

SEMI ANNUAL RESEARCH REPORT

July – December 2014



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Contents

Contents	iii
Overview	1
Grants	2
Publications	2
Research Project Updates	3
A formative study to develop culturally valid psychosocial assessment tools and interventions to promote family well-being in Kenya	3
A Retrospective Analysis of Pregnancy Outcomes of HIV Infected Women Enrolled in the AMPATH Program.....	4
A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI)	5
A5225/HiFLAC Protocol - A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated Cryptococcal Meningitis.....	5
A5263 'A Randomized Comparison of Three Regimens of Chemotherapy with Compatible Antiretroviral Therapy for Treatment of Advanced AIDS-KS in Resource-Limited Settings'	6
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)	7
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	8
A5273 'Multicenter Study of Options for SEcond-Line Effective Combination Therapy (SELECT)'	9
A5274/REMEMBER Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens ' ..	10
A5288 'Management Using the Latest Technologies in Resource-limited Settings to Optimize Combination Therapy After Viral Failure (MULTI-OCTAVE)'	10
AMPATH - Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS	11
Anticoagulation Project.....	12
Antiretroviral Treatment Failure and Drug Resistance in HIV-infected Patients on Second Line Regimens in Western Kenya.....	13
Biomarkers of Vincristine Toxicity in Kenyan Children	14
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	15
Chama cha MamaToto: Evaluating a Peer Support Mechanism to Improve Maternal and Infant Health.....	15
Childhood Leukemia in Kenya Identified Through Malaria Slide Review	16
CHOICES: Reproductive and Sexual Health Decision making among Women in Western Kenya	17

Drug resistance in HIV infected Children after Failure of Prevention of Mother to Child Transmission in Western Kenya.....	18
Enhancing Training for Implementation Research in Chronic Disease: CITE/Kenya.....	19
Evaluating Handheld Clinical Decision Support Tools to Improve Community-Based Delivery of Reproductive and Pediatric Health Services.....	20
Evaluation of A Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy (CAMP study)	21
Evaluation of HIV drug resistance prevalence and consequences in the setting of the recent political crisis in Kenya	23
Evaluation of the growth and development of young children of HIV-infected mothers in western Kenya.	23
Feasibility of Ultrasound-guided Assessment of Volume Status in an Intensive Care Unit in Kenya: a Pilot Study	25
HI-Train: Health Informatics Training and Research in East Africa for Improved Health Care	26
HIV-1 Drug Resistance in Different Subtypes.....	27
HIV-1 Genotypic Diversity and Drug Resistance in Western Kenya	28
Indiana University-Moi University Academic Research Ethics Partnership.....	28
Innovative public-private partnership to target subsidized antimalarials in the retail sector	31
IU Health Cardiovascular Research Biobanking Project.....	32
Knowledge, Attitudes and Practices of Sepsis Management at Moi Teaching and Referral Hospital, Kenya	34
Linkage and Retention to Care in Western Kenya Following HIV Testing	35
MESA Malaria Prevention Study (MPS)	37
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.....	38
Mortality among street connected children and youth in Eldoret, Kenya: a retrospective chart review.....	39
Nurse Management of Hypertension Care in Rural Western Kenya	40
Optimizing Linkage and Retention to Hypertension Care in Rural Kenya	41
Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)	44
Prevalence and Impact of Alcohol Use in Patients Enrolling in HIV Care	45
SAFI (Stigma in AIDS Family Inventory) Validation Study	46
Street Youth's Perspectives on Sexual Health in Western Kenya	47
Tablet Computer-Based Disclosure Counseling for HIV-Infected Adolescents and their Families: A Pilot Study of Perspectives from Providers	48
Taking to the streets: a mixed-methods systematic review of the reasons children and youth become street-involved.....	49
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.....	50

The Role of Faith Leaders Towards Promotion HIV-Testing Alongside Voluntary Male Circumcision in Nyanza, Kenya	51
Treatment Outcomes of Childhood Cancer in Western Kenya.....	52
Vincristine Optimization in Kenyan Children with Cancer	53
Figures & Tables	56
AMPATH Research Bibliography	58
Index	62

Overview

The last year has brought a number of changes to the AMPATH Research Program. The program said goodbye to Dr. Tom Inui as the North American Co-Director of Research and welcomed Dr. Rachel Vreeman as his successor. IREC launched a new website, www.irec.or.ke, to help support a more efficient and transparent human subjects' review process. New research and clinical laboratories were established to better support AMPATH's research and care programs. The AMPATH Transformation Project (ATP) started the process of transitioning the Research and Sponsored Project Office (RSPO) from a paper based record and grants management system to an online system. Each of these changes has presented new challenges and new opportunities for the development of AMPATH's research program and shaped the program's growth.

The growth of the Research Program and its collaborations is evident in the number of collaborative research proposals reviewed by the AMPATH Research Working Groups in the last year. More than 100 new study proposals were reviewed by the working groups in 2014 including investigators from nearly 20 institutions in North America, Europe, and Africa.

Along with submitting a large number of new study proposals, AMPATH investigators continued to actively publish and participate in key global health research forums. In 2014, AMPATH investigators added more than 40 peer reviewed journal articles to AMPATH's research bibliography. Over 70 posters and abstracts were presented at major international conferences and meetings by AMPATH investigators – more than double the number presented in 2013. Efforts to translate research outcomes into better health policy and care continued with the quarterly publication of *AMPATH's Research Publications Compendium*, which summarizes the key lessons learned by AMPATH investigators from their research and recommends opportunities to strengthen care in Kenya and beyond.

Training opportunities for new AMPATH investigators also increased. Nearly 70 trainees from Moi University and MTRH were enrolled in research related training programs offered by Brown, Duke, and Indiana Universities.

Despite these strong gains, overall funding for new research was down in 2014. Investigators reported only 14 new research and training awards totaling US\$7 million – 25 percent less than previous five year average. The average award size in 2014 was 13 percent less than the five year average of US\$ 560,000.

The following report includes updates from 48 AMPATH research studies along with brief updates on the status of funding for research and publications produced in 2014. It was compiled with the assistance of AMPATH investigators, research coordinators, and assistants from more than 15 institutions in Kenya and North America. We begin the report with a brief summary of AMPATH research funding awarded in 2014 and continue with a description of the publications produced during the year. We conclude with brief project updates provided by AMPATH investigators listed alphabetically by the study title.

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www.medicine.iu.edu/ampathresearch.*

Grants

The number of new awards for AMPATH research projects remained low in the second half of 2014. Of the 14 new research awards reported for 2014, 50 percent were awarded in the second half of the year. Sluggish growth in the number of new awards may be the result of previous years' success in attracting new awards and the limited availability of AMPATH investigators to take on new projects because of ongoing work with existing projects. Despite this decrease in new awards, the number of new study proposals submitted to external funders increased from previous years and it is likely that 2015 will be on par with previous years. New awards in 2014 brought the total level of program direct awards to more than US\$ 88.6 million since the program received its first research award in 1998 (See Figure 1).

Funding from the National Institutes of Health (NIH) remains the largest source of funding for AMPATH's research projects. In 2014, NIH funding accounted for 96 percent of all new awards (See Figure 2). Philanthropic support from nonprofits and foundations and intramural support made-up the remaining 4 percent. While funding sources tend to fluctuate from year to year, 2014 was significantly more dependent on NIH support when compared to funding sources for the last 5 years (See Figure 3).

Publications

AMPATH investigators continued to publish at a steady rate. More than 40 manuscripts from AMPATH investigators appeared in peer reviewed journals. Steady publication rates this year increased the total number of publications produced by AMPATH investigators since 1989 to 335 (See Figure 4). A bibliography of publications from 2014 is included at the end of this report.

In addition, AMPATH investigators were actively involved in preparing publications for submission to a wide range of professional conferences and journals. The AMPATH Publications Committee, which reviews all publications produced from AMPATH research projects, reviewed a total of 132 draft publications. Around 51 percent of the publications reviewed were abstracts and nearly 16 percent were poster presentations presented at professional conferences. Manuscript submissions were up by about 10 percent from previous years and comprised 45 percent of the publications reviewed by the committee (See Figure 5).

Research Project Updates

Study Title	A formative study to develop culturally valid psychosocial assessment tools and interventions to promote family well-being in Kenya
Principal Investigator(s)	Eve Puffer, Duke University David Ayuku, Moi University
Co-Investigator(s)	
Working Group(s)	Behavioral & Social Science, Pediatrics
Description	<p>The purpose of this study is to assess family functioning and children's psychosocial well-being in a Kenyan context in order to develop culturally tailored measures and family-based intervention approaches. Many measures of child well-being, mental health, and behavior were developed in the West and are inappropriate or insufficient for use in Kenya. The same is true for measures of family well-being. Culturally tailored measures are needed to assess important aspects of family relationships, such as communication, conflict, and parenting. Such measures will be useful in identifying children and families who are in need of treatment and in measuring the impact of interventions for children and families to identify which treatments work best. We will use a variety of methods to develop assessment tools to measure family functioning and mental health. These will include focus groups with community members (both youth and adults), community leaders, and people already working in the field of mental health in the communities. Methods will also involve questionnaires and observational measures, in which family and child behaviors are directly observed and assessed. A family-based intervention to address psychosocial concerns will be developed using a community-based participatory approach.</p>
Site(s)	Other, Mihuu Community, Webuye, Burnt Forest Community, Pioneer Community
Project Period	5/28/2013 – 1/30/2014
Funding Status	Funded – Duke Global Health Institute, Other, Johnson and Johnson
Direct Award (USD)	\$29,500
Update	<p>Creation of a survey measure of family functioning and individual mental health progressed. We continue to pilot test this measure in Pioneer and Webuye communities. In addition, observational measures and in-depth interviews were piloted in Pioneer as part of the process to create and validate family functioning ratings scales within these measures. The formulation and piloting of these three measures prepares us for the quantitative validation of the survey in the future.</p>
Future Plans	<p>The validity portion of the study will include both survey administration as well as in-depth interviews and observations with families in these areas. The validity study will be done in order to determine whether the survey measure which is currently being pilot tested accurately predicts diagnosis of both family functioning issues and mental health</p>

	status of individuals within a family. Following the validity study we plan to begin the family therapy intervention pilot informed by community advisory committees. The family therapy intervention will address issues raised in the focus group qualitative data in order to make the intervention culturally relevant for peri-urban and rural communities in Kenya.
Publication(s)	
Study Title	A Retrospective Analysis of Pregnancy Outcomes of HIV Infected Women Enrolled in the AMPATH Program
Principal Investigator(s)	April Bell, Indiana University Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Were, E. Musick, B. Lane, K. Washington, S. Shen, C. Akhaabi, P. Hogan, J.
Working Group(s)	Reproductive Health
Description	<p>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:</p> <ul style="list-style-type: none"> • 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.
Site(s)	All AMPATH Sites
Project Period	3/1/2006 – 5/31/2013
Funding Status	Unfunded –
Direct Award (USD)	
Update	The dataset has been revised significantly. The analysis has also been revised extensively. We expect to submit the manuscript for publication during the next quarter.
Future Plans	We expect to submit the manuscript for publication during the next quarter.

Publication(s)	
Study Title	A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI)
Principal Investigator(s)	Rebecca Papas, Brown University B. Gakinya, Moi University
Co-Investigator(s)	Maisto, S. Martino, S. Baliddawa, J. Sidle, J. Hogan, J. Carroll, K.
Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	This study will determine whether a group cognitive-behavioral therapy intervention that demonstrates preliminary evidence of reducing alcohol use among HIV-infected outpatients in western Kenya is effective when compared against a group health education intervention in a large sample over a longer period of time. It will be delivered by paraprofessionals, individuals with limited professional training. This approach is consistent with successful cost-effective models of service delivery in resource-limited settings in which paraprofessionals (e.g., clinical officers, traditional birth attendants and peer counselors) are trained.
Site(s)	Iten District Hospital, Moi Teaching and Referral Hospital (MTRH), Turbo Health Centre, Webuye District Hospital
Project Period	11/1/2011 – 8/31/2016
Funding Status	Funded – NIH - National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Direct Award (USD)	\$2,268,832
Update	The 5-year RAFIKI RCT, which examines the efficacy of a group Cognitive Behavioral Therapy (CBT) intervention to reduce alcohol use when compared against a group health education intervention, is halfway through its third year of recruitment. We have randomized 448 total participants, and have completed recruitment and intervention for cohorts 1-16. In the July-December 2014 reporting period, we recruited and randomized 87 participants. Recruitment and retention are progressing within expectations according to our NIH specific aims. We have had no immediately reportable serious adverse events during the course of this study.
Future Plans	Continue the positive work already being done, while focusing on maintaining strong recruitment numbers.
Publication(s)	
Study Title	A5225/HiFLAC Protocol - A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated

Cryptococcal Meningitis

Principal Investigator(s)	John Sidle, Indiana University Abraham Siika, Moi University
Co-Investigator(s)	Lagat, D.
Working Group(s)	Adult Medicine, Basic Science
Description	<p>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 subsequent steps (Steps 2-4) based on their initial randomization and/or their response to treatment. The study steps are:</p> <ul style="list-style-type: none"> • 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)
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	5/18/2011 – 12/31/2013
Funding Status	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	Not Reported
Update	Approvals for version 3.0 of the protocol have been obtained from IREC, the Pharmacy and Poisons Board Expert Committee on clinical trials (PPB, ECCT) and the US Human Research Protections Office (HRPO). This sets up the stage for opening of stage 2 of the protocol. The fluconazole doses that will be evaluated in Stage 2 are 1600 mg daily and 2000 mg daily.
Future Plans	The next six months will see the site start enrollments into the second stage of the protocol. There are 72 slots up for enrollment. Having been the highest enrolling site in stage one, we will strive to replicate the high achievement in stage 2.
Publication(s)	

Study Title
A5263 'A Randomized Comparison of Three Regimens of Chemotherapy with Compatible Antiretroviral Therapy for

Treatment of Advanced AIDS-KS in Resource-Limited Settings'

Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Dr. Naftali Wisindi Busakhala Dr Evangeline Wawira Njiru
Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	This is an ACTG prospective, randomized, active-controlled clinical trial in which participants will be randomized 1:1:1 to oral etoposide (ET) plus antiretroviral therapy (ART), bleomycin and vincristine (BV) plus ART, or paclitaxel (PTX) plus ART. The primary objective will be to compare the clinical efficacy of two regimens, oral ET plus ART and BV plus ART, to PTX plus ART for initial treatment of advanced stage AIDS-KS.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	4/1/2014 – 2/28/2021
Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG), NIH - National Cancer Institute (NCI), NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	Not Reported
Update	Because of the complex nature of this study and the nature of the study products(cytotoxic agents), it was decided by the protocol team that additional training on the handling and administration of these agents be conducted. This was done in the third quarter of 2014. The protocol team is now ready to conduct the protocol
Future Plans	We hope to enroll our first participant into the A5263 study within the first half of 2015. The study will therefore strive to screen and enrol eligible participants for this study. An amendment (LOA2) has also been made to this study for which IREC approval has been obtained. We hope to get approvals from the pharmacy and Poisons board expert committee on clinical trials (ECCT) as well as the US Human Research Protections office (HRPO) within the coming six months.
Publication(s)	

Study Title

A5264/AMC067 A Randomized Evaluation of Antiretroviral Therapy Alone or with Delayed Chemotherapy versus Antiretroviral Therapy with Immediate Adjunctive Chemotherapy for Treatment of Limited Stage AIDS-KS in Resource-Limited Settings (REACT-KS)

Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Busakhala, N. Njiru, E.
Working Group(s)	Adult Medicine, Basic Science

Description	A5264/AMC 067 is a phase III, open-label, prospective, randomized study stratified by CD4+ lymphocyte cell count and antiretroviral therapy (ART) history. The study will compare the KS tumor outcomes of ART alone or with delayed Etoposide (ET) to ART with immediate ET, for initial treatment of limited stage AIDS-KS in chemotherapy and radiation treatment na? HIV-1 infected participants who are currently not receiving ART
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	11/28/2012 – 6/30/2014
Funding Status	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID), NIH - National Cancer Institute (NCI), NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	Not Reported
Update	There are currently 152 participants enrolled into this multi-centre, multi-national clinical trial. Of these, 13 are from the Eldoret site. The past six months were particularly difficult for our site as we managed to enroll only one participant. We however appreciate that many patients do not meet the enrollment criteria of being ART naive due to the great work done in the region in increasing ART coverage. The patients on follow up are doing well.
Future Plans	Focus in the next 6 months will be on ramping up enrollments and proper management of patients on study.
Publication(s)	

