

SEMI ANNUAL RESEARCH REPORT

July – December 2016



Acknowledgements

This report would not be possible without the hard work and dedication of the investigators, research coordinators, and administrative support staff who make up AMPATH's research community. We appreciate all their contributions to this report. AMPATH's co-directors of research, Professors Winstone Nyandiko and Rachel Vreeman deserve special recognition for their constant support in the development of this report. Their leadership continues to strengthen the Research Program.

Editorial Team

Shawn Grinter
Jepchirchir Kiplagat-Kirui
David Plater
Eunice Walumbe

Copyright © March 2017 – 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

Fax: +254 53 206 1992

David Plater

AMPATH Research Network Administrative Manager
(North America) & Assistant Director of Research,
Indiana University Center for Global Health
702 Rotary Circle, RO101E
Indianapolis, IN 46202

Email: research.manager@iukenya.org

Phone: +1-317-274-4189

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

Abbreviations	i
Overview	ii
Grants	ii
Publications	iv
Study Reports	1
A Formative Study to Develop Culturally Valid Psychosocial Assessment Tools and Interventions to Promote Family Well-Being in Kenya	1
A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI)	2
A5225/HiFLAC Protocol - A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated Cryptococcal Meningitis.....	3
A5263 'A Randomized Comparison of Three Regimens of Chemotherapy with Compatible Antiretroviral Therapy for Treatment of Advanced AIDS-KS in Resource-Limited Settings'	4
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)	4
A5273 'Multicenter Study of Options for Second-Line Effective Combination Therapy (SELECT)'	5
A5274/REMEMBER Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens '	6
A5288 'Management Using the Latest Technologies in Resource-limited Settings to Optimize Combination Therapy After Viral Failure (MULTI-OCTAVE)'	7
A5290 A Randomized, Phase 2b Study of a Double-Dose Lopinavir/Ritonavir-Based Antiretroviral Regimen with Rifampin-Based Tuberculosis Treatment versus a Standard-Dose Lopinavir/Ritonavir-Based Antiretroviral Regimen with Rifabutin-Based Tuberculosis Tre	8
AMPATH - Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS	8
Analysis of ICU Admissions and Outcomes at the Moi Teaching and Referral Hospital Intensive Care Unit.....	10
Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study.	11
Assessment of Airway Disease in Western Kenya	13
Biomarkers of Vincristine Toxicity in Kenyan Children	14
Bridging Income Generation with Group Interated Care(BIGPIC)	15
Can integration of effective family planning services into Anticoagulation Management Services (AMS) improve uptake?	17
Chama Cha Mama Toto: Evaluating A Peer Support Mechanism To Improve Maternal And Infant Health	18
Childhood Leukemia in Kenya Identified Through Malaria Slide Review	20
Community perceptions and perceived needs of street-connected children and youth in Eldoret Kenya: a qualitative investigation.....	20
Developing and Assessing a Community-Based Model of Antiretroviral Care	21

Effect of free maternity care on maternal and fetal outcomes of preeclampsia/eclampsia at a teaching hospital in Western Kenya: A retrospective chart review.....	22
Engaging Street Youth in HIV Interventions (EASY)	23
Enhancing Training for Implementation Research in Chronic Disease: CITE/Kenya.....	25
Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy.	26
Evaluation of the growth and development of young children of HIV-infected mothers in western Kenya.	27
FLTR Evaluation	28
HI-Train: Health Informatics Training and Research in East Africa for Improved Health Care.....	30
leDEA Comprehensive Adherence Measure for Pediatrics (ICAMP)	31
Incidence of and risk factors for toxicity among HIV-infected children receiving cART: Findings from a large observational cohort in western Kenya	33
Innovative public-private partnership to target subsidized antimalarials in the retail sector	34
IU Health Cardiovascular Research Biobanking Project.....	37
Linkage and Retention to Care in Western Kenya Following HIV Testing	38
MCH STUDY (Evaluations at Infant and Child Visits a MCHs in western Kenya: A Needs Assessment)	40
NEURODEV (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study)	40
Nurse Management of Hypertension Care in Rural Western Kenya	42
Optimizing Linkage and Retention to Hypertension Care in Rural Kenya	43
Pathways to better health	46
Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)	46
Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretroviral Treatment	48
Point in Time (PIT) Count of Street Children in Eldoret	49
'Point of Care CD4 testing for people who fail to engage in care after testing HIV positive'	50
Randomized, Phase II Trial of CHOP vs. Oral Chemotherapy with Concomitant Antiretroviral Therapy in Patients with HIV-associated Lymphoma in Sub-Saharan Africa	51
Rapid Case Ascertainment (RCA) to evaluate Kaposi's sarcoma at the Academic Model Providing Access to Healthcare (AMPATH) clinics, Eldoret, Kenya	51
REALITY 'Reduction of EARly mortaLITY in HIV-infected adults and children starting antiretroviral therapy'	52
SAFI (Stigma in AIDS Family Inventory) Validation Study	53
Tablet Computer-Based Disclosure Counseling for HIV-Infected Adolescents and their Families: A Pilot Study of Perspectives from Providers	55
Taking to the Streets: a Mixed-Methods Systematic Review of the Reasons Children and Youth Become Street-Involved.....	56
The Confluence of Pregnancy and New HIV Diagnosis Among Adolescents in Western Kenya.....	57

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.....	58
The Production and Reproduction of Kinship in CCIs in Uasin Gishu County.....	59
The Role of Faith Leaders Towards Promotion of Home Based HIV Counseling, Testing and Linkage to Treatment Program Around Kisumu, Kenya.....	60
The Role of PD-1 Pathway and Tissue Microenvironment in HIV-Kaposi Sarcoma and Endemic Kaposi Sarcoma Cohort in Western Kenya.....	61
Validation of Spirometry Prediction Equations in Western Kenya.....	62
Vincristine Optimization in Kenyan Children with Cancer.....	63
Virologic Treatment Failure and Drug Resistance in HIV-Infected Kenyan Children (RESPECT) study.....	65
Bibliography.....	66
Index.....	72

Abbreviations

ADAT	AMPATH Data Analysis Team
AMWG	Adult Medicine Research Working Group
BSWG	Basic Science Research Working Group
CVMD	Cardiovascular and Metabolic Disease Research Working Group
IREC	Institutional Review and Ethics Committee
ORWG	Oncology Research Working Group
PCWG	Pharmaceutical Care Research Working Group
PHPCWG	Public Health and Primary Care Research Working Group
PRWG	Pediatric Research Working Group
RHWG	Reproductive Health Research Working Group
RPO	Research Program Office
RSPO	Research and Sponsored Projects Office
SSRN	Behavioral and Social Science Research Working Group
TBWG	Tuberculosis Research Working Group

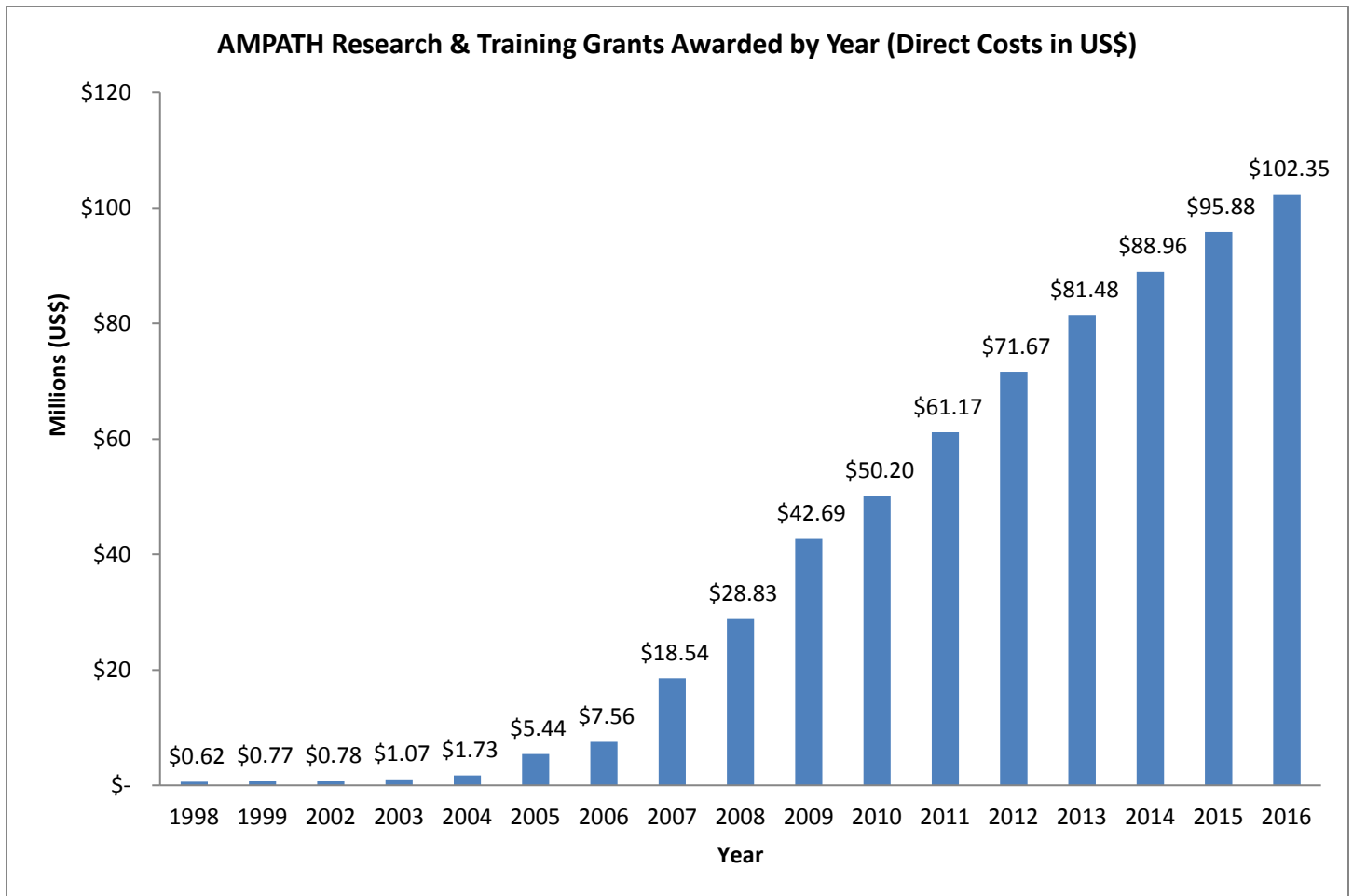
Overview

The AMPATH Research Program continued steady growth in the second half of 2016. Between July and December 2016, the cumulative total of direct research and training grants awarded to the program grew to \$102 million. The National Institutes of Health in the United States continued to be the largest sponsor of research and training grants at AMPATH and nearly all of the new awards reported this year were from NIH sources.

This year was another record breaking year for publications by AMPATH investigators in peer reviewed journals and other outlets. A total of 80 new publications were reported for 2016 – nearly double the annual average for the previous 5 years. In addition, nearly 120 new manuscripts, abstracts, posters, and articles were processed through the Publications Committee in 2016.

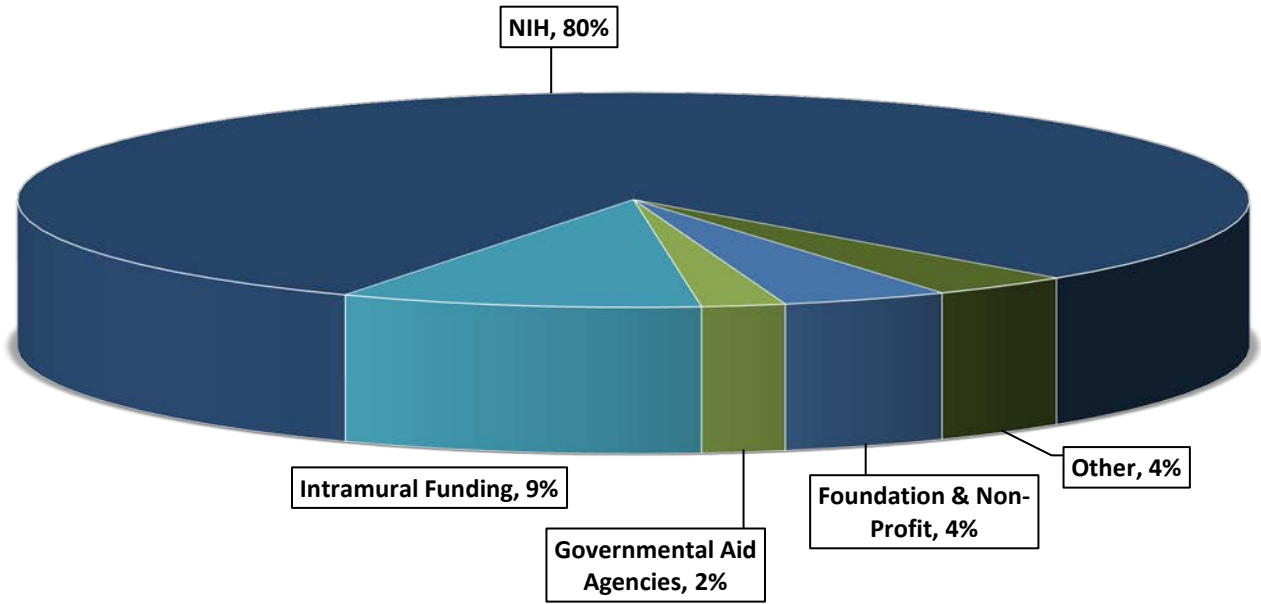
Grants

Investigators reported nearly US\$ 6.5 million in new awards in 2016. This increased AMPATH’s cumulative total of research direct awards to more than US\$102 million since the start of the program (See Figure 1).



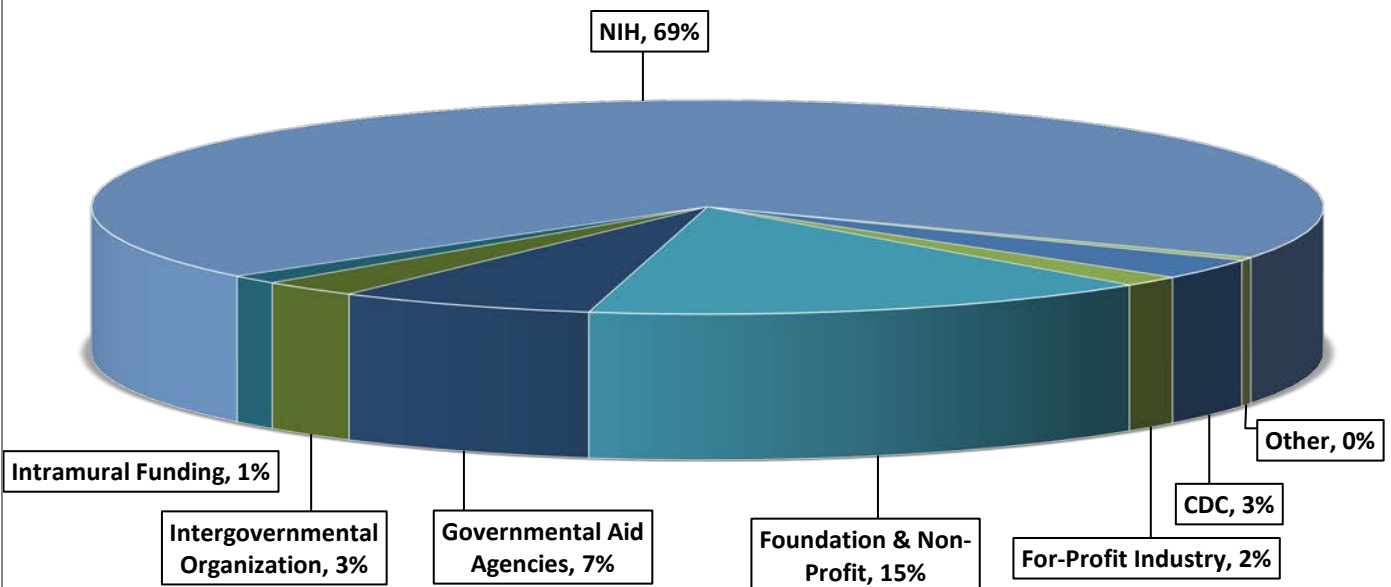
During this period, around 96 percent of new awards reported were from various institutes in the NIH (See Figure 2).

Figure 2: AMPATH Research Support by Sponsor Group (2016)



This continues trends from previous periods with the NIH as the largest sponsor of research grants at AMPATH (See Figure 3).

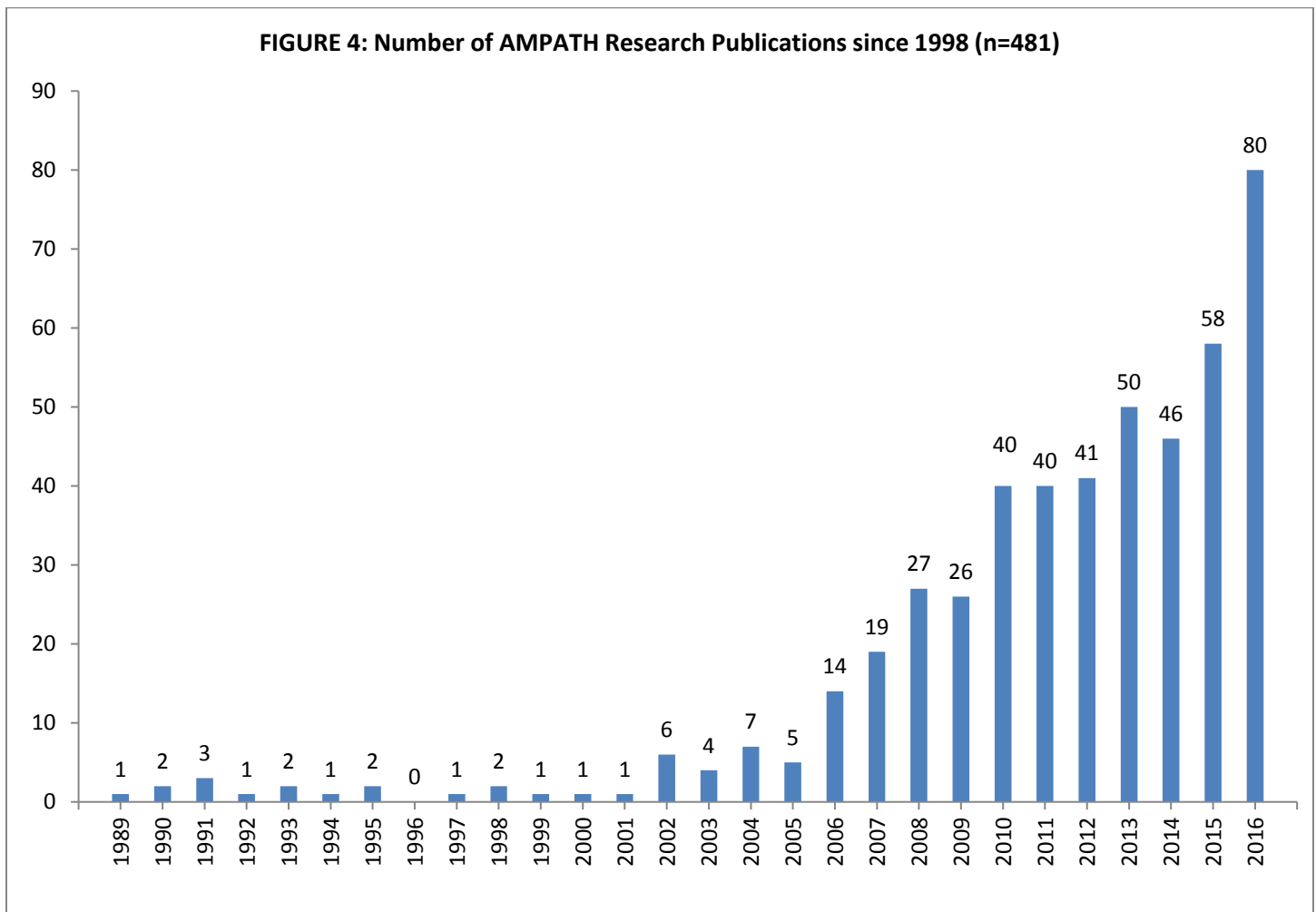
Figure 3: AMPATH Research Support by Sponsor Group (1998-2016)



Publications

A total of 80 manuscripts were published by AMPATH investigators in 2016. This is almost double the 5-year average of 47 publications per year and breaks the 2015 record of 58 publications in a single year (See Figure 4). A bibliography of all the publications produced in 2016 is available 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 118 draft publications during this period.



Study Reports

The following reports were provided by AMPATH investigators and their study teams and cover the period of July 1, and December 31, 2016.

Study Title	A Formative Study to Develop Culturally Valid Psychosocial Assessment Tools and Interventions to Promote Family Well-Being in Kenya
Principal Investigator(s)	Eve Puffer, Duke University David Ayuku, Moi University
Co-Investigator(s)	
Working Group(s)	PRWG, SSRN
Description	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)	Moi Teaching and Referral Hospital
Project Period	5/28/2013 - 12/31/2018
Funding Status	Funded – Grand Challenges Canada & Johnson and Johnson
Direct Award (USD)	\$129,000
Update	For the measures validation component of our work, we completed the pilot testing of over 800 items assessing various aspects of family relationships following a rigorous translation and cultural adaptation process. We are now validating these items further by comparing survey results with interview and direct observational assessment results. We have enrolled 12 families, and data collection is ongoing to reach the target sample size of 20. Related, we have completed the development of the novel direct observational measure of family functioning. We completed the GCC-funded component of the study (PI: David Ayuku): a pilot study of a family therapy intervention. Results documented improvements in mental health and family functioning, and we are now applying for NIH funding to conduct a larger trial.

Future Plans	We plan to conduct a follow-up pilot study of the family therapy intervention using the revised version based on the first pilot results. We will use a single-subject case series design to estimate impacts on family and individual well-being. For the measures validation component, we plan to complete the validity testing of the measures, resulting in finalized survey measures to be used for research and clinical purposes.
Publication(s)	Presentation: Puffer, E. S., Friis, E., King, K., Giusto, A., Fisher, C., Green, E. P., & Ayuku, D. (2016). Addressing Family Dynamics, Mental Health, and HIV Risk: Development and Pilot Study of a Family Therapy Intervention in Kenya. Poster presented at the 2016 Society of Research on Adolescence Biennial Meeting, Baltimore, MD.
Study Title	A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI)
Principal Investigator(s)	Rebecca Papas, Moi University B. Gakinya, Moi University
Co-Investigator(s)	Maisto, S. Martino, S. Baliddawa, J. Sidle, J. Hogan, J. Carroll, K.
Working Group(s)	AMWG, SSRN
Description	This study will determine whether a group cognitive-behavioral therapy intervention that demonstrates preliminary evidence of reducing alcohol use among HIV-infected outpatients in western Kenya is effective when compared against a group health education intervention in a large sample over a longer period of time. It will be delivered by paraprofessionals, individuals with limited professional training. This approach is consistent with successful cost-effective models of service delivery in resource-limited settings in which paraprofessionals (e.g. clinical officers, traditional birth attendants and peer counselors) are trained.
Site(s)	Iten District Hospital, Moi Teaching and Referral Hospital , Turbo Health Centre, Webuye District Hospital
Project Period	11/1/2011 - 8/31/2016
Funding Status	Funded – NIH - National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Direct Award (USD)	\$2,268,832
Update	The project ended in August 2016 and over the last six months we've been doing data cleaning and analysis. We've also managed to do two publication on associations between the Phosphatidylethanol alcohol biomarker and self-reported alcohol use, and Rates and covariates of recent sexual and physical violence against HIV-infected outpatient drinkers in western kenya. Other publications are in the pipeline
Future Plans	We plan to do all publications intended for this project.
Publication(s)	Associations Between the Phosphatidylethanol Alcohol Biomarker and Self-Reported Alcohol Use in a Sample of HIV-Infected Outpatient Drinkers inWestern Kenya Rebecca K. Papas, Benson N. Gakinya, Michael M. Mwaniki, Alfred K. Keter, Hana Lee,

Michelle P. Loxley, Debra A. Klein, John E. Sidle, Steve Martino, Joyce B. Baliddawa, Kathryn L. Schlaudt, and Stephen A. Maisto

Rates and Covariates of Recent Sexual and Physical Violence Against HIV-Infected Outpatient Drinkers in Western Kenya Rebecca K. Papas¹, Benson N. Gakinya², Michael M. Mwaniki, Hana Lee, Stella W. Kiarie, Steve Martino, Michelle P. Loxley, Alfred K. Keter, Debra A. Klein, John E. Sidle, Joyce B. Baliddawa, Stephen A. Maisto

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)	Abraham Siika, Moi University David Lagat, Moi University
Co-Investigator(s)	Lagat, D.
Working Group(s)	AMWG, SSRN
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 amphotericin B; Step 2: Induction following early amphotericin B intolerance (only for participants randomized to amphotericin 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
Project Period	5/18/2011 - 12/31/2013
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	Not Reported
Update	MUCRC managed to enrol two participants after the enrollment pause was lifted and the site obtained the necessary approvals to resume accrual. Follow up of the two participants was completed and there are currently no active patients at the site. Total site accrual was 26 and the target was 30. The A5225 protocol was closed to accrual effective August 19, 2016. A total of 167/168 participants (95/96 in Stage 1 and 72/72 in Stage 2) were enrolled across all participating sites. The study, being fully accrued, is closed to accrual.

