 month sessions. HIV transmission risk will be measured by self-reported unprotected sex with HIV-negative/unknown partner, and trends in C. trachomatis, N. gonorrhoeae, T. vaginalis. ART adherence will be measured by HIV-1 viral load at 0, 6, 9 months, and at all time points, by electronic monitoring, pharmacy refill, self-report, and clinic attendance. 2.3 Establish cost-effectiveness of computerized counseling in Kenya (Months 1-48). 2.3.A. Follow patients at the two clinics to evaluate standard of care counseling messages and collect patient time-spent data (n=100, at baseline), to determine unmet patient counseling need.		

2.3.B. Economically evaluate CARE+Kenya. If RCT shows the intervention reduces viral load and transmission risks, we will use a Bernoulli transmission dynamics model to estimate number of secondary HIV infections prevented; then create a cost-effectiveness model to calculate 2 incremental cost-effectiveness ratios: 1) cost/HIV infection averted, and 2) cost/disability adjusted life year (DALY) saved.

2.3.C. If CARE+ Kenya is efficacious and efficient, we will develop a proposal for a cluster-randomized trial to assess translational effectiveness of CARE+ Kenya throughout the AMPATH system.

Update:
(Last updated: 7/12/2013)

Achievements

1. *Study Exits*
   The majority of study participants were successfully exited at MTRH Module 1 and Burnt Forest by end of April 2013. Below is a summary table of clients exiting the study for both MTRH Module 1 and Burnt Forest:

Study Site	**Study ARM**	**Control ARM**	**Totals**
Burnt Forest	53	55	108
MTRH Module 1	60	55	115
Totals	*113*	*110*	*223*

2. *Lost to Follow-up*
   Lost to Follow-up has been reduced considerably from the last report. The following table below summarizes current numberof study subjects lost to follow up.

Study Site	**Study ARM**	**Control ARM**	**Totals**
Burnt Forest	0	0	0
MTRH Module 1	4	5	9
Totals	*4*	*5*	*9*

3. *No Cost Extension*
   We are planning to initiate activities for the no cost extension that will add an implementation phase to the current project. Activities will focus on real-world implementation of the tested ACASI Computerized Counseling Tool. Because of budget and time limitations, the study will focus on implementation only at the AMPATH Centre in MTRH. Our experiences from this implementation period will inform development of larger applications to NIH and foundations for more widespread implementation of the tool.
4. *Support Visits*
   Care+ Programme Director from NYU came to Kenya for two weeks (One week in April and one week in May 2013) to oversee the CARE Plus Kenya team during the exit of study participants in MTRH Module 1 and Burnt Forest and hold talks with the data team on the study timelines.
5. *QA/QC*
   Study investigator, Joyce Baliddawa, has been submitting weekly Quality Assurance (QA) reports for the RCT procedures and documentation to Principal Investigators
6. *Psychological Findings*

The psychological findings we have documented for MTRH Module 1 and Burnt Forest since recruitment began are summarized in the following table:

Site	IPV	Depression	Suicide
MTRH Module 1	120	43	80
Burnt Forest	80	13	22
Totals	*200*	*56*	*102*

All participants were referred to AMPATH Psychosocial Department for further intervention purposes by the study protocol (including following assessment with Psychiatry), especially for those with potentially suicidal thoughts.

7. *Lab Testing Results*

All MTRH Module1 lab results have been filed to the respective participant's files and another copy into their regular AMPATH file. All those with positive Trichomonas Vaginalis results, are recalled for further care. Test result and treatment guideline sheets are provided for reporting test results and suggested treatment back to the clinics. All Viral Load results that come back and copies/ml is >5000, Trichomonas, GC or CT is Positive are added to the patient's file for further treatment. The following table summarizes the lab findings since recruitment began.

Burnt Forest

	Baseline	Exit	Totals
Viral Load >5000 copies/ml	16	11	27
Neisseria gonorrhea Positive	2	2	4
Chlamydia trachomatis Positive	2	0	2
Trichomonas Positive	10	3	13

MTRH Module 1

	Baseline	Exit	Totals
Viral Load >5000 copies/ml	25	15	40
Neisseria gonorrhoeae Positive	4	4	8
Chlamydia trachomatis Positive	2	1	3
Trichomonas Positive	3	1	4

8. *Communications*

The study team has kept abreast with the study activities on a weekly basis via Skype conference calls. The study coordinator and NYUCN research scientists have provided weekly reports and study updates to the study team.

9. *Challenges*

Death of Participants – We had three dead study participants (2 from MTRH Module 1 and 1 from the Burnt Forest study site). It is not believed that these participant's death were as a result of their enrollment in the CARE+ Kenya study but rather as a direct result of their complicated AIDS diseases.

10. *Publications*

Several scientific presentations have been made since the beginning of the studies and have already been reported including the following:

Kurth A, Baliddawa J, Were M, Sidle J, Ayuku D, Koster A, Owino R, Ochieng D, Jakait B,

	Chirchir T, Abiero C, Macharia S, Mule C, Siika A. *Adapting a patient-centered computerized counseling tool to support positive prevention and ART adherence*. International AIDS Society Scientific Meeting, Rome July 2011. Kurth A, Baliddawa J, Were M, Sidle J, Ayuku D, Koster A, Owino R, Ochieng D, Jakait B, Chirchir T, Abiero C, Macharia S, Mule C, Siika A. *User-centered Design for Mobile Health Intervention Content in a Low-Income Setting.* NIH mHealth Summit, Washington DC, November 2010. Kurth A, Kitani T. *Information & communication technologies for HIV: Sustainability*. Panel lead, Collaborative Group Meeting, Nairobi Kenya January 2010. Kurth A ,Sidle J, Siika A, Macharia S, Baliddawa J, Sirois A, Kessler J, Wools-Kaloustian K. *Randomized controlled trial of a computerized counseling tool for persons living with HIV in western Kenya: Baseline characteristics*. IAS Intl AIDS Conference (July DC, USA). The time motion subs-study data have been analyzed and a manuscript has been submitted. The CARE+ Kenya study team would like to thank AMPATH for their ongoing support and the opportunity to report our progress.

Project Name:	Cross-Cultural Histories of Family Care-Giving to AIDS Orphans in Western Kenya		
Investigator(s):	Dickerson-Putman, J. Maithya, H.		
Start Date:	9/1/2009	**End Date:**	5/30/2014
Source of Funds:	IUPUI Research Support Funds Grant	**Direct Cost (USD):**	$35,000
Site(s):	Chulaimbo Sub-District Hospital Mosoriot Rural Health Training Centre		
Project Description:	The overall goal of the project is to complete an anthropological and clinic-based study that seeks to understand the history of the care-giving experiences of primary providers of care-giving to AIDS orphans in Kenya among two different cultural groups served by the same AMPATH support program.		
Update: (Last updated: 7/12/2013)	Data collection and follow-ups were completed on both sites. Codebook completed for one site and first draft completed for second site. Coding and formal analysis to begin September 2013.		

Project Name:	Descriptive Study of Patients Seeking Emergency Care in Western Kenya		
Investigator(s):	House, D. Nyabera, S. Kurt, Y.		
Start Date:	1/1/2011	**End Date:**	12/20/2012
Source of	Not Reported	**Direct Cost (USD):**	Not Reported

Funds:			
Site(s):	MTRH Accident & Emergency Department		
Project Description:	Descriptive study of patients seeking emergency care at MTRH for the year of 2011. Data includes demographics, diagnosis, and disposition. The data will allow for assessment of needs for the department.		
Update: (Last updated: 7/12/2013)	Collected information regarding demographics, chief complaints, diagnoses, admission for all patients seen in the MTRH Accident and Emergency Department for the 2011 calendar year. Study has been completed, written up and accepted for publication by *African Journal of Emergency Medicine*		
Project Name:	Diabetes Mellitus and Glucose Intolerance in HIV Patients in Western Kenya		
Investigator(s):	Carter, J. Kirui, N. Kamano, J. Diero, L. Chege, P. Pastakia, S. Gardner, A. Mwangi, A.		
Start Date:	9/3/2012	**End Date:**	8/31/2015
Source of Funds:	Not Reported	**Direct Cost (USD):**	Not Reported
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4) Webuye District Hospital		
Project Description:	The goal of this study is to determine the association between diabetes mellitus, glucose intolerance, and HIV among HIV positive patients in Western Kenya. In this study, we propose that HIV and ART use increases the risk of diabetes mellitus and glucose intolerance among HIV patients in Western Kenya.		
Update: (Last updated: 12/31/2012)	Not Reported		
Project Name:	Drug resistance in HIV infected Children after Failure of Prevention of Mother to Child Transmission in Western Kenya		
Investigator(s):	Kantor, R. Nyandiko, W. Vreeman, R. Songok, J. Diero, L. Kosgei, R. Ayaya, S.		

Start Date:	5/3/2011	**End Date:**	4/10/2014
Source of Funds:	Not Reported	**Direct Cost (USD):**	Not Reported
Site(s):	Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Turbo Health Centre		
Project Description:	The project seeks to determine the proportion of children becoming HIV infected despite interventions of pMTCT,and the type, if any of antiretroviral drug resistance in those children who get HIV infected after failure of pMTCT.		
Update: (Last updated: 7/12/2013)	To date, the study has enrolled a total of 14 study participants, 9 at MTRH, 5 at Kitale and 0 at Turbo. These 14 participants have all been consented. One participant was enrolled since the last update. This participant was recruited at Kitale site. No participants have withdrawn from the study. The recruitment is ongoing and is still slow due to few patients turning positive after undergoing the vibrant PMTCT program offered by AMPATH.		
Project Name:	EARNEST: A randomised controlled trial to evaluate options for second-line therapy in patients failing a first-line 2NRTI+ NNRTI regimen in Africa		
Investigator(s):	Wools-Kaloustian, K. Siika, A.		
Start Date:	2/9/2011	**End Date:**	12/31/2014
Source of Funds:	European and Developing Countries Clinical Trials Partnership (EDTP), Medical Research Coucil, Institito de Salud Carlos, Irish Aid, Swedish International Development Cooperation Agency (SIDA), and Istituto Superiore di Sanita (ISS)	**Direct Cost (USD):**	Not Reported
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	EARNEST is a three arm parallel group, open-label, multi-centre, randomised controlled trial. 1200 patients will be included who are HIV-infected adults who have taken a first-line NNRTI-based regimen continuously for a total period of at least 12 months, and developed treatment failure defined by modified WHO 2010 criteria as one of the following: • New WHO Stage 4 event (with CD4 < 200 cells/mm3 and viral load (VL) > 400 copies/ml) • CD4 < 100 cells/mm3, or CD4 fall to pre-treatment baseline or below, or CD4 < 200 cells/mm3 X 2 with previous CD4 > 400 cells/mm3 (with VL > 400 copies/ml) • VL > 5,000 copies/ml ×2 The trial aims to determine whether, in patients failing a first-line NRTI and NNRTI-containing regimen 1. bPI plus raltegravir (an integrase inhibitor) is superior to standard of care (bPI plus 2 new NRTIs) in achieving good HIV disease control at 96 weeks after randomisation. 2. bPI monotherapy is non-inferior to standard of care in achieving good HIV disease control at 96 weeks after randomisation		

