

SEMI-ANNUAL RESEARCH REPORT

January-June 2012

**Research Project Updates** 

Project Name:	A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated			
	- ' '	A5225/HiFLAC (Protocol Vei	rsion 1.0)	
Investigator(s):	Siika, A			
	Sidle, J.			
	Lagat, D.			
	Kwobah, C.			
	Nzioka, J.			
Start Date:	5/18/2011	Project End Date:	12/31/2012	
Site(s):	MTRH	•		
Project	A5225/HiFLAC is a phase	I/II dose escalation and valid	dation study of the safety, tolerability,	
Description:	•	an induction-consolidation tococcal meningitis (CM) in	strategy of high-dose fluconazole alone HIV-infected participants.	
	The 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. In each stage, participants will be randomized at entry into Step 1.  Over the course of the study, participants will register to subsequents steps (Steps 2-4) based on their initial randomization and/or their response to treatment. The study steps are:  • Step 1: Induction therapy with either high dose fluconazole or ampho B  • Step 2: Induction following early ampho B intolerance (only for participants randomized to ampho B treatment in Step 1) (fluconazole at 400-800 mg daily)  • Step 3: Consolidation therapy (fluconazole 400 mg daily)			
Lindata:		nce therapy (fluconazole 20		
Update:	A total of 13 participants have been enrolled. Five into cohort 1 (Fluconazole 1200mg) and 8 into cohort 2 (Fluconazole 1600mg). Five participants have completed study follow-up visits; three have since died. Five are active on follow up.			
Dreiset Neme	A December 2 de Herre	December 1 of the contract	- December of Manhau Kana	
Project Name:	<u>'</u>	-Based Study of Hypertensic	on Prevalence in Western Kenya.	
Investigator(s):	Velazquez, E.			
	Kimaiyo, S.			
	Bloomfield, G.			
	Akwanalo, C			
	Hogan, J.			
	Maghasi, M			
	Anstrom, K.			
Start Date:	1/7/2011	Project End Date:	7/31/2012	
Site(s):	Mosoriot			
Project	Hypertension is one of th	e increasingly important hea	alth challenges facing the African	
Description:	continent and yet data or	n true community prevalenc	e of hypertension in sub-Saharan Africa uly rural populations was said to be a	

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. 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 micro albuminuria or history of				
We obtained IREC approval in the month of August 2011 and NHLBI approval in December 2011. We have carried out training of counselors and Research Assistant on Diabetes and Hypertension screening and use of phone technology in data entry. They have also completed the online CITI Human Subjects Protection course. Recruitment and screening for this study started in February 2012. So far, the team has screened 377 patients in the community (Kosirai Division). Of these, 46 patients were referred to the clinic for confirmation of high blood pressure. 20 of those referred have already presented to the clinic and 13 have been diagnosed to have Hypertension. No diagnosis of diabetes has been recorded. The challenges encountered so far include:  • Challenges in transport health facility  • Stigma related to HIV since HIV testing is being performed at the same time as blood				
	sis Of Pregnancy Outcomes Of H	HIV-Infected Women Enrolled In The		
Bell, A. Were, E. Musick, B. Lane, K. Washington, S. Shen, C. Akhaabi, P. Hogan, J. Wools-Kaloustian, K.				
3/1/2006	Project End Date:	11/30/2012		
All Sites	<u>'</u>	·		
All Sites  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:  • 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				
	indicate that the previncreasing in SSA, more study will be conducted which will be conducted which will be conducted division, to assess for diabetes will be based phase of the study the 193 cases) will be assed 2 ratio. Target organ delectrocardiogram-left a stroke.  We obtained IREC appreceded the online this study started in Frommunity (Kosirai Diconfirmation of high become of the challen	increasing in SSA, more in the urban compared to ser study will be conducted in two phases. Phase one of which will be conducted on persons aged 18yrs or old division, to assess for hypertension and diabetes mell diabetes will be based on the JNC 7 and American dia phase of the study those individuals who are newly d 193 cases) will be assessed for target organ damage a 2 ratio. Target organ damage will be defined as the delectrocardiogram-left ventricular hypertrophy (ECG-a stroke.  We obtained IREC approval in the month of August 2 2011. We have carried out training of counselors and Hypertension screening and use of phone technology completed the online CITI Human Subjects Protection this study started in February 2012. So far, the team I community (Kosirai Division). Of these, 46 patients w confirmation of high blood pressure. 20 of those refectinic and 13 have been diagnosed to have Hypertens recorded. The challenges encountered so far include:  Challenges in transport health facility  Stigma related to HIV since HIV testing is being perpressure; and diabetes testing.  A Retrospective Analysis Of Pregnancy Outcomes Of I AMPATH Program  Bell, A.  Were, E.  Musick, B.  Lane, K.  Washington, S.  Shen, C.  Akhaabi, P.  Hogan, J.  Wools-Kaloustian, K.  3/1/2006  Project End Date:  All Sites  This is a retrospective analysis of pregnancy outcome with CD4 < 200 begin cART immediately and those wigestation. The pregnancy outcomes are being comparprogram enrollment (BE) and those who became pregram enrollment (BE)		

