SEMI ANNUAL RESEARCH REPORT

January - June 2021

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*	

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Vision, Mission, & Values

In consultation with our stakeholders and investigators, the AMPATH Research Program is driven by the following vision, mission, and 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

Strategic Priorities

After internal and external stakeholders' surveys and interviews, the AMPATH Research Program Office (RPO) convened a two-day strategic planning meeting in September 2019 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 three 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 beyond 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 AMPATH Research Semi-Annual Report July – December 2019.

Activities & Achievements

In the first half of 2021, the AMPATH Research Program made progress in a number of key areas in line with our strategic plan:

New Onboarding Course for AMPATH Staff – Following a training needs assessment conducted by the AMPATH Research Program in 2020 (see Appendix A for the final report in the Semi-Annual Report January – June 2020), an onboarding course was developed for new AMPATH research staff. The purpose of the course is to introduce new research assistants, coordinators, and other staff in Kenya and from partner AMPATH consortium schools to the AMPATH Research Program, research offices, and policies and procedures. The course was launched in June 2021 and is hosted on Indiana University's Canvas e-learning platform with modules consisting of video presentations from program leaders, downloadable presentation slides for reference, additional readings and a short quiz. Additional modules may be added in the future. Prior to launching the course in June, the curriculum was pilot tested by eight research coordinators who provided valuable input in the final development of the modules and content. The course can be accessed by going to this link and registering for a Guest account.

AMPATH Research Facilities Statement Now Available – To support investigators in the showcasing of the available resources for research at AMPATH, the Research Program Office finalized a 2021 AMPATH Research Facilities Statement. This 10-page document is intended for use by AMPATH-affiliated investigators during grant application to describe the rich AMPATH research environment and infrastructure. The Facilities Statement is available as a Word document (so that it can be edited to fit investigator's needs) on the AMPATH Research webpage under Policies and Procedures – Project and Grant Development Resources. The Research Program office will update this document annually and release a new version on July 1.

Supporting AMPATH Research Replication – Drs. Wools-Kaloustian and Winstone Nyandiko co-chair the AMPATH Research Replication Working Group, which was created in October 2020 to support the replication of AMPATH in Ghana (led by New York University and the University of Development Studies) and in México (led by University of Texas Austin and Benemérita Universidad Autónoma de Puebla). Based on the 30-year AMPATH partnership in Kenya and literature reviews, led by Michael Scanlon, Drs. Wools-Kaloustian, Nyandiko, and members of the Research Program Office created a comprehensive Research Infrastructure Assessment and accompanying Tool to assist replication partners in assessing research infrastructure at replication partner sites and identify areas for collaboration as they build their respective research programs. Replication partners began adapting and using the tool in May 2021, with feedback on early adoption of the assessment strategy informing modifications. A manuscript describing the creation of the Research Infrastructure Assessment and Tool and early adoption and adaptation by replication partner sites is being planned for 2022.

Continued Collaboration with Indiana CTSI – The AMPATH Research Program continues to collaborate with the Indiana CTSI Global Health Program specifically around efforts in "reciprocal innovation," an approach largely informed by experiences from the AMPATH partnership that describes the power of mutual learning and benefits that emerge from long-standing, equitable global heath partnerships. After a successful Indiana CTSI Reciprocal Innovation Stakeholders meeting in December 2020 that was co-hosted by co-directors of Research Drs. Wools-Kaloustian and Nyandiko, in the first half of 2021 two AMPATH-affiliated investigators were awarded Indiana CTSI reciprocal innovation grants. Dr. Megan McHenry was awarded a Reciprocal Innovation Planning grant titled, "Community-based caregiver training intervention for children with autism" and Dr. Matthew Turissini was awarded a Reciprocal Innovation Demonstration grant titled, "Assessing implementation of delivering community-based, peer-led interventions for mental health problems among youth in Eldoret, Kenya."

Projects in Development – In the first half of 2021, several projects were in development which are briefly described below. Updates related to these activities will be provided in the next Semi-Annual Report.

AMPATH Research Working Groups **–** AMPATH Research Working Groups (ARWG) were established as an interface between clinical care and research, a platform for mentorship and collaboration particularly between Kenyan and North American investigators, and to ensure equitable access to research resources. In early 2021, the AMPATH Research Program undertook a strategic effort to revive and support ARWG to better fulfill their original mandate and has been working with the ARWG leaders and members on strategies and SOPs moving forward. The program is requiring established ARWG to provide updated terms of reference for their respective groups by September 2021 and present on their groups at the monthly Research Executive Committee meeting. The AMPATH Research Program is excited to announce the newest ARWG, the Mental Health ARWG led by Dr. Martin Keller (Brown University) and Dr. Edith Kwobah (Moi Teaching and Referral Hospital) that was established in March 2021.

AMPATH Research Facility Fee **–** The AMPATH Research Program assembled a team to review and propose a restructuring plan for the AMPATH Research Facility Fee. As AMPATH investigators are aware, the current AMPATH Research Facility Fee supports the robust and unique collaborative research infrastructure at AMPATH and is based on total % FTE of North American investigators (see SOP for Research Project and Grant Proposal Development) administered by the Indiana University Center for Global Health. A restructured AMPATH Research Facility Fee was proposed in May 2021 that simplifies the administration of the fee by moving it to Moi/MTRH and uses a fee calculation model that more accurately represents the use of resources for a particular project while not increasing overall costs of doing research at AMPATH. At the time of this report, the proposal was still under review by AMPATH leadership and being vetted by external experts including research funders like the NIH. The new AMPATH Research Facility Fee is planned to be rolled out by July 2022.

SOP on Exchange Rates – In early 2021, the Research and Sponsored Projects Office (RSPO) created a new SOP on Exchange Rates Management in consultation with the Indiana University Office of Research Administration. The purpose of the SOP is to ensure the efficient and effective management of exchange rates, outline the general rules and regulations guiding applicable exchange rates, and to ensure exchange losses are avoided or minimized. As of the publishing of this report, the SOP was being reviewed by AMPATH leadership and will be implemented in the second half of 2021.

AMPATH Research Projects Webpage – The Research Program Office, with support from the Indiana University Center for Global Health Communications team, has developed a research project profile database on the AMPATH research webpage to highlight ongoing and recently concluded research projects at AMPATH. The website will be a resource for AMPATH affiliated and non-affiliated members to better understand what types of research projects are happening at AMPATH, and will have functionality to search projects by investigator and/or keywords. The webpage will be launched on the main AMPATH website in the second half of 2021.

To stay updated on important activities at the AMPATH Research Program as well as new grant and funding opportunities, published articles from AMPATH investigators, and calendar events such as the AMPATH Works in Progress meetings, please be sure to subscribe to the AMPATH Research Newsletter. The Newsletter was re-launched in 2020 as a monthly publication. Contact the AMPATH Research Program Office (research.manager@iukenya.org) to subscribe.

COVID-19

The AMPATH Research Program office has continued to provide guidance to AMPATH investigators and research teams for the safe conduct of research amidst the ongoing COVID-19 pandemic. In March and June 2021, AMPATH Research investigators and staff in Kenya were eligible for the first and second doses of Astra Zeneca vaccines at Moi Teaching and Referral RAFIKI vaccination center. The Research Program Office has continued to be available to assist in setting up conferencing lines for researchers and staff during the COVID-19 pandemic period. Investigators and research teams are encouraged to continue to remain flexible and have contingency plans in place should in-person research activities need to be restricted. Investigators and researcher teams continue to adhere to minimum safety requirements as described in the Return to Work Policy for AMPATH Research Program Staff.

Grants

In the first half of 2021, AMPATH-affiliated investigators received US$ 5.97 million in extramural funding for new or continuing research activities, increasing AMPATH's cumulative total of research and training awards to over US$ 195.6 million. Consistent with previous years, NIH funding remained strong (82% of funding in the reporting period) and five new NIH awards were received in the first half of 2021. Individual study reports provided by projects' principal investigator(s) or their designee that describes the study's specific aims, sites, project period, sponsors, and project status are available in Appendix - Study Reports.

For more data regarding AMPATH grants and publications, please see our data dashboard in Google Data Studio.

Figure 1: January – June 2021 semi-annual grant highlights.

Figure 2: How do awards in quarters 1 and 2 in 2021 compare to recent years?

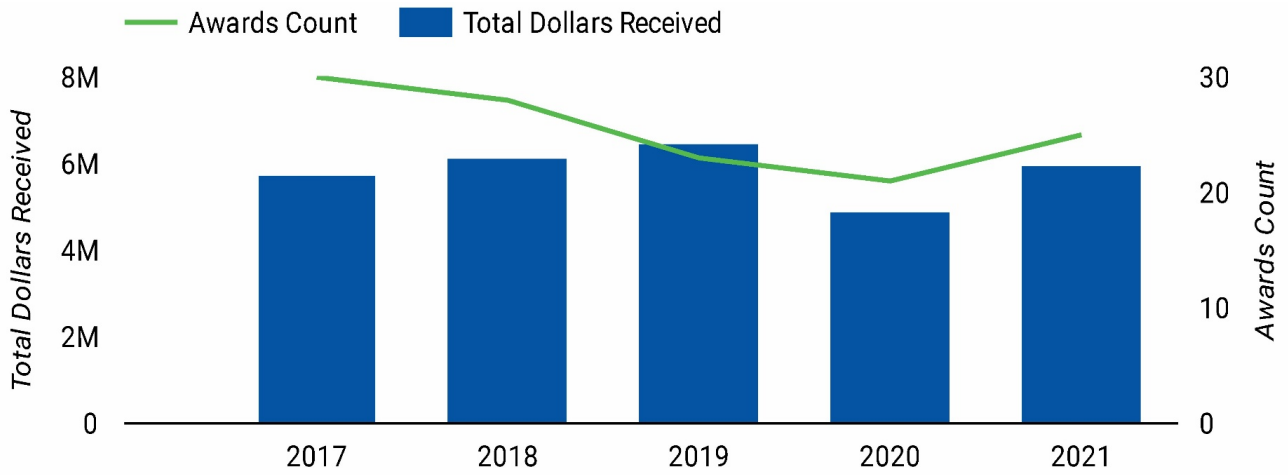
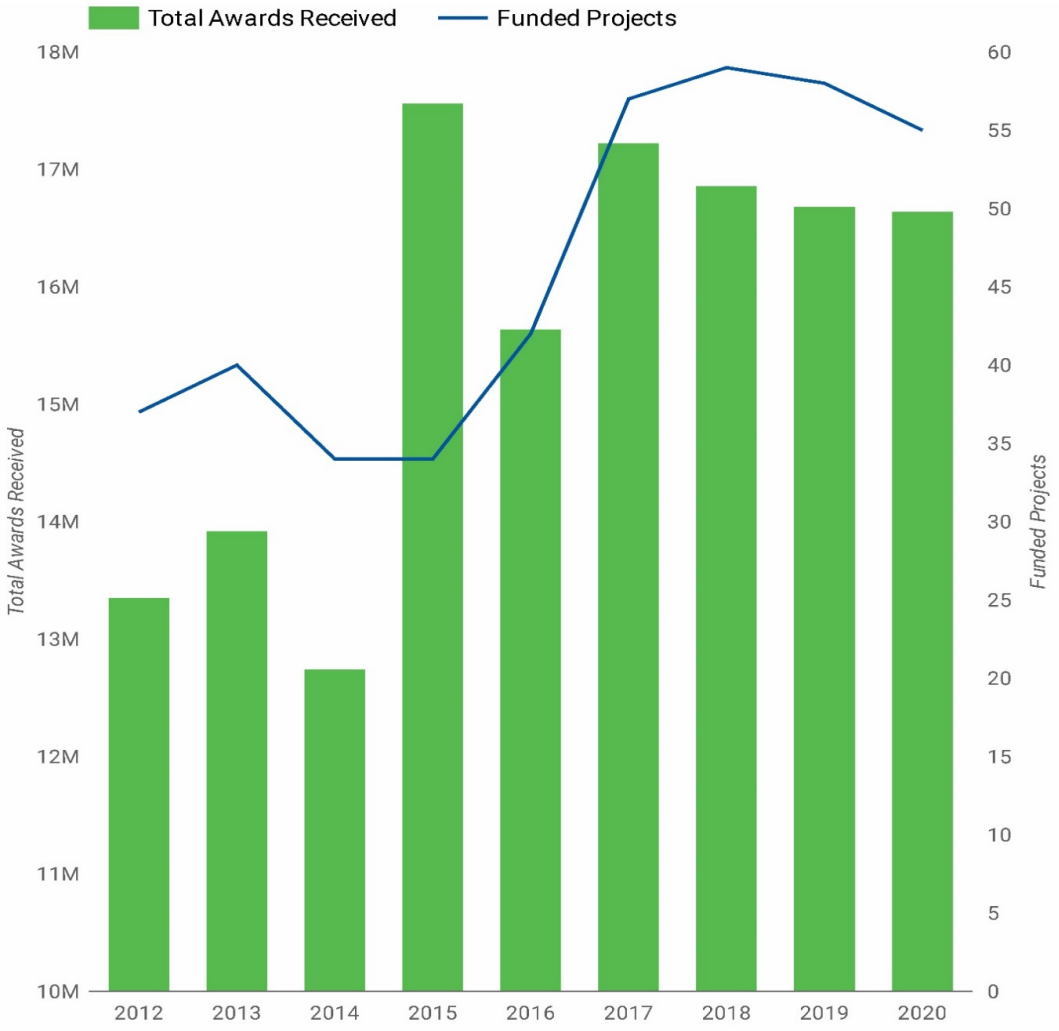


Figure 3: Percentage of awards received by sponsor type (all time, 1998-2020).