Update: (Last updated: 7/12/2013)	The study closed to accrual in April 2011. Majority of the participants are now on their week 112 of study follow-up and are doing well. Participants will complete the study follow-up period (week 144) between December 2013 and April 2014.		
Project Name:	Enhancing Infant Feeding Options for HIV Infected Mothers		
Investigator(s):	Wools-Kaloustian, K. Nyandiko, W. Bucher, S. Musick, B. Nyunya, B. Yiannoutsos, C.		
Start Date:	1/10/2006	**End Date:**	12/1/2012
Source of Funds:	Indiana University Center for AIDS Research	**Direct Cost (USD):**	$20,000
Site(s):	Burnt Forest Sub-District Hospital Chulaimbo Sub-District Hospital		
Project Description:	The purpose of this study is to determine if questionnaires administered within the clinic can be used to help decide which HIV- infected women should be encouraged to breastfeed and which should be educated about formula feeding their infants. In addition this study will help us to understand why some women choose to mix breast feeding with other types of foods.		
Update: (Last updated: 12/31/2012)	Not Reported		
Project Name:	Enhancing Training for Implementation Research in Chronic Disease: CITE/Kenya		
Investigator(s):	Inui, T. Ayuo, P. Siika, A. Litzelman, D.		
Start Date:	10/1/2012	**End Date:**	9/30/2016
Source of Funds:	NIH (Fogarty)	**Direct Cost (USD):**	$862,970
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	An innovative clinical and implementation research training program for Kenyan investigators, one built on the foundation of the highly successful and mature clinical and implementation research core curriculum for young investigators within our IUSM CTSI, will be developed. This program will attract graduate trainees nominated by faculty at Moi University schools of medicine, public health, dentistry, nursing, and possibly young faculty from health-related behavioral and social science programs at Moi. This curriculum will be presided over by seasoned Eldoret-based investigators from the AMPATH		

	research network (especially Dr. Thomas Inui and his 5 co-directors of the AMPATH Field Research program). Trainees who complete the core curriculum will be eligible to compete for resources to propose and conduct research in an implementation research practicum under the supervision of a tailored mentorship panel populated by Moi and international faculty. This research will focus upon a chronic disease of importance to the health of the populations in Western Kenya and will contribute to the improvement of health care processes, including village-based processes, medical and psycho-social services, and integration of care for chronic conditions within the MOH delivery system. The 'laboratory' for this research will be the AMPATH-MOH chronic disease program. The training program will build on the successful AMPATH multi-disciplinary and multi-institutional research foundation already in place, supported by AMPATH's remarkable e-Health infrastructure. This program's graduate training will enable Kenyans to acquire knowledge and skills in health systems and implementation research, enhance their capacity to promote continuous improvement of health care, inform health policy, and acquire leadership and management skills needed to develop, manage and improve chronic disease control programs. The ultimate aim of this proposal is to prepare Moi health professionals to serve as effective change agents and scientific leaders in Kenya's evolving system of care.
Update: (Last updated: 7/12/2013)	The first cohort of CITE/Kenya trainees have successfully completed their first quarter of training in Indianapolis, are establishing their mentor panels and deliberating their options for practicum research. After semester break in Eldoret, they will return to Indianapolis, IN, for their second quarter of courses in September. The second cohort of (3) trainees has been selected. The core curriculum for the Eldoret-based CITE curriculum is being recorded for DVD production and is scheduled for launching in September 2013.

Project Name:	Evaluating Handheld Clinical Decision Support Tools to Improve Community-Based Delivery of Reproductive and Pediatric Health Services		
Investigator(s):	Christoffersen-Deb, A. Chemwolo, B.		
Start Date:	12/1/2011	**End Date:**	9/1/2013
Source of Funds:	Grand Challenges Canada	**Direct Cost (USD):**	$97,361
Site(s):	Mosoriot Rural Health Training Centre		
Project Description:	The primary aim is to evaluate the effectiveness of a handheld CDS system in a cluster randomized-controlled trial among 89 community health workers (CHWs) in Kosirai district over a 4-month enrollment period. By using data collected on the existing CHW Initial Encounter Form and interfacing with AMPATH's electronic medical record system, we will identify and categorize women according to well-defined antenatal risk criteria and deliver patient-specific 'Smart Forms' to each pregnant woman served by enrolled CHWs. This research has four objectives: 1) Evaluate comparatively the effectiveness of handheld CDS to improve community-based health service delivery 2) Evaluate the effectiveness of incorporating patient-specific multimedia Information, Education and Communication (IEC) materials into Smart Forms for generating behavior change among clients		

	3) Determine the cost-effectiveness of a CDS Smart Forms system employed by CHWs and 4) Assess qualitatively the process of implementation of the Smart Forms system, including the technical specifications, human capacity requirements, and acceptability among providers and clients.		
Update: (Last updated: 7/12/2013)	No cost-extension granted until September 2013.		
Project Name:	Evaluation of A Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy (CAMP study)		
Investigator(s):	Vreeman, R. Nyandiko, W. Inui, T. Tierney, W. Tu, W. Marrero, D. Ayaya, S. Blaschke, T. Arpadi, S. Caroll, A. Bell, D.		
Start Date:	9/11/2009	**End Date:**	2/28/2014
Source of Funds:	National Institute of Mental Health (NIH-NIMH) and USAID PEPFAR	**Direct Cost (USD):**	$1,336,011
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	The primary objective of this study is to develop and test a reliable, valid instrument to measure pediatric ART adherence for children ages 0 to 14 years in western Kenya and to evaluate which administration strategy yields the most accurate information about children's ART adherence. We will pursue the following four specific aims: • Aim 1: Develop a reliable, valid comprehensive pediatric ART adherence measurement questionnaire (CAMP - Comprehensive ART Measure for Pediatrics); • Aim 2: Develop a reliable, valid, short-form version of the pediatric ART adherence measurement tool (SF-CAMP) for use as an adherence screening measure in busy clinical care environments; • Aim 3: Evaluate the field- readiness, implementation feasibility, and clinical utility of CAMP and SF-CAMP within the AMPATH HIV clinical care system in western Kenya; and • Aim 4: Evaluate the reliability and validity of this measurement tool in a clinic-based care setting compared to a home-based care setting.		
Update: (Last updated: 7/12/2013)	Validation of Adherence Measures (CAMP Phases 1 and 2): *Phase 1* A battery of ART adherence measurement items were compiled for testing in Kenya from both		

literature review and formative qualitative work. Items were compiled, translated into Kiswahili, and adapted to increase face validity through cognitive interviews with pediatric caregivers and HIV-infected children ages 13-18 years. The interviews were transcribed and coded, with data for each measurement item summarized qualitatively and quantitatively. A testing report with recommendations for item adaptation was created and used to modify the adherence measurement items. A manuscript describing the findings of the cognitive interviews on adherence measurement items is now in press at the International Journal of Behavioral Medicine.

Phase 2

The clinical research phase of the project assessing the reliability and validity of the pediatric ART adherence measurement items for HIV-infected children in Kenya was completed. A total of 211 participants were enrolled with 200 HIV-infected children on ART completing six months of comprehensive monthly adherence assessments, MEMS® monitoring of dose timing, plasma drug concentrations, and clinical follow-up including CD4 counts. Data analyses to finalize a validated, comprehensive adherence measurement questionnaire (the CAMP questionnaire) are almost complete. Extraction of questionnaire items to test as a short form (SF-CAMP), to evaluate as per Specific Aim 2 in a cohort of 100 children is ongoing.

Phase 3

Phase 3 is currently assessing the validity of a short-form adherence assessment tool in a sample of 100 children. A total of 105 children have been enrolled thus far. Monthly follow-ups with these children will be conducted for a period of six months.

Comparison of Home-Based and Clinic-Based Adherence Measurement (Phases 4 and 5, PEPFAR PHE Funding)

These research activities examine home vs. clinic-based strategies of adherence measurement yield in this setting. The study will assess whether administering the comprehensive adherence assessment items in a home setting yields more reliable or valid data than the clinic-based assessments using the same questionnaire items.

Phase 4

The feasibility of these measurement strategies were assessed, enrolling 41 children from the Turbo and MTRH clinics and ultimately assessing 40 with either home- or clinic-based evaluations.

Phase 5

Phase 5 was successfully implemented over the past 6 months and focused on activities to eliminate longitudinal follow-up. Comprehensive pediatric adherence assessments were conducted at four AMPATH clinical sites: MTRH, Turbo, Webuye, and Kitale. A total of 408 participants were enrolled in the MTRH, Webuye and Turbo and Kitale sites, of which 302 were randomized to clinic assessments and 105 to the home and clinic group. Only 11 participants have withdrawn from the study. Adherence assessments have been completed for 387 children. Data entry and subsequent analysis of the home- vs. clinic-based adherence assessments are ongoing.

