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SEMI-ANNUAL RESEARCH REPORT

January – June 2011

Project Name:	A Pharmacokinetic Pharmacogenetic Study of HIV - Positive Patients on Combined Anti-Retroviral Theraphy with Kaposis Sarcoma Being Treated with Single Agent Oral Etoposide.		
Investigators:	RM Strother, N. Busakhala, P. Loehrer and E. Njiru		
Start Date:	03/31/2010	**Project End Date:**	03/14/2012
Project Description:	The study explores the influence of genetic variability in drug metabolizing and transport enzymes on the pharmacokinetic parameters of etoposide on patients with cytological/histological confirmation of kaposis Sarcoma and should have been on cART for at least 8 weeks prior to enrolment.		
Update:	The study has enrolled 19 males and 7 females totaling to 26/30. These were from all Oncology clinic sites with Chulaimbo having the highest number of 9, Busia 7, kitale 4, webuye 3 and MTRH 3. Challenges focus mainly on recruitment; - Some patients come very sick , with visceral Kaposis sarcoma - Recruitment process takes a minimum of 8 hours to collect samples. some patient consider it too long.		
Project Name:	A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated Cryptococcal Meningitis		
Investigators:	J. Sidle, A. Siika, W. Owino-Ong'or, D. Lagat K. Wools-Kaloustian		
Start Date:	5/31/2011	**Project End Date:**	Depends on overall accrual rate
Project Description:	A5225/HiFLAC is a phase I/II dose escalation and validation study of the safety, tolerability, and therapeutic effect of an induction-consolidation strategy of high-dose fluconazole alone for the treatment of cryptococcal meningitis (CM) in HIV-infected participants. The goal is to determine the maximum tolerated dose (MTD) of fluconazole and to provide pilot data on its efficacy. HIV-infected participants with CM will be assigned to one of up to 3 induction doses of fluconazole alone: 1200, 1600, or 2000 mg/day. The current study will proceed in two stages. In Stage 1, Dose Escalation, up to three induction doses of fluconazole will be tested in sequentially enrolled cohorts. Stage 2, Dose Validation, will not open until the maximum tolerated dose (MTD) of fluconazole has been identified in Stage 1. In Stage 2, induction doses of fluconazole that are found to be safe in Stage 1 will be tested in simultaneously enrolled cohorts.		
Update:	Overall current accrual is 12 participants. Locally 1 participant has been enrolled.		
Project Name:	A Population Based Study of Hypertension, Diabetes and Target Organ Damage in Western Kenya		
Investigators:	E. Velazquez, S. Kimaiyo, G. Bloomfield, J. Hogan, M. Maghasi, C. Akwanalo		
Start Date:	07/2011	**Project End Date:**	05/2012
Project Description:	Hypertension is one of the increasingly important health challenges facing the African continent and yet data on true community prevalence of hypertension in sub-Saharan Africa (SSA) is limited. The prevalence of hypertension in truly rural populations was said to be a rarity but this must have changed because of adoption of Western lifestyle. Recent studies indicate that the prevalence of hypertension and its clinically important outcomes is steadily increasing in SSA, more in the urban compared to semi urban and rural communities. Similarly, the prevalence of diabetes mellitus is increasing and its presence augments the severity		

	of renal and cardiac disease caused by hypertension. Methodology: The study will be conducted in two phases. Phase one of the study will be a cross sectional study which will be conducted on persons aged 18yrs or older from Mutwot location, Kosirai division, to assess for hypertension and diabetes mellitus. Diagnosis of hypertension and diabetes will be based on the JNC 7 and American diabetes association criteria. In the second phase of the study those individuals who are newly diagnosed with hypertension (at least 193 cases) will be assessed for target organ damage and compared to controls (386) in a 1 to 2 ratio. Target organ damage will be defined as the detection of any of the following: electrocardiogram-left ventricular hypertrophy (ECG-LVH) or microalbuminuria or history of a stroke.		
Update:	The study has been submitted to Moi University IREC and has not yet been approved.		
Project Name:	A Retrospective Analysis of Pregnancy Outcomes of HIV-infected Women Enrolled in the AMPATH Program		
Investigators:	A. Bell, E. Were, B. Musick, K. Lane, C. Shen, P. Akhaabi, J. Hogan, K. Wools-Kaloustian		
Start Date:	3/1/2006	**Project End Date:**	12/31/2011
Project Description:	This is a retrospective analysis of pregnancy outcomes of HIV-infected women enrolled in the AMPATH program from January 2006 to March 2009. Per protocol, pregnant women with CD4 < 200 begin cART immediately and those with a CD4 ≥ 200 start at 28 weeks gestation. The pregnancy outcomes are being compared between women pregnant at program enrollment (BE) and those who became pregnant after enrollment (AE). The specific hypotheses include: 1. Women who are already enrolled in the AMPATH program at the time of pregnancy diagnosis are more likely to initiate ART sooner (at a lower gestational age) than those who are not in the program prior to pregnancy diagnosis. 2. Women who are already enrolled in AMPATH at the time of pregnancy diagnosis are less likely to give birth to an HIV-infected baby than those who are not enrolled in the program prior to pregnancy diagnosis. 3. Women who are already enrolled in AMPATH at the time of pregnancy diagnosis will have better retention and adherence rates than those who are not enrolled in the program prior to pregnancy diagnosis. 4. Women who are already enrolled in the AMPATH program will have a lower rate of stillbirth and infant loss than those who are not enrolled in the program prior to pregnancy diagnosis.		
Update:	We are awaiting the dataset for analysis.		
Project Name:	A Stage 2 Cognitive-Behavioral Trial: Reduce Alcohol First In Kenya Intervention (RAFIKI)		
Investigators:	R. Papas, B. Gakinya, J. Baliddawa, J. Sidle		
Start Date:	9/1/2011	**Project End Date:**	8/31/2016
Project Description:	This study will determine whether a group cognitive-behavioral therapy intervention that demonstrates preliminary evidence of reducing alcohol use among HIV-infected outpatients in western Kenya is effective when compared against a group health education intervention in a large sample over a longer period of time. It will be delivered by paraprofessionals, individuals with limited formal education and little or no relevant professional experience. This approach is consistent with successful cost-effective models of service delivery in resource-limited settings in which paraprofessionals (e.g., clinical officers, traditional birth attendants and peer counselors)		

	are trained.		
Update:	hasn't begun yet		
Project Name:	A5208/OCTANE Optima Combination Therapy After Nevirapine Exposure (OCTANE)		
Investigators:	K. Wools-Kaloustian, A. Siika, S. Kimaiyo, D. Owino-Ong'or, J. Sidle		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	The study enrolled two groups of female participants, one group are those who took single dose nevirapine for PMTCT and others are those who did not, all were ARV naïve participants. A total of 64 participants were enrolled. 58 were enrolled to step 3 (an observational step) where they will be followed for up to 72 weeks after study discontinuation.		
Update:	No update		
Project Name:	A5221/STRIDE "A Strategy Study of immediate versus Deferred Initiation of Antiretroviral Therapy for HIV infected persons Treated for TB with CD4<200 cells/mm3" Version 1.0 dated 14 March, 2009.		
Investigators:	J. Sidle, A. Siika, F. Some		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	The study enrolled participants with CD 4 count <200 and had TB. One group was started on ARVs within 2 weeks of initiating anti TBs and another between 8-12 weeks. The study seeks to determine if immediate (within 2 weeks) or deferred (8- 12 weeks) initiation of ART reduces mortality and AIDS defining events in participants.		
Update:	No update		
Project Name:	Acceptance of HIV Testing for Children Identified Through a Program of Voluntary Home-Based HIV Counseling and Testing in Western Kenya		
Investigators:	R. Vreeman, W. Nyandiko, P. Braitstein, M. Were, S. Wiehe		
Start Date:	1/2009	**Project End Date:**	12/2011
Project Description:	Analyses of rates of acceptance of pediatric HIV testing and prevalence of pediatric HIV determined through home-based counseling and testing.		
Update:	Initially conducted a multivariable analysis of HCT data from Turbo assessed which factors are associated with pediatric testing uptake. These findings were published in Journal of Acquired Immune Deficiency Syndromes in October of 2010. Planning additional analyses with data being collected prospectively on barriers to acceptance of pediatric testing in HCT and data from Webuye and other sites to assess the variance in pediatric testing acceptance in HCT.		
Project Name:	ALARM International Program Evaluation		
Investigators:	R. Spitzer, E. O'rango, S. Taleski, A. Bocking, D. Caloia		
Start Date:	10/2009	**Project End Date:**	08/15/2011
Project Description:	Before and after evaluation of the AIP EMOC training program looking at maternal and neonatal outcomes.		
Update:	After evaluation was started May 15/11 and will end Aug 15/11 after which analysis will begin.		
Project Name:	Alcohol & HIV in Kenya: Stage 1 Trial of Peer-led Alcohol Behavior Intervention		
Investigators:	R. Papas, D. Ayuku, J. Baliddawa, O. Omolo, J. Sidle, W. Owino-Ong'or, C. Ojwang, R. Songole		

Start Date:	7/1/2007	**Project End Date:**	12/31/2010
Project Description:	Study closed 12/10		
Update:	This project ended December 2010.		
Project Name:	Anticoagulation Project		
Investigators:	S. Pastakia, I. Manji, M. Ouma, C. Akwanalo, E. Schellhase, R. Karwa, C. Saina		
Start Date:	12/1/2008	**Project End Date:**	12/31/2012
Project Description:	A comprehensive pharmacist run anticoagulation care management system customized to a resource constrained setting has been created and implemented. The primary interventional element of this program is the creation of an organized system for INR monitoring of patients requiring anticoagulation with warfarin.		
Update:	The program is continuing to expand as more patients are being enrolled. Publications include: 1) Pastakia SD, Fohl AL, Schellhase EM, Manji I, Ringenberg K. "Needs assessment analysis for vitamin K antagonist anticoagulation in the resource-constrained setting of Eldoret, Kenya" J Am Pharm Assoc. 2010;50:723–725. 2) Pastakia SD, Crisp WI, Schellhase EM, Manji I, Ouma MN, Akwanalo C. "Implementation of a pharmacist managed anticoagulation clinic in Eldoret, Kenya" Southern Med Review (2010) 3;2:20-23 A third paper comparing the performance of the anticoagulation monitoring service to clinics in resource rich settings has been submitted for publication and is under review. The impact of drug interactions, specifically ART and TB medications, on warfarin dose requirement is currently being investigated and analysis of this data is underway.		
Project Name:	Assessing Impact of Kenya Post-Election Crisis on Children in AMPATH		
Investigators:	R. Vreeman, W. Nyandiko, S. Wiehe, R. Smith Yoder, S. Ayaya, P. Gisore, C. Tenge, P. Braitstein		
Start Date:	1/2008	**Project End Date:**	12/2011
Project Description:	This project involves several retrospective analyses of the medical records of pediatric HIV-infected patients in AMPATH to determine the degree of changes in clinic adherence and medication adherence following the post-election crisis in Kenya and the factors associated with non- adherence. It also involves a qualitative component with key informant interviews with pediatric healthcare providers regarding clinic and medication adherence in the post-crisis time period.		
Update:	We completed two retrospective analyses of the de-identified medical records of pediatric HIV-infected patients in the AMPATH program in western Kenya to determine changes in antiretroviral therapy adherence and clinic adherence following the post-election crisis in Kenya and the factors associated with their return to clinic or with adherence to medications. One analysis focused on the immediate post-crisis period (through April 2008), and the second looking longitudinally through December 2008. We also completed nine key informant interviews with healthcare providers in the AMPATH system in Kenya in order to offer complementary information on what factors constituted barriers or facilitators for returning to clinic or taking the antiretroviral medicines during this time. Findings were published in Conflict and Health, entitled "Impact of the Kenya post-election crisis on clinic attendance and medication adherence" (2009 April 4:3(1):5.) Findings of the longitudinal analyses will be presented at the 2011 International AIDS Society		

	meeting as a poster presentation in Rome, Italy. A manuscript describing this analysis has also been drafted and is currently under review at JAIDS.		
Project Name:	Assessment and Treatment of Pain at Moi Teaching and Referral Hospital		
Investigators:	G. Gramelspacher, C. Owino, R. Vreeman, F. Njuguna, R. Matthew Strother, K. Huang		
Start Date:	03/26/2011	**Project End Date:**	07/31/2011
Project Description:	Pain assessment is not routinely conducted at Moi Teaching and Referral Hospital (MTRH) in Eldoret, Kenya, and underutilization of analgesics, particularly strong opioids, remains a significant problem. The objectives of this study are to assess the prevalence and intensity of pain in patients at MTRH, and to describe the utilization of pain medications in this setting. The rationale for measuring pain and pain treatment in hospitalized patients is to develop a baseline understanding of the extent of pain in this population and of whether that pain is being recognized and treated by clinicians. In this study, will assess pain in pediatric and adult inpatients at MTRH using two well-established pain scales, the Numerical Rating Scale and the Faces Pain Scale-Revised, and gather pertinent patient data such as admission diagnosis and pain medications received. In our analysis, we will describe the prevalence and intensity of pain among patients surveyed, report any differences in pain levels among subcategories of patients, and determine whether pain is being adequately treated using the Pain Management Index. We expect to find that inpatients at MTRH experience a considerable amount of untreated or undertreated pain.		
Update:	We have completed Phase One of our project, which consisted of 15 cognitive interviews with adult and pediatric patients to test the face validity and cultural acceptability of two pain scales. We have recruited 355 patients for Phase Two of the study, which consists of administering the two pain scales to inpatients at MTRH.		
Project Name:	Biomarkers Of Vincristine Peripheral Neuropathy In Kenyan Children With Cancer		
Investigators:	J. Rennberger, F. Njuguna, M. Strother		
Start Date:	08/2011	**Project End Date:**	08/2012
Project Description:	This is a study to look for genetic polymorphisms in kenyan children that may affect vincristine metabolism.		
Update:	We have received comments from the reviewers, done the necessary corrections and re-submitted the proposal		
Project Name:	Building Competencies through Bilateral International Exchanges-Using Qualitative Methods to Measure the Impact on Pediatric Residents from Host and Visiting Countries in Professionalism, Communication and Systems-Based Care		
Investigators:	D. Litzelman, S. Ayaya, R. Umoren, J. Woodward, R. Vreeman, E. Liechty, L. Diero, D. Lorant, S. Stelzner, M. Palmer		
Start Date:	11/27/2009	**Project End Date:**	6/30/2012
Project Description:	Focus groups to assess the impact of resident exchange project on participating residents from Indiana University School of Medicine (IUSOM), Moi University School of Medicine (MUSM), and Universidad Autonoma del Estado de Hidalgo Health Sciences Campus (UAEH) particularly related competencies in Professionalism, communication, Systems Based Practice, and Practice Based learning and improvement.		
Update:	We conducted focus groups and key informant interviews with 32 participants from all three institutions. Data analysis used the grounded theory process. We have presented the results and		

	two manuscripts are under review for publication. Ongoing recruitment of study participants continues with the goal of comparing experiences between the participating foreign institutions. Presentations 1. Umoren, RA, Woodward, J, Vreeman, RC, Lorant, DE, Stelzner, S, Litzelman, D, Liechty, EA. Building Competencies through Bilateral Medical Exchanges. Platform Presentation 2010 International Association for Service Learning and Community Engagement Annual Conference, Indianapolis, Indiana. 2. Umoren, RA, Woodward, J, Vreeman, RC, Palmer MM, Stelzner, S, Lorant, DE, Riner, ME, Liechty, EA, Litzelman, D. Building Bridges to Competency Through Global Health Electives. Poster Presentation. Pediatric Academic Societies and Asian Society for Pediatric Research 2011 Joint Meeting, Denver, Colorado Papers under review 1. Umoren R, Einterz R, Litzelman D, Pettigrew R, Ayaya SO, Liechty EA. Reciprocity in Global Health Partnerships: Hosting International Exchange Physicians. 2. Umoren, RA, Woodward, J, Vreeman, RC, Palmer MM, Stelzner, S, Lorant, DE, Riner, ME, Liechty, EA, Litzelman D. Can Core ACGME Competencies Be Learned Through Global Health Experiences?		
Project Name:	Causes of Early Mortality in HIV-infected Africans on Antiretroviral Therapy		
Investigators:	A. Siika, D. Chumba, N. Buziba, R. Ayikukwei, W. Tierney, K. Wools-Kaloustian, J. Carter, C. Yiannoutsos		
Start Date:	07/2009	**Project End Date:**	06/2013
Project Description:	The autopsy study aims to determine the causes of early mortality in AMPATH -enrolled HIV-infected African patients on ART. The central hypothesis in this study is that the vast majority of early deaths in HIV-infected African patients on ART are caused by treatable infectious complications. The rationale behind this research study is that interventions to interrupt early death in HIV-infected patients on ART are more likely to succeed if they target cause-specific mortality. Further, solutions to HIV care and treatment challenges in sub-Saharan Africa are more likely to be found if the research conducted addresses the region's specific healthcare needs and the results of such research can be translated into local practice. The study has two specific aims:1. To establish the causes of death by performing detailed pathological autopsies in patients who die in the first 12 months of ART.2. To develop a verbal autopsy questionnaire that is accurate, specific to HIV infection, and appropriate for identifying causes of death in resource constrained settings.		
Update:	Kennedy Kenina joined the team as a Data Assistant in May 2011. He works on 50% effort Autopsy and 50% effort M-DART Study. He is responsible for all data entries for the study. Training The study team who had not done their training on ART are currently undertaking the course. Autopsy Electronic Database We have developed an electronic database for the study. The data base is complete and Ken is currently undertaking data entry. Some of our preliminary findings have been forwarded to our Biostatician for analysis, further information on this shall be provided in our forthcoming semi annual report. Central Review Board The study is planning to hold Central Review Board (CRB) Round 2 on the 22nd July 2011 and assign cause of death for the next batch of 100 participants. In December the study held a separate CRB for assinging cause of death using information acquired from the Verbal Autopsy, this is in line with our objective ii.		

