

# SEMI ANNUAL RESEARCH REPORT

January – June 2017



## Acknowledgements

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

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# Contents

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<b>Abbreviations</b> .....	<b>i</b>
<b>Overview</b> .....	<b>ii</b>
<b>Grants</b> .....	<b>ii</b>
<b>Publications</b> .....	<b>iii</b>
<b>Study Reports</b> .....	<b>1</b>
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) .....	5
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
Adapting, piloting, and evaluating an innovative HIV prevention intervention integrated with group-led matched-savings for street-connected young people in western Kenya .....	9
AMPATH - Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS .....	10
Analysis of ICU Admissions and Outcomes at the Moi Teaching and Referral Hospital Intensive Care Unit .....	11
Assessment of Airway Disease in Western Kenya .....	12
Biomarkers of Vincristine Toxicity in Kenyan Children .....	13
Bridging Income Generation with Group Interated Care(BIGPIC) .....	13
Can integration of effective family planning services into Anticoagulation Management Services (AMS) improve uptake? .....	15
Childhood Leukemia in Kenya Identified Through Malaria Slide Review .....	17
Community perceptions and perceived needs of street-connected children and youth in Eldoret Kenya: a qualitative investigation.....	17
Developing and Assessing a Community-Based Model of Antiretroviral Care .....	18

Effect of free maternity care on maternal and fetal outcomes of preeclampsia/eclampsia at a teaching hospital in Western Kenya: A retrospective chart review.....	19
Enhancing Preventive Therapy of Malaria In children with Sickle cell anemia in East Africa (EPITOMISE).....	20
Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy. 21	
ESYHI study - Identification, adaptation and piloting of innovative interventions to engage street-connected children and youth in the HIV prevention-care continuum in a resource-constrained setting.....	22
Ethnic Specific Risk Stratification in Early Pregnancy for Identifying Mothers at Risk of Gestational Diabetes Mellitus in Eldoret, Kenya .....	23
Evaluation of the growth and development of young children of HIV-infected mothers in western Kenya. ....	24
FLTR Evaluation .....	25
HI-Train: Health Informatics Training and Research in East Africa for Improved Health Care .....	26
leDEA Comprehensive Adherence Measure for Pediatrics (ICAMP) .....	27
Innovative Community Sourcing Techniques to Investigate Reproductive Health Issues in a Population Aged 13-65 Years in Western Kenya .....	29
Innovative public-private partnership to target subsidized antimalarials in the retail sector .....	30
Linkage and Retention to Care in Western Kenya Following HIV Testing .....	32
Making Inroads to Strengthen the Health of Adolescents (MaISHA) .....	34
MCH STUDY (Evaluations at Infant and Child Visits a MCHs in western Kenya: A Needs Assessment) .....	36
NEURODEV (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study) .....	36
Nurse Management of Hypertension Care in Rural Western Kenya .....	38
One Year Morbidity and Mortality of Infants Diagnosed with Perinatal Asphyxia or Low Birth Weight Admitted to The New Born Unit at Moi Teaching and Referral Hospital.....	39
Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK) .....	40
Pathways to better health .....	42
Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI) .....	43
Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretroviral Treatment .....	44
Phylogenetic Inference of Vertical versus Horizontal HIV Transmission among Adolescents in Western Kenya .....	45
Point in Time (PIT) Count of Street Children in Eldoret .....	47
'Point of Care CD4 testing for people who fail to engage in care after testing HIV positive' .....	47
Randomized, Phase II Trial of CHOP vs. Oral Chemotherapy with Concomitant Antiretroviral Therapy in Patients with HIV-associated Lymphoma in Sub-Saharan Africa .....	48
REALITY 'Reduction of EARly mortaLITY in HIV-infected adults and children starting antiretroviral therapy' .....	49
SAFI (Stigma in AIDS Family Inventory) Validation Study .....	50
Spatial scales of Plasmodium falciparum generations; implications for elimination .....	52

Study of Newly Diagnosed Kaposi's Sarcoma .....	53
Tablet Computer-Based Disclosure Counseling for HIV-Infected Adolescents and their Families: A Pilot Study of Perspectives from Providers .....	54
Taking to the Streets: a Mixed-Methods Systematic Review of the Reasons Children and Youth Become Street-Involved.....	55
The Confluence of Pregnancy and New HIV Diagnosis Among Adolescents in Western Kenya.....	56
The Epidemiology of Trauma and Trauma-Related Resources 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 Testing and Treatment Programs 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
Using Narrative Films to Combat HIV Stigma: Perspectives from HIV-Infected Adolescents and their Caregivers .....	62
Validating an Integrated Community Based Strategy of Peer Support in Pregnancy and Infancy .....	63
Validation of Spirometry Prediction Equations in Western Kenya .....	64
Vincristine Optimization in Kenyan Children with Cancer .....	65
Viral Suppression among HIV-infected Children and Caregivers in Western Kenya .....	67
Virologic Treatment Failure and Drug Resistance in HIV-Infected Kenyan Children (RESPECT) study.....	67
<b>Bibliography.....</b>	<b>69</b>
<b>Appendix A: East Africa leDEA Annual Report .....</b>	<b>74</b>
<b>Index.....</b>	<b>101</b>

## Abbreviations

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

## Overview

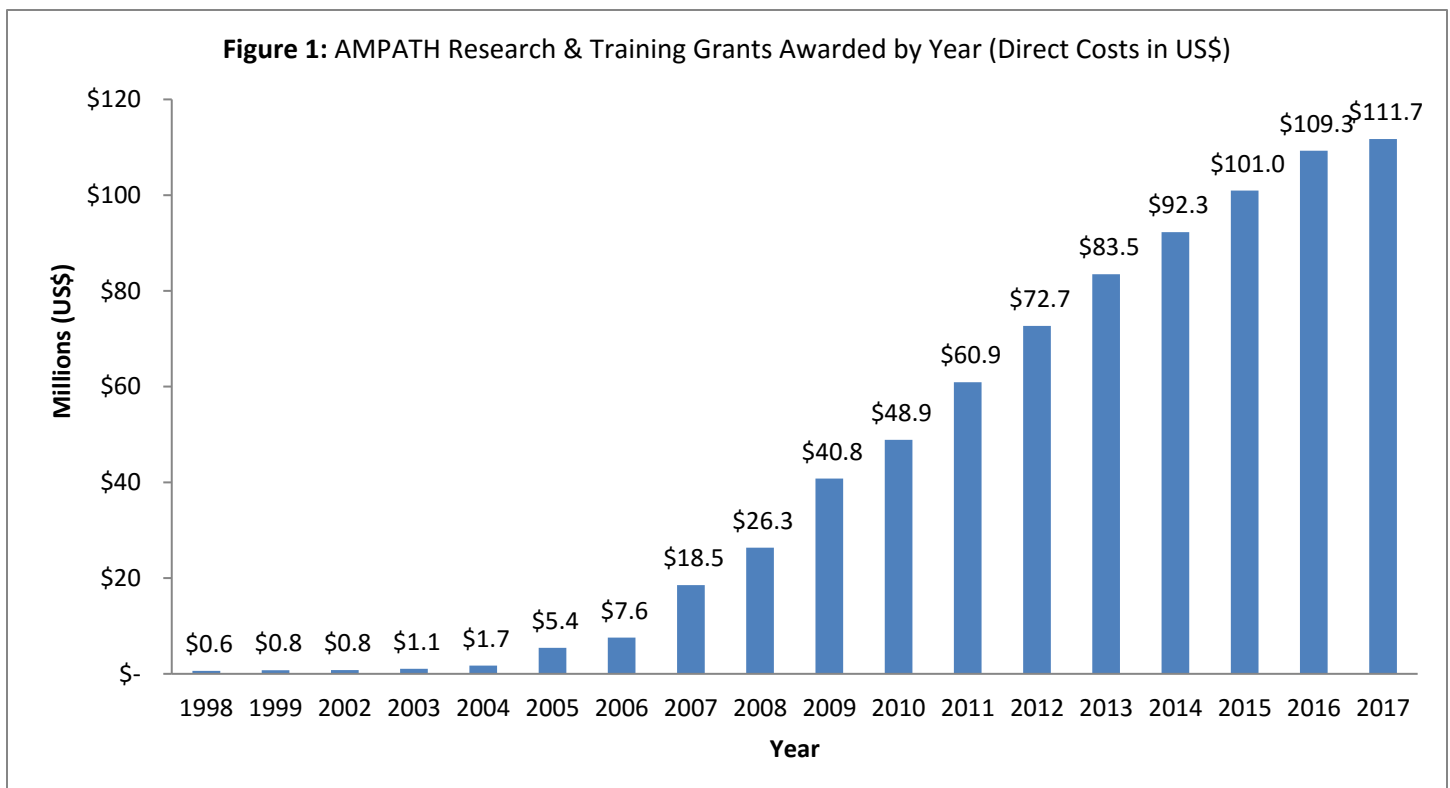
The AMPATH Research Program continued to grow in the first half of 2017. Since the year began nearly \$2.5 million was awarded for research projects at AMPATH. Awards from the NIH accounted for all of these new awards. Despite positive growth during this period, the total amount of awards was slower than in previous years. Despite a sluggish start, the program remains on track to continue growth trends from previous years.

In contrast, 2017 is shaping-up to be a strong year for peer reviewed publications. Since the start of the year, investigators have published 56 articles in peer reviewed journals. This is a significantly higher rate than in previous years and puts the program on track to surpass last year’s record number of publications. .

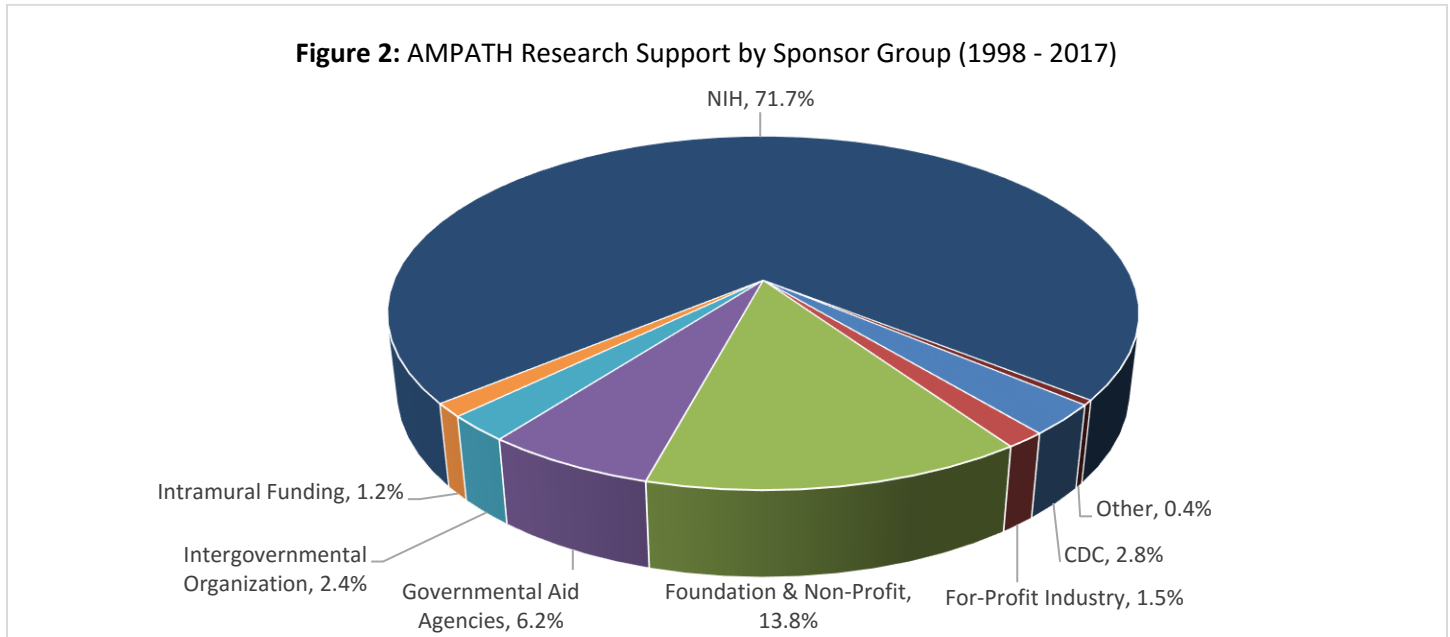
The Moi University College of Health Sciences held its first research symposium titled *Healthcare Informed by Evidence*. The symposium included 16 oral presentations from Moi researchers and 21 poster presentations on topics ranging from home based counseling and testing for HIV in western Kenya to evaluations of mentorship programs for marginalized youth. This successful symposium provided an important opportunity for members of the research community in Kenya and will continue as an annual event.

## Grants

Investigators reported nearly US\$ 2.5 million in new awards in the first six months of 2017. This increased AMPATH’s cumulative total of research direct awards to almost US\$112 million since the start of the program (See Figure 1).

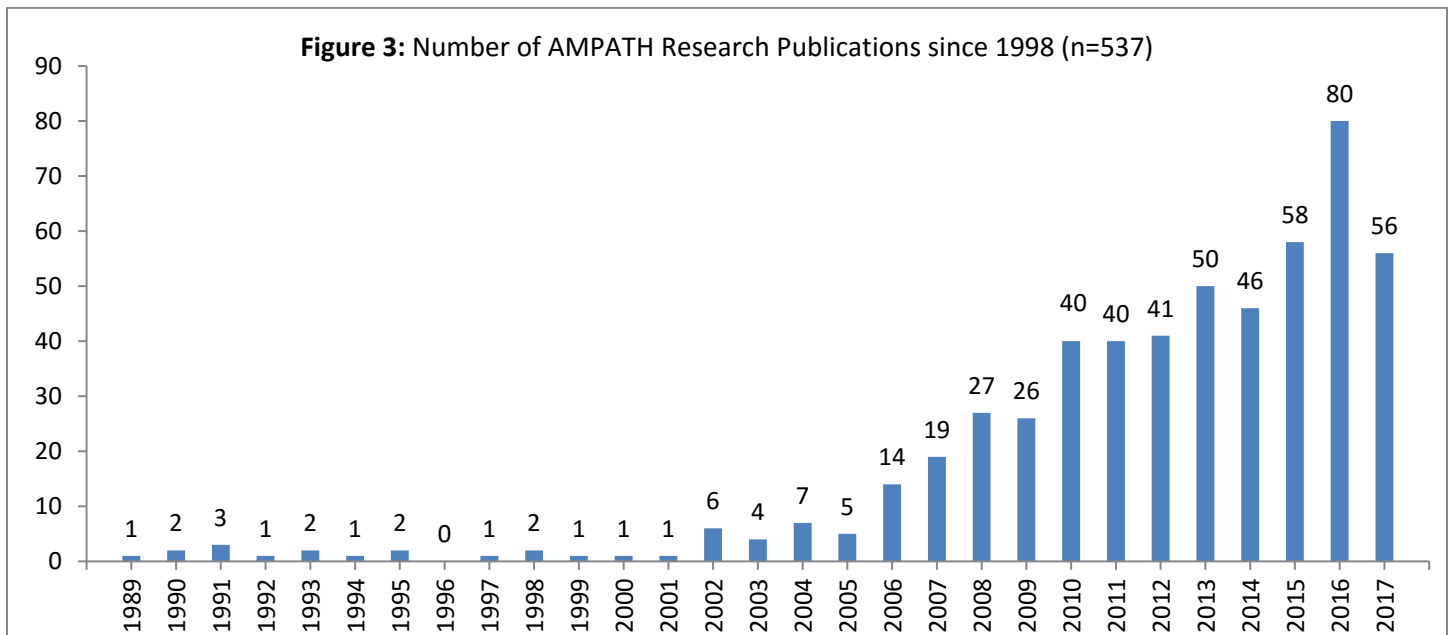


All of the new awards reported during this period were from the NIH. Since 1998, 72 percent of research awards were from the NIH, 14 percent were from charitable foundations and non-profits, and 6 percent were from the Government Aid Agencies (See Figure 2).



## Publications

A total of 56 manuscripts were published by AMPATH investigators during the first six months of 2017. A bibliography of all the publications produced from January – June of 2017 is available at the end of this report. The AMPATH Publications Committee, which reviews all publications produced from AMPATH research projects, reviewed a total of 73 draft publications during this period.





## Study Reports

The following reports were provided by AMPATH investigators and their study teams and cover the period of January 1 – June 30, 2017.

<b>Study Title</b>	<b>A Formative Study to Develop Culturally Valid Psychosocial Assessment Tools and Interventions to Promote Family Well-Being in Kenya</b>
<b>Principal Investigator(s)</b>	Eve Puffer, Duke University
<b>Co-Investigator(s)</b>	David Ayuku, Moi University Wilter Rono,
<b>Working Group(s)</b>	PRWG, SSRN
<b>Description</b>	This study aims to contribute to the evidence base related to effective interventions for families in low-resource settings who are experiencing conflict and difficulties in relationships that affect child and caregiver wellbeing alike. Results of this study will (a) inform whether a family therapy approach is feasible and promising in communities in and surrounding Eldoret, Kenya and (b) inform how family wellbeing and mental health can be measured in culturally-valid ways in this context. Our long-term research goal is to establish an evidence-based and culturally-anchored family therapy intervention for very low-resource settings to improve family functioning, thereby preventing negative outcomes including mental health problems and HIV risk. Our objectives in this study are to create a new measure of family functioning and to develop and pilot a family therapy intervention. We will first develop a measure of family functioning that includes both survey and direct observation to complement self-report. We will then use a community-based participatory research process to develop a family therapy intervention that integrates evidence-based family therapy strategies with existing community solutions. Specific Aim #1: Develop new measures of family functioning including both survey measures and direct observation of family interactions. Specific Aim #2: Develop a family therapy intervention that integrates evidence-based family therapy strategies with existing community-based strategies for solving family problems. Specific Aim #3: Conduct a pilot study of the intervention with families to test feasibility and acceptability.
<b>Site(s)</b>	Moi Teaching and Referral Hospital (MTRH)
<b>Project Period</b>	5/28/2013 - 12/31/2018
<b>Funding Status</b>	Funded – Grand Challenges Canada & Johnson and Johnson
<b>Direct Award (USD)</b>	\$129,000
<b>Update</b>	For the measures validation component of our work, we completed data collection and also have completed the main analyses that has led to the selection of items assessing family functioning and parent-child relationships. These items can now be used in our current and future work as measures validated in this context. The analysis related to the direct observational measure are still underway. For our intervention evaluation component, we are conducting the follow-up study of the family therapy intervention.

	This study uses a single-subject case series design to estimate clinical effects. We also are delivering the program through religious congregations to examine this approach as a potential scale-up strategy for future dissemination. At the end of June 2017, we had engaged local religious leaders in the process of identifying congregations, and participant recruitment and counselor training are now underway.
<b>Future Plans</b>	We plan to complete the final analysis on the measures validation study, including the validation of the observational family functioning measure. We are in the beginning stages of publications related to this, one of which we hope to submit within the next 6 months. We plan to continue the intervention study, with expected completion of the intervention and data collection in approximately February 2018.
<b>Publication(s)</b>	Conference Presentations: Puffer, E. S., Friis, E. A., Giusto, A., & Ayuku, D. (2017). Development of a family therapy intervention in Kenya: A community-based and culturally anchored approach. Paper presented at the Society for the Study of Psychiatry and Culture Annual Meeting, Princeton, NJ. Friis, E. A.,* Green, E. P., & Puffer, E. S. (2017). Utilizing technology in provision of a culturally grounded family therapy by religious lay counselors in Kenya. Paper presented at the Society for the Study of Psychiatry and Culture Annual Meeting, Princeton, NJ. Friis, E. A.* & Puffer, E. S. (2017). Family-Based Adolescent Maltreatment in Kenya: Development of a Culturally Grounded Model. Paper presented at the Society for the Study of Psychiatry and Culture Annual Meeting, Princeton, NJ. Winner of the Charles Hughes Award Giusto, A.* & Puffer, E. S. (2017). A direct observational measure of family functioning for a low-resource setting: Adaptation and feasibility in a Kenyan sample. Paper presented at the Society for the Study of Psychiatry and Culture Annual Meeting, Princeton, NJ.
<b>Study Title</b>	<b>A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI)</b>
<b>Principal Investigator(s)</b>	Rebecca Papas, Brown University
<b>Co-Investigator(s)</b>	B. Gakinya, Moi University Michael Mwaniki, Maisto, S. Martino, S. Baliddawa, J. Sidle, J. Hogan, J. Carroll, K.
<b>Working Group(s)</b>	AMWG, SSRN
<b>Description</b>	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.
<b>Site(s)</b>	Iten District Hospital, Moi Teaching and Referral Hospital , Turbo Health Centre, Webuye District Hospital

<b>Project Period</b>	11/1/2011 - 8/31/2016
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$2,268,832
<b>Update</b>	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 one publication on Rates and Covariates of Recent Sexual and Physical Violence Against HIV-Infected Outpatient Drinkers in Western Kenya. Other publications are in the pipeline
<b>Future Plans</b>	We plan to do more publications.
<b>Publication(s)</b>	<p>Associations Between the Phosphatidylethanol Alcohol Biomarker and Self-Reported Alcohol Use in a Sample of HIV-Infected Outpatient Drinkers in Western 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</p> <p>Rates and Covariates of Recent Sexual and Physical Violence Against HIV-Infected Outpatient Drinkers in Western Kenya Rebecca K. Papas<sup>1</sup> • Benson N. Gakinya<sup>2</sup> • Michael M. Mwaniki<sup>3</sup> • Hana Lee<sup>4</sup> • Stella W. Kiarie<sup>5</sup> • Steve Martino<sup>6</sup> • Michelle P. Loxley<sup>4</sup> • Alfred K. Keter<sup>3</sup> • Debra A. Klein<sup>7</sup> • John E. Sidle<sup>8</sup> • Joyce B. Baliddawa<sup>2</sup> • Stephen A. Maisto</p>

<b>Study Title</b>	<b>A5225/HiFLAC Protocol - A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated Cryptococcal Meningitis</b>
<b>Principal Investigator(s)</b>	Abraham Siika, Moi University
<b>Co-Investigator(s)</b>	David Lagat, Moi University Priscilla Cheruiyot, Lagat, D.
<b>Working Group(s)</b>	AMWG, SSRN
<b>Description</b>	A5225/HiFLAC is a phase I/II dose escalation and validation study of the safety, tolerability, and therapeutic effect of an induction-consolidation strategy of high-dose fluconazole alone for the treatment of cryptococcal meningitis (CM) in HIV-infected participants. The study will proceed in two stages. In Stage 1, Dose Escalation, up to three induction doses of fluconazole will be tested in sequentially enrolled cohorts. Stage 2, Dose Validation, will not open until the maximum tolerated dose (MTD) of fluconazole has been identified in Stage 1. In Stage 2, induction doses of fluconazole that are found to be safe in Stage 1 will be tested in simultaneously enrolled cohorts. In each stage, participants will be randomized at entry into Step 1. Over the course of the study, participants will register to subsequent steps (Steps 2-4) based on their initial randomization and/or their response to treatment. The study steps are: Step 1: Induction therapy with either high dose fluconazole or ampho B; Step 2: Induction following early ampho B intolerance (only for participants randomized to ampho B treatment in Step 1) (fluconazole at 400-800 mg daily); Step 3: Consolidation therapy (fluconazole 400 mg daily); and Step 4: Maintenance therapy (fluconazole 200 mg daily).