Study Title	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
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Lagat, D.
Working Group(s)	Adult Medicine, Basic Science
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.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	2/1/2012 – 12/31/2012
Funding Status	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID), NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	Not Reported
Update	Study is closed.
Future Plans	Study closed. No further updates/plans
Publication(s)	

Study Title	A5273 'Multicenter Study of Options for SEcond-Line Effective Combination Therapy (SELECT)'
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Dr Faraj Some
Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	A5273 is a phase III, dual-arm, open-label, randomized, non-inferiority study for participants who are on a failing non-nucleoside reverse transcriptase inhibitor (NNRTI)-containing first-line regimen. The study will evaluate the difference in virologic failure rate between two treatment arms: lopinavir/ritonavir plus raltegravir (LPV/r + RAL) and LPV/r plus best available nucleos(t)ide reverse transcriptase inhibitors (NRTIs). The NRTIs to be used will be specified by the site prior to randomization. The primary objective for this study will be to determine whether the combination of LPV/r + RAL is associated with virologic efficacy that is non-inferior to that achieved with LPV/r + best-available NRTIs by 48 weeks of follow-up.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	1/22/2013 – 10/3/2016
Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	All the participants enrolled into this study in the Moi University Clinical Research Centre have been exited from the study.
Future Plans	The patient phase of the study is effectively closed. Data analysis is ongoing and we hope to see literature from the study in the coming six months.
Publication(s)	

Study Title	A5274/REMEMBER Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens '
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Dr David K Lagat
Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	In this randomized, open-label, phase IV strategy trial, participants from resource-limited settings (RLS) who present with advanced HIV disease and no probable or confirmed tuberculosis (TB), as defined in the current ACTG diagnosis appendix, and who are initiating antiretroviral treatment (ART) will be randomized to one of two strategy arms: immediate, empiric TB treatment (public health approach) or local standard of care TB treatment (individualized approach). The primary endpoint is survival status in the two arms 24 weeks after randomization. AIDS progression (any new WHO Stage 3 or 4 condition), virologic and CD4+ cell response, HIV and TB drug resistance, AND safety and tolerability of, and adherence to HIV and TB drugs will be evaluated, as will the cost-effectiveness of the two strategies. The primary objective is to compare survival probabilities between the two study arms 24 weeks after randomization.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	10/10/2012 – 12/31/2016
Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	Study follow up is ongoing. Of the 70 participants that were enrolled on the study, 20 have exited the study.
Future Plans	Follow up of patients according to the research protocol to continue in the next 6 months. It is anticipated that within this period more of the participants will complete follow up and exit the study.
Publication(s)	

Study Title	A5288 'Management Using the Latest Technologies in Resource-limited Settings to Optimize Combination Therapy After Viral Failure (MULTI-OCTAVE)'
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Dr Beatrice Wangari Ndege

Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	A5288 is an open-label phase IV, prospective interventional, strategy study in resource-limited settings (RLS) for HIV-infected participants with triple-class experience or resistance to [nucleoside reverse transcriptase inhibitors (NRTIs), non-NRTIs (NNRTIs), and protease inhibitors (PIs)] and who are failing their current regimen. The use of novel agents and contemporary management tools that include standard genotyping, plasma viral load (VL) monitoring will be evaluated. The screening genotype results and antiretroviral (ARV) history will be used to allocate potential participants to one of the four cohorts and for selection of ARV regimen for each potential participant. At sites where feasible and relevant(including MTRH) the study will also conduct an adherence study. This will be a randomized comparison of cell phone-based adherence intervention plus local standard-of-care adherence procedures (CPI+SOC) versus the SOC adherence procedures. The primary objective of the study is to use novel agents and contemporary management tools, including standard genotyping to select an appropriate third-line regimen, interventions to improve adherence and plasma viral load (VL) monitoring, in order to achieve a ? 65% rate of virologic control at 48 weeks of follow-up
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	12/18/2013 – 12/31/2015
Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	There are currently 169 participants enrolled into the study in all the sites internationally. At the Moi University Clinical Research Centre, a total of 29 patients have been screened for entry into this study. Of the 29 potential participants 7 have met the enrollment criteria and have therefore been recruited into the study. 9 did not meet the criteria and therefore did not qualify to participate in the study. There are 13 patients screened who are awaiting screening results to determine whether or not they qualify for the study. The 7 participants enrolled are going on well and are undergoing study follow up as prescribed in the protocol.
Future Plans	The Moi University Clinical Research Centre has a target of contributing 60 participants into this study. At the current rate of enrollment, the enrollment slots may get filled up before the end of the year. With such projections, the site is planning to scale up screening and enrollment in order to meet the set targets.
Publication(s)	
Study Title	AMPATH - Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS
Principal Investigator(s)	Patrick Loehrer, Indiana University - Purdue University in Indianapolis (IUPUI) Darron Brown,Indiana University - Purdue University in Indianapolis (IUPUI)

Co-Investigator(s)	Omenge, Orango - CO-Principal Investigator MTRH Kaaria, Alice - Project 1 MTRH Cu-Uvin, Susan - Project 2 Brown
Working Group(s)	Oncology
Description	The core objective of this project is to better understand the natural history of oncogenic HPV infections in HIV-infected Kenyan women, and to identify potentially modifiable (and non-modifiable) factors that are associated with progression of oncogenic HPV infection to clinical disease, including cervical cancer. Our central hypothesis is that the incidence, persistence, and spectrum of HPV are all substantially greater in HIV-infected versus non-HIV-infected Kenyan women, and that this explains a higher incidence of cervical neoplasia in HIV-infected populations. We further hypothesize that these and other modifiable factors (such as concurrent STIs, sexual behaviors, nutrition, and environment) disproportionately and adversely impact outcomes of local therapies such as cryotherapy and Loop Electrosurgical Excision Procedure (LEEP) in HIV-infected women. The specific aims of this AMPATH-Oncology Institute are to: 1. Expand the capabilities and expertise of the current laboratories and biobanking capabilities in Kenya through AMPATH and the Kenya Medical Research Institute (KEMRI) 2. Identify potentially modifiable behavioral and biological factors that are associated with the duration of infection with oncogenic HPV and cervical dysplasia in HIV-infected and non-HIV-infected women from western Kenya 3. Assess the risk factors associated with the short and long term results of cryotherapy and LEEP in VIA- positive (including LEEP-eligible) HIV-infected and non-HIV-infected women in western Kenya. 4. Provide biostatistical and data management support for proposed projects in this application and for future pilot projects, and 5. To establish a sustainable, multi-institutional and transdisciplinary mentoring program fostering the development of new cancer researchers in Kenya
Site(s)	Moi Teaching and Referral Hospital (MTRH), Other, Center for Global Health Research - KEMRI at Kisumu City, Kenya
Project Period	9/19/2014 – 8/31/2019
Funding Status	Funded – NIH - National Cancer Institute (NCI)
Direct Award (USD)	\$2,132,402
Update	From the project's commencement in September of 2014, the project team has obtained IRB and IREC approvals and has put in place all subcontracts needed with the different partner institutions. In this period, there have been no patients enrolled in the project.
Future Plans	Over the next 6 months we hope to start Project 1 and Project 2 and to fully implement the Translational Biology Core, Biostatistics and Data Management Core, Mentoring Core, and to enroll our first patients.
Publication(s)	
Study Title	Anticoagulation Project

Principal Investigator(s)	Sonak Pastakia, Indiana University Imran Manji, Moi University
Co-Investigator(s)	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.
Working Group(s)	Adult Medicine
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.
Site(s)	Moi Teaching and Referral Hospital (MTRH), Webuye District Hospital
Project Period	12/1/2008 – 12/31/2017
Funding Status	Funded – Purdue University College of Pharmacy, Indiana Hemophilia and Thrombosis Center (IHTC), Other, Celgene Corporation
Direct Award (USD)	\$100,000
Update	The service continues to grow having enrolled over 1300 patients with over 1000 patients being actively managed. The clinic continues to serve as a model for other hospitals in Kenya who are developing their own anticoagulation monitoring services. Again, as per the last update, sustainability is still a challenge and MTRH is yet to absorb some of our staff to ensure the service can continue to be provided.
Future Plans	In conjunction with the reproductive health working group, we plan to carry out a retrospective review of the knowledge and uptake of family planning amongst patients being followed up in the clinic. It is hoped that this will pave the way for increased use of family planning services in order to avoid conception in women using warfarin.
Publication(s)	

Study Title	Antiretroviral Treatment Failure and Drug Resistance in HIV-infected Patients on Second Line Regimens in Western Kenya
Principal Investigator(s)	Rami Kantor, Brown University Lameck Diero, Moi University
Co-Investigator(s)	Nathan Buziba Wildred Emonyi
Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	To determine prevalence and correlates of second line virological failures, research patterns and implications of drug resistance and examine predictors of drug resistance evolution in patients failing second line antiretroviral therapy in western Kenya.

Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	6/30/2011 – 2/20/2014
Funding Status	Funded – Brown University - Center For AIDS Research
Direct Award (USD)	\$225,220
Update	Finalizing papers publication. Continuing laboratory assays for additional genes and more sensitive assays.
Future Plans	Finalize papers publication and laboratory assays for additional genes and more sensitive assays.
Publication(s)	M Coetzer, L Ledingham, L Diero, E Kemboi, M Orido, W Emonyi, R Kantor. Alternative Mechanisms of HIV Protease Inhibitor Resistance during 2nd line Failure. 24th International HIV Drug Resistance Workshop, February 21-22, 2015, Seattle, WA.

Study Title	Biomarkers of Vincristine Toxicity in Kenyan Children
Principal Investigator(s)	J. Renbarger, Indiana University F. Njuguna, Moi University
Co-Investigator(s)	Skiles, J.
Working Group(s)	Oncology, Pediatrics
Description	This study evaluates the presence of peripheral neuropathy induced by Vincristine in Kenyan children receiving chemotherapy. The main purpose is to assess whether the genetic makeup of each child (particular the genotype of CYP3A5) influences drug exposure and subsequent vincristine toxicity.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	6/23/2011 – 6/30/2014
Funding Status	Funded – NIH
Direct Award (USD)	\$8,743
Update	The first of the manuscripts that will result from this work was submitted to NEJM in May 2014. It received good comments, but was ultimately rejected. It was then resubmitted to Journal of Clinical Oncology where it received constructive feedback and the request for the planned 2nd manuscript to be submitted to support the methodology used in this paper. We are currently finalizing the 2nd supporting manuscript, which we hope to submit this month. Once it is submitted, the original manuscript will be re-submitted to Clinical Cancer Research. The remaining 2 manuscripts are still in progress but are anticipated to be submitted within the next 6 months.
Future Plans	Submission/acceptance of 2 additional manuscripts

Publication(s)	
Study Title	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
Principal Investigator(s)	Debra Litzelman, Indiana University Samuel Ayaya, Moi University
Co-Investigator(s)	Umoren, R. Woodward, J. Vreeman, R. Palmer, M. Stelzner, S. Lorant, D. Riner, M.
Working Group(s)	Pediatrics
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.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	11/27/2007 – 6/30/2014
Funding Status	Funded – Indiana University - Office of Research in Medical Education
Direct Award (USD)	Not Reported
Update	No additional study data collected. Analysis of study data in progress.
Future Plans	completion of data analysis and preparation of manuscript for publication
Publication(s)	
Study Title	Chama cha MamaToto: Evaluating a Peer Support Mechanism to Improve Maternal and Infant Health
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto Julia Songok, Moi University
Co-Investigator(s)	Laura Ruhl Louis Fazen
Working Group(s)	Reproductive Health
Description	The project involves recruiting pregnant and women with women below the age of one and put them into groups (chamas) where they are taught on different health and

	<p>medical topics. In addition, the program has micro finance component that helps women to save and borrow loans from their savings in the group. Pregnant women enrolled in the chamas (~300) will be compared to a matched group of women attending their first antenatal clinic who did not enroll in chamas. The primary outcome will be the proportion of women with skilled birth attendance. Secondary outcomes will include the proportion of women attending 4 ANC visits, the proportion of infants receiving OPV 0, the median duration of exclusive breastfeeding, the proportion of women receiving a visit by a CHV within 48 hours of birth and the proportion of women using long-term family planning within 6 months of delivery. To assess community acceptability of this program, we will carry out focus group discussions and in-depth interviews with women, community health workers and community leaders. Finally, to assess the future sustainability of the program, we will collect costs associated with this program, as well as the income generated by the chamas.</p>
Site(s)	Port Victoria Sub-District Hospital
Project Period	6/4/2013 – 6/11/2014
Funding Status	Funded – Grand Challenges Canada
Direct Award (USD)	\$125,000
Update	The program started as a care program rather than a research. In the past 6 months the program has been doing data collection from the field. The team collected both qualitative and quantitative data for the purpose of analysis. Several focus group discussions with the community health are workers, facility providers, women in both chamas and those who are non chamas and finally the provincial administration leaders.
Future Plans	In the next 6 months, analysis of both qualitative and quantitative data will happen and probably development of a manuscript out of it.
Publication(s)	



Study Title	Childhood Leukemia in Kenya Identified Through Malaria Slide Review
Principal Investigator(s)	Terry Vik, Indiana University F. Njuguna, Moi University
Co-Investigator(s)	Skiles, J. Moormann, A.
Working Group(s)	Oncology, Pediatrics
Description	The aim of this study is to improve the case detection rate of leukemia by retrospectively reviewing blood smears done for malaria screening to identify children with leukemia in defined population cohorts. If the case detection rate can be improved by utilizing a common and well established procedure, then there is potential to identify children, refer them earlier for treatment and save lives.

Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital (MTRH), Turbo Health Centre
Project Period	7/1/2012 – 6/30/2015
Funding Status	Funded – Alex's Lemonade Stand Foundation
Direct Award (USD)	\$200,000
Update	We have completed slide collections at our two study sites. We have reviewed a total of 36,000 slides. Data analysis is ongoing. We are planning a prospective study to use this slide screening technique for early referral of possible cases of leukemia. We have asked for a final 6 month no cost extension for our study to complete review of slides collected for the study. We will finalize the review in this study period. We presented the results of the study at a poster for the Society International Oncology Paediatric (SIOP) meeting in October. We are writing a manuscript to describe our results.
Future Plans	We will finish reviewing a last set of slides for the third aim of our study, then determine if those results can be published as well.
Publication(s)	



Study Title	CHOICES: Reproductive and Sexual Health Decision making among Women in Western Kenya
Principal Investigator(s)	April Bell, Indiana University Edwin Were, Moi University
Co-Investigator(s)	Wools-Kaloustian, Kara Zimet, Gregory
Working Group(s)	Reproductive Health
Description	It is estimated that contraceptive needs are met for only 18% of Kenyan women. There is poor uptake of modern contraceptive methods and a general lack of knowledge about the available methods. This study will use a multi-disciplinary approach to better understand reproductive and sexual health decision-making among women attending HIV care clinics operated by the Academic Model Providing Access to Healthcare (AMPATH). Existing scientific literature and focus group data from other studies conducted among the target population were reviewed to identify the constructs (including fertility desires) that may influence women's reproductive and sexual health decision-making. Themes identified included: age, education, employment status, HIV status, number of living children, ethnic group, contraceptive knowledge, cultural norms, and costs. A survey instrument has been developed, which includes: (1) demographics, (2) knowledge of family planning (FP) methods and sexually transmitted infections (STI), (3) fertility desires, and (4) an assessment of perceived pleasure related to the use of FP methods. Additionally, a matrix will be used for discrete choice analysis to ascertain the relative importance of factors in determining if FP methods are used and how they are chosen. This method assesses the weights (importance) women assign to various attributes and will provide a better understanding of the tradeoffs when making decisions about sexual and reproductive

	health. The survey will be implemented in a rural and an urban AMPATH clinic and 300 women recruited. This project will identify factors with the greatest influence on family planning decision-making and make recommendations regarding appropriate interventions. Findings from this research will assist AMPATH with providing appropriate reproductive health counseling and services, thereby reducing sequelae including unintended pregnancy and STI acquisition.
Site(s)	Moi Teaching and Referral Hospital (MTRH), Turbo Health Centre
Project Period	8/1/2013 – 9/30/2014
Funding Status	Unfunded –
Direct Award (USD)	
Update	Data collection was completed in August 2014. Analysis is underway.
Future Plans	An abstract is being submitted for APHA. We expect to have the first manuscript out by fall 2015.
Publication(s)	



Study Title	Drug resistance in HIV infected Children after Failure of Prevention of Mother to Child Transmission in Western Kenya
Principal Investigator(s)	Winstone Nyandiko, Moi University Rami Kantor, Brown University
Co-Investigator(s)	Vreeman, R. Songok, J. Diero, L. Kosgei, R. Ayaya, S.
Working Group(s)	Pediatrics, Reproductive Health
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.
Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital (MTRH), Turbo Health Centre
Project Period	5/3/2011 – 4/10/2014
Funding Status	Unfunded –
Direct Award (USD)	
Update	We have not enrolled any study participant since the last update. We have had challenges in getting eligible patients to be recruited. This is due to few children turning positive after undergoing the PMTCT intervention within AMPATH. This is as a result of a vibrant PMTCT program within AMPATH. We have so far enrolled a total of fourteen patients into the study up to date. None of the study participants has either withdrawn or defaulted. The study is still open to enrolment. We are in the process of closing up the study.

