

The AMPATH Kenya Research Program Annual Report

January – December
2023



Acknowledgments

The AMPATH Kenya 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 health for all in Kenya and around the world.

Editorial Team

Winstone Nyandiko

Edith Kwobah

Jepchirchir Kiplagat-Kirui

Michael Mwaniki

Eunice Walumbe

Kara Wools-Kaloustian

Michael Scanlon

Chris Rice

Whitney Turientine

Kristie Wallace

Copyright© 2024 – AMPATH Kenya Research Program Office

Contacts	
Michael Mwaniki Deputy Research Program Manager AMPATH Kenya Research Program AMPATH Centre P.O. Box 4606 Eldoret, Kenya Email: research.manager@ampath.or.ke Phone: +254 53 203 3471 Fax: +254 53 206 1992	Whitney Turientine Research Program Manager AMPATH Kenya Research Program Indiana University Center for Global Health Equity 702 Rotary Circle, RO131 Indianapolis, IN 46202 Email: research.manager@ampath.or.ke Phone: +1-317-274-4189 Fax: +1-317-274-9124
Please visit the AMPATH Research Program website to learn how our research programs are helping improve the health of people in Kenya and around the world. https://www.ampathkenya.org/research	

Table of Contents

DIRECTORS' NOTE4

RESEARCH PROGRAM VISION, MISSION & VALUES5

STRATEGIC PRIORITIES5

GRANTS.....6

PUBLICATIONS.....7

GEOGRAPHIC REACH OF AMPATH RESEARCH ACTIVITIES.....8

OTHER ACTIVITIES & ACHIEVEMENTS9

APPENDIX 1. BIBLIOGRAPHY 14

APPENDIX 2. STUDY REPORTS 27

Directors' Note

The AMPATH Research Program is an internationally recognized global health research collaboration that stands out for its commitment to the values of humility, partnership, integrity, mutual benefit, equity, and sustainability. We are proud to host some of the world's most innovative, impactful and rigorous global health research. This past year alone (2023), AMPATH-affiliated investigators received more than US \$19 million in research awards and published 115 articles in peer-reviewed journals. Our new awards include research focusing on climate change adaptation, interventions for sickle cell disease, and training in HIV implementation science and dissemination. This year we also advanced a number of strategic initiatives and activities in line with our strategic priorities, including implementing: the restructured AMPATH Research Facility Fee at the Research and Sponsored Programs Office (RSPO), a manuscript writing course for early stage investigators, a new initiative in research translation and policy, and the opening of Moi University-MTRH Bio-Repository in Eldoret.

After a successful research retreat in January this year, we look forward to launching a bold plan to guide the next five years of the AMPATH Kenya Research Program to achieve AMPATH's strategic goals for research. New initiatives in research mentorship and training, data science and the Moi University Centre of Excellence in Biomedical Research, Innovation and Development (MU-CeBRID) will continue to propel our program forward while remaining committed to strengthening our existing research cores and working groups and supporting AMPATH investigators across a wide range of disciplines. Emerging partnerships with new AMPATH sites in Ghana, Mexico and Nepal represent new opportunities for research collaboration and impact.

However, as we enter into 2024, we must also acknowledge significant loss of Dr. Edith Kwobah who died early this year. Dr. Kwobah was the Director of Mental Health & Rehabilitative Services at Moi Teaching & Referral Hospital and had been appointed as Deputy Executive Director for AMPATH Research during in 2023. A seasoned psychiatrist and researcher, Dr. Kwobah brought expertise in clinical research and care, along with a passion for stigma reduction, community education and increasing mental healthcare for all. In her role, she served as part of the research program's leadership team providing strategic guidance on the direction of the research program. Her absence from the program will be missed.

We appreciate all of your efforts and commitment to the AMPATH Kenya Research Program and look forward to working with you in 2024 and beyond to continue to move our program and research efforts forward to address the health needs of all in Kenya and around the world.

Sincerely,

Directors of Research, AMPATH Kenya

Research Program Vision, Mission & Values

Vision

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

Mission

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

Values

In our work, we embrace:

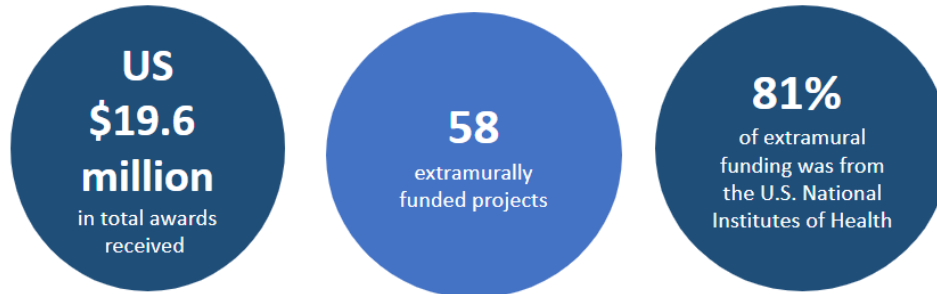
- Service with humility
- A spirit of collaboration and partnership
- Integrity in relationships
- Mutual respect and mutual benefit in organizational partnerships
- Efforts to eliminate health disparities
- A sustainable infrastructure for research

Strategic Priorities

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.**

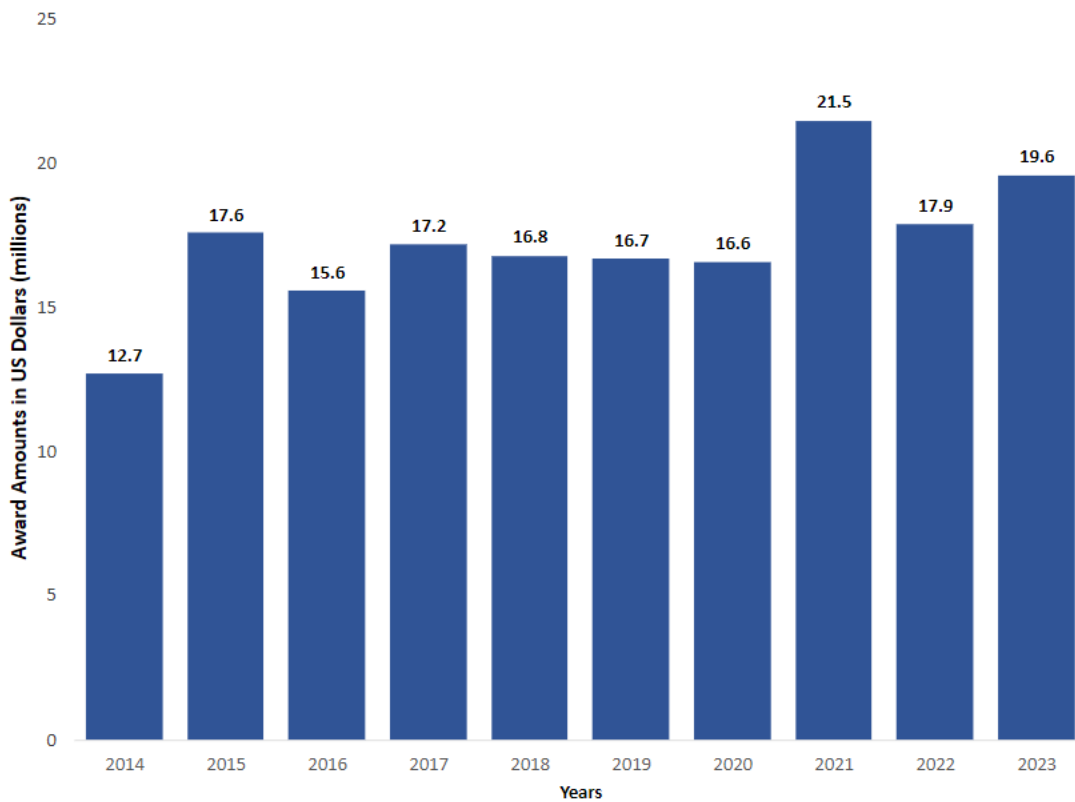
Grants

January - December 2023 Research Metrics At-a-Glance



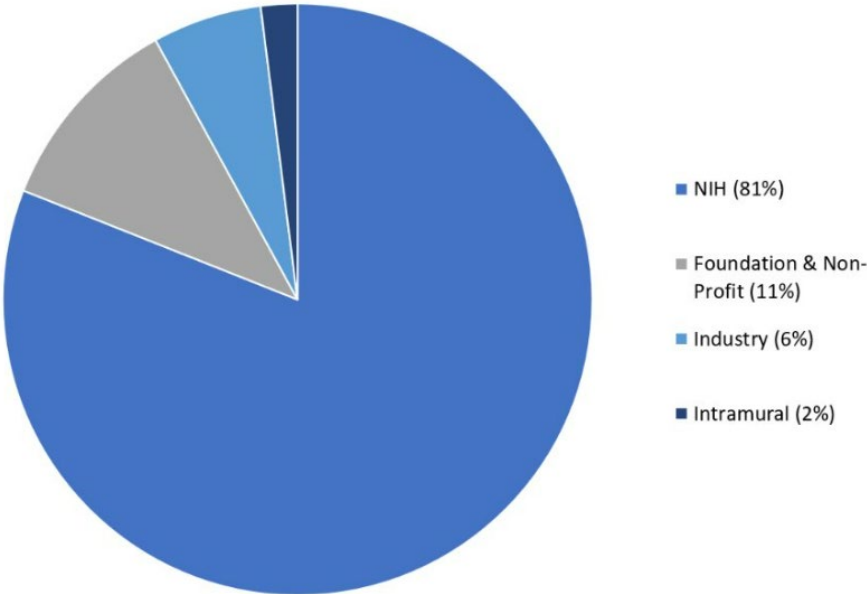
In 2023, AMPATH-Kenya affiliated investigators received a total of US \$19.6 million in awards for research and training activities, including US \$3.8 million in funding for new research projects and US \$15.8 million in funding for continuing research projects. This is the second highest single year total for research awards in AMPATH’s history (Figure 1) and increases AMPATH’s cumulative total of research and training awards to US \$247 million.

Figure 1. Ten-Year Trend in Total Awards, 2014 – 2023

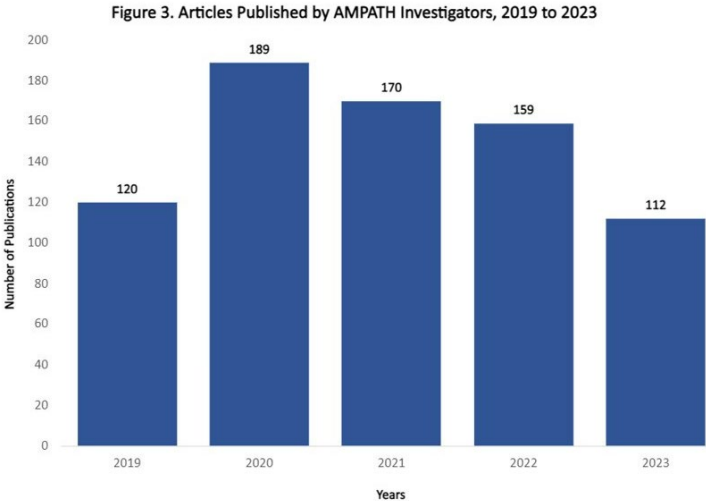


Consistent with previous years, NIH funding remained strong in 2023, representing 81 percent of the total funding received, while funding from industry sponsors, foundations/non-profits and intramural awards made up the remaining 19 percent (Figure 2).

Figure 2. Research Funding Received by Sponsor Type, 2023



Publications



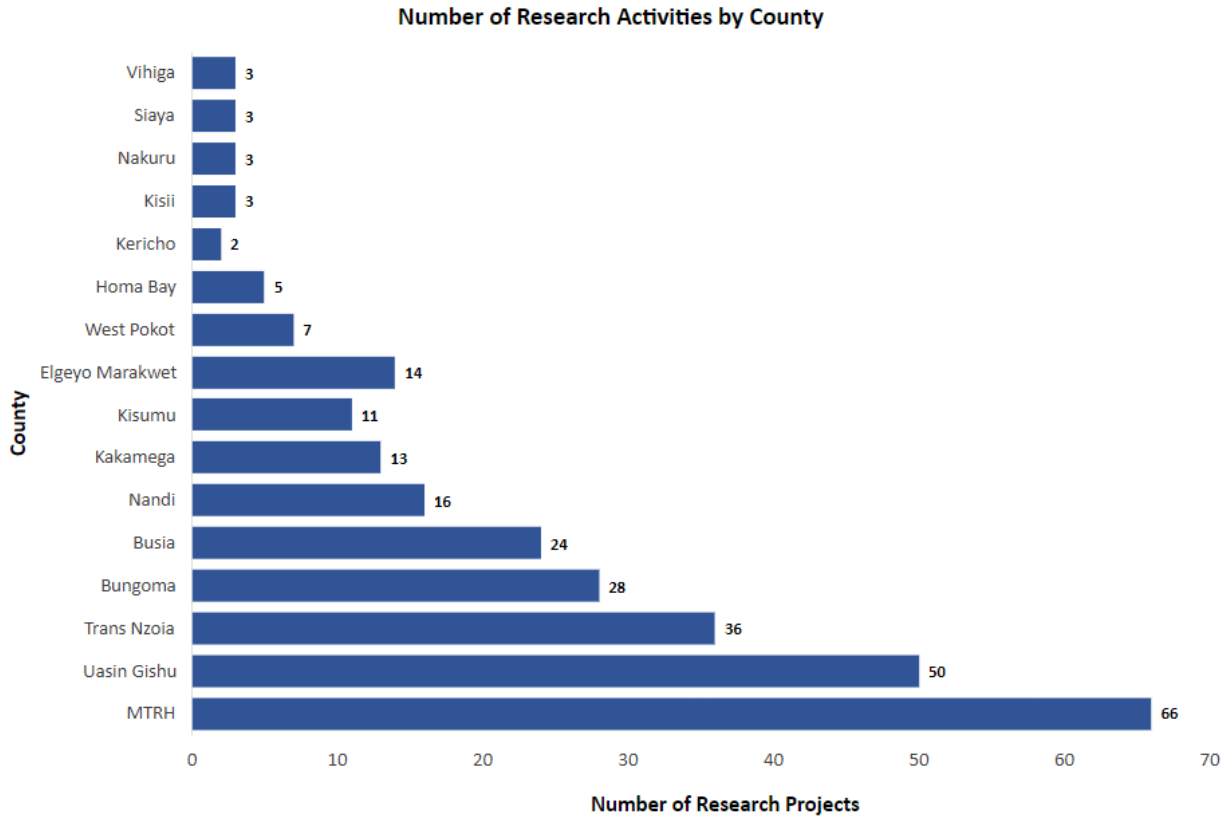
Investigators from Moi University, Moi Teaching and Referral Hospital (MTRH), and AMPATH Consortium institutions published 115 articles in 2023 (Figure 3). HIV-related research publications remained strong in 2023 (over 25 publications) with a diverse array of research including: adolescent health, disclosure and stigma, mental health outcomes, HIV drug resistance, HIV-related co-morbidities, and treatment services within care settings. AMPATH investigators also published widely in oncology research and care (10),

COVID-19 related topics (7), and mental health (5). Researchers contributed to several publications from regional and/or global studies through several research networks and collaborations. See **Appendix 1** for a full list of publications by AMPATH affiliated investigators during the reporting period.

Geographic Reach of AMPATH Research Activities

A total of 63 ongoing and 22 new research projects completed requests for information during the reporting period. Project details can be found in **Appendix 2**. As shown in Figure 4, while Uasin Gishu County (home to the city of Eldoret and Moi Teaching and Referral Hospital (MTRH)) is the most common location for research activities, AMPATH researchers are engaged in research activities across western Kenya in 18 different counties. AMPATH investigators are also part of regional and global research and training activities through a number of projects and consortia funded by the NIH and other major funders.

Figure 4. Research Activities by County* in Kenya



**Several projects take place in more than one county. Projects reported all counties where research activities were taking place. Research projects taking place at MTRH, which is in Uasin Gishu County, are listed separately. Additionally, other counties with at least one research project include: Bomet, Migori, and Turkana.*

Other Activities & Achievements

The AMPATH Kenya Research Program made progress in several key areas in line with its strategic plan, including:

Hiring New Program Office Staff – Michael Mwaniki, MS, joined RPO as the new deputy research program manager based in Eldoret. Mr. Mwaniki has a background in psychology with experience in research project management spanning over a decade within the AMPATH Kenya Program. He has supported coordination for two clinical trials and a capacity building project in health informatics, prior to joining the Research Program Office (RPO). In his new role, he will support all aspects of the research program office's operation.

Kristie Wallace, MS, joined RPO as an administrative assistant based in Indianapolis. Ms. Wallace's background is in education as a teacher and principal. Prior to working in education, she worked in the healthcare field in human resources, budgets, operations, and medical practice management. In her current role, she will support the administrative functions of the AMPATH Kenya Research and East Africa leDEA programs.

Chris Rice, MPA/MA, is serving as the IU Center for Global Health Equity's (IUCGHE) inaugural Research Translation and Policy Lead. Rice has background in public policy, international development and communications and has previously worked in research translation with the IUCGHE. At AMPATH he will focus on developing expertise in research translation and creating processes, tools, and strategies to maximize the research program's impact on local, national, and global health policy and practice. He is championing the development of the Research translation core.

Launching Initiative on Health Policy and Research Translation – To maximize the impact of AMPATH's research on healthcare practice and policy, the research program launched a new initiative on health policy and research translation. In 2023, the program held initial discussions with AMPATH investigators, drafted a concept note on preliminary strategies and priorities, and wrote newsletter articles on [research translation](#), [partnership](#), [stakeholder engagement](#), and [research products](#) to increase awareness. In 2024, the research program will launch a formal research translation needs assessment that will inform the basis for an AMPATH Research Translation Core. More information on this initiative can be found [here](#).