Project Name:	Exploring factors that support a sustainable model for engaging and retaining CHWs in the PHC program of AMPATH (CHW Incentive Project)		
Investigator(s):	Mitra, S. Menya, D. Jackson, S. Christoffersen-Deb, A.		
Start Date:	1/7/2013	**End Date:**	8/9/2013
Source of Funds:	Dalla Lana School of Public Health, University of Toronto	**Direct Cost (USD):**	$5,000
Site(s):	Port Victoria Sub-District Hospital Turbo Health Centre		
Project Description:	Since 2011, AMPATH has supported approximately 1,200 Government of Kenya Community Health Workers (CHWs) in various health promoting primary health care activities, such as maternal and child health and nutrition, by providing CHWs with individual financial compensation of 2,000 Kenyan Shillings (approximately $23 US dollars) per month, according to Kenyan government policy recommendations. However, AMPATH plans to end individual compensation to CHWs in the Fall of 2013. Thus, it is important to determine some of the other forces, which influence CHW motivation in this particular context. This qualitative research study will explore the work of AMPATH's primary health care CHW's in the context of Western Kenya and inform the development of a more sustainable model for AMPATH's primary health care program from the perspective of AMPATH-supported CHWs and primary health care staff in close proximity to CHWs. The study aims to: (1) Explore ways in which CHWs perceive their expected roles as manageable or unmanageable; (2) Determine financial and nonfinancial factors that motivate CHWs to perform their expected roles; and (3) Explore some of the environmental and contextual factors, specific to Western Kenya that are essential to keeping CHWs motivated to perform their expected roles.		
Update: (Last updated: 7/12/2013)	The project received ethics approval from University of Toronto in April 2013, and IREC approval from Moi University on June 26, 2013. Four focus groups are scheduled to be conducted with approximately 40 community health volunteers in July. Additionally 10 to 12 key interviews with staff who work with CHVs will be done in July. The data will be analyzed and a final report will be written by the end of August 2013.		
Project Name:	Facilitators and Barriers to Initiation of Antiretroviral Treatment Among Pregnant Women Living with HIV Receiving Antenatal Care in Western Kenya: An Evaluation		
Investigator(s):	Robinson, S. Braitstein, P. Kaaria, A.		
Start Date:	5/20/2013	**End Date:**	8/9/2013
Source of Funds:	Not Reported	**Direct Cost (USD):**	Not Reported
Site(s):	Chulaimbo Sub-District Hospital		

	Kitale District Hospital Moi Teaching and Referral Hospital (Modules 1-4) Kitale Nursing Home, Chemasiri Dispensary, Akichelesit Dispensary, others to be selected
Project Description:	This project is a Masters of Public Health student practicum and involves an internal evaluation in collaboration with the PMTCT team. The main purpose of the evaluation is to explore the factors affecting the initiation of antiretroviral treatment (ART) among pregnant HIV positive women attending AMPATH-affiliated antenatal clinics in western Kenya. The main objectives are as follows: 1. To explore and evaluate factors related to ART initiation among pregnant HIV-positive women, enrolled in care at AMPATH sites in western Kenya 2. To highlight facilitators and barriers to initiation of ART: a. for women attending antenatal care facilities; and b. for women newly enrolled at HIV CCCs 3. To provide recommendations based on the findings to increase uptake of ART among HIV positive pregnant women attending AMPATH-affiliated antenatal and HIV CCCs. Data will be collected through clinic observations and interviewer-led questionnaires with health care providers.
Update: (Last updated: 7/12/2013)	This project commenced in May 2013. Preliminary observational data has been collected from three sites. Quarterly PMTCT data has been reviewed and sites providing antenatal services have been selected for targeted clinic observations and interviewer-led questionnaires. A data request was logged and following receipt of the data, analysis and site selection will take place to target HIV CCCs for inclusion in the evaluation. A literature review and conceptual model have been completed. The expected end date for this project is August 2013.

Project Name:	Feasibility Intervention Trial of Two Types of Improved Cook Stoves in Three Developing Countries		
Investigator(s):	Miranda, J. Menya, D. Checkley, W. Carter, J. Ogaro, F. Diero, L. Mwangi, A.		
Start Date:	7/1/2011	**End Date:**	6/30/2014
Source of Funds:	NHLBI	**Direct Cost (USD):**	$76,239
Site(s):	Ndanai Sub-Location Burnt Forest		
Project Description:	This is a multi-center community-based feasibility trial in which improved cook stoves with a chimney will be installed in 40 rural households of women aged 20 to 49 years at each of the three sites. All households will have a baseline observational period of 4 months in which outcome, environmental, and behavioral data will be collected longitudinally. Thereafter, 20 households will		

	be randomly assigned to receive a commercially-available, improved cook stove with a chimney or a locally-constructed improved cook stove with a chimney. Behavioral, compliance, outcome and exposure data will be collected longitudinally for 4 months. Exposure assessments will include particulate matter and carbon monoxide. Respiratory outcome assessments will include spirometry, carboxyhemoglobin, exhaled nitric oxide and diffusing capacity of the lung for carbon monoxide. At the end of the 4 month period, households that received the Envirofit improved cook stoves will have their cook stoves switched with the locally-constructed improved cook stoves and vice versa, and all households will be followed for another 4 months. At the end of the year, all participants will be asked which cook stove they prefer and will be asked provide information on preferences, practices, and use patterns that influenced their final choice.		
Update: (Last updated: 7/12/2013)	Completed enrolment on 9 January 2013 and follow-up is ongoing.		
Project Name:	Health Facility Incentives to Improve Adherence to Malaria Diagnostic Test Results		
Investigator(s):	O'Meara, W. Menya, D. Armstrong, J. Manji, I.		
Start Date:	4/1/2012	**End Date:**	3/31/2014
Source of Funds:	NIH	**Direct Cost (USD):**	$250,000
Site(s):	Not Reported		
Project Description:	Global investments in controlling malaria have led to some exciting reductions in the burden of malaria. In some areas, malaria-related deaths have dropped by more than 90 percent. As malaria transmission declines, a greater fraction of pediatric fevers are from other causes. However, these fevers continue to be treated as malaria, often despite the availability of diagnostic testing. In a typical rural health facility in Kenya, more than 90 percent of febrile patients are prescribed an antimalarial when no diagnostic tests are available. Even when microscopy or rapid diagnostic tests (RDTs) are available, between 50-80 percent of patients with a negative test are nonetheless prescribed antimalarials. Inappropriately treated fevers in children can lead to serious consequences for the patient and can accelerate the spread of drug resistance. In addition to the risk to patients, overuse of antimalarials also puts a financial strain on the government health system. This project aims to test an innovative, sustainable financial incentive designed to reduce the number of non-malarial fevers that are treated inappropriately with antimalarial drugs. This study will test a financial incentive targeted at the health facility to determine if it improves adherence to diagnostic results and clinical protocols. Eighteen rural health facilities in western Kenya will be enrolled and randomly allocated to one of two arms. We will compare the effectiveness of clinical and technical training in diagnosis of malaria alone (Arm 1) to training plus financial incentives linked to prescription practices (Arm 2) in improving diagnosis and treatment of malaria and non-malaria fevers. The practice of prescribing antimalarials to patients with a negative diagnostic will be compared between facilities with and without the incentive structure. Secondary outcomes will include sensitivity and specificity of routine microscopy at health centers,		

	use of alternative treatments for slide negative fevers, and frequency of stock-outs of antimalarial drugs. This project will be conducted in collaboration with Kenya's Division of Malaria Control and avenues to roll-out the intervention, if successful, will be actively explored.		
Update: (Last updated: 7/12/2013)	The Study is currently in the third quarter of the financial incentives calculation`for all the facilities, both in Western province and Rift-Valley province. There has been an increase in the sensitivity and specificity of malaria diagnosis in all the facilities. A reduction in AL consumption has been observed as well.		
Project Name:	HIV Testing Uptake and Prevalence Among Adolescents and Adults in a Large Home-Based HIV Testing Program in Western Kenya		
Investigator(s):	Braitstein, P. Wachira, J. Ndege, S. Koech, J. Vreeman, R. Ayuo, P.		
Start Date:	Not Reported	**End Date:**	9/30/2013
Source of Funds:	USAID	**Direct Cost (USD):**	Not Reported
Site(s):	Not Reported		
Project Description:	The objective of the study was to describe HIV testing uptake and prevalence among adolescents and adults in a home-based HIV counseling and testing (HBCT) program in Western Kenya. We used AMPATH-HBCT data collected between November 2009 and January 2012 from five of the eight catchment areas (Burnt Forest, Chulaimbo, Teso, Port Victoria and Kapsaret). All individuals aged ≥13 years, eligible for HBCT, were included in the analysis. The study applied descriptive statistics and multivariate logistic regression to examine testing uptake and HIV prevalence among adolescents (13-18 years), younger adults (19-24 years), and older adults (≥25 years).		
Update: (Last updated: 7/12/2013)	From our findings we made a poster presentation at the 2013 International Workshop on HIV Observational Databases (IWHOD) in Croatia and an oral presentation at the 2013 International Association for Adolescent Health (IAAH) Conference in Turkey. Our manuscript, *HIV testing uptake and prevalence among adolescents and adults in a large home-based HIV testing program in western Kenya*, has been accepted for publication in the Journal of Acquired Immune Deficiency Syndromes.		
Project Name:	Improving Diabetes Management and Cardiovascular Risk Factors Through Diabetes Peer Group Education In Western Kenya		
Investigator(s):	Bloomfield, G. Kamano, J. Nyabundi, J. Pastakia, S. Park, P. Wambui, C.		
Start Date:	2/13/2013	**End Date:**	12/31/2013

Source of Funds:	Fogarty - NIH, NHLBI - NIH, Duke Global Health Institute	**Direct Cost (USD):**	$15,000
Site(s):	MTRH Ziwa		
Project Description:	This project will seek to assess the hypothesis that diabetes education through peer support groups in western Kenya will be feasible and significantly improve diabetes knowledge-base and diabetes control in comparison to routine care.		
Update: (Last updated: 7/12/2013)	Sonak Pastakia has been added as a PI and Sabina Atieno has been added as a research assistant. Enrollement has been completed and education of Peer Leaders has been completed. Peer groups have started meeting in June 2013 and will continue through November 2013.		
Project Name:	Increasing Animal Source Foods in Diets of HIV-Infected Kenyan Women and their Children		
Investigator(s):	Ernst, J. Ettyang, G. Neumann, C. Nyandiko, W. Siika, A.		
Start Date:	10/1/2006	**End Date:**	7/31/2013
Source of Funds:	NIH	**Direct Cost (USD):**	$2,943,346
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4) Soy Health Centre Turbo Health Centre Mautuma		
Project Description:	The study is a three arm randomized, blinded and controlled nutrition intervention trial that tests the effect of iso-caloric biscuit supplements of meat, soy or wheat protein added to the diets of drug naive HIV-infected Kenyan women and their children-8 years and younger and who live in the Turbo environs and who receive care at one of the AMPATH clinics (Turbo, Soy, Mautuma, and MTRH). The women are of reproductive age and at enrollment WHO stage I or II. The biscuits are provided five days a week (Monday to Friday) to subject mother and child, using directly observed therapy (DOT) for 18 months. The outcome variables include estimates of lean and fat mass, quality of life, strength measures, biochemical indicators of nutritional status, indicators of immune function, measures of inflammation, nutrient intake, food security, measures of growth and development in children and activities of daily living.		
Update: (Last updated: 12/31/2012)	Data collection was completed June 2012. Project activities included data entry and data cleaning. A no cost extension was granted until July 31, 2013.		
Project Name:	Indiana University-Moi University Academic Research Ethics Partnership		
Investigator(s):	Meslin, E. Ayuku, D		

