

SEMI ANNUAL RESEARCH REPORT

July – December 2013



Acknowledgements

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

Editorial Team

Shawn Grinter
Jepchirchir Kiplagat-Kirui
David Plater
Eunice Walumbe

Copyright © April 2014 – AMPATH Research Program Office

Contacts

Jepchirchir Kiplagat-Kirui

AMPATH Research Network Administrative Manager
(Kenya)
AMPATH Center
P.O. Box 4606
Eldoret, Kenya

Email: research.manager@iukenya.org

Phone: +254 53 203 3471 ext. 3719

Fax: +254 53 206 1992

David Plater

AMPATH Research Network Administrative Manager
(North America)
Regenstrief Institute, Inc.
1050 Wishard Boulevard, RG 5
Indianapolis, IN 46202

Email: research.manager@iukenya.org

Phone: +1-317-274-9189

Fax: +1-317-274-9124

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

www.medicine.iu.edu/ampathresearch

Contents

Overview	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 Population-wide Home-Based Study of Hypertension Prevalence in Western Kenya	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)'	8
A5274/REMEMBER Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens '	9
A5288 'Management Using the Latest Technologies in Resource-limited Settings to Optimize Combination Therapy After Viral Failure (MULTI-OCTAVE)'	10
Accuracy of Oral HIV Self-tests in Kenya	10
Addressing the Fourth Delay: Improving Communitybased Accountability for Maternal and Newborn Health.....	12
Anticoagulation Project.....	12
Antiretroviral Treatment Failure and Drug Resistance in HIV-infected Patients on Second Line Regimens in Western Kenya.....	13
Assessment and Treatment of Pain in Hospitalized Patients at MTRH	14
Biomarkers of Vincristine Toxicity in Kenyan Children	15
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
Cervical Cancer See and Treat: How Best to Follow-up.....	16
Childhood Leukemia in Kenya Identified Through Malaria Slide Review	17
Computerized Counseling to Promote Positive Prevention and HIV Health in Kenya (CARE+ Kenya).....	18

Cross-Cultural Histories of Family Care-Giving to AIDS Orphans in Western Kenya	21
Descriptive Study of Patients Seeking Emergency Care in Western Kenya	21
Diabetes Mellitus and Glucose Intolerance in HIV Patients in Western Kenya	22
Drug Resistance in HIV Infected Children after Failure of Prevention of Mother to Child Transmission in Western Kenya	22
EARNEST: A Randomised Controlled Trial to Evaluate Options for Second-line Therapy in Patients Failing a First-line 2NRTI+ NNRTI Regimen in Africa	23
Enhancing Training for Implementation Research in Chronic Disease: CITE/Kenya.....	24
Evaluating Handheld Clinical Decision Support Tools to Improve Community-Based Delivery of Reproductive and Pediatric Health Services.....	25
Evaluation of A Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy (CAMP study)	26
Evaluation of HIV Drug Resistance Prevalence and Consequences in the Setting of the Recent Political Crisis in Kenya	28
Exploring factors that support a sustainable model for engaging and retaining CHWs in the PHC program of AMPATH (CHW Incentive Project).....	29
Facilitators and Barriers to Initiation of Antiretroviral Treatment Among Pregnant Women Living with HIV Receiving Antenatal Care in Western Kenya: An Evaluation.....	30
Feasibility Intervention Trial of Two Types of Improved Cook Stoves in Three Developing Countries	31
Health Facility Incentives to Improve Adherence to Malaria Diagnostic Test Results	32
HIV Prevalence and Ante-natal Care Attendance Among Pregnant Women in a Large Home-Based HIV Counseling and Testing Program in Western Kenya.....	33
HIV Testing Uptake and Prevalence Among Adolescents and Adults in a Large Home-Based HIV Testing Program in Western Kenya	34
HIV-1 Drug Resistance in Different Subtypes.....	34
HIV-1 Genotypic Diversity and Drug Resistance in Western Kenya.....	35
Improving Diabetes Management and Cardiovascular Risk Factors Through Diabetes Peer Group Education in Western Kenya.....	35
Increasing Animal Source Foods in Diets of HIV Infected Kenyan Women and their Children	36
Indiana University-Moi University Academic Research Ethics Partnership.....	37
Inhalants and the Pathway to HIV Infection Among Street Youth in Western Kenya	40
International epidemiologic Databases to Evaluate AIDS (IeDEA).....	41
IU Health Cardiovascular Research Biobanking Project.....	42
Linkage and Retention to Care in Western Kenya Following HIV Testing.....	43
MESA Malaria Prevention Study (MPS)	45
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.....	46

Mortality Among Street Connected Children and Youth in Eldoret, Kenya: a Retrospective Chart Review	47
National Cancer Institute Supplement to East African leDEA: Improving Kaposi's Sarcoma, Lymphoma Diagnostics, and Assessing Kaposi's Sarcoma Incidence in Western Kenya	48
Nurse Management of Hypertension Care in Rural Western Kenya	49
Optimizing Linkage and Retention to Hypertension Care in Rural Kenya.....	51
Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)	53
Patient-Reported Outcomes of Cancer Care in Eldoret, Kenya	55
Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretroviral Treatment	56
Physical and Sexual Abuse in Orphaned Compared to Non-Orphaned Children and Youth in Sub-Saharan Africa: A Systematic Review & Meta-Analysis	57
Prevalence and Impact of Alcohol Use in Patients Enrolling in HIV Care	58
REACH Informatics Center of Excellence	59
REALITY 'Reduction of EARly mortaLITY in HIV-infected adults and children starting antiretroviral therapy'.....	60
Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens (REMEMBER).....	61
Renal Study	62
SAFI (Stigma in AIDS Family Inventory) Validation Study	62
Sexual Health Risks and HIV and STI Prevalence Among Street Involved Youth in Western Kenya.....	63
STEPwise Approach to Cardiovascular Diseases Risk Factors Revalence Study in Webuye Adults.....	64
Street Youth's Perspectives on Sexual Health in Western Kenya	65
Survival Among HIV-infected Patients with Kaposi's Sarcoma in sub-Saharan Africa in the Era of Potent Antiretroviral Therapy	65
Taking a LEEP! Implementing a 'See and LEEP' strategy for women in Western Kenya with positive cervical cancer screening.....	67
Taking to the Streets: a Mixed-Methods Systematic Review of the Reasons Children and Youth Become Street-Involved.....	68
TB/HIV Integration Study	69
The Epidemiology of Substance use Amongst Street Children in Resource-constrained Settings: a systematic review and meta-analysis	69
The Implementation of a Neonatal Nurse Training Program at the Riley Mother Baby Hospital of Kenya.....	70
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.....	71
Treatment Outcomes of Childhood Cancer in Western Kenya.....	72
Utility of Handheld Echocardiogram Among Clinical Officers in Patient Referred for Routine Echocardiography at Moi Teaching and Referral Hospital, Kenya	73

Figures & Tables 75
AMPATH Research Bibliography 78
Index 81

Overview

The end of 2013 was an active time for AMPATH's Research Program. Despite facing increased financial pressures including the effects of sequestration in the US and work disruptions around the Kenyan national elections, AMPATH's Research Program had a strong second half of the year. The number of active research studies rose from 62 at the end of July 2013 to 72 by the end of December. While sequestration delayed the start of some projects and reduced the overall award amounts for many, the research program was able to attract nearly US\$ 10 million in new awards in 2013.

Along with increases in the number of new studies and research awards, 2013 turned out to be a strong year for AMPATH research publications. At least 40 publications from AMPATH investigators were published in peer review journals. More than 30 posters and abstracts were presented by investigators at major conferences in Africa, Europe, and North America. New efforts also began in the second half of the year to disseminate AMPATH research findings to clinical leaders and policy makers and encourage the application of lessons learned from research to critical global health challenges.

Progress has been made towards achieving a number of the Research Program's strategic priorities. More research training for registrars, medical officers, and MPH graduates is now available at Moi. Renewed efforts to strengthen the role of community engaged research and communicate the benefits of research to the community began at the end of 2013 and have continued with the creation of a task force to support community engaged research at AMPATH. Finally, data and biostatistics support has continued to grow.

While the AMPATH research program made progress on its strategic priorities in 2013, there is work left to be done and a number of key challenges persist. The availability of protected time for Kenyan investigators, support for the reference laboratory, and improving Kenyan participation in the research working groups continue to be critical issues for the research program. Increased financial pressures have also had real impacts on the program's capacity to fully provide necessary administrative support needed for research.

The following report includes updates from 72 research studies at AMPATH along with brief updates on the status of funding for research and publications produced in 2013. 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 2013 and continue with a description of the publications produced during the year. We conclude with brief project updates provided by AMPATH investigators and listed alphabetically by the study title.

*Please visit the AMPATH Research Network Website to download a copy of this and past reports,
www.medicine.iu.edu/ampathresearch.*

Grants

After a slow start, the number of new awards for AMPATH research projects increased significantly in the second half of 2013. Of the 19 new research awards reported for 2013, 63 percent were awarded in the second half of the year. The slow start was partly the result of United States federal government budget delays and automatic spending cuts that went into effect as part of sequestration early in 2013. However, the year ended with a total of US\$ 9.97 million in new research awards slightly below the program's 5 year annual average of US\$10.6 million. New awards in 2013 brought the total level of program direct awards to more than US\$ 83.4 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 2013, NIH funding accounted for more than 50 percent of all awards (See Figure 2). Philanthropic support from nonprofits and foundations was the second largest source of funds (16 percent) followed by support from intergovernmental organizations like the World Health Organization (11 percent) and governmental aid organizations like NORAD and USAID (11 percent).

The sources of program funding remain consistent with program averages since 1998. However, NIH funding for AMPATH research was down by 5 percent when compared to the average for the previous five years (See Figure 3). This decrease can likely be attributed to sequestration cuts that reduced many project budgets by 5-10 percent in 2013. At the same time NIH funding was decreasing, support from philanthropic sources was up by 2 percent over the last five years and funding from intergovernmental organizations 7 percent more than in previous years. Increased support from sources other than the NIH helped lessen the impact of sequestration on the program overall but illustrates the importance of continuing to increase the diversity of sponsors supporting research at AMPATH.

Publications

In the last year, AMPATH investigators published 40 manuscripts in peer reviewed journals. This matched the previous year's totals and was nearly double the number of publications produced just five years ago. Strong publication rates this year helped to increase the total number of publications produced by AMPATH investigators since 1989 to 272 (See Figure 4). A bibliography of publications from 2013 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 137 draft publications. Around 46 percent of the publications reviewed were abstracts and nearly 17 percent were poster presentations presented at professional conferences. Manuscript submissions (35 percent) made-up most of the remaining publications submitted for review (See Figure 5).

The Publications Committee has also launched a new effort to collect and disseminate information about research outcomes that might be useful to AMPATH clinical leaders and policy makers. Starting in April 2013, the Committee began asking authors who submitted publications for review to also provide a one paragraph statement describing what key issues policy makers should know about their research. These statements were compiled into a quarterly research publications compendium and distributed to policy makers, clinical leaders, and members of the AMPATH research community. Copies of the research publications compendium can be accessed through the AMPATH Research Member Access Portal, www.medicine.iu.edu/ampathresearch/member-access.

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)	
Description	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.
Site(s)	Mihuu Community, Webuye; Burnt Forest Community; Pioneer Community
Project Period	5/28/2013 – 1/30/2014
Funding Status	Funded by Duke Global Health Institute, Johnson and Johnson
Direct Award (USD)	\$29,500
Update	Focus group discussions about family functioning, child mental health, marital relationships, and other related topics were completed in all three communities. Focus groups were held with female caregivers, male caregivers, male youth, and female youth at all sites. Additionally, key informant interviews were conducted in each field site and interviews were conducted with individuals already working in various types of psychosocial services. Analysis of the qualitative data collected is currently taking place in order to inform the future validity and pilot intervention phases of research.
Future Plans	IREC approved a protocol for the continuation of the current study entitled 'Tuko Pamoja' which focuses on further measures validation and intervention piloting. For the measures validation component of the study, there will be two phases: (a) piloting of assessment tools, including observational assessments and survey items and (b) validity and reliability testing that includes administering the questionnaire and comparing the results with other measures of the same constructs, such as clinical interviews; other measures of reliability also will be assessed by administering the questionnaires with different

	interviewers and at different times. For the family therapy intervention component, we will use a community-based participatory research process to develop an intervention that integrates evidence-based family therapy strategies with existing community solutions. This process will include recruiting community leaders and members from different sectors of the community to work with the research team to develop the intervention approaches and manual. Second, we will conduct a small feasibility pilot of the intervention.
Publication(s)	
Study Title	A Population-wide Home-Based Study of Hypertension Prevalence in Western Kenya
Principal Investigator(s)	Eric Velazquez, Duke University Sylvester Kimaiyo, Moi University
Co-Investigator(s)	Akwanalo, C. Bloomfield, J. Hogan, J. Maghasi, M. Anstrom, K.
Description	Hypertension is one of the increasingly important health challenges facing the African continent and yet data on true community prevalence of hypertension in Sub-Saharan Africa (SSA) is limited. The prevalence of hypertension in truly rural populations was said to be a rarity but this must have changed because of adoption of Western lifestyle. Recent studies indicate that the prevalence of hypertension and its clinically important outcomes is steadily increasing in SSA, more in the urban compared to semi urban and rural communities. The study will be conducted in two phases. Phase one of the study will be a cross sectional study which will be conducted on persons aged 18 years or older from Mutwot location, Kosirai division, to assess for hypertension and diabetes mellitus. Diagnosis of hypertension and diabetes will be based on the JNC 7 and American diabetes association criteria. In the second phase of the study those individuals who are newly diagnosed with hypertension (at least 193 cases) will be assessed for target organ damage and compared to controls (386) in a 1 to 2 ratio. Target organ damage will be defined as the detection of electrocardiogram left ventricular hypertrophy (ECG/LVH), micro albuminuria, or history of a stroke.
Site(s)	Mosoriot Rural Health Training Centre
Project Period	2/1/2012 – 12/31/2013
Funding Status	Funded by NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	\$20,000
Update	No Update
Future Plans	
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.
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 by NIH - National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Direct Award (USD)	\$2,268,832
Update	Recruitment for the trial began in July 2012. The study has since completed recruitment and randomization of 9 intervention cohorts. Participants have completed a 6-week group cognitive behavioral therapy or health education intervention delivered by paraprofessional counselors. Follow-ups for participants who have completed the intervention stage began in October 2012 and are ongoing. Four cohorts have completed all follow-ups. Target goals for recruitment and retention have been met.
Future Plans	Recruitment, intervention, and follow ups will continue.
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.

Description	A5225/HiFLAC is a phase I/II dose escalation and validation study of the safety, tolerability, and therapeutic effect of an induction-consolidation strategy of high-dose fluconazole alone for the treatment of cryptococcal meningitis (CM) in HIV-infected participants. The study will proceed in two stages. In Stage 1, Dose Escalation, up to three induction doses of fluconazole will be tested in sequentially enrolled cohorts. Stage 2, Dose Validation, will not open until the maximum tolerated dose (MTD) of fluconazole has been identified in Stage 1. In Stage 2, induction doses of fluconazole that are found to be safe in Stage 1 will be tested in simultaneously enrolled cohorts. In each stage, participants will be randomized at entry into Step 1. Over the course of the study, participants will register to subsequent steps (Steps 2-4) based on their initial randomization and/or their response to treatment. The study steps are: Step 1: Induction therapy with either high dose fluconazole or ampho B; Step 2: Induction following early ampho B intolerance (only for participants randomized to ampho B treatment in Step 1) (fluconazole at 400-800 mg daily); Step 3: Consolidation therapy (fluconazole 400 mg daily); and 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 by NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	Not Reported
Update	Since the last reporting period, one more participant was enrolled into cohort 3 to make the total number enrolled into this cohort three (3). In total, 17 participants were enrolled into this multi-centre trial from the Eldoret site. All the 17 have completed study follow up and the study is now temporarily closed to accrual pending analysis of stage one safety data.
Future Plans	We anticipate the release of a new protocol version informed by the stage one safety data findings. Once the new protocol version is released the site will embark on acquiring the necessary approvals before enrollment can be reopened.
Publication(s)	

Study Title	A5263 'A Randomized Comparison of Three Regimens of Chemotherapy with Compatible Antiretroviral Therapy for Treatment of Advanced AIDS-KS in Resource-Limited Settings'
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Naftali Wisindi Busakhala Evangeline Wawira Njiru
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 by NIH - AIDS Clinical Trials Group (ACTG), NIH - National Cancer Institute (NCI), NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	
Update	The protocol has been in the regulatory review phase. All regulatory approvals have been granted and is awaiting protocol activation for the MTRH site which will enable enrollment of study participants.
Future Plans	It is hoped that within the coming six months, recruitment will have started at the site.
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.
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 by 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	An additional 6 participants have been enrolled since July 2013. There are now 12 participants enrolled into the study. Many potential participants are excluded from the study due to the fact that they are either already started on ART or have advanced stage KS which are exclusion criteria.
Future Plans	We hope to ramp up enrollments for this study by expanding our catchment to clinics that see more cases of KS.
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.
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 <i>Candida</i> 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 by NIH - National Institute of Allergy and Infectious Diseases (NIAID), NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	Not Reported
Update	The protocol team found that it would not be possible to incorporate the DSMB recommendations into a new version of the protocol. This study has now been permanently closed.
Future Plans	We do not anticipate any activities for this protocol apart from activities associated with close out.
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)	Faraj Some
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 by NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	
Update	A total of 16 participants were enrolled into this study from the Eldoret site between June and October 2013. This made the total number of participants recruited at the site to be 48. The study is now closed to accrual and study participants are on follow up.
Future Plans	Since no new recruitment's are underway, the study staff will continue to follow up and clinically manage the participants already on study.
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)	David K Lagat
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 by NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	
Update	Between July 2013 and January 2014, 21 participants were recruited into this study. The total current enrollment is now 54 participants. Recruitment into this study has been hampered by the fact that baseline CD4 are not done for all AMPATH participants any more. As such getting potential participants to screen has been a problem.

Future Plans	Enrollment is still ongoing for this study. Hoepfully the site will attain its target of enrolling 100 participants into this study within the next six months. Meanwhile, study follow up will continue for those already recruited.
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)	Beatrice Wangari Ndege
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 $\geq 65\%$ 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 by NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	
Update	The project eventually got all the regulatory approvals and ACTG activation at the end of 2013. Since then several participants have been screened and are awaiting enrollment into the study. This is a study that has a relatively long screening period but will help many of the patients within the AMPATH program who are already failing second line therapy and who may be eligible for the study.
Future Plans	It is anticipated that in the coming six months more potential participants will have been screened and enrolled into the study.
Publication(s)	
Study Title	Accuracy of Oral HIV Self-tests in Kenya

Principal Investigator(s)	Ann Kurth, New York University Abraham Siika, Moi University
Co-Investigator(s)	Were, Edwin Naanyu, Violet Emonyi, Wilfred
Description	<p>Knowledge of HIV status is key to earlier access to HIV treatment and prevention services. In resource limited settings such as in sub-Saharan Africa, the shortage of health care workers has been identified as a barrier in the effort to scale up HIV prevention and treatment service. Given the public health implications of unknown HIV status, availability of self-testing for rapid scale up of HIV testing is compelling; increasing awareness of HIV status is an important step towards reducing HIV transmission and enabling antiretroviral therapy (ART) that reduces mortality as well as secondary HIV transmission. Performance and accuracy parameters of HIV self-testing (HST) will be determined. We hypothesize: Aim 1: Kenyan populations can accurately determine their oral fluid (OF) HST results (expected sensitivity of $\geq 96\%$ and specificity of 99%) Aim 2: OF HST will be acceptable and feasible ($\geq 95\%$ say HST is acceptable/easy to use) Aim 3: The proportion of those who are preliminary positives (confirmed by ELISA), who are referred to care, will attend clinic within one month post HST confirmed result will be the same or higher levels as seen in those who test through regular VCT (AMPATH EHR anonymous data).</p>
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	7/1/2013 – 2/28/2014
Funding Status	Funded by International Initiative for Impact Evaluation (3ie)
Direct Award (USD)	\$76,358
Update	<p>1. Institutional Research and Ethics Committee (IREC, Kenya) IRB approved our amendment (for study protocol changes requested by NASCOP/3ie) on October 7, 2013. NYU's IRB amendment was approved on October 25, 2013. 2. Recruitment occurred from November 11 - 29, 2013. Aims 1 and 2 were completed over this period. We successfully achieved our Arm 1 'enhanced' recruitment target of 240 participants (original approved target was 180) and Arm 2, video observation of 20 participants performing the self-testing (usability portion). 3. Preliminary data were analyzed and presented by PI, Ann Kurth, and co-I Edwin Were, at 3ie's pre-completion workshop on December 12, 2013 in South Africa.</p>
Future Plans	<p>The primary study objective is to evaluate the ability of participants with unknown HIV status to correctly perform and interpret a rapid oral fluid (OF) HIV test, and to determine accuracy of HST results compared to staff/lab testing. Aims 1 and 2 (the performance and accuracy parameters of the HST) have been completed. We are in the process of fulfilling Aim 3. Follow-up phone calls to ELISA-confirmed positive study participants have been completed and information captured in the one-month follow-up phone survey has been entered into a database. We have submitted a research data request to AMPATH for medical record extraction so that we can complete Aim 3, which is to determine linkage to care.</p>
Publication(s)	

Study Title	Addressing the Fourth Delay: Improving Communitybased Accountability for Maternal and Newborn Health
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto J. Songok, Moi University
Co-Investigator(s)	Ruhl, L. Fazen, L.
Description	This project seeks to address a critical fourth delay that sustains high rates of maternal and neonatal mortality in western Kenya: the delay in a community's accountability to its mothers and infants. An innovative information technology platform that fosters rapid communication and feedback between mothers, their communities, and their healthcare providers called the Mother-Baby Health Network will be developed. This information platform will accomplish three primary objectives: (1) Facilitate home and group-based care through Community Health Workers (CHWs) to improve collective advocacy; (2) Provide communities with the capabilities to activate an emergency alert system; and (3) Foster transparency in community and health system responsiveness to maternal and newborn health. CHWs will be equipped to use clinical decision-support on Android phones to correctly triage women and newborns for care. Integrated with SMS messaging, they will be capable of notifying healthcare providers, alerting nearby GPS-tracked Mother-Baby Taxis in an emergency transport system, and activating a personalized community of Mother-Baby Advocates to mobilize local resources. The Mother-Baby Health Network will strengthen dialogue between communities and facilities to create a sustainable, community-driven demand for accountable maternal and newborn care at all levels of care. Recognizing that 'it takes a village', the Mother-Baby Health Network will provide communities in western Kenya with the information and communication tools they need to ensure that every mother and child has access to essential care at time of delivery and within the first 48 hours of birth.
Site(s)	Mosoriot Rural Health Training Centre, Port Victoria Sub-District Hospital, Teso District Hospital
Project Period	12/1/2011 – 12/1/2013
Funding Status	Funded by Grand Challenges Canada
Direct Award (USD)	\$248,000
Update	No Update
Future Plans	
Publication(s)	
Study Title	Anticoagulation Project
Principal Investigator(s)	Sonak Pastakia, Purdue University Imran Manji, Moi University

Co-Investigator(s)	Schellhase, Ellen Jakait, Beatrice Akwanalo, Constantine Karwa, Rakhi Saina, Collins Nabwire, Mercy Kanyi, John Maina, Mercy
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 by Purdue University College of Pharmacy, Indiana Hemophilia and Thrombosis Center (IHTC), Celgene Corporation
Direct Award (USD)	\$100,000
Update	The clinic has continued to enrol patients from all areas of MTRH and the AMPATH clinics in Eldoret and Webuye. Over 800 patients have been enrolled and more than 400 are actively being managed in the clinic. One of the challenges we face is continuing to provide this essential service sustainably without external funding. The clinic charges a small fee for the services but this is not enough to cover all the costs of the care we provide. Moreover, not all patients are paying for the services and we do not turn away those who cannot pay. As a result, in October 2013, we partnered with the social work department to assist in assessing patients for the ability to pay and since then, the proportion of patients who pay has increase from 30% to more than 60%, with those unable to afford being linked to the variety of safety net programs in AMPATH
Future Plans	The medical records system for the clinic is still under development and we hope to begin piloting parts of the system in the next few months. Some of the features are already being tested including the fingerprint identification of patients which is linked to a text message reminder system for clinic appointments. This will eventually be incorporated into the larger medical records system that will track all patient information.
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

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 by Brown University - Center For AIDS Research
Direct Award (USD)	\$225,220
Update	Study finalized. Data dissemination ongoing.
Future Plans	Dissemination.
Publication(s)	Diero L, DeLong A, Schreier L, Kemboi E, Orido M, Rono M, Reitsma M, Emonyi W, Buziba N, Hogan J, Kantor R. High HIV Resistance and Mutation Accrual at low Viral Loads upon 2nd-Line Failure in Western Kenya. CROI 2014.