Site(s)	Moi Teaching and Referral Hospital
Project Period	5/18/2011 - 12/31/2013
Funding Status	Funded
Direct Award (USD)	Not Reported
Update	There were no study activities over the reporting period for this study
Future Plans	All study activities at the site are closed
Publication(s)	
Study Title	<b>A5263 'A Randomized Comparison of Three Regimens of Chemotherapy with Compatible Antiretroviral Therapy for Treatment of Advanced AIDS-KS in Resource-Limited Settings'</b>
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Naftali Busakhala, Moi University Priscilla Cheruiyot, 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
Direct Award (USD)	Not Reported
Update	Enrollment into the protocol is ongoing. The site was able to enrol 11 participants during the first half of the year. These participants have benefited from closer attention to care, free chemotherapy and lab tests.
Future Plans	The protocol team plans to close this protocol in November 2017. As a site, we will plan to enrol another 15 participants into the study.
Publication(s)	

<b>Study Title</b>	<b>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)</b>
<b>Principal Investigator(s)</b>	Abraham Siika, Moi University
<b>Co-Investigator(s)</b>	Priscilla Cheruiyot, Busakhala, N. Njiru, E.
<b>Working Group(s)</b>	AMWG, SSRN, ORWG
<b>Description</b>	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
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	11/28/2012 - 6/30/2014
<b>Funding Status</b>	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID) NIH - National Cancer Institute (NCI) NIH - National Institute of Dental and Craniofacial Research (NIDCR)
<b>Direct Award (USD)</b>	Not Reported
<b>Update</b>	Of the 17 participants enrolled at the Eldoret site, 12 have been exited from the study and 5 are still on study follow up. These participants have continued to come to the clinic once every six months on their study visits. There are currently no safety concerns to report.
<b>Future Plans</b>	The site will continue to provide care to the 5 participants still on study follow up. The study visits are once every 6 months with the intention of monitoring long term safety of etoposide.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>A5273 'Multicenter Study of Options for Second-Line Effective Combination Therapy (SELECT)'</b>
<b>Principal Investigator(s)</b>	Abraham Siika, Moi University
<b>Co-Investigator(s)</b>	Priscilla Cheruiyot, Faraj Some
<b>Working Group(s)</b>	None
<b>Description</b>	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	There were no ongoing activities for this study in the current reporting period.
Future Plans	No further activities are anticipated
Publication(s)	



Study Title	<b>A5274/REMEMBER Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens '</b>
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Priscilla Cheruiyot, David K Lagat
Working Group(s)	AMWG, SSRN, TBWG
Description	In this randomized, open-label, phase IV strategy trial, participants from resource-limited settings (RLS) who present with advanced HIV disease and no probable or confirmed tuberculosis (TB), as defined in the current ACTG diagnosis appendix, and who are initiating antiretroviral treatment (ART) will be randomized to one of two strategy arms: immediate, empiric TB treatment (public health approach) or local standard of care TB treatment (individualized approach). The primary endpoint is survival status in the two arms 24 weeks after randomization. AIDS progression (any new WHO Stage 3 or 4 condition), virologic and CD4+ cell response, HIV and TB drug resistance, AND safety and tolerability of, and adherence to HIV and TB drugs will be evaluated, as will the cost-effectiveness of the two strategies. The primary objective is to compare survival probabilities between the two study arms 24 weeks after randomization.
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/10/2012 - 12/31/2016
Funding Status	Funded
Direct Award (USD)	Not Reported
Update	The last participant enrolled into the study completed follow up on April 22, 2016. The protocol team is currently finalizing data analysis for the study.

<b>Future Plans</b>	We anticipate release of publications for this study
<b>Publication(s)</b>	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
<b>Study Title</b>	<b>A5288 'Management Using the Latest Technologies in Resource-limited Settings to Optimize Combination Therapy After Viral Failure (MULTI-OCTAVE)'</b>
<b>Principal Investigator(s)</b>	Abraham Siika, Moi University
<b>Co-Investigator(s)</b>	Priscilla Cheruiyot, Beatrice Wangari Ndege
<b>Working Group(s)</b>	AMWG, SSRN
<b>Description</b>	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
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	12/18/2013 - 12/31/2015
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	Not Reported
<b>Update</b>	Of the total 22 participants enrolled at the Eldoret site, 14 have completed study follow up while 8 are still on follow up as they were enrolled to step 3 of the protocol. The 8 participants continue to receive closer attention to care, medication that would not otherwise be available in standard of care and more frequent labs at no cost.

Future Plans	Since all enrollments have been closed, the site will continue following up and providing care to the 8 participants who are on study.
Publication(s)	
Study Title	<b>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</b>
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Fatuma Some, Moi University Priscilla Cheruiyot,
Working Group(s)	TBWG
Description	A5290 is a prospective, randomized (1:1:1), open-label, phase 2b study comparing three lopinavir/ritonavir (LPV/r)-based antiretroviral (ARV) regimens among participants in high tuberculosis (TB) endemic resource-constrained settings undergoing treatment for confirmed or probable TB and requiring protease inhibitor (PI)-based antiretroviral therapy (ART). A two accrual period design will be used, including a full pharmacokinetic (PK) and safety evaluation to be conducted when 54-60 participants enrolled during the accrual period 1 have completed 28 days of ARV treatment and day 12 2 (after initiation of ART) drug levels are available (an early interim PK and safety evaluation will also be completed when 10-12 participants per arm have completed 28 days of ARV treatment and day 12 2 drug levels are available). Primary Objective: To compare rates of virologic suppression to < 400 copies/mL at 48 weeks for the two standard dose LPV/r and RBT arms versus the double-dose LPV/r and RIF arm.
Site(s)	Moi Teaching and Referral Hospital
Project Period	5/13/2015 - 11/30/2018
Funding Status	Funded
Direct Award (USD)	Not Reported
Update	The A5290 study was designed to have 2 accrual periods (Accrual period 1 and Accrual period 2). Only 90 participants were to be enrolled into accrual period 1 after which 381 participants would be enrolled into accrual period 2. However due to feasibility concerns, accrual period 2 was not opened and the study was closed to accrual. At Eldoret, we were able to enroll 9 participants who were followed up for 72 weeks as prescribed by the protocol. The last participant on study had their last visit around July 4 2017. All study participants have therefore completed study follow up. The protocol team is currently analyzing the data and findings will be made available as soon as they become available.
Future Plans	There will be no further study activities for this protocol at the Eldoret site
Publication(s)	



<b>Study Title</b>	<b>Adapting, piloting, and evaluating an innovative HIV prevention intervention integrated with group-led matched-savings for street-connected young people in western Kenya</b>
<b>Principal Investigator(s)</b>	Lonnie Embleton, University of Toronto
<b>Co-Investigator(s)</b>	Paula Braitstein, University of Toronto
<b>Working Group(s)</b>	PRWG
<b>Description</b>	<p>The overall objective of this proposal is to adapt, implement, and evaluate an HIV prevention intervention for street-connected young people aged 16-24 in Eldoret, Kenya. This will be achieved by adapting Stepping Stones combined with a livelihood-strengthening program, to the local social, cultural, and economic context of street-connected young people in Kenya. This proposal asks the following questions: 1) Is it feasible to adapt and implement the proposed intervention for street-connected young people aged 16-24 in Eldoret, Kenya? 2) Will the HIV prevention be acceptable and well received among the population? 3) Will the HIV prevention intervention lead to changes in HIV knowledge and gender equity, and secondarily, condom use self-efficacy, economic resources, and sexual practices? The following specific aims and hypotheses will guide answering these research questions: AIM 1: To adapt Stepping Stones combined with a livelihood-strengthening program to form a 16-week HIV prevention program for street-connected young people aged 16-24. AIM 2: To evaluate the feasibility, acceptability, and uptake of the adapted HIV prevention intervention. Hypothesis 2.1: That the intervention will be well received and acceptable to street-connected young people, program facilitators, and community-based stakeholders. Hypothesis 2.2: That the intervention sessions will be well attended and that greater than 75% of participants will complete the intervention satisfactorily by attending 80% of sessions. AIM 3: To evaluate the impact of the intervention on changing HIV knowledge (primary outcome), gender equity (primary outcome), condom use self-efficacy, economic resources, and sexual practices (condom use, transactional sex, number of sexual partners). Hypothesis 3.1: Intervention participants will have a positive change in their mean HIV knowledge score from baseline to endline. Hypothesis 3.2: Participants will have a positive change in their mean gender equity score from baseline to endline.</p>
<b>Site(s)</b>	Moi Teaching and Referral Hospital (MTRH)
<b>Project Period</b>	5/7/2017 - 12/21/2017
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$12,000 CAD (~ \$9,500 US)
<b>Update</b>	This project received IREC and REB approval from the University of Toronto. Four facilitators were hired and trained and focus groups conducted for adaptation.
<b>Future Plans</b>	Over the next six months we will finalize the HIV prevention curriculum and pilot the intervention.

Publication(s)	
Study Title	<b>AMPATH - Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS</b>
Principal Investigator(s)	Patrick Loehrer, Indiana University - Purdue University in Indianapolis (IUPUI)
Co-Investigator(s)	Darron Brown, Indiana University - Purdue University in Indianapolis (IUPUI) Neil Flick,
Working Group(s)	ORWG, RHWG
Description	<p>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</p>
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/19/2014 - 8/31/2019
Funding Status	Funded
Direct Award (USD)	2132402
Update	Nearly all of the planned subjects have been recruited to the trial. A total of 223 women have been recruited to Project 1 and 149 have been recruited to project 2. A patient tracker was hired to follow up with patients in an effort to increase the return rate for regularly scheduled visits. Testing on cervical and vaginal swabs on stored samples for Neisseria gonorrhoea and Chlamydia trachomatis has begun. Those found to have STIs were provided treatment. Training has been provided for the Roche Linear Array HPV Genotyping Test and preliminary assays were run on control specimens. The group

	hosted a U54 Consortia Meeting and Grant Writing Workshop in Eldoret for all awardees in March, 2017.
<b>Future Plans</b>	The study will continue to accrue patients to complete the total number for Project 2 as outlined in the protocol. To accomplish this we have already expanded our coverage to rural sites within the AMPATH catchment area. We will have another face to face meeting in Indianapolis in October, 2017 with Senior Leadership (Loehrer, Omenge, and Moormann) and local staff and mentees during the bi-annual AMPATH Summit. We have had difficulty procuring reagents for HPV testing, but the process has been improved and we now have sufficient supplies to run the next cohort of patients for HPV serotyping. We anticipate completion of the serotyping for all patients within this calendar year.
<b>Publication(s)</b>	
<b>Study Title</b>	<b>Analysis of ICU Admissions and Outcomes at the Moi Teaching and Referral Hospital Intensive Care Unit</b>
<b>Principal Investigator(s)</b>	Peter Kussin, Duke University
<b>Co-Investigator(s)</b>	Wangari Waweru-Siika, Moi Teaching and Referral Hospital Lalani, Hussain; Mwogi, Thomas
<b>Working Group(s)</b>	AMWG
<b>Description</b>	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.
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	10/26/2015 - 6/1/2016
<b>Funding Status</b>	Unfunded
<b>Direct Award (USD)</b>	
<b>Update</b>	We have presented the results of our general analysis of icu outcomes and a parallel analysis of neurocritical care outcomes as posters at the American Thoracic Society international meeting in may of 2017. The manuscript for the general outcomes is ready for submission pending final review by authors

<b>Future Plans</b>	1. submit general outcomes manuscript 2. complete neurologic outcomes manuscript 3. begin analysis of pediatric outcomes
<b>Publication(s)</b>	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
<b>Study Title</b>	<b>Assessment of Airway Disease in Western Kenya</b>
<b>Principal Investigator(s)</b>	Peter Kussin, Duke University
<b>Co-Investigator(s)</b>	David Lagat, Moi University Elcy Birgen, O'Chieng, Nancy
<b>Working Group(s)</b>	AMWG, PRWG
<b>Description</b>	The World Health Organization (WHO) has identified chronic respiratory diseases as the 3rd leading cause of death globally. <sup>1,2</sup> 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. <sup>3</sup> We will also examine risk factors associated with airway disease including occupational history, TB, HIV, and biomass fuel use. Finally, we will compare our phenotypes to novel exhaled gas signatures based on levels of exhaled carbon monoxide and nitric oxide as surrogates of air pollution and eosinophilic airway inflammation, respectively, providing insights into the underlying biology of chronic lung disease in our population as well as estimates of the impact of air pollution on lung health.
<b>Site(s)</b>	Other, community based research study across Uasin Gishu
<b>Project Period</b>	8/31/2016 - 12/31/2017
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$91,873
<b>Update</b>	We are continuing enrollment for the study. Major delays occurred surrounding equipment failure requiring obtaining new parts, as well as delays from obtaining NACOSTI approvals.
<b>Future Plans</b>	We hope to finish enrollment and begin data cleaning and analysis.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>Biomarkers of Vincristine Toxicity in Kenyan Children</b>
<b>Principal Investigator(s)</b>	Jodi Skiles, Indiana University
<b>Co-Investigator(s)</b>	F. Njuguna, Moi University Sandra Langat, Skiles, J.
<b>Working Group(s)</b>	ORWG, PRWG
<b>Description</b>	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.
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	6/23/2011 - 6/30/2014
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$8,743
<b>Update</b>	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 was ultimately rejected. It was resubmitted to Pediatric Blood and Cancer in and is on the 2nd round of minor revisions.
<b>Future Plans</b>	Final acceptance of manuscript with formal completion of the study.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>Bridging Income Generation with Group Integrated Care(BIGPIC)</b>
<b>Principal Investigator(s)</b>	Rajesh Vedanthan, Mount Sinai School of Medicine
<b>Co-Investigator(s)</b>	Jemima Kamano, Moi Teaching and Referral Hospital Peninah Kiptoo
<b>Working Group(s)</b>	AMWG, CVMD
<b>Description</b>	The objective of this proposal is to utilize a trans disciplinary implementation research approach to address the challenge of reducing CVD risk in low-resource settings. The research aims at integration of group medical visits and microfinance with the additional social network characteristics. Aim 1: Identify the contextual factors, facilitators, and barriers that may impact integration of group medical visits and microfinance for CVD risk reduction, using a combination of qualitative research methods: 1) baraza; and 2) focus group discussions among individuals with diabetes or at increased risk for diabetes, microfinance group members, and rural health workers. Then develop a contextually and culturally appropriate integrated group medical visit-microfinance model. Aim 2: Evaluate the effectiveness of group medical visits and

	microfinance groups for CVD risk reduction among individuals with diabetes or at increased risk for diabetes, by conducting a four-arm cluster randomized trial comparing: 1) usual clinical care; 2) usual clinical care plus microfinance groups only; 3) group medical visits only (no microfinance); and 4) group medical visits integrated into microfinance groups. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the trial.
Site(s)	Angurai Health Centre, Bumala A Health Centre, Bumala B Health Centre, Chulaimbo Sub-District Hospital, Endebess Sub-District Hospital, Kapsara District Hospital, Khunyangu Sub-District Hospital, Matayos Health Centre, Mois Bridge Health Centre, Saboti Su
Project Period	4/1/2015 - 1/1/2020
Funding Status	Funded – NIH
Direct Award (USD)	\$2,478,465
Update	<p>Administrative</p> <ul style="list-style-type: none"> <li>• All-Investigator conference call held in February 2017 -</li> <li>• Positive feedback attained from participants on call</li> <li>• Capacity building of the study personnel with specialized and targeted skills complete</li> <li>• Procurement of necessary supplies both for point of care testing and stationery ongoing</li> </ul> <p>Aim 1: Barriers/facilitators/contextual factors</p> <ul style="list-style-type: none"> <li>• Content analysis for all focus group discussions is ongoing</li> </ul> <p>Aim 1.1 (Barriers, Facilitators, &amp; Contextual Model):</p> <ul style="list-style-type: none"> <li>• FGD-Content analysis for all focus group discussions (FGDs) to address acceptability and feasibility have been completed at baseline, 3 months, and 6 months.</li> <li>• Manuscript is currently being written</li> <li>• Feasibility Pilot: 3-month feasibility pilot completed 6 month pilot feasibility assessment implemented</li> </ul> <p>Aim 2 (Cluster RCT):</p> <ul style="list-style-type: none"> <li>• Logistics of trial Roll Out: - <ul style="list-style-type: none"> <li>○ Working with AMPATH's Chronic Disease Management (CDM) and Safety Net teams regarding logistics of trial rollout</li> <li>○ Intervention rollout is ongoing; thus far 13 facilities have been rolled out( 3-GMV, 4-GMV-MF, 4-UC, 2-MF)</li> <li>○ Group Facilitation Training of community health workers (CHWs) is ongoing</li> <li>○ Operations manual completed</li> </ul> </li> <li>• Data collection, entry, &amp; management: <ul style="list-style-type: none"> <li>○ Data collection, entry, and management procedures ongoing. A total of 511 participants (Male=161, Female=350) have been enrolled thus far.</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>• Process evaluation:             <ul style="list-style-type: none"> <li>○ Protocol for Process Evaluation completed, REDCap programming of data collection instruments is ongoing</li> <li>○ Randomization completed</li> </ul> </li> </ul> <p>Aim 2.1( Mediation &amp; Moderation Analysis):</p> <ul style="list-style-type: none"> <li>• Social network survey (SNS):             <ul style="list-style-type: none"> <li>○ SNS currently being administered. Total of 511(Male-161, Female 350)</li> </ul> </li> </ul> <p>Aim 3 (Cost Effectiveness Analysis):</p> <ul style="list-style-type: none"> <li>• Costing questionnaire survey (CQS):             <ul style="list-style-type: none"> <li>○ CQS currently administered to study participants</li> <li>○ Intervention cost tracking done, second quarter report nearly finalized</li> </ul> </li> </ul>
<p><b>Future Plans</b></p>	<p>Aim 1:</p> <ul style="list-style-type: none"> <li>• Complete qualitative analysis</li> <li>• Manuscript preparation</li> </ul> <p>Aim 1.1</p> <ul style="list-style-type: none"> <li>• Complete qualitative analysis</li> <li>• Manuscript preparation</li> </ul> <p>Aim 2:</p> <ul style="list-style-type: none"> <li>• Continue with enrollment of individuals into the trial</li> <li>• Complete CDSMP training of research staff and community health workers who will be involved in the group medical visit-microfinance intervention Finalize SOP for resolving AMRS missing and mismatched numbers ○ Initiate process evaluation once REDCap programming of data collection instruments is complete.</li> </ul> <p>Aim 2.1:</p> <ul style="list-style-type: none"> <li>• Administer social network survey to study participants at appropriate assessment periods</li> </ul> <p>Aim 3: Administer survey to study participants at appropriate assessment periods</p>
<p><b>Publication(s)</b></p>	<p>Manuscript: Vedanthan, R., J. H. Kamano, H. Lee, B. Andama, G. S. Bloomfield, A. K. DeLong, D. Edelman, E. A. Finkelstein, J. W. Hogan, C. R. Horowitz, S. Manyara, D. Menya, V. Naanyu, S. D. Pastakia, T. W. Valente, C. C. Wanyonyi and V. Fuster (2017). 'Bridging Income Generation with Group Integrated Care for cardiovascular risk reduction: Rationale and design of the BIGPIC study.' <i>Am Heart J</i> 188: 175-185.</p> <p>Pastakia, S. D., S. M. Manyara, R. Vedanthan, J. H. Kamano, D. Menya, B. Andama, C. Chesoli and J. Laktabai (2017). 'Impact of Bridging Income Generation with Group Integrated Care (BIGPIC) on Hypertension and Diabetes in Rural Western Kenya.' <i>J Gen Intern Med</i> 32(5): 540-548.</p>
<p><b>Study Title</b></p>	<p><b>Can integration of effective family planning services into Anticoagulation Management Services (AMS) improve uptake?</b></p>
<p><b>Principal Investigator(s)</b></p>	<p>Astrid Christoffersen-Deb, University of Toronto</p>
<p><b>Co-Investigator(s)</b></p>	<p>Imran Manji, Moi Teaching and Referral Hospital</p>

	Christabell Umukagah,
<b>Working Group(s)</b>	RHWG
<b>Description</b>	The purpose of the study is to evaluate whether integration of family planning education and free, on-site provision of all reversible family planning methods in Anticoagulation Monitoring Service (AMS) Clinic can improve uptake of long-acting reversible contraception (LARC; specifically intrauterine contraceptive devices (IUCDs) and contraceptive implants) in this high-risk population. Our hypothesis is that implementation of an educational intervention emphasizing long-acting reversible contraception (LARC) combined with free on-site provision of LARC within Anticoagulation Monitoring Service (AMS) can improve uptake of these methods by 250% in this population. Our objectives are to: 1) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) is feasible. 2) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) can improve uptake of long-acting reversible contraceptive methods (IUCDs and contraceptive implants). 3) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within an Anticoagulation Monitoring Services (AMS) Clinic can prevent unplanned pregnancies. In order to evaluate these objectives we will provide the intervention and follow the participants for the following 1 year time period. At 3-month, 6-month, and 12-month follow-up we will evaluate whether they are using any method of family planning and whether they have experienced subsequent unplanned pregnancies. This data will be compared to the same group of women prior to implementation of the education intervention and free, on-site provision of all reversible contraceptive methods.
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	4/20/2015 - 8/31/2016
<b>Funding Status</b>	Unfunded
<b>Direct Award (USD)</b>	
<b>Update</b>	A manuscript with the three month follow-up data was submitted to American Journal of Obstetrics & Gynecology (AJOG) but did not make it to the publication phase. Twelve month follow-up data collection was done and concluded. In addition, approval was given by Moi Referral Hospital and the County Health Director at Uasin Gishu to conduct outreaches to healthcare providers at other facilities with the aim of providing information about optimizing family planning services for women with chronic medical conditions.
<b>Future Plans</b>	Over the next six months, we plan to continue with data analysis to evaluate our primary outcome of increasing use of Tier 1 contraceptive methods as well as looking into impact of partner involvement in use of family planning 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 in addition to providing information about optimizing family planning services for women with chronic medical conditions.
Publication(s)	
<b>Study Title</b>	<b>Childhood Leukemia in Kenya Identified Through Malaria Slide Review</b>
<b>Principal Investigator(s)</b>	Terry Vik, Indiana University
<b>Co-Investigator(s)</b>	F. Njuguna, Moi University Priscilla Cheruiyot, Skiles, J. Moormann, A.
<b>Working Group(s)</b>	ORWG, PRWG
<b>Description</b>	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.
<b>Site(s)</b>	Kitale District Hospital
<b>Project Period</b>	7/1/2012 - 6/30/2015
<b>Funding Status</b>	Funded Alex's Lemonade Stand Foundation
<b>Direct Award (USD)</b>	\$200,000
<b>Update</b>	Continue to finalize manuscripts.
<b>Future Plans</b>	Submit 2 manuscripts for publication.
Publication(s)	
<b>Study Title</b>	<b>Community perceptions and perceived needs of street-connected children and youth in Eldoret Kenya: a qualitative investigation</b>
<b>Principal Investigator(s)</b>	Lonnie Embleton, University of Toronto
<b>Co-Investigator(s)</b>	David Ayuku, Moi University, Braitstein Paula, Kamanda Allan, Wachira Juddy.
<b>Working Group(s)</b>	PRWG, SSRN
<b>Description</b>	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

	<p>interventions for this vulnerable population. When youth are involved in the design and development of programs they are more likely to uptake services and seek care that is responsive to their needs. Similarly, exploring the opinions and perspectives of local policymakers, community members, and healthcare providers concerning street-connected children and youth, which influence their decision-making (ethical or unethical) in regards to the provision of programs, services, treatment, support, and care for this population is vital to reduce the harms associated with street-involvement. Gathering this data represents the first step in designing and developing effective evidenced-based interventions and policies, in a community-based participatory manner, which are responsive to the perspectives of street-connected children and youth and community members within the local social-cultural context. SPECIFIC AIMS  AIM 1: Explore and describe the perceptions of community members across different social strata about the causes, characters, and needs of street-connected youth in Eldoret, Kenya. AIM 2: Describe the experiences of street-connected youth in Eldoret, Kenya, aged 15-24, with stigma and discrimination on the streets and when accessing services and healthcare. AIM 3: Elucidate ideas concerning appropriate service delivery and care for street-connected youth in Eldoret, Kenya from community members across different social strata 3.1) Identify street-connected youth's opinions on what will assist or facilitate access to healthcare and specifically explore their needs in relation to HIV prevention.</p>
Site(s)	Other community-based sites in Eldoret
Project Period	9/5/2016 - 12/31/2016
Funding Status	
Direct Award (USD)	
Update	The study is now collecting data. There are three FGDs remaining and 5 Key informant interviews. We aim to be done data collection by the end of July. Transcription and translation of audio recordings is underway.
Future Plans	Finish data collection by the end of July. Transcription and translation to be complete by September. Followed by analysis and preparation of manuscripts in the next six months.
Publication(s)	
Study Title	<b>Developing and Assessing a Community-Based Model of Antiretroviral Care</b>
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Kara-Wools Kaloustian, Indiana University Colma Kibet, Naanyu Violet, PhD Goodrich Suzanne, MD Yiannoutsos Constantin, PhD Mwangi Ann, PhD Thirumurthy Harsha, PhD Batenganya Moses, MD Spira Thomas, MD Nyunya Boaz
Working Group(s)	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
Direct Award (USD)	\$924,042
Update	1. Enrollment was completed in March 2017, 584 patients were consented, 423 met all enrollment criteria. Two hundred and ten patients were randomized to the intervention arm creating 15 ART Co-ops. 2. An amendment to the protocol was approved by IREC on the 9th of March 2017. The amendment discontinued 6 sub-locations (3 control & 3 Intervention) due inability to effectively enroll patients since October 2016. The amendment also changed the group size from 12-15 to 6-15 to allow for slow enrolling groups. 3. FHI 360 monitored the study as from the 5th-6th June 2017. They recommended that logic checks be conducted on the study database to improve the quality of data.
Future Plans	1. Community groups follow up phase to continue. 2. 6 Month surveys (Stigma & Quality of life questionnaires) to be administered. 2. FHI 360 will monitor the study as from the 28th of August 2017.
Publication(s)	