Future Plans	Continue responding to data queries in preparation for data cleaning and analysis.
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 Naftali Busakhala, Moi University
Co-Investigator(s)	Naftali Wisindi Busakhala, Evangeline Wawira Njiru
Working Group(s)	AMWG, ORWG
Description	This is an ACTG prospective, randomized, active-controlled clinical trial in which participants will be randomized 1:1:1 to oral etoposide (ET) plus antiretroviral therapy (ART), bleomycin and vincristine (BV) plus ART, or paclitaxel (PTX) plus ART. The primary objective will be to compare the clinical efficacy of two regimens, oral ET plus ART and BV plus ART, to PTX plus ART for initial treatment of advanced stage AIDS-KS.
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/1/2014 - 2/28/2021
Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG) NIH - National Cancer Institute (NCI) NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	Not Reported
Update	The site has enrolled a total of 10 participants (7 after lifting of enrollment pause). This is out of the total accrual of 254 across all participating sites. The protocol sample size is 446 (version 3.0). Follow up of participants is ongoing.
Future Plans	Continue with recruitment efforts to identify, screen and enroll participants into the study as well as follow them up according to the protocol.
Publication(s)	
Study Title	A5264/AMC067 A Randomized Evaluation of Antiretroviral Therapy Alone or with Delayed Chemotherapy versus Antiretroviral Therapy with Immediate Adjunctive Chemotherapy for Treatment of Limited Stage AIDS-KS in Resource-Limited Settings (REACT-KS)
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Busakhala, N. Njiru, E.
Working Group(s)	AMWG, SSRN, ORWG

Description	A5264/AMC 067 is a phase III, open-label, prospective, randomized study stratified by CD4+ lymphocyte cell count and antiretroviral therapy (ART) history. The study will compare the KS tumor outcomes of ART alone or with delayed Etoposide (ET) to ART with immediate ET, for initial treatment of limited stage AIDS-KS in chemotherapy and radiation treatment na- HIV-1 infected participants who are currently not receiving ART
Site(s)	Moi Teaching and Referral Hospital
Project Period	11/28/2012 - 6/30/2014
Funding Status	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID) NIH - National Cancer Institute (NCI) NIH - National Institute of Dental and Craniofacial Research (NIDCR)
Direct Award (USD)	Not Reported
Update	At an interim review in March 2016, the Data and Safety Monitoring Board (DSMB) recommended that enrollment be discontinued immediately because of futility. Participants who had received ET during the course of the study were entered into Step 3 for safety follow-up. The duration of follow-up in Step 3 is 5 years from study entry to monitor for long-term safety. Participants who had not received ET during the course of the study completed the study discontinuation visit and were transitioned to primary care provider, AMPATH in September 2016.
Future Plans	The site plans to continue follow of participants who were randomized to step 3.
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
Working Group(s)	AMWG, SSRN
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
Project Period	1/22/2013 - 10/3/2016

Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	The protocol is closed to follow up and was deregistered with the DAIDS Protocol Registration Office in February 2016.
Future Plans	Interested site investigators to participate in secondary analysis where applicable.
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
Working Group(s)	AMWG, SSRN, TBWG
Description	In this randomized, open-label, phase IV strategy trial, participants from resource-limited settings (RLS) who present with advanced HIV disease and no probable or confirmed tuberculosis (TB), as defined in the current ACTG diagnosis appendix, and who are initiating antiretroviral treatment (ART) will be randomized to one of two strategy arms: immediate, empiric TB treatment (public health approach) or local standard of care TB treatment (individualized approach). The primary endpoint is survival status in the two arms 24 weeks after randomization. AIDS progression (any new WHO Stage 3 or 4 condition), virologic and CD4+ cell response, HIV and TB drug resistance, AND safety and tolerability of, and adherence to HIV and TB drugs will be evaluated, as will the cost-effectiveness of the two strategies. The primary objective is to compare survival probabilities between the two study arms 24 weeks after randomization.
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/10/2012 - 12/31/2016
Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	The study is closed to follow up and data analysis is ongoing
Future Plans	Continue with data analysis and disseminate information to participants.
Publication(s)	Lancet Mar/19/2016;387(10024):1198-209. Empirical tuberculosis therapy versus isoniazid in adult outpatients with advanced HIV initiating antiretroviral therapy (REMEMBER): a multicountry open-label randomised controlled trial.MC Hosseinipour GP Bisson S Miyahara X Sun A Moses C Riviere FK Kirui S Badal-Faesen D Lagat M Nyirenda K Naidoo J Hakim P Mugenyi G Henostroza PD Leger JR Lama L Mohapi J Alave V Mave VG Veloso S Pillay N Kumarasamy J Bao E Hogg L Jones A Zolopa J Kumwenda A Gupta

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
Working Group(s)	AMWG, SSRN
Description	A5288 is an open-label phase IV, prospective interventional, strategy study in resource-limited settings (RLS) for HIV-infected participants with triple-class experience or resistance to [nucleoside reverse transcriptase inhibitors (NRTIs), non-NRTIs (NNRTIs), and protease inhibitors (PIs)] and who are failing their current regimen. The use of novel agents and contemporary management tools that include standard genotyping, plasma viral load (VL) monitoring will be evaluated. The screening genotype results and antiretroviral (ARV) history will be used to allocate potential participants to one of the four cohorts and for selection of ARV regimen for each potential participant. At sites where feasible and relevant(including MTRH) the study will also conduct an adherence study. This will be a randomized comparison of cell phone-based adherence intervention plus local standard-of-care adherence procedures (CPI+SOC) versus the SOC adherence procedures. The primary objective of the study is to use novel agents and contemporary management tools, including standard genotyping to select an appropriate third-line regimen, interventions to improve adherence and plasma viral load (VL) monitoring, in order to achieve a ? 65% rate of virologic control at 48 weeks of follow-up
Site(s)	Moi Teaching and Referral Hospital
Project Period	12/18/2013 - 12/31/2015
Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	The final Step 1 or Step 2 visit for all participants took place beginning November 22, 2016, final visit for all participants who did not enter step 3 was completed. Participants who will enter Step 3 (i.e., those whose A5288 ART regimen includes RAL, DRV/RTV, or ETR and who are located in countries in which these drugs are not otherwise available) were registered to Step 3 at their final Step 1 or Step 2 visit. Raltegravir, darunavir, and etravirine will be available through the study only for participants entering Step 3 for up to an additional 96 weeks.
Future Plans	Continue follow up of participants randomized to step 3.
Publication(s)	

Study Title	A5290 A Randomized, Phase 2b Study of a Double-Dose Lopinavir/Ritonavir-Based Antiretroviral Regimen with Rifampin-Based Tuberculosis Treatment versus a Standard-Dose Lopinavir/Ritonavir-Based Antiretroviral Regimen with Rifabutin-Based Tuberculosis Tre
Principal Investigator(s)	Abraham Siika, Moi University Fatuma Some, Moi University
Co-Investigator(s)	
Working Group(s)	TBWG
Description	A5290 is a prospective, randomized (1:1:1), open-label, phase 2b study comparing three lopinavir/ritonavir (LPV/r)-based antiretroviral (ARV) regimens among participants in high tuberculosis (TB) endemic resource-constrained settings undergoing treatment for confirmed or probable TB and requiring protease inhibitor (PI)-based antiretroviral therapy (ART). A two accrual period design will be used, including a full pharmacokinetic (PK) and safety evaluation to be conducted when 54-60 participants enrolled during the accrual period 1 have completed 28 days of ARV treatment and day 12 ± 2 (after initiation of ART) drug levels are available (an early interim PK and safety evaluation will also be completed when 10-12 participants per arm have completed 28 days of ARV treatment and day 12 ± 2 drug levels are available). Primary Objective: To compare rates of virologic suppression to < 400 copies/mL at 48 weeks for the two standard dose LPV/r and RBT arms versus the double-dose LPV/r and RIF arm.
Site(s)	Moi Teaching and Referral Hospital
Project Period	5/13/2015 - 11/30/2018
Funding Status	Funded – NIH - AIDS Clinical Trials Group (ACTG)
Direct Award (USD)	Not Reported
Update	Follow up of enrolled participants went on well. Each participant will be transitioned after 72 weeks of follow up as per the protocol.
Future Plans	Follow up of participants will continue. Additionally, transitioning of active participants after completion of protocol required follow up period will continue for the next 6 months
Publication(s)	

Study Title	AMPATH - Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS
Principal Investigator(s)	Patrick Loehrer, Indiana University - Purdue University in Indianapolis (IUPUI) Darron Brown, Indiana University - Purdue University in Indianapolis (IUPUI)
Co-Investigator(s)	Omenge, Orango - Co-Principal Investigator MTRH Kaaria, Alice - Project 1 MTRH Cu-Uvin, Susan - Project 2 Brown

Working Group(s)	ORWG, RHWG
Description	The core objective of this project is to better understand the natural history of oncogenic HPV infections in HIV-infected Kenyan women, and to identify potentially modifiable (and non-modifiable) factors that are associated with progression of oncogenic HPV infection to clinical disease, including cervical cancer. Our central hypothesis is that the incidence, persistence, and spectrum of HPV are all substantially greater in HIV-infected versus non-HIV-infected Kenyan women, and that this explains a higher incidence of cervical neoplasia in HIV-infected populations. We further hypothesize that these and other modifiable factors (such as concurrent STIs, sexual behaviors, nutrition, and environment) disproportionately and adversely impact outcomes of local therapies such as cryotherapy and Loop Electrosurgical Excision Procedure (LEEP) in HIV- infected women. The specific aims of this AMPATH-Oncology Institute are to: 1. Expand the capabilities and expertise of the current laboratories and biobanking capabilities in Kenya through AMPATH and the Kenya Medical Research Institute (KEMRI) 2. Identify potentially modifiable behavioral and biological factors that are associated with the duration of infection with oncogenic HPV and cervical dysplasia in HIV-infected and non-HIV-infected women from western Kenya 3. Assess the risk factors associated with the short and long term results of cryotherapy and LEEP in VIA- positive (including LEEP-eligible) HIV-infected and non-HIV-infected women in western Kenya 4. Provide biostatistical and data management support for proposed projects in this application and for future pilot projects, and 5. To establish a sustainable, multi-institutional and transdisciplinary mentoring program fostering the development of new cancer researchers in Kenya
Site(s)	Moi Teaching and Referral Hospital, Center for Global Health Research - KEMRI at Kisumu City, Kenya
Project Period	9/19/2014 - 8/31/2019
Funding Status	Funded – NIH - National Cancer Institute (NCI)
Direct Award (USD)	\$2,132,402.00
Update	July 2016 through December 2016 saw an increase of study enrollment in both Project 1 and Project 2. Project 1 increased from 187 women to 219 women. 111 were HIV positive and 108 were HIV negative. Project 2 increased from 54 women to 124 women. There were 51 HIV positive and 73 HIV negative participants. An amendment was submitted to IREC to reduce Project 2 enrollment from 220 to 180 due to an observed decrease in women who meet the criteria to be enrolled in the project. In August a face-to-face meeting was held in Eldoret involving local study staff as well as those based in North America. Mentee selection for year 3 was discussed at that time bringing the total number of current mentees to 10 with 2 having completed their projects. The first Internal Advisory Board Meeting was held during the same week in the CCCDC. The project has faced some delays in performing HPV analysis and STI tests due to logistics and procurement of the appropriate supplies.
Future Plans	Over the next 6 months the project plans to continue enrollment for Project 2 until the enrollment target is met. An additional patient tracker starts with the study in January 2017 to assist in patient follow-up to reduce the loss of study participants returning for

	quarterly visits. HPV analysis is projected to begin at KEMRI with preliminary results available for the U54 Consortium meeting being hosted in Eldoret at the Boma Inn from March 22 through 24.
Publication(s)	
Study Title	Analysis of ICU Admissions and Outcomes at the Moi Teaching and Referral Hospital Intensive Care Unit
Principal Investigator(s)	Peter Kussin, Duke University Wangari Waweru-Siika, Moi Teaching and Referral Hospital
Co-Investigator(s)	Lalani, Hussain; Mwogi, Thomas
Working Group(s)	AMWG
Description	This study aims to explore the outcomes and mortality of patients admitted to the intensive care unit (ICU) at Moi Teaching and Referral Hospital by conducting a retrospective chart review of all patients admitted during 2011 through 2015. We aim to describe the demographic and clinical characteristics of these patients, evaluate specific procedures performed while patients are admitted to the ICU, investigate microbiological lab data specifically surrounding sepsis, and to establish the general cost of a hospital stay at MTRH. The overall goal is to develop a strong foundational data set that can be used to evaluate future clinical interventions. Furthermore, we intend for the prospective arm of this study, which is completely tablet-based, to serve as one step closer to the first electronic medical record for inpatient care at MTRH.
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/26/2015 - 6/1/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	We analyzed the data collected in the study and started writing abstracts. Our Doris Duke fellow, Hussain Lalani, submitted an internal abstract to Duke School of Medicine for this third year research project on this topic. He gave a short platform presentation at the annual research day, AOA day, at Duke in early August. It was well received. Our team had 2 abstracts that were accepted to the American Thoracic Society (ATS) 2017 International Conference. Preliminary findings include: the mortality prediction model-II (MPM-II) has acceptable discrimination with poor calibration in the sample of ICU patients at MTRH. The crude ICU mortality rate is 54% and there is a high incidence of brain death among patients with neurologic conditions (21%).
Future Plans	Our plan is to continue analyzing data and preparing manuscripts. There are a variety of research questions we are interested in from the data collected in our ICU database, and we will proceed to investigate them. We plan to submit our first manuscript for publication after review by AMPATH Pubs Committee, continue writing subsequent manuscripts, and hope to present our findings at the ATS meeting in May 2017 in Washington, DC.

Publication(s)	<p>Two abstracts were accepted to American Thoracic Society 2017 International Conference Evaluation of Intensive Care Unit Outcomes and Mortality at a Referral Hospital in Western Kenya Hussain S. Lalani, Wangari Waweru-Siika, Thomas Mwogi, Protus Kituyi, Peter S. Kussin Neurologic Critical Care: Outcomes of Patients Admitted to the Intensive Care Unit of a Referral Hospital in Western Kenya Hussain S. Lalani, Wangari Waweru-Siika, Thomas Mwogi, Protus Kituyi, Chrispine Odouor, Peter S. Kussin, Carmelo Graffagnino</p>
Study Title	<p>Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study</p>
Principal Investigator(s)	<p>Megan McHenry, Indiana University Eren Oyungu, Moi University</p>
Co-Investigator(s)	
Working Group(s)	<p>PRWG</p>
Description	<p>With the success of preventing mother-to-child HIV transmission and improving infrastructure for HIV care, fewer children born to HIV-infected mothers are infected themselves. Those who are infected are increasingly able to access appropriate care, which transforms HIV from a fatal disease to a chronic illness. Despite these advances, the children of HIV-infected mothers are more likely to have neurodevelopmental delays (NDDs) than HIV-unexposed children.¹ The mean scores on motor and cognitive testing of children born to HIV-infected mothers are consistently below population means. Moreover, despite controlling for prematurity and low birth weight, HIV-infected infants -- particularly those with early HIV-seropositive conversion, worse disease stage, and higher viral loads -- fare much worse developmentally than their uninfected peers. In addition, HIV-exposed, yet uninfected children in resource-limited settings (RLS) also appear to have lower global developmental scores and increased deficits in language and behavior. In sub-Saharan Africa, where over 90 percent of HIV-infected children live and HIV is most prevalent in women, the risk of this population not reaching its full developmental potential could affect quality of life, educational achievement, and earning potential. While it is clear that these children are at a significantly increased risk for NDDs compared to the general population, current data on the risks of both HIV exposure and perinatal antiretroviral therapy (ART) exposure on children's neurodevelopment are limited and heterogeneous. Thus, it is unclear to what extent exposure to either antiretroviral medications or to the virus itself, or infection with HIV, may impact neurodevelopment. To further complicate the picture, developmental risk factors, such as malnutrition and orphan-hood, disproportionately affect children born to HIV-infected mothers. With limited access to primary care, children in RLS do not undergo routine, age-appropriate developmental screening and thus are less likely to access any available interventions in these settings. Data from a retrospective chart review within the comprehensive Academic Model Providing Access To Healthcare (AMPATH) clinical care system in western Kenya, where HIV-exposed children are followed relatively closely, still show that only 10 percent of pediatric encounters have a documented clinician assessment of development, even though it is a standard element of the clinical encounter form. Currently, little is known about the training and experience of healthcare providers to assess for delays and to</p>

refer to available resources for interventions within specific communities in resource-limited, highly HIV-impacted settings. How clinicians or caregivers perceive children with NDDs and their beliefs surrounding these conditions, particularly for children born to HIV-infected mothers, are not known. Few developmental screening tools have been developed or adapted for RLS, and existing screening tools may be too lengthy for practical use in busy, overwhelmed healthcare systems. In order to make gains in how to screen and refer children appropriately for NDDs, further research is needed regarding how these delays are understood and discussed among child caregivers and clinicians. Determining these perceptions and assessing potential developmental screening instruments for this setting are crucial first steps to improve identification of NDDs in children born to HIV-infected mothers and to develop sustainable interventions appropriate for this setting. **Study Objectives:** The objective of the research proposed is to understand caregiver and clinical providers' perceptions of NDDs, including screening for NDDs and their treatment, for children in western Kenya to guide future design of a brief, culturally appropriate screening tool for NDDs. **Specific Aims:** To meet this objective, we will undertake the following specific aims: 1. We will utilize qualitative methods to determine the perceived etiology, manifestations, and intervention options for child NDDs from the perspectives of clinical staff and caregivers of HIV-infected and HIV-exposed children in Kenya. 2. We will develop brief, candidate neurodevelopmental screening questions that are clinically relevant and culturally acceptable by utilizing developmental assessments validated in other settings and incorporating contextual caregiver and clinicians' perspectives. 3. We will evaluate the feasibility of implementing a validation study to examine NDD screening methods in a pilot sample of children under three years of age born to HIV-infected mothers.

Site(s) Kitale District Hospital, Moi Teaching and Referral Hospital, Port Victoria Sub-District Hospital, Turbo Health Centre

Project Period 1/1/2016 - 12/30/2016

Funding Status Funded – Indiana University - Center for AIDS Research

Direct Award (USD) \$8,500.00

Update The specific aims for Neurodev (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study) are: Aim 1. To utilize qualitative methods to determine the perceived etiology, manifestations, and intervention options for child NDDs from the perspectives of clinical staff and caregivers of HIV-infected and HIV-exposed children in Kenya. Aim 2: To develop brief, candidate neurodevelopmental screening questions that are clinically relevant and culturally acceptable by utilizing developmental assessments validated in other settings and incorporating contextual caregiver and clinicians' perspectives. Aim 3 : To evaluate the feasibility of implementing a validation study to examine NDD screening methods in a pilot sample of children under three years of age born to HIV-infected mothers. In Phase One, we utilized semi-structured interviews (SSIs) and focus group discussions (FGDs) with caregivers and clinicians to understand current knowledge and beliefs about NDDs. FGDs were chosen for caregivers to generate information on collective views of neurodevelopment and the meanings and implications that lie behind those views. SSIs were chosen for clinical staff to address several key questions

	<p>specific to their individual training and experiences, while allowing both the interviewer and clinical staff to further pursue an idea or response in more detail. Phase Two will allow us to pilot key methods needed for future validation testing of these items. As we aim towards a large validation study to assess the reliability and validity of these screening questions in this setting, we will conduct prospective feasibility testing, piloting these questions during cognitive interviews with caregivers and clinical officers, in the clinical setting in Kenya and also piloting the implementation of the gold standard for developmental screenings - lengthy, comprehensive developmental assessments of young children. No modifications have been made to the specific aims as stated in the original proposal. We have ongoing Institutional Review Board and local ethics committee approval for the aims. Over the last six months data was collected through semi-structured interviews on 25 clinical staff and focus group discussions on 67 caregivers to understand the current knowledge and beliefs about Neurodevelopmental delays. For caregivers we generated information on collective views of neurodevelopment and for clinical staff it addressed several key questions specific to their individual training and experiences.</p>
<p>Future Plans</p>	<p>In the next 6 months, we plan to recruit 10 caregivers for cognitive interviewing and asking screening questions to them to determine the feasibility of methods and measure reliability. These findings will be compared to potential gold-standard developmental assessments to determine validity by having a research staff perform the assessments on forty children. Also a research staff was trained to administer the Bayley Scales of Infant and Toddler Development(a neurodevelopmental assessment tool), which will be culturally adapted for this study during the adaptive phase which we are awaiting approval of amendment from the Institutional bodies to commence, the adaptive phase aim is to culturally adapt the Bayley Scales for use in our population of young children here in Kenya.</p>
<p>Publication(s)</p>	
<p>Study Title</p>	<p>Assessment of Airway Disease in Western Kenya</p>
<p>Principal Investigator(s)</p>	<p>Peter Kussin, Duke University David Lagat, Moi University</p>
<p>Co-Investigator(s)</p>	<p>Paul, Devon Birgen, Elcy Ng'eno, Titus</p>
<p>Working Group(s)</p>	<p>AMWG, PRWG</p>
<p>Description</p>	<p>The World Health Organization (WHO) has identified chronic respiratory diseases as the 3rd leading cause of death globally. Unfortunately, the prevalence of these diseases and their underlying biology in much of sub-Saharan Africa is unknown. To this end we propose to first describe the prevalence of obstructive respiratory disease in Uasin Gishu County, Kenya using medical histories, validated questionnaires, and pre-and post-bronchodilator spirometry. We will then classify obstructive airway disease phenotypes as either bronchodilator responsive (FEV1 or FVC >12% post-bronchodilator) or unresponsive.³ We will also examine risk factors associated with airway disease including occupational history, TB, HIV, and biomass fuel use. Finally, we will compare our phenotypes to novel exhaled gas signatures based on levels of</p>

	exhaled carbon monoxide and nitric oxide as surrogates of air pollution and eosinophilic airway inflammation, respectively, providing insights into the underlying biology of chronic lung disease in our population as well as estimates of the impact of air pollution on lung health.
Site(s)	Other, community based research study across Uasin Gishu
Project Period	8/31/2016 - 12/31/2017
Funding Status	Funded - NIH - Fogarty International Center (FIC)
Direct Award (USD)	\$91,873
Update	We have begun enrollment and are progressing well. We had initial difficulties due to requirement of NACOSTI approval, which was unanticipated.
Future Plans	We plan to continue and possibly complete enrollment of our target sample size.
Publication(s)	

Study Title	Biomarkers of Vincristine Toxicity in Kenyan Children
Principal Investigator(s)	Jodi Skiles, Indiana University F. Njuguna, Moi University
Co-Investigator(s)	Skiles, J.
Working Group(s)	ORWG, PRWG
Description	This study evaluates the presence of peripheral neuropathy induced by Vincristine in Kenyan children receiving chemotherapy. The main purpose is to assess whether the genetic makeup of each child (particular the genotype of CYP3A5) influences drug exposure and subsequent vincristine toxicity.
Site(s)	Moi Teaching and Referral Hospital
Project Period	6/23/2011 - 6/30/2014
Funding Status	Funded - NIH
Direct Award (USD)	\$8,743.00
Update	The 2 manuscripts referenced in the previous report have been merged due to feedback from reviewers. The merged manuscript was re-submitted to Clinical Pharmacology and Therapeutics and is currently under review there with anticipated acceptance since it was an invited manuscript.
Future Plans	Publication of the above manuscript with completion of the study
Publication(s)	