Study Title	Assessment and Treatment of Pain in Hospitalized Patients at MTRH
Principal Investigator(s)	Rachel Vreeman, Indiana University C. Owino, Moi University
Co-Investigator(s)	Gramelspacher, G. Huang, K. Njuguna, F. Hagembe, M. Strother, R. Monahan, P. Tabbey, R.
Description	Pain is often inadequately evaluated and treated in sub-Saharan Africa. The objectives of this study were to assess pain and pain treatment in 400 hospitalized patients at a national referral hospital in western Kenya, and to identify factors associated with pain and pain treatment. Using validated Kiswahili versions of two single-item pain assessment tools, the Numerical Rating Scale and the Faces Pain Scale-Revised, patients' pain levels were determined. Additional data collected included patient demographics, prescribed analgesics, and administered analgesics. Mean pain ratings and Pain Management Index (PMI) scores were calculated. Averaged between the NRS and FPS-R, 80.5 percent of patients endorsed pain and 30 percent of patients reported moderate to severe pain. Older patients, patients with HIV, and cancer patients had higher pain ratings. 66 percent of patients had been prescribed analgesics at some point during their hospitalization, the majority of which were non-opioids. A majority of patients (66 percent) had undertreated pain (negative scores on the PMI). In conclusion, this study shows that hospitalized patients in Kenya are experiencing pain and that this pain is often under-treated.
Site(s)	Moi Teaching and Referral Hospital (MTRH)

Project Period	3/28/2011 – 6/30/2013
Funding Status	Funded by Indiana University - School of Medicine
Direct Award (USD)	\$1,000
Update	This project is complete and the manuscript has been published.
Future Plans	
Publication(s)	Huang KT, Owino C, Gramelspacher GP, Monahan PO, Tabbey R, Hagembe M, Strother RM, Njuguna F, Vreeman RC. Prevalence and Correlates of Pain and Pain Treatment in a Western Kenya Referral Hospital. J Palliat Med. 2013 Oct;16(10):1260-1267. Epub 2013 Sep 13

Study Title	Biomarkers of Vincristine Toxicity in Kenyan Children
Principal Investigator(s)	Jodi Skiles, Indiana University F. Njuguna, Moi University
Co-Investigator(s)	Skiles, J.
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 by NIH
Direct Award (USD)	\$8,743
Update	This study is now closed to accrual as of January 2014. In total, 112 subjects were enrolled on this study. The preliminary data was presented at ASCO in 2012 and full publication is about to be submitted to Journal of Clinical Oncology after publications committee review. The new dose escalation study mentioned in the last report has been approved by IREC and began enrolling subjects in February 2014.
Future Plans	Three publications are anticipated from this work. The first will be submitted to the Journal of Clinical Oncology after publications committee review. The last two publications are in progress.
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.
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 by Indiana University - Office of Research in Medical Education
Direct Award (USD)	Not Reported
Update	No activity during the reporting period
Future Plans	
Publication(s)	
Study Title	Cervical Cancer See and Treat: How Best to Follow-up
Principal Investigator(s)	Susan Cu-Uvin, Indiana University E. Omenge, Moi University
Co-Investigator(s)	Mabeya, H. Washington, S. Itsura, P.
Description	This is a cross sectional study involving 660 HIV-infected women attending 4 AMPATH-CCSPP (Cervical cancer Screening and Prevention Program) sites who have undergone VIA and cryotherapy >6 months for cervical dysplasia. Demographic information as well as a full medical history will be obtained. They will undergo a gynecologic examination. Women with suspected frank cervical cancer or current genital tract infection will not be enrolled and will be referred for standard of care. Women with genital tract infection will undergo syndromic treatment and will be eligible to be enrolled 3 weeks after treatment if they have cleared the infection. During the gyn exam, the following will be done for all study participants: VIA, conventional Pap smear, endocervical cytobrush for HPV typing.

	All women with positive VIA result will undergo colposcopy and biopsy at the next available colpo/biopsy clinic day. Those with negative VIA result will return in 4-6 weeks to receive the results of their Pap smear and HPV typing. If either the Pap smear or HPV typing is abnormal, they will undergo colposcopy with biopsy on the next available colpo/biopsy clinic day. Women with negative VIA, PAP smear and HPV will follow standard of care that is annual screening with VIA. Histological diagnosis will be the gold standard. Women will be asked several questions regarding their experience.
Site(s)	Chulaimbo Sub-District Hospital, Moi Teaching and Referral Hospital (MTRH), Mosoriot Rural Health Training Centre, Turbo Health Centre
Project Period	9/1/2011 – 6/30/2013
Funding Status	Unfunded
Direct Award (USD)	
Update	The study closed to recruitment on 30 June 2013. A total of 517 women were recruited to the study. Data entry, cleaning and analysis has been completed. Manuscript writing is on going. An abstract was accepted for poster presentation during CROI 2014 to be held on 3rd to 6th March 2014 in Boston, USA. The study is now closed.
Future Plans	In the next 6 months we plan to complete manuscript writing and submit for publication.
Publication(s)	CROI 2014 poster presentation.

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.
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 – 6/30/2014
Funding Status	Funded by Alex's Lemonade Stand Foundation
Direct Award (USD)	\$200,000
Update	No Update
Future Plans	

Publication(s)	
Study Title	Computerized Counseling to Promote Positive Prevention and HIV Health in Kenya (CARE+ Kenya)
Principal Investigator(s)	Ann Kurth, New York University Abraham Siika, Moi University
Co-Investigator(s)	John Sidle Joyce Baliddawa David Ayuku
Description	<p>The specific aims of this project are:</p> <ol style="list-style-type: none"> 1. Adapt a theoretically driven computerized counseling intervention (CARE+ Kenya) for use in Western Kenya (1st 18 months). <ol style="list-style-type: none"> 2.1.A. Conduct interviews with up to 25 HIV-positive urban and up to 25 rural men and women patients from the Academic Model Providing Access to Healthcare (AMPATH) to understand HIV and computer training needs. Conduct two staff focus groups (n~16) to assess positive prevention and ART adherence support practices, beliefs about patient computer use and training needs. 2.1.B. Using above, modify intervention content, translate and record audio files into local Kiswahili, and adapt skill-building videos on 'positive health' (prevention, disclosure, ART adherence, reproductive health, etc.). 2.1.C. Conduct iterative software usability testing with 10 urban and 10 rural patients (n=20) and 8 staff. Perform three day test-retest reliability assessment to establish psychometric performance of measures. 2.2 RCT. Establish biological and behavioral efficacy of a longitudinal HIV computerized counseling intervention in Kenya ('CARE+Kenya') (Months 18-42). <ol style="list-style-type: none"> 2.2.A. Longitudinal RCT in an urban and a rural clinic. Randomly assign HIV-positive adults with missed ART doses on self-report, pharmacy refill or pill counts; or unprotected sex in last 6 months, >1 partner in last year, or sexually transmitted infection (STI) in last 3 years; to intervention (n=125) or risk-assessment control (n=125) for baseline, 3, 6, and 9 month sessions. HIV transmission risk will be measured by self-reported unprotected sex with HIV-negative/unknown partner, and trends in C. trachomatis, N. gonorrhoeae, T. vaginalis. ART adherence will be measured by HIV-1 viral load at 0, 6, 9 months, and at all time points, by electronic monitoring, pharmacy refill, self-report, and clinic attendance. 2.3 Establish cost-effectiveness of computerized counseling in Kenya (Months 1-48). <ol style="list-style-type: none"> 2.3.A. Follow patients at the two clinics to evaluate standard of care counseling messages and collect patient time-spent data (n=100, at baseline), to determine unmet patient counseling need. 2.3.B. Economically evaluate CARE+Kenya. If RCT shows the intervention reduces viral load and transmission risks, we will use a Bernoulli transmission dynamics model to estimate number of secondary HIV infections prevented; then create a cost-effectiveness model to calculate 2 incremental cost-effectiveness ratios: 1) cost/HIV infection averted, and 2) cost/disability adjusted life year (DALY) saved. 2.3.C. If CARE+ Kenya is efficacious and efficient, we will develop a proposal for a cluster-randomized trial to assess translational effectiveness of CARE+ Kenya throughout the AMPATH system. 4.0 Specific CARE Study Aim 4 : Explore the ethical issues affecting participants who used the computerized counseling tool in the HIV/AIDS clinical setting for both rural and urban clinics during the RCT. <ol style="list-style-type: none"> 4.0 A. We will look specifically at issues surrounding privacy of information for computerized tools, and the effect of computerized counseling on the ethical practice of

care. 4.0 B. We will target 102 patients in both the clinics, including 55 participants enrolled from MTRH and 47 participants enrolled from Burnt Forest. We will employ a descriptive and explanatory research design. 5.0 Specific CARE Study Aim 5 : Implement the CARE+ Tool in the real-world clinic setting at MTRH clinics to gain experience with logistics and usefulness of the tool outside the more controlled RCT environment. 5.0 A. Our experiences from this implementation period will inform development of larger applications to NIH and foundations for more widespread implementation of the tool throughout AMPATH clinics following the study.

Site(s)

Burnt Forest, Moi Teaching and Referral Hospital (MTRH)

Project Period

8/14/2009 – 6/30/2014

Funding Status

Funded by NIH - National Institute of Mental Health (NIMH)

Direct Award (USD)

\$1,810,361

Update

Accrual Update - Target approval by the IREC/IRB:

CARE + Study Site	Computer sessions per day	Patient seen per the first week of launch of the project	Patient seen per the last week of the project
Module 1,2 and 3	40	100	200

Accrual Update - Accrual since beginning of No Cost Extension (N.C.E):

CARE + Study Site	Computer sessions per day	Patient seen per the first week of launch of the project	Patient seen per the last week of the project
Module 1,2 and 3	3	10	N/A

Accrual Update - Accrual since last update of the N.C.E :

CARE + Study Site	Computer sessions per day	Patient seen per the first week of launch of the project	Patient seen per the last week of the project
Module 1,2 and 3	3	10	N/A

ACHIEVEMENTS:

We are currently in the No Cost Extension and final year of the study. Recruitment for the No Cost Extension started on the 5th November 2013. Patients from three AMPATH sites (Module 1, 2 and 3) were referred by providers, psychosocial department and the pharmacy, as well as self-referral. Logs are being kept on whether a patient is referred by anyone or if he/she is a self-referral. Recruitment has been slow due some challenges

encountered. As of Tuesday, December 31st, 2013, we had recruited a total of 45 participants. Of the 45 patients, 17 are male and 28 are female. Of the 38 patients, 35 are from module 2, 6 from module 3, and 4 from module 1. All those being identified by the computer for domestic violence (IPV) were first referred for assessment to psychosocial department and then the psychosocial department referred all those with issues to the legal department for further action. After assessment to ascertain if the referred clients had issues going on in their lives, a report was made and a referral copy given back to psychosocial and CARE Plus Study. For cases like Depression and Suicidal, the patients were first referred for assessment to Psychosocial department and then referred to the mental health department for further action and treatment if necessary. After assessment, a report was made and a copy given back to CARE Plus Study. Below is a summary of cases captured and referred to Psychosocial department.

Site	Suicidal	Depression	IPV
Module 1	1	0	0
Module 2	5	6	5
Module 3	2	1	1

Over the past couple of weeks of recruitment, we faced the following challenges;
CHALLENGES:

1. Lack of cooperation from some AMPATH Providers. There was lack of cooperation from some module providers and frontline health workers to refer patients to the study area. Their reasoning was that we had added to them more paperwork but with no incentives. Some of the counselors, for example, believed that we were duplicating their work and we were out to make them redundant. Some of the nurses and doctors claimed that it was more paper work which made them slow down on actual patient care. They suggested we have designated providers specifically for the study.
2. Computer Connection. Study Staff in collaboration with the IT Department managed to setup the Access Points, Virtual Machine for our CARE Database. However, the biggest challenge was how to have our study tablets communicate with the virtual machine server and setting up the two wireless printers. IT team was not able to figure out why study tablets and vm server did not communicate. Due to issues of migration of our CARE Kenya stand alone databases to AMPATH virtual machine server, we had to start the No Cost Extension (NCE) phase with our already existing CARE Domain system. In the meantime, Carter, the programmer from resources online, worked with Kenya IT team to figure out what the issue was. The AMPATH IT department created a remote log in access for Ronline. Carter was given rights to access the SQL Server and finish the server set-up. The server was finally set-up in January/February 2014.
3. Long holidays. We saw a drop in total number of referrals from providers due to low patient turnout during the holiday season, especially from the end of November and on. Most of them were given return dates for 2014 unless they had health issues. This contributed to the low turn outs of patients for all the three recruitment all the modules in the month of December 2013 in Ampath center.

Implement the CARE+ Tool in the real-world clinic setting at MTRH clinics to gain experience with logistics and usefulness of the tool outside the more controlled RCT

	environment. The experiences from this implementation period will inform development of larger applications to NIH and foundations for more widespread implementation of the tool throughout AMPATH clinics following the study.
Future Plans	Implement the CARE+ Tool in the real-world clinic setting at MTRH clinics to gain experience with logistics and usefulness of the tool outside the more controlled RCT environment. The experiences from this implementation period will inform development of larger applications to NIH and foundations for more widespread implementation of the tool throughout AMPATH clinics following the study.
Publication(s)	
Study Title	Cross-Cultural Histories of Family Care-Giving to AIDS Orphans in Western Kenya
Principal Investigator(s)	Jeanette Dickerson-Putman, Indiana University - Purdue University in Indianapolis (IUPUI) H. Maithya, Moi University
Co-Investigator(s)	
Description	The overall goal of the project is to complete an anthropological and clinic-based study that seeks to understand the history of the care-giving experiences of primary providers of care-giving to AIDS orphans in Kenya among two different cultural groups served by the same AMPATH support program.
Site(s)	Chulaimbo Sub-District Hospital, Mosoriot Rural Health Training Centre
Project Period	9/1/2009 – 5/30/2014
Funding Status	Funded by IUPUI - Research Support Funds
Direct Award (USD)	\$35,000
Update	Coding and formal analysis with the Mosoriot data began on January 2014.
Future Plans	We hope to begin the coding and analysis of the Chulaimbo data in the next 6 months.
Publication(s)	
Study Title	Descriptive Study of Patients Seeking Emergency Care in Western Kenya
Principal Investigator(s)	Darlene House, Indiana University Saratiel Nyabera, Moi Teaching and Referral Hospital
Co-Investigator(s)	Kurt, Y.
Description	Descriptive study of patients seeking emergency care at MTRH for the year of 2011. Data includes demographics, diagnosis, and disposition. The data will allow for assessment of needs for the department.
Site(s)	Moi Teaching and Referral Hospital (MTRH)

Project Period	1/1/2011 – 12/20/2012
Funding Status	Unfunded
Direct Award (USD)	
Update	
Future Plans	None to report
Publication(s)	House DR, Nyabera SL, Yusi K, Rusyniak DE. Descriptive Study of an Emergency Centre in Western Kenya: Challenges and Opportunities. African Journal of Emergency Medicine. Accepted Aug 20, 2013.

Study Title	Diabetes Mellitus and Glucose Intolerance in HIV Patients in Western Kenya
Principal Investigator(s)	Jane Carter, Brown University N. Kirui, Moi University
Co-Investigator(s)	Kamano, J. Diero, L. Chege, P. Pastakia, S. Gardner, A. Mwangi, A.
Description	The goal of this study is to determine the association between diabetes mellitus, glucose intolerance, and HIV among HIV positive patients in Western Kenya. In this study, we propose that HIV and ART use increases the risk of diabetes mellitus and glucose intolerance among HIV patients in Western Kenya.
Site(s)	Moi Teaching and Referral Hospital (MTRH), Webuye District Hospital
Project Period	9/3/2012 – 8/31/2015
Funding Status	Unfunded
Direct Award (USD)	
Update	The study has not received any funding and the study has not started.
Future Plans	The study will continue to seek new sources for funding to support a research assistant and begin recruitment.
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.
Description	The project seeks to determine the proportion of children getting 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 – 4/10/2015
Funding Status	Funded by NIH – Fogarty International Center (FIC), AITRP Grant-Brown University.
Direct Award (USD)	\$20,000
Update	We have not enrolled any study participants since the last update. We have had challenges recruiting eligible patients because there are 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.
Future Plans	We are hoping that we shall be able to get eligible participants for us to improve on the rate of recruitment.
Publication(s)	Manuscript is under development. Abstract submitted to AIDS conference in Australia this year.

Study Title	EARNEST: A Randomised Controlled Trial to Evaluate Options for Second-line Therapy in Patients Failing a First-line 2NRTI+ NNRTI Regimen in Africa
Principal Investigator(s)	Abraham Siika, Moi University Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Mabeya, H. Washington, S. Itsura, P.
Description	EARNEST is a three arm parallel group, open-label, multi-centre, randomised controlled trial. 1200 patients will be included who are HIV-infected adults who have taken a first-line NNRTI-based regimen continuously for a total period of at least 12 months, and developed treatment failure defined by modified WHO 2010 criteria as one of the following: New WHO Stage 4 event (with CD4 < 200 cells/mm ³ and viral load (VL) > 400 copies/ml); CD4 < 100 cells/mm ³ , or CD4 fall to pre-treatment baseline or below, or CD4 < 200 cells/mm ³ X 2 with previous CD4 > 400 cells/mm ³ (with VL > 400 copies/ml); VL > 5,000 copies/ml; 2 The trial aims to determine whether, in patients failing a first-line NRTI and NNRTI-containing regimen 1. bPI plus raltegravir (an integrase inhibitor) is superior to standard of care (bPI plus 2 new NRTIs) in achieving good HIV disease control at 96

	weeks after randomisation. 2. bPI monotherapy is non-inferior to standard of care in achieving good HIV disease control at 96 weeks after randomisation
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	2/9/2011 – 12/31/2014
Funding Status	Funded by European & Developing Countries Clinical Trials Partnership (EDCTP), Medical Research Council, Instituto de Salud Carlos III, Irish Aid, Swedish International Development Cooperation Agency (SIDA)
Direct Award (USD)	Not Reported
Update	All study participants have now been exited form the study. This is because they have completed the 144 week follow up period.
Future Plans	The data analysis team will now embark on analyzing the data from the study. Hopefully, preliminary results will be released within the next reporting period.
Publication(s)	Presentation by Prof. Nick Patton in IAS 2013
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.
Description	An innovative clinical and implementation research training program for Kenyan investigators, one built on the foundation of the highly successful and mature clinical and implementation research core curriculum for young investigators within our IUSM CTSI, will be developed. This program will attract graduate trainees nominated by faculty at Moi University schools of medicine, public health, dentistry, nursing, and possibly young faculty from health-related behavioral and social science programs at Moi. This curriculum will be presided over by seasoned Eldoret-based investigators from the AMPATH research network (especially Dr. Thomas Inui and his 5 co-directors of the AMPATH Field Research program). Trainees who complete the core curriculum will be eligible to compete for resources to propose and conduct research in an implementation research practicum under the supervision of a tailored mentorship panel populated by Moi and international faculty. This research will focus upon a chronic disease of importance to the health of the populations in Western Kenya and will contribute to the improvement of health care processes, including village-based processes, medical and psycho-social services, and integration of care for chronic conditions within the MOH delivery system. The 'laboratory' for this research will be the AMPATH-MOH chronic disease program. The training program will build on the successful AMPATH multi-disciplinary and multi-institutional research foundation already in place, supported by AMPATH's remarkable e-Health infrastructure. This program's graduate training will enable Kenyans to acquire knowledge and skills in health systems and implementation

	research, enhance their capacity to promote continuous improvement of health care, inform health policy, and acquire leadership and management skills needed to develop, manage and improve chronic disease control programs. The ultimate aim of this proposal is to prepare Moi health professionals to serve as effective change agents and scientific leaders in Kenya's evolving system of care.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	10/1/2012 – 9/30/2016
Funding Status	Funded by NIH - Fogarty International Center (FIC)
Direct Award (USD)	\$862,970
Update	The first two trainees have completed both quarters of the Indianapolis-based CITE curriculum, including writing research practicum protocols, and have returned to Eldoret. The second cohort of three trainees have completed two month's core CITE/Kenya seminars in September and November 2013, including CITE lectures, discussion sessions, and homework assignments.
Future Plans	Final core seminar lectures should be recorded in January-February 2014. The D43 CITE/Kenya steering committee has scheduled a site visit to Eldoret in June, 2014. Candidates for selection into the third cohort should be identified in May and review and selection completed in June 2014. June will also be a good time for presentation of practicum project projects by cohort 1 trainees and plans for practical projects by cohort 2 trainees.
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 B. Chemwolo, Moi University
Co-Investigator(s)	
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 by Grand Challenges Canada
Direct Award (USD)	\$97,361
Update	No Update
Future Plans	
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.
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 by NIH - National Institute of Mental Health (NIMH), PEPFAR - United States

