SEMI ANNUAL RESEARCH REPORT

January – June 2020

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

https://www.ampathkenya.org/research

Table of Contents

Abbreviations

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

Vision, Mission, & Values

Vision

We envision 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 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

Overview

Strategic priorities and progress

In September 2019, the AMPATH Research Program Office (RPO) convened a two-day strategic planning meeting in Eldoret, Kenya. The meeting included more than 40 key research program leaders and stakeholders tasked with reviewing and evaluating the program's strategic priorities and developing a new strategic plan for the next 3 years. The following strategic priorities were identified:

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**

Based on these strategic priorities, the AMPATH RPO created a 2020-2023 work plan with input from key stakeholders and leadership to implement the program's new strategic plan. The work plan was included in the previous AMPATH RPO Semi-Annual Report July – December 2019.

Training and Mentorship Needs Assessment

As part of its strategic work plan, in early 2020 the AMPATH RPO conducted a comprehensive training and mentorship needs assessment among investigators and research staff to understand the current state of research training and mentorship, including identifying gaps, barriers, and opportunities to strengthen the research training and mentorship available to AMPATH affiliated researchers and program staff. The RPO conducted two dynamic online surveys in REDCap; one survey targeted AMPATH-affiliated investigators and the other targeted AMPATH research coordinators and assistants. In addition, RPO staff conducted interviews with academic leadership at Moi University and MTRH and a focus group discussion with research coordinators. Overall, we found that while investigators and research coordinators were highly interested in training and mentorship opportunities, there were several barriers and a lack of resources to support these activities. A number of recommendations were made by participants including the creation of a formal mentorship and training curriculum at AMPATH. The Training and Mentorship Needs Assessment final report is included in Appendix A. Informed by the results of the needs assessment, the AMPATH RPO is working to develop several training and mentorship modules, which will be piloted in late-2020. Updates on these activities will be provided in the next semi-annual report.

Response to COVID-19

Kenya reported its first case of COVID-19 on March 15, 2020. Two days prior to the announcement of the first documented case, the AMATH Consortium restricted all new travel to Kenya and required all non-essential travelers in Kenya to return home as soon as possible. The AMPATH RPO closely monitored the spread of COVID-19 in Kenya and globally to inform research operations at AMPATH. On March 18, 2020, the AMPATH RPO requested AMPATH investigators to: (1) take immediate actions to suspend all non-essential study activities requiring in-person contact, (2) coordinate with study coordinators and staff to develop contingency work plans to allow research activities to continue during temporary closures, (3) shift in-person meetings to teleconferencing, (4) allow non-essential staff to work remotely when possible, (5) suspend new subject recruitment for prospective studies, and (6) communicate with enrolled study subjects regarding any suspension of study activities. The RPO held a virtual town hall on March 26, 2020 with leaders from AMPATH Research Network, Research and Sponsored Projects office (RSPO), and Moi/MTRH Institutional Research and Ethics Committee (IREC) and investigators and research staff to discuss contingency planning for research projects interrupted by COVID-19. The AMPATH RPO issued weekly COVID-19 updates to the AMPATH Research Network from March 18, 2020 to May 14, 2020, which included updated information about COVID-19 in Kenya, research resources related to COVID-19, and guidelines from the AMPATH RPO about research activities.

AMPATH Research Restart Post COVID-19 Shut Down

By the end of this reporting period in late June, the AMPATH RPO was working on updated guidelines to allow the restart of non-essential research activities on July 1, which would require investigators and staff to complete and adhere to a number of requirements to ensure research staff and participant safety and compliance with local public health regulations and guidance.

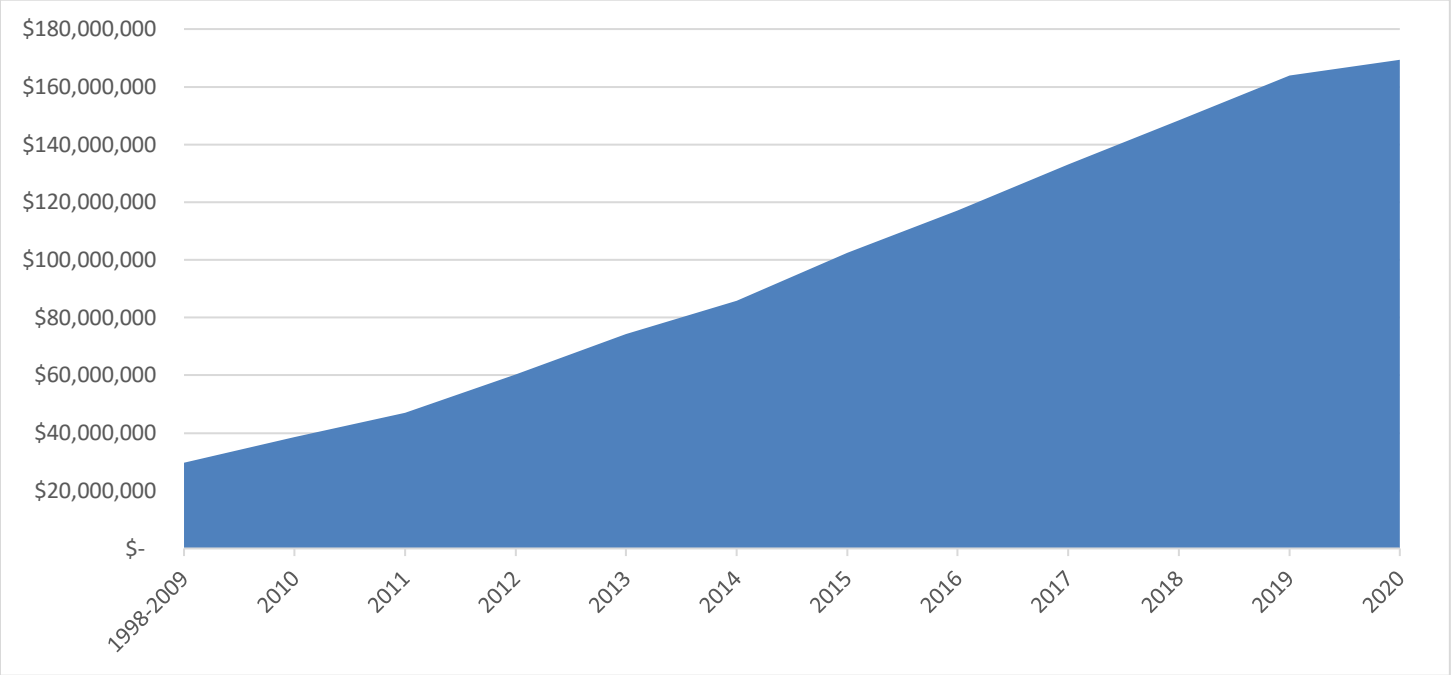
COVID-19 Research

Several AMPATH investigators launched COVID-19 related research projects to better understand the clinical and psychosocial impacts of the disease on communities in western Kenya. Investigators from the East Africa International Epidemiologic Databases to Evaluate AIDS (EA IeDEA), led by Dr. Suzanne Goodrich (Indiana University), created and implemented a phone survey to assess the impact of COVID-19 among participants in three EA IeDEA prospective cohort studies in Kenya. The COVID-19 survey was adapted by AMPATH-affiliated investigators to use in research projects in New York and Indiana. Drs. Rami Kantor (Brown University), Winstone Nyandiko (Moi University), and Rachel Vreeman (Mount Sinai) were awarded an NIH supplement grant to their existing R01 on HIV drug resistance among children to conduct surveys about the impact of COVID-19 and antibody testing with almost 500 children and adolescents living with HIV at AMPATH. Results of these studies are forthcoming and we look forward to sharing their findings in the next semi-annual report.

Grants

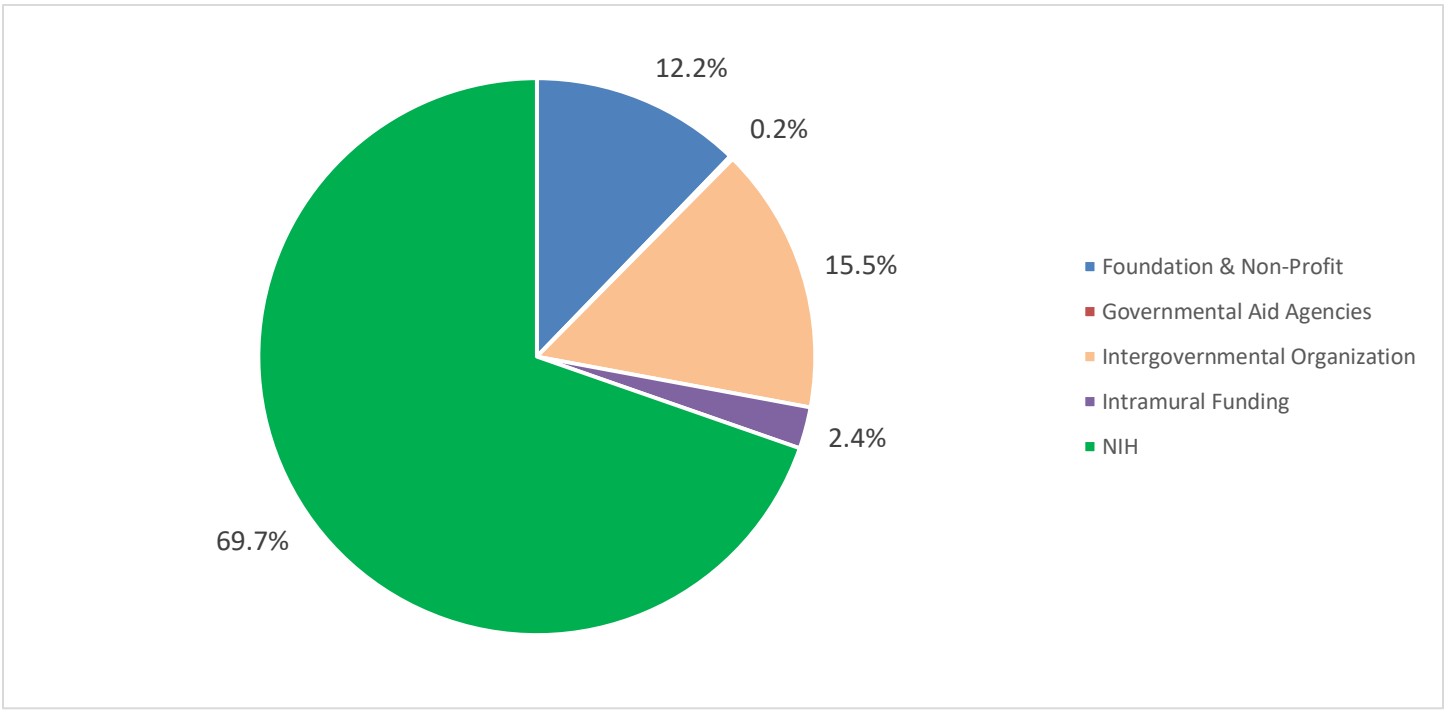
Investigators reported more than US$ 5.3 million in new awards in the first six months of 2020. The amount awarded in the first half of the year increased AMPATH's cumulative total of research and training awards to US$ 169 million (Figure 1).

Figure 1: Cumulative Research and Training Awards Received (1998-June 30, 2020)



The majority of research funding awarded in the first half of 2020 was from the US National Institutes of Health (NIH), which accounted for 70% of total awards (Figure 2).

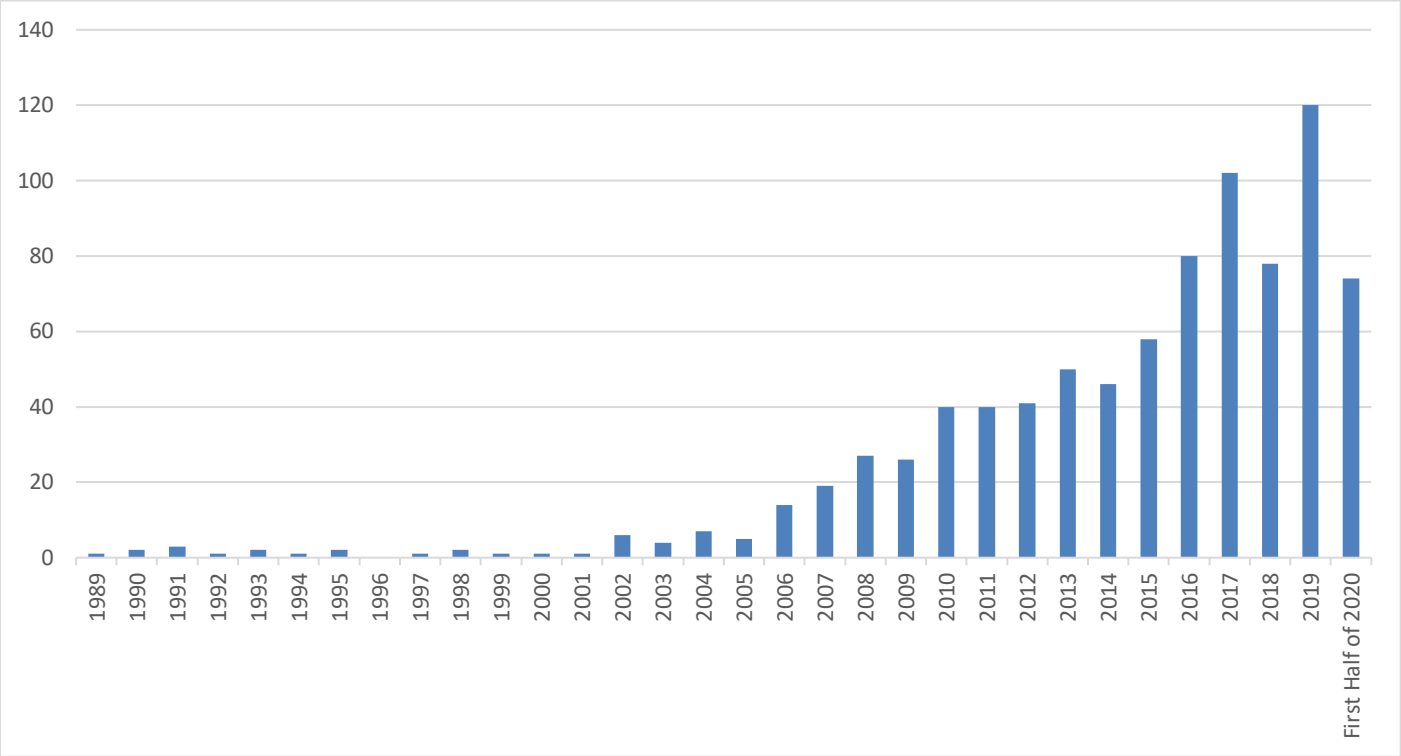
Figure 2: Percentage of Funding by Sponsor, January 1 – June 30, 2020