Future Plans	We are hoping that we shall be able to get eligible participants for us to improve on the rate of recruitment. We are also in the process of closing up the project. Dr. Rami Kantor said that his CITI certificate plus biosketch had been earlier send to your office.
Publication(s)	
Study Title	Enhancing Training for Implementation Research in Chronic Disease: CITE/Kenya
Principal Investigator(s)	Tom Inui, Indiana University Paul Ayuo, Moi University
Co-Investigator(s)	Siika, A. Litzelman, D.
Working Group(s)	Adult Medicine
Description	<p>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.</p>
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	10/1/2012 – 9/30/2016
Funding Status	Funded – NIH - Fogarty International Center (FIC)
Direct Award (USD)	\$862,970

Update	Cohort 3 has completed 9 of the core curriculum seminars and discussions about integration of the D43 seminars in the Registrar core curriculum have been initiated. Two cohort 1 fellows served as faculty for two sessions of the 9. Matriculation in the ongoing seminars has expanded to as many as 18 participants. All fellows have submitted progress reports that are being reviewed and critiqued by core faculty.
Future Plans	We will complete the core seminar series for cohort 3, meet with all CITE fellows individually to provide feedback on progress. Dr. Litzelman plans a visit in March to stimulate progress on practicum projects, and Dr. Inui will host a practicum project presentation session in June, 2015.
Publication(s)	

Study Title	Evaluating Handheld Clinical Decision Support Tools to Improve Community-Based Delivery of Reproductive and Pediatric Health Services
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto Julia Songok, Moi University
Co-Investigator(s)	
Working Group(s)	Reproductive Health
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.
Site(s)	Mosoriot Rural Health Training Centre
Project Period	12/1/2011 – 9/1/2013
Funding Status	Funded – Grand Challenges Canada
Direct Award (USD)	\$97,361
Update	Over the last 6 months, transcription and translation of the qualitative has been happening and now has been completed. The qualitative data that has been transcribed

	includes both focus group discussions and key informant interviews.
Future Plans	Over the next 6 months, the team intends to carry out data analysis of both focus group discussion and key informant interviews data. When completed, we intend to develop a manuscript out of it.
Publication(s)	
Study Title	Evaluation of A Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy (CAMP study)
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Inui, T. Tierney, W. Tu, W. Marrero, D. Ayaya, S. Blaschke, T. Arpadi, S. Caroll, A. Bell, D.
Working Group(s)	Pediatrics
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.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	9/11/2009 – 2/28/2014
Funding Status	Funded – NIH - National Institute of Mental Health (NIMH), PEPFAR - United States President's Emergency Plan for AIDS Relief - Public Health Evaluation (PHE)
Direct Award (USD)	\$1,336,011
Update	Over the last 6 months, we have made significant progress in many areas of data analysis and dissemination. We continue to work with the Phase 2 data to explore the validity of our CAMP adherence questionnaire and factors associated with adherence to treatment among children in this setting. We presented 2 abstracts at last year's International AIDS Society meeting in Melbourne, Australia. One abstract reported on agreement between caregiver-reported adherence and electronic dose monitoring adherence and another investigated factors associated with electronic dose monitoring adherence rates. Both abstracts were presented as oral presentations. We had one manuscript describing

adherence patterns of our Phase 2 patients accepted for publication at the Journal of the International AIDS Society. Another manuscript describing the validation of the CAMP adherence questionnaire is currently being revised for resubmission to AIDS and Behavior. We are making progress on finalizing the analyses of the Phase 3 data that evaluates the performance of the adherence questions selected through our Phase 2 analysis and formed the CAMP Short-Form Adherence Questionnaire. We are currently in the final stages of revalidating these adherence questions against the longer original CAMP Adherence Questionnaire. Preliminary analyses show that the questions perform well against electronic dose monitoring adherence (our 'gold standard') and provide good evidence for the reliability and validity of the CAMP Short-Form Adherence Questionnaire. We continue to make progress with the Phase 5 data, which seeks to test the performance of the CAMP Adherence Questionnaire in a clinic-based versus a home-based setting. We were delayed in the progress of cleaning and preliminary analysis because of difficulties with the database, which have now been resolved. The AMPATH biostatistics team is now working on preliminary analyses and should have results in the next few months. We have made very exciting progress using the CAMP data for pharmacokinetic modeling (PK). Using a previously developed PK model by Profs Nyandiko and Vreeman, we have been working with biostatisticians at Indiana University to use the model to evaluate PK properties and drug exposure among CAMP Phase 2 patients. These are very novel data in the pediatric population, particularly in the detailed use of adherence data we have through our use of Medication Event Monitoring Systems for CAMP patients as well as the blood samples we have at 2 time points. We are currently preparing an abstract for submission (see section below).

Future Plans

Over the next 6 months, we aim to achieve the following:

1. Using a pharmacokinetic (PK) model developed by Profs Nyandiko and Vreeman among a previous sample of children, we are currently working with our biostatistics team to retrospectively use the PK model to evaluate PK properties of nevirapine and adherence among our Phase 2 CAMP patients. This PK model is novel in that the PK parameters incorporate adherence data from Medication Event Monitoring Systems (MEMS) - electronic drug monitors - and offer a unique opportunity to evaluate the proximity of the patients' actual drug exposure to its intended level. In this next 6 months, these analyses will be complete and a manuscript will be written. We are currently working on an abstract to submit to the International AIDS Society meeting in July 2015.
2. We have completed preliminary analyses on Phase 3 data that investigates the performance of the CAMP long-form adherence questionnaire (~40 questions) versus the CAMP short-form adherence questionnaire (10 questions). In the next 6 months, we will finalize these analyses and draft a manuscript describing the results. These data will be critical in re-evaluating the validity of the short-form version of the questionnaire and preliminary analyses show good reliability and validity.
3. Complete data analysis for Phase 5 that examines the performance of the CAMP adherence questionnaire in clinic settings versus home settings. By the next progress reporting period, we aim to have completed data analysis and began preparation of a manuscript describing the findings of this analysis.
4. We have submitted an R01 application to the NIH to examine stored blood samples from CAMP Phase 2 patients for viral load and drug resistance. As part of the proposal, we also aim to re-enroll all CAMP Phase 2 patients for an additional assessment, including another blood draw so we may investigate the longitudinal nature of drug resistance evolution. Depending on the success of the application, in the next 6 months we hope to begin work

	on this supplementary project that will rely heavily on the work completed as part of the CAMP study.
Publication(s)	Manuscripts: 1. Vreeman RC, Nyandiko WM, Liu H, Tu W, Scanlon ML, Slaven JE, Ayaya SO, Inui TS. Measuring adherence to antiretroviral therapy in children and adolescents in western Kenya. Journal of the International AIDS Society 2014,17(1): 19227. PMCI
Study Title	Evaluation of HIV drug resistance prevalence and consequences in the setting of the recent political crisis in Kenya
Principal Investigator(s)	Rami Kantor, Brown University Lameck Diero, Moi University
Co-Investigator(s)	Nathan Buziba Wilfred Emonyi
Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	Determine and compare prevalence of virological failure and drug resistance at the time of post-crisis resumption of care, in Kenyan patients with and without crisis-induced antiretroviral treatment interruption.
Site(s)	Burnt Forest Sub-District Hospital, Turbo Health Centre
Project Period	11/24/2009 – 2/20/2014
Funding Status	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID), Other, Friendship Foundation
Direct Award (USD)	\$54,652
Update	Additional resistance analyses and publication preparation ongoing.
Future Plans	Finalize resistance analyses and publication preparation.
Publication(s)	1. Mann M, Diero L, Kemboi E, Mambo F, Rono M, Injera W, Delong A, Schreier L, Wools-Kaloustian K, Sidle J, Buziba N, Kantor R. Antiretroviral treatment interruptions induced by the Kenyan postelection crisis are associated with virological failure. J Acq
Study Title	Evaluation of the growth and development of young children of HIV-infected mothers in western Kenya.
Principal Investigator(s)	Megan McHenry (maiden name: Uhl), Indiana University
Co-Investigator(s)	Apondi, Edith Vreeman, Rachel Ayaya, Samuel
Working Group(s)	Pediatrics

<p>Description</p>	<p>Children under five years of age are at significant risk for mortality in resource-limited settings. One in nine children in sub-Saharan Africa die before they reach five years of age. Approximately 45% of child deaths are related to poor growth and malnutrition. Children born to HIV-infected mothers are at increased risk for stunting, wasting, and being underweight, and children with HIV and AIDS are even more likely to be malnourished. Without treatment, 50% of HIV-infected and 7% of HIV-exposed, but uninfected infants will die before two years of age. My long-term research goal is to provide evidence to improve the nutritional status and, in turn, decrease under-5 mortality for children born to HIV-infected women in resource-limited settings. As access to HIV care expands and we push towards the Millennium Development Goal of reducing child mortality, we must address the risks faced by young children exposed to or infected with HIV. The Academic Model Providing Access To Healthcare (AMPATH) in Kenya provides an ideal setting in which to evaluate the growth and development of this vulnerable population, and to explore effective interventions to improve their health. AMPATH is a long-standing, academic partnership, created between the Moi University School of Medicine, Moi Teaching and Referral Hospital, and the Indiana University School of Medicine, that provides care for over 15,000 HIV-infected and HIV-exposed children, one of the world's largest pediatric HIV cohorts. Few current data focus on the best strategies to foster the growth and development of HIV-exposed and HIV-infected children under five years of age and living in resource-limited settings. The objective of this study is to evaluate the growth and development of young children of HIV-infected mothers in western Kenya, with attention to identifying areas to target for future interventions. We plan to accomplish our research objective by pursuing the following four specific aims: Aim 1: Evaluate the changes in anthropometrics over time for children under the age of five who are born to HIV-infected mothers enrolled in AMPATH clinics. Hypothesis: Among those enrolled in AMPATH, HIV-infected children will have lower Z-scores for measured anthropometrics (WAZ, HAZ, WHZ) than HIV-exposed children. Aim 2: Determine factors associated with poor weight gain in this population of children. Hypothesis: Factors such as being orphaned, being HIV-infected, having developmental delays, having been hospitalized, and lower immunization rates will be associated with lower Z-scores for measured anthropometrics in both HIV-exposed and HIV-infected children under 5. . Aim 3: Evaluate the rates at which clinical providers detect failure-to-thrive in children under 5 years during routine AMPATH clinic visits. Hypothesis: Clinical providers will have low rates of identifying failure-to-thrive as a problem for children under-five requiring follow-up. Aim 4: Describe the mortality rates and rates of losses to follow-up in this population. Hypothesis4a: Mortality rates will be higher among those children who are HIV-infected and malnourished. Hypothesis 4b: Losses to follow-up are more common among HIV-exposed children compared to HIV-infected children. Rates of those lost to follow-up for both groups will be <20%, which is generally considered acceptable in research studies.</p>
<p>Site(s)</p>	<p>All AMPATH Sites</p>
<p>Project Period</p>	<p>7/1/2015 – 6/30/2017</p>
<p>Funding Status</p>	<p>Unfunded –</p>
<p>Direct Award (USD)</p>	<p></p>
<p>Update</p>	<p>Still waiting to hear back about the cost of obtaining data through AMRS.</p>

Future Plans	I would love to have the data from AMRS for analysis.
Publication(s)	
Study Title	Feasibility of Ultrasound-guided Assessment of Volume Status in an Intensive Care Unit in Kenya: a Pilot Study
Principal Investigator(s)	Virginia Radcliff, Duke University
Co-Investigator(s)	Peter Kussin PK Werunga Wangari Siika
Working Group(s)	Adult Medicine
Description	<p>Critical illness is a worldwide phenomenon, though critical-care resources vary widely among nations and little data exists to accurately define the global burden. Low- and middle-income countries (LMICs) have a disproportionately high incidence of trauma and infectious diseases, coupled with a profound lack of resources available to treat these critically ill patients. Hypotension is frequently encountered in any intensive care unit (ICU) and requires accurate determination of intravascular volume status and appropriate fluid management in order to restore tissue perfusion and prevent end-organ damage. Volume assessment in high-income countries is based, not only on physical exam, but also on hemodynamic monitoring that requires complex and invasive technologies. In LMICs, fluid administration is guided by clinical signs of adequate tissue perfusion, which have proven repeatedly to be unreliable. Yet it is in these settings, where mechanical ventilation and dialysis may not be readily available, that the risks of volume overload are compounded. Bedside ultrasound is a relatively inexpensive, portable, and noninvasive tool that has been gaining in popularity in both HICs and LMICs in recent years. Inferior vena cava (IVC) diameter can be easily measured with ultrasound, and several studies have shown that it can be used to accurately assess preload and predict fluid responsiveness. To our knowledge, no previous study has evaluated the use of bedside ultrasound in the assessment of volume status in a resource-limited setting. We hypothesize that early recognition and management of hypotension could be improved using a simple, noninvasive hemodynamic target such as IVC diameter and collapsibility. This prospective observational study will serve as a pilot study assessing the use of bedside ultrasound to evaluate volume status in critically ill patients in a resource-limited setting. Over a two-month period, we plan to enroll 50 adult patients admitted to MTRH with hypotension or tachycardia. After collection of basic data (history and physical examination, vital signs, relevant laboratory values, and current therapies), bedside ultrasound will be performed by the investigator to measure IVC diameter and collapsibility. Prior to each ultrasound assessment, the treating medical officer will be asked to classify the patient as hypovolemic, euvolemic, or hypervolemic. The primary outcome is concordance between physician determination of volume status and that based on ultrasound measurements. Other outcomes of interest include investigator rating of adequacy of resuscitation as well as 48-hour and in-hospital mortality.</p>
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	8/1/2014 – 10/1/2014

Funding Status	Funded – Duke Global Health Institute
Direct Award (USD)	\$5,000
Update	Our study was successfully conducted at Moi Teaching and Referral Hospital in August and September of 2014. We were able to enroll 37 adult patients with hypotension on the medical wards and in the intensive care unit at MTRH. We collected basic data (demographics, vital signs, labs, and treatments) as well as ultrasonographic IVC measurements for each patient. We were also able to obtain survey data regarding the treatment team's independent assessment of volume status.
Future Plans	We are currently analyzing the collected data. Over the next few months, we plan to complete statistical analysis and write a manuscript. We expect to submit a manuscript for publication within the next 4-5 months.
Publication(s)	

Study Title	HI-Train: Health Informatics Training and Research in East Africa for Improved Health Care
Principal Investigator(s)	Abraham Siika, Moi University Martin Were, Indiana University
Co-Investigator(s)	Ayuo, Paul Nabukenya, Josephine Mughal, Khalid Tylleskar, Thorkild
Working Group(s)	Adult Medicine
Description	With increased deployment of eHealth systems, comes the need for an appropriate health information technology workforce. This workforce includes: (a) Local level: Health IT professionals, eHealth specialized programmers, data managers, implementation managers, support specialists and reporting personnel, (b) Institutional level: chief medical information officers, and health information management specialists, (c) administrative: regional and national eHealth coordinators and eHealth monitoring and evaluation specialists, and (d) Other: health information privacy and security specialists and HI researchers. End users, institutional managers and policy makers also need to be appropriately trained on the relevant eHealth systems. Alarming, most sub-Saharan countries remain woefully unprepared to systematically train an adequate workforce to support the eHealth systems already being deployed. Countries like Uganda and Kenya recognize an emergent need for national strategies to build health informatics human capacity. These countries have appropriately developed national eHealth capacity-building strategies Implementing the strategies however requires direct leadership by Higher Education Institutions in the relevant countries. The urgency for sustainable mechanisms to increase HI workforce and research capacity in developing countries is self-evident. This goal can only be realized by having enough faculty members from developing countries fully trained in Health Informatics. These staff faculty can then be part of a well-functioning and high quality HI program moving forward. Recognizing this need, and the multidisciplinary competencies needed for HI training and research, our team identified partner institutions with complementary capabilities to support advanced

