

# SEMI ANNUAL RESEARCH REPORT

July - December 2019



## Acknowledgements

The AMPATH Research Program Office is grateful to our sponsors and research partners who contribute to the success of our research program. Thank you to everyone who contributed to this report and our efforts to improve the health of people in Kenya and resource limited settings around the world.

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<https://www.ampathkenya.org/research>

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## ABBREVIATIONS

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ADAT	AMPATH Data Analysis Team
AMPATH	Academic Model Providing Access to Healthcare
AMWG	Adult Medicine Research Working Group
BSWG	Basic Science Research Working Group
CVMD	Cardiovascular and Metabolic Disease Research Working Group
IREC	Institutional Review and Ethics Committee
MTRH	Moi Teaching and Referral Hospital
MUCHS	Moi University College of Health Sciences
NCDs	Non-Communicable Diseases
ORWG	Oncology Research Working Group
PCWG	Pharmaceutical Care Research Working Group
PHPCWG	Public Health and Primary Care Research Working Group
PRWG	Pediatric Research Working Group
RHWG	Reproductive Health Research Working Group
RPO	Research Program Office
RSPO	Research and Sponsored Projects Office
SSRN	Behavioral and Social Science Research Working Group
TBWG	Tuberculosis Research Working Group

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## OVERVIEW

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In 2019, the AMPATH Research Program continued its strong record of growth publishing more than 120 articles in peer reviewed journals – a 53 percent increase from the previous year. AMPATH researchers were awarded more than US\$12.8 million in new research and training grants – the second highest award amount since 1998.

The following report provides a snapshot of AMPATH’s research activities from July 1 – December 31, 2019. It includes progress updates from **52 research projects** active during this period. Each update includes a summary abstract of the project’s aims, an update on progress made during the reporting period, and the project’s objectives for the next 6 months. Each report was provided by the project’s Principal Investigator or their designee and, with the exception of formatting, are presented here largely unedited.



*Attendees of the 2019 Strategic Planning meeting in Eldoret, Kenya.*

### ***A New Strategic Direction***

Every three years the AMPATH Research Program engages program stakeholders in a strategic planning process to evaluate the current state of the program and set strategic priorities for the next three years. The AMPATH Research Program began this process in the second half of 2019 with an online SWOT analysis and one-on-one interviews that engaged both internal and external program stakeholders. Nearly 200 program stakeholders from North America and Kenya were asked to complete a brief online survey identifying program’s internal strengths and weaknesses and external opportunities and threats that could impact the development of the program in the future (See Table 1).

**Table 1:** Stakeholder Identified Internal Strengths and Weaknesses and External Threats and Opportunities

<b>Internal</b>	<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>Strong Relationships with Key Stakeholders</li> <li>Multidisciplinary Approach to Research</li> <li>Working Group Peer Review Process</li> <li>Research Working Groups</li> <li><b>Clear Policies &amp; Procedures</b></li> <li>Access to Training</li> <li>Record of Success</li> <li>Research Program Office Support</li> <li><b>Strength of Research Partnerships</b></li> <li>Website &amp; Newsletter</li> <li>Access to Mentorship</li> <li>Leadership</li> <li>Skilled Researchers</li> <li>Publications Review Process</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>Inadequate Staffing in Core Administrative Units</li> <li>Lack of Local Funding</li> <li>Lack of Transparency about Policies</li> <li>No Career Path for Kenyan Faculty Researchers</li> <li>Approval Process Not Supportive of Research</li> <li><b>Lack of Kenyan PIs</b></li> <li>Procurement Process</li> <li>No Protected Time for Research</li> <li>Absentee North American PIs</li> <li>Lack of Integration into MTRH</li> <li>Limited Integration Outside School of Medicine</li> <li>Policies Don't Support Research</li> <li>Slow Processes</li> <li>Lack of Leadership Support</li> <li>Lab Financial Instability</li> <li>Lack of Grant Writers</li> <li>Low Working Group Attendance</li> <li>Lack of Engagement by Certain Schools</li> </ul>
<b>External</b>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>New diagnostic tools</li> <li>Political Support</li> <li>Engagement with Pharma &amp; Clinical Trials</li> <li>New Funding Opportunities for International Faculty</li> <li>Access to Good Mentors</li> <li>NHIF Expansion</li> <li><b>Population Health Expansion</b></li> <li>External Reputation</li> <li>Community Support</li> <li>Partnerships</li> <li>Support for Multidisciplinary Research</li> <li>Local Funding</li> <li>Emerging Biomedical Engineering Program</li> <li>New Research Trends</li> <li>High Demand for Evidence Based Policy</li> </ul>	<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>Economic Downturn</li> <li>Community Fatigue</li> <li>Collapsing Public Health System</li> <li>Fracturing of Partnerships</li> <li>Growing Competition with Private Institutions in Kenya</li> <li><b>Changing Donor Priorities</b></li> <li>Devolution</li> <li>Inadequate Technology</li> <li>Growing NCD Disease Burden</li> <li>Brain Drain</li> <li>Strikes</li> <li>Kenyan Regulatory Restrictions</li> </ul>

In September 2019, the AMPATH Research Program Office (RPO) convened a strategic planning meeting in Eldoret, Kenya. The meeting included more than 40 key research program leaders and stakeholders tasked with reviewing the program’s vision, mission, values, and strategic priorities and developing a new strategic plan for the next 3 years. Participants in the two day meeting revised the Research Program’s vision, mission, and values for the first time in nearly a decade and expanded the program’s strategic priorities by adding a fifth priority lending support to AMPATH’s new efforts to replicate the program outside of Kenya (See Table 2).

**Table 2:** 2019 Changes to the AMPATH Research Program’s Vision, Mission, Values, and Strategic Priorities

	2015	2019 Revisions
<b>Vision</b>	A vibrant, world-class, Kenyan-led community of international researchers in health and health care.	A vibrant, world-class, Kenyan-led community of researchers engaged in the continuous improvement of health globally.
<b>Mission</b>	To improve the health of people in resource-limited settings, through the identification, development and dissemination of relevant and timely information on health and health care systems for use by decision-makers in medical care, public health, and public policy in Kenya and elsewhere in resource-limited settings.	Guided by the principle of leading with care, we work in partnership to develop local research talent and to identify, develop and disseminate relevant and timely information to improve the health of underserved populations.
<b>Values</b>	In our work we will embrace:	In our work we will embrace:



2015	2019 Revisions
<ul style="list-style-type: none"> <li>• Service with humility</li> <li>• A spirit of collaboration and partnership</li> <li>• Integrity in relationships</li> <li>• Mutual respect and mutual benefit in organizational partnerships</li> <li>• A focus on vulnerable populations</li> <li>• Efforts to eliminate health disparities</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Service</b> with humility</li> <li>• A spirit of <b>collaboration</b> and <b>partnership</b></li> <li>• <b>Integrity</b> in relationships</li> <li>• <b>Mutual respect</b> and <b>mutual benefit</b> in organizational partnerships</li> <li>• Efforts to <b>eliminate health disparities</b></li> <li>• A <b>sustainable</b> infrastructure for research</li> </ul>
<b>Goal 1</b> Stable, resourced infrastructure for research that enables the efficient conduct of high-quality, high-priority research	Strengthen development of a well-resourced and sustainable infrastructure for research that enables the efficient conduct of high-quality research
<b>Goal 2</b> Successful independent investigators working in collaborative, interdisciplinary research teams to improve global health	Increase the number of successful independent investigators working in collaborative, interdisciplinary research teams by providing better access to high-quality training and mentorship.
<b>Goal 3</b> Supportive, global health research-intensive cultures within the schools and departments of all AMPATH partners	Enhance supportive, research-intensive cultures within the schools and departments of all AMPATH partners
<b>Goal 4</b> Growth in key, high-yield, research-related initiatives relevant to population health, policy-makers’ questions, and healthcare delivery systems and contextualized to resource-limited settings, including Basic and Translational Sciences Research, Biobanking, Oncology and NCDs, Population-focused Health, Informatics and Decision Support Systems, and Implementation Research dissemination.	Accelerate growth in relevant, high-yield research initiatives that will improve policy and strengthen the health systems and communities we serve including Biomedical innovations, Health Economics/ Equity, Population Health, Informatics, and Implementation Science Research.
<b>Goal 5</b> None	Incorporate research into ongoing efforts to expand AMPATH innovations to additional underserved populations outside Kenya

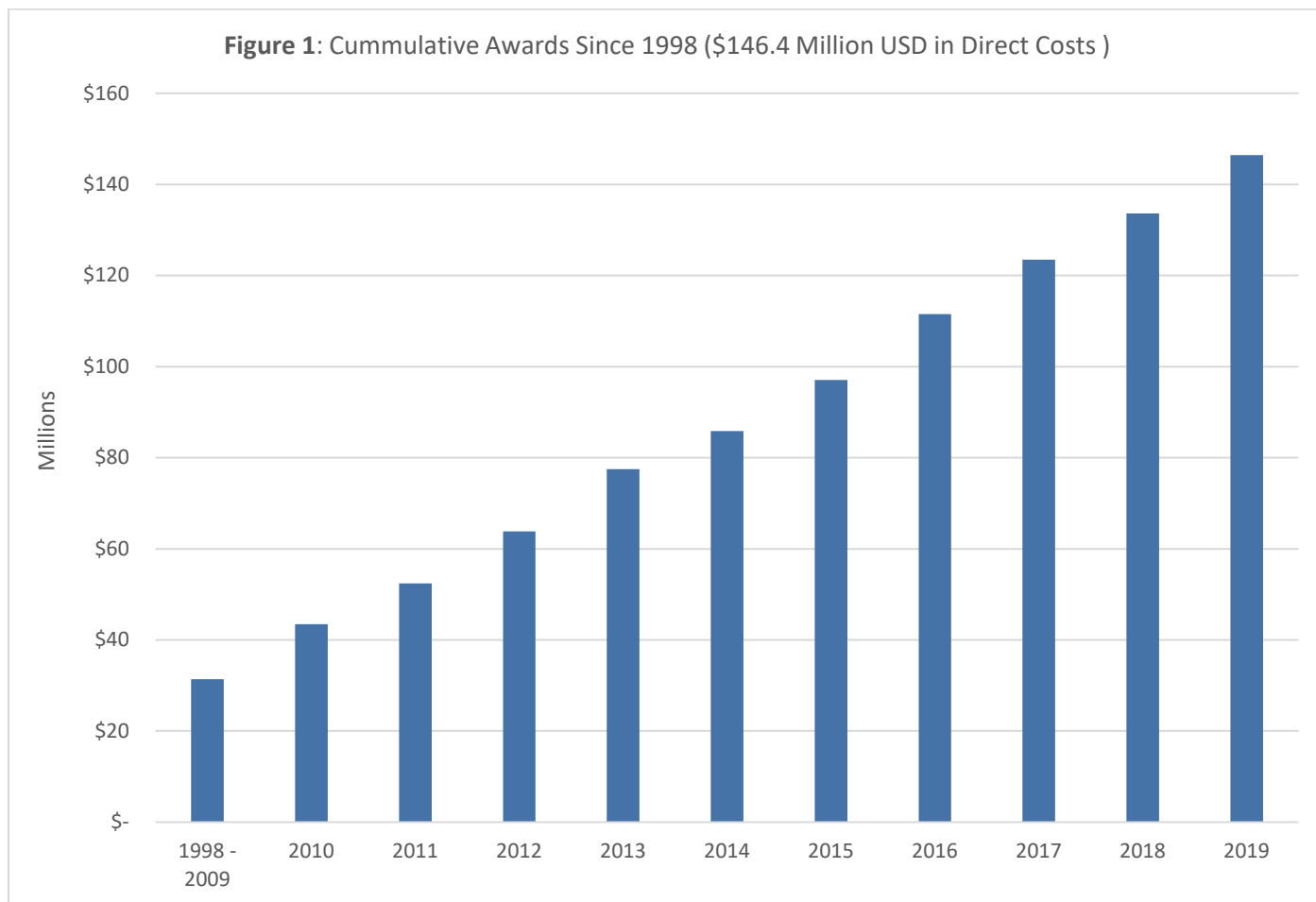
Following September’s strategic planning meeting, the AMPATH Research Program Office drafted a work plan with input from key stakeholders and program leadership to implement the program’s new strategic plan. See Appendix A for the complete work plan.

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## GRANTS

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Investigators reported more than US\$ 12.8 million in new and continuing awards from NIH for 2019. This is the second largest amount received from the NIH during a calendar year. The awards received increased AMPATH’s cumulative total of research and training awards from the NIH to US\$112.5 million since the start of the program in 1998. Including non-NIH awards, the AMPATH Research Program has received more than US \$146 million (See Figure 1).



## PILOT AWARDS

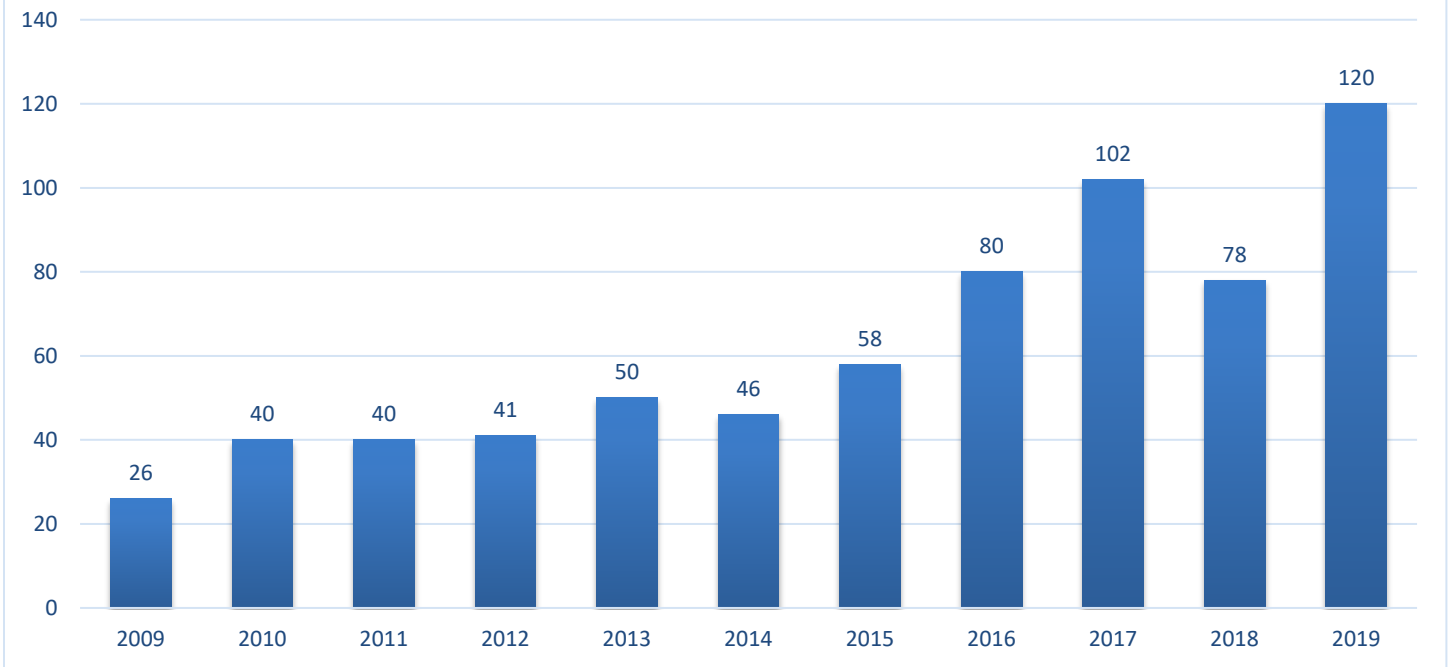
In the second half of the 2019, an AMPATH collaborative research team led by Dr. Laura Ruhl received \$50,000 for a pilot grant from the Indiana Clinical and Translational Sciences Institute (Indiana CTSI) and Indiana University Center for Global Health Research Pilot Grant Competition in 2019. Dr. Ruhl will partner with Dr. Julia Songok of Moi Teaching and Referral Hospital to implement a peer support group focusing on health, social, and financial literacy for pregnant adolescent women in western Kenya. This program will also be evaluated for replicability in Indiana. Ruhl’s award adds to the \$70,000 awarded in the first half of 2019 bringing the total amount of pilot grants awarded by CTSI and Indiana University to \$120,000 for the calendar year.

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## PUBLICATIONS

AMPATH investigators published 42 articles in peer-reviewed journals from July to the end of December 2019. The output in 2019 set a new record of publications in the AMPATH Program (See Figure 3). A bibliography of all the publications produced from July – December 2019 is available at the end of this report (See Appendix B).

**Figure 3: AMPATH Research Publications per Year since 2009**



## STUDY REPORTS

The following reports were provided by AMPATH investigators and their study teams and cover the period of July – December 2019. The views expressed in these reports do not necessarily reflect the views of the AMPATH Research Program, its partners, or sponsors.

<b>Study Title</b>	<b>A cluster randomized trial of "Teach HADITHI" teacher training intervention to reduce classroom HIV-related stigma in Kenya"</b>
<b>Principal Investigator(s)</b>	Rachel Vreeman, Indiana University
<b>Co-Investigator(s)</b>	Winstone Nyandiko, Moi University
<b>Working Group(s)</b>	Pediatric (PRWG)
<b>Description</b>	<p>The objective of this study is to evaluate an innovative film-based, curricular intervention to reduce H/A stigma in school contexts and thereby reduce H/A stigma learned, perceived or experienced by youth. We will assess whether the intervention reduces the H/A stigma in their teaching and classrooms as experienced by HIV-infected youth enrolled in AMPATH. Our primary endpoint will be decreased teacher self-reports of stigmatizing knowledge, attitudes, and beliefs (K/A/B) about HIV six months after undergoing the Teach HADITHI teacher training. Secondary endpoints include reported H/A stigma and clinical outcomes among HIV-infected youth whose teachers have or have not gone through the training. The central hypothesis is that that introducing culturally relevant media and interactions that increase knowledge about HIV, its treatment, and living with HIV, while also engaging empathy and emotional connections, will alter both teachers' K/A/B about HIV, as well as the H/A stigma within their classrooms hence creating an environment that supports positive living with HIV. The specific aims are: Aim 1: Assemble a multimedia teacher training module, focused on HIV and H/A stigma and adapted for maximum cultural relevance, curricular cohesion, and impact among Kenyan primary and secondary school teachers. Aim 2: Assess the impact of the Teach HADITHI intervention on Kenyan teachers' attitudes, beliefs, and knowledge about HIV and the level of HIV-related stigma among teachers. Exploratory Aim 3: Examine whether HIV-infected children and adolescents in classrooms with teachers who have received the Teach HADITHI intervention report less perceived, enacted, or internalized stigma compared to those in classrooms with teachers who have not. We will take a phased approach to study activities. In Phase One (PHASE ONE: QUALITATIVE INQUIRY AND INTERVENTION DEVELOPMENT) we will conduct qualitative inquiry and intervention development to achieve Aim 1 to revise the HADITHI stigma module and materials. In Phase Two (PHASE TWO: RANDOMIZED TRIAL OF INTERVENTION), the "Teach HADITHI" modular package developed in Aim 1, will be evaluated with a pre- and post-intervention design that compares teachers who complete the training with those at control schools in second sub-county who do not. Phase 2 will include testing the objectives of Aim 2 and the exploratory Aim 3.</p>
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	6/1/2018 - 5/30/2020
<b>Funding Status</b>	Funded - NIH - Fogarty International Center (FIC)

Direct Award (USD)	\$261,673
Update	<p>The study "Teach HADITHI" teacher training intervention to reduce classroom HIV-related stigma in Kenya" originally received approvals from MTRH/Moi University Institutional Research Ethics Committee (IREC), the Indiana University Institutional Review Board (IRB) and the National Commission for Science, Technology and Innovation (NACOSTI). In the last six months, the study was also reviewed and approved by the Icahn School of Medicine at Mount Sinai Institutional Review Board (IRB), where Rachel Vreeman (PI) has since transferred employment. In preparation for the launch of study activities, the study team met with the County Director of Education and a representative for the Teacher Service Commission in Uasin Gishu County. In the last six months, we completed Phase One of the study, which included cognitive interviews with the key informants around the proposed Teach HADITHI teacher training curriculum. This included interviewing a total of 50 key informants and 14 Adolescent Community Advisory board members. These interviews ended on 14th September 2019, and we were able to revise the Teach HADITHI teacher training curriculum immediately after. We identified the control and intervention schools randomly selected for Phase 2 of this protocol and began to carry out both the intervention group trainings and the assessment of the control group teachers. A total of 68 teachers from intervention schools have been trained on the curriculum, and a questionnaire administered to them to assess their perception about stigma in schools and classrooms. We also developed a RedCap database and data entry, as well as verification, is ongoing for the quantitative data. Dr. Vreeman presented about the objectives and progress of the Teach HADITHI study at both the Fogarty International Center (Stigma Network, May 2019) and for the Department of Health System Design and Global Health at the Icahn School of Medicine at Mount Sinai (December 2019.)</p>
Future Plans	<p>In the next six months, we plan to:</p> <p>Complete phase 2 of the study:</p> <ol style="list-style-type: none"> <li>Complete interviews for the control schools</li> <li>Complete teacher workshops to deliver the Teach HADITHI intervention.</li> <li>Conduct 6-month follow-up assessments for both intervention and control schools.</li> </ol> <p>Complete data entry of quantitative data of the study. Begin data cleaning and analysis of the data. Publish a systematic review from our Phase One work, reviewing the literature on stigma interventions in schools.</p>
Publication(s)	
Study Title	<b>A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector.</b>
Principal Investigator(s)	Jeremiah Laktabai, Moi University
Co-Investigator(s)	Diana Menya, Moi University
Working Group(s)	Public Health and Primary Care (PHPCWG)