Publications

AMPATH investigators published 74 articles in peer-reviewed journals in the first six months of 2020, increasing the total number of AMPATH publications to 855 (Figure 3). AMPATH investigators continued to produce publications in a wide range of research in basic and clinical science research, epidemiology, implementation science, health services and systems research, and bioethics. The most common research focus remained HIV and related conditions among publications in the first half of 2020. The Moi University Clinical Research Centre was one of 11 AIDS Clinical Trials Group sites in Brazil, Kenya, Malawi, South Africa, Uganda, and Zimbabwe to participate in a three-arm, randomized, non-inferiority trial for the treatment of advanced AIDS-associated Kaposi sarcoma, which was published in April 2020 in *The Lancet* (see reference 25, Appendix B). In addition to research in the area of HIV, publications in the areas of maternal and child health, substance use, mental health, and non-communicable diseases such as hypertension and heart disease illustrate the variety of research being conducted at AMPATH. A bibliography of all the publications produced from January – June 2020 is available at the end of this report (Appendix B).

Figure 3: Number of AMPATH Articles per Year since 1989 (n = 855).



Study Reports

The following report provides a snapshot of AMPATH's research activities from 1 January – 30 June 2020. It includes updates and progress from 56 research projects that were 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. The views expressed in these reports do not necessarily reflect the views of the AMPATH Research Program, its partners, or sponsors.

Study Title	**A cluster randomized trial of "Teach HADITHI" teacher training intervention to reduce classroom HIV-related stigma in Kenya"**
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Other Investigator (s)	Edith Apondi, Juddy Wachira, Tu Wanzhu
Working Group(s)	Pediatric Research Working Group (PRWG)
Description	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.

Site(s)	Moi Teaching and Referral Hospital
Project Period	6/1/2018 - 5/30/2020
Funding Status	Funded - NIH - Fogarty International Center (FIC)
Direct Award (USD)	$261,673
Update	The objective of this study is to evaluate an innovative film-based, curricular intervention to reduce HIV/AIDS-related (H/A) stigma in school contexts and thereby reduce H/A stigma learned, perceived or experienced by youth. We are assessing 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. Exploratory Aim 4: Examine the impact of H/A stigma training on stigmatizing K/A/B about COVID-19. 4.1 Examine whether teachers trained on H/A stigma will report less negative and stigmatizing K/A/B about COVID-19. 4.2 Examine whether HIV-infected, disclosed adolescents enrolled in AMPATH who are also enrolled in intervention group schools will report less perceived, enacted and internalized COVID-19 stigma. 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, exploratory Aim 3 and exploratory Aim 4. Phase One of the study which included cognitive interviews with the key informants around the proposed Teach HADITHI teacher training curriculum was completed on14th September 2019, with a total of 64 interviews . This included interviewing 50 key informants and 14 Adolescent Community Advisory board members. 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 developed a RedCap database for quantitative data entry. Findings from the cognitive interviews have been submitted for poster presentation at the International Workshop for HIV and Adolescence 2020. In the last six months, we completed the training of 184 teachers from the intervention group on the Teach HADITHI module and administered

	questionnaires to assess their perception about stigma in schools and classrooms. We also completed interviews for 128 teachers in the control group. Post training assessments are ongoing with a total of 66 teachers interviewed and interviews proceeding by phone because of the COVID-related restrictions. During the 6-month follow-up assessments, we have also assessed stigma related to COVID-19 as a preliminary examination of interactions between HIV-related stigma and COVID-related stigma. Out of the 376 participants enrolled, 124 have completed the study. Data entry and verification of quantitative data is ongoing. In May 2020, Dr. Vreeman presented the preliminary findings from Teach HADITHI to date in an oral presentation for the Fogarty International Center HIV Stigma Network Meeting. Both systematic review and qualitative data analysis are ongoing. We also applied for and received a no-cost extension for this award because of our delays in being able to launch the pilot study, compounded by the COVID-related delays. The activities planned during this extension period are described below.
Future Plans	In the next six months, we plan to: *Complete the follow-up assessments for both intervention and control schools. *Begin assessment with HIV-infected, disclosed adolescents enrolled in AMPATH who are also enrolled in intervention group schools *Complete data entry, cleaning for analysis of quantitative data of the study. *Publish a systematic review from our Phase One work, reviewing the literature on stigma interventions in schools. *Publish a manuscript on the findings from interviews with SME.
Publication(s)	Yes
Study Title	**A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector.**
Principal Investigator(s)	Jeremiah Laktabai, Moi University
Co-Investigator(s)	Diana Menya, Moi University
Other Investigator (s)	
Working Group(s)	Public Health and Primary Care (PHPC)
Description	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. 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 subsides, 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.
Site(s)	Webuye District Hospital
Project Period	9/14/2018 - 8/31/2019
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	Not Reported
Update	We conducted study team training in February 2020 which covered the study protocol, country-specific standard operating procedures and field visit session to familiarize the team with the study site. The training was attended by both Kenya and Nigeria study team members. We received Aim 2 protocol approval from IREC in February 2020. We enrolled 40 outlets in March 2020. Due to COVID-19, we had to pause a few planned activities scheduled for April and May as staff had to work from home. The paused activities included; supervisor training, outlet training and baseline outlet survey. Study activities resumed in June 2020 and upon resumption we trained study supervisors on study operations and supervision activities. We completed the baseline outlet survey in over 36 outlets and look forward to completing the remaining surveys in July. In June we trained 32 of the 40 outlets on malaria RDT administration and on a mobile app that will assist with tracking and administering arm-specific study payments as well as client illness information at the outlets. We continue with outlet supervision to monitor and support outlets before arm specific training.
Future Plans	We expect to complete outlet training for the remaining 9 outlets in July. We also plan to randomly assign the outlets to study specific arms (1,2,3 & 4) in July and conduct arm-specific training in August.
Publication(s)	Yes
Study Title	**A5349/TBTC S31 Rifapentine-containing treatment shortening regimens for pulmonary tuberculosis: A randomized, open-label, controlled phase 3 clinical trial**
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	David Lagat, Moi University
Other Investigator (s)	
Working Group(s)	None

Description	This will be 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 study achieved its international accrual target of 1600 participants by the end of 2018. Of these, 29 were from the MUCRC in Eldoret. Given the 96 week follow up period, the last participant of the study in Eldoret exited on January 30, 2020. Data analysis is currently ongoing and results will be sent to IREC and disseminated to participants once they become available. All activities at the site for this study have been completed.
Future Plans	The database closes on 27th July 2020 and the data analysis will commence. There being no activities at the site, we will wait for the results from the CDC team.
Publication(s)	No

Study Title	**Addressing HIV drug resistance research gaps in a cohort of perinatally infected Kenyan children and adolescents**
Principal Investigator(s)	Rami Kantor, Brown University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Other Investigator (s)	Rachel Vreeman, Joe Hogan, Vladamir Novitsky
Working Group(s)	Pediatric (PRWG)
Description	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 Bioline for children older than 18 months of age; (ii) Age â‰¤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.
Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital, Turbo Health Centre, Webuye District Hospital
Project Period	7/1/2019 - 6/30/2024
Funding Status	Funded - NIH
Direct Award (USD)	$16,385
Update	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 modified to adapt the database for this new study phase. Data collection tools have been adapted, finalized, and submitted to IREC and IRB for approval. In the last six months, data collection tools have been reviewed and approved by the IREC and IRB, REDCap database is ready and we have trained all study staff on the study protocol. Though we were ready to begin enrollment of participants in March 2020, we did not initiate enrollment because of the evolving COVID-19 pandemic. In the meantime, we applied for and have received two supplement grants under this parent R01 -- one specifically seeking to conduct research on bioethical issues involving the participation of adolescents in HIV-focused research and biospecimen collection and storage and the other to conduct COVID-19-related survey assessments and antibody testing with participants enrolled in this cohort.

Future Plans	In the next six months, we plan to: *Begin participant enrolment and follow up *Begin data entry into the REDCap database. *Start the qualitative interviews for the bioethical supplement. *Start to conduct COVID-19 antibody testing for the supplement.
Publication(s)	No
Study Title	**AMPATH - Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS**
Principal Investigator(s)	Patrick Loehrer, Indiana University - Purdue University in Indianapolis (IUPUI)
Co-Investigator(s)	Darron Brown, Indiana University - Purdue University in Indianapolis (IUPUI)
Other Investigator (s)	Omenge Orango,
Working Group(s)	Oncology (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)	Center for Global Health Research - KEMRI at Kisumu City, Kenya
Project Period	9/19/2014 - 8/31/2019
Funding Status	Funded - NIH - National Cancer Institute (NCI)
Direct Award (USD)	$2,132,402
Update	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: ï‚§ 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). ï‚§ Fewer HIV-infected women (35.7%) were married than HIV-uninfected women (67.3%) (p< .001). ï‚§ 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< .0001). ï‚§ 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. ï‚§ Low risk HPV types were detected in 32.2% of HIV-infected women and 17.3% of HIV-uninfected women (p=.0113) ï‚§ 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. 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. Following national guidelines, the COVID-19 pandemic resulted in a pause in study participants returning to clinic sites for follow up. Study participant follow up visits resumed in July.
Future Plans	A renewal for this project was submitted. A just-in-time request was received, completed, and submitted. We are hopeful to have this continuation approved in the next 6 months. Follow up with the study participants will continue.
Publication(s)	No
Study Title	**Analyzing the Adolescent HIV Care Cascade in East Africa Through the International Epidemiologic Databases Evaluating AIDS (IeDEA ACE Study)**
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Edith Apondi, Moi University
Other Investigator (s)	Elul Batya , Rami Kantor, Ayaya Samuel, Kara Wools-Kaloustian, Giorgos Bakoyannis, Leslie Enane, Awuor Okoko Nicollate
Working Group(s)	Pediatric (PRWG)
Description	The objective of this study is to refine estimates of key outcomes and associated correlates among a subset of PIA in the East Africa IeDEA 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, 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.
Site(s)	FACES Lumumba
Project Period	8/1/2018 - 7/31/2019
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	$259,480
Update	Over the last six months, participant enrolment continued in all three IeDEA ACE study sites - Moi Teaching and Referral AMPATH, Kitale AMPATH, and FACES, Lumumba site. We have enrolled a total of 355 PIA (286 Engaged in care and 69 Lost To Program), including those from MTRH (n=129), Kitale (n=150) and FACES Lumumba (n=76). All enrolled adolescents undergo assessments using a battery of questionnaires to assess their physical, mental, and social health, and clinic care preferences. In addition, the PIA 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 specimens (N=80) shipped from the AMPATH Reference lab to Dr. Kantor's Lab in the USA for resistance testing. Study assessments and tracing were immediately put on hold in March 2020 related to the spread of the COVID-19 pandemic and have not yet resumed. Data cleaning in the RedCap database for the quantitative portion of the study is ongoing. An associated effort to conduct phone surveys to assess the direct and indirect impact of the COVID-19 pandemic on these PIA has now been improved by IREC and will be initiated in the near future. In the last six months, additional qualitative interviews were done with a subset of 53 adolescents engaged in care to assess HIV stigma and impact on their health status and care preferences. Analysis is ongoing: In 30 interviews (60% male), nearly all participants reported experiencing perceived stigma; many related the source of this fear to previous experiences of enacted stigma or stories of stigma recounted to them by caregivers, schoolmates, and community-based peers. ALWH were most concerned about their friends and peers who were not living with HIV stigmatizing them. When asked what might happen if their friends discovered their HIV status, they shared concerns of vengeful disclosure, being the subject of gossip, and social isolation. In order to protect themselves from stigma, participants stressed the importance of secrecy and purposely not disclosing their status within their community. Secrecy was a major theme

	for participants and was directly related to the key domains of mental health, adherence, and peer support. Several participants identified feelings of isolation, estrangement and fear as a result of secrecy. Coupled with purposeful non-disclosure, this secrecy led to non-adherence. Nearly every participant reported purposeful non-adherence when in the presence of friends, extended family, and visitors. When asked how their medication-taking behaviors would be different if their peers were also living with HIV, nearly every participant reported that it would be easier to maintain adherence. Despite identifying the impact of open status and having an HIV-positive community on treatment adherence, most participants reported not knowing other ALWH. Several adolescents identified the need for secrecy as a barrier to developing a network of peers living with HIV. Although clinic-based peer networks, called peer support programs, were well-known to the participants, many also reported lacking access to such groups. Participants suggested that having both in-clinic and mobile-based platforms for peer support could expand access and preserve secrecy. Participants who had previously accessed these groups endorsed them as beneficial to adherence by providing education around medication-taking behaviors and creating a network for reminders and encouragement between peers. ALWH stressed that a peer support network was most helpful for knowing that they were not alone. An abstract entitled, "A Qualitative Examination of Perceived Stigma and Its Impact on Health Status and Care Preferences Among Kenyan Adolescents Living with HIV" was submitted to AIDS Peds 2020. In addition, qualitative analysis related to procedures for and development of a verbal autopsy strategy and tool to use with families with children who have died is ongoing underway. These analyses are being used to adapt a verbal autopsy interview tool that will be implemented within the next month to do assessments of PIA found to be deceased. Dr. Vreeman and Dr. Elul submitted a revised 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 interruptions and those disengaged from care.
Future Plans	In the next six months, we will: *Complete tracing and enrollment of adolescents who are lost to program. *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. *Prepare abstracts and manuscripts for publications on our findings.
Publication(s)	Yes
Study Title	**Bridging Income Generation with Group Interated Care(BIGPIC)**
Principal Investigator(s)	Rajesh Vedanthan, New York University
Co-Investigator(s)	Jemima Kamano, Moi Teaching and Referral Hospital
Other Investigator (s)	B. Andama, C. Wanyonyi, D. Menya, D. Edelman, E. Finkelstein, G. Bloomfield, J. Kamano, C. Horowitz, S. Pastakia, V. Fuster, V. Naanyu
Working Group(s)	Cardiovascular and Metabolic (CVMD)