Study Title	<b>Effect of free maternity care on maternal and fetal outcomes of preeclampsia/eclampsia at a teaching hospital in Western Kenya: A retrospective chart review.</b>
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Co-Investigator(s)	VINCENT KIBET, Parks caitlin Millar Heather Kosgey Wycliffe Thorne Julie Kipchumba Bett
Working Group(s)	RHWG
Description	The aim of this study is to determine the incidence of diagnosis and treatment of pre-eclampsia and eclampsia at MTRH. We will measure the maternal and neonatal outcomes in women with these diagnoses. We will evaluate the data in order to determine areas for improvement in our diagnosis and management of pre-eclampsia/eclampsia in order to decrease maternal and neonatal morbidity and mortality at MTRH. Finally, we would like to evaluate the effect free maternal care has

	played in the measured incidence and outcomes of pre-eclampsia and eclampsia at our institution. Specifically, we will: 1. Determine and compare the incidences of pre-eclampsia within our institution in the year before and the year after the initiation of free maternal care in June, 2013 2. Evaluate the maternal and neonatal outcomes, including major causes of morbidity and mortality in each group. Again we will compare these before and after the initiation of free maternal care in June, 2013. 3. Evaluate the risk factors for adverse maternal and neonatal outcomes 4. Evaluate the adherence of treatment in our facility in accordance with World Health Organization standards, again comparing treatment before and after the initiation of free maternity care in June, 2013. The data for this study is collected using a comprehensive 100-item data collection form, including patient demographics, symptomatology, documented clinical signs and laboratory results, delivery details, and maternal and neonatal outcomes
Site(s)	Moi Teaching and Referral Hospital, Saboti Sub-District Hospital
Project Period	1/12/2015 - 12/31/2015
Funding Status	Unfunded
Direct Award (USD)	
Update	Data analysis on the maternal mortality files collected was done. A total of 24 maternal death as a result of preeclampsia/eclampsia were noted. of these, most deaths (19) occurred in the period post initiation of the free maternity care.
Future Plans	We hope to complete the discussion the manuscript - Effect of free maternity services on the maternal and neonatal outcomes of free maternity on pre-eclampsia/eclampsia. We then hope to start data analysis data for a second manuscript on expectant management of pre-eclampsia/eclampsia
Publication(s)	

Study Title	<b>Enhancing Preventive Therapy of Malaria In children with Sickle cell anemia in East Africa (EPiTOMISE)</b>
Principal Investigator(s)	Festus Njuguna, Moi University
Co-Investigator(s)	Steve Taylor, Duke University Joseph Kirui, Wendy P O'Meara PhD, Duke Global Health Institute Chite Asirwa MD, Indiana University School of Medicine
Working Group(s)	PRWG
Description	Children with SCA are particularly vulnerable to infectious diseases and in malaria endemic areas, malaria is one of the leading causes of hospitalization and death among children with SCA. The current recommendation is chemoprevention with daily proguanil. However, this regimen suffers from suspected low adherence rates and probable reduced efficacy due to parasite resistance to antifolate drugs. We are conducting a randomized, three-arm, open-label, clinical trial of malaria chemoprevention in children with sickle-cell anemia at a single site in Homa Bay, Kenya

	<p>in order to identify more effective chemotherapy regimens for malaria in children with SCA. Our primary objective is to compare the efficacy of daily proguanil with monthly sulfadoxine/pyrimethanine-amodiaquine (SP-AQ) and with monthly dihydroartemisinin-piperazine (DP) on the incidence of falciparum malaria in children with SCA. The secondary objective is to compare the efficacy of these malaria chemoprevention strategies on the incidence of major complications of SCA. We will enroll 246 children of both genders between 1 and 10 years of age with laboratory-confirmed SCA living in malaria-endemic portions of Homa Bay or Migori Counties, randomize to one of three (1:1:1) malaria chemoprevention regimens, and followed up monthly for 12 months in order to record clinical episodes of malaria or SCA-related morbidity. Analyses will compare the efficacy of each regimen to prevent malaria and SCA morbidity. Blood samples will be taken every three months (5 time points - baseline, 3, 6, 9, 12 months) for laboratory testing and dried bloodspots will also be collected. Participants will also receive a malaria rapid diagnostic test using a finger-prick blood sample when they are ill.</p>
Site(s)	Homabay County Hospital
Project Period	6/1/2016 - 2/28/2017
Funding Status	Funded
Direct Award (USD)	\$621,633 US
Update	<p>We have received IRB approvals from both Duke and Moi and we are in the process of seeking Kenya Pharmacy and Poison Board Expert Committee on Clinical Trials (ECCT) approval. As the PPB application process continues, we are also working on SOPs and manual of procedure/operation consisting of administrative, clinical and laboratory SOPs. We are in the process of hiring two clinical officers and two nurses who will form the site clinical team. In addition to hiring, we have initiated laboratory discussions with the AMPATH reference laboratory manager in order to figure out how laboratory samples will be transported and performed at the AMPATH Labs. We are working with Homabay County Hospital to secure a clinic space within the hospital. The data team is working on data platform using Redcap and we hope to have it ready before enrollment starts in October.</p>
Future Plans	<p>We plan to have a three-day training of research staff on study protocol, data collection and management of sickle cell. We also plan for sensitization meeting/CME of Homabay County Hospital staff prior to enrollment of participants. Enrollment is set to commence the first week of October. We are also working on improtation process for SPAQ Co from Guilin Pharmaceutical China.</p>
Publication(s)	
Study Title	<b>Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy.</b>
Principal Investigator(s)	Beatrice Jakait, Moi Teaching and Referral Hospital
Co-Investigator(s)	Rena Patel, University of Washington

	Caroline Kerich,
<b>Working Group(s)</b>	RHWG
<b>Description</b>	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
<b>Site(s)</b>	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,
<b>Project Period</b>	5/23/2016 - 2/28/2017
<b>Funding Status</b>	Funded - NIH
<b>Direct Award (USD)</b>	\$12,727
<b>Update</b>	Between January and March 2017, we completed all our planned file reviews (~2000+) and client interviews (~900+). Since March 2017, we have entered the data cleaning and analysis phases. Over the next few months, we anticipate further refining our dataset and conducting our planned analyses.
<b>Future Plans</b>	For July to December 2017, we anticipate finalizing our data analyses and preparing our main/primary publication from this dataset.
<b>Publication(s)</b>	We had a late breaker poster presentation accepted to IAS, Paris July 2017. Find the author names, title, and abstract itself attached below (it has not yet been published in the conference abstract).



<b>Study Title</b>	<b>ESYHI study - Identification, adaptation and piloting of innovative interventions to engage street-connected children and youth in the HIV prevention-care continuum in a resource-constrained setting</b>
<b>Principal Investigator(s)</b>	Paula Braitstein, University of Toronto David Ayuku, Moi University
<b>Co-Investigator(s)</b>	Pooja Shah, Milllar, Heather Wachira, Judy Lobun, Regina Apondi, Edith Gayapersad, Allison Embleton, Lonnie MacDonald, Katherine
<b>Working Group(s)</b>	PRWG
<b>Description</b>	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
Direct Award (USD)	\$79,100
Update	<p>In May 2017, we completed the final two groups of VMMC, bringing our total participant sample to 116 out of our targeted 120, and completing our first HIV intervention for the study. At the end of the intervention, preliminary findings suggest an increase in HIV knowledge. All youth recovered quickly from the VMMC procedure, there were no complications. The educational modules, especially on life skills, were very well received. We are currently in the process of analyzing our data for this intervention and planning two manuscripts. For the RH clinic, we have finalized clinical encounter forms and are in the process of receiving supplies. Our amendment to IREC has been approved. Our clinic will be located in the grounds of the Adolescent clinic and is currently undergoing renovations to make the space fit for clinical use. Staff are in the process of being hired. Focus group guides are in the process of being finalized. These will be used to elicit information on developing an HIV intervention specifically for the girls as an alternate coming of age ceremony that includes education on HIV and parenting, and teaching life skills. We have also compiled a guide for focus groups with the general SCY population, which will be aimed at receiving information on how to best improve treatment uptake and retention in care. We are disseminating data collected from the Peer Navigator programme, analyzing the results, and writing up a paper on the feasibility and effectiveness of Peer Navigators to increase uptake of HIV testing, care, and treatment among SCY.</p>
Future Plans	<p>We would like to get the RH clinic up and running. Once staff have been hired, we will conduct clinical and sensitivity training and run the clinic over six months, providing comprehensive reproductive healthcare to the street youth. Data will be collected and individuals linked to Ampath or the Adolescent clinic as necessary. We will be piloting the FGDs and amending the guide as needed, then conduct the rest of the focus groups and transcribe and translate the information. Once finished, the results will be analyzed and in conjunction with the wider team, healthcare professionals, and community leaders, we will develop a suitable intervention specifically for female SCY. We will also be in a position to discuss SCYs' views on how to best enhance treatment rates. The VMMC papers and PN papers will be completed and sent to journals for publication. The Senior Research Assistant will be attending the International Association of Adolescent Health World Congress to present the results of the VMMC intervention.</p>
Publication(s)	
Study Title	<b>Ethnic Specific Risk Stratification in Early Pregnancy for Identifying Mothers at Risk of Gestational Diabetes Mellitus in Eldoret, Kenya</b>
Principal Investigator(s)	Wycliffe Kosgei, Moi Teaching and Referral Hospital
Co-Investigator(s)	Astrid Christoffersen-Deb, University of Toronto

	Vincent Kibet, Pastakia Sonak
<b>Working Group(s)</b>	RHWG
<b>Description</b>	Gestational diabetes mellitus (GDM) is a form of diabetes that develops in pregnancy and can lead to adverse maternal and fetal outcomes. There is not currently a screening program to identify women with GDM in Kenya and other low and middle income countries. The aim of the study is to determine the prevalence of GDM in a rural and urban Kenyan population, develop an accurate score based on easily obtainable risk factors to stratify women at risk of GDM in this population, and determine if a selective screening strategy would be cost-effective in Kenya. This is a prospective cohort study aiming to recruit 4000 women who are <20wks gestation attending antenatal clinic at different project sites.
<b>Site(s)</b>	Huruma Sub-District Hospital, Moi Teaching and Referral Hospital (MTRH), Uasin Gishu District Hospital, Reale Hospital, Langas Hospital
<b>Project Period</b>	7/14/2015 - 7/13/2018
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$56,4629
<b>Update</b>	A total of 1652 pregnant women have been recruited into the study with 1152 having completed Visit 2 (Fasting/Random sugar before 20 weeks ) and 554 having done Visit 3 (OGTT at 24-32 weeks). We are also working in data entry into our database Challenges: Despite the follow ups, education and transport reimbursement being offered to the mothers, only about 34% of the total enrolled participants have completed the oral glucose tolerance test. Among the reasons for this is inadequate transport reimbursement and lack of partner support.
<b>Future Plans</b>	We hope recruit more women, improve on the update of the OGTT visit and to this end have increased transport reimbursement and offering information to willing partners about the study.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>Evaluation of the growth and development of young children of HIV-infected mothers in western Kenya.</b>
<b>Principal Investigator(s)</b>	Megan McHenry, Indiana University
<b>Co-Investigator(s)</b>	Edith Apondi, Samuel Ayaya, Rachel Vreeman
<b>Working Group(s)</b>	PRWG
<b>Description</b>	Understanding growth patterns and associated factors for children born to HIV-infected mothers is critical for reducing morbidity and mortality. By performing a retrospective chart review on the prospectively collected and stored data within the AMPATH medical record system, we evaluated anthropometrics and factors associated with underweight status for children born to HIV-infected mother in western Kenya. The results show large



	number of children who have been moderately and severely underweight and stunted during some point of the study period. These results also indicate there appears to be a difference in the overall weight-for-age Z score trend between boys and girls, and between HIV-infected and HIV-exposed, uninfected. We hope that these preliminary results will lead to further investigation of the factors associated with poor growth in our young children at AMPATH and eventually to interventions to improve their growth and development.
Site(s)	Chulaimbo Sub-District Hospital
Project Period	3/1/2015 - 10/1/2017
Funding Status	Funded
Direct Award (USD)	\$1,800
Update	No changes since the last update. We continue to work on the analysis
Future Plans	We hope to finalize our analysis and submit our work for publication
Publication(s)	

<b>Study Title</b>	<b>FLTR Evaluation</b>
Principal Investigator(s)	Paula Braitstein, University of Toronto
Co-Investigator(s)	Sylvester Kimaiyo, Moi University 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	Completed the manual matching of HBCT/PHCT data with AMRS for the HIV-positives in Bunyala, Teso, and Chulaimbo. We have been supporting 50% each of two data managers and 50% of one biostatistician (all in Kenya through the research program) and they continue to work on analysis from this work as well as others.
Future Plans	Publish 3-5 papers.

<b>Publication(s)</b>	<p>Using double-sampling methods to estimate linkage to HIV care among individuals newly diagnosed with HIV through home-based counseling and testing in western Kenya Becky L. Genberg,<sup>1</sup> Joseph W. Hogan,<sup>1</sup> Yizhen Xu,<sup>1</sup> Samson Ndege,<sup>2</sup> Monicah Nyambura,<sup>3</sup> Caren Tarus,<sup>3</sup> Elyne Rotich,<sup>3</sup> Catherine Kafu,<sup>3</sup> Juddy Wachira,<sup>2,3</sup> Suzanne Goodrich,<sup>4</sup> Paula Braitstein<sup>2,3,4,5,6</sup> IAPAC 2017</p> <p>The incidence and risk factors for pregnancy among HIV-positive adolescents enrolled in a large HIV treatment program in western Kenya from 2005-2014 Heather Millar, MD, MIPH, FRCS(C)<sup>1,2,3</sup>, Alfred Keter, MSc<sup>1</sup>, Gerald Bove PhD<sup>4</sup>, Edith Apondi, MMED<sup>1,5</sup>, Alice Kaaria, MMED<sup>5,6</sup>, Juddy Wachira, PhD<sup>1,7</sup>, Katherine MacDonald, MD<sup>1,8</sup>, Rachel F. Spitzer, MD, MPH, FRCS(C)<sup>1,3,9</sup>, Paula Braitstein*, PhD<sup>1,7,10</sup> NASPAG 2017</p> <p>The Confluence of Pregnancy and New HIV Diagnosis Among Adolescents in Western Kenya Katherine MacDonald, MD<sup>1</sup>• Edith Apondi, MMED<sup>2</sup>• Mary A Ott, MD, MS<sup>1</sup>• Juddy Wachira, PhD<sup>3</sup>• Alfred Keter, Msc<sup>3</sup>• Monicah Nyambura, MPH<sup>3</sup>• Heather Millar, MD<sup>4</sup>• Paula Braitstein, PhD<sup>4, 3, 1</sup> Society for Adolescent Medicine conference, 2017</p>
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<b>Study Title</b>	<b>HI-Train: Health Informatics Training and Research in East Africa for Improved Health Care</b>
<b>Principal Investigator(s)</b>	Abraham Siika, Moi University
<b>Co-Investigator(s)</b>	Martin Were, Indiana University Eileen Immaculate, Ayuo, Paul Nabukenya, Josephine Mughal, Khalid Tylleskar, Thorkild
<b>Working Group(s)</b>	TBWG
<b>Description</b>	<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. Alarming, most sub-Saharan countries remain woefully unprepared to systematically train an adequate workforce to support the eHealth systems already being deployed. Countries like Uganda and Kenya recognize an emergent need for national strategies to build health informatics human capacity. These countries have appropriately developed national eHealth capacity-building strategies Implementing the strategies however requires direct leadership by Higher Education Institutions in the relevant countries. The urgency for sustainable mechanisms to increase HI workforce and research capacity in developing countries is self-evident. This goal can only be realized by having enough faculty members from developing countries fully trained in Health Informatics. These staff faculty can then be part of a well-functioning and high quality HI program moving forward. Recognizing this need, and the multidisciplinary competencies needed for HI training and research, our team identified partner institutions with complementary capabilities to support</p>

	advanced Health Informatics training in East Africa for our project. Aims 1) Provide post-graduate (Masters and PhD) level training in Health Informatics and research. The focus will be on post-graduate training for health professionals and computer science personnel to help them become HI faculty at their institutions. 2) Increase number of women and marginalized populations in faculty-level training in Health Informatics and research at the LMIC higher education institutions. 3) Improve the quality and quantity of Health Informatics research conducted primarily by re-searchers based in the LMIC countries in collaboration with our Northern partners. 4) Provide model curricula, educational programs and approaches for faculty-level health informatics training that can be emulated by regional higher education institutions.
Site(s)	Moi University, Makerere University, University of Bergen
Project Period	12/5/2013 - 6/30/2019
Funding Status	Funded – NORAD - Norwegian Agency for Development Cooperation
Direct Award (USD)	\$2,757,830 US
Update	The MSc. enrolled students (14) are in session. The second years are working on their research projects where different students are at different levels of their research. The second year students are going on with their learning. The project conducted the HI-Train leadership annual meeting in Uganda which brought together all the students from Kenya and Uganda. The MSc. Curriculum was reviewed in March and April 2017 with the view of converting to Online distance learning. However the programme has been approved to be moved to Nairobi. One second year female student received the child care support to allow her proceed with studies without breaking. The redcap training was conducted in Kemri Nairobi in April and one of our own facilitated the training. The Hackathon and Mobile Application workshop was held in Moi University Main campus in May and this included students from three external universities Kibabii, Maseno and Masinde Muliro. The gender mainstreaming /mentoring workshop was held in Boma Inn in July where mentoring was done to our MSc. and PH.d students.
Future Plans	The first class to graduate. Dissemination programmes to continue as expected. The Annual meeting with Norad is coming up in October, 2017.
Publication(s)	Presentations. Milka Gesicho - Ethical issues in implementing Health Data warehouses in Developing Countries Philomena Waruhari-Advancing HI programs in LMICs Dr. Mwogi-Setting the Agenda for Personal health records in developing countries Noah Kasiti-
Study Title	<b>IeDEA Comprehensive Adherence Measure for Pediatrics (ICAMP)</b>
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University Silas Wakoli, 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 <a href="mailto:annette.sohn@treatasia.org">annette.sohn@treatasia.org</a> Mary-Ann Davies, MB ChB School of Public Health
<b>Working Group(s)</b>	PRWG
<b>Description</b>	<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>
<b>Site(s)</b>	Busia District Hospital, HIV-NAT Clinic, Bangkok, Thailand; Rahima Moosa Mother and Child Hospital, Johannesburg, South Africa
<b>Project Period</b>	8/1/2014 - 7/31/2016
<b>Funding Status</b>	Funded – NIH - National Institute of Allergy and Infectious Diseases (NIAID)
<b>Direct Award (USD)</b>	\$171,257 US

Update	<p>The primary objective of the ICAMP (IeDEA Comprehensive Adherence Measure for Pediatrics) study is to validate an adherence questionnaire for pediatric and adolescent patients at 3 IeDEA sites using electronic dose monitors (Medication Event Monitoring Systems, or 'MEMS', MWV/AARDEX, Switzerland) as external criterion for adherence. While the adherence questionnaire (known as the Comprehensive Adherence Measure for Pediatrics - Short Form, or 'CAMP-SF') was previously validated in a large, urban referral site at AMPATH in the East Africa IeDEA region, re-validation is warranted to ensure external and internal validity is upheld across resource-limited sites. In conducting this validation study, we will also collect valuable, detailed prospective data on adherence to ART among this sample of HIV-infected children and adolescents using electronic dose monitoring. The study has the following specific aims and hypotheses: Specific Aim 1: Validate a 10-item adherence questionnaire for routine use as an adherence measurement tool in resource-limited settings.. Specific Aim 2: Describe pediatric adherence to ART prospectively over 6 months using electronic dose monitoring (i.e., MEMS) and the CAMP-SF among a sample of HIV-infected children and adolescents at 3 IeDEA sites. Specific Aim 3: Evaluate factors associated with adherence among a sample of HIV-infected children and adolescents at 3 IeDEA sites. 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. Study follow up and data collection for 6 months have been completed in all three IeDEA study sites - Busia clinic at AMPATH (Kenya), HIV-NAT clinic (Bangkok, Thailand) and Rahima Moosa Mother Child Hospital (Johannesburg, South Africa) with approximately 100 pediatric patients and their caregivers at each site and a close-out study visit done. In the last six months, we have been in a phase of data cleaning and preparation for analysis. Analyses for individual sites has been undertaken, but the combined final analysis is currently underway. Data from the Thai site were also presented at the 2016 International HIV Pediatrics Workshop in Durban, South Africa.</p>
Future Plans	<p>Over the next 6 months, we plan to:</p> <ul style="list-style-type: none"> <li>• We expect to complete data cleaning and data analysis.</li> <li>• Prepare manuscripts for publication with our partner sites and conference presentations</li> </ul>
Publication(s)	

Study Title	<b>Innovative Community Sourcing Techniques to Investigate Reproductive Health Issues in a Population Aged 13-65 Years in Western Kenya</b>
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Co-Investigator(s)	Faith Kosgei, Moi University Vincent Kibet, Bernard Caitlin Omukagah Christabell Hodgett Mary
Working Group(s)	PHPC
Description	<p>In this project, we will use innovative community-sourcing technologies (the TIMBY suite of tools) to generate a series of investigative stories to help answer arising questions on maternal and child health matters as well as surrounding and related issues. We aim to demonstrate feasibility of using TIMBY phone application to generate evidence on</p>

	reproductive health matters as well as in developing targeted interventions and disseminate them to key stakeholders.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	5/26/2017 - 5/26/2018
Funding Status	Funded
Direct Award (USD)	\$20,860
Update	TIMBY developers have worked to adapt the app to suit our needs and requirements. We have identified reporters who will be working with the TIMBY team to collect and write reports. The investigative team had an informational session with the reporters to roll out the project concept. We have attended sessions with adolescents at the RAFIKI Health Center to get their input on the design of the app that will be launched. The app was launched on 12th June 2017 with reporters starting to conduct interviews. We conducted a workshop on design thinking on 14th July, 2017 with the objective of improving the reporters experience with the app in order to make the reporting process more seamless and also encourage collection of more reports.
Future Plans	Over the next six months, reports received on the TIMBY dashboard from our reporters will be verified and stories generated from these. Publication of reports will be done weekly on AMPATH's social media platforms as well as the TIMBY website. Additionally, we plan to partner with Nation Media to have the stories published on print. We aim to recruit and train more reporters overtime to increase our coverage and diversity in reports collected . More workshops will be done with the reporters to improve their reporting skills and experience in using the TIMBY phone application.
Publication(s)	

Study Title	<b>Innovative public-private partnership to target subsidized antimalarials in the retail sector</b>
Principal Investigator(s)	Wendy Prudhomme, Duke University
Co-Investigator(s)	Diana Menya, Moi University Joseph Kipkoech, 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.

<b>Site(s)</b>	Bungoma East Subcounty in Bungoma County and Kiminini Subcounty in Trans-Nzoia County
<b>Project Period</b>	1/1/2014 - 12/31/2018
<b>Funding Status</b>	Funded - NIH
<b>Direct Award (USD)</b>	\$1,654,917
<b>Update</b>	Between February to May 2017, Community Health Workers (CHWs) continued to provide on-demand, free malaria rapid diagnostic testing (RDT) to eligible community

members. In the same period, the study team continued 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. Carried out 18th month endpoint community based survey between April and May in both intervention and control units in Kiminini and Bungoma. A total 757 households with recent fever were enrolled in control (355 households) and intervention (402 households) CUs for the 18-month survey. Towards the end of May, we carried out dissemination meetings on study survey findings with the Subcounty Health Management Teams (SCHMTs) and the CHWs. Meetings with SCHMTs and CHWs took place at the Sub-county health facilities and at the community level. The objective of the meeting was provide preliminary study findings as well as acknowledge the participation of the CHWs. CHWs were issued with certificates to acknowledge their participation in the study. As part of process evaluation, we conducted CHWs endpoint survey interview targeting a sample 200 CHWs in both intervention and comparison CUs. This was done in the months of June and July. The objective of the survey was to evaluate CHWs satisfaction and motivation in their role as well as determine key attributes in their role. Data from the survey is aimed at informing feasibility and scalability of future CHWs led interventions. Data entry is in process using REDcap and we hope to proceed with analysis in the next coming month. We conducted four (4) Focused Group Discussion (FGDs) comprising of an average of 8 participants from enrolled private medicine outlets in the intervention community units in the month June. The FGDs was designed to understand private medicine outlets experience and perceptions about their participation in the study. FGD recordings have been transcribed and qualitative analysis is underway.

**Future Plans**

Data entry for CHWs Analysis of Aim 2 data is underway and will continue throughout the upcoming project period with an emphasis on primary and secondary study endpoints, 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. *BMJ Global Health*, 1(2),e000101. <http://dx.doi.org/10.1136/bmjgh-2016-000101>.