	who are not in the prog	gram prior to pregnancy diag	gnosis	
			e time of pregnancy diagnosis are less	
		•	ose who are not enrolled in the	
	program prior to pregna	•	are the emoned in the	
			e time of pregnancy diagnosis will	
	have better retention and adherence rates than those who are not enrolled in the			
	program prior to pregna			
		•	rolled in the program prior to	
	pregnancy diagnosis.		, ,	
Update:	The preliminary findings we	ere presented on January 10	at the 2nd International Conference	
-	on HIV and Women in Beth	esda, Maryland. Feedback	from the conferees was incorporated	
	into the analysis plan. The	analysis is underway. We e	xpect to submit the manuscript for	
	publication during the next	quarter.		
Project Name:		oral Trial, Reduce Alcohol Fir	st in Kenya Intervention (RAFIKI)	
Investigator(s):	Papas, R.			
	Gakinya, B.			
	Martino, S.			
	Maisto, S			
	Baliddawa, J.			
	Sidle, J.			
	Hogan, J.			
Ctart Data	Carroll, K.	Drainet Fred	0/24/2046	
Start Date:	11/1/2011	Project End Date:	8/31/2016	
Site(s):	MTRH, Turbo, Burnt Forest,	Webuye Hospital, Iten		
Project	This study will determine w	hether a group cognitive-be	ehavioral therapy intervention that	
Description:	demonstrates preliminary e	evidence of reducing alcoho	l use among HIV-infected outpatients	
	in western Kenya is effectiv	e when compared against a	group health education intervention	
	in a large sample over a lon	ger period of time. It will be	e delivered by para-professionals,	
	individuals with limited pro-	fessional training. This appr	oach is consistent with successful	
		•	nited settings in which para-	
		officers, traditional birth att	endants and peer counselors) are	
	trained.			
Update:	-	•	reparing for the trial. We adapted	
	·		I in the U.S. We did this through	
	multidisciplinary panel review and patient focus group discussion. We also revised and added survey items not employed in the pilot survey. We ran focus groups in February and			
	-			
		•	nty outpatients participated in the	
		•	Itients participated in the discussion rther tailoring study instruments to	
	-		both the survey and the HL protocol.	
			rvention protocols and the Research	
			is expected to begin in July 2012.	
	7.0515tarito ili Stady ilictilous	. According to the that	S expected to begin in July 2012.	
Project Name:	A5265 'A Phase III. Open-La	bel. Randomized. Assessme	ent-Blinded Clinical Trial to Compare	
	1	20., 110.1001111200, 71030031110	zaca cnear rriar to compare	