Description	The objective of this proposal is to utilize a trans disciplinary implementation research approach to address the challenge of reducing CVD risk in low-resource settings. The research aims at integration of group medical visits and microfinance with the additional social network characteristics.Aim 1: Identify the contextual factors, facilitators, and barriers that may impact integration of group medical visits and microfinance for CVD risk reduction, using a combination of qualitative research methods: 1) baraza; and 2) focus group discussions among individuals with diabetes or at increased risk for diabetes, microfinance group members, and rural health workers. Then develop a contextually and culturally appropriate integrated group medical visit-microfinance model. Aim 2:Evaluate the effectiveness of group medical visits and microfinance groups for CVD risk reduction among individuals with diabetes or at increased risk for diabetes, by conducting a four-arm cluster randomized trial comparing: 1) usual clinical care; 2) usual clinical care plus microfinance groups only; 3) group medical visits only (no microfinance); and 4) group medical visits integrated into microfinance groups. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the trial.
Site(s)	Trans-Nzoia and Kisumu West
Project Period	4/1/2015 - 1/1/2020
Funding Status	Funded - NHLBI
Direct Award (USD)	Not Reported
Update	Administrative -Capacity building of the study personnel with specialized and targeted training completed -Project contracts completed for all field staff in Eldoret, Kenya, as well as all subcontracts -NIH R01 grant successfully extended for additional 12 months (through January 31st, 2021). -DSMB Meeting conducted on September 12, 2019 (meeting minutes compiled by DSMB chair are included with this submission). -Biostatistician hired at NYUGSoM Aim 1: Barriers/facilitators/contextual factors -Manuscript currently under review Aim 1.1 (Barriers, Facilitators, & Contextual Model): -Manuscript published in BMC Health Services Research Aim 2 (Cluster RCT): -Logistics of trial Roll Out: ● Rollout by health facility: completed (December 2018) - 24 facilities were rolled out (6-GMV, 6-GMV-MF, 6-UC, 6-MF) ● Enrollment: completed (December 2018) - A total of 2890 participants were enrolled. ● 3-month follow-ups: completed (April 2019) - Total participants: 2684 (92%) ● 12-month follow-ups now complete (December 2019) - Total participants: 2710 (94%) ● Training of community health workers (CHWs) in group facilitation and microfinance process completed ● Data collection, entry, & management: Data collection instruments have been programmed in REDCap. Continuous testing and feedback occurred throughout project implementation. Real-time data entry through REDCap completed, Syncing of entered data also occurred when real-time network access was not available

	● Data analysis ongoing: Outcomes manuscript in preparation ● Process evaluation: Implementation and data collection completed; Data analysis ongoing Aim 2.1 (Mediation & Moderation Analysis): Social network survey (SNS) ● SNS data collection completed and Analysis ongoing Aim 3 (Cost Effectiveness Analysis): -Costing questionnaire survey (CQS): CQS administration and data collection completed and Qualitative data collection has been completed
Future Plans	Aim 1: ● Publish manuscript Aim 1.1 oContinue secondary manuscript preparation Aim 2: oComplete data analysis oComplete and submit outcomes abstract oContinue manuscript preparation Aim 2.1: oContinue data analysis oManuscript preparation Aim 3: oContinue data analysis oManuscript preparation
Publication(s)	Yes
Study Title	**Can integration of effective family planning services into Anticoagulation Management Services (AMS) improve uptake?**
Principal Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Co-Investigator(s)	Imran Manji, Moi Teaching and Referral Hospital
Other Investigator (s)	Christabell Umukagah
Working Group(s)	Reproductive Health (RHWG)
Description	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: 1) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) is feasible. 2)

	Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within Anticoagulation Monitoring Services (AMS) can improve uptake of long-acting reversible contraceptive methods (IUCDs and contraceptive implants). 3) Determine whether integration of education about and free provision of highly effective long-acting reversible contraceptive methods within an Anticoagulation Monitoring Services (AMS) Clinic can prevent unplanned pregnancies. In order to evaluate these objectives we will provide the intervention and follow the participants for the following 1 year time period. At 3-month, 6-month, and 12-month follow-up we will evaluate whether they are using any method of family planning and whether they have experienced subsequent unplanned pregnancies. This data will be compared to the same group of women prior to implementation of the education intervention and free, on-site provision of all reversible contraceptive methods.
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/20/2015 - 8/31/2016
Funding Status	Unfunded -
Direct Award (USD)	
Update	Plans that were underway to conduct longitudinal analyses in the past 6 months had to be put on hold due to other overriding issues that took precedence.
Future Plans	In 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)	No

Study Title	**Caregiver Interventions for Developmental Delays in Young Kenyan Children**
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi Teaching and Referral Hospital
Other Investigator (s)	
Working Group(s)	Pediatric (PRWG)
Description	PROBLEM STATEMENT: 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.6,7 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.6 The program is adaptable cross-culturally and has been used in over 4 countries.6,8 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 and 24 months of age, compared with a control group.9 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.5 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 effectives 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,1 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 have finalized 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.
Future Plans	Data analysis and establishing a dataset for the data.The abstract has been under reviews. A manuscript is underway.
Publication(s)	Yes
Study Title	**Chamas for Change: Adapting a community-based peer-support and health education model for pregnant and parenting adolescents in Kenya**
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	Edith Apondi, Moi University
Other Investigator (s)	Laura J. Ruhl, Lauren Y. Maldonado, Michael L. Scanlon, Julie Thorne, Astrid Christoffersen
Working Group(s)	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 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.
Site(s)	Busia District Hospital, Huruma Sub-District Hospital, Kitale District Hospital, Port Victoria Sub-District Hospital, Uasin Gishu District Hospital
Project Period	6/30/2020 - 6/29/2021
Funding Status	Indiana CTSI
Direct Award (USD)	$10,000
Update	Progress for our study has been significantly impacted over the COVID 19 pandemic. Since January 2020, we collected and analysed data to inform design of the program. Data analysis is now ~90% complete. In total, we conducted a total of 14 focus group discussions with pregnant and/or parenting adolescents, caregivers of pregnant and/or parenting adolescents, health care providers, and community health volunteers. We further conducted 4 key informant interviews with officials from the Ministries of Health, Education, and Youth and Gender to assess acceptability and feasibility adapting the Chamas for Change program for adolescents. Focus groups were recorded in English or Kiswahili, and transcribed. Team-based inductive analysis has been used to uncover important themes. To date, this data has led to modifications to our educational curriculum for pregnancy and parenting. This includes 15 new topics. A local youth artist was contracted to develop accompanying youth-friendly images. Delayed activities include stakeholder meetings to confirm the final adaptation model of Chamas for Change for adolescents, trainings with CHVs and youth leaders, and launching our first recruitment and pilot groups.
Future Plans	The new curriculum will be translated into Kiswahili and printed into flipcharts. We will plan our CHV training and devise a strategy for training that respects social distancing requirements. Pilot groups were meant to be recruited for July 2020; given the pandemic we do not anticipate starting until January 2021; as with other programs we are monitoring when it might be safe for us to move forward.
Publication(s)	No
Study Title	**Clinical Assessment for Retention and Engagement (CARE)**
Principal Investigator(s)	Leslie Enane, Indiana University
Co-Investigator(s)	Edith Ogalo, Moi Teaching and Referral Hospital
Other Investigator (s)	Rachel Vreeman, Winstone Nyandiko
Working Group(s)	Pediatric (PRWG)
Description	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.
Site(s)	Lumumba Health Center, Kisumu
Project Period	3/1/2017 - 6/30/2018
Funding Status	Funded - NIH
Direct Award (USD)	$22,624 (USD) - For the first year
Update	Recruitment and in-depth interviews with disengaged adolescents and their caregivers traced in the adolescent sentinel cohort study (ACE Study) in MTRH (Module 4 and Rafiki) and Kitale AMPATH clinics continued. We recruited 8 adolescents and 6 caregivers, as summarized in the following table. Our recruitment had to come to a halt in early March due to COVID-19 pandemic. At that time we had reached sufficient thematic saturation to analyze our qualitative findings. Enrolled(10-14) years(15-19) yearsTotal Female 2 2 4 Male 3 1 4 TOTALS 5 3 8 EnrolledMaleFemaleTotal Caregivers246 Data entry and verification of the surveys were completed during this period, and qualitative data analysis also continued.
Future Plans	Over the next reporting period, we hope to conclude our analysis of Aim 1 qualitative work. We will consolidate all the findings from our Aim 1 work, previous qualitative work on barriers and facilitators to retention in care among adolescents, systematic literature review, and quantitative findings from the ACE study. Our findings will be used in the development of a tool to assess risk for disengagement from care among HIV infected adolescents (CARE tool). In the next reporting period, we will begin interviews for the development and refinement of CARE tool questions. We also hope to incorporate questions to healthcare providers on new challenges and strategies for retaining adolescents during the covid-19 pandemic.
Publication(s)	No

Study Title	**Community-based provision of urine pregnancy tests as linkage to reproductive health services**
Principal Investigator(s)	Faith Yego, Moi University
Co-Investigator(s)	Caitlin Bernard, Indiana University
Other Investigator (s)	Violet Naanyu, Julie Thorne, Astrid Christoffersen-Deb
Working Group(s)	Reproductive Health (RHWG)
Description	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 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.
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)	$14,139
Update	Qualitative and quantitative data analysis is ongoing.
Future Plans	We plan to complete both qualitative and quantitative data analysis and disseminate the findings to stakeholders. We also plan to write manuscripts
Publication(s)	No

Study Title	**Developing Capacity of Moi Teaching and Referral Hospital / Moi University Institutional Research Ethics Committee (MTRH/MU IREC), Kenya to Prevent and Manage Research Misconduct.**
Principal Investigator(s)	Edwin Were, Moi University
Co-Investigator(s)	Jepchirchir Kiplagat, AMPATH
Other Investigator (s)	
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 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
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/31/2017 - 8/31/2020
Funding Status	Funded
Direct Award (USD)	$276,000
Update	1. Development of Contextualized RCR curriculum: The team worked on finalizing the training material after piloting training which was conducted late last year. An evaluation of the training was conducted and the results of the evaluation used to improve the training modules. 2.Data analysis and publications: One paper has been published and the second paper is in draft stage. Analysis of data continues and we anticipate to complete more manuscripts. 3. Moi RIO Office setup (policy development): As part of the prevention module, we engaged the MU Directorate of research to set up a Research Integrity Office for Moi University. Office supplies and furniture have been purchased. We have also engaged experts to guide in developing the policies and SOPs, these are being finalized. 4. TAC Meeting: Throughout the period, we have engaged our Technical advisory committee. The role of TAC is to provide project oversight to ensure that the project is implemented in line with the project proposal and it is consistent with MUCHS/MTRH

	overall strategic plan and National Commission for Science, Technology and Innovation (NACOSTI) policies. The committee has held 1 meeting during this period. 5. Application for No Cost Extension: The grant period ends in July 2020 but due to the COVID-19 pandemic, some project activities are still pending. We submitted a no cost extension request to NIH for another year to allow completion of pending activities and close out of the project.
Future Plans	Conduct 2 trainings on Responsible conduct of Research, continue working on publications, finalize the MU-RIO policy and sops and conduct a sensitization workshop for Moi University.
Publication(s)	Yes
Study Title	**Enhancing Preventive Therapy of Malaria In children with Sickle cell anemia in East Africa (EPiTOMISE)**
Principal Investigator(s)	Festus Njuguna, Moi University
Co-Investigator(s)	Steve Taylor, Duke University
Other Investigator (s)	Joseph Kirui, Wendy P O'Meara, Chite Asirwa
Working Group(s)	Pediatric (PRWG)
Description	Children with SCA are particularly vulnerable to infectious diseases and in malaria endemic areas, malaria is one of the leading causes of hospitalization and death among children with SCA. The current recommendation is chemoprevention with daily proguanil. However, this regimen suffers from suspected low adherence rates and probable reduced efficacy due to parasite resistance to antifolate drugs. We are conducting a randomized, three-arm, open-label, clinical trial of malaria chemoprevention in children with sickle-cell anemia at a single site in Homa Bay, Kenya 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-piperaquine (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.
Site(s)	Homabay County Hospital
Project Period	6/1/2016 - 2/28/2017
Funding Status	Funded - NIH