Launching the AMPATH Kenya Research Project Database – In the second quarter of 2023, RPO launched the online, central data repository on active and completed AMPATH research projects. This database now serves as an open resource providing details on research teams, key research areas, funding sources, and publications. The database will be updated annually and is accessible using the following link: <https://www.ampathkenya.org/project-database#/>.

PRINCIPAL INVESTIGATOR
[Constantine Akwanalo, Moi Teaching and Referral Hospital](#)
[Jemima Kamano, Moi University](#)

COLLABORATORS
 Jemima Kamano, Moi University
 Ann Mwangi, Moi University
 Benson Njuguna, Moi Teaching and Referral Hospital
 Rajesh Vedanthan, New York University
 Sonak Pastakia, Purdue University
 Timothy Mercer, University of Texas Austin

SPONSORS
 NIH-National Heart, Lung and Blood Institute

RESEARCH AREAS
[Non-Communicable Diseases](#),
[Implementation Science](#)

PROJECT DATES
 09/01/17 - 05/31/22

PROJECT STATUS
 Active

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

The aims of this study are to: (1) Evaluate the effectiveness of health information technology and peer support on one-year change in SBP and CVD risk reduction; (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; (3) Conduct a process evaluation using the Saunders framework, evaluating key implementation measures related to fidelity, dose delivered, dose received, recruitment, reach, and context; and (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.

SELECTED PUBLICATIONS:

Thakkar A, Valente T, Andesia J, Njuguna B, Miheso J, Mercer T, Mugo R, Mwangi A, Mwangi E, Pastakia SD, Pathak S, Pillsbury MKM, Kamano J, Naanyu V, Williams M, Vedanthan R, Akwanalo C, Bloomfield GS. Network characteristics of a referral system for patients with hypertension in Western Kenya: results from the Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS) study. *BMC Health Serv Res.* 2022 Mar 7;22(1):315. doi: 10.1186/s12913-022-07699-8. PMID: 35255913; PMCID: PMC8903732.

A snapshot of a project page in the online AMPATH Research Project Database.

Initiating Course Development & Recruitment Activities for D43 Training Grant – In the second quarter of 2023, Indiana University School of Medicine (PI: Dr. Kara Wools-Kaloustian) and Moi University College of Health Sciences (PIs: Prof. Mabel Nangami and Prof. Winstone Nyandiko) were awarded a [five-year, NIH funded grant](#) aimed at building a sustainable educational infrastructure to support training in HIV implementation science and dissemination in western Kenya. The grant is supporting the development of four courses, which will strengthen the educational infrastructure at Moi, expand local human resource capacity, promote sustained research engagement, enhance mentorship capacity, and support research collaboration with the county health teams.

The first curriculum development meeting convened in July 2023 at the Ciala Resort in Kisumu, Kenya and brought together teams of expert faculty from both Indiana University and Moi University to develop and outline the titles, objectives, learning outcomes, content outlines, and teaching resources for each of the four courses: HIV Across the Life Course, Implementation Science, Health Research Translation, and Grant Writing and Management.



Members of the D43 curriculum development and administrative teams following a curriculum development meeting at the Ciala Resort in Kisumu, July 2023. (First row - seated from right): Prof. Mabel Nangami, Prof. Winstone Nyandiko, Prof. Kara Wools-Kaloustian, Prof. Simeon Mining, and Prof. Paul Ayuo. (Second row - standing from right): Dr. Peter Koskei, Mr. Robert Rono, Dr. Judy Wachira, Dr. Samson Ndege, Dr. Nyawira Gitahi, Prof. Ann Mwangi, Ms. Eunice Walumbe, Dr. Suzanne Goodrich, Dr. Jepchirchir Kiplagat, and Prof. Abraham Siika. (Third row - standing from right): Dr. Judy Mang'eni, Prof. Edwin Were, and Dr. Faith Yego.

During the last quarter of 2023, the MPIs, along with leadership at Moi University's School of Public Health, initiated recruitment activities to attract qualified trainees to the program. A virtual student orientation was held in October, which led to multiple applications. Two trainees from the MSc in Infectious Disease and Global Health program were selected at the end of 2023. Final recruitment activities for two additional trainees from the MSc in Field Epidemiology and Laboratory Training Program were planned for 2024 to complete the first cohort.

Crafting an AMPATH Data Science Strategy -- AMPATH Kenya leadership and key stakeholders met in fourth quarter of 2023 to discuss ongoing and planned data science-related activities across the program. The purpose of the meeting was to identify a path forward in developing a coordinated data science strategy across research, training, and clinical care at AMPATH Kenya. One key strategy that emerged from the meeting was the development of a Data Science Center of Excellence. Discussions around the role of the center included providing data science support to funded projects, strategic guidance on implementing artificial intelligence, health data expertise for the Ministry of Health, amongst other roles.

Preparing for Biobanking Initiative Launch -- The AMPATH Research Program Office supported the AMPATH Reference Laboratory to expand its infrastructure to include a fully-fledged biobank. The biobank will strengthen the existing specimen storage facility at MTRH and Moi University and strengthen collaborative research endeavors in the future, while advancing preventive and treatment aspects of

genomics in cancer, hereditary and inborn diseases, chronic, non-communicable diseases, and emerging infectious diseases. Researchers will be able to access a large pool of high-quality human samples and associated data for research. The Biobank team received mentorship from expert faculty and staff from Indiana University in September 2023 in Eldoret to help review policies and standard operating procedures (SOPs). This visit proved instrumental in finalizing the development of the Biobank's framework, SOPs, and governing operations.



Inside the Moi University/MTRH Biobank. Top left photo taken during the ribbon cutting ceremony to commemorate the launch of the Biobank in January 2024. Pictured from right to left at the ceremony: Dr. Hilary Kahn, Prof. Simeon Mining, Prof. Robert Tenge, Prof. Kara Wools-Kaloustian, Dr. Ronald Tonui, Prof. Kirtika Patel, and Dr. Elias Melly.

Expanding Professional Development Opportunities

Hosting the Fundamentals of Global Health Research Course – During the second quarter of 2023, RPO served as an official online host site for the University of Washington's Fundamentals of Global Health Research: Planning, Implementation, and Dissemination course. This virtual course was designed to train participants in research conduct fundamentals, with an emphasis on resource-limited settings. RPO provided free enrollment to Kenyan junior faculty and research staff. All 40 participants successfully matriculated through the course and received certificates of completion.

Facilitating the 2023-2024 Manuscript Writing Workshop Series – Dr. Kara Wools-Kaloustian, with participation from Indiana University, New York University (NYU), and Moi University faculty and staff, facilitated the annual Manuscript Writing Series starting in August 2023. During this six-month long series, over 30 participants across the AMPATH Consortium participated in the following sessions:

- “Conducting a literature review” led by Dr. Pooja Gala (NYU)
- “An introduction to scientific manuscript writing” led by Dr. Jimmy Carlucci (IU)

- “Writing an introduction and an abstract for a conference” led by Dr. Megan McHenry (IU).
- “Writing the methods section” led by Drs. Jepchirchir Kiplagat (Moi) and John Humphrey (IU).
- “Discussing the results” led by Dr. Benson Njuguna (Moi) and Beverly Musick (IU).
- “Crafting a discussion” led by Dr. Kara Wools-Kaloustian (IU).

Lecture 3: Introduction section and abstract writing for conferences



Module 3. Overview

Lecture 3: Writing an introduction and an abstract

Session Learning Objectives

The overall goals of this workshop are to:

- Recognize the purpose of an introduction section
- Understand the structural components of the introduction section of a manuscript
- Understand the structure, considerations, and priorities for abstract writing
- Discuss examples from your projects to inform development of an introduction

If you have any questions for the session presenter, Dr. Megan McHenry, kindly reach out to her directly at: msuhl@iuou.edu

Readings and Resources

Please familiarize yourself with the following readings and resources:

- [Trends over time for adolescents enrolling in HIV care in Kenya, Tanzania, and Uganda from 2001 to 2014. Apondi et. al.pdf](#) ↓
- [Early metformin in gestational diabetes: a randomized clinical trial. Dunne et. al.pdf](#) ↓
- [Family level domains influencing HIV care engagement among disengaged adolescents in Kenya. Myers et. al.pdf](#) ↓
- [Duration of birth depression and neurodevelopmental outcomes after whole body hypothermia.pdf](#) ↓

Watch Video

Please find below the link to the recorded lecture, “Writing a scientific paper: introduction and abstract”

Link to lecture: https://iu.mediaspace.kaltura.com/media/t/1_trn18c1

Notes and Resources

PDF of slides used during the lecture: [Writing an introduction and abstract.pdf](#) ↓

An example of the Manuscript Writing Workshop session materials available on Canvas to participants.

Twelve of the participants were selected to receive one-on-one writing mentorship from course instructors, with the goal of submitting a scientific manuscript to a peer-reviewed journal upon completion of the workshop. All workshop materials, including session recordings, articles and other resources are available on Canvas, an online learning platform. Please contact RPO (research.manager@ampath.or.ke) for access to the course.

Appendix 1. Bibliography

The following bibliography includes all AMPATH research publications published in 2023 (115 in total). Please contact the Research Program Office at research.manager@ampath.or.ke for a complete [bibliography of AMPATH research publications](#) published since 1989 along with full text articles.

1. Amick E, Naanyu V, Bucher S, Henry BW. Perceptions of Global Health Engagements in Relation to the COVID-19 Pandemic Among Kenyan Health Care Workers and Administrators in Western Kenya: Protocol for Multi-stage Qualitative Study. *JMIR Res Protoc*. 2023 Jun 7. doi: 10.2196/41836. Epub ahead of print. PMID: 37315197.
2. Amisi JA, Cuba-Fuentes MS, Johnston EM, Makwero M, Prasad S, Ras T, Szkwarko D, von Pressentin K. A pragmatic approach to equitable global health partnerships in academic health sciences. *BMJ Glob Health*. 2023 May;8(5):e011522. doi: 10.1136/bmjgh-2022-011522. PMID: 37230545.
3. Apedaile D, DeLong A, Sang E, Ayuku D, Atwoli L, Galárraga O, Hogan J, Braitstein P. HIV incidence and death among orphaned and non-orphaned children and adolescents living in family-based settings in western Kenya: a prospective cohort analysis. *J Pediatr*. 2023 Apr 6:113410. doi: 10.1016/j.jpeds.2023.113410. Epub ahead of print. PMID: 37030609.
4. Araújo-Pereira M, Krishnan S, Salgame P, Manabe YC, Hosseinipour MC, Bisson G, Severe DP, Rouzier V, Leong S, Mave V, Sawe FK, Siika AM, Kanyama C, Dadabhai SS, Lama JR, Valencia-Huamani J, Badal-Faesén S, Laloo UG, Naidoo K, Mohapi L, Kityo C, Andrade BB, Gupta A. Effect of the relationship between anaemia and systemic inflammation on the risk of incident tuberculosis and death in people with advanced HIV: a sub-analysis of the REMEMBER trial. *EClinicalMedicine*. 2023 Jun 2; 60:102030. doi: 10.1016/j.eclinm.2023.102030. PMID: 37287871; PMCID: PMC10242630.
5. Baker FS, Wang J, Vargas OF, Brand NR, Ogwang MD, Kerchan P, Reynolds SJ, Tenge CN, Were PA, Kuremu RT, Wekesa WN, Masalu N, Kawira E, Kinyera T, Otim I, Legason ID, Nabalende H, Chagaluka G, Mutalima N, Borgstein E, Liomba GN, Kamiza S, Mkandawire N, Mitambo C, Molyneux EM, Newton R, Prokunina-Olsson L, Mbulaiteye SM. *IFNL4* Genotypes and Risk of Childhood Burkitt Lymphoma in East Africa. *J Interferon Cytokine Res*. 2023 Jun 27. doi: 10.1089/jir.2023.0014. Epub ahead of print. PMID: 37366802.
6. Bansal D, Davidson A, Supriyadi E, Njuguna F, Ribeiro RC, Kaspers GJL. SIOP PODC adapted risk stratification and treatment guidelines: Recommendations for acute myeloid leukemia in resource-limited settings. *Pediatr Blood Cancer*. 2023 Nov;70(11):e28087. doi: 10.1002/pbc.28087. Epub 2019 Nov 27. PMID: 31774234.
7. Beima-Sofie K, Njuguna I, Concepcion T, DeLong SM, Donenberg G, Zanoni BC, Dow D, Braitstein P, Wagner A. Addressing the Know-Do Gap in Adolescent HIV: Framing and Measuring Implementation Determinants, Outcomes, and Strategies in the AHISA Network. *AIDS Behav*. 2023 May;27(Suppl 1):24-49. doi: 10.1007/s10461-023-04021-3. Epub 2023 Mar 11. PMID: 36905496; PMCID: PMC10007651.
8. Bhatia MB, Anderson CM, Hussein AN, Opondo B, Aruwa N, Okumu O, Fisher SG, Joplin TS, Hunter-Squires JL, Gray BW, Saula PW. Bilateral Exchange: Enteral Nutrition Clinical Decision Making in Pediatric Surgery Patients. *J Surg Res*. 2023 Nov 25; 295:139-147. doi: 10.1016/j.jss.2023.10.017. Epub ahead of print. PMID: 38007861.

9. Bhatia MB, Hunter-Squires JL, Busakhala N. ASO Author Reflections: Breast Cancer Early Detection: If You Build It, She Will Come. *Ann Surg Oncol*. 2023 Dec 14. doi: 10.1245/s10434-023-14719-2. Epub ahead of print. PMID: 38097877.
10. Bhatia MB, Kisilu N, Kiptoo S, Limenik I, Adaniya E, Kibiwot S, Wabende LN, Jepkirui S, Awuor DA, Morgan J, Loehrer PJ, Hunter-Squires JL, Busakhala N. Breast Health Awareness: Understanding Health-Seeking Behavior in Western Kenya. *Ann Surg Oncol*. 2023 Dec 4. doi: 10.1245/s10434-023-14575-0. Epub ahead of print. PMID: 38044347.
11. Bhatia MB, Muema NK, Kiptoo S, Limenik I, Adaniya E, Kibiwot S, Wabende LN, Jepkirui S, Awuor DA, Morgan J, Loehrer PJ, Hunter-Squires JL, Busakhala N. Uptake and Outcomes of a Clinical Breast Exam Program in Western Kenya. *Ann Surg Oncol*. 2023 Dec 5. doi: 10.1245/s10434-023-14657-z. Epub ahead of print. PMID: 38051440.
12. Bhatia MB, Munda B, Okoth P, Carpenter KL, Jenkins P, Keung CH, Hunter-Squires JL, Saruni SI, Simons CJ. Bilateral trauma case conferences: an approach to global surgery equity through a virtual education exchange. *Global Surgical Education-Journal of the Association for Surgical Education*. 2023 Apr 3;2(1):47.
13. Boshe J, Brtek V, Beima-Sofie K, Braitstein P, Brooks M, Denison J, Donenberg G, Kemigisha E, Memiah P, Njuguna I, Poku O, Roberts ST, Shayo AM, Dow DE. Integrating Adolescent Mental Health into HIV Prevention and Treatment Programs: Can Implementation Science Pave the Path Forward? *AIDS Behav*. 2023 May;27(Suppl 1):145-161. doi: 10.1007/s10461-022-03876-2. Epub 2022 Nov 2. PMID: 36322219; PMCID: PMC9629193.
14. Bourgi K, Ofner S, Musick B, Wools-Kaloustian K, Humphrey JM, Diero L, Yiannoutsos CT, Gupta SK. Preswitch Regimens Influence the Rate of Weight Gain After Switch to Tenofovir Disoproxil Fumarate, Lamivudine, and Dolutegravir (TLD): Study from an East African Cohort. *Open Forum Infect Dis*. 2023 Dec 12;10(12):ofad581. doi: 10.1093/ofid/ofad581. PMID: 38088979; PMCID: PMC10715773.
15. Brazier E, Maruri F, Wester CW, Musick B, Freeman A, Parcesepe A, Hossmann S, Christ B, Kimmel A, Humphrey J, Freeman E, Enane LA, Lancaster KE, Ballif M, Golub JE, Nash D, Duda SN; International epidemiology Databases to Evaluate AIDS (IeDEA) consortium. Design and implementation of a global site assessment survey among HIV clinics participating in the International epidemiology Databases to Evaluate AIDS (IeDEA) research consortium. *PLoS One*. 2023 Mar 14;18(3):e0268167. doi: 10.1371/journal.pone.0268167. PMID: 36917598; PMCID: PMC10013879.
16. Broen, K., Dickens, J., Trangucci, R., Ogwang, M.D., Tenge, C.N., Masalu, N., Reynolds, S.J., Kawira, E., Kerchan, P., Were, P.A. and Kuremu, R.T., 2023. Burkitt lymphoma risk shows geographic and temporal associations with Plasmodium falciparum infections in Uganda, Tanzania, and Kenya. *Proceedings of the National Academy of Sciences*, 120(2), p.e2211055120.
17. Bucher S, Nowak K, Otieno K, Tenge C, Marete I, Rutto F, Kemboi M, Achieng E, Ekhaguere OA, Nyongesa P, Esamai FO, Liechty EA. Birth weight and gestational age distributions in a rural Kenyan population. *BMC Pediatr*. 2023 Mar 8;23(1):112. doi: 10.1186/s12887-023-03925-2. PMID: 36890485; PMCID: PMC9993805.
18. Buitendyk M, Kosgei W, Thorne J, Millar H, Alera JM, Kibet V, Bernard CO, Payne BA, Bernard C, Christoffersen-Deb A. Impact of free maternity services on outcomes related to hypertensive disorders of pregnancy at Moi Teaching and Referral Hospital in Kenya: a retrospective analysis. *BMC Pregnancy Childbirth*. 2023 Feb 6;23(1):98. doi: 10.1186/s12884-023-05381-3. PMID: 36747137; PMCID: PMC9901094.