	Major Challenges Experienced We still experience some challenges in recruitment: largely because of mismatch in records. Deceased subjects who were on record in the ward as being on ART do not appear in the AMPATH database. We have since established 2 major reasons this happens a. Some participants register at AMPATH with proxy names b. Some participants attend non-AMPATH clinics c. Some participants are being admitted while very sick hence no time to enroll in AMPATH database d. Some participants are newly diagnose hence not on ARVs.		
Project Name:	CD4 Decline		
Investigators:	J. Hogan, L. Diero, K. Wools-Kaloustian, A. Siika, C. Shen, B. Musick		
Start Date:	n/a	**Project End Date:**	n/a
Project Description:	A Retrospective analysis to assess the optimal testing strategy for CD4 counts in patients who do not require ART immediately on presentation to AMPATH		
Update:	Analysis and Analysis update complete This project has been turned over to J. Hogan to identify an junior biostats faculty member to complete the paper.		
Project Name:	CDC- Reproductive Health Records Study		
Investigators:	H. Mabeya, W. Aruasa, R. Spitzer, D. Caloia, E. Omenge		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Identifying if the switch to electronic records for antenatal care improves the experience of antenatal care for staff and patients, improves the satisfaction of staff and patients involved in antenatal care and improves the inclusion of vital antenatal care information in the charts at MTRH clinic.		
Update:	No update received		
Project Name:	Cervical Cancer See and Treat: How Best to Follow-Up		
Investigators:	Susan Cu-Uvin, E. O'rango, Hillary Mabeya, S. Washington		
Start Date:	09/01/2011	**Project End Date:**	08/31/2011
Project Description:	This is a cross sectional study involving 660 HIV-infected women attending 3 AMPATH-CCSPP (Cervical cancer Screening and Prevention Program) sites who have undergone VIA and cryotherapy >6 months for cervical dysplasia. Demographic information as well as a full medical history will be obtained. They will undergo a gynecologic examination. Women with suspected frank cervical cancer or current genital tract infection will not be enrolled and will be referred for standard of care. Women with genital tract infection will undergo syndromic treatment and will be eligible to be enrolled 3 weeks after treatment if they have cleared the infection. During the gyn exam, the following will be done for all study participants: VIA, conventional Pap smear, endocervical cytobrush for HPV typing. All women with positive VIA result will undergo colposcopy and biopsy at the next available colpo/biopsy clinic day. Those with negative VIA result will return in 4-6 weeks to receive the results of their Pap smear and HPV typing. If either the Pap smear or HPV typing is abnormal, they will undergo colposcopy with biopsy on the next available colpo/biopsy clinic day. Women with negative VIA , PAP smear and HPV will follow standard of		

	care that is annual screening with VIA. Histological diagnosis will be the gold standard. Women will be asked several questions regarding their experience.		
Update:	We now have IREC approval for amendments that were suggested by NIH reviewers. The most significant amendment was that we will no longer do blind biopsies on 30% of women who test negative for all three tests i.e VIA, PAP smear, and HPV. We also proposed to increase sample size from 500 to 660. Cryotherapy services took long to be initiated in the three clinics due to logistical reasons. Now the services are up and running since March 2011 and therefore we will enroll the first study participants in September 2011.		
Project Name:	Chulaimbo Adherence and Phone Study (CAPS)		
Investigators:	H. Thirumurthy, D. Ngare, J. Sidle, J. Habyarimana, C. Pop-Eleches, M. Goldstein, J. Graff Zivin, D. DeWalque		
Start Date:	6/13/2007	**Project End Date:**	6/30/2012
Project Description:	This study seeks to understand whether phone-based text message reminders can be used to improve adherence among adult patients receiving ART. The study is an RCT of text message reminders and it measures adherence using medication event monitoring system (MEMS) caps. The project is conducted at the Chulaimbo Rural Health Training Center. 721 new ART patients were enrolled in the study between June 2007 and August 2008. Data collection ended in July 2009.		
Update:	1. Pop-Eleches C, Thirumurthy H, Habyarimana JP, Zivin JG, Goldstein MP, de Walque D, MacKeen L, Haberer J, Kimaiyo S, Sidle J, Ngare D, Bangsberg DR. Mobile phone technologies improve adherence to antiretroviral treatment in a resource-limited setting: a randomized controlled trial of text message reminders. AIDS. 2011 Mar 27;25(6):825-34. 2. Thirumurthy H, Haberer J, Habyarimana JP, Pop-Eleches C, Bangsberg DR. Response to Kelly and Giordano. AIDS. 25(8):1138-1139.		
Project Name:	Comparison of of Protein-Energy Malnutrition and P. falciparum Malaria levels in AMPATH and Non- AMPATH COBES centres in Western Kenya.		
Investigators:	K. Taylor, M. McDowell, A. Kwena, S. Mining, J. Wakhisi		
Start Date:	08/2011	**Project End Date:**	08/2013
Project Description:	There are a number of AMPATH Centres that are also used for community based Education and service (COBES) student placement by the school of Medicine of Moi University on an annual basis. The main objective of the proposed study is to compare the levels of protein energy malnutrition and malaria in these centres using non- AMPATH COBES centres as controls. This may elucidate the role played by AMPATH in the study areas.		
Update:	Not yet.		
Project Name:	Computerized Counseling to Promote Positive Prevention and HIV Health in Kenya (CARE+ Kenya)		
Investigators:	A. Kurth, A. Siika, D. Ayuku, J. Beatrice, N. Baliddawa, J. Fortenberry, J. Sidle, K. Wool-Kaloustain		
Start Date:	08/14/2009	**Project End Date:**	06/30/2013, NIH award 1R01MH085577
Project Description:	Specific Aim 1: Adaptation. Adapt a theoretically driven computerized counseling intervention (CARE+_Kenya) for		

	use in western Kenya. [1st 18 months] 2.1.A. Conduct interviews with up to 25 HIV-positive urban and up to 25 rural patients (n <_50 males/females) of the Academic Model for the Prevention & Treatment of HIV/AIDS (AMPATH®) to understand HIV and computer training needs. Conduct two staff focus groups (n~16) to assess positive prevention and ART adherence support practices, beliefs about patient computer use and training needs. 2.1.B. Using above, modify intervention content; translate and record audio files into local Kiswahili. Adapt skill-building videos on 'positive health' (prevention, disclosure, ART adherence, reproductive health, etc.). 2.1.C. Conduct iterative software usability testing with 10 urban and 10 rural patients (n=20) and n=8 staff. Perform 3-day test-retest reliability assessment to establish psychometric performance of measures. 2.2 Specific Aim 2: RCT. Establish biological and behavioral efficacy of a longitudinal HIV computerized counseling intervention in Kenya ('CARE+_Kenya') [Months 18-42] 2.2.A. Longitudinal RCT in an urban and a rural clinic. Randomly assign HIV-positive adults with missed ART doses on self-report, pharmacy refill or pill counts; or unprotected sex in last 6 months, >1 partner in last year, or sexually transmitted infection (STI) in last 3 years; to intervention (n=125) or risk-assessment control (n=125) for baseline, 3, 6, and 9 month sessions. HIV transmission risk will be measured by self-reported unprotected sex with HIV-negative/unknown partner, and trends in C. trachomatis, N. gonorrhoeae, T. vaginalis. ART adherence will be measured by HIV-1 viral load at 0, 6, 9 months, and at all time points, by electronic monitoring, pharmacy refill, self-report, and clinic attendance. 2.3 Specific Aim 3: Establish cost-effectiveness of computerized counseling in Kenya. [Months 1-48] 2.3.A. Follow patients at the two clinics to evaluate standard of care counseling messages and collect patient time-spent data (n=100, at baseline), to determine unmet patient counseling need. 2.3.B. Economically evaluate CARE+_Kenya. If RCT shows the intervention reduces viral load and transmission risks, we will use a Bernoulli transmission dynamics model to estimate number of secondary HIV infections prevented; then create a cost-effectiveness model to calculate 2 incremental cost-effectiveness ratios: 1) cost/HIV infection averted, and 2) cost/disability adjusted life year (DAILY) saved. 2.3.C. If CARE+_Kenya is efficacious and efficient, we will develop a proposal for a cluster-randomized trial to assess translational effectiveness of CARE+_Kenya throughout the AMPATH system.
Update:	Administrative: USA: 1. Part time program coordinator Adam Sirois has been hired at NYU to provide additional technical assistance to the study to prepare for the Usability and RCT phases of the research. Adam replaced Alma Cruz at the beginning of the year. 2. Prof. Marcia Weaver was replaced by Scott Braithwaite, MD, MSc, Associate Professor and Chief of the Section on Value and Comparative Effectiveness (SOLVE) at New York University School of Medicine, has been engaged to conduct the economic evaluation of the study and has also worked with previous AMPATH projects, so he is familiar with the logistics. Economic evaluation work is scheduled for years 3-4 of the study. 3. Dr. Martin C Were has finished his consultation since him main responsibility was for re-

	programming the PDA tool for overseeing the time-motion part of the study which was concluded during the formative phase. Sirois is working on time-motion manuscript for relevant team co-authors to review. 4. Changyu Shen was involved in the time-motion data analyses. Moving forward, Kurth is coordinating with J. Hogan to determine which US-Moi biostatistician support/individuals will be involved with the RCT analysis. Kenya: 1. Two additional Research Assistants have been hired to support the study bringing the total number of full time field staff to 4; 1 study coordinator and 3 research assistants. 2. A data manager/IT specialist also is engaged to support the project in setting up and maintenance of the CARE setup. Achievements: - We electronically convened the DSMB members to keep them abreast of achievements made so far and to get their input on the upcoming RCT expected to start in July. These included individuals from both clinical and social science backgrounds, from all 3 universities involved (Moi, NYU, and Indiana University). All had the opportunity to review progress, SoP format, list of SoPs, and study protocol. - - IRB modifications were successfully submitted to Moi IREC, IU, and once approvals received, to NYU for to adapted recruitment criteria, study phone number and newly hired research assistants. - - The Expert Advisory Panel met to review current Beta CARE+ tool to be rolled out during the Usability Phase content and suggested best ways to enroll and retain study participants. - Study operating procedures (SOPs) have been developed for enrollment, followup, data management, laboratory procedures, and administration during Usability and RCT Phase. - The digital pill tracking eCap bottles arrived in February 2011 and staffs have trained with them. Plans - Software is being finalized in Seattle with input and monitoring Convene regular DSMB meetings/reviews - Launch the RCT phase of the study early July - Produce time-motion and 'cultural adaptation of computer counseling' articles. - Conduct usability testing in June - Begin recruiting for RCT in July/once final software available. Challenges - Due to logistical problems in procurement of Tablet and Server, it will be shipped from the US in preparation for RCT. - Budget for year 2 has been somewhat underspent, in part due to delays in having final software tool / being able to initiate RCT phase. Presentations - Kurth A, Baliddawa J, Were M, Sidle J, Ayuku D, Koster A, Owino R, Ochieng D, Jakait B, Chirchir T, Abiero C,Macharia S, Mule C, Siika A. Adapting a patient-centered computerized counseling tool to support positive prevention and ART adherence. Int'l AIDS Society Scientific Meeting, Rome July 2011 (electronic poster) Publications

	- Two manuscripts are being drafted: a. Time-motion manuscript b. Cultural adaptation of intervention manuscript (will cover Qualitative data, media work, and usability testing) Thanks AMPATH for the support and opportunity to report our progress.		
Project Name:	Conceptual Model of Factors Sustaining Pediatric Adherence to Antiretroviral Therapy in Western Kenya (Qualitative Inquiry into Pediatric Adherence)		
Investigators:	R. Vreeman, W. Nyandiko, S. Ayaya, D. Marrero, E. Walumbe, T. Inui		
Start Date:	3/2007	**Project End Date:**	01/2010
Project Description:	Qualitative research project involving focus groups and individual key informant interviews with parents and caregivers of HIV-infected children taking ART, older children on ART, and healthcare providers of children with ART. The objective was to identify key factors sustaining children's adherence to ART in western Kenya.		
Update:	From this study, we were able to develop a conceptual model to describe pediatric adherence to antiretroviral therapy in the setting of western Kenya. We continue to make use of the transcripts of the interviews and focus groups for grounded theory data analysis and in the development of our pediatric ART adherence measurement strategy and questionnaires. The conceptual model for pediatric ART adherence was published in Qualitative Health Research in December 2009 (Authors and title: Vreeman RC, Nyandiko WM, Ayaya SO, Walumbe EG, Marrero DG, Inui TS. Factors sustaining pediatric adherence to antiretroviral therapy in Western Kenya.)		
Project Name:	Cross-Cultural histories of family care giving to AIDS orphans in Western Kenya		
Investigators:	J. Dickerson, H. Maythia,		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	The goal of the project is to complete a collaborative anthropological clinic-based study that seeks to understand the history of the care-giving experiences of AMPATH supported primary providers of care to AIDS orphans from two different cultural groups in Western Kenya.		
Update:	No update		
Project Name:	Descriptive Analysis of Patients Seen in an Emergency Department in Western Kenya		
Investigators:	R. House, N. Ongaro, Nyabera		
Start Date:	1/1/2011	**Project End Date:**	12/31/2011
Project Description:	We are collecting data regarding all patients presenting to Accident & Emergency, including basic demographics, chief complaints, diagnosis, disposition. This data will better enable the department to focus its resources and education.		
Update:	We have been using several data logs to collect all of the information regarding patients seen in A&E. It has required much time to collect this data as well as locate files for patients with missing information. We will continue to collect data over the course of the year.		
Project Name:	Disclosure of HIV Status to Children: Evaluating the Prevalence and Impact of Telling Children about Their HIV Status in Western Kenya.		
Investigators:	R. Vreeman, W. Nyandiko, Ayaya, Marete, Tenge, Songok, Gisore, Nabakwe, Inui, Wiehe, Hartsell		
Start Date:	3/2011	**Project End Date:**	12/2012

Project Description:	HIV-infected children must eventually learn of their HIV status, but neither the prevalence of disclosure to children nor the impact of disclosure on HIV-infected children have been clearly delineated within the AMPATH HIV care program in western Kenya. The objectives of this study are to measure the disclosure prevalence in the AMPATH clinics, with special attention to whether there are changes in disclosure after AMPATH pediatric disclosure training and protocols are implemented, and to assess how disclosure may impact children. We will assess what information about their HIV status is known by HIV-infected children enrolled in AMPATH. In addition, given the potential for disclosure to impact other areas of the child's life and medical care, we will gather information on the impact of disclosure on key areas in order to measure any changes after the implementation of the disclosure process. The factors that will be closely monitored include adherence to medication, experiences of stigma, and psychosocial issues related to disclosure.		
Update:	IRB approval secured in 12/2010, but continue to wait for IREC review and approval more than 8 months after submission of proposal. Disclosure training curriculum developed and planned. Implementation of evaluation of disclosure prevalence to be implemented first in Module 4 MTRH as soon as approvals secured. If able to gather pilot data with this un-funded evaluation, hope to apply for R01 in November 2011 in response to NICHD RFA for proposals related to disclosure to children in resource-limited settings.		
Project Name:	Disease Outcomes in HIV Infected Patients with Invasive Cervical Cancer		
Investigators:	S. Washington, E. O'rango, B. Rosen, G. Del Priore, C. Lynch		
Start Date:	10/17/2011	**Project End Date:**	5/1/2012
Project Description:	This is a retrospective review of the Cervical Cancer Surgical Database which intends to determine the relationship between HIV serostatus and disease outcomes in invasive cervical cancer patients. Objectives include immediate postoperative morbidity and mortality rates, progression free survival rates at 2 years, radiation tolerance, and correlation with CD4 counts. This analysis will also provide a general description of HIV infection rates in the local invasive cervical cancer population.		
Update:	This is a resident research project. Dr. Lynch, IU Ob Gyn Resident, will be on site in October/November 2011.		
Project Name:	Does Home-Based Counseling and Testing Work: The Clinical Impact of HCT		
Investigators:	P. Braitstein, S. Ndege, S. Kimaiyo, J. Wachira, R. Kioko, J. Mamlin		
Start Date:	2009	**Project End Date:**	not indicated
Project Description:	This is a retrospective analysis based on the hypothesis that persons testing HIV-positive through HCT will have a higher CD4 count and less advanced disease stage at first enrolment to AMPATH compared to individuals testing HIV-positive through PITC, the TB clinic, or VCT. Background: Our objective was to describe what effect the 'point of entry' into the HIV care program (where the patient self-reportedly tested HIV-positive) had on the enrolment CD4 and WHO clinical stage of adults presenting for the first time to USAID-AMPATH Partnership clinics for HIV care. Methods: All individuals aged ≥13 years residing in the catchment were offered Home-Based Counseling and Testing (HBCT). We identified the point of entry to USAID-AMPATH clinics and compared the enrolment WHO clinical stage and CD4 count between them using Pearson's Chi-Square and Kruskal-Wallis tests. Points of entry/testing were HBCT vs. provider-initiated testing and counseling (PITC) vs. tuberculosis (TB) clinic vs. voluntary counseling and testing (VCT).		