Sponsor Type	Total ▾
NIH	77.14%
Foundation & Non-Profit	8.14%
Governmental Aid Agencies	6.33%
Intergovernmental Organization	5.14%
For-Profit Industry	1.77%

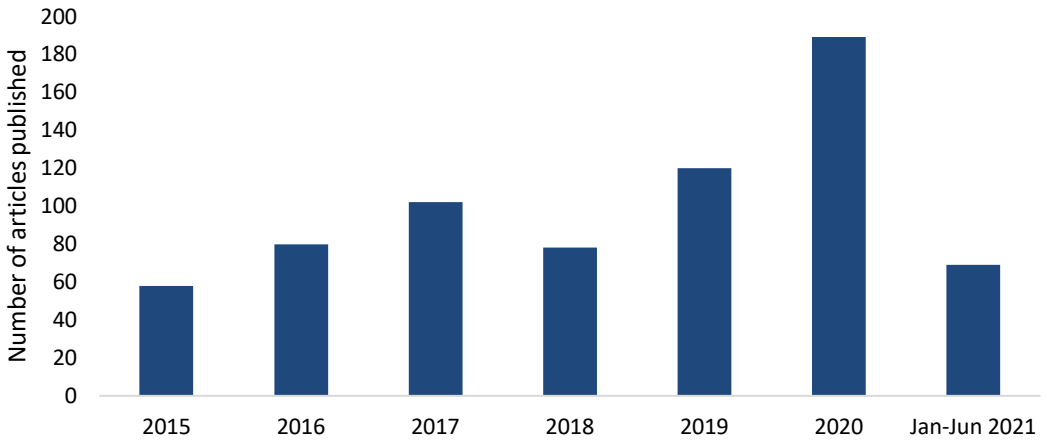
Figure 4: Total award dollars received and number of funded projects, by year (2012-2020).



Publications

AMPATH investigators published 68 articles in the first half of 2021, increasing the total number of AMPATH publications to 1,038 since the beginning of the AMPATH partnership in 1989. 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. In addition to research in the area of HIV, publications in the areas of maternal and child health, substance use, mental health, non-communicable diseases such as hypertension and heart disease, and now COVID-19 illustrate the variety of research being conducted at AMPATH. Researchers at AMPATH also continued to contribute to multi-region and global publications, including experiences of research fellows in programs in sub-Saharan Africa, safety of low-dose aspirin during pregnancy as part of the Global Network for Women's and Children's Health Research, characteristics and outcomes among children following universal ART in sub-Saharan Africa as part of the International Epidemiology Databases to Evaluate AIDS (IeDEA), and whole genome sequencing as part of the Neuropsychiatric Genetics of African Population (Neuro-GAP). AMPATH-affiliated investigators contributed to publications to inform national and international policy and guidelines, including to the Kenya NCDI Poverty Commission. A bibliography of publications in 2020 can be found in the Appendix - Bibliography.

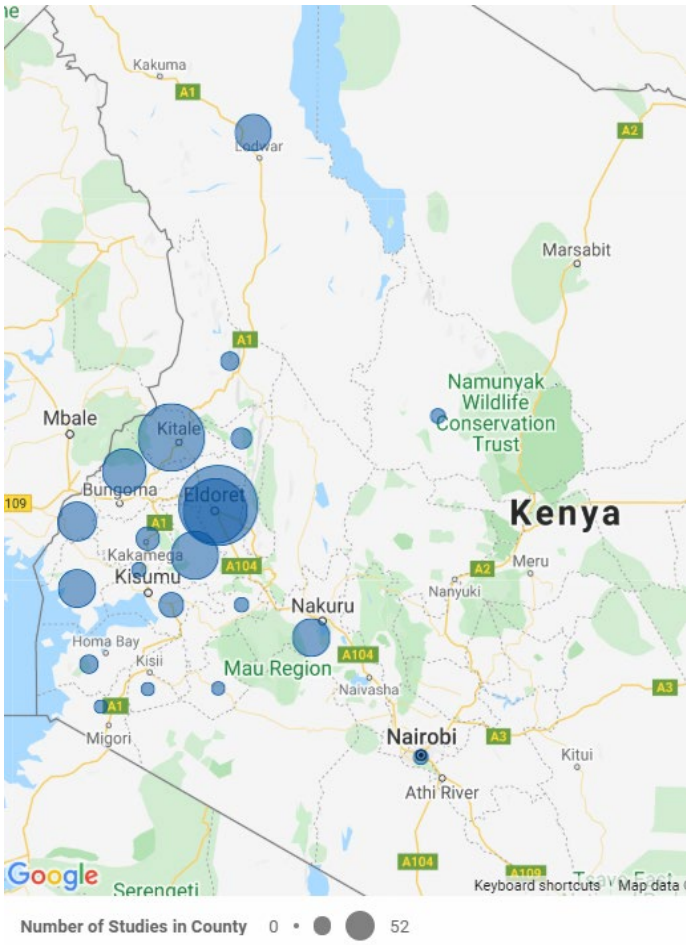
Figure 5: Articles Published by AMPATH Affiliated Investigators, 2015 to First Half of 2021



Geographic Reach of AMPATH Research Program Activities

A total of 66 research projects at AMPATH completed AMPATH Research Program Office requests for information related to new or ongoing studies during the reporting period, January to June 2021. As depicted in the map below (Figure 6), while Uasin Gishu County (home to Eldoret and MTRH) is the most common location for research activities, AMPATH researchers are engaged in research activities across western Kenya. As noted earlier, AMPATH investigators are also part of regional and global research and training activities through a number of projects and consortia, including the NICHD-funded Global Network for Women's and Children's Health Research, NIH-funded East Africa International Epidemiology Databases to Evaluate AIDS (IeDEA), Fogarty-funded Global Health Program for Fellows and Scholars, and clinical trials such as BREATHER-Plus funded by the European and Developing Countries Clinical Trials Partnership, among others.

Figure 6: Map of study sites in Kenya and number of studies per site.



	Region	Number of Studies in County/State
1.	Uasin Gishu	52
2.	Trans Nzoia	42
3.	Nandi	27
4.	Bungoma	24
5.	Busia	20
6.	Siaya	19
7.	Nakuru	19
8.	Turkana	18
9.	Kisumu	9
10.	Kakamega	8
11.	Elgeyo Marakwet	6
12.	Homa Bay	4
13.	West Pokot	4
14.	Samburu	1
15.	Rhode Island	1
16.	Indiana	1
17.	Vihiga	1
18.	Nairobi	1
19.	Kericho	1

Note: 40 projects reported being conducted at Moi Teaching and Referral Hospital. These projects were included with Uasin Gishu's numbers.

Appendix - *Bibliography and Study Reports*

Bibliography

The following bibliography includes AMPATH research publications that were published in the first half of 2021. Please contact the Research Program Office, research.manager@iukenya.org, for a complete bibliography of AMPATH research publications published since 1989 along with full text articles.

1. Amisi, J.A., Carter, E.J., Masini, E. and Szkwarko, D., *Closing the loop in child TB contact management: completion of TB preventive therapy outcomes in western Kenya.* BMJ Open, 2021. **11**(2): p. e040993.
2. Anyango, R., Ojwando, J., Mwita, C. and Mugalo, E., *Diagnostic accuracy of [-2]proPSA versus Gleason score and Prostate Health Index versus Gleason score for the determination of aggressive prostate cancer: a systematic review.* JBI Evid Synth, 2021.
3. Ayaya, S., DeLong, A., Embleton, L., Ayuku, D., Sang, E.*, et al.*, *Prevalence, incidence and chronicity of child abuse among orphaned, separated, and street-connected children and adolescents in western Kenya: What is the impact of care environment?* Child Abuse Negl, 2021: p. 104920.
4. Balogun, F.M., Malele-Kolisa, Y., Nieuwoudt, S.J., Jepngetich, H., Kiplagat, J.*, et al.*, *Experiences of doctoral students enrolled in a research fellowship program to support doctoral training in Africa (2014 to 2018): The Consortium for Advanced Research Training in Africa odyssey.* PLoS One, 2021. **16**(6): p. e0252863.
5. Berlacher, M., Mercer, T., Apondi, E.O., Mwangi, W., Were, E.*, et al.*, *Integrating Prevention of Mother-to-Child Transmission of HIV Care into General Maternal Child Health Care in Western Kenya.* Int J MCH AIDS, 2021. **10**(1): p. 19-28.
6. Boakye, M.D.S., Owek, C.J., Oluoch, E., Atakora, S.B., Wachira, J.*, et al.*, *Needs assessment of community health workers to enhance efficient delivery of their services for community case management of malaria in Kenya.* Malar J, 2021. **20**(1): p. 102.
7. Bresnahan, B.W., Vodicka, E., Babigumira, J.B., Malik, A.M., Yego, F.*, et al.*, *Cost estimation alongside a multi-regional, multi-country randomized trial of antenatal ultrasound in five low-and-middle-income countries.* BMC Public Health, 2021. **21**(1): p. 952.
8. Chang, A.Y., Mungai, M., Coates, S.J., Chao, T., Odhiambo, H.P.*, et al.*, *Implementing a Locally Made Low-Cost Intervention for Wound and Lymphedema Care in Western Kenya.* Dermatol Clin, 2021. **39**(1): p. 91-100.
9. Chory, A., Nyandiko, W., Martin, R., Aluoch, J., Scanlon, M.*, et al.*, *HIV-Related Knowledge, Attitudes, Behaviors and Experiences of Kenyan Adolescents Living with HIV Revealed in WhatsApp Group Chats.* J Int Assoc Provid AIDS Care, 2021. **20**: p. 2325958221999579.
10. Davda, J., Kibet, H., Achieng, E., Atundo, L. and Komen, T., *Assessing the acceptability, reliability, and validity of the EORTC Quality of Life Questionnaire (QLQ-C30) in Kenyan cancer patients: a cross-sectional study.* J Patient Rep Outcomes, 2021. **5**(1): p. 4.
11. Dong, R., Leung, C., Naert, M.N., Naanyu, V., Kiptoo, P.*, et al.*, *Chronic disease stigma, skepticism of the health system, and socio-economic fragility: Qualitative assessment of factors impacting receptiveness to group medical visits and microfinance for non-communicable disease care in rural Kenya.* PLoS One, 2021. **16**(6): p. e0248496.
12. Enane, L.A., Apondi, E., Omollo, M., Toromo, J.J., Bakari, S.*, et al.*, *"I just keep quiet about it and act as if everything is alright" - The cascade from trauma to disengagement among adolescents living with HIV in western Kenya.* J Int AIDS Soc, 2021. **24**(4): p. e25695.
13. Faraone, S.V., Banaschewski, T., Coghill, D., Zheng, Y., Biederman, J.*, et al.*, *The World Federation of ADHD International Consensus Statement: 208 Evidence-based Conclusions about the Disorder.* Neurosci Biobehav Rev, 2021.
14. Fonn, S., Ray, S., Couper, I., Ezeh, A., Omigbodun, A.*, et al.*, *Acceptability and feasibility of inter-related activities to improve agency among African district health managers: A four-country study.* Glob Public Health, 2021: p. 1-15.
15. Garg, C.C., Tshefu, A., Longombe, A.L., Kila, J.N., Esamai, F.*, et al.*, *Costs and cost-effectiveness of management of possible serious bacterial infections in young infants in outpatient settings when referral to a hospital was not*