	Were, E.		
Start Date:	5/31/2012	**End Date:**	5/31/2017
Source of Funds:	NIH – Fogarty International Center	**Direct Cost (USD):**	$1,250,000
Site(s):	MTRH Moi University		
Project Description:	The IU-Moi AREP is funded for five years with a $1.25 million grant from the Fogarty International Center at the National Institutes of Health to establish a new research ethics training partnership with colleagues at Moi University in Eldoret, Kenya. IU-Moi AREP is a curriculum development and training initiative that builds on longlasting partnerships and collaborations in East Africa. IU-Moi AREP has developed two Masters' degree programs:one at Indiana University-Purdue University Indianapolis and one at Moi University in Eldoret, Kenya.These graduate programs have common overlapping components,joint advisory committes,shared dissemination plans and harmonized evaluation strategies. Both programs include a curriculum involving required core courses, electives and a practicum experience, part of which is taken at the counterpart university. Besides, each IU-Moi AREP partner convenes an annual Teaching Skills in International Research Ethics(TaSkR) workshop to provide training to approximately 40 faculty and students each year.		
Update: (Last updated: 7/12/2013)	The fifth annual Teaching Skills in International Research Ethics (TaSkR V) workshop to provide training to faculty and students was held in Indianapolis on 17-19 April 2013, and the theme for the workshop was *Personhood*. The keynote address during the workshop focused on bioethics and an African value system and was presented by Segun Gbadegesin. The agenda included topics on Ubuntu for International Research Ethics, Teaching Research Methods for Empirical Research on Research Ethics, Personhood: African and Western Perspectives, Finding what you need? Open Access and International Research Ethics as well as Community Engagement to Shape Consent Processes for Vulnerable Populations in Kenya. Moi was represented by Prof. David Ayuku, Prof. Joseph Kahiga and Prof. Eunice Kamaara. Short course training in International Health Research Ethics for researchers and administrators was not conducted during this period due to budgetary issues resulting from the funding of the program at 50% at the beginning of the year.		
Project Name:	Indoor Air Pollution and Its Resultant Health Effects in Kenya and Bangladesh		
Investigator(s):	Alam, D. Menya, D.		
Start Date:	7/1/2012	**End Date:**	6/30/2013
Source of Funds:	NHLBI	**Direct Cost (USD):**	Not Reported
Site(s):	Turbo Area Kaptagat Area		
Project Description:	This study is a pre-post interventional trial in 50 randomly selected households in one community in the Kaptagat Forest region of Western Kenya. The purpose of this study is to evaluate the potential respiratory health benefits of reducing indoor air pollution (IAP) by replacing traditional solid fuel stoves with more fuel-efficient, low emission locally improved stove among 50 women and 50 children <10 years of age. The study will also perform a randomized controlled trial of 25 households to evaluate the potential benefit of an enhanced stove education program in		

	improving acceptance of the locally improved stove. Similarly, we will conduct a pre-post interventional trial in 50 randomly selected households in the Turbo region of Western Kenya. However, in this community, we will first undertake a 3 month long stove sensitization program prior to placement of the locally improved stoves.
Update: (Last updated: 7/12/2013)	Enrollment is expected to start in July 2013.

Project Name:	International epidemiologic Databases to Evaluate AIDS (IeDEA)		
Investigator(s):	Wools-Kaloustian, K. Ayaya, S. Diero, L. Busakhala, N. Chite, F. Buziba, N. Patel, K. Sidle, J. Omeara, W. Cohen, C. Bukusi, E. Ssali, J. Bwana, B. Muyindike, W. Martin, J. Geng, E. Kambugu, A. Easterbrook, E. Nalugoda, F. Kiggundu, V. Somi, G. R. Swai, R. Ramadahn, A. Lyamuy		
Start Date:	6/20/2006	**End Date:**	7/31/2016
Source of Funds:	NIH	**Direct Cost (USD):**	$2,533,231
Site(s):	All Sites		
Project Description:	The International epidemiologic Databases to Evaluate AIDS Initiative (IeDEA) will establish international regional centers for the collection and harmonization of data and the establishment of an international research consortium to address unique and evolving research questions in HIV/AIDS currently unanswerable by single cohorts. High quality data is being collected by researchers throughout the world. The IeDEA initiative provides a means to establish and implement methodology to effectively pool the collected data		

	and thus providing a cost effective means of generating large data sets to address the high priority research questions. Combination of data collected under various protocols is frequently very difficult and not as efficient as the collection of pre-determined and standardized data elements. By developing a pro-active mechanism for the collection of key variables, this initiative will enhance the quality cost effectiveness and speed of HIV/AIDS research.
Update: (Last updated: 7/12/2013)	As of mid-February 2013, there were a total 149,604 ever enrolled patients, HIV exposed/known HIV positive included in the IeDEA database. AMPATH has over 70,000 active patients with about 52,000 active on highly active retroviral therapy. Of the 116, 600 adults ever enrolled, over 55,500 are active and almost 47,000 are on highly active retroviral therapy. Of the 33, 004 children ever enrolled, close 15,000 are active, of these over 4,800 are on highly active retroviral therapy. *Current Ongoing IeDEA Projects* 1. National Cancer Institute Supplement to East Africa IeDEA: Improving Kaposi's Sarcoma and Lymphoma Diagnostics as well as Assessing Sarcoma Incidence in Western Kenya 2. Building off the HIV Platform: Extension of Pharmacovigilance to Populations with Tuberculosis or Malignancies. 3. TB supplement to IeDEA. *New IeDEA Projects* 1. Prevalence and impact of Alcohol Use in Patients enrolling in HIV care - New: Approval by IREC end of March 2013, study to commence momentarily IREC has recently approved the study end of March 2013. The study commence early June 2013. Currently, as of 28th June we had 57 subjects enrolled. It is estimated that about 300 patients will be enrolled into this study from The MTRH adult Module 2 and 3. Enrolment of subject will begin, and data entry and cleaning to follow. 2. Survival among HIV-infected Patients with Kaposis's sarcoma in Sub-Saharan Africa in the Era of potent Antiretroviral Therapy - IREC Approved and the study is ready to commence. A list is being currently generated for patient follow-up. At AMPATH we anticipate to enroll about 270 patients with KS, 100 with Crypto and 100 asymptomatic. These patients have randomly been distributed among most AMPATH sites. Patient charts will be pulled and reviewed by the outreach workers assigned to follow the lost patients. Data collection and entry will commence immediately the study begins. 3. Enhancing TB Data Collection within East African IeDEA New, Paper work submitted to IREC in 02 April 2013 - pending approval
Project Name:	IU Health Cardiovascular Research Biobanking Project
Investigator(s):	Inui, T. Kimaiyo, S. Bloomfield, G.

Start Date:	4/30/2012	**End Date:**	4/28/2017
Source of Funds:	IU Health	**Direct Cost (USD):**	$1,060,000

Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	Atrial fibrillation is the most common sustained arrhythmia in high-income countries. Recent insights have been made with regard to the genetic variations that may predispose an individual to developing atrial fibrillation. There has long been observed a disproportionately low prevalence of atrial fibrillation among Africans and African-American compared to people of European descent. Whether mutations in the genes known to cause atrial fibrillation are also causing AF among Kenyan patients with this disorder is unknown. Identification of the frequency of mutations in these genes in patients with atrial fibrillation in Kenya may shed light into the causal pathways of atrial fibrillation in this population. Using a case-control (1:2) research design in a Kenyan population with atrial fibrillation, we propose to perform mutational analysis of the coding sequence and flanking splice sites of the KCNQ1, KCNJ2, KCNE2 and KCNA5 genes known to be mutated in familial and lone atrial fibrillation in patients from high-income countries. A thorough phenotyping protocol will be employed which will include clinical assessment, a medical history, echocardiography and electrocardiography. Genetic material will be collected, stored and processed in Eldoret as the first initiative of the Genetic Biorepository Initiative (PI: Inui, Co-PI: Emonyi) and subsequently shipped for analysis of specific alleles at Indiana University. Using a convenience sample of approximately 140 patients with atrial fibrillation and 140 controls, we will demonstrate the frequency of pathological mutations in the aforementioned genes and provide a thorough clinical description of patients with atrial fibrillation including echocardiographic descriptions and the burden of other comorbid illnesses.		
Update: (Last updated: 7/12/2013)	This project has now generated a protocol that will enroll as many as 220 patients with valvular and non-valvular atrial fibrillation and controls in the AMPATH cardiology clinic, anticoagulation clinic and MTRH adult inpatient services for characterization of their arrthymia and echocardiographic findings with banking of blood for targeted genomics. The protocol is in the process of approval by Moi, IU, and Duke insitutional review boards. Project staff positions are being filled and it is hoped that patient recruitment might begin in July-August.		
Project Name:	Linkage and Retention to Care in Western Kenya Following HIV Testing		
Investigator(s):	Genberg, B. Wachira, J. Braitstein, P. Hogan, J. Naanyu, V. Operario, D. Ware, N. Wilson, I. Inui, T. Ayuo, P. Sitienei, J. Puffer, E. Rachlis, B.		
Start Date:	8/1/2013	**End Date:**	7/31/2018
Source of Funds:	Lily Foundation, Gates, and NIH	**Direct Cost (USD):**	Pending

Site(s):	Not Reported		
Project 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.		
Update: (Last updated: 7/12/2013)	The project is at the early stages is currently in the process of obtaining approval from IREC and the IRB at Brown University. Data on self-reported linkage to care following HCT has been analyzed and presented this work at two meetings: the 17th International Workshop on HIV Observational Databases and the 8th International Conference on Treatment and Prevention Adherence. With support from the Gates Foundation, efforts to merge data from HBCT and AMRS are underway. This process has been completed in Port Victoria and data analysis has started. The qualitative phase of the project has been submitte to the IRB and is awaiting approval. NIH funding is pending.		
Project Name:	MESA Malaria Prevention Study (MPS)		
Investigator(s):	O'Meara, W. Obala, A. Mangeni, J. Menya, D.		
Start Date:	1/1/2013	**End Date:**	9/30/2014
Source of Funds:	Malaria Eradication Scientific Alliance (MESA)	**Direct Cost (USD):**	$197,500