	Results: There were 11,558 individuals eligible for analysis: 65% female, median age 35.8 years. Of these, 3911 individuals tested HIV-positive in PITC, 183 in the TB clinic, 7000 through VCT, and 464 through HBCT. There were no major differences in the proportions of men and women or in median age between the groups. The median (interquartile range, IQR) enrolment CD4 count among those who tested HIV-positive in PITC was 196 (76-372), vs. 164 (74-300) in the TB clinic, 208 (87-394) in VCT, and 280 (147-471) in HCT (p< 0.001). Only 2% of persons who tested HIV-positive in HBCT were WHO Stage IV at enrolment, compared to 8% from PITC, 9% from the TB clinic, and 5% from VCT. Similarly, 70% of those tested in HBCT enrolled at WHO Stage 1, compared to 35% from PITC, 13% from the TB clinic, and 38% from VCT (p< 0.001). Conclusion: These data demonstrate that HCT is effective at getting HIV-infected persons to enroll in HIV care at much earlier stages of HIV disease and while their immune systems are still relatively intact.		
Update:	The manuscript is presently under review; finalizing responses to Clinical Infectious Disease Journal		
Project Name:	Eldoret Cancer Registry		
Investigators:	C. Chuani, R. Rono,		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	A population based registry which collects data on cancer patients in former Uasin Gishu District and selected District in Western		
Update:	No update received		
Project Name:	Electronic Medical Records to Improve Patient Care & Public Health in Rural Kenya		
Investigators:	W. Tierney, L. Diero, K. Wools-Kaloustian, J. Sidle, M. Were, D. Caloia, R. Spitzer, S. Ayaya, J. Songok, Ngetich , B. Chemwolo		
Start Date:	10/01/2007	**Project End Date:**	09/30/2011
Project Description:	Implementing a primary care EHR for Mosoriot, Turbo, and Burnt Forest Rural Health Centres and for the TB/Chest, Well and Sick Child, Antenatal, and Post-Natal Clinics at MTRH. Once implemented, the EHR will be used to provide summaries and computer-based reminders to coordinate care between these primary care clinics and AMPATH clinics for shared patients		
Update:	The EHR has been implemented in all sites including the Well- and Sick Child clinics in MTRH. The computer summaries have been rolled out in the ANC clinic at MTRH. Reports to the MOH are being provided for the rural health centers and the TB clinic. Pre-implementation time-motion studies have been performed at Turbo, Burnt Forest, and the MTRH Well-Child Clinic. A pre-implementation quality assessment was done in the MTRH ANC. Post-implementation time-motion and quality assessment studies have also been performed at Turbo and Burnt Forest sites. MOH reports, patient summaries, and computer reminders will be rolled out and assessed at all sites by the end of the study on 30 Sept 2011. Several manuscripts are now in preparation. Funding for this project ends 30 Sept 2011, but manuscripts will continue to be written during the following 6-12 months.		
Project Name:	Enhancing Infant Feeding Options for HIV Infected Mothers		
Investigators:	K. Wools-Kaloustian, W. Nyandiko, B. Nyunya, S. Bucher, C. Yiannoutsos, B. Musick		
Start Date:	10/01/2006	**Project End Date:**	12/30/2010
Project Description:	The purpose of this study is to determine if questionnaire administered within the clinic can be		

	used to help decide which HIV (the virus that causes AIDS) infected women should be encouraged to breast feed and which should be educated about formula feeding their infants. In addition this study will help us to understand why some women choose to mix breast feeding with other types of foods.		
Update:	Study complete, analysis complete, manuscript in progress		
Project Name:	Enhancing Research Grant Management Capability and Administrative Infrastructure		
Investigators:	C. Chuani, R. Rono,		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	This project aims to enhance the research grant management capability and administrative infrastructure of the Research and Sponsored Projects Office-MUSOM/MTRH		
Update:	No update received		
Project Name:	Estimating Kidney Function In HIV Infected Patients in Kenya		
Investigators:	K. Wools-Kaloustian, Owino-Ong'or, C. Wyatt, J. Sidle, J. Abuya		
Start Date:	10/12/2007	**Project End Date:**	6/1/2010
Project Description:	The study will compare the 2 current equations used to estimate kidney function with a direct measurement of kidney function in Kenyan patients with HIV. Patients with HIV infection/ AIDS who have not yet started taking anti-HIV medications will be recruited from the HIV clinic at the Moi University Hospital. Subjects will be asked to participate in one study visit, lasting approximately 8-10 hours. During this visit, a physical examination and blood and urine tests will be performed, and kidney function will be measured by a technique called “iohexol clearance.” Briefly, this technique involves giving a small amount of iohexol (a contrast agent which is also used for CAT scans and cardiology procedures) intravenously, and following the disappearance or “clearance” from the blood by measuring the level of iohexol in 3-5 timed blood samples. Blood samples will be drawn from the IV catheter to avoid repeated venipuncture. “Iohexol clearance” directly measures kidney function, and these results will be used to determine whether the current equations used to estimate kidney function are reliable in African patients with HIV infection or AIDS. The results of this test may also be used to guide medication dosing in subjects who start anti-HIV medications as part of standard clinical care.		
Update:	75% of lab specimens have been run. We are awaiting the report on them and the final 25% of the specimens prior so that the manuscript can be written.		
Project Name:	Estimating the Weight of Children in Kenya: Do the Broselow Tape and Age-Based Formulas Measure Up?		
Investigators:	R. House, E. Ngetich,		
Start Date:	04/19/2011	**Project End Date:**	07/30/2011
Project Description:	We are evaluating the accuracy of the Broselow tape and age-based formulas at predicting the weight of children that present to the sick child clinic.		
Update:	We have received approval and begun data collection. At this point, we are nearly done with collection and about to begin analysis.		
Project Name:	Evaluating ASANTE: Perceptions of a Medical Exchange Program Among Kenyan Medical Students		
Investigators:	E. J. Carter, J. Baliddawa, J. Frank, M. Owiti, D. Shah		

Start Date:	unknown	**Project End Date:**	unknown
Project Description:	The project is a qualitative study consisting of 29 individualized interviews of medical students at the Moi University School of Medicine. The study aims to describe the experiences of the Kenyan students training within the AMPATH Consortium and probe their perceptions of the successes and failures of the program in achieving its mission of a collaborative exchange impacting education, patient care and research.		
Update:	No update received		
Project Name:	Evaluation of a Comprehensive Strategy to Measure Mediatric Adherence to Antiretroviral Therapy (CAMP study)		
Investigators:	R. Vreeman, W. Nyandiko, T. Inui, S. Ayaya, S. Downs, A. Carroll, W. Tu, W. Tierney, D. Marrero		
Start Date:	9/2009	**Project End Date:**	08/2014
Project Description:	The objectives of this application are to develop and test a reliable, valid instrument to measure pediatric ART adherence for children ages 0 to 14 years in western Kenya and to evaluate which administration strategy yields the most accurate information about children's ART adherence. We will pursue the following four specific aims: Aim 1: Develop a reliable, valid comprehensive pediatric ART adherence measurement questionnaire (CAMP – Comprehensive ART Measure for Pediatrics); Aim 2: Develop a reliable, valid, short-form version of the pediatric ART adherence measurement tool (SF-CAMP) for use as an adherence screening measure in busy clinical care environments; Aim 3: Evaluate the field- readiness, implementation feasibility, and clinical utility of CAMP and SF-CAMP within the AMPATH HIV clinical care system in western Kenya; Aim 4: Evaluate the reliability and validity of this measurement tool in a clinic-based care setting compared to a home-based care setting.		
Update:	Received funding for Aims 1, 2 and 3 via K23 career development to R. Vreeman via NIH-NIMH. IRB and IREC approvals secured. Approved IRB/IREC accrual target is 770. Completed cognitive interviews with 20 participants from urban and rural clinics to develop and modify the questionnaire. Project staff were hired and trained. For the adherence validation study, we have enrolled 211 patients (with 8 withdrawals). 100 children have completed the adherence validation study. With funding from a PEPFAR Public Health Evaluation, we have begun to carry out Aim 4, recruiting patients from the Turbo clinic site in addition to MTRH and evaluating the adherence measurement in a home-based vs. clinic-based care setting. 7 children (out of a planned 10 for the pilot phase) have been randomized to have home-based adherence assessments.		
Project Name:	Evaluation of Pill Count Data Compared to a Patient Self-Report Adherence Measure among Kenyan HIV/AIDS Patients at USAID-AMPATH Partnership Burnt Forest Clinic.		
Investigators:	J. Sidle, B. Jakait, H. Some, A. Mwangi, S. Pastakia, K. Wools-Kaloustian, S. Muchiri, T. Chirchir, V. Waweru, S. Kimaiyo		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Burnt Forest pill count paper		
Update:	No update received		
Project Name:	Exploring Low uptake of Skilled Delivery Services and Post-Partum Family Planning Services among Women Living in Western Kenya		
Investigators:	S. Mookherji, V. Naanyu,		
Start Date:	unknown	**Project End Date:**	unknown
Project	Moi University, in collaboration with The George Washington School of Public Health and Health		

Description:	Services, is conducting qualitative research (focus group discussions and in-depth interviews) to better understand and explain the complex interrelationship among factors that influence postpartum FP uptake and women's decisions surrounding childbirth. In Western Kenya health facilities report relatively high antenatal clinic attendance and child health visits, yet despite these positive health-seeking behaviors, a surprisingly large percentage of women have an unmet need for FP and deliver without a skilled attendant. To better understand how to address this issue in an attempt to decrease maternal and infant mortality, the research team will conduct the study in two sites: in the rural site of Port Victoria and urban Eldoret town to study the key factors, beliefs, and perceptions that affect postpartum FP use, contribute to where women choose to deliver, and decide who attends the delivery.		
Update:	No update received		
Project Name:	Factors Underlying Taking a Child to HIV Care: Implication for Reducing Loss to Follow up among HIV infected and Exposed Children		
Investigators:	P. Braitstein, J. Wachira, S. Middlestadt, R.Vreeman		
Start Date:	05/01/2010	**Project End Date:**	08/31/2010
Project Description:	Objective: With the aim of reducing pediatric loss to follow-up (LTFU), we sought to understand the personal and socio-cultural factors associated with the behavior of caregivers taking HIV-infected and exposed children for care in western Kenya. Methods: Between June- August, 2010, in-depth interviews were conducted with 26 purposively sampled caregivers caring for HIV infected (7), HIV-exposed (17) and HIV unknown status (2) children, documented as LTFU from an urban and rural HIV care clinic. All were women with a majority (77%) being biological parents. Interviews were audiorecorded, transcribed and content analyzed. Results: Thematic content analysis of the women's perceptions revealed that their decision about routinely taking their children to HIV care involved multiple levels of factors including: 1) Intrapersonal - transport costs, food availability, time constraints due to work commitment, disclosure of HIV status for both mother and child, perception that child is healthy, religious beliefs; 2) Interpersonal - stigma by the family and community, cultural norms, unsupportive male partner, family conflicts, changing community dynamics; 3) Healthcare system- clinic location, lack of patient-centered care, delays at the clinic, different appointment schedules (mother and child). Furthermore, the factors across these different levels interacted with each other in a complex way, illustrating the challenges women face in taking their children to HIV care. Conclusion: The complexity and interconnectedness of the factors underlying retention of children in HIV care perceived by these women caregivers suggests that interventions to reduce pediatric LTFU need to be holistic and address multiple socioecological levels.		
Update:	The abstract has been submitted to the International AIDS Society meeting for 2011 and the manuscript will be under review by January 2011. Article is in press: SAHARA Journal		
Project Name:	Global Network for Women's and Children's Health Research: Maternal Newborn Health Registry		
Investigators:	F. Esamai, E. Liechty, I. Marete, C. Tenge, S. Bucher		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	The purpose of the Global Network for Women's and Children's Health Research is to develop and		

	test feasible, sustainable interventions to improve the outcome of women and children and to develop research capacity in the resource-poor setting. Because most of the sites have weak health care systems, unacceptably high rates of maternal and neonatal mortality and lack of birth and death registries, they lack precise data on outcomes and measures of care. A vital registry system will allow the Global network to document maternal and neonatal mortality, design trials to address the major causes of poor outcome, assess the outcome of our interventions, and ultimately, disseminate the results as the basis of public health policy.		
Update:	No update received		
Project Name:	Global Network for Women's and Children's Health Research: Evaluation of an Emergency Obstetric and Neonatal Care Intervention Package to Reduce Adverse Pregnancy Outcomes in Low-Resource Settings (The EmONC Trial)		
Investigators:	F. Esamai, E. Liechty, P. Gisore, H. Mabeya, S. Bucher		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	We propose to evaluate a comprehensive intervention encompassing community mobilization through an assets-based approach to establish and sustain mechanisms of transport and payment and drive client-oriented emergency obstetrical and neonatal care. The intervention includes teaching recognition of prolonged labor, infection, preeclampsia and hemorrhage, and the use of appropriate stabilization methods by all community birth attendants and addresses poor access to quality emergency obstetric and neonatal care in a sustainable manner. To evaluate the effectiveness of this approach, a cluster-randomized trial is required to assess whether Cluster EmONC teams can work with the community and health care system to reduce adverse pregnancy outcomes in diverse settings where the majority of deliveries occur at home or at a health clinic with few or no available EmONC interventions. Within each country, an EmONC Country Team, comprised of the Senior Foreign Investigator (SFI), EmONC Country Coordinator, Country trainers (EmONC Facility, Birth Attendant and Community Mobilization activities), senior physicians, government health officials, birth attendant representatives, and community/maternal representatives will oversee the intervention. We propose to conduct this trial in 16 communities in Western Province of Kenya. These communities are largely rural, geographically distinct communities (clusters), each with approximately 500 annual deliveries. Within the clusters health care is primarily provided by traditional birth attendants or nurse/midwives; each cluster is organized around a primary health care clinic, with 2 district hospitals and 1 referral hospital serving all the clusters. All are associated with a primary health care center covered by the Moi University FWA.		
Update:	No update received		
Project Name:	Global Network: A Survey of Community Birth Attendants' Knowledge, Practices and Role within the Health Care System		
Investigators:	F. Esamai, E. Liechty,		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	There is a general lack of information on the practices of CBAs, many of whom conduct a significant proportion of the births and therefore directly impact maternal and perinatal mortality. Governments and policy makers have little valid information on which to base policies about birth attendants' roles, both in terms of managing low risk childbirth, as well as setting up effective referral systems. Assessing birth attendants' demographic data, their skills in reading and the use of numbers, previous trainings and relationship with health services will be important in designing the best strategies for training and to improve their practices, both for the policy makers as well as		

	for planning Global Network research projects. The primary objective of the proposed study is to describe the CBAs´ role, practices and training for those serving in the Global Network study catchment area. In addition to the benefits described above, this information will enhance the implementation of studies within the Global Network study sites.		
Update:	No update received		
Project Name:	Helping Babies Breathe: Expanded Field Test in Kenya		
Investigators:	F. Esamai, S. Bucher, P. Gisore		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Funded by the American Academy of Pediatrics and the United States Agency for International development, we are conducting two phases of expanded field testing for the Helping Babies Breathe (HBB) neonatal resuscitation curriculum. The HBB neonatal resuscitation (NR) curriculum was developed by the American Academy of Pediatrics Global Implementation Task Force in conjunction with the World Health Organization. The American Academy of Pediatrics seeks to standardize the educational curriculum for use in resource-poor environments around the world. USAID has agreed to provide additional funding to expand the field test efforts. Field testing of this curriculum will involve a "train the trainer" method, in which 24 Kenyan "Teachers," (i.e., nurses, nurse-midwives, and other birth attendant personnel) will be recruited. Teachers will be presented with the HBB curriculum; teachers will then, in turn, be asked to return to their communities and each teach two local groups of birth attendants (i.e., "Learners") neonatal resuscitation principles using the HBB curriculum and materials. Evaluation of the curriculum will be conducted among "Teacher" and "Learner" groups via focus group discussions, key informant interviews, paper questionnaires, and skills performance assessments. No personal health or medical information will be collected from study participants. Training sessions will be videotaped. Focus group discussions and key informant interviews will be audio-taped and transcribed; no identifying information will appear on the transcripts, nor on the paper questionnaires. All study participants will be issued a study ID. Only de-identified data will be transmitted to the study data management group at the University of Calgary		
Update:	No update received		
Project Name:	HIV Diversity and Drug Resistance in Western Kenya		
Investigators:	L. Diero, R. Kantor,		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Pilot study to examine HIV subtype and drug resistance in naïve and treated people		
Update:	No update received		
Project Name:	HIV Treatment Failure and Drug Resistance in Adults after Political Crisis		
Investigators:	L. Diero, R. Kantor, N. Buziba		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Drug resistance study investigates genotypic diversity and its impact after unplanned treatment interruption due to political crisis. It aims at determining and comparing prevalence of drug resistance at the time of post election resumption of care in 200 patients on WHO recomended first line ART who had an unplanned treatment interruption and 200 who did not experience treatment interruption.		