	Health Informatics training in East Africa for our project. Aims 1) Provide post-graduate (Masters and PhD) level training in Health Informatics and research. The focus will be on post-graduate training for health professionals and computer science personnel to help them become HI faculty at their institutions. 2) Increase number of women and marginalized populations in faculty-level training in Health Informatics and research at the LMIC higher education institutions. 3) Improve the quality and quantity of Health Informatics research conducted primarily by re-searchers based in the LMIC countries in collaboration with our Northern partners. 4) Provide model curricula, educational programs and approaches for faculty-level health informatics training that can be emulated by regional higher education institutions.
Site(s)	Moi University, Makerere University, University of Bergen
Project Period	12/5/2013 – 6/30/2019
Funding Status	Funded – Other, NORAD - Norwegian Agency for Development Cooperation
Direct Award (USD)	\$2,757,830
Update	PhD candidate documents have been received and are being reviewed by University of Bergen facility. The Masters program was approved for Moi University at the Senate level. PhD mentor panels have been established for incoming students.
Future Plans	Curricula for PhD course in health informatics will be developed for Moi and Makerere University. The Institute for Biomedical Informatics will be established for Moi University in the first part of 2015. Advertisement for the Masters Application to commence in March 2015.
Publication(s)	

Study Title	HIV-1 Drug Resistance in Different Subtypes
Principal Investigator(s)	Rami Kantor, Brown University Lameck Diero, Moi University
Co-Investigator(s)	Nathan Buziba Wilfred Emonyi
Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	Examine drug resistance upon tenofovir-containing first line antiretroviral therapy in multiple subtypes in western Kenya using different analytes.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	5/12/2012 – 2/20/2014
Funding Status	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	\$98,168

Update	Laboratory work completed. Data analyses and manuscript writing ongoing.
Future Plans	Present in conferences. Finalize publication.
Publication(s)	1. R Kantor, K Brooks, M Balamane, L Schreier, M Orido, E Kemboi, M Chepkenja, PA Chan, W Emonyi, L Diero. HemaSpotâ„¸: a Novel Blood Storage Device for HIV Drug Resistance Testing. Conference on Retroviruses and Opportunistic Infections, February 23-26,

Study Title	HIV-1 Genotypic Diversity and Drug Resistance in Western Kenya
Principal Investigator(s)	Rami Kantor, Brown University Lameck Diero, Moi University
Co-Investigator(s)	Nathan Buziba Wilfred Emonyi
Working Group(s)	Adult Medicine, Behavioral & Social Science
Description	Identify circulating HIV-1 subtypes and recombinant forms, determine genotypic background in drug-naïve persons and determine drug resistance in persons failing antiretroviral therapy in western Kenya, using multiple testing analytes.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	5/17/2006 – 2/20/2014
Funding Status	Funded – Brown University - Center For AIDS Research, Other, Rhode Island Foundation
Direct Award (USD)	\$40,000
Update	Paper published. Analysis of additional HIV genes and more sensitive resistance assays ongoing.
Future Plans	Finalize analysis of additional HIV genes and more sensitive resistance assays ongoing.
Publication(s)	1. R Kantor, A DeLong, M Balamane, L Schreier, RM Lloyd, W Injera, L Kamle, F Mambo, S Muyonga, D Katzenstein, J Hogan, N Buziba, L Diero. HIV Diversity and drug resistance from plasma and non-plasma analytes in a large treatment program in Western Kenya

Study Title	Indiana University-Moi University Academic Research Ethics Partnership
Principal Investigator(s)	Eric Meslin, Indiana University David Ayuku, Moi University
Co-Investigator(s)	Were, E.

Working Group(s)	Bioethics
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 longstanding 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 committees, 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.
Site(s)	Moi Teaching and Referral Hospital (MTRH), Other
Project Period	5/31/2012 – 5/31/2017
Funding Status	Funded – NIH - Fogarty International Center (FIC)
Direct Award (USD)	\$1,250,000
Update	<p>Summary of progress made between July 1 and December 31, 2014</p> <p>a. Student Progress towards Completion of Training At Moi: Three students were enrolled in the fifth cohort (2014/2015) of Moi MSc. students. The first graduate from the Moi program, Dr. Eunice Kamaara BA, MA, PHD, received her degree this October after successfully defending her thesis titled: Challenges of obtaining valid informed consent in International HIV research in western Kenya. Dr. Kamaara also serves as a member of the Médecins Sans Frontières (MSF) Ethics Review Board. David Nderitu BA, MA who completed his practicum in Indianapolis in 2011 was appointed an Assistant Lecturer at Egerton University Faculty of Arts and Social Sciences in the Department of Philosophy, History and Religious Studies. At IU: Of the two students currently enrolled, one (Avril Rua) is completing her research titled Biobanking in Kenya: Challenges for Policy and Governance, and is expected to graduate May 2015, while Dr. Scott Saxman is completing his coursework this semester, and is working on preparations for his practicum experience in Eldoret.</p> <p>b. Practicum Experience, Fall 2014 Practicum Experience for Moi MSc. Students: IU-Moi AREP hosted and provided support for five students from the MSc. in International Health Research Ethics at Moi University from October 6 - November 14, 2014. Five student were selected from the eleven enrolled in their cohort to complete their practicum experience in Indianapolis. The remaining completed their practicum experience in Eldoret at AMPATH, at the Moi/MTRH Institutional Ethics Review Committee, and in Nairobi at the Kenya Medical Research Institute (KEMRI). The five students were each paired with mentors from the IU campus who are experts in the student's research area. They attended core lectures as per the NIH requirements for Responsible Conduct of Research as well as other interests. This included conflict of interest, research with animals, history of research with human subjects, policies concerning research with human subjects, peer review, data acquisition and management and safe laboratory practices. They audited three IUPUI research ethics courses: GRAD-G 504 Introduction to Research Ethics (Instructor: Prof. Kimberly Quaid) , PHIL-P547</p>

Foundations of Bioethics (Instructor: Prof. Peter Schwartz), PHIL 555: Ethical and Policy Issues in International Research (Instructor: Prof. Eric Meslin) and participated in a two-day intensive Research Coordinator Education Program. They conducted visits to the IU Simon Cancer Center, the Regenstrief Institute, the IU - Kenya Partnership, the Indiana Biobank, the IU Animal Labs, the Hall Center for Law and Health at the McKinney School of Law, and had a day-long visit to Eli Lilly and Company where they were hosted by the Lilly Bioethics program. The students also had an opportunity to interact with the School of Medicine Global Health Track for IU Residents and presented on their research projects.

Future Plans

Planned Activities for the Next Six Months

a. Further development of Nairobi location as satellite for Moi program. There has been increased interest in research ethics programs. Specifically, interest has been expressed by Nairobi based professionals for a research ethics program similar to the one in Eldoret. To serve this need, plans are underway to offer the Msc. in International Health Research Ethics in Nairobi. The Moi University Nairobi campus will serve as the satellite site for this evening program, which will hold classes from 5:00 pm - 10:00 pm EAT weekdays on Monday to Friday, and including weekends. Advertisements for enrollment will be disseminated in March, 2015.

b. Short courses and training programs. Global Bioethics Seminar Series: The IU Center for Bioethics, in partnership with the IUPUI Medical Humanities and Health Studies Program the IU Hall Center for Law and Health, the IUPUI Office of International Affairs, and the IU Center for Global Health are convening an 8-part seminar series on Global Bioethics as part of its ongoing commitment to studying ethical issues in international health and research. The goals are to, provide a venue for in-depth discussion of emerging (and persistent) ethical issues in global health, identify gaps in knowledge and practice that present research and collaboration opportunities, and develop and expand local capacity. The topics have been selected from current developments in the academic literature, on the ground, and in the media, including epidemic preparedness and response, international clinical trials, humanitarian intervention, and the use of new technologies to support global health. The seminars will be moderated discussions using cases, pre-circulated readings, and other relevant information. The full schedule is here: <http://bioethics.iu.edu/education/global-bioethics-seminar-series/> Short Course in Health Research Ethics: Moi University will hold a short-course from February 16 - 27. This short-course aims at building capacity in the area of international research ethics. This capacity will assure ethical and a scientific review of research protocols developed by local and international scientists. The course will cover topics in: Metaphysics & Theories of knowledge, Research Methods, Contemporary Issues in International Research, Management of International Research Ethics, Research Ethics Committees & Consultation, Gender Issues in Research Ethics, Principles of Healthcare and Health Research Ethics, Qualitative and Quantitative Data Analysis, Ethical Theories, and Culture, Policy and Ethical Issues in International Research. The learning methods that will be utilized are lectures, small group discussions, case studies, group-work, self-directed learning and written and oral presentations. Seventh Annual Teaching Skills in International Research Ethics (TaSkR VII) Workshop: The IU-Moi AREP will be convening a TaSkR workshop in Indianapolis from April 15 - 17, 2015. The theme for the workshop is Epidemic Ethics. The recent Ebola outbreak has brought to the fore ethical issues in epidemics, and it is hoped that the workshop will extend beyond Ebola to other epidemics. The workshop has been organized into panels and round-table sessions on

	<p>humanitarian action, clinical trial design, ethics review, regulatory issues and scientific communication. There will also be a 'House-of-Commons' style debate and a session on information sources for International Research Ethics. Plans are underway to finalize the agenda. Now in its seventh year, the TaSkR workshop series attracts local, regional and international experts from Indiana University, Moi University and the community. The workshop will be held in room 3100, Health Information and Translational Sciences Building (HITS). More information and registration can be found at http://bioethics.iu.edu/programs/arep/taskr/ c. Collaboration with Other Programs We intend a set of activities designed to enhance IU Moi AREP's reach in global bioethics. First, we have offered to host the Planning Committee of the Global Forum for Bioethics Research in Indianapolis as it develops the schedule for its next international meeting in November. Second, Meslin has been invited to join the advisory committee of Vanderbilt University's Fogarty-funded bioethics program in Mozambique. Both activities will ensure greater outreach of our program.</p>
<p>Publication(s)</p>	<p>Publications Meslin EM, Were E, Ayuku D. 'Because it Was Hard' . . . Some Lessons Developing a Joint IRB between Moi University (Kenya) and Indiana University (USA). Open Peer Commentary, American Journal of Bioethics 2014, 14: 17-19. DOI10.1080/152651.2</p>

<p>Study Title</p>	<p>Innovative public-private partnership to target subsidized antimalarials in the retail sector</p>
<p>Principal Investigator(s)</p>	<p>Wendy O'Meara, Duke University Dr. Diana Menya, Moi University</p>
<p>Co-Investigator(s)</p>	<p>Laktabai, Jeremiah Mohanan, Manoj Turner, Elizabeth</p>
<p>Working Group(s)</p>	<p>Public Health & Primary Care</p>
<p>Description</p>	<p>In most of the malaria-endemic world, fevers are often treated with medicine purchased over the counter in pharmacies, drug shops and general stores. Antimalarials of varying quality and efficacy are widely available in a range of regulated and unregulated outlets. Effective artemisinin combination therapies (ACTs) recommended by the World Health Organization are considerably more expensive than counterfeit drugs or older antimalarials to which high levels of resistance exist. As a result, fewer than 15% of fevers treated for malaria receive appropriate, effective therapy. This project therefore seeks to implement and evaluate an innovative public-private partnership designed to improve targeting of ACTs to individuals with confirmed malaria infection. The partnership will leverage an existing network of trained community health workers and a vibrant retail medicine sector that has been shown to be an efficient conduit for subsidized antimalarials. Unlike other approaches that attempt to improve targeting of ACTs by offering subsidized RDTs, our approach allows the subsidy itself to be targeted through linking the subsidy to a positive malaria test using a coupon system. The proposed work addresses a time-sensitive problem with significant policy implications, both nationally and internationally. In Aim 1, we will determine the effect of varying levels of subsidy on patients' decision to purchase ACTs, and determine the level of subsidy required to</p>

	maximize targeting of ACTs to clients with confirmed malaria infection. This approach will allow us to quickly generate information that will 1) assist the Division of Malaria Control to set subsidy levels nationwide and 2) guide Aim 2 to set subsidy levels for ACTs to maximize the community-level impact of expanding availability of malaria diagnosis on appropriate treatment. In Aim 2, we will scale up and evaluate an innovative public-private partnership between government-trained community health workers (CHWs) and retail outlets designed to target the subsidized antimalarials to those people with confirmed malaria infection. CHWs will be trained to perform malaria rapid diagnostic tests (RDTs) at the household level and give a coupon to those individuals who have a positive malaria test. The coupon will entitle the holder to a discount on a subsidized, quality-assured ACT purchased in the retail sector. The subsidy is provided by the coupon rather than directly to the wholesaler/retailer. This strategy allows not just the ACT, but the subsidy to be targeted to those individuals with confirmed infection.
Site(s)	Other
Project Period	2/15/2014 – 1/31/2018
Funding Status	Funded – NIH
Direct Award (USD)	Not Reported
Update	313 participants have been enrolled so far in two community units (Marinda and Misimo) in Bungoma East Sub County and we are now in the third community unit (Lutacho). The major challenge encountered is the slow recruitment of participants due to several reasons. Preparations are underway to start off aim 2 of the study. The team has already visited several possible sites for the next phase of the study and we are yet to decide on the most suitable areas.
Future Plans	We hope to complete the piloting and move on to the next phase of the study over the next 6 months.
Publication(s)	

Study Title	IU Health Cardiovascular Research Biobanking Project
Principal Investigator(s)	Tom Inui, Indiana University Sylvester Kimaiyo, Moi University
Co-Investigator(s)	Bloomfield, G.
Working Group(s)	Adult Medicine, Cardiovascular & Metabolic Disease
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

	<p>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.</p>
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	4/30/2012 – 4/28/2017
Funding Status	Funded – IU Health
Direct Award (USD)	\$1,060,000
Update	<p>An attempt was made to ship all available PBMC pellet samples to IU for DNA extraction and genomic analysis. -After processing in the IU Biobank lab, 259 samples of the pellets extracted were sent to Matteo Vatta's lab for genomic analysis. - 22 of the samples failed DNA extraction. Of the 22, 13 were controls and 9 were AF cases. Attempts will be made in Eldoret to contact patients in order to redraw blood from 8 of the cases. One patient with AF is now deceased. - In addition. 5 samples were never sent to IU, Of the 5 we will redraw 3 samples that were from the cases. Giving us a total of 11 samples that we could potentially redraw. We have already redrawn one sample and scheduled most of the others for January and early February 2015. - Of the 22 samples that failed DNA extraction,19 of their duplicate samples in the Ampath lab can be shipped to IU. Of the five samples that were never shipped to I.U 4 of them have been verified and can be shipped giving us a total of 23 samples currently at AMPATH that can be shipped to I.U A protocol for collecting follow-up information on the clinical status of all patients in the original cohort of cases and controls was drafted and submitted to IREC for review. After initial approval, IREC suspended approval and asked for a formal revision of the protocol to be submitted. Work to produce this revised protocol is underway.</p>
Future Plans	<p>A revised protocol for one-year follow-up of the cohort should be submitted. We are in a dialogue with principals in a large international study of AF about contributing case information (and potentially biomaterials) to their combine. Drafting of a study methods manuscript has been initiated.</p>
Publication(s)	