19. Byrne JA, Banaszak AT, Carpenter JE, Carroll SL, Castelhana MG, Espinal PS, Henderson MK, Hettiaratchi A, Maseme M, Ng W, Patel K, Popescu I, Prada SI, Schleif WS, Smith M, Wee S, Weil CJ, Woods K. Priorities in Biobanking Research: A Report on the 2021 ISBER Round Table. *Biopreserv Biobank*. 2023 Feb;21(1):111-113. doi: 10.1089/bio.2021.0178. Epub 2022 May 4. PMID: 35507966; PMCID: PMC9963461.
20. Chory A, Gillette E, Callen G, Wachira J, Sam-Agudu NA, Bond K, Vreeman R. Gender differences in HIV knowledge among adolescents and young people in low-and middle-income countries: a systematic review. *Front Reprod Health*. 2023 Jun 26;5:1154395. doi: 10.3389/frph.2023.1154395. PMID: 37434701; PMCID: PMC10332462.
21. Chory A, Nyandiko W, Gillette E, Scanlon M, Aluoch J, Koros H, Munyoro D, Ashimosi C, Beigon W, Lidweye J, Nyagaya J, DeLong A, Kantor R, Vreeman R, Naanyu V. Ethical Considerations for Engaging Youth Living with HIV in Research: Perspectives from Youth, Their Caregivers and Subject Matter Experts in Kenya. *J Empir Res Hum Res Ethics*. 2023 Aug 13:15562646231193949. doi: 10.1177/15562646231193949. Epub ahead of print. PMID: 37574803.
22. Chupradit S, Wamalwa DC, Maleche-Obimbo E, Kekitiinwa AR, Mwanga-Amumpaire J, Bukusi EA, Nyandiko WM, Mbutia JK, Swanson A; DNDi Clinical Team; Cressey TR, Punyawudho B, Musiime V. Abacavir Drug Exposures in African Children Under 14 kg Using Pediatric Solid Fixed Dose Combinations According to World Health Organization Weight Bands. *J Pediatric Infect Dis Soc*. 2023 Nov 30;12(11):574-580. doi: 10.1093/jpids/piad082. PMID: 37798141; PMCID: PMC10756690.
23. Cornetta K, Nyariki S, Manji I, Kiplimo I, Korir M, Muinga E, Busakhala N, Elias H. Telehospice for Cancer Patients Discharged from a Tertiary Care Hospital in Western Kenya. *Journal of Pain and Symptom Management*. 2023 May 1;65(5):378-87.
24. DeLong SM, Kafu C, Wachira J, Knight JM, Braitstein P, Operario D, Genberg BL. Understanding motivations and resilience-associated factors to promote timely linkage to HIV care: a qualitative study among people living with HIV in western Kenya. *AIDS Care*. 2023 Jul 27:1-7. doi: 10.1080/09540121.2023.2240066. Epub ahead of print. PMID: 37499119.
25. DeLong SM, Xu Y, Genberg BL, Nyambura M, Goodrich S, Tarus C, Ndege S, Hogan JW, Braitstein P. Population-Based Estimates and Predictors of Child and Adolescent Linkage to HIV Care or Death in Western Kenya. *J Acquir Immune Defic Syndr*. 2023 Dec 1;94(4):281-289. doi: 10.1097/QAI.0000000000003288. Epub 2023 Oct 26. PMID: 37643416.
26. Dickinson FM, Allott H, Nyongesa P, Eyinda M, Muchemi OM, Karangau SW, Ogoti E, Shaban NA, Godia P, Nyaga L, Ameh CA. "It's complicated...": Exploring second stage caesarean sections and reasons for non-performance of assisted vaginal births in Kenya: A mixed methods study. *PLOS Glob Public Health*. 2023 Nov 17;3(11):e0001495. doi: 10.1371/journal.pgph.0001495. PMID: 37976293; PMCID: PMC10656000.
27. El Ayadi AM, Alway J, Matityahu D, Kichwen C, Wilson S, Mabeya H. Impact of Beyond Fistula programming on economic, psychosocial and empowerment outcomes following female genital fistula repair: A retrospective study. *Int J Gynaecol Obstet*. 2023 Sep 25. doi: 10.1002/ijgo.15133. Epub ahead of print. PMID: 37746937.
28. El Salih I, Njuguna FM, Widjajanto PH, Kaspers G, Bailey A, Mostert S. Impact of COVID-19 measures on the health and healthcare of children in East-Africa: Scoping review. *Int J Health Plann Manage*. 2023 Jan 23. doi: 10.1002/hpm.3612. Epub ahead of print. PMID: 36691260.

29. Embleton L, Logie CH, Ngure K, Nelson L, Kimbo L, Ayuku D, Turan JM, Braitstein P. Intersectional Stigma and Implementation of HIV Prevention and Treatment Services for Adolescents Living with and at Risk for HIV: Opportunities for Improvement in the HIV Continuum in Sub-Saharan Africa. *AIDS Behav.* 2023 May;27(Suppl 1):162-184. doi: 10.1007/s10461-022-03793-4. Epub 2022 Jul 30. PMID: 35907143; PMCID: PMC10192191.
30. Embleton L, Murphy K, Kirwa S, Okal EO, Makori D, Logie CH, Di Ruggiero E, Lachman J, Ayuku D, Braitstein P. Factors Influencing the Implementation of Evidence-Based Interventions with Street-Connected Children and Youth: Two Case Studies from Eldoret, Kenya. *Global Implementation Research and Applications.* 2023 May 10:1-7.
31. Embleton L, Shah P, Apondi E, Ayuku D, Braitstein P. "If they had a place to live, they would be taking medication": a qualitative study identifying strategies for engaging street-connected young people in the HIV prevention-care continuum in Kenya. *J Int AIDS Soc.* 2023 Jun;26(6):e26023. doi: 10.1002/jia2.26023. PMID: 37267115; PMCID: PMC10237327.
32. Epeldegui M, Chang D, Lee J, Magpantay LI, Borok M, Bukuru A, Busakhala N, Godfrey C, Hosseinipour MC, Kang M, Kanyama C, Langat D, Mngqibisa R, Mwelase N, Nyirenda M, Samaneka W, Hoagland B, Campbell TB, Martínez-Maza O, Krown SE; A5264/AMC-067 team. Predictive Value of Serum Biomarkers for Response of Limited-Stage AIDS-Associated Kaposi Sarcoma to Antiretroviral Therapy with or Without Concomitant Chemotherapy in Resource-Limited Settings. *J Acquir Immune Defic Syndr.* 2023 Oct 1;94(2):165-173. doi: 10.1097/QAI.0000000000003236. PMID: 37368929; PMCID: PMC10527582.
33. Gillette E, Naanyu V, Nyandiko W, Chory A, Scanlon M, Aluoch J, Koros H, Ashimosi C, Beigon W, Munyoro D, Lidweye J. HIV-Related Stigma Shapes Research Participation for Youth Living with HIV in Kenya. *Journal of the International Association of Providers of AIDS Care (JIAPAC).* 2023 Apr;22:23259582231170732.
34. Giusto A, Vander Missen MR, Kosgei G, Njiriri F, Puffer E, Kamaru Kwobah E, Barasa J, Turissini M, Rasmussen J, Ott M, Binayo J, Rono W, Jaguga F. Peer-delivered Problem-solving Therapy for Adolescent Mental Health in Kenya: Adaptation for Context and Training of Peer-counselors. *Res Child Adolesc Psychopathol.* 2023 May 23. doi: 10.1007/s10802-023-01075-8. Epub ahead of print. PMID: 37219680.
35. Gyamfi J, Iwelunmor J, Patel S, Irazola V, Aifah A, Rakhra A, Butler M, Vedanthan R, Hoang GN, Nyambura M, Nguyen H, Nguyen C, Asante KP, Nyame S, Adjei K, Amoah J, Apusiga K, Adjei KGA, Ramierz-Zea M, Hernandez D, Fort M, Sharma H, Jarhyan P, Peprah E, Ogedegbe G. Implementation outcomes and strategies for delivering evidence-based hypertension interventions in lower-middle-income countries: Evidence from a multi-country consortium for hypertension control. *PLoS One.* 2023 May 25;18(5):e0286204. doi: 10.1371/journal.pone.0286204. PMID: 37228144; PMCID: PMC10212179.
36. Heng YY, Nafiseh A, Oyungu E, Ombitsa AR, Cherop C, McHenry MS. 'I bring her up with love:' Perspectives of caregivers of children with neurodevelopmental delays in western Kenya. *Child: Care, Health and Development.* 2023 Jan;49(1):201-9.
37. Hillow MA, Atwoli L, Kwobah EK. "Association between Traumatic Life Events and Psychosis: A case-control study in western Kenya". *Heliyon.* 2023 Jul 10;9(7):e18144. doi: 10.1016/j.heliyon.2023.e18144. PMID: 37483688; PMCID: PMC10362348.
38. Hong HG, Gouveia MH, Ogwang MD, Kerchan P, Reynolds SJ, Tenge CN, Were PA, Kuremu RT, Wekesa WN, Masalu N, Kawira E, Kinyera T, Wang X, Zhou J, Leal TP, Otim I, Legason ID,

- Nabalende H, Dhudha H, Mumia M, Baker FS, Okusolubo T, Ayers LW, Bhatia K, Goedert JJ, Woo J, Manning M, Cole N, Luo W, Hicks B, Chagaluka G, Johnston WT, Mutalima N, Borgstein E, Liomba GN, Kamiza S, Mkandawire N, Mitambo C, Molyneux EM, Newton R, Hutchinson A, Yeager M, Adeyemo AA, Thein SL, Rotimi CN, Chanock SJ, Prokunina-Olsson L, Mbulaiteye SM. Sickle cell allele HBB-rs334(T) is associated with decreased risk of childhood Burkitt lymphoma in East Africa. *Am J Hematol*. 2023 Nov 27. doi: 10.1002/ajh.27149. Epub ahead of print. PMID: 38009642.
39. Humphrey J, Wanjama E, Carlucci JG, Naanyu V, Were E, Muli L, Alera M, McGuire A, Nyandiko W, Songok J, Wools-Kaloustian K, Zimet G. Preferences of Pregnant and Postpartum Women for Differentiated Service Delivery in Kenya. *J Acquir Immune Defic Syndr*. 2023 Dec 15;94(5):429-436. doi: 10.1097/QAI.0000000000003303. Epub 2023 Nov 10. PMID: 37949446; PMCID: PMC10642693.
 40. Humphrey JM, Alera M, Enane LA, Kipchumba B, Goodrich S, Scanlon M, Songok J, Musick B, Diero L, Yiannoutsos C, Wools-Kaloustian K. Effects of the COVID-19 pandemic on late postpartum women living with HIV in Kenya. *PLOS Glob Public Health*. 2023 Mar 29;3(3):e0001513. doi: 10.1371/journal.pgph.0001513. PMID: 36989321; PMCID: PMC10058168.
 41. Ishimwe MCS, Kiplagat J, Kadam Knowlton A, Livinski AA, Kupfer LE. Reversing the trend: a scoping review of health innovation transfer or exchange from low- and middle-income countries to high-income countries. *BMJ Glob Health*. 2023 Nov;8(Suppl 7):e013583. doi: 10.1136/bmjgh-2023-013583. PMID: 37967892; PMCID: PMC10660955.
 42. Jaguga F, Kirwa P, Gakinya B, Manji I, Andale T, Kinyanjui D, Kwobah EK, Mwangi F, Werunga K, Kerema J, Kwobah C, Temet E, Songok J, Aruasa WK. Intravenous ketamine for severe alcohol use disorder at Moi Teaching & Referral Hospital, Kenya: a case report. *Subst Abuse Treat Prev Policy*. 2023 Feb 17;18(1):11. doi: 10.1186/s13011-023-00519-0. PMID: 36803380; PMCID: PMC9936629.
 43. Jaguga F, Kwobah EK, Giusto A, Apondi E, Barasa J, Korir M, Rono W, Kosgei G, Puffer E, Ott M. Feasibility and acceptability of a peer provider delivered substance use screening and brief intervention program for youth in Kenya. *BMC Public Health*. 2023 Nov 16;23(1):2254. doi: 10.1186/s12889-023-17146-w. PMID: 37974158; PMCID: PMC10652467.
 44. Jaguga F, Mathai M, Ayuya C, Francisca O, Musyoka CM, Shah J, Atwoli L. 12-month substance use disorders among first-year university students in Kenya. *PLoS One*. 2023 Nov 27;18(11):e0294143. doi: 10.1371/journal.pone.0294143. PMID: 38011101.
 45. Jansen S, Apondi E, Ayaya SO, Kim J, McHenry MS. Growth Anthropometrics as a Metric of Malnutrition Disparities Among Young Children Affected by HIV who are Orphaned Maternally, Paternally, or Totally in Western Kenya: A Retrospective Chart Review. *Glob Pediatr Health*. 2023 Feb 17;10:2333794X231156045. doi: 10.1177/2333794X231156045. PMID: 36814531; PMCID: PMC9940225.
 46. Jessani S, Saleem S, Fogleman E, Billah SM, Haque R, Figueroa L, Lokangaka A, Tshetu A, Goudar SS, Kavi A, Esamai F, Mwenchanya M, Chomba E, Patel A, Das P, Mazariegos M, Bauserman M, Petri WA Jr, Krebs NF, Derman RJ, Carlo WA, Bucher S, Hibberd PL, Koso-Thomas M, Bann CM, McClure EM, Goldenberg RL. Trends over time in the knowledge, attitude and practices of pregnant women related to COVID-19: A cross-sectional survey from seven low- and middle-income countries. *BJOG*. 2023 Aug 15. doi: 10.1111/1471-0528.17630. Epub ahead of print. PMID: 37581947.
 47. Jesson J A-AM, Belfrage E, Davies MA, Pinto J, Teasdale C, Nguyen Van Lam, Vreeman R, EA authors, Lymuya R, Apondi E, Odhiambo F, Wools-Kaloustian K, Wanless S, Williams P, Yotebieng M, Leroy

- V, Goodall R. . Global variations in pubertal growth spurts in adolescents living with perinatal HIV. *Aids*. 2023 37(10),1603- 15, doi:10.1097/QAD.0000000000003602. PMC10355801
48. Johnson SL, Rasmussen JM, Mansoor M, Ibrahim H, Rono W, Goel P, Vissoci JRN, Von Isenburg M, Puffer ES. Correlates of Intimate Partner Violence Victimization and Perpetration in Adolescents and Young Adults in Sub-Saharan Africa: A Systematic Review. *Trauma Violence Abuse*. 2023 May 25;15248380231173428. doi: 10.1177/15248380231173428. Epub ahead of print. PMID: 37226506.
 49. Kavi A, Goudar SS, Somannavar MS, Moore JL, Derman RJ, Saleem S, Naqvi S, Billah SM, Haque R, Figueroa L, Mazariegos M, Lokangaka A, Tshetu A, Esamai F, Mwenechanya M, Chomba E, Patel A, Das P, Bauserman M, Petri WA Jr, Krebs NF, Carlo WA, Bucher S, Hibberd PL, Koso-Thomas M, McClure EM, Goldenberg RL. COVID-19 symptoms and antibody positivity among unvaccinated pregnant women: An observational study in seven countries from the Global Network. *BJOG*. 2023 Jul 20. doi: 10.1111/1471-0528.17604. Epub ahead of print. PMID: 37470094.
 50. Kavi A, Hoffman MK, Somannavar MS, Metgud MC, Goudar SS, Moore J, Nielsen E, Goco N, McClure EM, Lokangaka A, Tshetu A, Bauserman M, Mwenechanya M, Chomba E, Carlo WA, Figueroa L, Krebs NF, Jessani S, Saleem S, Goldenberg RL, Das P, Patel A, Hibberd PL, Esamai F, Bucher S, Koso-Thomas M, Silver R, Derman RJ. Aspirin delays the onset of hypertensive disorders of pregnancy among nulliparous pregnant women: A secondary analysis of the ASPIRIN trial. *BJOG*. 2023 Jul 20. doi: 10.1111/1471-0528.17607. Epub ahead of print. PMID: 37470099.
 51. Kibel M, Nyambura M, Embleton L, Kiptui R, Galárraga O, Apondi E, Ayuku D, Braitstein P. Enabling Adherence to Treatment (EAT): a pilot study of a combination intervention to improve HIV treatment outcomes among street-connected individuals in western Kenya. *BMC Health Serv Res*. 2023 Nov 30;23(1):1331. doi: 10.1186/s12913-023-10215-1. PMID: 38037045; PMCID: PMC10691070.
 52. Kiburi SK, Paruk S, Kwobah EK, Chiliza B. Exploring user experiences of a text message-delivered intervention among individuals on opioid use disorder treatment in Kenya: A qualitative study. *PLOS Digit Health*. 2023 Nov 6;2(11):e0000375. doi: 10.1371/journal.pdig.0000375. PMID: 37930956; PMCID: PMC10627438.
 53. Kinyanjui DW, Sum AM. Personality traits and substance use among college students in Eldoret, Kenya. *PLoS One*. 2023 May 24;18(5):e0286160. doi: 10.1371/journal.pone.0286160. PMID: 37224120; PMCID: PMC10208453.
 54. Kirui J, Malinga J, Sang E, Ambani G, Abel L, Nalinya E, Namae J, Boyce M, Laktabai J, Menya D, O'Meara W. Supply-side and demand-side factors influencing uptake of malaria testing services in the community: lessons for scale-up from a post-hoc analysis of a cluster randomised, community-based trial in western Kenya. *BMJ Open*. 2023 Jun 26;13(6):e070482. doi: 10.1136/bmjopen-2022-070482. PMID: 37369403.
 55. Koros, H., Nolte, E., Kamano, J., Mugo, R., Murphy, A., Naanyu, V., Willis, R., Pliakas, T., Eton, D.T., Barasa, E. and Perel, P., 2023. Understanding the treatment burden of people with chronic conditions in Kenya: A cross-sectional analysis using the Patient Experience with Treatment and Self-Management (PETS) questionnaire. *PLOS Global Public Health*, 3(1), p.e0001407.
 56. Korte KJ, Jaguga F, Kim HH, Stroud RE, Stevenson A, Akena D, Atwoli L, Gichuru S, James R, Kwobah E, Kariuki SM, Kyebuzibwa J, Mwema RM, Newton CRJC, Zingela Z, Stein DJ, Alemayehu M, Teferra S, Koenen KC, Gelaye B. Psychometric properties of the mini international neuropsychiatric