Update:	No update received		
Project Name:	HIV/AIDS and Risk Reduction: Understanding the Cultural Contexts of Women's Vulnerability in Burnt Forest, Kenya		
Investigators:	E. Pfeiffer, H. Maythia,		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	This is a summer preliminary/feasibility (pre-dissertation) academic project. The international PI spent three months conducting preliminary ethnographic research that centered on women, commercial sex work, and HIV/AIDS in Burnt Forest, Kenya. The data acquired through this proposed research project is currently being used to develop a more specific and larger dissertation study to be conducted by the PI, Elizabeth J. Pfeiffer, a doctoral student in the Department of Anthropology at Indiana University, Bloomington, USA.		
Update:	No update received		
Project Name:	Impact of Disclosure on Pediatric ART Adherence (Qualitative Inquiry into Pediatric Adherence)		
Investigators:	R. Vreeman, W. Nyandiko, S. Ayaya, E. Walumbe, D. Marrero, T. Inui		
Start Date:	3/2007	**Project End Date:**	12/2011
Project Description:	Qualitative research project involving focus groups and individual key informant interviews with parents and caregivers of HIV-infected children taking ART, older children on ART, and healthcare providers of children with ART. Primary objective was to identify key factors sustaining children's adherence to ART in western Kenya. Disclosure to children of their own HIV status and disclosure of a child's status to others emerged as key factors for sustaining adherence; additional analyses of how caregivers perceive pediatric disclosure and its effects were then carried out.		
Update:	We were able to describe the influence of disclosure of a child's HIV status (both to the child and to other people) on pediatric adherence. These data were presented in oral and poster presentations at the AIDS 2008 meeting in Mexico City. Manuscript was published in AIDS Patient Care and STDs in October of 2010. (Authors and title: Vreeman RC, Nyandiko WM, Ayaya SO, Walumbe EG, Marrero DG, Inui TS. The perceived impact of disclosure of pediatric HIV status on pediatric antiretroviral therapy adherence, child well-being, and social relationships in a resource-limited setting)		
Project Name:	Impact of the High Risk Express Care Program on Clinical Outcomes in Adults (mortality and losses to follow-up)		
Investigators:	P. Braitstein, S. Kimaiyo, A. Siika, R. Kosgei, J. Hogan, E. Sang, B. Musick, J. Sidle, K. Wools-Kaloustian		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Objective: To evaluate the effect on survival and clinic retention of a nurse-based rapid assessment clinic for high risk individuals initiating cART in a resource-constrained setting. Methods: The USAID-AMPATH Partnership has enrolled >80,000 patients at 18 parent and 10 satellite clinics throughout western Kenya and is the largest provider of HIV care and treatment in Kenya. As of March 2007, High Risk Express Care (HREC) provides weekly or biweekly rapid contacts with nurses for individuals initiating cART with a CD4 of ≤100 cells/mm3. Sick patients are immediately referred to clinicians. All HIV-infected individuals aged ≥14 years initiating cART with a CD4 count of ≤100 cells/mm3 were eligible for referral to HREC. The primary analysis includes all patients meeting these criteria. Death is routinely ascertained in AMPATH by aggressive tracking of patients who miss a clinic visit by trained		

	peer outreach workers. LTFU was defined as no clinic visit for >3 months.		
Update:	No update		
Project Name:	Impact of using Nurses instead of Clinicians to Care for Stable HIV-infected patients		
Investigators:	A. Siika, M. Were, J. Gitau		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	This is a proposal to evaluate the effect of a new patient care model, Express Care, at two HIV clinics in the resource-poor setting of western Kenya. The EC model will shift patient care tasks from clinical officer and medical doctor, who are less expensive, to nurses. We will use time motion study before and after implementation of EC.		
Update:	No update received		
Project Name:	Incidence of Pregnancy among HIV-infected Women attending AMPATH Clinic		
Investigators:	P. Braitstein, W. Nyandiko, K. Wools-Kaloustian, E. Were, A. Katschke, B. Musick, A. Keter, E. Sang, H. Mabeya		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	This is a retrospective observational analysis of AMRS data examining the incidence of and risk factors for pregnancy among HIV-positive women in AMPATH.		
Update:	No updates		
Project Name:	Increasing Animal Source Foods in Diets of HIV-Infected Kenyan Women and Their Children		
Investigators:	J. Ernst, G. Ettyang, C. Neumann, W. Nyandiko, A. Siika		
Start Date:	10/1/2006	**Project End Date:**	7/31/2012
Project Description:	The study is a three arm randomized, blinded and controlled nutrition intervention trial that tests the effect of iso-caloric biscuit supplements of meat, soy or wheat protein added to the diets of drug naive HIV-infected Kenyan women and their children-8 years and younger and who live in the Turbo environs and who receive care at one of the AMPATH clinics (Turbo, Soy, Mautuma and MTRH). The women are of reproductive age and at enrollment WHO stage I or II. The biscuits are provided five days a week (Monday to Friday) to subject mother and child, using directly observed therapy (DOT) for 18 months. The outcome variables include estimates of lean and fat mass, quality of life, strength measures, biochemical indicators of nutritional status, indicators of immune function, measures of inflammation, nutrient intake, food security, measures of growth and development in children and activities of daily living.		
Update:	Update: Procedures were put into place to accommodate the field staff and participants as subjects reached the end of the 18 month intervention phase as well as the study completion follow-up at 24 months which is 6 months post the intervention completion and 24 months since enrollment. Key Event: Unfortunately Professor Duncan Ngare succumbed to his failing health. His passing on is a great loss to the project ; he was particularly expert in the area of Time Allocation assessment. Dr.		

	Charlotte Neumann invited Dr. Michael Baksh from San Diego State University , San Diego, California, USA, to assume the responsibilities of Prof. Ngare. Dr. Baksh trained Prof. Ngare in Time Allocation data collection and assessment and regarded him highly. Dr. Baksh will be visiting Moi University and Turbo In August, 2011 and we will welcome him warmly. Challenges: 1) As the participant numbers decline the need for some field staff also declines making it necessary to retrench some staff. This of course has been very difficult on both project management and field staff. 2) Since field activities will be ending in December, 2011, some key field staff left their positions for more secure government positions, leaving the project in a challenging situation for adequate staffing in specifically trained key areas of expertise. 3) Some clients do not return for the 24 month follow-up visit which is the 6 month post intervention phase visit. We have given up trying to reach these clients after several tries. Some who are contacted just refuse to have the assessment measures done either for themselves, their child or both. 4) Some clients have had an interruption in the intervention because of our inability to locate them. Once they were relocated and once again receiving the intervention, then the follow-up schedule was adjusted to reflect the overall protocol. Presentations/Publications : Three abstracts were submitted to the Nairobi AIDS Council meeting that was held in May, 2011. Two of the abstracts were accepted. Analysis is underway for presentation of theses abstracts in future.
Project Name:	Indiana University Moi University Academic Research Ethics Partnership
Investigators:	E. Meslin, D. Ayuku, E. Were, J. Eberl
Start Date:	05/31/2008 **Project End Date:** 05/31/2012
Project Description:	The Indiana University - Moi University Academic Research Ethic Partnership is funded by a $940,000 four-year grant from the Fogarty International Center at the National Institutes of Health to establish a new research ethics training partnership with colleagues at Moi University in Eldoret, Kenya. The Indiana University-Moi University Academic Research Ethics Partnership (IU-Moi AREP) is a curriculum development and training initiative that builds on longstanding partnerships and collaborations in East Africa. The IU-Moi AREP has developed two Master's degree programs: one at Indiana University-Purdue University Indianapolis (IUPUI) and one at Moi University in Eldoret, Kenya. These graduate programs have common and overlapping components, joint advisory committees, shared dissemination plans and harmonized evaluation strategies. Both programs include a curriculum involving required core courses and electives and a practicum experiece, part of which is taken at the counterpart university. In addition, each IU-Moi AREP partner convenes an annual Teaching Skills in International Research Ethics (TaSkR) workshop to provide training to approximately 40 faculty and students each year.
Update:	TaSkR The third annual Teaching Skills in International Research Ethics (TaSkR) workshop was held April

	12-14, 2011 in Indianapolis. This workshop focused primarily on the ethics of research involving human subjects—both behavioral and biomedical—conducted in an international forum, as well as developing stronger pedagogical skills. The workshop was attended by over 40 participants plus faculty facilitators. Participants included faculty who teach within the broad domain of international research ethics, whether this is in the classroom, through lectures, or mentoring students, fellows, and post-docs. Attendees included faculty who teach in medicine, public health, behavioral science, and a number of liberal arts subjects. MA/ MSc Program Two new students were admitted to the MA in Philosophy Program - International Research Ethics Concentration at IUPUI. There are now a total of 6 students enrolled. Nine new students were admitted to the MSc Program - Internatioanl Health Research Ethics Concentration at Moi University. There are now a total of 17 students enrolled. Publications Currently Under Review Papas RK, Gakinya BN, Baliddawa JB, Bryant KJ, Martino S, *Ngare DK, *Meslin EM, *Sidle JE. A Stage 1 cognitive-behavioral therapy feasibility study and trial to reduce alcohol use among HIV-infected outpatients in western Kenya: An ethics report card. (under review) Lipscomb ER, *Meslin EM Ethical issues in translating research into sustainable practice: an ethical assessment of the use of ready-to-use-therapeutic-food to prevent wasting in children 6-60 months in developing countries (under review) *Were, M. *Meslin EM. Ethics of Implementing Electronic Health Records in Developing Countries: Points to Consider (under review)		
Project Name:	Innovations in TB Control: Intensive Case Finding using the Cough Monitor Model in Traditional and Nontraditional Sites in Western Kenya		
Investigators:	E. J. Carter, N. Buziba, , T. Cohen, N. Bhakta, A.Fojo, A. Gardner, E. Odhiambo, D. Szkwarko, L. Kamule, P. Park, S.Washington, S.Pastika, R. Kosgei		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	We are conducting and ongoing retrospective programmatic, clinical and epidemiologic review of internal Tuberculosis Program Intensive Case Finding records. Since the intervention started nearly five years ago, we have compiled a significant amount of internal program data that has the potential to benefit TB monitoring and tracking in the Eldoret area. We continually analyze this information to learn more about the epidemiology of TB in the Eldoret, share our experience with other international active-case finding efforts and justify our reapplications for funding.		
Update:	No update received		
Project Name:	Integration of a Comprehensive Diabetes Database in a Resource-Constrained Setting		
Investigators:	S. Pastakia, J. Nyabundi,		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	This study will be designed to facilitate the implementation of a care focused diabetes database into patient care in the unstudied diabetes population receiving care in the resource constrained setting in Eldoret, Kenya. The primary purpose of this study is to improve the provision of diabetes care through the enhanced monitoring and tracking capabilities embedded within the database. Through the report generation features of the database, the quality of care provided to patients		

	before and after the implementation of the database will be studied. The database will also help facilitate a wide variety of continuous quality improvement initiatives designed to raise the level of care provided to all patients to the standards set forth in accepted guidelines. The electronic recording of data will also allow the clinic to generate much needed data regarding the burden of chronic diseases like diabetes in resource poor settings which have previously gone unstudied. The previous practice in the clinic relies on unorganized paper medical records which do not incorporate any electronic recording of information. This approach has created much inefficiency in the provision of care as many vital pieces of healthcare information are lost and unavailable for future use in the care of the patient. The inability to effectively search these records has also limited the clinic's abilities to identify the best strategies to manage the unique features associated with diabetes in resource-constrained settings like Eldoret.		
Update:	No update received		
Project Name:	International Epidemiologic Databases for Evaluation of AIDS(IeDEA)		
Investigators:	C. Yiannoutsos, K. Wools-Kaloustian, S. Ayaya, L. Diero, J. Otieno, G.R. Somi, R. Swai , K. Ngonyani, R. Lyamuya, H.B Mtiro, J. Sidle, P. Braitstein, J. Martin, D. Bangsberg, D. Glidden, S. Deeks, P. Hunt, L. Diero, S. Ayaya, D. Nash, E. Abrams, B. Elu		
Start Date:	06/20/2006	**Project End Date:**	07/31/2011
Project Description:	This initiative will establish international regional centers for the collection and harmonization of data and the establishment of an international research consortium to address unique and evolving research questions in HIV/AIDS currently unanswerable by single cohorts. High quality data is being collected by researchers throughout the world. This initiative provides a means to establish and implement methodology to effectively pool the collected data—thus providing a cost effective means of generating large data sets to address the high priority research questions. Combination of data collected under various protocols is frequently very difficult and not as efficient as the collection of pre-determined and standardized data elements. By developing a pro-active mechanism for the collection of key variables, this initiative will enhance the quality cost effectiveness and speed of HIV/AIDS research.		
Update:	Training: 1. The OpenMRS team and the IeDEA East Africa Data Management & Analysis core conducted Data Management training for all East Africa Data Managers/Analysts. Training took place at AMPATH Centre in February 2011 for a week and half. New Data Managers, are trained by more experienced data managers from participating site(s). They are oriented at AMPATH MTRH site. At the Mbale site, IT support went to the site to check, troubleshoot, and update the OpenMRS system as well as train the new Data Manager. The new Tumbi Data Manager and the Tanzania Country Coordinator were both trained on OpenMRS, Data Management and reporting. These trainings have continuously improved the quality of work the data managers are doing at the sites in terms of data management, data quality assurance and data quality control, analysis and reporting. 2. HSP Training to all IeDEA personnel All our personnel were required to take the CITI HSP certification course that is offered online by Indiana University. This has enhanced the way investigators treat data as well as how they do research. Research EA IeDEA co-investigators are actively involved in both international and local working groups. The international Phamaco-vigilance committee is co-chaired by Dr. Braitstein, and the Pediatric		

	working group is lead by Prof. Ayaya and Dr. Wool-Kaloustian,. Dr. Diero and Dr. Siika are actively involved with the TB working group. Dr. Martin leads the Oncology working group and Ms. Musick is actively involved in the Data harmonization working group. On-going Studies within IeDEA, East Africa Regional Consortium: 1. "International Epidemiologic Databases to Evaluate AIDS (IeDEA) East Africa Regional Consortium" – on going 2. "International Epidemiologic Databases To Evaluate AIDS (IeDEA); Proposal for Data Extraction and Analysis for the Initial Projects (Version 1.0.25 October 2007)" – on-going 3. "National Cancer Institute Supplement to East Africa IeDEA: Improving Kaposi's Sarcoma and Lymphoma Diagnostics as well as Assessing Sarcoma Incidence in Western Kenya" – on-going 4. "Engagement in Care Among HIV-Infected Patients in Resource limited Settings" A supplement to IeDEA East Africa- pending IREC approval Completed studies within IeDEA 5. "Outcomes and causes of Losses to follow-up among HIV-Infected and HIV-Exposed children attending USAID –AMPATH Partnership clinics (PEDI-UP)" – study ended 6. "Analysis of loss to follow up data of AMPATH patients using the AMPATH outreach Database" – study ended Presentations: 27th Feb – 3rd Mar 2011: PI Meeting Presentation In May 16-17 2011, the IeDEA PI meeting was held in Nyeri, Kenya. The presentation made during the meeting are as follows; 1. Didactics on the development of a concept sheet: Data Specifications. B.S. Musick.. 2. Concept Sheet Development: Developing the Question. K. Wools-Kaloustian. 3. Development and Pilot an automated Pregnancy and Birth Registry. K. Wools-Kaloustian. 4. Integrating TB/HIV Databases. L. Diero. 5. Pharmacovigilance & Toxicity Documentation in the Context of Antiretroviral Treatment: Comparative Evaluation of 4 strategies in a Resource-Constrained Setting. P. Braitstein 6. Engagement in care for HIV-Infected Patients in East Africa. E.H. Geng. 7. Failure to initiate ART, Loss to Follow-up and Mortality among HIV-infected Patients during the pre-ART period in Uganda. W. Muyindike 8. Population-based Research on HIV, other Infectious Diseases, Reproductive Health and Service delivery. F. Nalugoda. 9. Harmonizing Clinical Information Between Patient Record Systems: Distinguishing Information from Data. D. Kayiwa, B. Musick. 10. Outcomes of HIV-infected and HIV-exposed children who become LTFU. P. Braitstein 11. Integration of Reproductive Health and HIV/AIDS Services in Nyanza, Kenya. C. Cohen. 12. Attrition in HIV Care: Key Operational Challenge in implementing HIV Care and Treatment in Tanzania. G.R. Somi. Papers in Final Draft Form or Submitted to Journal's for Publication 1. Ayikukwei R, Wools-Kaloustian K, Were E, Nyandiko W, Qi R, Mabeya H, Braitstein P. Incidences of Pregnancies among HIV-infected Women in Western Kenya. (Senior author revising draft) 2. Billngton H, Buchner S, Nyandiko W, Otieno Nyunya B, Musick B, Tiannoutsos C, Wools-Kaloustian K. Validation of an Infant Formula Feeding Eligibility Instrument to Assist in Identifying Appropriate Infant feeding Strategies for HIV-infected Women in the USAID – Partnership in Western Kenya. (Final draft in progress) 3. Braithwaite RS, Nucifora K, C. Yiannoutsos C, Musick B, Kimaiyo S, Diero L, Bacon M,