Site(s):	Webuye District Hospital
Project Description:	International efforts to scale up malaria control have achieved considerable success and have pointed toward the possibility of global malaria eradication. Achieving the long-term goal of eradication requires effective implementation of current tools, development of new technologies, and ongoing surveillance of the successes and failures of both. As malaria transmission declines and becomes increasingly heterogeneous, a finer-grained picture of malaria burden and intervention efficacy is required. In Kenya, considerable reductions in malaria morbidity and mortality have been reported, but success has not been uniform. In Bungoma East district in western Kenya, data suggest that control efforts have not had the expected impact; despite the fact that Insecticide Treated Net (ITN) ownership exceeds 70%, malaria infection and morbidity remain high. The observation that malaria burden has not responded to control measures suggests a breakdown in effectiveness of ITN, but not due simply to ownership, a common measure of 'coverage'. Breakdown in prevention of malaria may be due to a number of different factors in addition to coverage, including improper use and low adherence by households, changing vector populations and reduced susceptibility of the vector. In the first phase of the proposed project, this study will seek to answer the question of why malaria morbidity has remained alarmingly high in an area with high coverage of effective interventions. We will use the efficacy decay framework to quantify barriers to effective prevention. In the second phase, the lessons from phase 1 will be applied to developing a tool that can generate local, timely information in a cost-effective manner to identify and address barriers to elimination. • Specific Aim 1: Quantify the efficacy decay at each step using case-control methodology. We will use a case control study to estimate the relative contribution of each step in the efficacy decay of ITNs to malaria prevention in an area where coverage is high but malaria burden has remained resistant to control measures. • Specific Aim 2: Develop a rapid assessment tool that can be implemented at sentinel health facilities to identify local bottlenecks to malaria elimination. Based on the results of the efficacy decay analysis, we will develop a tool that can be used by community health workers to identify local barriers to effective prevention and stimulate local solutions.
Update: (Last updated: 7/12/2013)	• On March 12, 2013, ethics approval for the study was granted from IREC at Moi University. On April 1, 2013 approval was also granted from the Duke University IRB. • During this period, we hired a study coordinator who is responsible for patient recruitment and organizing the field activities of our volunteers. We also hired an Assistant Field Entomologist to oversee all the mosquito and larval collection, mapping, identification and storage. • Community sensitization and community entry were accomplished through meetings with chiefs and assistant chiefs. The communities are very supportive of the project and are eager to learn the results of the study. • The investigators developed the data collection tools to be used during recruitment, household visits, and mosquito collection. The data manager for the project successfully programmed all the data collection tools for mobile phone data collection using the ODK platform and FormHub. • Five field enumerators were trained to safely and accurately perform RDTs in the community,

	capture data on the mobile phones according to the SOPs, and assist with mosquito collection. • Piloting of the tools and data validation activities took place in mid-April • Enrollment began on April 17, 2013. To date, we have enrolled and collected data from 87 patient's households and 87 matched controls. We are currently on target to finish enrollment within the one-year period.		
Project Name:	Modified Directly Observed Antiretroviral Therapy (M-DART): An Intensive, Nurse-Directed, Home-Centered, Treatment Strategy to Reduce Mortality and Loss to Follow-Up in High-Risk HIV-Infected Patients Initiating Antiretroviral Therapy		
Investigator(s):	Wools-Kaloustian, K. Siika, A. Murage, T. Thirumurthy, H. Goodrich, S.		
Start Date:	8/1/2011	**End Date:**	12/31/2013
Source of Funds:	USAID/PEPFAR	**Direct Cost (USD):**	$825,501
Site(s):	Busia District Hospital Chulaimbo Sub-District Hospital Khunyangu Sub-District Hospital Kitale District Hospital Port Victoria Sub-District Hospital		
Project Description:	The M-DART study is a randomized clinical trial comparing the effectiveness of a home-based modified directly observed antiretroviral (ART) treatment strategy to clinic-based standard of care in patients with HIV/AIDS in Port Victoria and Khunyangu, Kenya. The aim is to reduce both mortality and the number of patients lost to follow-up after ART therapy is initiated. In addition to these important objective outcomes, it also seeks to determine if M-DART can contribute to an increased quality of life for patients and help to diminish HIV related stigma.		
Update: (Last updated: 7/12/2013)	Continuing approval was provided by IREC on February 27, 2013. The study closed for enrollment on the January 11, 2013.		
Project Name:	National Cancer Institute Supplement to East African IeDEA: Improving Kaposi's Sarcoma, Lymphoma Diagnostics, and Assessing Kaposi's Sarcoma Incidence in Western Kenya		
Investigator(s):	Wools-Kaloustian, K. Diero, L. Wools-Kaloustian, K. Diero, L. Busakhala, N. Jeff, M. Toby, M. Loehrer, P. Strother, M.		

	Czader, M. Leboit, P. McCalmont, T. Asirwa, C. Patel, K. Yiannoutsos, C.		
Start Date:	8/1/2008	**End Date:**	7/31/2014
Source of Funds:	NIH - NCI	**Direct Cost (USD):**	Not Reported
Site(s):	All Sites		
Project Description:	The toxicity and potential side effects of therapy for malignancy justify a standard of care in cancer medicine of tissue-biopsy. Further, an accurate assessment of the epidemiology of HIV-related malignancy requires reliable pathologic diagnosis. This study will help validate local pathology for the diagnosis of Kaposi Sarcoma (KS). The limited resources available to local pathology mandate that most diagnoses are made via H&E staining and immunohistochemistry which are techniques, like many pathology diagnostic tools, open to inter-observer variability in interpretation. Thus the experience of the pathologist is a major determinant in diagnostic accuracy. Quality assurance efforts and continuing evaluation of diagnostic skills are routine practices in the United States to help ensure ongoing reproducibility between pathologists. The present effort will facilitate similar ongoing quality checks and thus increase the reliability of a biopsy-based diagnosis of KS and lymphoma at the selected sites.		
Update: (Last updated: 7/12/2013)	Punch biopsies continue to be done at the AMPATH oncology clinic. Visiting clinicians continue to visit the oncology sites at Busia, Chulaimbo, Kitale, and Webuye. As of this update, clinicians have been trained at at all AMPATH main clinics. As of June 2013, the study has completed 1306 biopsies – 1121 were AMPATH and 185 were Non-AMPATH.		
Project Name:	Nurse Management of Hypertension Care in Rural Western Kenya		
Investigator(s):	Vedanthan, R. Kimaiyo, S.		
Start Date:	9/17/2011	**End Date:**	7/30/2016
Source of Funds:	National Institutes of Health-Fogarty International Center	**Direct Cost (USD):**	$675,543
Site(s):	Mosoriot Rural Health Training Centre		
Project 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.
Update: (Last updated: 7/12/2013)	***Updates*** *Aim 1* • Focus groups: Further 2 focus groups (11 men; 8 women) have been conducted • Key Informant Interviews: 6 key informant interviews (5 men; 1 woman) conducted • Transcripts: 13 audio recordings (7 focus groups; 6 key informant interviews) have been transcribed, translated, and back-translated • Coding of 13 transcripts completed • Content analysis of transcripts is nearly complete *Aim 2* • DEcision Support and Integrated REcord-keeping (DESIRE) tool has been rolled out in the dispensaries of Turbo Division • Usability testing: think-aloud sessions (5) and mock-patient encounters (5) completed • Usability testing focus group discussion protocol pilot-testing completed • Feasibility testing protocol (semi-structured interviews and focus group discussion) pilot-testing completed • Audio recordings have been transcribed, translated, and back-translated • Content analysis of transcripts completed • Poster accepted to 14th World Congress on Medical and Health Informatics, Copenhagen (Aug 2013) *Aim 3* • Monthly data reports being received • Nurses have been trained to use tablets to perform data entry • Electronic data entry is initiated and ongoing *Aim 4* • Time stamp successfully considered as a formal 'field' or 'concept' for the AMPATH Medical Record System (AMRS) ***Significant Results*** *Aim 1* • Content analysis ongoing at this time *Aim 2* • Fifty-seven critical incidents were identified, 22 of which were unique ○ A severity ranking of the critical incidents found 5 incidents resulting in Task

	Failure ○ Eleven critical incidents were found to be Serious Problems • A source-of-error analysis resulted in 23 design change suggestions *Aim 3* • Data entry still ongoing Aim 4 • N/A ***Key Outcomes*** • Abstract accepted to 14th World Congress on Medical and Health Informatics, Copenhagen (Aug 2013) • Usability of Implementing a Tablet-Based Decision Support and Integrated Record-Keeping (DESIRE) Tool in the Nurse Management of Hypertension in Rural Kenya

Project Name:	Optimizing Linkage and Retention to Hypertension Care in Rural Kenya		
Investigator(s):	Fuster, V. Kamano, J. Vedanthan, R. Horowitz, C. Were, M. Inui, T. Hogan, J. Velazquez, E. Bloomfield, G. Naanyu, V. Menya, D. Kimaiyo, S. Akwanalo, C.		
Start Date:	5/4/2012	**End Date:**	3/31/2017
Source of Funds:	National Heart, Lung, and Blood Institute (NHLBI)	**Direct Cost (USD):**	$2,104,519
Site(s):	Mosoriot Rural Health Training Centre Turbo Health Centre		
Project 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 QRISK®2-2011 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.

Update: (Last updated: 7/12/2013)	Over the last six months the following progress has been made:
	
	Aim 1
	
	• Requisite staff has been hired: study coordinator, data manager, and research assistant
	• All qualitative work for Aim 1 conducted under the direct supervision and direction of Violet Naanyu, the co-investigator specialized in qualitative research
	• Community entry was successfully performed prior to the focus group discussions and mabaraza
	• Focus groups: 15 focus groups have been conducted
	  o 69 women and 76 men
	• Mabaraza: 6 mabaraza have been conducted
	  o 119 women and 123 men
	• Transcripts: All of the audio-transcripts have been transcribed and translated
	• Content analysis of transcripts has been initiated and is ongoing
	• Data saturation appears to have been attained, and we are therefore considering reducing the total number of focus group discussions and mabaraza to be conducted
	• Analysis of qualitative data will feed into subsidiary aims 1.1 and 1.2
	• Software programmer and information technology technician positions are in the process of being filled
	
	Aim 2
	
	• Biostatistician position is in the process of being filled
	• Engaging with the leadership of AMPATH Community Health Worker (CHW) programs in order to ensure smooth initiation of the study protocol in conjunction with AMPATH programmatic activities
	Aim 3
	
	• Consultant health economist remains engaged to initiate the data collection process required for cost-effectiveness analysis.
	
	The innovative potential of the project remains similar to that described in the original grant application. No technical problems have been encountered thus far. A few logistical difficulties have been encountered, including: 1) transportation to the rural areas of western Kenya especially in inclement weather; 2) procurement and hiring delays due to extensive and time-consuming administrative procedures required of the AMPATH-USAID partnership; and 3) upcoming elections in Kenya which may disrupt the timeline of planned activities depending on the results and potential civil unrest. We are actively working with the transportation, procurement, and human resource teams in order to address these logistical issues.