	President's Emergency Plan for AIDS Relief
Direct Award (USD)	\$1,336,011
Update	<p>Validation of Comprehensive ART Adherence Measures for Pediatrics (CAMP Phases 1 and 2):</p> <p>PHASE 1: A battery of ART adherence measurement items were compiled for testing in Kenya from both literature review and formative qualitative work. Items were compiled, translated into Kiswahili, and adapted to increase face validity through cognitive interviews with pediatric caregivers and HIV-infected children ages 13-18 years. The interviews were transcribed and coded, with data for each measurement item summarized qualitatively and quantitatively. A testing report with recommendations for item adaptation was created and used to modify the adherence measurement items. A manuscript describing the findings of the cognitive interviews on adherence measurement items was published at the International Journal of Behavioral Medicine.</p> <p>PHASE 2: The clinical research phase of the project assessing the reliability and validity of the pediatric ART adherence measurement items for HIV-infected children in Kenya was completed. A total of 211 participants were enrolled with 200 HIV-infected children on ART completing six months of comprehensive monthly adherence assessments, MEMS monitoring of dose timing, plasma drug concentrations, and clinical follow-up including CD4 counts. Data analyses to finalize a validated, comprehensive adherence measurement questionnaire (the CAMP questionnaire) are almost complete. Extraction of questionnaire items to test as a short form (SF-CAMP), to evaluate as per Specific Aim 2 in a cohort of 100 children is ongoing. Ten items that correlated well with adherence on MEMS were identified. We evaluated adherence to antiretroviral therapy (ART) prospectively for 6 months among HIV-infected children ages 0 to 14 years (mean 8.2 years) in care at AMPATH. Adherence was evaluated using electronic dose monitoring (MEMS), caregiver-reported missed doses, visual analog scale (VAS), and plasma drug concentrations. We found median adherence by MEMS was high (96.3% of all doses taken) and improved over the course of follow-up, although almost half of children had at least one MEMS treatment interruption of ≥ 48 hours. There was generally poor agreement between MEMS adherence and other adherence measures, suggesting that additional validation of adherence measures is needed. Fourteen percent of children on NVP and 27% on EFV had sub-therapeutic drug levels. PHASE 3: Phase 3 assessed the validity of a short-form adherence assessment tool in a sample of 100 children with clinic implementation of strong candidate adherence measurement items.. A total of 105 children were enrolled between February and May, 2013 in the MTRH site of AMPATH. Monthly follow-ups with these children were conducted for a period of six months. patient follow up and data entry for the participants enrolled in Phase 3 of CAMP study is complete. Participants were followed up for a period of six months, scheduled on a monthly basis. This follow up period ended on November 2013. We only had five withdrawals (reasons being relocation and for one of the patients the regimen was changed from first line to second line.) Data entry and cleaning has been completed. Data analyses are beginning. Comparison of Home-Based and Clinic-Based Adherence Measurement (Phases 4 and 5, PEPFAR PHE Funding) These research activities examine home vs. clinic-based strategies of adherence measurement yield in this setting. The study will assess whether administering the comprehensive adherence assessment items in a home setting yields more reliable or valid data than the clinic-based assessments</p>

	using the same questionnaire items. Phase 4 The feasibility of these measurement strategies were assessed, enrolling 41 children from the Turbo and MTRH clinics and ultimately assessing 40 with either home- or clinic-based evaluations. Phase 5 Phase 5 was successfully implemented over the past 6 months and focused on activities to eliminate longitudinal follow-up. Comprehensive pediatric adherence assessments were conducted at four AMPATH clinical sites: MTRH, Turbo, Webuye, and Kitale. A total of 408 participants were enrolled in the MTRH, Webuye and Turbo and Kitale sites, of which 302 were randomized to clinic assessments and 105 to the home and clinic group. Only 11 participants have withdrawn from the study. Adherence assessments have been completed for 387 children. Data entry and subsequent analysis of the home- vs. clinic-based adherence assessments are ongoing.
Future Plans	Over the next 6 months, we will publish the findings of our adherence validation phases and conduct the psychometric analyses for the short-form tool to measure adherence. We plan to implement this short-form to assess pediatric ART adherence broadly throughout the AMPATH clinical system. We have also proposed a global pediatric adherence evaluation that would utilize this form at pediatric HIV care sites worldwide.
Publication(s)	Vreeman RC, McHenry MS and Nyandiko WM. Adapting health behavior measurement tools for cross-cultural use. Journal of Integrated Psychology and Therapeutics. 2013;1:2. http://dx.doi.org/10.7243/2054-4723-1-2 Vreeman RC; Nyandiko WM; Liu H; Tu W; Scanlo

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
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, Turbo Health Centre
Project Period	11/24/2009 – 2/20/2014
Funding Status	Funded by NIH - National Institute of Allergy and Infectious Diseases (NIAID), Other, Friendship Foundation
Direct Award (USD)	\$54,652
Update	Patients after treatment crisis induced treatment interruptions who re-initiate same antiretroviral regimens are more likely to fail treatment compared to patients with no treatment interruptions.
Future Plans	We will finalize detailed resistance analyses in the next 6 months.

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	Exploring factors that support a sustainable model for engaging and retaining CHWs in the PHC program of AMPATH (CHW Incentive Project)
Principal Investigator(s)	Sanjana Mitra, University of Toronto Suzanne Jackson, University of Toronto
Co-Investigator(s)	Diana Menya Astrid Christoffersen-Deb
Description	<p>Since 2011, AMPATH has supported approximately 1,200 Government of Kenya Community Health Workers (CHWs) in various health promoting primary health care activities, such as maternal and child health and nutrition, by providing CHWs with individual financial compensation of 2,000 Kenyan Shillings (approximately \$23 US dollars) per month, according to Kenyan government policy recommendations. However, AMPATH plans to end individual compensation to CHWs in the Fall of 2013. Thus, it is important to determine some of the other forces, which influence CHW motivation in this particular context. This qualitative research study will explore the work of AMPATH's primary health care CHW's in the context of Western Kenya and inform the development of a more sustainable model for AMPATH's primary health care program from the perspective of AMPATH-supported CHWs and primary health care staff in close proximity to CHWs. The study aims to: (1) Explore ways in which CHWs perceive their expected roles as manageable or unmanageable; (2) Determine financial and nonfinancial factors that motivate CHWs to perform their expected roles; and (3) Explore some of the environmental and contextual factors, specific to Western Kenya that are essential to keeping CHWs motivated to perform their expected roles.</p>
Site(s)	Port Victoria Sub-District Hospital, Turbo Health Centre
Project Period	1/7/2013 – 8/9/2013
Funding Status	Funded by University of Toronto - Dalla Lana School of Public Health
Direct Award (USD)	\$5,000
Update	<p>Over the last six months, four focus group discussions with approximately 40 community health volunteers were conducted in Bunyala and Eldoret West. Additionally, approximately 8 individuals who worked as AMPATH staff (i.e. a combination of community health extension workers, district management health officers, and AMPATH primary health care office workers) were also interviewed. Focus group discussions and interviews were transcribed from Kiswahili to English, when necessary. Coding of the data was done by question as well as by theme across all answers, through familiarization of data, thematic analysis, indexing, mapping and interpretation. Qualitative thematic analysis of all data collected through coding and sub-coding was primarily conducted by the principal investigator. Presentations of preliminary findings were given in person to AMPATH's primary health care office, and over teleconference to the AMPATH primary health care working group. After completing data analysis, a report was written and</p>

	<p>distributed. There are several key motivational drivers in community health volunteerism that have been identified in this present study. The study has established that Government of Kenya AMPATH-supported CHVs are influenced by a combination of individual, community, organizational factors that keep them motivated in engaging in CHV activities. Moreover, the stipend and its importance in meeting basic necessities was found to be a significant motivating factor for CHVs to remain engaged in their work. With respect to the upcoming stipend change, CHVs had varied reactions, although there were concerns of drop-outs, particularly in the beginning stages of the transition, by those who are motivated heavily by the stipend. CHVs recommend that AMPATH provide them with adequate and frequent training sessions and resources to improve the quality of work, while also suggesting that AMPATH provide training sessions and support throughout the transition.</p>
Future Plans	<p>Over the next six months, we will develop a manuscript for publication. We will also be preparing to go into the field again in early 2015 to do a follow-up survey of the CHVs to evaluate their reactions to the stipend change to a pooled mechanism.</p>
Publication(s)	
Study Title	<p>Facilitators and Barriers to Initiation of Antiretroviral Treatment Among Pregnant Women Living with HIV Receiving Antenatal Care in Western Kenya: An Evaluation</p>
Principal Investigator(s)	<p>Samantha Robinson, University of Toronto Paula Braitstein, Indiana University</p>
Co-Investigator(s)	<p>Kaaria, A.</p>
Description	<p>This project is a Masters of Public Health student practicum and involves an internal evaluation in collaboration with the PMTCT team. The main purpose of the evaluation is to explore the factors affecting the initiation of antiretroviral treatment (ART) among pregnant HIV positive women attending AMPATH-affiliated antenatal clinics in western Kenya. The main objectives are as follows: 1. To explore and evaluate factors related to ART initiation among pregnant HIV-positive women, enrolled in care at AMPATH sites in western Kenya 2. To highlight facilitators and barriers to initiation of ART: a. for women attending antenatal care facilities; and b. for women newly enrolled at HIV CCCs 3. To provide recommendations based on the findings to increase uptake of ART among HIV positive pregnant women attending AMPATH-affiliated antenatal and HIV CCCs. Data will be collected through clinic observations and interviewer-led questionnaires with health care providers.</p>
Site(s)	<p>Chulaimbo Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital (MTRH), Kitale Nursing Home, Chemasiri Dispensary, Akichelesit Dispensary, others to be selected</p>
Project Period	<p>5/20/2013 – 8/9/2013</p>
Funding Status	<p>Unfunded</p>
Direct Award (USD)	

Update	This project was completed in August 2013. As this project comprised an internal evaluation, a detailed evaluation report was written and disseminated to the PMTCT team, for use in evaluating PMTCT services in antenatal clinics and other primary health centres in Western Kenya. The report outlined key findings and recommendations.
Future Plans	This project is now complete.
Publication(s)	
Study Title	Feasibility Intervention Trial of Two Types of Improved Cook Stoves in Three Developing Countries
Principal Investigator(s)	Diana Menya, Moi University J. Miranda,
Co-Investigator(s)	Checkley, W. Carter, J. Ogaro, F. Diero, L. Mwangi, A.
Description	This is a multi-center community-based feasibility trial in which improved cook stoves with a chimney will be installed in 40 rural households of women aged 20 to 49 years at each of the three sites. All households will have a baseline observational period of 4 months in which outcome, environmental, and behavioral data will be collected longitudinally. Thereafter, 20 households will be randomly assigned to receive a commercially-available, improved cook stove with a chimney or a locally-constructed improved cook stove with a chimney. Behavioral, compliance, outcome and exposure data will be collected longitudinally for 4 months. Exposure assessments will include particulate matter and carbon monoxide. Respiratory outcome assessments will include spirometry, carboxyhemoglobin, exhaled nitric oxide and diffusing capacity of the lung for carbon monoxide. At the end of the 4 month period, households that received the Envirofit improved cook stoves will have their cook stoves switched with the locally-constructed improved cook stoves and vice versa, and all households will be followed for another 4 months. At the end of the year, all participants will be asked which cook stove they prefer and will be asked provide information on preferences, practices, and use patterns that influenced their final choice.?
Site(s)	Burnt Forest, Ndanai Sub-Location
Project Period	7/1/2011 – 6/30/2014
Funding Status	Funded by NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	\$76,239
Update	No Update
Future Plans	
Publication(s)	

Study Title	Health Facility Incentives to Improve Adherence to Malaria Diagnostic Test Results
Principal Investigator(s)	Wendy O'Meara, Duke University Diana Menya, Moi University
Co-Investigator(s)	Armstrong, J. Manji, I.
Description	<p>Global investments in controlling malaria have led to some exciting reductions in the burden of malaria. In some areas, malaria-related deaths have dropped by more than 90 percent. As malaria transmission declines, a greater fraction of pediatric fevers are from other causes. However, these fevers continue to be treated as malaria, often despite the availability of diagnostic testing. In a typical rural health facility in Kenya, more than 90 percent of febrile patients are prescribed an antimalarial when no diagnostic tests are available. Even when microscopy or rapid diagnostic tests (RDTs) are available, between 50-80 percent of patients with a negative test are nonetheless prescribed antimalarials. Inappropriately treated fevers in children can lead to serious consequences for the patient and can accelerate the spread of drug resistance. In addition to the risk to patients, overuse of antimalarials also puts a financial strain on the government health system. This project aims to test an innovative, sustainable financial incentive designed to reduce the number of non-malarial fevers that are treated inappropriately with antimalarial drugs. This study will test a financial incentive targeted at the health facility to determine if it improves adherence to diagnostic results and clinical protocols. Eighteen rural health facilities in western Kenya will be enrolled and randomly allocated to one of two arms. We will compare the effectiveness of clinical and technical training in diagnosis of malaria alone (Arm 1) to training plus financial incentives linked to prescription practices (Arm 2) in improving diagnosis and treatment of malaria and non-malaria fevers. The practice of prescribing antimalarials to patients with a negative diagnostic will be compared between facilities with and without the incentive structure. Secondary outcomes will include sensitivity and specificity of routine microscopy at health centers, use of alternative treatments for slide negative fevers, and frequency of stock-outs of antimalarial drugs. This project will be conducted in collaboration with Kenya's Division of Malaria Control and avenues to roll-out the intervention, if successful, will be actively explored.</p>
Site(s)	
Project Period	4/1/2012 – 3/31/2014
Funding Status	Funded by NIH
Direct Award (USD)	\$250,000
Update	The Study has finished the four quarters of financial incentives and are currently collecting post-intervention data in all the facilities.
Future Plans	Two manuscripts are underway of which we presented results at two scientific conferences, The 6th Multilateral Initiative on Malaria (MIM) PAN-African Malaria Conference and The 62nd American Society of Tropical Medicine and Hygiene

	Conference. The Study is Scheduled to end in April and dissemination of Study findings will be done in that month.
Publication(s)	
Study Title	HIV Prevalence and Ante-natal Care Attendance Among Pregnant Women in a Large Home-Based HIV Counseling and Testing Program in Western Kenya
Principal Investigator(s)	Paula Braitstein, Indiana University S. Ndege, Moi University
Co-Investigator(s)	Washington, S. Kaaria, A. Prudhomme-O'Meara, W. Were, E. Nyambura, M. Keter, A. Wachira, J.
Description	Objective: To describe factors associated with HIV prevalence among pregnant women in a large-scale home-based HIV counseling and testing (HBCT) program in western Kenya. Methods: In 2007, the Academic Model Providing Access to Healthcare Program (AMPATH) initiated HBCT to all individuals aged ≥ 13 years and high-risk children < 13 years. Included in this analysis were females aged 13-50 years, from 6 catchment areas (11/08-01/12). We used descriptive statistics and logistic regression to describe factors associated with HIV prevalence. Results: There were 119,678 women eligible for analysis; median age 25 (interquartile range, IQR: 18-34) years. Of these, 7,396 (6.2%) were pregnant at the time of HBCT; 4599 (62%) had ever previously tested for HIV and 2,995 (40.5%) had not yet attended ANC for their current pregnancy. Testing uptake among pregnant women was high (97%). HBCT newly identified 241 (3.3%) pregnant HIV-positive women and overall HIV prevalence among all pregnant women was 6.9%. HIV prevalence among those who had attended ANC in this pregnancy was 5.4% compared to 9.0% among those who had not. Pregnant women were more likely to newly test HIV-positive in HBCT if they had not attended ANC in the current pregnancy (AOR: 6.85, 95% CI: 4.49-10.44). Conclusions: Pregnant women who had never attended ANC were about 6 times more likely to newly test HIV-positive, suggesting that the cascade of services for prevention of mother-to-child HIV transmission should optimally begin at the home and village level if elimination of perinatal HIV transmission is to be achieved.
Site(s)	
Project Period	1/1/2013 – 12/31/2013
Funding Status	Funded by USAID - United States Agency for International Development
Direct Award (USD)	Not Reported
Update	The manuscript is presently under review.
Future Plans	

Publication(s)	Presented at the Treatment as Prevention meeting in London, September 2013.
Study Title	HIV Testing Uptake and Prevalence Among Adolescents and Adults in a Large Home-Based HIV Testing Program in Western Kenya
Principal Investigator(s)	Paula Braitstein, Indiana University Juddy Wachira, Moi University
Co-Investigator(s)	Ndege, S. Koech, J. Vreeman, R. Ayuo, P.
Description	The objective of the study was to describe HIV testing uptake and prevalence among adolescents and adults in a home-based HIV counseling and testing (HBCT) program in Western Kenya. We used AMPATH-HBCT data collected between November 2009 and January 2012 from five of the eight catchment areas (Burnt Forest, Chulaimbo, Teso, Port Victoria and Kapsaret). All individuals aged 13 years, eligible for HBCT, were included in the analysis. The study applied descriptive statistics and multivariate logistic regression to examine testing uptake and HIV prevalence among adolescents (13-18 years), younger adults (19-24 years), and older adults (>25 years).
Site(s)	
Project Period	2/1/2012 – 9/30/2013
Funding Status	Funded by USAID - United States Agency for International Development
Direct Award (USD)	Not Reported
Update	The manuscripts was published in JAIDS.
Future Plans	The study is now closed
Publication(s)	Wachira J, Ndege S, Koech J, Vreeman R, Ayuo P & Braitstein P. HIV testing uptake and prevalence among adolescents and adults in a large home-based HIV testing program in western Kenya. JAIDS. 2014; 65:58-66
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
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 by NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	\$98,168
Update	Patient enrollment is completed, and drug resistance assays are being conducted.
Future Plans	In the next 6 months, we will finalize laboratory assays and conduct data analyses.
Publication(s)	
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
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 by Brown University - Center For AIDS Research, Rhode Island Foundation
Direct Award (USD)	\$40,000
Update	High levels of treatment failure misclassification using WHO immunological criteria were identified. Diverse HIV subtypes and recombinant forms, low transmitted resistance and high acquired resistance in treatment experienced patients were found.
Future Plans	Finalize detailed resistance analysis publication..
Publication(s)	1. R Kantor, L Diero, A DeLong, L Kamle, S Muyonga, F Mambo, W Emonyi, P Chan, EJ Carter, J Hogan, N Buziba. Misclassification of first-line antiretroviral treatment failure based on immunological monitoring of HIV infection in resource-limited settings.
Study Title	Improving Diabetes Management and Cardiovascular Risk Factors Through Diabetes Peer Group Education in Western Kenya
Principal Investigator(s)	Sonak Pastakia, Purdue University Gerald Bloomfield, Duke University
Co-Investigator(s)	Bloomfield, G. Kamano, J. Nyabundi, J.