- interview (MINI) psychosis module: a Sub-Saharan Africa cross country comparison. *Psychol Med*. 2023 Mar 10;1-11. doi: 10.1017/S0033291723000296. Epub ahead of print. PMID: 36896802.
57. Kwobah E, Koen N, Mwangi A, Atwoli L, Stein DJ. Prevalence of lifestyle cardiovascular risk factors and estimated framingham 10-year risk scores of adults with psychotic disorders compared to controls at a referral hospital in Eldoret, Kenya. *BMC Psychiatry*. 2023 Dec 5;23(1):909. doi: 10.1186/s12888-023-05409-0. PMID: 38053103; PMCID: PMC10699058.
 58. Kwobah EK, Turissini M, Barasa J, Kimaiyo M, Okeyo L, Araka J, Njiriri F, Matundura R, Jaguga F. Mental healthcare services in Kenyan counties: a descriptive survey of four counties in Western Kenya. *BMC Health Serv Res*. 2023 May 25;23(1):543. doi: 10.1186/s12913-023-09481-w. PMID: 37231439; PMCID: PMC10210267.
 59. Kwobah KE, Kiptoo SR, Jaguga F, Wangechi F, Chelagat S, Ogara F, Aruasa WK. Incidents related to safety in mental health facilities in Kenya. *BMC Health Serv Res*. 2023 Jan 28;23(1):95. doi: 10.1186/s12913-023-09074-7. PMID: 36707811; PMCID: PMC9883851.
 60. Laloo UG, Komarow L, Aberg JA, Clifford DB, Hogg E, McKhann A, Bukuru A, Lagat D, Pillay S, Mave V, Supparatpinyo K, Samaneka W, Langat D, Ticona E, Badal-Faesens S, Larsen RA; ACTG A5225 Team. Higher Dose Oral Fluconazole for the Treatment of AIDS-related Cryptococcal Meningitis (HIFLAC)-report of A5225, a multicentre, phase I/II, two-stage, dose-finding, safety, tolerability and efficacy randomised, amphotericin B-controlled trial of the AIDS Clinical Trials Group. *PLoS One*. 2023 Feb 13;18(2):e0281580. doi: 10.1371/journal.pone.0281580. PMID: 36780493; PMCID: PMC9925064.
 61. Langat S, Njuguna F, Olbara G, Martijn H, Sieben C, Haverkort M, Njenga D, Vik TA, Kaspers G, Mostert S. Influence of health-insurance on treatment outcome of childhood cancer in Western Kenya. *Support Care Cancer*. 2023 Jul 15;31(8):467. doi: 10.1007/s00520-023-07913-1. PMID: 37452971; PMCID: PMC10349750.
 62. Lemmen J, Njuguna F, Verhulst S, Vik TA, Ket JCF, Kaspers GJL, Mostert S. Late effects of childhood cancer survivors in Africa: A scoping review. *Crit Rev Oncol Hematol*. 2023 May;185:103981. doi: 10.1016/j.critrevonc.2023.103981. Epub 2023 Mar 30. PMID: 37003444.
 63. Lewis-Kulzer J, Mburu M, Obatsa S, Cheruiyot J, Kiprono L, Brown S, Apaka C, Koros H, Muyindike W, Kwobah EK, Diero L, Aluda M, Wools-Kaloustian K, Goodrich S. Patient perceptions of facilitators and barriers to reducing hazardous alcohol use among people living with HIV in East Africa. *Subst Abuse Treat Prev Policy*. 2023 Feb 3;18(1):8. doi: 10.1186/s13011-023-00520-7. PMID: 36737735; PMCID: PMC9896687.
 64. Lotspeich SC, Shepherd BE, Kariuki MA, Wools-Kaloustian K, McGowan CC, Musick B, Semeere A, Crabtree Ramírez BE, Mkwashapi DM, Cesar C, Ssemakadde M, Machado DM, Ngeresa A, Ferreira FF, Lwali J, Marcelin A, Cardoso SW, Luque MT, Otero L, Cortés CP, Duda SN. Lessons learned from over a decade of data audits in international observational HIV cohorts in Latin America and East Africa. *J Clin Transl Sci*. 2023 7(1),e245, doi:10.1017/cts.2023.659. PMC10685260 4
 65. Magill EB, Nyandiko W, Baum A, Aluoch J, Chory A, Ashimoshi C, Lidweye J, Njoroge T, Sang F, Nyagaya J, Scanlon M, Hogan J, Vreeman R. Factors associated with caregiver compliance to an HIV disclosure intervention and its effect on HIV and mental health outcomes among children living with HIV: *post-hoc* instrumental variable-based analysis of a cluster randomized trial in Eldoret, Kenya. *Front Public Health*. 2023 May 5; 11:1150744. doi: 10.3389/fpubh.2023.1150744. PMID: 37213654; PMCID: PMC10196043.

66. Maiyo AK, Korir BK, Kibet JK. The impact of puff frequency on respirable particulate matter in mainstream cigarette smoke. *Clin Respir J*. 2023 Jan 31. doi: 10.1111/crj.13592. Epub ahead of print. PMID: 36721214.
67. Maritim B, Koon AD, Kimaina A, Lagat C, Riungu E, Laktabai J, Ruhl LJ, Kibiwot M, Scanlon ML, Goudge J. "It is like an umbrella covering you, yet it does not protect you from the rain": a mixed methods study of insurance affordability, coverage, and financial protection in rural western Kenya. *Int J Equity Health*. 2023 Feb 6;22(1):27. doi: 10.1186/s12939-023-01837-2. PMID: 36747182; PMCID: PMC9901092.
68. Mburia-Mwalili A, Wagner KD, Kwobah EK, Atwoli L, Aluda M, Simmons B, Lewis-Kulzer J, Goodrich S, Wools-Kaloustian K, Syvertsen JL. Social support and the effects of the COVID-19 pandemic among a cohort of people living with HIV (PLWH) in Western Kenya. *PLOS Glob Public Health*. 2023 Feb 28;3(2):e0000778. doi: 10.1371/journal.pgph.0000778. PMID: 36962963; PMCID: PMC10022114.
69. McHenry MS, Roose A, Abuonji E, Nyalumbe M, Ayuku D, Ayodo G, Tran TM, Kaat AJ. A psychometric evaluation of the NIH Toolbox fluid cognition tests adapted for Swahili and Dholuo languages in Kenyan children and adolescents. *J Int Neuropsychol Soc*. 2023 Dec;29(10):933-942. doi: 10.1017/S1355617723000632. Epub 2023 Nov 22. PMID: 37989561; PMCID: PMC10669767.
70. Meharg DP, Naanyu V, Rambaldini B, Clarke MJ, Lacey C, Jebasingh F, Lopez-Jaramillo P, Gould GS, Aceves B, Alison JA, Chaiton M, Chen J, Gonzalez-Salazar F, Goodyear-Smith F, Gwynne KG, Lee KS, MacKay D, Maple-Brown L, Mishara BL, Nigenda G, Ramani-Chander A, Sherwood SG, Thomas N, Thrift AG, Anderson M. The Global Alliance for Chronic Diseases researchers' statement on non-communicable disease research with Indigenous peoples. *Lancet Glob Health*. 2023 Mar;11(3):e324-e326. doi: 10.1016/S2214-109X(23)00039-6. PMID: 36796972.
71. Meredith HR, Wesolowski A, Okoth D, Maraga L, Ambani G, Chepkwony T, Abel L, Kipkoach J, Lokoel G, Esimit D, Lokemer S, Maragia J, O'Meara WP, Obala AA. Characterizing mobility patterns and malaria risk factors in semi-nomadic populations of Northern Kenya. *medRxiv [Preprint]*. 2023 Dec 9:2023.12.06.23299617. doi: 10.1101/2023.12.06.23299617. PMID: 38106223; PMCID: PMC10723563.
72. Mezger NCS, Hämmerl L, Griesel M, Seraphin TP, Joko-Fru YW, Feuchtner J, Zietsman A, Péko JF, Tadesse F, Buziba NG, Wabinga H, Nyanchama M, Chokunonga E, Kéita M, N'da G, Lorenzoni CF, Akele-Akpo MT, Mezger JM, Binder M, Liu B, Bauer M, Henke O, Jemal A, Kantelhardt EJ. Guideline Concordance of Treatment and Outcomes Among Adult Non-Hodgkin Lymphoma Patients in Sub-Saharan Africa: A Multinational, Population-Based Cohort. *Oncologist*. 2023 Nov 2;28(11):e1017-e1030. doi: 10.1093/oncolo/oyad157. PMID: 37368350; PMCID: PMC10628567.
73. Mørkve ÅW, Sitienei J, Van den Bergh G. A qualitative case study of community experiences with Tungiasis in high prevalence villages of Bungoma County, Kenya: "The whole body aches and the jiggers are torturing me!". *PLoS Negl Trop Dis*. 2023 Apr 26; 17(4):e0011304. doi: 10.1371/journal.pntd.0011304. PMID: 37099605; PMCID: PMC10166527.
74. Muddu M, Jaffari A, Brant LCC, Kiplagat J, Okello E, Masyuko S, Su Y, Longenecker CT. Lifting all boats: strategies to promote equitable bidirectional research training opportunities to enhance global health reciprocal innovation. *BMJ Glob Health*. 2023 Dec 16;8(Suppl 7):e013278. doi: 10.1136/bmjgh-2023-013278. PMID: 38103895; PMCID: PMC10729234.
75. Muteti EN, Rotich GK, Opakas JE, de Souza AMG. Limb Salvage Surgery in Osteosarcoma of the Femur Using Liquid-Nitrogen-Frozen Free Femur Autograft in a Developing Country. *J Orthop Case*

- Rep. 2022;12(5):75-78. doi: 10.13107/jocr.2022.v12.i05.2824. PMID: 36660159; PMCID: PMC9826550.
76. Mwaliko E, Itsura P, Keter A, De Bacquer D, Buziba N, Bastiaens H, Jackie A, Obala A, Naanyu V, Gichangi P, Temmerman M. Survival of cervical cancer patients at Moi teaching and Referral Hospital, Eldoret in western Kenya. *BMC Cancer*. 2023 Nov 13;23(1):1104. doi: 10.1186/s12885-023-11506-w. PMID: 37957644; PMCID: PMC10644535.
 77. Mwanzia L, Baliddawa J, Biederman E, Perkins SM, Champion VL. Promoting childbirth in a rural health facility: A quasi-experimental study in western Kenya. *Birth*. 2023 Oct 30. doi: 10.1111/birt.12788. Epub ahead of print. PMID: 37902183.
 78. Mwenda V, Odeny L, Mohamed S, Gathecha G, Kendagor A, Kiptui D, Jaguga F, Mugi B, Mithi C, Okinda K, Mwai D, Njuguna D, Awuor W, Kitonyo-Devotsu R, Ong'ang'o JR. Prevalence, patterns, and factors associated with tobacco use among patients with priority tobacco related illnesses at four Kenyan national referral hospitals, 2022. *PLOS Glob Public Health*. 2023 Nov 10;3(11):e0002002. doi: 10.1371/journal.pgph.0002002. PMID: 37948351; PMCID: PMC10637644.
 79. Naanyu V, Njuguna B, Koros H, Andesia J, Kamano J, Mercer T, Bloomfield G, Pastakia S, Vedanthan R, Akwanalo C. Community engagement to inform development of strategies to improve referral for hypertension: perspectives of patients, providers and local community members in western Kenya. *BMC Health Serv Res*. 2023 Aug 11;23(1):854. doi: 10.1186/s12913-023-09847-0. PMID: 37568172; PMCID: PMC10422762.
 80. Naqvi S, Saleem S, Billah SM, Moore J, Mwenechanya M, Carlo WA, Esamai F, Bucher S, Derman RJ, Goudar SS, Somannavar M, Patel A, Hibberd PL, Figueroa L, Krebs NF, Petri WA, Lokangaka A, Bauserman M, Koso-Thomas M, McClure EM, Goldenberg RL. The Global Network COVID-19 studies: a review. *BJOG*. 2023 Aug 2. doi: 10.1111/1471-0528.17610. Epub ahead of print. PMID: 37530467.
 81. Nettle CN, Njuguna F, Dettinger J, Koima R, Nyamusi L, Kitembe E, Kinja S, Ndung'u M, Njenga D, Langat S, Olbara G, Moyer C, Vik T. Barriers to and facilitators of effective management of fever episodes in hospitalised Kenyan children with cancer: protocol for convergent mixed methods study. *BMJ Open*. 2023 Nov 2;13(11):e078124. doi: 10.1136/bmjopen-2023-078124. PMID: 37918936; PMCID: PMC10626801.
 82. Njie AE, Nyandiko WM, Ahoya PA, Moutchia JS. A comparative analysis of APGAR score and the gold standard in the diagnosis of birth asphyxia at a tertiary health facility in Kenya. *PLoS One*. 2023 May 24;18(5):e0285828. doi: 10.1371/journal.pone.0285828. PMID: 37224111; PMCID: PMC10208496.
 83. Nordberg B, van der Kop ML, Mwangi W, Mwangi J, Kaguiri E, Chamorro de Angeles KJ, Lester RT, Gabriel EE, Rautiainen S, Awiti PO, Kågesten AE, Were E, Ekström AM. The effect of an interactive weekly text-messaging intervention on retention in prevention of mother-to-child transmission of HIV care: a randomised controlled trial (WelTel PMTCT). *Sci Rep*. 2023 Jun 9;13(1):9389. doi: 10.1038/s41598-023-35817-x. PMID: 37296174; PMCID: PMC10256764.
 84. Nuss EE, Hoffman MK, Goudar SS, Kavi A, Metgud M, Somannavar M, Okitawutshu J, Lokangaka A, Tshetu A, Bauserman M, Mwapule A, Chomba E, Carlo WA, Figueroa L, Krebs PNF, Jessani S, Saleem PS, Goldenberg PRL, Kurhe K, Das P, Hibberd PPL, Achieng E, Nyongesa P, Esamai PF, Liechty PEA, Bucher S, Goco N, Hemingway-Foday J, Moore J, McClure EM, Silver PRM, Derman PRJ; ASPIRIN Study Group. The Impact of Risk Factors on Aspirin's Efficacy for the Prevention of Preterm Birth. *Am J ObstetGynecol MFM*. 2023 Aug 11:101095. doi: 10.1016/j.ajogmf.2023.101095. Epub ahead of print. PMID: 37574046.