Direct Award (USD)	$621,633
Update	Completed participants enrollment in January 2020. As at July 14, 2020, 135 participants have completed the study visits and this excludes 10 reported deaths and 14 reported lost to follow up cases. We had periodic monitoring by an external monitor in Feb 21-24, 2020. Amended the protocol to version 9.0 to include revisions made to Dholuo consent in April 2020. Received a continuing approval in June 2020. Due to the ongoing Covid-19 situation, the study PIs agreed to reduce the frequency of travel by participants considering they are already immunocompromised and starting April 1st we implemented a virtual visit plan where we have in-patient visits every other month and dispense two months of medication across all arms, and conduct a virtual visit every other month. This plan will continue until the Covid-19 pandemic has subsided. Progress of the virtual visits continues to be discussed in the weekly study calls. The study team has submitted the COVID-19 plan to IREC and will submit the same to Kenya PPB.
Future Plans	We continue to focus on the follow-up visits for the remaining participants, data cleaning and prepare for the completion of the study. Clinical activities will continue until January 2021. The study team is planning the final data cleaning and analysis 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.
Publication(s)	No
Study Title	**EPC: Feasibility and acceptability of Enhanced Patient Care (EPC) for adult HIV patients with unsuppressed viral loads in western Kenya**
Principal Investigator(s)	Juddy Wachira, Moi University
Co-Investigator(s)	
Other Investigator (s)	
Working Group(s)	Adult Medicine (AMWG)
Description	In Kenya retention rates have been shown to fall from 92% in the first 12 months to about 70% at 60 months following treatment initiation. Our previous qualitative work has identified a set of system-level barriers that we believe are experienced by many persons in SSA seeking HIV care such as lack of continuity of provider-patient relationship, limited provider training on communication skills, low provider-patient ratio and limited patient-provider interaction time have been identified. There is now need for the region to focus on the delivery of high quality HIV care, to effectively promote patient engagement beyond the existing efforts to promote HIV testing and ART uptake and adherence. This requires system-level changes that effectively utilize the limited available resources in the current provider-driven care programs which, this study hopes to address. Even though patient-centered care has been suggested as one of the approaches to improve patient engagement and health outcomes, this concept is not yet clearly understood and integrated in most health systems in SSA. The findings from this work will leverage ongoing efforts to promote patient-centered care in the region. Furthermore, our preliminary work supports the need for a more comprehensive approach to patient engagement that targets both the interpersonal and system-level barriers, collectively. Existing studies have proposed interventions either at the

	interpersonal or system level. This study provides a unique opportunity to collectively address interpersonal and system-level challenges within a supportive resource-constrained HIV care program. The AMPATH program, where the proposed study is nested, has embraced differentiated care in an effort to decongest the ART clinics. This provides an ideal environment to enhance patient care for those with unsuppressed viral loads through provider training within a reorganized care program. With the current emphasis on 'test and treat,' preliminary data from this work will inform us on a contextualized approach to promote patient engagement for the region. Finally, the inclusion of the cost-effectiveness arm of the study will help inform programs in this resource constrained setting of the practicability of having such patient-centered approaches and the implications for patient outcomes. Findings from the proposed study will aid in formulating a realistic, feasible, and cost-effective approaches for engaging and retaining patients in care. The central hypothesis of this work is that system-level interventions that enhance engagement of HIV patients with detectable viral loads will increase patient adherence to clinic appointments and improve clinical outcomes (increase viral suppression). AIM 1: Determine the impact of system-level factors on patient engagement (clinic adherence) among adult HIV patients. Retrospective multilevel analyses will be applied using patient and facility-level data retrieved from the AMPATH Medical Records System (AMRS). System-level factors such as patient waiting time, provider-patient interaction time, provider-patient ratio and continuity of provider-patient relationship can be derived from data routinely obtained during clinic encounters. Our working hypothesis is that health facilities performing poorly on system-level factors will have higher rates of patients who do not adhere to their clinic appointments. AIM 2: Assess the feasibility and acceptability of enhanced patient care (EPC) clinics for promoting patient engagement (clinic adherence) among patients with unsuppressed viral load (â‰¥400). EPC incorporates approaches that address clinic scheduling, treatment dialogue, and continuity of provider-patient relationship beyond the standard of care. Multifactorial design will be applied that will include two levels of intervention (EPC plus provider training vs. provider training only) and one control group (standard of care). Our working hypothesis is that receiving care at EPC clinics will promote better patient clinic adherence compared to standard care. AIM 3: Determine the cost effectiveness of EPC for engagement of patients with unsuppressed viral load. We will estimate the incremental cost per proportion of patients engaged in enhanced patient care as measured by clinical and ART medication adherence, to determine the cost utility and return to investment across the three intervention arms. Our working hypothesis is that care delivered to unsuppressed patients via EPC clinics will be more cost-effective for promoting patient clinic adherence compared to patients receiving standard care.
Site(s)	Khunyangu Sub-District Hospital, Port Victoria Sub-District Hospital
Project Period	7/1/2017 - 6/30/2022
Funding Status	Funded - NIH
Direct Award (USD)	$553,200
Update	Over the last six months we accomplished the following: *Approval: We were granted continuing approval from IREC *Follow-up of study participants in both intervention and control site: We continued to follow-up study participants as per the study protocol and collected relevant data on the implementation of EPC in the intervention site. *Post-test survey and in-depth interviews: We administered post-test surveys to study

	participants in both the intervention and control site for the 1st phase of follow up (6 month mark). We also administered in-depth interviews to patients and Health providers (intervention site) on the feasibility of the EPC intervention. *Analysis: Data analysis and manuscript development has been started for AIM 1& 2 *Abstracts: One abstract has been accepted for oral presentation for the adherence conference
Future Plans	*Follow-up: We will wind up the implementation of EPC in the intervention site and contact all the participants to inform them of the transition back to standard care. *In-depth Interviews: We will administer in-depth interviews to patients in the intervention site at the end of the 12 month follow up period and health providers in both the intervention and control sites *Dissemination of Study findings: Study findings will be disseminated to the AMPATH program and study participants. *Analysis: We plan to continue data analysis for all AIM 1 & 2 and to begin data analysis for AIM 3
Publication(s)	
Study Title	**Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy**
Principal Investigator(s)	Rena Patel, University of Washington
Co-Investigator(s)	Beatrice Jakait, Moi Teaching and Referral Hospital
Other Investigator (s)	
Working Group(s)	Adult Medicine (AMWG), Reproductive Health (RHWG)
Description	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, depomedroxyprosterone 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 nd/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.
Site(s)	All AMPATH Sites
Project Period	5/1/2016 - 1/25/2021
Funding Status	Funded - NIH - National Institute of Allergy and Infectious Diseases (NIAID)
Direct Award (USD)	$194,981
Update	Over the last 6 months we have completed the primary outcomes analysis and have a draft manuscript circulating with coauthors.
Future Plans	In the next 6 months, we hope to successfully publish the primary outcomes manuscript and embark on secondary analyses and publications.
Publication(s)	No
Study Title	**Ethnic Specific Risk Stratification in Early Pregnancy for Identifying Mothers at Risk of Gestational Diabetes Mellitus in Eldoret, Kenya**
Principal Investigator(s)	Wycliffe Kosgei, Moi Teaching and Referral Hospital
Co-Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Other Investigator (s)	Pastakia Sonak
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)	Reale Hospital, Langas Hospital, MTRH
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 data cleaning for Post delivery were completed. 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 . Manuscript writing started and for HIV and Strike papers. Participants samples were transferred to our collaborator in Warwick University.
Future Plans	In the next 6 months, data analysis will commence and hoping to finish writing the manuscripts. We are currently looking to submit HIV paper to journal.
Publication(s)	No

Study Title	**Evaluating Indicators of Poor Cardiac Function in Children and Adolescents Living with HIV in Western Kenya**
Principal Investigator(s)	Andrew McCrary, Duke University
Co-Investigator(s)	Winstone Nyandiko, Moi Teaching and Referral Hospital
Other Investigator (s)	Gerald Bloomfield, Piers Barker
Working Group(s)	Cardiovascular and Metabolic (CVMD), Pediatric (PRWG)
Description	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 unsurpressed 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.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/12/2017 - 12/31/2018
Funding Status	Funded - International AIDS Society, NIH - Fogarty International Center (FIC)
Direct Award (USD)	$136,199
Update	In the last 6 months, the primary funding grant through International AIDS Society concluded successfully. The primary manuscript was published: McCrary, Andrew W., Winstone M. Nyandiko, Alicia M. Ellis, Hrishikesh Chakraborty, Michael J. Muehlbauer,

	Myra M. Koech, Ibrahim Daud et al. "Early cardiac dysfunction in children and young adults with perinatally acquired HIV." Aids 34, no. 4 (2020): 539-548. We are currently working on 2 planned secondary analyses investigating circulating inflammation, cardiotropic viral co-infections, and cardiac function.
Future Plans	Complete analyses and manuscripts for 2 planned secondary analyses.
Publication(s)	Yes
Study Title	**Evaluating reproductive and HIV outcomes and decision making among HIV-positive women on dolutegravir: A prospective, observational cohort at AMPATH, Kenya**
Principal Investigator(s)	Mercy Maina, Moi Teaching and Referral Hospital
Co-Investigator(s)	Caitlin Bernard, Indiana University
Other Investigator (s)	Rena Patel, John Humphrey, Julie Thorne, Beatrice Jakait
Working Group(s)	Reproductive Health (RHWG)
Description	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.
Site(s)	Chulaimbo Sub-District Hospital, Moi Teaching and Referral Hospital, Saboti Sub-District Hospital
Project Period	4/17/2019 - 11/29/2019
Funding Status	Funded - University of Washington
Direct Award (USD)	$13,869
Update	Over the last 6 months, in-depth interviews were conducted with 11 women in the following age categories; 21-24 (3 Women), 25-34 (1 Women), +35 (1 Women), these participants currently use dolutegravir based ART regimen. 6 Participants who became pregnant while on DTG were also interviewed. The telephone interviews that have been conducted with women who attend various AMPATH clinics are 1360. In light of the COVID-19 outbreak, an amendment was submitted to the institutional research and ethics committee (IREC) review. Few questions were added to the data collection tool to ascertain whether the participants ART use, contraceptive use, and pregnancy intentions changed due to the COVID-19 outbreak and we have administered the survey on 327 participants. 4 abstracts were presented at the international AIDS conference (IAS) in July

Future Plans	We plan to complete data collection by the end of September and begin both qualitative and quantitative data analysis. Next steps include dissemination of findings to various stakeholders and manuscript writing and publications.
Publication(s)	Yes
Study Title	**Evaluation of locally-sourced compression therapy for treatment of chronic leg ulcers and management of Kaposi sarcoma leg lymphedema in western Kenya**
Principal Investigator(s)	Aileen Chang, University of California San Francisco
Co-Investigator(s)	Sonak Pastakia, Purdue University
Other Investigator (s)	Rakhi Karwa Sara Fletcher Phelix Were Edith Tonui Paul Wasike Naftali Busakhalla Frederick Chite Asirwa Samson Kiprono Toby Maurer Suzanne Goodrich
Working Group(s)	Adult Medicine (AMWG)
Description	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. 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. 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.
Site(s)	Turbo HC
Project Period	2/1/2018 - 2/3/2020
Funding Status	Unfunded
Direct Award (USD)	
Update	In the past 6 months, recruitment has finished and all study participants have completed the study.
Future Plans	We are currently cleaning the data for analysis. Over the next 6 months, we plan to complete data analysis, draft and submit a manuscript. We are also trying to submit the final invoices to wrap up the grant.
Publication(s)	No
Study Title	**Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups in Kenya**
Principal Investigator(s)	Omar Galarraga, Brown University
Co-Investigator(s)	Becky Lynn Genberg, John Hopkins
Other Investigator (s)	Juddy Wachira, Moi University
Working Group(s)	Adult Medicine (AMWG), Cardiovascular and Metabolic (CVMD)
Description	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 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, HIVrelated 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.
Site(s)	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
Project Period	7/5/2019 - 4/30/2024
Funding Status	Funded - NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	Not Reported
Update	*We have conducted mapping exercises from November to December 2019 and from January to February 2020 in three AMPATH-supported counties (Busia, Bungoma, Trans Nzoia). The purpose of the mapping exercises was to locate currently active microfinance groups, assess group eligibility for study participation (including the number of HIV positive active members), and assess group interest in study participation. Additionally, GIS data were collected during the mapping to inform randomization and further support easier implementation of the community-based care intervention. In the target counties, n=122 microfinance groups were mapped and n=77 microfinance groups have been identified as eligible for study participation, which is sufficient for achieving at least 80% power based on our statistical assumptions. *We have registered the cluster randomized trial in ClinicalTrials.gov (NCT04417127). *We have drafted the Overall Project Protocol and the Standard Operating Procedure (SOP) manuals for clinical HIV and CDM care delivery, and have finalized the Data Safety and Monitoring Plan. *Since the last AMPATH reporting period, the greatest challenges to study initiation have been due the outbreak of the novel coronavirus in Western Kenya and severe flooding in the study's catchment area. Following the implementation of coronavirus mitigation measures in the region (e.g., social distancing, restricted formal and informal sector activities, curfews), our research team has conducted telephone check-ins with the n=77 microfinance groups identified during the aforementioned mapping exercises. These check-ins have provided critical information concerning the

	capacity of microfinance groups to continue to engage in saving and lending activities. In response to these check-ins and the ongoing COVID-19 mitigation measures, we are currently transitioning our intervention delivery platforms to be able to deliver integrated care and microfinance within the context of social distancing.
Future Plans	In the next 6 months, we hope to accomplish the following activities: *Submit two manuscripts for publication in scientific, peer-reviewed journals. These manuscripts will present 1) the study's original Overall Project Protocol and 2) the methods used to identify and describe eligible microfinance groups for study recruitment. *Adapt and finalize the original project protocol to be able to deliver the integrated-community based (ICB) care intervention and microfinance through remote platforms. These adaptations will help to maintain access to ART and other chronic disease medications as well as access to income generating opportunities (e.g., MPesa) during periods of social distancing. *Begin community mobilization activities for the eligible groups that have already been identified in Trans Nzoia and Busia. The already-hired Research Assistant will play an integral part in community mobilization. *Begin baseline assessments and informed consent procedures in eligible MF groups by September 1, 2020.
Publication(s)	No