Project Name:	Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose

	Information and Talk about HIV Infection (HADITHI)		
Investigator(s):	Vreeman, R. Nyandiko, W. Marete, I. Inui, T. Mwangi, A. Hogan, J. Mc Henry, M.		
Start Date:	9/1/2012	**End Date:**	9/1/2016
Source of Funds:	National Institute of Mental Health NIH	**Direct Cost (USD):**	$1,886,804
Site(s):	Burnt Forest Sub-District Hospital Chulaimbo Sub-District Hospital Khunyangu Sub-District Hospital Kitale District Hospital Moi Teaching and Referral Hospital (modules 1-4) Mosoriot Rural Health Training Centre Turbo Health Centre Webuye District Hospital		
Project 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.		
Update: (Last updated: 7/12/2013)	Since the start of the project, the following progress has been made: • IRB and IREC approval was secured. • The study team has been hired and trained. • Phase One, with focus groups discussing disclosure and development of disclosure curriculum materials has been completed and qualitative analysis is ongoing. • Narrative-based videos for use in disclosure counseling and education were created in partnership with the IUPUI School of Informatics. • Prospective assessments of a cohort of families have now begun. • Recruitment of this cohort began in 22nd April 2013 and was completed in June 2013 with a total of 256 participants enrolled.		

	• Two years of family follow-up with return visits at eight clinics is now ongoing.		
Project Name:	Patient-Reported Outcomes of Cancer Care in Eldoret, Kenya		
Investigator(s):	Hess, L. Naanyu, V. Asirwa, C.		
Start Date:	3/4/2010	**End Date:**	4/1/2013
Source of Funds:	Walther Cancer Foundation IU International Development Fund	**Direct Cost (USD):**	$23,310
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4) Moi University IUPUI		
Project Description:	The proposed study is designed to validate and subsequently implement a standardized questionnaire to obtain patient perspectives of their physical and psychosocial well-being (quality of life) during and following cancer treatment. The primary objective of this research is to validate an instrument that can be used to obtain knowledge about the quality of life of cancer patients in Eldoret, Kenya, which will then guide future strategies to improve comprehensive cancer patient care. The specific aims are to determine the validity of the Kiswahili version of the Functional Assessment of Cancer Therapy General scale (FACT-G) by: (1) conducting focus groups of cancer patients in Eldoret to explore the constructs underlying the translation of the FACT-G instrument; (2) revising the translation wording as needed prior to implementation; and (3) administering the final version of the FACT-G along with the previously-validated Patient Health Questionnaire Nine Symptom Checklist (PHQ-9) longitudinally in this population. The FACT-G has been validated in more than 40 languages and is used worldwide to assess cancer therapy, but has yet to be validated in Kenya.		
Update: (Last updated: 12/31/2012)	The focus group was completed. The validation project is completed. Data QA/QC and analysis is ongoing.		
Project Name:	Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretroviral Treatment		
Investigator(s):	Braitstein, P. Jakait, B. Pastakia, S. Karwa, R. Ngetich, C. Inui, T. Sidle, J. Wools-Kaloustian, K. Nyandiko, W.		

	Pandit, J. Olsson, S. Maina, M. Olwande, C.		
Start Date:	10/1/2012	**End Date:**	12/31/2013
Source of Funds:	World Health Organisation	**Direct Cost (USD):**	$162,000
Site(s):	Moi Teaching and Referral Hospital (modules 1-4)		
Project 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).		
Update: (Last updated: 7/12/2013)	We have enrolled 683 of the 1000 patients required for study. Adults on 1st Line cART 242/250 Adult on 2nd Line cART 41/50 Adults Stable on cART 200/200 Children on 1st Line cART 17/150 Children on 2nd Line cART 2/50 Children Stable on cART 112/200 Pregnant women on cART 69/100 ***Challenges*** Random sampling of patients for TSR 3 and TSR 4 was not feasible for a variety of logistic reasons. We therefore changed the recruitment and enrollment strategy to invite all patients who meet our inclusion criteria and are willing to participate. Disclosure of HIV status to children and adolescents is occurring at a much later age than expected. This has posed a challenge in recruiting children and adolescents in to the study. In addition, adolescents usually attend their HIV care visits without a guardian. As a result, there is no guardian to provide consent for them to participate in the study.		

Project Name:	Physical and Sexual Abuse in Orphaned Compared to Non-Orphaned Children and Youth in Sub-Saharan Africa: A Systematic Review & Meta-Analysis		
Investigator(s):	Braitstein, P. Ayuku, D. Nichols, J. Embleton, L. Mwangi, A. Morantz, G. Vreeman, R. Ayaya, S.		
Start Date:	3/1/2012	**End Date:**	7/12/2013
Source of Funds:	Not Reported	**Direct Cost (USD):**	Not Reported
Site(s):	Not Reported		
Project Description:	This systematic review assessed the quantitative literature to determine whether orphans are more likely to experience physical and/or sexual abuse compared to non-orphans in sub-Saharan Africa (SSA). It also evaluated the quality of evidence and identified research gaps.		
Update: (Last updated: 7/12/2013)	Accepted at *Child Abuse and Neglect* for publication.		
Project Name:	Prevalence and Impact of Alcohol Use in Patients Enrolling in HIV Care		
Investigator(s):	Wools-Kaloustian, K. Diero, L. Hahn, J. Kulzer, J. Goodrich, S. Bwana, B. Oyaro, P. Aluda, M.		
Start Date:	3/1/2013	**End Date:**	3/1/2014
Source of Funds:	NIH-NIDA	**Direct Cost (USD):**	Not Reported
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	Though drug use (including inhalant use) is an increasing problem in East Africa, alcohol remains the most common substance of abuse in our populations. There are limited data on the impact of alcohol use on immune reconstitution, adherence and retention in care within sub-Saharan African HIV- infected populations. Given the high rates of food insecurity and resulting malnutrition, the impact of alcohol use on clinical outcomes in HIV-infected individuals in East Africa may be more profound than that seen in North America. Further exploration of the prevalence of and impact of alcohol use on the outcomes of HIV-infected individuals in sub-		

	Saharan Africa is needed in order to inform HIV-care and treatment programs and assess the need for systems adaptation targeted towards identifying and intervening in individuals with alcohol addiction issues.		
Update: (Last updated: 12/31/2012)	A protocol has been submitted to IREC for approval.		
Project Name:	REACH Informatics Center of Excellence		
Investigator(s):	Biondich, P. Siika, A. Braitstein, P. Diero, L. Sidle, J. Downs, S. Hogan, J. Kroenke, K. Mamlin, B. Meslin, E. Nyandiko, W. O'Meara, W. Palakal, M. Rotich, J. Shen, C. Vreeman, R. Were, M. Wools-Kaloustian, K. Yiannoutsos, C.		
Start Date:	6/1/2009	**End Date:**	6/30/2014
Source of Funds:	NIH - Fogarty International Centre	**Direct Cost (USD):**	$945,464
Site(s):	MTRH		
Project Description:	The project is a collaboration between Indiana and Moi Universities and the global leadership of the Regenstrief Institute. Theprogram will: 1. Provide post-doctoral informatics training to faculty at Moi University and Moi Teaching and Referral Hospital to implement and use health information technology to enhance research and improve health care quality, efficiency and outcomes. 2. Support the training of East Africans so as to support the development, implementation, maintenance, evolution and use electronic health records (EHRs) in low-income countries through didactic and mentored practicum training		
Update: (Last updated: 7/12/2013)	***Fellowship*** • The the first three cohorts of fellowship students have completed their Fellowship program. The first fellow finalized his Master in Health Informatics in July 2012, while the second and		

	third fellows finalized their Masters in Clinical Research and Masters in Health Informatics respectively in June 2013. • The fourth fellow completed his first year of study in clinical research and will begin his second year research work in Eldoret in the coming months. • The fifth fellow was accepted into the Masters in Health Informatics Program and will begin his first year of classes in July 2013 at Indiana University. ***Short Courses*** • 24 Participants attended the Kenya EMR Health Managers orientation workshop (Western Region) held 31 January to 1 February 2013 at the Kakamega Golf Hotel. • 25 participants attended the Kenya EMR Health Managers orientation workshop (North Rift Region) held from 4-5 February 2013, at the Noble Conference Centre Eldoret. • 16 participants attended the Kenya EMR System User Training (North Rift Region) held on 11 – 15 February 2013, at the Noble conference Centre Eldoret. • 15 participants attended the Kenya EMR System User Training (Western Region) held on 18 – 22 February 2013, at the Golf Hotel Kakamega. • RedCap Webinar Online training for Administrators, Implementers and users was held on 18-20,25-26, and 28 June 2013.

Project Name:	Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens (REMEMBER)		
Investigator(s):	Siika, A. Lagat, D.		
Start Date:	9/26/2012	**End Date:**	12/31/2014
Source of Funds:	NIAID, Gilead Sciences Inc., and Merck & Co., Inc.	**Direct Cost (USD):**	Not Reported
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	In this randomized, open-label strategy trial, participants from RLS who present with advanced HIV disease and will be initiating ART but are without evidence of probable or confirmed TB according to criteria in the current ACTG diagnosis appendix (which will be identified on the case report form [CRF]) will be randomized 1:1 to one of two strategy arms: empiric TB treatment (public health approach, Arm A) or local standard of care (individualized TB treatment approach, Arm B) at study entry. At the 48 week visit, participants will transition to a 48-week follow-up period of non-study-provided treatment and care, with total study duration being 96 weeks. The primary endpoint is survival status at 24 weeks post randomization. AIDS progression, virologic and immunologic response, development of plasma HIV drug resistance, resistance to TB drugs, safety and tolerability of ART and TB drugs, and adherence to ART and TB drugs will also be evaluated as will the relative cost-effectiveness of the two strategies.		
Update: (Last updated: 7/12/2013)	A total of 30 participants have been enrolled at Eldoret site. The current overall accrual is 420 out of the required sample size of 836 participants.		