possible: Results from randomized trials in Africa. PLoS One, 2021. **16**(3): p. e0247977.
16. Genberg, B.L., Wachira, J., Steingrimsson, J.A., Pastakia, S., Tran, D.N.T.*, et al.*, *Integrated community-based HIV and non-communicable disease care within microfinance groups in Kenya: study protocol for the Harambee cluster randomised trial.* BMJ Open, 2021. **11**(5): p. e042662.
17. Genberg, B.L., Wilson-Barthes, M.G., Omodi, V., Hogan, J.W., Steingrimsson, J.*, et al.*, *Microfinance, retention in care, and mortality among patients enrolled in HIV 2 Care in East Africa.* Aids, 2021.
18. Gesicho, M.B., Were, M.C. and Babic, A., *Evaluating performance of health care facilities at meeting HIV-indicator reporting requirements in Kenya: an application of K-means clustering algorithm.* BMC Med Inform Decis Mak, 2021. **21**(1): p. 6.
19. Giusto, A., Johnson, S.L., Lovero, K.L., Wainberg, M.L., Rono, W.*, et al.*, *Building community-based helping practices by training peer-father counselors: A novel intervention to reduce drinking and depressive symptoms among fathers through an expanded masculinity lens.* Int J Drug Policy, 2021. **95**: p. 103291.
20. Goodrich, S., Siika, A., Mwangi, A., Nyambura, M., Naanyu, V.*, et al.*, *Development, assessment and outcomes of a community-based model of anti-retroviral care in western Kenya through a cluster-randomized control trial.* J Acquir Immune Defic Syndr, 2021.
21. Hillow, M.A., Kwobah, E.K., Gakinya, B. and Omari, F., *Sudden Death After Electroconvulsive Therapy in the Context of Coronavirus Disease 2019.* J ect, 2021.
22. Ingabire, P.M., Ojji, D.B., Rayner, B., Ogola, E., Damasceno, A.*, et al.*, *High prevalence of non-dipping patterns among Black Africans with uncontrolled hypertension: a secondary analysis of the CREOLE trial.* BMC Cardiovasc Disord, 2021. **21**(1): p. 254.
23. Iyun, V., Technau, K.G., Vinikoor, M., Yotebieng, M., Vreeman, R.*, et al.*, *Variations in the characteristics and outcomes of children living with HIV following universal ART in sub-Saharan Africa (2006-17): a retrospective cohort study.* Lancet HIV, 2021. **8**(6): p. e353-e362.
24. Jaguga, F., *Clozapine-induced stuttering in the absence of known risk factors: a case report.* J Med Case Rep, 2021. **15**(1): p. 174.
25. Jessani, S., Saleem, S., Hoffman, M.K., Goudar, S.S., Derman, R.J.*, et al.*, *Association of hemoglobin levels in the first trimester and at 26 to 30 weeks with fetal and neonatal outcomes: A secondary analyses of the Global Network for Women's and Children's Health's ASPIRIN Trial.* Bjog, 2021.
26. Johnson, M., Piedrahita, R., Pillarisetti, A., Shupler, M., Menya, D.*, et al.*, *Modeling approaches and performance for estimating personal exposure to household air pollution: A case study in Kenya.* Indoor Air, 2021.
27. Kafu, C., Ligaga, D. and Wachira, J., *Exploring media framing of abortion content on Kenyan television: a qualitative study protocol.* Reprod Health, 2021. **18**(1): p. 12.
28. Kipkemoi, R.D., Abila, A.W., Nditika, M.E. and Lumadede, M.E., *Self-penile amputation: A case of Klingsor Syndrome.* Urol Case Rep, 2021. **38**: p. 101667.
29. Kiplimo, R., Kosgei, M., Mwangi, A., Onyango, E., Ogero, M.*, et al.*, *Longitudinal-Survival Models for Case-Based Tuberculosis Progression.* Front Public Health, 2021. **9**: p. 543750.
30. Kwobah, E., Koen, N., Mwangi, A., Atwoli, L. and Stein, D.J., *Prevalence and correlates of metabolic syndrome and its components in adults with psychotic disorders in Eldoret, Kenya.* PLoS One, 2021. **16**(1): p. e0245086.
31. Li, H.W., Saruni, S.I., Carpenter, K., Chepkemoi, E., Ochieng, N.A.*, et al.*, *Use of a Novel Trigger Tool to Identify Palliative Care Needs in Surgical Patients at a National Referral Hospital in Kenya: A Pilot Study.* J Palliat Med, 2021.
32. Mabeya, H., Odunga, J. and Broeck, D.V., *Mothers of adolescent girls and Human Papilloma Virus (HPV) vaccination in Western Kenya.* Pan Afr Med J, 2021. **38**: p. 126.
33. Manyega, K.M., Lotodo, T.C., Oduor, M.A., Namaemba, D.F., Omondi, A.A.*, et al.*, *Retrospective Analysis of Presentation, Treatment, and Outcomes of Multiple Myeloma at a Large Public Referral Hospital in Eldoret, Kenya.* JCO Glob Oncol, 2021. **7**: p. 391-399.
34. Martin, A.R., Atkinson, E.G., Chapman, S.B., Stevenson, A., Stroud, R.E.*, et al.*, *Low-coverage sequencing cost-effectively detects known and novel variation in underrepresented populations.* Am J Hum Genet, 2021.
35. Matoga, M.M., Bisson, G.P., Gupta, A., Miyahara, S., Sun, X.*, et al.*, *Urine LAM Testing in Advanced HIV Positive Adults in a Trial of Empiric TB Therapy.* Clin Infect Dis, 2021.
36. Mboowa, G., Aruhomukama, D., Sserwadda, I., Kitutu, F.E., Davtyan, H.*, et al.*, *Increasing Antimicrobial Resistance in Surgical Wards at Mulago National Referral Hospital, Uganda, from 2014 to 2018-Cause for*

Concern? Trop Med Infect Dis, 2021. **6**(2).
37. McHenry, M.S., Oyungu, E., Yang, Z., Hines, A.C., Ombitsa, A.R.*, et al.*, *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.* Res Dev Disabil, 2021. **110**: p. 103837.
38. McMahon, D.E., Semeere, A., Laker-Oketta, M., Byakwaga, H., Mugglin, C.*, et al.*, *Global disparities in skin cancer services at HIV treatment centers across 29 countries.* J Invest Dermatol, 2021.
39. Mwaliko, E., Van Hal, G., Bastiaens, H., Van Dongen, S., Gichangi, P.*, et al.*, *Early detection of cervical cancer in western Kenya: determinants of healthcare providers performing a gynaecological examination for abnormal vaginal discharge or bleeding.* BMC Fam Pract, 2021. **22**(1): p. 52.
40. Mwangi, K., Gathecha, G., Nyamongo, M., Kimaiyo, S., Kamano, J.*, et al.*, *Reframing Non-Communicable Diseases and Injuries for Equity in the Era of Universal Health Coverage: Findings and Recommendations from the Kenya NCDI Poverty Commission.* Ann Glob Health, 2021. **87**(1): p. 3.
41. Mwenda, N., Nduati, R., Kosgei, M. and Kerich, G., *Skewed logit model for analyzing correlated infant morbidity data.* PLoS One, 2021. **16**(2): p. e0246269.
42. Mwenda, N., Nduati, R., Kosgey, M. and Kerich, G., *Effect of Bacterial Vaginosis (BV)-HIV-1 Co-existence on Maternal and Infant Health: A Secondary Data Analysis.* Front Pediatr, 2021. **9**: p. 544192.
43. Narh, C.T., Dzamalala, C.P., Mmbaga, B.T., Menya, D., Mlombe, Y.*, et al.*, *Geophagia and risk of squamous cell esophageal cancer in the African esophageal cancer corridor - Findings from the ESCCAPE multi-country case-control studies.* Int J Cancer, 2021.
44. Narh, C.T., Dzamalala, C.P., Mmbaga, B.T., Menya, D., Mlombe, Y.*, et al.*, *Geophagia and risk of squamous cell esophageal cancer in the African esophageal cancer corridor: Findings from the ESCCAPE multicountry case-control studies.* Int J Cancer, 2021.
45. Ngugi, P., Babic, A., Kariuki, J., Santas, X., Naanyu, V.*, et al.*, *Development of standard indicators to assess use of electronic health record systems implemented in low-and medium-income countries.* PLoS One, 2021. **16**(1): p. e0244917.
46. Nyandiko, W.M., Kiptoon, P. and Lubuya, F.A., *Neonatal hypothermia and adherence to World Health Organisation thermal care guidelines among newborns at Moi Teaching and Referral Hospital, Kenya.* PLoS One, 2021. **16**(3): p. e0248838.
47. Oduor, M.A., Lotodo, T.C., Vik, T.A., Manyega, K.M., Loehrer, P.*, et al.*, *Building a Sustainable Comprehensive Multiple Myeloma Program in Western Kenya.* JCO Glob Oncol, 2021. **7**: p. 400-407.
48. Omari, F., Chrysanthopoulou, S.A., Embleton, L.E., Atwoli, L., Ayuku, D.O.*, et al.*, *The impact of care environment on the mental health of orphaned, separated and street-connected children and adolescents in western Kenya: a prospective cohort analysis.* BMJ Glob Health, 2021. **6**(3).
49. Ontiri, S., Mutea, L., Naanyu, V., Kabue, M., Biesma, R.*, et al.*, *A qualitative exploration of contraceptive use and discontinuation among women with an unmet need for modern contraception in Kenya.* Reprod Health, 2021. **18**(1): p. 33.
50. Oyungu, E., Roose, A.W., Ombitsa, A.R., Yang, Z., Vreeman, R.C.*, et al.*, *Anemia and Iron-Deficiency Anemia in Children Born to Mothers with HIV in Western Kenya.* Glob Pediatr Health, 2021. **8**: p. 2333794x21991035.
51. Panuganti, B.A., Jafari, A., Shen, S., Qualliotine, J.R., Schueth, E.A.*, et al.*, *Predictors of Quality-of-Life Improvements Following Global Head and Neck Surgery Trips to Underserved Regions.* Laryngoscope, 2021.
52. Pastakia, S.D., Kosgei, W.K., Christoffersen-Deb, A., Kiragu, B., Hector, J.N.*, et al.*, *Risk of Dysglycemia in Pregnancy amongst Kenyan Women with HIV Infection: A Nested Case-Control Analysis from the STRiDE Study.* Journal of Diabetes Research, 2021. **2021**: p. 8830048.
53. Peprah, S., Ogwang, M.D., Kerchan, P., Reynolds, S.J., Tenge, C.N.*, et al.*, *Inverse association of falciparum positivity with endemic Burkitt lymphoma is robust in analyses adjusting for pre-enrollment malaria in the EMBLEM case-control study.* Infect Agent Cancer, 2021. **16**(1): p. 40.
54. Puri, D., Nisar, Y.B., Tshefu, A., Longombe, A.L., Esamai, F.*, et al.*, *Prevalence of clinical signs of possible serious bacterial infection and mortality associated with them from population-based surveillance of young infants from birth to 2 months of age.* PLoS One, 2021. **16**(2): p. e0247457.
55. Rolfe, R., Jr., Kwobah, C., Muro, F., Ruwanpathirana, A., Lyamuya, F.*, et al.*, *Barriers to implementing antimicrobial stewardship programs in three low- and middle-income country tertiary care settings: findings from a multi-site qualitative study.* Antimicrob Resist Infect Control, 2021. **10**(1): p. 60.