	Park, P. Wambui, C.
Description	This project will seek to assess the hypothesis that diabetes education through peer support groups in western Kenya will be feasible and significantly improve diabetes knowledge-base and diabetes control in comparison to routine care.
Site(s)	Moi Teaching and Referral Hospital (MTRH), Ziwa Sub-District Hospital
Project Period	2/1/2012 – 12/31/2013
Funding Status	Funded by NIH - Fogarty International Center (FIC), NIH - National Heart, Lung, and Blood Institute (NHLBI), Duke Global Health Institute
Direct Award (USD)	\$15,000
Update	Rollout of peer group meetings continued and concluded (6 month pilot) in November 2013. We are now in the data collection process. Preliminary results were reported in abstract format at the International Diabetes Federation conference in Melbourne.
Future Plans	In the next 6 months, the study team will complete data collection and analysis and begin work on a manuscript.
Publication(s)	Park PH, Wambui CK, Atieno S, Pastakia SD, Bloomfield GS, Kamano JH, Nyabundi JS. 'Improving diabetes management and cardiovascular risk factors through diabetes self-management support groups in western Kenya.' Abstract presented at 2013 World Diabetes



Study Title	Increasing Animal Source Foods in Diets of HIV Infected Kenyan Women and their Children
Principal Investigator(s)	Judy Ernst, Indiana University G. Ettyang, Moi University
Co-Investigator(s)	Neumann, C. Nyandiko, W. Siika, A.
Description	The study is a three arm randomized, blinded and controlled nutrition intervention trial that tests the effect of iso-caloric biscuit supplements of meat, soy or wheat protein added to the diets of drug naive HIV-infected Kenyan women and their children 8 years and younger and who live in the Turbo environs and who receive care at one of the AMPATH clinics (Turbo, Soy, Mautuma, and MTRH). The women are of reproductive age and at enrollment WHO stage I or II. The biscuits are provided five days a week (Monday to Friday) to subject mother and child, using directly observed therapy (DOT) for 18 months. The outcome variables include estimates of lean and fat mass, quality of life, strength measures, biochemical indicators of nutritional status, indicators of immune function, measures of inflammation, nutrient intake, food security, measures of growth and development in children and activities of daily living.
Site(s)	Moi Teaching and Referral Hospital (MTRH), Soy Health Centre, Turbo Health Centre,

	Mautuma
Project Period	10/1/2006 – 7/31/2014
Funding Status	Funded by NIH
Direct Award (USD)	\$2,943,346
Update	Data collection was completed June 2012. Project activities included data cleaning. Issues related to the data entry of nutrient intake data were identified. An oral presentation focused on the intervention biscuits was delivered as part of a symposium at the International Nutrition Congress in September, 2013. All presentations will be developed into papers and published in the Food & Nutrition Bulletin. A no cost extension was granted until July 31, 2014.
Future Plans	Over the next 6 months, we hope to clarify and reorganize the nutrient intake data and complete the statistical analysis. Complete data cleaning of the remaining data and complete the statistical analysis. Draft, submit and publish the paper for the Food & Nutrition Bulletin. Draft and submit other papers as the statistical analyses is completed. Use data as preliminary data in research proposals. Correction of the nutrient intake data entry is ongoing and will then allow statistical analysis. Cleaning of other data will be finalized. Publications (abstracts and manuscripts) will be drafted by co-investigators and submitted for publication. Some data will be used in preliminary data sections of new grant proposals.
Publication(s)	Ernst J, Ettyang G, Neumann C. High Nutrition Biscuits as a Supplement to Increase Animal Protein in Diets of HIV-infected Kenyan Women and Their Children. Abstract presented, Sept 14, 2013 as an oral presentation at the International Nutrition Congress

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.
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), Moi University
Project Period	5/31/2012 – 5/31/2017
Funding Status	Funded by NIH - Fogarty International Center (FIC)
Direct Award (USD)	\$1,250,000
Update	<p>Progress with Moi Students. Of the 12 students currently enrolled in the Moi University Master of Science in International Health Research Ethics program in academic year 2012-2013, four were selected to attend the practicum at Indiana University. The decision to invite four (4) of twelve (12) Moi is consistent with our revised policy for permitting students to travel for their practicum only if they were adequately prepared, had an approved practicum proposal (generally a component of their approved Master's project) at their home institution and that there were local mentors willing to provide support and guidance during the practicum. These criteria were applied to the 12 admitted students by the Moi University site director (Dr. Ayuku) and 4 students satisfied them. All students are aware that there is no commitment by IU Moi AREP to support all students admitted to the Moi graduate program. All students are aware of the published criteria for participating in the Indianapolis practicum. Moi students participating in the 2013 practicum in Indianapolis at Indiana University came for six weeks, October 7-November 15. The practicum experience was comprehensive (see Appendix for full schedule), components of which included:</p> <ul style="list-style-type: none"> • Lectures specifically designed to satisfy NIH required topics in the Responsible Conduct of Research: Conflict of Interest; Research with Animals; History of Research with Human Subjects; Policies Concerning Research with Human Subjects; Research Misconduct Policies; Safe Laboratory Practices; Mentor/Mentee Relationships; Research with Human Biological Materials; Scientists as Responsible Members of Society; Data Acquisition/Management; Responsible Authorship/Publication; Peer Review; and Interdisciplinary Approaches to Contemporary Issues in Bioethics. . • Regular attendance at three IUPUI research ethics courses: Grad-G 504 Introduction to Research Ethics (Instructor: Prof. Kimberly Quaid) ; PHIL-P547 Foundations of Bioethics (Instructor: Prof. Peter Schwartz); PHL 555: Ethical and Policy Issues in International Research (Instructor: Prof. Eric Meslin) • Participation in a two-day intensive Research Coordinator Education Program offered to all faculty and staff at Indiana University • Day-long tour of Eli Lilly and Company and engagement with the Lilly Bioethics Program. • Attendance at a meeting of IU's IRB and the IU Conflict of Interest Committee meeting • A visit to the IU Simon Cancer Center, and the Hall Center for Law and Health at McKinney School of Law. • Multiple sessions on academic research using electronic media, PubMed, citation management software, and the research resources provided by the Ruth Lilly Medical Library at the Indiana University School of Medicine. In addition, One-on-one sessions to assist the students while conducting research on their individual topics were provided by IU's digital library team <p>In addition to the group activities, each student met regularly with their IU faculty</p>

member mentor, selected for their expertise to advise the Moi student on their capstone research project. Students met weekly with their mentors. All students also met weekly with PI Eric Meslin to ensure that needs were met and progress was being made. The one-on-one mentoring was seen as a very positive component of the Practicum. One student said: 'The concept is just amazing! It is new at Moi University College of Health Sciences compared to IU. It has not been embraced and I believe it is either the institution that is ignorant or is not aware. By knowing the importance and its value in students and research, it is to the best of my knowledge.' A complete list of the Moi students enrolled in the academic year 2012-2013 and their research proposals is provided in Appendix B. One innovation we introduced in 2013 was for students to present their research at a 'Works in Progress' session convened at the IU Center for Bioethics on November 11, 2013. A copy of the poster is provided in Appendix C. Evaluation of the students' practicum experience is in progress and will be forwarded as soon as it is completed. However initial feedback on the six-week stay was uniformly positive. When asked how their practicum experience benefited them, one student said: 'The practicum provided an opportunity to develop presentation skills as well as networking which are important in research. I have also obtained training in information search that I think is quite valuable not only for my thesis but in future research endeavours [sic].' Another said: 'The experience gained will help me in achieving this career, because I intend to do more research, interact and network with people in the research and ethics community as well as initiate projects for partnerships with colleagues. Also I intend to initiate the culture of peer mentorship in the department of behavioural sciences, school of medicine and be among the first to offer mentorship to our students.' Progress with Indianapolis Students. There are currently 3 students enrolled in the IUPUI Master of Philosophy, International Research Ethics Concentration. Of these, 2 are still completing their coursework, 1 has completed coursework and is undertaking her final research/capstone project. It is anticipated that 1 will be completing her MA requirements in 5/2014. Moi University convened two short courses both focusing on curriculum development, on 'International Health Research Ethics Curriculum Review and Development Workshop on August 7-18 and August 16, 2013. Following short courses developed at Moi in prior years, many beneficiaries have joined the masters program, and others have strongly recommended that a Postgraduate diploma in International Health Research be developed to cater for interested parties that may not get sufficient time to pursue the master's program yet there have an interest in research ethics. Several of our previous trainees have been calling to check on the progress of the postgraduate diploma program. Furthermore, the Master's program at MU has completed its full cycle recommended by Moi University rules and regulations for review and thus the curriculum review exercise was due within the regulations. Therefore, the curriculum review workshop served more than one purpose where the master's program was reviewed and both the certificate and Postgraduate diploma were developed simultaneously. We targeted participants in the workshop to include tutors of International Health Research Ethics Masters program, short-course, post-training students of Research Ethics; and other stakeholders especially AMPATH and KEMRI. The participants were informed that during the workshop they will have a chance to review the master's program and also develop the other two curriculums

Future Plans

Continue to offer on an annual basis alternating between Kenya and Indianapolis, the Teaching Skills in International Research Ethics (TaSkR) workshop for Moi and IU faculty

	<p>and students while opening it to other researchers, institutions and organizations in East Africa. TaSkR VI planning is already well underway for the next workshop to be held on February 19-21, 2014 in Eldoret, Kenya. The theme for TaSkR VI is focusing on Genomics and Bio-Banking.</p>
<p>Publication(s)</p>	<p>Meslin EM, Were E, Ayuku D. Taking Stock of the Ethical Foundations of International Health Research: Pragmatic Lessons from the IU-Moi Academic Research Ethics Partnership. <i>Journal of General Internal Medicine</i> (2013) 28:639-645 DOI: 10.1007/s11606-013-2</p>
<p>Study Title</p>	<p>Inhalants and the Pathway to HIV Infection Among Street Youth in Western Kenya</p>
<p>Principal Investigator(s)</p>	<p>Paula Braitstein, Indiana University David Ayuku, Moi University</p>
<p>Co-Investigator(s)</p>	<p>Atwoli, L Ayaya, S Ott, M Marshall, B Hogan, J Auerswald, C Kwena, Z Bukusu, E</p>
<p>Description</p>	<p>This proposal is under review at NIDA. Our long-term goal is to develop innovative, evidenced-based, developmentally-appropriate interventions that build resilience, promote health, prevent substance use, and reduce health-related risks among street-involved adolescents (SIA). The objective of this ground-breaking application is to describe the epidemiology of volatile substance misuse (VSM) and HIV among SIA in an HIV endemic region, and determine whether and how VSM increases their risk of HIV acquisition. Our central hypothesis is that those who use VS will be at higher risk of acquiring HIV compared to those who do not. To achieve our objectives, we will enroll a quasi-random sample of 800 HIV-negative adolescents aged 12-18 years living full-time on the streets of 3 cities in western Kenya and follow them for 48 months, collecting self-reported data on HIV risk behaviors and other relevant data while conducting HIV testing at baseline and every 6 months. Our specific aims (SA) are to: SA1: Characterize the epidemiology of VSM and other substance use among SIA in the region. SA1A: Determine the prevalence of VSM and other substance use at baseline and investigate its relationship to baseline environmental (city of enrolment), social network (involvement of an adult in their life, network diversity), mental health (post-traumatic stress, depression), and resilience characteristics (participation in religious or community activities). SA1B: Estimate the distribution of time to first VS use among non-users at baseline, and identify baseline determinants of initiation, cessation and relapse during follow-up. SA1C: Evaluate the longitudinal determinants of VS initiation, cessation and relapse including environmental, social network, mental health, poly-substance use, and resilience characteristics. SA2: Estimate the effect of VSM on HIV risk and HIV incidence, independently and in the context of poly-substance use (PSU). SA2A: Determine the relationship between VSM, PSU, and prevalence of HIV risk behaviors at baseline. SA2B:</p>

	Estimate the effect of baseline VSM and PSU on changes in HIV risk behaviors during follow-up. SA2C: Estimate the effect of baseline and longitudinal measures of VSM on HIV incidence at 3 and 5 years of follow-up. SA2D: Investigate the degree to which the total effect of VSM on HIV incidence is mediated by initiation of or changes in poly-substance use and HIV risk behaviors. A key secondary sub-aim will be to describe uptake of and retention in care among HIV-infected participants.
Site(s)	Moi Teaching and Referral Hospital (MTRH), Nakuru and Kisumu
Project Period	9/1/2014 – 9/1/2018
Funding Status	Unfunded
Direct Award (USD)	
Update	
Future Plans	In the next six months we aim to commence preparatory work to implement this study should our funding application be successful at NIDA.
Publication(s)	



Study Title	International epidemiologic Databases to Evaluate AIDS (IeDEA)
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University S. Ayaya, Moi University
Co-Investigator(s)	Wools-Kaloustian, K. Ayaya, S. Diero, L. Busakhala, N. Chite, F. Buziba, N. Pate, I K. Sidle, J. Omeara, W. Cohen, C. Bukusi, E. Ssali, J. Bwana, B. Muyindike, W. Martin, J. Geng, E. Kambugu, A. Easterbrook, E. Nalugoda,
Description	The International epidemiologic Databases to Evaluate AIDS Initiative (IeDEA) will establish international regional centers for the collection and harmonization of data and the establishment of an international research consortium to address unique and evolving

	research questions in HIV/AIDS currently unanswerable by single cohorts. High quality data is being collected by researchers throughout the world. The leDEA initiative provides a means to establish and implement methodology to effectively pool the collected data and thus providing a cost effective means of generating large data sets to address the high priority research questions. Combination of data collected under various protocols is frequently very difficult and not as efficient as the collection of pre-determined and standardized data elements. By developing a pro-active mechanism for the collection of key variables, this initiative will enhance the quality cost effectiveness and speed of HIV/AIDS research.
Site(s)	
Project Period	5/4/2012 – 7/31/2016
Funding Status	Funded by NIH
Direct Award (USD)	\$2,533,231
Update	Currently ongoing leDEA Projects: 1. National Cancer Institute Supplement to East Africa leDEA: Improving Kaposi's Sarcoma and Lymphoma Diagnostics as well as Assessing Sarcoma Incidence in Western Kenya. - Please see separate progress report 2. TB supplement to leDEA. 3. Prevalence and impact of Alcohol Use in Patients enrolling in HIV care - Please see separate progress report 4. Survival among HIV-infected Patients with Kaposi's sarcoma in Sub-Saharan Africa in the Era of potent Antiretroviral Therapy - Please see separate progress report 5. Enhancing TB Data Collection within East African leDEA New - received supplemental IREC approval under the current leDEA Study. Data collection to commence in March 2014.
Future Plans	Continuous monitoring, data entry and cleaning for the new projects, and ongoing concepts. Manuscripts, Abstracts, Concept proposals continue to be written by the leDEA team.
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.
Description	Atrial fibrillation is the most common sustained arrhythmia in high-income countries. Recent insights have been made with regard to the genetic variations that may predispose an individual to developing atrial fibrillation. There has long been observed a disproportionately low prevalence of atrial fibrillation among Africans and African-American compared to people of European descent. Whether mutations in the genes known to cause atrial fibrillation are also causing AF among Kenyan patients with this disorder is unknown. Identification of the frequency of mutations in these genes in patients with atrial fibrillation in Kenya may shed light into the causal pathways of atrial fibrillation in this population. Using a case-control (1:2) research design in a Kenyan

	<p>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 by IU Health
Direct Award (USD)	\$1,060,000
Update	In the six-month interval July-December 2013, staff recruitment for the atrial fibrillation genomics study was completed. IREC approval was achieved, as well as approval by the Duke and IU IRBs. A post-doctoral trainee, Tecla Temu, enrolled 100 patients in the protocol. Completion of electrocardiographic, cardiac echo and biobanking of specimens for genomic analysis for this initial cohort was less complete than interviewing and clinical data.
Future Plans	The initial cohort should complete full data collection and the second cohort of about 100 enrolled.
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)	Elizabeth Pfeiffer
Description	<p>This project is focused on identifying the individual, psychosocial, and structural barriers to timely linkage and retention. This project has three specific aims: 1. To comprehensively describe linkage and retention to HIV care following home-based counseling and testing by examining time from testing to linkage and the socioeconomic, demographic and structural determinants of linking to care. We will conduct retrospective and multilevel analyses using existing de-identified clinical and facility-level data collected within AMPATH, defining linkage to care as the completion of an initial HIV clinical encounter with a provider following testing. We will also examine factors that predict retention in HIV care over time. 2. To characterize the psychosocial and structural facilitators and barriers to linkage and retention to care following positive HIV diagnosis</p>

through HBCT and PITC. We will conduct a qualitative study to examine the psychosocial factors inhibiting or motivating linkage to care, experiences in accessing care, and factors that promote or interrupt retention among those who tested positive via HBCT or PITC. We will also collect data from clinicians and community health workers to examine how features of the healthcare system facilitate or constrain linkage and retention to care.

3. To develop and implement a feasibility study of a pilot psychosocial intervention aimed at increasing linkage to care among individuals testing positive for HIV. The content of this intervention pilot will be informed by the results of Aims 1 and 2. The first aim of this study involves secondary analysis of data collected during home-based counseling and testing linked to medical records data. This data will include information collected as part of routine testing procedures and care, for those who successfully linked to care. AIM 2 will employ qualitative approaches to identify barrier and facilitators to linkage and retention. AIM 3 will include information collected as part of routine care, for those who successfully linked to care. Specifically, medical record reviews at baseline and post-intervention.

Site(s)

Project Period

6/4/2012 – 12/20/2013

Funding Status

Funded by NIH - National Institute of Mental Health (NIMH), NIH - National Institute of Allergy and Infectious Diseases (NIAID), NIH

Direct Award (USD)

\$152,806

Update

We received IREC and Brown IRB approval for this study in August 2013. We successfully merged the data necessary for Aim 1 from Port Victoria. We are currently working on a similar merge of HCT and AMRS data from up to three additional catchment areas. We have completed the initial analysis of data from Port Victoria examining linkage to care following HBCT and have presented this work at the Treatment as Prevention (TasP) Summit in London in September 2013. Our main findings demonstrated that 58% of HIV-positive individuals living in Port Victoria engaged with HIV care. Only 12% of those newly diagnosed linked to care by April 2013. We are preparing a manuscript of this analysis for submission. We also have an abstract accepted for presentation at the 18th International Workshop on HIV Observational Databases in March 2014 and have submitted work for consideration at the 9th International Conference on HIV Treatment and Prevention Adherence. For retention analysis, we recently examined the impact of point of testing on retention over time and found that those testing via HBCT were less likely to be lost-to-follow-up compared with those testing via VCT or PITC. This work was submitted to the AIDS 2014 conference. A manuscript is also currently underway that describes the outcomes of a randomly sampled group of HIV positive adults and children (including ART and pre-ART) who were lost to follow-up. We determined that of the 2540 (of 14,811) patients identified as LTFU during the study period, 326 were misclassified as LTFU. There were 323 patients who were unreachable in spite of repeated attempts. Over 70% (n=1800, 71%) of patients overall were ultimately successfully tracked including 1540 (71%) of adults and 260 (72%) of children. 21% of patients had disengaged from care completely. A majority of patients who had disengaged from care did so because they felt well enough they did not need care or lacked transport money. As well, we are currently preparing a data request that will specifically identify 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. In terms of qualitative work, our findings to date have identified salient barriers that reflected on patients' satisfaction with HIV care. There were similarities in some of the barriers cited for linkage and retention including access to health facilities, stigma associated with health facilities, service efficiency, poor provider-patient interactions, and lack of patient incentives. Barriers unique to linkage were reported as quality of post-test counseling and coordination between HIV testing and care. Obstacles unique to retention were frequency of clinic appointments, different appointments for mother and child, lack of HIV care for institutionalized populations including students and prisoners, lack of food support, and inconsistent linkage data. Our manuscript 'Health Facility Barriers to HIV Linkage and Retention in Western Kenya' is currently under review. The abstract has been submitted for consideration at the upcoming International Symposium HIV and Emerging Diseases (ISHIED) conference.

Future Plans

We are currently in the planning phase for additional qualitative work to be conducted under Aim 2 of the study. Our goal is to begin work collecting additional qualitative data in the next 6 months. We are also currently developing studies that will: 1) evaluate the impact of care navigators in HIV care, 2) explore clinicians perceptions on physician-patient relationships and patient adherence, and 3) determine the reasons why men are less likely to link and remain in HIV care.

Publication(s)

Braitstein P, Genberg BL, Naanyu V, Hogan J. Linkage to care following home-based counseling and testing in western Kenya. Poster presentation at: Controlling the HIV Epidemic with Antiretrovirals: from Consensus to Implementation, Treatment as Prevention

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.

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

	<p>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.</p>
Site(s)	Webuye District Hospital
Project Period	1/1/2013 – 9/30/2014
Funding Status	Funded by Malaria Eradication Scientific Alliance (MESA)
Direct Award (USD)	\$197,500
Update	Enrollment began on April 17, 2013. To date, we have enrolled and collected data from 272 patient's households and 272 matched controls.
Future Plans	We will finish enrollment (450 malaria cases and 450 age-matched controls) and we will send mosquito samples to KEMRI-CDC to be analyzed for infectivity, species and resistance to insecticides.
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.
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 by USAID - United States Agency for International Development, PEPFAR - United States President's Emergency Plan for AIDS Relief
Direct Award (USD)	\$825,501
Update	1. 31 patients who were considered lost to follow up in the control arm of the study were tracked. Results of the tracking is as follows; 10 deceased, 15 alive and 6 unknown. 2. As of December 31st 2013, 503 patients out of the total 510 had completed follow up. The remaining 7 patients completed follow up on the 10th of Jan 2013.
Future Plans	M-DART will officially come to an end on the 31st of March, 2013. For the next three months, this is what we intend to achieve. 1. Data cleaning on all data collected. 2. Final analysis of data. 3. Study closeout.
Publication(s)	



Study Title	Mortality Among Street Connected Children and Youth in Eldoret, Kenya: a Retrospective Chart Review
Principal Investigator(s)	Lonnie Embleton, University of Toronto Paula Braitstein, Indiana University
Co-Investigator(s)	Ayuku David Kamanda Allan Makori Dominic Nalyanya
Description	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. 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	We have commenced to ascertain data on 49 deaths that occurred among street connected children and youth in Eldoret, Kenya between January 2010 to present. 31 deaths occurred among males and 18 among females. The majority of reported deaths occurred in 2013 (20/49, 41%). However, it is expected that this may be a limitation of the quality of the community advocates documentation in previous years and that deaths occurred that were not documented. We have found that the majority of deaths are due to communicable and non-communicable diseases (20/49, 41%), followed by homicide (13/49, 27%), and accidents (8/49, 16%). We are still in the process of ascertaining information on remaining cases as it is challenging retrospectively ascertaining hospital records on street connected children and youth when lacking their hospital ID or if they died out of hospital.
Future Plans	In the next 6 months we aim to complete data extraction, analysis and produce two manuscripts for publication.
Publication(s)	
Study Title	National Cancer Institute Supplement to East African IeDEA: Improving Kaposi's Sarcoma, Lymphoma Diagnostics, and Assessing Kaposi's Sarcoma Incidence in Western Kenya
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University Nafthali Busakhala, Moi University
Co-Investigator(s)	Busakhala, N. Jeff, M. Toby, M. Loehrer, P. Strother, M. Czader, M.

	Leboit, P. McCalmont, T. Asirwa, C. Patel, K. Yiannoutsos, C.
Description	The toxicity and potential side effects of therapy for malignancy justify a standard of care in cancer medicine of tissue biopsy. Further, an accurate assessment of the epidemiology of HIV-related malignancy requires reliable pathologic diagnosis. This study will help validate local pathology for the diagnosis of Kaposi Sarcoma (KS). The limited resources available to local pathology mandate that most diagnoses are made via H&E staining and immunohistochemistry which are techniques, like many pathology diagnostic tools, open to inter-observer variability in interpretation. Thus the experience of the pathologist is a major determinant in diagnostic accuracy. Quality assurance efforts and continuing evaluation of diagnostic skills are routine practices in the United States to help ensure ongoing reproducibility between pathologists. The present effort will facilitate similar ongoing quality checks and thus increase the reliability of a biopsy based diagnosis of KS and lymphoma at the selected sites.
Site(s)	
Project Period	7/1/2012 – 7/31/2014
Funding Status	Funded by NIH - National Cancer Institute (NCI)
Direct Award (USD)	Not Reported
Update	Punch biopsy services continue at AMPATH sites. As of 31st December 2014 we had done 1408 biopsies of which 1180 are AMPATH patients and 228 were non-AMPATH. The last shipment was at the end of November 2013 to UCSF. Results of several have been updated and disseminated to the Kenyan pathologist and oncologist.
Future Plans	The study continues to do punch biopsy, send shipment to UCSF for over reads every 2-3 months and continuous data entry and cleaning.
Publication(s)	1. Semeere A, Busakhala N, Martin J N: Impact of Antiretroviral Therapy on the incidence of Kaposi's sarcoma in resource-rich and resource-limited settings. <i>Current Opinion in Oncology</i> ; 522-30 24 22729153. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC34184

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)	
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.