**Study Title**

**Linkage and Retention to Care in Western Kenya Following HIV Testing**

**Principal Investigator(s)**

Becky Genberg, Brown University

**Co-Investigator(s)**

Juddy Wachira, Moi University  
Catherine Kafu, Elizabeth Pfeiffer

**Working Group(s)**

AMWG, SSRN, PHPCWG



<b>Description</b>	<p>This project is focused on identifying the individual, psychosocial, and structural barriers to timely linkage and retention. This project has three specific aims: 1. To comprehensively describe linkage and retention to HIV care following home-based counseling and testing by examining time from testing to linkage and the socioeconomic, demographic and structural determinants of linking to care. We will conduct retrospective and multilevel analyses using existing de-identified clinical and facility-level data collected within AMPATH, defining linkage to care as the completion of an initial HIV clinical encounter with a provider following testing. We will also examine factors that predict retention in HIV care over time. 2. To characterize the psychosocial and structural facilitators and barriers to linkage and retention to care following positive HIV diagnosis through HBCT and PITC. We will conduct a qualitative study to examine the psychosocial factors inhibiting or motivating linkage to care, experiences in accessing care, and factors that promote or interrupt retention among those who tested positive via HBCT or PITC. We will also collect data from clinicians and community health workers to examine how features of the healthcare system facilitate or constrain linkage and retention to care. 3. To develop and implement a feasibility study of a pilot psychosocial intervention aimed at increasing linkage to care among individuals testing positive for HIV. The content of this intervention pilot will be informed by the results of Aims 1 and 2. The first aim of this study involves secondary analysis of data collected during home-based counseling and testing linked to medical records data. This data will include information collected as part of routine testing procedures and care, for those who successfully linked to care. AIM 2 will employ qualitative approaches to identify barrier and facilitators to linkage and retention. AIM 3 will include information collected as part of routine care, for those who successfully linked to care. Specifically, medical record reviews at baseline and post-intervention.</p>
<b>Site(s)</b>	<p>Other</p>
<b>Project Period</b>	<p>6/4/2012 - 12/20/2013</p>
<b>Funding Status</b>	<p>Funded – NIH - National Institute of Mental Health (NIMH)NIH - National Institute of Allergy and Infectious Diseases (NIAID)</p>
<b>Direct Award (USD)</b>	<p>\$152,806</p>
<b>Update</b>	<p>From January to June 2017 we have been focused nearly entirely on analyzing data from our qualitative studies that were conducted as part of Aim 2 of the overall proposal. We have data from two samples: 1) health care providers and 2) individuals who did or did not link to HIV care following diagnosis via home-based counseling and testing. With respect to the first sample, we have submitted one manuscript focused on provider perspectives on patient-provider relationships for publication. We have presented another analysis, system and facility-level factors that impact engagement in HIV care, at the recent IAS conference (July 2017). Another analysis focused on gender and the patient-provider relationship was presented at the International Conference on HIV Treatment and Prevention Adherence in June. Two additional manuscripts are currently in process. From the second data set, we presented an analysis on linkage to care following home-based counseling and testing at the recent International Conference on HIV Treatment and Prevention Adherence in June 2017. This paper, and another focused on stigma, are currently under development.</p>

<b>Future Plans</b>	During the next 6 months, we will complete the analysis of qualitative data from the health care providers and individuals who did and did not link to care. We have begun our formative work for Aim 3 of this project. This will entail having peers work with individuals newly diagnosed with HIV to encourage linkage to care in a timely manner. We expect that those who are newly diagnosed who are matched with a peer will be more likely to link to care than those who receive a referral and follow-up from an HIV counselor only.
<b>Publication(s)</b>	Genberg BL, Wachira J, Kafu C, Wilson IB, Ware NC, Kamene-Owino R, Akinyi J, Koech B, Braitstein P. Provider perspectives on delivering HIV care in western Kenya: Results from a qualitative study. Poster presented at: The 9th IAS Conference on HIV Science, July 23-26, 2017, Paris, France. Abstract no. MOPED1082. Genberg BL, Hogan JW, Xu Y, Ndege S, Nyambura M, Tarus C, Rotich E, Kafu C, Wachira J, Goodrich S, Braitstein P. Using double-sampling to estimate linkage to HIV care among individuals newly diagnosed with HIV through home-based counseling and testing in western Kenya. Poster presented at: The 12th International Conference on HIV Treatment and Prevention Adherence, June 4-6, 2017, Miami, Florida. Abstract no. 341. Genberg BL, Wachira J, Knight J, Kafu C, Ware NC, Naanyu V, Braitstein P. Linkage to care following home-based counseling and testing: Results from a qualitative study in Kenya, with implications for test-and-treat. Poster presented at: The 12th International Conference on HIV Treatment and Prevention Adherence, June 4-6, 2017, Miami, Florida. Abstract no. 340. Knight J, Wachira J, Kafu C, Braitstein P, Wilson IB, Harrison A, Kamene R, Akinyi J, Koech B, Genberg BL. Role of gender in patient-provider relationships: A qualitative study of HIV care providers in western Kenya with implications for retention in care. Poster presented at: The 12th International Conference on HIV Treatment and Prevention Adherence, June 4-6, 2017, Miami, Florida. Abstract no. 268. Genberg BL, Naanyu V, Keter A, Ngeresa A, Wachira J, Hogan JW, Braitstein P. The Impact of Care Navigators on Engagement in HIV Care in western Kenya. Poster presentation at: Conference on Retroviruses and Opportunistic Infections (CROI), Seattle, WA, February 13-17, 2017. Abstract no. 1851.



<b>Study Title</b>	<b>Making Inroads to Strengthen the Health of Adolescents (MaISHA)</b>
<b>Principal Investigator(s)</b>	Leslie Enane, Indiana University
<b>Co-Investigator(s)</b>	Edith Apondi, Moi Teaching and Referral Hospital Judith Toromo, Vreeman Rachel Nyandiko Winstone Lowenthal Elizabeth
<b>Working Group(s)</b>	PRWG
<b>Description</b>	The objective of this project is to investigate critical gaps in care for adolescents with HIV, and the underlying barriers complicating care for adolescents. The direct causes of severe illness among adolescents with HIV will also be explored. To achieve our project objective, we will pursue the following specific aims: Aim 1. To quantify missed opportunities along the HIV care cascade among adolescents prior to hospitalization in western Kenya, by examining timing and outcomes of HIV diagnosis, linkage to and retention in care, and viral suppression. This will be accomplished through a prospective study of hospitalized adolescents in western Kenya. Measures of engagement in HIV

	<p>care prior to hospitalization will also be assessed. Secondary Aim: To determine the causes of hospitalization and mortality among adolescents with HIV in western Kenya. Hospital record data and consultation with care providers will be utilized to determine causes of hospitalization and mortality. Aim 2. To define critical barriers contributing to delays or failures in the care cascade, as well as facilitators to care, and to identify areas of potential intervention. Barriers and facilitators to the long-term retention of adolescents in care will be specifically explored. This will be accomplished through qualitative inquiry of youth with HIV and their caregivers. Phase I will be a prospective mixed-methods study of youth with HIV that will specifically investigate barriers and facilitators to long-term retention of adolescents in HIV care. This will include interviews with key informants: hospitalized youth and their caregivers, and peer mentors; and focus groups of youth engaged in HIV care and their caregivers. Phase II will be a prospective mixed-methods study of hospitalized adolescents that will determine outcomes along the care cascade, causes of hospitalization and mortality, and qualitative barriers and facilitators to care at each stage.</p>
<b>Site(s)</b>	Chulaimbo Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital (MTRH), Webuye District Hospital
<b>Project Period</b>	10/1/2016 - 6/30/2019
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$57,500
<b>Update</b>	<p>The project was approved by the relevant Institutional Ethics boards in March 2017. We began recruitment in April 2017. We have recruited a total of 48 participants (caregiver-adolescent dyads) to date. A total of 16 were hospitalized adolescents at the MTRH hospital wards. We did interviews with 12 caregivers of these adolescents; five adolescents who were medically stable to participate were also interviewed. Information about their causes and outcomes of hospitalization were recorded. From the clinic cohort we have recruited 32 participants. Seventeen were non-disclosed adolescents. Of these, ten have been interviewed, two were not able to participate in interviews, while five will be doing their interviews when they come to the clinic for their return visit. Fifteen disclosed adolescents have been recruited and scheduled for a focus group discussion when they break from school for holidays. We have also had two focus group discussions with female caregivers of adolescents aged 10-19 years. Transcriptions and translations have been produced for the completed interviews and focus group discussions. Preliminary analysis of the transcripts has allowed for exploration of themes and refinement of the interview and focus group guides.</p>
<b>Future Plans</b>	<p>Over the next six months, we will continue recruitment and qualitative data collection until we have reached saturation of themes regarding barriers and facilitators to retention. We will then evaluate barriers along the cascade for hospitalized patients. We will continue to collect data on causes of hospitalization and mortality. We will begin recruitment of peer mentors for key informant interviews, as well as focus group discussions to consider areas of intervention to improve adolescent retention. We will perform data entry and verification. Clinical and demographic data will be analyzed by descriptive statistics. For the qualitative work, we will conduct first- and second-cycle coding of the data by multiple members of our team, and from these codes will establish</p>

	a cohesive set of themes and concepts, as well as an overarching theoretical framework grounded in the data. We will prepare a meeting abstract and develop a manuscript.
Publication(s)	

<b>Study Title</b>	<b>MCH STUDY (Evaluations at Infant and Child Visits a MCHs in western Kenya: A Needs Assessment)</b>
<b>Principal Investigator(s)</b>	Megan McHenry, Indiana University
<b>Co-Investigator(s)</b>	Eren Oyungu, Moi University Roselyne Ananda, Roselyne Ananda
<b>Working Group(s)</b>	PRWG
<b>Description</b>	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.
<b>Site(s)</b>	Busia District Hospital, Matayos Health Centre, Mois Bridge Health Centre, Mt. Elgon District Hospital, Uasin Gishu District Hospital, Ziwa Sub-District Hospital
<b>Project Period</b>	9/26/2016 - 9/26/2017
<b>Funding Status</b>	Unfunded
<b>Direct Award (USD)</b>	
<b>Update</b>	We have written an abstract for the study and routed it in the Ampath publications committee hopefully to present it to PAS meeting.
<b>Future Plans</b>	Presenting the abstract to PAS meeting and finalize with the analysis with manuscript writing
Publication(s)	

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

<b>Co-Investigator(s)</b>	Eren Oyungu, Moi University Roselyne Ananda,
<b>Working Group(s)</b>	PRWG
<b>Description</b>	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.
<b>Site(s)</b>	Matayos Health Centre, Mois Bridge Health Centre, Saboti Sub-District Hospital, Uasin Gishu District Hospital, Ziwa Sub-District Hospital
<b>Project Period</b>	1/10/2016 - 9/30/2017
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$597,800 US
<b>Update</b>	The adaptive phase of the bayley scales of infant and toddler development is currently on going, we have so far recruited 15 participants (children 18-36 months) who have been involved to culturally adapt the assessment tool in the children population with our main site being MTRH.
<b>Future Plans</b>	Over the next six months we plan to recruit children with three different categories of HIV exposure: HIV-infected, HIV-exposed but uninfected, and HIV-unexposed. They will be enrolled, and administered the BSID-III to a total of 225 children, 37-38 in each HIV exposure classification and age group (18 and 30 months). To further explain

	developmental delay among these children, we will document psychosocial factors related to developmental delay based on results of previous results. All the recruited children will also be requested to provide blood for determination of biological factors associated with developmental delay.
Publication(s)	
Study Title	<b>Nurse Management of Hypertension Care in Rural Western Kenya</b>
Principal Investigator(s)	Rajesh Vedanthan, Mount Sinai School of Medicine
Co-Investigator(s)	Sylvester Kimaiyo, Moi Teaching and Referral Hospital Peninah Kiptoo,
Working Group(s)	None
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	Marked progress has been made on this project over the last six months. This progress is delineated below. <ul style="list-style-type: none"> <li>o Administrative</li> <li>o All-Investigator conference call held in January 2017 and May 2017</li> <li>o Faculty and study team visits to Eldoret, Kenya for the purposes of site monitoring, capacity building, and training are ongoing</li> <li>o Capacity building of the study personnel with specialized and targeted training ongoing</li> <li>o Procurement of necessary supplies for completion of 12 month assessments ongoing</li> <li>o Aim 1 (Barriers &amp; Facilitators to Linkage/Retention):</li> <li>o Secondary qualitative manuscript in preparation</li> </ul>

	<p>Subsidiary Aim 1.1 (Behavioral Assessment and Communication Strategy):</p> <ul style="list-style-type: none"> <li>o Content validity manuscript in preparation</li> </ul> <p>Subsidiary Aim 1.2 (Smart-phone-based tool):</p> <ul style="list-style-type: none"> <li>o Smartphone-based assessment tools and MUzima-based data collection tool (both linkage and retention) continue to be utilized in the field</li> </ul> <p>Aim 2 (Cluster RCT):</p> <ul style="list-style-type: none"> <li>o Community Health Workers (CHWs) and Community Health Extension Workers (CHEWs) in the tech-based arm continue with the data collection of Behavioral assessment tools.</li> <li>o 12 month follow-ups are ongoing (1079 of 1458 completed).</li> <li>o Assessment tool: - As of June 2017 a total of 444 behavioral assessment tools have been administered by CHWs - Web-based entry of paper behavioral assessment tools ongoing</li> <li>o Data Management - Data cleaning is ongoing</li> </ul> <p>Aim 3 (Cost Effectiveness Analysis):</p> <ul style="list-style-type: none"> <li>o Costing questionnaire survey (CQS): - Administration of 12 month follow-up costing questionnaires is ongoing - Preliminary data analysis is ongoing</li> <li>o Intervention cost tracking procedures has been implemented</li> </ul>
<p><b>Future Plans</b></p>	<p>Administration:</p> <ul style="list-style-type: none"> <li>o Prepare the staff for final closure of the study inclusive of employment implications.</li> </ul> <p>Aim 1:</p> <ul style="list-style-type: none"> <li>o Complete and submit secondary qualitative analysis manuscript</li> </ul> <p>Aim 1.1</p> <ul style="list-style-type: none"> <li>o Complete and submit content validity manuscript</li> </ul> <p>Aim 1.2</p> <ul style="list-style-type: none"> <li>o Continue device management and mentorship of use of devices</li> </ul> <p>Aim 2:</p> <ul style="list-style-type: none"> <li>o Complete 12 month follow-up visits for all trial arms</li> <li>o Continue data management and interim analyses</li> <li>o Baseline manuscript</li> </ul> <p>Aim 3:</p> <ul style="list-style-type: none"> <li>o Complete administration of 12-month f/u costing questionnaire</li> <li>o Complete tool (spreadsheet) for cost tracking analysis of intervention delivery</li> </ul>
<p><b>Publication(s)</b></p>	<p>The following manuscripts are in preparation:</p> <ul style="list-style-type: none"> <li>o Perceptions of the Role of Community Health Workers in Hypertension Management: A Qualitative Study from Rural Kenya</li> <li>o Development and Validation of a Behavioral Assessment Tool to Optimize Linkage and Retention to Hypertension Care in Kenya: LARK Hypertension Study</li> <li>o Process Evaluation</li> <li>o Health care utilization, costs, insurance, and poverty</li> </ul>
<p><b>Study Title</b></p>	<p><b>One Year Morbidity and Mortality of Infants Diagnosed with Perinatal Asphyxia or Low Birth Weight Admitted to The New Born Unit at Moi Teaching and Referral Hospital.</b></p>
<p><b>Principal Investigator(s)</b></p>	<p>Julia Songok, Moi University</p>
<p><b>Co-Investigator(s)</b></p>	<p>Joy Marsha, Ruhl Laura Nyandiko Wiston Ng'etich Eric Christoffersen-Deb Astrid Brown Morgan Kunkel Melissa Alera Joy Kibet Vincent Bernard Christian Kosgei Faith</p>
<p><b>Working Group(s)</b></p>	<p>PRWG</p>
<p><b>Description</b></p>	<p>A prospective cross-sectional study looking at the one year morbidity and mortality of infants with low birth weight (LBW) and perinatal asphyxia admitted to the new born unit (NBU) at Moi Teaching and Referral Hospital (MTRH). We hope to enroll 420 infants and follow them up until they are one year of age. Data will be collected on admission diagnosis, demographics, anthropometric measurements, treatment and follow-up and outcomes during admission and at one year of age. The objectives of the study are to determine the one year mortality rate of infants admitted to the NBU, determine the</p>

	attrition and readmission rate, to determine the proportion of newborns with perinatal asphyxia or low birth weight and grade the severity and to determine the obstetric, medical and socio-economic factors associated with better short term and long term outcomes.
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	10/23/2017 - 10/23/2019
Funding Status	Unfunded
Direct Award (USD)	
Update	Ethical approval through IREC was gained. We were also able to complete creating a REDCAP database that will be used to input data.
Future Plans	We hope to start consenting and enrolling infants into the study. We will also start collecting data and follow-up of all enrolled infants admitted to the NBU.
Publication(s)	

<b>Study Title</b>	<b>Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK)</b>
<b>Principal Investigator(s)</b>	Jemima Kamano, Moi Teaching and Referral Hospital
<b>Co-Investigator(s)</b>	Rajesh Vedanthan, Mount Sinai School of Medicine Josephine Kisato,
<b>Working Group(s)</b>	None
<b>Description</b>	The objective of this application is to utilize a multi-disciplinary implementation research approach to address the challenge of linking and retaining hypertensive individuals to a hypertension management program. The central hypothesis is: community health workers (CHWs), equipped with a tailored behavioral communication strategy and a smartphone-based tool linked to an electronic health record, can increase linkage and retention of hypertensive individuals to a hypertension care program and thereby significantly reduce blood pressure among these patients. We further hypothesize that these interventions will be cost-effective. To test these hypotheses and achieve the overall objectives, we will pursue the following specific aims: Aim 1: Identify the facilitators and barriers to linking and retaining individuals with high blood pressure to a hypertension care delivery program, using a combination of qualitative research methods: 1) baraza (traditional community gathering) form of inquiry; 2) focus group discussions among individuals with elevated blood pressure during home-based testing; and 3) focus group discussions among CHWs. Subsidiary Aim 1.1: Using identified facilitators and barriers, develop a tailored behavioral communication strategy guided by the Health Belief Model modified by incorporating emotional elements for the CHWs to use with hypertensive patients, focusing on regular and timely attendance at hypertension clinic. We will test the communication strategy for face and content validity using focus group discussions with CHWs and individuals with elevated blood



pressure. Subsidiary Aim 1.2: Using identified facilitators and barriers, develop a smartphone-based tool linked to the AMPATH Medical Record System (AMRS) to be used by CHWs to optimize linkage and retention of hypertensive patients to the care program, and evaluate the usability and feasibility of this tool using think-aloud technique, mock patient encounters, focus group discussions, and participant observation. Aim 2: Evaluate the effectiveness of CHWs equipped with a tailored behavioral communication strategy and a smartphone-based tool in improving linkage and reducing blood pressure among hypertensive patients, by conducting a cluster randomized trial comparing: 1) usual care (CHWs with standard training on recruitment of individuals with any chronic condition); 2) CHWs with an additional tailored behavioral communication strategy; and 3) CHWs with a tailored behavioral communication strategy and also equipped with smartphone-based tool linked to the AMRS. The co-primary outcome measures will be: 1) documented linkage to care following home-based testing, and 2) one year change in systolic blood pressure among hypertensive individuals. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial. Cost effectiveness will be presented both in terms of costs per unit decrease in blood pressure and in terms of costs per reductions in cardiovascular disease (CVD) risk by extrapolating one-year blood pressure reductions. 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

4/1/2012 - 3/31/2018

Funding Status

Direct Award (USD)

Update

Marked progress has been made on this project over the last six months. This progress is delineated below.

- Administrative
  - o All-Investigator conference call held in January 2017 and May 2017
  - o Faculty and study team visits to Eldoret, Kenya for the purposes of site monitoring, capacity building, and training are ongoing
  - o Capacity building of the study personnel with specialized and targeted training ongoing
  - o Procurement of necessary supplies for completion of 12 month assessments ongoing
- Aim 1 (Barriers & Facilitators to Linkage/Retention):
  - o Secondary qualitative manuscript in preparation
- Subsidiary Aim 1.1 (Behavioral Assessment and Communication Strategy):
  - o Content validity manuscript in preparation
- Subsidiary Aim 1.2 (Smart-phone-based tool):
  - o 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 continue with the data collection of Behavioral assessment tools.
  - o 12 month follow-ups are ongoing (1079 of 1458 completed).
  - o Assessment tool: - As of June 2017 a total of 444 behavioral assessment tools have been administered by CHWs - Web-based entry of paper behavioral assessment tools ongoing
  - o Data Management - Data cleaning is ongoing
- Aim 3 (Cost Effectiveness Analysis):
  - o Costing questionnaire survey (CQS): - Administration of 12 month follow-up costing questionnaires is ongoing
  -

	Preliminary data analysis is ongoing - Intervention cost tracking procedures has been implemented
<b>Future Plans</b>	Administration: o Prepare the staff for final closure of the study inclusive of employment implications. Aim 1: o Complete and submit secondary qualitative analysis manuscript Aim 1.1 o Complete and submit content validity manuscript Aim 1.2 o Continue device management and mentorship of use of devices Aim 2: o Complete 12 month follow-up visits for all trial arms o Continue data management and interim analyses o Baseline manuscript Aim 3: o Complete administration of 12-month f/u costing questionnaire o Complete tool (spreadsheet) for cost tracking analysis of intervention delivery
<b>Publication(s)</b>	The following manuscripts are in preparation: o Perceptions of the Role of Community Health Workers in Hypertension Management: A Qualitative Study from Rural Kenya o Development and Validation of a Behavioral Assessment Tool to Optimize Linkage and Retention to Hypertension Care in Kenya: LARK Hypertension Study o Process Evaluation o Health care utilization, costs, insurance, and poverty

<b>Study Title</b>	<b>Pathways to better health</b>
<b>Principal Investigator(s)</b>	Paula Braitstein, University of Toronto
<b>Co-Investigator(s)</b>	Monica Nyambura,
<b>Working Group(s)</b>	AMWG, PRWG
<b>Description</b>	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.
<b>Site(s)</b>	The catchments of Bunyala, Teso, and Chulaimbo
<b>Project Period</b>	1/4/2016 - 10/31/2016
<b>Funding Status</b>	Funded – Regenstrief Institute
<b>Direct Award (USD)</b>	\$45,000
<b>Update</b>	We completed the manual matching of data from HBCT/PHCT with AMRS for Bunyala, Chulaimbo, and Teso.
<b>Future Plans</b>	Publish the data.
<b>Publication(s)</b>	Using double-sampling methods to estimate linkage to HIV care among individuals newly diagnosed with HIV through home-based counseling and testing in western Kenya Becky L. Genberg, <sup>1</sup> Joseph W. Hogan, <sup>1</sup> Yizhen Xu, <sup>1</sup> Samson Ndege, <sup>2</sup> Monicah Nyambura, <sup>3</sup> Caren Tarus, <sup>3</sup> Elyne Rotich, <sup>3</sup> Catherine Kafu, <sup>3</sup> Juddy Wachira, <sup>2,3</sup> Suzanne Goodrich, <sup>4</sup> Paula Braitstein <sup>2,3,4,5,6</sup> IAPAC 2017

<b>Study Title</b>	<b>Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)</b>
<b>Principal Investigator(s)</b>	Rachel Vreeman, Indiana University
<b>Co-Investigator(s)</b>	W. Nyandiko, Moi University Josephine Okoyo,
<b>Working Group(s)</b>	PRWG
<b>Description</b>	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.
<b>Site(s)</b>	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
<b>Project Period</b>	9/1/2012 - 9/1/2016
<b>Funding Status</b>	Funded – NIH - National Institute of Mental Health (NIMH)
<b>Direct Award (USD)</b>	\$1,886,804
<b>Update</b>	In the HADITHI (Helping AMPATH Disclose Information and Talk about HIV Infection) trial, the objective was to evaluate the efficacy of an intensive, culturally adapted, narrative-based disclosure intervention for HIV-infected Kenyan children compared to the less intensive disclosure process currently used as the standard of care. Our primary endpoint was disclosure status over two- years follow-up, with secondary endpoints related to clinical, psychological, and social outcomes. 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