56. Said, J., Lagat, D., Kimaina, A. and Oduor, C., *Beta cell function, insulin resistance and vitamin D status among type 2 diabetes patients in Western Kenya.* Sci Rep, 2021. **11**(1): p. 4084.
57. Short, V.L., Hoffman, M., Metgud, M., Kavi, A., Goudar, S.S.*, et al.*, *Safety of daily low-dose aspirin use during pregnancy in low-income and middle-income countries.* AJOG Glob Rep, 2021. **1**(1).
58. Sikka, N., DeLong, A., Kamano, J., Kimaiyo, S., Orango, V.*, et al.*, *Sex differences in health status, healthcare utilization, and costs among individuals with elevated blood pressure: the LARK study from Western Kenya.* BMC Public Health, 2021. **21**(1): p. 948.
59. Sitienei, J., Manderson, L. and Nangami, M., *Community participation in the collaborative governance of primary health care facilities, Uasin Gishu County, Kenya.* PLoS One, 2021. **16**(3): p. e0248914.
60. Snelgrove, J.W., Alera, J.M., Foster, M.C., Bett, K.C.N., Bloomfield, G.S.*, et al.*, *Prevalence of Rheumatic Heart Disease and Other Cardiac Conditions in Low-Risk Pregnancies in Kenya: A Prospective Echocardiography Screening Study.* Glob Heart, 2021. **16**(1): p. 10.
61. Sumner, K.M., Freedman, E., Abel, L., Obala, A., Pence, B.W.*, et al.*, *Genotyping cognate Plasmodium falciparum in humans and mosquitoes to estimate onward transmission of asymptomatic infections.* Nat Commun, 2021. **12**(1): p. 909.
62. Sumner, K.M., Freedman, E., Mangeni, J.N., Obala, A.A., Abel, L.*, et al.*, *Exposure to diverse Plasmodium falciparum genotypes shapes the risk of symptomatic malaria in incident and persistent infections: A longitudinal molecular epidemiologic study in Kenya.* Clin Infect Dis, 2021.
63. Talukdar, F.R., Soares Lima, S.C., Khoueiry, R., Laskar, R.S., Cuenin, C.*, et al.*, *Genome-wide DNA methylation profiling of esophageal squamous cell carcinoma from global high-incidence regions identifies crucial genes and potential cancer markers.* Cancer Res, 2021.
64. Tran, D.N., Were, P.M., Kangogo, K., Amisi, J.A., Manji, I.*, et al.*, *Supply-chain strategies for essential medicines in rural western Kenya during COVID-19.* Bull World Health Organ, 2021. **99**(5): p. 388-392.
65. Vedanthan, R., Kamano, J.H., Chrysanthopoulou, S.A., Mugo, R., Andama, B.*, et al.*, *Group Medical Visit and Microfinance Intervention for Patients With Diabetes or Hypertension in Kenya.* Journal of the American College of Cardiology, 2021. **77**(16): p. 2007-2018.
66. Vreeman, R.C., Rakhmanina, N.Y., Nyandiko, W.M., Puthanakit, T. and Kantor, R., *Are we there yet? 40 years of successes and challenges for children and adolescents living with HIV.* J Int AIDS Soc, 2021. **24**(6): p. e25759.
67. Wachira, J., Genberg, B., Chemutai, D., Mwangi, A., Galarraga, O.*, et al.*, *Implementing enhanced patient care to promote patient engagement in HIV care in a rural setting in Kenya.* BMC Health Services Research, 2021. **21**(1): p. 515.
68. Woolsey, A.M., Simmons, R.A., Woldeghebriel, M., Zhou, Y., Ogunsola, O.*, et al.*, *Incentivizing appropriate malaria case management in the private sector: a study protocol for two linked cluster randomized controlled trials to evaluate provider- and client-focused interventions in western Kenya and Lagos, Nigeria.* Implement Sci, 2021. **16**(1): p. 14.

Study Reports

The following study reports provide summaries of active AMPATH research projects at the end of the reporting period (June 30, 2021). Study reports for 66 studies were provided by the projects' principal investigator(s) or their designee and provide details on study team specific aims, sites, project period, sponsors, project status, and publications. Summaries are organized alphabetically based on the study title.

Study Title	**A cluster randomized trial of 'Teach HADITHI' teacher training intervention to reduce classroom HIV-related stigma in Kenya.**
Principal Investigator(s)	Rachel Christine Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Edith Apondi (MTRH), Juddy Wachira (Moi University), Wanzhu Tu (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Assemble a multimedia teacher training curriculum package, focused on HIV and HIV 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. 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. Aim 4: Examine the impact of HIV stigma training on stigmatizing knowledge, attitudes and beliefs about COVID-19.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	7/1/2018 - 4/30/2021
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction and follow-up. Research activities are limited to data analysis.
Study Title	**A Phase 3, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of TNX-102 SL in Participants with PTSD Taken Daily at Bedtime**
Principal Investigator(s)	Lukoye Atwoli (Moi University)
Collaborator(s)	Edith Kwobah, Frank Njenga, Linet Ongeri, Sylvia Kemunto, Gabriel Kigen
Study Type	Double-blind randomized clinical trial.
Specific Aim(s)	Aim 1: To evaluate the efficacy of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in treatment of PTSD. Aim 2: To evaluate the safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in the treatment of PTSD.

Site(s)	Moi Teaching and Referral Hospital, KEMRI Nairobi, Aga Khan University
Project Period	7/1/2020 - 6/30/2023
Sponsor(s)	TONIX Pharmaceuticals
Status	Not started -- Study activities have not begun.
Study Title	**A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 1**
Principal Investigator(s)	Jeremiah Laktabai (Moi University)
Collaborator(s)	Diana Menya (Moi University), Wendy O'Meara (Duke University)
Study Type	Randomised controlled trial
Specific Aim(s)	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: Decision to purchase an ACT stratified by testing status: (a.) Positive mRDT (b.) Negative mRDT (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.
Site(s)	Bungoma, Trans Nzoia
Project Period	10/1/2018 - 9/30/2023
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 2**
Principal Investigator(s)	Jeremiah Laktabai (Moi University)
Collaborator(s)	Diana Menya (Moi University), Wendy O'Meara (Duke University)
Study Type	Randomised controlled trial
Specific Aim(s)	The objective of this study is to test the effect of provider-directed and patient-directed incentives on improving the management of suspected malaria fevers that receive care in the retail sector. Provider-directed incentives include small payments for taking the time to conduct malaria-RDT testing for participants with malaria-like illness. Patient-directed incentives are inexpensive RDT testing coupled with a conditional ACT discount. Outcomes will be measured by exit interviews on random days each month at each participating outlet. The primary outcome

	will be the proportion of all ACTs that are sold to individuals with a positive malaria diagnostic test. The major secondary outcome is the proportion of suspected malaria cases that are tested. This outcome will allow us to determine whether the conditional subsidy can drive demand for testing.
Site(s)	Bungoma, Trans Nzoia
Project Period	10/1/2018 - 9/30/2023
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**A5300B/I2003B/PHOENIx Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients (PHOENIx MDR-TB)**
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	David Lagat (Moi University)
Study Type	Phase III, open-label, multicenter trial with a cluster-randomized superiority design
Specific Aim(s)	Aim 1: To compare the efficacy of 26 weeks of DLM versus 26 weeks of INH for preventing confirmed or probable active TB during 96 weeks of follow-up. Aim 2: To compare the safety (permanently stopping study drug due to treatment-related adverse events) of 26 weeks of DLM versus 26 weeks of INH for the treatment of presumed latent TB infection (LTBI) with MDR-TB.
Site(s)	Bungoma, Busia, Elgeyo Marakwet, Homa Bay, Kakamega, Kericho, Kisumu, Moi Teaching and Referral Hospital, Nakuru, Nandi, Siaya, Trans Nzoia, Uasin Gishu, Vihiga, West Pokot
Project Period	10/21/2020 - ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**A5381 Observational Cohort to Assess Therapeutic Efficacy and Emergence of HIV Drug Resistance Following Initiation of Tenofovir-Lamivudine-Dolutegravir (TLD) for First- or Second-Line ART or with Rifampicin-Containing TB Treatment**
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	Fatuma Some (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Among participants still on TLD at 6 months of followup, to estimate the proportion achieving virologic success (HIV-1 RNA ≤1000 copies/mL) and the proportion with new DTG resistance mutations in each of the following groups: (a) Participants switching from first-line

	NNRTI-containing therapy with HIV-1 RNA >1000 copies/mL at start of TLD (Group 1a); (b) Participants switching from second-line PI-containing therapy with HIV-1 RNA >1000 copies/mL at start of TLD (Group 2a); (c) Participants switching from first-line NNRTI-containing therapy with HIV-1 RNA ≤1000 copies/mL at start of TLD (Group 1b); (d) Participants switching from second-line PI-containing therapy with HIV-1 RNA ≤1000 copies/mL at start of TLD (Group 2b); (e) Participants who are ART-naïve when starting TLD (Group 4). Aim 2: Among participants taking concomitant TLD (including an additional daily dose of DTG 50 mg) and RIF-containing TB treatment (Group 3), to estimate the proportion achieving virologic success (HIV-1 RNA ≤1000 copies/mL) and the proportion with new DTG resistance mutations at the end of concomitant treatment.
Site(s)	Busia, Elgeyo Marakwet, Homa Bay, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu, West Pokot
Project Period	10/5/2020 - ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Addressing bioethical research gaps in research with young people living with HV in Kenya**
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai), Violet Naanyu (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Examine ethical issues in longitudinal clinical research with YPLWH in Kenya from the patient, caregiver, and other key informant perspective. Aim 2: Identify and analyze key bioethics guidelines and policies, as well as academic and grey literature relevant to research with YPLWH across key areas: children and YPLWH, people living with HIV, biological sampling and biobanking, and research in resource-limited settings.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	8/18/2020 - 5/30/2024
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

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)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai), Joseph Hogan (Brown University), Vladamir Novitsky (Miriam Hospital)
Study Type	Prospective
Specific Aim(s)	Aim 1: Investigate genotype-phenotype correlations in HIV-1 subtypes A, C and D. Aim 2: Evaluate etiologies for treatment failure in the presence of a 'susceptible genotype'. Aim 3: Evaluate etiologies for treatment success in the presence of a 'resistant genotype'.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	6/27/2021 - 5/31/2024
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**An Overview of the Mental Health Care System in 4 Counties in Western Kenya: Findings from an Assessment Using the World Health Organization's Assessment Instrument for Mental Health Systems (WHO-AIMS)**
Principal Investigator(s)	Edith Kwobah (Moi Teaching and Referral Hospital)
Collaborator(s)	Matthew Turissini (Indiana University), Florence Jaguga (Moi Teaching & Referral Hospital), Julius Barasa, Richard Matundura, Joyce Nato (World Health Organization)
Study Type	Cross-Sectional
Specific Aim(s)	To collect systems-level mental health care data using the WHO-AIMS in Uasin Gishu, Bungoma, Trans-Nzoia and Busia Counties in western Kenya.
Site(s)	Bungoma, Busia, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	07/02/2020 - Ongoing
Sponsor(s)	
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**APPROACH**
Principal Investigator(s)	Hussein Elias (Moi University)
Collaborator(s)	Eric Finkelstein (Duke University)