	<p>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.</p>
<p>Site(s)</p>	<p>Mosoriot Rural Health Training Centre, Turbo Health Centre</p>
<p>Project Period</p>	<p>9/17/2011 – 7/30/2016</p>
<p>Funding Status</p>	<p>Funded by NIH - Fogarty International Center (FIC)</p>
<p>Direct Award (USD)</p>	<p>\$675,543</p>
<p>Update</p>	<p>Updates for Aim 1: All transcripts have been transcribed, translated, and back-translated for Aim 1 related key informant interview and focus groups. Content analysis of transcripts has been completed. A manuscript related to the study findings is being developed and an abstract was accepted to be presented at the World Congress of Cardiology Scientific Sessions 2014 Conference titled, Barriers and Facilitators to Nurse Management of Hypertension in Rural Western Kenya: A Qualitative Analysis. Updates for Aim 2: Aim 2: DEcision Support and Integrated REcord-keeping (DESIRE) tool was rolled out in the dispensaries of Turbo Division. Usability testing: transcripts from think-aloud sessions (5) and mock-patient encounters (5) have been transcribed and translated. Content analysis has been completed for these encounters. One further Usability Testing focus group was also completed (6 women, 2 men). For Feasibility testing, we completed additional semi-structured interviews (5 women, 1 man) and one further Feasibility focus group (5 women). All audio recordings have been transcribed, translated, and back-translated and content analysis of transcripts has been completed. Poster was successfully presented 14th World Congress on Medical and Health Informatics, Copenhagen (Aug 2013) by Evan Blank. Poster title, 'Usability of Implementing a Tablet-Based Decision Support and Integrated Record-Keeping (DESIRE) Tool in the Nurse Management of Hypertension in Rural Kenya'. A manuscript related to Aim 2 activities is currently in preparation. Aim 3: Monthly data reports being received. Nurses have been trained to use tablets to perform data entry and electronic data entry is initiated and ongoing. Aim 4: We are developing a more specific protocol for the workforce estimation model.</p>
<p>Future Plans</p>	<p>Below is the progress we hope to accomplish over the next 6 months pertaining to each of the study aims: Aim 1: complete manuscript; present results at WCC for abstract titled, 'Barriers and Facilitators to Nurse Management of Hypertension in Rural Western Kenya: A Qualitative Analysis' Aim 2: complete research manuscript; awaiting decision</p>

	from APHA re: abstract submission titled, 'Feasibility of Implementing a Tablet-Based Decision Support and Integrated Record-Keeping (DESIRE) Tool in the Nurse Management of Hypertension in Rural Kenya' Aim 3: complete data entry of nurse dispensary data; initiate analyses Aim 4: update protocol as required to conduct the workforce estimation; initiate research activities per updated protocol
Publication(s)	Abstract titled, 'Barriers and Facilitators to Nurse Management of Hypertension in Rural Western Kenya: A Qualitative Analysis' was accepted to be presented as a poster at the World Congress of Cardiology Scientific Sessions 2014 Conference. (see abstrac



Study Title	Optimizing Linkage and Retention to Hypertension Care in Rural Kenya
Principal Investigator(s)	Valentin Fuster, 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.
Description	Hypertension awareness, treatment, and control rates are low in most regions of the world. A critical component of hypertension management is to facilitate sustained access of affected individuals to effective clinical services. In partnership with the Government of Kenya, the Academic Model Providing Access to Healthcare (AMPATH) Partnership is expanding its clinical scope of work in rural western Kenya to include hypertension and other chronic diseases. However, linking and retaining individuals with elevated blood pressure to the clinical care program has been difficult. To address this challenge, we propose to develop and evaluate innovative community-based strategies and initiatives supported by mobile technology. The objective of this project is to utilize a multi-disciplinary implementation research approach to address the challenge of linking and retaining hypertensive individuals to a hypertension management program. The central hypothesis is: community health workers (CHWs), equipped with a tailored behavioral communication strategy and a smartphone-based tool linked to an electronic health record, can increase linkage and retention of hypertensive individuals to a hypertension care program and thereby significantly reduce blood pressure among these patients. We further hypothesize that these interventions will be cost-effective. To test these hypotheses and achieve the overall objectives, we will pursue the following specific aims: Aim 1: Identify the facilitators and barriers to linking and retaining individuals with high blood pressure to a hypertension care delivery program, using a combination of qualitative research methods: 1) baraza (traditional community gathering) form of inquiry; 2) focus group discussions among individuals with elevated blood pressure during home-based testing; and 3) focus group discussions among CHWs. Subsidiary Aim 1.1:

Using identified facilitators and barriers, develop a tailored behavioral communication strategy guided by the Health Belief Model modified by incorporating emotional elements for the CHWs to use with hypertensive patients, focusing on regular and timely attendance at hypertension clinic. We will test the communication strategy for face and content validity using focus group discussions with CHWs and individuals with elevated blood pressure. Subsidiary Aim 1.2: Using identified facilitators and barriers, develop a smartphone-based tool linked to the AMPATH Medical Record System (AMRS) to be used by CHWs to optimize linkage and retention of hypertensive patients to the care program, and evaluate the usability and feasibility of this tool using think-aloud technique, mock patient encounters, focus group discussions, and participant observation. Aim 2: Evaluate the effectiveness of CHWs equipped with a tailored behavioral communication strategy and a smartphone-based tool in improving linkage and reducing blood pressure among hypertensive patients, by conducting a cluster randomized trial comparing: 1) usual care (CHWs with standard training on recruitment of individuals with any chronic condition); 2) CHWs with an additional tailored behavioral communication strategy; and 3) CHWs with a tailored behavioral communication strategy 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 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 by NIH - National Heart, Lung, and Blood Institute (NHLBI)

Direct Award (USD)

\$2,104,519

Update

Several new personnel have been hired for the study including: Biostatistician, Software Programmer, IT Support Technician, Driver, and two research assistants. Qualitative work for Aim 1 has been conducted under the supervision and direction of Dr. Violet Naanyu. The following activities have been completed: community entry was successfully performed prior to the qualitative research sessions; two focus groups were conducted (12 women and 12 men), aimed at identifying facilitators and barriers to linkage and retention; all of the audio-transcripts have been transcribed and translated; content analysis of transcripts was completed; analysis of qualitative data was completed and the qualitative findings were categorized into the modified Health Belief Model which informed subsidiary aims 1.1 and 1.2. We also presented the results of Aim 1 activities at the American Heart Association Scientific Sessions in November 2013, and are preparing a manuscript at this time. For Subsidiary Aim 1.1, we created a 'Design Team'--consisting of two community health workers, two hypertensive patients and four research team

members who met on regular basis over two months. The Design Team developed behavioral assessment tools and a communication strategy. Eleven focus groups (57 women and 50 men) were conducted to evaluate content validity of behavioral assessment tool. Final version of behavioral assessment tool was developed after input was collected from the Design Team, content validity testing, and investigator input. The communication strategy is now in the final stages of development and all content has been finalized. Presentation media has been decided and audio-visual material is being developed. For Subsidiary Aim 1.2, smartphones and SD cards have been procured and software (Muzima APK running on android platform) development is being finalized. Programming of assessment tool has been initiated and the protocol for usability and feasibility testing is nearly finalized. For Aim 2, Community units have been randomly allocated into three arms for the trial. 334 community health workers and 26 community health extension workers (CHEWs) have been trained on overview of study and behavioral assessment tool for linkage and retention. 22 CHEWs completed a Training of Trainers workshop on Motivational Interviewing. In addition, our data management plan has been finalized and access to the AMPATH Medical Record System has been secured. Research databases will be merged with clinical data in Redcap server soon. For Aim 3, a costing questionnaire was developed and five focus group discussions were conducted to complete content validity of the tool (19 men and 22 women). Pilot testing of the questionnaire was completed with five hypertensive patients (2 men, 3 women). There was a site visit by consultant health economist in order to conduct content validity testing and programming of the costing questionnaire into handheld tool has been initiated.

Future Plans

We will conduct aim-specific plans/activities as described below.

Aim 1:

- Subsidiary Aim 1.1:
 - Finalize face validity testing and pilot testing of the communication strategy
 - Manuscript preparation related to Subsidiary Aim 1.1 activities
- Subsidiary Aim 1.2:
 - Finish programming of behavioral assessment tool and communication strategy
 - Conduct usability and feasibility testing
- Complete manuscript related to Aim 1 activities
- Complete trainings for CHEWs and CHVs
- Initiate enrollment of individuals into trial
- Ensure data collection quality, proper data entry, connection to Redcap server
- Monitoring, debriefing, and repeat training activities as required
- Preliminary analyses to be provided to DSMB
- Finalize programming of costing questionnaire
- Initiate collection of baseline costing data after enrollment and informed consent

Publication(s)

Author names: Rajesh Vedanthan, Violet Naanyu, Jemima H. Kamano, Jackson K. Rotich, Kennedy K. Lagat, Peninah Kiptoo, Claire Hutchinson, Diana Menya, Sylvester Kimaiyo, Valentin Fuster, Carol R. Horowitz, Thomas S. Inui
Abstract Title: Barriers to Link

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.
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, 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 by NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	\$1,886,804
Update	In the HADITHI (Helping AMPATH Disclose Information and Talk about HIV Infection) trial, the objective is to evaluate the efficacy of an intensive, culturally adapted, narrative-based disclosure intervention for HIV-infected Kenyan children compared to the less intensive disclosure process currently used as the standard of care. The aims are to: Aim 1: Expand and modify an existing pediatric HIV disclosure intervention used in western Kenya to include culturally relevant, patient-centered components. Aim 2: Perform a cluster randomized trial to compare the impact of clinic implementation of the culturally adapted pediatric disclosure intervention on the prevalence of disclosure and on the medical, psychological, and social outcomes for HIV-infected Kenyan children ages 10-15 years compared to children exposed to standard disclosure protocols. Over the last 6 months of the study, we have begun Phase 2 (Aim 2) of the project. We have completed recruitment for all subjects, for a total of 276 participants at MTRH, Mosoriot, Burnt Forest, Turbo, Webuye, Kitale, Chulaimbo, and Khunyangu clinics. For those who were recruited in April-July, monthly evaluations and 6-month full evaluations were completed. For the intervention clinics, the counselors have been using our novel video tools and

	disclosure curriculum to enhance communication with patients and caregivers about disclosure. Each intervention clinic conducted at least one peer support group for the adolescent participants, which discussed issues pertaining to post-disclosure functioning. Ongoing training sessions for research assistants and counselors have been conducted. Counselors have begun to report increasing rates of disclosure among the families with whom they are providing counseling.
Future Plans	Over the next six months, we plan on conducting Focus Group Discussions with three clinics to discuss HIV related stigma. We will then conduct qualitative analysis from the focus group discussions and revise questionnaire items to add stigma-related questions to our broad assessments. We also plan on conducting the second peer support group for intervention clinics. Within the next six months, most of the 12-month full evaluations will have been completed for the participants. We will also be converting our video-based disclosure counseling curriculum to be used on smaller, interactive tablets with caregivers and adolescents.
Publication(s)	Rachel Vreeman, Winstone Nyandiko, Colin Klein, Josephine Aluoch, Thomas Inui, Irene Marete, Thomas Lewis. Culturally Adapted Filmed Narratives to Promote HIV Disclosure to HIV-Infected Children in Kenya. Submitted to Pediatric Academic Societies' 2014 meeting

Study Summary

Study Title	Patient-Reported Outcomes of Cancer Care in Eldoret, Kenya
Principal Investigator(s)	Lisa Hess, Indiana University - Purdue University in Indianapolis (IUPUI) V. Naanyu, Moi University
Co-Investigator(s)	Asirwa, C.
Description	The proposed study is designed to validate and subsequently implement a standardized questionnaire to obtain patient perspectives of their physical and psychosocial well-being (quality of life) during and following cancer treatment. The primary objective of this research is to validate an instrument that can be used to obtain knowledge about the quality of life of cancer patients in Eldoret, Kenya, which will then guide future strategies to improve comprehensive cancer patient care. The specific aims are to determine the validity of the Kiswahili version of the Functional Assessment of Cancer Therapy General scale (FACT-G) by: (1) conducting focus groups of cancer patients in Eldoret to explore the constructs underlying the translation of the FACT-G instrument; (2) revising the translation wording as needed prior to implementation; and (3) administering the final version of the FACT-G along with the previously-validated Patient Health Questionnaire Nine Symptom Checklist (PHQ-9) longitudinally in this population. The FACT-G has been validated in more than 40 languages and is used worldwide to assess cancer therapy, but has yet to be validated in Kenya.
Site(s)	Moi Teaching and Referral Hospital (MTRH), Moi University
Project Period	3/4/2010 – 4/1/2013
Funding Status	Funded by Walther Cancer Foundation, Indiana University - International Development Fund
Direct Award (USD)	\$23,310

Update	All data collection is now complete for the validation of this instrument. The data are undergoing final cleaning and quality review for analysis and publication. The Cancer Center Biostatistics Core has been funded to complete this analysis.
Future Plans	Within the next six months, we plan to complete the analysis and submit the work for publication.
Publication(s)	
Study Title	Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretroviral Treatment
Principal Investigator(s)	Paula Braitstein, Indiana University B. Jakait, Moi University
Co-Investigator(s)	Pastakia, S. Karwa, R. Ngetich, C. Inui, T. Sidle, J. Wools-Kaloustian, K. Nyandiko, W. Pandit, J. Olsson, S. Maina, M. Olwande, C.
Description	Little is known about the toxicity profile of combination antiretroviral treatment (cART) in African populations where genetic differences, co-morbidities, and malnutrition together may influence the adverse reactions of cART in this population. The purpose of this project is to evaluate the feasibility and effectiveness of five approaches to Targeted Spontaneous Reporting (TSR) for documenting SADR in the resource constrained clinical setting in western Kenya. The approaches include; TSR 1: The completion of the Kenya National Suspected Adverse Drug Reaction form for patients with a change or discontinuation in their cART. These forms are then forwarded on to the National pharmacovigilance (PV) office at the Pharmacy and Poisons Board (PPB) in Nairobi. TSR 2: Use of routinely-used clinical encounter forms that have been enhanced to specifically collect a relatively small amount of SADR data to be collected by the provider seeing the patient during the clinical visit. TSR 3 and TSR 4: Involve conducting in-depth interviews on 1,000 patients receiving cART treatment to prompt patients about SADR and their impact on patient adherence and quality of life. Patients undergoing interviews are randomly assigned to be interviewed by an HIV peer (TSR 3) or a pharmacy personnel (TSR 4) who will have received the same training for the project. The interviews will be conducted over 12 months or a maximum of 12 scheduled clinical visit (Whichever comes first). TSR 5: Use of data routinely captured in the pharmacy when clinicians substitute or change a patient's regimen, including documentation if such an event occurred on the prescription form and the cause of the event (i.e. toxicity, treatment failure, TB drug interaction, pregnancy, other).

Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	10/1/2012 – 12/31/2013
Funding Status	Funded by World Health Organization (WHO)
Direct Award (USD)	\$162,000
Update	Accomplishments over the stated period included presenting the preliminary results from the project at a WHO technical review meeting in Geneva in November. On 31st December 2013 we completed the pilot of the TSR approaches. Over the study period, there were 262 cases of treatment-limiting SADRs documented on the PPB SADR forms (TSR 1) and reported to the national pharmacovigilance center. Data from TSR 2 has not yet been analyzed. A total of 844 participants out of the planned 1000 were enrolled in to the study. All categories of participants to be interviewed under TSR 3 and TSR 4 were filled with the exception of children on 1st Line ART regimen (38 out of 150) and children on 2nd ART regimen (6 out of 50) . From the pharmacy data (TSR 5) we documented 747 cases of changes in ART regimen over the period with SADRs accounting for 61.3% of the changes.
Future Plans	Over the next 6 months, we are planning on submitting the final technical report to WHO. Also, we are planning on submitting data requests for the extraction of data in AMRS and Redcap so as to analyze and report on the data collected. In addition the team hopes to write, submit and publish manuscripts related to the project over the next 6 months.
Publication(s)	Oral Presentation at the WHO technical review meeting on ART toxicity surveillance in Geneva in November, 2013. Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretr

Study Title	Physical and Sexual Abuse in Orphaned Compared to Non-Orphaned Children and Youth in Sub-Saharan Africa: A Systematic Review & Meta-Analysis
Principal Investigator(s)	Paula Braitstein, Indiana University David Ayuku, Moi University
Co-Investigator(s)	Nichols, J. Embleton, L. Mwangi, A. Morantz, G. Vreeman, R. Ayaya, S.
Description	This systematic review assessed the quantitative literature to determine whether orphans are more likely to experience physical and/or sexual abuse compared to non-orphans in sub-Saharan Africa (SSA). It also evaluated the quality of evidence and identified research gaps.
Site(s)	
Project Period	3/1/2012 – 7/12/2013

Funding Status	Unfunded
Direct Award (USD)	
Update	This review was completed and published in Child Abuse and Neglect. The main findings are as follows: Our search identified 10 studies, all published after 2005, from Zimbabwe, South Africa, Kenya and Uganda. The studies consisted of a total 17,336 participants (51% female and 58% non-orphans). Of those classified as orphans (n = 7,315), 73% were single orphans, and 27% were double orphans. The majority of single orphans were paternal orphans (74%). Quality assessment revealed significant variability in the quality of the studies, although most scored higher for general design than dimensions specific to the domain of orphans and abuse. Combined estimates of data suggested that, compared to non-orphans, orphans are not more likely to experience physical abuse (combined OR = 0.96, 95% CI [0.79, 1.16]) or sexual abuse (combined OR = 1.25, 95% CI [0.88, 1.78]). These data suggest that orphans are not systematically at higher risk of experiencing physical or sexual abuse compared to non-orphans in sub-Saharan Africa. However, because of inconsistent quality of data and reporting, these findings should be interpreted with caution.
Future Plans	Not Applicable
Publication(s)	Physical and sexual abuse in orphaned compared to non-orphaned children in sub-Saharan Africa: A systematic review and meta-analysis. Nichols J, Embleton L, Mwangi A, Morantz G, Vreeman R, Ayaya S, Ayuku D, Braitstein P. Child Abuse Negl. 2013 Nov 5. pi

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 Lameck Diero Mwebesa Bosco Bwana Patrick Oyaro Maurice Aluda
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	6/3/2013 – 7/31/2014
Funding Status	Funded by NIH - National Institute on Drug Abuse (NIDA)
Direct Award (USD)	\$36,000
Update	The NIDA -Prevalence and Impact of Alcohol Use among Patients Enrolling in HIV Care study started enrollment on 3rd June 2013. Enrollment closed on 1st November 2013 having successfully recruited 277 study subjects. Patient Follow up: Follow up of study subjects who had missed clinic for more than two months since their clinic schedule date started in September and by end of 31st December, currently, 75 of them are lost to follow up. 46 study subjects (72%) have been successfully tracked and found with known outcomes. Patient follow-up will stop end of May 2014. 156 patients have already had their baseline CD4 count. Due To lack of CD4 reagents within the AMPATH Program, Many of our enrolled patients missed their baselines and 6th month CD4 draws. leDEA has taken the initiative pay lab fees for the patients enrolled patients to have their CD4 done. A separate modified CD4 lab request was prepared and the Clinical Officers in the clinics together with the Project Research Assistant will be flagging and sending patients to the lab. We anticipate that all study subjects too will have their 6th month CD4 done. Among the challenges faced include lack of CD4 reagents hence lack of baseline and 6th month CD4 counts and many lost to follow up patients.
Future Plans	We are currently following up the lost to follow up patients and those who are due for their CD4 counts both baseline and 6th month to come to the clinic and have it drawn. the last .of the patients to be followed up will be at the end of May 2014
Publication(s)	

Study Title	REACH Informatics Center of Excellence
Principal Investigator(s)	Paul Biondich, Indiana University Abraham Siika, 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.