85. Nyandiko W, Chory A, Baum A, Aluoch J, Ashimosi C, Scanlon M, Martin R, Wachira J, Beigon W, Munyoro D, Apondi E, Vreeman R. Multi-media teacher training and HIV-related stigma among primary and secondary school teachers in Western Kenya. *AIDS Care*. 2023 May;35(5):643-650. doi: 10.1080/09540121.2022.2119473. Epub 2022 Sep 5. PMID: 36062364; PMCID: PMC9985657.
86. Nyandiko W, Enjema NA, Mugo R, Apondi E, Sang E, Mwangi A. Predictors of Mortality Among Children and Adolescents Living with HIV on Antiretroviral Therapy in Western Kenya. *J Acquir Immune Defic Syndr*. 2023 Dec 15. doi: 10.1097/QAI.0000000000003361. Epub ahead of print. PMID: 38133591.
87. Nyongesa P, Ekhuagere OA, Marete I, Tenge C, Kemoi M, Bann CM, Bucher SL, Patel AB, Hibberd PL, Naqvi F, Saleem S, Goldenberg RL, Goudar SS, Derman RJ, Krebs NF, Garces A, Chomba E, Carlo WA, Mwenechanya M, Lokangaka A, Tshetu AK, Bauserman M, Koso-Thomas M, Moore JL, McClure EM, Liechty EA, Esamai F. Maternal age extremes and adverse pregnancy outcomes in low-resourced settings. *Front Glob Womens Health*. 2023 Nov 28;4:1201037. doi: 10.3389/fgwh.2023.1201037. PMID: 38090046; PMCID: PMC10715413.
88. Odhiambo FO, O'Meara WP, Abade A, Owiny M, Odhiambo F, Oyugi EO. Adherence to national malaria treatment guidelines in private drug outlets: a cross-sectional survey in the malaria-endemic Kisumu County, Kenya. *Malar J*. 2023 Oct 11;22(1):307. doi: 10.1186/s12936-023-04744-7. PMID: 37821868; PMCID: PMC10568760.
89. Ogwang MO, Diero L, Ng'ong'a F, Magoma G, Mutharia L, Imbuga M, Ngugi C. Strain structure analysis of Mycobacterium tuberculosis circulating among HIV negative, positive and drug resistant TB patients attending chest clinics in Western Kenya. *BMC Pulm Med*. 2023 Dec 9;23(1):497. doi: 10.1186/s12890-023-02802-z. PMID: 38071287; PMCID: PMC10709907.
90. Okunola AO, Baatjes KJ, Zemlin AE, Torrorey-Sawe R, Conradie M, Kidd M, Erasmus RT, van der Merwe NC, Kotze MJ. Pathology-supported genetic testing for the application of breast cancer pharmacodiagnosics: family counselling, lifestyle adjustments and change of medication. *Expert Rev Mol Diagn*. 2023 May;23(5):431-443. doi: 10.1080/14737159.2023.2203815. Epub 2023 Apr 20. PMID: 37060281.
91. Omwodo KA, Were E. Comparing adverse maternal and perinatal outcomes in primary caesarean delivery during first versus second-stage of labour in Kenya: An institution-based cohort study. *PLoS One*. 2023 Nov 27;18(11):e0294266. doi: 10.1371/journal.pone.0294266. PMID: 38011095.
92. Orang'o, E.O., Bocage, A.E., Liu, T.D., Itsura, P.M., Tonui, P.K., Muthoka, K., Stephen, K., Caliendo, A.M., Sam, S.S. and Cu-Uvin, S., 2023, January. Human Immunodeficiency Virus Type 1 RNA Genital Tract Shedding After Cryotherapy for Cervical Intraepithelial Neoplasia in Western Kenya. In *Open Forum Infectious Diseases* (Vol. 10, No. 1, p. ofac662). US: Oxford University Press.
93. Owino C, Sirera B, Tarus F, Ganda B, Oduor C, Siika A. Ischemic stroke at first presentation of Takayasu arteritis in a young African male from Kenya, East Africa: Case report and brief literature review. *Clin Case Rep*. 2023 May 28;11(6):e7412. doi: 10.1002/ccr3.7412. PMID: 37255613; PMCID: PMC10225614.
94. Oyando R, Were V, Koros H, Mugo R, Kamano J, Etyang A, Murphy A, Hanson K, Perel P, Barasa E. Evaluating the effectiveness of the National Health Insurance Fund in providing financial protection to households with hypertension and diabetes patients in Kenya. *Int J Equity Health*. 2023 Jun 1;22(1):107. doi: 10.1186/s12939-023-01923-5. PMID: 37264458; PMCID: PMC10234077.
95. Oyando R, Were V, Willis R, Koros H, Kamano JH, Naanyu V, Etyang A, Mugo R, Murphy A, Nolte E, Perel P, Barasa E. Examining the responsiveness of the National Health Insurance Fund to people

- living with hypertension and diabetes in Kenya: a qualitative study. *BMJ Open*. 2023 Jul 4;13(7):e069330. doi: 10.1136/bmjopen-2022-069330. PMID: 37407061; PMCID: PMC10335555.
96. Parcesepe AM, Stockton M, Remch M, Wester CW, Bernard C, Ross J, Haas AD, Ajeh R, Althoff KN, Enane L, Pape W, Minga A, Kwobah E, Tlali M, Tanuma J, Nsonde D, Freeman A, Duda SN, Nash D, Lancaster K; leDEA Consortium. Availability of screening and treatment for common mental disorders in HIV clinic settings: data from the global international epidemiology Databases to Evaluate AIDS (leDEA) Consortium, 2016-2017 and 2020. *J Int AIDS Soc*. 2023 Aug;26(8):e26147. doi: 10.1002/jia2.26147. PMID: 37535703; PMCID: PMC10399924.
 97. Patterson JK, Neuwahl S, Goco N, Moore J, Goudar SS, Derman RJ, Hoffman M, Metgud M, Somannavar M, Kavi A, Okitawutshu J, Lokangaka A, Tshefu A, Bose CL, Mwapule A, Mwenechanya M, Chomba E, Carlo WA, Chicuy J, Figueroa L, Krebs NF, Jessani S, Saleem S, Goldenberg RL, KurheK, Das P, Patel A, Hibberd PL, Achieng E, Nyongesa P, Esamai F, Bucher S, Liechty EA, Bresnahan BW, Koso-Thomas M, McClure EM. Cost-effectiveness of low-dose aspirin for the prevention of preterm birth: a prospective study of the Global Network for Women's and Children's Health Research. *Lancet Glob Health*. 2023 Mar;11(3):e436-e444. doi: 10.1016/S2214-109X(22)00548-4. PMID: 36796987.
 98. Patterson JK, Thorsten VR, Eggleston B, Nolen T, Lokangaka A, Tshefu A, Goudar SS, Derman RJ, Chomba E, Carlo WA, Mazariegos M, Krebs NF, Saleem S, Goldenberg RL, Patel A, Hibberd PL, Esamai F, Liechty EA, Haque R, Petri B, Koso-Thomas M, McClure EM, Bose CL, Bauserman M. Building a predictive model of low birth weight in low- and middle-income countries: a prospective cohort study. *BMC Pregnancy Childbirth*. 2023 Aug 22;23(1):600. doi: 10.1186/s12884-023-05866-1. PMID: 37608358.
 99. Petricca K, Kambugu J, Githang'a J, Macharia WM, Njuguna F, McLigeyo A, Nyangasi M, Orem J, Kanyamuhunga A, Laiti R, Katabalo D, Schroeder K, Rogo K, Maguire B, Wambui L, Nkurunziza JN, Wong B, Neposlan J, Kilawe L, Gupta S, Denburg AE. Access to essential cancer medicines for children: a comparative mixed-methods analysis of availability, price, and health-system determinants in east Africa. *Lancet Oncol*. 2023 Apr 3:S1470-2045(23)00072-4. doi: 10.1016/S1470-2045(23)00072-4. Epub ahead of print. PMID: 37023781.
 100. Raciti CG, Marsha J, Nafiseh AA, Masese ER, Apondi E, McHenry MS. "If it benefits someone, it will be good:" perspectives on research participation from pregnant women living with HIV. *AIDS Care*. 2023 Mar;35(3):366-373. doi: 10.1080/09540121.2022.2057411. Epub 2022 Mar 27. PMID: 35341423.
 101. Ruhl LJ, Kiplagat J, O'Brien R, Wools-Kaloustian K, Scanlon M, Plater D, Thomas MR, Pastakia S, Gopal-Srivastava R, Morales-Soto N, Nyandiko W, Vreeman RC, Litzelman DK, Laktabai J. A Global Health Reciprocal Innovation grant programme: 5-year review with lessons learnt. *BMJ Glob Health*. 2023 Nov;8(Suppl 7):e013585. doi: 10.1136/bmjgh-2023-013585. PMID: 37977589; PMCID: PMC10660845.
 102. Samandari T, Ongalo J, McCarthy K, Biegon RK, Madiaga P, Mithika A, Orinda J, Mboya GM, Mwaura P, Anzala O, Onyango C, Oluoch FO, Osoro EM, Dutertre CA, Tan N, Hang SK, Hariharaputran S, Lye DC, Herman-Roloff A, Le Bert N, Bertoletti A. Prevalence and functional profile of SARS-CoV-2 T cells in asymptomatic Kenyan adults. *J Clin Invest*. 2023 May 23:e170011. doi: 10.1172/JCI170011. Epub ahead of print. PMID: 37219944.
 103. Simba H, Menya D, Mmbaga BT, Dzamalala C, Finch P, Mlombe Y, Mremi A, Narh CT, Schüz J, McCormack V. The contribution of smoking and smokeless tobacco to oesophageal squamous cell

- carcinoma risk in the African oesophageal cancer corridor: Results from the ESCCAPE multicentre case-control studies. *Int J Cancer*. 2023 Feb 2. doi: 10.1002/ijc.34458. Epub ahead of print. PMID: 36733225.
104. Thirugnanasampanthar SS, Embleton L, Di Ruggiero E, Braitstein P, Oduor C, Dibaba Wado Y. School attendance and sexual and reproductive health outcomes among adolescent girls in Kenya: a cross-sectional analysis. *Reprod Health*. 2023 Feb 6;20(1):29. doi: 10.1186/s12978-023-01577-0. PMID: 36747291; PMCID: PMC9901832.
 105. Thomadakis C, Yiannoutsos CT, Pantazis N, Diero L, Mwangi A, Musick BS, Wools-Kaloustian K, Touloumi G. The Effect of HIV Treatment Interruption on Subsequent Immunological Response. *Am J Epidemiol*. 2023 Jul 7;192(7):1181-1191. doi: 10.1093/aje/kwad076. PMID: 37045803; PMCID: PMC10326612.
 106. Tita ATN, Carlo WA, McClure EM, Mwenechanya M, Chomba E, Hemingway-Foday JJ, Kavi A, Metgud MC, Goudar SS, Derman R, Lokangaka A, Tshefu A, Bauserman M, Bose C, Shivkumar P, Waikar M, Patel A, Hibberd PL, Nyongesa P, Esamai F, Ekhuaguere OA, Bucher S, Jessani S, Tikmani SS, Saleem S, Goldenberg RL, Billah SM, Lennox R, Haque R, Petri W, Figueroa L, Mazariegos M, Krebs NF, Moore JL, Nolen TL, Koso-Thomas M; A-PLUS Trial Group. Azithromycin to Prevent Sepsis or Death in Women Planning a Vaginal Birth. *N Engl J Med*. 2023 Mar 30;388(13):1161-1170. doi: 10.1056/NEJMoa2212111. Epub 2023 Feb 9. PMID: 36757318.
 107. Tong Y, Tonui P, Orang'o O, Zhang J, Maina T, Muthoka K, Groopman J, Smith J, Madeen E, Ermel A, Loehrer P, Brown DR. Association of plasma aflatoxin with persistent detection of oncogenic human papillomaviruses in cervical samples from Kenyan women enrolled in a longitudinal study. *BMC Infect Dis*. 2023 Jun 6;23(1):377. doi: 10.1186/s12879-023-08323-8. PMID: 37280534; PMCID: PMC10242809.
 108. Turner PJ, Mamula J, Laktabi J, Patel N. How Common Are Allergic Reactions During Commercial Flights? A Systematic Review and Meta-Analysis. *J Allergy Clin Immunol Pract*. 2023 Nov;11(11):3400-3406.e4. doi: 10.1016/j.jaip.2023.07.025. Epub 2023 Jul 26. PMID: 37507067.
 109. Vreeman RC, Yiannoutsos CT, Yusoff NKN, Wester CW, Edmonds A, Ofner S, Davies MA, Leroy V, Lumbiganon P, de Menezes Succi RC, Twizere C, Brown S, Bolton-Moore C, Takassi OE, Scanlon M, Martin R, Wools-Kaloustian K; IeDEA. Global HIV prevention, care and treatment services for children: a cross-sectional survey from the International Epidemiology Databases to Evaluate AIDS (IeDEA) consortium. *BMJ Open*. 2023 Mar 13;13(3):e069399. doi: 10.1136/bmjopen-2022-069399. PMID: 36914183; PMCID: PMC10016275.
 110. Wachira J, Genberg BL, Wilson IB. Promoting patient-centered care within HIV care settings in sub-Saharan Africa. *Current Opinion in HIV and AIDS*. 2023 Jan 1;18(1):27-31.
 111. Were E, Kiplagat J, Kaguir E, Ayikukwei R, Naanyu V. Institutional capacity to prevent and manage research misconduct: perspectives from Kenyan research regulators. *Res Integr Peer Rev*. 2023 Jul 12;8(1):8. doi: 10.1186/s41073-023-00132-6. PMID: 37434258; PMCID: PMC10337100.
 112. Wilson SF, Alway J, Hotchkiss E, Aluku C, Matityahu D, Mabeya H, El Ayadi AM. Fertility desires and sexual behaviours among women recovering from genital fistula repair in Eldoret, Kenya. *Trop Med Int Health*. 2023 Dec 8. doi: 10.1111/tmi.13959. Epub ahead of print. PMID: 38069534.
 113. Yang J, Mwangi AW, Kantor R, Dahabreh IJ, Nyambura M, Delong A, Hogan JW, Steingrimsson JA. Tree-based subgroup discovery using electronic health record data: heterogeneity of treatment effects for DTG-containing therapies. *Biostatistics*. 2023 Jul 20:kxad014. doi: 10.1093/biostatistics/kxad014. Epub ahead of print. PMID: 37475638.

114. Zhou W, Bakoyannis G, Zhang Y, Yiannoutsos CT. Semiparametric marginal regression for clustered competing risks data with missing cause of failure. *Biostatistics*. 2023 24(3),795-810, doi:10.1093/biostatistics/kxac012. PMC10345995
115. Zhou W, Fischer A, Ogwang MD, Luo W, Kerchan P, Reynolds SJ, Tenge CN, Were PA, Kuremu RT, Wekesa WN, Masalu N, Kawira E, Kinyera T, Otim I, Legason ID, Nabalende H, Ayers LW, Bhatia K, Goedert JJ, Gouveia MH, Cole N, Hicks B, Jones K, Hummel M, Schlesner M, Chagaluka G, Mutalima N, Borgstein E, Liomba GN, Kamiza S, Mkandawire N, Mitambo C, Molyneux EM, Newton R, Glaser S, Kretzmer H, Manning M, Hutchinson A, Hsing AW, Tettey Y, Adjei AA, Chanock SJ, Siebert R, Yeager M, Prokunina-Olsson L, Machiela MJ, Mbulaiteye SM. Mosaic chromosomal alterations in peripheral blood leukocytes of children in sub-Saharan Africa. *Nat Commun*. 2023 Dec 6;14(1):8081. doi: 10.1038/s41467-023-43881-0. PMID: 38057307; PMCID: PMC10700489.

Appendix 2. Study Reports

The following study reports provide summaries of active AMPATH research projects at the end of the reporting period (December 31, 2023). Study reports and updates 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 by order of submission and a linked index is listed below for easy navigation.

Index of Study Reports

A cluster randomized trial of 'Teach HADITHI' teacher training intervention to reduce classroom HIV-related stigma in Kenya.	32
A parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults 18 years of age and older as a primary series and open-label extension to assess immunogenicity, safety, efficacy of a monovalent booster dose of SARS-CoV2 Adjuvanted Recombinant Protein Vaccine.....	32
A Phase 2, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Daily Bedtime TNX-102 SL in Participants with PTSD	33
A Phase 3b, Randomized, Multicenter, Open-Label Study Evaluating the Efficacy, Safety, and Tolerability of Switching to Long-Acting Cabotegravir Plus Long-Acting Rilpivirine from Current Antiretroviral Regimen in HIV-1 Infected, Virologically Suppressed Adults in Sub-Saharan Africa	33
A pilot study to evaluate the feasibility and acceptability of a peer-mentor delivered substance use screening and brief intervention for adolescents in Kenya.	34
A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 1	34
A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 2	35
A5300B/I2003B/PHOENix Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients (PHOENix MDR-TB)	35
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	36

Addressing bioethical research gaps in research with young people living with HIV (YPLWH) in Kenya	36
Addressing HIV drug resistance research gaps in a cohort of perinatally infected Kenyan children and adolescents	37
Adolescent and youth-friendly health services in Uasin Gishu County Kenya: a mixed methods study.....	37
Assessing Implementation of Delivering Community-based, Peer-led Interventions for Mental Health Problems among Youth in Eldoret, Kenya	37
BREATHER Plus A randomised open-label 2-arm, 96-week trial evaluating the efficacy, safety and acceptability of short cycle (five days on, two days off) dolutegravir/tenofovir-based triple antiretroviral therapy (ART) compared to daily dolutegravir/tenofovir-based triple ART in virologically suppressed HIV-infected adolescents aged 12 to 19 years of age in sub-Saharan Africa	38
Bridging Income Generation with Group Integrated Care (BIGPIC)	39
Brown Moi partnership for biostatistics training in HIV-NAMBARI.....	39
CBA Intervention.....	40
Chamas for Change: Adapting a community-based peer-support and health education model for pregnant and parenting adolescents in Kenya	40
Clinical Assessment for Retention and Engagement (CARE Study)	41
Co-Benefits of Co-Delivery of Long-Acting Antiretrovirals and Contraceptives.....	41
CoVPN 3008 (Ubuntu) Multi-Center, Randomized, Efficacy Study of COVID-19 mRNA Vaccine in Regions with SARS-CoV-2 Variants of Concern	42
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.....	42
Data Science for Decision Support in the HIV Care Cascade	43
Determining The Frequency of Cytogenetic Abnormalities among Multiple Myeloma Patients in Kenya using an Artificial Intelligence-based Approach: A Retrospective Cohort Study	43
Developing Capacity of Moi Teaching and Referral Hospital / Moi University Institutional Research Ethics Committee (MTRH/MU IREC), Kenya to Prevent and Manage Research Misconduct	44

EA-IeDEA: A longitudinal survey study of the impact of COVID-19 preparedness and response efforts on people living with HIV in East Africa.....	44
EA-IeDEA: ACE Study	45
EA-IeDEA: Adolescent and Young Adult Network of IeDEA (AYANI).....	45
EA-IeDEA: HIV-1 subtype-specific drug resistance in patients failing dolutegravir-based first-line, second-line or third-line regimens: multiregional study	46
EA-IeDEA: Jozi Study (Determining Long-Term Clinical Outcomes for HIV-Affected Mother-Infant Dyads in Western Kenya: Sub-Study to the Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO) Study).....	46
EA-IeDEA: Main Study.....	47
EA-IeDEA: Measuring Adverse Pregnancy and Newborn Outcomes (MANGO)	47
EA-IeDEA: MANGO CA Study.....	48
EA-IeDEA Networks in Kenya.....	49
EA-IeDEA: NIDA Study	49
EA-IeDEA: PHQ 9 Study	50
EA-IeDEA: PMTCT Plus Study: Improving Estimates of Mother-to-Child Transmission in Western Kenya: A Mixed Methods Prospective Cohort Study	50
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	51
EA-IeDEA: Sentinel Research Network (SRN)	51
EA-IeDEA: Syndemics Study	52
EA-IeDEA: The Desire to Avoid Pregnancy Post-partum (DAPP Study).....	52
EA-IeDEA: Tuberculosis Sentinel Research Network (IeDEA-EA TB-SRN).....	53
Epidemiology and Genetics of Post traumatic Stress Disorder Among Participants in the Neurogap-P Study	54
Ethnic Specific Risk Stratification in Early Pregnancy for Identifying Mothers at Risk of Gestational Diabetes Mellitus in Eldoret Kenya	54
Evaluation of Chronic Hypoxemia from Cardiopulmonary Disease Among Patients Admitted to a Referral Hospital in Western Kenya and Their Perspectives on Oxygen Use.	54