	<p>functioning. In the last six months, key analysis is ongoing. The MEMS adherence data has been cleaned by the IU biostats team in preparation for further analysis in accordance with the specific aims. The HADITHI counselling materials created during the study include counseling pamphlets, disclosure and stigma videos, and an animation tool, all of which were created using cross-cultural adaptation techniques and continued to be used in most clinics.</p>
Future Plans	<p>Over the next 6 months, we plan to:</p> <ul style="list-style-type: none"> <li>• Complete key data analyses for each of the study objectives.</li> <li>• Complete the evaluation of drug level concentrations on hair samples sent to UCSF to the laboratory of Dr. Monica Gandhi, as well as compile evaluations assessing the feasibility and validity of this type of testing in our population.</li> <li>• Prepare manuscripts and conference presentations.</li> <li>• Continue to implement the HADITHI counseling tools in AMPATH clinics to guide disclosure practices with pediatric patients</li> </ul>
Publication(s)	<p>Vreeman RC, McCoy BM, Lee S. Mental health challenges among adolescents living with HIV. <i>J Int AIDS Soc.</i> 2017 May 16;20(Suppl 3):100-109. doi: 10.7448/IAS.20.4.21497.</p> <p>Sohn AH, Vreeman RC, Judd A. Tracking the transition of adolescents into adult HIV care: a global assessment. <i>J Int AIDS Soc.</i> 2017 May 16;20(Suppl 3):1-3. doi: 10.7448/IAS.20.4.21878</p> <p>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. <i>J Int Assoc Provid AIDS Care.</i> 2016 Sep 21. pii: 2325957416668995. [Epub ahead of print] PMID: 27655835</p> <p>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. <i>J Int AIDS Soc.</i> 2016 Oct 6;19(1):21204. doi: 10.7448/IAS.19.1.21204. Review. PMID: 27717409</p> <p><u>Presentations:</u></p>
Study Title	<b>Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretroviral Treatment</b>
Principal Investigator(s)	Paula Braitstein, University of Toronto
Co-Investigator(s)	B Jakait, Moi Teaching and Referral Hospital Mercy Maina, Pastakia S. Karwa R. Ngetich C. Inui T. Sidle J. Wools-Kaloustian, K. Nyandiko W. Pandit J. Olsson S. Maina M. Olwande C.
Working Group(s)	PRWG, AMWG, PCWG
Description	<p>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</p>

	constrained clinical setting in western Kenya. The approaches include; TSR 1: The completion of the Kenya National Suspected Adverse Drug Reaction form for patients with a change or discontinuation in their cART. These forms are then forwarded on to the National pharmacovigilance (PV) office at the Pharmacy and Poisons Board (PPB) in Nairobi. TSR 2: Use of routinely-used clinical encounter forms that have been enhanced to specifically collect a relatively small amount of SADR data to be collected by the provider seeing the patient during the clinical visit. TSR 3 and TSR 4: Involve conducting in-depth interviews on 1,000 patients receiving cART treatment to prompt patients about SADR and their impact on patient adherence and quality of life. Patients undergoing interviews are randomly assigned to be interviewed by an HIV peer (TSR 3) or a pharmacy personnel (TSR 4) who will have received the same training for the project. The interviews will be conducted over 12 months or a maximum of 12 scheduled clinical visit (Whichever comes first). TSR 5: Use of data routinely captured in the pharmacy when clinicians substitute or change a patient's regimen, including documentation if such an event occurred on the prescription form and the cause of the event (i.e. toxicity, treatment failure, TB drug interaction, pregnancy, other).
Site(s)	Moi Teaching and Referral Hospital (MTRH)
Project Period	10/1/2012 - 12/31/2013
Funding Status	Funded
Direct Award (USD)	\$162,000
Update	We received preliminary data analysis results from the study which indicated the peer and pharmacy technician interviews were associated with a statistically significant decline in loss to follow up. We are awaiting a final analysis after including more patients who met the inclusion criteria.
Future Plans	We anticipate that we will share the results with the program and start working on the manuscripts over the next 6 months.
Publication(s)	

Study Title	<b>Phylogenetic Inference of Vertical versus Horizontal HIV Transmission among Adolescents in Western Kenya</b>
Principal Investigator(s)	John Humphrey, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University , Kara Wools-Kaloustian, Joe Hogan, Rachel Vreeman, Rami Kantor
Working Group(s)	PRWG
Description	HIV is the leading cause of death among adolescents in sub-Saharan Africa. However, the identification and epidemiologic impact of different modes of HIV transmission within the adolescent population remain unclear. For adolescents newly diagnosed with HIV who also have an HIV-positive mother, it can be unclear whether the adolescent's infection occurred through vertical (i.e. mother-to-child) or horizontal (e.g. unprotected

sex) transmission. Characterizing the contributions of vertical and horizontal transmission among adolescents in sub-Saharan Africa is important, as it can enhance understanding of the epidemiologic drivers of HIV infections and inform the implementation of tailored prevention and treatment strategies. The objective of this proposed pilot study is to identify methods to distinguish modes of HIV infections among Kenyan adolescents 10-19 years of age via the following specific aims: 1) examine the feasibility of phylogenetic inference to determine HIV infection through vertical versus horizontal transmission in adolescents, and 2) compare demographic, clinical and laboratory characteristics of vertical and horizontal predicted-infection in HIV-infected adolescents and their mothers. This study will be conducted at the Academic Model Providing Access to Healthcare (AMPATH) Center, a large HIV treatment and research facility in western Kenya, in collaboration with Indiana University and Brown University. We will enroll 20 HIV-infected adolescent-mother dyads in whom the mode of infection is uncertain and 10 HIV-infected child-mother dyads in whom vertical infection is highly likely. HIV viral load testing and pol sequencing will be performed for all subjects, including those with undetectable viral load by archived DNA genotyping. The epidemiologic linkage and clustering of HIV sequences among adolescent-mother dyads will be inferred phylogenetically and compared to (i) phylogenetic clusters of child-mother dyads that likely represent vertical transmission; and (ii) non-phylogenetic prediction of mode of infection, based on demographic and clinical risk factors elicited through a chart review and epidemiologic survey. We hypothesize that phylogenetic inference will differentiate vertically and horizontally-acquired infections, and that characteristics will differ between horizontally and vertically infected adolescents. This study will also add insight into the natural history of perinatally infected individuals who are diagnosed as adolescents, as current estimates of survival and disease progression are limited by an inability to confirm vertical infection in these individuals. This proposal will employ an innovative phylogenetics approach to address a key priority for HIV research in sub-Saharan Africa, namely, the uncertain impact of vertical and horizontal transmission among adolescents living in HIV-affected families.

<b>Site(s)</b>	Moi Teaching and Referral Hospital (MTRH)
<b>Project Period</b>	5/1/2017 - 4/30/2018
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$20,000
<b>Update</b>	We have submitted the protocol to IREC and are awaiting approval. We had a preliminary meeting with the laboratory staff involved in the project and are currently finalizing the REDCap data collection tools.
<b>Future Plans</b>	We anticipate obtaining IRB approval and other regulatory approvals by July 2017, initiating enrollment by August 2017, completing enrollment by October 2018, and completing viral load testing and phylogenetic sequencing of samples by December 2017.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>Point in Time (PIT) Count of Street Children in Eldoret</b>
<b>Principal Investigator(s)</b>	Paula Braitstein, University of Toronto
<b>Co-Investigator(s)</b>	David Ayuku, Moi University Carren Taru,
<b>Working Group(s)</b>	PRWG
<b>Description</b>	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.
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	5/1/2016 - 12/31/2016
<b>Funding Status</b>	Funded – Canadian Institutes of Health Research
<b>Direct Award (USD)</b>	\$35,000 Canadian (~\$27, 600 US)
<b>Update</b>	We have been working on writing up the paper.
<b>Future Plans</b>	Publish the paper.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>'Point of Care CD4 testing for people who fail to engage in care after testing HIV positive'.</b>
<b>Principal Investigator(s)</b>	Paula Braitstein, University of Toronto
<b>Co-Investigator(s)</b>	Samson Ndege, Moi University Carren Tarus,
<b>Working Group(s)</b>	AMWG
<b>Description</b>	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	We completed the tracing of patients and have been working on updating the analyses. A poster was presented on the updated estimates of linkage to care at IAPAC earlier this year. Our main findings demonstrated that although sub-optimal, linkage to HIV care following HBCT may be underestimated in settings without universal identifiers. These findings imply that health systems strengthening is urgently needed, with universal electronic medical records and national unique identifiers for improved harmonization of data across programs. To measure progress toward 90-90-90, we must invest in data systems in resource-limited settings.
Future Plans	We hope to publish the paper and receive additional funding to do additional outcomes ascertainment.
Publication(s)	Using double-sampling methods to estimate linkage to HIV care among individuals newly diagnosed with HIV through home-based counseling and testing in western Kenya Becky L. Genberg, <sup>1</sup> Joseph W. Hogan, <sup>1</sup> Yizhen Xu, <sup>1</sup> Samson Ndege, <sup>2</sup> Monicah Nyambura, <sup>3</sup> Caren Tarus, <sup>3</sup> Elyne Rotich, <sup>3</sup> Catherine Kafu, <sup>3</sup> Juddy Wachira, <sup>2,3</sup> Suzanne Goodrich, <sup>4</sup> Paula Braitstein <sup>2,3,4,5,6</sup> Presented at IAPAC 2017

Study Title	<b>Randomized, Phase II Trial of CHOP vs. Oral Chemotherapy with Concomitant Antiretroviral Therapy in Patients with HIV-associated Lymphoma in Sub-Saharan Africa</b>
Principal Investigator(s)	Naftali Busakhala, Moi University
Co-Investigator(s)	Evangeline Njiru, Moi Teaching and Referral Hospital Job Kisuya,
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)	



Project Period	9/1/2015 - 8/31/2018
Funding Status	Funded - NIH
Direct Award (USD)	\$75,000
Update	The study is open for enrollment, we have managed to enroll one study participant so far into study and we have had two screen failures. We have developed innovative methods for recruitment in order to ensure we are able recruit more study participants into the study.
Future Plans	The study hopes to continue to recruit more study participants into the study participants in next 6 months and hopefully activate all the other study sites in Africa to recruit.
Publication(s)	

Study Title	<b>REALITY 'Reduction of EARly mortaLITY in HIV-infected adults and children starting antiretroviral therapy'</b>
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Abraham Siika, Moi University Priscilla Cheruiyot, Prof. Winstone Nyandiko
Working Group(s)	AMWG, PRWG
Description	A 2x2x2 open-label factorial multi-centre trial, conducted in 9 centres in 4 countries (Kenya, Malawi, Uganda, 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)	Kenya, Malawi, Uganda, Zimbabwe
Project Period	8/1/2013 - 8/1/2017
Funding Status	Funded – Medical Research Council
Direct Award (USD)	Not Reported

<b>Update</b>	This protocol was closed to accrual in 2016. There have been no activities at the site in the past 6 months. However, data analysis has been ongoing and a manuscript done
<b>Future Plans</b>	No further activities. Protocol is closed
<b>Publication(s)</b>	<p>Hakim, J., et al., Enhanced Prophylaxis plus Antiretroviral Therapy for Advanced HIV Infection in Africa. <i>N Engl J Med</i>, 2017. 377(3): p. 233-245.</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. Mallewa<sup>4</sup>, 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. Lugemwa, S.L. Pett, M. Bwakura-Dangarembizi, A.J. Prendergast, A.S. Walker, D.M. Gibb, REALITY trial team</p>
<b>Study Title</b>	<b>SAFI (Stigma in AIDS Family Inventory) Validation Study</b>
<b>Principal Investigator(s)</b>	Rachel Vreeman, Indiana University
<b>Co-Investigator(s)</b>	Winstone Nyandiko, Moi University Josephine Aluoch Okoyo, Irene Marete Hai Liu Violet Naanyu
<b>Working Group(s)</b>	PRWG
<b>Description</b>	<p>For families raising HIV-infected children in resource-limited settings, HIV/AIDS-related stigma shapes every aspect of the children's HIV management, from daily adherence to medication to decisions about pediatric HIV disclosure. We do not know the most effective strategies to reduce stigma for HIV-infected children and their families in resource-limited settings nor how to measure its effects on physical, emotional, or social outcomes. We want to learn more about how stigma affects families. As part of the HADITHI study, SAFI aims to develop and test a reliable, valid instrument to measure HIV/AIDS stigma as perceived, enacted, and internalized by Kenyan families with HIV-infected children. The specific aims for the SAFI validation study are to: Aim 1: Identify and modify H/A stigma questionnaire items for maximum reliability and content validity to measure perceived, enacted and internalized H/A stigma among Kenyan families with HIV-infected children. Aim 2: Assess the validity of the measures of perceived, enacted and internalized H/A stigma compared to independent construct measures including pediatric adherence to therapy and children's physical, psychological and social outcomes. Aim 3: Examine whether disclosure of a child's HIV status to the</p>

	child reduces perceived, enacted, or internalized stigma for families with disclosed children compared to families with non-disclosed children. We thus propose assembling, adapting, and then validating measurement items for assessing the relevant domains of H/A stigma experienced by HIV-infected children and their caregivers in sub-Saharan Africa.
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	12/17/2013 - 11/30/2015
Funding Status	Funded
Direct Award (USD)	\$567,828
Update	In the SAFI (Stigma in AIDS Family Inventory) validation study, we proposed to build on our experience validating developmentally and culturally appropriate measurement instruments and the platform of this family cohort to validate a strategy for measuring family HIV/AIDS (H/A) stigma. Our primary objective was to develop and test a reliable, valid instrument to measure H/A stigma as perceived, enacted, and internalized by Kenyan families with HIV-infected children ages 10-15 years. We used the HADITHI cohort of families, followed longitudinally at eight clinics in Kenya, to assess the validity of the measures of family stigma compared to independent construct measures including medication adherence, and HIV-infected children's clinical, psychological, and social outcomes. The specific aims for the SAFI validation study are: 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. In the last 6 months, we completed data cleaning for the questionnaire data collected through the SAFI study to provide a comprehensive and validated family HIV/AIDS-related stigma measure for assessing H/A stigma. Data cleaning for our adherence monitoring data collected through MEMS® monitors are ongoing. The analyses to assess the validity of the measures of stigma are currently underway. We have also published work from our critical reviews of HIV/AIDS stigma assessment worldwide. In addition, we launched a community-based assessment of the impact of the stigma-related adolescent films that were created through this project.
Future Plans	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 continue implementing the stigma films as educational and moving tools to help reduce the impact of HIV/AIDS stigma in the community.

Publication(s)	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. <i>J Int Assoc Provid AIDS Care</i> . 2017 May/Jun;16(3):215-225. doi: 10.1177/2325957416668995.
Study Title	<b>Spatial scales of Plasmodium falciparum generations; implications for elimination</b>
Principal Investigator(s)	Andrew Obala, Moi University
Co-Investigator(s)	Wendy O'meara, Duke University Joseph Kirui, Judy Mangeni, PhD, MSc Lecturer, Moi University College of Health Sciences, Dpt of Nursing P.O. Box 4606-30100 MTRH Complex Nandi Road, Eldoret, Kenya +254722647415 nakholi2001@yahoo.com
Working Group(s)	PHPC
Description	<p>Malaria is a major public health problem, with an estimated 198 million cases occurring world-wide in 2013. Effective strategies to reduce malaria transmission and disease have been highly successful leading to a 40% reduction in malaria cases in sub-Saharan Africa since 2000. It has been observed that infections cluster geographically and such clustering becomes more pronounced as transmission declines. The science of identifying 'hotspots' of infection or foci of transmission is a growing area that promises to help target interventions more effectively. However, it has not been shown whether infected individuals in close physical proximity (i.e. in the same household) are jointly infected due to simply living in a risky place, or because an infected household member is a risk factor for nearby susceptible individuals. If the former, then targeting hotspots should focus on reducing environmental risk factors in the area around a hotspot. If the latter, then interventions to identify and treat 'transmitters' will reduce transmission and reduce the incidence of new cases. Therefore, we need to understand the spatial scale of malaria transmission to predict the impact of community case detection and hotspot targeting. To shed light on this important issue, we propose two scientific objectives. First, we will measure the genetic relatedness of infections within the same household compared to the relatedness of infections at further distances. We will determine whether this relationship differs in fever 'hotspots' (geographic clusters of high fever incidence) and fever 'coldspots'. Parasite DNA from dried blood spots collected from a moderate endemic study area in western Kenya (approximately 15 km by 28 km encompassing more than 80 villages) will be sequenced at a moderately polymorphic gene using deep sequencing techniques. This will provide evidence for local, focal transmission if nearby infections are more closely related or will point to mixed transmission whereby infections only begin to differ as you reach the distance of mosquito flying ranges. Our second objective is to trap malaria mosquito vectors and identify infected mosquitoes. We will determine the source of the mosquito's infection by sequencing parasites in the mosquito salivary glands and comparing to parasite genotypes in humans. By doing so, we can find out whether infections are being transmitted at a household scale or transmission is 'well mixed' geographically and only limited by the range of the mosquito. If successful, this will be the first report of linking individual infections in mosquitoes to their human source. The ability to track infections</p>

	from human to mosquito and back again would allow us to understand the dynamics and scale of transmission in a way that has not previously been possible. We expect to scale up this approach to larger populations in subsequent studies. These results will provide insight into the expected impact of interventions designed to target hotspots.
Site(s)	Webuye District Hospital
Project Period	2/15/2017 - 1/31/2019
Funding Status	Funded
Direct Award (USD)	
Update	Procured study supplies in the month of May in anticipation for the start of study activities. Started study activities in June 2017. We Trained the study team on the study protocol, Mosquito collection, Dried Blood Spot (DBS) procedure and data collection tool on 8th and 9th June. Data collection tool was programmed into tablets. In preparation for roll-out, approval to conduct the study in Bungoma East subcounty was sought from the Sub-county Medical Officer of Health (SCMOH). The SCMOH was also instrumental in introducing the study team to the facilities within the study area. Started enrollment during the week of 12th June and so far we have enrolled 36 household in three sentinel villages (Kinesamo, Maruti and Sitabicha) The Households are enrolled in clusters of about 0.25 km radius. Each enrolled household, is scheduled for monthly follow up for 18 months. Field research team continue to visit the enrolled households monthly to collect basic demographic and behavioral information including who slept in the home, how frequently bednets were used, and to collect dried blood spot samples from each eligible member. On demand malaria diagnostic tests is also provided to household members with suspected malaria illness. We have also enrolled six private medicine outlets to provide free antimalarials to patients with confirmed malaria illness. Mosquitoes collected from household continue to be sorted by genus and archived for dissection to identify infection in the salivary glands and abdomen.
Future Plans	Study households will be visited weekly for entomology collections and monthly for survey and DBS collections over the next 18 months. We will begin to test samples (mosquito and DBS) for parasites by PCR under the direction of collaborators at Duke University.
Publication(s)	
Study Title	<b>Study of Newly Diagnosed Kaposi's Sarcoma</b>
Principal Investigator(s)	Dr. Naftali Busakhala, Moi University
Co-Investigator(s)	
Working Group(s)	ORWG
Description	To achieve our scientific objectives, we will identify a community-based sample of HIV-infected adults with newly diagnosed KS. We propose to use a rapid case ascertainment (RCA) approach to quickly evaluate patients suspected to have KS. RCA refers to the

	swift and thorough evaluation of a patient with a new disease diagnosis. We note that RCA does not refer to a new technique for making diagnoses of KS, but it instead refers to the process of rapidly assessing status and extent of disease once the diagnosis has been made. It is most useful for diseases that are potentially rapidly progressive and potentially fatal. It involves the establishment of a system whereby when a diagnosis is made, a central team is made aware, and the affected patient is rapidly evaluated. It has been mainly used in the cancer field to facilitate epidemiologic research for establishing population-level incidence and stage of cancer at time of diagnosis.
Site(s)	
Project Period	9/1/2015 - 8/31/2019
Funding Status	Funded
Direct Award (USD)	\$750,186
Update	We have managed to enroll 70 cases into study and managed to follow up to the study participants. We have managed to enroll our cases from different AMPATH sites.
Future Plans	We will continue to enroll our cases into study and start the process of selection and recruitment of controls for the cases in the next 6 months. The study will continue to follow up the identified study participants as stipulated in the protocol.
Publication(s)	

<b>Study Title</b>	<b>Tablet Computer-Based Disclosure Counseling for HIV-Infected Adolescents and their Families: A Pilot Study of Perspectives from Providers</b>
<b>Principal Investigator(s)</b>	Megan McHenry (maiden: Uhl), Indiana University
<b>Co-Investigator(s)</b>	Vreeman, Rachel Apondi, Edith Nyandiko, Winstone McAteer, Carole Scanlon, Michael Fischer, Lydia
<b>Working Group(s)</b>	PRWG
<b>Description</b>	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.
Site(s)	Bumala A Health Centre, Bumala B Health Centre, Busia District Hospital
Project Period	2/13/2015 - 8/19/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	The manuscript has been under review by the African Journal for AIDS research and we should be hearing from them soon on their decisions.
Future Plans	We expect to hear from the African Journal for AIDS research soon on their decisions on our manuscript.
Publication(s)	

<b>Study Title</b>	<b>Taking to the Streets: a Mixed-Methods Systematic Review of the Reasons Children and Youth Become Street-Involved</b>
Principal Investigator(s)	Lonnie Embleton, Moi University
Co-Investigator(s)	Paula Braitstein, Indiana University Ayuku David
Working Group(s)	PRWG
Description	A wide variety of reasons children take to the streets to work or live have been cited in the literature; yet there lacks any compiled data on this topic by geographic region. It is suspected the dynamics that drive children to the streets are quite diverse and vary between high income and low-to-middle income countries. This systematic review aims to identify similarities and differences internationally for children living or working on the streets. In turn this literature should help identify future research needs as well as policy changes to best suit the needs for the millions of children worldwide before or after they turn to the streets as a way of survival. Overall objective To compile and critically analyze the literature regarding reasons why children and youth, aged <1-24, turn to the streets as a way to survive in order inform public health research and policy, while identifying gaps in knowledge and evaluating the strength of existing evidence. Specific Aim To describe the reasons children and youth become street-involved in both

	high and low to middle income countries including but not limited to: differences between street connected children in resource-constrained and very-high income settings, children on and of the street and males and females for street-involvement and the age they start living on the streets. Specific Questions: 1. What are the reasons children and youth come to the street both from quantitative and qualitative literature and are the reasons between the two methodologies similar or different? 2. What are the differences in reasons between children on the street versus of the street for coming to the streets? (if able to distinguish based on reporting) 3. What are the differences between children/youth in high versus low/middle income countries? 4. What are the differences between genders?
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/1/2013 - 5/1/2014
Funding Status	Unfunded
Direct Award (USD)	
Update	This study has now been published. This study is complete.
Future Plans	This study has now been published. This study is complete.
Publication(s)	

<b>Study Title</b>	<b>The Confluence of Pregnancy and New HIV Diagnosis Among Adolescents in Western Kenya</b>
<b>Principal Investigator(s)</b>	Katherine MacDonald, Indiana University
<b>Co-Investigator(s)</b>	Edith Apondi, Moi Teaching and Referral Hospital , Keter, Alfred; Nyambura, Monicah
<b>Working Group(s)</b>	PRWG, RHWG
<b>Description</b>	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.
<b>Site(s)</b>	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 six months, the we had a poster presentations at the Society of Adolescent Health and Medicine Conference. We re-framed the manuscript to look focus more on the association of HIV new diagnosis and teen pregnancy with secondary analysis to compare the risk factors of new HIV diagnosis and teen pregnancy. We found no association between teen pregnancy and new HIV diagnosis when doing a multivariate analysis. Because of the refocusing the manuscript, it has not yet been submitted.
Future Plans	The manuscript will completed and submitted for publication.
Publication(s)	MacDonald, K., Apondi, E., Ott, M. A., Wachira, J., Keter, A., Nyambura, M., Millar, H., Kaaria, A., Braitstein, P. (2017). The Confluence of Pregnancy and New Diagnosis of HIV among Adolescent Women in Western Kenya [Abstract]. Journal of Adolescent Health, 60, S83.