Study Title	Knowledge, Attitudes and Practices of Sepsis Management at Moi Teaching and Referral Hospital, Kenya
Principal Investigator(s)	Elizabeth Mathenge, Duke University
Co-Investigator(s)	
Working Group(s)	Adult Medicine
Description	<p>Study objectives: Sepsis is the presence of suspected or confirmed infection, in addition to systemic manifestations of infection. In many developing countries the data on sepsis - causes, prevalence, morbidity, mortality and current practices - is sparse. This study aims to understand sepsis related intervention practices among health care providers within a referral center in Kenya. This study will also look at the main attitudinal and health system barriers to adequate care for patients with sepsis. Methods: This is an analytical cross-sectional study. Knowledge Attitude and Practice (KAP) questionnaires will be distributed to health care providers at the Moi Teaching and Referral hospital in Eldoret, Kenya. The target population is physicians, clinical officers, and senior nurse practitioners working at the ICU, casualty and Nyayo wards between June 2014 and August 2014. Data analysis: Data will be presented using descriptive statistics in the form of frequencies and percentages for similar open form questions, and standard deviations for quantitative variables. Chi-square and fisher's exact test will be used for categorical variables and the level of significance will be set at 0.05. Open format responses will be analyzed qualitatively into nominal categories using NVIVO. Certain themes that represent the objectives of the study will be identified.</p>
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	7/13/2014 – 3/31/2015
Funding Status	Funded – Duke Global Health Institute
Direct Award (USD)	\$1,000
Update	<p>Project Progress (July 2014 - December 2014) Sepsis is the presence of suspected or confirmed infection, in addition to systemic manifestations of infection. In many developing countries, the data on sepsis - causes, prevalence, morbidity, mortality and current practices - is sparse. This aim of the study was to understand sepsis related intervention practices among health care providers within a referral center in Kenya. This study also looked at the main attitudinal and health system barriers to adequate care for patients with sepsis. To accomplish this, an analytical cross-sectional survey assessing knowledge attitude and practice (KAP) was administered to health care providers at the Moi Teaching and Referral Hospital in Eldoret (MTRH), Kenya. The target population was physicians, clinical officers, and senior nurse practitioners working at the ICU, casualty and Nyayo. After getting the necessary approvals, data was collected between July 2014 and August 2014. (December 2014 - present) Numeric data was manually entered into a Microsoft Excel and STATA data files. Responses to the two open form questions were transcribed into Microsoft Word files. Quantitative data was analyzed using STATA version 13, yielding descriptive statistics (bivariate analysis pending) Closed ended questions and Likert scale questions were coded into binary variables, after which</p>

associations were sought between knowledge and practices, practices and attitudes, and knowledge and attitudes. Differences between two categorical variables are currently being explored using Chi square and Fishers Exact test and the level of significance is set at 5%. Open format responses were qualitatively into nominal categories using NVIVO. Themes representing the objectives of the study were identified. This study's data is currently being analyzed. A total of 87 health service providers participated in this study. One provider was a nutrition consultant and was thus not considered eligible for this study. All completed surveys were included (100% response rate). Of the 86 participants, 39 (45%) were physicians, 36 (42%) were nurse practitioners and 11(12.8%) were clinical officers. Of the 39 physicians, 14 (16%) were registrars, 12 (14%) were medical officers and 12 (14%) were interns. Some of the descriptive preliminary results show that over 70% of the providers utilize fever and tachycardia as the major diagnostic criterion for sepsis. More than half of the providers (51%) will typically not perform a lactate test. When prompted to indicate what lactate threshold was commonly used, an overwhelming majority (80%) of the providers declined to input any value. The most common antibiotics in use are Ceftriaxone and Flagyl, with 85% of the providers stating that this was the most common antibiotic in their departments. In accordance with the SCC guidelines, 76% of the time, antibiotics were administered within an hour of the patient's arrival at the department. However, only about half - 50% - stated that this antibiotic was frequently available in their department. Thematic analyses of open form questions indicated that barriers to institutional capacity to deal with patients fall into five main categories 1. Lack of sufficient staff - Many concerns centered around the number of staff in the specific departments with the comment 'employ more staff' being the most common response. Further, staff empowerment was a concern for many of the respondents - 'CME on management of sepsis' and "frequent continuous education sessions to the doctors' 2. Lack of antibiotics 3. Lack of monitoring equipment, replacement of faulty equipment and a need for increased frequency of monitoring 4. Lab efficiency, especially blood cultures 5. Lack of ICU space / lack of critical care facilities

Future Plans

This will include finishing data analysis, results presentation and discussion, thesis defense and submission to journals

Publication(s)

Study Title

Linkage and Retention to Care in Western Kenya Following HIV Testing

Principal Investigator(s)

Becky Genberg, Brown University
Juddy Wachira, Moi University

Co-Investigator(s)

Paula Braitstein Violet Naanyu Beth Rachlis Hana Lee Joseph Hogan

Working Group(s)

Adult Medicine

Description

This project is focused on identifying the individual, psychosocial, and structural barriers to timely linkage and retention. This project has three specific aims: 1. To

comprehensively describe linkage and retention to HIV care following home-based counseling and testing by examining time from testing to linkage and the socioeconomic, demographic and structural determinants of linking to care. We will conduct retrospective and multilevel analyses using existing de-identified clinical and facility-level data collected within AMPATH, defining linkage to care as the completion of an initial HIV clinical encounter with a provider following testing. We will also examine factors that predict retention in HIV care over time. 2. To characterize the psychosocial and structural facilitators and barriers to linkage and retention to care following positive HIV diagnosis through HBCT and PITC. We will conduct a qualitative study to examine the psychosocial factors inhibiting or motivating linkage to care, experiences in accessing care, and factors that promote or interrupt retention among those who tested positive via HBCT or PITC. We will also collect data from clinicians and community health workers to examine how features of the healthcare system facilitate or constrain linkage and retention to care. 3. To develop and implement a feasibility study of a pilot psychosocial intervention aimed at increasing linkage to care among individuals testing positive for HIV. The content of this intervention pilot will be informed by the results of Aims 1 and 2. The first aim of this study involves secondary analysis of data collected during home-based counseling and testing linked to medical records data. This data will include information collected as part of routine testing procedures and care, for those who successfully linked to care. AIM 2 will employ qualitative approaches to identify barrier and facilitators to linkage and retention. AIM 3 will include information collected as part of routine care, for those who successfully linked to care. Specifically, medical record reviews at baseline and post-intervention.

Site(s)

Other

Project Period

6/4/2012 – 12/20/2013

Funding Status

Funded – Eli Lilly Foundation, Bill and Melinda Gates Foundation, NIH

Direct Award (USD)

Not Reported

Update

We have made significant progress during the period from July 1 - December 31, 2014. The analysis examining linkage to care following home-based counseling and testing in Bunyala is complete and has been published (see below for details). Our main findings were: 1) nearly 40% of individuals living with HIV in the sub-County of Bunyala were not aware of their HIV status, 2) of those who had previously known HIV diagnosis, 84% had ever engaged with HIV care, 3) among those newly diagnosed, only 15% had an initial encounter with a clinician in the median of 3.4 years since their diagnosis, and 4) among the entire population of HIV-positive individuals living in this sub-County, 58% of them had engaged with HIV care. For retention analysis, we have several ongoing analyses. First we are examining how the point of entry into care (i.e., testing program) is related to longer term retention in HIV care and mortality. We are also examining the patterns and predictors of gaps in care (defined as missing a visit by at least 3 months but returning to care within 1 year) among adult HIV patients. These two analyses will be presented at the upcoming Conference on Retroviruses and Opportunistic Infections (CROI). We have also submitted analyses examining the HIV cascade of care among patients enrolling in AMPATH to the International Workshop on Observational Databases. In addition we have a number of ongoing qualitative activities to address Aim 2 of this study. First we completed qualitative data collection consisting of 60 in-depth interviews with health

	care providers (e.g., nurses, clinical officers) to understand how patient-provider relationships and communication, as well as facility-level factors, are related to linkage and retention in HIV care, from the perspectives of providers. We are currently analyzing this data. We have completed and submitted several manuscripts examining how health facility factors and community perceptions of community-health workers are related to linkage and retention in HIV and other chronic disease care. One of these papers has been published (see list below).
Future Plans	During the next 6 months, we plan to complete qualitative data collection for Aim 2 of this study. We will interview 60 adults who tested positive via home-based counseling and testing and did and did not link to care following their new diagnosis. This valuable information will allow us to understand the barriers and facilitators to linking to care from the point of HBCT and adapt care models and programs to appropriately engage newly diagnosed individuals in care.
Publication(s)	1. Wachira J, Naanyu, Genberg B, Koech B, Akinyi J, Kamene R, Ndege S, Siika A, Kimaiyo S, Braitstein P. Health facility barriers to HIV linkage and retention in western Kenya. BMC Health Services Research 2014, [epub ahead of print].

Study Title	MESA Malaria Prevention Study (MPS)
Principal Investigator(s)	Wendy O'Meara, Duke University A. Obala, Moi University
Co-Investigator(s)	Mangeni, J. Menya, D.
Working Group(s)	Public Health & Primary Care
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.
Site(s)	Webuye District Hospital
Project Period	1/1/2013 – 9/30/2014
Funding Status	Funded – Malaria Eradication Scientific Alliance (MESA)
Direct Award (USD)	\$197,500
Update	Eighteen Community Health Volunteers (CHVs) were successfully trained on data collection using the rapid assessment tool and they were able to collect data around six facility catchment areas in Bungoma East Sub County.
Future Plans	Manuscripts in preparation Project to soon close out
Publication(s)	

Study Title	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
Principal Investigator(s)	Abraham Siika, Moi University Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Murage, T. Thirumurthy, H. Goodrich, S.
Working Group(s)	Adult Medicine
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.
Site(s)	Busia District Hospital, Chulaimbo Sub-District Hospital, Khunyangu Sub-District Hospital, Kitale District Hospital, Port Victoria Sub-District Hospital

Project Period	8/1/2011 – 12/31/2013
Funding Status	Funded – USAID - United States Agency for International Development, PEPFAR - United States President's Emergency Plan for AIDS Relief - Public Health Evaluation (PHE)
Direct Award (USD)	\$825,501
Update	Continuing approval was provided by IREC on February 27, 2013. The study closed for enrollment on the January 11, 2013.
Future Plans	
Publication(s)	
Study Title	Mortality among street connected children and youth in Eldoret, Kenya: a retrospective chart review
Principal Investigator(s)	Lonnie Embleton, Moi University Paula Braitstein, Indiana University
Co-Investigator(s)	Ayuku David, Kamanda Allan, Makori Dominic, Nalyanya
Working Group(s)	Pediatrics
Description	<p>There are increasing reports of deaths among street connected children and youth in Eldoret, Kenya. A number of deaths have been documented by a community advocate since January 2010 and brought to the attention of our research team as a major concern. It is known that many of these children and youth engage in high risk behaviours, such as substance use, transactional sex, are subject to physical and sexual violence, perform hazardous labour and in general have harsh living conditions on the streets, all of which heighten their risk for death. It is suspected that many of the reported deaths among this population are preventable and require the urgent attention of service providers and policymakers to implement programs and services to decrease mortality in this marginalized population. In light of the increased reports of death among this vulnerable population in Eldoret, Kenya, this present proposal seeks to perform a case-series review of deaths among street connected children and youth through a retrospective chart review at Moi Teaching and Referral Hospital (MTRH). This proposal seeks to ascertain cause of death and HIV status from MTRH and mortuary records for known deaths among street connected children and youth aged less than 25 who have passed away from January 2010-December 2013 in and out of the hospital. Currently there are no reports in the literature concerning mortality among street connected children and youth in sub-Saharan Africa, yet it is vital to understand the causes of death in this population in order to prevent unnecessary deaths. This case series in Eldoret, Kenya will provide valuable preliminary data and insight into the causes of mortality among street connected children and youth. Ascertaining causes of death will assist local service providers and policymakers to target key public health areas to decrease mortality. Aim 1. To estimate the number of deaths that have occurred among street children and youth aged 0 to <25 years, in and out of hospital, in Eldoret Kenya between January 2010 and December 2013.</p>

	Aim 2. To determine the causes of death among street children and youth aged 0 to <25, utilizing hospital and mortuary records from MTRH, in Eldoret Kenya between January 2010 and December 2013. Aim 3. To determine the HIV status of deceased street children and youth aged 0 to <25, utilizing hospital and mortuary records from MTRH, in Eldoret Kenya between January 2010 and December 2013.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	10/30/2013 – 4/30/2014
Funding Status	Unfunded –
Direct Award (USD)	
Update	This project is complete and the paper is still under review.
Future Plans	As the paper is under review, we hope the findings will be published.
Publication(s)	

Study Title	Nurse Management of Hypertension Care in Rural Western Kenya
Principal Investigator(s)	Rajesh Vedanthan, Mount Sinai School of Medicine Sylvester Kimaiyo, Moi University
Co-Investigator(s)	
Working Group(s)	Adult Medicine, Cardiovascular & Metabolic Disease
Description	This project aims to evaluate barriers and facilitators to nurse management of hypertensive patients in rural western Kenya, using a qualitative research approach. The four specific aims for attaining this objective are: Aim 1: To evaluate facilitators and barriers to nurse-based management of hypertensive patients in rural western Kenya. This will be accomplished by conducting a rapid assessment procedure involving key informant interviews, focus group discussions, and field observations. Aim 2: To develop and evaluate an innovative smartphone-based DEcision Support and Integrated REcord-keeping (DESIRE) tool utilizing a participatory, iterative, human-centered design process, to assist nurses taking care of hypertensive patients. We will evaluate the usability and feasibility of the DESIRE tool using qualitative methods (e.g. think-aloud, mock patient encounters, semi-structured interviews, and focus groups). Aim 3: To conduct an impact evaluation of a pilot program for nurse-based management of hypertension to be implemented by AMPATH, by performing secondary analysis of routine clinical data collected by AMPATH. The primary outcome measure will be change in systolic blood pressure in hypertensive patients assigned to nurse-based management after one year. Aim 4: To estimate the nurse workforce requirements for stable, long-term treatment of hypertension throughout western Kenya, using a needs-based workforce estimation model.

Site(s)	Mosoriot Rural Health Training Centre, Turbo Health Centre
Project Period	9/17/2011 – 7/30/2016
Funding Status	Funded – NIH - Fogarty International Center (FIC)
Direct Award (USD)	\$675,543
Update	For Aim 1 . Data analysis finalized and manuscript is in the final process of preparation. For Aim 2, a manuscript titled, 'Feasibility of Implementing a Tablet-Based Decision Support and Integrated Record-Keeping (DESIRE) Tool in the Nurse Management of Hypertension in Rural Kenya' has been published in the International Journal of Medical Informatics. A related abstract was presented as a poster at the APHA Conference in New Orleans in November 2014. For Aim 3 data entry has been completed and data extraction/cleaning is ongoing. For Aim 4, data collection is complete. We conducted six key informant interviews and 6 focus group discussions were done with a total of 60 participants. In addition, 118 participants were recruited for the time motion study. Transcription and coding in Nvivo is near complete. Content analysis is ongoing. A Delphi exercise was also performed, and those results have been analyzed.
Future Plans	We hope to complete the following activities pertaining to each study aim: Aim 1: Complete qualitative manuscript. Aim 2: Explore the possibility of assessing patient perceptions of the mHealth interventions in the CDM program. Aim 3: Ensure data analysis is complete, ensure accuracy and cleaning of data, conduct preliminary and final data analyses, submit abstracts to professional conferences. Aim 4: Complete data analysis, estimation model completion, run estimation model with inputs from data collection, and submit abstracts to professional conferences.
Publication(s)	Vedanathan R, Blank E, Tuikong N, Kamano J, Misoi L, Tulienge D, Hutchinson C, Ascheim DD, Kimaiyo S, Fuster V, Were MC. Usability and Feasibility of a Tablet-Based Decision-Support and Integrated Record-Keeping (DESIRE) Tool in the Nurse Management of Hypertension in Rural Western Kenya. International Journal of Medical Informatics 2015, DOI: 10.1016/j.ijmedinf.2014.12.005 Blank E, Tuikong N, Kamano J, Misoi L, Tulienge D, Hutchinson C, Ascheim D, Kimaiyo S, Fuster V, Were M, Vedanathan R. Feasibility of Implementing a Tablet-Based Decision Support and Integrated Record-Keeping (DESIRE) Tool in the Nurse Management of Hypertension in Rural Kenya. American Public Health Association Annual Meeting. 2014 November, New Orleans, USA

Study Title	Optimizing Linkage and Retention to Hypertension Care in Rural Kenya
Principal Investigator(s)	Rajesh Vedanathan, Mount Sinai School of Medicine J. Kamano,
Co-Investigator(s)	Fuster, V. Horowitz, C. Were, M. Inui, T. Hogan, J. Velazquez, E. Bloomfield, G. Naanyu, V. Menya, D. Kimaiyo, S. Akwanalo, C.