	Wools-Kaloustian K. Alternative antiretroviral monitoring strategies for HIV-infected patients in resource-limited settings: Opportunities to save more lives? (Final Draft Circulating) 4. Carter EJ, Diero L, Siika Am, Kimaiyo S, Gardner A, C. Yiannoutsos C, Musick BS, Wools-Kaloustian K. The Experience and Outcomes of Isoniazid Preventative Therapy in an HIV Treatment Program in Western Kenya. (Final Draft Under revision) 5. Siika A, C. Yiannoutsos C, Wools-Kaloustian K, Musick B, Mwangi A, Diero L, Kimaiyo S, Tierney W and Carter EJ. Tuberculosis adversely impacts survival, incident opportunistic infections and CD4 cell and weight gain in HIV-infected African patients initiating antiretroviral therapy. (Final Draft Circulating)		
Project Name:	Low Risk Express Care		
Investigators:	K. Wools-Kaloustian, A. M. Siika, R. Kosgei, C. Yiannoutsos, B. Musick, E. Sang, S. Wafula		
Start Date:	Retrospective	**Project End Date:**	30/01/2010
Project Description:	An assessment of the impact on patient outcomes of introducing the low risk express care model into the clinics.		
Update:	A revised analysis is going to take place within the next 2 months and the manuscript is being developed.		
Project Name:	Merck Vaccine Network-Africa		
Investigators:	E. Liechty, Esamai FO, S. Ayaya, J. Conway		
Start Date:	2003	**Project End Date:**	07/2011
Project Description:	Project has traine over 400 midlevel managers of immunization in Kenya. Remaining with Central province and Nairobi only.		
Update:	No problems.		
Project Name:	Misclassification of Antiretroviral Therapy Failure Using Immunologic and Clinical Monitoring in HIV Infected Children and Adolescents in Western Kenya		
Investigators:	E. Dufort, W. Nyandiko, A. DeLong, K. Wools-Kaloustian, S. Ayaya, R. Vreeman, J. Hogan, R. Kantor		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Background: In resource-limited settings (RLS) HIV-infected children on antiretroviral therapy (ART) are assessed for treatment failure based on clinical and immunologic criteria. Studies in adults show that this means of assessment is associated with a high rate of misclassification of ART failure. Methods: We assessed the rate of treatment failure misclassification when based on immunologic and clinical criteria compared to virologic failure in children enrolled in the USAID-AMPATH program in western Kenya from January 2006 to January 2009. Inclusion criteria were: 0-18 years, on WHO-recommended first line ART for > 6 months, with suspected clinical and/or immunologic failure, and a viral load (VL). VL>400 copies/ml defined virologic failure. We also assessed the association between detectable VL and age, time on therapy and CD4 measures using Wilcoxon rank sum tests. Results: 125 patients were eligible, 54% male, median age 10 years (range 1.5 – 17.5 years), 59% WHO stage 3 or 4, median VL 18,700 copies/ml (range<400-750,000 copies/ml), median CD4 238 cells/□L (range 4 - 2,569 cells/□L), median CD4% 12% (range 0-47%). Median time on ART was 15		

	months (range 6-32 months), with stavudine, lamivudine and nevirapine the most commonly used regimen. 29/125 (23%) patients classified as failing ART had undetectable VL. Failure was more likely in patients with shorter time on ART (p=0.02), a low CD4 count and a low CD4 percent (p<0.001 for each). Change in CD4 count and percent change in CD4 count 6 months prior to VL were not associated with virologic failure (p=0.3 and 0.2), while changes in CD4% and percent change in CD4% were (p=0.01 and 0.003). Conclusions: Treatment failure misclassification in children is common when utilizing clinical and immunologic criteria and could lead to unnecessary and costly changes to second line ART. An affordable and technologically simple VL assay is vitally needed in RLS.		
Update:	No update received		
Project Name:	Modified Directly Observed Antiretroviral Therapy (M-DART): An intensive, nurse-directed, home-centered, treatment strategy to reduced mortality and loss to follow-up in high-risk HIV-infected patients initiating antiretroviral therapy.		
Investigators:	A. Siika, K.Wools-Kaloustian, T. Murage, H. Thirumurthy, S. Goodrich		
Start Date:	1/8/2011	**Project End Date:**	1/8/2013
Project Description:	M-DART is a randomized clinical trial comparing the effectiveness of a home-based modified directly observed antiretroviral (ART) treatment strategy to clinic-based standard of care in patients with HIV/AIDS in Port Victoria and Khunyangu, Kenya. The aim is to reduce both mortality and the number of patients lost to follow-up after ART therapy is initiated. In addition to these important objective outcomes, it is desirable to know if M-DART is also contributing to an increased quality of life for patients and helping to diminish HIV related stigma.		
Update:	The Study Protocol was amended and submitted to IREC,approval is pending.Study staff were trained on GCP/HSP and Comprehensive ART management.		
Project Name:	Molecular Diagnostics for Chronic Myeloid Leukaemia		
Investigators:	C. J. Ingles, D. Chumba, S. Kelley, E. Sargent, S. Kamel-Reid, N.Busakhala, E.Njiru, L. Diero, R. Strother		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	We are proposing to conduct a clinical field trial of a new nucleic acid-based diagnostic paradigm for rapid simple low cost diagnosis of CML suitable for use in resource- and technology-limited settings such as exists in Africa. Molecular diagnosis of CML will open the door to Novartis's free Glivac GIVAP program. Glivac is the drug of choice for CML patents with ~ 90% five-year survival rates. The project began in August 15, 2010 and is anticipated to end in June 30, 2013.		
Update:	No update received		
Project Name:	National Cancer Institute Supplement to East African IeDEA: Improving Kaposi's Sarcoma and Lymphoma Diagnostics as Well as Assessing Kaposi's Sarcoma Incidence in Western Kenya.		
Investigators:	C. Yiannoutsos, K. Wools-Kaloustian, L. Diero, N. Buziba, N. Busakhalla, J. Martin, T. Maurer, P. Loehrer, M. Strother, M. Czader, P. Leboit, T. McCalmont		
Start Date:	10/2008	**Project End Date:**	10/2011
Project Description:	The toxicity and potential side effects of therapy for malignancy justify a standard of care in cancer medicine of tissue-biopsy. Further, an accurate assessment of the epidemiology of HIV-related malignancy requires reliable pathologic diagnosis. This study will help validate local pathology for the diagnosis of KS. The limited resources available to local pathology mandate that most diagnoses are made via H&E staining and immunohistochemistry which are techniques, like many		

	pathology diagnostic tools, open to inter-observer variability in interpretation – thus the experience of the pathologist is a major determinant in diagnostic accuracy. Quality assurance efforts and continuing evaluation of diagnostic skills are routine practices in the United States to help ensure ongoing reproducibility between pathologists. The present effort will facilitate similar ongoing quality checks and thus increase the reliability of a biopsy-based diagnosis of Kaposi's sarcoma and lymphoma at the selected sites.		
Update:	We continue to be done at the Oncology clinic, AMPATH Centre. Visiting clinicians continue to go for Oncology clinic days are various AMPATH clinics namely, Busia, Chulaimbo, Kitale, and Webuye and Port Victoria. Currently 833 punch biopsy have been done both AMPATH and Non-AMPATH patients. Of These 767 are AMPATH patients' samples. 752 samples have been read and results available, 388(51.6%) turned positive for KS, 271(36.0) turned negative, and 93(12.4%) are indeterminate. Specimen samples are shipped to UCSF for a re-reads every 2-3 months. Data collection and entry is continues.		
Project Name:	Novel Drug Formulations for Pediatric TB		
Investigators:	R. Vreeman, W. Nyandiko, G. Knipp, C. Kissinger, T. Blaschke, S. Ayaya		
Start Date:	1/2009	**Project End Date:**	6/2011
Project Description:	The aim of this study is to utilize the porcine model as a surrogate for human pediatric patient PK studies in order to develop a novel, fast-melt pediatric formulation of rifampicin that can be safely and efficaciously used to treat children diagnosed with tuberculosis. Fast-melt film formulations were developed and tested according to the USP methodology. Dissolution and assay experiments were carried out according to the USP monograph for rifampicin capsules and selected film formulations. To determine the PK parameters of the dosage form, pigs were modified with a jugular catheter, externalized in the dorsal scapular region. Whole blood samples were collected using the Culex-L large animal automated blood sampling system, and plasma samples were analyzed by LC-MS/MS for rifampicin content.		
Update:	We have formed several films with rifampicin entrapped inside. The films were reformulated using equipment in a collaborators laboratory and we were able to dramatically reduce the "bubble" formation under vacuum. We also obtained good content uniformity. Specimens were brought to Kenya and examined and discussed by the pediatric clinical team. However, the net drug load for the films was not adequate to meet our targeted dose range of 25 and 50 mg/film utilizing this approach. We have begun preparing a small microparticle formulation that is coated. The current coating is blue to mask the color differences between the rifampicin and the placebo, which will be an important aspect for bias in clinical trials. As is well established, organoleptic properties need to be masked for true blinding of studies. Final project testing in pigs using opaque capsules in a double-blind, crossover study design has been completed. The team from Purdue is applying for additional funding through an R01 mechanism that will utilize our team's existing nevirapine pharmacokinetics data to validate the juvenile porcine model for pediatric anti-infective agents.		
Project Name:	Nutritional Status of Children Attending AMPATH Clinics in Western Kenya		
Investigators:	Y. Constantine, S. Ayaya, W. Nyandko, E. Nabakwe, Rachel CV		
Start Date:	2002	**Project End Date:**	2012
Project Description:	Studying describing the nutritional status of all the children seen within the AMPATH clinics in western Kenya.		

Update:	Data being re-analyzed.		
Project Name:	Orphaned and Separated Children's Assessments Related to their (OSCAR's) Health and Well-Being Project		
Investigators:	P. Braitstein, D. Ayuku, P. Gisore, L. Atwoli, W. Nyandiko, S. Ayaya, J. Dickerson-Putman, W. Tierney, R. Vreeman, J. Hogan		
Start Date:	09/01/2009	**Project End Date:**	08/31/2014
Project Description:	UNICEF estimates that sub-Saharan Africa will have over 53 million orphaned children by 2010, of whom 30% will be orphaned by AIDS. Half of orphaned children today are adolescents; two-thirds of these are double orphans. Being an orphan can mean a child or adolescent is very vulnerable to economic and sexual exploitation, sexual risk taking behaviour, excessive drug and alcohol use, depression, post-traumatic stress disorder, malnutrition, and tuberculosis. Although orphaned children are not yet recognized by UNAIDS as a high risk population for acquiring HIV infection they are an exceptionally high risk group because of their social and economic vulnerability. Although strengthening the capacity of families and communities to protect and care for orphans and vulnerable children is the ideal strategy for mitigating the impact of AIDS on family and community structures, there are numerous indicators to suggest that families and communities are overwhelmed by the numbers of orphans requiring care, thereby potentially compromising the quality of care and support children receive. In addition to various configurations of care provided by extended family, several additional care models are emerging. These include formal and informal foster homes, orphanages, community-based programs, government detention centres, homes and schools run by religious institutions or other non-governmental organizations, and children providing self-care from being on or of the street. The overall intention of this study is to improve the health and well-being of orphaned children by evaluating the potential short and medium term mediating effects of their care environment on their physical health and psychosocial well-being. Using standardized site assessments, medical examinations, and psychosocial assessments every year for 5 years, we specifically aim to: A.1. Describe existing models of care for children who are orphaned or separated (i.e. actual or virtual orphaned children) in the Uasin Gishu District of Western Kenya. A.2. Measure the effect of care model and key care characteristics (e.g. ratio of care-givers to children, number of beds to a room, quality of diet) on the physical health of the resident children (e.g. nutritional status, HIV infection, active tuberculosis, mortality). A.3 Measure the effect of care model and key care characteristics (e.g. trusted long-term caregiver, recreational facilities, contact with family of origin) on the psychosocial well-being of the resident children (e.g. post-traumatic stress disorder, school attendance, depression).		
Update:	Enrolled 2170 children including 21 Charitable Children Institutions (CCIs), 191 Households and 100 street children. Second round assessments have started		
Project Name:	Outcomes and Causes of Losses to Follow-up among HIV-Infected and HIV-Exposed Children attending USAID- MPATH Partnership Clinics (PEDI-UP).		
Investigators:	P. Braitstein, W. Nyandiko, C. Yiannoutsos, S. Ayaya, R. Vreeman, P. Gisore, C. Tenge, A. Katshcke, C. Shen, E. Sang, V. Ochieng, K. Wools-Kaloustian		

Start Date:	11/1/2009	**Project End Date:**	07/31/2010
Project Description:	Background: Losses to follow-up (LTFU) are an important challenge for HIV programs, particularly in resource-constrained settings. Little is known about LTFU among HIV-affected children. The objectives of this analysis were to describe incidence rates and risk factors for LTFU among HIV-infected and HIV-exposed children in a large HIV treatment program in Western Kenya. Methods: The USAID-AMPATH partnership has enrolled > 95,000 patients (20% children) at 23 clinic sites throughout western Kenya. LTFU is defined as being absent from the clinic for >3 months if on combination antiretroviral treatment (cART) and >6 months if not. Included in this analysis were children aged <14 years, HIV-exposed or infected at enrollment, and enrolled between 04/02-03/09. Incidence rates (IR) are presented per 100 child-years (CY) of follow-up. Proportional hazards models with time independent and dependent covariates were used to model factors associated with LTFU. Z-scores were calculated using EpiInfo, with severe malnutrition being defined as a Z-score ≤-3.0. Immune suppression was defined as per WHO age-specific categories. Results: There were 13,510 children eligible for analysis, including (at enrolment) 3106 who were HIV-infected, and 10,404 who were HIV-exposed. The overall IR of LTFU was 18.4 (17.8-18.9) per 100 CY. Among HIV-infected children, 15.2 (13.8-16.7) and 14.1 (13.1-15.8)/100 became LTFU, pre- and post-cART initiation respectively. The only independent risk factor for becoming LTFU among the HIV-infected children was severe immune suppression (AHR: 2.17, 95%CI: 1.51-3.12). Among the HIV-exposed children, 20.1 per 100 (19.4-20.7) became LTFU and independent risk factors for LTFU among them were being severely low weight for height (AHR: 1.69, 95%CI: 1.25-2.28), being orphaned at enrolment (AHR: 1.57, 95% CI: 1.23-1.64), being CDC Class B or C (AHR: 1.41, 95% CI: 1.14-1.74), and receiving cART (AHR: 1.56, 95% CI: 1.23-1.99). Protective against becoming LTFU among the HIV-exposE. Were testing HIV-positive (AHR: 0.26, 95%CI: 0.21-0.32), older age (AHR: 0.90, 95% CI: 0.85-0.96), enrolling in later time periods, and receiving food supplementation (AHR: 0.58, 95% CI: 0.32-1.04). Conclusions: There is a high rate of LTFU among these children, particularly among HIV exposed infants. These HIV-infected and HIV-exposed children are at especially high risk for LTFU if they are sick or malnourished, suggesting they may in fact be deceased.		
Update:	Published by JAIDS in March 2011		
Project Name:	Outcomes of a Focused pMTCT program using cART, safe water, infant formula and community based follow-up in Western Kenya CIFF vs. non CIFF		
Investigators:	R. Einterz, W. Nyandiko, K. Lane, K. Wools-Kaloustian, B. Nyunya, P. Akhaabi, S. Bucher, B. Musick		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	This intervention strategy was completed in May of 2007. Currently we are comparing the outcomes of exposed infants between those that were a part of the CIFF funded intervention using household based community care, formula and safe water and infants who received the standard package of care within the AMPATH program		
Update:	No update received		
Project Name:	Outcomes of the AMPATH PMTCT program since March 2009		
Investigators:	K. Lane, W. Nyandiko, K. Wools-Kaloustian, E. Were, P. Akhaabi, B. Musick, E. Sikuku, A. Kat, H. Lui		
Start Date:	unknown	**Project End Date:**	unknown

Project Description:	This is a descriptive paper examining maternal and infant outcomes from the initiation of the new PMTCT protocols in March 2008 which included providing positive mothers with ARVs throughout the duration of breastfeeding.		
Update:	No update received		
Project Name:	Parallel Comparison of Tenofovir and Emtricitabine/tenofovir Pre-Exposure Prophylaxis to Prevent HIV-1 Acquisition within HIV-1 Discordant Couples		
Investigators:	K. Fife, E. Were		
Start Date:	2/9/2008	**Project End Date:**	2/9/2013
Project Description:	This is a Phase III, multi-site, randomized, double-blind, placebo-controlled trial in HIV-discordant couples.		
Update:	The site continues to have very good adherence rates (97%). Retention rates are however a little low (93%). Many participants have separated and relocated hence tracing them becomes a problem when they miss their scheduled appointments. Some participants come from distances of over 150km hence tracing them and /or facilitating their transport to the clinic is challenging .		
Project Name:	Patient-Reported Outcomes of Cancer Care in Eldoret, Kenya		
Investigators:	L. Hess, V. Naanyu, C. Asirwa		
Start Date:	10/14/2010	**Project End Date:**	12/31/2011
Project Description:	This project is designed to validate and subsequently implement a standardized questionnaire to obtain patient perspectives of their physical and psychosocial well-being (quality of life) during and following cancer treatment. First, the instrument will be tested for validity in a cancer patient population in Eldoret in a two-phase study. Second, it will be implemented into standard data collection practices for routine clinical care for the validation study. Knowledge about the quality of life of cancer patients in Eldoret will help us to understand the broader context of wellness among cancer patients and will help guide future strategies to improve comprehensive cancer patient care.		
Update:	The focus groups are complete (n=27). The FACT survey tool was revised by slightly modifying the wording to be more understandable to the population in which it is to be administered. Part II (validation study, target n=120) has enrolled 66 participants, 15 of whom have completed all three study assessments. Accrual to Part II is ongoing.		
Project Name:	Pediatric ART Pharmacokinetics and Adherence Feasibility Study (also titled, Development and Evaluation of a Tool to Measure Pediatric Adherence to Antiretroviral Therapy – Phase 1 – Feasibility)		
Investigators:	R. Vreeman, W. Nyandiko, N. Busakhala, S. Ayaya, L. Labbe, E. Liechty, T. Blaschke		
Start Date:	4/2008	**Project End Date:**	12/2011
Project Description:	The primary objective of this study was to establish feasibility of pediatric pharmacokinetics (PK) modeling, body water assessment, and comprehensive adherence assessment in a resource-limited setting. The secondary objectives were to model the PK parameters of nevirapine (NVP) in children in western Kenya, including oral clearance, apparent volume of distribution, and half-life, and to use mixed-effects modeling to assess sources of variation in NVP pharmacokinetic parameters, focusing on body composition.		
Update:	20 children were enrolled in the study and have completed all of the study procedures. Participants underwent two inpatient assessments, one at ART initiation and one 3-4 months later.		