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
Other Investigator (s)	Eileen Immaculate, Paul Ayuo, Josephine Nabukenya, Khalid Mughal, Thorkild Tylleskar
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. Alarmingly, most sub-Saharan countries remain woefully unprepared to systematically train an adequate workforce to support the eHealth systems already being deployed. Countries like Uganda and Kenya recognize an emergent need for national strategies to build health informatics human capacity. These countries have appropriately developed national eHealth capacity-building strategies Implementing the strategies however requires direct leadership by Higher Education Institutions in the relevant countries. The urgency for sustainable mechanisms to increase HI workforce and research capacity in developing countries is self-evident. This goal can only be realized by having enough faculty members from developing countries fully trained in Health Informatics. These staff faculty can then be part of a well-functioning and high quality HI program moving forward. Recognizing this

	need, and the multidisciplinary competencies needed for HI training and research, our team identified partner institutions with complementary capabilities to support advanced Health Informatics training in East Africa for our project. Aims 1) Provide post-graduate (Masters and PhD) level training in Health Informatics and research. The focus will be on post-graduate training for health professionals and computer science personnel to help them become HI faculty at their institutions. 2) Increase number of women and marginalized populations in faculty-level training in Health In-formatics 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	One PhD student defended her project and graduated. Three (3) MSc HI students submitted their intent letters and we admitted 8 new MSc students. Makerere University graduated five (5) MSc HI students. We are working with the Ministry of Health on the COVID-19 response, especially on use of technology for contact tracing. Additionally one of the MSc HI students received a state commendation from the President for his outstanding service in helping steer the country through the COVID-19 pandemic. We also had a mUzima implementation with the CDC in Uganda. The COVID-19 pandemic has greatly slowed down project operations and a good number of planned activities did not happen.
Future Plans	We are looking forward to graduating at least 3 MSc HI students and two PhD Stude and a couple more present in a pre-defense. We intend to continue putting more focus on Departmental research seminars to fast track students projects. We also intend to have students publish their projects after completion. At the same time mentor students duirng the Gender mentoring meetings.
Publication(s)	Yes
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, Moi University School of Medicine
Other Investigator (s)	Bett Kipchumba, Solomon Omarimba, Wycliffe Kosgei, Winfred Mwangi, Felix Chumba, Megan McHenry, Beverly Musick, Constantin Yiannoutsos, Kara Wools-Kaloustian
Working Group(s)	Pediatric (PRWG), Reproductive Health (RHWG)
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 IeDEA 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	We have completed the analysis. Data collection at Kitale and MTRH has been suspended due to COVID. However, we are planning to resume data collection at Kitale once the data clerk can safely return to the facility.
Future Plans	Complete the manuscript and submit to a peer-reviewed journal.
Publication(s)	No
Study Title	**IeDEA Sentinel Research Network (IeDEA-SRN)**
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Diero Lameck, Moi University School of Medicine
Other Investigator (s)	
Working Group(s)	CVWG, 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), NIH - National Institute on Alcohol Abuse and Alcoholism (NIAAA), NIH - National Heart, Lung, and Blood Institute (NHLBI), NIH - National Institute of Diabetes and Digestive and Kidney D
Direct Award (USD)	Not Reported
Update	The SRN study submitted the protocol and data collection tools to Moi IREC in March 2020, and received comments in April 2020 and the study submitted responses. A new set of comments has been received on 30 July 2020 and the team is working on responding within a week to IREC. Most of the supplies available locally have been procured for the study. The study also hopes to ship some equipment from the United States such as the Fibroscan and POC testing machine.
Future Plans	Once the project is approved, we hope to accomplish the following: - Obtain IREC approval - Hire and Train staff - Finalize study SOPs - Initiate project by enrolling study participants
Publication(s)	No
Study Title	**Implementation Analysis of an Inpatient Family Planning Consultation Services**
Principal Investigator(s)	Caitlin Bernard, Indiana University
Co-Investigator(s)	Wycliffe Kosgei, Moi Teaching and Referral Hospital
Other Investigator (s)	Julie Thorne, Astrid Christoffersen-Deb, Martha Smith
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	Over the past 6 months, Focused Group Discussion (FGD) with the nurse managers and their deputies from Internal Medicine, Surgery& Orthopedic, Cardiac Care Unit and Gynecologic wards at MTRH was conducted. Additionally, an FGD with representative female patients from these wards was held with the aim of ensuring inclusivity of all the key stakeholders' opinions and feedback for maximum impact and effectiveness of this project. An amendment to the ethics board to include some qualitative scales was submitted and approval received. The planned roll-out of the project has been put on hold due to the prevailing pandemic. In the meantime, transcription of the FGD materials has been completed and qualitative analysis is currently underway.
Future Plans	In the next 6 months, we plan to complete the qualitative analysis of the FGDs data. We also aim to roll out the project activities in the aforementioned wards at MTRH. 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. Upon completion of this, preliminary analysis will be carried out.
Publication(s)	No

Study Title	**Making Inroads to Strengthen the Health of Adolescents (MaISHA)**
Principal Investigator(s)	Leslie Enane, Indiana University
Co-Investigator(s)	Edith Apondi, Moi Teaching and Referral Hospital
Other Investigator (s)	Rachel Vreeman, Winstone Nyandiko, Elizabeth Lowenthal
Working Group(s)	Pediatric (PRWG)
Description	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 FundIndiana University - Center for AIDS Research, Indiana CTSI, IU Center for Global Health
Direct Award (USD)	$57,500
Update	We completed analysis for the project, and started preparing multiple manuscripts for publication in peer-reviewed journals. A previous manuscript from this work has been published.
Future Plans	We presented an abstract at AIDS 2020 in July, and will be submitting additional abstracts for conferences later in the year. We will submit multiple manuscripts for publication in peer review journals in the coming months.
Publication(s)	No
Study Title	**MCH STUDY (Evaluations at Infant and Child Visits a MCHs in western Kenya: A Needs Assessment)**
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi University
Other Investigator (s)	Roselyne Ananda
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	Two manuscripts are under review for publication: Preventive health service coverage among infants and children at six maternal-child health clinics in western Kenya: A cross-sectional assessment. Andrew R. Deathe, Eren Oyungu, Samuel O. Ayaya, Ananda R. Ombitsa, Carole I. McAteer, Rachel C. Vreeman, Megan S. McHenry. Under review by Maternal and Child Health Journal Survey of development monitoring in well-baby clinics in rural health facilities in Western Kenya. Eren Oyungu, MBChB, MMED, Roselyne Ananda Ombitsa, Anna W. Roose, MD, Rachel C. Vreeman, MD, MS, Megan S. McHenry, MD, MS. Under review by Global Pediatric Health
Future Plans	Two manuscripts for publication after their review: Preventive health service coverage among infants and children at six maternal-child health clinics in western Kenya: A cross-sectional assessment. Andrew R. Deathe, Eren Oyungu, Samuel O. Ayaya, Ananda R. Ombitsa, Carole I. McAteer, Rachel C. Vreeman, Megan S. McHenry. Under review by Maternal and Child Health Journal Survey of development monitoring in well-baby clinics in rural health facilities in Western Kenya. Eren Oyungu, MBChB, MMED, Roselyne Ananda Ombitsa, Anna W. Roose, MD, Rachel C. Vreeman, MD, MS, Megan S. McHenry, MD, MS. Under review by Global Pediatric Health
Publication(s)	No

Study Title	**Mental Health Screening and Phone-Based Counselling Support for Adolescents with HIV in Kenya**
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Other Investigator (s)	Bree Weaver, Edith Apondi
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	The study "Mobile Mental Health Monitoring and support for Adolescents with HIV in Kenya" project successfully enrolled 30 adolescents aged 10-19 years from Turbo clinic in western Kenya and each were assigned a smartphone and a WhatsApp group for tele-counseling, in addition to in-person peer support groups at the clinic. The adolescent participants participated in two peer support groups at the Turbo clinic, totaling five peer support groups at Turbo clinic during the study period. Participants were also involved in monthly individual counseling meetings with the counselor at Turbo clinic on their return-clinic day. Participants 'adherence to medication was monitored using an Electronic Dose monitors (MEMS caps) during the study period. The six-month follow up ended with 29 participants (one participant withdrew from the study) and study intervention activities are completed. Data entry and verification of individual patient characteristics into a REDCap database as well as transcription and translation of the qualitative data collected through WhatsApp discussions completed. Quantitative analysis has been completed, and a manuscript detailing the findings has been submitted to the Journal of the International Association of Providers of AIDS Care. Twenty-nine out of the 30 participants initially recruited completed the intervention and follow up and were included for analysis (one participant did not complete the study due to barriers experienced at boarding school that made it difficult to fully participate in the intervention). The mean age of participants was 15.4 years and the majority (56.7%, N=17) were female. Qualitative analysis of the WhatsApp chat transcripts has been completed and submitted as an abstract for poster presentation at the International Workshop for HIV and Adolescence 2020. Participants demonstrated particular interest in conversations around HIV literacy, navigating relationships, and experiences with stigma. Adolescents discussed side effects of ARVs, provided support and suggestions to ALWH experiencing challenges around adherence, and HIV transmission methods. Participants shared the value of trustworthy relationships and the importance of intentional disclosure to friends and romantic partners. They identified the emotional impact of non-disclosure in their relationships and the steps they take to maintain secrecy, including hiding medication bottles and sneaking away from a group to keep time. Adolescents described challenges in the school setting, including maintaining adherence without accidental disclosure and navigating HIV-related stigma by teachers and classmates. Participants described similar stigma and disclosure related experiences in the home, and offered tactics and solutions to these challenges. Religion played a significant role, providing a sense of hope and protection for the ALWH.

Future Plans	In the next 6 months, we hope to complete and submit a manuscript detailing the qualitative study findings, as well as to move the quantitative manuscript to publications. We have recently submitted an R01 application for a telehealth-delivered differentiated care strategy for adolescents that draws heavily on the pilot intervention and data from this study.
Publication(s)	Yes
Study Title	**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"**
Principal Investigator(s)	Abraham Siika, Moi University
Co-Investigator(s)	Charles Kwoba, Moi University
Other Investigator (s)	
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	Funded - Not Reported
Direct Award (USD)	$289,162
Update	Participants are still on follow up. They're all receiving study medication. One participant died although the death was not related to study medications. This SAE was reported to IREC.
Future Plans	The participants are approaching week 48 study visit. We will be able to assess one of the study's primary objectives
Publication(s)	No
Study Title	**NEURODEV (Assessing Neurodevelopmental Delays in Children Born to HIV-infected Mothers in Western Kenya: A Pilot Study)**
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi University