<b>Description</b>	<p>The ultimate goal of the proposed work is to improve antimalarial stewardship in the retail sector, which is responsible for distributing the majority of antimalarials in sub-Saharan Africa. Through a combination of diagnosis and treatment subsidies and provider-directed incentives, our approach will align provider and customer incentives with appropriate case management and thereby improve health outcomes.</p> <p>Specific Aim 1: Identify the combination of testing subsidies and conditional ACT subsidies that maximizes uptake of testing within specific budget constraints. Several studies, including our own, have shown that uptake of testing and ACT treatment are both sensitive to price. However, very little is known about how these prices should be related in order to maximize appropriate behavior and what effect conditional subsidies will have on treatment decisions. We will use an individually-randomized experiment to determine how different combinations of subsidies, allocated between testing and treatment, affect the decision to be tested for malaria before treatment among clients seeking care in the retail sector. The objective of this experiment is to identify the combination of RDT and conditional (diagnosis-dependent) ACT subsidies that maximize the percent of clients receiving an RDT. We will test two different RDT price levels and two discounted ACT price levels in a factorial design. ACT discounts are conditional on a positive RDT result. The primary outcome measure is the decision to purchase an RDT before purchasing a drug. Secondary outcome measures are: 1). Decision to purchase an ACT stratified by testing status; a)Positive mRDT, b) Negative mRDT and c)No malaria test. All outcomes will be measured by interviewing the participant after they make their decision about whether to be tested and which medicines to purchase. Specific Aim 2: Test the impact of the subsidy package on targeting of ACTs in the retail sector. We will test the combination of subsidies (selected from Aim 1) in a cluster-randomized controlled trial to evaluate their impact on the proportion of ACTs sold to individuals with parasitologically-confirmed malaria among those seeking care in the retail sector.</p>
<b>Site(s)</b>	Webuye District Hospital
<b>Project Period</b>	9/14/2018 - 8/31/2019
<b>Funding Status</b>	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
<b>Direct Award (USD)</b>	Not Reported
<b>Update</b>	<p>For Aim 1, We completed the study recruitment of participants at shops enrolled in our study at the end of October 2019. Overall, we enrolled 10 shops and randomized 833 eligible participants into four arms via scratch cards. This excludes 6 participants who were pregnant women, who according to the protocol were excluded from receiving treatment but provided with malaria testing. We had a good balance across all arms (208, 206, 211, 208 in arms 1, 2, 3, 4 respectively). Our preliminary results show that there was high RDT uptake, over 95%, across all arms, showing a willingness amongst our study population to have an RDT test for malaria diagnosis. We have used the preliminary results of Aim 1 where we tested different subsidy levels for RDTs and ACTs to help inform our strategy for setting subsidy levels for Aim 2. We will continue to work further on analysis of our results and possibly publish Aim 1 outcome paper before the end of 2020. Aim 2 protocol has been developed and submitted to both Duke IRIS and Moi-IREC for review and approval. Implementation plans in both Kenya and Nigeria are ongoing.</p>

Future Plans	We expect to receive Aim 2 protocol approval before February 2020 and we plan to train the study team on the protocol and study SOP before end of February 2020. We also plan to enrol and train the participating medicine outlets in March 2020. After training, we will collect baseline outlet data that will be used in arm allocations.
Publication(s)	
Study Title	<b>A5349/TBTC S31 Rifapentine-containing treatment shortening regimens for pulmonary tuberculosis: A randomized, open-label, controlled phase 3 clinical trial</b>
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	David Lagat, Moi University
Working Group(s)	None
Description	This is an international, multicenter, randomized, controlled, open-label, 3-arm, phase 3 non-inferiority trial. The primary objectives are: 1. To evaluate the efficacy of a rifapentine-containing regimen to determine whether the single substitution of rifapentine for rifampin makes it possible to reduce to seventeen weeks the duration of treatment for drug-susceptible pulmonary tuberculosis 2. To evaluate the efficacy of a rifapentine-containing regimen that in addition substitutes moxifloxacin for ethambutol and continues moxifloxacin during the continuation phase to determine whether it is possible to reduce to seventeen weeks the duration of treatment for drug-susceptible pulmonary tuberculosis
Site(s)	
Project Period	10/12/2017 - 1/31/2021
Funding Status	Unfunded
Direct Award (USD)	
Update	The site was able for follow up participants and transition those who needed standard of care treatment accordingly. There were no major challenges to be reported.
Future Plans	Continue to follow up active participants as per protocol requirements.
Publication(s)	
Study Title	<b>Addressing HIV drug resistance research gaps in a cohort of perinatally infected Kenyan children and adolescents"</b>
Principal Investigator(s)	Rami Kantor, Brown University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Working Group(s)	Pediatric (PRWG)

<p><b>Description</b></p>	<p>The purpose of this project is to address existing drug resistance research gaps in a previously established, carefully characterized cohort of 499 children and adolescents living with HIV in Kenya. To do this, we will use our successful collaboration at AMPATH in Kenya, one of the largest HIV programs in sub-Saharan Africa, and uniquely leverage existing resources from our ongoing R01 AI120792 on perinatally-infected children and adolescents at AMPATH (MPI Kantor and Vreeman). We hypothesize that comprehensive investigations of genotypic-phenotypic and resistance-treatment outcome discordances in diverse non-B subtypes will resolve some of these existing research gaps and optimize patient care in settings where it is most needed. The specific aims of this study are to: Aim 1: Determine geno-pheno correlations and examine inter-subtype differences. Aim 2: Evaluate etiologies for ART failure with a 'susceptible genotype' and investigate association with minority DR variants and/or alternative DR mechanisms. Aim 3: Evaluate etiologies for ART success with a 'resistant genotype', and their associations with geno-pheno discordance and new compensatory mutations, in diverse HIV-1 sub-types. We will recruit children and adolescents at AMPATH who participated in our previous CAMP and RESPECT studies. The original inclusion criteria were that these children were (i) HIV-infected documented by DNA-PCR (Amplicor, Roche, Basel, Switzerland) for children less than 18 months of age and by 2 parallel HIV rapid ELISA tests using Determine and Bionline for children older than 18 months of age; (ii) Age ≤14 years; and (iii) Currently on or beginning an NNRTI-based ART regimen that included NVP or EFV. We hope to enroll 499 children who participated in the previous CAMP and RESPECT studies for prospective follow up in the current study. We will longitudinally follow this cohort for 4 years. Every 6 months, we will administer an adherence questionnaire and collect a blood sample. Blood samples will be analyzed for viral load at the AMPATH Reference Laboratory, where we will also store any remaining plasma and buffy coat samples. Part of participant's blood samples will be shipped to Rami Kantor's lab at Miriam Hospital for drug resistance analyses and as appropriate to two additional labs in the United States for drug level testing and phenotyping - to Kashuba Lab at the University of North Carolina and to Monogram/Labcorp. Participants' entire medical history will be extracted from the AMPATH Medical Records System. All participants will be required to provide informed consent or assent (as well as parental consent for those under 18 years of age). Study data will be maintained on a secure electronic REDCap database hosted on the AMPATH server.</p>
<p><b>Site(s)</b></p>	<p>Kitale District Hospital, Moi Teaching and Referral Hospital, Turbo Health Centre, Webuye District Hospital</p>
<p><b>Project Period</b></p>	<p>7/1/2019 - 6/30/2024</p>
<p><b>Funding Status</b></p>	<p>Funded - NIH</p>
<p><b>Direct Award (USD)</b></p>	<p>\$16,385</p>
<p><b>Update</b></p>	<p>The study "Addressing HIV drug resistance research gaps in a cohort of perinatally infected Kenyan children and adolescents" has received approvals from MTRH/Moi University Institutional Research Ethics Committee (IREC), the Icahn School of Medicine at Mount Sinai (IRB) and the National Commission for Science, Technology and Innovation (NACOSTI). Protocol development, including the creation of multiple manuals and study SOPs was undertaken. The RESPECT database for the original cohort was reviewed and criteria determined for modifications needed to adapt the database for this new study</p>



	phase. Data collection tools have been adapted, finalized, and submitted to IREC and IRB for approval. In the last six months, we hired and trained all study staff on the study protocol.
Future Plans	In the next six months, we plan to: Begin participant enrolment and follow up. Have the REDCap database ready. Apply for an administrative supplement specifically seeking to conduct research on bioethical issues.
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)
Working Group(s)	Oncology Research Working Group (ORWG)
Description	The core objective of this project is to better understand the natural history of oncogenic HPV infections in HIV-infected Kenyan women, and to identify potentially modifiable (and non-modifiable) factors that are associated with progression of oncogenic HPV infection to clinical disease, including cervical cancer. Our central hypothesis is that the incidence, persistence, and spectrum of HPV are all substantially greater in HIV-infected versus non-HIV-infected Kenyan women, and that this explains a higher incidence of cervical neoplasia in HIV-infected populations. We further hypothesize that these and other modifiable factors (such as concurrent STIs, sexual behaviors, nutrition, and environment) disproportionately and adversely impact outcomes of local therapies such as cryotherapy and Loop Electrosurgical Excision Procedure (LEEP) in HIV-infected women. The specific aims of this AMPATH-Oncology Institute are to: 1. Expand the capabilities and expertise of the current laboratories and biobanking capabilities in Kenya through AMPATH and the Kenya Medical Research Institute (KEMRI) 2. Identify potentially modifiable behavioral and biological factors that are associated with the duration of infection with oncogenic HPV and cervical dysplasia in HIV-infected and non-HIV-infected women from western Kenya 3. Assess the risk factors associated with the short and long term results of cryotherapy and LEEP in VIA- positive (including LEEP-eligible) HIV-infected and non-HIV-infected women in western Kenya. 4. Provide biostatistical and data management support for proposed projects in this application and for future pilot projects, and 5. To establish a sustainable, multi-institutional and transdisciplinary mentoring program fostering the development of new cancer researchers in Kenya
Site(s)	Moi Teaching and Referral Hospital, Center for Global Health Research - KEMRI at Kisumu City, Kenya
Project Period	9/19/2014 - 8/31/2019
Funding Status	Funded - NIH - National Cancer Institute (NCI)

<b>Direct Award (USD)</b>	\$2,132,402
<b>Update</b>	<p>Enrollment began in the fall of 2015. A total of 223 women have been recruited into the study (2 enrollees had inadequate specimens and one had unknown HIV status and therefore all 3 were excluded from analysis). Of the 220 evaluable subjects, 115 were HIV-infected with median age of 36 years, and 105 were HIV-uninfected with median age 33 years (p-value = 0.0009). This enrollment represents 100% of our planned total of 220 Kenyan women. Women have begun returning for follow-up quarterly visits as well. Results: i,§ Among HIV-infected women, 86.8% were receiving ART; median duration between HIV diagnosis and enrollment was 7.2 years (IQR 4.1-10.3); median CD4 count was 471 (IQR 310-612). i,§ Fewer HIV-infected women (35.7%) were married than HIV-uninfected women (67.3%) (p&lt;.001). i,§ The percentage of participants who reported using a condom less than 25% of the time was significantly lower for HIV-infected participants (27.8%) compared to HIV-uninfected women (73.3%) (p&lt;.0001). i,§ HIV-infected women had a median of 4 lifetime sexual partners (IQR 3-8) compared to HIV-uninfected women (median 3, IQR 1.5-4), p=.0001. HPV of any type, all HR-HPV, and HPV 16 were detected significantly more often in HIV-infected women than in HIV-uninfected women in spite of ART use by most HIV-infected women. i,§ Low risk HPV types were detected in 32.2% of HIV-infected women and 17.3% of HIV-uninfected women (p=.0113) i,§ Of 223 patients followed in year 1, there were 15 positive STDs noted in 8 individuals, of which 10 received treatment and 2 are still awaiting treatment. In the second year, 11 women had 19 positive STDs results. All patients on study were treated with antibiotics based on syndromic presentations. Conclusions: This study was initiated in Kenya to study HPV and cervical cancer epidemiology and treatment response. Several behavioral variables differed between HIV-infected and HIV-uninfected women. All HPV, all HR-HPV, and HPV 16 were detected significantly more often in HIV-infected women than in HIV-uninfected women, in spite of the use of ART. This study will continue to follow women on a quarterly basis, collecting a wealth of behavioral and clinical samples for the purpose of better understanding cervical cancer in HIV-infected and HIV-uninfected Kenyan women.</p>
<b>Future Plans</b>	We have completed accrual to both projects, but we are continuing to perform the follow-up visits as per protocol. We are planning to complete HPV testing results and have submitted preliminary results for publication from the early phase of the study..
<b>Publication(s)</b>	
<b>Study Title</b>	<b>Analyzing the Adolescent HIV Care Cascade in East Africa Through the International Epidemiologic Databases Evaluating AIDS" (ACE STUDY)</b>
<b>Principal Investigator(s)</b>	Rachel Vreeman, Indiana University
<b>Co-Investigator(s)</b>	Edith Apondi, Moi University
<b>Working Group(s)</b>	Pediatric (PRWG)
<b>Description</b>	The objective of this study is to refine estimates of key outcomes and associated correlates among a subset of Perinatally-Infected Adolescents (PIA) in the East Africa

	<p>leDEA cohort. We will use in-depth assessment and prospective tracing of adolescents to create an Adolescent Sentinel Cohort in order to address the following specific aims: Aim 1: Describe the engagement status (engaged, Loss to Program (LTP) with care disengagement, LTP with re-engagement, or LTFU), virologic suppression status (viral suppression or viral non-suppression), and vital status (alive, dead, or LTFU) for PIA. Aim 1.a (Exploratory): Among PIA who are dead, assess the feasibility of implementing a modified verbal autopsy tool to assess cause of death. Aim 2: Provide in-depth characterization of the populations of PIA engaged in and disengaged from care, including describing current HIV care-related characteristics (ART regimen, adherence to treatment, experiences of HIV-related stigma, HIV care preferences); virologic outcomes (viral suppression, viral failure, and drug resistance patterns); pregnancy status; and mental and behavioral health characteristics (depression, substance use). Aim 3: Describe virologic, mental and behavioral health outcomes and HIV care preferences by HIV care status (engaged, LTP with care disengagement, LTP with re-engagement, or LTFU). Aim 4: Identify patient-level factors (including clinical characteristics, mental and behavioral characteristics, and HIV care preferences) associated with HIV care status (engaged, LTP with care disengagement, or LTP with re-engagement), viral suppression, and death.</p>
<b>Site(s)</b>	Kitale District Hospital, Moi Teaching and Referral Hospital, FACES Lumumba
<b>Project Period</b>	8/1/2018 - 7/31/2019
<b>Funding Status</b>	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
<b>Direct Award (USD)</b>	\$259,480
<b>Update</b>	<p>Over the last six months, participant enrolment has been going on in all the three leDEA ACE study sites - Moi Teaching and Referral AMPATH, Kitale AMPATH, and FACES, Lumumba site. We have enrolled a total of 325 PIA (264 Engaged in care and 61 Lost To Program), including those from MTRH (n=128), Kitale (n=125) and FACES Lumumba (n=72). All enrolled adolescents undergo assessments using a battery of questionnaires to assess their physical, mental, and social health, as well as have blood samples taken for Viral Load and CD4 testing at AMPATH Reference lab. Those who are not virally suppressed have additional viral resistance testing done at Dr. Kantor's lab in the USA. Thirty-five participants (10 at FACES, 10 at Kitale and 15 at MTRH) have been identified as Lost To Follow up (LTFU) after unsuccessful tracing. We have received Viral Load and CD4 results for the tests done and shipped specimen from the AMPATH Reference lab to Dr. Kantor's Lab in the USA for resistance testing. Additional activities of the project team have included developing a Discrete Choice Experiment (DCE) tool to measure adolescent clinic preferences, and data collection using this tool with the adolescents is ongoing. In addition, we conducted a qualitative analysis related to procedures for and development of a verbal autopsy strategy and tool to use with families with children who have died. This qualitative analysis included 30 participants (15 caregivers and 15 health care providers), and analysis is now underway. Data entry into the RedCap database for the quantitative portion of the study is ongoing. Dr. Vreeman and Dr. Elul submitted an R01 application to the NIMH that would extend the follow-up and assessments of this cohort to identify feasible, acceptable and scalable approaches for sustained care engagement across the spectrum of highly vulnerable adolescents, including those with care</p>

	interruptions and those disengaged from care. Although the initial application was not funded, they are preparing a revised R01 application for May 2020.
<b>Future Plans</b>	In the next six months, we will: Continue study enrolment and patient assessments at all sites, with particular emphasis on completing tracing and enrollment of adolescents who are lost to program. Complete analysis of the qualitative data from Verbal autopsy preparatory interviews and begin conducting verbal autopsy interviews with families with deceased children. Continue with data entry and verification in RedCap database. Shipment of specimens from the AMPATH Reference lab to Dr. Kantor's Lab in the USA for resistance testing. Begin analyses according to specific aims. Submit revised R01 application to extend the ACE cohort. Prepare abstracts and manuscripts for publications on our findings.
<b>Publication(s)</b>	
<b>Study Title</b>	<b>Bridging Income Generation with Group Interated Care(BIGPIC)</b>
<b>Principal Investigator(s)</b>	Rajesh Vedanthan, New York University
<b>Co-Investigator(s)</b>	Jemima Kamano, Moi Teaching and Referral Hospital
<b>Working Group(s)</b>	Cardiovascular and Metabolic Disease (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.
<b>Site(s)</b>	Busia District Hospital, Uasin Gishu District Hospital, Trans-Nzoia and Kisumu West
<b>Project Period</b>	4/1/2015 - 1/1/2020
<b>Funding Status</b>	Funded
<b>Direct Award (USD)</b>	<b>\$2,287,314</b>

<p><b>Update</b></p>	<p>Administrative - Capacity building of the study personnel with specialized and targeted training ongoing - NIH R01 grant No Cost Extension approved</p> <p>Aim 1: Barriers/facilitators/contextual factors - Manuscript writing ongoing</p> <p>Aim 1.1 (Barriers, Facilitators, &amp; Contextual Model): - Data analysis and manuscript writing ongoing</p> <p>Aim 2 (Cluster RCT): - Logistics of trial Roll Out: o Enrollment completed - A total of 2891 participants enrolled. o 3-month follow-ups completed. - Total participants: 2660 (92%) o 12 month follow-ups are now complete - Total participants: 2710 (94%) - Data collection, entry, &amp; management: o All data collection activities have been completed. o Data cleaning ongoing o Data analysis ongoing - Process evaluation: o Process evaluation data collection activities have been completed. o Qualitative and quantitative data analysis ongoing</p> <p>Aim 2.1( Mediation &amp; Moderation Analysis): - Social network survey (SNS): o SNS collection is now complete o Analysis ongoing Aim 3 (Cost Effectiveness Analysis): - Costing questionnaire survey (CQS): o CQS administering now complete o Analysis ongoing</p>
<p><b>Future Plans</b></p>	<p>Aim 1: o Manuscript preparation</p> <p>Aim 1.1 o Manuscript preparation</p> <p>Aim 2: o Complete analysis of baseline data o Complete analysis of outcome data o Complete study dissemination activities at appropriate stages o Manuscript preparation</p> <p>Aim 2.1: o Continue data analysis o Manuscript preparation</p> <p>Aim 3: o Continue data analysis o Manuscript preparation</p>
<p><b>Publication(s)</b></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>
<p><b>Working Group(s)</b></p>	<p>Reproductive Health (RHWG)</p>
<p><b>Description</b></p>	<p>The purpose of the study is to evaluate whether integration of family planning education and free, on-site provision of all reversible family planning methods in Anticoagulation Monitoring Service (AMS) Clinic can improve uptake of long-acting reversible contraception (LARC; specifically intrauterine contraceptive devices (IUCDs) and contraceptive implants) in this high-risk population. Our hypothesis is that implementation of an educational intervention emphasizing long-acting reversible contraception (LARC) combined with free on-site provision of LARC within Anticoagulation Monitoring Service (AMS) can improve uptake of these methods by 25% in this population. Our objectives are to:</p>

	<p>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.</p> <p>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).</p> <p>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.</p> <p>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.</p>
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/20/2015 - 8/31/2016
Funding Status	Unfunded
Direct Award (USD)	
Update	In the past 6 months, plans to conduct longitudinal analyses were put on hold due to other overriding issues that took precedence.
Future Plans	Over the next 6 months, we still aim to conduct longitudinal analysis for data collected at 6 & 12-months. Upon completion of this, we plan to prepare a manuscript.
Publication(s)	
Study Title	<b>Caregiver Interventions for Developmental Delays in Young Kenyan Children</b>
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi Teaching and Referral Hospital
Working Group(s)	Pediatric (PRWG)
Description	<p><b>PROBLEM STATEMENT:</b> One promising intervention for neurodevelopmental delays in resource-limited settings is the Care for Child Development Intervention (CCDI) Program developed by UNICEF, in partnership with the World Health Organization.<sup>6,7</sup> In the CCDI program, trained providers support families by promoting sensitive and responsive caregiver-child interactions and teaching them about cognitive stimulation and social support.<sup>6</sup> The program is adaptable cross-culturally and has been used in over 4 countries.<sup>6,8</sup> While few published evaluation studies look at the outcomes of implementing the CCDI program, one study performed in Pakistan showed that the program improved cognitive, language, and motor neurodevelopmental outcomes at 12</p>



and 24 months of age, compared with a control group.<sup>9</sup> In resource-limited settings, like Kenya, implementation of a neurodevelopmental intervention for neurologically typical children may divert significant resources from a smaller population who may gain greater benefits from the intervention. Additionally, most of the preventative services, such as weight checks and immunizations, are performed within the Maternal-Child Health clinics, and community health workers do not have the reach necessary to promote child health promotion on a large scale. There are reports indicating that care for child development has been implemented in some parts of Kenya as part of on-going child survival or nutrition programs. However, there hasn't been any evaluation of the intervention to produce data that could guide further implementation and escalation. **JUSTIFICATION:** Neurodevelopmental interventions are most effective if administered early, when the brain is growing rapidly and has the greatest plasticity.<sup>5</sup> However, due to the overwhelmed healthcare systems in resource-limited settings, new interventions are often challenging to introduce and must be carefully evaluated to determine their benefits. Effective, sustainable interventions that can be integrated into the current models of care in resource-limited settings are critically needed to improve the neurodevelopmental outcomes of young children in these settings. Without such interventions, millions of children will be unable to reach their full developmental potential. In our study, we will only administer the intervention to children known to have neurodevelopmental delays. By focusing on adapting the intervention to be only a clinic-based treatment, a small number of community members could be trained to administer the program and increase the potential for sustainability. If the clinic-based group sessions prove to be effective for young children with neurodevelopmental delays, this would help inform the key areas of fidelity needed to maintain effectiveness of the intervention. This study is a critical first step to evaluating the CCDI program's potential as a cross-cultural intervention that is sustainable and effective for the children at highest risk for neurodevelopmental delay. These results will have significant impacts in improving early childhood neuro development both in Kenya and worldwide.