	At each of these inpatient assessments, timed blood samples were drawn at 0, 1, 3, 8, and 12 hours after an observed nevirapine (NVP) dose. Plasma NVP was measured by a rapid enzyme immunoassay (ARK Diagnostics, Sunnyvale, CA, USA), which was successfully introduced and implemented using the existing chemistry analyzer in the AMPATH reference lab in Eldoret, Kenya. The participants also received deuterium-labeled water, allowing body water composition assessment from the timed plasma samples. Serum proteins, anthropometrics, and saliva for CYP2B6 genotype analysis were also collected. Participants also underwent 3-4 months of adherence monitoring, using Medication Event Monitors (MEMS®), pill counts or volume measures, and questionnaires. Preliminary pharmacokinetics modeling based on these data were completed. Population pharmacokinetics parameters for nevirapine were determined. %H2O explained 7.4% of the variability of CL/F. Participants' TBW% affected CL/F ($p<0.05$): a 30% lower value increased CL/F by 12%. Lower weight-for-age Z scores also tended to reduce CL/F. These findings suggest that, as weight increases, total body water percentage decreases and this increases the clearance. Abstract was presented at the National Clinical & Translational Research Education Annual Meeting, April 2009; 2nd International Workshop of HIV Pediatrics, Vienna, Austria. July 2010; and AIDS 2010 Conference, Vienna, Austria. July 2010. Manuscript development underway and awaiting revised pharmacokinetics modeling.		
Project Name:	Post-Crisis Evaluation		
Investigators:	K. Wools-Kaloustian, S. Ndege		
Start Date:	1/1/2008	**Project End Date:**	02/30/2011
Project Description:	Retrospective look at how AMPATH dealt with the post Election violence, including a look at how soon patients returned to clinic and a case study of how the Burnt Forest Clinic dealt with the Crisis.		
Update:	Suzanne Goodrich a fellow working with Dr. Wools-Kaloustian has taken-up work on this paper. The numbers and basic analysis that is needed for this paper has been complete. Dr. Goodrich did interviews with the authors during the month of May and will be working on the Manuscript in July.		
Project Name:	Pregnancy Outcomes		
Investigators:	A. Bell, E. Were, B. Musick, K. Lane, A. Katschke, C. Shen, P. Akhaabi, E. Were, J. Hogan, K. Wools-Kaloustian		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	This is a retrospective analysis of pregnancy outcomes of HIV-infected women enrolled in the AMPATH program from January 2006 to March 2009. Per protocol, pregnant women with CD4 < 200 begin cART immediately and those with a CD4 ≥ 200 start at 28 weeks gestation. The pregnancy outcomes are being compared between women pregnant at program enrollment (BE) and those who became pregnant after enrollment (AE).		
Update:	No update received		
Project Name:	Progression of HIV Infection among Children Attending AMPATH Clinics in Western Kenya		
Investigators:	C. Yiannoutsos, S. Ayaya, R. Vreeman, W. Nyandiko, K. Wools-Kaloustian		
Start Date:	2004	**Project End Date:**	2011
Project	Study is looking at the latency period and the AIDS surival time among children receving treatment		

Description:	in the AMPATHY clinics.		
Update:	Data being re-analyzed		
Project Name:	Qualitative Assessment of Barriers to Antiretroviral Therapy Adherence among Adolescents (Qualitative Inquiry into Pediatric Adherence)		
Investigators:	R. Vreeman, W. Nyandiko, C. J. Zeunik, S. Ayaya, D. Marrero, T. Inui		
Start Date:	3/2007	**Project End Date:**	12/2011
Project Description:	Qualitative research project involving focus groups and individual key informant interviews with parents and caregivers of HIV-infected children taking ART, older children on ART, and healthcare providers of children with ART. Objective was to identify key factors sustaining children's adherence to ART in western Kenya. This analysis focuses on adolescent-identified factors impacting the experience of medication-taking and creating barriers and facilitators to adherence.		
Update:	In western Kenya, the need to maintain secrecy about ART emerged as a key theme related to adolescent ART adherence. We presented "'I can't be free to tell them': A qualitative assessment of barriers to antiretroviral therapy adherence among adolescents in western Kenya" as a poster presentation at the 2009 International AIDS Society meeting in Cape Town, South Africa. The manuscript is now under review by the co-authors and should be submitted to a journal for consideration shortly.		
Project Name:	Qualitative study to understand factors associated with loss to follow-up among HIV-infected and HIV-exposed children attending USAID- AMPATH Partnership clinics (PEDI-UP Sub-Study). Duplicate??		
Investigators:	P. Braitstein, C. Yiannoutsos, K. Wools-Kaloustian, S. Ayaya, R. Vreeman, P. Gisore, W. Nyandiko, C. Tenge , J. Wachira		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Losses to follow-up (LTFU) are an important clinical and epidemiological challenge to HIV programs, particularly in resource-constrained settings. Little is known about LTFU among HIV-affected children. The objective of the qualitative study is to: 1) determine the personal, social and cultural influencing caregivers not to bring their children to care 2) document ideas of how to overcome barriers identified.		
Update:	No update received		
Project Name:	Quinolone Use by Patients with Tuberculosis in a Large HIV Treatment Program in Western Kenya		
Investigators:	A. Gardner, A. Siika, S. Pastakia, L.Diero, T. Cohen, B.Musik, G. Simiyu, J. E. Carter		
Start Date:	1/12/2009	**Project End Date:**	1/12/2011
Project Description:	Retrospective analysis of pharmacy and AMRS data to characterize the extent and indications for use of fluoroquinolones among patients in AMPATH and understand the implications for TB control.		
Update:	Abstract presented at International Union Against TB and Lung Disease Annual Conference. Awaiting complete data set from AMRS.		
Project Name:	Rationing of Combination Antiretroviral tTherapy (cART): Impact on Morbidity, Mortality, and Loss to Follow-up in a Large HIV Treatment Program in Western Kenya		
Investigators:	A. Bell, S. Kimaiyo, K. Wools-Kaloustian, A. Katschke, C. Shen, H. Liu, G. Simiyu, B. Musick, J.Sidle, A. Siika, P. Braitstein		

Start Date:	00/00/0000	**Project End Date:**	8/31/2011
Project Description:	From March 12 – August 31, 2007 (approximately 6 months), Kenya experienced a shortage of HIV-related medications. The United States Agency for International Development (USAID) funded Academic Model Providing Access to Healthcare (AMPATH) was asked by the Kenyan government to limit new cART initiation. The program agreed to limit the new cART starts to 1000 patients per month. For the 6 month period, AMPATH continued to start new patients with CD4<100 cells per cubic millimeter, but limited the number started with the usual criteria, effectively "capping" new cART initiations. The objective of this retrospective analysis was to determine the impact of the restriction on morbidity, mortality, and loss-to-follow-up. We conducted an analysis of all patients who were (i) non-pregnant adults (age 14 or older); (ii) enrolled either during the six-month period with restricted cART (the "cap" period) or the six months prior (the "pre-cap" period); and (iii) eligible for cART at enrollment by the pre-cap standard, that is, (1) CD4 < 200; (2) WHO stage 4 illness; or (3) WHO stage 3 AND CD4 < 350. Primary endpoints are compared between the cap and pre-cap cohorts. Descriptive statistics are used to summarize key variables. Kaplan-Meier estimators are used to estimate survival probabilities. Cox proportional hazard model is used to adjust for potential confounders.		
Update:	The data has been analyzed. A manuscript is in progress and expected to be submitted for consideration for publication in August 2011.		
Project Name:	REACH Informatics C.O.E - Fogarty Grant.		
Investigators:	P. Biondich, A. Siika, P. Braitstein, L. Diero, J. Sidle, S. Downs, J. Hogan, K. Kroenke, B. Mamlin, E. Meslin, D. Ngare, W. Nyandiko, W. O'Meara, M. Overhage, M. Palakal, J. Rotich, C. Shen, R. Vreeman, M. Were, K. Wools-Kaloustian, C. Yiannoutsos		
Start Date:	01/06/2009	**Project End Date:**	06/30/2014
Project Description:	The project is a collaboration between Indiana and Moi Universities and the global leadership of the Regenstrief Institute. The project/program is mandated to; 1. Provide post-doctoral informatics training to faculty at Moi University and Moi Teaching and Referral Hospital to implement and use health information technology to enhance research and improve health care quality, efficiency and outcomes. 2. Support the training of East Africans so as to support the development, implementation, maintenance, evolution and use EHRs in low-income countries through didatic and mentored practicum training programs.		
Update:	Events; - 2 week Data Management & Analysis trainings was conducted in January 2011 where 38 participants drawn from Kenya, Uganda and Tanzania successfully completed the course - 2 weeks Developers/Programmers training was conducted in May with 8 participants from Kenya and Botswana attending. - 3 days OpenMRS Implementers workshop was held in June 2011. 18 participants and 12 AMPATH staff engaged in the workshop. Updates: - 2 Fellowship candidates leaving Kenya for Indiana for the Fellowship program in Health Informatics. - Planning on advertisement for the next intake of fellowship for 2011-2012 program due in August. Challenges - Adequacy and availability of training venue Presentations - None		

	Publications - None		
Project Name:	Reactive Plasma Reagent		
Investigators:	J. Sidle, R. Drobner		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Cost effectiveness of doing PRP tests for all HIV positive patients		
Update:	No update received		
Project Name:	REnal Function at Baseline as Predictor of Outcomes in an HIV Care Program (Working Title)		
Investigators:	K. Wools-Kaloustian, O. Ong'or, S. Gupta, M. Goldman, L. Diero, A. Siika, S. Kimaiyo, B. Musick, S. Wafula, C. Schen		
Start Date:	1/1/2009	**Project End Date:**	02/30/2011
Project Description:	Background: WHO's has recently recommended that antiretrovirals be initiated in all individuals with CD4 counts less than 350 cells/µl. For countries with resources too limited to expand care to all such patients it would be of value to able to identify and target populations at highest risk of HIV progression. Renal disease has been identified as a risk factor for disease progression or death in some populations. Methods: Times to meeting cART initiation criteria (developing either a CD4 count <200cells/µl or WHO stage 3 or 4 disease) and overall mortality were evaluated in HIV-infected Kenyan adults. Cox proportional hazard regression models were used to evaluate the associations between renal function and these endpoints. Results: 7,383 subjects with median follow-up time of 59 (interquartile, 27-97) weeks were analyzed. In Cox regression analyses adjusted for age, sex, WHO disease stage, CD4 cell count, and hemoglobin, estimated creatinine clearance (CrCl) <60mL/min was significantly associated with shorter times to meeting cART initiation criteria [HR 1.48 (95% CI, 1.29-1.69)] and overall mortality [HR 1.71 (95% CI, 1.02-2.86)] compared to CrCl ≥90mL/min. Estimated glomerular filtration rate (GFR) <60mL/min/1.73m2 was associated with shorter times to meeting cART initiation criteria [HR 1.47 (95% CI, 1.23-1.63)] but not with overall mortality. CrCl and GFR remained associated with shorter times to cART initiation criteria, but neither was associated with mortality, in weight-adjusted analyses. Conclusions: In this large natural history study, reduced renal function was strongly associated with faster HIV disease progression in Kenyans not initially meeting cART initiation criteria. As such, renal function measurement in resource-limited settings may be an inexpensive alternative to viral load testing to identify those most in need of cART to prevent progression to AIDS. The initial association between reduced CrCl, but not reduced GFR, and greater mortality was explained by the low weights in this population.		
Update:	Published: Gupta SK, Owino Ong'or W, Shen S, Musick B, Goldman M, Wools-Kaloustian K. Reduced renal function is associated with progression to AIDS but not with overall mortality in HIV-infected Kenyan Adults not initially requiring combination antiretroviral therapy. JIAS 2011 In press		
Project Name:	Renal Study		
Investigators:	C. Wyatt, O. Ong'or, Joseph Abuya, K. Wools-Kaloustian, J. Sidle		
Start Date:	12/10/2007	**Project End Date:**	10/09/2010

Project Description:	This study is comparing the performance of equations to estimate kidney functions to a direct measure of kidney functions based on the plasma disappearance of iohexol, following an injection in HIV infected patients.		
Update:	The study has been permanently closed to accrual after achieving the target number of participants.No more follow-up of participants. Date analysis is going on. We hope to start another study soon.		
Project Name:	Reproductive Health Impact of Integrating Family Planning and HIV Care Services: A Retrospective Cohort Study		
Investigators:	K. Wools-Kaloustian, R. Kosgei, K. Lubano, C.Shen, B.Musick, A.Siika , H.Mabeya, E. J. Carter, A. Mwangi, J. Kiarie		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Impact of integrating family planning services with HIV care		
Update:	No update received		
Project Name:	Restricting cART Initiation: Impact on Morbidity, Mortality, and Loss to Follow-up		
Investigators:	K. Wools-Kaloustian, S. Kimaiyo, A. Bell, A. Katschke, C. Shen, G. Simiyu, B. Musick, A. Siika, P. Braitstein		
Start Date:	not indicated	**Project End Date:**	not indicated
Project Description:	We performed a retrospective analysis of all patients who were (i) non-pregnant adults (age 14 or older); (ii) enrolled either during the six-month period with restricted cART (the "cap" period) or the six months prior (the "pre-cap" period); and (iii) eligible for cART at enrollment by the pre-cap standard, that is, (1) CD4 < 200; (2) WHO stage 4 illness; or (3) WHO stage 3 AND CD4 < 350. Primary endpoints are compared between the cap and pre-cap cohorts. Descriptive statistics are used to summarize key variables. Kaplan-Meier estimators are used to estimate survival probabilities. Cox proportional hazard model is used to adjust for potential confounders.		
Update:	No update		
Project Name:	Revising Mortality Estimates for HIV-infected Children based on Vital Status Findings of Children Lost to Follow-up		
Investigators:	P. Braitstein, W. Nyandiko, S. Ayaya, C. Yiannoutsos, K.Wools-Kaloustian, R. Vreeman		
Start Date:	NA	**Project End Date:**	NA
Project Description:	Based on the findings in the Pedi-Up study where we identified that 16% of HIV-infected children LTFU are in fact deceased, the true mortality estimates among them needs to be revised.		
Update:	Analysis is underway		
Project Name:	RH Records Study		
Investigators:	R. Spitzer, B.Chemwolo, D. Caloia, CDC Records Study group		
Start Date:	June 2009	**Project End Date:**	August 2011
Project Description:	Before/after evaluation of the impact of electronic records on antenatal care by chart quality and patient and staff satisfation		
Update:	After evaluation planned for July/August 2011 to be followed by analysis.		

Project Name:	Screening for Cervical Cancer in HIV-Positive Kenyan Women: The Role of Human Papillomavirus Typing		
Investigators:	E. Dainty, E. O'rango, J. Carter, D. Walmer, S. Washington, D. Westriech		
Start Date:	08/15/2011	**Project End Date:**	06/30/2011
Project Description:	Among HIV positive women in Kenya, cervical cancer has the highest incidence of any malignancy. In order to effectively screen HIV-infected women for cervical cancer, an understanding of the natural history of human papillomavirus (HPV) and HIV co infection is critical, as HPV infection in the causative agent for cervical cancer. Emerging data supports the existence of geographically disparate types of HPV, particular those causing invasive cervical cancer in HIV positive women. This study will investigate HPV genotype distribution in HIV-infected Kenyan women with the following objectives: 1. Objective #1: To describe the prevalence of HPV genotypes in HIV infected women with cervical dysplasia and invasive cervical cancer in Eldoret, Kenya. 2. Objective #2: To determine how CD4 count relates to HPV genotype distribution between women with cervical dysplasia and cervical cancer. Samples for HPV genotyping will be collected as one-time cervical swabs from patient encounters. These samples will be sent to Innogenetics, a lab in Mombasa, Kenya that is owned by collaborators from Belgium. Study investigators are currently exploring the possibility of performing the HPV genotyping at the immunology lab at Moi Teaching and Referral Hospital. Our hope is that we will be able to introduce this test at Moi Teaching and Referral Hospital, and thus build the local capacity for diagnostics on site.		
Update:	Study has not yet commenced enrollment, still undergoing IREC review		
Project Name:	Sexual Health Risks and HIV Prevalence in Street-Involved Youth in western Kenya		
Investigators:	P. Braitstein, A. Chirchir, D. Ayuku, J. Carter, S. Winston		
Start Date:	02/01/2011	**Project End Date:**	12/31/2011
Project Description:	This is a cross-sectional study to evaluate the sexual health risks, behaviors, and outcomes among Street youth in Eldoret, Kenya. The study population will consist of youth ages 12 to 21 years, who spend their days or night and days on the streets within Eldoret Specific Aim 1: Characterize the sexual risk behaviors of the street youth in Eldoret. Objective: Determine the presence of specific risk factors, including early age of sexual debut, age discrepancy of partners, exchange sex, number of partners, and condom use. Specific Aim 2: Determine the prevalence of and risk factors for sexual abuse and rape of street youth. Objectives: Characterize the history of sexual abuse and assault, prior to street life, once on the street, and recently. Determine any correlation of sexual abuse and assault to high risk sexual behaviors, drug use, STIs, and HIV infection. Specific Aim 3: Assess access to reproductive health care for street youth in Elodret. Objective: Assess knowledge of places to go for care, previous use of clinics, STI screening including HIV, access to condoms, contraception. Specific Aim 4: Determine the prevalence of and risk factors for HIV and STIs among street youth. Objective: measure the frequency of self report of STIs (symptoms, prior diagnosis or treatment) and screen for STI and HIV infection and calculate prevalence within the study population. Specific Aim 5: Assess acceptance of self-collection of rectal and vaginal samples for STI screening		