Other Investigator (s)	Roselyne Ananda
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.Aim3 : To evaluate the feasibility of implementing a validation study to examine NDD screening methods in a pilot sample of children under three years of age born to HIV-infected mothers. In Phase One, we utilized semi-structured interviews (SSIs) and focus group discussions (FGDs) with caregivers and clinicians to understand current knowledge and beliefs about NDDs. FGDs were chosen for caregivers to generate information on collective views of neurodevelopment and the meanings and implications that lie behind those views. SSIs were chosen for clinical staff to address several key questions specific to their individual training and experiences, while allowing both the interviewer and clinical staff to further pursue an idea or response in more detail. Phase Two will allow us to pilot key methods needed for future validation testing of these items. As we aim towards a large validation study to assess the reliability and validity of these screening questions in this setting, we will conduct prospective feasibility testing, piloting these questions during cognitive interviews with caregivers and clinical officers, in the clinical setting in Kenya and also piloting the implementation of the gold standard for developmental screenings - lengthy, comprehensive developmental assessments of young children. No modifications have been made to the specific aims as stated in the original proposal. We have ongoing Institutional Review Board and local ethics committee approval for the aims.
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	4 manuscripts are currently underway. The following manuscript will be submitted to Research in Developmental Disabilities in August 2020: Cultural Adaptation of the Bayley Scales of Infant and Toddler Development, 3rd Edition for use in Kenyan Children Aged 18-36 Months: A Psychometric Study 1. Megan S. McHenry 2. Eren Oyungu 3. Ziyi Yang 4. Abbey C. Hines 5. Ananda R. Ombitsa 6. Rachel C. Vreeman 7.Amina Abubakar 8. Patrick O. Monahan
Future Plans	submittion of following 4 manuscripts to Research in Developmental Disabilities in August 2020: Cultural Adaptation of the Bayley Scales of Infant and Toddler Development, 3rd Edition for use in Kenyan Children Aged 18-36 Months: A Psychometric Study 1.Megan S. McHenry 2.Eren Oyungu 3.Ziyi Yang 4. Abbey C. Hines 5. Ananda R. Ombitsa 6. Rachel C. Vreeman 7. Amina Abubakar 8. Patrick O. Monahan

Publication(s)	Yes
Study Title	**Neuropsychiatric Genetics of African Population-P**
Principal Investigator(s)	Lukoye Atwoli, Moi University
Co-Investigator(s)	Edith Kwobah, Moi University
Other Investigator (s)	Emonyi Wilfred, Kigen Gabriel
Working Group(s)	Behavioral and Social Science (SSRN)
Description	In the recent years there have been significant insights into the complex etiologies of neuropsychatric brain disorders. For example, neuropsychiatric genetics has achieved success with the identification of 18 loci for schizophrenia according t the Schizophrenia Working Group 214. Furthermore, meta-analyses of genome-wide association study results encompassing thousands of samples have been completed for other psychiatric disorders including attention-deficit disorders, bipolar disorder autism spectrum disorder, and major depressive disorder. However published results on neuropsychiatric disorders have often not included samples of Africa ancestry. The study takes 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. Specific Aims 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 populations. 4. To provide opportunities for training of African scientists in neuropsychiatric genetics research. The Moi site will recruit a total of 4 participants over 4 years, consisting of 2 cases and 2 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 fro insights from the genetic research.
Site(s)	Kakamega and Kapsabet County Hospitals
Project Period	2/28/2017 - 3/1/2022
Funding Status	Funded - Broad Institute of MIT and Harvard
Direct Award (USD)	$252,150
Update	ACCOMPLISHMENT 1.Continued data collection,extraction and shipment. 2. Continuous training of staff on quality data collection. 3.We had data collection at site clinics. PROGRESS We have recruited 310 participants in the study for the last six months (Jan2020-June2020) both cases and controls.We have had regular meetings and reviews with the project team and projections which has helped us in having quality data. CHALLENGES The study was stopped on 17th of March 2020 due to Covid 19 pandemic hence there was no participant recruitment.
Future Plans	Resume data collection when it is safe to do so. We plan to continue with data collection and scale up to the sites to help us reach our target We plan to continue doing the case - control matching and ethnicity as we do our site recruitment
Publication(s)	Yes

Study Title	**One Year Morbidity and Mortality of Infants Diagnosed with Perinatal Asphyxia or Low Birth Weight Admitted to The New Born Unit at Moi Teaching and Referral Hospital**
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	
Other Investigator (s)	Ruhl Laura Nyandiko Wiston Ng'etich Eric Christoffersen-Deb Astrid Browm Morgan Kunkel Melissa Alera Joy Kibet Vincent Bernard Christian Kosgei Faith
Working Group(s)	Pediatric (PRWG)
Description	
Site(s)	MTRH
Project Period	10/23/2017 - 10/23/2019
Funding Status	Unfunded
Direct Award (USD)	
Update	Over the last 6 months, subsequent follow up of participants has been ongoing. In addition to the follow up being conducted during their scheduled visits to the Neonate Outpatient Clinic (NOPC) at MTRH, development assessment of the neonates has been ongoing at different stages. 6 months phone follow up was completed in June 2020 with a follow up rate of 64%. 9 months follow up began in February with a current follow up rate of 87% and a follow up rate of 88% for the 12 months follow up that commenced in May. For the qualitative aspect of the study, 1 in-depth interview was conducted and transcription done.
Future Plans	In the next 6 months, we aim to continue conducting 9 &12 months developmental assessment with file reviews and follow up during clinic appointments. Due to the prevailing pandemic, the in-depth interviews are going to be conducted over phone in order to ensure safety of both the participants and the research team. Data cleaning will be done concurrently with data collection activities. Once all the base data have been collected, and interviews transcribed, preliminary data analysis will be done
Publication(s)	No

Study Title	**Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK)**
Principal Investigator(s)	Valentin Fuster, Mount Sinai School of Medicine
Co-Investigator(s)	Jemima Kamano, Moi University
Other Investigator (s)	Rajesh Vedanthan Violet Naanyu Diana Menya Carol Horowitz Allison Delong Joe Hogan
Working Group(s)	Cardiovascular and Metabolic (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 an 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.

Site(s)	Mosoriot Rural Health Training Centre, Turbo Health Centre
Project Period	4/1/2012 - 3/31/2019
Funding Status	Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	$2,104,519
Update	Progress for the project is delineated below. Aim 1 (barriers & Facilitators to Linkage/Retention - All activities complete at this time. Subsidiary Aim 1.1 (Behavioral Assessment and Communication Strategy) - Manuscript in preparation Subsidiary Aim 1.2 (Smart-phone-based tool) - All activities complete at this time. Aim 2 (Cluster RCT) - Final outcomes analysis ● Final outcomes analysis completed and manuscript published as previously reported ● Process evaluation analysis ongoing, and manuscript in preparation Aim 3 (Cost Effectiveness Analysis) - All activities complete at this time.
Future Plans	Preparation and finalization of manuscripts
Publication(s)	No

Study Title	**Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)**
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Other Investigator (s)	
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. In addition,we are continuing to work on analyses in two primary areas. The first is describing adherence patterns in this cohort using detailed adherence data from electronic dose monitors and investigating whether adherence to treatment was associated with disclosure status and any change in disclosure status over time. Data from the electronic dose monitors are still being cleaned for analysis; this process has been challenged by staff turnover and the time-intensive process of cleaning electronic adherence data. The second is investigating the performance of our mental and behavioral health screening tools by comparing the results of self-reported questionnaires (e.g., PHQ-9 for depression) with detailed counseling logs kept by study counselors for each patient interaction. We hypothesize that some mental and behavioral health issues are missed when using the standardized tools that may be identified during counseling sessions. We will compare quantitative questionnaire results with qualitative counseling profiles to better understand how standardized mental and behavioral health instruments perform in this setting.
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)	No
Study Title	**Phylogenetic Inference of Vertical versus Horizontal HIV Transmission among Adolescents in Western Kenya**
Principal Investigator(s)	John Humphrey, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Other Investigator (s)	Kara Wools-Kaloustian, Joe Hogan, Rachel Vreeman, Rami Kantor
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 (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.
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 have completed recruitment and are in the analysis phase.
Future Plans	Completion of HIV sequencing and initial drafting of manuscript.
Publication(s)	No

Study Title	**Prevalence of Postpartum Hypertension among Kenyan Women with Preeclampsia (PET): A Prospective Cohort Study**
Principal Investigator(s)	Rebecca Lumsden, Duke University
Co-Investigator(s)	Gerald Bloomfield, Duke University
Other Investigator (s)	
Working Group(s)	Cardiovascular and Metabolic (CVMD), Reproductive Health (RHWG)
Description	The burden of cardiovascular disease (CVD) is rising in sub-Saharan Africa (SSA). Preeclampsia, a type of hypertensive disorder of pregnancy, is a unique risk factor for CVD among women and carries significantly increased risk of early hypertension postpartum. However, little is known about the postpartum cardiovascular risk among women with preeclampsia in SSA, where large barriers to postpartum care exist. This gap in care results in a potential missed opportunity for early CVD prevention among this high-risk population. Our study aims to define the prevalence of hypertension at three months postpartum among women with preeclampsia in western Kenya and identify risk factors associated with the development of postpartum hypertension, including clinical, laboratory and echocardiographic factors. All pregnant women admitted to MTRH for delivery who have a diagnosis of PET will be enrolled. Echocardiograms will be done at the time of delivery to assess baseline cardiac function. Women will be prospectively followed for 3 months using home blood pressure (BP) monitoring to track the trajectory of BP over the postpartum period. Women will return for a follow up visit at 3 months to assess their BP. Women will participate in semi-structured interviews aimed at understanding challenges/barriers to health-seeking behavior in the postpartum period.
Site(s)	Moi Teaching and Referral Hospital
Project Period	1/1/2020 - 6/30/2021
Funding Status	Funded - NIH - Fogarty International Center (FIC), Duke Global Health Institute
Direct Award (USD)	$15,000
Update	We started study enrollment in January 2020. We successfully enrolled ~87 women with a PET diagnosis who were admitted to MTRH. All women completed baseline data collection (including echocardiograms) and were undergoing home BP monitoring and follow-up. We were planning for our first, in-person 3-month follow up visit at the end

	of March 2020. However, all study activities were paused on 17 March 2020 unexpectedly due to the COVID pandemic. We halted recruitment and all, planned in-person follow up. We were able to continue collecting data on the home BP monitoring/follow-up for participants. As of July 2020, we were approved to resumed to resume our non-essential research through AMPATH Research Office (after securing PPE and training our study staff on new COVID monitoring protocols). We submitted an amendment to IREC to adjust out study timeline and follow-up period. As a result of these unexpected changes, we have amended our protocol to follow women for 6 months postpartum and we will now conduct follow up echocardiograms on all women at 6-months, as well as expand our current interview/surveys to understand how COVID has affected postpartum women and their follow up care. We will resume research activity (enrollment and follow up) in August 2020. We have applied for and been granted a no cost extension of our NIH grant by the Fogarty International Center/Vanderbilt University to be able to continue our project through June 2021.
Future Plans	If we are able to resume study recruitment and in-person follow up for those women recruited prior to our study pausing, we hope to complete all recruitment and ~1/2 of all study follow-up. During this time, we hope to begin data analysis and manuscript preparation and plan for presentation of results for 2021 local and international meetings.
Publication(s)	

Study Title	**Prospective study of Lopinavir based ART for HIV Infected childreN Globally (LIVING study)**
Principal Investigator(s)	Winstone Nyandiko, Moi University
Co-Investigator(s)	Samuel Ayaya, Moi University
Other Investigator (s)	Wamalwa Dalton, Obimbo Elizabeth, Bukusi Elizabeth, Otieno Godfrey Allan Prof Musoke Rachel Dr Oyaro Patrick Dr Mbuthia Joseph K Dr Koech Lucy
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	The major progress done over the past six months has been data cleaning. So far we are almost done. There are no preliminary findings to share at the moment
Future Plans	We hope that we can have the database lock done, we hope we can have the data analysis process begin
Publication(s)	No

Study Title	**Randomized, Phase II Trial of CHOP vs. Oral Chemotherapy with Concomitant Antiretroviral Therapy in Patients with HIV-associated Lymphoma in Sub-Saharan Africa**
Principal Investigator(s)	Naftali Busakhala, Moi University
Co-Investigator(s)	Evangeline Njiru, Moi Teaching and Referral Hospital
Other Investigator (s)	
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 - Not Reported
Direct Award (USD)	$75,000
Update	The study has been closed for enrollment in all sites and follow-up is still on going in one site (Malawi), but we have completed follow-ups of the enrolled participants.
Future Plans	We anticipate data analysis to start once follow-up of study participants is completed in other participating study sites in Sub-Saharan African.