**OBJECTIVES** The Broad objective of this proposal is to pilot the CCDI program as an intervention to treat neurodevelopmental delays among 56 young children in Kenya

**SPECIFIC AIMS** Aim 1: Determine the feasibility of a randomized controlled trial protocol to examine the effectiveness of the CCDI Program for Kenyan children with neurodevelopmental delays aged 18-24 months within a public Maternal-Child Health (MCH) clinic setting. Hypothesis: The CCDI Program will be feasible, as measured by ?9% of participants being willing to be randomized to either the intervention or the control group; ? 8% attending all 1 biweekly caregiver meetings; ?8% of children returning for their 6 month follow-up; and ?8% returning for 12 month follow-up. Aim 2: Determine the acceptability, facilitators, and barriers of the CCDI Program for use in eligible children. Hypothesis: The CCDI Program will be acceptable, as determined by an analysis of prospective, concurrent, and retrospective acceptability,<sup>1</sup> and specific facilitators and barriers to the program will be identified. Using focus group discussions and semi-structured interviews with caregivers, clinical providers, and community leaders, we will determine aspects of the program are acceptable, facilitators, and barriers to improved neurodevelopmental care and allow the CCDI program to function optimally in this setting. Aim 3: Estimate the effect size of the CCDI Program to reduce neurodevelopmental delays in young Kenyan children. Hypothesis: We can demonstrate a 4% decrease in the number of children with neurodevelopmental delays, as determined

	by a culturally adapted Bayley Scales of Infant and Toddler Development, 3rd edition (BSID-III), 11, 12 standardized score with implementation of the CCDI Program. This data will inform sample size justification for a future intervention study.
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/9/2018 - 7/1/2019
Funding Status	Funded - Indiana CTSI, Thrasher Early Investigator Award
Direct Award (USD)	\$45,000
Update	We did month 12 follow up and evaluations of the 31 enrolled cohort of children that we followed for a period of one year since enrolment to participate in the study. The study participants were in two groups (Intervention and Control). We performed month 12 BSID-III assessments and obtained caregiver questionnaires on all participants. We had the CCDI program on the second intervention group with biweekly caregiver groups for a total of 10 sessions, while the Sequence control group were invited to return to access the normal child care at the clinic for background exposures and other potential benefits of visiting the health center. We conducted semi-structured interviews, focused group discussions to gather qualitative data from caregivers, clinical providers, and community leaders, using the Health Belief Model (HBM).
Future Plans	We are finalizing on data entry, data verification and cleaning in readiness for analysing the data and get the findings on our objectives and aims we were working on.
Publication(s)	

Study Title	<b>Chamas for Change: Adapting a community-based peer-support and health education model for pregnant and parenting adolescents in Kenya</b>
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	Edith Apondi, Moi University
Working Group(s)	Pediatric (PRWG) Public Health and Primary Care (PHPCWG) Reproductive Health (RHWG)
Description	The program sought to address the inequities that drive adolescent maternal and infant mortality by adapting our existing Chamas for Change (Chamas) program in western Kenya. By leveraging a long-standing international partnership between the Uasin-Gishu and Trans-Nzoia County Ministries of Health (MOH) and the Academic Model Providing Access to Healthcare (AMPATH) - including partners Indiana University, Moi University, Moi Teaching and Referral Hospital (MTRH) and the Rafiki Center of Excellence in Adolescent Health - we plan to adopt a well-established Chamas community-based, peer-support and health education model based on a three-year curriculum to a new population of pregnant and parenting adolescents ages 15-19. Chamas represents a service delivery platform that is low-cost, community-run, independently sustainable, and culturally acceptable. Central to this approach is the integration of health, social, and financial literacy to improve health outcomes. Preliminary studies demonstrate women



	<p>participating in Chamas are significantly more likely to practice positive health and parenting behaviors that reduce maternal and infant mortality. An early pilot study demonstrated participating women are significantly more likely to attend at least four prenatal visits, deliver in health facilities with skilled birth attendants, exclusively breastfeed to 6 months, and receive a health provider home visit within 48 hours of delivery. Among women and children participating in our third-year parenting program, we found significant reductions in parental stress and harsh punishment, as well as the potential for improvements in early child development. Further, our program's expansion to three counties with over 2,500 participating women, children and men demonstrate Chamas' potential to serve as a highly adaptable vehicle to meet the unique needs of diverse populations and accelerate health impact at scale. The overall goal (or general objective) of this research is to adapt and evaluate a community-led, peer-based model to meet the needs of pregnant adolescents and adolescent mothers, a population that disproportionately suffers from socio-economic marginalization and poor health outcomes. In doing so, we hope to demonstrate that this adapted program yields positive outcomes across these domains, as well as potential reproducibility in a North American context.</p>
<b>Site(s)</b>	Busia District Hospital, Huruma Sub-District Hospital, Kitale District Hospital, Port Victoria Sub-District Hospital, Uasin Gishu District Hospital
<b>Project Period</b>	6/30/2020 - 6/29/2020
<b>Funding Status</b>	Funded - Indiana CTSI
<b>Direct Award (USD)</b>	50,000
<b>Update</b>	<p>During this phase, we focused on holding sensitization meetings with key stakeholders and data collection. So far we have had introductory meetings with the County Ministry of Health (MoH) who introduced us to the Ministry of Education (MoE) officials for both Busia and Trans Nzoia counties. Through these meetings, the two departments selected key people that we needed to consider as participants for the Key Informant Interviews. For Busia County, 1 KII was done with the County Public Health Nurse who is also standing in as the County Reproductive Health Coordinator. We are meant to have an additional KII with the Director of Medical Services which is scheduled for completion in February 2019. We also did a combined KII with the Ministry of Education officials (Teachers Service Commission representative and Director of Education). This was after the MoE officials for both counties proposed having a combined KII due to their busy schedule as the national exams were ongoing. For TransNzoia and Busia counties, the MoE officials recommended interviewing the County In charge- Children's Rights whom we interviewed for both counties. In Trans Nzoia, we held 2 combined KIIs, 1 with 2 officials from the MoE and 1 from the MoH(Director of Education, Quality Assurance Coordinator and County Public Health Officer) and the 2nd with 3 MoH officials(Reproductive Health Coordinator, Community Strategy Focal Person-County and County Planning Coordinator). In total, we have done 6 KIIs, 2 pending (1- MoH Director Busia, 1- Adolescent representative at the national level). We later carried out 2 FGDs with Community Health Volunteers who have had the experience of handling pregnant/parenting adolescents, 2 FGDs with adolescent(pregnant/parenting) women, 2 FGDs with adolescent health providers and 2 FGDs with adolescent caregivers or their representatives for each site (TransNzoia and</p>

	Busia Counties). In Uasin Gishu County, we conducted 2 FGDs with the adolescents (pregnant/parenting) and 2 FGDs with caregivers or their representatives. In total, we have done 20 FGDs. We are yet to complete 2 FGDs with school-based staff in TransNzoia and Busia respectively. These are scheduled for completion in February 2019.
<b>Future Plans</b>	Currently transcription is complete and we plan to have an analysis workshop to inform how best we can design Chamas to meet the needs of pregnant adolescents, adolescent mothers and their children. We have developed the curriculum and we hope to have it reviewed before actual use. We plan to finalize data collection and share the findings of this study with different stakeholders before the actual implementation kicks off in July 2019.
<b>Publication(s)</b>	
<b>Study Title</b>	<b>Clinical Assessment for Retention and Engagement (CARE)</b>
<b>Principal Investigator(s)</b>	Leslie Enane, Indiana University
<b>Co-Investigator(s)</b>	Edith Ogalo, Moi Teaching and Referral Hospital
<b>Working Group(s)</b>	Pediatric (PRWG)
<b>Description</b>	HIV is a leading cause of death among adolescents globally, due to challenges that result in poor outcomes in the care cascade, including poor rates of retention. There is an urgent need to identify adolescents at high risk for disengagement from HIV care, and to intervene early to retain these adolescents. The objectives of this project are 1) to use a mixed-methods approach to investigate factors underlying disengagement among adolescents with HIV in East Africa, and 2) to develop an instrument to identify adolescents at risk for disengagement, for whom proactive interventions may support retention. This project will utilize the infrastructure of the NIH-funded International Epidemiologic Database to Evaluate AIDS East Africa Consortium (IeDEA-EA). We will first refine a conceptual model for adolescent disengagement from HIV care. This will be achieved through systematic literature review, qualitative inquiry, and synthesis of these findings with quantitative work in IeDEA-EA. We will work from this model to develop and pilot a reliable, developmentally- and culturally-relevant instrument to assess adolescent risk for disengagement from HIV care, the Clinical Assessment for Retention and Engagement (CARE). CARE will be designed for utility in clinical settings, to identify adolescents at risk for disengagement, for whom early interventions should be implemented. We will then develop an evidence-based algorithm to support intervention for vulnerable adolescents. Findings will support a future proposal to study CARE as part of an intervention package to improve retention and HIV outcomes for adolescents.
<b>Site(s)</b>	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training CentreTurbo Health Centre, Webuye District Hospital, Lumumba Health Center, Kisumu
<b>Project Period</b>	3/1/2017 - 6/30/2018
<b>Funding Status</b>	Funded - NIH

<b>Direct Award (USD)</b>	\$146,794												
<b>Update</b>	<p>Our Aim 1 qualitative work towards refining a conceptual model for adolescent retention and disengagement in HIV care continued over this reporting period. We continued recruitment and in-depth interviews with disengaged adolescents and their caregivers traced in the adolescent sentinel cohort study (ACE Study) in MTRH and Kitale AMPATH clinics (Module 4, Rafiki and Kitale). During this period, the numbers recruited were 24 adolescents and 21 caregivers, as summarized in the following table.</p> <table border="1"> <thead> <tr> <th>Enrolled</th> <th>Adolescents</th> <th>Caregivers</th> <th>Female</th> <th></th> <th></th> </tr> </thead> <tbody> <tr> <td>17</td> <td>17 Male</td> <td>7</td> <td>4</td> <td>TOTALS</td> <td>24      21</td> </tr> </tbody> </table> <p>Analysis of qualitative data from interviews with healthcare workers and with disengaged adolescents and their caregivers began during this period, and is ongoing. We also set up a database for accompanying questionnaire data from questionnaires done alongside the qualitative interviews. Entry and verification of this data is ongoing.</p>	Enrolled	Adolescents	Caregivers	Female			17	17 Male	7	4	TOTALS	24      21
Enrolled	Adolescents	Caregivers	Female										
17	17 Male	7	4	TOTALS	24      21								
<b>Future Plans</b>	<p>In the next reporting period, we hope to complete enrollment and in-depth interviews with the disengaged adolescents and their caregivers. We also hope to conclude qualitative analysis of interviews with healthcare workers, adolescents, and caregivers. We will synthesize the findings from this analysis with our ongoing systematic review of the literature, quantitative findings from the ACE study, and findings from our previous qualitative work on barriers and facilitators to retention in care among adolescents. The emerging key factors that influence retention will be incorporated in the development of a tool to assess risk for disengagement from care among HIV infected adolescents.</p>												
<b>Publication(s)</b>													
<b>Study Title</b>	<b>Community-based provision of urine pregnancy tests as linkage to reproductive health services</b>												
<b>Principal Investigator(s)</b>	Faith Yego, Moi University												
<b>Co-Investigator(s)</b>	Caitlin Benard, Indiana University												
<b>Working Group(s)</b>	Reproductive Health (RHWG)												
<b>Description</b>	<p>Kenyan families experience persistently high rates of maternal and neonatal mortality, which disproportionately affects women with low income and education and those who live far from health services. Key proven interventions include prevention of pregnancy and birth spacing, early entry to antenatal care, and facility delivery. However, creative, cost-effective interventions are urgently needed to link particularly vulnerable populations with these important health services. Previous research has shown that equipping community health volunteers (CHVs) with a tool as simple as a urine pregnancy test and training to provide post-test counseling is effective in improving linkages to antenatal care and family planning services. Our proposal includes a multi-phase process to collect qualitative data through a needs assessment (Phase 1), use community input to develop (Phase 2) and implement a pilot intervention study (Phase 3) assessing the ability of CHV-based provision of urine pregnancy tests with CHV-provided and phone-based</p>												

	<p>post-test counseling to link women with antenatal care and family planning services, and collect qualitative program evaluation data (Phase 4). This will provide much-needed information for how to effectively utilize and strengthen CHVs as part of a sustainable reproductive health care delivery system to improve maternal and neonatal mortality. Our broad objectives are to determine whether the use of community-based provision of urine pregnancy tests with post-test counseling and referral to care is acceptable to community health volunteers (CHVs) and participants and to determine which method of post-test counseling and referral to care, CHV-provided or phone-based, is more acceptable and more effective. Participant outcomes, including the primary outcome of utilization of ANC or family planning care, will be measured by telephone questionnaires one to three months post-enrollment. CHV outcomes will be determined by telephone questionnaires as well as review of CHV log books.</p>
Site(s)	Port Victoria Sub-District Hospital, Turbo Health Centre
Project Period	4/2/2018 - 4/2/2020
Funding Status	Funded - Indiana CTSI
Direct Award (USD)	\$20,000
Update	Over the last six months, one FGD was carried out in Turbo sub county with 15 CHVs. All participants were enrolled were followed up with the help of the CHVs. All recordings from the FGDs were transcribed. Logistical challenges we faced included poor-network connectivity, women participants not having their own phones, and organizing a safe abortion referral.
Future Plans	We plan to analyze the qualitative and the quantitative components of the study. Thereafter, hold community knowledge dissemination forums with key stakeholders and write manuscripts. We plan to scale up the community-based provision of UPTs to a larger number of CHVs and recommended to the counties.
Publication(s)	
Study Title	<b>Developing Capacity of Moi Teaching and Referral Hospital/ Moi University Institutional Research Ethics Committee (MTRH/MU IREC), Kenya to Prevent and Manage Research Misconduct.</b>
Principal Investigator(s)	Edwin Were, Moi University
Co-Investigator(s)	Jepchirchir Kiplagat, AMPATH
Working Group(s)	None
Description	Research Integrity and Oversight (RIO) is a 3-year project whose overall goal is to increase the capacity of Moi Teaching and Referral Hospital / Moi University Institutional Research and Ethics Committee (MTRH/MU IREC) to prevent, detect and manage research misconduct in Moi University College of Health Sciences, Kenya by developing and implementing a scalable modular institutional framework for preventing, detecting and managing research misconduct. The aims of the project are to: 1. To estimate the

	<p>prevalence of research misconduct in recent HIV research and document perceptions on occurrence of the research misconduct 2. To document perceptions on the current capacity to prevent, detect and manage research and the characteristics of a model institutional framework to manage research misconduct 3. To identify and document international best practices through broad literature review and benchmarking visits to United States and sub-Saharan Africa institutions where such capacity exists and is functional and utilize the body of knowledge gathered and involve local research stakeholders and international bioethics experts, to adapt the international best practices to the local setting and formulate a scalable modular institutional framework for prevention, detection and management of RM in Kenya 4. Implement, on a pilot basis, the model institutional framework in MTRH/MU IREC specifically and Moi University, broadly, and document the lessons learned</p>
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/31/2017 - 8/31/2020
Funding Status	Funded
Direct Award (USD)	\$292,000
Update	<p>The following is the summary progress from July to December 2019</p> <ol style="list-style-type: none"> <li>1. Trainings on Responsible conduct of Research: We conducted 2 trainings on responsible conduct of research. The first training was held in Kisumu between 31st July and 2nd August 2019 and the other took place between 28th and 29th Novembers 2019 in Eldoret</li> <li>2. Development of RCR modules: The project team engaged a team of local experts to develop training modules on responsible conduct of research (RCR). The experts held a meeting on 8th November 2019 to review and collate the material. The materials are being finalized</li> <li>3. Data analysis and publications: Two publications are being developed and are near completion.</li> <li>4. Moi RIO Office setup: We have engaged the Moi University Directorate of research to open a RIO office for Moi University. We have held a meeting with the representative and the process of setting up the office is ongoing.</li> <li>5. TAC Meeting: 2 meetings were held with the Technical Advisory Committee during this period. The first one was on 9th July 2019 and the other was on 19th Nov 2019. The main aim of the meeting was to update the committee on the project progress and get feedback on the same.</li> </ol>
Future Plans	Conduct more training sessions on Responsible conduct of Research, continue developing the publications, continue working towards Moi University RIO Office set up, conduct an end line survey on Research misconduct and hold a dissemination workshop.
Publication(s)	

<b>Study Title</b>	<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>
<b>Principal Investigator(s)</b>	Astrid Christoffersen-Deb, University of Toronto
<b>Co-Investigator(s)</b>	
<b>Working Group(s)</b>	Pediatric (PRWG) Reproductive Health (RHWG)
<b>Description</b>	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, 213 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, 213. 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, 213. The data for this study is collected using a comprehensive 1-item data collection form, including patient demographics, symptomatology, documented clinical signs and laboratory results, delivery details, and maternal and neonatal outcomes
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	1/12/2015 - 12/31/2015
<b>Funding Status</b>	Unfunded
<b>Direct Award (USD)</b>	
<b>Update</b>	Manuscript writing and we recently submitted irec continue review
<b>Future Plans</b>	We are currently in the plans of finalizing the manuscript writing. Our continue review is currently under review at irec
<b>Publication(s)</b>	
<b>Study Title</b>	<b>Enhancing Preventive Therapy of Malaria In children with Sickle cell anemia in East Africa (EPiTOMISE)</b>
<b>Principal Investigator(s)</b>	Festus Njuguna, Moi University

<b>Co-Investigator(s)</b>	Steve Taylor, Duke University
<b>Working Group(s)</b>	Pediatric (PRWG)
<b>Description</b>	Children with Sickle Cell Anemia (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 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 1 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.
<b>Site(s)</b>	Homabay County Hospital
<b>Project Period</b>	6/1/2016 - 2/28/2017
<b>Funding Status</b>	Funded - NIH
<b>Direct Award (USD)</b>	\$621,633
<b>Update</b>	Amended the protocol to version 8.0 to include additional statistical consideration in response to NIH/NHLBI DSMB suggested protocol changes after the study pause. The protocol was approved by IREC and implemented in November 2019. We had a monitoring visit on 31st July to 1st August 2019 and the report showed no major weakness or deviations. As of 20th January 2020, the study had enrolled a total of 240 participants (cumulative in all treatment groups).
<b>Future Plans</b>	We are continuing with enrollment as planned. Planning for the 5th study monitoring visit by an independent monitor within six weeks after enrollment completes. Final data cleaning and analysis is still expected to take place in the first half of 2021, with a manuscript planned for submission and the final report submitted to NHLBI by the end of 2021. The study team continues with weekly calls throughout the year.
<b>Publication(s)</b>	



<b>Study Title</b>	<b>Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy</b>
<b>Principal Investigator(s)</b>	Rena Patel, University of Washington
<b>Co-Investigator(s)</b>	Beatrice Jakait
<b>Working Group(s)</b>	Adult Medicine (AMWG) Reproductive Health (RHWG)
<b>Description</b>	<p><b>ABSTRACT</b> The use of effective hormonal contraceptives among HIV-positive women on antiretroviral therapy (ART) to prevent unwanted pregnancies in resource-limited settings can significantly reduce maternal-to-child HIV transmission as well as improve the woman's overall health. However, there is concern that potential drug-drug interactions between hormonal contraceptives and antiretrovirals (ARVs), particularly between Levonorgestrel-based (LNG) implants and efavirenz-based ART, may compromise the contraceptive's efficacy. To address this uncertainty, evidence from analysis of participant charts in Academic Model Providing Access to Healthcare (AMPATH), a large HIV treatment and care program, will help guide policy changes. We have conducted an initial data analysis with AMPATH electronic medical record system (AMRS) and charts from nearly 800 women; however, we lack key information, such as implant initiation and removal dates, and need to conduct further file reviews and brief phone interviews to obtain such information. Objectives: To help develop the evidence base for the relative effectiveness of LNG implants with concomitant efavirenz-based ART by conducting a data validation process among a random subsample of HIV-positive women attending AMPATH-supported HIV treatment facilities. Methods: We will conduct a rigorous data validation process by randomly sampling approximately 10% of HIV-positive women of reproductive age (15-45 years) attending AMPATH-supported HIV treatment facilities using hormonal contraceptives including implants, depomedroxyprogesterone acetate (DMPA), and oral contraceptives, or no contraceptives and on nevirapine-, efavirenz-, and lopinavir/ritonavir-based ART regimens or no ART (16 exposure categories with approximately total n=6,000 women. Based on our findings from this subsample, we will use inverse probability weights to adjust our estimates for incident pregnancies for the overall cohort. The data validation process will include two steps: 1) thorough file reviews including, but not limited to, HIV clinic charts, family planning (FP) registers from both the HIV treatment and/or antenatal facilities, and pharmacy records, and 2) brief phone interviews with the female participants to confirm the findings of the file reviews. The goal of this data validation process is to determine the initiation, continuation, and discontinuation dates for the contraceptive methods, ART regimens, and likely date of conception for those women becoming pregnant. Anticipated Results: Based on this data validation process, we will be able to calculate point estimates for incident pregnancies for the 16 combination exposure groups in our random subsample, and then use these validated point estimates to refine our point estimates for the overall cohort data from AMPATH.</p>
<b>Site(s)</b>	All AMPATH Sites
<b>Project Period</b>	5/1/2016 - 1/25/2021
<b>Funding Status</b>	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)



Direct Award (USD)	\$194,981
Update	We continue data analysis, and preliminary findings will be presented at CROI 2020, which were also presented to the All Africa meeting in SA in Oct 2019.
Future Plans	We hope to finalize the primary analysis (and submit it for publication), as well as to continue work on several of the secondary analyses.
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
Working Group(s)	Pharmacy Research Working Group (PHARMCRWG) Reproductive Health (RHWG)
Description	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 4 women who are <2wks gestation attending antenatal clinic at different project sites.
Site(s)	Huruma Sub-District Hospital, Moi Teaching and Referral Hospital, Uasin Gishu District Hospital, Reale Hospital, Langas Hospital,
Project Period	7/14/2015 - 7/13/2018
Funding Status	Funded - Medical Research Council
Direct Award (USD)	\$564,629
Update	Over the past 6 months Post delivery and data entry were completed. Part of Data cleaning were completed as well . Preliminary analysis of the 2149 mothers screened indicates 3.02% prevalence of GDM with 65 positive case. Identified risk factors contributing to positive diagnosis include a previous history of GDM, family history of GDM or diabetes, high social-economic status, high BMI and age. In all these loss to follow up has been a major challenge .
Future Plans	In the next 6 months, final data cleaning will be finalized, data analysis to commence after all the data has been cleaned. Manuscript writing to start after we have all the data cleaned. Samples collected from participants are set to be transferred to our collaborator in Warwick university for storage.