Study Title	Bridging Income Generation with Group Integrated Care (BIGPIC)
Principal Investigator(s)	Rajesh Vedanthan, Mount Sinai School of Medicine Jemima Kamano, Moi Teaching and Referral Hospital
Co-Investigator(s)	Pastakia, Sonak Naanyu, Violet Chesoli, Cleophas Andama, Benjamin Fuster, Valentin Horowitz, Carol Manyara, Simon Menya, Diana
Working Group(s)	AMWG, CVMD
Description	The objective of this proposal is to utilize a trans disciplinary implementation research approach to address the challenge of reducing Cardiovascular Disease (CVD) risk in low-resource settings. The research aims at integration of group medical visits and microfinance with the additional social network characteristics. Aim 1: Identify the contextual factors, facilitators, and barriers that may impact integration of group medical visits and microfinance for CVD risk reduction, using a combination of qualitative research methods: 1) baraza; and 2) focus group discussions among individuals with diabetes or at increased risk for diabetes, microfinance group members, and rural health workers. Then develop a contextually and culturally appropriate integrated group medical visit-microfinance model. Aim 2: Evaluate the effectiveness of group medical visits and microfinance groups for CVD risk reduction among individuals with diabetes or at increased risk for diabetes, by conducting a four-arm cluster randomized trial comparing: 1) usual clinical care; 2) usual clinical care plus microfinance groups only; 3) group medical visits only (no microfinance); and 4) group medical visits integrated into microfinance groups. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the trial.
Site(s)	Bumala A Health Centre, Bumala B Health Centre, Chulaimbo Sub-District Hospital, Endeless Sub-District Hospital, Kapsara District Hospital, Khunyangu Sub-District Hospital, Matayos Health Centre, Mois Bridge Health Centre, Angurai, Moding, Akichelesit, Mal
Project Period	4/1/2015 - 4/1/2015
Funding Status	Funded – NIH
Direct Award (USD)	\$2,478,465
Update	<p>Administrative</p> <ul style="list-style-type: none"> • All-Investigator conference call held in September 2016 <ul style="list-style-type: none"> ○ Positive feedback attained from participants on call • Capacity building of the study personnel with specialized and targeted training ongoing • Procurement of necessary supplies for point of care testing nearly complete • Additional staff in Kenya hired: research assistants and clinical officers <p>Aim 1: Barriers/facilitators/contextual factors</p> <ul style="list-style-type: none"> • Transcription complete • Content analysis codebook has been completed • Inter-rater reliability of coders has been achieved

- Coding of transcripts and content analysis is ongoing

Aim 1.1 (Barriers, Facilitators, & Contextual Model):

- Focus group discussions (FGDs) to address acceptability and feasibility have been completed at baseline and month 3
 - Transcription complete - Inter-rater reliability of coders has been achieved - Content analysis ongoing
- Feasibility Pilot:
 - 3-month feasibility pilot complete
 - Extension of pilot to 6 months proposed: approval has been granted by both IREC and Mount Sinai PPHS/IRB office

Aim 2 (Cluster RCT):

- Logistics of trial initiation:
 - Working with AMPATH's Chronic Disease Management (CDM) and Safety Net teams regarding logistics of trial initiation
 - Planning of rollout by county has been completed
 - Training of community health workers (CHWs) in group process ongoing
 - Operations manual is in development
- Data collection, entry, & management:
 - Data collection instruments are finalized
 - Data collection, entry, and management procedures have been established
 - Data collection instruments have been programmed in REDCap
 - Testing of electronic forms nearly complete
 - Process evaluation:
 - Protocol for Process Evaluation finalized

Aim 2.1(Mediation & Moderation Analysis):

- Social network survey (SNS):
 - SNS instruments have been finalized, reviewed and approved by overseeing ethics and research review committees (IREC and IRB)
 - Instruments have been programmed into REDCap, as above

Aim 3 (Cost Effectiveness Analysis):

- Costing questionnaire survey (CQS):
 - CQS instruments have been finalized, reviewed and approved by governing ethics and research review committees
 - Instruments have been programmed into REDCap, as above Intervention cost tracking procedures nearly finalized

Future Plans

Aim 1:

- Complete content analysis of transcripts
- Manuscript preparation

Aim 1.1:

- Implement 6 month pilot feasibility assessment
- Manuscript preparation

Aim 2:

- Initiate enrollment of individuals into the trial

	<ul style="list-style-type: none"> • Complete training of rural clinicians, community health workers, and research staff who will be involved in the group medical visit-microfinance intervention • Finalize operations manual • Finalize data management SOP • Initiate process evaluation after trial is started <p>Aim 2.1:</p> <ul style="list-style-type: none"> • Administer survey to study participants at appropriate time period <p>Aim 3:</p> <ul style="list-style-type: none"> • Administer survey to study participants at appropriate time period
Publication(s)	<p>Pastakia S., Manyara S., Vedanthan R., Kamano J.H., Menya D., Andama B., Laktabai J. (2016). Impact of Bridging Income Generation with Group Integrated care (BIGPIC) on Hypertension and Diabetes in Rural Western Kenya. <i>Journal of General Internal Medicine</i>. Retrieved from http://link.springer.com/article/10.1007%2Fs11606-016-3918-5</p>



Study Title	<p>Can integration of effective family planning services into Anticoagulation Management Services (AMS) improve uptake?</p>
Principal Investigator(s)	<p>Astrid Christoffersen-Deb, University of Toronto Imran Manji, Moi Teaching and Referral Hospital</p>
Co-Investigator(s)	
Working Group(s)	<p>RHWG</p>
Description	<p>The purpose of the study is to evaluate whether integration of family planning education and free, on-site provision of all reversible family planning methods in Anticoagulation Monitoring Service (AMS) Clinic can improve uptake of long-acting reversible contraception (LARC; specifically intrauterine contraceptive devices (IUCDs) and contraceptive implants) in this high-risk population. Our hypothesis is that implementation of an educational intervention emphasizing long-acting reversible contraception (LARC) combined with free on-site provision of LARC within Anticoagulation Monitoring Service (AMS) can improve uptake of these methods by 250% in this population. Our objectives are to: 1) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) is feasible. 2) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) can improve uptake of long-acting reversible contraceptive methods (IUCDs and contraceptive implants). 3) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within an Anticoagulation Monitoring Services (AMS) Clinic can prevent unplanned pregnancies. In order to evaluate these objectives we will provide the intervention and follow the participants for the following 1 year time period. At 3-month, 6-month, and 12-month follow-up we will evaluate whether they are using any method of family planning and whether they have experienced subsequent unplanned pregnancies. This data will be compared to the same group of women prior to</p>

	implementation of the education intervention and free, on-site provision of all reversible contraceptive methods.
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/20/2015 - 8/31/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	In the last six months, we conducted and concluded analysis for the three month follow-up data available for 186 participants. Our initial findings show a significant increase in LARC use from 13.9% to 25.8% (RR=1.67, 95% CI=1.53-1.82) and injectable contraceptive use from 12.4% to 22% (RR=2.72, 95% CI=2.72-2.72) after the intervention. The use of no method or abstinence decreased from 52.7% to 35.5%. A draft of a manuscript with this finding is ready to be submitted to a peer-reviewed journal. Six month follow-up was concluded in September 2016. In this follow up stage, data could not be collected for 33 participants(14.7%). Six (18.2%) of the lost cases were due to death, while the other 27(81.8%) could not be reached. 12 month follow-up is still being conducted.
Future Plans	Over the next six months, we plan to submit the manuscript with the three month follow-up data to a peer-reviewed journal. We aim to finish the twelve month follow-up data collection by March 2017. We will continue to conduct data analysis over time to evaluate our primary outcome of increased use of Tier 1 contraceptive methods. Additionally, we aim to prepare and submit another manuscript with our final data for publication. We also plan to continue conducting educational sessions and outreach programs in the region with an aim to improve uptake of long-term family planning methods.
Publication(s)	
Study Title	Chama Cha Mama Toto: Evaluating A Peer Support Mechanism To Improve Maternal And Infant Health
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto Julia Songok, Moi University
Co-Investigator(s)	Ruhl, Laura
Working Group(s)	PRWG, RHWG
Description	Chama cha Mama Toto are mother-child groups tailored to the needs of mothers and their children living in rural areas of western Kenya. The study is being performed in two phases. Phase I of the study sort to show the effectiveness of Chamas in Bunyala Sub-county, in enhancing women, child health and child development. This Phase ended in August 2014 paving way for Phase II. Phase II entailed the integration of a positive parenting curriculum into Chamas known as Malezi Mema Parenting Programme in February 2016. The programme was adapted from the South African 'Sinovuyo Parenting programme' in consultation with Jamie McLaren Lachman. This is

	<p>the first time that the adapted Sinovuyo Parenting program is being implemented in a real-world setting at scale rather than in a research program. The curriculum comprises of 18 topics that address the key main areas of parenting. The curriculum is divided into two main sections. Section 1 provides mothers with knowledge on positive parenting while section 2 provides mothers with ways of managing maternal stress, alternative methods of dealing with difficult behaviour in children as opposed to harsh punishment and helping children through stressful situations. The sessions are delivered in a Chama using a collaborative approach with the guidance of trained CHVs. The sessions are also supervised by 'Malaikas' who consist of program assistants who have been trained in supervision. The parents are led through a discussion that involves group discussions/ brainstorm, role plays, exercises, song, dance and a homework practice to go and implement what they learned and give feedback in the next session. This second phase aims to validate the integration of parenting curriculum into Chama cha Mama Toto Program. The study also seeks to show the effectiveness of peer support mechanisms in improving maternal confidence and esteem, to alleviate maternal stress, to reduce incidence of harsh parenting, to change the attitude towards punishment in Bunyala Sub- County and to determine the acceptability of the program among Chama women, their partners, and the community at large.</p>
<p>Site(s)</p>	<p>Mukhobola Health Centre, Osieko Dispensary, Port Victoria Sub-District Hospital, Rwambua Dispensary, Rugunga Dispensary, Not at facilities, but located in the community units attached to the facilities.</p>
<p>Project Period</p>	<p>5/1/2015 - 10/31/2016</p>
<p>Funding Status</p>	<p>Funded – Grand Challenges Canada</p>
<p>Direct Award (USD)</p>	<p>\$250,000</p>
<p>Update</p>	<p>The parenting curriculum that was translated into Kenyan context was delivered to the Chama women. The program had 18 sessions and all the sessions were completed at the end of November. After the completion of delivery of the program, the team embarked on assessments of children in both intervention and control groups. We also carried out parental stress interviews with women in both groups. Preliminary analysis There was 52% absolute increase in facility deliveries. Facility delivery was 88.6% (M&E data) in chama compared to community-wide rate (36.6%) KDHS 2. CHV 48 hrs visit (Estimated 40% increase) 92.1% absolute increase in 48-hour follow-up visit. Exclusive breastfeeding (Estimated 30% increase) 90.2% of women with young infants exclusively breastfed to 6 months compared to 58.5% in the community (KDHS). Children fully immunized (15% increase) 17.6% absolute increase in OPV 0. 100% OPV 0 compared to community wide 82.4%; Data on measles is inaccurate so unable to report . Newborn death (50% fewer deaths) 3 neonatal deaths in 106 live-births for chama women extrapolated to 28 per 1000 livebirths compared to 19 per 1000 live-births reported in 2015 KDHS rate. Stunting and Wasting (20% decrease) Wasting was reduced by 0.17 SD in intervention compared to control (p = 0.585). Wasting of >2SD from the mean was 18.8% in chamas compared to 30% in community (KDHS), which is equivalent to 11.2% absolute decrease. Stunting was reduced by 0.397 SD in intervention compared to control (p = 0.086). Stunting of > 2SD was 8.45% in chama compared to 12.7% in community (KDHS). Equivalent to a 4.2% absolute</p>

	decrease. Preschool enrolment (20% increase) There was 11% absolute increase in school enrolment before and after the intervention. The enrolment rates were 77% at baseline and 88% at endline. 4 or more 4 ANC visits(20% increase) 100% of pregnant women in chamas attended 4 ANC visits compared to the 44.9 percent in the community (KDHS). This was equivalent to 55.1% absolute increase. Long term family planning (10% increase) There was a 42.4% uptake of long-term family planning methods by six weeks in our chamas. However, we have no data to compare this finding. Maternal death (30% fewer) There were no maternal deaths in chamas during the project period.
Future Plans	We intend to complete analysis and start writing a manuscript
Publication(s)	

Study Title	Childhood Leukemia in Kenya Identified Through Malaria Slide Review
Principal Investigator(s)	Terry Vik, Indiana University F. Njuguna, Moi University
Co-Investigator(s)	Skiles, J. Moormann, A.
Working Group(s)	ORWG, PRWG
Description	The aim of this study is to improve the case detection rate of leukemia by retrospectively reviewing blood smears done for malaria screening to identify children with leukemia in defined population cohorts. If the case detection rate can be improved by utilizing a common and well established procedure, then there is potential to identify children, refer them earlier for treatment and save lives.
Site(s)	Kitale District Hospital
Project Period	7/1/2012 - 6/30/2015
Funding Status	Funded – Alex's Lemonade Stand Foundation
Direct Award (USD)	\$200,000
Update	The DNA analysis for the whole cohort has been completed. Manuscripts are being written and circulated.
Future Plans	Complete and submit the manuscripts.
Publication(s)	

Study Title	Community perceptions and perceived needs of street-connected children and youth in Eldoret Kenya: a qualitative investigation
Principal Investigator(s)	Lonnie Embleton, University of Toronto David Ayuku, Moi University

Co-Investigator(s)	Braitstein Paula, Kamanda Allan, Wachira Juddy.
Working Group(s)	PRWG, SSRN
Description	<p>Very little research exists that explores public perceptions and reactions to street-connected children and youth in low- and middle-income settings and how this impacts the care and services they receive; and no one has explored this topic to date in our setting. Moreover, no one has investigated street-connected youth's opinions and perceptions of their treatment by the public and their needs in relation to the provision of healthcare and services in Eldoret. Gathering youth's opinions and perspectives on their treatment and care will assist with the design and development of services and interventions for this vulnerable population. When youth are involved in the design and development of programs they are more likely to uptake services and seek care that is responsive to their needs. Similarly, exploring the opinions and perspectives of local policymakers, community members, and healthcare providers concerning street-connected children and youth, which influence their decision-making (ethical or unethical) in regards to the provision of programs, services, treatment, support, and care for this population is vital to reduce the harms associated with street-involvement. Gathering this data represents the first step in designing and developing effective evidenced-based interventions and policies, in a community-based participatory manner, which are responsive to the perspectives of street-connected children and youth and community members within the local social-cultural context.</p> <p>SPECIFIC AIMS</p> <p>AIM 1: Explore and describe the perceptions of community members across different social strata about the causes, characters, and needs of street-connected youth in Eldoret, Kenya.</p> <p>AIM 2: Describe the experiences of street-connected youth in Eldoret, Kenya, aged 15-24, with stigma and discrimination on the streets and when accessing services and healthcare.</p> <p>AIM 3: Elucidate ideas concerning appropriate service delivery and care for street-connected youth in Eldoret, Kenya from community members across different social strata</p> <p>3.1) Identify street-connected youth's opinions on what will assist or facilitate access to healthcare and specifically explore their needs in relation to HIV prevention.</p>
Site(s)	Moi Teaching and Referral Hospital, Other community-based sites in Eldoret
Project Period	9/5/2016 - 12/31/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	In the past six months this study received ethics approval from MTRH and Moi University IREC and the University of Toronto REB.
Future Plans	In the next six months we hope to conduct qualitative interviews and commence to analyze the qualitative data.
Publication(s)	
Study Title	Developing and Assessing a Community-Based Model of Antiretroviral Care

Principal Investigator(s)	Abraham Siika, Moi University Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Naanyu Violet, Goodrich Suzanne, Yiannoutsos Constantin, Mwangi Ann, Thirumurthy Harsha, Batenganya Moses, Spira Thomas, Nyunya Boaz
Working Group(s)	AMWG
Description	ART Co-ops study will develop and assess an alternative care model that is established on the platform of a HIV-infected peer-group (ART Co-op) and facilitated by community health workers (CHWs). This model of care is intended to decentralize ART services and bring them closer to the patients. Specifically, we will: 1. Develop an acceptable and sustainable model for extending HIV care and treatment into the community. 2. Perform a pilot study comparing the outcomes of patients enrolled in the ART Co-ops program to those receiving standard of care. 3. Determine the cost savings and cost effectiveness of ART Co-ops.
Site(s)	Kitale District Hospital
Project Period	2/9/2015 - 2/9/2017
Funding Status	Funded – Centers for Disease Control and Prevention (CDC)
Direct Award (USD)	\$924,042
Update	1. Continuing review for the study was requested on the 11th of August 2016 and approval was granted by IREC on the 2nd of October 2016. 2. Amendments to the study protocol were submitted to IREC and approval was granted on the 28th of July 2016 & 30th November 2016. 3. Consenting and enrollment of study participants started on the 21st of October 2016. As of 31st December 2016, 150 participants had qualified to participate in the study. 4. The study was monitored by FHI 360 as from the 5th - 9th of December 2016. Recommendations from the monitor have since been implemented.
Future Plans	1. We plan to Complete enrollment of participants and formation of study community groups. 2. Follow up participants who are already in community groups. 3. The third monitoring visit by FHI 360 is scheduled for April 2017.
Publication(s)	



Study Title	Effect of free maternity care on maternal and fetal outcomes of preeclampsia/eclampsia at a teaching hospital in Western Kenya: A retrospective chart review.
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Co-Investigator(s)	Parks Caitlin, Millar Heather, Kosgey Wycliffe, Thorne Julie, Kipchumba Bett
Working Group(s)	RHWG
Description	The aim of this study is to determine the incidence of diagnosis and treatment of pre-eclampsia and eclampsia at MTRH. We will measure the maternal and neonatal

	<p>outcomes in women with these diagnoses. We will evaluate the data in order to determine areas for improvement in our diagnosis and management of pre-eclampsia/eclampsia in order to decrease maternal and neonatal morbidity and mortality at MTRH. Finally, we would like to evaluate the effect free maternal care has played in the measured incidence and outcomes of pre-eclampsia and eclampsia at our institution. Specifically, we will: 1. Determine and compare the incidences of pre-eclampsia within our institution in the year before and the year after the initiation of free maternal care in June, 2013 2. Evaluate the maternal and neonatal outcomes, including major causes of morbidity and mortality in each group. Again we will compare these before and after the initiation of free maternal care in June, 2013. 3. Evaluate the risk factors for adverse maternal and neonatal outcomes 4. Evaluate the adherence of treatment in our facility in accordance with World Health Organization standards, again comparing treatment before and after the initiation of free maternity care in June, 2013. The data for this study is collected using a comprehensive 100-item data collection form, including patient demographics, symptomatology, documented clinical signs and laboratory results, delivery details, and maternal and neonatal outcomes</p>
Site(s)	Moi Teaching and Referral Hospital, Saboti Sub-District Hospital
Project Period	1/12/2015 - 12/31/2015
Funding Status	Unfunded
Direct Award (USD)	
Update	<p>A dramatic difference between the maternal mortality files retrieved in the periods before and after initiation of the free maternity care program was noted. This phenomena was thought to be due to the low file retrieval rate for the period before free maternity care and thus we made an amendment to the proposal in order to allow us to obtain all maternal mortality files within the study period. IREC approval was granted and maternal mortality files were then identified, retrieved and reviewed. Data from the files was then input into the REDCAP database. We have therefore completed data collection and entry for the entire study. One manuscript - The Effect of Free Maternity on PET, was completed.</p>
Future Plans	Data collected from the additional maternal mortality files will be analyzed. We also hope to complete manuscript writing for the remaining three papers.
Publication(s)	

Study Title	Engaging Street Youth in HIV Interventions (EASY)
Principal Investigator(s)	Paula Braitstein, University of Toronto David Ayuku, Moi University
Co-Investigator(s)	Shah, Pooja Kamanda, Allan Makori, Dominic Galarraga, Omar Ott, Mary
Working Group(s)	PRWG

Description	This is an 18-month project funded by the Canadian Institutes for Health Research (CIHR) aiming to identify, adapt, and pilot interventions to engage street-connected children and youth (SCY) into HIV prevention, care and treatment. The first stage requires a comprehensive literature review identifying potential interventions from the literature; the second stage requires narrowing down the possible selection of interventions by their feasibility, cost, ethics, and potential effectiveness; and the third stage is to pilot and evaluate 2-3 interventions.
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/1/2016 - 9/30/2017
Funding Status	Funded – Canadian Institutes of Health Research
Direct Award (USD)	\$76,150
Update	A Senior Research Assistant was hired for the project. The protocol was developed and approved by IREC. Two mabaraza (community meetings) were held with male and female street youth respectively to inform them of the study, and ask them their opinions of our shortlisted interventions. From the mabaraza and through several on-site meetings and conference calls, it was decided that two interventions would be piloted in the first instance. These were a voluntary medical male circumcision and educational retreat (VMMC) and a reproductive health clinic (RH clinic). A detailed costing of the interventions was done, and amendments were made to the protocol for each of the interventions. The VMMC intervention is a 10-day retreat for male street youth and involves the medical circumcision procedure followed by a period of recovery and teaching of educational modules that cover various life skills and knowledge about HIV, safe sex behaviours, and gender based violence. On the last day, there is a graduation ceremony and the boys return to the street as men. In December, 45 male street youth aged 12-18 participated in the intervention. At the beginning and end of the 10 days, they completed quantitative questionnaires collecting information on demographics, HIV knowledge, attitudes, and perceptions, and self-esteem and resiliency. At the end they also completed an evaluation form. The retreat was a great success and very well received by the street youth community. In addition to the planning of the VMMC intervention, there were regular conference calls discussing its progress as well as developing the RH clinic intervention in more detail. The RH clinic intervention will take place over a period of 6 months. Adolescent SCY will be able to access a range of reproductive health services and information on safe sex behaviours, HIV/AIDS, and other sexually transmitted infections. This will be implemented in 2017.
Future Plans	Two groups of VMMC will be scheduled over the next few months, ensuring that a total of 120 male street youth participate in the study. Data entry and analysis will be completed for this intervention. A manuscript will be written with the aim of a publication. The possibility of developing an educational programme for the female street youth will be discussed in conference calls and local meetings with community leaders. Focus groups and key informant interviews will be held with street youth to determine their opinions on what should be covered in the programme and about other possible interventions. Regular meetings and conference calls will take place to actively plan for the implementation of the RH clinic. Tasks will include submitting a protocol amendment to IREC, hiring and training of staff, procuring supplies,

	advertising and developing data collection tools. It is estimated that implementation of the clinic will occur in around May or June.
Publication(s)	
Study Title	Enhancing Training for Implementation Research in Chronic Disease: CITE/Kenya
Principal Investigator(s)	Deb Litzelman, Indiana University Paul Ayuo, Moi University
Co-Investigator(s)	
Working Group(s)	AMWG
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
Project Period	10/1/2012 - 9/30/2016
Funding Status	Funded – NIH - Fogarty International Center (FIC)
Direct Award (USD)	\$862,970

Update	<p>This project is in its final stages. The core didactic curriculum has been successfully integrated into the MUSOM’s existing MMed program. The eight D43 fellows are at variable stages of completion of their mentored research practicum ranging from publication of their findings in peer-reviewed manuscripts to final stage of data collection for their project. Two fellows were able to extend data collection to evaluate long-term (1-year) outcome measures with an additional, small amount of supplemental funds. One Fellow was able to design and implement a second research project during her fellowship training period. (Refer to Table for list of fellow’s practicum topics and publications). The D43 fellows benefited from a scientific writing retreat organized by MUSOM’s Department of Medicine in November 2016, but had prioritized the need for assistance with scientific writing skills as integral to their ability to publish in peer reviewed journals and write competitive research grants to help ensure sustainability of Specific Aim 2.</p> <p>In response to the fellow’s request for additional professional development in scientific writing, a capstone week-long writing workshop on “The Science of Scientific Writing” to be facilitated by Dr. George Gopen was scheduled for February 6-10, 2017. For almost 30 years Dr. Gopen has acted as a consultant on written communication for scientific research institutes, corporations, universities, and governmental agencies. Dr. Gopen’s large and small group sessions planned with the D43 fellows was intended to assist them with successful completion of manuscripts reporting the results of their D43 research projects and to assist them with their grant writing. Unfortunately, due to illness, Dr. Gopen needed to cancel the workshop but has made himself available in September of 2017 if NCE is approved.</p>
Future Plans	<p>At the time of this report, the project had requested a second no-cost-extension to allow for final publication work by the fellows, participation in a NIH meeting, and participation in a writing workshop.</p>
Publication(s)	

Study Title	Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy.
Principal Investigator(s)	Beatrice Jakait, Moi University Rena Patel, University of Washington
Co-Investigator(s)	
Working Group(s)	RHWG
Description	This project aims to study the effect of antiretroviral medications (particularly Efavirenz) on the effectiveness of hormonal contraceptives. The main output to help develop the evidence base for the relative effectiveness of implants with concomitant efavirenz-based ART among HIV positive women in western Kenya
Site(s)	Bumala A Health Centre, Bumala B Health Centre, Burnt Forest Sub-District Hospital, Busia District Hospital, Huruma Sbu-District Hospital, Khunyangu Sub-District Hospital, Matayos Health Centre, Moi Teaching and Referral Hospital, Mukhobola Health Centre,