Feasibility and acceptability of Enhanced Patient Care (EPC) for adult HIV patients with unsuppressed viral loads in western Kenya.....	55
Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups in Kenya	55
Impact of COVID-19 on adolescents living with HIV in Kenya.....	56
Impact of Infection Prevention Care Bundles on Surgical Site Infections Post Cesarean Section in Moi Teaching and Referral Hospital.....	56
Implementing a Model of Improved Care for Infectious Diseases and Antibiotic Stewardship across Multiple Levels of the Health System in Western Kenya	57
Integrating hypertension and diabetes screening and management with HIV care services for older adults: Feasibility study.....	57
JSVCT109 "A global multicenter, randomized, double-blind, placebo-controlled, phase III clinical trial to evaluate the efficacy, safety, and immunogenicity of recombinant COVID-19 vaccine (Sf9 cell) for the prevention of COVID-19 in adults aged 18 years and older "	58
Making Inroads to Strengthen the Health of Adolescents (MAISHA)	58
Maternal Newborn Health Registry	59
Mobile Mental Health Monitoring and Support for Adolescents with HIV in Kenya	59
Multicenter Study of Pomalidomide Monotherapy in HIV-Infected Individuals with Kaposi Sarcoma (KS) in Sub-Saharan Africa (SSA)	60
NeonInnovate Collaborative Consortium.....	60
Neurodevelopmental Screening in Children Born to HIV-Infected Mothers in Kenya.....	61
Neurogap-Psychosis Follow-up Study on Anhedonia, Obsessive Compulsive Disorder, Discrimination, and Suicidality	61
NIH Chemopad.....	62
Optimizing HIV treatment monitoring strategies under resource constraints	62
Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK)	63
Participatory research approach to the development of an enhanced mentor mother strategy (PaRADE-MMS)	63
Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI).....	64

Prevalence and Impact of SARS-CoV-2 Among Pregnant Women in Low- and Middle-income Countries	64
Prevalence of hypertension among postpartum women with preeclampsia (PET) in Kenya: a prospective cohort study	65
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)	65
PT4A (Peers and Technology for Adherence, Access, Accountability, and Analytics)	66
SAFI (Stigma in AIDS Family Inventory) Validation Study.....	66
Scaling Up Primary Health Integrated Care for Chronic Conditions in Kenya: An Implementation Research Project (PIC4C Scale Up Study)	67
Spatial scales of Plasmodium falciparum generations; implications for elimination	67
Stated Preference Analysis to Refine PMTCT Service Delivery in Kenya (SPARK) study.....	68
Stawisha Jamii - Development of a Family-Level Problem Solving Intervention for Adolescents Living with HIV	68
Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS).....	69
Study of Suspected Kaposi's Sarcoma at the Academic Model Providing Access to Healthcare (AMPATH) clinics, Eldoret, Kenya	70
Subclinical Cardiac Dysfunction in Children and Adolescents with and without HIV	70
The East Africa Consortium for HPV and Cervical Cancer in Women living with HIV/AIDS.	71
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)	71
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	72
The Prevalence of and Risk Factors for Non-Alcoholic Fatty Liver Disease in Kenya	72
Training in HIV Implementation Science and Dissemination in Kenya.....	73
Tuko Pamoja.....	73
Tujenge Akina Baba Study (TAB Study)	74
Virologic Treatment Failure and Drug Resistance in HIV-infected Kenyan Children	74

Study Title	A cluster randomized trial of 'Teach HADITHI' teacher training intervention to reduce classroom HIV-related stigma in Kenya.
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Edith Apondi (Moi Teaching and Referral Hospital), Juddy Wachira (Moi University), Wanzhu Tu (Indiana University)
Study Type	Prospective intervention study
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 parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults 18 years of age and older as a primary series and open-label extension to assess immunogenicity, safety, efficacy of a monovalent booster dose of SARS-CoV2 Adjuvanted Recombinant Protein Vaccine
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	Charles Kwobah (Moi University), Charity Wambui (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To assess, in participants who are SARS-CoV-2 naïve, the clinical efficacy of the CoV2 preS dTM-AS03 vaccines for the prevention of symptomatic COVID-19 occurring ≥ 14 days after the second injection. Aim 2: To assess, in all participants regardless of prior SARSCoV-2 infection, the clinical efficacy of the CoV2 preS dTM-AS03 vaccines for prevention of symptomatic COVID-19 ≥ 14 days after the second injection Aim 3: To assess the safety of the CoV2 preS dTM-AS03 vaccines compared to placebo throughout the study

Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	11/1/2021
Sponsor(s)	Sanofi Pasteur, Inc
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	A Phase 2, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Daily Bedtime TNX-102 SL in Participants with PTSD
Principal Investigator(s)	Lukoye Atwoli (Aga Khan University)
Collaborator(s)	Edith Kwobah (Moi Teaching and Referral Hospital), Frank Njenga (Chiromo Hospital), Linet Onger (Harvard University), Sylvia Kemunto (Mathari Hospital), Gabriel Kigen (Moi University)
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 has been suspended)

Study Title	A Phase 3b, Randomized, Multicenter, Open-Label Study Evaluating the Efficacy, Safety, and Tolerability of Switching to Long-Acting Cabotegravir Plus Long-Acting Rilpivirine from Current Antiretroviral Regimen in HIV-1 Infected, Virologically Suppressed Adults in Sub-Saharan Africa
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	Charity Wambui (Moi University)
Study Type	Prospective
Specific Aim(s)	To demonstrate the non-inferior antiviral activity of switching to IM CAB LA+RPV LA administered every 2 months compared with continuation of cART administered daily over 12 months in HIV-1 infected participants in a resource limited setting.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	3/1/2022 -
Sponsor(s)	Joint Clinical Research Centre (JCRC) & Janssen EMEA
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	A pilot study to evaluate the feasibility and acceptability of a peer-mentor delivered substance use screening and brief intervention for adolescents in Kenya.
Principal Investigator(s)	Florence Jaguga (Moi Teaching and Referral Hospital)
Collaborator(s)	Matthew Aalsma (Indiana University), Matthew Turissini (Indiana University), Mary Ott (Indiana University), Edith Kwobah (Moi Teaching and Referral Hospital), Edith Apondi (Moi University), Julius Barasa (AMPATH), Yvonne Olando (National Agency for the Campaign Against Drug Abuse), Leslie Enane (Indiana University)
Study Type	Single-blind RCT Pilot Study Design
Specific Aim(s)	Aim 1: Test the feasibility and acceptability of the SBI for adolescents with moderate and high-risk substance use; Aim 2: Test the feasibility of the full-scale RCT by addressing questions such as can we recruit and successfully randomize our target population and are we able to retain study participants.
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/28/2022 - 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	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	Randomized controlled trial
Specific Aim(s)	This study's objective 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 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	Complete -- Follow up and data analysis are complete and the study is closed.

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), Charity Wambui (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. No update provided for the current reporting period.

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 cohort study
Specific Aim(s)	Aim 1: Among participants still on TLD at 6 months of follow up, to estimate the proportion achieving virologic success (HIV-1 RNA \leq 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 \leq 1000 copies/mL at start of TLD (Group 1b); (d) Participants switching from second-line PI-containing therapy with HIV-1 RNA \leq 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 \leq 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 - 3/31/2023
Sponsor(s)	NIH
Status	Complete -- Follow up and data analysis are complete, and the study is closed.

Study Title	Addressing bioethical research gaps in research with young people living with HIV (YPLWH) 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 -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	Adolescent and youth-friendly health services in Uasin Gishu County Kenya: a mixed methods study
Principal Investigator(s)	Irene Marete (Moi University), Lonnie Embleton (Mount Sinai)
Collaborator(s)	Florence Jaguga (Moi University), Edith Apondi (Moi University), Mary Ott (Indiana University), Wan-Ju Wu (Mount Sinai), Rachel Vreeman (Mount Sinai), Ashley Chory (Mount Sinai), Dennis Munyoro (AMPATH)
Study Type	Cross-sectional
Specific Aim(s)	Aim 1: Characterize the adolescent and youth-friendliness of a sample of public health facilities in urban, per-urban, and rural settings in UG county. Aim 2: Describe and explore health service delivery preferences from the perspective of young people aged 10 to 24 years, caregivers, healthcare providers, community leaders, and policymakers in UG county.
Site(s)	Uasin Gishu
Project Period	12/1/2023 - 4/30/2024
Sponsor(s)	Icahn School of Medicine at Mount Sinai, New York, New York, USA
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	Assessing Implementation of Delivering Community-based, Peer-led Interventions for Mental Health Problems among Youth in Eldoret, Kenya

Principal Investigator(s)	Matthew Turissini (Indiana University)
Collaborator(s)	Edith Kwobah (Moi Teaching and Referral Hospital), Florence Jaguga (Moi Teaching and Referral Hospital), Eve Puffer (Duke University), Ali Giusto (Columbia University), Edith Apondi (Moi Teaching and Referral Hospital), Julius Barasa (AMPATH), Joseph Binayo (Family Health Options Kenya), Mary A. Ott (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To pilot a community-based peer-led screening process for internalizing mental health problems among youth in Eldoret. a) To screen for mental health problems in adolescents via peer mentors (18-24 years) using the SDQ, YTP, PHQ-9, and GAD-7. b) To describe the Reach, Effectiveness, Adoption, Implementation, and Maintenance of the screening process. Aim 2: To pilot a community-based peer-led PST intervention for mental health problems among youth in Eldoret. a) To train and supervise peer mentors in delivering 5 sessions of low-intensity, evidence-based PST for adolescents who screened positive for mental health problems. b) To assess the Reach, Adoption, preliminary Effectiveness, Implementation, and Maintenance of the PST at multiple levels.
Site(s)	Uasin Gishu
Project Period	1/1/2022 - 12/31/2024
Sponsor(s)	Indiana CTSI
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	BREATHER Plus A randomised open-label 2-arm, 96-week trial evaluating the efficacy, safety and acceptability of short cycle (five days on, two days off) dolutegravir/tenofovir-based triple antiretroviral therapy (ART) compared to daily dolutegravir/tenofovir-based triple ART in virologically suppressed HIV-infected adolescents aged 12 to 19 years of age in sub-Saharan Africa
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	Winstone Nyandiko (Moi University), Cecilia Kiilu (Moi University)
Study Type	Prospective
Specific Aim(s)	The overarching objective of this trial is to evaluate an innovative and contemporary ART strategy in HIV-infected adolescents to provide choice for young people facing life-long treatment. Output from this RCT will provide evidence on efficacy, safety and acceptability of a novel treatment approach in HIV-infected adolescents in sub-Saharan Africa.
Site(s)	Elgeyo Marakwet, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	3/1/2023 - ongoing
Sponsor(s)	EDCTP
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still 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), Violet Naanyu (Moi University), Sonak Pastakia (Purdue University), Chesoli Cleophas Wanyonyi (Moi University), Benjamin Andama (AMPATH), Diana Menya (Moi University), Eric Finkelstein (Duke University), Gerald Bloomfield (Duke University), David Edelman (Duke University), Joseph Hogan (Brown University), Stavroula Chrysanthopoulou (Brown University), Carol Horowitz (Mount Sinai), Valentin Fuster (Mount Sinai)
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 (69.9percent 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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	Brown Moi partnership for biostatistics training in HIV-NAMBARI
Principal Investigator(s)	Ann Mwangi (Moi University)
Collaborator(s)	Joseph Hogan (Brown University)
Study Type	Other - Training
Specific Aim(s)	Aim 1: Long term training to expand the cohort of professional and academic HIV biostatisticians. Aim 2: Expand base of faculty expertise in biostatistics at Moi University to enable revision of graduate program. Aim 3: Promote dissemination of advanced statistical methods and facilitate networking of biostatisticians in sub-

	Saharan Africa. Aim 4: Initiate planning process for Centre for Health Data Science at Moi University
Site(s)	Moi Teaching and Referral Hospital
Project Period	3/31/2023 - 3/31/2024
Sponsor(s)	NIH
Status	Other
Study Title	CBA Intervention
Principal Investigator(s)	Jepchirchir Kiplagat (Moi University)
Collaborator(s)	Kara Wools-Kaloustian (Indiana University), Jemima Kamano (Moi University), Rajesh Vedanthan (New York University), Omar-Galarraga (Brown University), Benson Njuguna (Moi Teaching and Referral Hospital)
Study Type	Prospective
Specific Aim(s)	Aim 1: Co-design a novel CHV-led model for medication adherence support (CBA intervention) for OALWH using a human-centered design (HCD) approach. Aim 2: Conduct a pilot of CBA intervention and evaluate its feasibility. Aim 3. Conduct costing and budget impact analysis (BIA) on CBA intervention.
Site(s)	N/A
Project Period	7/1/2023 - 6/30/2028
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and 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 (University of Southern California), Michael Scanlon (Indiana University), Julie Thorne (University of Toronto), Edith Apondi (Moi Teaching and Referral Hospital), 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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

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	Co-Benefits of Co-Delivery of Long-Acting Antiretrovirals and Contraceptives
Principal Investigator(s)	Rena Patel (University of Alabama at Birmingham)
Collaborator(s)	Edwin Were (Moi University), Beatrice Jakait (Moi Teaching and Referral Hospital), Edith Apondi (Moi University), Caitlin Bernard (Indiana University), Kimberly Scarsi (University of Nebraska), David Erickson (Oregon Health & Science University), Kenneth Sherr (University of Washington), Deborah Donnell (University of Washington), Randy Stalter (University of Washington), Catherine Ngugi (NASCOP)
Study Type	Prospective
Specific Aim(s)	Aim 1: To collect foundational data to better inform design of an effectiveness-implementation trial. Aim 1a: To determine if combined cabotegravir/rilpivirine injectable use has bidirectional drug-drug interactions with injectable (depot medroxyprogesterone acetate [DMPA]) or implantable (etonogestrel or levonorgestrel) contraceptives. Aim 1b: To qualitatively explore points of convergence and divergence, preferences and values, and health systems readiness around wider-scale co-delivery of LA ART and contraceptives. Aim 2: To

	evaluate the impact of clinic-provided, co-delivery of LA ART and contraceptives among AGYW/LHIV. Aim 2a: To evaluate the impact on effectiveness outcomes of HIV treatment (viral suppression and adherence/persistence) and contraception (uptake and continuation rates). Aim 2b: To evaluate the impact on implementation outcomes of acceptability, feasibility, and fidelity.
Site(s)	Moi Teaching and Referral Hospital
Project Period	4/1/2021 – 3/31/2026
Sponsor(s)	NIH
Status	Not started -- Study activities have not begun.