<b>Publication(s)</b>	
<b>Study Title</b>	<b>Evaluating Indicators of Poor Cardiac Function in Children and Adolescents Living with HIV in Western Kenya</b>
<b>Principal Investigator(s)</b>	Andrew McCrary, Duke University
<b>Co-Investigator(s)</b>	Winstone Nyandiko, Moi Teaching and Referral Hospital
<b>Working Group(s)</b>	Cardiovascular and Metabolic Disease (CVMD) Pediatric (PRWG)
<b>Description</b>	The Ped HIV - Echo Study (PHES) seeks to define predictors of poor cardiac function in children and adolescents living with HIV. PHES has several core components that hold significant potential for defining the prevalence of cardiac dysfunction in this population, elucidating predictors of poor cardiac function, and begin to illuminate etiologies of cardiac dysfunction. Our central hypothesis is that echocardiographic evidence of early cardiac dysfunction is present in children and adolescents living with HIV and the dysfunction can be defined in terms of patient's immune status, HIV history, and same day biomarker levels. The specific aims for the PHES project are to: 1) Define the prevalence of early cardiac dysfunction using strain imaging compared in a large cohort of children and adolescents living with HIV, and compare with traditional echocardiographic measures of function. 2) Determine the impact of concurrent HIV viral load level on strain values. Additionally, we will model the impact of time with unsuppressed viral replication as the study population were almost entirely perinatally infected. 3) Measure the correlation between cardiac dysfunction (defined by strain) and inflammatory (IL-6 and tnf-?) and cardiovascular (pro-BNP) biomarkers.
<b>Site(s)</b>	Moi Teaching and Referral Hospital
<b>Project Period</b>	9/12/2017 - 12/31/2018
<b>Funding Status</b>	Funded - International AIDS Society
<b>Direct Award (USD)</b>	\$136,199
<b>Update</b>	Over the last 6 months, we have worked on publication of our primary manuscript. The primary manuscript, "Early cardiac dysfunction in children and young adults with perinatally acquired HIV" was accepted by AIDS in December 2019. Additionally, quantitative CMV testing has continued.
<b>Future Plans</b>	Complete quantitative CMV testing and complete sub-analysis of factors associated with inflammatory profile in children and young adults living with HIV.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>Evaluating reproductive and HIV outcomes and decision making among HIV-positive women on dolutegravir: A prospective, observational cohort at AMPATH, Kenya</b>
<b>Principal Investigator(s)</b>	Mercy Maina, Moi Teaching and Referral Hospital
<b>Co-Investigator(s)</b>	Caitlin Bernard, Indiana University
<b>Working Group(s)</b>	Reproductive Health (RHWG)
<b>Description</b>	This is a prospective ,observational cohort study that aims to evaluate reproductive health outcomes and decision-making among women exposed to dolutegravir. Specific aims include: To evaluate key reproductive health and HIV outcomes among women initially on DTG-containing ART. Specifically, we will determine the proportion of women continuing to use DTG vs. switching to EFV. We will also determine contraceptive outcomes (uptake, method choice, and continuation rates and HIV outcomes (viral suppression rates) among these women. To investigate factors facilitating provider and patient decision-making for HIV-infected women choosing between ART and contraceptive choices.
<b>Site(s)</b>	Chulaimbo Sub-District Hospital, Moi Teaching and Referral Hospital, Saboti Sub-District Hospital
<b>Project Period</b>	4/17/2019 - 11/29/2019
<b>Funding Status</b>	Funded - University of Washington
<b>Direct Award (USD)</b>	\$13,869
<b>Update</b>	Over the last 6 months, in-depth interviews were conducted with 9 healthcare providers, 1 peer mentor, and 31 women in the following age categories; 21-24 (4 Women), 25-34 (5 Women), +35 (6 Women), these participant currently use dolutegravir based ART regimen. 16 Participants who were switched off dolutegravir onto Efavirenz based ART regimen were also interviewed and are spread across the following age categories: 21-24 (2 Women), 25-34 (4 Women), +35 (10 Women). We have transcribed 9 healthcare provider recordings and 25 women recordings. The telephone interviews that have been conducted with women who attend various Ampath clinics are: 598 of the anticipated 3000 women. Some of the challenges experienced are: Poor internet connectivity/Phone Access.
<b>Future Plans</b>	Over the next 6 months, we plan to conduct another 5-800 telephone interviews, 29 in-depth interviews with women and we also plan to transcribe all in-depth interview recordings. Next steps include qualitative and quantitative data analysis and dissemination of findings to the various stakeholders. Thereafter manuscript publication.
<b>Publication(s)</b>	
<b>Study Title</b>	<b>Evaluation of locally-sourced compression therapy for treatment of chronic leg ulcers and management of Kaposi sarcoma leg lymphedema in western Kenya</b>

Principal Investigator(s)	Aileen Chang, University of California San Francisco
Co-Investigator(s)	Sonak Pastakia, Purdue University
Working Group(s)	Adult Medicine (AMWG)
Description	<p>Compression therapy is a well-established cornerstone therapy and part of routine clinical care for chronic leg ulcers from venous disease and lymphedema, including Kaposi sarcoma (KS)-associated lymphedema. Chronic leg ulcers, from trauma or chronic venous disease, and lymphedema have a significant impact on quality of life, driven by pain, foul odor, and restricted mobility. The provision of compression therapy in resource-limited settings, as in western Kenya and other regions of East Africa, is a major challenge. In western Kenya, locally available elastic stockings are priced at 10-15 USD (1000-1500 kshs) per pair. Pre-packaged brand name kits are not locally available or affordable for patients, as imported kits costs 7-20 USD (700-2000 kshs) per package. However, materials used routinely in wound care, namely elastic crepe, gauze, and zinc oxide, are readily available and affordable for patients. Supplies required to dress one affected leg for a week cost 2 USD (200 kshs). The use of locally-sourced routine wound care supplies for compression therapy is poised to have significant impact on reducing morbidity, social stigma, and economic loss associated with chronic leg ulcers and Kaposi sarcoma-associated lymphedema. Demonstration of its feasibility and efficacy in treating chronic leg ulcers and Kaposi sarcoma-associated lymphedema in western Kenya could have far-reaching implications for the treatment of these prevalent conditions across East Africa and sub-Saharan Africa. This project will utilize a 1) retrospective study design to evaluate the efficacy of compression therapy for the treatment of chronic leg ulcer patients seen at Turbo Health Center, one of the Academic Model for Providing Access to Healthcare (AMPATH) sites and 2) randomized controlled trial to evaluate the efficacy of compression therapy in the management of Kaposi sarcoma leg lymphedema patients seen at AMPATH/MTRH oncology clinics. If the outcomes of this project support the use of locally-sourced compression therapy in the treatment of chronic leg ulcers and Kaposi sarcoma-associated lymphedema, future studies for chronic leg ulcers will focus on scaling up use of locally-sourced compression therapy at other AMPATH clinics and exploring feasibility of community-based care. Future studies for Kaposi sarcoma lymphedema will focus on exploring feasibility of community or home-based lymphedema care.</p> <p>Specific Aim 1: Evaluate the efficacy of compression therapy for the treatment of chronic leg ulcer patients in western Kenya. We will conduct a retrospective study to evaluate the efficacy of paste bandage compression therapy for chronic leg ulcers, from trauma or chronic venous disease, with the use of locally available supplies routinely used in wound care. We will compare our primary outcome measure to a population mean.</p> <p>Specific Aim 2: Evaluate the efficacy of compression therapy in the management of KS leg lymphedema patients in western Kenya. We will conduct a randomized trial of immediate vs. delayed compression therapy to explore the impact of paste bandage compression therapy for management of KS lymphedema with the use of locally available supplies routinely used in lymphedema care. We will compare the change in our primary outcome measure before and after compression therapy between the immediate vs. delayed compression arms.</p>
Site(s)	

<b>Project Period</b>	2/1/2018 - 2/3/2020
<b>Funding Status</b>	Unfunded
<b>Direct Award (USD)</b>	
<b>Update</b>	For the randomized controlled trial for KS lymphedema (KICKS study), we are now closed for enrollment due resource limitations, challenges with enrollment, and preliminary data suggesting a positive effect of immediate compression therapy at time of chemotherapy initiation for KS. In addition to preliminary data, key accomplishments of the study include management of cases of chronic leg ulcers and lymphedema related to Kaposi Sarcoma, with the use of zinc oxide paste bandage (Unna boot). This has made the health facility where the study is being carried out to adopt the dressing technique of using the zinc oxide paste bandage to treat some chronic leg ulcers (mainly traumatic and venous) and they believe it is effective. Challenges with the study include: difficulty achieving the targeted number of study participants due to: 1) irregular occurrence of oncology clinic at Chulaimbo where patients are recruited and 2) transport subsidy does not cover the cost of transportation for patients, many of whom travel from Homa Bay and Migori county. For the retrospective chart review aim, we have completed data extraction and are in the process of data analysis. We have also compiled a case series illustrating the various uses of the compression bandages.
<b>Future Plans</b>	During the next 6 months, we have several goals. 1) As mentioned, the KICKS study is now closed for enrollment. Assessment of study participants will be completed by May 2020. At that point, we will begin data analysis and abstract/manuscript preparation. 2) We will be submitting the case series for publication. 3) For the retrospective chart review, we will complete data analysis and abstract/manuscript preparation.
<b>Publication(s)</b>	
<b>Study Title</b>	<b>Harambee: Integrated Community-Based HIV/NCD Care &amp; Microfinance Groups in Kenya</b>
<b>Principal Investigator(s)</b>	Omar Galarraga, Brown University
<b>Co-Investigator(s)</b>	Becky Lynn Genberg, Other
<b>Working Group(s)</b>	Adult Medicine (AMWG) Cardiovascular and Metabolic Disease (CVMD)
<b>Description</b>	Sustained viral suppression (VS) continues to present major challenges to HIV treatment and prevention. Retention in care is a particularly challenging issue for persons living with HIV (PLHIV) because of lack of convenient access and issues related to economic stability. Our long-term goal is to help achieve the 90-90-90 goals through improved care delivery based on rigorous implementation research. The objective of this project is to demonstrate the effectiveness and longer-term sustainability of a differentiated care delivery model for improving HIV treatment outcomes. The central hypothesis is that the integration of HIV care delivery and community-based primary care with group-based microfinance will improve retention and rates of VS among PLHIV in Kenya via two

	<p>mechanisms: improved household economic status and easier access to care. Thus, the specific aims are as follows: (1) To evaluate the extent to which integrated community-based HIV care with group microfinance affects retention in care and VS among PLHIV in rural western Kenya using a cluster randomized intervention design of existing (fully HIV+) microfinance groups to receive either: (A) integrated community-based HIV care, or (B) standard care. We will also augment trial data with a matched contemporaneous control group of patients in standard care (group C) comparing outcomes in groups A, B and C; (2) To identify specific mechanisms through which microfinance and integrated community-based care impact VS: Using a mixed methods approach, we will characterize the mechanisms of effect on patient outcomes. We will conduct quantitative mediation analysis to examine two main mediating pathways (household economic conditions and easier access to care), as well as exploratory mechanisms (food security, social support, HIV-related stigma). We will also use qualitative methods and multi-stakeholder panels to contextualize the implementation of the intervention; and (3) To assess the cost-effectiveness of microfinance and integrated community-based care delivery to maximize future policy and practice relevance of this promising intervention strategy. Our working hypothesis is that the differentiated model will be cost-effective in terms of cost per HIV suppressed person-time, cost per patient retained in care, and cost per disability-adjusted life year saved. This project is part of the Academic Model Providing Access to Healthcare (AMPATH) program in western Kenya which cares for more than 150,000 PLHIV at over 500 sites in western Kenya since 2001. The main expected outcomes will be rigorous evidence of effectiveness, mechanisms and cost-effectiveness of a differentiated model for achieving the last key step in the HIV care continuum. These results are expected to have an important positive impact in terms of improved, high-quality services that address known individual and structural barriers to care and promote long-term sustainability of care for PLHIV in rural settings with high HIV prevalence.</p>
<b>Site(s)</b>	<p>Burnt Forest Sub-District Hospital, Busia District Hospital, Cherangany Health Centre, Chulaimbo Sub-District Hospital, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mois Bridge Health Centre, Mosoriot Rura</p>
<b>Project Period</b>	<p>7/5/2019 - 4/30/2024</p>
<b>Funding Status</b>	<p>Funded - NIH - National Institute of Mental Health (NIMH)</p>
<b>Direct Award (USD)</b>	<p>Not Reported</p>
<b>Update</b>	<p>Over the past 6 months, the following major activities have been accomplished: The study was reviewed and approved by the Institutional Review and Ethics Committee (IREC) at Moi University/Moi Teaching and Referral Hospital. An IRB Authorization Agreement (IAA) has been established between Brown University and Moi University such that IREC will serve as the IRB of record for the project duration. A two-week mapping exercise aimed at identifying eligible microfinance (MF) groups was completed in the three counties targeted for study implementation: Busia, Bungoma and Trans Nzoia. Study personnel in Kenya have verified the availability of all laboratory and diagnostic equipment in the target counties. This laboratory equipment will be used to perform viral load testing which will inform the study's primary outcome: HIV viral suppression (HIV-RNA &lt;1,000 copies) at 18 months. A research assistant has been hired to support community mobilization and study implementation in Trans Nzoia county. Standard</p>



Operating Procedures are currently being developed to guide standardized implementation of the intervention across all MF groups. These SOPs are expected to be ready for pilot testing by 2/1/2020. Biweekly meetings of the internal research team and monthly meetings with all investigators have been established and are ongoing. Preliminary findings from the mapping exercise (conducted in November 2019) indicate that 22 of the 46 identified MF groups had 100% HIV positive members and 7 of the 46 had >70% HIV positive members. In Busia and Bungoma counties, there are existing AMPATH community ART groups that are functioning well but that do not currently include a microfinance component. In Tranz Nzoia county, there is a high level of interest from existing MF groups to participate in the study. The mapping exercise identified some MF groups that were not initially mentioned for inclusion by the Family Preservation Initiative but that may offer some additional opportunities for study recruitment. The greatest challenge to study progress thus far has been identifying a sufficient number of existing microfinance groups that are eligible for study participation. During the mapping exercise, our reach team discovered that there were significantly fewer MF groups for which 100% of members were persons living with HIV (PLHIV) than originally anticipated. We are unable to move forward with implementation of the intervention until we identify enough groups to ensure that our study is at least 80% powered to detect an effect size.

#### Future Plans

In the next 6 months, we hope to accomplish the following activities:  
 Complete a second round of mapping in Busia and Bungoma counties to identify additional MF groups who are eligible for study participation. This second round of mapping has already begun such that we anticipate being able to finalize the list of MF groups to invite to participate by the beginning of February 2020.  
 Finalize the Overall Project Protocol and the Aim 1 standard operating procedures (SOPS) by the beginning of February 2020 so that we can begin pilot testing these protocols in select MF groups starting in April 2020.  
 Begin community mobilization activities for the eligible groups that have already been identified in Trans Nzoia. The already hired Research Assistant will play an integral part in community mobilization.  
 Begin baseline assessments and informed consent procedures in eligible MF groups beginning in April 2020 in Trans Nzoia county.

#### Publication(s)

#### Study Title

**HI-Train: Health Informatics Training and Research in East Africa for Improved Health Care**

#### Principal Investigator(s)

Abraham Siika, Moi University

#### Co-Investigator(s)

Martin Were, Other

#### Working Group(s)

None

#### Description

With increased deployment of eHealth systems, comes the need for an appropriate health information technology workforce. This workforce includes: (a) Local level: Health IT professionals, eHealth specialized programmers, data managers, implementation managers, support specialists and reporting personnel; (b) Institutional level: chief

medical information officers; and health information management specialists, (c) administrative: regional and national eHealth coordinators and eHealth monitoring and evaluation specialists, and (d) Other: health information privacy and security specialists and HI researchers. End users, institutional managers and policy makers also need to be appropriately trained on the relevant eHealth systems. Alarming, most sub-Saharan countries remain woefully unprepared to systematically train an adequate workforce to support the eHealth systems already being deployed. Countries like Uganda and Kenya recognize an emergent need for national strategies to build health informatics human capacity. These countries have appropriately developed national eHealth capacity-building strategies. Implementing the strategies however requires direct leadership by Higher Education Institutions in the relevant countries. The urgency for sustainable mechanisms to increase HI workforce and research capacity in developing countries is self-evident. This goal can only be realized by having enough faculty members from developing countries fully trained in Health Informatics. These staff faculty can then be part of a well-functioning and high quality HI program moving forward. Recognizing this need, and the multidisciplinary competencies needed for HI training and research, our team identified partner institutions with complementary capabilities to support advanced Health Informatics training in East Africa for our project.

Aims

- 1) Provide post-graduate (Masters and PhD) level training in Health Informatics and research. The focus will be on post-graduate training for health professionals and computer science personnel to help them become HI faculty at their institutions.
- 2) Increase number of women and marginalized populations in faculty-level training in Health Informatics and research at the LMIC higher education institutions.
- 3) Improve the quality and quantity of Health Informatics research conducted primarily by re-searchers based in the LMIC countries in collaboration with our Northern partners.
- 4) Provide model curricula, educational programs and approaches for faculty-level health informatics training that can be emulated by regional higher education institutions.

Site(s)

Moi University, Makerere University, University of Bergen

Project Period

12/5/2013 - 6/30/2019

Funding Status

Funded - NORAD - Norwegian Agency for Development Cooperation

Direct Award (USD)

\$2,757,830

Update

Six of MSc. HI Students graduated in August 2019. Four of our female students presented papers in Greece in July 2019 while Two students plus One Faculty presented papers in the Helena Conference in Bostwana in November 2019. We face the challenges of having students who are working and doubling with studies manage and maintain their classes.

Future Plans

Publication(s)

Study Title

**HIV-related Outcomes After Integration of HIV and Maternal and Child Health Services at Moi Teaching and Referral Hospital in Kenya (HAMMoCK)**



Principal Investigator(s)	John Humphrey, Indiana University
Co-Investigator(s)	Julia Songok, American Medical Informatics Association (AMIA)
Working Group(s)	Adult Medicine (AMWG) Pediatric (PRWG)
Description	The integration of HIV services within maternal and child health (MCH) services is a recently implemented strategy to improve outcomes for pregnant and postpartum women and their HIV-exposed infants (HEI) in Kenya. However, there are significant evidence gaps concerning the outcomes of HIV-infected pregnant and postpartum women and their HEIs who receive integrated HIV-MCH services. The overall objective of this study is to understand the outcomes of HIV-infected pregnant and postpartum women and their HEIs who receive integrated HIV-MCH services at Moi Teaching and Referral Hospital. Our specific aims are: 1) Describe HIV-infected women's engagement in the HIV care (time to ART initiation, adherence to clinic visits, retention, linkage of infant into care, retention of infant to post-breastfeeding HIV testing) cascade during pregnancy and the subsequent 2 years; 2) Determine the viral suppression rates for HIV-infected pregnant and postpartum women attending integrated HIV-MCH clinics at MTRH; 3) Determine the MTCT rate for infants of HIV-infected women enrolled in integrated HIV-MCH clinics at MTRH at 2 months, 12 months, and 18 months post-delivery, and following cessation of breastfeeding. To accomplish these aims, we will utilize leDEA infrastructure to review the AMPATH electronic medical record to identify all HIV-infected pregnant and postpartum women and their HEIs who have received care at an MCH clinic at MTRH from 216 to 217 (n = 1, mother-infant dyads). This research is significant because it will inform strategies for optimal service delivery in the era of Option B+/universal ART eligibility and integrated HIV-MCH services.
Site(s)	Moi Teaching and Referral Hospital
Project Period	3/5/2018 - 6/1/2019
Funding Status	Unfunded
Direct Award (USD)	
Update	An abstract based on the data from this study was developed and submitted to CROI but it was not accepted. We are revising the analysis and planning to move forward with the paper.
Future Plans	Complete a manuscript
Publication(s)	
Study Title	<b>leDEA Comprehensive Adherence Measure for Pediatrics (ICAMP)</b>
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, American Medical Informatics Association (AMIA)

<b>Working Group(s)</b>	Pediatric (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 1-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
<b>Update</b>	The enrollment began at Busia clinic at AMPATH (Busia, Kenya) on 3rd June 2015 and ended on 23rd July 2015. A total of 110 participants were recruited, one withdrew and having 109 completing the study. Children were followed for 6 months of adherence monitoring using Medication Event Monitoring Systems (MEMS <sup>if</sup> ) with at least one viral

load measure. At month 3 and 6, children or their caregivers were administered a 10-item adherence questionnaire. Repeated measures analyses were used to compare responses on questionnaire items to: MEMSif' dichotomized adherence (i.e., 90% of doses taken vs. <90%), 48-hour MEMSif' treatment interruptions, and viral suppression (<1,000 copies/mL). Items associated with outcomes (p<.10) were coefficient-weighted to calculate a total adherence score, which was tested in multivariate regression against MEMSif' and viral suppression outcomes. Odds ratios (OR) and 95% confidence intervals (95%CI) were calculated. In the last 6 months, we finished our analysis and found evidence that using the adherence questionnaire non-adherence was still a major concern for children in Kenya with a mean MEMSif' adherence 75%. Child-reported adherence and caregiver-reported adherence using the questionnaire were consistent with external adherence criteria. Child-reported adherence was significantly associated with dichotomized MEMSif' adherence (OR 1.8, 95%CI 1.4-2.4), 48-hour treatment interruptions (OR 0.41, 95%CI 0.3-0.6), and viral suppression (OR 3.4, 95%CI 1.7-6.7). In conclusion, we found high levels of non-adherence to ART in this cohort of children, while demonstrating the validity of a short questionnaire to screen for nonadherence across diverse global settings. There is no blood specimen remaining in the ARL after doing viral load tests. Other data collected as part of the study will be maintained in a locked cabinet (hard copies) and protected with passwords (soft copies) for 7 years following the last publication after which they will be destroyed. The close-out for this project has been acknowledged by IREC.