Project Period	5/23/2016 - 2/28/2017
Funding Status	Funded - NIH
Direct Award (USD)	\$12,727
Update	Since the start of the project in May 2016, we have completed 2455 file reviews. All intended file reviews have been completed, resulting in a 72% success rate of finding the intended files. Over the next two months, we plan to complete phone client interviews (only 868 of the client interviews have been completed to date). Therefore, in the next six months, we should finalize data collection, conduct data cleaning and analysis.
Future Plans	In the next six months, we plan to finalize data collection, conduct data cleaning and analysis, and move into manuscript writing phases of this project.
Publication(s)	
Study Title	Evaluation of the growth and development of young children of HIV-infected mothers in western Kenya.
Principal Investigator(s)	Megan McHenry (maiden name: Uhl), Indiana University
Co-Investigator(s)	Apondi, Edith Vreeman, Rachel Ayaya, Samuel
Working Group(s)	PRWG
Description	Children under five years of age are at significant risk for mortality in resource-limited settings. One in nine children in sub-Saharan Africa die before they reach five years of age. Approximately 45% of child deaths are related to poor growth and malnutrition. Children born to HIV-infected mothers are at increased risk for stunting, wasting, and being underweight, and children with HIV and AIDS are even more likely to be malnourished. Without treatment, 50% of HIV-infected and 7% of HIV-exposed, but uninfected infants will die before two years of age. My long-term research goal is to provide evidence to improve the nutritional status and, in turn, decrease under-5 mortality for children born to HIV-infected women in resource-limited settings. As access to HIV care expands and we push towards the Millennium Development Goal of reducing child mortality, we must address the risks faced by young children exposed to or infected with HIV. The Academic Model Providing Access To Healthcare (AMPATH) in Kenya provides an ideal setting in which to evaluate the growth and development of this vulnerable population, and to explore effective interventions to improve their health. AMPATH is a long-standing, academic partnership, created between the Moi University School of Medicine, Moi Teaching and Referral Hospital, and the Indiana University School of Medicine, that provides care for over 15,000 HIV-infected and HIV-exposed children, one of the world's largest pediatric HIV cohorts. Few current data focus on the best strategies to foster the growth and development of HIV-exposed and HIV-infected children under five years of age and living in resource-limited settings. The objective of this study is to evaluate the growth and development of young children of HIV-infected mothers in western Kenya, with attention to identifying areas to target for future interventions. We plan to accomplish our research objective by

	<p>pursuing the following four specific aims: Aim 1: Evaluate the changes in anthropometrics over time for children under the age of five who are born to HIV-infected mothers enrolled in AMPATH clinics. Hypothesis: Among those enrolled in AMPATH, HIV-infected children will have lower Z-scores for measured anthropometrics (WAZ, HAZ, WHZ) than HIV-exposed children. Aim 2: Determine factors associated with poor weight gain in this population of children. Hypothesis: Factors such as being orphaned, being HIV-infected, having developmental delays, having been hospitalized, and lower immunization rates will be associated with lower Z-scores for measured anthropometrics in both HIV-exposed and HIV-infected children under 5. . Aim 3: Evaluate the rates at which clinical providers detect failure-to-thrive in children under 5 years during routine AMPATH clinic visits. Hypothesis: Clinical providers will have low rates of identifying failure-to-thrive as a problem for children under-five requiring follow-up. Aim 4: Describe the mortality rates and rates of losses to follow-up in this population. Hypothesis4a: Mortality rates will be higher among those children who are HIV-infected and malnourished. Hypothesis 4b: Losses to follow-up are more common among HIV-exposed children compared to HIV-infected children. Rates of those lost to follow-up for both groups will be <20%, which is generally considered acceptable in research studies.</p>
Site(s)	
Project Period	7/1/2015 - 6/30/2017
Funding Status	Unfunded
Direct Award (USD)	
Update	The abstract was accepted and presented orally at the AIDS conference in South Africa. We have received the data pull from December 2015 and our bio-statistician is analyzing the data now.
Future Plans	We hope to complete the data analysis and write up the paper for submission.
Publication(s)	McHenry MS, Apondi E, Ayaya SO, Tu W, Bi G, Sang E, Vreeman RC. 'Evaluation of the growth of young children born to HIV-infected mothers in western Kenya.' Abstract presented orally at AIDS 2016 in Durban, South Africa. Manuscript underway.

Study Title	FLTR Evaluation
Principal Investigator(s)	Paula Braitstein, University of Toronto Sylvester Kimaiyo, Moi University
Co-Investigator(s)	Samson Ndege Juddy Wachira Becky Genberg Joseph Hogan
Working Group(s)	AMWG, PRWG
Description	The FLTR evaluation aims to evaluate the core aspects of the HIV prevention-care continuum, using a combination of quantitative and qualitative methods. We investigate issues related to Finding, Linking, Treating, and Retaining people living with HIV in AMPATH catchments, involving behavioral scientists, biostatisticians, epidemiologists, among others.

Site(s)	Bunyala, Chulaimbo, Teso
Project Period	7/1/2014 - 7/31/2017
Funding Status	Funded – Eli Lilly Foundation
Direct Award (USD)	\$300,000
Update	<p>Description: In 2007 AMPATH initiated its trademark home-based HIV counseling and testing (HBCT) program as a strategic mechanism to identify people living with HIV earlier in their disease stage in order to treat them more effectively and prevent the many negative downstream consequences of uncontrolled HIV (serious health and socioeconomic declines, transmission of the virus from mother to child, creation of orphaned children, etc.). Since then we have demonstrated that HBCT is feasible and effective in this context at diagnosing people who did not previously know they were HIV-positive, and to diagnose people in earlier stages of disease. A dataset has been developed which contains data on 14,060 unique individuals living with HIV from two rounds of HBCT (i.e. HCT and PHCT) in three high burden AMPATH catchments (Bunyala, Chulaimbo, Teso) together with the care and treatment data for those who have linked to care from the AMRS into what we are calling the 'FLTR dataset'. As HBCT has been able to reach a majority of people living in these catchments, these data can be considered population-based. These data allowed us to demonstrate the effectiveness of the FLTR strategy, and hopefully find that AMPATH actually has come very close, and closer than the national and regional estimates of the same, to achieving the UNAIDS 'Three 90's': 90% of people living with HIV knowing their status; 90% of people living with HIV receiving antiretroviral treatment (ART); and 90% of people receiving ART, being virally suppressed, effectively controlling the HIV epidemic in this region of Kenya. Data from a separate study evaluating the outcomes of persons not in care (either failed to link or linked and become lost to follow-up) are available at the request of the Principal Investigators. Also available is the master dataset from the baseline round of HBCT for Bunyala, Chulaimbo, Teso, Burnt Forest, and Webuye. The FLTR dataset is a valuable resource for the AMPATH research program because all AMPATH investigators now have access to population-based sampling frames of both HIV-positive and HIV-negative individuals in these catchments, and can layer on their own research. These datasets are also useful for measurement and evaluation of AMPATH's population health strategy. Other activities: In addition, data quality activities were done and completed for the FLTR datasets in 4 catchment areas; Teso, Port Victoria, Mukhobola and Chulaimbo during the month of September 2016. Specific activities done included; manual matching of HCT and PHCT data and peer reviews of the data by Data Assistants within themselves so as to compare and see the differences. Longitudinal and cross-sectional matching of HCT, PHCT and AMRS data was also done. A FLTR Master dataset has been developed as a resource for use by all the AMPATH Investigators in line with the approved Standard Operating Procedures. Two major challenges found at the sites include; misfiling of the encounter forms and Laboratory findings duplicated in the encounters. Development of a new FLTR protocol by the project team is on-going to be submitted to IREC for ethical approval.</p>
Future Plans	In the coming 6 months, the Project team intends to complete development of the FLTR protocol and submit to IREC for approval. Implementation of data quality

	activities will continue in all AMPATH Catchment Counties. Writing and publication of papers will also be the focus during this period.
Publication(s)	
Study Title	HI-Train: Health Informatics Training and Research in East Africa for Improved Health Care
Principal Investigator(s)	Abraham Siika, Moi University Martin Were, Vanderbilt University
Co-Investigator(s)	Ayuo, Paul Nabukenya, Josephine Mughal, Khalid Tylleskar, Thorkild
Working Group(s)	TBWG
Description	<p>With increased deployment of eHealth systems, comes the need for an appropriate health information technology workforce. This workforce includes: (a) Local level: Health IT professionals, eHealth specialized programmers, data managers, implementation managers, support specialists and reporting personnel; (b) Institutional level: chief medical information officers; and health information management specialists, (c) administrative: regional and national eHealth coordinators and eHealth monitoring and evaluation specialists, and (d) Other: health information privacy and security specialists and HI researchers. End users, institutional managers and policy makers also need to be appropriately trained on the relevant eHealth systems. Alarmingly, most sub-Saharan countries remain woefully unprepared to systematically train an adequate workforce to support the eHealth systems already being deployed. Countries like Uganda and Kenya recognize an emergent need for national strategies to build health informatics human capacity. These countries have appropriately developed national eHealth capacity-building strategies Implementing the strategies however requires direct leadership by Higher Education Institutions in the relevant countries. The urgency for sustainable mechanisms to increase HI workforce and research capacity in developing countries is self-evident. This goal can only be realized by having enough faculty members from developing countries fully trained in Health Informatics. These staff faculty can then be part of a well-functioning and high quality HI program moving forward. Recognizing this need, and the multidisciplinary competencies needed for HI training and research, our team identified partner institutions with complementary capabilities to support advanced Health Informatics training in East Africa for our project. Aims 1) Provide post-graduate (Masters and PhD) level training in Health Informatics and research. The focus will be on post-graduate training for health professionals and computer science personnel to help them become HI faculty at their institutions. 2) Increase number of women and marginalized populations in faculty-level training in Health Informatics and research at the LMIC higher education institutions. 3) Improve the quality and quantity of Health Informatics research conducted primarily by re-searchers based in the LMIC countries in collaboration with our Northern partners. 4) Provide model curricula, educational programs and approaches for faculty-level health informatics training that can be emulated by regional higher education institutions.</p>
Site(s)	Moi University, Makerere University, University of Bergen

Project Period	12/5/2013 - 6/30/2019
Funding Status	Funded – NORAD - Norwegian Agency for Development Cooperation
Direct Award (USD)	\$2,757,830
Update	The 12 students enrolled in the Master's programme in Health Informatics managed to sit for the end of year exams in September 2016. One student from the initial enrolled, deferred his studies and one other student was undertaking the pre-requisite courses for enrollment in the PhD programme at University of Bergen, Norway. In the 2016 September intake 4 students were enrolled where 2 are currently on HI-TRAIN scholarship programme. During the period, the project hosted the REDCap training at Moi University where over 30 participants attended the two day training the the College of Health Science - Medical Education Centre. The project conducted the annual meeting with NORHED in November including the leadership and project management sessions with partners from Makerere and University of Bergen. The Masters and PhD students showcased their research work during the meeting that included site visits to mHealth implementation sites at AMPATH. In December 4 PhD students and 2 staff members were sponsored to attend the OpenMRS annual conference that was held in Kampala Uganda. The project supported students on scholarship programmes through computer and book allowance support including payment of tuition fee for the 1st year and 2nd year students. One female student got the child-care support to facilitate her attend classes.
Future Plans	The project plans to conduct more dissemination activities that will include hackatons and workshops within the region. Students and staff are also expected to present at regional and international conferences during the next 6 months. The project will initiate animated process for the approval of the PhD curriculums at Moi and Makerere universities. It is also expected that partner institutions at LMIC will initiate processes for the review of the approved Masters in Health informatics curricula. The project will also establish the scholarship programmes for faculty to facilitate their enrollment into the PhD programmes at University of Bergen, Norway.
Publication(s)	Were, M. C., Kamano, J. H., & Vedanthan, R. (2016). Leveraging Digital Health for Global Chronic Diseases. <i>Global Heart</i> , 11(4), 459-462. http://doi.org/10.1016/j.gheart.2016.10.017

Study Title	IeDEA Comprehensive Adherence Measure for Pediatrics (ICAMP)
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Samuel Ayaya, MBChB, MMED Department of Child Health and Paediatrics Moi University School of Medicine samuel.ayaya@gmail.com Annette Sohn, MD Director TREAT Asia/amfAR annette.sohn@treatasia.org Mary-Ann Davies, MB ChB School of Public Health
Working Group(s)	PRWG

<p>Description</p>	<p>The primary objective of the proposed study is to validate an adherence questionnaire for pediatric and adolescent patients at 3 leDEA sites using electronic dose monitors (Medication Event Monitoring Systems®, or 'MEMS', MWV/AARDEX, Switzerland) as external criterion for adherence. While the adherence questionnaire (known as the Comprehensive Adherence Measure for Pediatrics - Short Form, or 'CAMP-SF') has been previously validated in a large, urban referral site at AMPATH in the East Africa leDEA region, re-validation is warranted to ensure external and internal validity is upheld across resource-limited sites. In conducting this validation study, we will also collect valuable, detailed prospective data on adherence to ART among this sample of HIV-infected children and adolescents using electronic dose monitoring. The study has the following specific aims and hypotheses: Specific Aim 1: Validate a 10-item adherence questionnaire for routine use as an adherence measurement tool in resource-limited settings. Hypothesis 1a: Adherence estimates from the CAMP-SF will be reliable and valid across 3 leDEA sites in East Africa, Southern Africa and Asia-Pacific when compared with MEMS electronic dosing data. Specific Aim 2: Describe pediatric adherence to ART prospectively over 6 months using electronic dose monitoring (i.e., MEMS) and the CAMP-SF among a sample of HIV-infected children and adolescents at 3 leDEA sites. Hypothesis 2a: Rates of adherence to ART will be similar for children across different leDEA sites. Hypothesis 2b: More pediatric non-adherence will be reported during prospective evaluation using the CAMP-SF than in existing rates reported in leDEA datasets for children. Specific Aim 3: Evaluate factors associated with adherence among a sample of HIV-infected children and adolescents at 3 leDEA sites. Hypothesis 3a: Risk of medication non-adherence is increased among older children, children with lower disease stages, children with higher CD4 counts, children with a higher medication burden, and orphaned children. Hypothesis 3b: Sites will differ in factors that may influence adherence, including number of children initiating ART; availability of nutritional support, adherence support, disclosure support, and pediatric formulations; and routine use of standardized adherence measures. Specific Aim 4: Assess evidence of the impact of ART non-adherence on clinical outcomes such as treatment failure and mortality, and programmatic factors such as loss-to-follow up. Hypothesis 4a: Medication non-adherence by MEMS is associated with increased risk of changing to second-line antiretroviral medications. Hypothesis 4b: Medication non-adherence by MEMS is associated with increased risk of mortality. Hypothesis 4c: Medication non-adherence by MEMS is associated with high risk of loss to follow-up.</p>
<p>Site(s)</p>	<p>Busia District Hospital, HIV-NAT Clinic, Bangkok, Thailand; Rahima Moosa Mother and Child Hospital, Johannesburg, South Africa</p>
<p>Project Period</p>	<p>8/1/2014 - 7/31/2016</p>
<p>Funding Status</p>	<p>Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID)</p>
<p>Direct Award (USD)</p>	<p>\$171,257.00</p>
<p>Update</p>	<p>The primary objective of the proposed study is to validate an adherence questionnaire for pediatric and adolescent patients at 3 leDEA sites using electronic dose monitors (Medication Event Monitoring Systems®, or 'MEMS', MWV/AARDEX, Switzerland) as external criterion for adherence. While the adherence questionnaire (known as the Comprehensive Adherence Measure for Pediatrics - Short Form, or 'CAMP-SF') has</p>

been previously validated in a large, urban referral site at AMPATH in the East Africa leDEA region, re-validation is warranted to ensure external and internal validity is upheld across resource-limited sites. In conducting this validation study, we will also collect valuable, detailed prospective data on adherence to ART among this sample of HIV-infected children and adolescents using electronic dose monitoring. The study has the following specific aims and hypotheses: Specific Aim 1: Validate a 10-item adherence questionnaire for routine use as an adherence measurement tool in resource-limited settings. Hypothesis 1a: Adherence estimates from the CAMP-SF will be reliable and valid across 3 leDEA sites in East Africa, Southern Africa and Asia-Pacific when compared with MEMS electronic dosing data. Specific Aim 2: Describe pediatric adherence to ART prospectively over 6 months using electronic dose monitoring (i.e., MEMS) and the CAMP-SF among a sample of HIV-infected children and adolescents at 3 leDEA sites. Hypothesis 2a: Rates of adherence to ART will be similar for children across different leDEA sites. Hypothesis 2b: More pediatric non-adherence will be reported during prospective evaluation using the CAMP-SF than in existing rates reported in leDEA datasets for children. Specific Aim 3: Evaluate factors associated with adherence among a sample of HIV-infected children and adolescents at 3 leDEA sites. Hypothesis 3a: Risk of medication non-adherence is increased among older children, children with lower disease stages, children with higher CD4 counts, children with a higher medication burden, and orphaned children. Hypothesis 3b: Sites will differ in factors that may influence adherence, including number of children initiating ART; availability of nutritional support, adherence support, disclosure support, and pediatric formulations; and routine use of standardized adherence measures. Specific Aim 4: Assess evidence of the impact of ART non-adherence on clinical outcomes such as treatment failure and mortality, and programmatic factors such as loss-to-follow up. Hypothesis 4a: Medication non-adherence by MEMS is associated with increased risk of changing to second-line antiretroviral medications. Hypothesis 4b: Medication non-adherence by MEMS is associated with increased risk of mortality. Hypothesis 4c: Medication non-adherence by MEMS is associated with high risk of loss to follow-up. In the last six months, all three leDEA study sites - Busia clinic at AMPATH (Kenya), HIV-NAT clinic (Bangkok, Thailand) and Rahima Moosa Mother Child Hospital (Johannesburg, South Africa) - have completed 6 months of study follow-up and data collection with approximately 100 pediatric patients and their caregivers at each site. A close-out study visit was made by PI Vreeman in July to the Johannesburg site. Data have been cleaned and we are now working on preliminary analyses.

Future Plans

Over the next 6 months, we plan to:

- We expect to complete data analysis over the next six months.
- Prepare manuscripts for publication with our partner sites and conference presentations

Publication(s)

Study Title

Incidence of and risk factors for toxicity among HIV-infected children receiving cART: Findings from a large observational cohort in western Kenya

Principal Investigator(s)

Beatrice Jakait, Moi Teaching and Referral Hospital
Paula Braitstein, University of Toronto

Co-Investigator(s)	Prof. Nyandiko, Prof. Vreeman, Dr. Rakhi Karwa, Dr. Sonak Pastakia, Dr. Celia Ng'etich, Mr. Alfred Keter
Working Group(s)	PRWG
Description	This is a retrospective study whose aim is to find out the incidence of adverse drugs reactions in children and the factors associated with it in children on antiretroviral therapy in AMPATH.
Site(s)	
Project Period	12/16/2014 - 9/15/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	In the last six months we have written the manuscript.
Future Plans	In the next six months we hope to finish revisions to the manuscript and send it out for publication after going through the publications committee.
Publication(s)	

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

of ACTs opened the door to over-treatment and overuse of ACTs. The overall objective of this study is to evaluate the public health impact of targeted antimalarial subsidies through scale-up by determining the community-wide effects of targeting an antimalarial subsidy through a partnership between CHVs and the private retail sector. Cluster-randomized design was used to assign community units to either an intervention or control arm. The study is being carried out in two sub-counties in Western Kenya (Bungoma East and Kiminini) with similar malaria burden but different access to health services. Community Units (CUs) in each sub-county were clustered and randomized. There are 32 CUs in total across both sub-counties, 20 in Bungoma East and 12 in Kiminini. Half of the community units in each study area (10 in Bungoma East sub-county and 6 in Kiminini) were randomly allocated to the intervention and the remainder of the community units to the comparison arm. In the intervention arm a conditional subsidy is offered in the form of a voucher providing for the purchase of a WHO-qualified ACT at a reduced, fixed price to those with a positive malaria test that can be redeemed at a local drug retailer, while individuals in the comparison arm only receive standard community health volunteer (CHV) visits. Cross-sectional household surveying at pre-intervention, and 6 months, 12 months, and 18 months post-baseline will be used to determine any change in the percent of fevers that are tested for malaria and the effect of testing on subsequent drug purchasing decisions. The primary hypothesis to be tested is that offering a fixed-price voucher that reduces the cost for ACT purchase in the retail sector conditional on a positive malaria test (targeted subsidy) can improve uptake of testing for malaria and will increase the proportion of fevers tested for malaria before treatment. The primary outcome of this study is to compare the percent of fevers that receive a malaria test from any source between the intervention and control arms. The secondary outcomes of this study will also be measured and compared between intervention and control arms. The main secondary outcome is the percent of all ACTs used that were taken by people with a malaria positive test. Additional secondary outcomes are: the percent of all ACTs used that were taken by people without a test, the percent of those with a positive test who got an ACT, and the percent of those with a negative test who got an ACT.

Site(s) Bungoma East Subcounty in Bungoma County and Kiminini Subcounty in Trans-Nzoia County

Project Period 1/1/2014 - 12/31/2018

Funding Status Funded - NIH

Direct Award (USD) \$1,654,917

Update Community Health Workers (CHWs) continued to provide on-demand, free malaria rapid diagnostic testing (RDT) to eligible community members. Collectively, these participating CHWs serve a total population of more than 100,000 people. The study team continues to provide oversight and conduct meetings with each community unit (CU: a group of approximately 20 CHWs that serve approximately 5,000-7,000 people; also the unit of randomization for our study) once per month to review the quality of their work, discuss challenges, and distribute supplies. These meetings are conducted in collaboration with the Ministry of Health directors of CHW programs. Our interactions with enrolled private medicine retailers continue on a bi-weekly basis.

During visits to shops the study team collects the vouchers that have been redeemed by malaria-positive study participants and thus continuously tracks intervention uptake throughout the study. During this project period, we undertook significant sensitization activities in both communities and health facilities. In these communities, we enacted door-to-door sensitization campaigns to explain the services, including RDT testing, available through community health workers. Community Health Workers (CHWs) continued to provide on-demand, free malaria rapid diagnostic testing (RDT) to eligible community members. Collectively, these participating CHWs serve a total population of more than 100,000 people. The study team continues to provide oversight and conduct meetings with each community unit (CU: a group of approximately 20 CHWs that serve approximately 5,000-7,000 people; also the unit of randomization for our study) once per month to review the quality of their work, discuss challenges, and distribute supplies. These meetings are conducted in collaboration with the Ministry of Health directors of CHW programs. Our interactions with enrolled private medicine retailers continue on a bi-weekly basis.

During visits to shops the study team collects the vouchers that have been redeemed by malaria-positive study participants and thus continuously tracks intervention uptake throughout the study. During this project period, we undertook significant sensitization activities in both communities and health facilities. In these communities, we enacted door-to-door sensitization campaigns to explain the services, including RDT testing, available through community health workers. As part of that process evaluation, we conducted a mid-term assessment of CHW participation in community-based malaria diagnostic testing between May and June 2016. Given the central role of motivation and satisfaction in the sustainability of a program implemented by a volunteer workforce, we designed a tool to measure CHWs' satisfaction with their role in the malaria project and the feasibility of their continued involvement. Secondary objectives included eliciting the main challenges the CHWs have faced in implementing the study, especially unanticipated constraints on the CHWs' other activities. Analyses of these data are ongoing but preliminary results were out in October 2016. We found that CHWs reported high levels of satisfaction with their role in the project. Encouragingly, we also identified a positive association between CHW satisfaction and the number of years worked as a CHW. Increasing community awareness about malaria diagnosis and the importance of appropriate drug usage, and the CHWs' role in facilitating diagnosis, could improve the perception of CHWs and enhance their role in the community. In addition to CHW perceptions, we also incorporated an evaluation to measure the quality and accuracy of testing by CHWs at the intervention mid-point. We randomly selected 100 participating CHWs to perform an RDT in the presence of a trained observer who used a 22-point checklist to record their adherence to each step. On average, CHWs correctly performed 89% of steps, and specifically 95% of safety steps. These findings provide strong evidence for safe and accurate diagnosis in the community by trained lay-persons and demonstrate that skills are maintained over time. In July-September 2016, we conducted the twelve-month planned follow-up surveys. 1750 households were interviewed in the twelve month surveys. Data have been processed, cleaned, and preliminary analyses and comparisons with baseline data are underway. The local government health teams continued to support and actively participate in the program, CHW readings of RDTs have been highly accurate as determined by review of the used cassettes, and drug shop participation has generally been good. Given the complexity of the intervention and the size of the study

	population, we are very pleased with both the community and health system reception and participation, as well as smooth project operation.
Future Plans	Implementation of the subsidy intervention will continue in the study sites until the 18-month endpoint (Mar-Apr 2017). The final community-based survey will take place in April-May of 2017 at the end of the intervention period, we will conduct final interviews and focus group discussions with both the CHWs and retail shop owners, designed to understand their perceptions about the partnership/intervention as part of our multi-arm process evaluation. Analysis of Aim 2 data will occur throughout the upcoming project period with an emphasis on 1) primary and secondary study endpoints, 2) determinants of high uptake and impact of the intervention, 3) process evaluation to describe the actual implementation vis a vis the intended implementation, and 4) projection of costs, scale-up feasibility, and sustainability of the public-private partnership compared to traditional subsidy approaches.
Publication(s)	Prudhomme O'Meara, W., Mohanan, M., Laktabai, J., Lesser, A., Platt, A., Maffioli, E., Turner, E. L., & Menya, D. (2016). Assessing the independent and combined effects of subsidies for antimalarials and rapid diagnostic testing on fever management decisions in the retail sector: results from a factorial randomised trial in western Kenya. <i>BMJ Global Health</i> , 1(2),e000101. http://dx.doi.org/10.1136/bmjgh-2016-000101 .