Description	The project is a collaboration between Indiana and Moi Universities and the global leadership of the Regenstrief Institute. The program will: 1. Provide post-doctoral informatics training to faculty at Moi University and Moi Teaching and Referral Hospital to implement and use health information technology to enhance research and improve health care quality, efficiency and outcomes. 2. Support the training of East Africans so as to support the development, implementation, maintenance, evolution and use electronic health records (EHRs) in low-income countries through didactic and mentored practicum training
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	6/1/2009 – 6/30/2014
Funding Status	Funded by NIH - Fogarty International Center (FIC)
Direct Award (USD)	\$945,464
Update	No Update
Future Plans	
Publication(s)	

Study Title	REALITY 'Reduction of EARly mortaLITY in HIV-infected adults and children starting antiretroviral therapy'
Principal Investigator(s)	Kara Wools, Indiana University Abraham Siika, Moi University
Co-Investigator(s)	Winstone Nyandiko
Description	A 2x2x2 open-label factorial multi-centre trial, conducted in 9 centres in 4 countries (Kenya, Malawi, Uganda, Zimbabwe). Study participants will be 1800 HIV-infected patients including adults, adolescents and children aged 5 years or older with low CD4 counts about to initiate combination antiretroviral therapy (ART). There will be Three methods to reduce early mortality following ART initiation (i) increasing the potency of ART with a 12 week induction period using 4 antiretroviral drugs from 3 classes (ii) augmented prophylaxis against opportunistic/bacterial infections and helminths for 12 weeks (iii) macronutrient intervention using ready-to-use supplementary food for 12 weeks. Each intervention will be compared with standard of care, which in previously untreated patients presenting late with very low CD4 counts is to initiate ART with 3 drugs from 2 classes, together with cotrimoxazole prophylaxis and macronutrient intervention only for those with low BMI (or low weight-for-height/mid-upper arm circumference in children). The primary objective of the trial is to identify effective, safe and acceptable interventions to reduce early mortality (all-cause) in HIV-infected adults, adolescents, and older children (5 years or more) initiating ART.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	8/1/2013 – 8/1/2017

Funding Status	Funded by Medical Research Council
Direct Award (USD)	
Update	This study acquired all the required approvals and was approved to start recruiting in August 2013. So far 45 participants have been enrolled. There are however challenges recruiting children. This is because the CD4 cutoffs set by the study (<100) exclude many potential participants. Enrolment into this study has also been hampered by lack of baseline CD4's for AMPATH patients from which the study draws its participants
Future Plans	The site hopes to ramp up enrollments into the study and offer services to more participants. there is a concerted effort to increase recruitment as the site is still way below the approved target of 250 participants.
Publication(s)	
Study Title	Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens (REMEMBER)
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Lagat, D.
Description	In this randomized, open-label strategy trial, participants from RLS who present with advanced HIV disease and will be initiating ART but are without evidence of probable or confirmed TB according to criteria in the current ACTG diagnosis appendix (which will be identified on the case report form [CRF]) will be randomized 1:1 to one of two strategy arms: empiric TB treatment (public health approach, Arm A) or local standard of care (individualized TB treatment approach, Arm B) at study entry. At the 48 week visit, participants will transition to a 48-week follow-up period of non-study-provided treatment and care, with total study duration being 96 weeks. The primary endpoint is survival status at 24 weeks post randomization. AIDS progression, virologic and immunologic response, development of plasma HIV drug resistance, resistance to TB drugs, safety and tolerability of ART and TB drugs, and adherence to ART and TB drugs will also be evaluated as will the relative cost-effectiveness of the two strategies.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	9/26/2012 – 12/31/2014
Funding Status	Funded by NIH - National Institute of Allergy and Infectious Diseases (NIAID), Gilead Foundation, Merck Company Foundation
Direct Award (USD)	Not Reported
Update	No Update
Future Plans	
Publication(s)	

Study Title	Renal Study
Principal Investigator(s)	Christina Wyatt, University of Massachusetts W. Owino Ong'or, Moi University
Co-Investigator(s)	Abuya, J. Wools-Kaloustian, K.
Description	This study is comparing the performance of equations to estimate kidney functions to a direct measure of kidney function based on the plasma disappearance of iohexol in HIV-infected adults.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	12/10/2007 – 12/10/2013
Funding Status	Funded by Gilead Foundation
Direct Award (USD)	\$165,000
Update	No Update
Future Plans	
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
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, 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 by NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	\$567,828
Update	We initiated this project at the beginning of 2014, hiring and training staff, securing IRB and IREC approval, and setting up accounts. We are now recruiting individuals to participate in two types of focus groups on HIV-related stigma: 1. Groups with parents or caretakers of HIV-infected children 2. Groups with HIV-infected children aged 10-15 years who know their HIV status We are also conducting a systematic review of stigma measurement tools used in resource-limited settings.
Future Plans	We plan to use qualitative methods, cognitive interviewing, and incorporation of elements identified in a critical literature review will produce culturally adapted, age-appropriate, and field-ready questionnaire items with high content validity and desirable psychometric properties as elements of measures for assessing H/A stigma among both HIV-infected children and their caregivers. These questionnaire items will then be integrated into assessments for the cohorts of caregivers and adolescents followed in the HADITHI study procedures.
Publication(s)	
Study Title	Sexual Health Risks and HIV and STI Prevalence Among Street Involved Youth in Western Kenya
Principal Investigator(s)	Paula Braitstein, Indiana University
Co-Investigator(s)	Amon Chirchir Susanna Winston David Ayuku E Jane Carter Winstone Nyandiko
Description	This is a cross sectional study characterizing the sexual health risks, behaviors and outcomes in street-involved youth in Eldoret. The specific aims of this study are to: 1) characterize the sexual risk behaviors (including age of sexual debut, age discrepancy of partners, exchange/survival sex, number of partners, and condom use) of the street youth in Eldoret; 2) determine the prevalence of and risk factors for sexual abuse and assault of street youth; 3) assess access to reproductive health care for street youth in Eldoret, and 4) determine the prevalence of and risk factors for HIV and STIs among street youth. The

	study population will consist of street-involved youth ages 12-21 in Eldoret, Kenya, with a goal of enrolling 200 youth. Subjects will participate in a structured interview to complete a questionnaire regarding street life and sexual health, and undergo STI screening tests (blood tests for HSV-2Ab and syphilis, self-collected genital and rectal swabs for chlamydia, gonorrhea, trichomoniasis) and HIV counseling and testing. Data analysis will include descriptive statistics for demographics, sexual behaviors and risk factors. We will use multivariable logistic regression analyses to identify independently associated demographics, risk factors (sexual abuse, drug use, lack of access to healthcare) and specific risk behaviors, with STI and HIV infections
Site(s)	Moi Teaching and Referral Hospital (MTRH), OSCAR Clinic, Berur
Project Period	9/1/2011 – 7/1/2014
Funding Status	Funded by Brown University - Center For AIDS Research, Other, Brown Framework in Global Health
Direct Award (USD)	\$40,000
Update	Data analysis and manuscript preparation continue.
Future Plans	Complete and submit manuscripts on STI and HIV prevalence, and acceptability and feasibility of self collected swabs for STI screening.
Publication(s)	

Study Title	STEPwise Approach to Cardiovascular Diseases Risk Factors Relevance Study in Webuye Adults
Principal Investigator(s)	Gerald Bloomfield, Duke University P. Chege, Moi University
Co-Investigator(s)	
Description	Study of the prevalence of cardiovascular disease risk factors among rural adults in population whose demographic details is monitored in demographic surveillance system The WHO STEPwise approach (three steps that included interviews followed by determination of anthropometric measurements, pulse and blood pressure and finally determination of a fasting lipid profile and blood sugars).
Site(s)	Webuye District Hospital, Moi University HDSS Site
Project Period	3/15/2010 – 8/9/2013
Funding Status	Funded by Other, Moi-VLIR project, NIH - Fogarty International Center (FIC)
Direct Award (USD)	Not Reported
Update	Results published 2013.
Future Plans	Project completed.

Publication(s)	Bloomfield et al. Multiple cardiovascular risk factors in Kenya: evidence from a health and demographic surveillance system using the WHO STEPwise approach to chronic disease risk factor surveillance. Heart (British Cardiac Society) (2013) vol. 99 (18) pp
-----------------------	---

Street Youth's Perspectives on Sexual Health in Western Kenya

Study Title	Street Youth's Perspectives on Sexual Health in Western Kenya
Principal Investigator(s)	Paula Braitstein, Indiana University David Ayuku, Moi University

Co-Investigator(s)	Naanyu, V. Ott, M. Wachira, J. Embleton, L. Kamanda, A. Winston, S.
---------------------------	--

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)	
----------------	--

Project Period	8/1/2013 – 6/30/2014
-----------------------	----------------------

Funding Status	Funded by NIH
-----------------------	---------------

Direct Award (USD)	Not Reported
---------------------------	--------------

Update	We have completed data collection and are currently conducting the analysis.
---------------	--

Future Plans	Based on the study findings we hope to develop at least three manuscripts (for publication in related journals) that will describe the 1) initiation process to street life, 2) sex language used by street youths, 3) reproductive issues among street youth. We also hope to submit abstracts to various local and international conferences.
---------------------	---

Publication(s)	
-----------------------	--

Survival Among HIV-infected Patients with Kaposi's Sarcoma in sub-Saharan Africa in the Era of Potent Antiretroviral Therapy

Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University Naftali Busakhala, Moi University
Co-Investigator(s)	Aggrey Semeere Esther Freeman Mwebesa Bwana Chite Asirwa Naftali Busakhala Constantin Yiannoutsos David Glidden Jeffrey Martin Antoine Jaquet Francois Dabis Habakkuk Yumo Eugene Mutimura Kathryn Anastos Julia Bohlius Matthias Egger
Description	<p>In sub-Saharan Africa, the intersection between endemic human herpesvirus 8 and epidemic HIV infections has resulted in Kaposi's sarcoma (KS) becoming one of the most commonly reported malignancies amongst all adults in the region. Not only is incidence of KS high but the clinical manifestations are substantial as well. Specifically, in the era prior to potent antiretroviral therapy (ART), cumulative one year mortality after HIV-associated KS diagnosis was as high as 60 to 70 percent. Fortunately, based on data following the advent of ART in resource-rich settings, there is now hope for improved KS survival in sub-Saharan Africa now that ART is becoming available. The many differences, however, between resource-rich and resource-limited settings -- particularly in availability of chemotherapy and supportive cancer care -- make extrapolation from resource-rich settings to Africa problematic. While early reports from sub-Saharan Africa in the ART era do show what appear to be improvements in KS survival compared to historical data, these studies are clouded by either substantial losses to follow-up, many patients not actually on ART, small sample sizes and hence imprecise estimates, or being conducted in difficult-to-generalize trial settings. In particular, the studies conducted in the most representative settings also suffer from between 15 to 37 percent lost to follow-up. Because of the obvious concern that these lost may be dead, the nominal survival estimates are nearly uninteruptable. Thus, while ART is now being administered to over 5 million HIV-infected patients in sub-Saharan Africa, we do not yet know its impact on the survival of the most common malignancy of the HIV epidemic. To address these limitations, the overarching objective of this study is to definitively study survival after KS diagnosis in Africa in the contemporary ART era. Our specific aims are to: 1. Determine survival after a diagnosis of HIV-associated KS in the ART era in sub-Saharan Africa; 2. Assess among HIV-infected individuals who initiate ART in Sub-Saharan Africa, if presence of KS is associated with excess mortality compared to other HIV-infected patients with concurrent opportunistic infections or equivalent CD4+T cell counts; and 3. Evaluate the pace and determinants of initiation of ART after a diagnosis of HIV-associated KS in Sub-Saharan Africa.</p>
Site(s)	

Project Period	7/31/2013 – 7/31/2014
Funding Status	Funded by NIH - National Cancer Institute (NCI)
Direct Award (USD)	\$55,671
Update	<p>This study started in July 2013 with the total sample of 470 patients identified for inclusion in the study. The reasons for tracking were subdivided into KS, and comparative groups of TB/CRYPTO and CD4 >250. At the time of this report, the number of true Lost To Follow Up (LTFU) stands at 401 and we have successfully tracked a total of 279 subjects. Evaluation of patient charts revealed that 13 subjects died and 39 were transferred officially to other clinics out of network. The number that we have tracked but were not successful is 54 but are yet for re-tracking and the number closed with no info stands at 10 and the number not yet tracked is 58. 6 patients were not truly LTFU and 11 more were missing files.</p> <p>There are a number of challenges faced trying to track patients. First, some locator information for some patients has not been written and others are inadequate to make the tracking possible. Second, some patients gave wrong locator information or wrong identities which make tracking difficult. Also some patients transfer out of clinic to other health care facilities without following proper transfer procedures hence difficult to trace them. Moreover, some who have defaulted for long periods come and enroll as new patients so that they cannot be identified as defaulters. Patients who live within the urban set up are difficult to follow because they keep moving from one neighborhood to another without leaving behind an address to enable to update the locator.</p>
Future Plans	By 31 July 2014, we intend to track pending patients(not yet tracked or tracked but not yet successful) route distant patients and try to look for demographics from other sources like AMRS for those with missing charts, inadequate or no locators. Review cases closed with no info for possible re-tracking and also do some re-visits for those open cases as well as general data cleaning until end of July 2014.
Publication(s)	
Study Title	Taking a LEEP! Implementing a 'See and LEEP' strategy for women in Western Kenya with positive cervical cancer screening
Principal Investigator(s)	Barry Rosen, University of Toronto Omeng Orange, Moi University
Co-Investigator(s)	
Description	We propose a 'See and LEEP' strategy in rural Kenya to provide a point-of-need service for women with a positive cancer screen. LEEP is highly effective at treating pre-malignant disease, has low morbidity and can be used in a low-resource setting. Using a 'See and Treat' strategy we have noted that 30% of women treated with cryotherapy continue to have precancerous cervical lesions or worse, and 35% of women with an abnormal VIA screen never return for further care. We can do better. Using a nurse-led model of care, we can provide access to more effective treatment (LEEP) at the point-of-need to reduce the burden of cervical cancer.

Site(s)	Chulaimbo Sub-District Hospital, Iten District Hospital, Moi Teaching and Referral Hospital (MTRH), Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital, AMPATH Centre
Project Period	10/1/2013 – 3/31/2015
Funding Status	Funded by Grand Challenges Canada
Direct Award (USD)	\$100,000
Update	Research protocols have been submitted to the various IRECs.
Future Plans	In the next 6 months, we hope to obtain approvals from IRCs and begin work on project activities.
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
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	After searching the literature we have identified approximately 120 articles that meet our inclusion criteria. We are in the phase of finalizing articles for inclusion based on reviewer consensus prior to commencing study quality evaluation and data extraction.
Future Plans	We aim to complete data extraction, analysis and write-up of two manuscripts for publications.
Publication(s)	
Study Title	TB/HIV Integration Study
Principal Investigator(s)	P. Owiti, Moi University
Co-Investigator(s)	Zachariah, R. Bisell, K. Kumar, A. Diero, L. Carter, J. Gardner, A.
Description	The objective of the project is to assess the uptake of and timing to CPT and ART initiation before and after introduction of integration of TB-HIV care in these facilities.
Site(s)	Bumala B Health Centre, Busia District Hospital, Huruma Sub-District Hospital, Iten District Hospital, Khunyangu Sub-District Hospital, Mt. Elgon District Hospital, Mukhobola Health Centre, Port Victoria Sub-District Hospital, Teso District Hospital, Turb
Project Period	1/1/2013 – 12/31/2013
Funding Status	Funded by International Union Against TB and Lung Disease, International Society for Infectious Diseases
Direct Award (USD)	\$6,000
Update	No Update
Future Plans	
Publication(s)	
Study Title	The Epidemiology of Substance use Amongst Street Children in Resource-constrained Settings: a systematic review and meta-analysis
Principal Investigator(s)	L. Embleton, David Ayuku, Moi University
Co-Investigator(s)	Braitstein, P.

	Mwangi, A. Vreeman, R.
Description	To compile and critically analyze the literature published on street children and substance use in resource constrained settings.
Site(s)	
Project Period	9/1/2011 – 7/12/2013
Funding Status	Unfunded
Direct Award (USD)	
Update	This project was completed and published in Addiction with a follow-up commentary.
Future Plans	
Publication(s)	1. The epidemiology of substance use among street children in resource-constrained settings: a systematic review and meta-analysis. Embleton L, Mwangi A, Vreeman R, Ayuku D, Braitstein P. Addiction. 2013 Oct;108(10):1722-33. doi: 10.1111/add.12252. Epub 2

Study Title	The Implementation of a Neonatal Nurse Training Program at the Riley Mother Baby Hospital of Kenya
Principal Investigator(s)	J. Lemons, Indiana University P. Gisore, Moi University
Co-Investigator(s)	Bucher, S. Songok, J. Trautman, M. Hawk, S.
Description	The goal of this study is to evaluate the effectiveness of a neonatal nurse training program in improving the knowledge, patient care practices and processes of nurses working in a neonatal intensive care unit in a resource limited setting. The primary outcome of this study is the impact of the Neonatal Nurse Training Program on nurse competency related to three crucial domains of neonatal nursing care (i.e., thermoregulation, respiratory monitoring, and infection control). The impact of the Neonatal Nurse Training Program on nursing competency will be measured in regards to both (1) knowledge (as evaluated by a multiple-choice questionnaire administered pre/post the training program) and (2) actual patient care practices (as assessed by pre/post training program observations by a trained evaluator in the nursery). Secondary outcomes will include evaluation of process changes related to documenting patient care, as well as outcomes such as NICU mortality rate and length of stay in the nursery. These outcomes will be evaluated primarily via pre/post training program retrospective chart review, and augmented by observational data. We hypothesize that a neonatal nurse training program will significantly improve nurse competency and the quality of patient care as measured by improvement in knowledge, practices, processes and patient outcomes such as mortality. The results of this study will help validate the importance of

	nursing education and its effect on patient care in the resource limited setting, and if successful, will make an important contribution toward the improvement of nursing practices among staff at one of the largest and busiest referral NICUs in East Africa.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	6/4/2012 – 12/20/2013
Funding Status	Funded by Indiana University - School of Medicine
Direct Award (USD)	\$40,000
Update	The research has been submitted for publication and is awaiting the journal's response.
Future Plans	
Publication(s)	The research was presented at Riley Hospital for Children Grand Rounds July 31, 2013

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.
Description	Kenya, like much of the developing world, is rapidly undergoing an 'epidemiologic transition' from a health scene dominated by infectious diseases to one in which the major causes of death and disability are cancer and other chronic diseases. Under these circumstances, applying science to the management and control of cancer has become as relevant to Kenya as it is in the United States. Similarly, what is learned about the prevention and treatment of cancer in the developing world literally has direct relevance to care in the United States. Cancer care and attendant research in Kenya, whose population is the most genetically diverse in the world, will catalyze the discovery of new genes of importance to our fight against cancer, new genomic predictors of cancer, and new genetic variants that predict response to therapy. Recognizing both emerging threats to population health and potential for advancing care and science, the IU Simon Cancer Center (IUSCC) and the IU-Kenya AMPATH Program have been actively pursuing resources to respond. The focus of the partnership is to develop a sustainable and comprehensive academic clinical care program that will serve the citizens of western Kenya, and in the process, create a unique program of international collaboration for patients with, or at risk for, malignancies. The mission of the AMPATH Oncology Institute (AOI) is to be the premier cancer program in Sub-Saharan Africa, noted for excellence in cancer prevention, treatment and palliative care. AOI activities will directly contribute to advances in cancer care, accelerate discoveries in the biology and treatment of cancer, and provide support for the IU Simon Cancer Center's quest to become a federally designated Comprehensive Care Center. Naftali Busakhala will characterize the awareness, beliefs, attitudes and behaviors of women coming to AMPATH's clinician breast exam screening as volunteers, comparing these beliefs to those of a community-

	<p>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, Kapsakworny
Project Period	10/1/2011 – 7/1/2014
Funding Status	Funded by Walther Cancer Foundation
Direct Award (USD)	\$1,200,000
Update	<p>During the July-December 2013 interval, data cleaning and analysis was completed for the two survey cohorts, one that volunteered for clinical exam breast cancer screening and a contemporaneous community non-volunteer sample. Beliefs among both cohorts of women were dominated by perceptions of the cancer at a late and advanced stage. Interestingly, the community women reported more prior screening than the current-year volunteers, suggesting that they needed to know that periodic screening was needed, not a single exam. Analysis results are being drafted for publication, one that contrasts community and screening volunteers and a second that can report psychometric properties of the BCAM. The third protocol, one that focuses on cervical cancer and cervical cancer screening, was drafted and reviewed by IREC.</p>
Future Plans	The breast cancer manuscripts should be submitted for peer review. Data collection for the cervical cancer protocol should be largely completed.
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
Co-Investigator(s)	Hugo Martin Saskia Mostert Terry Vik Floor Abbink Gertjan Kaspers Gilbert Olbara

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	IREC approved the research September 2013. We have collected data of 281 files so far and I assume that we will retrieve approximately 25 more files. Because registry was incomplete in 2010 and mid-2011, finding records from this time period has been more challenging than originally anticipated. We hope to be finished with the data collection by June 2014, at which point data analysis can begin.
Future Plans	We hope to have this data submitted for publication by December 2014.
Publication(s)	

Study Title	Utility of Handheld Echocardiogram Among Clinical Officers in Patient Referred for Routine Echocardiography at Moi Teaching and Referral Hospital, Kenya
Principal Investigator(s)	Eric Velasquez, Duke University Sylvester Kimaiyo, Moi University
Co-Investigator(s)	Barasa, F. Bloomfield, G . Koech, M.
Description	Cardiovascular diseases (CVDs) are increasingly common in Kenya. Five conditions are responsible for the majority of the CVD burden: Dilated Cardiomyopathy (DCM), Hypertensive heart disease (HHD), Cor Pulmonale, Pericardial effusion and Rheumatic heart disease (RHD). Standard echocardiography is the gold standard for diagnosing these conditions but a hand held echocardiogram (HHE), in well trained hands, can accurately identify them. Early and accurate diagnosis should be made at the earliest entry into the health care system (e.g., primary care health centers and district hospitals); unfortunately, the diagnostic ability is very limited in terms of expertise and equipment in these settings. Specific Objectives are: 1. To assess the usefulness of a HHE compared to physical examination by clinical officers in recognizing major cardiac abnormalities

after a one day training period, in patients referred for routine echocardiography at Moi Teaching and Referral Hospital (MTRH). Usefulness will be evaluated by comparing sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of physical examination compared to HHE. Improvement in sensitivity of 25 percent or greater using the HHE compared to physical examination will be considered clinically relevant. 2. To determine the sensitivity and specificity of diagnosing RHD at MTRH using a combination of physical examination plus HHE compared to physical examination alone by clinical officers, in patients referred for routine echocardiography.

Methodology An 8 hour training program will be conducted for the Clinical officers with at least one year post- internship experience at MTRH Emergency department to train them on the use of the hand held device conducted with the assistance of a faculty member from Duke University. Afterwards, two clinical officers, are randomly selected from the group and shall be stationed at the cardiac centre to participate in the study. They shall alternate with each other in examining recruited patients for the study. The patients shall be 18 years and above and shall be recruited consecutively as they come in after being consented. Each clinical officer will have 30 minutes to make a clinical diagnosis of the patient's cardiac condition and a further 30 minutes to perform a HHE and make an echocardiographic diagnosis. The patient shall then undergo a standard echocardiographic study conducted by a qualified technician blinded to the findings of the clinical officer's findings. The 3 diagnoses shall be captured on case report forms (CRFs) for analysis. In addition, the HHE images shall be digitally acquired and stored in a lap top computer to be read by a cardiologist with expertise in echocardiography (i.e., performance and interpretation) and compared with those of the standard machine. Sensitivity, specificity, positive and negative predictive values of the physical examination and HHE diagnosis shall be determined by using the standard echocardiogram diagnosis as the gold standard.

Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	2/1/2013 – 10/31/2013
Funding Status	Funded by NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	\$17,625
Update	The project received IREC approval on 28 June 2013, and donor approval on 20 December 2013. They recruited the Clinical Officers and trained them in January 2013. It began enrollment on 4 February 2013. They have recruited 92 participants as of June 2013.
Future Plans	
Publication(s)	

Figures & Tables

Figure 1: AMPATH Research & Training Awards (1998 – 2013)

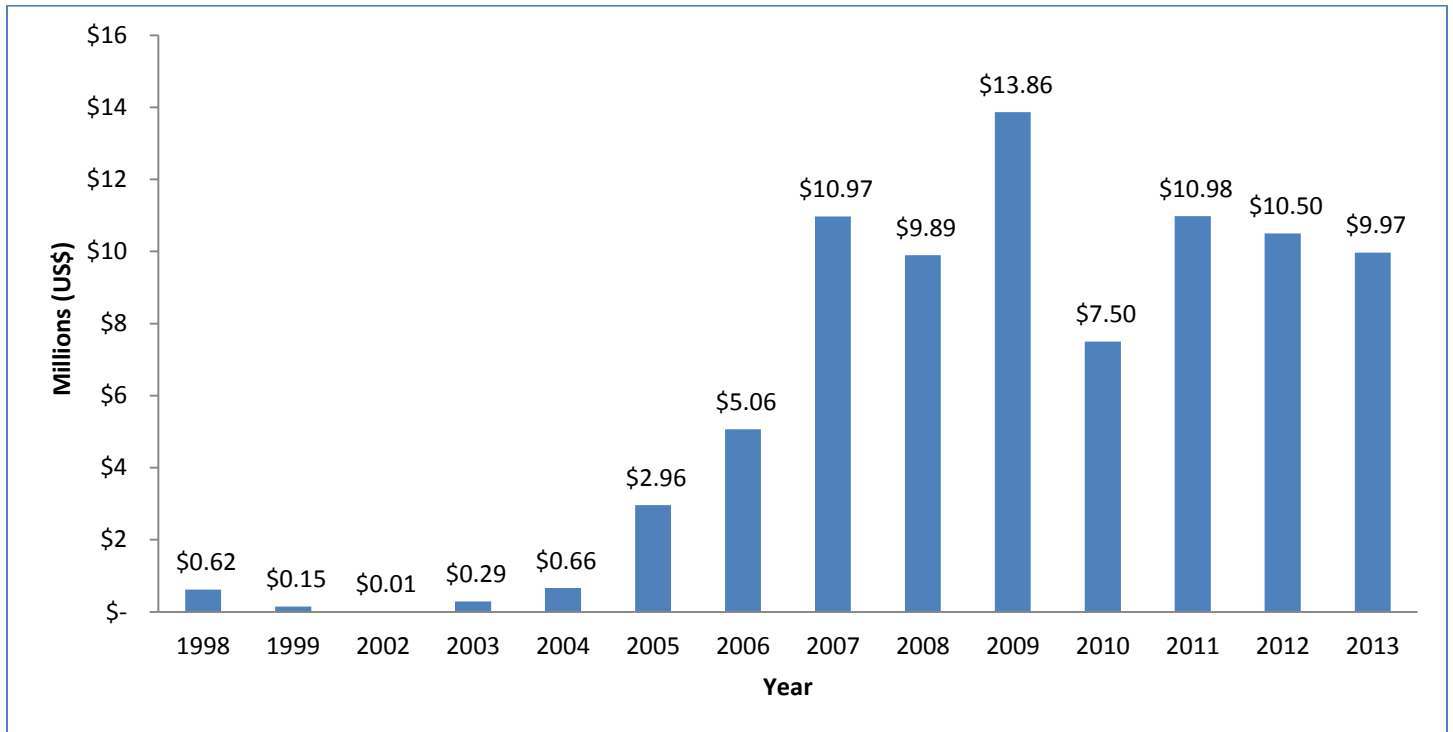


Figure 2: Sponsors of AMPATH Research (January - December 2013) (Total Directs = US\$ 9.97 million)

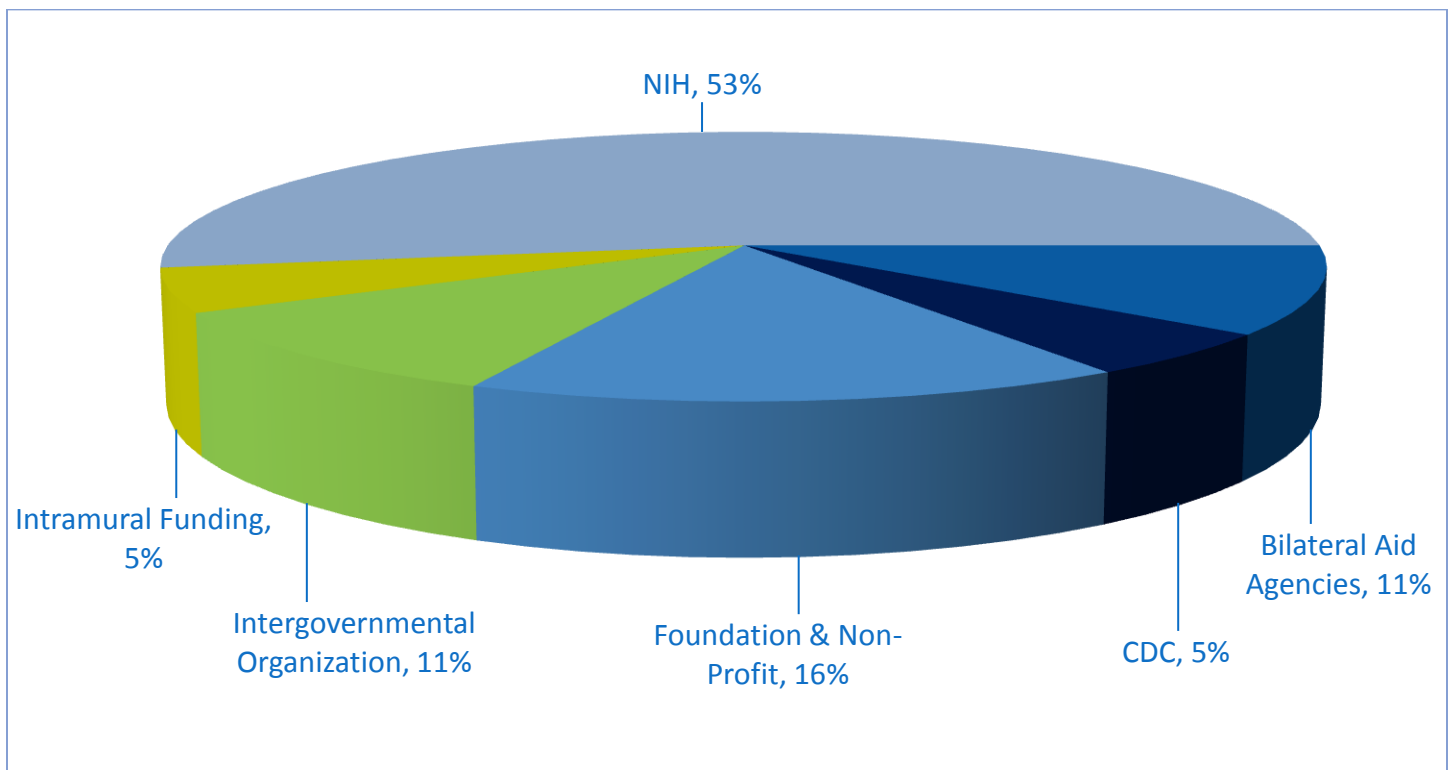


Figure 3: AMPATH Research Sponsors (1998-2013) (Total Directs = US\$83.4 million)

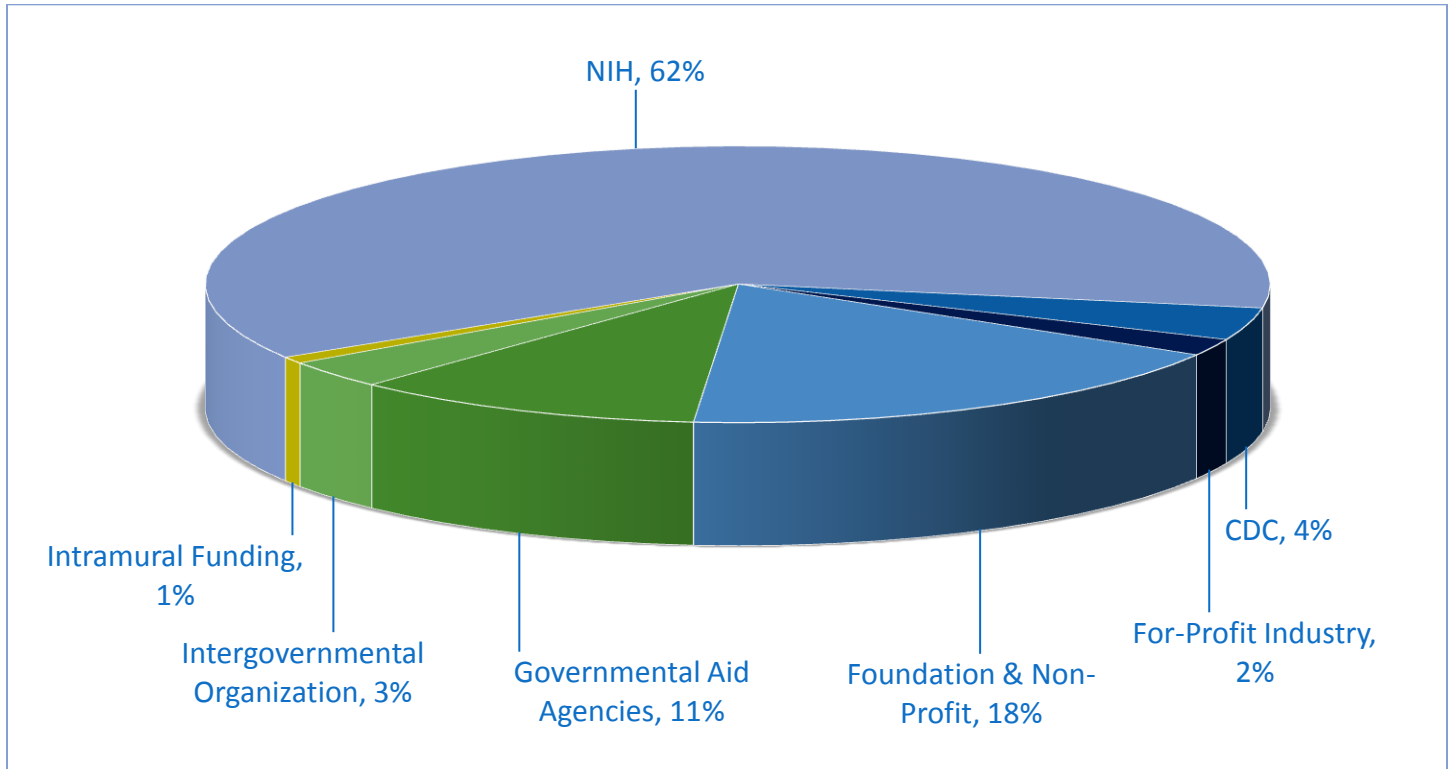


Figure 4: AMPATH Publications by year published (1989-2013) (Total Publications = 272)

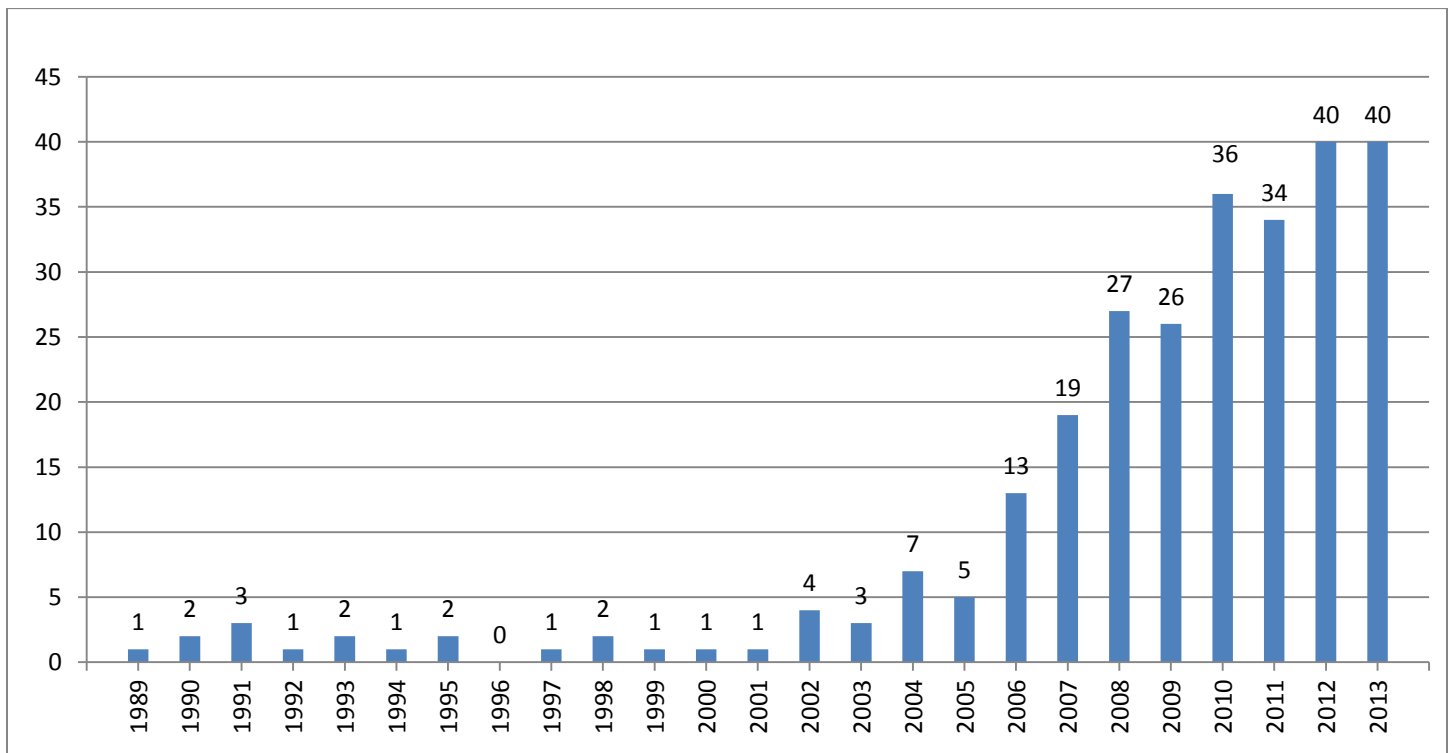
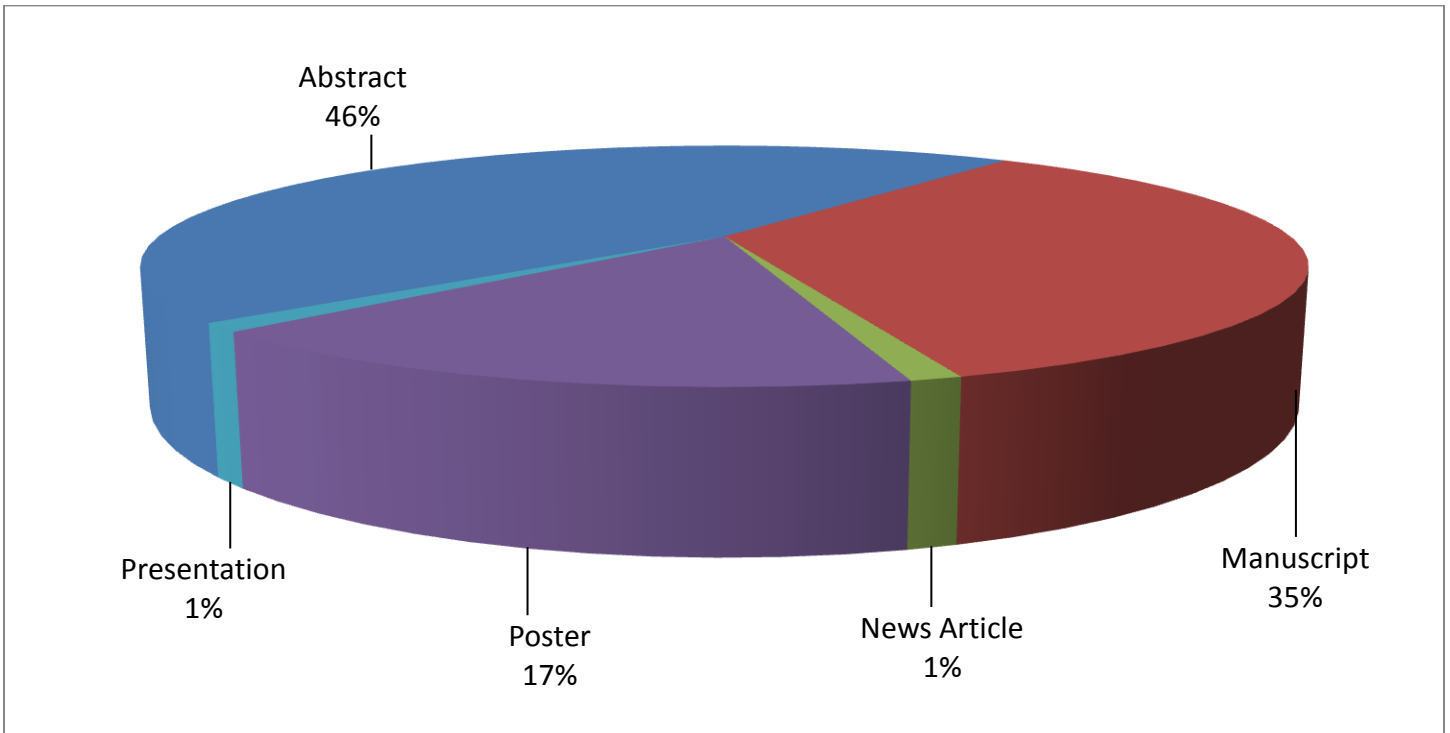


Figure 5: Types of Publications Reviewed by the AMPATH Publications Committee in 2013
(Total Reviewed = 137)



AMPATH Research Bibliography

The following bibliography includes AMPATH research publications that were published between January and December 2013. 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.

1. Ayuo, P., B. Musick, H. Liu, P. Braitstein, W. Nyandiko, B. Otieno-Nyunya, A. Gardner, and K. Wools-Kaloustian, *Frequency and factors associated with adherence to and completion of combination antiretroviral therapy for prevention of mother to child transmission in western Kenya*. Journal of the International AIDS Society, 2013. **16**(1).
2. Bloomfield, G.S., F.A. Barasa, J.A. Doll, and E.J. Velazquez, *Heart failure in sub-Saharan Africa*. Current cardiology reviews, 2013. **9**(2): p. 157-73.
3. Bloomfield, G.S., A. Mwangi, P. Chege, C.J. Simiyu, D.F. Aswa, D. Odhiambo, A.A. Obala, P. Ayuo, and B.O. Khwa-Otsyula, *Multiple cardiovascular risk factors in Kenya: evidence from a Health and Demographic Surveillance System using the WHO STEPwise approach to chronic disease risk factor surveillance*. Heart, 2013.
4. Bloomfield, G.S. and E.J. Velazquez, *HIV and cardiovascular disease in sub-Saharan Africa: the Sutton Law as applied to global health*. Journal of the American College of Cardiology, 2013. **61**(23): p. 2395.
5. Braitstein, P., S. Ayaya, W.M. Nyandiko, A. Kamanda, J. Koech, P. Gisore, L. Atwoli, R.C. Vreeman, C. Duefield, and D.O. Ayuku, *Nutritional Status of Orphaned and Separated Children and Adolescents Living in Community and Institutional Environments in Uasin Gishu County, Kenya*. PLoS ONE [Electronic Resource], 2013. **8**(7): p. e70054.
6. Campbell, M.S., E.M. Kahle, C. Celum, J.R. Lingappa, S. Kapiga, A. Mujugira, N.R. Mugo, K.H. Fife, J.I. Mullins, and J.M. Baeten, *Plasma viral loads during early HIV-1 infection are similar in subtype C- and non-subtype C-infected African seroconverters*. The Journal of infectious diseases, 2013. **207**(7): p. 1166-70.
7. Cheng, S., J. Kamano, N.K. Kirui, E. Manuthu, V. Buckwalter, K. Ouma, and S.D. Pastakia, *Prevalence of food insecurity in patients with diabetes in western Kenya*. Diabetic medicine : a journal of the British Diabetic Association, 2013.
8. Embleton, L., L. Atwoli, D. Ayuku, and P. Braitstein, *The Journey of Addiction: Barriers to and Facilitators of Drug Use Cessation among Street Children and Youths in Western Kenya*. PLoS ONE [Electronic Resource], 2013. **8**(1): p. e53435.
9. Embleton, L., D. Ayuku, and P. Braitstein, *Lost indeed, but not in translation*. Addiction, 2013. **108**(10): p. 1735-6.
10. Embleton, L., A. Mwangi, R. Vreeman, D. Ayuku, and P. Braitstein, *The epidemiology of substance use among street children in resource-constrained settings: a systematic review and meta-analysis*. Addiction, 2013.
11. Goodrich, S., S. Ndege, S. Kimaiyo, H. Some, J. Wachira, P. Braitstein, J.E. Sidle, J. Sitienei, R. Owino, C. Chesoli, C. Gichunge, F. Komen, C. Ojwang, E. Sang, A. Siika, and K. Wools-Kaloustian, *Delivery of HIV care during the 2007 post-election crisis in Kenya: a case study analyzing the response of the Academic Model Providing Access to Healthcare (AMPATH) program*. Conflict and health, 2013. **7**(1): p. 25.
12. Hawkins, L., R.F. Spitzer, A. Christoffersen-Deb, J. Leah, and H. Mabeya, *Characteristics and surgical success of patients presenting for repair of obstetric fistula in western Kenya*. International Journal of Gynecology & Obstetrics, 2013. **120**(2): p. 178-182.
13. House, D.R., E. Ngetich, R.C. Vreeman, and D.E. Rusyniak, *Estimating the weight of children in kenya: do the broselow tape and age-based formulas measure up?* Annals of emergency medicine, 2013. **61**(1): p. 1-8.