**Future Plans**

None

**Publication(s)**

**Study Title**

**IeDEA Sentinel Research Network (IeDEA-SRN)**

**Principal Investigator(s)**

Kara Wools-Kaloustian, Indiana University

**Co-Investigator(s)**

**Working Group(s)**

Adult Medicine (AMWG)

**Description**

Create the IeDEA Sentinel Research Network (IeDEA-SRN), designed to prospectively capture, merge and analyze standardized data on NCDs and implement proof of concept studies focused on cardiovascular disease, liver disease, and alcohol and substance use. Through SRN research, we will enhance data collection capacity, including identification (where applicable), development (where necessary), and validation (where necessary) of standardized instruments for assessments of NCDs and behavioral data. We also will develop laboratory capacity at the sentinel sites, including introduction of rapid point-of-care diagnostics, where appropriate. In collaboration with the Harmonist Team we will expand the IeDEA Data Exchange standard (IeDEA-DES) to facilitate analysis of data drawn from across the IeDEA-SRN. These activities will the following sub-aims (S- SA) in the SRN cohort: S-SA 1a - Determine the prevalence of cardiovascular and metabolic risk factors; S-SA 1b - Examine the burden of alcohol and substance use and the co-occurrence of depressive, anxiety, and PTSD symptoms and their collective impact on HIV treatment

	outcomes; and S-SA 1c - Determine the prevalence of liver fibrosis and liver steatosis and examine associated etiologic factors, including infectious and noninfectious conditions.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/1/2019 - 7/31/2021
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	Not Reported
Update	Award was received last fall 2019 and the protocol and study documents are in their final stages of approval by the Global leDEA regions. EA-leDEA will obtain IU approval after IREC has approved the study. Protocol and study documents are still under revision.
Future Plans	Obtain regulatory approval of mulit-regional protocol and initiate study.
Publication(s)	



Study Title	<b>Implementation Analysis of an Inpatient Family Planning Consultation Services</b>
Principal Investigator(s)	Caitlin Bernard, Indiana University
Co-Investigator(s)	Wycliffe Kosgei, Moi Teaching and Referral Hospital
Working Group(s)	Reproductive Health (RHWG)
Description	We propose the design and implementation of an inpatient family planning service that will address the gap in contraceptive uptake through comprehensive family planning education in addition to the provision of free, effective contraceptive methods in the inpatient setting. The main objectives of this study are to: 1) Determine whether the integration of education and free provision of contraceptive methods as part of an inpatient contraceptive service is feasible, appropriate and acceptable to providers and patients on select wards at MTRH. 2) Evaluate the implementation of an inpatient contraceptive service using measures from the RE-AIM framework.
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/1/2019 - 6/30/2020
Funding Status	Funded - Society for Family Planning
Direct Award (USD)	\$24,942
Update	In the last 6 months, the project proposal including data collection tools were drafted and submitted to the ethics board at MTRH. Approval was granted in Dec 2019. Preliminary meetings with different hospital stakeholders have been held in preparation to initiating the study process.
Future Plans	Over the next 6 months, we aim to conduct in-depth interviews with both caregivers and female patients from different wards in the hospital. We will also hold workshops based

	<p>on Human-Centred Design with all key stakeholders involved to come up with the best solutions and ways of implementing this project. Afterward, the project will be rolled out in gynecology, cardiac care unit, surgery, and internal medicine wards. Patients will be given family planning counseling and offered a method that is appropriate based on existing medical condition(s). They will also be invited to participate in a study on a voluntary basis hence data collection and data cleaning will be done during this period.</p>
<p>Publication(s)</p>	
<p>Study Title</p>	<p><b>Improvements of diagnosis, staging, and support of children with Burkitt Lymphoma</b></p>
<p>Principal Investigator(s)</p>	<p>Terry Vik, Indiana University</p>
<p>Co-Investigator(s)</p>	<p>Festus Njuguna, American Medical Informatics Association (AMIA)</p>
<p>Working Group(s)</p>	<p>Oncology (ORWG) Pediatric (PRWG)</p>
<p>Description</p>	<p>The first objective and aim of this administrative supplement is to improve diagnostic testing including flow cytometry and genetic analysis by Fluorescence in situ Hybridization (FISH), to increase the speed and accuracy of diagnosing Burkitt Lymphoma (BL) in children in Kenya. A second objective and aim will be to use financial interventions that have been shown to decrease the rate of abandonment in other cohorts of patients with BL in Africa to test feasibility to decrease the high abandonment rate at our hospital, MTRH, based on our historical control group. The pilot project to be supported by this supplement will improve infrastructure and train clinical staff in the methods of clinical trial management of children with BL in western Kenya. The research support team for the project will ensure collection of diagnostic and staging information, and coordinate follow-up of patients enrolled on the study. The study will be extended to a second hospital, JOORTH, through collaborators in Kisumu. The study pathologists will coordinate the performance of diagnostic tests including immunohistochemistry, flow cytometry, and eventually FISH studies. Dr. Vance will train the research staff in FISH techniques at the primary performance site, and transfer the technology back to Kenya. The numbers of patients available for study at both the hospitals, MTRH and JOORTH, should make completion of this project feasible, as only 4 confirmed BL patients are needed, and up to 5 patients are diagnosed annually at the combined sites. AMPATH and MTRH will provide infrastructure for the clinical testing and care of patients. The parent cancer center clinical research staff will aid in the auditing of patient charts of children enrolled on the study. Study data will be audited periodically throughout the study to ensure accuracy, completeness of data and compliance with research ethics. The main outcomes to be monitored include: percent of required observations completed, number of patients confirmed to be eligible for the trial, Number confirmed to have a diagnosis of BL by each of the three tests of immunohistochemistry, flow cytometry, or FISH, and number of patients with complete staging by Murphy staging criteria. Additionally, number of patients who abandon treatment will be tracked, along with the time point that they abandon. Finally, overall one-year survival points will also be captured. The aim to improve diagnosis and decrease abandonment by comparing results at the end of the</p>

	study to historical rates will measure the success of this project. Assuming the success of this project, next steps will be to partner with other sites in the region to propose a larger trial with a potential treatment outcome that can be measured and validated across multiple countries and treatment centers, ultimately improving the outcome for children with BL.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/1/2016 - 8/31/2018
Funding Status	Funded - NIH - National Cancer Institute (NCI)
Direct Award (USD)	\$225,072
Update	We have presented study results as posters at 4 meetings. We are writing 2 manuscripts, plus a possible third manuscript is being considered.
Future Plans	Continue to write and edit manuscripts on diagnostics and patient outcomes.
Publication(s)	

<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
<b>Working Group(s)</b>	Pediatric (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 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.
Site(s)	Chulaimbo Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Webuye District Hospital
Project Period	10/1/2016 - 6/30/2019
Funding Status	Funded - Thrasher Research FundYesIU Center for Global Health
Direct Award (USD)	\$57,500
Update	Our recruitment of study participants concluded in the previous period and therefore we had no more recruitment during this period. Within this reporting period, we completed qualitative analysis of previously done key informant interviews and focus group discussions with peer mentors and with adolescents. We presented five abstracts at international conferences. We also had one manuscript published in AIDS Care. Further manuscripts from this project are in preparation.
Future Plans	We hope to complete analysis of quantitative data. We also expect to submit multiple papers for publication in peer-reviewed journals.
Publication(s)	

Study Title	<b>MCH STUDY (Evaluations at Infant and Child Visits a MCHs in western Kenya: A Needs Assessment)</b>
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, American Medical Informatics Association (AMIA)
Working Group(s)	Pediatric (PRWG)
Description	The specific aims for MCH study are : Aim 1: To identify the evaluations and preventative care performed at MCH clinics and identify additional preventative areas that MCH clinical staff are interested in investigating further. Aim 2 :To determine the frequency of visits for children attending MCH clinics and also identify at what ages a child is more likely to have visited the MCH. Aim 3.:To determine the scope to which child development is currently evaluated at the MCH clinics and documented in the Mother and Baby Booklets. The study took place in western Kenya at the following MCH clinics: MTRH, Turbo, Webuye, Mosoriot, Burnt Forest, and Kitale. During this study, we recruited two groups of study participants. The first was clinical staff working at each of the MCHs. The second group were caregivers who brought young children to the MCH. This study was reviewed and approved by the Indiana University School of Medicine Institutional Review Board and the Moi University Institutional Research and Ethics Committee.
Site(s)	Burnt Forest Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training CentreTurbo Health Centre, Webuye District Hospital



Project Period	9/26/2016 - 9/26/2017
Funding Status	Unfunded
Direct Award (USD)	
Update	Results from this study were included within the thesis of Emory University Masters in Public Health graduate, Andrew Deathe, in 2018. His thesis can be seen here: <a href="https://etd.library.emory.edu/concern/etds/4m90dv63t?locale=zh">https://etd.library.emory.edu/concern/etds/4m90dv63t?locale=zh</a> The abstract has been under reviews by the International Journal for Equity in Health Manuscript of the same has also been under reviews Manuscript under review by BMC Health Services Research Editorial Office
Future Plans	Results from this study were included within the thesis of Emory University Masters in Public Health graduate, Andrew Deathe, in 2018. His thesis can be seen here: <a href="https://etd.library.emory.edu/concern/etds/4m90dv63t?locale=zh">https://etd.library.emory.edu/concern/etds/4m90dv63t?locale=zh</a> The abstract has been under reviews by the International Journal for Equity in Health Manuscript of the same has also been under reviews Manuscript under review by BMC Health Services Research Editorial Office
Publication(s)	



Study Title	<b>Mental Health Screening and Phone-Based Counselling Support for Adolescents with HIV in Kenya</b>
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, American Medical Informatics Association (AMIA)
Working Group(s)	Pediatric (PRWG)
Description	The objective of this pilot study is to explore options to provide mental health services and support to Kenyan youth living with HIV (YLWH) using a readily available potential tool-WhatsApp (WA) - and a counselor-guided WhatsApp group designed to provide education and counseling to YLWH. We will gather critical preliminary data related to the use of tele-therapy and tele-peer support for HIV-infected adolescents in Kenya to achieve the study aims. Throughout six months of follow-up, the enrolled group of adolescents will receive group and individual counseling via WhatsApp, with the option for peer group chatting related to key topics as well. In addition, they will receive adherence monitoring, testing for viral suppression, and mental health evaluations at baseline and at 6 months of follow-up. The specific aims are: Aim 1: Assess the feasibility, acceptability, and usability of a cell phone-based intervention to provide mental health services (tele-therapy and tele-peer support) for HIV-infected adolescents in Kenya. Aim 2: Evaluate the user engagement with both the cell phone-based intervention and the clinical care system throughout the monitoring period using counselor reports, usage tracking, and clinical database evaluation. Aim 3: Describe key clinical, mental, and emotional health outcomes for this cohort during the monitoring period, including medication and clinic adherence, viral suppression, depression symptoms and other behavioral or emotional symptom reports, and engagement with support services such as peer support groups.

Site(s)	Turbo Health Centre
Project Period	1/1/2017 - 7/31/2018
Funding Status	Funded - Indiana University - Center for AIDS Research
Direct Award (USD)	\$10,000
Update	<p>Over the last six months adherence data retrieved from electronic dose monitors (MEMS caps) were cleaned and ready for analysis. Quantitative data analysis is ongoing. Twenty-nine ALWH completed the study (1 relocated). Mean age was 15.5 years and 17 (59%) were female. In pre-intervention interviews with 25 participants, ALWH identified important topics to address in the WhatsApp® groups: issues related to "stress" and "anxiety," myths and misconceptions of HIV, confidentiality, and disclosure of HIV status to friends, partners, and others in the community. In post-intervention interviews with 15 ALWH, participants expressed a number of benefits. First, participants used the platform to communicate and build relationships with other ALWH. Second, participants liked having access to a counselor, either through the group chat or one-on-one, to ask HIV-related and general health-related questions. They reported feeling uncomfortable asking their regular health provider these questions. There were several challenges to feasibility and acceptability, including network and power issues with phones, scheduling conflicts for regular chats, and parents not feeling comfortable with the ALWH having access to a phone. Parents' concerns prompted the counselor on several occasions to open up productive communication channels at the family level, that were ultimately deemed helpful to understand the home environment for ALWH. Finally, the younger age group was much less active on the WhatsApp® platform compared to the older group, suggesting that older ALWH may be a more appropriate target for this type of intervention. Preliminary analysis of the qualitative data collected during pre- and post-intervention interviews are described in an abstract entitled "A pilot study of the acceptability and feasibility of a mobile application for peer and counseling support among adolescents living with HIV in Kenya." This was accepted and presented at the 2nd Annual HIV Adolescence Workshop in Nairobi in June 2019 as a poster presentation.</p>
Future Plans	<p>In the next six months, we plan to complete the qualitative and quantitative data analysis on the feasibility and acceptability of the pilot WhatsApp project to support mental health among this cohort of adolescents living with HIV. With these data, we hope to submit more abstracts to conferences for presenting these analyses. These analyses will also be used to support the development of a larger research grant that incorporates WhatsApp technology as a novel telehealth intervention for mental health counseling among adolescents living with HIV.</p>
Publication(s)	
Study Title	<b>NADIA "A randomised controlled trial of darunavir versus dolutegravir and tenofovir versus zidovudine in second-line antiretroviral therapy regimens for the public health approach in sub-Saharan Africa"</b>
Principal Investigator(s)	Abraham Siika, Moi University

Co-Investigator(s)	Charles Kwoba, Moi University
Working Group(s)	None
Description	This is a phase IIIb, open-label, multicenter, factorial (2x2) randomized controlled trial to determine whether a regimen of Dolutegravir (DTG) with two NRTIs is non-inferior to a regimen of DRV/r with two NRTIs as second-line therapy in patients failing on an NNRTI-based first-line regimen in the setting of the public health approach in sub-Saharan Africa. The study also aims to determine whether continuing tenofovir and lamivudine is non-inferior to switching to zidovudine and lamivudine in a second-line therapy regimen in patients failing on an NNRTI-based first-line regimen in the setting of the public health approach.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/5/2019 - 12/31/2022
Funding Status	Not Reported
Direct Award (USD)	\$289,161.65
Update	Screening commenced on 09/September/2019 with a total of 90 participants screened. Out of these, 51 participants were enrolled into the trial and will be followed up for 96 weeks. This being a multi centre trial, enrollment closed on 13th December 2019 because the protocol sample size had been attained.
Future Plans	Continue follow up of participants as per protocol schedule.
Publication(s)	

Study Title	<b>NEURODEV (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study)</b>
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, American Medical Informatics Association (AMIA)
Working Group(s)	Pediatric (PRWG)
Description	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

	<p>clinicians to understand current knowledge and beliefs about NDDs. FGDs were chosen for caregivers to generate information on collective views of neurodevelopment and the meanings and implications that lie behind those views. SSIs were chosen for clinical staff to address several key questions specific to their individual training and experiences, while allowing both the interviewer and clinical staff to further pursue an idea or response in more detail. Phase Two will allow us to pilot key methods needed for future validation testing of these items. As we aim towards a large validation study to assess the reliability and validity of these screening questions in this setting, we will conduct prospective feasibility testing, piloting these questions during cognitive interviews with caregivers and clinical officers, in the clinical setting in Kenya and also piloting the implementation of the gold standard for developmental screenings - lengthy, comprehensive developmental assessments of young children. No modifications have been made to the specific aims as stated in the original proposal. We have ongoing Institutional Review Board and local ethics committee approval for the aims.</p>
Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital, Port Victoria Sub-District Hospital, Turbo Health Centre, Webuye District Hospital
Project Period	1/10/2016 - 9/30/2017
Funding Status	Funded - Indiana University - Center for AIDS Research
Direct Award (USD)	\$597,800
Update	We shipped our existing stored study samples to the U.S. for further testing of immunological and inflammatory factors associated with development delays in this population
Future Plans	Data entry, data cleaning and verification was done and currently we are data analysis stage.
Publication(s)	



Study Title	<b>Neuropsychiatric Genetics of African population-P</b>
Principal Investigator(s)	Prof. Lukoye Atwoli, Moi University
Co-Investigator(s)	Dr Edith Kwobah, Moi University
Working Group(s)	Behavioral and Social Sciences (SSRN)
Description	<p>The study takes a control a case-control design.Cases will be individuals with Schizophrenia or Bipolar disorder and controls will be age,sex and ancestry matched individuals from the same geographic locations.SpecificAims 1.To determine the phenotypic presentation of psychotic disorders in African population.2 To describe the genetic variation between patients with psychotic disorders and those without in African Population. 3. To examine the association between genetic variation and risk for schizophrenia and bipolar disorder in African population. 4. To provide opportunities for</p>

	training of African scientists in Neuropsychiatric Genetics research. The Moi site will recruit a total of 4000 participants over 4 years consisting of 2000 cases and 2000 controls. The study is an opportunity for Kenya to be involved in Neuropsychiatric Genetic Research and therefore contribute to subsequent treatment innovations that may arise from insights from the Genetic research.
Site(s)	Iten District Hospital, Kapenguria District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Webuye District Hospital, Kakamega and Kapsabet County Hospitals
Project Period	2/28/2017 - 7/1/2021
Funding Status	Funded - Broad Institute of MIT and Harvard.
Direct Award (USD)	\$467,000
Update	We have recruited 617 participants in the last six months. We have had regular meetings and continuous training as per the protocol which has enabled us to get quality data.
Future Plans	1. Continue with site recruitment 2. Focus on recruiting Female Case participants. 3. Ship more samples to the Broad Institute for Analysis. 4. Matching the case - control participants.
Publication(s)	

Study Title	<b>Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK)</b>
Principal Investigator(s)	Valentin Fuster, Mount Sinai School of Medicine
Co-Investigator(s)	Jemima Kamano, Moi University
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)
Description	Hypertension awareness, treatment, and control rates are low in most regions of the world. A critical component of hypertension management is to facilitate sustained access of affected individuals to effective clinical services. In partnership with the Government of Kenya, the Academic Model Providing Access to Healthcare (AMPATH) Partnership is expanding its clinical scope of work in rural western Kenya to include hypertension and other chronic diseases. However, linking and retaining individuals with elevated blood pressure to the clinical care program has been difficult. To address this challenge, we propose to develop and evaluate innovative community-based strategies and initiatives supported by mobile technology. The objective of this project is to utilize a multi-disciplinary implementation research approach to address the challenge of linking and retaining hypertensive individuals to a hypertension management program. The central hypothesis is: community health workers (CHWs), equipped with a tailored behavioral communication strategy and a smartphone-based tool linked to an electronic health record, can increase linkage and retention of hypertensive individuals to a hypertension care program and thereby significantly reduce blood pressure among these patients. We further hypothesize that these interventions will be cost-effective. To test these hypotheses and achieve the overall objectives, we will pursue the following specific aims: Aim 1: Identify the facilitators and barriers to linking and retaining individuals with high

blood pressure to a hypertension care delivery program, using a combination of qualitative research methods: 1) baraza (traditional community gathering) form of inquiry; 2) focus group discussions among individuals with elevated blood pressure during home-based testing; and 3) focus group discussions among CHWs. **Subsidiary Aim 1.1:** Using identified facilitators and barriers, develop a tailored behavioral communication strategy guided by the Health Belief Model modified by incorporating emotional elements for the CHWs to use with hypertensive patients, focusing on regular and timely attendance at hypertension clinic. We will test the communication strategy for face and content validity using focus group discussions with CHWs and individuals with elevated blood pressure. **Subsidiary Aim 1.2:** Using identified facilitators and barriers, develop a smartphone-based tool linked to the AMPATH Medical Record System (AMRS) to be used by CHWs to optimize linkage and retention of hypertensive patients to the care program, and evaluate the usability and feasibility of this tool using think-aloud technique, mock patient encounters, focus group discussions, and participant observation. **Aim 2:** Evaluate the effectiveness of CHWs equipped with a tailored behavioral communication strategy and a smartphone-based tool in improving linkage and reducing blood pressure among hypertensive patients, by conducting a cluster randomized trial comparing: 1) usual care (CHWs with standard training on recruitment of individuals with any chronic condition); 2) CHWs with an additional tailored behavioral communication strategy; and 3) CHWs with a tailored behavioral communication strategy and also equipped with smartphone-based tool linked to the AMRS. The co-primary outcome measures will be: 1) documented linkage to care following home-based testing, and 2) one year change in systolic blood pressure among hypertensive individuals. **Aim 3:** Evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial. Cost effectiveness will be presented both in terms of costs per unit decrease in blood pressure and in terms of costs per reductions in cardiovascular disease (CVD) risk by extrapolating one-year blood pressure reductions to CVD risk reductions based on the QRISK2-211 CVD risk calculator specific for Black African populations. This research will generate innovative and productive solutions to the expanding global problem of hypertension, and will add to existing knowledge on scalable and sustainable strategies for effectively managing hypertension and other chronic diseases in low- and middle-income countries.

<b>Site(s)</b>	Mosoriot Rural Health Training Centre, Turbo Health Centre
<b>Project Period</b>	4/1/2012 - 3/31/2019
<b>Funding Status</b>	Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)
<b>Direct Award (USD)</b>	\$2,104,519
<b>Update</b>	Aim 1 (barriers & Facilitators to Linkage/Retention 1. All activities complete at this time. <b>Subsidiary Aim 1.1 (Behavioral Assessment and Communication Strategy)</b> 1. Manuscript in preparation <b>Subsidiary Aim 1.2 (Smart-phone-based tool)</b> 1. All activities complete at this time. <b>Aim 2 (Cluster RCT)</b> 1. Final outcomes analysis a) Final outcomes analysis completed and manuscript published in the Journal of the American College of Cardiology 2. Process evaluation analysis ongoing, and manuscript in preparation <b>Aim 3 (Cost Effectiveness Analysis)</b> 1. All activities complete at this time.