	among street youth. Objective: Determine the percentage of study population willing to perform self-collected rectal and vaginal swabs for STI screening.		
Update:	We received a CFAR international developmental award as funding for this project which has allowed us to include STI screening in the study. However, this has required revisions to the protocol, and are awaiting approval of amendments in order to start enrollment.		
Project Name:	Sexual Health Risks and HIV Prevalence in Street-Involved Youth in western Kenya		
Investigators:	P. Braitstein, D. Ayuku, A. Chirchir, S. Winston		
Start Date:	NA	**Project End Date:**	NA
Project Description:	This is a cross-sectional study to evaluate the sexual health risks, behaviors, and outcomes among Street youth in Eldoret, Kenya. The study population will consist of youth ages 12 to 21 years, who spend their days or night and days on the streets within Eldoret. Specific Aim 1: Characterize the sexual risk behaviors of the street youth in Eldoret. Objective: Determine the presence of specific risk factors, including early age of sexual debut, age discrepancy of partners, exchange/survival sex, number of partners, and condom use. Specific Aim 2: Determine the prevalence of and risk factors for sexual abuse and rape of street youth. Objectives: Characterize the history of sexual abuse and rape, prior to street life, once on the street, and recently. Determine any correlation of sexual abuse and rape to high risk sexual behaviors, drug use, STIs, and HIV infection. Specific Aim 3: Assess access to reproductive health care for street youth in Elodret. Objective: Assess knowledge of places to go for care, previous use of clinics, STI screening including HIV, access to condoms, contraception. Specific Aim 4: Determine the prevalence of and risk factors for HIV and STIs among street youth. Objective: measure the frequency of self report of STIs (symptoms, prior diagnosis or treatment) and test for HIV infection and calculate prevalence within the study population.		
Update:	Awaiting release of funds from NIH providing and for STI screening.		
Project Name:	Simplified Regimens for Management of Possible Serious Bacterial Infections in Neonates and Young Infants for Use in Outpatient and Community Settings: A Multi-Centre Randomized Controlled Trial in Africa		
Investigators:	F. Esamai, E. Liechty, P. Gisore, S. Bucher		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Objective: To conduct a multi-centre randomized controlled trial in three countries in Africa (Democratic Republic of Congo, Kenya and Nigeria) to test the safety and efficacy of simplified antibiotic regimens for treating possible serious bacterial infection in 0-59 day-old infants Participants: Study participants will be young infants 0 to 59 days old, from settings in low- and middle-income countries with a high infant mortality (at least 60/1000 live births), with clinical signs of possible serious bacterial infection whose families do not accept or cannot access referral level care. Infants who are critically ill will be excluded, and the study participants will be stratified into two groups according to the severity of the possible serious bacterial infection on admission: - Severe infection: not feeding well, movement only when stimulated, severe chest in-drawing, axillary temperature >38.0oC or <35.5 oC; and		

	- Fast breathing alone: respiratory rate 60 or more per minute. The study will enroll a total of 6,200 young infants -- 3,600 in the stratum of young infants with possible severe infection and 2,600 in the stratum of less severe infection. Reference treatment (Comparison): The comparison group will receive injection gentamicin once daily and injection procaine penicillin once daily for 7 days (Treatment Regimen A, 14 injections in total). Experimental treatments (Intervention): The treatment regimens under evaluation will be: 1. For severe infection: Treatment Regimen B: injection gentamicin once daily and oral amoxicillin twice daily for 7 days (7 injections in total); Treatment Regimen C: injection gentamicin once daily and injection procaine penicillin once daily for 2 days, thereafter oral amoxicillin for 5 days (4 injections in total) Treatment Regimen D: injection gentamicin once daily and oral amoxicillin twice daily for 2 days, thereafter oral amoxicillin twice daily for 5 days (2 injections in total) 2. Fast breathing alone: Treatment Regimen E: oral amoxicillin twice daily for 7 days Outcomes: Treatment failure in the first week following initiation of treatment (primary outcome); death in the first week following initiation of treatment, death the week following completion of treatment, relapse in the week following completion of treatment, and severe adverse effects related to the antibiotics (secondary outcomes).
Update:	No update received
Project Name:	Street Children & Substance Abuse: Knowledge, Attitudes & Practices in Kenya
Investigators:	P. Braistein, D. Ayuku, L. Embleton
Start Date:	05/23/2011 **Project End Date:** 07/20/2011
Project Description:	This is a cross-sectional study of street youth. Overall objective: To a) describe the knowledge, attitudes, and practices (KAP) of street-involved children and youth aged 10 to 19 in Eldoret, Kenya; b) to describe the frequency of drug and alcohol use among this population; and c) describe factors associated with the use of all substances used by street-involved children and youth in Eldoret, Kenya. Data obtained from this study will inform policy, programs and services directed towards street-involved children and youth in resource-constrained settings. Streets throughout the world have absorbed tens of millions of children 1 who are enduring hardships and injustices while struggling to survive. These children spend either a portion or majority of their time on the street engaging in activities to generate income that often involve child abuse and exploitation, while falling into patterns of substance misuse 2-5. However, research on street children and their substance abuse habits in resource-poor settings has been very limited, yet the problem poses a serious threat to the health and well-being of millions of children around the world. An in-depth review of the literature demonstrates a high prevalence of substance use and misuse, with inhalants being nearly ubiquitously used by street-involved children and youth in resource-constrained settings. However beyond the prevalence of substance use, very little is known about street children's substance abuse habits and the impact on detrimental health outcomes both short- and long-term, risky health behaviours, access to services, and psychological dependence and addiction. The dearth of pertinent information in association with substance abuse in street children in resource-poor settings points to the immediate need for future research to fill the current gaps in knowledge. This literature review will address these issues and set the stage for a research agenda related to street-involved children and youth and drug use.

Update:	Approval was obtained from IREC at Moi University, REB at the University of Toronto and IRB at Indiana University. The study started enrollment on May 23, 2011 and 102 subjects have been enrolled to date. >50% street children enrolled.		
Project Name:	Street Children and Substance Use in Resource-Constrained Settings		
Investigators:	P. Braitstein, D. Ayuku, L. Embleton		
Start Date:	1/6/2011	**Project End Date:**	NA
Project Description:	Streets throughout the world have absorbed tens of millions of children 1 who are enduring hardships and injustices while struggling to survive. These children spend either a portion or majority of their time on the street engaging in activities to generate income that often involve child abuse and exploitation, while falling into patterns of substance misuse 2-5. However, research on street children and their substance abuse habits in resource-poor settings has been very limited, yet the problem poses a serious threat to the health and well-being of millions of children around the world. An in-depth review of the literature demonstrates a high prevalence of substance use and misuse, with inhalants being nearly ubiquitously used by street-involved children and youth in resource-constrained settings. However beyond the prevalence of substance use, very little is known about street children's substance abuse habits and the impact on detrimental health outcomes both short- and long-term, risky health behaviours, access to services, and psychological dependence and addiction. The dearth of pertinent information in association with substance abuse in street children in resource-poor settings points to the immediate need for future research to fill the current gaps in knowledge. This literature review will address these issues and set the stage for a research agenda related to street-involved children and youth and drug use.		
Update:	Revising to make a systematic review		
Project Name:	Systematic Review of TB Diagnosis in Children		
Investigators:	E. Pearce, J. Woodward, S. Ayaya		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Systematic review of studies evaluating diagnostic scoring criteria in children.		
Update:	No update received		
Project Name:	TB Screening in Antenatal Clinics in Western Kenya		
Investigators:	E. J. Carter, R. Kosgei, S. Washington, D. Szkwarko		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Screening of TB among pregnant women. Project began in October 2010 and is expected to end in June 2011.		
Update:	No update received		
Project Name:	The Effect of Third Trimester Pregnancy on the Pharmacokinetics of Efavirenz among TB/HIV Co-Infected Pregnant Women in Western Kenya		
Investigators:	E. J. Carter, R. Kosgei, H. Mabeya, S. Cu-Uvin, T. Blaschke, R.Vreeman, D. Zeruesenay, W. Nyandiko, S. Kimaiyo, A. Siika, K.Wools-Kaloustian		
Start Date:	unknown	**Project End Date:**	unknown

Project Description:	Phamarcokinetic study; the effect of pregnancy on EFV. The project is expected to begin in March 1, 2011 and end in March 1, 2012.		
Update:	No update received		
Project Name:	The Impact of Non-Adherence to Clinic Visits on Mortality and Losses to Follow-up Among HIV-infected Children		
Investigators:	P. Braitstein, W. Nyandiko, S. Shangani, P. Ayuo, S. Ayaya, R. Vreeman		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	This is a retrospective analysis to evaluate the impact of non-adherence to clinic visits on death and loss to follow-up among HIV-infected children attending AMPATH clinics.		
Update:	No update received		
Project Name:	The IU Simon Cancer Center (IUSCC) AMPATH-Oncology Institute (AOI): An Exemplar of Care for the Developing World and a Population-Based Research Environment for IUSCC		
Investigators:	T. Inui, C. Asirwa, N. Busakhala, M. Strother		
Start Date:	1/7/2011	**Project End Date:**	12/31/2014
Project Description:	Kenya, like much of the developing world, is rapidly undergoing an 'epidemiologic transition' from a health scene dominated by infectious diseases to one in which the major causes of death and disability are cancer and other chronic diseases. Under these circumstances, applying science to the management and control of cancer has become as relevant to Kenya as it is in the United States. Similarly, what is learned about the prevention and treatment of cancer in the developing world literally has direct relevance to care in the United States. Cancer care and attendant research in Kenya, whose population is the most genetically diverse in the world, will catalyze the discovery of new genes of importance to our fight against cancer, new genomic predictors of cancer, and new genetic variants that predict response to therapy. Recognizing both emerging threats to population health and potential for advancing care and science, the IU Simon Cancer Center (IUSCC) and the IU-Kenya AMPATH Program have been actively pursuing resources to respond. The focus of the partnership is to develop a sustainable and comprehensive academic clinical care program that will serve the citizens of western Kenya, and in the process, create a unique program of international collaboration for patients with, or at risk for, malignancies. The mission of the AMPATH Oncology Institute (AOI) is to be the premier cancer program in Sub-Saharan Africa, noted for excellence in cancer prevention, treatment and palliative care. AOI activities will directly contribute to advances in cancer care, accelerate discoveries in the biology and treatment of cancer, and provide support for the IU Simon Cancer Center's quest to become a federally designated Comprehensive Care Center		
Update:	Not yet initiated.		
Project Name:	The Prevalence of Markers of Atherosclerosis Among Adult Patients with Congestive Cardiac (Heart) Failure		
Investigators:	E. Velazquez, S. Kimaiyo, G. Bloomfield, J. Carter, M. Maghasi, C. Akwanalo, Joseph		
Start Date:	05/24/2010	**Project End Date:**	12/31/2011
Project Description:	Using a case-control research design in a Kenyan population with heart failure, this project will describe the range of etiologies of heart failure within this population. This project will collect pilot data on the burden of atherosclerosis and malnutrition among patients with heart failure at Moi Teaching and Referral Hospital (MTRH) Inpatient ward, Primary Care and Cardiology Clinics, through the collection of both echocardiographic and serologic studies coupled with clinical assessments; thereby informing hypotheses for larger prospective, regionally-relevant analyses in		

	the future.		
Update:	The study is currently closed to enrollment. Collection of lab results, data entry and follow up of participants to complete study related procedures is currently ongoing.		
Project Name:	The Prevalence of Rheumatic Heart Disease in Western Kenya: An Echocardiographic Study		
Investigators:	G. Corey, S. Kimaiyo, T. Holland, M. Koech, E. J. Carter		
Start Date:	12/02/2010	**Project End Date:**	12/31/2011
Project Description:	We propose to describe the prevalence of rheumatic heart disease in western Kenya by performing echocardiography in a representative hospital-based sample of 500 subjects. Our hypothesis is that if echocardiographic screening is conducted on this population, ages 5-30, we will find more silent RHD and detect a prevalence that is similar to that reported in the recent literature. Thus, the principal aim of our study is: 1. To investigate the prevalence of RHD, as determined by transthoracic echocardiography, in patients (ages 5-30) hospitalized on the orthopedic and surgical wards Our intent is to more precisely define the burden of rheumatic heart disease in Western Kenya with the most definitive diagnostic modalities. Results from these investigations would be important in elucidating more inclusive screening criteria for patients at risk for rheumatic heart disease in the general population. More importantly, epidemiologic data derived from our investigations would be central to the development of any community-based primary and secondary prevention campaigns against group A streptococcal infection, acute rheumatic fever and rheumatic heart disease.		
Update:	The study is ongoing and open to enrollment. Recruitment is ongoing and has accelerated in the past 6 months.		
Project Name:	The Relationship of Indoor Air Pollution (IAP) Exposure to Isolated Right Heart Failure (IRHF) in Women in Western Kenya		
Investigators:	J. Carter, S. Kimaiyo, D. Lagat, C. Sherman, L. Diero, J. Hogan, K. Anstrom, E. Velazquez		
Start Date:	12/10/2010	**Project End Date:**	11/30/2011
Project Description:	Several studies have shown that isolated right heart failure (IRHF) is more prominent in African women than in those living in resource rich nations. Its prognosis is thought to be worse among African women relative to similar patients from the richer economies given their general lack of access to health care and often late presentation of disease. COPD is the leading cause of IRHF in resource rich nations. It remains unclear whether this relationship exists in African women. COPD remains the 7th leading cause of morbidity and mortality worldwide. In resource rich nations it is related to cigarette smoking. Risk factors for the development of COPD in Africa include combustion of biomass/traditional fuels and coal, previous tuberculosis infection, and childhood respiratory infections. Biomass fuels are used extensively throughout Africa, especially in the sub-Saharan area. Typical pollutants that result from the poor burning and ventilation of these fuels include particulate matter, aldehydes, carbon monoxide, hydrocarbons, volatile organic compounds, and nitrogen dioxide. Worldwide, women exposed to indoor smoke are 3 times as likely to develop COPD as those who cook and heat with electricity, gas, and other cleaner burning fuels. A study of rural South African women found an increased prevalence of COPD due to the burning of cow dung in poorly ventilated houses. The relationship between IAP and COPD needs further investigation in sub-Saharan women.		

	Several studies have shown that a form of heart disease called isolated right heart failure (IRHF) is more prominent in African women than in those living in resource rich nations. This heart disease is thought to have a worse outcome in the form of poorer quality of life and earlier death among African women given their general lack of access to health care and often late presentation of disease, relative to patients from the resource-rich nations. It is exceptionally important therefore to understand the risk factors of the ailment for the purposes of setting up preventive strategies. Research question or hypothesis: Specific Aim #1 To delineate the level of indoor air pollution exposure among women presenting with isolated right heart failure in western Kenya. Hypothesis #1: Women in Kenya with echocardiographic proven IRHF have higher levels of exposure to IAP than women without IRHF. Specific Aim #2 To describe the degree of pulmonary function abnormalities in women presenting with isolated right heart failure in western Kenya. Hypothesis #2: The degree of pulmonary function abnormalities in women with echocardiographic proven IRHF in Kenya will be greater than those women without IRHF. Specific Aim #3 To delineate the level of indoor air pollution among women presenting with isolated right heart failure and abnormal pulmonary functions in western Kenya. Hypothesis 3. Women in Kenya with echocardiographic proven IRHF and pulmonary function abnormalities have higher levels of exposure to IAP than women without either IRHF or pulmonary function abnormalities. Design: A case-control study. Sample population: All female patients undergoing echocardiograhic evaluation at the Moi Teaching and Referral Hospital in Eldoret, Kenya will be eligible for participation. We aim to enroll 100 women with echocardiograhic proven, isolated right heart failure and 100 women with no evidence of echocardiograhic right heart failure. The women must be above 35 years of age		
Update:	The study is still ongoing. To date we have screened 292 individuals and recruited 80 participants. We have visited homes of 34 participants for environmental assessment. Several amendments have been made to the study (i.e. to include former smokers and only women who live within an area reached by 60 minutes of driving from MTRH). These amendments have been approved by Moi IREC and Duke University IRB. The amendments have also been submitted to Lifespan IRB for approval.		
Project Name:	The Use of Traditional Medicine in Management of HIV and AIDS in Western Kenya		
Investigators:	P. Braitstein, A. Atwoli, E. Kamaara, W. Folk, H. Maithya, G. Nduru, N. Shitemi, T. Inui, P. Ayuo,		
Start Date:	NA	**Project End Date:**	NA
Project Description:	This was an exploratory pilot study designed to generate hypotheses towards establishing the role of traditional medicine in the management of HIV/AIDS in Western Kenya with the goal of improving health care and services for persons living with HIV and AIDS.		
Update:	Working on comments from Journal of IAS		
Project Name:	Treatment Faliure Misclassification in Children in Western Kenya		
Investigators:	E. Dufort, W. Nyandiko, R. Kantor		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Examine misclassification of treatment failure in children		
Update:	No update received		