Publication(s)	No
Study Title	**SAFI (Stigma in AIDS Family Inventory) Validation Study**
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi Univerisity
Other Investigator (s)	Irene Marete, Hai Liu, Violet Naanyu
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, Khunyangu Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	12/17/2013 - 11/30/2015
Funding Status	Funded - NIH - National Institute of Mental Health (NIMH)
Direct Award (USD)	$567,828
Update	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 Â® adherence, and viral loads. The stigma measurement items showing the highest construct validity were questions related to: *Experiencing discrimination *Feeling stressed and/or anxious due to HIV stigma *Feeling depressed and/or sad due to HIV stigma *Hopes for future changing negatively due to HIV 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.
Future Plans	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.
Publication(s)	Yes
Study Title	**Spatial scales of Plasmodium falciparum generations; implications for elimination**
Principal Investigator(s)	Andrew Obala, Moi University
Co-Investigator(s)	Wendy O'meara, Duke University
Other Investigator (s)	Joseph Kirui, Judy Mangeni
Working Group(s)	Public Health and Primary Care (PHPC)
Description	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 2. 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 hotpsot. 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.
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	In January the study team began data collection on the expanded cohort, including annual and monthly household data collection, monthly dried bloodspot (DBS) sample collection, and on-demand RDT testing for any participants who call with malaria-like illness. The study team also engaged in entomology work that included collecting, rearing (1 week per month), dissection and processing of mosquitoes collected from enrolled households on a weekly basis. The first shipment of samples, both mosquito and human DBS, from the cohort, were sent to the US laboratory for processing in March 2020. Due to Covid-19, study activity was interrupted in April and May. We resumed activities in June and we look forward to continuing and adhering to return to work guidelines as provided by AMPATH.
Future Plans	We hope to continues field and lab works. We also look forward to starting some preliminary analysis of the sample collected.
Publication(s)	Yes
Study Title	**Starting at The Roots: Using Human-Centered Design To Develop an Adolescent Pregnancy Program in Eldoret, Kenya**
Principal Investigator(s)	Edith Apondi, Moi Teaching and Referral Hospital

Co-Investigator(s)	Heather Millar, University of Toronto
Other Investigator (s)	Thorne Julie Mogeni Richard
Working Group(s)	Reproductive Health (RHWG)
Description	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.
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/1/2018 - 7/31/2020
Funding Status	Funded - SICK KIDS, TORONTO
Direct Award (USD)	$20,000
Update	Data collection and analysis for this study title Starting at the Roots: Using Human-Centered Design to Develop an Adolescent Pregnancy Program in Eldoret, Kenya was completed in the fall of 2018. Several programmatic changes have been made, including health-care provider training in provision of adolescent-friendly sexual and reproductive health (SRH) services to healthcare workers in Uasin Gishu public health facility. We have further developed an SRH peer navigator training program and are collaborating through Rafiki Center and with RMNCAH to host these trainings. This is all as a programmatic response to the research findings. Data are being synthesized into a manuscript for publication. This is anticipated to be submitted to a peer-reviewed journal by December 2020.
Future Plans	As above, we anticipate manuscript completion and submission by the end of 2020. We continue to look out how we can develop care programs in response to our research findings, and hope to develop further REBs that will allow critical inquiry into our care-based strategies.
Publication(s)	No

Study Title	**Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS)**
Principal Investigator(s)	Constantine Akwanalo, Moi University

Co-Investigator(s)	Jemima Kamano, Moi University
Other Investigator (s)	Violet Naanyu, Ann Mwangi, Benson Njuguna, Tim Mercer, Rajesh Vedanthan, JJ Dick, Sonak Pastakia
Working Group(s)	Cardiovascular and Metabolic (CVMD)
Description	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) 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.
Site(s)	Burnt Forest Sub-District Hospital, Kitale District Hospital, Moi Teaching and Referral Hospital, Mosoriot Rural Health Training Centre, Turbo Health Centre, Webuye District Hospital
Project Period	6/1/2018 - 5/1/2019
Funding Status	Funded - NIH - National Heart, Lung, and Blood Institute (NHLBI)
Direct Award (USD)	$268,469
Update	Achievements 1. Human centered design -Multiple perspectives on the same problem in one room (patient, peer, clinician, researcher) -Enhanced intervention (referral outcome feedback, averted referrals) 2. Dissemination post contextual evaluation -Clearer understanding of the problem -Buy-in for clinical trial 3. Collaborating with existing care programs -Population health & PIC4C - shared resource use -Research innovations directly improving care e.g. referral POC -Care infrastructure being leveraged for research 4. Clinical trial -DSMB established and approval for commencement -Two visits from PPD (site initiation and interim monitoring visit) -Enrolled 78 participants into the cluster RCT prior to COVID-19 interruption -Currently implementing recommendations from IMV 5. Capacity Building Training of staff with regards to the aim two activities(Intervention phase. Peer Navigators training and hiring with regards to their roles and responsibilities. All the staff in the study completed the GCP training course. 6. Virtual presentations of our study activities to the GRIT CC consortium. 7. Visit by the clinical monitor to check on the study progress. 8. Amendment of the study sites from the previously submitted ones. Removal of Burnt Forest and Turbo and replacing with Kwanza and Nambale. Challenges 1.Lack of political goodwill in some counties where the research is conducted. 2.Delayed and then initially slow recruitment 3.COVID-19 which has delayed the project activities 4.Holding of field activities as result of PPd monitoring report. 5.Termination of the staff contacts as we await for approvals from the Donor and subsequently IREC before we resume our study.
Future Plans	Immediate next steps Continue with the enrolments as per the accrual plan Amendment approvals and follow up PPD visit Publications from contextual evaluation Resume and complete recruitment Retraining of staff before resumption of field activities
Publication(s)	No
Study Title	**Study of Newly Diagnosed Kaposi's Sarcoma**
Principal Investigator(s)	Naftali Busakhala, Moi University

Co-Investigator(s)	Jeffrey Martin, UCSF
Other Investigator (s)	
Working Group(s)	Oncology (ORWG)
Description	To achieve our scientific objectives, we will identify a community-based sample of HIV-infected adults with newly diagnosed KS. We propose to use a rapid case ascertainment (RCA) approach to quickly evaluate patients suspected to have KS. RCA refers to the swift and thorough evaluation of a patient with a new disease diagnosis. We note that RCA does not refer to a new technique for making diagnoses of KS, but it instead refers to the process of rapidly assessing status and extent of disease once the diagnosis has been made. It is most useful for diseases that are potentially rapidly progressive and potentially fatal. It involves the establishment of a system whereby when a diagnosis is made, a central team is made aware, and the affected patient is rapidly evaluated. It has been mainly used in the cancer field to facilitate epidemiologic research for establishing population-level incidence and stage of cancer at time of diagnosis.
Site(s)	
Project Period	9/1/2015 - 8/31/2019
Funding Status	Funded - NIH
Direct Award (USD)	$750,186
Update	As end of June 2020, the Study has managed to enroll 219 Cases. 118 participants are currently in active follow-up, while 75 are deceased. All Deaths have been documented. We have so far done a total of 870 follow-ups visits. The study has also enrolled 89 Controls matched to 15 Cases.
Future Plans	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
Publication(s)	Yes

Study Title	**IeDEA Syndemics**
Principal Investigator(s)	Kara Wools-Kaloustian, Indiana University
Co-Investigator(s)	Suzanne Goodrich, Indiana University
Other Investigator (s)	Lukoye Atwoli, Edith Kwoba
Working Group(s)	None
Description	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 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.
Site(s)	Moi Teaching and Referral Hospital
Project Period	12/17/2018 - 12/17/2020
Funding Status	Unfunded
Direct Award (USD)	
Update	PSA4. Qualitative interviews with a sub-sample of participants to explore access, use, and experiences with substance use and mental health services was scheduled to begin in January 2020 but began a little later afterwards. Covid-19 pandemic came in and active participants engagement was stopped in March 2020. By this time, 2 participants had gone through the qualitative interviews.
Future Plans	As soon as normal clients scheduling resume in AMPATH care program, qualitative interviews will continue at Eldoret site.
Publication(s)	No

Study Title	**The Role of PD-1 Pathway and Tissue Microenvironment in HIV-Kaposi Sarcoma and Endemic Kaposi Sarcoma Cohort in Western Kenya**
Principal Investigator(s)	Patrick Loehrer, Indiana University
Co-Investigator(s)	Asirwa Chite, Indiana University
Other Investigator (s)	Evangeline Njiru Toby Maurer Mike Rosenblum Stefanie Sowinski
Working Group(s)	Oncology (ORWG)
Description	Even before the HIV pandemic, equatorial Africa had among of the highest KS incidences in the world. In this area, 'endemic KS' (the term given to the HIV-unassociated form of KS) was manifested primarily as indolent localized disease in men and represented 4 to 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.
Site(s)	
Project Period	10/1/2015 - 9/30/2018
Funding Status	Funded - NIH
Direct Award (USD)	$158,406
Update	The study was closed for enrollment and we managed to enroll a total of 59 participants into the study. Data collection and entry have been completed.
Future Plans	Data analysis is ongoing.
Publication(s)	No
Study Title	**Using a mobile application to improve pediatric presumptive TB identification in western Kenya**
Principal Investigator(s)	Daria Szkwarko, Brown University
Co-Investigator(s)	James Amisi, Moi University
Other Investigator (s)	Carter, Jane
Working Group(s)	Pediatric (PRWG), Tuberculosis (TBWG)
Description	BACKGROUND: 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. GAP: 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. SPECIFIC AIMS 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. METHODS: 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 < 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.
Site(s)	Webuye District Hospital
Project Period	1/1/2019 - 6/30/2020
Funding Status	Funded - Thrasher Foundation
Direct Award (USD)	Not Reported
Update	We have completed post-intervention data collection. Data analysis and manuscript writing is underway. Between August 2019-January 2020, 1787 children age â‰¤15 were screened for presumptive TB using the mobile application, 376 of which met the criteria for presumptive TB. There was a statistically significant increase in the proportion of children to all patients between the pre-and post-mobile application periods (97/908 (10.7%) vs. 160/989 (16.2%) respectively, p=0.0005). In the active TB register, there was an increase in the proportion of children to all patients between the pre-and post-mobile application periods (17/117 (14.5%) vs. 15/83 (18.1%) respectively, P=0.5) but this was not statically significant. Our study has demonstrated that a mobile intervention used by a CHV is feasible and significantly increases presumptive TB screening.
Future Plans	Completion of data analysis Manuscript submission to a peer-reviewed journal Dissemination meeting with local TB partners and NTP
Publication(s)	No
Study Title	**Using Narrative Films to Combat HIV Stigma: Perspectives from HIV-Infected Adolescents and their Caregivers**
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Other Investigator (s)	Brittany McCoy; Carole McAteer; Josephine Aluoch
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)	No

Study Title	**Validating an Integrated Community Based Strategy of Peer Support in Pregnancy and Infancy**
Principal Investigator(s)	Julia Songok, Moi University
Co-Investigator(s)	Astrid Christoffersen-Deb, University of Toronto
Other Investigator (s)	Laura Ruhl Justus Elung'at
Working Group(s)	Public Health and Primary Care (PHPC), 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 facilitates processes of accountability using CHV-led women's groups (Chamas). Chama cha MamaToto (chamas) is a peer-support model that groups together pregnant women in the same community. Central to our approach is the integration of health, social and financial literacy education with a savings/loans program. Chamas are designed to improve MNCH by generating positive peer support for women to advocate for themselves and account for the care they receive. We have combined best practices from women's health groups and microfinance programs to design an integrated service delivery platform that is low-cost, self-sustaining and self-managed. Its a randomized

	cluster trial to be implemented in 4 sub counties in Trans Nzoia county where a cluster is a community unit.
Site(s)	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	Our focus over the past 6 months has been completion of data collection, preliminary, data analyses for the RCT study and the supplemental study ("Impact of health workers strike"), developing write ups for publication as well as continuing to provide care for women participating in Chamas. Preliminary analysis We enrolled 1920 particpants from 37 intervention and 37 control clusters. A total of 1550 (80.7%) from 37 intervention and 37 control clusters. A total of 1550 (80.7%) participants completed the study with 822 (82.5%) and 728 (78.8%) in the intervention and control arms, respectively. Facility-based deliveries improved in the intervention arm (80.9% vs 73.0%; Risk Difference (RD) 7.4%, 95% CI 3.0-12.5, OR=1.58, 95% CI 0.97-2.55, p=0.057). Chamas participants also demonstrated higher rates of 48-hour postpartum visits (RD 15.3%, 95% CI 12.0-19.6), exclusive breastfeeding (RD 11.9%,95% CI 7.2-16.9), contraceptive adoption (RD 7.2%, 95% CI 2.6-12.9), and infant immunization completion (RD 15.6%,, 95% CI 11.5-20.9). From the study, Chamas participation was associated with significantly improved MNCH outcomes compared with the standard of care. This trial will contribute to robust data from sub-Saharan Africa to support community-based, women's health education groups for MNCH in resource-limited settings. Data on financial activities was collected upon completion of a year's participation in financial activities within Chamas. The analysis on financial activities is yet to be completed. For the supplemental study ("Impact of health workers strike") we conducted a mixed methods study to investigate maternal and child health during the 150-day nationwide strike by public sector nurses in Kenya. We used retrospective surveys with women who were pregnant during the 2017 nurses' strike to measure utilization and outcomes and compared survey responses to a different cohort of women who were pregnant in 2018 when there were no major strikes. We also conducted qualitative interviews and focus group discussions (FGDs) with a range of stakeholders about maternal and child health care during the 2017 nurses' strike, including women who were pregnant during the strike, community health volunteers (CHVs) involved in community-based maternal and child health services, and health facility managers at public and private facilities. Out of 1,341 women recruited in 2017, our team relocated and consented 843 women (63%) to participate in surveys. Out of 924 women recruited in 2018 and randomized to the control arm, a total of 728 were relocated and consented (79%). The majority of women who were not relocated could not be reached using the contact information provided during their initial enrollment. The average number of days between when a woman delivered and when they completed the survey about their pregnancy was 611 days (standard deviation, SD, 63 days) for women recruited in 2017 and 324 days (SD 68 days) for women recruited in 2018. Most interviews were conducted in-person by research assistants (84% for women recruited in 2017 and 88% for women recruited in 2018) with the remainder conducted by phone. There were no significant differences in age, marital status, employment status, or poverty level between women recruited in 2017 and 2018. Women recruited in 2018 were significantly more likely to have health insurance at the time of delivery compared to women recruited in 2017 (15% versus 59%,