Future Plans	Preparation and finalization of manuscripts.
Publication(s)	
Study Title	<b>Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)</b>
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	W. Nyandiko, American Medical Informatics Association (AMIA)
Working Group(s)	Pediatric (PRWG)
Description	The purpose of this study is to assess the effect of a patient- and family-centered intervention guiding disclosure to HIV-infected Kenyan children using a randomized trial comparing the intervention to routine care. The primary endpoint will be probability of disclosure among children, with secondary endpoints of adherence, clinical outcomes, psychological distress and social outcomes. Phase One, which will last 6 months, focuses on cultural adaptation of the intervention materials through intensive patient participation, including focus groups and cognitive interviewing; selecting narrative components; and training dedicated disclosure counselors. Phase Two consists of a randomized design to examine whether the culturally adapted, multi-component HADITHI intervention increases the prevalence of disclosure to HIV-infected children in western Kenya compared to children receiving usual care. HIV-infected children ages 1-15 years who are enrolled in HIV care within the eight selected AMPATH clinics in western Kenya will be eligible for study enrollment and have a comprehensive patient assessment every 6 months for 2 years.
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	9/1/2012 - 9/1/2016
Funding Status	Funded - NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	\$1,886,804
Update	This was a cluster-randomized trial of a counseling intervention that consisted of a curriculum for disclosure and adherence counseling (video-taped narratives and animated, tablet-based educational modules), dedicated counselors to provide family and one-on-one, facilitated peer support groups, and additional materials including pamphlets, FAQ summaries, written narratives for discussion. The primary outcome was disclosure status, treated as a time-to-event outcome, measured on a discrete time scale. All study intervention and follow-up of patients are complete, and continued with analyses of the data. We followed 285 child-caregiver dyads (children ages 10-14) attending eight HIV clinics (randomized to intervention or control) in Kenya. Participants at intervention clinics received intensive counseling with trained disclosure counselors and culturally-tailored materials, compared to control clinics with standard care. Disclosure was treated as a time-to-event outcome, measured on a discrete time scale,



with assessments at 0, 6, 12, 18, and 24 months. Mental health and behavioral outcomes were assessed using standardized questionnaires. The Mean age was 12.3 years (standard deviation [SD] 1.5), 52% were female, with average time-on-treatment of 4.5 years (SD 2.4). Between 0 and 6 months, disclosure prevalence increased from 47% to 58% in the control group and from 50% to 70% in the intervention group. Differences in disclosure were not sustained over the following 18 months. The prevalence of depression symptoms was significantly higher in the intervention compared to the control group at 6 months (odds ratio 2.07, 95%CI 1.01, 4.25); however, there was no evidence that these differences were sustained after 6 months. The clinic-based intervention increased disclosure of HIV status to children living with HIV in the short-term, resulting in earlier disclosures, but had less clear impacts longer-term. Though well-tailored interventions may support disclosure, children may still experience increased levels of depression symptoms immediately following disclosure. A manuscript detailing the analyses related to the first specific aim of HADITHI, entitled "Evaluating a patient-centered intervention to increase disclosure and promote resilience for children living with HIV in Kenya," was published in the journal AIDS. Vreeman RC, Nyandiko WM, Marete I, Mwangi A, McAteer CI, Keter A, Scanlon ML, Ayaya SO, Aluoch J, Hogan J. Evaluating a patient-centred intervention to increase disclosure and promote resilience for children living with HIV in Kenya. AIDS. 2019 June 1;33 (Suppl 1):S93-S101.

**Future Plans**

Over the next 6 months, we plan to:  
 Complete data analyses for all study objectives.  
 Complete analyses of drug level concentrations on hair samples to assess drug adherence that were sent to University of California San Francisco.  
 Draft additional manuscripts for publications on our findings.

**Publication(s)**

**Study Title**

**Pharmacovigilance in a Resource-Limited Setting: Approaches to Targeted Spontaneous Reporting for Suspected Adverse Drug Reactions to Antiretroviral Treatment**

**Principal Investigator(s)**

Paula Braitstein, University of Toronto

**Co-Investigator(s)**

B Jakait, Moi Teaching and Referral Hospital

**Working Group(s)**

None

**Description**

Little is known about the toxicity profile of combination antiretroviral treatment (cART) in African populations where genetic differences, co-morbidities, and malnutrition together may influence the adverse reactions of cART in this population. The purpose of this project is to evaluate the feasibility and effectiveness of five approaches to Targeted Spontaneous Reporting (TSR) for documenting SADR in the resource constrained clinical setting in western Kenya. The approaches include; TSR 1: The completion of the Kenya National Suspected Adverse Drug Reaction form for patients with a change or discontinuation in their cART. These forms are then forwarded on to the National pharmacovigilance (PV) office at the Pharmacy and Poisons Board (PPB) in Nairobi. TSR 2: Use of routinely-used clinical encounter forms that have been enhanced to specifically

	collect a relatively small amount of SADR data to be collected by the provider seeing the patient during the clinical visit. TSR 3 and TSR 4: Involve conducting in-depth interviews on 1, 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)	Khunyangu Sub-District Hospital, Moi Teaching and Referral Hospital
Project Period	10/1/2012 - 12/31/2013
Funding Status	Funded - World Health Organization (WHO)
Direct Award (USD)	\$162,000
Update	We are analyzing and summarizing the data within AMRS.
Future Plans	We hope to have completed the analyses of data
Publication(s)	

<b>Study Title</b>	<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, American Medical Informatics Association (AMIA)
Working Group(s)	Adult Medicine (AMWG) Pediatric (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 1-19 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

	<p>(AMPATH) Center, a large HIV treatment and research facility in western Kenya, in collaboration with Indiana University and Brown University. We will enroll 2 HIV-infected adolescent-mother dyads in whom the mode of infection is uncertain and 1 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.</p>
Site(s)	Moi Teaching and Referral Hospital
Project Period	5/1/2017 - 4/30/2018
Funding Status	Funded - Indiana CTSI
Direct Award (USD)	\$20,000
Update	We are 90% completed with recruitment; the first batch of patient samples have been shipped to Brown University Dr. Rami Kantor for analysis, likely to start in the Spring of 2020.
Future Plans	We hope to begin HIV sequencing and ship the remaining samples from Kenya to the Kantor lab.
Publication(s)	
Study Title	<b>Pregnancy and Infancy</b>
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	
Working Group(s)	Pediatric (PRWG)
Description	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 42 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 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
Project Period	10/23/2017 - 10/23/2019
Funding Status	Unfunded
Direct Award (USD)	
Update	Over the last 6 months, enrolment was conducted and stopped at a total of 280 participants in October 2019. Of these, 2 participants withdrew. Of the remaining 278 participants, there have been 39 cases of death spread over the period of admission at the NBU and post-discharge up to the 6th month follow up and 1 case of a baby being abandoned by guardians. Also, an amendment was submitted to the ethics board (IREC) to perform in-depth interviews from the group of participants already enrolled in the larger study. The objective of this is to identify which outcomes are important to parents of children affected by Perinatal Asphyxia up to one year of age. Approval has been granted. With all of the active participants having been discharged, we are currently conducting subsequent follow up of the participants at the Neonate Outpatient Clinic (NOPC) at MTRH as well as completing development assessment of the neonates at the age of 6 months based on corrected age.
Future Plans	In the next 6 months, we aim to continue conducting follow up of the neonates at the NOPC clinic in MTRH as well as conducting the 6-months development assessment. We also aim to begin 9 & 12 months development assessment follow up in February and May 2020 respectively as well conduct the additional in-depth interview aspect of the study. Data cleaning will be done concurrently with data collection activities. Once all the baseline data has been collected, a preliminary data analysis will be done.
Publication(s)	
Study Title	<b>Prospective study of Lopinavir based ART for HIV Infected children Globally (LIVING study)</b>
Principal Investigator(s)	Prof. Winstone Nyandiko, Moi University
Co-Investigator(s)	Prof. Samuel Ayaya, American Medical Informatics Association (AMIA)
Working Group(s)	Pediatric (PRWG)
Description	The study entitled Prospective study of Lopinavir based ART for HIV Infected children Globally (LIVING study) is an open-label, prospective, non-randomized, multi-centre, single arm phase IIIb clinical study. It is looking at a new formulation of lopinavir/ritonavir (LPV/rtv) that has been developed as pellets (very small tablets) that do not require refrigeration, do not contain alcohol and are expected to be more acceptable than LPV/rtv

	liquid for infants and young children. This implementation study is being carried out to provide supportive clinical data on the feasibility, effectiveness, safety, and tolerance, pharmacokinetics and acceptability of LPV based therapies in routine treatment setting. Primary objective: Evaluate the effectiveness of LPV/r pellets in addition to AZT/3TC (or ABC/3TC) paediatric fixed dose combination (FDCs) tablet under routine treatment conditions in HIV infected infants and young children who cannot swallow tablets. Secondary objectives: Document the safety of LPV/r pellets and AZT/3TC or ABC/3TC. Assess the population pharmacokinetics of LPV/r and NRTIs when administered as LPV/r pellets plus AZT/3TC or ABC/3TC. Measure adherence to the new formulation. Evaluate children acceptability of the LPV/r pellets and associated dual NRTIs as well as ease of use by the caregiver. (It has to be noted that this study is not intended to compare the treatment modalities, but rather to evaluate in field/programmatic conditions their individual effectiveness and safety in different settings of some of the most affected endemic countries.)
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu District Hospital
Project Period	6/1/2016 - 12/31/2018
Funding Status	Funded - Drugs for Neglected diseases initiative - Geneva
Direct Award (USD)	\$225,180
Update	Progress made so far in the last six months has been on data cleaning. All the queries raised by the data management team have been responded to and now we are waiting for database lock. An abstract has been prepared for presentation to international and regional conferences. Attached is one of them on "Lopinavir/ritonavir pellets acceptability to caregivers, infants and children in the LIVING study" The Abstract is being submitted to the Publication Review Committee
Future Plans	The major progress expected over is to have the data cleaning process completed and analysis to be done for the whole data set for manuscript writing and publication
Publication(s)	

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
Working Group(s)	Oncology (ORWG)
Description	Patients will be randomized to one of two treatment arms: either standard, intravenously delivered CHOP, delivered over six 3-week cycles or oral chemotherapy delivered over three 6-week cycles. Formal assessment of objective response (complete response [CR]/partial response [PR]/stable disease [SD]) will be performed following cycle 6 for CHOP and following cycle three for the oral regimen, and the patient will then be followed

	for relapse and survival. Patients found to have progressive disease (PD) at any time will come off study and receive the local standard of care treatment for their disease.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/1/2015 - 8/31/2018
Funding Status	Funded
Direct Award (USD)	\$75,000
Update	The study has been closed for enrollment at our site and we have also completed following up the enrolled study participants.
Future Plans	Data analysis is expected to start once follow-up of study participants is completed in other participating study sites in Sub-Saharan Africa.
Publication(s)	



Study Title	<b>SAFI (Stigma in AIDS Family Inventory) Validation Study</b>
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, American Medical Informatics Association (AMIA)
Working Group(s)	Pediatric (PRWG)
Description	For families raising HIV-infected children in resource-limited settings, HIV/AIDS-related stigma shapes every aspect of the children's HIV management, from daily adherence to medication to decisions about pediatric HIV disclosure. We do not know the most effective strategies to reduce stigma for HIV-infected children and their families in resource-limited settings nor how to measure its effects on physical, emotional, or social outcomes. We want to learn more about how stigma affects families. As part of the HADITHI study, SAFI aims to develop and test a reliable, valid instrument to measure HIV/AIDS stigma as perceived, enacted, and internalized by Kenyan families with HIV-infected children. The specific aims for the SAFI validation study are to: Aim 1: Identify and modify H/A stigma questionnaire items for maximum reliability and content validity to measure perceived, enacted and internalized H/A stigma among Kenyan families with HIV-infected children. Aim 2: Assess the validity of the measures of perceived, enacted and internalized H/A stigma compared to independent construct measures including pediatric adherence to therapy and children's physical, psychological and social outcomes. Aim 3: Examine whether disclosure of a child's HIV status to the child reduces perceived, enacted, or internalized stigma for families with disclosed children compared to families with non-disclosed children. We thus propose assembling, adapting, and then validating measurement items for assessing the relevant domains of H/A stigma experienced by HIV-infected children and their caregivers in sub-Saharan Africa.
Site(s)	Burnt Forest Sub-District Hospital, Chulaimbo Sub-District Hospital, Khunyang 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>	12/17/2013 - 11/30/2015
<b>Funding Status</b>	Funded - NIH - National Institute of Mental Health (NIMH)
<b>Direct Award (USD)</b>	\$567,828
<b>Update</b>	<p>We were able to complete and publish analyses for validating this stigma measurement questionnaire among children and their caregivers. In these analyses, we found that our stigma evaluations revealed a significant degree of HIV-related stigma with which families in western Kenya are coping. Among our cohort of 285 children and their caregivers, almost half of children reported that it was important to keep HIV status secret. About 10% reported delays taking their medicines so that others would not see. Between 7%-14% of children and caregivers reported feeling stress, anxiety, depression, and sadness due to child's HIV status. The stigma instrument showed high validity compared to emotional and behavioral outcomes, and our findings were able to contribute to the limited literature on the reliability and validity of stigma measures for children living with HIV in sub-Saharan Africa. Test-retest reliability was high; responses by both children and caregivers were consistent from month 18 to 24. Both child and caregivers' stigma questionnaire item responses showed high construct validity with the Strengths and Difficulties Questionnaire (SDQ), while several caregiver stigma items also showed construct validity with the GHAC General Health domain, MEMS <sup>®</sup> adherence, and viral loads. The stigma measurement items showing the highest construct validity were questions related to:</p> <ul style="list-style-type: none"> <li>• Experiencing discrimination</li> <li>• Feeling stressed and/or anxious due to HIV stigma</li> <li>• Feeling depressed and/or sad due to HIV stigma</li> <li>• Hopes for future changing negatively due to HIV</li> </ul> <p>Thus, this initial study of the SAFI questionnaire reveals that HIV-infected children and their caregivers in this Kenyan cohort reported fearing or experiencing HIV stigma, with caregivers generally reporting higher levels of stigma. The SAFI instrument has utility for screening for HIV-related stigma among children and their families, as demonstrated by construct validity with primary criterion constructs.</p>
<b>Future Plans</b>	<p>We will continue analyses to assess whether the utility of the SAFI instrument could be improved by testing to reduce number of items for a short-form questionnaire. The PIs have worked to incorporate the SAFI questionnaire in several ongoing or new studies, including the Adolescent Cohort Evaluation being conducted through East Africa IeDEA and the planned global IeDEA adolescent cohort (the Adolescent and Young Adult Network of IeDEA - AYANI.) We also have supported a Fogarty scholar (Grant Callen) to begin additional qualitative work specifically focused on further evaluating the impact of stigma on adolescents and young adults living with HIV and how it might shape their experiences of care services and support services. A manuscript describing the results of this study has been published. Citation provided under publication.</p> <p>Note: Analyses still underway through December 2020.</p>
<b>Publication(s)</b>	Vreeman RC, Scanlon ML, Tu W, Slaven JE, McAteer CI, Aluoch J, Ayaya S, Nyandiko WM. Validation of an HIV/AIDS stigma measure for children living with HIV and their families.



Journal of the International Association of Providers in AIDS Care. 2019 Jan-Dec;18:2325958. PMID: 31581890

<b>Study Title</b>	<b>Spatial scales of Plasmodium falciparum generations; implications for elimination</b>
<b>Principal Investigator(s)</b>	Andrew Obala, Moi University
<b>Co-Investigator(s)</b>	Wendy O'Meara, Duke University
<b>Working Group(s)</b>	Public Health and Primary Care (PHPCWG)
<b>Description</b>	<p>Malaria is a major public health problem, with an estimated 198 million cases occurring world-wide in 213. Effective strategies to reduce malaria transmission and disease have been highly successful leading to a 4% reduction in malaria cases in sub-Saharan Africa since 2002. 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 8 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 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.</p>

Site(s)	Moi Teaching and Referral Hospital, Webuye District Hospital
Project Period	2/15/2017 - 1/31/2019
Funding Status	Funded - NIH
Direct Award (USD)	Not Reported
Update	<p>The Aim 2 extension period of 24 months rather than 18 months ended in July 2019. During the extension period, weekly entomology collections and monthly survey and DBS collections continued through July 2019. DBS and Mosquito samples have all been shipped to Dr. Taylor's lab at Duke in the U.S and are now undergoing processing. Preliminary analysis has been done and the results were presented at the ASTMH conference in Maryland in December 2019. Main outcome paper is under development with prospects of publishing it before the end of 2020. After the end of the study period in July 2019, we immediately received R01 funding which has enabled study extension for five years. The protocol has been amended and approved by IREC and Duke IRB to expand the period of observation to 60 months, increased the number of villages to 5 and expanded the number of households to 75. A lab assay to match parasites found in mosquitoes to those found in household members has been added to determine which individuals are bitten most frequently by malaria vectors. We have developed the SOPs and trained staff on the revised study protocol. We started the annual, monthly DBS and on-demand sick visit surveys in January 2020. The household mosquito collection also started in January 2020.</p>
Future Plans	<p>We plan to publish the R21 main outcome paper before the end of the year. We will continue with study activities; monthly DBS visit, on-demand sick visit surveys and household mosquito collections. Abstract presentation: Estimating contributions to malaria transmission by measuring individual human-to-mosquito Plasmodium falciparum transmission events in a natural setting using parasite genotyping and longitudinal host sampling. Kelsey M. Sumner, Elizabeth Freedman... Steven Taylor, Wendy Prudhomme-O'Meara Children with clinical Plasmodium falciparum infection have increased sharing of haplotypes with household members as well as temporally-proximal, symptomatic peers. Cody S. Nelson, Kelsey M. Sumner, Betsy Freedman... Steve M. Taylor, Wendy P. O'Meara Epidemiology of subpatent P falciparum infections identified by high-sensitivity real-time PCR detection during community-based proactive and reactive case detection in Western Kenya Steve M. Taylor, Kelsey M. Sumner, Betsy Freedman... Wendy P. O'Meara</p>
Publication(s)	
Study Title	<b>Starting at The Roots: Using Human-Centered Design To Develop an Adolescent Pregnancy Program in Eldoret, Kenya</b>
Principal Investigator(s)	Edith Apondi, Moi Teaching and Referral Hospital
Co-Investigator(s)	Heather Millar, University of Toronto
Working Group(s)	Reproductive Health (RHWG)

<b>Description</b>	<p>Our proposed project involves using a participatory design process (human centred design) to create an adolescent-friendly antenatal care clinic in line with Kenya's National Adolescent Sexual and Reproductive Health Policy. The organizations coming together are AMPATH and IDEA Couture from Toronto, Canada. We are proposing to improve adolescent pregnancy services in Uasin Gishu County with two objectives: Objective 1: Develop an adolescent pregnancy care intervention to improve maternal, newborn and child health care using a human-centered, participatory, iterative design process. Objective 2: Evaluate the impact of this adolescent pregnancy care program on uptake of services and pregnancy outcomes. By employing a human-centered design strategy, local participation in and ownership of the design outcome will enable a more effective and sustainable approach to the development of a care program for pregnant adolescents. This program will address current barriers to care utilization and outcomes as they relate to the experience of pregnancy at the patient and provider level. In doing so, this approach will lead to overall improvements in antenatal care attendance, facility delivery, maternal and neonatal outcomes, postnatal care attendance, exclusive breastfeeding, and family planning uptake.</p>
<b>Site(s)</b>	<p>Moi Teaching and Referral Hospital</p>
<b>Project Period</b>	<p>8/1/2018 - 7/31/2020</p>
<b>Funding Status</b>	<p>Funded - SICK KIDS, TORONTO</p>
<b>Direct Award (USD)</b>	<p>\$20,000</p>
<b>Update</b>	<p>In the last 6 months, we have continued to work on data synthesis from the human-centered into a manuscript. We are also continuing on idea-generating to address the programmatic prototypes. One such prototype is being piloted through an adolescent adaptation of Chamas for Change. This will be reported on separately. We are also working on an adolescent-friendly sexual and reproductive health education and activity curriculum that will contribute to a peer support program at Rafiki center as another output from the human-centered design process in Starting at the Roots. Finally, we have developed a healthcare provider empathy training program in adolescent sexual and reproductive health. This was provided for healthcare providers from Uasin Gishu County in December. Feedback from this training was very positive. We are currently working on a new proposal that includes evaluation metrics to test whether or not such training improves empathy.</p>
<b>Future Plans</b>	<p>Over the next 6 months, we intend to continue to develop program and proposal ideas that address the programmatic prototypes from the human-centered design process in Starting at the Roots. This will include growing and establishing peer support programs for pregnant and parenting girls through Rafiki Centre, maturing and initiating the pilot program for the adolescent adaptation for Chamas for Change, and building further community relationships to start skills-building workshops with the adolescents. The Empathy Training Program will be submitted to IREC as a proposal for adapting and evaluating an empathy scale. The curriculum development and the findings of the human-centered design process will be presented at CUGH in March. We expect to submit a manuscript for review.</p>

Publication(s)	
Study Title	<b>Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS)</b>
Principal Investigator(s)	Constantine Akwanalo, Moi University
Co-Investigator(s)	Jemima Kamano, American Medical Informatics Association (AMIA)
Working Group(s)	Cardiovascular and Metabolic Disease (CVMD)
Description	<p>Hypertension is a major risk factor for cardiovascular disease (CVD), and 8% of global mortality due to CVD occurs in low- and middle-income countries (LMICs). In LMICs, lack of coordination between different levels of the health system threatens the ability to provide the care necessary to control hypertension and prevent CVD-related morbidity. Strong referral networks have improved health outcomes for chronic disease in a variety of settings. Health information technology (HIT) and peer-based support are two strategies that have improved care coordination and clinical outcomes. However, their effectiveness in strengthening referral networks to improve blood pressure (BP) control and reduce CVD risk in low-resource settings is not known. The Academic Model Providing Access to Healthcare (AMPATH) partners with the Kenya Ministry of Health (MOH) to provide care for non-communicable chronic diseases (NCDs), including hypertension and CVD, at all levels of the health system. The Kenya MOH Health Sector Referral Strategy 214-218 calls for improving the referral system at every level of the health system. AMPATH has piloted both HIT and peer support for NCDs, and both strategies are feasible in this setting. However, the impact of integrating HIT and peer support to strengthen referral networks for hypertension control is not known. The objective of this proposal is to utilize the PRECEDE-PROCEED framework to conduct transdisciplinary, translational implementation research focused on strengthening referral networks for hypertension control. The central hypothesis is that HIT integrated with peer support will be effective and cost-effective in strengthening referral networks, improving BP control, and reducing CVD risk among patients with hypertension in western Kenya. We hypothesize that HIT and peer support will synergistically address barriers to hypertension control at the patient, provider and health system levels. We further hypothesize that changes in referral network characteristics may mediate the impact of the intervention on the primary outcome, and that baseline referral network characteristics may moderate the impact of the intervention. To test these hypotheses and achieve the overall objective, we propose the following specific aims: Aim 1: Conduct a baseline needs and contextual assessment for implementing and integrating HIT and peer support to strengthen referral networks for hypertension control, using a mixed-methods approach, including: observational process mapping and gap assessment; baseline referral network analysis; and qualitative methods to identify facilitators, barriers, contextual factors, and readiness for change. Sub-Aim 1.1: Use data from the baseline needs and contextual assessment to develop a contextually and culturally appropriate intervention to strengthen referral networks for hypertension control using a participatory, iterative design process. Conduct pilot acceptability and feasibility testing of the intervention. Aim 2: Evaluate the effectiveness of HIT and peer support for hypertension control by conducting a two-arm cluster randomized trial comparing: 1)</p>