Project Name:	Renal Study

Investigator(s):	Wyatt, C. Owino Ong'or, W. Abuya, J. Wools-Kaloustian, K.		
Start Date:	12/10/2007	**End Date:**	12/10/2013
Source of Funds:	Gilead Foundation	**Direct Cost (USD):**	$165,000
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	This study is comparing the performance of equations to estimate kidney functions to a direct measure of kidney function based on the plasma disappearance of iohexol in HIV-infected adults.		
Update: (Last updated: 7/12/2013)	The primary publication has been accepted for publication in PLoS ONE. We are seeking funding to measure a more sensitive marker of kidney function, cystatin C, in banked study samples.		
Project Name:	Screening for Cervical Cancer in HIV positive Kenyan women		
Investigator(s):	Dainty, E. Omenge, O. Cu-Uvin, S. Walmer, D.		
Start Date:	10/11/2011	**End Date:**	5/1/2013
Source of Funds:	NIH (Fogarty International Center) Duke Center for AIDS Research	**Direct Cost (USD):**	$37,000
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4) Mosoriot Rural Health Training Centre Turbo Health Centre		
Project Description:	This project involves the collection of demographic data as well as cervical swab specimens for HPV genotyping from women with HIV who receive cervical cancer screening through the AMPATH supported program.		
Update: (Last updated: 12/31/2012)	Data collected, participant recruitment ended April 11, 2012. The study is currently in the data analysis and manuscript preparation phase.		
Project Name:	Sexual Health Risks and HIV Prevelance Among Street Involved Youth in Western Kenya		
Investigator(s):	Braitstein, P. Kiplagat, J.		
Start Date:	Not Reported	**End Date:**	Not Reported
Source of Funds:	Not Reported	**Direct Cost (USD):**	Not Reported
Site(s):	Not Reported		

Project Description:	Not Reported		
Update: (Last updated: 7/12/2013)	Enrollment has been completed and data analysis and writing-up results is underway. Preliminary results have been presented as a poster in June at the 2013 World Congress of the International Association of Adolescent Health in Istanbul, Turkey.		
Project Name:	STEPwise Approach to Cardiovscular Diseases Risk Factors Revalence Study in Webuye Adults		
Investigator(s):	Bloomfield, G. Chege, P.		
Start Date:	3/15/2010	**End Date:**	Not Reported
Source of Funds:	NIH - Fogarty International Center Moi University Vlir-OUS project	**Direct Cost (USD):**	Not Reported
Site(s):	Webuye District Hospital		
Project Description:	Study of the prevalence of cardiovascular disease risk factors among rural adults in population whose demographic details is monitored in demographic surveillance system The WHO STEPwise approach (three steps that included interviews followed by determination of anthropometric measurements, pulse and blood pressure and finally determination of a fasting lipid profile and blood sugars).		
Update: (Last updated: 7/12/2013)	The population of about 40,000 adults was sampled where about 4,000 adults were interviewed in Step 1 while about 200 had steps 2 and 3 The smaller sample for step 2 and 3 was due to funding constraints. The data has been analyzed and we are publishing the results.		
Project Name:	Street Youth's Perspectives on Sexual Health in Western Kenya		
Investigator(s):	Braitstein, P. Ayuku, D. Naanyu, V. Ott, M. Wachira, J. Embleton, L. Kamanda, A. Winston, S.		
Start Date:	8/1/2013	**End Date:**	6/30/2014
Source of Funds:	OSCAR-NIH funded	**Direct Cost (USD):**	Not Reported
Site(s):	Not Reported		
Project Description:	This is a qualitative study that aims to provide a preliminary understanding of sex from the perspective of street youth. Specifically, we will examine the language, types and functions of sexual behaviors among Kenyan street youth aged 11-24 years. The study has three main aims which include: 1. AIM 1: Describe the self-reported sexual terminology and behaviors of street youth aged 11-		

	24 years, including terminology for and examples of sexual violence. 2. AIM 2: Describe the self-reported understanding among street youth about official non-vernacular words, including sex, rape/sexual assault, abuse, sexual abuse, consensual sex, non-consensual sex, and the sexual behaviors that may or may not characterize each. 3. AIM 3: Describe the role of sex among street youth including initiation rites and transactional sex. The study findings are hoped to inform and improve the design of sexual health interventions geared towards reducing the associated morbidity rates in this region.
Update: (Last updated: 7/12/2013)	The study is at the initial stage and has obtained IREC approval. IRB approval is underway and expected soon.

Project Name:	Survival Among HIV-infected Patients with Kaposi's Sarcoma in sub-Saharan Africa in the Era of Potent Antiretroviral Therapy		
Investigator(s):	Wools-Kaloustian, K. Busakhala, N. Martin, J.		
Start Date:	4/1/2013	**End Date:**	4/1/2014
Source of Funds:	NIH-NCI	**Direct Cost (USD):**	Not Reported
Site(s):	All Sites		
Project Description:	In sub-Saharan Africa, the intersection between endemic human herpesvirus 8 and epidemic HIV infections has resulted in Kaposi's sarcoma (KS) becoming one of the most commonly reported malignancies amongst all adults in the region. Not only is incidence of KS high but the clinical manifestations are substantial as well. Specifically, in the era prior to potent antiretroviral therapy (ART), cumulative one year mortality after HIV-associated KS diagnosis was as high as 60 to 70 percent. Fortunately, based on data following the advent of ART in resource-rich settings, there is now hope for improved KS survival in sub-Saharan Africa now that ART is becoming available. The many differences, however, between resource-rich and resource-limited settings -- particularly in availability of chemotherapy and supportive cancer care -- make extrapolation from resource-rich settings to Africa problematic. While early reports from sub-Saharan Africa in the ART era do show what appear to be improvements in KS survival compared to historical data, these studies are clouded by either substantial losses to follow-up , many patients not actually on ART , small sample sizes and hence imprecise estimates, or being conducted in difficult-to-generalize trial settings . In particular, the studies conducted in the most representative settings also suffer from between 15 to 37 percent lost to follow-up . Because of the obvious concern that these lost may be dead, the nominal survival estimates are nearly uninterruptable. Thus, while ART is now being administered to over 5 million HIV-infected patients in sub-Saharan Africa, we do not yet know its impact on the survival of the most common malignancy of the HIV epidemic. To address these limitations, the overarching objective of this study is to definitively study survival		

	after KS diagnosis in Africa in the contemporary ART era. Our specific aims are to: 1. Determine survival after a diagnosis of HIV-associated KS in the ART era in sub-Saharan Africa; 2. Assess among HIV-infected individuals who initiate ART in Sub-Saharan Africa, if presence of KS is associated with excess mortality compared to other HIV-infected patients with concurrent opportunistic infections or equivalent CD4+T cell counts; and 3. Evaluate the pace and determinants of initiation of ART after a diagnosis of HIV-associated KS in Sub-Saharan Africa.		
Update: (Last updated: 12/31/2012)	IREC application is under development.		
Project Name:	TB/HIV Integration Study		
Investigator(s):	Owiti, P. Zachariah, R. Bisell, K. Kumar, A. Diero, L. Carter, J. Gardner, A.		
Start Date:	1/1/2013	**End Date:**	12/31/2013
Source of Funds:	International Union Against TB and Lung Disease International Society for Infectious Diseases	**Direct Cost (USD):**	$6,000
Site(s):	Bumala B Health Centre Busia District Hospital Huruma Sub-District Hospital Iten District Hospital Khunyangu Sub-District Hospital Mt. Elgon District Hospital Mukhobola Health Centre Port Victoria Sub-District Hospital Teso District Hospital Turbo Health Centre Uasin Gishu District Hospital Webuye District Hospital Kabarnet DH, Nambale, Sio port, Amukura, Naitiri HC		
Project Description:	The objective of the project is to assess the uptake of and timing to CPT and ART initiation before and after introduction of integration of TB-HIV care in these facilities		
Update: (Last updated: 7/12/2013)	Abstract submitted to The Union conference. Manuscript ready for submission to The International Journal of Tuberculosis and Lung Disease (IJTLD).		

Project Name:	The Epidemiology of Substance use Amongst Street Children in Resource-constrained Settings: a systematic review and meta-analysis		
Investigator(s):	Embleton, L. Ayuku, D. Braitstein, P. Mwangi, A. Vreeman, R.		
Start Date:	9/1/2011	**End Date:**	7/12/2013
Source of Funds:	Not Reported	**Direct Cost (USD):**	Not Reported
Site(s):	Not Reported		
Project Description:	To compile and critically analyze the literature published on street children and substance use in resource constrained settings.		
Update: (Last updated: 7/12/2013)	Published: Embleton L, Mwangi A, Vreeman R, Ayuku D, Braitstein P. *The Epidemiology of Substance use Amongst Street Children in Resource-constrained Settings: a systematic review and meta-analysis*. Addiction, in press		

Project Name:	The Implementation of a Neonatal Nurse Training Program at the Riley Mother Baby Hospital of Kenya		
Investigator(s):	Lemons, J. Gisore, P. Bucher, S. Songok, J. Trautman, M. Hawk, S.		
Start Date:	6/4/2012	**End Date:**	12/20/2013
Source of Funds:	Indiana University School of Medicine, Department of Neonatal-Perinatal Medicine	**Direct Cost (USD):**	$40,000
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	The goal of this study is to evaluate the effectiveness of a neonatal nurse training program in improving the knowledge, patient care practices and processes of nurses working in a neonatal intensive care unit in a resource limited setting. The primary outcome of this study is the impact of the Neonatal Nurse Training Program on nurse competency related to three crucial domains of neonatal nursing care (i.e., thermoregulation, respiratory monitoring, and infection control). The impact of the Neonatal Nurse Training Program on nursing competency will be measured in regards to both (1) knowledge (as evaluated by a multiple-choice questionnaire administered pre/post the training program) and (2) actual patient care practices (as assessed by pre/post training program observations by a trained evaluator in the nursery). Secondary outcomes will include evaluation of process changes related to documenting patient care, as well as outcomes		

	such as NICU mortality rate and length of stay in the nursery. These outcomes will be evaluated primarily via pre/post training program retrospective chart review, and augmented by observational data. We hypothesize that a neonatal nurse training program will significantly improve nurse competency and the quality of patient care as measured by improvement in knowledge, practices, processes and patient outcomes such as mortality. The results of this study will help validate the importance of nursing education and its effect on patient care in the resource limited setting, and if successful, will make an important contribution toward the improvement of nursing practices among staff at one of the largest and busiest referral NICUs in East Africa.		
Update: (Last updated: 7/12/2013)	The study evaluated the effectiveness of a neonatal nurse training program in improving knowledge, patient care practices and processes of nurses in a neonatal intensive care unit in a resource-limited setting. It was a pre-post intervention design assessing a nurse training program in Kenya. We found a significant improvement in the primary outcome of nursing competency assessed on measures of knowledge and patient care practices post-intervention. There was a decrease in the median length of stay post-intervention. After controlling for birth weight, mortality rate was significantly reduced post-intervention. In conclusion, a nurse training program, using a modified S.T.A.B.L.E. Program, among nurses in a resource-limited setting can significantly improve nurse competency and the quality of patient care as measured by improvement in knowledge, processes and crucial patient outcomes such as mortality.		
Project Name:	The IU Simon Cancer Center (IUSCC) AMPATH-Oncology Institute (AOI): An Exemplar of Care for the Developing World and a Population-Based Research Environment for IUSCC		
Investigator(s):	Inui, T. Busakhala, N. Asirwa, C.		
Start Date:	7/1/2011	**End Date:**	6/30/2014
Source of Funds:	Walther Cancer Foundation	**Direct Cost (USD):**	$1,200,000
Site(s):	Mosoriot Rural Health Training Centre Turbo Health Centre Kapsakworny		
Project Description:	Kenya, like much of the developing world, is rapidly undergoing an 'epidemiologic transition' from a health scene dominated by infectious diseases to one in which the major causes of death and disability are cancer and other chronic diseases. Under these circumstances, applying science to the management and control of cancer has become as relevant to Kenya as it is in the United States. Similarly, what is learned about the prevention and treatment of cancer in the developing world literally has direct relevance to care in the United States. Cancer care and attendant research in Kenya, whose population is the most genetically diverse in the world, will catalyze the discovery of new genes of importance to our fight against cancer, new genomic predictors of cancer, and new genetic variants that predict response to therapy. Recognizing both emerging threats to population health and potential for advancing care and science, the IU Simon Cancer Center (IUSCC) and the IU-Kenya AMPATH Program have been		