Study Title	<b>The Epidemiology of Trauma and Trauma-Related Resources in Western Kenya</b>
Principal Investigator(s)	Connie Keung, Indiana University
Co-Investigator(s)	Jessica Hogan, Other Dr. Joshua Kisorio
Working Group(s)	AMWG
Description	General: To better understand the burden of trauma in Western Kenya as well as the feasibility of implementing a GIS-enabled trauma registry in one referral and two district hospitals. Specific Aim #1: To retrospectively review trauma charts over 6 months from Moi Teaching & Referral Hospital, Iten District Hospital, and Kapsabet District Hospital using a tailored trauma data collection form. Specific Aim #2: To prospectively collect trauma data over 6 months from Moi Teaching & Referral Hospital, Iten District Hospital, and Kapsabet District Hospital using a tailored trauma data collection form. Analysis of this data will help to better understand the burden of trauma in Western Kenya as well as the challenges and applications of implementing a trauma data form in these facilities. Specific Aim #3: Geographic data on where patients are being injured, where health care facilities exist, as well as other relevant geospatial information will then be uploaded to a geographical information system (GIS) platform. This analysis will help to better understand where patients are being injured most often, which health facilities they use, and how they transport to those centres, along with other relevant geospatial questions.
Site(s)	Iten District Hospital, Moi Teaching and Referral Hospital (MTRH), Kapsabet Referral Hospital
Project Period	9/1/2017 – 4/30/2018

<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$20,000
<b>Update</b>	Over the last six months, progress has been made on the surgery/trauma project. We have received IREC approval for our project, as well as approvals from all three hospitals this project entails (Iten/MTRH/Kapsabet). We have University of Alberta's IRB approval as well. We have worked on developing relationships with the medical records personnel at all three hospitals. In addition to that, we were able to conduct two CME classes at MTRH/Iten regarding the importance of a trauma registry. However, due to the ongoing nurses strike, these classes were discontinued. The nurses/COs will be assisting in data collection, coordinated by a research assistant. Through RSPO, we have created a position for a research assistant, and interviewed for the position.
<b>Future Plans</b>	Currently, we are waiting for IRB approval from Indiana University. Once that is finalized, our grant can then be distributed and the research assistant can be hired. Over the next 6 months, we hope to complete the retrospective data collection and initiate the prospective trauma registry at the three hospitals. This is pending resolution of the nurses strike.
<b>Publication(s)</b>	



<b>Study Title</b>	<b>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</b>
<b>Principal Investigator(s)</b>	Tom Inui, Indiana University
<b>Co-Investigator(s)</b>	Naftali Busakhala, Moi University Job Kisuya, Asirwa, C.
<b>Working Group(s)</b>	AMWG, ORWG
<b>Description</b>	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

	<p>Oncology Institute (AOI) is to be the premier cancer program in Sub-Saharan Africa, noted for excellence in cancer prevention, treatment and palliative care. AOI activities will directly contribute to advances in cancer care, accelerate discoveries in the biology and treatment of cancer, and provide support for the IU Simon Cancer Center's quest to become a federally designated Comprehensive Care Center. Naftali Busakhala will characterize the awareness, beliefs, attitudes and behaviors of women coming to AMPATH's clinician breast exam screening as volunteers, comparing these beliefs to those of a community-based sample of women. He will also characterize the yield of the AMPATH screening program, the kinds of cancers detected, and the quality of care achievable in Western Kenya at present, with comparison against an international standard of care. Chite Asirwa will similarly characterize the awareness, beliefs, attitudes and behaviors of a community-based sample of women, comparing their beliefs to those of their husbands, often a key influence on behavior in traditional societies. Taken together these two studies should reveal a great deal about how to influence women's behaviors and encourage participation in the only breast cancer screening program available presently - clinician examination. Both of these studies will use the BCAM (Breast Cancer Awareness Measure), a survey tool developed in Great Britain. We have worked carefully through the standard BCAM to sort questions into theoretically sound domains, using the Health Belief Model as a framework. Violet Naanyu will be conducting field testing and focus groups to do a culturally appropriate Kiswahili version.</p>
Site(s)	Moi Teaching and Referral Hospital (MTRH) Mosoriot Rural Health Training Centre Turbo Health Centre Webuye District Hospital Kapsokorny
Project Period	10/1/2011 - 6/30/2016
Funding Status	Funded
Direct Award (USD)	1,200,000
Update	The last peer-reviewed publication from this project was finally printed. The project was otherwise closed out.
Future Plans	None - the project activities are completed.
Publication(s)	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. BMC Health Services Res. 2017, 17:110. DOI: 10.1186/s12913-017-2058-x. URL: <a href="http://www.biomedcentral.com/1472-6963/17/110">http://www.biomedcentral.com/1472-6963/17/110</a> .
Study Title	<b>The Production and Reproduction of Kinship in CClIs in Uasin Gishu County</b>
Principal Investigator(s)	Allison Gayapersad, University of Toronto
Co-Investigator(s)	Paula Braitstein, Caroline Ombok, Allan Kamanda
Working Group(s)	SSRN

<b>Description</b>	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.
<b>Site(s)</b>	Charitable Children's Institutions in Uasin Gishu County
<b>Project Period</b>	8/1/2016 - 12/15/2017
<b>Funding Status</b>	Unfunded
<b>Direct Award (USD)</b>	
<b>Update</b>	IREC and University of Toronto REB approved amendments. Data collection was completed May 3, 2017. Transcription is almost completed. Data analysis is concurrent and ongoing. Final report is expected within the next 3 - 4 months.
<b>Future Plans</b>	Complete the data analysis and write final report.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>The Role of Faith Leaders towards Promotion of Home Based HIV Testing and Treatment Programs around Kisumu, Kenya</b>
<b>Principal Investigator(s)</b>	Eunice Kamaara, Moi University
<b>Co-Investigator(s)</b>	Amy Nunn, Brown University Dismas Oketch,
<b>Working Group(s)</b>	SSRN
<b>Description</b>	This was an exploratory qualitative study on how to access untapped resources, influence, and opportunities that faith leaders have in promoting home-based HIV testing and treatment towards prevention and control of HIV in western. It explored whether and how faith leaders can enhance uptake of home-based HIV testing, treatment and linkage to care programs in Kisumu.
<b>Site(s)</b>	Chulaimbo Sub-District Hospital, Mukhobola Health Centre, Port Victoria Sub-District Hospital
<b>Project Period</b>	1/1/2014 - 6/30/2017

<b>Funding Status</b>	Unfunded
<b>Direct Award (USD)</b>	
<b>Update</b>	<p>Project activities done to date include:</p> <p>1.All data collected through FGDs and one to one indepth oral interviews 2 Data analysis completed. 3. Dissemination to community of research and Validation workshop held. 4. Dissemination to community of science: We made a presentation on our work in progress at an AMPATH forum on 5th May 2015; presented a paper at the Moi University Annual Conference, 2016; and at the AMECEA Gaba Conference on the theme Evangelization and Inter-religious Dialogue in Africa in 2016. We have developed a paper for the Journal of Public Health and are looking out for opportunities to carry out further research guided by the findings of this pilot study. 5. We have now closed the project.</p>
<b>Future Plans</b>	We have closed the project.
<b>Publication(s)</b>	
<b>Study Title</b>	<b>The Role of PD-1 Pathway and Tissue Microenvironment in HIV-Kaposi Sarcoma and Endemic Kaposi Sarcoma Cohort in Western Kenya</b>
<b>Principal Investigator(s)</b>	Patrick Loehrer, Indiana University
<b>Co-Investigator(s)</b>	Asirwa Chite, Indiana University Job Kisuya, Evangeline Njiru Toby Maurer Mike Rosenblum Stefanie Sowinski
<b>Working Group(s)</b>	ORWG
<b>Description</b>	<p>Even before the HIV pandemic, equatorial Africa had among of the highest KS incidences in the world. In this area, 'endemic KS' (the term given to the HIV-unassociated form of KS) was manifested primarily as indolent localized disease in men and represented 4 to 10% of adult cancers. Although sub-Saharan Africa was already a hotbed for KS, the clinical manifestations and impact of the disease dramatically changed with the onset of the HIV epidemic in the 1980's when the incidence of KS and other HIV associated malignancies exploded. The advent of anti-retroviral therapy (ART) improved prognosis of HIV-associated KS, but survival remains unacceptably poor in low to middle income countries(LMIC). A recent Cochrane review on late stage KS showed that in 6 studies in which chemotherapy was added to HAART, no survival benefit was seen above that of ART therapy alone nor amongst the different types of chemotherapy. Endemic KS, while less likely to progress to visceral disease, leaves patients with profound functional disabilities often requiring treatment. Because this population is HIV negative, ART is not used. Research that leads to a better understanding of the biology of KS must be explored to provide alternative therapies to ART and standard chemotherapy. Based upon preliminary data from UCSF which supports the role of PD1 pathway and tissue micro-environment in KS, we propose to conduct a prospective analysis on two patient cohorts. Cohort 1: KS in HIV-infected subjects who have failed at least one KS-directed chemotherapeutic intervention; and Cohort 2: KS in HIV-negative patients (i.e. endemic KS) who have failed at least one KS-directed chemotherapeutic intervention.</p>

Site(s)	
Project Period	10/1/2015 - 9/30/2018
Funding Status	Funded
Direct Award (USD)	158406
Update	We conducted a pilot of the study, where samples were collected and processed as per the study protocol in the month of March. KS punch biopsies were shipped to IDI, Kampala from Eldoret for processing. However, there were challenges experienced with the processing of KS biopsies samples. The experimental runs at IDI were did not yield results due to suspected cell death. It is suspected that the problem was not caused transportation from Eldoret, but rather a step in the processing or run. It is also important to note that Sheila was able to complete this experiment while at UCSF therefore it is not an issue of her skills. Plans have been made to send an experienced PhD fellow from UCSF to IDI for two weeks in mid-July to work trouble shoot with Sheila to try and identify the problem.
Future Plans	Once samples processing challenges are sorted out, we will embark on study participants enrollment and samples collection.
Publication(s)	



Study Title	<b>Using Narrative Films to Combat HIV Stigma: Perspectives from HIV-Infected Adolescents and their Caregivers</b>
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University Josephine Aluoch, McCoy Brittany; McAteer Carole ; Aluoch Josephine
Working Group(s)	PRWG
Description	The objective of this pilot study is to assess the cultural acceptability, credibility, and quality of narrative films created to illuminate the experiences of HIV-infected adolescents coping with HIV-related stigma, as well as to identify ideal viewing audiences and potential settings in which to show these films. In addition, we will gather preliminary data on the films' efficacy at reducing HIV stigma. The long-term goal of this study is to better understand how the HADITHI films can be implemented within communities in western Kenya in a culturally-appropriate and sensitive manner. The specific aims are: Aim 1: To explore the perspectives of HIV-infected adolescents and their caregivers on the cultural acceptability, quality, credibility, potential audiences, and potential settings for showing the four HADITHI narrative films addressing adolescents' experiences with HIV stigma in Kenya. Aim 2: To describe the impact of the HADITHI films on the attitudes, beliefs, and knowledge about HIV and HIV-related stigma held by HIV-infected adolescents and their caregivers. Aim 3: To evaluate whether viewing the HADITHI films alter experienced, perceived, or internalized stigma reported by HIV-infected adolescents and their caregivers.

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

Study Title	<b>Validating an Integrated Community Based Strategy of Peer Support in Pregnancy and Infancy</b>
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	Astrid Christoffersen-Deb, University of Toronto Laura Ruhl Justus Elung'at
Working Group(s)	PHPC, RHWG
Description	This project seeks to address the inequities that drive maternal and infant mortality in sub-Saharan Africa by validating an intervention that builds community empowerment in MNCH and facilitates processes of accountability using CHV-led women's groups (Chamas). Chama cha MamaToto (chamas) is a peer-support model that groups together pregnant women in the same community. Central to our approach is the integration of health, social and financial literacy education with a savings/loans program. Chamas are designed to improve MNCH by generating positive peer support for women to advocate for themselves and account for the care they receive. We have combined best practices from women's health groups and microfinance programs to design an integrated service delivery platform that is low-cost, self-sustaining and self-managed. Its a randomized cluster trial to be implemented in 4 sub counties in Trans Nzoia county where a cluster is a community unit.
Site(s)	Cherangany Health CentreSaboti, Kiminini, Cherangani and Kwanza Sub counties
Project Period	10/1/2017 - 10/1/2018
Funding Status	Funded

Direct Award (USD)	\$197,509
Update	Over the last 6 months, The team managed to get an Irec approval to carry out the study. The team met the county leadership and all community stake holders in preparation for the study. Baseline data collection was done after hiring and training of the enumerators in the 74 facilities. CHVs who will be the implementors of the program have already been trained. With this progress however, we have experienced a lot of challenges that made the program not to start. The baseline and recruitment of mothers happened in the facility and with the strike being on and off, it took 2 months to do recruitment. At the moment, the nurses are still on strike which means we cant implement the project because we can measure an impact unless all the facilities are operational
Future Plans	We hope to start the project implementation hoping the nurses strike will end. we will do a refresher training for all the CHVs and enumerators. Recruitment will start a fresh for women below 24 weeks gestation.
Publication(s)	
Study Title	<b>Validation of Spirometry Prediction Equations in Western Kenya</b>
Principal Investigator(s)	Peter Kussin, Duke University
Co-Investigator(s)	David Lagat, Moi University , Paul, Devon
Working Group(s)	AMWG
Description	This is a cross-sectional study of healthy adult Kenyans living in and around Eldoret. The purpose of the study is to validate a set of spirometry prediction equations for the local population. Adults age 18 years and older who are HIV negative, with no history of chronic cardiac or pulmonary disease and with <5 pack year smoking history are eligible for participation. Specific Aim: Determine pulmonary function reference equations that can accurately predict normal spirometric values in a Kenyan population. 1A: Statistically compare phenotypically normal Kenyan spirometric profiles with values obtained from published pulmonary function reference equations to determine the most accurate equation set. 1B: If published reference equations do not accurately reflect normal Kenyan lung function profiles, develop new reference equations.
Site(s)	Moi Teaching and Referral Hospital
Project Period	1/1/2015 - 3/1/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	We are in the publication phase. I presented data from the project in poster format at the ATS annual conference. A manuscript from the project is under review for publication.



Future Plans	We hope to publish our manuscript.
Publication(s)	VALIDATION OF SPIROMETRY PREDICTION EQUATIONS FOR WESTERN KENYA Paul, DW; Lagat, DK; Egger, JR, Murdoch, DM, Que, LG, and Kussin, PS Annual Meeting of the American Thoracic Society
Study Title	<b>Vincristine Optimization in Kenyan Children with Cancer</b>
Principal Investigator(s)	Jodi Skiles, Indiana University - Purdue University in Indianapolis (IUPUI)
Co-Investigator(s)	Festus Njuguna, Moi University 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	<p>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,</p>

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

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)

<b>Study Title</b>	<b>Viral Suppression among HIV-infected Children and Caregivers in Western Kenya</b>
<b>Principal Investigator(s)</b>	John Humphrey, Indiana University
<b>Co-Investigator(s)</b>	Edith Apondi, Moi University Becky Genberg, Adrian Gardner, Joseph Hogan, Kara Wools-Kaloustian
<b>Working Group(s)</b>	PRWG
<b>Description</b>	The suppression of HIV viral load through administration of antiretroviral therapy is a key objective for all HIV-infected patients. However, optimal approaches to family-centered HIV management are not well known, particularly when children and their caregivers are both in need of HIV treatment. In order to better understand viral suppression among HIV-infected children who also have HIV-infected parents or caregivers, we will conduct a retrospective review of all HIV-infected child-caregiver dyads receiving HIV care at the AMPATH program in western Kenya from January 2015 to December 2016. We will achieve the following specific aims: (1) Characterize viral suppression in HIV-infected children and in their HIV-infected caregivers; (2) Estimate the association between viral non-suppression in children and their HIV-infected caregivers; (3) Identify factors associated with viral non-suppression among HIV-infected child-caregiver dyads. The knowledge gained from this study will inform our understanding of the management of HIV in HIV-affected families. This may lead to better strategies to improve the delivery and monitoring of antiretroviral therapy in these families in the future.
<b>Site(s)</b>	
<b>Project Period</b>	1/1/2017 - 12/31/2017
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$12,500
<b>Update</b>	We obtained IRB approval obtained the preliminary dataset. We are currently in the analysis stage of the project in collaboration with ADAT.
<b>Future Plans</b>	We hope to finish the analysis by September 2017, submit the results as an abstract for CROI 2018, and complete a draft of the manuscript by November 2017.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>Virolgic Treatment Failure and Drug Resistance in HIV-Infected Kenyan Children (RESPECT) study.</b>
<b>Principal Investigator(s)</b>	Rachel Vreeman, Indiana University
<b>Co-Investigator(s)</b>	Winstone Nyandiko, Moi University

	Josephine Aluoch, Rami Kantor, MD Department of Medicine Brown University School of Medicine rkantor@brown.edu Samuel Ayaya, MBChB, MMED Department of Child Health and Paediatrics, Moi University School of Medicine ayaya.samuelaluanga@gmail.co Joe Hogan, Ph
<b>Working Group(s)</b>	PRWG
<b>Description</b>	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.
<b>Site(s)</b>	Matayos Health Centre, Mois Bridge Health Centre, Uasin Gishu District Hospital, Ziwa Sub-District Hospital
<b>Project Period</b>	8/2/2016 - 7/31/2020
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	\$613,511
<b>Update</b>	The objective of the 'HIV Failure and Resistance in Kenyan Children' study (known as the RESPECT study) is to determine the prevalence of viral failure and ART resistance among a highly characterized and established cohort of 685 HIV-infected children on ART through AMPATH, and to investigate their association with detailed adherence data, drug levels, and other demographic and clinical factors over time. The specific aims are: 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. Aim 2: Investigate associations between specific adherence patterns, ART drug levels and other demographic and clinical factors, with viral failure and drug resistance. Aim 3: Study long-term immunologic, virologic and drug resistance outcomes and their associations in prospectively re-enrolled study participants. 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). 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. Over the last six months archived samples for the cohort of children (who were previously enrolled in a study to validate an adherence measurement tool) have been shipped to the Dr. Rami Kantor's laboratory at Brown University for viral load and resistance testing. Recruitment for re-enrollment of this cohort began on 24th April 2017, and a total of 267 participants have been enrolled for the additional prospective assessments including blood draws for viral load levels, CD4 counts and resistance testing. Three-month follow-up with MEMS adherence monitoring is now ongoing for a subset of about 28% of the enrolled participants, with 13 participants having completed this additional monitoring.

#### Future Plans

We plan to continue with participant enrollment and follow-up to evaluate the participants' immunologic, virologic and drug resistance outcomes. In the next 6 months, we plan to complete data entry and cross-checking in the REDCap database, as well as to determine current viral load and CD4 count levels and send blood samples for all participants to Brown University for phenotyping and resistance testing. We also plan to submit an abstract to the 17th International Workshop on HIV Drug Resistance and Treatment Strategies that highlights the initial viral resistance results from the original cohort.

#### Publication(s)

An abstract entitled, 'HIV-1 Treatment Failure and Extensive Drug Resistance in Perinatally-Infected Children Failing 1st-Line Antiretroviral Therapy in Western Kenya' was submitted to the 17th International Workshop on HIV Drug Resistance and Treatment Strategies in Johannesburg, South Africa.

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The following bibliography includes AMPATH research publications that were published between January 1, and June 30, 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](http://www.medicine.iu.edu/ampathresearch/member-access).

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## **Appendix A: East Africa IeDEA Annual Report**

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# **East Africa International Epidemiologic Database to Evaluate AIDS (IeDEA) Year 11 Science Report**

**Grant Year: August 1, 2016 - July 31, 2017**

Kara Wools-Kaloustian M.D. M.S.  
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**A. Specific Aims:**

No change in specific aims from the cycle three original application

**B. Studies and Results**

**B1. Infrastructure:**

Structure of the consortium

The consortium consists of nine active HIV-treatment programs (Kenya-2, Tanzania-3, Uganda-4), the Tanzanian National AIDS Control Program (NACP), five U.S. universities and the University of Toronto. In year 12 of the grant the sub-contract currently held by Ohio State University will be transitioned to the University of California, Riverside as Jennifer Syvertsen, a key investigator in the Syndemics Project, will be transitioning her employment. The composition of the consortium is outlined in Table 1. The EA leDEA Executive Committee is composed of the Regional PIs at Indiana University (Yiannoutsos, Wools- Kaloustian), the senior Regional Data Manager (Musick), and the site PI from each site. The EA leDEA EC meets on a bi-monthly basis. The EA leDEA EC is responsible for approving all concept sheets for new projects, meeting abstracts, and manuscripts.

**Table 1: Composition of Consortium and Data Infrastructure**

Country	Site	EMR Platform	Date Data Transfer to RDC
Canada	University of Toronto	N/A	N/A
Kenya	Academic Model Providing Access to Health Care (AMPATH), Eldoret	OpenMRS (AMPATH Medical Records System)	15 Feb 2017
	Family AIDS Care and Education Services (FACES),	OpenMRS	20 Feb 2017
Tanzania	National AIDS Control Program	N/A	N/A
	Tumbi Regional Hospital	OpenMRS	expected May 2017
	Morogoro Regional Hospital	OpenMRS	20 Feb 2017
	Kisesa Health Center	Microsoft Access	02 Mar 2017
Uganda	Infectious Diseases Institute, Kampala	Custom system	23 Jan 2017
	Mbarara University ISS Clinic	OpenMRS	23 Feb 2017
	Masaka Regional Hospital	OpenMRS	14 Feb 2017
	Rakai Health Sciences Program, Rakai	OpenMRS Express	14 Feb 2017
U.S.	Indiana University	N/A	N/A
	Brown University	N/A	N/A
	Columbia University	N/A	N/A
	University of California, Riverside (currently: Ohio)	N/A	N/A
	University of California, San Francisco	N/A	N/A

Each of the four specific aims is managed by a project (Specific Aim) working group, which meet on a monthly basis in order to develop new projects and monitor existing projects falling within their purview. The leaders of the project working groups join the EA leDEA EC every fourth month in order to report on project progress. During Year 11 an EA-leDEA PI meeting was held in Eldoret Kenya from Oct 24<sup>th</sup>- 26<sup>th</sup>. This meeting provided an opportunity for EA-leDEA

Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara  
 affiliated investigators to discuss challenges with data collection and management, review updated standard operating procedures and work on operationalizing the projects outlined within the EA-leDEA grant renewal.

**Data Infrastructure and Management:**

All clinical sites contributing data to the consortium have stable electronic medical records systems (EMRS), which have not had significant issues over the last year. The EMR platform being used by each site as well as the data of last data transfer to the Regional Data Center (RDC) is outlined in Table 1. The current composition of the East African leDEA Regional Database is outlined in Table 2. The EA RDC has generated analysis data sets for 10 concept proposals and has updated existing analysis data sets for 6 other proposals since May 2016. The EA leDEA Concept Tracker can be found on the EA-leDEA website [www.iedea-ea.org](http://www.iedea-ea.org) (Password available upon request).

**Table 2: Patient Enrollment as of March 2017**

Country	Program /Site	Adults Enrolled		Adults Receiving ART		Children Enrolled		Children HIV Infected		Children Receiving ART	
		No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Kenya	AMPATH	162,616	51.1	116,959	71.9	49,227	76.0	18,983	38.6	14,084	74.2
	FACES	33,494	10.5	26,046	77.8	9,526	14.7	3,379	35.5	2,825	83.6
Uganda	Masaka	25,966	8.2	20,006	77.0	2,601	4.0	2,523	97.0	1,938	76.8
	Mbarara	27,818	8.7	16,766	60.3	77	0.1	77	100.0	31	40.3
	IDI	31,030	9.7	17,324	55.8	11	0.01	11	100.0	1	9.1
	Rakai	14,647	4.6	10,815	73.8	1,022	1.6	969	94.8	788	81.3
Tanzania	Morogoro	10,401	3.3	7,199	69.2	1,189	1.8	1,062	89.3	832	78.3
	Tumbi	9,115	2.9	4,802	52.7	913	1.4	889	97.4	520	58.5
	Kisesa	3,385	1.1	2,509	74.1	195	0.3	192	98.5	156	81.3
TOTAL		318,472	83.0	222,426	69.8	64,761	17.0	28,085	43.4	21,175	75.4

**Regulatory:**

The dates of original approvals and continuing reviews are outlined in Table 3. Projects with prospective data collection are submitted for regulatory approval separately from the core approvals and are not outlined in Table 3 due to space constraints.

**Table 3: Status of Regulatory Approvals 04.24.17**

Country	Site	Formal Name of IRB/IREC	Original Approval	Latest CR	Expiration
Kenya	AMPATH	Moi University College of Health Sciences & Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC)	20 Jun 2006	28 Oct 2015	27 Oct 2017 Consortium 31 Jan 2018 Database
	FACES	Kenya Medical Research Institute/National Ethics Review Committee (ERC)	11 Nov 2008	18 Nov 2015	8 Feb 2018
Tanzania	Morogoro Regional Hospital	The United Republic of Tanzania National Institute for Medical Research Coordinating Committee	25 May 2007	15 April 2016	24 May 2017
	Tumbi Regional Hospital		25 May 2007		
	Kisesa		11 Sept 2012		
Uganda	Mbarara University ISS Clinic	Mbarara University of Science & Technology Institutional Review Committee (MUST- IRC)	Local IRB: 20 Jun 2006 UNCST: 20 Jul 2006	10 Jun 2016 27 Jun 2016	10 Jun 2017 2 Jul 2019
	Masaka Regional Hospital		Local IRB: 20 Jun 2006 UNCST: 20 Jul 2006	10 Jun 2016 27 Jun 2016	10 Jun 2017 2 July 2019
	IDI	Makerere University School of Medicine Research & Ethics Committee (MUSOMREC)	Local IREC: 3 Sep 2008 UNCST: 3 Feb 2009	25 Aug 2016 02 Jul 2013	2 Sept 2017 2 July 2019
	Rakai	Uganda Virus Research Institute Science & Ethics Committee (UVRI-SEC)	Local IREC: 9 Nov 2010 UNCST: 8 Apr 2011	03 Nov 2015 02 Jul 2013	9 Nov 2017 16 Jul 2016
CANADA	University of Toronto EA IeDEA Consortium	HIV Research Ethics Board	2 June 2015 Protocol #31597	30 May 2016	1 June 2017
US	Indiana University Consortium (10/13/17) & Database (10/16/17)	Indiana University Institutional Review Board	24 May 2006	14 Oct 2016 17 Oct 2016	13 Oct 2017 16 Oct 2017
	University of California at San Francisco (UCSF)	University of California at San Francisco Committee on Human Research	20 June 2006	09 Mar 2016	3 April 2018
	Columbia University	Columbia University Medical Center Institutional Review Board	8 July 2006	Exempt	NA
	Ohio State University	NA	Project not started		
	Brown University/Miriam Hospital	NA	Project not started		

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 leDEA-EA continues to serve as a platform for training and mentoring of PhDs, post-Doctoral Fellows, and junior faculty both in the U.S. and internationally. Details of individuals mentored during Year 11 of this grant are outlined in Table 4.