	<p>usual care vs. 2) referral networks strengthened with an integrated HIT and peer support intervention. The primary outcome will be one-year change in systolic blood pressure (SBP) and a key secondary outcome will be CVD risk reduction. Sub-Aim 2.1: Conduct mediation analysis to evaluate the influence of changes in referral network characteristics on intervention outcomes, and a moderation analysis to evaluate the influence of baseline referral network characteristics on the effectiveness of the intervention. Sub-Aim 2.2: Conduct a process evaluation using the Saunders framework, evaluating key implementation measures related to fidelity, dose delivered, dose received, recruitment, reach, and context. Aim 3: Evaluate the incremental cost-effectiveness of the intervention, in terms of costs per unit decrease in SBP, per percent change in CVD risk score, and per disability-adjusted life year (DALY) saved. This research project will add to the existing knowledge base on innovative and scalable strategies for strengthening referral networks to improve control of NCDs in lower-MICs. If proven to be effective, it has the potential to be a scalable model for other low-resource settings globally.</p>
<b>Site(s)</b>	<p>Burnt Forest Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital</p>
<b>Project Period</b>	<p>6/1/2018 - 5/1/2019</p>
<b>Funding Status</b>	<p>Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)</p>
<b>Direct Award (USD)</b>	<p>\$268,469</p>
<b>Update</b>	<p>In the past six months, we have hired and trained Peer Navigators who will be working in the intervention sites (Webuye and Kocholya). They will be responsible for providing navigation, psychosocial support, adherence to referral and help document completion of referral. We hired the Executive DSMB secretary who will be working for the DSMB. Four Research Assistants have also been hired to help with the study activities in the other clusters. Training has been done for the Research team in preparation for the study roll out. The team was trained on the study protocol, Research Ethics, protocol deviations and violations, scientific misconduct, Human resource policies. Redcap data entry among others. Providers from our study sites were also trained on hypertension Management and referrals for hypertension. This was done in collaboration of other stakeholders involved in the care of hypertension clusters in our respective sites. We completed a pilot study of the intervention where we had total of 15 participants participate in the pilot study that took place as from. This was implemented in 3 facilities: 1 primary, 1 secondary, and 1 tertiary drawn from the same AMPATH cluster, so that they are organized in a single referral chain. Completed assessment of the acceptability and feasibility of the intervention by engaging key stakeholders in two focus group discussions. These included patients, clinicians, and clinic staff in drawn from primary, secondary, and tertiary facilities. A Completed our human centered design approach where we had six design team meetings that constituted of 10-14 participants. This included group facilitator, STRENGTHS team members, clinicians, peer navigators, patients with hypertension, informatics team members, and other relevant clinical staff. These were recruited from across the health system and represent all levels of care (primary, secondary, tertiary). They helped to develop a contextually and culturally appropriate integrated peer support</p>

	<p>intervention for strengthening referral networks and improving hypertension control. We have continued to have our weekly team calls and quarterly all Investigator conference calls to discuss the study progress. Approval for NACOSTI and IREC continuing review for year 2020. The Data Safety and Monitoring Board met and gave approval for the study to continue. Completed data analysis for qualitative work and writing of the manuscript ongoing. Development, programming and testing of the Case Report Forms was finalized. Writing of the process evaluation protocol and submission to IREC for approval. We have also continued with capacity building of the staff. We has the study Coordinator attend Entry level Clinical Trials Monitoring Course 07 -12 October 2019. The data Analyst also attended a workshop going by title mathematical modelling for infectious Disease: Theory and practice. Site Initiation Visit was done on 29/Jul/2019 by Pharmaceutical Product Development (PPD) which is a contract research organization (CRO) that provides expertise in clinical trial development, management, and post approval services. Two representatives from the Kenyan team attended the Bi-Annual NHLBI T4 Translational Research Capacity Building Initiative in Low Income Countries (TREIN) and Hypertension Outcomes for T4 Research within Lower Middle Income Countries (Hy-TREC) Consortium Workshop and meeting in Antigua, Guatemala from the 5th to the 7th of September 2019. Ongoing systematic review to evaluate the current literature regarding referral networks. Referral Network Analysis abstract titled: Network characteristics of a hypertension referral system in western Kenya from was accepted as a poster presentation to the ESC conference in August 31-Sept 4. Observational Process Mapping abstract was accepted for the 23rd Annual Scientific Conference for Kenya Association of Physicians in March 2019</p>
<p><b>Future Plans</b></p>	<p>Next steps Conduct feedback meetings for our qualitative portions of the study. Community entry for the intervention phase of the study Begin enrolment in all our study sites Data collection and management. Finalize writing of Manuscripts and publication for the qualitative portions of the study Conduct follow up visits after every six months and 12 months Evaluation and monitoring of the study Continue to engage stakeholders as we implement the study through review of the results Plan for annual all investigators meeting and Translation Research Capacity Building Initiatives in Lower Middle Income Counties /Hypertension Outcomes for T4 REsearch within Lower Middle-Income Countries (TREIN/Hy-TREC) together with NHLBI tentatively scheduled for March. Submit our amendments to IREC for the change of clusters.</p>
<p><b>Publication(s)</b></p>	<p>Published the STRENGTHS methods paper Mercer T, Njuguna B, Bloomfield GS, Dick J, Finkelstein E, Kamano J, Mwangi A, Naanyu V, Pastakia SD, Valente TW, Vedanthan R, Akwanalo C. StrengtheningReferral Networks for Management of Hypertension Across the Health System (STRENGTHS) in western Kenya: a study protocol of a cluster randomized trial.Trials. 2019 Sep 9;20(1):554. doi: 10.1186/s13063-019-3661-4. PubMed PMID: 31500661</p>
<p><b>Study Title</b></p>	<p><b>Study of Newly Diagnosed Kaposi's Sarcoma</b></p>
<p><b>Principal Investigator(s)</b></p>	<p>Dr. Naftali Busakhala, Moi University</p>
<p><b>Co-Investigator(s)</b></p>	



<b>Working Group(s)</b>	Oncology (ORWG)
<b>Description</b>	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.
<b>Site(s)</b>	
<b>Project Period</b>	9/1/2015 - 8/31/2019
<b>Funding Status</b>	Funded - NIH
<b>Direct Award (USD)</b>	\$750,186
<b>Update</b>	As end of Dec 2019, the Study has managed to enroll 211 Cases. 119 participants are currently in active follow-up, while 66 are deceased. All Deaths have been documented. We have so far done 631 total follow-ups visits. The study has also enrolled 89 Controls matched to 15 Cases.
<b>Future Plans</b>	The study continues to enroll cases and controls over the next several months. Follow-up of cases will also continue as stipulated in the protocol.
<b>Publication(s)</b>	

<b>Study Title</b>	<b>Syndemics</b>
<b>Principal Investigator(s)</b>	Kara Wools-Kaloustian, Indiana University
<b>Co-Investigator(s)</b>	Suzanne Goodrich, Indiana University
<b>Working Group(s)</b>	Adult Medicine (AMWG)
<b>Description</b>	This project uses a syndemic (two or more linked epidemics that synergistically interact to effect outcomes) approach to understand how mental health disorders and substance use shape engagement and retention in care and clinical outcomes among HIV+ individuals enrolled in three IeDEA clinics in Kenya (AMPATH, FACES) and Uganda (Mbarara). Despite the potential negative implications of mental health disorders and substance use on the HIV epidemic, little is known about the prevalence of these conditions among HIV+ clinic attendees in sub-Saharan Africa or the subsequent effect on their clinical outcomes. More information is needed to guide the development and delivery of care to keep these high risk individuals retained at every step of the HIV care cascade and to provide the quantitative data needed to prioritize further diagnostic and



	<p>treatment interventions. Specific Objectives: AIM 1: Identify community and clinic-based services available for treatment of substance use and mental health disorders in the four research sites. AIM 2: Determine the prevalence of substance use (drug and alcohol) and mental health disorders in patients enrolling into care. AIM3: Assess the impact of substance use, mental health disorders and dual diagnoses on patient adherence and retention in the cascade AIM 4: Conduct qualitative interviews with a sub-sample of cohort patients to explore access, use, and experiences with substance use and mental health services.</p>
Site(s)	Moi Teaching and Referral Hospital
Project Period	12/17/2018 - 12/17/2020
Funding Status	Unfunded
Direct Award (USD)	
Update	<p>PSA1: All qualitative interviews have been completed, transcribed and coded at the three participating sites. Analysis of the questions, coding scheme and themes is to start in January 2020. A concept sheet for abstract/manuscript will be submitted in early 2020. A literature review of prior work in this area is complete. PSA2: Enrollment at AMPATH and FACES is complete (200 each). Enrollment at Mbarara is at 147 and will close on January 31, 2020. Twenty-four month follow up of each participant is underway. All enrolled participants were screened for substance use disorder (SUD) and mental disorders (MD). Interim analysis of 527 patients to date showed 58% had a least one SUD or MD. Depression was the most frequent problem, seen in over a third, followed by anxiety (25%), alcohol abuse (22%) and PTSD (21%). Nearly half of patients had at least 1 MD, while 11% had both SUD and MD. Men were three times more likely to use alcohol and drugs, while women had a higher prevalence of any mental health issue, and significantly more multiple MD diagnoses. PSA3: Participants have been followed up between 0-11 months. Adherence to clinic, retention in care and viral load values are being monitored. At interim analysis of the 527 participants enrolled to date their care status (median 117 (IQR 84-207) care days) were: in-care at enrollment site (89.5%); transferred to another health-care facility (4.9%); lost-to-follow-up (2.6%); deceased (1.7%); out-of-care (1.3%). PSA4: Qualitative interviews with a sub-sample of participants to explore access, use, and experiences with substance use and mental health services will begin in January 2020 (must have a least 12 months of follow-up). An abstract/poster on interim analysis findings will be presented at IWHOD in March 2020 in Sitges, Spain.</p>
Future Plans	<p>PSA1: Complete analysis. Submit an abstract of findings (TBD) and begin draft of a manuscript. PSA2: Complete enrollment at Mbarara and get final analysis of enrollment data. Write concept sheet for an abstract/manuscript. PSA3: Continue ongoing 24-month follow-up of all participants including adherence and retention in care and viral loads. PSA4: Initiate qualitative interviews at all three sites (20 interviews per sites) with a purposive sample of patients in care for at least 12 months.</p>
Publication(s)	

<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
<b>Working Group(s)</b>	Oncology (ORWG)
<b>Description</b>	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 1% 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 198'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.
<b>Site(s)</b>	
<b>Project Period</b>	10/1/2015 - 9/30/2018
<b>Funding Status</b>	Funded - NIH
<b>Direct Award (USD)</b>	\$158,406
<b>Update</b>	The study has been closed for enrollment; we managed to enroll a total of 59 study participants. Data entry has been completed.
<b>Future Plans</b>	Data analysis is currently on-going.
<b>Publication(s)</b>	
<b>Study Title</b>	<b>Using a mobile application to improve pediatric presumptive TB identification in western Kenya</b>
<b>Principal Investigator(s)</b>	Daria Szkwarko, Brown University

<b>Co-Investigator(s)</b>	James Amisi, Moi University
<b>Working Group(s)</b>	Pediatric (PRWG) Tuberculosis (TBWG)
<b>Description</b>	<p><b>BACKGROUND:</b> Early recognition of TB symptoms in children is critical in order to link children to appropriate TB treatment and decrease complications. Healthcare workers in pediatric outpatient clinics in limited resources settings like Webuye County Hospital in western Kenya are often overburdened with competing clinical priorities, leading to incomplete symptom screening for presumptive TB. <b>GAP:</b> The implementation of screening tools such as a presumptive pediatric TB mobile application show promise; however, although this tool has been implemented for care in both Bangladesh and Kenya, it has never been formally evaluated for feasibility, appropriateness, and effectiveness.</p> <p><b>SPECIFIC AIMS</b> 1) Pilot and adapt a community health volunteer led presumptive pediatric TB mobile application in a rural county hospital in western Kenya. 2) Assess the impact of the presumptive pediatric TB mobile application on presumptive TB identification and pediatric TB case detection in a retrospective chart review. <b>METHODS:</b> Using a mixed-methods implementation science framework, we will first use a participatory, iterative approach to pilot and adapt the presumptive pediatric TB mobile application based on feedback from healthcare workers in pediatric outpatient clinics (pediatric outpatient clinic, nutrition, and maternal child health). We will review data for children &lt; 15 years who attended pediatric outpatient clinic, nutrition clinic, and maternal child health clinics before and after the implementation of the mobile application, and we will compare the proportion of children identified in the paper presumptive TB registers and pediatric TB registers.</p>
<b>Site(s)</b>	Webuye District Hospital
<b>Project Period</b>	1/1/2019 - 6/30/2020
<b>Funding Status</b>	Funded - Thrasher Foundation
<b>Direct Award (USD)</b>	Not Reported
<b>Update</b>	<p>To date, pre-intervention data collection has been completed. The mobile application intervention was implemented over a four month period with monthly follow up interviews to adapt the intervention design. -In total, 32 qualitative interviews were completed and professionally transcribed between March and early July. Between August 2018-January 2019 at Webuye County Hospital, there were 903 individuals in the presumptive TB registers. Out of these, there were 89 children &lt;math&gt;\leq&lt;/math&gt; 15 years documented in six presumptive TB registers in the facility. Median age for the children was 10 years [IQR 7-12 years]. 13.5% were less than 5 years of age. 48% were female. Six of these children were diagnosed with TB disease (median age = 12 years, 66% female). 31 (35%) of the children documented in the presumptive TB register were documented in the chest clinic register followed by the special clinic register 21 (24%), the OPD clinic register 15 (17%), the ward register 10 (11%), the MCH clinic register 8 (9%), and the CCC register 4 (4%). There were 10 additional pediatric TB cases in the TB clinic register during the six-month period who were not listed in the presumptive TB registers. (median age = 3.95 years, 50% female). -Ideal app design was implemented in July-December 2019</p>

Future Plans	Post-intervention data collection. Analysis of pre and post data.
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, American Medical Informatics Association (AMIA)
Working Group(s)	Pediatric (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. 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
Project Period	4/1/2017 - 4/30/2018
Funding Status	Unfunded
Direct Award (USD)	
Update	This project is currently in the analysis and dissemination phase. Over the last six months, analysis of both quantitative and qualitative data has been going on. In preliminary analyses of the quantitative data, participants performed significantly worse on the Genberg Discrimination questions immediately after watching the films. This likely indicates that they more strongly recognize and identify the extent to which persons living with HIV in the community are experiencing stigma after being sensitized by the films. However, they show significant improvement from baseline in Discrimination, Equity, and Total Genberg scores at 3-month follow-up. Considering adolescents and caregivers separately, it seems that the improvements at follow-up are primarily attributable to improvements in caregivers' scores. The mean differences in scores for adolescents at follow-up are smaller in magnitude and not statistically different. Given that caregivers' mean scores were lower at baseline, though, caregivers had a greater potential for improvement than adolescents. These preliminary results have been used to shape the implementation of the "Teach HADITHI" R21 grant, which uses the HADITHI stigma films

	as part of a teacher training intervention to modify teachers' knowledge, attitudes, and beliefs about HIV, in a randomized controlled trial using multimedia training sessions with primary and secondary school teachers in Uasin Gishu County
Future Plans	Within the next six months, we plan to complete qualitative and quantitative data analyses and present our findings through abstracts and manuscripts.
Publication(s)	



Study Title	<b>Validating an Integrated Community Based Strategy of Peer Support in</b>
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Working Group(s)	Pediatric (PRWG) Reproductive Health (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 facilities processes of accountability using CHV-led women's groups (Chamas). Chama cha Mama Toto (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. It is 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 Centre, Saboti, Kiminini, Cherangani and Kwanza Sub counties
Project Period	10/1/2017 - 10/1/2018
Funding Status	Funded - Grand Challenges Canada, ABBVIE
Direct Award (USD)	\$197,510
Update	We have been implementing the study for 1 year in TransNzoia in all the 4 sub-counties (Kwanza, Kiminini, Cherangany, and Saboti). We assessed 4235 pregnant women for eligibility, 1312 were ineligible and 2923 were eligible therefore ended up being enrolled in the study. This being a randomized control trial, our study participants(N= 2923) were randomly assigned using their community units to the control arm which has 40 community units(1320 women) and the intervention arm which has 37 community units (1603 women). We have 92 Community Health Volunteers (CHVs) and 66 Community Health Extension Workers (CHEWs) who are supporting the implementation of the study in the 77 community units. As per our study protocol, we only provided basic MoH care through the CHVs whom we gave names of women (1320) in their community units for follow up. Out of 1320, 396 were lost to follow up while 924 were successfully located by

the CHV and followed up for one year. At the end-line, during data collection, we engaged the CHVs to support the enumerators in locating 924 women to enable data collection. We ended up collecting data from 728 women as 196 were lost to follow up. We have been able to meet the control CHVs five times to ensure they are maintaining the standard MOH care as required, provide updates on the end-line data collection. We also plan to meet CHVs from our control arm so as to provide feedback on data collected and discuss our next implementation plan over the next 2 years. For the intervention arm (1603), 607 were lost to follow up, 996 were successfully located by the CHVs and invited to participate in the intervention- Chamas for 1 year. We trained 92 CHVs on Chama facilitation, leadership skills, group dynamics, and conflict resolution. We also sensitized the Sub County Health Management Team members from the 4 sub-counties and the CHEWs on the Chama program. During the delivery of the program, 174 were lost to follow-up and 822 completed the end-line questionnaires. To enable us to carry out an intention to treat analysis based on the protocol, we monitored Chama attendance and of the 822, 223 never attended Chamas. 599 women attended Chamas- 286 attended < 50 % of the sessions and 313  $\leq$  50% of the sessions. The program is an integration of medical education, social education, and the microfinance component, all the 49 groups were taken through 24 medical topics and 24 social topics and out of the 49 groups 37 groups (308 women) participated in microfinance: Group Integrated Savings for Health Empowered (GISHE). To strengthen the implementation of GISHE in our groups we trained GISHE officials (n=108) on record keeping, money counting, and group account management. We also have 3 Male groups(33 men) that were initiated due to the successes of women 's participation in Chamas. In this phase, we focused strengthening the implementation of Chamas by holding monthly meetings with the CHVs for the 1st three months then proceeded with quarterly meetings with the CHVs and the SCHMT members, partnering with the County MOH to sensitize the community on the program and advocate for upholding of Chama goals and male involvement, finalizing the implementation of the study, getting Family Preservative Initiative (FPI) officials from our sister program at AMPATH to support GISHE in the groups that were participating and data collection and data cleaning. We currently have received all the data, finished data cleaning that delayed the process as we were relying on micro-finance records for this. Analysis for both quantitative data and qualitative data is ongoing and actual results will be disseminated with various stakeholders including TransNzoia MoH and details of the comprehensive report will be shared in the next report. In addition, we conducted a supplemental study to follow up a cohort of pregnant women that was previously enrolled in Chamas but never followed up in 2017 due to several major strikes by health workers in that year. As part of the supplemental study, we proposed to relocate as many of the women that were recruited in 2017 but never followed up as possible and to assess what happened during their pregnancy in 2017. A total of 1,341 women were enrolled in 2017. A team of research assistants working with CHVs in TransNzoia traced these women using previous contact information, and to those that they located, consented women to participate in a short survey questionnaire administered on REDCap. The survey asked women about their ANC visits, pregnancy outcomes, immunization status, and any disruptions and barriers that they faced in accessing pregnancy-related care in 2017. A total of 843 women were located and participated in a follow up assessment. Preliminary analyses of these data are currently ongoing. In addition, we conducted 4 focus groups with a subset of these women, 3 focus groups with CHVs working in TransNzoia in 2017,



	and 8 key informant interviews with facility providers (mostly nurses) to qualitatively explore pregnancy related healthcare, specifically in 2017 in relation to significant strike-related disruptions. These qualitatively data are also currently being analyzed.
Future Plans	We plan to have data analysis completed by May, 2020 to enable the publish of various studies within the main study. We will continue providing care as we are retain our cohort; both control and intervention arms and we are recruiting more women to join our Cycle 2 (year 2) group. The inclusion criteria for the women is that they should have children below 2 years to match with our intervention and are willing to join and participate actively in Chamas. We are also recruiting pregnant women to form our new Cycle (year 1) for the intervention of community units. We will continue with bi-weekly Chama sessions. We are reviewing the curriculum to better meet the needs of women participating. As a program, we are committed to strengthening our partnership with the Ministry of Health officials at the county level and we plan to have a dissemination meeting on the findings of our study and continue partnering to ensure awareness of the program in Trans Nzoia County. For the supplemental study, we will completed preliminary analyses on the both the survey instrument and qualitative focus groups and interviews by May 2020, and will write up the results for publication by July 2020.
Publication(s)	
Study Title	<b>Virologic Treatment Failure and Drug Resistance in HIV-Infected Kenyan Children (RESPECT) study.</b>
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, American Medical Informatics Association (AMIA)
Working Group(s)	Pediatric (PRWG)
Description	This study will involve retrospective and prospective analysis of blood sampling from patients enrolled in a previous NIH-funded (Vreeman, 1K23MH87225) 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 21 and October 213. 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>	Kitale District Hospital, Moi Teaching and Referral Hospital, Webuye District Hospital
<b>Project Period</b>	8/2/2016 - 7/31/2020
<b>Funding Status</b>	Funded - NIH
<b>Direct Award (USD)</b>	\$613,511
<b>Update</b>	<p>Over the last six months, we completed cleaning all study data, including retrospective data from AMRS and study databases, prospective data and MEMS adherence data. Multiple data mergers and additional data cleaning and management were involved in this phase. Now, analyses of viral suppression, adherence, and drug resistance are ongoing. Of 482 PHIC (Perinatally HIV Infected Children) enrolled, 52% were female, median age 8.4 years (range 1-15), median CD4% 28 (range 0-53), 79% on zidovudine (AZT)/abacavir (ABC)+lamivudine(3TC)+efavirenz (EFV)/nevirapine (NVP) for median 2.3 years. Treatment failure was seen in 31%, associated with lower CD4% and count. Genotypes were available in 124, 47% female, median 8.3 years (range 2-15), median CD4% 22 (range 0-45), 81% on AZT/ABC+3TC+EFV/NVP for median 2.5 years, median VL 7,515 copies/mL. Subtypes were A-76%, C-3%, D-15%, recombinants-6%. Reverse transcriptase mutations were in 93%; 93%-NNRTIs, median 2/patient, most common Y181C (44%); 89%-NRTIs, median 3/patient, most common M184V (85%); and 89%-dual class, median 5/patient. Intermediate-high resistance to potential 2nd-line drugs included 62%-etravirine, 66%-rilpivirine and 19%-tenofovir. Of 92/124 (74%) PHIC with follow-up data, 27% remained on NNRTI-based 1st-line (median CD4 count 461), of who 24% had suppressed VL and 48% died; and 73% switched to PI-based 2nd-line (median CD4 count 591), of who 72% had suppressed VL and 6% died (P&lt;0.05 for both). PHIC in western Kenya had high rates of treatment failure on NNRTI-based 1st-line therapy and extensive drug resistance, with poor clinical outcomes. The initial analyses from these data have been submitted and presented as conference abstracts at multiple relevant international meeting venues during the last six months. An abstract entitled "HIV-1 Treatment Failure and Extensive Drug Resistance in Perinatally-Infected Children Failing 1st-Line Antiretroviral Therapy in Western Kenya" was presented an oral presentation at IDWeek 2019TM, October 2-6, 2019 at the Walter E. Washington Convention Center, in Washington, DC. An abstract entitled "Drug Resistance Evolution Using Sanger and NGS in Kenyan Youth Living with HIV" was presented at the 2019 Drug Resistance Workshop. An abstract entitled, "Non-Adherence and Low Drug Levels Impact Viral Outcomes in HIV-Infected Kenyan Youth" was submitted to the CROI meeting, subsequently rejected, and then submitted to the AIDS 2020 meeting to be held in San Francisco, CA, USA in July 2020. Additional analyses and manuscripts describing the findings in each of these abstracts are now underway. .</p>
<b>Future Plans</b>	<p>Send the remaining blood samples for all participants to Brown University for phenotyping and resistance testing;</p> <p>Continue with analyses and complete manuscript drafts for publications on our findings</p>
<b>Publication(s)</b>	