Project Name:	Tuberculosis (TB) Among Participants of an Academic, Global Health Medical Exchange Program		
Investigators:	A. Gardner, E. J. Carter, T. Cohen		
Start Date:	1/1/2010	**Project End Date:**	1/4/2011
Project Description:	We conducted a survey of participants in the medical exchange program to evaluate risk of TB infection		
Update:	Study completed and manuscript published in Journal of General Internal Medicine.		
Project Name:	Understanding the Challenges Faced by Contemporary Nandi Widows		
Investigators:	J. Dickerson, H. Maythia, E. Kamaara, E. Choge		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	The goal of the project is to undertake a qualitative comparison of the challenges faced by Nandi widows living in the Western Kenyan communities of Kesses Dam and Burnt Forest. This data will be used to contribute to the design of better support programs for these women.		
Update:	No update received		
Project Name:	Uptake of HIV Testing Among Men Versus Women in HCT		
Investigators:	J. Wachira, S. Ndege, S. Kimaiyo, P. Ayuo, R. Kioko, V. Chepgeno, S. Wafula, P. Braitstein		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	Introduction: The USAID-AMPATH Partnership is implementing Home-based Counseling and Testing (HBCT) in western Kenya. We assessed whether women vs. men would be more likely to accept HBCT, and what factors affect testing uptake among them. Methodology: Data were collected between August-December 2008. All persons ≥13 years participating in HBCT were eligible. Multivariable logistic regression was used to identify factors associated with testing uptake. Results: A total of 41,066 adults were included in the analysis: 57% female. Only 32% of women and 18% of men had previously been tested for HIV ($p<0.001$). Men were less likely to accept counseling (94%) vs. women (96%) (AOR 0.66 95% CI: 0.60-0.73), but 89% of both men and women counseled, agreed to testing. Among men, older age (per 10 years) (AOR: 1.12, 95% CI: 1.02-1.23), higher number of household members (per member increase) (AOR: 1.27, 95% CI: 1.17-1.37) and higher number of children (AOR: 0.72, 95% CI: 0.65-0.81) were associated with accepting testing, while men who had ever tested for HIV before (AOR: 0.53, 95% CI: 0.41-0.68) were less likely to accept testing in HBCT. Younger women (per 10 years) (AOR: 0.87, 95% CI: 0.82-0.91) were more likely to accept testing, whereas women who had ever before tested for HIV (AOR: 0.57, 95% CI: 0.48-0.68) and those who lived in households headed by a HIV infected person (AOR: 0.70, 95% CI: 0.55-0.88) were less likely to accept testing. More men than women (67% vs. 33%, $p>0.001$) utilized the standalone VCT services offered during the exercise. HIV prevalence was 4.6% in women and 2.6% in men ($p<0.001$). Conclusion: Although men were less likely to accept counseling, HBCT uptake in both men and women was high. The determinants of HBCT suggest the need to address the unique differences among men and women. Continuous education and regular counseling and testing services are needed to reinforce testing for persons at risk.		
Update:	No update received		

Project Name:	Uptake of Preventive Interventions in AMPATH Communities		
Investigators:	W. O'Meara, S. Ndege, W. Nyandiko		
Start Date:	unknown	**Project End Date:**	unknown
Project Description:	The objective of the proposed work is to identify and characterize populations in the AMPATH catchment area that are most at risk of inadequate coverage and uptake of health interventions. Specifically: 1. Characterize physical access (using spatial techniques) to health care in communities that have received HCT and identify underserved communities 2. Spatial analysis of socioeconomic status (SES) with respect to population density and access to health facilities 3. Compare immunization and ANC coverage in communities identified as "underserved"		
Update:	No update received		

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Under Consideration

1. Hillary Mabeya, Tao Liu, Kareem Khozaim, Omenge Orango, David Chumba, Latha Pisharodi, Susan Cu-Uvin. Comparison of Conventional Cervical Cytology versus Visual Inspection with Acetic Acid (VIA) among HIV-Infected Women in Western Kenya. Journal of Lower Genital Tract Diseases.

Appendix 2: Research Grants and Contracts Table

Research and Training Grants and Contracts Awarded to the AMPATH Research Program

TITLE	PI(s)	INSTITUTION	DIRECT COSTS	SOURCE OF FUNDS	DATES
Regenstrief-Moi Medical Informatics Fellowship Program	W. Tierney	Indiana University	$617,383	Fogarty International Center, NIH	9/30/98-5/31/05
Indiana University – Moi University Exchange Faculty Development Program	Robert Einterz	Indiana University	$138,424	ECFMG	1/1/99-9/30/03
IUSM-MUFHS Exchange Faculty Development Program	Robert Einterz	Indiana University	$10,000	Indiana University International Development Fund	09/01/99-7/1/06
Causes of Infection Requiring Hospitalization in Patients with HIV/AIDS in Western Kenya	Ken Fife L. Diero	Indiana University and Moi University	$10,000	NIH (ACTG)	6/1/02-5/30/04
The Economic Impacts of HIV/AIDS and Treatment	Markus Goldstein	World Bank	$71,575	Economic and Social Research Council	2003-2004
Directly Observed Therapy for TB/HIV in Western Kenya	Tim Flannigan	Brown University	$120,000	NIH	9/1/03-8/30/07
Establishing HIV/AIDS Research in Western Kenya	L. Diero	Moi University	$100,000	National Institute of Allergy and Infections Diseases, NIH	9/1/03-8/31/05
The Economic Impacts of Disease and Treatment on Household Welfare in Western Kenya	Markus Goldstein	World Bank	$45,000	World Bank	2004-2006
Needs Assessment for Implementing the IU/Moi MOU in Research Ethics	Eric Meslin	Indiana University	$11,860	Indiana University International Development Fund	4/1/04-3/31/05
AIDS Associated Assessment of TB Transmission	J. Carter	Brown University	$30,000	NIH	7/1/04-6/30/06
Tuberculosis Active Case Finding in Traditional and Non-traditional Sites in Western Kenya	Nathan Buziba	Moi University	$199,000	FIDELIS: The International Union Against TB and Lung Disease	7/1/04-6/30/05
Electronic Medical Records: A Critical Tool in the Battle Against HIV/AIDS in Africa	Joseph Mamlin W. Tierney	Indiana University	$222,934	Rockefeller Foundation	5/1/04-7/31/06
The Economic Impacts of Disease and Treatment on Household Welfare in North Rift Region of Kenya	Markus Goldstein	World Bank	$150,055	USAID	2004-2005
Partners in Prevention Study (Phase III Randomized Placebo-Controlled Trial of HSV-2 Suppression to Prevent HIV Transmission Among HIV-Discordant Partners)	Ken Fife	Indiana University	$1,845,260	University of Washington (Bill and Melinda Gates Foundation)	2/1/05-4/30/08

TITLE	PI(s)	INSTITUTION	DIRECT COSTS	SOURCE OF FUNDS	DATES
ACTG: A5208 Clinical Trial	Mitchell Goldman A. Siika	Indiana University and Moi University	$285,616	National Institute for Allergy and Infectious Diseases (NIH)	1/1/05-completion
Supporting Collaboration of US and Kenyan Investigators	C. Yiannoutsos	Indiana University	$13,660	Indiana University International Development Fund	6/1/05-5/31/06
Implementation of the AMPATH Medical Record System in East Africa	W. Tierney W. Nyandiko	Moi University and Indiana University	$450,000	Rockefeller Foundation	10/1/05-9/30/08
Implementation of the AMPATH Medical Record System in East Africa	W. Tierney W. Nyandiko	Moi University and Indiana University	$268,120	WHO	10/1/05-9/30/08
Implementation of the AMPATH Medical Record System in East Africa	W. Tierney W. Nyandiko	Moi University and Indiana University	$50,000	UN Development Program	10/1/05-9/30/08
The Impact of a Nutrition Program for AIDS Patients and its Role in their Coping Strategies	Mabel Nangami	Moi University	$45,000	International Food Policy Research Institute	11/1/05-10/31/06
AMPATH Evaluation Program	J. Sidle Thomas Inui	Indiana University	$500,000	PVF Foundation	5/1/06-6/1/08
Extending HIV Care Beyond the Rural Health Center	K. Wools-Kaloustian	Indiana University	$200,000	Doris Duke Charitable Foundation	1/1/06-12/31/07
East Africa IeDEA Consortium	C. Yiannoutsos W. Tierney	Indiana University	$4,006,401	NIAID	8/5/06-7/31/11
Enhancing Infant Feeding Among HIV-infected Mothers	K. Wools-Kaloustian	Indiana University	$20,000	Indiana University Center for AIDS Research	4/1/06-3/31/07
DOTS Expansion: Lab to Community Mobilization in North Rift Valley, Western Kenya	Nathan Buziba	Moi University	$250,000	FIDELIS	4/1/06-3/31/07
Kenya Cancer Project	P. Loehrer	Indiana University	$50,000	Eli Lilly Company	5/1/06-4/30/09
Increasing Animal Source Foods in Diets of HIV-Infected Kenyan Women and Their Children	J. Ernst	Indiana University	$2,943,436	Global Livestock Collaborative Research Support Program (GL-CRSP) funded by USAID	7/1/06-9/30/09
Monitoring and evaluation, patient surveillance, and loss to follow-up	C. Yiannoutsos	Indiana University	$92,412	NIH-NIAID	9/1/06-8/31/07
Use of Rapid TB Culture Technology: Impact on the Diagnosis of Smear Negative Tuberculosis in the Developing World	Haroun Mengech Fabian Esamai	Moi University	$250,000	FIND Diagnostics	10/1/06-9/30/08
HIV-1 Geontypic Diversity and Drug Resistance in Western Kenya	Rami Kantor	Brown University	$40,000	Brown University Center For AIDS Research	01/01/06-12/31/06

TITLE	PI(s)	INSTITUTION	DIRECT COSTS	SOURCE OF FUNDS	DATES
Adherence to ARV Treatment and its Effects on Socio-Economic Outcomes: Evidence from Western Kenya	Damien DeWalque	World Bank	$250,000	World Bank	2007-2008
Alcohol and HIV in Kenya: Stage 1 trial of a peer-led alcohol behavior intervention	R. Papas	Yale University	$278,921	NIH-NIAAA	7/10/07-6/30/09
Electronic Medical Records to Improve Patient Care & Public Health in Rural Kenya	W. Tierney	Indiana University	$1,046,022	CDC	09/30/07-09/29/10
NCI Supplement to the East Africa IeDEA Consortium	C. Yiannoutsos	Indiana University	$230,000	NIH-NIAID	9/1/07-8/31/08
NICHD Supplement to the East Africa IeDEA Consortium	C. Yiannoutsos	Indiana University	$77,680	CDC	9/1/07-8/31/08
Cervical Cancer Screening in HIV Positive Women, Moi University, Eldoret Kenya	Hillary Mabeya	Moi University and Brown University	$96,340	NIH-Fogarty International Center	06/01/07-05/31/08
Computer simulation of the Sub-Saharan HIV pandemic that can estimate value and benefit from alcohol interventions	Scott Braithwaite	Yale University	$2,144,325	NIH-NIAAA	09/30/07-08/31/12
Cancer Training and Resource Development in Western Kenya	Anthony Mega	Moi University and Brown University	$96,102	NIH-Fogarty International Center and NCI	06/01/07-05/31/08
Traditional Medicine in the Management of HIV/AIDS	Eunice Kamaara	Moi University	$27,778	University of Missouri	07/01/07-06/30/08
Partners Pre-Exposure Prophylaxis (PrEP) Study	Kenneth Fife	Indiana University	$2,245,883	Gates Foundation to the University of Washington	10/1/07-6/30/10
Merck Vaccine Network–Africa	Edward Liechty	Indiana University	$600,000	Merck Company Foundation	11/01/07-10/31/10
Kenya Cancer Project	P. Loehrer	Indiana University	$80,000	Eli Lilly Company	12/01/07-11/30/08
Kenya Cancer Project	P. Loehrer	Indiana University	$250,000	Anonymous	2007-2008
Open Medical Records System - Concept Cooperative (OpenMRS-CC)	Paul Biondich	Indiana University	$112,360	Northrup Corporation-2	1/1/08-8/31/08
Cross-Cultural Histories of Family Care-Giving to AIDS Orphans in Western Kenya	Jeanette Dickerson-Putman	Indiana University	$34,999	IUPUI Research Support Funds	03/01/08-02/30/09
Integration of a Care-Focused Diabetes Database into Outpatient Diabetes Care in a Resource-Constrained Setting	S. Pastakia W. Tierney	Purdue University and Indiana University	$50,000	IUPUI Collaboration Biomedical Research Grant Program	01/01/08-12/31/08
Global Network for Women's and Children's Health Research	Edward Liechty	Indiana University	$3,100,630	NIH-NICHD	04/01/08-05/31/13
Impact of using nurses instead of clinicians to care for stable HIV-infected patients	M. Were	Indiana University	$94,017	Tibotec REACH Initiative	10/1/08-09/30/09

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Increasing Animal Source Foods in Diets of HIV-infected Kenyan Women and Their Children	J. Ernst	Indiana University	$1,000,000	NIH-NICHD	10/01/08-7/31/12
Moi University Clinical Research Site	A. Siika	Moi University	$2,275,000	NIH – AIDS Clinical Trials Group	2008-2013
AMIA Global Biomedical and Health Informatics Fellowship Program	Don Detmer W. Tierney	AMIA and Indiana University	$1,188,700	Bill and Melinda Gates Foundation	11/1/08-4/30/10
Indiana University-Moi University Academic Research Ethics Partnership	Eric Meslin	Indiana University	$951,846	NIH: Fogarty International Center	07/01/09-06/30/13
Evaluation of a Comprehensive Strategy to Measure Pediatric Adherence to Antiretroviral Therapy	R. Vreeman	Indiana University	$185,002	USAID-PEPFAR	1/1/09-12/31/10
Improving Decision Support in AMPATH	M. Were	Indiana University	$350,000	Abbott Foundation	1/1/09-12/31/09
HIV-1 Genotypic Diversity and Drug Resistance in Western Kenya at Times of Political Crisis	C. Yiannoutsos Rami Kantor	Indiana University and Brown University	$136,442	NIH-IEDEA supplement	1/1/09-12/31/09
HIV Drug Resistance and Treatment Outcomes in Adults in Western Kenya after a Period of Crisis	Rami Kantor	Brown University	$2,500	Friendship Foundation	1/1/09-12/31/09
Enhancing research grant management capability and administrative infrastructure	Christine Chuani Robert Rono	Moi University	$190,000	NIH-NIAID	3/1/09-2/28/14
Enhancing cardiac care and research in AMPATH (Fogarty FIRCS Fellowship)	G. Bloomfield	Duke University	$66,700	NIH–Fogarty International Center	8/1/09-7/31/10
Computerized Counseling to Promote Positive Prevention and HIV Health in Kenya	Ann Kurth A. Siika	New York University and Indiana University	$1,810,361	NIH-NIMH	5/1/09-4/30/13
Development of Novel Pediatric Formulations for the Treatment of Infectious Diseases	Gregory Knipp R. Vreeman	Purdue University and Indiana University	$75,000	Indiana CTSI	3/1/09-2/28/10
ASANTE Cardiovascular and Pulmonary Diseases Center of Excellence	S. Kimaiyo E. Velazquez	Moi University and Duke University	$2,355,715	NIH-NHLBI	7/1/09-6/30/14
Orphaned & Separated Children's Assessment Related to their Health & Well-Being	P. Braitstein	Indiana University	$2,531,943	NIH-NICHD	9/1/09-8/31/14
Development of an Antiretroviral Therapy Adherence Measure for Pediatrics	R. Vreeman	Indiana University	$864,712	NIH-NIMH	8/1/09-4/30/14
Development of "Derived Concepts" in OpenMRS in support of IEDEA	Paul Biondich	Indiana University	$882,409	NIH-NIAID	7/1/09-6/30/11

TITLE	PI(s)	INSTITUTION	DIRECT COSTS	SOURCE OF FUNDS	DATES
Emergency Obstetrical Training in Western Kenya	Elkanah Orango Omenge A. Bocking	MTRH and the University of Toronto	$150,000	Development Partnerships in Higher Education (DelPHE), United Kingdom	9/1/09-8/31/12
An East African Center of Excellence in Health Informatics	W. Tierney A. Siika	Indiana University and Moi University	$1,263,216	Fogarty International Center	10/1/09-9/30/14
Expansion of Chronic Disease Management in Western Kenya	S. Pastakia	Purdue University	$300,000	Eli Lilly Foundation	10/1/09-1/1/2013
Helping Babies Breathe Kenya: Expanded Field Test	Sherri Bucher	Indiana University	$7,000	USAID and American Association of Pediatrics	11/1/09-5/31/10
Helping Babies Breathe Kenya: Expanded Field Test	Sherri Bucher	Indiana University	$60,000	Save the Children Foundation	12/15/09-9/30/10
Causes of early mortality in HIV-infected Africans on antiretroviral therapy	A. Siika	Moi University	$448,880	NIH-NIAID	7/1/09-6/30/13
Research Endowment to the IU Center for Global Health	Craig Brater	Indiana University	$2,000,000	Lilly Endowment	12/15/09
Patient-reported outcomes of cancer care in Eldoret, Kenya	Lisa Hess	Indiana University	$15,000	IU International Development Fund	1/1/10-12/31/10
Methods to Optimize Use of Limited Resources for Monitoring Treatment of HIV/AIDS in the Developing World	Tao Liu	Brown University	$34,366	CFAR	2/1/10-1/31/11
Building a Joint International IRB for Moi University and Indiana University	Eric Meslin	Indiana University	$940,000	NIH – Fogarty International Center	9/15/10-9/14/11
Improving Deaf Access to Reproductive Healthcare in Kenya: A Cultural Model	Susan Shepherd	Indiana University	$15,000	IU International Development Fund	1/1/11-12/31/11
Modified Directly Observed Antiretroviral Therapy	A. Siika	Moi University/AMPATH	$891,400	PEPFAR PHE	10/01/10 – 09/30/12
The Contribution of Multidrug-resistant (MDR), Extensively-drug resistant (XDR), and Quinolone-resistant (QDR) Tuberculosis (TB) to Early Mortality Among HIV-Infected Individuals Starting Anti-Retroviral Therapy (ART) in Western Kenya	A. Gardner A. Siika	Warren Alpert Medical School of Brown University	$25,000	Department of Medicine at Brown	12/01/10 – 12/01/11
ALL GRANTS AND CONTRACTS FUNDED TO DATE (N=77)			$44,867,385		