**Table 4: leDEA-EA Mentees and Trainees**

Trainee/Mentee	Affiliation	Position	Mentor	Project	Mentorship Focus
Apondi, Edith	AMPATH	Associate Lecturer	Vreeman	Project 1.2: The Adolescent care cascade	Leadership Project design & implementation
Byakwaga, Helen	IDI	Lecturer	Martin	Project 3.1 Knowledge, attitudes and behaviors: Providers and their impact on patient outcomes	Leadership Project design & implementation
Enane, Leslie	IUSM	Assistant Professor	Vreeman Wools-Kaloustian	Project 1.2: The Adolescent care cascade	Project design & implementation
Goodrich, Suzanne	IUSM AMPATH	Research Assistant Professor	Wools-Kaloustian	Project 2.1: Prevalence and impact of alcohol use in patients enrolling in HIV care	Leadership
Humphrey, John	IUSM AMPATH	Research Assistant Professor	Wools-Kaloustian	Aspirational Project SA1: Integration of data from decentralized PMTC services into the AMRS	Project design & implementation
Ioannis, Pat	University of Athens	MSc Student	Yiannoutsos	SA 2: Previous Grant Cycle Project: Alcohol Use Assessment Sentinel Cohort (AUAC)	Analytic Methods
Kiragga, Agnes	IDI	Postdoctoral	Yiannoutsos Wools-Kaloustian	Supplement: Tracing non-Retained HIV Positive Pregnant Women and Their Babies (STEPWISE)	Analytic Methods Project design & implementation
Miles, Caleb	UC Berkeley	Postdoctoral Fellow	Petersen	SA 1 Previous Grant Cycle Project: Low Risk Express Care	Analytic Methods
Park, Jun	IU	PhD Student	Yiannoutsos	Methods Innovation: Inference on the cumulative incidence in studies with double- sampling designs	Analytic Methods
Semeere, Aggrey	IDI MUST	Physician / Research Fellow	Martin	Project 4.1: KS presentation, Incidence and survival in the ART era	Leadership
Tran, Linh	UC Berkeley	Quantitative analyst Google	Petersen	SA1 Previous Grant Cycle Project: Low Risk Express Care	Analytic Methods

*Innovations in Data Harmonization Methods:*

Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara

Under the leadership of Ms. Beverly Musick with funding through BD2K, in 2016, the leDEA Data Exchange Standard (leDEA-DES) was extended and aligned with other global research standards, including the European HIV Cohorts Data Exchange Protocol (HICDEP). This expansion involved leDEA data managers, informaticians, clinicians, and statisticians along with representatives from HICDEP, the Collaborative Initiative for Paediatric HIV Education and Research (CIPHER), RePORT-TB, and the Centre of Excellence for Health, Immunity, and Infections (CHIP). To develop a globally applicable data standard for HIV cohorts, the team aligned HICDEP variables suited for high-income clinical care settings with existing leDEA variables designed for resource-limited settings, wherever possible.

The original leDEA-DES contained nine data tables, five of which were expanded by 23 variables to include more detailed information on ART, AIDS diagnosis, orphan status, AIDS-defining events and visit-related information. Fifteen new data tables were added: 7 (56 variables) are related to maternal, infant and child health, 6 (44 variables) relate to laboratory testing and results, one (12 variables) containing medication information and one (6 variables) relating to cancer. Documentation of the expanded leDEA-DES can be found at <http://bit.ly/2erkEHR>, and is freely available for public use. EA-leDEA is also contributing to expansion of the data standard and to innovations in data harmonization by contributing to projects led by CCASANET (HARMONIST) and Southern Africa (GRADUATE).

Expansion of the leDEA-DES and harmonization with other global data standards enhance its usability and impact in facilitating multi-regional collaboration within and beyond leDEA. Although there remain data domains beyond the scope of the revised leDEA-DES, it is an accessible standard that continues to be adapted based on feedback from global collaborators and shaped by the evolving HIV epidemic and new research interests. This standardization effort and the increased awareness of the benefits of global data harmonization will significantly improve collaborations seeking to understand the impact of the global response to the HIV epidemic.

#### Analytic Innovation:

The EA-leDEA analytic team spearheaded by Dr. Bakoyannis, has been working on solving important problems related to competing risks data analysis that arise in the vast majority of research projects within EA-leDEA Consortium. The most important competing risk outcomes in EA-leDEA studies are disengagement from HIV care and death while in care. One major problem in sub-Saharan Africa is the severe death under-reporting which results in seriously biased cumulative incidence and risk factor effect estimates of death and disengagement from HIV care. Dr. Bakoyannis has developed both nonparametric and semiparametric pseudolikelihood approaches to deal with this problem when outreach data from a small sample of lost patients are available (double-sampling design). Such double-sampling data are available in AMPATH and IDI within EA-leDEA. Dr. Bakoyannis work on nonparametric inference for the cumulative incidence in studies with double sampling designs has been submitted for publication in *Statistica Sinica* and won a 2017 travel award from the American Statistical Association - Section on Statistics in Epidemiology. This work will also be presented in the 50th Conference of the Society for Epidemiologic Research in June 2017. His second work on semiparametric analysis of competing risks data for studies with double-sampling designs has been submitted for publication in *Biometrics* and has received a 2016 ENAR poster awarded from the International Biometric Society - Eastern North American Region during the 2016 ENAR Spring Meeting. Dr. Bakoyannis has also presented this work as an invited speaker in the 2016 International Chinese Statistical Association Meeting in China and in the meeting of the Reference Group on Estimates Modeling and Projections of the United Nations Programme for HIV/AIDS. Dr. Bakoyannis is currently working on the issue of adjusting for outcome misclassification in studies without double-sampling designs (as it is the case in most leDEA sites and studies informing the UNAIDS estimates) in semiparametric competing risks models. These works of Dr. Bakoyannis serve the purpose of the EA-leDEA and the UNAIDS for valid predictions and risk factor estimates of death while in HIV care and disengagement from care under death under-reporting.

In addition, Dr. Bakoyannis has developed methodology for semiparametric regression of the cumulative incidence function with interval-censored competing risks data. This method is being designed to deal with the fact that disengagement from care is defined by some programs as no clinic visits for at least three months and therefore the actual time at which the patient disengaged from care is not precisely known but is known to lie within a 3-month period.

**Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara**

Ignoring this issue and assuming that disengagement from care happened at 1.5 months after the last clinic visit (midpoint imputation) can lead to biased estimates due to measurement error in event time. Dr. Bakoyannis methodology effectively addresses this problem via a B-spline-based sieve maximum likelihood approach. This paper has been submitted in *Statistics in Medicine* and will be presented as an invited talk at the Eastern Mediterranean Region of the International Biometric Society conference in Greece in May 2017.

In collaboration with the team at the University of California, Berkley (Caleb Miles, Linh Tran, Mark van der Laan, and Maya Petersen) leDEA EA has been exploring how to account for stratified interference in evaluating the impact of programmatic interventions such as Low Risk Express Care. Initial analysis of the Low Risk Express Care data suggested that immediate availability of and enrollment into the task-shifting program causes a small, yet significant improvement in patients' risk of death or drop out over immediate availability and no enrollment, and that similarly, no immediate availability causes a small, yet significant improvement over immediate availability and no enrollment.



Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara

One concern in this analysis is that patients’ outcomes may be affected by other patients’ treatment assignment (shifting some care tasks from clinical officers to nurses). Specifically, it is possible that on top of the individual shift decisions themselves, the proportion of patients shifted will have an effect on patients’ outcomes. Such a phenomenon, known as *stratified interference*, renders patients’ outcomes dependent, and presents challenges not addressed by classical causal inference methods. The UC Berkley team is addressing this issue by accounting for this form of interference in a simplified point-treatment setting. Development and results of this approach was submitted by Caleb Miles to the Atlantic Causal Inference Conference.

**Table 5: Data Harmonization and Analytic Innovations**

EA Concept Number	Concept Title	Concept Leader	Status	Product (Year 11)
Supplement 104	BD2K Accounting for Stratified Interference in Evaluating the Impact of a HIV Low-risk Express Care Task shifting Program	Yiannoutsos Petersen	Completed Analysis Underway	Oral Abstract <sup>(1)</sup> Submitted Abstract
83	Statistical designs and methods for double-sampling for HIV/AIDS Studies	Yiannoutsos Bakoyannis	Work ongoing	3 Papers under review (3-5) Oral <sup>(6)</sup>
82A	Adjusting for incomplete failure ascertainment in joint models: A multiple	Yiannoutsos		Oral <sup>(7)</sup>

Contributions to Global leDEA:

leDEA-EA continues to contribute to the global administration of leDEA. In Year 11, EA-leDEA was responsible for organizing the Global leDEA PI meeting held in conjunction with CROI in Seattle, WA. A series of breakfast and lunch work group meetings for Mental Health, Cancer, Strategic Data, Clinical Outcome, Renal, Data Harmonization, Pediatrics, TB, Executive Committee, and Site Assessment were conducted between February 13<sup>th</sup> -17<sup>th</sup>, 2017. EA-leDEA responsibilities included working with the CROI affiliated activities committee to select a hotel, negotiating contracts for the meeting venue, food service, audio/visual and other meeting needs. The on-site staff from EA-leDEA who coordinated these meetings included the Program Manager, a Data Manager, the Senior Data Manager as well as the Global leDEA Operations Coordinator from NA ACCORD. Dr

leDEA-EA continues to provide leadership for the global leDEA Working Groups with four of the current working groups being chaired by members of the EA-leDEA Consortium: Ms. Beverly Musick, Data Harmonization; Dr. Jeff Martin, Cancer; Dr. Rachel Vreeman, Pediatrics; and Dr. Constantin Yiannoutsos, Strategic Data. Dr. Wools-Kaloustian has provided back-up for the global leDEA EC Chair Dr. Annette Sohn for conference calls and meetings and for Dr. Rachel Vreeman at Pediatric Working Group Activities at CROI 2017.

EA-leDEA contributes both data and leadership to the Multiregional leDEA Analyses as outlined in Table 6.

**Table 6: Multi-regional Projects**

EA Concept Number	Global Concept Number	Concept Title	Concept Leader	Status	Product (Year 11)
40	MR019	Clinic and Patient-level determinants of durability of first-line regimen and time from first-line failure to second-line ART initiation in children in the International IeDEA Cohort	Wools-Kaloustian	Draft manuscript circulated to co- authors	NA
50	MR006	Pediatric cancer burden and treatment resources within the Pediatric IeDEA Consortium	Wools-Kaloustian	Completed	Paper (8)
51	MR017	Antiretroviral therapy initiation, durability and outcomes according to region and gender	Giles Law Braitstein	Analysis completed	Manuscript Submitted (9)
58	MR043	Adherence to antiretroviral therapy (ART) for HIV-infected children and adolescents followed in Global IeDEA sites	Vreeman	Analysis in process	NA
59	MR014	Duration of first-line antiretroviral regimens in children: a global perspective	Wools-Kaloustian	Drafting Manuscript	Poster(10)
61	MR013	Global epidemiology of adolescents with perinatal HIV-infection	Leroy (Wools-Kaloustian)	Manuscript circulating to co-authors	Poster(11) Oral(12)
63	MR064	Trends and disparities in the overall and cause-specific mortality between HIV-positive women from Europe, North America and sub-Saharan Africa	del Amo (Yiannoutsos)	Data Analysis Nearly Complete	NA
66	MR045	Developing global surveillance estimates for perinatally infected adolescents on antiretroviral therapy transitioning to adulthood SPECTRUM	Sohn	Data submitted; Model updated	Letter to Editor (13)
67	MR048	SiZER maps to investigate significant features of weight changes in HIV-infected patients	Yiannoutsos	Drafting Manuscript	NA
68	MR047	Changes in the comprehensiveness of care provided at HIV care and treatment programs in the IeDEA collaboration from 2009 to 2014	Fritz	Completed	Paper (14)
70	MR053* MR090 MR091	Age-, CD4-, and viral load-stratified rates of opportunistic infections and mortality in youth ages 0-24: Descriptive analyses and derivation of inputs for simulation models	Desmonde (Wools-Kaloustian) (Yiannoutsos)		2 Posters (15, 16)
71	MR066	Diagnosis and Treatment of TB HIV co- infected children	Pettit Sterling	Completed	Paper (17)
73	MR031	Liver disease in HIV treatment	Wandeler	Completed	Paper (18)

Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara

EA Concept Number	Global Concept Number	Concept Title	Concept Leader	Status	Product (Year 11)
		programmes within the leDEA network: A survey on diagnostic, preventive and treatment practices	Egger		
74	MR049	Empirical evaluation of propensity score matching utilizing leDEA observational cohort data evaluating 48-week treatment outcomes among ART-treated adults	Rutherford	Analysis in progress	Poster (19) Submitted Abstract(20)
76	MR080 MR059	leDEA-WHO Collaboration: Global analysis of delays from ART eligibility to antiretroviral treatment initiation among adults	Nash, (Yiannoutsos)	Analysis Completed	WHO Report(21)
78	MR068	Evaluation of Xpert MTB/RIF implementation among HIV programs in the leDEA Consortium	Clouse	Complete	Paper (22)
79	MR016	Collection of key Tuberculosis (TB) variables in ART Programs within the leDEA consortium: diagnostics, treatment and risk factors for the incident TB	Pettit	Drafting Manuscript	NA
80	MR011	Increases in Regimen Durability Associated with the Introduction of Tenofovir in Adults on standard first-line ART in the International leDEA Cohort	Brennan	Completed	Paper (23)
82	MR070	Update of mortality estimates of HIV-infected patients for Spectrum	Egger Johnson Yiannoutsos	Completed	2 Papers (24) (25)
84	MR056	Survival among HIV-infected individuals with KS in sub-Saharan Africa in the Era of Potent ART	Martin Bohlius	Manuscripts in prep: <input checked="" type="checkbox"/> Corrected survival <input checked="" type="checkbox"/> Excess mortality <input checked="" type="checkbox"/> Pace of ART initiation	Manuscript Submitted (26) Poster (27)
85	MR042	Models of support for disclosure of HIV status to infected children and adolescents in resource-limited settings	Arrivé Ayaya Vreeman	Drafting Manuscript	NA
87	MR065	Evaluating Global HIV Prevention, Care and Treatment Services available for Children in leDEA regions (Pediatric site assessment 2.0)	Vreeman	Analysis Underway	NA
88	MR071	Association between clinic-level factors and individual retention, engagement, and loss to follow up following ART initiation in the IEDEA	Rebeiro Duda	Data merging and cleaning in process	NA

Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara

EA Concept Number	Global Concept Number	Concept Title	Concept Leader	Status	Product (Year 11)
		collaboration from 2009-2014.			
91	MR078 MR058 MR098	leDEA-WHO Collaboration: Global analysis of retention in care in initial HIV care and treatment program	Egger	Analysis Complete Drafting Manuscript	Report (28)
92 105	MR074	Adolescent outcomes in the leDEA global consortium (leDEA-WHO collaboration 2016)	Sohn	Analysis Complete Drafting manuscript	Report (29)
93 106	MR063 MR079	leDEA-WHO collaboration: global analysis of the pre-ART cascade and delay from diagnosis to start of antiretroviral therapy in HIV-infected children aged 0-19 years.	Leroy Dabis	Analysis Complete Drafting manuscript	Report (30)
97	MR075 Adults only	Diagnosis, treatment and outcomes of extra- pulmonary Tuberculosis in HIV-co-infected adults and children	Zurche r Ballif	Manuscript circulating to co-authors	Poster (31)
97	MR066 Children only	Diagnosis, treatment and outcomes of extra- pulmonary Tuberculosis in HIV-co-infected adults and children	Ballif Lindgren	Complete	Paper (17)
98	MR076	Description and outcomes of HIV-infected patients treated for tuberculosis without microbiological confirmation in HIV care programs within the leDEA Consortium	Goodrich	Analysis in progress	NA
99	MR082	Growth of HIV-infected adolescents (10-19 years) in Africa and Asia	Leroy Jesson	EA Data to be submitted	Abstract (32) (no EA data)
101	MR081	Use of cotrimoxazole prophylaxis in children starting antiretroviral therapy	Boettiger	Analysis in progress	NA
103	MR085 MR046*	2016 Update of concept "Immunodeficiency at the start of ART "a global view" (adults) COHERE collaboration	Egger	manuscript circulating to coauthors	Oral (33)
107	MR069	Site Capacity to screen, prevent, diagnose and Manage NCDs in low- to Middle-Income Countries	Mugglin Wester Egger	Data collection nearly complete	Poster (34)
108	MR096	Screening and treatment of mental disorders in HIV clinic settings in low- and middle- income countries within the global leDEA network	Parcesepe	Data collection nearly complete	Poster discussion (35)
109	MR097	Cohort profile update: The International Epidemiologic Databases to Evaluate AIDS (leEA)	Egger Fenner	New concept	NA

Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara

EA Concept Number	Global Concept Number	Concept Title	Concept Leader	Status	Product (Year 11)
		in sub-Saharan Africa			
Supplement	<b>Not on MR list</b>	ICAMP: Prospective validation of an adherence monitoring tool among HIV- infected children and adolescents at leDEA sites	Vreeman	Data collection complete; Analysis underway	N/A
Supplement	<b>MR015</b>	Impact of HIV infection on the population genomics of drug-resistant Mycobacterium tuberculosis: insights from macro-evolutionary analyses	Egger Fenner (Carter)	Analysis Underway	Abstracts Submitted <sup>(36, 37)</sup>

EA-leDEA will also be contributing to the four recently approved WHO analyses which have not yet been assigned a EA-leDEA reference number and include: Retention in Adults and Children (Egger, Zaniewski, Haas); Delay to ART Start –Adults (Nash, Tymejczyk, Brazier); Delay in ART start – Children/Adolescents (Leroy, Desmonde, Malateste); and Viral Load in Adults and Children (Law, Kariminia, Jiamsakul).

## B2. Scientific Productivity:

Please note that all East African Concept Sheets may be accessed through the Project Tracking Document at <https://www.iedea-ea.org> (Password will be provided on request)

**SA-1: We will describe movement through the cascade and outcomes of HIV care with emphasis on the impact of life stage transitions.**

### Project 1.1. Estimating the HIV Care Cascade

**Project Specific AIM (PSA) 1:** *Estimate the HIV care cascade, inclusive of pre-ART outcomes*

**Project Description:** This study will use the leDEA-EA *Clinic Cohort* restricted to ART-naïve patients  $\geq 15$  years enrolled in HIV care during 2016 only, to ensure homogeneity of program structure and adequate follow-up time. A multi-state model will be used to estimate retention in 5 steps of the HIV care cascade: (1) enrollment; (2) rates of ART eligibility within 3 months of enrollment; (3) ART start rates in eligible patients within 3 months of eligibility; (5) retention in the cascade after ART initiation or enrollment (for ART-ineligible patients). Retention rates at each step will be adjusted for attrition by tracing data at AMPATH and IDI.

**Progress:** This concept sheet is in the final stages of development and will be circulated to the EA-leDEA EC for approval within the next month. It is anticipated that construction of the analysis dataset will begin during the summer of 2017 and analysis will begin in the fall of 2017.

### Project 1.2: The Adolescent care cascade

**PSA1:** *(Descriptive) Identifying the models of care used for managing perinatally-infected adolescents*

**Project Description:** This project will develop and implement a facility-level survey of care programs for adolescents that will assess transition-related procedures, protocols and availability of adolescent-friendly services. Postulated models include transition from pediatric to adult clinics co-located in the same health facility or in another facility or a system where adolescents remain in the same HIV clinic, assume increasing responsibility for their care and are evaluated with

Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara  
adult-focused measures.

Progress: A pilot survey was developed by Professor Ayaya and data collection has begun. It is anticipated that the pilot data collection will be complete in the spring of 2017 and that analysis will be completed during the summer of 2017. The concept for subsequent broader survey will be finalized and circulated to the EA- leDEA EC in May 2017. The protocol for a broader survey and the broader survey instrument (based on the pilot data) will be finalized in August 2017 and submitted to the appropriate regulatory bodies. We anticipate that the broader survey will be put into the field by fall of 2017.

**PSA2: *Estimating the Adolescent Care Cascade***

Project Description: Our objective in PSA 2 is to estimate the HIV care cascade for perinatally HIV-infected adolescents. Using leDEA's Clinic Cohort Data, we will estimate the HIV care cascade—from diagnosis to enrollment in care to CD4 testing to retention in care to ART initiation to viral suppression to transitions from one form of service provision to another. The cascade will be estimated separately for the two most common models of care identified in PSA 1, to highlight gaps in care for each approach to managing perinatally-infected adolescents. We hypothesize that key outcomes like loss to program are associated with healthcare environment and patient-level factors.

Progress: The concept sheet will be finalized in May 2017. As this concept is dependent on site level variables that will be collected in PSA1 the plan is to develop the analysis code with the patient level master datasets finalized in Spring 2017; Implement the site survey in Fall 2017 (see above); Clean survey data in early 2018; Rerun the codes, developed on the 2017 master datasets, on the 2018 master datasets and incorporate the survey data in Spring 2018.

**PSA 3: *Refine estimates of key adolescent outcomes utilizing a sampling-based approach.***

Project Description: PSA 3 will utilize a sampling-based approach to create an *Adolescent Sentinel Cohort*, from the *Clinic Cohort Database* for AMPATH and FACES, which will include perinatally infected adolescents (200 patients, anticipating tracing 180 of whom 150 will be alive and matched controls (300 patients) retained in care with characteristics (gender; current age; CD4 and age at enrollment, etc.) similar to traced patients to assess the impact of loss to program on death, viral suppression and resistance. Tracing procedures and the leDEA-EA Lost to follow-up (LTFU) tracking form utilized in previous studies will be used for data capture.

Blood will be collected from traced subjects and control patients using finger stick and dried blood spot (DBS)/Hemaspot collection methods previously used by our team. Viral loads will be run at the AMPATH research lab and duplicate samples with detectable viral load will be shipped to Dr. Kantor's lab at Brown University for resistance testing.

Progress: The concept sheet will be finalized in May 2017. We anticipate that the protocol for this project will be completed in June/July 2017 and submitted to the appropriate regulatory bodies in July/August 2017. We anticipate that prospective data collection for this project will begin in the spring of 2018.

**Project 1.3: Pregnancy in the era of B+**

**PSA 1: *Temporal trends in incident pregnancy in leDEA-EA***

**PSA 2: *Patient and healthcare environment factors associated with incident pregnancy***

Project Description: In the previous grant cycle, we examined the effect of ART on incident pregnancy among HIV-positive women at HIV clinics in Kenya and Uganda. During this cycle we will rerun a similar analysis to determine if universal test and treat has impacted fertility trends.

Progress: This project has not yet been initiated.

Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara  
**Supplements SA 1:**

Funded Supplements SA1:

Supplement 1.1: Tracing non-retained HIV Positive Pregnant Women enrolled in Option B+ and ascertaining their Babies outcomes (STEPWISE)

Project Description: The overall goal of this proposal is to conduct a pilot study that will utilize a sampling based approach to assess the outcomes of mothers who have been enrolled in option B+ and to use these data to improve estimates of mother to child HIV transmission. This project will trace women, who initiated ART under option B+ and subsequently disengaged from care as well as enrolling a cohort of retained women. It will assess reasons for disengagement, as well as obtain corrected estimates of retention by evaluating the proportion of mothers who have re-engaged or died. It will also assess and compare HIV transmission rates among infants born to retained and disengaged mothers.

Progress: A site visit was conducted by Dr. Wools-Kaloustian and Dr. Yiannoutsos in March 2018. Final site selection was undertaken at that time. The protocol and the data collection instruments have been finalized. The protocol was submitted to and received approval from the Makerere University IRB, the Indiana University IRB and the Uganda National Council for Science and Technology. The Standard Operating Procedures (SOPs) have been finalized and the study database is being designed and tested. Hiring for this study is in process and study training will be conducted in May. It is anticipated that prospective data collection will begin in early June.

Submitted Supplements SA1: EA-leDEA has six supplements under review for this specific aim.