Study Title	CoVPN 3008 (Ubuntu) Multi-Center, Randomized, Efficacy Study of COVID-19 mRNA Vaccine in Regions with SARS-CoV-2 Variants of Concern
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	Jamil Said (Moi University), Charles Kwobah (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: PRE-MONTH 6 STAGE: to assess the relative risk of symptomatic COVID-19 in Group 1 (PLWH who are SARS-CoV-2 negative at baseline) who receive a 2-dose mRNA-1273 vaccine regimen vs. in Group 2 (PLWH who are SARS-CoV-2 positive at baseline) who receive a 1-dose mRNA-1273 regimen, counting endpoints starting 1 day after Month 0 dose until Month 6 dose. Aim 2: PRE-MONTH 6 STAGE: to assess the relative risk of severe COVID-19 in Group 1 (PLWH who are SARS-CoV-2 negative at baseline) who receive a 2-dose mRNA-1273 vaccine regimen vs. in Group 2 (PLWH who are SARS-CoV-2 positive at baseline) who receive a 1-dose mRNA-1273 regimen, counting endpoints starting 1 day after Month 0 dose until Month 6 dose. Aim 3: POST-MONTH 6 STAGE: to assess the relative risk of symptomatic COVID-19 after the Month 6 dose among those who received mRNA-1273 at Month 6 vs. those who received mRNA-1273.222 at Month 6, counting endpoints at least 14 days after the Month 6 dose until end of follow up. Aim 4: POST-MONTH 6 STAGE: to assess the relative risk of severe COVID-19 after the Month 6 dose among those who received mRNA-1273 at Month 6 vs. those who received mRNA-1273.222 at Month 6, counting endpoints at least 14 days after the Month 6 dose until end of follow up. Aim 5: To assess the safety and tolerability of mRNA-1273 and mRNA-1273.222 in adults who are at risk of severe COVID-19 in both the pre-Month 6 and post-Month 6 stages
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	3/1/2022 - ongoing
Sponsor(s)	South African Medical Research Council (SAMRC)
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still 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)	Joyce Baliddawa (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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	Data Science for Decision Support in the HIV Care Cascade
Principal Investigator(s)	Joseph Hogan (Brown University), Ann Mwangi (Moi University), Hamish Frasier (Brown University)
Collaborator(s)	Juddy Wachira (Moi University), Edwin Sang (AMPATH), Lameck Diero (Moi University), Jonathan Dick (Indiana University), Rami Kantor (Brown University), Jonathan Teich (Brigham and Women's Hospital), Arman Oganisian (Brown University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Develop and validate statistical machine learning models and algorithms for clinical and programmatic decision support. Aim 2. Develop, implement and field test decision support and data visualization tools to enhance data-driven decision making by physicians and program managers. Aim 3: Conduct evaluation of the impact and efficacy of the clinical decision support tools in Kenya.
Site(s)	All AMPATH sites
Project Period	11/1/2021 - 10/31/2026
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Determining The Frequency of Cytogenetic Abnormalities among Multiple Myeloma Patients in Kenya using an Artificial Intelligence-based Approach: A Retrospective Cohort Study
Principal Investigator(s)	Teresa Lotodo (Moi University)
Collaborator(s)	Mercy Atieno Oduor (AMPATH), Kelvin Manyega (Kabarak University), Beatrice Melly (Moi Teaching and Referral Hospital), Austin Omondi (AMPATH), Diana Flora Namaemba (AMPATH), Yvette Oyolo (AMPATH), Ola Landgren (University of Miami), Francesco Maura (University of Miami)
Study Type	Retrospective
Specific Aim(s)	Aim 1: To determine, by using AI methods, the frequency of suspected cytogenetic abnormalities in multiple myeloma patients at diagnosis based on scanned images

	of H&E and CD138 stained slides. Aim 2: To correlate the AI classification of MM patients at diagnosis with their survival.
Site(s)	Uasin Gishu, Moi Teaching and Referral Hospital
Project Period	10/1/2021 - 12/1/2022
Sponsor(s)	University of Miami
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	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	EA-leDEA: 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), Aggrey Sameere (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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	EA-leDEA: ACE Study
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Kara Wools-Kaloustian (Indiana University), Winstone Nyandiko (Moi University), Batya Elul (Columbia University), Rami Kantor (Brown University), Samuel Ayaya (Moi University), Giorgos Bakoyannis (Indiana University), Leslie Enane (Indiana University), Zachary Kwena (The Family AIDS Care and Education Services)
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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	EA-leDEA: Adolescent and Young Adult Network of leDEA (AYANI)
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Kara Wools-Kaloustian (Indiana University), Zachary Kwena (The Family AIDS Care and Education Services), Batya Elul (Columbia University), Leslie Enane (Indiana University), and Irene Marete (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Describe care engagement patterns (retention, losses-to-follow up), transition indicators (e.g., self-care, socio-demographic data), viral suppression, and mortality among the group of ALWH, both prior to cohort formation and at

	follow-up. Aim 2: Examine the correlates of key clinical and socio-demographic factors with retention and viral non-suppression among ALWH. Factors to be assessed include: gender, HIV-disclosure age, transitions in care, self-reported adherence, pregnancy, stigma, depression, anxiety, trauma, sexual risk behaviors, and substance use. Aim 3: To assess the feasibility of establishing a multiregional cohort of ALWH for in-depth data collection. Feasibility measures include numbers of ALWH eligible, enrolled and retained.
Site(s)	Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia
Project Period	7/1/2021 - 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	EA-leDEA: HIV-1 subtype-specific drug resistance in patients failing dolutegravir-based first-line, second-line or third-line regimens: multiregional study
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University),
Collaborator(s)	Lameck Diero (Moi University), Shamim Ali (Moi University), Suzanne Goodrich (Indiana University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To determine the patterns and spectrum of InSTI DRMs in adults and adolescents with virologic failure on DTG-based ART by ART regimen and HIV-1 subtype. Aim 2: To identify risk factors for virologic failure, InSTI DRMs, and InSTI drug resistance in adolescents and adults on DTG-based ART, including drug, host and health system factors. Aim 3: To investigate correlations between novel resistance genotypes and phenotypic DTG resistance across HIV-1 subtypes.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/15/2023 - ongoing
Sponsor(s)	NIH
Status	Ongoing – Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow-up.

Study Title	EA-leDEA: Jozi Study (Determining Long-Term Clinical Outcomes for HIV-Affected Mother-Infant Dyads in Western Kenya: Sub-Study to the Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO) Study)
Principal Investigator(s)	Jimmy Carlucci (Indiana University)
Collaborator(s)	Audrey Chepkemoi (Moi University), John Humphrey (Indiana University), Kara Wools-Kaloustian (Indiana University), Rena Patel (University of Alabama at Birmingham), Megan McHenry (Indiana University), Edwin Were (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 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). Hypothesis 1: Virologic failure will be more common in WLHIV who are lost to follow-up (LTFU) from the PMTCT program compared to WLHIV who are retained in care. Aim 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. Hypothesis 2: Favorable maternal virologic and retention outcomes will be associated with completion of EID testing, definitive testing after cessation of breastfeeding, and HIV seronegative status (i.e., mitigation of vertical transmission) among HIV-exposed infants.
Site(s)	Uasin Gishu, Moi Teaching and Referral Hospital
Project Period	8/1/2021 - 7/31/2023
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	EA-leDEA: Main Study
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University), Constantin Yiannoutsos (Indiana University), Aggrey Semeere (Makerere University)
Collaborator(s)	Lameck Diero (Moi University), Winstone Nyandiko (Moi University), Edwin Were (Moi University), Ann Mwangi (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)	Fogarty International Center, National Institute of Allergy and Infectious Diseases (NIAID), Eunice Kennedy Shriver, National Institute of Child Health and Human Development (NICHD), National Institute of Drug Abuse (NIDA), National Cancer Institute (NCI), National Institute of Mental Health (NIMH), National Institute Diabetes and Digestive and Kidney Diseases (NIDDK), National Heart, Lung, and Blood Institute (NHLBI)
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	EA-leDEA: Measuring Adverse Pregnancy and Newborn Outcomes (MANGO)
Principal Investigator(s)	Edwin Were (Moi University)
Collaborator(s)	Rena Patel (University of Alabama at Birmingham), Julia Songok (Moi University), Bett Kipchumba (AMPATH), Audrey Chepkemboi (Moi University), Wycliffe Kosgei (Moi Teaching and Referral Hospital), Joy Marsha (AMPATH), Catlin Bernard (Indiana University), Beverly Musick (Indiana University), Laura Oyiengo (AMPATH), Elvis Oyungi (AMPATH), Molly McPheron (Indiana University), Meghan McHenry

	(Indiana University), Edward Leichty (Indiana University), Ushma Mehta (University of Cape Town), Emma Kalk (University of Cape Town), Amy Slogrove (Stellenbosch University), Andrew Boule (University of Cape Town), Mary-Ann Davies (University of Cape Town), Constantin Yiannoutsos (Indiana University), Kara Wools-Kaloustian (Indiana University), Jimmy Carlucci (Indiana University)
Study Type	Mixed prospective and retrospective cohort study
Specific Aim(s)	Aim 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. Aim 2: To create standardized protocols and data exchange standards within IU and leDEA. By leveraging the existing and extensive leDEA 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-leDEA: MANGO CA Study
Principal Investigator(s)	Audrey Chepkemoi (Moi Teaching and Referral Hospital)
Collaborator(s)	John Humphrey (Indiana University), Edwin Were (Moi University), Julia Songok (Moi University), Bett Kipchumba (AMPATH), Wycliffe Kosgei (Moi Teaching and Referral Hospital), Caitlin Bernard (Indiana University), Beverly Musick (Indiana University), Steve Brown (Indiana University), Molly McPheron (Indiana University), James Carlucci (Indiana University), Megan McHenry (Indiana University), Kara Wools-Kaloustian (Indiana University), and Rena Patel (University of Alabama at Birmingham)
Study Type	Retrospective
Specific Aim(s)	The objective of this study is to develop a user-centered model for service delivery optimized to meet the needs of families with infants diagnosed with major congenital abnormalities in resource-limited settings. Aim 1. Explore community perceptions, lived experiences and care needs of families with infants diagnosed with congenital abnormalities in resource-limited settings. Aim 2. Develop a service delivery model optimized to meet the needs of families with infants diagnosed with congenital abnormalities in resource-limited settings.
Site(s)	Moi Teaching and Referral Hospital
Project Period	11/24/2022 - 11/23/2023
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-leDEA Networks in Kenya
Principal Investigator(s)	Jennifer Syvertsen (University of California, Riverside)
Collaborator(s)	Lukoye Atwoli (Aga Khan University), Edith Kwobah (Moi Teaching and Referral Hospital), Suzanne Goodrich, (Indiana University), Karla D Wagner (University of Nevada), Maurice Aluda (KEMRI/FACES), Jayne Kulzer (University of California San Francisco), 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 leDEA-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 - 3/13/2020
Sponsor(s)	NIH
Status	Ongoing – manuscript in process

Study Title	EA-leDEA: NIDA Study
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Lameck Diero (Moi University), Suzanne Goodrich (Indiana University), Edith Kwobah (Moi Teaching and Referral Hospital), Patrick Oyaro (FACES/RCTP/KEMRI), Maurice Aluda (FACES/RCTP/KEMRI), Jayne Kulzer (University of California, San Francisco)
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 leDEA 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 – Manuscripts in process.

Study Title	EA-leDEA: PHQ 9 Study
Principal Investigator(s)	Marcel Yotebieng (Albert Einstein College of Medicine)
Collaborator(s)	Kathryn Lancaster (Ohio State University), Lukoye Atwoli (Aga Khan 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 regions 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	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	EA-leDEA: 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 (Moi Teaching and Referral Hospital), Marsha Alera (AMPATH), Libby Pfeiffer (Rhode Island College), Julia Songok (Moi University), Winfred Mwangi (Moi Teaching and Referral Hospital), Wycliffe Kosgei (Moi Teaching and Referral Hospital), Beverly Musick (Indiana University), Constantin Yiannoutsos (Indiana University), Juddy Wachira (Moi University), Kara Wools-Kaloustian (Indiana University)
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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	EA-leDEA: 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 (Mount Sinai), Winstone Nyandiko (Moi University), Patrick Monahan (Indiana University), Alka Khaitain (Indiana University), Zeruesenay Desta (Indiana University), Amy Slogrove (Stellenbosch University), Rena Patel (University of Alabama at Birmingham)
Study Type	Longitudinal follow up of the enrolled study participants for 2 years.
Specific Aim(s)	Aim 1: 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	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	EA-leDEA: Sentinel Research Network (SRN)
Principal Investigator(s)	Niharika Samala (Indiana University)
Collaborator(s)	Kara Wools-Kaloustian (Indiana University), Lameck Diero (Moi University), Suzanne Goodrich (Indiana University), Edith Kwobah (Moi Teaching and Referral Hospital), Mercy Karoney (Moi University), Felix Barasa (Moi Teaching and Referral Hospital), Alexa Monroy (Children's Hospital Los Angeles), Samir Gupta (Indiana University), Fatuma Some (Moi University)
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 - 5/31/2027
Sponsor(s)	NIH
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	EA-leDEA: Syndemics Study
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Suzanne Goodrich (Indiana University), Jennifer Syvertsen (University of California, Riverside), Jayne Kulzer (University of California, San Francisco), Maurice Aluda (FACES/RCTP/KEMRI), Lukoye Atwoli (Aga Khan University), Edith Kwobah (Moi Teaching and Referral Hospital)
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 - Data analysis work is complete. Two manuscripts are under review.

Study Title	EA-leDEA: The Desire to Avoid Pregnancy Post-partum (DAPP Study)
Principal Investigator(s)	Wycliffe Kosgei (Moi Teaching and Referral Hospital)
Collaborator(s)	Caitlin Bernard (Indiana University)
Study Type	Tool development/validation
Specific Aim(s)	Aim 1: Conduct focus group discussions (FGDs) and field-testing, we will engage women and providers living in western Kenya to modify the existing scale items and responses and test the performance of these modified items to develop a final adapted DAP scale. Aim 2: Evaluate the psychometric performance of the adapted DAP scale, including internal consistency, confirmatory fit to a one-factor model, and predictive validity, including whether DAP scale score predicts contraceptive use postpartum. Aim 3: Compare the performance of the adapted DAP scale between Women living with HIV vs Women Not Living with HIV.— We will leverage the cohort of women enrolled in the MANGO-Kenya study, which plans to recruit up to 400 women living with HIV and 400 women not living with HIV enrolling in ANC at MTRH. The 800 participants will be contacted and asked to participate in this sub-study during the postpartum period.
Site(s)	Uasin Gishu, Moi Teaching and Referral Hospital
Project Period	9/7/2020 – ongoing
Sponsor(s)	NIH
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	EA-IeDEA: Tuberculosis Sentinel Research Network (IeDEA-EA TB-SRN)
Principal Investigator(s)	Leslie A. Enane (Indiana University)
Collaborator(s)	Neelima Navuluri (Duke University), Lameck Diero (Moi University), Winnie Muyindike (Mbarara University of Science and Technology), Francesca Odhiambo (Kenya Medical Research Institute), Hong-Ha Truong (University of California, San Francisco), Aggrey Semeere (Makerere University), Kara Wools-Kaloustian (Indiana University), Constantin Yiannoutsos (Indiana University), Beverly Musick (Indiana University), Helen Byakwaga (Mbarara University of Science and Technology), David Lagat (Moi University), Cornelius Kipchirchir (AMPATH), Suzanne Goodrich (Indiana University), Jayne Lewis Kulzer (University of California, San Francisco), Michael Bergin (Duke University), Mark Janko (Duke University), Mercedes Bravo (Duke University)
Study Type	Prospective
Specific Aim(s)	<p>Aim 1: To collect and analyze clinical and treatment data among people treated for pulmonary TB with or without HIV-co-infection, in order to improve understanding of the prognosis of TB disease and its health-related outcomes, including quality of life and survival. Regional Objective 1.1: Examine associations between clinical and environmental factors and unfavorable TB treatment outcomes (treatment failure, relapse, death, LTFU). H1.1A: Delays in TB treatment initiation, rifampin-resistance, HIV co-infection, and age are associated with poor treatment outcomes. H1.1B: Exposure to tobacco or indoor air pollution is associated with poor TB treatment outcomes. Regional Objective 1.2: Assess the association between socioeconomic, mental health, and stigma factors with delays in TB treatment initiation, unfavorable TB treatment outcomes, and health-related quality of life. We apply the conceptual model developed of the HIV care continuum (Figure 1) to TB. H1.2: Depression, use of alcohol, and stigma are associated with delays in treatment initiation, unfavorable TB treatment outcomes, and poorer health-related quality of life. Aim 2: To assess the individual-level effects of HIV and antiretroviral therapy (ART) on TB symptomatology, diagnosis, treatment response, and survival. As part of this aim, investigators also will explore the effect of site-level TB and HIV management and integration of TB and HIV services on pulmonary TB treatment and longer-term outcomes. Aim 3: To describe post-TB lung disease (PTLD) and associations with HIV infection, diabetes, chronic lung disease, and tobacco and alcohol use, including measuring physiologic, structural, and functional impairment, health-related quality of life, and survival. Regional H3A: >15% of patients will have evidence of PTLD at 24 months from TB treatment completion. Regional H3B: HIV co-infection, tobacco exposure, indoor air pollution and delays in TB treatment initiation will be associated with post-TB lung disease at 24 months from TB treatment completion.</p>
Site(s)	Kisumu, Moi Teaching and Referral Hospital
Project Period	6/1/2023 - 5/31/2025
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Epidemiology and Genetics of Post traumatic Stress Disorder Among Participants in the Neurogap-P Study
Principal Investigator(s)	Lukoye Atwoli (Aga Khan University)
Collaborator(s)	Gabriel Kigen (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	To understand the prevalence, distribution, and genetics of PTSD in a large Kenyan population of persons utilizing mental health services.
Site(s)	Bungoma, Elgeyo Marakwet, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, West Pakot
Project Period	6/7/2022 -
Sponsor(s)	Broad Institute
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

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-Deb (University of British Columbia), 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	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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

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 Siika (Moi University), Omar Galarraga (Brown University), Paula Braitstein (University of Toronto), Ann Mwangi (Moi University), Sylvester 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	Complete -- Follow up and data analysis are complete, and the study is closed.