Study Title	IU Health Cardiovascular Research Biobanking Project
Principal Investigator(s)	Tom Inui, Indiana University Sylvester Kimaiyo, Moi University
Co-Investigator(s)	
Working Group(s)	AMWG
Description	Atrial fibrillation is the most common sustained arrhythmia in high-income countries. Recent insights have been made with regard to the genetic variations that may predispose an individual to developing atrial fibrillation. There has long been observed a disproportionately low prevalence of atrial fibrillation among Africans and African-American compared to people of European descent. Whether mutations in the genes known to cause atrial fibrillation are also causing AF among Kenyan patients with this disorder is unknown. Identification of the frequency of mutations in these genes in patients with atrial fibrillation in Kenya may shed light into the causal pathways of atrial fibrillation in this population. Using a case-control (1:2) research design in a Kenyan population with atrial fibrillation, we propose to perform mutational analysis of the coding sequence and flanking splice sites of the KCNQ1, KCNJ2, KCNE2 and KCNA5 genes known to be mutated in familial and lone atrial fibrillation in patients from high-income countries. A thorough phenotyping protocol will be employed which will include clinical assessment, a medical history, echocardiography and electrocardiography. Genetic material will be collected, stored and processed in Eldoret as the first initiative of the Genetic Biorepository Initiative (PI: Inui, Co-PI: Emonyi) and subsequently shipped for analysis of specific alleles at Indiana University. Using a convenience sample of approximately 140 patients with atrial fibrillation and 140 controls, we will demonstrate the frequency of pathological mutations in the

	aforementioned genes and provide a thorough clinical description of patients with atrial fibrillation including echocardiographic descriptions and the burden of other comorbid illnesses.
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/30/2012 - 12/31/2015
Funding Status	Funded – IU Health
Direct Award (USD)	\$1,060,000
Update	Over the past six months (July-December, 2016), the clinical manuscript was rejected in its first journal submission and has been revised to submission to an arrhythmia journal. Validation of genomic risk factor findings has been completed and a manuscript is being prepared for submission on these findings by Dr. Matteo Vatta. An opportunity is being explored to contribute the SIGNAL AF data to a collaborative project that has materialized under the auspices of H3 Africa. Monthly team conference calls continue for coordination of activities. Drs. Bloomfield and Temu are serving as anchors.
Future Plans	The next six months should see resubmission of the clinical AF in Africa manuscript and completion of a genomic arrhythmia risk factor manuscript.
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)	
Working Group(s)	AMWG, SSRN, PHPCWG
Description	This project is focused on identifying the individual, psychosocial, and structural barriers to timely linkage and retention. This project has three specific aims: 1. To comprehensively describe linkage and retention to HIV care following home-based counseling and testing by examining time from testing to linkage and the socioeconomic, demographic and structural determinants of linking to care. We will conduct retrospective and multilevel analyses using existing de-identified clinical and facility-level data collected within AMPATH, defining linkage to care as the completion of an initial HIV clinical encounter with a provider following testing. We will also examine factors that predict retention in HIV care over time. 2. To characterize the psychosocial and structural facilitators and barriers to linkage and retention to care following positive HIV diagnosis through HBCT and PITC. We will conduct a qualitative study to examine the psychosocial factors inhibiting or motivating linkage to care, experiences in accessing care, and factors that promote or interrupt retention among those who tested positive via HBCT or PITC. We will also collect data from clinicians and community health workers to examine how features of the healthcare system facilitate or constrain linkage and retention to care. 3. To develop and implement a

	<p>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.</p>
Site(s)	Other
Project Period	6/4/2012 - 12/20/2013
Funding Status	Funded – NIH - National Institute of Mental Health (NIMH)NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	\$152,806
Update	<p>During the second half of 2016, we finished data collection for the second aim of the study. We conducted qualitative research to characterize the psychosocial and structural facilitators and barriers to linkage and retention to care following positive HIV diagnosis through home-based counseling and testing from the perspective of 'adults who linked to care' and 'adults who did not link to care'. In July 2016, we completed recruitment for 30 in-depth interviews with adults who did not link to care following an HIV-positive test result through home-based counseling and testing in the Bunyala region of western Kenya. From July-September 2016, we completed transcription and translation of this data set, as well as from the in-depth interviews completed earlier in the year among adults who linked to care following testing. Data quality monitoring and coding of this data was carried out from October 2016. We have finished the initial rounds of coding this data. We are currently analyzing this data. We are also completing analysis of the qualitative data collected last calendar year from n=60 health care providers.</p>
Future Plans	<p>Over the following 6 months, we plan to finish five planned manuscripts from our health care providers data set focused on the following topics: 1) Provider perspectives on patient-provider relationships; 2) System and facility level factors that impact engagement in HIV care; 3) Communication dynamics between providers and patients; 4) Provider perspectives on the role of the patient during medical encounters; and 5) Challenges specific to gender in patient-provider relationships. These manuscripts focus on the role of the health care system and providers in encouraging engagement in the HIV care cascade. Additionally we aim to complete coding of the linkage qualitative data. We are currently in the early phases of analysis and expect two manuscripts from this data: 1) Facilitators and barriers to linkage to care following home-based counseling and testing; and 2) The role of stigma in engagement in the HIV care cascade.</p>
Publication(s)	

Study Title	MCH STUDY (Evaluations at Infant and Child Visits a MCHs in western Kenya: A Needs Assessment)
Principal Investigator(s)	Megan McHenry, Indiana University Eren Oyungu, Moi University
Co-Investigator(s)	Roselyne Ananda
Working Group(s)	PRWG
Description	The specific aims for MCH study are : Aim 1: To identify the evaluations and preventative care performed at MCH clinics and identify additional preventative areas that MCH clinical staff are interested in investigating further. Aim 2 :To determine the frequency of visits for children attending MCH clinics and also identify at what ages a child is more likely to have visited the MCH. Aim 3.:To determine the scope to which child development is currently evaluated at the MCH clinics and documented in the Mother and Baby Booklets. The study took place in western Kenya at the following MCH clinics: MTRH, Turbo, Webuye, Mosoriot, Burnt Forest, and Kitale. During this study, we recruited two groups of study participants. The first was clinical staff working at each of the MCHs. The second group were caregivers who brought young children to the MCH. This study was reviewed and approved by the Indiana University School of Medicine Institutional Review Board and the Moi University Institutional Research and Ethics Committee.
Site(s)	Burnt Forest Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	9/26/2016 - 9/26/2017
Funding Status	Unfunded
Direct Award (USD)	
Update	Data that was collected through oral interviews from the study participants 33 clinical staff and 78 caregivers ,enabled us to learn what aspects of the Mother and Baby Booklet that are typically completed at each visit, and what areas MCH clinical staff feel may need more attention, and how often caregivers are coming with their children to the MCH, if there are particular ages when caregivers ensure their children are seen at the MCH, and what pages in their book are typically completed when they come.
Future Plans	In the next 6 months, we plan to complete the analysis of data collected from the oral interviews to determine strategies to improve the preventative healthcare that MCH clinics provide, with a focus on child development.
Publication(s)	



Study Title	NEURODEV (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study)
Principal Investigator(s)	Megan McHenry, Indiana University

	Eren Oyungu, Moi University
Co-Investigator(s)	Roselyne Ananda
Working Group(s)	PRWG
Description	<p>The specific aims for Neurodev (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study) are: Aim 1. To utilize qualitative methods to determine the perceived etiology, manifestations, and intervention options for child NDDs from the perspectives of clinical staff and caregivers of HIV-infected and HIV-exposed children in Kenya. Aim 2: To develop brief, candidate neurodevelopmental screening questions that are clinically relevant and culturally acceptable by utilizing developmental assessments validated in other settings and incorporating contextual caregiver and clinicians' perspectives. Aim 3 : To evaluate the feasibility of implementing a validation study to examine NDD screening methods in a pilot sample of children under three years of age born to HIV-infected mothers. In Phase One, we utilized semi-structured interviews (SSIs) and focus group discussions (FGDs) with caregivers and clinicians to understand current knowledge and beliefs about NDDs. FGDs were chosen for caregivers to generate information on collective views of neurodevelopment and the meanings and implications that lie behind those views. SSIs were chosen for clinical staff to address several key questions specific to their individual training and experiences, while allowing both the interviewer and clinical staff to further pursue an idea or response in more detail. Phase Two will allow us to pilot key methods needed for future validation testing of these items. As we aim towards a large validation study to assess the reliability and validity of these screening questions in this setting, we will conduct prospective feasibility testing, piloting these questions during cognitive interviews with caregivers and clinical officers, in the clinical setting in Kenya and also piloting the implementation of the gold standard for developmental screenings - lengthy, comprehensive developmental assessments of young children. No modifications have been made to the specific aims as stated in the original proposal. We have ongoing Institutional Review Board and local ethics committee approval for the aims.</p>
Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital, Port Victoria Sub-District Hospital, Turbo Health Centre, Webuye District Hospital
Project Period	1/10/2016 - 9/30/2017
Funding Status	Funded – Indiana University – Center for AIDS Research
Direct Award (USD)	\$597,800
Update	Data that was collected through semi-structured interviews on 25 clinical staff and focus group discussions on 67 caregivers to understand the current knowledge and beliefs about Neurodevelopmental delays. For caregivers we generated information on collective views of neurodevelopment and for clinical staff it addressed several key questions specific to their individual training and experiences.
Future Plans	In the next 6 months, we plan to recruit 10 clinical officers for cognitive interviewing and asking screening questions to them to determine the feasibility of methods and measure reliability. These findings will be compared to potential gold-standard

	developmental assessments to determine validity by having a research staff perform the assessments on forty children. Also a research staff was trained to administer the Bayley Scales of Infant and Toddler Development(a neurodevelopmental assessment tool), which will be culturally adapted for this study during the adaptive phase which we are awaiting approval of amendment from the Institutional bodies to commence, the adaptive phase aim is to culturally adapt the Bayley Scales for use in our population of young children here in Kenya.
Publication(s)	
Study Title	Nurse Management of Hypertension Care in Rural Western Kenya
Principal Investigator(s)	Rajesh Vedanthan, Mount Sinai School of Medicine Sylvester Kimaiyo, Moi Teaching and Referral Hospital
Co-Investigator(s)	
Working Group(s)	AMWG, CVMD
Description	This project aims to evaluate barriers and facilitators to nurse management of hypertensive patients in rural western Kenya, using a qualitative research approach. The four specific aims for attaining this objective are: Aim 1: To evaluate facilitators and barriers to nurse-based management of hypertensive patients in rural western Kenya. This will be accomplished by conducting a rapid assessment procedure involving key informant interviews, focus group discussions, and field observations. Aim 2: To develop and evaluate an innovative smartphone-based DEcision Support and Integrated REcord-keeping (DESIRE) tool utilizing a participatory, iterative, human-centered design process, to assist nurses taking care of hypertensive patients. We will evaluate the usability and feasibility of the DESIRE tool using qualitative methods (e.g. think-aloud, mock patient encounters, semi-structured interviews, and focus groups). Aim 3: To conduct an impact evaluation of a pilot program for nurse-based management of hypertension to be implemented by AMPATH, by performing secondary analysis of routine clinical data collected by AMPATH. The primary outcome measure will be change in systolic blood pressure in hypertensive patients assigned to nurse-based management after one year. Aim 4: To estimate the nurse workforce requirements for stable, long-term treatment of hypertension throughout western Kenya, using a needs-based workforce estimation model.
Site(s)	Mosoriot Rural Health Training Centre, Turbo Health Centre
Project Period	9/17/2011 - 7/30/2016
Funding Status	Funded – NIH – Fogarty International Center (FIC)
Direct Award (USD)	\$675,543
Update	Progress for this project over the last six months is delineated below. Aim 1: Manuscript published in Ethnicity and Disease (2016) Aim 2: Secondary sub-aim: Patient perspectives on mHealth Focus group discussions and key informant interviews

	complete Transcription/translation nearly complete Aim 3: Manuscript in preparation, nearly complete Aim 4: Manuscript in preparation
Future Plans	Aim 2: Secondary sub-aim- Complete transcriptions/translations; Initiate manuscript Aim 3: Complete and submit manuscript Aim 4: Complete and submit manuscript
Publication(s)	Vedanthan R., Tuikong N., Kolfer C., Blank E., Kamano J.H., Naanyu V., Kimaiyo S., Inui T.S., Horowitz, C.R., Fuster V., (2016). Barriers and Facilitators to Nurse Management of Hypertension: A Qualitative Analysis from Wester Kenya. <i>Ethnicity & Disease</i> , 26(3)315-322. DOI: 10.18865/ed.26.3.315



Study Title	Optimizing Linkage and Retention to Hypertension Care in Rural Kenya
Principal Investigator(s)	Valentin Fuster, Mount Sinai School of Medicine Jemima Kamano, Moi University
Co-Investigator(s)	Fuster, V. Horowitz, C. Were, M. Inui, T. Hogan, J. Velazquez, E. Bloomfield, G. Naanyu, V. Menya, D. Kimaiyo, S. Akwanalo, C.
Working Group(s)	AMWG, CVMD
Description	<p>Hypertension awareness, treatment, and control rates are low in most regions of the world. A critical component of hypertension management is to facilitate sustained access of affected individuals to effective clinical services. In partnership with the Government of Kenya, the Academic Model Providing Access to Healthcare (AMPATH) Partnership is expanding its clinical scope of work in rural western Kenya to include hypertension and other chronic diseases. However, linking and retaining individuals with elevated blood pressure to the clinical care program has been difficult. To address this challenge, we propose to develop and evaluate innovative community-based strategies and initiatives supported by mobile technology. The objective of this project is to utilize a multi-disciplinary implementation research approach to address the challenge of linking and retaining hypertensive individuals to a hypertension management program. The central hypothesis is: community health workers (CHWs), equipped with a tailored behavioral communication strategy and a smartphone-based tool linked to an electronic health record, can increase linkage and retention of hypertensive individuals to a hypertension care program and thereby significantly reduce blood pressure among these patients. We further hypothesize that these interventions will be cost-effective. To test these hypotheses and achieve the overall objectives, we will pursue the following specific aims: Aim 1: Identify the facilitators and barriers to linking and retaining individuals with high blood pressure to a hypertension care delivery program, using a combination of qualitative research methods: 1) baraza (traditional community gathering) form of inquiry; 2) focus group discussions among individuals with elevated blood pressure during home-based testing; and 3) focus group discussions among CHWs. Subsidiary Aim 1.1: Using identified facilitators and barriers, develop a tailored behavioral communication strategy guided by the Health Belief Model modified by incorporating emotional elements for the CHWs to use with hypertensive patients, focusing on regular and timely attendance at hypertension clinic. We will test the communication strategy for face and content validity using focus group discussions with CHWs and individuals with</p>

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 also equipped with smartphone-based tool linked to the AMRS. The co-primary outcome measures will be: 1) documented linkage to care following home-based testing, and 2) one year change in systolic blood pressure among hypertensive individuals. **Aim 3:** Evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial. Cost effectiveness will be presented both in terms of costs per unit decrease in blood pressure and in terms of costs per reductions in cardiovascular disease (CVD) risk by extrapolating one-year blood pressure reductions to CVD risk reductions based on the QRISK2-2011 CVD risk calculator specific for Black African populations. This research will generate innovative and productive solutions to the expanding global problem of hypertension, and will add to existing knowledge on scalable and sustainable strategies for effectively managing hypertension and other chronic diseases in low- and middle-income countries.

Site(s)

Mosoriot Rural Health Training Centre, Turbo Health Centre

Project Period

5/4/2012 - 3/31/2017

Funding Status

Funded – NIH - National Heart, Lung, and Blood Institute (NHLBI)

Direct Award (USD)

\$2,104,519

Update

Administrative

- All-Investigator conference call held in August 2016 and January 2017
 - Positive feedback attained from participants on call
- Capacity building of the study personnel with specialized and targeted training ongoing
- Procurement of necessary supplies for completion of 12 month assessments ongoing
- New research assistant was hired
- Faculty and study team visits to Eldoret, Kenya for the purposes of site monitoring, capacity building, and training are ongoing

Aim 1 (Barriers & Facilitators to Linkage/Retention): ◦ Secondary qualitative manuscript in preparation

Subsidiary Aim 1.1 (Behavioral Assessment and Communication Strategy):

- Content validity manuscript in preparation

Subsidiary Aim 1.2 (Smart-phone-based tool):

- Smartphone-based assessment tools and MUzima-based data collection tool (both linkage and retention) continue to be utilized in the field

Aim 2 (Cluster RCT):

- o Community Health Workers (CHWs) and Community Health Extension Workers (CHEWs) in the tech-based arm have received follow-up training smartphone use, device management, app/software use, and troubleshooting o Enrollment has been closed (n=1508) and 12 month follow-ups are ongoing (725 of 1508 completed).
- o Assessment tool:
 - o As of December 2016 a total of 348 behavioral assessment tools have been administered by CHWs
 - o Web-based entry of paper behavioral assessment tools ongoing
- Data Management
 - o Data management protocol developed and in use
 - o SAS Script and Concept dictionary developed and in use
 - o Data cleaning ongoing
- Process Evaluation
 - o Content Analysis of Focus Group Discussions ongoing
 - o Analysis of usability focus groups and questionnaires ongoing
 - o Process Evaluation manuscript is in preparation

Aim 3 (Cost Effectiveness Analysis):

- Costing questionnaire survey (CQS):
 - o Administration of 12 month follow-up costing questionnaires is ongoing
 - o Preliminary data analysis is ongoing Intervention cost tracking procedures are being implemented

Future Plans

Administration:

- Submit a no-cost extension request to NIH/NHLBI to continue data cleaning, data analysis, and manuscript preparation

Aim 1:

- Complete and submit secondary manuscript

Aim 1.1

- Complete and submit manuscript

Aim 1.2

- Continue device management and mentorship of use of devices

Aim 2:

- Complete 12 month follow-up visits for all trial arms
- Continue data management and interim analyses
- Baseline manuscript re: health care utilization, costs, insurance, and poverty

Aim 3:

- Complete administration of 12-month f/u costing questionnaire
- Complete tool (spreadsheet) for cost tracking analysis of intervention delivery

Publication(s)	<p>The following manuscripts are in preparation:</p> <ul style="list-style-type: none"> o Perceptions of the Role of Community Health Workers in Hypertension Management: A Qualitative Study from Rural Kenya • Development and Validation of a Behavioral Assessment Tool to Optimize Linkage and Retention to Hypertension Care in Kenya: LARK Hypertension Study • Process Evaluation • Health care utilization, costs, insurance, and poverty
-----------------------	--

Study Title	Pathways to better health
Principal Investigator(s)	Paula Braitstein, University of Toronto
Co-Investigator(s)	
Working Group(s)	AMWG, PRWG
Description	The goal of this study is to merge together data from the home-based HIV counseling and testing program with HIV care and treatment data from the AMRS.
Site(s)	The catchments of Bunyala, Teso, and Chulaimbo
Project Period	1/4/2016 - 10/31/2016
Funding Status	Funded – Regenstrief Institute
Direct Award (USD)	\$45,000
Update	Data merging and data quality activities have been done in 3 AMPATH Catchment areas; Teso, Bunyala (Port Victoria and Mukhobola) and Chulaimbo and currently ongoing at the AMPATH Central Modules. The patient matching module could not work as planned, therefore we used manual matching of only the HIV positives in all the catchment areas. No Cost Extension of the Grant of \$19,340 was requested for 6 months until 30th April 2017. A budget was done to include personnel, travel, communication, training and rent for sitting space for the Data Assistants. The No Cost Extension request was approved in November 2016. This will facilitate completion of data quality activities.
Future Plans	In the next 6 months, the project team intends to further train the Data Assistants, continue with data merging and data quality activities and regularly hold monthly feedback meeting to monitor the progress of the work.
Publication(s)	

Study Title	Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)
Principal Investigator(s)	Rachel Vreeman, Indiana University W. Nyandiko, Moi University
Co-Investigator(s)	Marete, I. Inui, T. Mwangi, A. Hogan, J. MC Henry, M.

Working Group(s)	PRWG
Description	The purpose of this study is to assess the effect of a patient- and family-centered intervention guiding disclosure to HIV-infected Kenyan children using a randomized trial comparing the intervention to routine care. The primary endpoint will be probability of disclosure among children, with secondary endpoints of adherence, clinical outcomes, psychological distress and social outcomes. Phase One, which will last 6 months, focuses on cultural adaptation of the intervention materials through intensive patient participation, including focus groups and cognitive interviewing; selecting narrative components; and training dedicated disclosure counselors. Phase Two consists of a randomized design to examine whether the culturally adapted, multi-component HADITHI intervention increases the prevalence of disclosure to HIV-infected children in western Kenya compared to children receiving usual care. HIV-infected children ages 10-15 years who are enrolled in HIV care within the eight selected AMPATH clinics in western Kenya will be eligible for study enrollment and have a comprehensive patient assessment every 6 months for 2 years.
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital , Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	9/1/2012 - 9/1/2016
Funding Status	Funded – NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	\$1,886,804
Update	Phase 1: The first phase of the HADITHI study was a qualitative inquiry into the experiences of HIV-infected adolescents and caregivers of HIV-infected children with HIV disclosure to children in terms of their beliefs, practices and preferences. Dissemination of early findings are proceeding. Phase 2: Phase 2 of the HADITHI study aimed to evaluate the impact of clinic-level disclosure intervention that involves multiple counseling components, including peer support groups and individual counseling. All 286 patients were recruited for Phase 2, and data collection for all active participants in the 24 months of patient follow-up has been completed. Month 24 assessments included blood samples for viral load testing and hair sampling for ARV concentrations, in addition to the multiple measures of adherence, depression, behavioral symptoms, stigma, quality of life, and social functioning. In the last six months, key analysis is ongoing. The HADITHI counseling materials created during the study includes counseling pamphlets, disclosure and stigma videos, an animation tool, which was created using cross-cultural adaptation techniques continued to be used in most clinics.
Future Plans	Over the next 6 months, we plan to: Complete key data analysis. Begin to evaluate drug level concentration on hair samples sent to USA, as well as compile evaluations assessing the feasibility and validity of this type of testing in our population. Prepare manuscripts and conference presentations. Continue to implement the HADITHI counseling tools in AMPATH clinics for helping disclosure practices with pediatric patients
Publication(s)	<u>Publications:</u>

1. McHenry MS, Nyandiko WM, Scanlon ML, Fischer LJ, McAteer CI, Aluoch J, Naanyu V, Vreeman RC. HIV Stigma: Perspectives from Kenyan Child Caregivers and Adolescents Living with HIV. *J Int Assoc Provid AIDS Care*. 2016 Sep 21. pii: 2325957416668995. [Epub ahead of print] PMID: 27655835

2. McAteer CI, Truong NT, Aluoch J, Deathe AR, Nyandiko WM, Marete I, Vreeman RC. A systematic review of measures of HIV/AIDS stigma in paediatric HIV-infected and HIV-affected populations. *J Int AIDS Soc*. 2016 Oct 6;19(1):21204. doi: 10.7448/IAS.19.1.21204. Review. PMID: 27717409

Presentations:

1. McAteer C, Aluoch J, Mutungi C, Ombitsa R, Marete I, Nyandiko W, Vreeman R. Assessment of the utilization of culturally-sensitive disclosure counseling tools for HIV-infected adolescents and caregivers in Western Kenya. International AIDS Society. Durban, South Africa. July 2016.

2. McHenry M, Apondi E, McAteer C, Nyandiko W, Fischer L, Ombitsa R, Aluoch J, Scanlon M, Vreeman R. Tablet-Based Resources for Disclosure Counseling for HIV-Infected Adolescents and their Families in Kenya: A Pilot Study of Perspectives from Providers. International AIDS Society. Durban, South Africa. July 2016.