Study Type	Prospective
Specific Aim(s)	To understand the perspectives of patients with advanced cancer regarding their quality of life and end of life care. We amended our sample size to 217 patients with stage IV admitted at the inpatient and outpatient clinic. We also amended the inclusion criteria to 1. All patients and races will be included in the study as long as they seek treatment at MTRH during the study period, meet the inclusion criteria and consent to participate in the study. 5. Can understand and speak English or Swahili
Site(s)	Moi Teaching and Referral Hospital
Project Period	1/1/2021 - 12/31/2021
Sponsor(s)	Duke Global Health
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Bridging Income Generation with Group Integrated Care (BIGPIC)**
Principal Investigator(s)	Rajesh Vedanthan (New York University)
Collaborator(s)	Jemima Kamano (Moi University School of Medicine), Violet Naanyu (Moi University School of Medicine), Sonak Pastakia (Purdue University), et al.
Study Type	Prospective
Specific Aim(s)	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 (traditional community gathering) form of inquiry; and 2) focus group discussions among individuals with diabetes or at increased risk for diabetes, microfinance group members, and rural health workers. 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. The primary outcome measure will be one-year change in systolic blood pressure (SBP), and a key secondary outcome will be change in QRISK2 CVD risk score, which has been validated for Black Africans. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the trial, in terms of costs per unit decrease in SBP, per percent change in CVD risk score, and per disability-adjusted life year saved. 1. Study Population: Enrollment remains closed for this study. 2890 individuals (69.9% women) were enrolled (708 UC, 709 MF, 740 GMV, and 733 GMV-MF). 2. Study end date: The anticipate study end date is now September 30th, 2022.
Site(s)	Busia, Kisumu, Trans Nzoia, Uasin Gishu
Project Period	4/1/2015 - 9/30/2022
Sponsor(s)	NIH-NHLBI

Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
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)
Collaborator(s)	Laura J. Ruhl (Indiana University), Lauren Y. Maldonado (USC), Michael Scanlon (Indiana University), Julie Thorne (University of Toronto), Edith Apondi (MTRH), Astrid Christoffersen-Deb (University of British Columbia)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To adapt the Chamas for Change model and curriculum for community-based, peer-support groups to specifically meet the needs of pregnant adolescents, adolescent mothers, and their children. Aim 2: To assess the feasibility and acceptability of an adapted adolescent Chamas for Change program; Aim 3: To assess the impact of participation on maternal, newborn, and child health outcomes, psychosocial outcomes (i.e. mental health, social support), school re-enrollment, and financial stability among adolescent participants; and Aim 4: To develop a case study to inform possible adaptations of the Chamas for Change model for adolescents to a North American context. For Phase II of the study this includes pregnant and parenting adolescents aged 15-19 with children aged 6 months or below and not only pregnant adolescents as initially stated.
Site(s)	Busia, Trans Nzoia, Uasin Gishu
Project Period	11/4/2019 - ongoing
Sponsor(s)	Indiana CTSI
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Chamas for Change: Validating an integrated community-based strategy of peer support in pregnancy and infancy**
Principal Investigator(s)	Julia Songok (Moi University)
Collaborator(s)	Laura Ruhl (Indiana University), Astrid Christoffersen-Deb (University of British Columbia)
Study Type	Prospective Randomized Controlled Trial
Specific Aim(s)	Validate Chama cha MamaToto as a scalable and effective population-wide strategy to rapidly and sustainably achieve high coverage of facility delivery, quality antenatal and postnatal care, long-term FP and EBF. The primary target was to demonstrate a 30% decrease in maternal (MMR), perinatal (PNR), and newborn (NMR) mortality rates.
Site(s)	Trans Nzoia

Project Period	11/1/2017 – 12/31/2020
Sponsor(s)	Grand Challenges Canada-Saving Lives at Birth
Status	Complete -- Follow up and data analysis are complete and the study is closed.
Study Title	**Clinical Assessment for Retention and Engagement (CARE Study)**
Principal Investigator(s)	Leslie Enane (Indiana University)
Collaborator(s)	Edith Apondi (Moi University), Rachel Vreeman (Mount Sinai), Winstone Nyandiko (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Refine a conceptual model for adolescent disengagement from HIV care in East Africa. Aim 2: Develop and pilot an instrument to assess adolescent risk for disengagement from HIV care - the Clinical Assessment for Retention and Engagement (CARE). Aim 3: Develop an evidence-based algorithm to support clinical evaluation and intervention for adolescents at risk for disengagement.
Site(s)	Bungoma, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	10/25/2018 - ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Comparison of Nutritional status of children aged 5 to 59 months in community based education and service (COBES)-AMPATH and non AMPATH centres post covid-19**
Principal Investigator(s)	Arthur Kwena (Moi University)
Collaborator(s)	J. Ballidawa (Moi University), K. Taylor (Notre Dame), M. McDowell (Notre Dame), S. Mining (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	To determine the nutritional status of children in selected COBES centres post Covid-19 and compare the nutritional status in AMPATH and non-AMPATH centres.
Site(s)	Bungoma, Busia, Elgeyo Marakwet, Kakamega, Nandi, Trans Nzoia, Uasin Gishu
Project Period	1/1/2014 - ongoing
Sponsor(s)	None

Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Compassion Fatigue, Satisfaction and Burnout Among Healthcare workers in the Context of the COVID 19 pandemic in Uasin Gishu County**
Principal Investigator(s)	Edith Kwobah (Moi Teaching and Referral Hospital)
Collaborator(s)	Jane Kariuki (Moi Teaching and Referral Hospital), Florence Jaguga (Moi Teaching and Referral Hospital)
Study Type	Cross-Sectional
Specific Aim(s)	1. To determine the prevalence of compassion fatigue, compassion satisfaction and burnout among health care workers in the context of the COVID 19 pandemic in Uasin Gishu County; 2. To determine social demographic factors associated with development of compassion fatigue, compassion satisfaction and burnout among health care workers in the context of the COVID 19 pandemic Uasin Gishu County; 3. To determine the association between health care workers' previous training in disaster/ emergency response and development of compassion fatigue and burnout among health care workers in the context of the COVID 19 pandemic in Uasin Gishu County
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/12/2021-Ongoing
Sponsor(s)	Mental Health RDF funds
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
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)
Collaborator(s)	Jepchirchir Kiplagat (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Estimate the prevalence of and explore stakeholder perceptions on research misconduct and how it can best be addressed in Kenya. Aim 2: Explore the perceptions on capacity to prevent, detect and manage research misconduct and the perceived critical components of a model framework for managing research misconduct. Aim 3. Develop and pilot test a model framework for detecting and managing research misconduct.
Site(s)	Kisumu, Moi Teaching and Referral Hospital, KNH, Research Ethics Committees in Kenya
Project Period	8/1/2017 - 7/31/2022

Sponsor(s)	NIH-FIC
Status	Ongoing -- In addition to data analysis, other project-related activities including trainings, sensitization workshop, and project evaluation and dissemination are planned for this year. The study team has requested a no-cost extension for 1 year.
Study Title	**EA-IeDEA: A longitudinal survey study of the impact of COVID-19 preparedness and response efforts on people living with HIV in East Africa**
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Lameck Diero (Moi University), Constantin Yiannoustos (Indiana University School of Medicine), Aggrey Sameere (College of Health Sciences Makerere University)
Study Type	Longitudinal observational cohort study
Specific Aim(s)	Aim 1: Assess COVID-19 related knowledge, attitudes, and beliefs among a diverse cohort of people living with HIV in East Africa. Aim 2: Describe the impact of COVID-19 on socio-economic well-being, health status, health services utilization, and health behaviors among a diverse cohort of people living with HIV in East Africa.
Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	6/9/2020 - ongoing
Sponsor(s)	None
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: ACE Study**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Kara Wools-Kaloustian (Indiana University), Edith Apondi (MTRH), Batya Elul (Columbia University), Rami Kantor (Brown University), Samuel Ayaya (Moi University), Giorgos Bakoyannis (Indiana University), Leslie Enane (Indiana University), Zachary Kwena (FACES -KEMRI)
Study Type	Cross-Sectional
Specific Aim(s)	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 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)	Moi Teaching and Referral Hospital, Trans Nzoia
Project Period	8/1/2018 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: Main Study**
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Constantin Yiannoutsos (Indiana University), Lameck Diero (Moi University), Samuel Ayaya (Moi University)
Study Type	Retrospective
Specific Aim(s)	To collaborate with clinical sites to identify and define key variables, harmonize and effectively analyze the data to generate large datasets.
Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu, West Pokot
Project Period	8/1/2006 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: Measuring Adverse Pregnancy and Newborn Outcomes (MANGO)**
Principal Investigator(s)	Edwin Were (Moi University)
Collaborator(s)	Rena Patel, Julia Songok, Bett Kipchumba, Audry Chepkemboi, Wycliffe Kosgei, Joy Marsha, Catlin Bernard, Beverly Musick, Laura Oyiengo, Elvis Oyungi, Molly MacPheron, Meghan McHenry, Edward Leichty, Ushma Mehta, Emma Kalk, Amy Slogrove, Andrew Boulle, Mary-Ann Davieis, Constantine Yiannoultsos, Kara Wools-Kaloustian, Jimmy Carlucci (IU) and Audrey Chepkemoi (Moi University College of Health Sciences)
Study Type	Mixed prospective and retrospective cohort study

Specific Aim(s)	1. Determine event rates for adverse pregnancy outcomes, congenital abnormalities (CAs) and other abnormal conditions in infants born to HIV+ and HIV- women and determine the associations between adverse pregnancy and infant outcomes and ART exposures during conception and pregnancy 2. To create standardized protocols and data exchange standards within IU and IeDEA. - By leveraging the existing and extensive IeDEA Data Exchange Standard (DES) and creating a Data Standards Task Force and a Data Coordinating Center for PV, we will add new tables and expand existing ones, as necessary, to include new concepts and fields responsive to the needs of pharmacovigilance among pregnant women.
Site(s)	Uasin Gishu
Project Period	8/3/2020 - 7/31/2025
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**EA-IeDEA: Measuring Adverse Pregnancy and Newborn Congenital Outcomes Study (MANGO) Sub-study- Determining Long-Term Clinical Outcomes for HIV-Affected Mother-Infant Dyads in western Kenya**
Principal Investigator(s)	Jimmy Carlucci, Indiana University
Collaborator(s)	Audrey Chepkemoi (Moi Teaching and Referral Hospital), Kara Wools-Kaloustian (Indiana University), John Humphrey (Indiana University), Edwin Were (Moi University), Rena Patel
Study Type	Prospective
Specific Aim(s)	1. Ascertain maternal outcomes in the prevention of mother-to-child transmission of HIV (PMTCT) service continuum, with emphasis on virologic outcomes for pregnant and postpartum women living with HIV (WLHIV). 2. Ascertain infant outcomes in the PMTCT service continuum, with emphasis on early infant diagnosis (EID) and definitive determination of HIV status of HIV-exposed children after cessation of breastfeeding.
Site(s)	Uasin Gishu,
Project Period	8/9/2021-7/31/2023
Sponsor(s)	None
Status	Not started -- Study activities have not begun.