Working Group(s)	Adult Medicine, Cardiovascular & Metabolic Disease
Description	<p>Hypertension awareness, treatment, and control rates are low in most regions of the world. A critical component of hypertension management is to facilitate sustained access of affected individuals to effective clinical services. In partnership with the Government of Kenya, the Academic Model Providing Access to Healthcare (AMPATH) Partnership is expanding its clinical scope of work in rural western Kenya to include hypertension and other chronic diseases. However, linking and retaining individuals with elevated blood pressure to the clinical care program has been difficult. To address this challenge, we propose to develop and evaluate innovative community-based strategies and initiatives supported by mobile technology. The objective of this project is to utilize a multi-disciplinary implementation research approach to address the challenge of linking and retaining hypertensive individuals to a hypertension management program. The central hypothesis is: community health workers (CHWs), equipped with a tailored behavioral communication strategy and a smartphone-based tool linked to an electronic health record, can increase linkage and retention of hypertensive individuals to a hypertension care program and thereby significantly reduce blood pressure among these patients. We further hypothesize that these interventions will be cost-effective. To test these hypotheses and achieve the overall objectives, we will pursue the following specific aims: Aim 1: Identify the facilitators and barriers to linking and retaining individuals with high blood pressure to a hypertension care delivery program, using a combination of qualitative research methods: 1) baraza (traditional community gathering) form of inquiry, 2) focus group discussions among individuals with elevated blood pressure during home-based testing, and 3) focus group discussions among CHWs. Subsidiary Aim 1.1: Using identified facilitators and barriers, develop a tailored behavioral communication strategy guided by the Health Belief Model modified by incorporating emotional elements for the CHWs to use with hypertensive patients, focusing on regular and timely attendance at hypertension clinic. We will test the communication strategy for face and content validity using focus group discussions with CHWs and individuals with elevated blood pressure. Subsidiary Aim 1.2: Using identified facilitators and barriers, develop a smartphone-based tool linked to the AMPATH Medical Record System (AMRS) to be used by CHWs to optimize linkage and retention of hypertensive patients to the care program, and evaluate the usability and feasibility of this tool using think-aloud technique, mock patient encounters, focus group discussions, and participant observation. Aim 2: Evaluate the effectiveness of CHWs equipped with a tailored behavioral communication strategy and a smartphone-based tool in improving linkage and reducing blood pressure among hypertensive patients, by conducting a cluster randomized trial comparing: 1) usual care (CHWs with standard training on recruitment of individuals with any chronic condition), 2) CHWs with an additional tailored behavioral communication strategy, and 3) CHWs with a tailored behavioral communication strategy and also equipped with smartphone-based tool linked to the AMRS. The co-primary outcome measures will be: 1) documented linkage to care following home-based testing, and 2) one year change in systolic blood pressure among hypertensive individuals. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial. Cost effectiveness will be presented both in terms of costs per unit decrease in blood pressure and in terms of costs per reductions in cardiovascular disease (CVD) risk by extrapolating one-year blood pressure reductions to CVD risk reductions based on the QRISK2-2011 CVD risk calculator specific for Black African populations. This research will generate innovative and productive solutions to the expanding global problem of</p>

	hypertension, and will add to existing knowledge on scalable and sustainable strategies for effectively managing hypertension and other chronic diseases in low- and middle-income countries.
Site(s)	Mosoriot Rural Health Training Centre, Turbo Health Centre
Project Period	5/4/2012 – 3/31/2017
Funding Status	Funded – NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	\$2,104,519
Update	<p>We have hired a new biostatistician to replace the previous one who resigned. We are currently sourcing a replacement software programmer to replace the previous one who resigned. Aim 1: Qualitative manuscript #1 is being finalized. A second qualitative manuscript, focusing on community perceptions of CHWs and implications for hypertension management, is being drafted. Subsidiary Aim 1.1: Content validity results for the linkage assessment tool were presented at the American Public Health Association Annual Conference. Content validity results for the retention assessment tool are being analyzed at the current time. Tailored communication strategy has been finalized, consisting of text messages, images and educational video clips. Subsidiary Aim 1.2: Programming of assessment tools (both linkage and retention) has been concluded. Software (Muzima APK running on android platform) finalized and upgraded for both the linkage and retention behavioral assessment tools, as well as the tailored communication strategy. Software, forms, and decision support logic installed onto the smartphones. Synchronization with AMPATH Medical Record System (AMRS) server, as well as internal research database server, completed. Usability and feasibility testing is ongoing. Aim 2: Roll-out of the study and enrollment continue and are ongoing. Rollout has been initiated in both Usual Care and Paper-based arms, constituting 16 community units. A total of 254 Community Health Workers (CHWs) and 24 Community Health Extension Workers (CHEWs) were trained on: overview of LARK Study, Behavioral Assessment Tools, Motivational Interviewing (MI) and Communication Strategy (restricted to Paper-based arm). Total enrollment as of December 31, 2014, was 621. Data management and data cleaning ongoing. Aim 3: Programming of costing questionnaire into tablets was accomplished. Paper-based entry of costing questionnaire was initiated, and then transitioned to tablet-based data entry when programming was complete. Paper-based data forms are being entered into electronic database. Data management and data cleaning ongoing.</p>
Future Plans	<p>Aim 1: Finalize qualitative manuscript #1, submit for publication Prepare and finalize qualitative manuscript #2, submit for publication Subsidiary Aim 1.1: o Finalize analysis of retention content validity results o Submit retention analyses for conference abstracts o Prepare manuscript related to content validity analyses of both linkage and retention data Subsidiary Aim 1.2: o Finalize programming and usability/feasibility testing Aim 2: Initiate rollout in tech-based arms of the trial Continue enrollment of individuals into trial Anticipated completion of enrollment: Mar 31, 2016 Ensure data collection quality, proper data entry, connection to research database Monitoring, debriefing, and repeat training activities as required Conduct process evaluation Initiate collection of 12-month follow-up data for individuals already enrolled Preliminary analyses of baseline data to</p>

	<p>be conducted oAbstract submission to conferences o Initiate manuscript related to baseline data oSubmit to DSMB as requested Aim 3: Continue collection of baseline costing data after enrollment and informed consent oInitiate collection of 12-month costing data for individuals already enrolled Preliminary analyses of baseline data to be conducted oAbstract submission to conferences o Initiate manuscript related to baseline data oSubmit to DSMB as requested</p>
Publication(s)	Vedanthan R, Kamano JH, Naanyu V, Delong AK, Were MC, Finkelstein EA, Menya D, Akwanalo CO, Bloomfield GS, Binanay CA, Velazquez EJ, Hogan JW, Horowitz CR, Inui TS, Kimaiyo S, Fuster V. Optimizing Linkage and Retention to Hypertension Care in Rural Kenya
Study Title	Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)
Principal Investigator(s)	Rachel Vreeman, Indiana University W. Nyandiko, Moi University
Co-Investigator(s)	Marete, I. Inui, T. Mwangi, A. Hogan, J. MC Henry, M.
Working Group(s)	Behavioral & Social Science, Pediatrics
Description	The purpose of this study is to assess the effect of a patient- and family-centered intervention guiding disclosure to HIV-infected Kenyan children using a randomized trial comparing the intervention to routine care. The primary endpoint will be probability of disclosure among children, with secondary endpoints of adherence, clinical outcomes, psychological distress and social outcomes. Phase One, which will last 6 months, focuses on cultural adaptation of the intervention materials through intensive patient participation, including focus groups and cognitive interviewing, selecting narrative components, and training dedicated disclosure counselors. Phase Two consists of a randomized design to examine whether the culturally adapted, multi-component HADITHI intervention increases the prevalence of disclosure to HIV-infected children in western Kenya compared to children receiving usual care. HIV-infected children ages 10-15 years who are enrolled in HIV care within the eight selected AMPATH clinics in western Kenya will be eligible for study enrollment and have a comprehensive patient assessment every 6 months for 2 years.
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital (MTRH), Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	9/1/2012 – 9/1/2016
Funding Status	Funded – NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	\$1,886,804
Update	Since the start of the project, the following progress has been made: IRB and IREC

	<p>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.</p>
Future Plans	
Publication(s)	
Study Title	Prevalence and Impact of Alcohol Use in Patients Enrolling in HIV Care
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University Lameck Diero, Moi University
Co-Investigator(s)	Judith Hahn, Jayne Kulzer, Suzanne Goodrich, Mswebesa Bosco Bwana, Patrick Oyaró, Maurice Aluda
Working Group(s)	Adult Medicine, Behavioral & Social Science
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.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	3/1/2013 – 3/1/2014
Funding Status	Funded – NIH - National Institute on Drug Abuse (NIDA)
Direct Award (USD)	Not Reported
Update	Study enrollment at AMPATH and the additional sites (FACES in Kenya and Mbarara in Uganda) was completed in December 2014. At total of 786 patients were enrolled, 277 from the AMPATH site. End of study CD4 counts and tracking of those patients lost to follow-up were attempted for all patients. Inconsistent availability of supplies to process CD4 counts hindered our ability to get prompt end-of-study counts for those

	enrolled at AMPATH.
Future Plans	Beginning January 2015 the assembly of data set for all three sites is underway. Data cleaning will likely be required. A separate data set of just those patients enrolled at the AMPATH site will be complete at the end of January 2015 and will be used to complete Specific Aim 2. A manuscript describing the Aim 2 findings (differences in reported drinking as reported to clinical officers and Research Assistants) will be ready for publication in spring 2015. The complete data set from all three sites will be completed during the spring of 2015 and used to complete Specific Aims 1 and 3. A manuscript describing these results will be prepared for mid-2015.
Publication(s)	
Study Title	SAFI (Stigma in AIDS Family Inventory) Validation Study
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Irene Marete, Hai Liu, Violet Naanyu
Working Group(s)	Pediatrics
Description	For families raising HIV-infected children in resource-limited settings, HIV/AIDS-related stigma shapes every aspect of the children's HIV management, from daily adherence to medication to decisions about pediatric HIV disclosure. We do not know the most effective strategies to reduce stigma for HIV-infected children and their families in resource-limited settings nor how to measure its effects on physical, emotional, or social outcomes. We want to learn more about how stigma affects families. As part of the HADITHI study, SAFI aims to develop and test a reliable, valid instrument to measure HIV/AIDS stigma as perceived, enacted, and internalized by Kenyan families with HIV-infected children. The specific aims for the SAFI validation study are to: Aim 1: Identify and modify H/A stigma questionnaire items for maximum reliability and content validity to measure perceived, enacted and internalized H/A stigma among Kenyan families with HIV-infected children. Aim 2: Assess the validity of the measures of perceived, enacted and internalized H/A stigma compared to independent construct measures including pediatric adherence to therapy and children's physical, psychological and social outcomes. Aim 3: Examine whether disclosure of a child's HIV status to the child reduces perceived, enacted, or internalized stigma for families with disclosed children compared to families with non-disclosed children. We thus propose assembling, adapting, and then validating measurement items for assessing the relevant domains of H/A stigma experienced by HIV-infected children and their caregivers in sub-Saharan Africa.
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital (MTRH), Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	12/17/2013 – 11/30/2015

Funding Status	Funded – NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	\$567,828
Update	Progress since the last 6 months: We generated a comprehensive set of stigma measurement items for reliability and validity testing. Since July 2014, we utilized the results of the stigma focus group discussions and a critical review of the global literature on HIV-related stigma to generate this comprehensive set of stigma measurement items to be used to measure stigma in households with a child living with HIV. We have begun the reliability and validity testing, utilizing the existing HADITHI cohort of families and administering the stigma measurement items during evaluations at months 18 and months 24 of HADITHI follow-up. We continue to conduct a systematic review to compile items used to measure pediatric and caregiver H/A stigma in other settings. The review is well underway, with data now being extracted from the systematically identified studies.
Future Plans	Next 6 months For the SAFI revision, in the next 6 months, we will complete the systematic review and use the HADITHI cohort of families to assess the validity of the questionnaire measures of family stigma compared to independent construct measures including medication adherence, and children's clinical, psychological, and social outcomes. The data collected through the SAFI revision will enable us to assemble a comprehensive family HIV/AIDS-related stigma measure with maximum reliability and validity for assessing all relevant domains of stigma, including perceived, enacted and internalized stigma, and for use with all members of the family unit.
Publication(s)	
Study Title	Street Youth's Perspectives on Sexual Health in Western Kenya
Principal Investigator(s)	Paula Braitstein, University of Toronto David Ayuku, Moi University
Co-Investigator(s)	Naanyu, V. Ott, M. Wachira, J. Embleton, L. Kamanda, A. Winston, S.
Working Group(s)	Pediatrics
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.

Site(s)	Other
Project Period	8/1/2013 – 6/30/2014
Funding Status	Funded – NIH
Direct Award (USD)	Not Reported
Update	Analysis and publication of these data are on-going. A paper on the knowledge, attitudes and practices of street youth with respect to sexual behaviours is under review, as is a paper on sexual violence including initiation rites. Two papers on their perspectives on sexually transmitted infections and pregnancy are in the final stages of development.
Future Plans	Finalize publications.
Publication(s)	



Study Title	Tablet Computer-Based Disclosure Counseling for HIV-Infected Adolescents and their Families: A Pilot Study of Perspectives from Providers
Principal Investigator(s)	Megan McHenry (maiden: Uhl), Indiana University
Co-Investigator(s)	Prof. Rachel Vreeman ^{1,2,3} , Dr. Edith Apondi ³ , Prof Winstone Nyandiko ^{2,3} , Carole McAteer ^{1,2} , Michael Scanlon ^{1,2} , Lydia Fischer ^{1,2} Affiliations: ¹ Indiana University School of Medicine, Department of Pediatrics, Indianapolis, Indiana, USA, ² Academic Mod
Working Group(s)	Pediatrics
Description	The objective of this study is to evaluate a pilot project using Google tablet computers for disclosure-related counseling with HIV-infected children and their caregivers in three AMPATH clinics. Google Nexus 7 Android tablets donated to the IU-AMPATH Android Program will be loaded with materials developed as part of the ongoing HADITHI disclosure intervention trial (PIs: Nyandiko and Vreeman) and includes educational materials on HIV and disclosure, counseling-based activities, and video narratives sharing experiences of HIV and disclosure. A plan was in place prior to this proposal of this study to implement the tablet computers in these clinic sites regardless of whether the benefits or hindrances of these devices are measured. This study is focused on understanding how this implementation affects the healthcare provider's disclosure practice or perspectives. The healthcare providers (HCPs) targeted in this study will include all healthcare workers who handle children in the clinics of study. This would include a clinical officer, nurse, counselor, social worker, or other similar position. Our central hypothesis is that AMPATH HCPs will find these tablet computers usable and helpful as a tool in disclosure counseling. The long-term goal of this study is to provide evidence to better support adolescents through the disclosure process and increase the number of adolescents who know their HIV status. We plan to accomplish our research objective by achieving the following specific aims: Aim 1: Describe current disclosure practices and barriers to disclosure at three clinics (Bumala, Busia, and Port Victoria) in Western Kenya through

	interviews with key clinic staff. Aim 2: Compare the prevalence of disclosure at these clinics for HIV-infected adolescents (10 to 14 years) before and after the introduction of the tablet computers using disclosure status data collected through AMRS. Aim 3: Evaluate provider acceptability and usability of the tablet computers for disclosure counseling through surveys, cognitive interviews, and focus group discussions. Sub-aim 3a: Describe any changes in providers' knowledge, comfort, and attitudes regarding disclosure after the introduction of the tablet computers.
Site(s)	Bumala A Health Centre, Bumala B Health Centre, Busia District Hospital, Port Victoria Sub-District Hospital
Project Period	2/9/2015 – 7/1/2016
Funding Status	Unfunded –
Direct Award (USD)	
Update	We are still in the process of IREC approval.
Future Plans	We hope to have approval from IREC so we may initiate our study.
Publication(s)	
Study Title	Taking to the streets: a mixed-methods systematic review of the reasons children and youth become street-involved
Principal Investigator(s)	Lonnie Embleton, Moi University Paula Braitstein, Indiana University
Co-Investigator(s)	Ayuku David
Working Group(s)	Pediatrics
Description	A wide variety of reasons children take to the streets to work or live have been cited in the literature, yet there lacks any compiled data on this topic by geographic region. It is suspected the dynamics that drive children to the streets are quite diverse and vary between high income and low-to-middle income countries. This systematic review aims to identify similarities and differences internationally for children living or working on the streets. In turn this literature should help identify future research needs as well as policy changes to best suit the needs for the millions of children worldwide before or after they turn to the streets as a way of survival. Overall objective To compile and critically analyze the literature regarding reasons why children and youth, aged <1-24, turn to the streets as a way to survive in order inform public health research and policy, while identifying gaps in knowledge and evaluating the strength of existing evidence. Specific Aim To describe the reasons children and youth become street-involved in both high and low to middle income countries including but not limited to: differences between street connected children in resource-constrained and very-high income settings, children on and of the street and males and females for street-involvement and the age they start living on the streets. Specific Questions: 1. What are the reasons children and youth

	come to the street both from quantitative and qualitative literature and are the reasons between the two methodologies similar or different? 2. What are the differences in reasons between children on the street versus of the street for coming to the streets? (if able to distinguish based on reporting) 3. What are the differences between children/youth in high versus low/middle income countries? 4. What are the differences between genders?
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	8/1/2013 – 5/1/2014
Funding Status	Unfunded –
Direct Award (USD)	
Update	This study completed data extraction and evaluation of the evidence. Analysis is on-going in association with manuscript development.
Future Plans	We aim to complete the analysis and submit a manuscript for publication.
Publication(s)	