3. Lewis CT, Dickerson-Putman J, McAteer C, Aluoch J, Ngare E, Odhiambo C, Nyandiko W, Vreeman R. Creating Contextualized Films Through Community Engagement to Address HIV-Stigma in Western Kenya. International AIDS Society. Durban, South Africa. July 2016.

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, Moi Teaching and Referral Hospital
B Jakait, Moi Teaching and Referral Hospital

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.

Working Group(s)

PRWG, AMWG, PCWG

Description

Little is known about the toxicity profile of combination antiretroviral treatment (cART) in African populations where genetic differences, co-morbidities, and malnutrition together may influence the adverse reactions of cART in this population. The purpose of this project is to evaluate the feasibility and effectiveness of five approaches to Targeted Spontaneous Reporting (TSR) for documenting SADR in the resource constrained clinical setting in western Kenya. The approaches include; TSR 1: The completion of the Kenya National Suspected Adverse Drug Reaction form for patients with a change or discontinuation in their cART. These forms are then forwarded on to the National pharmacovigilance (PV) office at the Pharmacy and Poisons Board (PPB) in Nairobi. TSR 2: Use of routinely-used clinical encounter forms that have been enhanced to specifically collect a relatively small amount of SADR data to be collected by the provider seeing the patient during the clinical visit. TSR 3 and TSR 4: Involve conducting in-depth interviews on 1,000 patients receiving cART treatment to prompt patients about SADR and their impact on patient adherence and quality of life. Patients undergoing interviews are randomly assigned to be interviewed by an HIV peer (TSR 3)

	or a pharmacy personnel (TSR 4) who will have received the same training for the project. The interviews will be conducted over 12 months or a maximum of 12 scheduled clinical visit (Whichever comes first). TSR 5: Use of data routinely captured in the pharmacy when clinicians substitute or change a patient's regimen, including documentation if such an event occurred on the prescription form and the cause of the event (i.e. toxicity, treatment failure, TB drug interaction, pregnancy, other).
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/1/2012 - 12/31/2013
Funding Status	Funded – World Health Organization (WHO)
Direct Award (USD)	\$162,000
Update	We cleaned the data within the Redcap database and the data is currently being analyzed.
Future Plans	We hope to summarized the data and developed a manuscript draft from the data.
Publication(s)	

Study Title	Point in Time (PIT) Count of Street Children in Eldoret
Principal Investigator(s)	Paula Braitstein, University of Toronto David Ayuku, Moi University
Co-Investigator(s)	
Working Group(s)	PRWG
Description	This is a one-time project funded by the Canadian Institutes for Health Research (CIHR) and aims at counting all the street children and youth in Eldoret Town and its Peri-urban areas namely; Langas, Huruma, Kapsoya, Town Bases; California, Juakali, Mangula, Asiz and Eastleigh. Counting will be facilitated using Fingerprint Scanners and related supplies, HIV and First Aid Services will be provided. The count will take place over a seven day period. The aims of the project are to determine whether counting street children in a low-income setting is feasible using PIT count techniques, used in homeless populations successfully in Canada and the United States, estimate the number of street-connected children and youth in Eldoret, and estimate HIV prevalence among them.
Site(s)	Moi Teaching and Referral Hospital
Project Period	5/1/2016 - 12/31/2016
Funding Status	Funded – Canadian Institutes of Health Research
Direct Award (USD)	\$26,653
Update	The Point-In-Time (PIT) Count Supplies that were ordered earlier were received during this reporting period, these are; fingerprint scanners, laminators and food supplies for

	<p>the participants. A series of PIT Count planning meetings were held to facilitate planning and organization of the exercise between July and August 2016. The actual PIT Count exercise took place from 4th-10th September 2016. The exercise involved counting of street children and youth using fingerprint scanners, provision of HIV Counseling and testing services, first aid services and data collection. The key accomplishment for the count was sensitization of the County Children Authorities of the exercise and the support received from them. Participants also turned up in large numbers to be counted. The preliminary results from the count includes; 1,903 street children and youth were counted, 76.3% (1,453) being male and 23.7% (450) being female. Out of the overall number counted, 70.2% (1,335) accepted HIV Counseling, 3% (40) were known HIV positive while 3.7% (46) had a HIV positive test; 63% (29) being female and 37% (17) being male.</p>
Future Plans	In the next 6 months, the study team plans to write and publish the PIT count paper as a way of disseminating the results and findings to the public.
Publication(s)	
Study Title	'Point of Care CD4 testing for people who fail to engage in care after testing HIV positive'.
Principal Investigator(s)	Paula Braitstein, University of Toronto Samson Ndege, Moi University
Co-Investigator(s)	
Working Group(s)	AMWG
Description	This supplement responds to unique aspects of Specific Aim 1 of the East Africa-International epidemiological Databases to Evaluate AIDS (IeDEA) grant, which seeks to 'Determine the short and long-term outcomes of adults and children along the entire spectrum of HIV care.' Our broad aim is to inform and evaluate the implementation of AMPATH's HIV treatment and prevention work by fully characterizing the cascade of HIV care in population-based settings and identifying gaps and opportunities for improvement. The primary objective of this study is to characterize the outcomes of HIV-positive adults who did not engage with HIV care following the catchment-wide HBCT campaign held from Dec 2009-Feb 2011 in Bunyala.
Site(s)	Bunyala Sub-county, could be others as well
Project Period	2/2/2015 - 2/1/2016
Funding Status	Funded - NIH
Direct Award (USD)	\$62,432
Update	IREC approval was received on 25th July 2016, as an amendment to introduce a tracking form to find out the Outcomes of patients Lost to follow up in Bunyala. This was implemented and completed in the month of August 2016. Preliminary findings showed that out of the 61 Lost to follow up patients tracked, 18 were found to be in

	care, 10 were not in care and 4 were deceased. Cleaning and further analysis of data is on-going.
Future Plans	Over the next 6 months, we hope to seek ethical approval from IREC to continue follow up activities of patients who did not link to care in Teso and Chulaimbo. The team will then train counselors in those areas after which data collection and supervision activities will commence. At the same time, writing of papers and publication will also be done during this period.
Publication(s)	

Study Title	Randomized, Phase II Trial of CHOP vs. Oral Chemotherapy with Concomitant Antiretroviral Therapy in Patients with HIV-associated Lymphoma in Sub-Saharan Africa
Principal Investigator(s)	Naftali Busakhala, Moi University Evangeline Njiru, Moi Teaching and Referral Hospital
Co-Investigator(s)	
Working Group(s)	ORWG
Description	Patients will be randomized to one of two treatment arms: either standard, intravenously delivered CHOP, delivered over six 3-week cycles or oral chemotherapy delivered over three 6-week cycles. Formal assessment of objective response (complete response [CR]/partial response [PR]/stable disease [SD]) will be performed following cycle 6 for CHOP and following cycle three for the oral regimen, and the patient will then be followed for relapse and survival. Patients found to have progressive disease (PD) at any time will come off study and receive the local standard of care treatment for their disease.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/1/2015 - 8/31/2018
Funding Status	Funded - NIH
Direct Award (USD)	\$75,000
Update	The study was opened to start enrolling study participants in October 2016, and we have managed to enroll one participant into the study.
Future Plans	The study will continue to enroll participants in next 6 months so that we can achieve our recruitment targets.
Publication(s)	

Study Title	Rapid Case Ascertainment (RCA) to evaluate Kaposi's sarcoma at the Academic Model Providing Access to Healthcare (AMPATH) clinics, Eldoret, Kenya
-------------	--

Principal Investigator(s)	Naftali Busakhala, Moi University
Co-Investigator(s)	
Working Group(s)	ORWG
Description	The Rapid Case Ascertainment (RCA) Kaposi's sarcoma (KS) study will swiftly and thoroughly evaluate patients with a new diagnosis of KS in order to confirm diagnosis, initiate treatment and facilitate research into why the patients developed the KS. Therefore the study will recruited newly diagnosed KS patients and will look at clinical and demographic factors to determine why individuals developed KS.
Site(s)	
Project Period	9/1/2014 - 8/31/2019
Funding Status	Funded - NIH
Direct Award (USD)	\$154,224
Update	We were able to complete the review of all study questionnaires and data collection tools as earlier planned. The study was open to recruit and so far we managed to recruit a total of 30 cases into the study.
Future Plans	We intend to continue with the recruitment process of both the cases and controls into the study.
Publication(s)	

Study Title	REALITY 'Reduction of EARly mortaLITY in HIV-infected adults and children starting antiretroviral therapy'
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University Abraham Siika, Moi University
Co-Investigator(s)	Winstone Nyandiko
Working Group(s)	AMWG, PRWG
Description	A 2x2x2 open-label factorial multi-centre trial, conducted in 9 centres in 4 countries (Kenya, Malawi, Uganda, 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
Project Period	8/1/2013 - 8/1/2017
Funding Status	Funded – Medical Research Council
Direct Award (USD)	Not Reported
Update	The study is closed to follow up and data analysis is ongoing
Future Plans	The site plans to disseminate study findings to participants. Trial investigators to continue with data analysis.
Publication(s)	<p>Enhanced infection prophylaxis reduces mortality in severely immunosuppressed HIV-infected adults and older children initiating antiretroviral therapy in Kenya, Malawi, Uganda and Zimbabwe: the REALITY trial Authors: J. Hakim¹, V. Musiime², A.J. Szubert³, A. Siika⁴, J. Mallewa⁵, C. Agutu, S.L. Pett, M. Bwakura-Dangarembizi¹, A. Lugemwa⁷, S. Kaunda⁵, M. Karoney⁴, K. Maitland⁶, A. Griffiths</p> <p>12-week raltegravir-intensified quadruple therapy versus triple first-line ART reduces viral load more rapidly but does not reduce mortality in severely immunosuppressed African HIV-infected adults and older children: the REALITY trial Authors: C. Kityo, A. Siika, A.J. Szubert, J. Mallewa⁴, M. Bwakura-Dangarembizi, S. Kabahenda, S. Mwaringa, S.L. Pett, A. Griffiths, A. Lugemwa, S. Wachira, G. Musoro, C. Rajapakse, T. Etyang, J. Abach, P. Wavamunno, L. Nyondo-Mipando, A. Reid, K. Nathoo, J. Hakim, D.M. Gibb, A.S. Walker, REALITY trial team</p> <p>Ready-to-Use Supplementary Food (RUSF) at ART initiation improves nutritional status but does not reduce mortality in severely immunosuppressed HIV-infected adults and older children in sub-Saharan Africa: the REALITY trial Authors: J. Mallewa, P. Mugenyi, J. Berkley, A.J. Szubert, E. Chidviza, M.J. Thomason, P. Chepkorir, G. Abongomera, K. Baleeta, A. Etyang, C. Warambwa, B. Melly, S. Mudzingwa, C. Kelly, C. Agutu, H. Wilkes, V. Musiime, A. Lugevma, S.L. Pett, M. Bwakura-Dangarembizi, A.J. Prendergast, A.S. Walker, D.M. Gibb, REALITY trial team</p>

Study Title	SAFI (Stigma in AIDS Family Inventory) Validation Study
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Irene Marete, Hai Liu, Violet Naanyu
Working Group(s)	PRWG
Description	For families raising HIV-infected children in resource-limited settings, HIV/AIDS-related stigma shapes every aspect of the children's HIV management, from daily adherence to medication to decisions about pediatric HIV disclosure. We do not know the most effective strategies to reduce stigma for HIV-infected children and their families in resource-limited settings nor how to measure its effects on physical, emotional, or

	<p>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:</p> <p>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.</p>
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital , Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	12/17/2013 - 11/30/2015
Funding Status	Funded – NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	\$567,828
Update	<p>The specific aims for the SAFI(Stigma in AIDS Family Inventory) validation study are:</p> <p>Aim 1:Identify and modify HIV/AIDS stigma questionnaire items for maximum reliability and content validity to measure perceived, enacted and internalized HIV/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 reduces perceived, enacted, or internalized stigma for families with disclosed children compared to families with non-disclosed children. No modifications have been made to the specific aims as stated in the original proposals. We have ongoing Institutional Review Board and local ethics committee approval for the aims. In the last 6 months data that was collected through the SAFI study to provide a comprehensive and validated family HIV/AIDS-related stigma measure for assessing HIV/AIDS (H/A) stigma in western Kenya, including perceived, enacted and internalized stigma analysis has been ongoing.</p>
Future Plans	In the next 6 months, we plan to complete the analysis of data collected from the HADITHI cohort of families to assess the validity of the HIV/AIDS Stigma questionnaire measures of family stigma compared to independent construct measures including medication adherence, and children's clinical, psychological, and social outcomes. We also plan to implement the stigma films as educational and moving tools to help reduce the impact of HIV/AIDS stigma in the community.
Publication(s)	

Study Title	Tablet Computer-Based Disclosure Counseling for HIV-Infected Adolescents and their Families: A Pilot Study of Perspectives from Providers
Principal Investigator(s)	Megan McHenry Indiana University
Co-Investigator(s)	Vreeman, Rachel Apondi, Edith Nyandiko, Winstone McAteer, Carole Scanlon, Michael Fischer, Lydia
Working Group(s)	PRWG
Description	<p>The objective of this study is to evaluate a pilot project using Google tablet computers for disclosure-related counseling with HIV-infected children and their caregivers in three AMPATH clinics. Google Nexus 7 Android tablets donated to the IU-AMPATH Android Program will be loaded with materials developed as part of the ongoing HADITHI disclosure intervention trial (PIs: Nyandiko and Vreeman) and includes educational materials on HIV and disclosure, counseling-based activities, and video narratives sharing experiences of HIV and disclosure. A plan was in place prior to this proposal of this study to implement the tablets in these clinic sites regardless of whether the benefits or hindrances of these devices are measured. This study is focused on understanding how this implementation affects provider practice or perspectives. Our central hypothesis is that AMPATH clinicians and other staff will find these tablets usable and helpful as a tool in disclosure counseling activities. The long-term goal of this study is to provide evidence to better support adolescents through the disclosure process and increase the number of adolescents who know their HIV status. We plan to accomplish our research objective by achieving the following specific aims: Aim 1: Describe current disclosure practices and barriers to disclosure at three clinics (Bumala, Busia, and Port Victoria) in Western Kenya through interviews with key clinic staff. Aim 2: Compare the prevalence of disclosure at these clinics for HIV-infected adolescents (10 to 14 years) before and after the introduction of the tablet devices using disclosure status data collected through AMRS. Aim 3: Evaluate provider perspectives on the acceptability and usability of the tablets for disclosure counseling through surveys, cognitive interviews, and focus group discussions. Sub-aim 3a: Describe any changes in providers' knowledge, comfort, and attitudes regarding disclosure after the introduction of the tablet devices. Sub-aim 3b: To describe adolescents perspectives on the use of tablet devices for HIV disclosure to better understand their use by providers.</p>
Site(s)	Bumala A Health Centre, Bumala B Health Centre, Busia District Hospital, Port Victoria Sub-District Hospital
Project Period	2/13/2015 - 8/19/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	We have completed analysis, written the manuscript, and submitted the manuscript to AIDS and Behavior. We recently received feedback regarding recommended revisions. Unfortunately, the journal suggested that it be submitted elsewhere. However, their suggestions will allow us to strengthen our paper moving forward.

Future Plans	Make the necessary revisions to the manuscript and resubmit it to another journal, such as AIDS Patient Care and STDs.
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, University of Toronto
Co-Investigator(s)	Ayuku David
Working Group(s)	PRWG
Description	<p>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?</p>
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/1/2013 - 5/1/2014
Funding Status	Unfunded
Direct Award (USD)	
Update	This study has now been published.
Future Plans	This study is complete.

Publication(s)	Embleton L, Lee H, Gunn J, Ayuku D, Braitstein P. Causes of child and youth homelessness in developed and developing countries: a systematic review and meta-analysis. JAMA Pediatr. 2016;Apr 4. doi:10.1001/jamapediatrics.2016.0156. Embleton L, & Braitstein P. An important cause of child and youth homelessness - In Reply. JAMA Pediatr. 2016; Jul 25; doi: 10.1001/jamapediatrics.2016.1390
Study Title	The Confluence of Pregnancy and New HIV Diagnosis Among Adolescents in Western Kenya
Principal Investigator(s)	Katherine MacDonald, Indiana University Edith Apondi, Moi Teaching and Referral Hospital
Co-Investigator(s)	Keter, Alfred; Nyambura, Monicah
Working Group(s)	PRWG, RHWG
Description	This study is a sub-analysis of the adolescent population who were selected in the study 'HIV Prevalence and Antenatal Care Attendance among Pregnant Women in a Large Home-Based HIV Counseling and Testing Program in Western Kenya' by Ndege et al. We will focus on examining factors associated with pregnancy, ANC attendance, and enrollment in HIV and antenatal care. This cross sectional retrospective study can facilitate identifying adolescents who are at risk of becoming pregnant and yet less likely to receive antenatal care. Most importantly the study could identify factors associated with poor linkage to HIV and ANC care, and could uncover an opportunity to identify pregnant adolescents who are unknowingly living with HIV by utilizing the home-based counseling and testing (HBCT) platform. We aim to describe the adolescents who participated in HBCT, and determine associated socioeconomic and health factors related to pregnancy, ANC attendance, HIV infection and enrollment in HIV and ANC care.
Site(s)	Burnt Forest, Chulaimbo, Kapsaret, Port Victoria, and Teso communities (not health centre or hospital based)
Project Period	7/12/2016 - 4/30/2017
Funding Status	Unfunded
Direct Award (USD)	
Update	Over the last 6 months, we completed the initial data analysis and completed the abstract which was accepted for a poster presentation at the Society of Adolescent Health and Medicine conference in March 2017. From our data analysis, we found that 18,112 adolescents participated in HBCT. Pregnant adolescents were significantly more likely to be married (AOR: 8.5, 95% CI: 5.85 -12.38). Catchment area, older age, lower educational status, and being a maternal orphan were also significantly associated with pregnancy (p<0.001). Only 65% of pregnant adolescents had attended at least one ANC visit for that pregnancy. Among all participants, 13.1% had previous HIV testing, of whom 3.8% reported themselves to be HIV-positive. Among participants not reporting a previous positive HIV test, almost all (99.5%) agreed to be tested for HIV and 0.7% newly tested positive. Compared to non-pregnant

	<p>adolescents, pregnant adolescents were 4 times more likely to be newly diagnosed with HIV during HBCT (2.8% versus 0.6%, $p < 0.0001$). Overall HIV prevalence was 4% among pregnant adolescents (7 previously HIV+, 14 newly diagnosed HIV+). While pregnant adolescents were more likely than non-pregnant adolescents to have had previous HIV testing (AOR 3.22 CI 2.34-4.42), of those pregnant, only 57% had ever been tested for HIV. Among pregnant adolescents, those who reported any prior HIV testing were more likely to have attended ANC ($p < 0.001$), but prior HIV positivity was not associated with ANC attendance.</p>
<p>Future Plans</p>	<p>In the next 6 months, we will complete a manuscript and it will be submitted for publication.</p>
<p>Publication(s)</p>	<p>Title: The Confluence of Pregnancy and New HIV Diagnosis Among Adolescents in Western Kenya Authors: Dr. Katherine MacDonald, MD, Dr. Edith Apondi MMED, Dr. Mary Ott MD, MS, Dr. Juddy Wachira PhD, Alfred Keter Msc, Monicah Nyambura, Dr. Heather Millar, Dr. Alice Kaaria, and Dr. Paula Braitstein PhD Journal of Adolescent Health Volume 60, Issue 2, Supplement 1, February 2017, Pages S83-S84</p>
<p>Study Title</p>	<p>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</p>
<p>Principal Investigator(s)</p>	<p>Tom Inui, Indiana University Naftali Busakhala, Moi University</p>
<p>Co-Investigator(s)</p>	<p>Asirwa, C.</p>
<p>Working Group(s)</p>	<p>AMWG</p>
<p>Description</p>	<p>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</p>

	<p>support for the IU Simon Cancer Center's quest to become a federally designated Comprehensive Care Center. Naftali Busakhala will characterize the awareness, beliefs, attitudes and behaviors of women coming to AMPATH's clinician breast exam screening as volunteers, comparing these beliefs to those of a community-based sample of women. He will also characterize the yield of the AMPATH screening program, the kinds of cancers detected, and the quality of care achievable in Western Kenya at present, with comparison against an international standard of care. Chite Asirwa will similarly characterize the awareness, beliefs, attitudes and behaviors of a community-based sample of women, comparing their beliefs to those of their husbands, often a key influence on behavior in traditional societies. Taken together these two studies should reveal a great deal about how to influence women's behaviors and encourage participation in the only breast cancer screening program available presently - clinician examination. Both of these studies will use the BCAM (Breast Cancer Awareness Measure), a survey tool developed in Great Britain. We have worked carefully through the standard BCAM to sort questions into theoretically sound domains, using the Health Belief Model as a framework. Violet Naanyu will be conducting field testing and focus groups to do a culturally appropriate Kiswahili version.</p>
Site(s)	Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital, Kapsokorny
Project Period	10/1/2011 - 6/30/2016
Funding Status	Funded – Walther Cancer Foundation
Direct Award (USD)	\$1,200,000
Update	A close-out report was submitted to the Walther Cancer Foundation in August 2016. The co-investigators now await publication of the study's final manuscript, accepted but not yet published by BMC Health Svcs Res.. Wachira J, Busakhala N, Chite F, Naanyu V, Kisuya J, Otieno G, Keter A, Mwangi A, and Inui T. Refining a Questionnaire to Assess Breast Cancer Knowledge and Barriers to Screening in Kenya: Psychometric Assessment of the BCAM. In Press: BMC Health Services Res.
Future Plans	We hope to see the final publication make its appearance.
Publication(s)	

Study Title	The Production and Reproduction of Kinship in CCIs in Uasin Gishu County
Principal Investigator(s)	Allison Gayapersad, University of Toronto
Co-Investigator(s)	Supervisor: Paula Braitstein CI: Caroline Ombok CI: Allan Kamanda
Working Group(s)	SSRN
Description	This is a qualitative social science project that seeks to explore how residents of Charitable Children's Institutions (CCIs; including orphanages) produce and understand kinship relations. Based on a structural-functionalist theoretical orientation, we hypothesize that when children move to CCIs, they will create new fictive kin

	relationships. We hope to map these relations and explore the directionality of things like authority and hierarchy, and to understand the sorts of privileges and obligations inherent in these relationships. We will conduct a series of open-ended, semi-structured interviews with current and former residents and staff of CCIs in Uasin Gishu county, Eldoret. Our survey instrument is designed to elicit information about the nature of kin networks at the CCI, and how traditional life milestones (such as marriage or coming of age) are manifest in these networks. We will also ask residents to draw kinship diagrams to better visualize their relationship networks. The data will be analyzed with an emphasis on functionalism and symbolic anthropology.
Site(s)	Webuye District Hospital, Bungoma East Subcounty in Bungoma County and Kiminini Subcounty in Trans-Nzoia County
Project Period	8/1/2016 - 12/1/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	Ethics clearance has been received from the Institutional Research and Ethics Committee (IREC), Moi Teaching and Referral Hospital and the Research Ethics Board, University of Toronto. Michael Callaghan is no longer associated with the project. Allison Gayapersad, Post Doctoral Fellow, University of Toronto, replaced Dr. Callaghan on Jan 1, 2017. As a result of Dr. Callaghan leaving the project, data collection has been delayed. Amendments have been submitted to the respective ethics committees to have the primary investigator replaced on the study. We hope to begin data collection within the next 2 weeks.
Future Plans	Data collection will begin mid-February and is expected to take 8 weeks. Data analysis will be conducted concurrently and after data collection. Data analysis and the final report is expected to take an additional 3 - 4 months. Therefore, we expect to complete data collection, data analysis and final report in the next 6 months.
Publication(s)	

Study Title	The Role of Faith Leaders Towards Promotion of Home Based HIV Counseling, Testing and Linkage to Treatment Program Around Kisumu, Kenya
Principal Investigator(s)	Eunice Kamaara, Moi University Amy Nunn, Brown University
Co-Investigator(s)	
Working Group(s)	SSRN
Description	The Nyanza region of Kenya has high rates of HIV infection, even among individuals. The faith community plays an important role in shaping social norms about HIV testing, prevention treatment and retention in care. Local home based HIV testing efforts have been effective in reducing AIDS related morbidity and mortality. This proposed study will explore the role of faith leaders in promoting HIV testing, treatment and linkage to