<b>Study Title</b>	<b>WEZESHA (Neurodevelopmental Screening in Children Born to HIV-Infected Mothers in Kenya)</b>
<b>Principal Investigator(s)</b>	Megan McHenry, Indiana University
<b>Co-Investigator(s)</b>	Eren Oyungu, Moi University
<b>Working Group(s)</b>	Pediatric (PRWG)
<b>Description</b>	<p>Goal: implement an effective neurodevelopmental (ND) screening and intervention program to combat neurodevelopmental delays in children born to HIV-infected mothers in resource limited settings. Specific objectives: 1. Identify appropriate Neurodevelopmental instruments for use in HIV-exposed Kenyan children. 2. Evaluate an integrated Neurodevelopmental screening program within the existing care system. This will be done in three study sites: MTRH Maternal Child Health clinic, Turbo and Burnt Forest Maternal Child Health Clinics respectively. Study Aims: 1. Determine and compare the reliability and validity of neurodevelopmental screening tools and assessments for use among children aged 18-36 months in Kenya- by identifying an optimal screening tool and assessment for use in Kenya, conducting cross-cultural adaptation, comparing the psychometric properties of two Neurodevelopmental screening tools (DSQ; PEDS:DM) and two assessments (RNDA; MDAT) among 240 Kenyan children, using BSID-III as a reference standard. The findings from this aim will provide validated tools for implementation. 2. Evaluate neurodevelopmental screening implementation in an existing healthcare system in Kenya. Develop a contextualized implementation plan: engaging with the community and key stakeholders to create an implementation plan for Neurodevelopmental screening and referral for assessments in local MCH clinics.</p> <p>Pilot a Neurodevelopmental screening program at one MCH clinic in Kenya: perform a pilot evaluation of a neurodevelopmental screening tool within a routine clinical setting. We will measure implementation outcomes, including acceptability, feasibility, fidelity, implementation cost, and sustainability. In addition, we will assess effectiveness of neurodevelopmental screening, as determined by sensitivity; specificity; and positive and negative predictive values. 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 approvals for the aims.</p>
<b>Site(s)</b>	Burnt Forest Sub-District Hospital, Moi Teaching and Referral Hospital, Turbo Health Centre
<b>Project Period</b>	9/21/2018 - 9/21/2022
<b>Funding Status</b>	Funded - NIH
<b>Direct Award (USD)</b>	\$46,055
<b>Update</b>	In the last six months we did an amendmend to add the age of primary caregiver of the child to be captured in our data collection tool-Questionnaire and it has been approved by IREC.We have so so far enrolled 107 children against our target of 240 young children between the ages of 18-36 months from the HIV-infected, HIV-exposed but uninfected children and Non-exposed children

**Future Plans**

We will be starting enrollments at our semi urban MCH clinics (Turbo and Burnt Forest) where we are to enroll 60 children from each site respectively, conduct interviews and focused group discussions, this was delayed by getting an approval from Nacosti which we recently received. We are continuing with administration of the DSQ, PEDS: DM, MDAT, RDNA, and BSID-III to each of the 240 children we are enrolling. With BSID-III being the goal reference standard of the two assessments (MDAT and RDNA).

**Publication(s)**

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## APPENDIX A: WORK PLAN

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### VISION

A vibrant, world-class, Kenyan-led community of researchers engaged in the continuous improvement of health globally.

### MISSION

Guided by the principle of leading with care, we work in partnership to develop local research talent and to identify, develop and disseminate relevant and timely information to improve the health of underserved populations.

### VALUES

In our work we will embrace:

- **Service** with humility
- A spirit of **collaboration** and **partnership**
- **Integrity** in relationships
- **Mutual respect** and **mutual benefit** in organizational partnerships
- Efforts to **eliminate health disparities**
- A **sustainable** infrastructure for research

### STRATEGIC GOALS

1. Strengthen development of a well-resourced and sustainable infrastructure for research that enables the efficient conduct of high-quality research
2. Increase the number of successful independent investigators working in collaborative, interdisciplinary research teams by providing better access to high-quality training and mentorship.
3. Enhance supportive, research-intensive cultures within the schools and departments of all AMPATH partners
4. Accelerate growth in relevant, high-yield research initiatives that will improve policy and strengthen the health systems and communities we serve including Biomedical innovations, Health Economics/ Equity, Population Health, Informatics, and Implementation Science Research.
5. Incorporate research into ongoing efforts to expand AMPATH innovations to additional underserved populations outside Kenya

### IMPLEMENTATION STRATEGY

**Goal 1: Strengthen development of a well-resourced and sustainable infrastructure for research that enables the efficient conduct of high-quality research**

*Implementation Strategies Proposed by Small Groups at 2019 Strategic Planning Meeting*

- Set up a resource mobilization office to source for infrastructure funds
- Apply for Infrastructure grants
- Engage new partners interested in building research infrastructure
- Include an aspect of infrastructure in the budgets for new grants
- Promote professional development for the research team

- Building human and technological capacity through Training
- Sustainable financial streams through innovative income generation
- Shared financing responsibilities between North American institutions, Kenyan government, and local institutions
- Creation of Kenyan research fees for Moi faculty time to be included in grants
- Develop advocacy strategy at the university level to push for research infrastructure support from government
- Identify philanthropic funding for research
- Continue engaging local host institutions to demonstrate ownership of the infrastructure
- Integrate local seed grant opportunities with AMPATH infrastructure (i.e. CTSI)

**Goal 1: Proposed Objectives**

Objective	Deadline	Expected Outcome(s)	Performance Metric	Champion
<b>1. Establish a Kenya-based infrastructure model to more fully support research infrastructure.</b>	1 July 2021	<ul style="list-style-type: none"> <li>• Simplified fee structure and reduced administrative burden/cost for researchers</li> <li>• Elimination of North American Facility Fee and streamlined cost requirements</li> <li>• More stable and direct revenue stream for critical AMPATH core research infrastructure including RSPO, RPO, and IREC</li> <li>• Increased control over research program infrastructure business operations by Kenyan leadership</li> <li>• Tiered fee structure to allow non-AMPATH Consortium research and provide enhanced support for research infrastructure</li> </ul>	<ul style="list-style-type: none"> <li>• Implementation of new model</li> <li>• Residual revenue v. program expenses</li> </ul>	J. Kiplagat-Kirui R. Rono D. Plater M. Kidney A. Onchere W. Okinda
<b>2. Implement a sustainable business model for the AMPATH Reference Laboratory and Biobank</b>	1 July 2020	<ul style="list-style-type: none"> <li>• Stable lab management structure and leadership</li> <li>• Reduction of lab debt obligations</li> <li>• Enhanced lab capacity, quality, and support</li> <li>• </li> </ul>	<ul style="list-style-type: none"> <li>• Appointment of a lab manager</li> <li>• Appointment of an AMPATH Consortium Lab Team Leader</li> <li>• Average annual residual amount (income less expenses) of US\$10,000 or more</li> </ul>	R. Tonui K. Woos-Kaloustian W. Nyandiko

Objective	Deadline	Expected Outcome(s)	Performance Metric	Champion
		<ul style="list-style-type: none"> <li>Established functional biobank</li> </ul>	<ul style="list-style-type: none"> <li>Implementation of new prices</li> <li>Increase customer base by engaging with private hospital and patients.</li> <li>Obtain NHIF accreditation.</li> <li>Established mechanism to assess customer satisfaction</li> <li>Formal opening/launching of the biobank</li> </ul>	
<b>3. Obtain AAHRPP Accreditation for IREC</b>	31 December 2023	<ul style="list-style-type: none"> <li>IREC able to serve as single IRB of record for US federally funded research</li> <li>Improved efficiency of IREC reviews and reduced administrative burden for researchers</li> <li>Enhanced reputation for world class research infrastructure in Kenya</li> </ul>	<ul style="list-style-type: none"> <li>Hiring of accreditation consultant</li> <li>Completion of stage 1 self-assessment</li> <li>Completion of accreditation of site visit</li> </ul>	E. Were J. Baumann C. Okwiri
<b>4. Implement ongoing professional development plan for core administrative staff including RSPO, RPO, and key project staff (RAs, Research Coordinators, etc.)</b>	31 December 2020	<ul style="list-style-type: none"> <li>Improved capacity and efficiency in core administrative (RSPO and RPO) services provided to researchers</li> <li>High performing staff retained</li> <li>Greater accountability and performance measurement systems</li> <li>Well trained and accountable project staff</li> </ul>	<ul style="list-style-type: none"> <li>Training Curriculum/Plan Developed</li> <li>Number of trainings completed &amp; participants trained</li> <li>Development of key performance metrics for core services</li> <li>Greater utilization of existing performance appraisal tools to assess personnel performance</li> </ul>	J. Kiplagat- Kirui D. Plater R. Rono J. Wagner M. Kidney

**Goal 2: Increase the number of successful independent investigators working in collaborative, interdisciplinary research teams by providing better access to high-quality training and mentorship.**

*Implementation Strategies Proposed by Small Groups at 2019 Strategic Planning Meeting*

- Develop expectations for mentorship
- Have clear expectations for investigators in grants
- Work closely with institutional departments to identify potential new researchers
- Develop a directory of potential investigators and a strategy to actively engage them
- Disseminate strategy for working groups activities
- Mentorship and training
- Increase seed research funding
- Revisit/Enhance working group efficiency
- Protected research time for Kenyan researchers
- Create opportunities for young talent
- Create incentives to draw local faculty to research (i.e. fellowship training opportunities primarily based in Kenya with brief stints in the US through D43's , etc.)
- Pilot grant program availability for junior investigators
- Better match senior North American investigators with young faculty at Moi
- Advocate for development of career paths for young investigators
- Develop and implement short term trainings on research methods

**Goal 2: Proposed Objectives**

Objective	Deadline	Expected Outcome(s)	Performance Metric	Champion
<b>1. Completion of a comprehensive training and mentorship needs assessment for AMPATH Research and develop a comprehensive training plan</b>	30 March 2020	<ul style="list-style-type: none"> <li>• A report outlining currently available training and mentorship programs and the remaining gaps in training and mentorship</li> <li>• A plan that leverages existing mentorship and training opportunities and addresses the identified training and mentorship gaps.</li> <li>• Better coordination of training and mentorship in research</li> </ul>	<ul style="list-style-type: none"> <li>• Needs Assessment Report</li> <li>• Training and mentorship plan</li> <li>• Number of investigators linked to training and mentoring opportunities</li> </ul>	J. Wagner J. Kiplagat-Kirui
<b>2. Implementation of comprehensive training and mentorship plan and creation of research career tracks supported by Moi University leadership</b>	31 December 2023	<ul style="list-style-type: none"> <li>• Coordinated plan adopted for strengthening training and mentorship opportunities for research</li> <li>• White paper on career pathway for research, clinical and education track faculty</li> <li>• Increased number of independent and</li> </ul>	<ul style="list-style-type: none"> <li>• Training Plan</li> <li>• Conduct training on mentorship</li> <li>• Number of Training Opportunities Implemented</li> <li>• Approval of a formal research, clinical and education career pathway by senate</li> </ul>	W. Nyandiko K. Wools-Kaloustian D. Litzelman



Objective	Deadline	Expected Outcome(s)	Performance Metric	Champion
		successful Kenyan investigators	<ul style="list-style-type: none"> <li>Number of new faculty funded as PIs of grants</li> </ul>	
<b>3. Increase the number of training awards (D43 or equivalent) supporting strategic AMPATH training and mentorship objectives</b>	31 January 2022	<ul style="list-style-type: none"> <li>Increased training and mentorship opportunities</li> <li>Increased pilot and training funding</li> <li>Larger pool of trained researchers</li> <li>More strategic coordination of training programs</li> </ul>	<ul style="list-style-type: none"> <li>Number of training awards</li> <li>Number of trainees</li> <li>Absence of overlap and increased coordination between training grants.</li> </ul>	K. Wools-Kaloustian W. Nyandiko
<b>4. Establish a monthly training and professional development series focusing on topics in research</b>	31 January 2020	<ul style="list-style-type: none"> <li>Increased coordination of training activities</li> <li>Increased access to ongoing training and mentorship in Kenya</li> <li>Coordination of curriculum with certifying institutions</li> </ul>	<ul style="list-style-type: none"> <li>Series Program</li> <li>Number of Participants trained</li> <li>Training Certification Numbers</li> </ul>	J. Kiplagat-Kirui J. Wagner

**Goal 3: Enhance supportive, research-intensive cultures within the schools and departments of all AMPATH partners**

*Implementation Strategies Proposed at 2019 Strategic Planning Meeting*

- Integrate AMPATH working groups with Moi university departments (strategic communication plan)
- Convert working groups into pilot study section reviews that offer grant support to people who go through the process
- Encourage established researchers to have someone “new” in their team
- Shared responsibilities across the research process
- Incorporating relevant stake holders into research teams (patient groups, government)
- Advocate for research track system linked to promotion criteria
- Strictly enforce FTE as mechanism for holding investigators accountable for research
- Provide opportunities in local host institutions to organize frequent forums for sharing research results/grants and have an incentive linked to it
- Advocate for internal funding for researchers
- Implement didactic training on different aspects of research and writing (identify folks in Kenya and America to teach these and provide monetary support)
- Outreach and needs assessment with HOD’s
- Better align structures to research productivity
- Target and engage with other departments in local host institutions to participate in research
- Build an institutional mentorship system for developing new investigators
- Assist with the creation of viable tracks for faculty interested in research
- Identify gaps in research that HOD’s face and have AMPATH RPO fill them where possible

**Goal 3: Proposed Objectives**

Objective	Deadline	Expected Outcome(s)	Performance Metric	Champion
<b>1. Restructure AMPATH research working group model</b>	31 December 2021	<ul style="list-style-type: none"> <li>Streamlined process for working group review and approval of AMPATH research</li> <li>Reduced administrative burden for researchers</li> <li>Access pathway for non-AMPATH consortium research partners and enhanced revenue</li> </ul>	<ul style="list-style-type: none"> <li>New structure implemented</li> <li>Number of studies reviewed</li> <li>Number of studies funded</li> </ul>	W. Nyandiko K. Woos-Kaloustian J. Kiplagat-Kirui D. Plater
<b>2. Establish a monthly work in progress session series focusing on topics in research</b>	31 January 2020	<ul style="list-style-type: none"> <li>Access to Peer feedback and support for research development through WIP sessions</li> <li>Increased participation in programs by research faculty &amp; staff from underrepresented departments</li> </ul>	<ul style="list-style-type: none"> <li>Series Program</li> <li>Number of Participants</li> </ul>	J. Kiplagat-Kirui J. Wagner
<b>3. Implement a communications &amp; outreach strategy to strengthen participation of HODs and their departments</b>	31 December 2020	<ul style="list-style-type: none"> <li>Increased participation in AMPATH research by faculty from underrepresented schools &amp; departments</li> <li>Greater integration of AMPATH research into schools &amp; departments</li> <li>Stronger support &amp; ownership by HODs</li> </ul>	<ul style="list-style-type: none"> <li>Implementation of communications plan</li> <li>New faculty participation rates</li> <li>Perception survey results</li> <li>Bi-annual CHS Research Conference</li> </ul>	W. Nyandiko K. Woos-Kaloustian

**Goal 4: Accelerate growth in relevant, high-yield research initiatives that will improve policy and strengthen the health systems and communities we serve including Biomedical innovations, Health Economics/ Equity, Population Health, Informatics, and Implementation Science Research.**

*Implementation Strategies Proposed at 2019 Strategic Planning Meeting*

- Have expectations for researchers for dissemination of their research/COBES way
- Have an expectation for policy statements from our research
- Engage the corporate communications department e.g. Newsletter
- Disseminate findings to various fora
- Enforce translation of research findings into practice.
- Develop basic science research and infrastructure
- Establish partnerships to foster basic and translational research

- Align research initiatives with county and national health needs
- Develop joint faculty recruitment efforts
- Engaging the leadership of county government to understand their needs
- Define the community needs (Driven by the need of the community rather than the funding)

**Goal 4: Proposed Objectives**

Objective	Deadline	Expected Outcome(s)	Performance Metric	Champion
1. <b>Develop advisory council to identify strategies and resources to catalyze growth in key research priorities and facilitate dissemination of research findings</b>	1 January 2022	<ul style="list-style-type: none"> <li>• Increased alignment of researcher and stakeholder priorities for research</li> <li>• Systematic forum for dissemination of key research outcomes</li> </ul>	<ul style="list-style-type: none"> <li>• Formation of stakeholder advisory council</li> <li>• AMPATH Board</li> <li>• Brochures describing impact of research on care</li> </ul>	W. Nyandiko J. Kiplagat-Kirui
2. <b>Increase access to pilot grant opportunities to promote research, training, and infrastructure development activities that will support growth in Biomedical Innovation, Health Economics/ Equity, Population Health, Informatics, and Implementation Science Research</b>	1 January 2021	<ul style="list-style-type: none"> <li>• Increased research activity in priority areas</li> <li>• Increased number of researchers engaging in priority areas</li> </ul>	<ul style="list-style-type: none"> <li>• Number of funded research projects/activities in priority areas</li> </ul>	K. Woos-Kaloustian W. Nyandiko

**Goal 5: Incorporate research into ongoing efforts to expand AMPATH innovations to additional underserved populations outside Kenya**

*Implementation Strategies Proposed at 2019 Strategic Planning Meeting*

- Discuss further with this group and the leadership in charge of some of these efforts.
- Address contextualized research priorities

**Goal 5: Proposed Objectives**

Objective	Deadline	Expected Outcome(s)	Performance Metric	Champion
1. <b>Organize a stakeholder meeting in Kenya to create prioritized agenda for reciprocal innovation in cooperation with the Indiana CTSI</b>	31 December 2020	<ul style="list-style-type: none"> <li>• Alignment with Indiana CTSI Reciprocal Innovation Program &amp; Funding Opportunities</li> <li>• Enhanced opportunity for external collaboration</li> <li>• Incorporation of AMPATH research outcomes/innovations into</li> </ul>	<ul style="list-style-type: none"> <li>• Prioritized Agenda</li> </ul>	R. O’Brien J. Kiplagat-Kirui D. Plater

Objective	Deadline	Expected Outcome(s)	Performance Metric	Champion
<b>2. Develop and implement a comprehensive dissemination and communications strategy for AMPATH research outcomes</b>	1 July 2020	Indiana CTSI online repository <ul style="list-style-type: none"> <li>• Increased dissemination of key research findings to key decision makers and health practitioners</li> <li>• Improved reputation</li> </ul>	<ul style="list-style-type: none"> <li>• Written dissemination strategy</li> <li>• Media Performance Metrics</li> </ul>	D. Ungar J. Kiplagat-Kirui J. Wagner
<b>3. Establish a replication resource team to coordinate with the AMPATH secretariat in assisting and advising on replication of AMPATH research programs</b>	1 July 2020	<ul style="list-style-type: none"> <li>• Transfer of lessons learned &amp; best practices for research to AMPATH replication sites</li> <li>• Development of stronger policies &amp; procedures for replication</li> <li>• Patenting of AMPATH</li> </ul>	<ul style="list-style-type: none"> <li>• Identification of resource team members</li> <li>• Resource team member participation in replication activities</li> <li>• Patented AMPATH</li> </ul>	K. Woolls-Kaloustian W. Nyandiko

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## APPENDIX B: BIBLIOGRAPHY

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The following bibliography includes AMPATH research publications that were published between July 1, and December 31, 2019. 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.

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