	p<.0001). The majority of women recruited in 2017 (76%) reported that there was a health service disruption related to health workers' strikes during their pregnancy, while only 4% of women recruited in 2018 reported the same. We found that access to and utilization of basic maternal and child health services were negatively impacted among pregnant women in Trans-Nzoia during nationwide 2017 nurses' strike. There were few systems-level interventions to maintain basic services during the strike, but health facility managers, CHVs, and communities employed various ad hoc and individual strategies in an attempt to adapt and cope. Long-term challenges and areas for future research in the post-strike period include rebuilding trusting relationships with communities that support the critical role played by CHVs in delivering maternal and child health services. Efforts have been geared towards publishing this paper and feedback will be provided during the next reporting period. To strengthen partnership in implementing the program as care after completion of the research piece, we held 1 feedback meeting with the CHVs, CHEWs and the SCHMTs of the 4 sub-counties in Trans Nzoia where we are implementing the program. We also held a meeting with CHVs from the control arm to appreciate their support of providing standard MoH care to women within this arm and also to mark an end to the RCT study. We also partnered with the Trans Nzoia County Ministry of Health to provide a platform; local radio, for creating awareness and sensitization about evidence based MNCH strategies implemented through Chamas to prevent negative pregnancy outcomes. Chamas being a 3-year longitudinal program, and given the fact that we would want it to continue as a care program, women who participated in the RCT during their first year of participation proceeded to the second year as part of the Chamas care program. Currently 477 women are participating in the second year as part of care. We recruited additional women with children below 2 years and were willing to join and actively participate in Chamas. We also recruited 187 pregnant women from the intervention community clusters to form new cycle(year) 1. Towards ensuring provision of feedback, we held 2 meetings with the CHMT members to share findings from the RCT study.
Future Plans	We intend to publish several papers from the main and supplemental studies. As a program, we are committed to strengthening our partnership with the Ministry of Health officials at the county level and so far we had 1 dissemination meeting on preliminary findings of the RCT study with the County MoH team. We intend to share with the County after final analysis as well. We will also continue implementing the project as a care program. We intend to develop a Chama toolkit that includes a revised curriculum that will be complete by end of 2020. For the supplemental study, we plan to finalize a write up by September 2020. This information will be disseminated to different stakeholders and also submitted for publication
Publication(s)	No
Study Title	**Virologic Treatment Failure and Drug Resistance in HIV-Infected Kenyan Children (RESPECT) study.**
Principal Investigator(s)	Rachel Vreeman, Indiana University
Co-Investigator(s)	Winstone Nyandiko, Moi University
Other Investigator (s)	Rami Kantor, Samuel Ayaya, Joe Hogan
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.
Site(s)	Kitale District Hospital, Moi Teaching and Referral Hospital, Webuye District Hospital
Project Period	8/2/2016 - 7/31/2020
Funding Status	Funded - NIH
Direct Award (USD)	$613,511
Update	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 analyses are now underway, examining viral suppression, adherence, and drug resistance. 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<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. We have applied for and were awarded a no-cost extension period of 12 months. We will use this extension to publish several manuscripts detailing our findings under Specific Aims 1 and 2 and to complete laboratory and statistical analyses of longitudinal and prospective data planned within Specific Aims 3 and 4. We now have a complete study database with individual patients linked across several major data sources (clinical, laboratory, study) that will allow for

	these analyses to move forward, as we await some of the final RNA and DNA lab results. A statistical analysis plan has been written and approved by the PIs, and our lead biostatisticians have conducted preliminary analyses of the data. An abstract was accepted for poster presentation and presented IAS AIDS 2020. The abstract is entitled 'Non-Adherence and Low Drug Levels Impact Viral Outcomes in HIV-Infected Kenyan Youth.' The author list includes: Rachel Vreeman, Winstone Nyandiko, Allie DeLong, Michael Scanlon, Akarsh Manne, Mia Coetzer, Antony Ngeresa, Josephine Aluoch, Vlad Novitsky, Festus Sang, Celestine Ashimosi, Samuel Ayaya, Eslyne Jepkemboi, Milicent Orido, Ashley Chory, Joe Hogan and Rami Kantor.
Future Plans	In the next 6 months, we plan to: *Send the remaining blood samples for all participants to Brown University for phenotyping and resistance testing; *Continue with analysis and draft additional manuscripts for publications on our findings.
Publication(s)	Yes
Study Title	**WEZESHA (Neurodevelopmental Screening in Children Born to HIV-Infected Mothers in Kenya)**
Principal Investigator(s)	Megan McHenry, Indiana University
Co-Investigator(s)	Eren Oyungu, Moi University
Other Investigator (s)	
Working Group(s)	Pediatric (PRWG)
Description	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. *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.
Site(s)	Burnt Forest Sub-District Hospital, Moi Teaching and Referral Hospital, Turbo Health Centre
Project Period	9/21/2018 - 9/21/2022
Funding Status	Funded - NIH
Direct Award (USD)	$46,055 year 1 budget
Update	We continued to enroll young children between ages 18-36months for both screening by our questionnaire tools and neurodevelopmental assessments being performed on the children, we are at 160 children against our 240 target and this was slowed down due to the ongoing pandemic that we hope to catch up with enrollments in due course.
Future Plans	We aim to continue recruiting and enroll for our 240 young children target between the ages of 18-36 months from the HIV-infected, HIV-exposed but uninfected children and Non-exposed children. 120 from MTRH MCH clinic, 60 from Turbo and Burnt Forest MCH clinics respectively. We also be doing interviews to families with children to help us understand how to improve development in children living in the communities and hopefully to improve child development in the future.
Publication(s)	No

Appendix A: Training Needs Assessment Report

2020 Training and Mentoring Needs Assessment Report

Rationale: In response to the 2019 Research Strategic Plan's goal of increasing the number of successful independent investigators, the Research Program Office (RPO) conducted a research training and mentoring needs assessment to understand the current state of research training and mentorship, including identifying gaps, barriers, and opportunities to strengthen the research training and mentorship available to AMPATH affiliated researchers and program staff. The information collected in this needs assessment is intended to inform the development of research training and mentorship materials and curricula for AMPATH affiliated investigators and research staff.

Methods: As part of this assessment, RPO conducted two dynamic online surveys in REDCap. One 30-minute confidential survey centered on investigators and another 30-minute confidential survey focused on research coordinators and assistants. To help validate and inform the survey results, key informant interviews (KIIs) with Heads of Department (HODs) and investigators were held in-person in Eldoret, Kenya. All interviews were conducted using a standardized script. Interviews were audio-recorded and were subsequently stored on a secure platform. Notes were also taken. Last, a focus group discussion with research coordinators was held using participatory analysis for community action tools. The discussion was audio-recorded and noted. All data were collected in January and February 2020. Data were then synthesized using a coding process in February and March 2020.

Response rate and respondents demographics: A total of 182 AMPATH affiliated investigators were invited to participate in the online survey, 46 (25%) of whom completed the survey. Respondents were more likely to be Kenyan, 57%, or male, also 57%. When applying an objective criteria for an investigator's research status, we found that 43% of respondents were early-stage, 31% were mid-stage, and 26% were senior investigators (See appendix for investigator status criteria). Participation in the key informant interviews included 11 heads of department and 5 investigators of whom 14 were Kenyan and the sex distribution was equal.

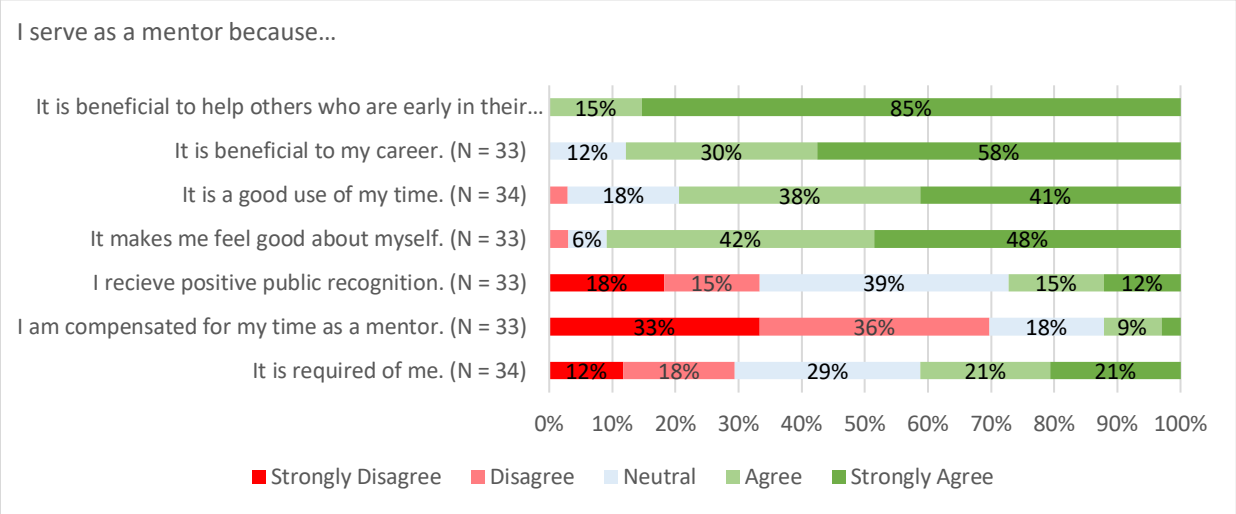
For the research coordinators and assistants survey, 26 of the 62 (41%) invited to participate completed the online survey. Of those that completed the survey, 80% were Kenyan and the sex distribution was equal. The focus group discussion included 10 research coordinators. All of the participants were Kenyan and the sex distribution was equal.

Investigator Training and Mentoring Results:

I. 90% responded that they would participate if AMPATH offered an ongoing training series
II. 50% responded that they had participated in a research training program while with AMPATH
III. Of those who did not participate in research training:
    a. 43% said there were not enough opportunities
    b. 22% were unaware of training opportunities
    c. 13% did not think it would be helpful for their careers

IV. The most frequent barriers identified to implementing an effective research training or mentoring program were:
    a. lack of protected time
    b. lack of resources
    c. absence of a research culture at Moi
V. The three training topics identified to be the most helpful in continuing investigator development were:
    a. grant writing
    b. statistical analysis for research
    c. research dissemination
VI. With regard to frequency and time of training opportunities
    a. Quarterly training opportunities were the top preference frequency, 38 %, followed by monthly 27 %
    b. The preferred time for training was prior to the start of the work day
VII. 96% suggested that AMPATH should create a formal mentoring program
VIII. More than 90% of those surveyed indicated that they would be willing to mentor
    a. Only 18% of the willing mentors have had mentorship training
IX. Of those that said they have not mentored:
    a. 45% replied that they were not asked
    b. 36% replied that they did not have sufficient time
    c. 36% replied that they thought that they were too junior in their research career
X. Of active mentors, 90% said that they mentor because it makes them feel good about themselves

Figure 1: Surveyed investigator level of agreement as to why they mentor.



<u>Investigator Training and Mentoring Recommendations:</u>

I. Develop and implement a formal research training program
    a. A standardized curriculum needs to be developed

b. A standardized evaluation process that includes an assessment of participant knowledge and includes participant feedback needs to be developed
c. Trainings should be widely accessible
    i. E.g. record training sessions and make them easily available to AMPATH affiliated investigators

II. Develop and implement a formal mentorship curriculum
    a. The curriculum should have components directed towards mentees as well as mentors

III. Create opportunities for protected time
    a. Engage with HODs to encourage protected time for training and mentorship
    b. Advocate for a research career track within Moi University

Research Coordinator and Assistants Results:

I. The following topics ranked highest priority for training are:
    a. project implementation policy
    b. finding grant opportunities
    c. managing a project budget
    d. compliance issues within procurement
    e. staff performance management
    f. SOP development and maintenance
    g. protocol development
    h. work-life balance

II. Nearly 77% of respondents said that the training they have received while at AMPATH has been useful in their roles

III. The majority (65%) requested that their training be part of a certificate program

IV. The preferred time for training was in the mornings, prior to the beginning of the work day

V. Additional training topics identified:
    a. grant writing (47%)
    b. dissemination of findings (32%)
    c. leadership training (26%)

Research Coordinator and Assistants Recommendations:

I. Develop and implement a formal curriculum for research coordinators and assistants.
    a. A standardized curriculum needs to be developed
    b. A standardized evaluation process that includes an assessment of participant knowledge and includes participant feedback needs to be developed
    c. Trainings should be widely accessible
        i. E.g. record training sessions and make them easily available to AMPATH affiliated research staff
    d. Reward completed training modules with certificates

De-identified data may be requested by emailing research.manager@iukenya.org

Table 1: Kenyan Survey Participant Investigator Status Criteria

Early-stage Investigator	Investigator has between $0-1 million of external research funding, has authored between 0-10 publications in peer reviewed journals, attained their highest degree within the last 5 years (Tutorial Fellow, Post-Docs, Assistant Lecturer, and Lecturer) and has not successfully competed for a substantial NIH independent research award.
Mid-stage Investigator	Investigator has between $1.1-5 million of external research funding, has authored or co-authored between 11-60 publications in peer reviewed journals, attained their highest degree in the last 10 years but not later than the last five years (Lecturer, Senior lecturer) and has successfully competed for a substantial NIH independent research award either as a lead PI or a Co-PI.
Senior Investigator	Investigator has over $5 million of external research funding, has authored or co-authored over 60 publications in peer reviewed journals, attained their highest degree more than 10 years prior (Professor, Associate Professor) and has successfully competed for a substantial NIH independent research award either as a lead PI or a Co-PI.

Table 2: North American Survey Participant Investigator Status Criteria

Early-stage Investigator	An individual with the title of assistant professor and have a K08 or K23 award.
Mid-stage Investigator -	An individual with the title of associate professor.
Senior Investigator	An individual with the title of professor.

Appendix B: Bibliography

The following bibliography includes AMPATH research publications that were published between January 1 – June 30, 2020. 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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Index