	<p>care. In spite of increased national success in HIV testing and treatment, HIV prevalence in Nyanza has increased from 14.9 in 2007 to 15.1 % in 2011. Unfaithfulness combines with ignorance of HIV status to register new infections. The proposed exploratory study will use qualitative interviews and focus group discussions (FGDs) with purposively selected participants to explore the role of faith leaders in promoting home based HIV testing and linkage to care. The aim of the proposed study is to better understand the role that faith leaders could play in promoting and normalizing home based HIV testing, treatment and linkage to care in Nyanza. This will inform and help expand home-based HIV testing program of AMPATH in Nyanza for improved prevention, control and management of HIV and AIDS. The specific objectives include: 1. To explore the beliefs of faith leaders about home-based HIV testing and treatment 2. To investigate barriers to home based HIV testing and treatment 3. To identify opportunities for promotion of home-based HIV testing, treatment and linkage to care. 4. To conduct a pilot study about the role of faith leaders in promoting HIV testing, treatment and linkage to care in home-based HIV testing program of AMPATH in Nyanza.</p>
Site(s)	Chulaimbo Sub-District Hospital, Mukhobola Health Centre, Port Victoria Sub-District Hospital
Project Period	11/1/2014 - 10/30/2015
Funding Status	Funded – Brown University – Center for AIDS Research
Direct Award (USD)	\$25,000
Update	Since our last report, we have not done anything substantive. We are keeping the project open because My Co PI, Dr. Amy Nunn from Brown University is still keen to visit Kenya for face to face discussions and review of draft papers. She hasn't managed to do this yet.
Future Plans	I hope that Dr. Nunn can visit Kenya so that we publish and close the project.
Publication(s)	

Study Title	The Role of PD-1 Pathway and Tissue Microenvironment in HIV-Kaposi Sarcoma and Endemic Kaposi Sarcoma Cohort in Western Kenya
Principal Investigator(s)	Patrick Loehrer, Indiana University Asirwa Chite, Indiana University
Co-Investigator(s)	Evangeline Njiru Toby Maurer Mike Rosenblum Stefanie Sowinski
Working Group(s)	ORWG
Description	Even before the HIV pandemic, equatorial Africa had among of the highest KS incidences in the world. In this area, 'endemic KS' (the term given to the HIV-unassociated form of KS) was manifested primarily as indolent localized disease in men and represented 4 to 10% of adult cancers. Although sub-Saharan Africa was already a hotbed for KS, the clinical manifestations and impact of the disease dramatically changed with the onset of the HIV epidemic in the 1980's when the incidence of KS and

	<p>other HIV associated malignancies exploded. The advent of anti-retroviral therapy (ART) improved prognosis of HIV-associated KS, but survival remains unacceptably poor in low to middle income countries(LMIC). A recent Cochrane review on late stage KS showed that in 6 studies in which chemotherapy was added to HAART, no survival benefit was seen above that of ART therapy alone nor amongst the different types of chemotherapy. Endemic KS, while less likely to progress to visceral disease, leaves patients with profound functional disabilities often requiring treatment. Because this population is HIV negative, ART is not used. Research that leads to a better understanding of the biology of KS must be explored to provide alternative therapies to ART and standard chemotherapy. Based upon preliminary data from UCSF which supports the role of PD1 pathway and tissue micro-environment in KS, we propose to conduct a prospective analysis on two patient cohorts. Cohort 1: KS in HIV-infected subjects who have failed at least one KS-directed chemotherapeutic intervention; and Cohort 2: KS in HIV-negative patients (i.e. endemic KS) who have failed at least one KS-directed chemotherapeutic intervention.</p>
Site(s)	
Project Period	10/1/2015 - 9/30/2018
Funding Status	Funded – NIH - National Cancer Institute (NCI)
Direct Award (USD)	\$158,406
Update	Lab personnel has been trained in the US (Mike Rosenblum lab at UCSF) so that samples from AMPATH can be processed and analyzed. Training of personnel at AMPATH has also taken place so that subjects can be properly recruited and that samples can be obtained. All SOP's and IRB's in place
Future Plans	Await a transfer agreement so that samples can be shipped to Uganda for processing. Lab staff at AMPATH will be evaluated re: training on lab Subjects will be recruited Samples will be processed Lab data to be entered and cleaned.
Publication(s)	

Study Title	Validation of Spirometry Prediction Equations in Western Kenya
Principal Investigator(s)	Peter Kussin, Duke University David Lagat, Moi University
Co-Investigator(s)	Paul, Devon
Working Group(s)	AMWG
Description	<p>This is a cross-sectional study of healthy adult Kenyans living in and around Eldoret. The purpose of the study is to validate a set of spirometry prediction equations for the local population. Adults age 18 years and older who are HIV negative, with no history of chronic cardiac or pulmonary disease and with <5 pack year smoking history are eligible for participation. Specific Aim: Determine pulmonary function reference equations that can accurately predict normal spirometric values in a Kenyan population. • 1A: Statistically compare phenotypically normal Kenyan spirometric</p>

	profiles with values obtained from published pulmonary function reference equations to determine the most accurate equation set. • 1B: If published reference equations do not accurately reflect normal Kenyan lung function profiles, develop new reference equations.
Site(s)	Moi Teaching and Referral Hospital
Project Period	1/1/2015 - 3/1/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	Our original publication was declined by one journal with comments. We redid the statistical analysis with the assistance of our statistician, and have submitted a new manuscript to IJTLD. We have also submitted an abstract to the annual ATS conference.
Future Plans	We hope to publish our manuscript, at which point we will close the study.
Publication(s)	

Study Title	Vincristine Optimization in Kenyan Children with Cancer
Principal Investigator(s)	Jodi Skiles, Indiana University Festus Njuguna, Moi University
Co-Investigator(s)	G Olbara, MBBS S Langat J Musimbi T Vik, MD S Mostert, MD,PhD GJL Kaspers,MD,PhD N Busakhala F Asirwa P Loehrer J Renbarger, MD1
Working Group(s)	ORWG, PRWG
Description	In resource-limited settings, access to chemotherapeutic agents is confined to a few therapies. Vincristine (VCR) is a mainstay in such settings due to its low cost and lack of myelosuppression, however, little is known regarding its disposition and true optimal dosing, especially in the pediatric population. Negative clinical outcomes, such as serious side effects due to drug overdosing or lack of efficacy due to sub-therapeutic dosing, may result. VCR is associated with highly variable cumulative dose-dependent peripheral neuropathy (VIPN). While pediatric oncology patients in the U.S. who receive VCR experience significant VIPN and excellent disease outcomes, Kenyan children with cancer who receive VCR experience little to no VIPN, highlighting the opportunity for optimization of VCR in this population. While there are clearly multiple factors that contribute to poor disease outcomes in Kenya, suboptimal dosing of VCR is the piece we aim to address in this study. The biological basis for the minimal VIPN we have observed in Kenyan children is uncertain but includes such things as genetic differences in VCR pharmacologic pathways as well as genetic variability in susceptibility to neuropathy. This gap in knowledge provides a clear opportunity to optimize use of this medication in Kenyan children with cancer and evaluate genetic associations with VIPN in order to personalize this medication for individual children once VCR dosing is augmented. Preliminary data has shown that Kenyan children with cancer (n=100) experience minimal VIPN. Despite the negligible neuropathy observed,

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

SA1: To determine the maximum tolerated dose (MTD) of VCR administered in conjunction with conventional chemotherapy in cohorts of Kenyan children with ALL or Wilms tumor receiving VCR as part of their anti-cancer treatment.

SA2: To validate our pilot study findings and to further evaluate the association between common or functional variants in genes in the vinca alkaloid pharmacologic pathway and across the human genome with VCR PK, VIPN, and disease response in the same populations as SA1.

SA3: To further develop our pharmacologic prediction model of VIPN describing associations between pharmacogenetic, pharmacokinetic, and clinical biomarkers and carefully characterized VIPN in the same population of patients as SA1.

SA4: To evaluate the validity and reliability of several chemotherapy-induced peripheral neuropathy (CIPN) measurement approaches when used to quantify neuropathy and associated neuropathic pain in Kenyan children receiving vincristine.

Site(s)

Project Period

2/3/2014 - 1/31/2018

Funding Status

Funded – NIH - National Cancer Institute (NCI); NIH - Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Direct Award (USD)	\$103,254
Update	This study commenced in February 2014 and 31 subjects were enrolled and enrollment to Phase I is now complete. Based on our data, Dose level 2 is the maximum tolerated dose. Data analysis is ongoing with hopeful submission of a manuscript in the next 6 months. We have decided that Phase II of this study will not be completed as originally planned due to ongoing issues with abandonment of care in this population making it difficult to draw any meaningful conclusions about whether the dose escalation schema has any impact on outcomes/survival. Instead, we hope to submit a revised proposal for real-time PK targeted dose escalation with collaboration from the VU team in Amsterdam.
Future Plans	Completion of data analysis and submission of manuscript from the Phase I portion of the study
Publication(s)	
Study Title	Virologic Treatment Failure and Drug Resistance in HIV-Infected Kenyan Children (RESPECT) study.
Principal Investigator(s)	Rachel Vreeman, Indiana University Winstone Nyandiko, Moi University
Co-Investigator(s)	Rami Kantor, MD Department of Medicine Brown University School of Medicine rkantor@brown.edu Samuel Ayaya, MBChB, MMED Department of Child Health and Paediatrics, Moi University School of Medicine ayaya.samuelaluanga@gmail.co Joe Hogan, Ph
Working Group(s)	PRWG
Description	This study will involve retrospective and prospective analysis of blood sampling from patients enrolled in a previous NIH-funded (Vreeman, 1K23MH087225) randomized controlled trial titled, 'Evaluation of a Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy' or the 'CAMP study.' That was conducted between May 2010 and October 2013. This particular cohort provides an unprecedented and timely opportunity to characterize longitudinal processes that lead to treatment failure and drug resistance development among HIV-infected children in a sub-Saharan African setting, and its translation into evidence-based interventions. The specific aims of this study are: Specific Aim 1: Determine prevalence of viral failure and examine resistance mutations among a retrospective study cohort of 685 prenatally HIV-infected Kenyan children on 1st-line ART. Specific Aim 2: Investigate associations between specific adherence patterns, ART drug levels and other demographic and clinical factors, with viral failure and drug resistance. Specific Aim 3: Study long-term immunologic, virologic and drug resistance outcomes and their associations in prospectively re-enrolled study participants Specific Aim 4: Enhance analyses of viral failure, drug resistance accumulation and associated demographic and clinical factors by examining the longitudinal banked samples available for a subset of the study cohort (n=327). Specific Aim 5: Develop a data-driven intervention algorithm to identify children at risk for viral failure and resistance.

Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital, Turbo Health Centre, Webuye District Hospital
Project Period	8/2/2016 - 7/31/2020
Funding Status	Funded - NIH
Direct Award (USD)	\$613,511
Update	Over the last 6 months, IREC and IRB approvals have been secured and the study team has been hired and trained. Both the import and export permit for samples' shipment to the USA have been obtained. Archived CAMP samples have been identified and demographic data obtained.
Future Plans	Over the next six months we plan to begin participants' enrollment into the study and follow up. We also plan to begin shipment of blood samples to the USA for viral resistance testing.
Publication(s)	

Bibliography

The following bibliography includes AMPATH research publications that were published between January 1, and December 31, 2016. 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. Ali Im, Guyah B, Ng'wena Gi, Mutai K, Emonyi W. Gene Xpert Mtb/Rif Specificity And Sensitivity In Tuberculosis Diagnosis Using Urine Samples From Hiv Patients With Signs Of Tuberculosis At The Moi Teaching and Referral Hospital In Western Kenya. *Journal of Disease and Global Health*. 2016;8(3):112-7.
2. Althabe F, Belizán JM, McClure EM, Hemingway-Foday J, Berrueta M, Mazzoni A, Ciganda A, Goudar SS, Kodkany BS, Mahantshetti NS, Dhaded SM. A Population-based, Multifaceted Strategy to Implement Antenatal Corticosteroid Treatment Versus Standard Care for the Reduction of Neonatal Mortality Due to Preterm Birth in Low-income and Middle-income Countries: The ACT Cluster-randomized Trial. *Obstetric Anesthesia Digest*. 2016 Mar 1;36(1):40-1.
3. Althabe F, Thorsten V, Klein K, McClure EM, Hibberd PL, Goldenberg RL, Carlo WA, Garces A, Patel A, Pasha O, Chomba E. The Antenatal Corticosteroids Trial (ACT)'s explanations for neonatal mortality-a secondary analysis. *Reproductive health*. 2016 May 24;13(1):62.
4. Amerson E, Woodruff CM, Forrestel A, Wenger M, McCalmont T, LeBoit P, Maurer T, Laker-Oketta M, Muyindike W, Bwana M, Buziba N. Accuracy of clinical suspicion and pathologic diagnosis of Kaposi sarcoma in East Africa. *JAIDS Journal of Acquired Immune Deficiency Syndromes*. 2016 Mar 1;71(3):295-301.
5. Atwoli L, Platt JM, Basu A, Williams DR, Stein DJ, Koenen KC. Associations between lifetime potentially traumatic events and chronic physical conditions in the South African Stress and Health Survey: a cross-sectional study. *BMC psychiatry*. 2016 Jul 7;16(1):214.
6. Atwoli L, Stein DJ, King A, Petukhova M, Aguilar-Gaxiola S, Alonso J, Bromet EJ, Girolamo G, Demyttenaere K, Florescu S, Maria Haro J. Posttraumatic stress disorder associated with unexpected death of a loved one: Cross-

- national findings from the world mental health surveys. Depression and anxiety. 2016 Nov 1.
7. Awiti PO, Grotta A, van der Kop M, Dusabe J, Thorson A, Mwangi J, Bellico R, Lester R, Ternent L, Were E, Ekström AM. The effect of an interactive weekly mobile phone messaging on retention in prevention of mother to child transmission (PMTCT) of HIV program: study protocol for a randomized controlled trial (WELTEL PMTCT). BMC Medical Informatics and Decision Making. 2016 Jul 11;16(1):86.
 8. Ayua E, Mugalavai V, Simon J, Weller S, Obura P, Nyabinda N. Ascorbic acid content in leaves of Nightshade (*Solanum* spp.) and spider plant (*Cleome gynandra*) varieties grown under different fertilizer regimes in Western Kenya. African Journal of Biotechnology. 2016;15(7):199-206.
 9. Bang A, Patel A, Bellad R, Gisore P, Goudar SS, Esamai F, Liechty EA, Meleth S, Goco N, Niermeyer S, Keenan W. Helping Babies Breathe (HBB) training: What happens to knowledge and skills over time?. BMC Pregnancy and Childbirth. 2016 Nov 22;16(1):364.
 10. Bellad RM, Bang A, Carlo WA, McClure EM, Meleth S, Goco N, Goudar SS, Derman RJ, Hibberd PL, Patel A, Esamai F. A pre-post study of a multi-country scale up of resuscitation training of facility birth attendants: does Helping Babies Breathe training save lives?. BMC Pregnancy and Childbirth. 2016 Aug 15;16(1):222.
 11. Berrueta M, Hemingway-Foday J, Thorsten VR, Goldenberg RL, Carlo WA, Garces A, Patel A, Saleem S, Pasha O, Chomba E, Hibberd PL. Use of antenatal corticosteroids at health facilities and communities in low-and-middle income countries. Reproductive health. 2016 May 27;13(1):66.
 12. Bloomfield GS, DeLong AK, Akwanalo CO, Hogan JW, Carter EJ, Aswa DF, Binanay C, Koech M, Kimaiyo S, Velazquez EJ. Markers of atherosclerosis, clinical characteristics, and treatment patterns in heart failure: a case-control study of middle-aged adult heart failure patients in rural Kenya. Global heart. 2016 Mar 31;11(1):97-107.
 13. Bromet EJ, Atwoli L, Kawakami N, Navarro-Mateu F, Piotrowski P, King AJ, Aguilar-Gaxiola S, Alonso J, Bunting B, Demyttenaere K, Florescu S. Post-traumatic stress disorder associated with natural and human-made disasters in the World Mental Health Surveys. Psychological Medicine. 2016 Aug 1:1-5.
 14. Brooks K, DeLong A, Balamane M, Schreier L, Orido M, Chepkenja M, Kemboi E, D'Antuono M, Chan PA, Emonyi W, Diero L. HemaSpot, a Novel Blood Storage Device for HIV-1 Drug Resistance Testing. Journal of clinical microbiology. 2016 Jan 1;54(1):223-5.
 15. Brooks K, Diero L, DeLong A, Balamane M, Reitsma M, Kemboi E, Orido M, Emonyi W, Coetzer M, Hogan J, Kantor R. Treatment failure and drug resistance in HIV-positive patients on tenofovir-based first-line antiretroviral therapy in western Kenya. Journal of the International AIDS Society. 2016;19(1).
 16. Bucher S, Konana O, Liechty E, Garces A, Gisore P, Marete I, Tenge C, Shipala E, Wright L, Esamai F. Self-reported practices among traditional birth attendants surveyed in western Kenya: a descriptive study. BMC Pregnancy and Childbirth. 2016 Aug 12;16(1):219.
 17. Busakhala NW, Chite FA, Wachira J, Naanyu V, Kisuya JW, Keter A, Mwangi A, Njiru E, Chumba D, Lumarai L, Biwott P. Screening by clinical breast examination in Western Kenya: Who comes?. Journal of Global Oncology. 2016 Jan 27;2(3):114-22.
 18. Charity KW, Kumar AM, Hinderaker SG, Chinnakali P, Pastakia SD, Kamano J. Do diabetes mellitus patients adhere to self-monitoring of blood glucose (SMBG) and is this associated with glycemic control? Experiences from a SMBG program in western Kenya. Diabetes research and clinical practice. 2016 Feb 29;112:37-43.
 19. Coleman JS, Cespedes MS, Cu-Uvin S, Kosgei RJ, Maloba M, Anderson J, Wilkin T, Jaquet A, Bohlius J, Anastos K, Wools-Kaloustian K. An insight into cervical cancer screening and treatment capacity in sub Saharan Africa. Journal of lower genital tract disease. 2016 Jan 1;20(1):31-7.
 20. Dufort EM, DeLong AK, Mann M, Nyandiko WM, Ayaya SO, Hogan JW, Kantor R. Misclassification of Antiretroviral Treatment Failure Using WHO 2006 and 2010/2013 Immunologic Criteria in HIV-Infected Children and Adolescents in Western Kenya. Journal of the Pediatric Infectious Diseases Society. 2016 Apr 29:piw018.
 21. Embleton L, Lee H, Gunn J, Ayuku D, Braitstein P. Causes of Child and Youth Homelessness in Developed and Developing Countries: A Systematic Review and Meta-analysis. JAMA pediatrics. 2016 May 1;170(5):435-44.
 22. Embleton L, Wachira J, Kamanda A, Naanyu V, Ayuku D, Braitstein P. Eating sweets without the wrapper: perceptions of HIV and sexually transmitted infections among street youth in western Kenya. Culture, health & sexuality. 2016 Mar 3;18(3):337-48.

23. Embleton L, Braitstein P. An Important Cause of Child and Youth Homelessness—Reply. *JAMA pediatrics*. 2016 Sep 1;170(9):909-10.
24. Feinstein MJ, Bogorodskaya M, Bloomfield GS, Vedanthan R, Siedner MJ, Kwan GF, Longenecker CT. Cardiovascular Complications of HIV in Endemic Countries. *Current cardiology reports*. 2016 Nov 1;18(11):113.
25. Genberg BL, Hogan JW, Braitstein P. Home testing and counselling with linkage to care. *The Lancet HIV*. 2016 Jun 1;3(6):e244-6.
26. Genberg BL, Shangani S, Sabatino K, Rachlis B, Wachira J, Braitstein P, Operario D. Improving engagement in the HIV care cascade: A systematic review of interventions involving people living with HIV/AIDS as peers. *AIDS and Behavior*. 2016 Oct 1;20(10):2452-63.
27. Goldenberg RL, Thorsten VR, Althabe F, Saleem S, Garces A, Carlo WA, Pasha O, Chomba E, Goudar S, Esamai F, Krebs NF. The global network antenatal corticosteroids trial: impact on stillbirth. *Reproductive health*. 2016 Jun 2;13(1):68.
28. Grzesiak KM, Vargo CA, Schellhase EM, Miller ML, Karwa R, Pastakia SD, Jakait B. Learning to Sew: A Student Pharmacist's Service-Learning Experience. *Purdue Journal of Service-Learning and International Engagement*. 2016;3(1):13.
29. Hakim, J., V. Musiime, A.J. Szubert, A. Siika, J. Mallewa, C. Agutu, S.L. Pett, M. Bwakura-Dangarembizi, A. Lugemwa, S. Kaunda, M. Karoney, K. Maitland, A. Griffiths, C. Kityo, P. Mugenyi, A.J. Prendergast, A.S. Walker, D.M. Gibb, and R.T. Team, Enhanced infection prophylaxis reduces mortality in severely immunosuppressed HIV-infected adults and older children initiating antiretroviral therapy in Kenya, Malawi, Uganda and Zimbabwe: the REALITY trial, in *AIDS 2016* 2016: Durban, South Africa.
30. Hibberd PL, Hansen NI, Wang ME, Goudar SS, Pasha O, Esamai F, Chomba E, Garces A, Althabe F, Derman RJ, Goldenberg RL. Trends in the incidence of possible severe bacterial infection and case fatality rates in rural communities in Sub-Saharan Africa, South Asia and Latin America, 2010-2013: a multicenter prospective cohort study. *Reproductive health*. 2016 May 24;13(1):1-3.
31. House DR, Marete I, Meslin EM. To research (or not) that is the question: ethical issues in research when medical care is disrupted by political action: a case study from Eldoret, Kenya. *Journal of medical ethics*. 2016 Jan 1;42(1):61-5.
32. Jezmir J, Cohen T, Zignol M, Nyakan E, Hedt-Gauthier BL, Gardner A, Kamle L, Injera W, Carter EJ. Use of Lot Quality Assurance Sampling to Ascertain Levels of Drug Resistant Tuberculosis in Western Kenya. *PloS one*. 2016 May 11;11(5):e0154142.
33. Kanyi J, Karwa R, Pastakia SD, Manji I, Manyara S, Saina C. Venous Thromboembolism Requiring Extended Anticoagulation Among HIV-Infected Patients in a Rural, Resource-Constrained Setting in Western Kenya. *Annals of Pharmacotherapy*. 2016 Dec 1:1060028016686106.
34. Kingery FP, Naanyu V, Allen W, Patel P. Photovoice in Kenya: Using a Community-Based Participatory Research Method to Identify Health Needs. *Qualitative health research*. 2016 Jan;26(1):92-104.
35. Klein K, McClure EM, Colaci D, Thorsten V, Hibberd PL, Esamai F, Garces A, Patel A, Saleem S, Pasha O, Chomba E. The Antenatal Corticosteroids Trial (ACT): a secondary analysis to explore site differences in a multi-country trial. *Reproductive health*. 2016 May 24;13(1):64.
36. Koech MK, Owiti MO, Owino-Ong'or WD, Koskei AK, Karoney MJ, D'Agati VD, Wyatt CM. Absence of HIV-associated nephropathy among antiretroviral naïve adults with persistent albuminuria in Western Kenya. *Kidney International Reports*. 2016 Nov 30.
37. Kumar A, Kamano J, Too K, Tulienge D, Wambui C, Okidi E, Porter C, Fitzpatrick J, Kimaiyo S, Fuster V, Vedanthan R. Effect of Nurse-Based Management of Hypertension in Rural Western Kenya. *Journal of the American College of Cardiology*. 2016 Apr 5;67(13):1944.
38. Kurth AE, Cleland CM, Chhun N, Sidle JE, Were E, Naanyu V, Emonyi W, Macharia SM, Sang E, Siika AM. Accuracy and acceptability of oral fluid HIV self-testing in a general adult population in Kenya. *AIDS and Behavior*. 2016 Apr 1;20(4):870-9.
39. Kwobah CM, Braitstein P, Koech JK, Simiyu G, Mwangi AW, Wools-Kaloustian K, Siika AM. Factors associated with late engagement to HIV care in Western Kenya: a cross-sectional study. *Journal of the International*