Study Title	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
Principal Investigator(s)	Tom Inui, Indiana University Naftali Busakhala, Moi University
Co-Investigator(s)	Asirwa, C.
Working Group(s)	Oncology
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

	<p>(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.</p>
Site(s)	Mosoriot Rural Health Training Centre, Turbo Health Centre, Other, Kapsakworny
Project Period	10/1/2011 – 7/1/2014
Funding Status	Funded – Walther Cancer Foundation
Direct Award (USD)	\$1,200,000
Update	Walther Kenyan personnel continue to lead consensus development work to establish cancer care standards for the Ministry of Health. Breast cancer survey finding analysis is complete and a manuscript summarizing findings from the community survey combined with findings from the health centre-based breast cancer screening surveys is in preparation. Four manuscripts have been completed. One has been published by the East African Medical Journal, and three are under review. The cervical cancer screening surveys are complete, data cleaned, and analysis is underway. We have identified key drivers to breast cancer screening in these communities.
Future Plans	The major emphases in the next six months will focused on writing for publication, both in breast cancer and cervical cancer domains. We will also plan on a strategy to provide feedback to the communities.
Publication(s)	Wachira J, Chite AF, Naanyu, V, Busakhala N, Kisuya J, Keter A, Mwangi A, Inui T and The Walther Project Team. Barriers to uptake of breast cancer screening in Kenya. East African Medical Journal 2014, 91(11): 1-7.
Study Title	The Role of Faith Leaders Towards Promotion HIV-Testing

Alongside Voluntary Male Circumcision in Nyanza, Kenya

Principal Investigator(s)	EUNICE KAMAARA, Moi University Amy Nunn, Brown University
Co-Investigator(s)	
Working Group(s)	Behavioral & Social Science
Description	The Nyanza region of Kenya has high rates of HIV infection, even among individuals. The faith community plays an important role in shaping social norms about HIV testing, prevention treatment and retention in care. Local home based HIV testing efforts have been effective in reducing AIDS related morbidity and mortality. This proposed study will explore the role of faith leaders in promoting HIV testing, treatment and linkage to care. In spite of increased national success in HIV testing and treatment, HIV prevalence in Nyanza has increased from 14.9 in 2007 to 15.1 % in 2011. Unfaithfulness combines with ignorance of HIV status to register new infections. The proposed exploratory study will use qualitative interviews and focus group discussions (FGDs) with purposively selected participants to explore the role of faith leaders in promoting home based HIV testing and linkage to care. The aim of the proposed study is to better understand the role that faith leaders could play in promoting and normalizing home based HIV testing, treatment and linkage to care in Nyanza. This will inform and help expand home-based HIV testing program of AMPATH in Nyanza for improved prevention, control and management of HIV and AIDS. The specific objectives include: 1. To explore the beliefs of faith leaders about home-based HIV testing and treatment 2. To investigate barriers to home based HIV testing and treatment 3. To identify opportunities for promotion of home-based HIV testing, treatment and linkage to care. 4. To conduct a pilot study about the role of faith leaders in promoting HIV testing, treatment and linkage to care in home-based HIV testing program of AMPATH in Nyanza.
Site(s)	Mosoriot Rural Health Training Centre, Mukhobola Health Centre, Port Victoria Sub-District Hospital
Project Period	11/1/2014 – 10/30/2015
Funding Status	Funded – Brown University - Center For AIDS Research
Direct Award (USD)	\$25,000
Update	IREC Approval received, participants selected. All FGDs conducted.
Future Plans	We hope to collect all the remaining data and make preliminary data analysis.
Publication(s)	

Study Title

Treatment Outcomes of Childhood Cancer in Western Kenya

Principal Investigator(s)	Jodi Skiles, Indiana University - Purdue University in Indianapolis (IUPUI) Festus Njuguna, Moi University
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Co-Investigator(s)	Hugo Martin Saskia Mostert Terry Vik Floor Abbink Gertjan Kaspers Gilbert Olbara Floor Abbink
Working Group(s)	Oncology, Pediatrics
Description	While basic epidemiologic information in on childhood cancer in Western Kenya has been recently reported, little is known about outcomes of cancer treatment in this population. This is a major pitfall in improving the care and cure for children in this part of the world. Our study aims to provide a retrospective review of childhood cancer treatment outcomes in Western Kenya since implementation of standard treatment protocols in 2009. This retrospective analysis of childhood malignancies and treatment outcomes in Western Kenya will be carried out using information from patients seen at the Moi Teaching and Referral Hospital. Patients who were first seen at the hospital between 1st January 2009 and 31st December 2013 will be included. All children up to 18 years of age will be included. Information on patient demographics, diagnosis, treatment provided and treatment outcomes will be collected from the patients' medical records.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	9/16/2013 – 12/31/2014
Funding Status	Unfunded –
Direct Award (USD)	
Update	Data cleaning is almost finished and a draft manuscript is in progress.
Future Plans	Completion of data analysis with a goal to have a manuscript submitted for publication
Publication(s)	



Study Title	Vincristine Optimization in Kenyan Children with Cancer
Principal Investigator(s)	Jodi Skiles, Indiana University - Purdue University in Indianapolis (IUPUI) Festus Njuguna, Moi University
Co-Investigator(s)	G Olbara, MBBS S Langat J Musimbi T Vik, MD S Mostert, MD, PhD GJL Kaspers, MD, PhD N Busakhala F Asirwa P Loehrer J Renbarger, MD1
Working Group(s)	Oncology, Pediatrics
Description	In resource-limited settings, access to chemotherapeutic agents is confined to a few therapies. Vincristine (VCR) is a mainstay in such settings due to its low cost and lack of myelosuppression, however, little is known regarding its disposition and true optimal dosing, especially in the pediatric population. Negative clinical outcomes, such as serious side effects due to drug overdosing or lack of efficacy due to sub-therapeutic dosing, may result. VCR is associated with highly variable cumulative dose-dependent peripheral neuropathy (VIPN). While pediatric oncology patients in the U.S. who receive VCR experience significant VIPN and excellent disease outcomes, Kenyan children with cancer who receive VCR experience little to no VIPN, highlighting the opportunity for

optimization of VCR in this population. While there are clearly multiple factors that contribute to poor disease outcomes in Kenya, suboptimal dosing of VCR is the piece we aim to address in this study. The biological basis for the minimal VIPN we have observed in Kenyan children is uncertain but includes such things as genetic differences in VCR pharmacologic pathways as well as genetic variability in susceptibility to neuropathy. This gap in knowledge provides a clear opportunity to optimize use of this medication in Kenyan children with cancer and evaluate genetic associations with VIPN in order to personalize this medication for individual children once VCR dosing is augmented. Preliminary data has shown that Kenyan children with cancer (n=100) experience minimal VIPN. Despite the negligible neuropathy observed, subclinical VIPN can be detected using a very detailed, non-invasive assessment tool that we developed for detecting even very minor toxicity. Utilization of this tool in Kenyan children allowed us to identify an association between VIPN severity, CYP3A5 genetic polymorphisms, and an individual's ability to metabolize VCR, such that children with an allelic variant of CYP3A5 that results in a high VCR metabolizer phenotype experience less VIPN. Variability in VCR response and toxicity may be particularly significant within Africa, where human genetic variability is greatest, and where ~90% of Kenyans patients were fast VCR metabolizers. In one recent study, pharmacokinetic (PK) variability was linked to overall survival in children with acute lymphoblastic leukemia (ALL), such that children with faster VCR clearance had a greater chance of relapse. If VCR disposition, response, and neurotoxicity are linked, it may be possible to optimize dosing based on easily obtained knowledge of genetic polymorphisms responsible for disposition and subsequent neurotoxicity variability. This research is of particular importance in Africa, where VCR is one of few available anticancer drugs and is used in the treatment of over half of all cancer patients. Furthermore, given that most Kenyan children are CYP3A5 high expressers and thus VCR fast metabolizers, they may tolerate and benefit from higher doses of vincristine than are conventionally used in the U.S. and Africa. This proposed prospective study will be conducted in two parts, which will both enroll pediatric patients age 1-18 years with newly diagnosed acute lymphoblastic leukemia or nephroblastoma. Part I will be a VCR dose escalation phase (in combination with routine multi-agent chemotherapy) to determine the maximum tolerated dose of VCR in a population of Kenyan children with cancer. Part II will be utilize the maximum tolerated dose of vincristine determined from Part I in place of the standard dose of VCR in combination with routine multi-agent chemotherapeutic protocols. DNA and pharmacokinetic samples will be collected on all subjects to allow determination of biomarkers of development of VIPN. Subjects will be monitored closely for development of toxicity with laboratory assessments as well as detailed neuropathy assessments. The specific aims (SA) for this proposal are as follows:

- SA1: To determine the maximum tolerated dose (MTD) of VCR administered in conjunction with conventional chemotherapy in cohorts of Kenyan children with ALL or Wilms tumor receiving VCR as part of their anti-cancer treatment.
- SA2: To validate our pilot study findings and to further evaluate the association between common or functional variants in genes in the vinca alkaloid pharmacologic pathway and across the human genome with VCR PK, VIPN, and disease response in the same populations as SA1.
- SA3: To further develop our pharmacologic prediction model of VIPN describing associations between pharmacogenetic, pharmacokinetic, and clinical biomarkers and carefully characterized VIPN in the same population of patients as SA1.
- SA4: To evaluate the validity and reliability of several chemotherapy-induced peripheral neuropathy (CIPN) measurement approaches when used to quantify

	neuropathy and associated neuropathic pain in Kenyan children receiving vincristine.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	2/3/2014 – 1/31/2018
Funding Status	Funded – NIH - National Cancer Institute (NCI), NIH - Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Direct Award (USD)	\$103,254
Update	This study commenced in February 2014 and 12 subjects have been enrolled to date and we are currently recruiting subjects for Phase I, Dose level 3. To date, no toxicity has been observed and dose escalation is still ongoing. Recruitment has been slower than anticipated due to issues with access to chemotherapeutic agents, however that issue is now resolved and recruitment is starting to pick back up. Additionally, it took longer than anticipated to get the NCI/Leidos Biomedical contract with IU (and subcontract with Moi) in place, which delayed the hiring of a dedicated study nurse. All contract issues have now been resolved and the study nurse has been hired.
Future Plans	Ideally, we would like to complete recruitment for Phase I of this study within the next 6 months. At that time, we will conduct an interim analysis in preparation for Phase II of this study, although funds have not yet been secured to conduct Phase II of this study. To this end, the other objective over the next 6 months is to secure funding for Phase II
Publication(s)	

Figures & Tables

Figure 1: Cumulative Total of AMPATH Research & Training Awards (1998 – 2014)

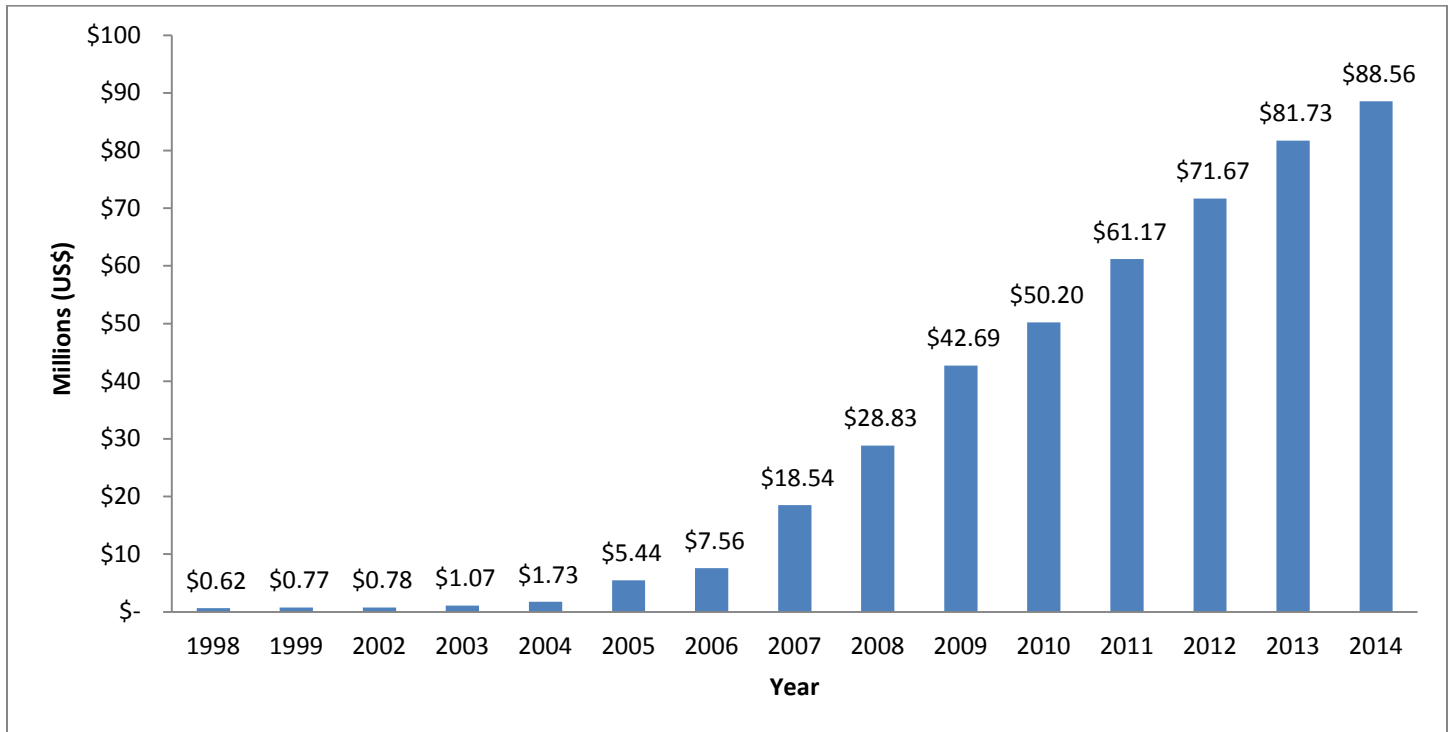


Figure 2: Sponsors of AMPATH Research (January - December 2014)

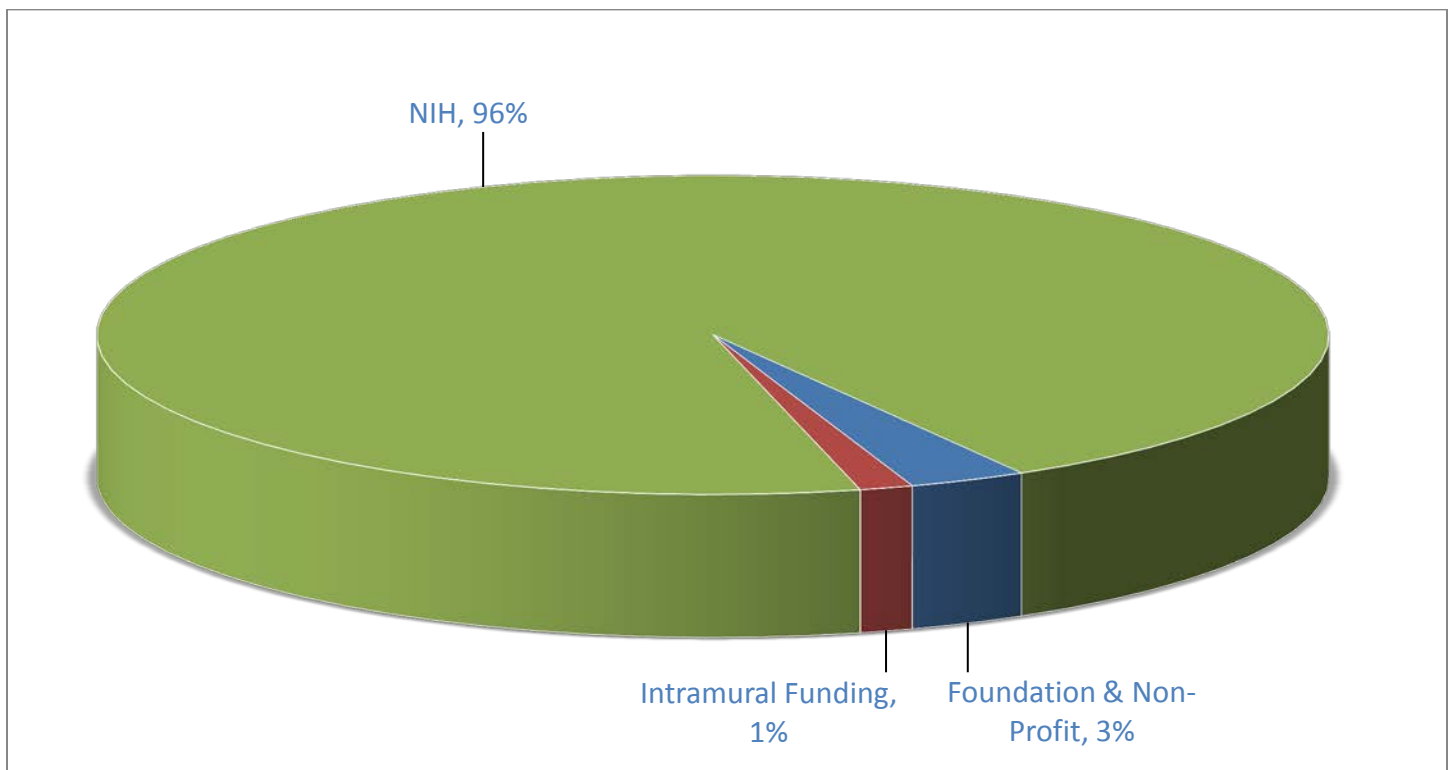


Figure 3: AMPATH Research Sponsors (1998-2014) (Total Directs = US\$88.6 million)