**Table 7: Submitted Supplements SA 1**

PI	Title	Aims
PI: Elul	Enhancing the leDEA East Africa Adolescent Sentinel Cohort for Longitudinal Assessments of Factors Critical to Adolescent Health	<p><b>SA1:</b> To determine the prevalence of understudied adolescent health care preferences, health behaviors, risk factors, and outcomes among PIA LTP and engaged in care</p> <p><b>SA2:</b> To characterize the health behaviors, risk factors, and outcomes of PIA in the Adolescent Sentinel Cohort longitudinally over time</p> <p><b>SA3:</b> To assess the feasibility of using verbal autopsy to determine causes of death among PIA found to have died</p>
PI: Syvertsen	Characterizing the effects of alcohol and other drug use on engagement in the HIV care cascade among patients in leDEA-affiliated clinics in East Africa: A Social Network Approach	<p><b>SA1:</b> To examine how social network factors (e.g., network size, structure, composition) are associated with patterns of AOD, sexual behaviors, engagement in care, and HIV clinical outcomes among a sample of EA leDEA- affiliated clinic patients who screen positive for alcohol and/or drug use and a comparison group.</p> <p><b>SA2:</b> To qualitatively describe the nature and overlap of key relationships (e.g., risky and supportive) within patients' networks and assess their associations with HIV outcomes.</p> <p><b>SA3:</b> To use mixed methods to explore the feasibility, acceptability, and potential format of a social network intervention to reduce AOD, improve HIV clinical outcomes, and increase linkages to HIV testing and care among networks of HIV+ people who use alcohol and/or</p>

**Table 7 Continued: Submitted Supplements**

PI	Title	Aims
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Program Director/Principal Investigator (Last, First, Middle): Wools-Kaloustian, Kara

<b>PI:</b> Braitstein	Getting engaged: Rates, predictors and outcomes of HIV- positive children and adolescents identified or diagnosed through home-based HIV testing failing to link to HIV care in rural western Kenya	<b>SA1:</b> Determine the proportion of children and adolescents (age <18 years at HBCT) with known HIV infection (through HBCT) who have linked to care and initiated ART. <b>SA2:</b> Characterize the risk and protective factors for linkage to HIV-care (defined as having an initial clinical encounter documented in the system) and ART initiation for children and adolescents living with HIV. <b>SA3:</b> Determine the outcomes of children and adolescents living with HIV who failed to link to care and initiate ART
<b>PI:</b> Humphrey	Improving Estimates of Mother- to-Child Transmission in Western Kenya: A Mixed Methods Prospective Cohort Study	<b>SA1:</b> To compare mother to-child transmission rates among mothers who are retained in antenatal care and mothers who disengaged from antenatal care. <b>SA2:</b> To compare HIV viral suppression rates among pregnant and postpartum women who are retained in care and who are disengaged from care. <b>SA3:</b> To understand the barriers and enhancers to linkage and retention
<b>PI:</b> Kieser	Improving Estimates of Mother- to-Child Transmission in Malawi: A Mixed Methods Prospective Cohort Study	<b>SA-1:</b> To compare mother to-child transmission rates among mothers who are retained in antenatal care and mothers who disengaged from antenatal care. <b>SA-2:</b> To compare HIV viral suppression rates among pregnant and postpartum women who are retained in care and who are disengaged from care. <b>SA-3:</b> To understand the barriers and enhancers to linkage and retention in care for HIV-infected pregnant women and mother
<b>PI:</b> Yiannoutsos	Pediatric and Adolescent Methods and Modeling Group for Policy and Decision Making	<b>Core Aim:</b> To carry out all functions related to analytical method development, data generation, collection and analysis and simulation modeling, in order to inform policy and decision making related to the HIV/AIDS pediatric and adolescent worldwide epidemic.

### SA 1 Projects from Previous Grant Cycles:

EA-IeDEA continues to work on finalizing projects related to this SA that were initiated under previous funding cycles. The status of these projects are outlined in Table 8.

**Table 8: SA1 - Projects From Previous Grant Cycle**

Concept Number	Concept Title	Concept Leader	Status	Product (Year)
13	Models of patient outreach and their associated rates of loss to follow-up in the East African IeDEA	Braitstein	Completed	Publication <sup>(38)</sup>
19	Estimates and correlates of pediatric ART adherence	Vreeman	Completed	Manuscript under
20	Adolescent Care in East Africa	Apondi	Manuscript circulated to co-	N/A
27	Predicators and factors associated with treatment failure among HIV-infected children on ARVs	Marete	Manuscript circulated to co-	N/A
32	Revising mortality estimates and predictors of mortality among HIV-infected children in western	Braitstein	Analysis in process	N/A



**Table 8 Continued: SA1 - Projects From Previous Grant Cycle**

Concept Number	Concept Title	Concept Leader	Status	Product (Year)
39	Characteristics of Patient at enrollment into HIV care and outcomes of prior to therapeutic ART eligibility or initiation in the leDEA East Africa Cohort	Elul	Concept revised; Awaiting updated dataset	N/A
42	The incidence of first-line ART failure and incidence and determinants of initiation of second-line ART in adults meeting local criteria for first-line failure	Goodrich	Manuscript to be circulated to co-authors May 2017	N/A
43	Comparative effectiveness and opportunity costs of outreach strategies within antiretroviral treatment	Rebeiro	Complete	Manuscript under
45	Clinical characteristics and outcomes of adolescents attending HIV clinics in leDEA East Africa	Nuwagaba-Biribonwoha	Drafting Manuscript	Poster Discussion (41)
46	PEPFAR: Programmatic and Clinical HIV Treatment Outcomes in Pregnancy	Holmes	Completed Analysis; Resubmission	Rejected PLOS
52	<b>Supplement:</b> Engagement in care among HIV-infected patients in resource limited settings: A Protocol for Assessing the Magnitude of and Reasons for Failure to Engage in Care among HIV-infected	Geng Martin	Completed	Paper (42)
56	HIV among adults aged 50 years and older over the continuum of care (testing and diagnosis, clinic registration and ART initiation) in East Africa:	Easterbrook	Analysis to be rerun on updated data set	N/A
89	Pregnancy rates among HIV+ women using various combinations of ART and contraception	Patel	Data Collection Complete; Analysis in Process; Planned Manuscripts: <ul style="list-style-type: none"> <li>• Cohort analysis</li> <li>• Analysis of BMI/TB meds</li> </ul>	N/A
Supplement	Point of care CD4 Testing for people who fail to engage in care after testing HIV positive	Braitstein	Analysis in Process	Poster(44)
Supplement	A Qualitative study of bottlenecks in access to HIV care and treatment in Kisesa, Tanzania Study	Waymoi	Completed	9 Submitted manuscripts (45-

**SA-2: We will examine the impact of behavioral factors on retention within the cascade and subsequent outcomes concentrating on the syndemics of substance use and mental illness.**

**Project 2.1: Prevalence and impact of alcohol use in patients enrolling in HIV care**

**PSA1:** Determine the long term (2-3 year) outcomes of the AUAC.

**PSA2:** Assess strategies utilized by patients to address their hazardous alcohol use.

**PSA3:** (Bridging Aim to Project 2.2): Identify community, and clinic-based services available for the treatment of substance use and mental health disorders in clinics participating in Project 2.2.

**Project Description:** PSA1 will utilize the established *Alcohol Use Assessment Sentinel Cohort* (AUAC) at FACES, AMPATH and Mbarara to assess the impact of hazardous alcohol consumption at baseline and follow-up on adherence, mortality, loss to program and re-engagement. Data from the Clinic Cohort Database, the leDEA-EA LTFU

tracking form and the AUDIT will be used for data capture. Patients LTP will be traced per existing AUAC procedures. An audio recorded one-hour semi-structured interview will be conducted on 25% of patients with an AUDIT score >8 (about 50 patients). These interviews will ask questions related to interventions utilized or recommended, the perceived quality of intervention services, barriers and enablers to care and the perceived need of the patient to get help. A study specific semi-structured qualitative interview will be designed to identify and describe community and healthcare facility services available for management of substance use and mental health disorders, which will be conducted with key clinic personnel (the clinical officers-in charge, social workers) at the clinics in *Project 2.2*.

Progress: The protocol has been finalized for Project 2.1 including finalization of the data collection instruments. The protocol has been submitted for review to the regulatory bodies affiliated with AMPATH, FACES, Mbarara and Indiana University. Regulatory approval has been received from AMPATH and Indiana University. Research assistants have been hired at AMPATH and FACES has posted their research assistant positions. Training will occur during the last week of May or first week of June for the AMPATH research assistants. It is anticipated that the study will begin in June at AMPATH. Study initiation dates at FACES and Mbarara are dependent on the timing of regulatory approval at these facilities. Concept sheets for the analyses associated with this project are in development and anticipated to be finalized mid-summer 2017.

**Project 2.2: *Assessing the syndemics of substance use and mental illness***

**PSA 1:** *Descriptive: Determine the prevalence of substance use (drug and alcohol) and mental health disorders in patients enrolling into care.*

**PSA 2:** *Assess the impact of substance use, mental health disorders and dual diagnoses on patient adherence and retention in the cascade*

**PSA 3:** *Map the substance use and mental health treatment services utilized by the Behavioral Cohort.*

Project Description: Project 2.2 will establish a Sentinel Behavioral Cohort of 800 HIV-infected adults ( $\geq 18$  years) newly enrolled at AMPATH, FACES, Mbarara and Tumbi. Subjects will undergo standardized validated assessments for mental health and substance use issues. The Sentinel Behavioral Cohort will be followed for 24 months. Cohort members who fail to return for a scheduled visit within 2 months will be tracked per existing protocols including use of the leDEA-EA lost to follow-up tracking form. After 12 months of follow-up, a sample of patients found in the initial assessment as having mental health or substance use issues will be assessed by a semi-structured interview.

Progress: The project protocol and selection of evaluation instruments will be finalized in May/June 2017. It is anticipated that the protocol will be submitted for regulatory review in July/August 2017. It is anticipated that the project will begin in January 2018.

**Supplements SA 2:**

Submitted Supplements SA 2: EA-leDEA has two supplements under review for this specific aim.

**Table 9: Submitted Supplements SA 2**

PI	Title	Aims
PI: Syvertsen	Characterizing the effects of alcohol and other drug use on engagement in the HIV care cascade among patients in leDEA-affiliated clinics in East Africa: A Social Network Approach	<p><b>SA1:</b> To examine how social network factors (e.g., network size, structure, composition) are associated with patterns of AOD, sexual behaviors, engagement in care, and HIV clinical outcomes among a sample of EA leDEA- affiliated clinic patients who screen positive for alcohol and/or drug use and a comparison group.</p> <p><b>SA2:</b> To qualitatively describe the nature and overlap of key relationships (e.g., risky and supportive) within patients’ networks and assess their associations with HIV outcomes.</p> <p><b>SA3:</b> To use mixed methods to explore the feasibility, acceptability, and potential format of a social network intervention to reduce AOD, improve HIV clinical outcomes, and increase linkages to HIV testing</p>
PI: Castelnovo	Using task shifting for depression screening and management within the Infectious Diseases Institute supported clinics in Kampala, Uganda	<p><b>SA1:</b> To evaluate the uptake of depression screening using the Patient Health Questionnaire-2 (PHQ-2) and the Patient Health Questionnaire-9 (PHQ-9) in the Kampala City Council Authority (KCCA) Clinics.</p> <p><b>SA2:</b> To implement the management of depression using differentiated care models with linkage to an appropriate level of mental health care based on depression score.</p> <p><b>SA3:</b> To follow up a cohort of patients with clinical depression at ART start and evaluate the impact of ART and the proposed differentiated care model through repeated depression score evaluations.</p>

**SA 2 Projects from Previous Grant Cycles:**

EA-leDEA continues to work on finalizing the AUAC project related to this SA that was initiated under the previous funding cycle (Table 10).

**Table 10: Specific Aim 2 - Project From Previous Grant Cycle**

Concept Number	Concept Title	Concept Leader	Status	Product (Year 11)
Supplement	Alcohol Use Assessment Sentinel Cohort (AUAC)	Wools-Kaloustian Goodrich	Primary Data Collection Completed; Analysis Underway; 3 manuscripts	NA

**SA-3: To understand contextual issues of care, we will examine the impact of the health care environment on retention within the cascade and subsequent outcomes.**

**Project 3.1 Knowledge, attitudes and behaviors: Providers and their impact on patient outcomes PSA 1:**

*Enumerate providers and describe their knowledge, attitudes, professional social networks and behaviors regarding key evidence based practices.*

**PSA 2:** *Estimate the effect of provider characteristics on the quality of clinical practice*

**Project Description:** We will create a *Sentinel Provider Cohort* at Mbarara, FACES, and Morogoro. We will assess basic sociodemographic characteristics, educational and professional background and current job activities. Existing instruments will be used to assess workforce characteristics including motivation, burn-out and job satisfaction. In the second aim we will include provider characteristics as predictors of patient outcomes in multi-level analyses adjusting for patient-level characteristics for outcomes such as complete screening for TB the first visit; Documentation

completeness; ART initiation in eligible patients; Ordering monitoring and diagnostic tests.

Progress: The project protocol development and instrument selection is anticipated to be finalized in June 2017. Regulatory submissions will be undertaken thereafter. It is anticipated that this project will be initiated in the fall of 2017.

**SA-4: We will continue to explore HIV co-infections/co-morbidities and their outcomes with an emphasis on Kaposi's Sarcoma (KS) and cervical cancer.**

**Project 4.1. KS presentation, Incidence and survival in the ART era**

**PSA 1.** *Update estimates of the foundational elements — incidence and survival — of KS in East Africa.*

**PSA 2.** *Determine stage of KS at disease presentation and reasons for delayed presentation.*

Project Description: This project utilizes the *KS Sentinel Clinics* (AMPATH, IDI, Mbarara), which have integrated skin biopsies for histological confirmation of KS as part of routine clinical care. The diagnosis of KS is collected through the EA-IeDEA-supported biopsy services (i.e. the pathology-confirmed cases; QUESTgen Database) or from the *Clinic Cohort Database* (clinical diagnoses) along with clinical and epidemiologic data. A supplemental questionnaire is being administered to patients with newly diagnosed KS to measure the stage of the disease at presentation and reasons for delayed presentation.

Progress: We have established biopsy capacity at the Masaka clinic. The PSA 2 protocol has been finalized and regulatory approval for this project has been obtained for AMPATH. AMPATH is being utilized as the pilot site for PSA2. To date AMPATH has identified 69 newly diagnosed KS patients and obtain additional data on approximately two thirds of these patients, including the attainment of additional biologic specimens. The protocol is under regulatory review in Uganda. Once regulatory approval is obtained for the Uganda clinics (Masaka, IDI, and Mbarara) the pilot will be expanded to those sites.

**Project 4.2. Cervical cancer screening uptake and predictors of VIA positivity in rural western Kenya PSA 1:**

*Identify predictors of cervical cancer screening*

**PSA 2:** *Determine predictors of VIA positivity*

**PSA 3:** *Estimate the cervical cancer screening cascade from screening uptake to treatment*

Project Description: This study will utilize the *Clinic Cohort* restricted to FACES and AMPATH and merges the data with each programs' Cervical Cancer Screening Database.

Progress: The concept for this project has been developed and approved by the EA-IeDEA EC. Data from the cervical cancer screening programs have been cleaned. Data will be linked with the patient level data in the master datasets from FACES and AMPATH in the summer of 2017 and the analysis will be initiated in the fall of 2017.

**SA 4 Projects from Previous Grant Cycles:**

EA-IeDEA continues to work on finalizing projects related to this SA that were initiated under previous funding cycles. The status of these projects are outlined in Table 11.

**Table 11: Specific Aim 4 - Projects From Previous Grant Cycle**

Concept Number	Concept Title	Concept Leader	Status	Product (Year 11)
69	ART and congenital anomalies- a systematic review of mother baby data on association of ART and congenital anomalies in Western Kenya	Apondi	Dataset in development – awaiting data from FACES	NA
Supplement	Building off the HIV Platform: Extension of Pharmacovigilance to Populations with Tuberculosis or Malignancies	Karwa Pasaki	Data cleaning in process	NA
WHO/Gates Funded	Pharmacovigilance & Toxicity Documentation in the Context of Antiretroviral treatment-threatening: Comparative Evaluation of 4 Strategies in a Resource- constrained setting	Karwa Pasaki	Primary data collection complete Analysis underway	NA

**A. Significance:**

The overall significance of this work remains the same as that outlined in the initial grant application.

**B. Plans**

The plans for each project are outlined within the project narrative.

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## Index

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- ACTG, 4, 6  
ACTs, 32  
**ADAT**, i, 70  
adherence, 7, 20, 21, 29, 30, 44, 45, 46, 52, 53, 70, 71, 75, 88, 91, 92, 93  
Adult Medicine Research Working Group. *See* AMWG  
AIDS, 6  
AIDS Clinical Trials Group (ACTG), 6  
Alcohol, 2, 3  
AMPATH, ii, i, ii, iv, 1, 10, 11, 15, 22, 25, 26, 29, 30, 31, 34, 39, 42, 44, 45, 47, 49, 56, 60, 61, 63, 69, 72  
AMPATH Data Analysis Team. *See* ADAT  
AMPATH Research Program, ii  
**AMWG**, i, 2, 3, 4, 5, 6, 7, 12, 14, 19, 26, 34, 44, 46, 49, 51, 59, 60, 67  
Antenatal Care, 58  
Anticoagulation Monitoring Services (AMS), 16  
antiretroviral therapy, 7  
Antiretroviral Therapy, 4, 5, 50, 52, 70, 72, 76  
Apondi, 23, 25, 27, 35, 56, 58, 59, 69, 74  
ART, 4, 5, 6, 8, 19, 20, 22, 29, 30, 51, 52, 64, 70, 71  
ARV, 7, 8, 45  
Ayaya, 25, 29, 70, 72, 73  
Ayuku, 1, 2, 18, 23, 48, 57, 72, 73, 75  
Baliddawa, 2, 3, 75  
Basic Science Research Working Group. *See* BSWG  
Behavioral and Social Science Research Working Group. *See* SSRN  
Birgen, 12  
Braitstein, 9, 18, 23, 26, 27, 35, 43, 46, 48, 49, 57, 59, 62, 73, 74, 75  
Brown, 2, 10, 34, 48, 63, 70, 71  
Brown University, 2, 34, 48, 63, 70, 71, 72  
**BSWG**, i  
Burnt Forest Sub-District Hospital, 23, 45, 53  
Busakhala, 4, 5, 50, 55, 60, 61, 62, 67, 75, 76  
Busia District Hospital, 23, 29  
Canadian Institutes of Health Research, 49  
cancer, 10, 56, 60, 68, 73, 74, 76  
Cardiovascular and Metabolic Disease Research Working Group. *See* CVMD  
chemotherapy, 5, 13, 21, 50, 64, 68  
Cheruiyot, 3, 4, 5, 6, 7, 8, 17, 51  
Children, 13, 21, 38, 44, 48, 57, 62, 67, 69, 70, 71, 72, 74  
Chlamydia, 11  
Christoffersen-Deb, 16, 20, 24, 30, 41, 66, 74, 75  
chronic cardiac, 67  
Chulaimbo Sub-District Hospital, 45, 53  
College of Health Sciences, ii, 54, 80  
community based research, 13  
community solutions, 1  
condom use, 9  
contraceptives, 22  
cryptococcal meningitis, 3  
**CVMD**, i, 14  
Dried Blood Spot (DBS), 55  
Drinkers, 3, 75  
drug resistance, 7, 70, 71, 73, 98  
Duke University, 1, 11, 12, 21, 31, 54, 55, 66  
eclampsia, iv, 20, 21  
Eldoret, ii  
Embleton, 9, 18, 23, 57, 72, 73  
family functioning, 1, 2  
Family-Based, 2, 73  
Flick, 10  
FLTR, 26  
fluconazole, 3  
Gakinya, 2, 3, 73, 74  
Genotyping, 11  
Gestational diabetes mellitus (GDM), 24  
Grand Challenges Canada, 1  
Grants, ii  
Grinter, ii  
HADITHI, 44, 45, 52, 53, 56, 65  
HIV, ii, 1, 2, 3, 5, 6, 7, 9, 10, 13, 19, 22, 23, 24, 25, 26, 27, 29, 30, 34, 35, 36, 38, 39, 44, 45, 46, 47, 49, 50, 51, 52, 53, 54, 56, 58, 59, 62, 63, 64, 65, 67, 69, 70, 71, 72, 73, 74, 75, 76  
HIV treatment, 27, 47, 49, 69  
home-based counseling and testing (HBCT), 59  
HPV, iii, 10, 11  
Indiana University, 10, 13, 17, 19, 21, 25, 27, 28, 35, 37, 38, 44, 47, 48, 51, 52, 56, 57, 58, 59, 60, 63, 64, 67, 69, 70  
Indiana University - Purdue University in Indianapolis (IUPUI), 10, 67  
Informatics, 27  
Institutional Review and Ethics Committee. *See* IREC  
intensive care unit (ICU), 12  
**IREC**, i, 10, 20, 24, 41, 48, 60, 62, 65, 80

- Iten District Hospital, 3, 59, 60  
Kamaara, 62, 73  
Kamano, 14, 16, 41, 75  
Kenya, ii, iii, iv, v, ii, 1, 2, 3, 9, 11, 12, 13, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, 28, 30, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 43, 44, 46, 47, 50, 51, 53, 54, 57, 58, 59, 60, 62, 63, 65, 66, 68, 69, 72, 73, 74, 75, 76, 78, 79, 80, 89, 91, 95, 96, 100  
Kenya Medical Research Institute, 11, 80  
Keter, 3  
Kiplagat-Kirui, ii  
Kiptoo, 14, 39  
Kitale District Hospital, 45, 53  
KS, 4, 5, 56, 63, 64  
Kussin, 11, 12, 66, 67, 74, 75  
Lagat, 3, 6, 7, 12, 66, 67, 75  
Laktabai, 33  
Lalani, 12  
leadership, ii  
Loehrer, 10, 11, 63, 67  
long-acting reversible contraception (LARC), 16  
Loop Electrosurgical Excision Procedure (LEEP), 11  
malaria, 18, 21, 31, 33, 54, 55  
malaria chemoprevention, 21  
Manji, 16, 73, 75  
maternity, iv, 20, 21  
McHenry, 25, 37, 38, 46, 54, 56, 74  
Mental Health, 34, 45  
Menya, 33  
Moi Teaching and Referral Hospital, 3, 4, 5, 6, 7, 8, 12, 13, 17, 23, 45, 49, 53, 58, 67  
Moi Teaching and Referral Hospital (MTRH), 1, 10, 25, 31, 36, 41, 47, 48, 60, 65  
Moi University, ii, 1, 2, 3, 4, 5, 6, 7, 8, 12, 13, 17, 18, 19, 21, 23, 26, 27, 28, 29, 30, 31, 34, 37, 38, 41, 44, 47, 48, 49, 50, 51, 52, 54, 55, 57, 60, 62, 63, 64, 65, 66, 67, 69, 70  
Mosoriot Rural Health Training Centre, 40, 45, 53  
Mosquito collection, 55  
Mukhobola Health Centre, 23  
Mwogi, 12  
Naanyu, 46  
National Cancer Institute (NCI), 5  
National Institute of Allergy and Infectious Diseases (NIAID), 5, 29, 34  
neuropathy, 13, 68  
NIH, ii, iii, 5, 6, 14, 23, 29, 33, 34, 40, 45, 50, 70, 98  
Njiru, 4, 5, 50, 63  
NORAD - Norwegian Agency for Development Cooperation, 28  
Nyandiko, ii, 28, 36, 41, 44, 46, 47, 51, 52, 54, 56, 64, 70, 72, 73, 74  
Omenge, 11  
Oncology, i  
Oncology Research Working Group. *See* ORWG  
**ORWG**, i, 4, 5, 10, 13, 17, 50, 56, 60, 63, 67  
Papas, 2, 3, 73, 74  
parent-child relationships, 1  
Pastakia, 16, 24, 46, 72, 73, 74, 75  
**PCWG**, i, 46  
Pediatric Research Working Group. *See* PRWG  
Peer Support, 65  
pharmacovigilance, 46  
**PHPCWG**, i, 31, 34  
Plater, ii  
pre-eclampsia, 20, 21  
Prudhomme, 33  
**PRWG**, i, 1, 9, 12, 13, 17, 18, 21, 23, 25, 26, 29, 36, 37, 38, 41, 44, 46, 47, 48, 51, 52, 56, 57, 58, 65, 67, 69, 70  
Psychiatry, 2, 74  
Public Health and Primary Care Research Working Group. *See* PHPCWG  
publications, 72  
Puffer, 1, 2  
pulmonary disease, 67  
RAFIKI, 2, 31  
Reproductive Health Research Working Group. *See* RHWG  
Research and Sponsored Projects Office. *See* RSPO  
Research Program Office, ii, *See* RPO  
research symposium, ii  
**RHWG**, i, 10, 16, 20, 22, 24, 58, 66  
Rono, 1  
**RPO**, i  
**RSPO**, i, 60  
sexual practices, 9  
Siika, 3, 4, 5, 6, 7, 8, 12, 19, 27, 51, 52, 76  
Skiles, 13, 17, 67  
Some, 6, 8, 74  
**SSRN**, i, 1, 2, 3, 5, 6, 7, 18, 34, 62, 63  
stigma, 46  
street-connected young people, 9  
TB, 6, 8, 13, 47, 72, 82, 84, 85, 86, 92, 94, 97, 98  
**TBWG**, i, 6, 8, 27  
Tuberculosis Research Working Group. *See* TBWG  
Turbo Health Centre, 3, 40, 45, 53  
University of Toronto, 9, 10, 16, 18, 20, 23, 24, 26, 30, 43, 46, 48, 49, 62, 66  
Vedanthan, 14, 16, 39, 41, 72, 75  
viral load, 7, 45, 48, 52, 69, 71, 85, 89

Vreeman, ii, 25, 28, 36, 44, 45, 46, 47, 52, 54, 56, 64, 70,  
72, 73, 74, 76  
Wachira, 52  
Wagner, ii

Walumbe, ii  
Webuye District Hospital, 3, 36, 45, 53, 55  
Wools-Kaloustian, 46, 47, 51, 69, 75