Study Title	**EA-IeDEA: Networks In Kenya**
Principal Investigator(s)	Jennifer Syvertsen (University of California, Riverside, USA)

Collaborator(s)	Lukoye Atwoli (Moi University/Aga Khan University), Edith Kwobah (MTRH), Suzanne Goodrich (Indiana University), Karla D Wagner (University of Nevada), Maurice Aluda (KEMRI/FACES), Jayne Kulzer (UCSF), Kara Wools-Kaloustian (Indiana University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To examine how social network factors (e.g., network size, structure, composition) are associated with patterns of alcohol and other drug use (AOD), sexual behaviors, engagement in care, and HIV clinical outcomes among a sample of EA IeDEA-affiliated clinic patients who screen positive for alcohol and/or drug use and a comparison group. Aim 2: To qualitatively describe the nature and overlap of key relationships (e.g., risky and supportive) within patients' networks and assess their associations with HIV outcomes. Aim 3: To use mixed methods to explore the feasibility and acceptability of developing a social network intervention to reduce AOD risk behaviors, improve HIV clinical outcomes, and increase linkages to testing and care among people who use alcohol and/or drugs in East Africa.
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/29/2019 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**EA-IeDEA: NIDA Study**
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Lameck Diero (Moi University), Suzanne Goodrich (Indiana University), Edith Kwobah (MTRH), Patrick Oyaro (FACES/RCTP/KEMRI), Maurice Aluda (FACES/RCTP/KEMRI), Jayne Kulzer (UCSF)
Study Type	Prospective
Specific Aim(s)	Aim 1: Estimate the prevalence of hazardous alcohol consumption in patients enrolling in HIV-care and compare their baseline characteristic with those of non-drinkers. Aim 2: Compare clinician and research assistant collected AUDIT screening data at one clinic within the East African IeDEA consortium. Aim 3: Assess the impact of hazardous drinking on patient outcomes including time to antiretroviral therapy (ART) initiation, medication adherence, retention in care, and death at 6 months and again at 24-36 months. Aim 4: Assess strategies utilized by patients to address their hazardous alcohol use.
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/31/2017 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**EA-IeDEA: PHQ 9 Study**
Principal Investigator(s)	Marcel Yotebieng (Albert Einstein College of Medicine)
Collaborator(s)	Kathryn Lancaster (Ohio State University); Lukoye Atwoli (Moi University); Jennifer Syvertsen (University of California, Riverside), Kara Wools-Kaloustian (Indiana University), et al.
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Determine the region-specific differences in the quality of measurement afforded by the PHQ-9. Aim 2: Determine the dimensionality of PHQ-9 and assess whether a different scoring system or cut-point is needed among PLWH. Aim 3: Describe how PLWH in both region express mental distress and determine whether reformulation/adaptation of questions in PHQ-9 will improve its performance
Site(s)	Moi Teaching and Referral Hospital
Project Period	11/23/2020 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**EA-IeDEA: PMTCT Plus Study: Improving Estimates of Mother-to-Child Transmission in Western Kenya: A Mixed Methods Prospective Cohort Study**
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Bett Kipchumba, Marsha Alera, Libby Pfeiffer, Julia Songok, Winfred Mwangi, Wycliffe Kosgei, Beverly Musick, Constantin Yiannoutsos, Juddy Wachira, Kara Wools Kaloustian
Study Type	Prospective
Specific Aim(s)	Aim 1. Determine the barriers and enhancers to retention in care and viral suppression for postpartum women. Sub-Aim 1a: identify factors influencing retention and viral suppression using (i) statistical methods for observational data that incorporate LTFU outcomes, and (ii) qualitative interviews among 30 postpartum women and 15 of their male partners; Sub-Aim 1b: determine the prevalence of HIV resistance and its association with viral non-suppression by genotyping postpartum blood samples with detectable viremia and stored samples collected during pregnancy and earlier postpartum. We are now conducting follow-up study visits at 3 years postpartum for all enrolled women and infants.
Site(s)	Busia, Trans Nzoia, Uasin Gishu
Project Period	2/1/2021 - 2/1/2022
Sponsor(s)	NIH-NIAID

Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: Predicting Neurodevelopmental Risk in Children born to Mothers Living with HIV in Kenya: Sub-Study to the Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO) Study**
Principal Investigator(s)	Megan McHenry (Indiana University)
Collaborator(s)	Eren Oyungu-Moi University Rachel Vreeman-Mt Sinai Winstone Nyandiko-Moi University Patrick Monahan-Indiana University Alka Khaitain-Indiana University Zeruesenay Desta-Indiana University Amy Slogrove-Stellenbosch University Rena Patel-Univ. of Washington
Study Type	Longitudinal follow up of the enrolled study participants for 2 years.
Specific Aim(s)	Evaluate potential risk factors for worse ND outcomes in young Kenyan children who are HEU and HUU Compare ND outcomes between 24-month-old children who are HEU and HUU in Kenya Create a risk assessment tool to predict which children are at risk for worse ND outcomes at 24 months
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/1/2021-6/30/2026
Sponsor(s)	NIH
Status	Not started -- Study activities have not begun.
Study Title	**EA-IeDEA: Syndemics Study**
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Suzanne Goodrich (Indiana University), Jennifer Syvertsen (University of California Riverside), Jayne Kulzer (UCSF), Maurice Aluda (FACES/RCTP/KEMRI), Lukoye Atwoli (Moi University), Edith Kwobah (MTRH)
Study Type	Prospective
Specific Aim(s)	Aim 1: Identify community and clinic-based services available for treatment of substance use and mental health disorders in the three research sites. Aim 2: Determine the prevalence of substance use (drug and alcohol) and mental health disorders in patients enrolling into care. Aim 3: 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 - ongoing

Sponsor(s)	NIH-NIAID
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**Enhancing Preventive Therapy of Malaria in children with Sickle Cell Anemia (SCA) in East Africa (EPiTOMISE)**
Principal Investigator(s)	Festus Njuguna (Moi University)
Collaborator(s)	Steve Taylor (Duke University), Wendy O'Meara (Duke University)
Study Type	Randomized, three-arm, open-label, clinical trial
Specific Aim(s)	Aim 1: Compare the efficacy of daily Proguanil with that of monthly sulfadoxine/pyrimethamine-amodiaquine (SP-AQ) or monthly dihydroartemisinin-piperaquine (DP) to prevent P. falciparum malaria in children with sickle cell. Aim 2: Compare the efficacy of daily Proguanil, monthly SP-AQ, and monthly DP to prevent painful events in children with sickle cell anemia. Aim 3: Compare the impact of malaria chemoprophylaxis regimens on molecular markers of parasite drug resistance to Proguanil, SP-AQ, and DP.
Site(s)	Homa Bay
Project Period	6/1/2016 - 2/28/2021
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy**
Principal Investigator(s)	Rena Patel, University of Washington
Collaborator(s)	Beatrice Jakait (Moi Teaching and Referral Hospital), Caitlin Bernard (Indiana University)
Study Type	Retrospective
Specific Aim(s)	To assess the relative effectiveness of Levonorgestrel-based (LNG) implants with concomitant efavirenz-based ART among a random subsample of HIV-positive women attending AMPATH-supported HIV treatment facilities using chart reviews and phone interviews.
Site(s)	All AMPATH sites.
Project Period	5/1/2016-1/25/2021
Sponsor(s)	NIH - NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

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)
Collaborator(s)	Astrid Christoffersen (University of Toronto), Sonak Pastakia (Purdue University),
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence rates of GDM in rural and urban populations. Aim 2: To assess the impact of the risk factors of interest (age, BMI and family history) for GDM in early pregnancy. Aim 3: To develop and validate of composite risk score for GDM with the risk factors of interest and/or point-of-care HbA1c.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	6/13/2016 - ongoing
Sponsor(s)	UK Medical Research Council; Warwick University
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

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)	John Humphrey (Indiana University)
Collaborator(s)	Rena Patel, Mercy Maina, Julie Thorne, Beatrice Jakait, Caitlin Bernard
Study Type	Retrospective analysis of AMRS data and telephone surveys
Specific Aim(s)	Aim 1. To evaluate key reproductive health and HIV outcomes among women initially on DTG-containing ART. Aim 2: To investigate factors facilitating provider and patient decision-making for HIV-infected women choosing between ART and contraceptive choices.
Site(s)	
Project Period	7/9/2020 - ongoing
Sponsor(s)	NIH; Indiana University
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**Evaluation of Chronic Hypoxemia from Cardiopulmonary Disease Among Patients Admitted to a Referral Hospital in Western Kenya and Their Perspectives on Oxygen Use**

Principal Investigator(s)	Neelima Navuluri (Duke University)
Collaborator(s)	David Lagat (Moi University), Peter Kussin (Duke University), Lameck Diero (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Determine the prevalence of chronic hypoxemia from cardiopulmonary disease and the associated in-hospital mortality rate among patients admitted to Moi Teaching and Referral Hospital (MTRH) inpatient medicine wards from August 2019 - June 2021. Aim 2: Characterize patients with chronic hypoxemia admitted to MTRH by determining demographic and environmental risk factors, associated co-morbidities such as HIV, and underlying etiologies. Aim 3: Assess quality of life measures among patients with chronic hypoxemia and their perspectives on oxygen therapy.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	9/1/2019 - ongoing
Sponsor(s)	NIH-Fogarty
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**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)
Collaborator(s)	Becky Lynn Genberg (John Hopkins University), Ira Wilson (Brown University), Abraham M. Siika (Moi University), Omar Galarraga (Brown University), Paula Braitstein (University of Toronto) Ann Mwangi (Moi University), Sylvestor Kimaiyo (Moi University), Jonathan Dick (Indiana University), Michael Bart Laws (Brown University)
Study Type	Randomized Controlled Trial
Specific Aim(s)	Aim 1. Determine the impact of system-level factors on patient engagement (clinic adherence) among adult HIV patients. 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 (≥400). Aim 3. Determine the cost effectiveness of EPC for engagement of patients with unsuppressed viral load.
Site(s)	Busia
Project Period	7/3/2017 - 12/30/2022
Sponsor(s)	NIH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups in Kenya**
Principal Investigator(s)	Omar Galárraga (Brown University)
Collaborator(s)	Becky Lynn Genberg (Johns Hopkins University), Juddy Wachira (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To evaluate the extent to which integrated community-based HIV care with group microfinance affects retention in care and viral suppression among PLHIV in rural western Kenya using a pragmatic cluster randomized intervention design of 40 existing (majority HIV+) microfinance groups to receive microfinance plus either: (A) integrated community-based HIV care, or (B) standard care. Aim 2: To identify specific mechanisms through which microfinance and integrated community-based care impact viral suppression. Aim 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.
Site(s)	Busia, Trans Nzoia
Project Period	7/5/2019 - 4/30/2024
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**HIV-related outcomes at the AMPATH Drug Resistance Clinic in Kenya**
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Shamim Ali, Bilal Syed, Suzanne Goodrich, Celia Ngetch, Beatrice Jakait, Rami Kantor, Adrian Gardner
Study Type	Retrospective
Specific Aim(s)	Aim 1: Describe the clinical characteristics of patients attending the AMPATH HIV Drug Resistance Clinic, including the prevalence of drug resistance mutations. Aim 2: Describe the virologic and ART outcomes of patients failing second and third-line ART, including the proportion of patients who achieve viral suppression following enrollment in the clinic and the proportion experiencing an ART regimen change.
Site(s)	Uasin Gishu
Project Period	3/3/2020 - ongoing
Sponsor(s)	None
Status	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	**IeDEA: Sentinel Research Network (SRN)**
Principal Investigator(s)	Niharika Samala (Indiana University)
Collaborator(s)	Kara Wools-Kaloustian, Lameck Diero, Suzanne Goodrich, Edith Kwobah, Mercy Karoney, Ayub Barasa, Alexa Monroy, Samir Gupta, Fatuma Some
Study Type	Prospective
Specific Aim(s)	To establish a network of research sites, the Sentinel Research Network (SRN), and to capture and analyze standardized data among PLHIV in LMICs. Through this network, we further seek to implement studies on cardiovascular risk factors, mental health, alcohol and other substance use disorders, as well as liver disease prevalence and associated factors among PLHIV accessing care in LMICs.
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/1/2020 - 7/31/2022
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Impact of COVID-19 on adolescents living with HIV in Kenya**
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai)
Study Type	Prospective
Specific Aim(s)	Aim 1: Investigate changes in ART adherence, mental health and socio-economic well-being related to COVID-19, and their association with viral failure and DR outcomes in Kenyan ALWH. Aim 2: Estimate exposure to COVID-19 and association with viral failure and DR outcomes among Kenyan ALWH enrolled in the parent grant.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	8/20/2020 - 5/31/2024
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Implementing a Model of Improved Care for Infectious Diseases and Antibiotic Stewardship across Multiple Levels of the Health System in Western Kenya**

Principal Investigator(s)	Charles Kwobah (Moi University)
Collaborator(s)	Shamim Ali (Moi University), Suzanne Goodrich (Indiana University), Adrian Gardner (Indiana University)
Study Type	Prospective
Specific Aim(s)	To optimize appropriate antibiotic use in order to improve clinical outcomes while minimizing unintentional consequences of use, including the emergence of antimicrobial resistance.
Site(s)	Bungoma, Elgeyo Marakwet, Moi Teaching and Referral Hospital
Project Period	10/1/2019 - 9/30/2022
Sponsor(s)	Pfizer Foundation
Status	The clinical care project has five goals with timelines for achievements. this achievements are oncourse for the first year and second year respectively.