14. Huang, K.T., C. Owino, G.P. Gramelspacher, P.O. Monahan, R. Tabbey, M. Hagembe, R.M. Strother, F. Njuguna, and R.C. Vreeman, *Prevalence and correlates of pain and pain treatment in a Western Kenya referral hospital*. Journal of palliative medicine, 2013. **16**(10): p. 1260-7.
15. Kamaara, E., L. Atwoli, H. Maithya, N. Shitemi, G. Nduru, P. Braitstein, T.S. Inui, P. Ayuo, and W. Folk, *Holistic Healing: Use of Traditional Medicine and Complementary Alternative Medicine (TM/CAM) in the Context of HIV/AIDS in Western Kenya*. International Journal of Professional Practice, 2013. **3**(4): p. 342-355.
16. Kamanda, A., L. Embleton, D. Ayuku, L. Atwoli, P. Gisore, S. Ayaya, R. Vreeman, and P. Braitstein, *Harnessing the power of the grassroots to conduct public health research in sub-Saharan Africa: a case study from western Kenya in the adaptation of community-based participatory research (CBPR) approaches*. BMC Public Health, 2013. **13**(1): p. 91.
17. Karoney, M. and A.M. Siika, *Hepatitis C Virus (HCV) Infection in Africa: A Review*. Pan African Medical Journal, 2013. **14**(44).
18. Kigen, G., H. Ronoh, W. Kipkore, and J. Rotich, *Current trends of Traditional Herbal Medicine Practice in Kenya: A review*. African Journal of Pharmacology and Therapeutics, 2013. **2**(1): p. 32-37.
19. Kinyanjui, D.W. and L. Atwoli, *Substance use among inmates at the Eldoret prison in Western Kenya*. BMC psychiatry, 2013. **13**: p. 53.
20. Lingappa, J.R., K.K. Thomas, J.P. Hughes, J.M. Baeten, A. Wald, C. Farquhar, G. de Bruyn, K.H. Fife, M.S. Campbell, S. Kapiga, J.I. Mullins, and C. Celum, *Partner characteristics predicting HIV-1 set point in sexually acquired HIV-1 among African seroconverters*. AIDS research and human retroviruses, 2013. **29**(1): p. 164-71.
21. Mann, M., L. Diero, E. Kemboi, F. Mambo, M. Rono, W. Injera, A. Delong, L. Schreier, K.W. Kaloustian, J. Sidle, N. Buziba, and R. Kantor, *Antiretroviral Treatment Interruptions Induced by the Kenyan Postelection Crisis Are Associated With Virological Failure*. Journal of acquired immune deficiency syndromes, 2013. **64**(2): p. 220-224.
22. Marete, I., C. Tenge, O. Pasha, S. Goudar, E. Chomba, A. Patel, F. Althabe, A. Garces, E.M. McClure, S. Saleem, F. Esamai, B.S. Kodkany, J.M. Belizan, R.J. Derman, P.L. Hibberd, N. Krebs, P. Buekens, R.L. Goldenberg, W.A. Carlo, D. Wallace, J. Moore, M. Koso-Thomas, L.L. Wright, and E.A. Liechty, *Perinatal Outcomes of Multiple-Gestation Pregnancies in Kenya, Zambia, Pakistan, India, Guatemala, and Argentina: A Global Network Study*. American journal of perinatology, 2013.
23. Meslin, E.M., E. Were, and D. Ayuku, *Taking Stock of the Ethical Foundations of International Health Research: Pragmatic Lessons from the IU-Moi Academic Research Ethics Partnership*. Journal of General Internal Medicine, 2013.
24. Morantz, G., D. Cole, R. Vreeman, S. Ayaya, D. Ayuku, and P. Braitstein, *Child abuse and neglect among orphaned children and youth living in extended families in sub-Saharan Africa: What have we learned from qualitative inquiry?* Vulnerable Children and Youth Studies, 2013: p. 1-15.
25. Naanyu, V., F.F. Some, and A.M. Siika, *"I understood but some parts were confusing and hard to grasp:" Patients Perception of Informed Consent Forms and Clinical Trials in Eldoret, Kenya*. Journal of medical ethics, 2013.
26. Nderitu, D., N.L. Shitemi, and E. Kamaara, *Is there "Thrapeutic Misconception" in HIV/AIDS and Clinical Research in Western Kenya?* Journal of AIDS & Clinical Research, 2013. **4**(7): p. 9.
27. Nyandiko, W., R. Vreeman, H. Liu, S. Shangani, E. Sang, S. Ayaya, and P. Braitstein, *Non-adherence to Clinic Appointments among HIV-infected Children in an Ambulatory Care Program in Western Kenya*. Journal of acquired immune deficiency syndromes, 2013.
28. Odera, E.B., C. Kwobah, G. Stone, F. Some, and R.C. Vreeman, *Sickle Cell Disease and HIV: A Case Highlighting Management Challenges for Children in a Resource-Limited Setting*. Journal of the International Association of Providers of AIDS Care, 2013.

29. Pastakia, S.D., S.M. Ali, J.H. Kamano, C.O. Akwanalo, S.K. Ndege, V.L. Buckwalter, R. Vedanthan, and G.S. Bloomfield, *Screening for diabetes and hypertension in a rural low income setting in western Kenya utilizing home-based and community-based strategies*. *Globalization and health*, 2013. **9**: p. 21.
30. Scanlon, M. and R. Vreeman, *Current Strategies for Improving Adherence to Antiretroviral Therapies in Resource-Limited Settings*. HIV/AIDS Research and Palliative Care, 2013.
31. Siika, A.M., A.W. Mwangi, J.E. Carter, K. Wools-Kaloustain, B.S. Musick, and J. Hogan, *Early Antiretroviral Therapy Initiation Improves Survival in HIV and Tuberculosis Co-Infected Patients*. 2013.
32. Siika, A.M., C.T. Yiannoutsos, K. Wools-Kaloustain, B.S. Musick, A.W. Mwangi, L.O. Diero, S.N. Kimaiyo, W.M. Tierney, and J.E. Carter, *Tuberculosis Adversely Impacts Clinical Outcomes in HIV-Infected African Patients on Antiretroviral Therapy*. PLoS ONE [Electronic Resource], 2013.
33. Siika, A.M., C.T. Yiannoutsos, K.K. Wools-Kaloustian, B.S. Musick, A.W. Mwangi, L.O. Diero, S.N. Kimaiyo, W.M. Tierney, and J.E. Carter, *Active Tuberculosis Is Associated with Worse Clinical Outcomes in HIV-Infected African Patients on Antiretroviral Therapy*. PLoS ONE [Electronic Resource], 2013. **8**(1): p. e53022.
34. Szkwarko, D., F. Ogaro, P. Owiti, and E.J. Carter, *Implementing a tuberculosis child contact register to quantify children at risk for tuberculosis and HIV in Eldoret, Kenya*. *Public Health Action*, 2013. **3**(3): p. 209-213.
35. Turissini, M.L., W.M. Nyandiko, S.O. Ayaya, I. Marete, A. Mwangi, V. Chemboi, L. Warui, and R.C. Vreeman, *The Prevalence of Disclosure of HIV Status to HIV-Infected Children in Western Kenya*. *Journal of the Pediatric Infectious Diseases Society*, 2013. **2**(2): p. 136-143.
36. Wachira, J., S. Middlestadt, M. Reece, C.-Y.J. Peng, and P. Braitstein, *Psychometric Assessment of a Physician-Patient Communication Behaviors Scale: The Perspective of Adult HIV Patients in Kenya*. *AIDS Research and Treatment*, 2013. **2013**: p. 10.
37. Wachira, J., S. Ndege, J. Koech, R. Vreeman, P. Ayuo, and P. Braitstein, *HIV testing uptake and prevalence among adolescents and adults in a large home-based HIV testing program in western Kenya*. *Journal of acquired immune deficiency syndromes*, 2013.
38. Were, M.C., W.M. Nyandiko, K.T.L. Huang, J.E. Slaven, C. Shen, W.M. Tierney, and R.C. Vreeman, *Computer-Generated Reminders and Quality of Pediatric HIV Care in a Resource-Limited Setting*. *Pediatrics*, 2013. **131**(3): p. e789-e796.
39. Wolfe, D., *Risk and resilience in the context of child maltreatment: The way forward*. *Child Abuse & Neglect*, 2013(0).
40. Zeunik, C.J., W.M. Nyandiko, T.S. Inui, S.O. Ayaya, D.G. Marrero, and R.C. Vreeman, *A Qualitative Assessment of Barriers to Antiretroviral Therapy Adherence among Adolescents in Western Kenya*. *Journal of HIV/Aids and Social Services*, 2013.

Index

A

Abbink · 79
Abuya · 67
Academic Model Providing Access to Healthcare Program (AMPATH) · 37
adherence · 11, 12, 20, 29, 30, 31, 35, 49, 50, 59, 61, 64, 66, 68, 85, 87
AIDS · iii, iv, v, 7, 8, 10, 11, 12, 16, 20, 23, 24, 26, 30, 39, 45, 46, 48, 51, 66, 68, 69, 85, 86, 87, 88
AIDS Clinical Trials Group (ACTG) · 8, 10, 11, 12
AITRP · 26
Akwanalo · 5, 14, 55, 87
Aluda · 63
AMPATH research program · 1
AMRS · 48, 56, 62, 73
Anastos · 71
Anstrom · 5
Antenatal Care · iv, 33
Anticoagulation · iii, 14
antiretroviral therapy · v, 8, 12, 16, 30, 38, 65, 66, 72, 85
Antiretroviral Therapy · iii, iv, v, vi, 8, 29, 46, 50, 54, 71, 87, 88
AREP · 41, 42
Arpadi · 29
ART · 8, 9, 11, 12, 20, 25, 29, 30, 31, 34, 48, 51, 62, 66, 72, 75
ART adherence · 20, 29
Asirwa · 53, 60, 71, 77
Auerswald · 44
Ayaya · 18, 25, 29, 44, 45, 62, 63, 85, 86, 87, 88
Ayuku
David · 4, 20, 41, 42, 44, 51, 62, 63, 69, 70, 74, 76, 85, 86, 87
Ayuo · 27, 37, 38, 85, 86, 88

B

Baliddawa · 6, 20
Barasa · 79, 85
BCAM · 77, 78
Bell · 29
bibliography · 2, 85
Biondich · 64
Blaschke · 29
Bloomfield · 5, 39, 40, 47, 55, 70, 79, 85, 87
Bohlius · 71
Braitstein · 33, 36, 37, 38, 44, 49, 51, 61, 62, 63, 64, 69, 70, 74, 76, 85, 86, 87, 88
Breast Cancer Awareness Measure · 77
Brown University · 6, 16, 25, 26, 31, 38, 39, 48, 69

Bucher · 76
Bukusi · 45
Bukusu · 44
Burnt Forest · 4, 20, 21, 32, 35, 37, 59, 68
Burnt Forest Community · 4
Busakhala · 8, 45, 53, 54, 71, 77
Buziba · 16, 31, 32, 38, 39, 45, 86
Bwana · 45, 63, 71

C

CAMP · iv, 29, 30
cancer · vi, 16, 19, 53, 60, 72, 73, 77, 78, 79
carbon monoxide · 35
cardiovascular risk factors · 40, 70, 85
CARE Plus · 21
CARE+Kenya · 20
Caroll · 29
Carroll · 6
cART · 61
Carter · 21, 25, 34, 39, 69, 75, 87
CD4 · 8, 11, 26, 30, 64, 66, 72
Celgene Corporation · 15
Cervical Cancer · iv, 19
chemotherapy · 8, 17, 72
Chemotherapy · iii, 8
Chemwolo · 28
Child Abuse and Neglect · 63
Chite · 45, 71, 77
Christoffersen-Deb · 14, 28, 32, 86
Chronic Disease · iv, 27
Chulaimbo Sub-District Hospital · 19, 24, 34, 51, 59, 68, 73
CHWs · iv, 14, 28, 32, 56
Clinical Decision Support · iv, 28
Cohen · 45
combination antiretroviral treatment · 61
community engaged research · 1
Community Health Workers (CHWs) · 14, 32
Comprehensive ART Measure for Pediatrics · 29
Cook Stoves · iv, 34
CROI · 16, 19
Cryptococcal Meningitis · iii, 7
Cu-Uvin · 19

D

Dabis · 71
Dalla Lana School of Public Health · 33

Diabetes · iv, 25, 39, 40
Diero · 16, 25, 31, 32, 34, 38, 39, 45, 63, 64, 75, 86, 87
Diets · v, 40, 41
Downs · 64
Drug Resistance · iii, iv, 15, 25, 31, 38, 39
Duke Global Health Institute · 4, 40
Duke University · 4, 5, 35, 39, 49, 70, 79, 80

E

Early Morbidity · iii, v, 11, 66
Easterbrook · 45
Egger · 71
Eldoret · 2, v, 7, 10, 15, 27, 28, 33, 41, 44, 47, 51, 52, 60, 69, 86, 87
Embleton · 51, 62, 63, 70, 74, 76, 85, 86
Emonyi · 12, 16, 31, 38, 39, 47
Ernst · 40, 41
Ethics · v, 13, 41, 42, 43, 44, 86
Ettyang · 40, 41
European & Developing Countries Clinical Trials Partnership (EDCTP) · 27

F

Family Care-Giving · iv, 23
Family Well-Being · iii, 4
Fazen · 14
fingerprint identification · 15
Fluconazole Treatment · iii, 7
Fogarty International Center (FIC) · 28, 40, 42, 54, 65, 70
Freeman · 71
Fuster · 55, 58

G

Gardner · 25, 75, 85
Geng · 45
Gilead Foundation · 67
Glidden · 71
Goodrich · 51, 63, 85
Gramelspacher · 16, 17, 86
Grand Challenges Canada · 14, 29, 74
Grinter · 2
gynecologic examination · 19

H

HADITHI · v, 58, 59, 68, 69
Hagembe · 16, 17, 86

Hahn · 63
Hawk · 76
HIV-infected · iii, v, vi, 6, 7, 12, 15, 19, 26, 30, 40, 41, 44, 46, 59, 64, 65, 66, 67, 68, 69, 71, 72, 87
Hogan · 5, 6, 16, 39, 44, 49, 55, 58, 64, 87
Horowitz · 55, 58
House · 24, 86
HPV · 19
Huang · 16, 17, 86, 88
Human Biological Materials · 42
Human Subjects · 42
hypertension · 5, 54, 56, 87

I

IeDEA · v, 45, 46, 53, 64
Implementation Research · iv, 27
Incentives · iv, 35
Indiana Hemophilia and Thrombosis Center (IHTC) · 15
Indiana University · v, 7, 16, 17, 18, 19, 20, 23, 24, 26, 27, 29, 33, 36, 37, 40, 41, 42, 43, 44, 45, 47, 51, 53, 58, 60, 61, 62, 63, 64, 65, 68, 69, 70, 71, 74, 76, 77, 79
Insecticide Treated Net (ITN) · 50
Institutional Research and Ethics Committee · 13
Instituto de Salud Carlos III · 27
International Initiative for Impact Evaluation (3ie) · 13
Inui · 2, 27, 29, 47, 55, 58, 60, 61, 77, 86, 88
IREC · 4, 13, 17, 21, 46, 47, 48, 68, 78, 79, 81
Irish Aid · 27
Iten District Hospital · 6, 73, 75
Itsura · 19, 26
IU Health · v, 46, 47
IUPUI - Research Support Funds · 24

J

Jackson · 32, 58
Jakait · 14, 61
Jaquet · 71
Johnson and Johnson · 4

K

Kaaria · 34, 36
Kamanda · 51, 70, 85, 86
Kamano · 25, 39, 40, 55, 58, 85, 87
Kambugu · 45
Kantor · 16, 25, 31, 32, 38, 39, 86
Kanyi · 14
Kaposi's Sarcoma · v, vi, 46, 53, 71

Karwa · 14, 61
Kaspers · 79
KEMRI · 43, 50
Keter · 36
Khunyangu Sub-District Hospital · 51, 59, 68, 75
Kimaiyo · 5, 47, 54, 55, 58, 79, 85, 87
Kiplagat-Kirui · 2
Kirui · 2, 25, 85
Kisumu · 45
Kitale District Hospital · 20, 26, 34, 51, 59, 68
Koech · 37, 38, 79, 85, 88
KS · iii, 8, 9, 53, 72
Kulzer · 63
Kurt · 24
Kurth · 12, 13, 20
Kwena · 44

L

Lagat · 7, 9, 11, 58, 66
leukemia · 20
Litzelman · 18, 27
Liu · 31, 68, 85, 87
Lorant · 18
Loss to Follow-Up · v, 50
LTFU · 48, 72

M

Mabeya · 19, 26, 86
Maghasi · 5
Maina · 14, 61
Maisto · 6
Malaria · iv, v, 19, 35, 36, 49, 50
Mangeni · 49
Manji · 14, 35
Marete · 58, 60, 68, 86, 87
Marrero · 29, 88
Martin · 45, 54, 71, 79
Martino · 6
Mautuma · 40
Medical Research Council · 27, 66
Menya · 32, 34, 35, 49, 55, 58
Merck Company Foundation · 67
Meslin · 41, 42, 43, 44, 64, 86
Mihuu Community · 4
Mitra · 32
Moi Teaching and Referral Hospital · vi, 6, 7, 8, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19, 20, 21, 24, 25, 26, 27, 28, 30, 34, 38, 39, 40, 42, 45, 47, 52, 59, 60, 62, 64, 65, 66, 67, 68, 69, 73, 74, 77, 79, 80

Moi Teaching and Referral Hospital (MTRH) · 6, 7, 8, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19, 20, 21, 24, 25, 26, 27, 28, 30, 34, 38, 39, 40, 42, 45, 47, 52, 59, 60, 62, 64, 65, 66, 67, 68, 69, 73, 74, 77, 79, 80
Moi University · v, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 16, 17, 18, 19, 20, 23, 25, 26, 27, 28, 29, 31, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 47, 48, 49, 51, 53, 54, 58, 60, 61, 62, 63, 64, 65, 66, 67, 68, 70, 71, 73, 74, 75, 76, 77, 79
Monahan · 16, 17, 86
Moormann · 20
Mortality · iii, v, 11, 50, 51, 66
Mosoriot Rural Health Training Centre · 5, 14, 19, 24, 29, 54, 57, 59, 68, 73, 78
Mostert · 79
Mother-Baby Health Network · 14
Mount Sinai School of Medicine · 54, 55
MTRH · iii, 6, 7, 8, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 27, 28, 30, 31, 34, 38, 39, 40, 42, 45, 47, 52, 59, 60, 62, 64, 65, 66, 67, 68, 69, 73, 74, 77, 79, 80
Mutimura · 71
Muyindike · 45
Mwangi · 25, 34, 58, 62, 63, 76, 85, 87

N

Naanyu · 12, 49, 55, 57, 58, 60, 68, 70, 77, 87
Nabwire · 14
Nakuru · 45
Nalugoda · 45
NASCOP · 13
National Cancer Institute (NCI) · 8, 9, 53, 72
National Institute of Allergy and Infectious Diseases (NIAID) · 7, 9, 10, 32, 38, 48, 67
National Institute of Dental and Craniofacial Research (NIDCR) · 8, 9, 10
National Institute of Mental Health (NIMH) · 21, 30, 48, 59, 68
National Institute on Drug Abuse (NIDA) · 64
Ndege · 12, 36, 37, 38, 85, 87, 88
Neonatal Nurse Training Program · 76
Neumann · 40, 41
New York University · 12, 20
Newborn Health · iii, 13
Ngetich · 61, 86
NIH · 2, 5, 6, 7, 8, 9, 10, 11, 12, 17, 20, 21, 23, 28, 30, 32, 35, 36, 38, 40, 41, 42, 46, 48, 53, 54, 57, 59, 64, 65, 67, 68, 70, 71, 72, 80
Njiru · 8
Njuguna · 16, 17, 20, 79, 86
Nurse Management · v, 54, 55
nutrition · 32, 40
Nyabera · 24
Nyabundi · 39, 40
Nyambura · 36
Nyandiko · 2, 25, 29, 31, 40, 58, 60, 61, 64, 65, 68, 69, 85, 87, 88

O

Obala · 49, 85
Olbara · 79
Olsson · 61
Omeara · 45
O'Meara · 35, 49, 64
Omenga · 19, 73
Oncology · vi, 17, 18, 54, 77
Orphaned Children · v, 62
Ott · 44, 70
Owino Ong'or · 67
Owiti · 75, 87
Oyaro · 63

P

Pain Management Index (PMI) · 16
pain treatment · 16, 86
Palakal · 64
Palmer · 18
Pandit · 61
PAP smear · 19
Papas · 6
Park · 39, 40
Pastakia · 14, 25, 39, 40, 61, 85, 87
Patient-Centered Disclosure · v, 58
Pediatric · iv, 18, 28, 29, 60, 87, 88
PEPFAR · 30, 31, 51
Pfeiffer · 48
Pharmacovigilance · v, 61, 62
PHC · iv, 32
Pioneer Community · 4
Plater · 2
pMTCT · 25
PMTCT · 26, 34
Port Victoria Sub-District Hospital · 14, 33, 51, 75
Prevention of Mother to Child Transmission · iv, 25
Prudhomme-O'Meara · 36
psychosocial · 4, 21, 48, 60
Psychosocial Assessment · iii, 4
publications · 1, 2, 17, 18, 75, 85
Publications Committee · 2, 84
Puffer
 Eve · 4
Purdue University · 14, 15, 23, 39, 41, 60, 79

R

rape · 71

Regenstrief Institute · 2, 65
Reproductive · iv, 28
Rhode Island Foundation · 39
Riner · 18
Rotich · 58, 64, 86
Ruhl · 14
rural · 5, 20, 35, 54, 56, 70, 73, 87

S

Saina · 14
Schellhase · 14
Second-line Therapy · iv, 26
See and LEEP · vi, 73
Semeere · 54, 71
sequestration · 1, 2
sexual abuse · 63, 69, 71
Sexual Abuse · v, 62
sexual assault · 71
Shen · 64, 88
Sidle · 6, 7, 20, 32, 45, 61, 64, 85, 86
Siika · 7, 8, 9, 10, 11, 12, 20, 26, 27, 40, 51, 64, 65, 66, 85, 86, 87
Skiles · 17, 20, 79
Smart Forms · 28
SMS · 14
Some · 10
Songok · 14, 25, 76
Soy Health Centre · 40
Ssali · 45
Stelzner · 18
Street Involved Youth · v, 69
street-involved adolescents (SIA) · 44
Strother · 16, 17, 53, 86
Swedish International Development Cooperation Agency (SIDA) · 27

T

Tabbey · 16, 17, 86
TB · vi, 11, 46, 61, 66, 72, 75
Teso District Hospital · 14, 75
text message reminder system · 15
Tierney · 29, 87, 88
Topical Gentian Violet · iii, 9
Training · iv, vi, 5, 14, 19, 24, 27, 29, 54, 57, 59, 68, 73, 76, 78, 82
Trautman · 76
Tu · 29, 31
Tuberculosis · iii, v, 11, 66, 87
Turbo Health Centre · 6, 19, 20, 26, 32, 33, 40, 54, 57, 59, 68, 73, 78

U

Umoren · 18
Unfunded · 19, 24, 25, 34, 45, 52, 63, 75, 76, 79
Universidad Autonoma del Estado de Hidalgo Health Sciences
Campus (UAEH) · 18
University of Toronto · 14, 28, 32, 33, 51, 73
USAID - United States Agency for International Development · 37,
38, 51

V

Vedanthan · 54, 58, 87
Velasquez · 79
Velazquez · 5, 55, 85
VIA · 19, 73
Vik · 20, 79
Vincristine Toxicity · iii, 17
virological failure · 32
virological failures · 16
volatile substance misuse (VSM) · 44
Vreeman · 16, 17, 18, 25, 29, 31, 37, 38, 58, 60, 62, 63, 64, 68, 76,
85, 86, 87, 88

W

Wachira · 36, 37, 38, 48, 70, 85, 88
Walther Cancer Foundation · 60, 78
Walumbe · 2
Wambui · 39, 40
Washington · 19, 26, 36
Webuye · v, 4, 6, 15, 25, 31, 50, 59, 68, 70, 73
Webuye District Hospital · 6, 15, 25, 50, 59, 68, 70, 73
Were · 12, 13, 36, 41, 44, 55, 64, 86, 88
Woodward · 18
Wools-Kaloustian · 26, 32, 45, 51, 53, 61, 63, 64, 67, 71, 85, 87
World Health Organization (WHO) · 62
Wyatt · 67

Y

Yiannoutsos · 53, 71, 87
Yumo · 71

Z

Zachariah · 75