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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	Impact of Infection Prevention Care Bundles on Surgical Site Infections Post Cesarean Section in Moi Teaching and Referral Hospital
Principal Investigator(s)	Adrian Gardner (Indiana University)
Collaborator(s)	Wycliffe Kosgei (Moi Teaching and Referral Hospital), Faith Sila (Moi Teaching and Referral Hospital), Jackline Opondo (Moi Teaching and Referral Hospital), Shem Kinara (Moi Teaching and Referral Hospital), Betty Rop (Moi Teaching and Referral Hospital), Sarah Esendi (Moi Teaching and Referral Hospital), Mercy Jelimo (Moi Teaching and Referral Hospital), Vitalis Orango (Moi Teaching and Referral Hospital), Luke Sartino (IU Health), Catherine Sartino (IU Health), Marnie Sieber (IU Health), William Fadel (IU Health), Kristen Kelley (IU Health), Bilal Jawed (Indiana University)

Study Type	Pre-post study design
Specific Aim(s)	Aim 1: Identify the current healthcare provider antimicrobial prescribing patterns for patients undergoing cesarean section and implement cesarean section surgical site surveillance at MTRH. Aim 2: Determine the antimicrobial susceptibility patterns in cesarean section wound infections and compare against antimicrobials prescribed. Aim 3: Identify the baseline prevalence of surgical site infections and analyze the short- and long-term complications of SSI after cesarean section. Aim 4: Calculate and analyze the prevalence of health disparities in patients having cesarean section complications. Aim 5: Based on objectives 1-4, develop a surgical site infection practice bundle and policy designed around pertinent risk factors: determinants of health, antimicrobial use, modifiable risk factors and clinical gaps in care and implement surgical site infection bundle and policy and evaluate outcomes.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	1/1/2022 -
Sponsor(s)	Pfizer
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	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)	The aim of this project is 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, Uasin Gishu
Project Period	10/1/2019 – 9/30/22
Sponsor(s)	Pfizer Foundation
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

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 (Indiana University), Jemima Kamano (Moi University), Sonak Pastakia (Purdue University), Violet Naanyu (Moi University), Rajesh Vedanthan (New York University)

Study Type	Mixed methods
Specific Aim(s)	Aim 1: 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 OALWH ii) Assess feasibility and acceptability of utilizing AMPATH's HIV care platform to provide diabetes and hypertension screening and treatment services to older adults living with HIV.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	7/1/2021 – 6/30/2022
Sponsor(s)	NIH-Fogarty International Center
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	JSVCT109 "A global multicenter, randomized, double-blind, placebo-controlled, phase III clinical trial to evaluate the efficacy, safety, and immunogenicity of recombinant COVID-19 vaccine (Sf9 cell) for the prevention of COVID-19 in adults aged 18 years and older "
Principal Investigator(s)	Sylvester Kimaiyo (Moi University)
Collaborator(s)	Nicholas Kirui (Moi Teaching and Referral Hospital), Thomas Andale (Moi Teaching and Referral Hospital)
Study Type	Prospective
Specific Aim(s)	Aim 1: To evaluate the efficacy of recombinant COVID-19 vaccine (Sf9 cells) in preventing virologically confirmed (PCR positive) symptomatic COVID-19 cases first occurring 28 days after completion of 3 vaccination doses, regardless of severity. Aim 2: To evaluate the incidence of SAEs, MAAEs and AESIs from Day 0 through 6 months after completion of 3 doses vaccination and the reactogenicity (the incidence of solicited AEs and unsolicited AEs) in all participants.
Site(s)	Elgeyo Marakwet, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu, Vihiga
Project Period	10/4/2021 - 3/31/2023
Sponsor(s)	WestVac Biopharma Co., Ltd. and West China Hospital of Sichuan 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	Making Inroads to Strengthen the Health of Adolescents (MAISHA)
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 (Moi Teaching and Referral Hospital), 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	Complete -- Follow up and data analysis are complete and the study is closed.

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)	Evangeline Njiru (Moi University), Susan Krown (Memorial Sloan Kettering), Samantha Vogt (Johns Hopkins)
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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	NeoInnovate Collaborative Consortium
Principal Investigator(s)	Sherry 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)	Bungoma, Busia, Kakamega, Moi Teaching and Referral Hospital, Indiana
Project Period	07/01/2016 - ongoing

Sponsor(s)	None
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	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 the 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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	Neurogap-Psychosis Follow-up Study on Anhedonia, Obsessive Compulsive Disorder, Discrimination, and Suicidality
Principal Investigator(s)	Lukoye Atwoli (Aga Khan University)
Collaborator(s)	Edith Kwobah (Moi Teaching and Referral Hospital)
Study Type	Cross-sectional
Specific Aim(s)	The main aim of this project is to understand the prevalence, distribution, and genetics of anhedonia obsessive-compulsive symptoms, discrimination and suicidal behavior in a Kenyan population.
Site(s)	Bungoma, Elgeyo Marakwet, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, West Pokot
Project Period	8/16/2023
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	NIH Chemopad
Principal Investigator(s)	Jesse Opakas (Moi University)
Collaborator(s)	Imran Manji (Moi Teaching and Referral Hospital), Marya Lieberman (University of Notre Dame), Rakhi Karwa (Purdue University), Sonak Pastakia (Purdue University)
Study Type	
Specific Aim(s)	Aim 1: Pilot the ChemoPAD and its reader application as a SSFFC detection strategy for screening the quality of chemotherapeutic drugs in Kenya. Aim 2: Carry out a post-market surveillance of the quality of the chemotherapeutic drugs samples using a combination of ChemoPAD for screening and HPLC confirmatory test results. The ChemoPAD will be used for screening the quality of a medication and any suspicious samples will be analyzed by HPLC. Aim 3: Train healthcare providers who prepare patient doses to screen drug quality with the ChemoPAD and evaluate their proficiency. Aim 4: Compare results from screening real products with the ChemoPAD at the point of use, with the "gold standard" of HPLC testing. Aim 5: Improve access to safe and quality medication by reporting to the national regulatory body, Pharmacy and Poisons Board, and WHO Rapid Alert system on substandard or poor-quality chemotherapeutic drugs. The medication will be classified as substandard or poor quality using HPLC results.
Site(s)	Moi Teaching and Referral Hospital
Project Period	1/8/2022 - 7/31/2027
Sponsor(s)	NIH through University of Notre Dame
Status	Other
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)	Aim 1: Develop and apply scalable statistical framework for optimal targeting of gold standard diagnostic tests used to monitor HIV treatment under resource constraints; Aim 2: Apply causal inference techniques to calibrate decision rules using estimated decision utilities; Aim 3: Develop methods to optimize pooling strategies for viral load testing in resource limited settings; Aim 4: To implement and cross validate new algorithms for viral load pooling using samples from drug resistant patients
Site(s)	All AMPATH clinics
Project Period	2/3/2016 – 10/31/2022
Sponsor(s)	NIH-NIAID
Status	Complete -- Follow up and data analysis are complete and the study is closed.

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 (New York University), 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 and 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 (69.9percent 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	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	Participatory research approach to the development of an enhanced mentor mother strategy (PaRADE-MMS)
Principal Investigator(s)	James Carlucci (Indiana University)
Collaborator(s)	Rosa Chemwey (Moi University), Kara Wools-Kaloustian (Indiana University), Violet Naanyu (Moi University), Edwin Were (Moi University)
Study Type	Cross-sectional
Specific Aim(s)	Aim 1: Assess perceptions of existing MM services and the ability of these services to identify and then impact modifiable factors that influence HIV-affected mother-infant dyads' PMTCT outcomes. Aim 2: Develop an enhanced MM strategy that can respond to the specific needs of HIV-affected mother-infant dyads and that is acceptable and feasible for implementation in resource-constrained settings.
Site(s)	Busia, Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	10/27/2022 - ongoing

Sponsor(s)	NIH-NICHD
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), Thomas Inui (Indiana University), Ann Mwangi (Moi University), Michael Scanlon (Indiana University), Megan McHenry (Indiana University), Irene Marete (Moi University), Joseph Hogan (Brown University), Colin Klein (AMPATH)
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)	National Institute of Mental Health
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 (Indiana University), 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	Complete -- Follow up and data analysis are complete and the study is closed.
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 (Moi Teaching and Referral Hospital), Rebecca Lumsden (Duke University)
Study Type	Prospective
Specific Aim(s)	Aim 1: 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.

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. No updates provided for the current reporting period.
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 (New York University), Andrea Troxel (New York University), Benson Njuguna (Moi Teaching and Referral Hospital), Jeremiah Laktabai (Moi University), Imran Manji (Moi Teaching and Referral Hospital), Ann Mwangi (Moi University), Jonathan Dick (Indiana University), Dustin Duncan (Columbia University), 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 the impact on systolic blood pressure, medication adherence, and fidelity of implementation. We also included a retrospective control group to match these participants by sex, age, and initial blood pressure.
Site(s)	Bungoma, Trans Nzoia, Uasin Gishu
Project Period	9/25/2020 - 4/30/2024
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	SAFI (Stigma in AIDS Family Inventory) Validation Study
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Irene Marete (Moi University), Violet Naanyu (Moi University), Hai Liu (Indiana University)
Study Type	Prospective
Specific Aim(s)	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	Complete -- Follow up and data analysis are complete, and the study is closed.

Study Title	Scaling Up Primary Health Integrated Care for Chronic Conditions in Kenya: An Implementation Research Project (PIC4C Scale Up Study)
Principal Investigator(s)	Pablo Perel (London School of Hygiene and Tropical Medicine)
Collaborator(s)	Jemima Kamano (Moi University), Edwine Barasa (Kenya Wellcome Trust Research Programme), Ellen Nolte (London School of Hygiene and Tropical Medicine), A/P Gasparini (London School of Hygiene and Tropical Medicine), Adrianna Murphy (London School of Hygiene and Tropical Medicine), Ruth Willis (London School of Hygiene and Tropical Medicine), Prof. Hanson (London School of Hygiene and Tropical Medicine), Anthony Etyang (Kenya Wellcome Trust Research Programme), Vincent Were (Kenya Wellcome Trust Research Programme), Violet Naanyu (Moi University), Nicholas Kirui (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To understand the implementation process to assess the quality of leadership and management; levels of stakeholder involvement; adequacy of support mechanisms and resources; ability to adapt the intervention locally; and quality of communication and of monitoring and feedback; Aim 2: To understand the experiences of patients to assess whether and how well the PIC4C model meets the needs of those affected by the selected NCDs; Aim 3: To assess the health benefits (on hypertension, diabetes and cancer control) and potential unintended consequences (on HIV viral suppression) of the implementation of the PIC4C pilot; Aim 4: To evaluate the effectiveness of the NHIF chronic care benefit package to provide financial risk protection, to be responsive to the needs of individuals, to influence equity, efficiency, quality of care, and service delivery.
Site(s)	Busia, Trans Nzoia
Project Period	8/1/2020 – 8/31/2022
Sponsor(s)	UK Medical Research Council (MRC) through Global Alliance for Chronic Diseases
Status	Complete -- Follow up and data analysis are complete and the study is closed.

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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

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 (Moi University), Winstone Nyandiko (Moi University), Violet Naanyu (Moi University), Bett Kipchumba (Moi Teaching and Referral Hospital), Marsha Alera (AMPATH), Alan McGuire (Indiana University), Beverly Musick (Indiana University), James Carlucci (Indiana University), Constantin Yiannoutsos (Indiana University), Gregory Zimet (Indiana University), Kara Wools-Kaloustian (Indiana University)
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	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	Stawisha Jamii - Development of a Family-Level Problem Solving Intervention for Adolescents Living with HIV
Principal Investigator(s)	Leslie Enane (Indiana University)

Collaborator(s)	David Ayuku (Moi University), Eve Puffer (Duke University), Courtney Myers (Indiana University), Edith Apondi (Moi Teaching and Referral Hospital), Paula Braitstein (University of Toronto), Kara Wools-Kaloustian (Indiana University), Rachel Vreeman (Mount Sinai University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Engage key stakeholders to determine the relevant needs and preferences for a family-level problem solving intervention (FPSI) for vulnerable ALHIV. Aim 2: Develop an FPSI for vulnerable ALHIV that is adaptable to address a range of barriers to care experienced at the family or household level. Aim 3: Pilot an FPSI to support HIV care for vulnerable ALHIV.
Site(s)	Bungoma, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	4/11/2022 - ongoing
Sponsor(s)	Unfunded
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS)
Principal Investigator(s)	Constantine Akwanalo (Moi University)
Collaborator(s)	Jemima Kamano (Moi University), Benson Njuguna (Moi University), Violet Naanyu (Moi University), Ann Mwangi (Moi University), Timothy Mercer (University of Texas at Austin), Rajesh Vedanthan (New York University), Sonak Pastakia (Purdue University), Jonathan Dick (Indiana University), Makeda Williams (National Heart, Lung and Blood Institute)
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 - 5/31/2024
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	Study of Suspected Kaposi's Sarcoma at the Academic Model Providing Access to Healthcare (AMPATH) clinics, Eldoret, Kenya
Principal Investigator(s)	Samson Kiprono (Moi University)
Collaborator(s)	Toby Maurer (Indiana University), Aggrey Semeere (Makerere University), Helen Byakwaga (Infectious Diseases Institute), Esther Freeman (Harvard University), Sigrid Collier (University of Washington), Jeffrey Martin (University of California, San Francisco)
Study Type	Prospective
Specific Aim(s)	Aim 1: To monitor critical epidemiologic parameters of KS among HIV-infected individuals in East Africa, specifically stage of disease at time of KS diagnosis and survival after KS diagnosis. Aim 2: Assess the predictive accuracy of two approaches to distinguish KS from non-KS to enhance KS diagnosis: using deep-learning algorithms on KS lesion photographic images and using blood and tissue samples to detect KSHV via nucleic acid amplification. Aim 3: Monitor survival of persons diagnosed with KS and evaluate determinants of survival, including linkage to multidisciplinary KS care.
Site(s)	Busia, Moi Teaching and Referral Hospital, Clinics within the AMPATH Network
Project Period	7/1/2021
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	Subclinical Cardiac Dysfunction in Children and Adolescents with and without HIV
Principal Investigator(s)	Gerald Bloomfield (Duke University)
Collaborator(s)	Winstone Nyandiko (Moi University), Myra Maghasi Koech, (Moi Teaching and Referral Hospital), Andrew McCrary (Duke University), Piers Barker (Duke University), Svati Shah (Duke University), Nathan Thielman (Duke University)
Study Type	Prospective
Specific Aim(s)	To determine if advanced echocardiographic measures of cardiac function can detect early stages of cardiomyopathy in CALHIV and if the burden of subclinical changes on echocardiography is dissimilar from HEU and HU children.
Site(s)	Uasin Gishu, Moi Teaching and Referral Hospital
Project Period	9/21/2021 - 12/31/2022
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	The East Africa Consortium for HPV and Cervical Cancer in Women living with HIV/AIDS
Principal Investigator(s)	Patrick Loehrer (Indiana University)
Collaborator(s)	Darron Brown (Indiana University), Miriam Nakalembe (Makerere University), Omenge Orang'o (Moi Teaching and Referral Hospital), Jeff Bailey (Brown University), Susan Cu-Uvin (Brown University), Aaron Ermel (Indiana University), Peter Itsura (Moi Teaching and Referral Hospital), Rachel Katzenellenbogen (Indiana University), Agnes Kiragga (Makerere University), Robert Lukande (Makerere University), Ann Moormann (University of Massachusetts), Beverly Musick (Indiana University), Ann Mwangi (Moi University), Damalie Nakanjako (Makerere University), Elly Odongo (Moi Teaching and Referral Hospital), Kirtika Patel (Moi Teaching and Referral Hospital), Barry Rosen (Beaumont Health), Yan Tong (Indiana University), Philip Tonui (Moi Teaching and Referral Hospital), Ronald Tonui (Moi Teaching and Referral Hospital), Constantin Yiannoutsos (Indiana University), Benson Macharia (Moi Teaching and Referral Hospital)
Study Type	Prospective
Specific Aim(s)	Aim 1: To establish a sustainable research infrastructure for an international partnership to conduct impactful research in HPV and cervical cancer in women living with HIV/AIDS. Aim 2: To design and execute three integrated projects that advance the knowledge of the environmental and biologic factors leading to cervical cancer in East Africa: Project 1- Preventing cervical cancer in HIV-infected women Project 2- Understanding CIN2+ among HIV infected women after LEEP: An epidemiological and immunohistochemical study Project 3- Determining biological and viral factors associated with clinical progression of cervical dysplasia in HIV-infected women. Aim 3: To increase the research workforce capacity in East Africa through mentoring, training programs and targeted pilot projects
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Uasin Gishu, Kampala (Uganda)
Project Period	9/7/2020 - 8/31/2025
Sponsor(s)	NIH-NCI
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still 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 (WeTel 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 WeTel 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 WeTel 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	Complete -- Follow up and data analysis are complete, and the study is closed.

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 (Indiana University), Niharika Samala (Indiana University), Suzanne Goodrich (Indiana University), Mercy Karoney (Moi University), Alexa Monroy (Children's Hospital Los Angeles)
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 – 7/31/2022
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	Training in HIV Implementation Science and Dissemination in Kenya
Principal Investigator(s)	Mabel Nangami (Moi University), Winstone Nyandiko (Moi University), Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	
Study Type	Training Program
Specific Aim(s)	Aim 1: To build a sustainable educational infrastructure to support training in HIV implementation science and dissemination in western Kenya. This will be achieved by enhancing existing degree programs and supporting the establishment of emerging degree programs at Moi University School of Public Health. Aim 2: To expand human resource capacity in HIV implementation science and dissemination that promotes collaboration between academia and county health teams. This will be accomplished by supporting training for 12 masters and two doctoral students, including six masters students representing county health teams. Aim 3: To support continuation of trainees in HIV implementation science and dissemination. This will be accomplished by establishing a competitive post-graduate fellowship program to conduct research embedded in county health teams and by training 5 post-graduate fellows within this program.
Site(s)	N/A
Project Period	04/01/2023 - 03/31/2028
Sponsor(s)	NIH FIC
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	Tuko Pamoja
Principal Investigator(s)	Eve Puffer (Duke University)
Collaborator(s)	Florence Jaguga (Moi University)
Study Type	Prospective
Specific Aim(s)	Provide counseling intervention to families to decrease family conflicts and improve family functioning.
Site(s)	Uasin Gishu
Project Period	1/31/2014 - ongoing

Sponsor(s)	Duke University
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
<hr/>	
Study Title	Tujenge Akina Baba Study (TAB Study)
Principal Investigator(s)	Ali Giusto (Columbia University)
Collaborator(s)	Florence Jaguga (Moi Teaching and Referral Hospital)
Study Type	Prospective
Specific Aim(s)	Aim 1: Explore the preliminary effectiveness of the intervention on fathers' mental health; Aim 2: Use mixed methods to explore mechanisms driving change in fathers' mental health, father parenting, and child mental health; Aim 3: Explore the feasibility and acceptability of implementing task-shifted mental health treatment for fathers.
Site(s)	Uasin Gishu
Project Period	9/15/2022 - 8/31/2024
Sponsor(s)	National Institute of Mental Health (NIMH)
Status	Not started -- Study activities have not begun.
<hr/>	
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)	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; and 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; and 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.