Study Title	**Integrating hypertension and diabetes screening and management with HIV care services for older adults: Feasibility study**
Principal Investigator(s)	Jepchirchir Kiplagat, Moi University
Collaborator(s)	Kara Wools-Kaloustian, Jemimah Kamano, Sonak Pastakia, Violet Naanyu, Rajesh Vedanthan
Study Type	mixed-methods (Retrospective analysis of medical records, qualitative interviews and observational checklist)
Specific Aim(s)	To lay the groundwork for integrated HIV and NCD services, this project aims to; i) Determine unmet needs for hypertension and diabetes screening and treatment in older adults living with HIV (OALWH) ii) Assess feasibility and acceptability of utilizing AMPATH's HIV care platform to provide diabetes and hypertension screening and treatment services to OALWH
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/1/2021-6/30/2022
Sponsor(s)	NIH-FIC
Status	Not started -- Study activities have not begun.

Study Title	**Labor organizing and strikes by health care workers in Kenya**
Principal Investigator(s)	Michael Scanlon (Indiana University)
Collaborator(s)	Lukoye Atwoli (Aga Khan University)

Study Type	Qualitative case study
Specific Aim(s)	Aim 1. Describe labor relations and conflict in the Kenyan public health sector, with specific attention to: (a) key institutions, stakeholders, and their interests; (b) collective bargaining agreements and dispute resolution mechanisms; and (c) health systems governance and policy. Aim 2. Explore the perspectives of key actors (e.g., health workers, union/professional association representatives, health management and government officials, academics) on labor relations and strikes in the Kenyan health sector using a grounded theory approach with specific attention to health systems governance and policy.
Site(s)	Elgeyo Marakwet, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu, Samburu County
Project Period	12/6/2018-12/5/2021
Sponsor(s)	None
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Making Inroads to Strengthen the Health of Adolescents**
Principal Investigator(s)	Leslie Enane (Indiana University)
Collaborator(s)	Edith Apondi (Moi University), Rachel Vreeman (Mount Sinai), Winstone Nyandiko (Moi University), Elizabeth Lowenthal (University of Pennsylvania)
Study Type	Cross-Sectional
Specific Aim(s)	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. (Secondary Aim: To determine the causes of hospitalization and mortality among adolescents with HIV in western Kenya); 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.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/12/2017 - ongoing
Sponsor(s)	Indiana University
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**Maternal Newborn Health Registry**
Principal Investigator(s)	Fabian Esamai (Moi University)

Collaborator(s)	Sherri Bucher (Indiana University), Edward Liechty (Indiana University), Irene Marete (Moi University), Constance Tenge (Moi University)
Study Type	Prospective
Specific Aim(s)	A multicenter (8 sites in 7 countries) prospective, population-based registry which enrolls women during pregnancy and tracks pregnancy, delivery, and postnatal maternal and neonatal outcomes through 42 days postpartum. A vital registry system allows the Global Network to document maternal and neonatal mortality, design trials to address the major causes of poor outcomes, assess the outcome of our interventions, and ultimately, disseminate the results as the basis of public health policy.
Site(s)	Bungoma, Busia, Kakamega
Project Period	10/15/2008 - ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	**Mobile Mental Health Monitoring and Support for Adolescents with HIV in Kenya**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Edith Apondi (MTRH), Bree Weaver (Indiana University)
Study Type	Prospective
Specific Aim(s)	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)	Uasin Gishu
Project Period	1/1/2017 - 12/31/2018
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**Multicenter Study of Pomalidomide Monotherapy in HIV-Infected Individuals with Kaposi Sarcoma (KS) in Sub-Saharan Africa (SSA)**

Principal Investigator(s)	Naftali Busakhala (Moi University)
Collaborator(s)	Dr. Evangeline Njiru Dr. Susan Krown Dr. Samantha Vogt
Study Type	Prospective
Specific Aim(s)	The study objective is to determine if pomalidomide monotherapy induces an antitumor efficacy and whether it is safe and tolerable, in order to justify its further development for treatment of HIV-associated KS in sub-Saharan Africa.
Site(s)	Kisumu, Moi Teaching and Referral Hospital
Project Period	7/15/2021-Ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**NeoInnovate Collaborative Consortium**
Principal Investigator(s)	Sherri Bucher (Indiana University)
Collaborator(s)	Saptarshi Purkyastha (Indiana University), Fabian Esamai (Moi University)
Study Type	n/a
Specific Aim(s)	The NeoInnovate Collaborative Consortium is a multi-disciplinary international coalition of faculty, students, and post-graduate trainees led by IU School of Medicine and Alupe University College (Moi University) and partnering with Moi Teaching and Referral Hospital (Kenya), IUPUI, Purdue University, and University of Notre Dame. The Consortium builds, deploys, and evaluates innovative solutions by which to equip, empower, and strengthen health care providers, communities, and health systems. These efforts supply partners and stakeholders with the knowledge, skills, and tools by which to successfully disseminate, implement, scale-up, and sustain evidence-based, life-saving interventions to improve maternal and newborn outcomes.
Site(s)	n/a
Project Period	n/a
Sponsor(s)	None
Status	Preparing grant submissions.

Study Title	**Neurodevelopmental Screening in Children Born to HIV-Infected Mothers in Kenya**
Principal Investigator(s)	Megan McHenry (Indiana University)

Collaborator(s)	Eren Oyungu (Moi University)
Study Type	Prospective
Specific Aim(s)	AIM 1: Determine and compare the reliability and validity of neurodevelopmental screening tools and assessments for use among children aged 18-36 months in Kenya. The objective for this aim is to identify an optimal screening tool and assessment for use in Kenya. AIM 2: Evaluate neurodevelopmental screening implementation in an existing healthcare system in Kenya. •Sub-aim 2a: Develop a contextualized implementation plan and Sub-aim 2b: Pilot a ND screening program at one MCH clinic in Kenya. In addition, we will assess effectiveness of ND screening, as determined by sensitivity; specificity; and positive and negative predictive values.
Site(s)	Uasin Gishu
Project Period	9/30/2018 - 8/31/2022
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Neuropsychiatric Genetics of African Populations -Psychosis (NEUROGAP-P)**
Principal Investigator(s)	Lukoye Atwoli (Moi University/Aga Khan University)
Collaborator(s)	Gabriel Kigen, Edith Kwobah, Wilfred Emonyi
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To determine the phenotypic presentation of psychotic disorders in African populations. Aim 2: To describe the genetic variation between patients with psychotic disorders and those without in African populations. Aim 3: To examine the association between genetic variation and risk for schizophrenia and bipolar disorder in African populations Aim 4: To provide opportunities for training of African scientists in neuropsychiatric genetics research. Target number of participants has since been reviewed to 5,200
Site(s)	Bungoma, Elgeyo Marakwet, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, West Pokot
Project Period	7/1/2017 - 6/30/2022
Sponsor(s)	Broad Institute of MIT; Harvard University
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Optimizing HIV treatment monitoring strategies under resource constraints**

Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Ann Mwangi (Moi University), Lameck Diero (Moi University), Joseph Hogan (Brown University)
Study Type	The research will use previously collected data and blood samples stored from previously IREC approved AMPATH studies.
Specific Aim(s)	1) Develop and apply scalable statistical framework for optimal targeting of gold standard diagnostic tests used to monitor HIV treatment under resource constraints; 2) Apply causal inference techniques to calibrate decision rules using estimated decision utilities; 3) Develop methods to optimize pooling strategies for viral load testing in resource limited settings; 4) Establish and implement pooling protocols using extant samples from AMPATH patients
Site(s)	Samples stored at The Miriam Hospital, USA
Project Period	2/3/2016 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK)**
Principal Investigator(s)	Valentin Fuster (Mount Sinai)
Collaborator(s)	Jemima Kamano (Moi University), Violet Naanyu (Moi University), Diana Menya (Moi University), Sylvester Kimaiyo (Moi University), Rajesh Vedanthan (NYU Grossman School of Medicine), et al.
Study Type	Prospective
Specific Aim(s)	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. 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. 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. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial. Study population: Enrollment remains closed for this study. 2890 individuals (69.9% women) were enrolled (708 UC, 709 MF, 740 GMV, and 733 GMV-MF).
Site(s)	Nandi, Uasin Gishu

Project Period	4/1/2012 - 3/31/2022
Sponsor(s)	NHLBI; NYU Grossman School of Medicine
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
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 (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University),
Study Type	Prospective
Specific Aim(s)	Aim 1: Expand and modify an existing pediatric HIV disclosure intervention used in Kenya to include patient-centered components. Aim 2: Perform a randomized trial to compare the impact of clinic implementation of the culturally adapted, pediatric disclosure intervention on the prevalence of disclosure and on the medical, psychological and social outcomes for HIV-infected Kenyan children ages 10-15 years compared to children exposed to standard clinical care.
Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	1/9/2012 - 1/9/2016
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Prevalence and Impact of SARS-CoV-2 Among Pregnant Women in Low- and Middle-income Countries**
Principal Investigator(s)	Fabian Esamai (Moi University)
Collaborator(s)	Edward Liechty, Sherri Bucher (Indiana University), Irene Marete (Moi University), Constance Tenge (Moi University), Osayame Ekhaguere (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence of COVID-19 antibodies in pregnant/recently delivered women in 8 Global Network sites using antibody testing. Aim 2: To compare the maternal, fetal, and neonatal outcomes of COVID-19 antibody positive women vs. antibody negative women including low-birthweight, preterm birth, fetal growth restriction, stillbirth, and neonatal mortality. Aim 3: To assess knowledge, attitudes and practices of pregnant women related to COVID-19 and its prevention during pregnancy.
Site(s)	Bungoma, Busia, Kakamega

Project Period	11/15/2020 - ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Prevalence of hypertension among postpartum women with preeclampsia (PET) in Kenya: a prospective cohort study**
Principal Investigator(s)	Gerald Bloomfield (Duke University)
Collaborator(s)	Felix Barasa (MTRH), Rebecca Lumsden (Duke University)
Study Type	Prospective
Specific Aim(s)	Aim1: To determine the prevalence of hypertension at 6 months postpartum among Kenyan mothers with preeclampsia. Sub-aim 1.1: To define the BP trajectory during the postpartum period among Kenyan mothers with preeclampsia. Aim 2: To identify risk factors associated with persistent hypertension among Kenyan mothers with preeclampsia. Aim 3: To characterize the acute cardiac structural and functional abnormalities among Kenyan mothers with preeclampsia. Aim 4: To explore post-delivery follow-up care for women with PET, including knowledge, location, barriers and rates of follow up
Site(s)	Moi Teaching and Referral Hospital
Project Period	1/6/2020 - ongoing
Sponsor(s)	NIH-FIC
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. We completed study follow-up and data collection as of May 31, 2021. We are now in the process of data cleaning and analysis and will be preparing for manuscript writing over the next 6 months.
Study Title	**Prevention of maternal and neonatal death/infections with a single oral dose of Azithromycin in women in labor (in low- and middle-income countries): a Randomized Controlled Trial (The A-PLUS study)**
Principal Investigator(s)	Alan Tita (University of Alabama at Birmingham)
Collaborator(s)	Fabian Esamai (Moi University), Paul Nyongesa (Moi University), Ed Liechty (Indiana University), Sherri Bucher (Indiana University), Osayame Ekhaguere (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To test the effectiveness of a single dose of prophylactic intrapartum azithromycin compared to placebo in reducing the risk of the composite outcome of maternal death or sepsis. Aim 2: To separately test the effectiveness of a single oral dose of intrapartum azithromycin

	prophylaxis (2 g) compared to placebo in reducing the risk of the composite outcome of intrapartum/neonatal death or sepsis.
Site(s)	Bungoma, Busia, Kakamega
Project Period	10/30/2019 - ongoing
Sponsor(s)	NIH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Prospective study of Lopinavir based ART for HIV Infected childreN Globally (LIVING study) 2**
Principal Investigator(s)	Winstone Nyandiko (Moi University)
Collaborator(s)	Dalton Wamalwa (University of Nairobi), Samwel Ayaya (Moi University)
Study Type	Prospective
Specific Aim(s)	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: (1) Document the safety of LPV/r pellets and AZT/3TC or ABC/3TC; (2) Assess the population pharmacokinetics of LPV/r and NRTIs when administered as LPV/r pellets plus AZT/3TC or ABC/3TC; (3) Measure adherence to the new formulation; (4) Evaluate children acceptability of the LPV/r pellets and associated dual NRTIs as well as ease of use by the care giver.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/14/2016 - ongoing
Sponsor(s)	Drugs for Neglected Diseases initiative (DNDi)
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**PT4A (Peers and Technology for Adherence, Access, Accountability, and Analytics)**
Principal Investigator(s)	Rajesh Vedanthan (New York University)
Collaborator(s)	Sonak Pastakia (Purdue University), Antoinette Schoenthaler (NYU), Andrea Troxel (NYU), Benson Njuguna (MTRH), Jeremiah Laktabai (MTRHI), Imran Manji (MTRH), Ann Mwangi (MTRH), Jonathan Dick (Indiana University), Dustin Duncan (Columbia), Tina Tran (Temple University), Becky Genberg (Johns Hopkins University)
Study Type	Prospective