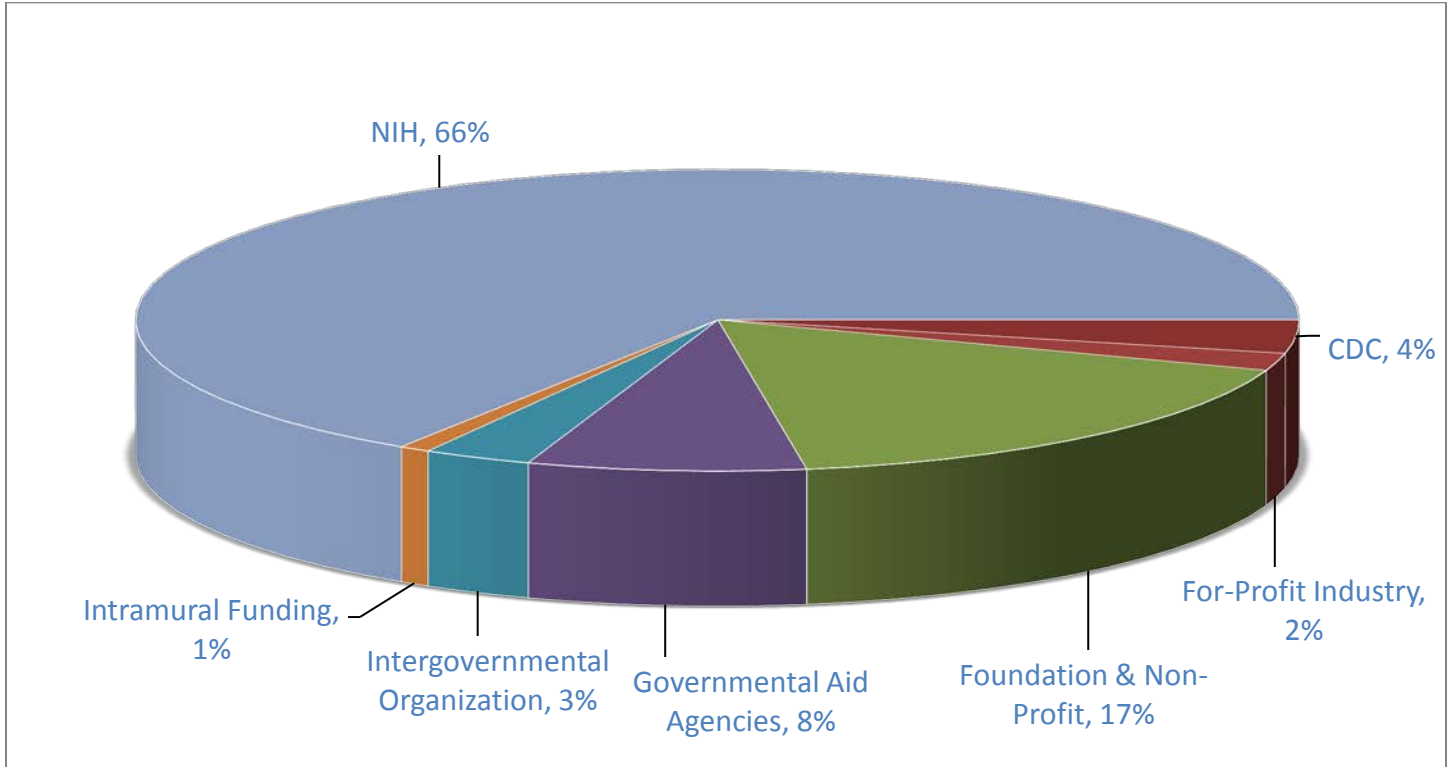
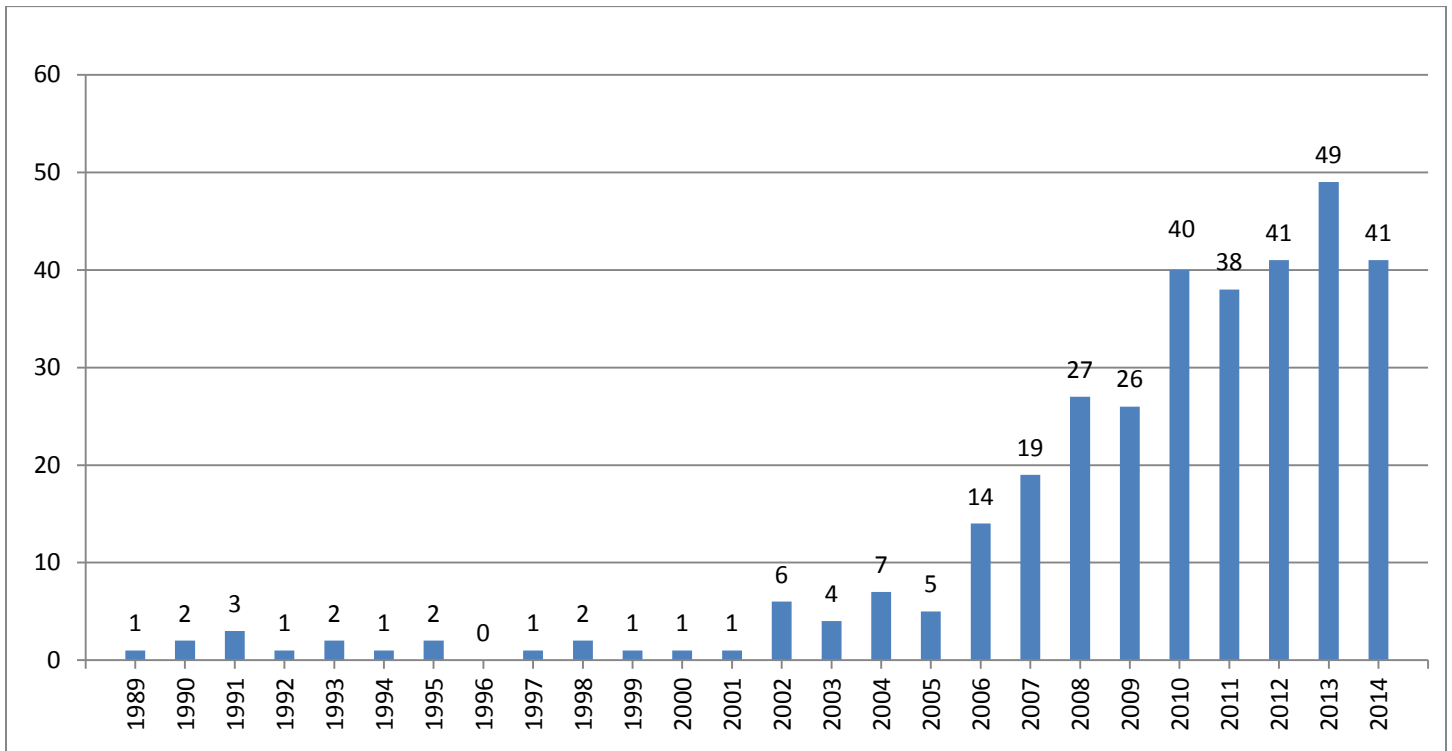


Figure 4: AMPATH Publications by year published (1989-2013) (Total Publications = 335)



AMPATH Research Bibliography

The following bibliography includes AMPATH research publications that were published between January and December 2014. A complete bibliography of AMPATH research publications published since 1989 along with full text articles is available online through the AMPATH Research Member Access Portal, www.medicine.iu.edu/ampathresearch/member-access.

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Index

A

adherence · 4, 10, 11, 22, 23, 24, 39, 47, 48, 49, 50, 64
Adult Medicine · 5, 6, 7, 8, 9, 10, 11, 14, 20, 24, 27, 28, 29, 30, 34, 36,
38, 40, 42, 44, 48
AIDS · iii, iv, 6, 7, 8, 10, 11, 12, 15, 23, 24, 25, 30, 40, 41, 49, 50, 55,
61, 62, 64
AIDS Clinical Trials Group (ACTG) · 7, 10, 11, 12
Akwanalo · 44, 46, 64
Alcohol · iii, iv, 5, 47
Aluda · 48
AMPATH Research Program · 2, 1
AMRS · 26, 45, 51
Arpadi · 22
Ayaya · 16, 19, 22, 24, 25, 61, 62, 63, 64
Ayuku · 3, 30, 33, 41, 50, 52, 61, 62, 63
Ayuo · 20, 28, 61

B

behavior · 3, 21, 53, 61
Behavioral & Social Science · 3, 5, 7, 10, 11, 14, 24, 29, 30, 47, 48, 55
Bell · 4, 18, 22
bibliography · 2, 61
Bioethics · 30, 31, 32, 33, 63
Blaschke · 22, 64
Bloomfield · 34, 44, 46, 62, 63, 64
Braitstein · 13, 37, 39, 41, 50, 52, 61, 62, 63, 64
Brown · 1, 5, 12, 14, 15, 19, 24, 29, 30, 37, 55
Busakhala · 7, 8, 53, 54, 56, 64
Buziba · 14, 24, 25, 29, 30, 62
Bwana · 48

C

Cancer · iii, v, 7, 8, 12, 13, 15, 31, 53, 54, 56, 58
Caroll · 22
Celgene Corporation · 14
child well-being · 3
children · iv, v, 3, 15, 18, 19, 20, 22, 23, 24, 25, 41, 47, 49, 50, 51, 52,
56, 57, 61, 62, 63, 64
Christoffersen-Deb · 17, 21, 64
community health workers (CHWs) · 21, 44
Cu-Uvin · 12

D

Diero · 13, 14, 15, 19, 24, 25, 29, 30, 48, 61, 62, 63
Downs · 13
Duke Global Health Institute · 3, 27, 36

E

Eldoret · 2
electronic drug monitors · 24
Embleton · 41, 50, 52, 61, 62, 63
Emonyi · 14, 15, 24, 29, 30, 34

F

Fuster · 43, 44, 46, 64

G

Goodrich · 40, 48
Grand Challenges Canada · 17, 22
Grinter · 2

H

Hahn · 48
HIV · iii, iv, v, 4, 5, 6, 8, 9, 10, 11, 12, 14, 15, 18, 19, 22, 24, 25, 29, 30,
31, 37, 38, 39, 40, 41, 46, 47, 48, 49, 50, 51, 55, 62, 63, 64
Hogan · 4, 5, 13, 30, 37, 44, 46, 61, 62, 63, 64
Horowitz · 44, 46, 64
Hypertension · iv, 42, 43, 44, 46, 63

I

Indiana Hemophilia and Thrombosis Center (IHTC) · 14
Indiana University · iv, 4, 6, 12, 13, 15, 16, 18, 20, 22, 23, 25, 28, 30,
31, 32, 33, 34, 40, 41, 46, 48, 49, 51, 52, 53, 56, 63
Indiana University - Office of Research in Medical Education · 16
Inui · 1, 20, 21, 22, 24, 34, 44, 46, 53, 54, 62, 64
IU Health · iv, 34, 35
IU Simon Cancer Center (IUSCC) · v, 53

K

Kaaria · 12
Kamanda · 41, 50, 61, 62
Kapsakworny · 54
Kimaiyo · 34, 39, 42, 43, 44, 46, 62, 63, 64
Kiplagat-Kirui · 2
Kirui · 2
Kroenke · 13
Kulzer · 48

L

Lagat · 6, 9, 10, 63
Liu · 24, 49, 64
Loehrer · 12, 56

M

Mamlin · 13
Marete · 46, 49
Marrero · 22
Martin · 28, 56
Mathenge · 36
mental health · 3
Menya · 33, 39, 44, 46, 64
Meslin · 13, 30, 31, 32, 33, 63
Moi Teaching and Referral Hospital (MTRH) · 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 23, 27, 29, 30, 31, 35, 36, 41, 42, 47, 48, 49, 53, 56, 58
Moi University · iv, 1, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 28, 29, 30, 31, 32, 33, 34, 37, 39, 40, 41, 42, 46, 48, 49, 50, 52, 53, 55, 56, 63
Mosoriot Rural Health Training Centre · 22, 43, 45, 47, 49, 54, 55
Mostert · 56, 63

N

Naanyu · 37, 39, 44, 46, 49, 50, 53, 54, 63, 64
National Cancer Institute (NCI) · 7, 8, 13, 58
National Heart, Lung, and Blood Institute (NHLBI) · 45
National Institute of Allergy and Infectious Diseases (NIAID) · 6, 8, 9, 25, 29
National Institute of Dental and Craniofacial Research (NIDCR) · 7, 8, 9
National Institute of Mental Health (NIMH) · 23, 47, 49
Ndege · 11, 39, 63, 64
NIH · 2, 5, 6, 7, 8, 9, 10, 11, 12, 13, 15, 21, 23, 24, 25, 29, 31, 34, 38, 43, 45, 47, 48, 49, 50, 58

NIH - National Institute on Alcohol Abuse and Alcoholism (NIAAA) · 5
Njiru · 7, 8
Njuguna · 15, 18, 56, 63
NORAD - Norwegian Agency for Development Cooperation · 29
Nyandiko · 2, 13, 19, 22, 23, 24, 46, 49, 51, 61, 62, 63, 64

O

O'Meara · 13, 33, 39
Omenga · 12, 64
Oncology · iii, v, 12, 15, 18, 53, 56, 57
Oyaro · 48

P

Palakal · 13
Pastakia · 13
Pediatrics · 3, 15, 16, 18, 19, 22, 25, 41, 47, 49, 50, 51, 52, 56, 57
PEPFAR - United States President's Emergency Plan for AIDS Relief - Public Health Evaluation (PHE) · 23, 41
Plater · 2
Public Health & Primary Care · 33, 39
publications · 1, 2, 61
Publications Committee · 2
Purdue University College of Pharmacy · 14

R

Regenstrief Institute · 2
Reproductive Health · 4, 17, 18, 19, 21
Research Publications Compendium · 1
Research Working Groups · 1
Rotich · 13, 62

S

Shen · 4, 13
Sidle · 5, 6, 13, 25, 63
Siika · 6, 7, 8, 9, 10, 11, 20, 26, 28, 39, 40, 63, 64
Some · 10, 33, 36, 61, 63
Songok · 17, 19, 21

T

Tierney · 22
Training · 59
Tu · 22, 24, 64
Turbo Health Centre · 5, 18, 19, 20, 25, 43, 45, 47, 49, 54

U

USAID - United States Agency for International Development · 41

V

Vedanthan · 42, 43, 44, 46, 62, 64

Velazquez · 44, 46, 62, 63, 64

Vik · 18, 56

Vincristine · iii, v, 15, 56, 57

Vreeman · 2, 1, 13, 16, 19, 22, 23, 24, 25, 46, 49, 51, 61, 62, 63, 64

W

Wachira · 37, 39, 50, 54, 64

Walumbe · 2

Were · 4, 13, 18, 28, 30, 33, 43, 44, 46, 62, 63, 64

Winston · 50, 63

Women · iii, iv, 4, 12, 18, 63

Wools-Kaloustian · 4, 13, 18, 25, 40, 48, 61, 62

Y

Yiannoutsos · 13, 61, 62

Z

Zimet · 18