- Association of Providers of AIDS Care (JIAPAC). 2016 Nov;15(6):505-11.
40. Lee ES, Vedanthan R, Jeemon P, Kamano JH, Kudesia P, Rajan V, Engelgau M, Moran AE. Quality improvement for cardiovascular disease care in low-and middle-income countries: a systematic review. *PloS one*. 2016 Jun 14;11(6):e0157036.
 41. Makokha EP, Mwalili S, Basiye FL, Zeh C, Mwangi J, Emonyi WI, Langat R, Luman ET. Using standard and institutional mentorship models to implement SLMTA in Kenya: original research. *African Journal of Laboratory Medicine*. 2016 Jan 1;3(2):1-8.
 42. Manji I, Manyara SM, Jakait B, Ogallo W, Hagedorn IC, Lukas S, Kosgei EJ, Pastakia SD. The Revolving Fund Pharmacy Model: backing up the Ministry of Health supply chain in western Kenya. *International Journal of Pharmacy Practice*. 2016 Feb 1.
 43. McAteer, C.I., N.T. Truong, J. Aluoch, A.R. Deathe, W.M. Nyandiko, I. Marete, and R.C. Vreeman, A systematic review of measures of HIV/AIDS stigma in paediatric HIV-infected and HIV-affected populations. *J Int AIDS Soc*, 2016. **19**(1): p. 21204.
 44. McHenry MS, Nyandiko WM, Scanlon ML, Fischer LJ, McAteer CI, Aluoch J, Naanyu V, Vreeman RC. HIV Stigma Perspectives from Kenyan Child Caregivers and Adolescents Living with HIV. *Journal of the International Association of Providers of AIDS Care (JIAPAC)*. 2016 Sep 21:2325957416668995.
 45. Mcintosh IS, Kamaara E. AMPATH: A Strategic Partnership in Kenya.
 46. Miller ML, Karwa R, Schellhase EM, Pastakia SD, Crowe S, Manji I, Jakait B, Maina M. Meeting the needs of underserved patients in Western Kenya by creating the next generation of global health pharmacists. *American journal of pharmaceutical education*. 2016 Mar 25;80(2):22.
 47. Naanyu V, Vedanthan R, Kamano JH, Rotich JK, Lagat KK, Kiptoo P, Kofler C, Mutai KK, Bloomfield GS, Menya D, Kimaiyo S. Barriers influencing linkage to hypertension care in Kenya: qualitative analysis from the lark hypertension study. *Journal of general internal medicine*. 2016 Mar 1;31(3):304-14.
 48. Nakanjako D, Kiragga AN, Musick BS, Yiannoutsos CT, Wools-Kaloustian K, Diero L, Oyaro P, Lugina E, Ssali JC, Kambugu A, Easterbrook P. Frequency and impact of suboptimal immune recovery on first-line antiretroviral therapy within the International Epidemiologic Databases to Evaluate AIDS in East Africa. *Aids*. 2016 Jul 31;30(12):1913-22.
 49. Nathan RO, Swanson JO, Swanson DL, McClure EM, Bolamba VL, Lokangaka A, Pineda IS, Figueroa L, López-Gomez W, Garces A, Muyodi D. Evaluation of Focused Obstetric Ultrasound Examinations by Health Care Personnel in the Democratic Republic of Congo, Guatemala, Kenya, Pakistan, and Zambia. *Current Problems in Diagnostic Radiology*. 2016 Nov 10.
 50. Ndege S, Washington S, Kaaria A, Prudhomme-O'Meara W, Were E, Nyambura M, Keter AK, Wachira J, Braitstein P. HIV prevalence and antenatal care attendance among pregnant women in a large home-based HIV counseling and testing program in Western Kenya. *PloS one*. 2016 Jan 19;11(1):e0144618.
 51. Neumann CG, Nyandiko W, Siika A, Drorbaugh N, Samari G, Etyang G, Ernst JA. Morbidity and nutrition status of rural drug-naïve Kenyan women living with HIV. *African Journal of AIDS Research*. 2016 Sep 30;15(3):283-91.
 52. Oduor OC, Apondi OE, Gye BK, Siika W, Kipkoeh MK. Anti-bacterial susceptibility patterns of blood culture isolates at a referral hospital in Eldoret. *East African Medical Journal*. 2016;93(1):3-8.
 53. Olney JJ, Braitstein P, Eaton JW, Sang E, Nyambura M, Kimaiyo S, McRobie E, Hogan JW, Hallett TB. Evaluating strategies to improve HIV care outcomes in Kenya: a modelling study. *The Lancet HIV*. 2016 Dec 31;3(12):e592-600.
 54. Orang'o E, Itsura P, Tonui P, Muliro H, Rosen B, van Lonkhuijzen L. Use of Palliative Cisplatinium for Advanced Cervical Cancer in a Resource-Poor Setting: A Case Series From Kenya. *Journal of Global Oncology*. 2016 Oct:JGO006411.
 55. Orang'o EO, Liu T, Christoffersen-Deb A, Itsura P, Oguda J, Washington S, Chumba D, Pisharodi L, Cu-Uvin S, Rositch AF. Use of visual inspection with acetic acid, Pap smear, or high-risk human papillomavirus testing in women living with HIV/AIDS for posttreatment cervical cancer screening: same tests, different priorities. *Aids*. 2017 Jan 14;31(2):233-40.
 56. Orang'o EO, Wachira J, Asirwa FC, Busakhala N, Naanyu V, Kisuya J, Otieno G, Keter A, Mwangi A, Inui T. Factors

- Associated with Uptake of Visual Inspection with Acetic Acid (VIA) for Cervical Cancer Screening in Western Kenya. *PLoS One*. 2016 Jun 16;11(6):e0157217.
57. Papas RK, Gakinya BN, Mwaniki MM, Keter AK, Lee H, Loxley MP, Klein DA, Sidle JE, Martino S, Baliddawa JB, Schlaudt KL. Associations Between the Phosphatidylethanol Alcohol Biomarker and Self-Reported Alcohol Use in a Sample of HIV-Infected Outpatient Drinkers in Western Kenya. *Alcoholism: Clinical and Experimental Research*. 2016 Aug 1;40(8):1779-87.
 58. Park PH, Chege P, Hagedorn IC, Kwena A, Bloomfield GS, Pastakia SD. Assessing the accuracy of a point-of-care analyzer for hyperlipidaemia in western Kenya. *Tropical Medicine & International Health*. 2016 Jan 1.
 59. Pastakia SD, Manyara SM, Vedanthan R, Kamano JH, Menya D, Andama B, Chesoli C, Laktabai J. Impact of Bridging Income Generation with Group Integrated Care (BIGPIC) on Hypertension and Diabetes in Rural Western Kenya. *Journal of General Internal Medicine*. 2016 Dec 5:1-9.
 60. Patel K, Matthew Strother R, Ndiangui F, Chumba D, Jacobson W, Dodson C, Resnic MB, Strate RW, Smith JW. Development of immunohistochemistry services for cancer care in western Kenya: Implications for low-and middle-income countries. *African Journal of Laboratory Medicine*. 2016;5(1):1-7.
 61. Pfeiffer EJ, Maithya HM. Bewitching sex workers, blaming wives: HIV/AIDS, stigma, and the gender politics of panic in western Kenya. *Global public health*. 2016 Sep 1:1-5.
 62. Prudhomme O'Meara, W., Mohanan, M., Laktabai, J., Lesser, A., Platt, A., Maffioli, E., Turner, E. L., & Menya, D. (2016). Assessing the independent and combined effects of subsidies for antimalarials and rapid diagnostic testing on fever management decisions in the retail sector: results from a factorial randomised trial in western Kenya. *BMJ Global Health*, 1(2),e000101.
 63. Rachlis B, Bakoyannis G, Easterbrook P, Genberg B, Braithwaite RS, Cohen CR, Bukusi EA, Kambugu A, Bwana MB, Somi GR, Geng EH. Facility-level factors influencing retention of patients in HIV care in East Africa. *PLoS One*. 2016 Aug 10;11(8):e0159994.
 64. Rachlis B, Karwa R, Chema C, Pastakia S, Olsson S, Wools-Kaloustian K, Jakait B, Maina M, Yotebieng M, Kumarasamy N, Freeman A. Targeted Spontaneous Reporting: Assessing Opportunities to Conduct Routine Pharmacovigilance for Antiretroviral Treatment on an International Scale. *Drug safety*. 2016 Oct 1;39(10):959-76.
 65. Rachlis B, Naanyu V, Wachira J, Genberg B, Koech B, Kamene R, Akinyi J, Braitstein P. Community Perceptions of Community Health Workers (CHWs) and their roles in management for HIV, tuberculosis and hypertension in Western Kenya. *PloS one*. 2016 Feb 22;11(2):e0149412.
 66. Rachlis B, Naanyu V, Wachira J, Genberg B, Koech B, Kamene R, Akinyi J, Braitstein P. Identifying common barriers and facilitators to linkage and retention in chronic disease care in western Kenya. *BMC Public Health*. 2016 Aug 8;16(1):741.
 67. Rich JD, Beckwith CG, Macmadu A, Marshall BD, Brinkley-Rubinstein L, Amon JJ, Milloy MJ, King MR, Sanchez J, Atwoli L, Altice FL. Clinical care of incarcerated people with HIV, viral hepatitis, or tuberculosis. *The Lancet*. 2016 Sep 16;388(10049):1103-14.
 68. Saito S, Mpofu P, Carter EJ, Diero L, Wools-Kaloustian KK, Yiannoutsos CT, Beverly MS, Tsiouris S, Somi GR, Ssali J, Nash D. Implementation and Operational Research: Declining Tuberculosis Incidence Among People Receiving HIV Care and Treatment Services in East Africa, 2007–2012. *JAIDS Journal of Acquired Immune Deficiency Syndromes*. 2016 Apr 1;71(4):e96-106.
 69. Sawe RT, Kerper M, Badve S, Li J, Sandoval-Cooper M, Xie J, Shi Z, Patel K, Chumba D, Ofulla A, Prosperi J. Aggressive breast cancer in western Kenya has early onset, high proliferation, and immune cell infiltration. *BMC cancer*. 2016 Mar 10;16(1):204.
 70. Semeere A, Wenger M, Busakhala N, Buziba N, Bwana M, Muyindike W, Amerson E, Maurer T, McCalmont T, LeBoit P, Musick B. A prospective ascertainment of cancer incidence in sub-Saharan Africa: The case of Kaposi sarcoma. *Cancer medicine*. 2016 Jan 1.
 71. Shangani S, Naanyu V, Mwangi A, Vermandere H, Mereish E, Obala A, Broeck DV, Sidle J, Operario D. Factors associated with HIV testing among men who have sex with men in Western Kenya: a cross-sectional study. *International journal of STD & AIDS*. 2016 Mar 11:0956462416638967.

72. Shubber Z, Mills EJ, Nachega JB, Vreeman R, Freitas M, Bock P, Nsanzimana S, Penazzato M, Appolo T, Doherty M, Ford N. Patient-Reported Barriers to Adherence to Antiretroviral Therapy: A Systematic Review and Meta-Analysis. *PLoS medicine*. 2016 Nov 29;13(11):e1002183.
73. Stein DJ, Karam EG, Shahly V, Hill ED, King A, Petukhova M, Atwoli L, Bromet EJ, Florescu S, Haro JM, Hinkov H. Post-traumatic stress disorder associated with life-threatening motor vehicle collisions in the WHO World Mental Health Surveys. *BMC psychiatry*. 2016 Jul 22;16(1):257.
74. Swanson JO, Plotner D, Franklin HL, Swanson DL, Bolamba VL, Lokangaka A, Pineda IS, Figueroa L, Garces A, Muyodi D, Esamai F. Web-Based Quality Assurance Process Drives Improvements in Obstetric Ultrasound in 5 Low-and Middle-Income Countries. *Global Health: Science and Practice*. 2016 Dec 23;4(4):675-83.
75. Szkwarko D, Mercer T, Kimani S, Braitstein P, Buziba N, Carter EJ. Implementing intensified tuberculosis case-finding among street-connected youth and young adults in Kenya. *Public Health Action*. 2016 Jun 21;6(2):142-6.
76. Wachira J, Kamanda A, Embleton L, Naanyu V, Ayuku D, Braitstein P. 'Pregnancy Has Its Advantages': The Voices of Street Connected Children and Youth in Eldoret, Kenya. *PloS one*. 2016 Mar 4;11(3):e0150814.
77. Were MC, Kamano JH, Vedanthan R. Leveraging Digital Health for Global Chronic Diseases. *Global Heart*. 2016 Dec; 11(4): p.459–62
78. Wilunda C, Tanaka S, Esamai F, Kawakami K. Prenatal anemia control and anemia in children aged 6–23 months in sub-Saharan Africa. *Maternal & child nutrition*. 2016 Jan 1.
79. Yarmoshuk AN, Guantai AN, Mwangi M, Cole DC, Zarowsky C. Mapping International University Partnerships Identified by East African Universities as Strengthening Their Medicine, Nursing, and Public Health Programs. *Annals of Global Health*. 2016.
80. Yoshida, S; Martines, J; Lawn, JE; Wall, S; Souza, JP; Rudan, I; Cousens, S; neonatal health research priority setting group; Aaby, P; Adam, I; Adhikari, RK; Ambalavanan, N; Arifeen, SE; Aryal, DR; Asiruddin, S; Baqui, A; Barros, AJ; Benn, CS; Bhandari, V; Bhatnagar, S; Bhattacharya, S; Bhutta, ZA; Black, RE; Blencowe, H; Bose, C; Brown, J; Bühner, C; Carlo, W; Cecatti, JG; Cheung, PY; Clark, R; Colbourn, T; Conde-Agudelo, A; Corbett, E; Czeizel, AE; Das, A; Day, LT; Deal, C; Deorari, A; Dilmen, U; English, M; Engmann, C; Esamai, F; Fall, C; Ferriero, DM; Gisore, P; Hazir, T; Higgins, RD; Homer, CS; Hoque, DE; Irgens, L; Islam, MT; de Graft-Johnson, J; Joshua, MA; Keenan, W; Khatoon, S; Kieler, H; Kramer, MS; Lackritz, EM; Lavender, T; Lawintono, L; Luhanga, R; Marsh, D; McMillan, D; McNamara, PJ; Mol, BW; Molyneux, E; Mukasa, GK; Mutabazi, M; Nacul, LC; Nakakeeto, M; Narayanan, I; Olusanya, B; Osrin, D; Paul, V; Poets, C; Reddy, UM; Santosham, M; Sayed, R; Schlabritz-Loutsevitch, NE; Singhal, N; Smith, MA; Smith, PG; Soofi, S; Spong, CY; Sultana, S; Tshetu, A; van Bel, F; Gray, LV; Waiswa, P; Wang, W; Williams, S; Wright, L; Zaidi, A; Zhang, Y; Zhong, N; Zuniga, I; Bahl, R; (2016) Setting research priorities to improve global newborn health and prevent stillbirths by 2025. *Journal of global health*, 6 (1). 010508. ISSN 2047-2978 DOI: 10.7189/jogh.06.010508

Index

ADAT i	Busakhala...4, 5, 53, 54, 61, 62, 66, 71, 73, 74	Genberg 30, 40, 71, 74
Adult Medicine Research Working Group <i>See</i> AMWG	Busia District Hospital.....28, 34, 58	Global Fund..... 36
Affordable Medicines Facility - malaria 36	Canadian Institutes of Health Research25, 52	Grand Challenges Canada 1, 20
AIDS..... 4, 6, 7, 8, 9, 13	Cardiovascular and Metabolic Disease Research Working Group..... <i>See</i> CVMD	Grants..... ii
AIDS Clinical Trials Group (ACTG)4, 6, 7, 8, 9	Cardiovascular Disease. <i>See</i> CVD or CVMD	Grinter..... 2
Alex's Lemonade Stand Foundation..... 21	CDC 23	group cognitive-behavioral therapy..... 2
AMPATH 2, 1, 70	Center for AIDS Research ... 13, 43, 64	HBCT..... 30, 40, 53, 60
AMPATH Data Analysis Team... <i>See</i> ADAT	Centers for Disease Control and Prevention <i>See</i> CDC	HIV....2, 3, 5, 6, 7, 9, 10, 11, 12, 13, 14, 22, 23, 25, 28, 29, 30, 33, 34, 35, 40, 41, 43, 48, 49, 50, 51, 52, 53, 55, 56, 57, 58, 60, 61, 63, 64, 65, 66, 68, 69, 70, 71, 72, 73, 74
AMPATH Oncology Institute (AOI) 61	cervical cancer9, 71, 73	HIV-infected mothers.... 12, 13, 28, 29, 30, 43
AMPATH Research Program..... 2, ii	Chama.....19, 20	HIV-infected outpatients 2
AMWG i, 2, 3, 4, 5, 6, 7, 10, 14, 16, 23, 26, 30, 39, 40, 44, 45, 48, 51, 53, 55, 61, 66	chemotherapy 5, 15, 54, 65, 67, 68	Hogan. 2, 30, 45, 49, 69, 70, 71, 73
Ananda 42, 43	Children .11, 13, 15, 20, 29, 43, 49, 52, 59, 63, 66, 68, 71, 75	home-based HIV counseling and testing <i>See</i> HBCT
Anticoagulation Monitoring Services (AMS) 18	Christoffersen-Deb ...18, 19, 24, 73	HPV..... 9, 10
antiretroviral therapy 4, 5, 7, 8, 12, 28, 36, 55, 56, 71, 72, 73	Chulaimbo Sub-District Hospital16, 49, 57, 64	Indiana University9, 11, 13, 15, 21, 23, 26, 28, 29, 33, 39, 42, 43, 49, 55, 56, 57, 60, 61, 65, 66, 68
Apondi.... 29, 30, 50, 58, 60, 61, 73	CHWs17, 23, 37, 39, 45, 47, 74	Indiana University - Purdue University in Indianapolis (IUPUI)..... 9
ART 4, 5, 6, 8, 12, 23, 28, 31, 33, 34, 55, 56, 65, 69	Community Health Extension Workers (CHEWs) 47	Institutional Review and Ethics Committee <i>See</i> IREC
Asirwa..... 61, 62, 65, 66, 73	contraception 18	Inui ... 26, 39, 45, 49, 51, 61, 62, 73
Ayaya..... 29, 30, 33, 69, 71	contraceptive implants.....18, 28	IRECi, 10, 17, 23, 24, 25, 26, 31, 53, 63, 69
Ayuku ... 1, 2, 22, 25, 52, 59, 71, 75	cryotherapy 9	IU Health 39, 40
Ayuo 26, 31	cryptococcal meningitis..... 3	IU Simon Cancer Center (IUSCC) 61
Basic Science Research Working Group <i>See</i> BSWG	CVD16, 46	Jakait 28, 35, 51, 72, 73, 74
Behavioral and Social Science Research Working Group <i>See</i> SSRN	CVMDi, 16, 44, 45	Johnson and Johnson..... 1
Biobanking 39	Data and Safety Monitoring Board 5	Kaaria 9, 61, 73
Braitstein22, 25, 30, 35, 48, 51, 52, 53, 59, 61, 63, 71, 72, 73, 74, 75	Duke University1, 10, 14, 36, 66	Kamaara 63, 73
Brown..... 9, 40, 64, 69, 75	Eldoret 2	Kamanda 22, 25, 63, 71, 75
Brown University..... 40, 64, 69	Embleton22, 59, 71, 75	Kamano . 15, 18, 33, 45, 71, 72, 73, 74, 75
BSWG i	Family Dynamics..... 2	Kantor 69, 71
Burnt Forest Sub-District Hospital 28, 42, 49, 57	Family Therapy 2	KEMRI..... 9, 10
	FLTR30, 31	Kenya 2
	fluconazole 3	Kenya Medical Research Institute <i>See</i> KEMRI
	focus group discussions (FGDs) 13, 43, 64	
	Fuster.....16, 45, 72	
	Gayapersad.....62, 63	

Keter.....	3, 35, 60, 61, 62, 71, 73
Kimaiyo...	30, 39, 44, 45, 70, 72, 73
Kiplagat-Kirui.....	2
Kitale District Hospital...	13, 21, 23, 42, 43, 49, 57, 69
KS4, 5, 54, 65	
Kussin	10, 11, 14, 66
Lagat.....	3, 6, 7, 14, 66, 73
Laktabai.....	18, 36, 39, 74
Lalani	10, 11
leadership.....	2
LEEP.....	9
leukemia.....	21, 67
Litzelman	26
Loehrer	9, 65, 66
long-acting reversible contraception.....	18
Loop Electrosurgical Excision Procedure.....	9
lymphoblastic leukemia	67
malaria	21, 36, 37
Manji	18, 72, 73
Maternal death	21
Maurer	65, 70, 74
McHenry 11, 28, 30, 42, 43, 50, 57, 73	
Medication Event Monitoring Systems	See MEMS
MEMS.....	33, 34
Mental Health 2, 41, 49, 57, 71, 75	
Menya	16, 18, 36, 39, 45, 73, 74
MMed program.....	27
Moi Teaching and Referral Hospital ..1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 13, 15, 18, 19, 22, 24, 25, 27, 28, 29, 35, 40, 42, 43, 44, 49, 51, 52, 54, 55, 57, 59, 60, 62, 63, 66, 69, 70	
Moi University. 1, 2, 3, 4, 5, 6, 7, 8, 11, 14, 15, 19, 21, 22, 23, 25, 26, 28, 29, 30, 31, 32, 33, 36, 39, 40, 42, 43, 45, 49, 52, 53, 54, 55, 56, 59, 61, 63, 66, 68, 69	
Mosoriot Rural Health Training Centre.....	42, 45, 46, 49, 57, 62
Mount Sinai School of Medicine15, 44, 45	
Mukhobola Health Centre... 20, 28, 64	
Mwangi..	23, 49, 62, 70, 71, 72, 73, 74
Mwogi.....	10, 11
Naanyu...16, 23, 45, 50, 56, 62, 71, 72, 73, 74, 75	
National Cancer Institute (NCI)4, 5, 10, 65	
National Institute of Allergy and Infectious Diseases (NIAID) .4, 5, 34, 41	
National Institute of Child Health and Human Development (NICHD).....	68
National Institute on Alcohol Abuse and Alcoholism (NIAAA) 2	
National Institutes of Health	See NIH
Ndege	7, 30, 53, 60, 73
Neurodevelopmental Delays	11, 13, 43
Newborn death.....	20
Ng'etich.....	35
NIH ...ii, iii, 2, 4, 5, 6, 7, 8, 9, 10, 15, 16, 27, 28, 34, 37, 41, 45, 46, 48, 49, 53, 54, 55, 57, 65, 68, 69	
NIH - Fogarty International Center (FIC).....	27
NIH - National Heart, Lung, and Blood Institute (NHLBI).....	46
Njuguna	15, 21, 66
Nyandiko..	2, 33, 35, 49, 50, 51, 55, 56, 58, 68, 71, 73
observational assessment	1
Omenga	9
Oncology.....	i, 9, 61, 71, 73
Oncology Research Working Group.....	See ORWG
ORWG .. i, 4, 5, 9, 15, 21, 54, 65, 66	
Osieko Dispensary	20
Oyungu	11, 42, 43
Parks	24
Pastakia..16, 18, 35, 51, 71, 72, 73, 74	
Patel.....	28, 70, 72, 74
Paul.....	14, 26, 31, 66, 75
PCWG.....	i, 51
Pediatric Research Working Group	See PRWG
PHPCWG	i, 36, 40
Plater.....	2
Port Victoria Sub-District Hospital	13, 20, 43, 58, 64
Preschool enrolment	21
Prudhomme	36, 39, 73, 74
PRWGi, 1, 12, 14, 15, 19, 21, 22, 25, 29, 30, 33, 35, 42, 43, 48, 49, 51, 52, 55, 56, 58, 59, 60, 66, 69	
Public Health and Primary Care Research Working Group.....	See PHPCWG
publications.....	ii, iv, 3, 27, 36, 70
Publications Committee.....	ii
Puffer	1, 2
Reproductive Health Research Working Group.....	See RHWG
Research and Sponsored Projects Office.....	See RSPO
Research Program Office	2, See RPO
RHWG	i, 9, 18, 19, 24, 28, 60
RPO	i
RSPO	i
Rugunga Dispensary.....	20
Ruhl	19
Rwambua Dispensary	20
Saboti Sub-District Hospital	24
Siika ..3, 4, 5, 6, 7, 8, 10, 11, 23, 31, 55, 56, 72, 73	
Skiles	15, 21, 66
SSRNi, 1, 2, 3, 5, 6, 7, 22, 40, 63, 64	
stigma.....	22, 41, 50, 56, 57, 73, 74
Stunting and Wasting.....	21
TBWG	i, 6, 8, 31
training and experience of healthcare providers.....	12
Tuberculosis Research Working Group	See TBWG
Turbo Health Centre . 2, 13, 42, 43, 45, 46, 49, 57, 62, 69	
Uganda.....	32, 33, 55, 56, 65, 72
UNAIDS.....	31
University of Toronto....	18, 19, 22, 23, 24, 25, 30, 35, 48, 52, 53, 59, 62, 63
University of Washington	28
Vedanthan... 15, 18, 33, 44, 45, 71, 72, 73, 74, 75	

VMMC	25, 26	Wachira .	22, 30, 40, 56, 61, 62, 71, 73, 74, 75	Were	31, 33, 45, 70, 72, 73, 75
voluntary medical male circumcision	See VMMC	Walther Cancer Foundation	62	Wools-Kaloustian	23, 51, 55, 71, 72, 73, 74
Vreeman..	2, 29, 30, 33, 35, 49, 50, 56, 58, 68, 69, 73, 74	Walumbe	2	World Health Organization (WHO)	14, 51
		Webuye District Hospital.	2, 42, 43, 49, 57, 62, 63, 69		