Specific Aim(s)	The overall objective of this project is to utilize the PRECEDE-PROCEED framework to conduct transdisciplinary, translational implementation research focused on improving medication adherence for hypertension control. Aim 1: will identify micro- and macro-level contextual factors that might influence the implementation of the PT4A strategy (individual, family, clinician, health system, and environment), using qualitative methods. Aim 2: We will then use a human-centered design approach to refine the PT4A intervention using the findings from Aim 1. Sub-Aim 2.1: will evaluate the intervention for acceptability and appropriateness using focus group discussions with patients, peers, and clinical staff. In Sub-Aim 2.2: we will then conduct a pilot of the intervention and conduct focus group discussions with patients, peers, and clinical staff to evaluate feasibility. We will also evaluate impact on systolic blood pressure, medication adherence, and fidelity of implementation.
Site(s)	Bungoma, Trans Nzoia, Uasin Gishu
Project Period	9/25/2020 - 8/31/2021
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**SAFI (Stigma in AIDS Family Inventory) Validation Study**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	WinstoneNyandiko (Moi University), Irene Marete (Moi University), Violet Nanyu (Moi University), Hai Liu (Indiana University)
Study Type	Prospective
Specific Aim(s)	The specific aims for the SAFI validation study were: Aim 1: Identify and modify HIV/AIDS stigma questionnaire items for maximum reliability and content validity to measure perceived, enacted and internalized HIV/A stigma among Kenyan families with HIV-infected children. Aim 2: Assess the validity of the measures of perceived, enacted and internalized H/A stigma compared to independent construct measures including pediatric adherence to therapy and children's physical, psychological and social outcomes. Aim 3: Examine whether disclosure of a child's HIV status reduces perceived, enacted, or internalized stigma for families with disclosed children compared to families with non-disclosed children.
Site(s)	Bungoma, Busia, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	12/17/2013 - 12/31/2015
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**Spatial scales of Plasmodium falciparum generations; implications for elimination**
Principal Investigator(s)	Andrew Obala (Moi University)
Collaborator(s)	Wendy O'Meara (Duke University), Diana Menya (Moi University)
Study Type	Prospective cohort
Specific Aim(s)	The overall goal is to match infections in malaria-infected mosquitoes to malaria infections in humans in order to understand what persons infected each mosquito and the distance between the donor and the location where the mosquito was trapped. Aim 1: Measure the genetic relatedness of infections within the same household compared to the relatedness of infections at further distances to determine whether this relationship differs in fever 'hotspots' (geographic clusters of high fever incidence) and fever 'coldspots'. Aim 2: Trap malaria mosquito vectors and identify infected mosquitoes to determine the source of the mosquito's infection by sequencing parasites in the mosquito salivary glands and comparing to parasite genotypes in humans.
Site(s)	Bungoma
Project Period	7/1/2019 - 6/30/2021
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	**Stated Preference Analysis to Refine PMTCT Service Delivery in Kenya (SPARK) study**
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Edwin Were, Winstone Nyandiko, Violet Naanyu, Bett Kipchumba, Marsha Alera, Alan McGuire, Beverly Musick, James Carlucci, Constantin Yiannoutsos, Gregory Zimet, Kara Wools-Kaloustian
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1. Identify the relative importance of key PMTCT services according to PPHIV in western Kenya. Aim 2. Explore the influence of various characteristics of PPHIV on their preferences for different PMTCT services.
Site(s)	Busia, Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	6/1/2021 - ongoing
Sponsor(s)	NICHD
Status	Not started -- Study activities have not begun.

Study Title	**Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS)**

Principal Investigator(s)	Constantine Olieba Akwanalo (Moi University)
Collaborator(s)	Jemima Kamano, Benson Njuguna, Violet Naanyu, Ann Mwangi, Timothy Mercer, Rajesh Vedanthan, Sonak Pastakia, Jonathan Dick, Makeda Williams
Study Type	Cluster randomized controlled trial
Specific Aim(s)	Aim 1: Evaluate the effectiveness of HIT and peer support on one-year change in SBP and CVD risk reduction. Aim 2: 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. Aim 3: Conduct a process evaluation using the Saunders framework, evaluating key implementation measures related to fidelity, dose delivered, dose received, recruitment, reach, and context. Aim 4: 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 DALY saved.
Site(s)	Bungoma, Busia, Nandi, Trans Nzoia, Uasin Gishu
Project Period	9/1/2017 - 5/31/2022
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**The Effect of Weekly Text Messaging to Improve Retention across the PMTCT Cascade for Pregnant HIV- infected Women: Study Protocol for a Randomized Controlled Trial (WelTel PMTCT)**
Principal Investigator(s)	Anna Mia Ekström (Karolinska Institutet)
Collaborator(s)	Edwin Were (Moi University)
Study Type	Prospective
Specific Aim(s)	The primary objective is to determine the effectiveness of the WelTel SMS intervention on retention of women living with HIV and their newborns in PMTCT care in urban and rural Kenya. Secondary Objectives 1: To assess adherence to the WelTel SMS intervention among pregnant women and newly delivered mothers living with HIV. Objective 2: To determine adherence to single components of PMTCT among pregnant women and newly delivered mothers living with HIV (ARVs, facility-based delivery, early infant HIV testing, and exclusive breastfeeding). Objective 3: To explore facilitators for and barriers to using WelTel SMS in order to inform any improvements on the model for PMTCT among pregnant women and newly delivered mothers living with HIV as well as PMTCT staff. Objective 4: To evaluate costs from a payer's perspective, of the WelTel SMS for retaining women living with HIV and HIV-exposed infants in clinical follow-up until 24 months post-delivery (discharge from PMTCT).
Site(s)	Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu

Project Period	6/25/2015 - ongoing
Sponsor(s)	Swedish Research Council
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**The Impact of Using Hemotype SCTM in Screening for Sickle Cell Disease in Neonates, Infants, and Children under Five Years of Age in a Resource-Limited Setting**
Principal Investigator(s)	Christopher Mwaniki (Duke University)
Collaborator(s)	Festus Njuguna (Moi University), Ann Greist (Indiana Hemophilia and Thrombosis Centre), Chris Roberson (Indiana Hemophilia and Thrombosis Centre)
Study Type	Prospective
Specific Aim(s)	Aim 1: To evaluate the uptake of HSST among immunization population. Aim 2: To evaluate the proportion of those screened with HSST and get followed up through the Hb Electrophoresis. Aim 3: To determine the rate of enrollment of those found to have sickle cell into the comprehensive sickle cell clinic. Aim 4: To evaluate the prevalence of sickle cell among screened children age 5 and below presenting in the immunization clinic at the Homabay county referral hospital.
Site(s)	Homabay County Referral Hospital
Project Period	12/1/2020 - 12/1/2022
Sponsor(s)	None
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**The Prevalence of and Risk Factors for Non-Alcoholic Fatty Liver Disease in Kenya**
Principal Investigator(s)	Fatuma Some (Moi University)
Collaborator(s)	Naga Chalasani, Niharika Samala, Suzanne Goodrich, Mercy Karoney, Alexa Monroy
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence of steatosis and hepatic fibrosis in PLHIV and in individuals without HIV infection where diagnosis is based on predefined clinical, laboratory, and imaging criteria. Aim 2: To develop a bio-specimen bank comprised of serum, plasma, and DNA obtained from PLHIV and in individuals without HIV infection to support the evaluation the independent effects of ART, HIV factors, gene variants, and metabolic abnormalities on risk of fatty liver.
Site(s)	Moi Teaching and Referral Hospital

Project Period	3/1/2021 - ongoing
Sponsor(s)	Indiana University
Status	Not started -- Study activities have not begun.
Study Title	**The Role of PD-1 Pathway and Tissue Microenvironment in HIV-Kaposo Sarcoma and Endemic Kaposi Sarcoma Cohort in Western Kenya**
Principal Investigator(s)	Patrick Loehrer (Indiana University)
Collaborator(s)	Toby Maurer, MD (Indiana University), Chite Asirwas (International Cancer Institute)
Study Type	Prospective
Specific Aim(s)	To look for the PD-1 pathway in Kaposis sarcoma (KS) tissue from an HIV cohort and endmic cohort
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/1/2015-8/31/2019
Sponsor(s)	NCI supplemental gratn
Status	Complete -- Follow up and data analysis are complete and the study is closed.
Study Title	**Virologic Treatment Failure and Drug Resistance in HIV-infected Kenyan Children**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Rami Kantor (Brown University), Samuel Ayaya (Moi University), Joe Hogan (Brown University)
Study Type	Prospective cohort (with additional retrospective analyses)
Specific Aim(s)	Aim 1: Determine prevalence of viral failure and examine resistance mutations among a retrospective study cohort of 685 prenatally HIV-infected Kenyan children on 1st-line ART. Aim 2: Investigate associations between specific adherence patterns, ART drug levels and other demographic and clinical factors, with viral failure and drug resistance. Aim 3: Study long-term immunologic, virologic and drug resistance outcomes and their associations in prospectively re-enrolled study participants Aim 4: Enhance analyses of viral failure, drug resistance accumulation and associated demographic and clinical factors by examining the longitudinal banked samples available for a subset of the study cohort (n=327). Aim 5: Develop a data-driven intervention algorithm to identify children at risk for viral failure and resistance.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	8/2/2017 - 7/31/2020
Sponsor(s)	NIH-NIAID

Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**World Bleeding Disorders Registry (WBDR)**
Principal Investigator(s)	Festus Njuguna (Moi University)
Collaborator(s)	Donna Coffin (World Federation of Hemophilia), Glenn Pierce (World Federation of Hemophilia), Alain Baumann (World Federation of Hemophilia)
Study Type	Prospective
Specific Aim(s)	WBDR will aim to address the following: Aim 1: Identify gaps in evidence related to diagnosis, access to care, treatment, and outcomes in patients that include: • Comparative evaluation of preventative treatment regimens (e.g., prophylaxis) • Identification of high-risk populations • Inhibitors and other complications of BD • Trends in treatment patterns over time • Discrepancies in quality of care • Data on factor utilization. Aim 2: Collection of data to support advocacy initiatives aimed at improving diagnosis and access to care around the world, such as: • Burden of disease data: • Annual bleeding rate • Functional assessment • Hospitalization • Lost days of school/work • Educational/employment attainment • Between country discrepancies in factor usage.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/6/2018 - ongoing
Sponsor(s)	None
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.