	actively pursuing resources to respond. The focus of the partnership is to develop a sustainable and comprehensive academic clinical care program that will serve the citizens of western Kenya, and in the process, create a unique program of international collaboration for patients with, or at risk for, malignancies. The mission of the AMPATH Oncology Institute (AOI) is to be the premier cancer program in Sub-Saharan Africa, noted for excellence in cancer prevention, treatment and palliative care. AOI activities will directly contribute to advances in cancer care, accelerate discoveries in the biology and treatment of cancer, and provide support for the IU Simon Cancer Center's quest to become a federally designated Comprehensive Care Center. Naftali Busakhala will characterize the awareness, beliefs, attitudes and behaviors of women coming to AMPATH's clinician breast exam screening as volunteers, comparing these beliefs to those of a community-based sample of women. He will also characterize the yield of the AMPATH screening program, the kinds of cancers detected, and the quality of care achievable in Western Kenya at present, with comparison against an international standard of care. Chite Asirwa will similarly characterize the awareness, beliefs, attitudes and behaviors of a community-based sample of women, comparing their beliefs to those of their husbands, often a key influence on behavior in traditional societies. Taken together these two studies should reveal a great deal about how to influence women's behaviors and encourage participation in the only breast cancer screening program available presently - clinician examination. Both of these studies will use the BCAM (Breast Cancer Awareness Measure), a survey tool developed in Great Britain. We have worked carefully through the standard BCAM to sort questions into theoretically sound domains, using the Health Belief Model as a framework. Violet Naanyu will be conducting field testing and focus groups to do a culturally appropriate Kiswahili version.
Update: (Last updated: 7/12/2013)	The Walther grant has now generated two operational research protocols and a third that is newly approved. The first (Kenyan PI Busakhala) and the second (Kenyan PI Asirwa) both involve use of the BCAM to characterize the knowledge, attitudes, and beliefs of Kenyans vis a vis breast cancer, its prevention, presentation, and treatment. In the past six months, BCAM survey data has been collected from more than 1,300 persons, some from centre-based breast cancer clinical examination screening events and others participating as community residents. These data are now being analyzed for the crafting of (1) more effective approaches to recruiting participants to screening events and (2) educational events as adjuncts to screening. The third Walther project protocol is a survey of target populations for cervical cancer screening and treatment. This survey used Health Belief Model theory domains to craft items for administration to women who are offered screening and may/may not choose to pursue this offer and who later may adhere to a treatment protocol (or not) in our search for predictors of participation and adherence. Data entry for Naftali Busakhala's study on Level of Breast Cancer Awareness Among Women Volunteering for breast Cancer Screening in Western Kenya and Dr. Chite Asirwa study on Awareness of Breast Cancer Among Men and Women in Western Kenya have been completed. Data analysis for both study is on going.
Project Name:	The Susan G. Komen for the Cure Tissue Bank at the IU Simon Cancer Center Kenya Project
Investigator(s):	Storniolo, A.

	Busakhala, N. Lugaria Lumarai, D.		
Start Date:	7/1/2012	**End Date:**	11/30/2013
Source of Funds:	Susan G. Komen for the Cure	**Direct Cost (USD):**	$500,000
Site(s):	Moi Teaching and Referral Hospital (Modules 1-4)		
Project Description:	Triple negative breast cancer, an aggressive form of breast cancer, disproportionately affects African women and premenopausal African-American women. A diagnosis of triple negative disease is particularly devastating because there are no targeted therapies against it and it carries with it an especially poor prognosis. Exactly why women of African descent are more prone to this malicious form of breast cancer is unclear. This question demands increased attention, and the Susan G. Komen for the Cure® Tissue Bank at the IU Simon Cancer Center ('Komen Tissue Bank') is ideally positioned to play a critical role. The Komen Tissue Bank is the first and only biorepository of normal breast tissue in the world. As with many other areas of breast cancer research, we believe that the availability of such normal tissue has the potential to revolutionize our understanding of triple negative disease. Specifically, we believe that comparing normal and triple negative tissue from African donors will allow researchers from Indiana University--and others from around the world--to uncover vital clues regarding the origin of triple negative disease in women of African ancestry and thus speed the discovery of promising therapeutics. After receiving IREC approval, a tissue collection event will be held in Kenya in the summer of 2013. A portion of the tissue collected will remain in Kenya for research and the remaining tissue will be deposited into the Komen Tissue Bank as a resource for breast cancer researchers around the world. As part of this project, there will be a community event to help educate residents about breast cancer and breast health.		
Update: (Last updated: 7/12/2013)	The North American team completed a site visit to Eldoret in January 2013. The regulatory documents were submitted to the IREC in February 2013, and after the initial review, the IREC had questions that needed to be addressed. After discussion and changes per IREC, the regulatory documents were re submitted in June of 2013. Once IREC approval is granted, educational and recruiment sessions will occur in Eldoret and surrounding communities. The tissue collection event is scheduled for January 2014. Since the previous report, the PIs decided to hold a breast cancer screening event the same day as the tissue collection event. Women can choose to just attend the breast screening event or attend the screening and tissue collection event and participate in the research study.		
Project Name:	The Tip of the Iceberg: HIV Testing Uptake, HIV Prevalence and Ante-Natal Care Attendance among Pregnant Women in a Large Home-Based HIV Counseling and Testing Program in Western Kenya		
Investigator(s):	Braitstein, P. Ndege, S. Washington, S. Kaaria, A.		

	Prudhomme-O'Meara, W. Were, E. Nyambura, M. Keter, A. Wachira, J.		
Start Date:	Not Reported	**End Date:**	12/31/2013
Source of Funds:	USAID	**Direct Cost (USD):**	Not Reported
Site(s):	Not Reported		
Project Description:	The objective of the study was to describe uptake of and factors associated with HIV testing and HIV prevalence among pregnant women in a large-scale home-based HIV counseling and testing (HBCT) program in western Kenya. We utilized HBCT from 6 catchment areas namely Kapsaret, Burnt Forest, Webuye, Chulaimbo, Teso and Port Victoria. Included in the analysis were females aged 13-50 years. We used descriptive statistics and logistic regression to describe factors associated with previous testing history, testing uptake, and HIV prevalence.		
Update: (Last updated: 7/12/2013)	The findings from this study were presented (poster presentation) at the IWHOD conference-2013 in Croatia. We are currently at the final stage of manuscript development.		
Project Name:	Utility of Handheld Echocardiogram Among Clinical Officers in Patient Referred for Routine Echocardiography at Moi Teaching and Referral Hospital, Kenya		
Investigator(s):	Velasquez, E. Kimaiyo, S. Barasa, F. Bloomfield, G. Koech, M.		
Start Date:	2/1/2013	**End Date:**	10/31/2013
Source of Funds:	NIH/NHLBI	**Direct Cost (USD):**	$17,625
Site(s):	Moi Teaching and Referral Hospital (modules 1-4)		
Project Description:	Cardiovascular diseases (CVDs) are increasingly common in Kenya. Five conditions are responsible for the majority of the CVD burden: Dilated Cardiomyopathy (DCM), Hypertensive heart disease (HHD), Cor Pulmonale, Pericardial effusion and Rheumatic heart disease (RHD). Standard echocardiography is the gold standard for diagnosing these conditions but a hand held echocardiogram (HHE), in well trained hands, can accurately identify them. Early and accurate diagnosis should be made at the earliest entry into the health care system (e.g., primary care health centers and district hospitals); unfortunately, the diagnostic ability is very limited in terms of expertise and equipment in these settings. Specific Objectives are: 1. To assess the usefulness of a HHE compared to physical examination by clinical officers in recognizing major cardiac abnormalities after a one day training period, in patients referred for routine echocardiography at Moi Teaching and Referral Hospital (MTRH). Usefulness will		

	be evaluated by comparing sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of physical examination compared to HHE. Improvement in sensitivity of 25 percent or greater using the HHE compared to physical examination will be considered clinically relevant. 2. To determine the sensitivity and specificity of diagnosing RHD at MTRH using a combination of physical examination plus HHE compared to physical examination alone by clinical officers, in patients referred for routine echocardiography. ***Methodology*** An 8 hour training program will be conducted for the Clinical officers with at least one year post-internship experience at MTRH Emergency department to train them on the use of the hand held device conducted with the assistance of a faculty member from Duke University. Afterwards, two clinical officers, are randomly selected from the group and shall be stationed at the cardiac centre to participate in the study. They shall alternate with each other in examining recruited patients for the study. The patients shall be 18 years and above and shall be recruited consecutively as they come in after being consented. Each clinical officer will have 30 minutes to make a clinical diagnosis of the patient's cardiac condition and a further 30 minutes to perform a HHE and make an echocardiographic diagnosis. The patient shall then undergo a standard echocardiographic study conducted by a qualified technician blinded to the findings of the clinical officer's findings. The 3 diagnoses shall be captured on case report forms (CRFs) for analysis. In addition, the HHE images shall be digitally acquired and stored in a lap top computer to be read by a cardiologist with expertise in echocardiography (i.e., performance and interpretation) and compared with those of the standard machine. Sensitivity, specificity, positive and negative predictive values of the physical examination and HHE diagnosis shall be determined by using the standard echocardiogram diagnosis as the gold standard.
Update: (Last updated: 7/12/2013)	The project received IREC approval on 28 June 2013, and Donor approval on 20 December 2012. They recruited the Clinical Officers and trained them in January 2013. It began enrollment on 4 February 2013. They have recruited 92 participants as of June 2013.

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