	-	•	at of Nystatin Oral Suspension for the	
Investigates/a).		ngeal Candidiasis in Hiv-1 inte	cted Participants in Non-U.S. Settings'	
Investigator(s):	Siika, A			
	Lagat, D.			
	Kwobah, C			
	Tanui, K. M.			
Start Date:	2/1/2012	Project End Date:	12/31/2012	
Site(s):	MTRH			
Project	· ·		ent-blinded clinical trial in non-U.S.	
Description:			ntian violet (GV) to that of oral nystatin.	
	Therapy will be conside	red as failed if participants have	ve no clinical improvement (assessed	
	by severity and extent of	of pseudomembranous candidi	iasis) during either treatment regimen.	
	Evaluation of signs and	symptoms of oral candidiasis (	OC) will be done by an evaluator who	
	is blinded to treatment	assignment. Quantification of	colony forming units (CFUs) of Candida	
	species (spp.) and asses	sment of the emergence of re	sistance will be performed using an	
	oropharyngeal swab an	d a second specimen from ora	I rinse/throat wash will be collected	
	and stored for future te	esting		
Update:	A total of 9 participants	have been enrolled. Five (5) h	ave completed study follow up and 4	
	are active on study.			
Project Name:	_	Delay: Improving community-b	ased accountability for maternal and	
	newborn health			
Investigator(s):	Christoffersen-Deb, A.			
	Songok, J.			
	Ruhl, L.			
	Fazen, L.			
Start Date:	1/1/2012	Project End Date:	1/1/2014	
Site(s):	Mosoriot		·	
Project	This project addresses t	he lack of community involver	ment in maternal and newborn health	
Description:	throughout Western Ke	enya. While the current PHC ac	ctivities focus on health systems	
		•	ressing the Fourth Delay will link both	
			sing a sustainable approach that aims	
			by capitalizing on existing mobile	
	_	•	alert system and clinical decision	
	· · ·		unication with the health facilities'	
	1		y developing an Android platform for	
	maternal and infant health, including emergency alert network, triage aids, Google map			
	integration, facility alert of delivery SMS system, and outcome SMS system. Hence, there			
	will be need to train CHWs and Community Health Extension Workers (CHEWs) on the use of			
		algorithm, and the emergency		
Update:	We are currently recruit			
	,			
Project Name:				
Project Name:	Antibiotic Sensitivity Pa	tterns Among Post-Mortem Ba	acterial Isolates. A Sub-Study In The	
Froject Name:		tterns Among Post-Mortem Ba 1.0, October 31, 2011 ( AST St		

	Siika, A			
	Mwangi, A. `			
	Swierczewski, B.			
	Odundo, E.			
Start Date:	4/12/2012	Project End Date:	6/30/2012	
Site(s):	MTRH KEMRI/Walter Reed Program, Kei	richo for sample pro	ocessing	
Project Description:	The Autopsy Study was initiated in February 2010. The study aims to determine causes of death in HIV-infected patients who die while on antiretroviral therapy (ART). Part of the study procedures include microbial (bacterial, mycobacterial and fungal) cultures from body fluids and tissues including blood, bone marrow, cerebrospinal fluid, lung, spleen, stool, pus and any abnormal collections of fluid found in the bodies during autopsies. The AST substudy aims to conduct antibiotic susceptibility testing on bacterial isolates.			
Update:	We have not published these pre	liminary results as w	ve await further accrual of AST results.	
Project Name:	Anticoagulation Project			
Investigator(s):	Pastakia, S. Manji, I.			
	Nabwire, O. M. Rakhi, K. Constantine, A. Collins, S. Schellhase, E. Miller, M Maina, M.			
Start Date:	12/1/2008	Project End Date:	12/31/2012	
Site(s):	MTRH Webuye Hospital			
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:	A case series on the drug interaction between warfarin and rifampicin was recently completed and submitted for publication. The manuscript is currently under peer review. A similar case series on the interaction between warfarin and antiretroviral drugs is also being prepared. Another analysis on the unique dynamics of venous thromboembolism in HIV patients is currently underway.			
Project Name:	Assessment and Treatment of De	in at Mai Taashis = =	and Deferral Hearital	
Project Name: Investigator(s):	Assessment and Treatment of Pail Vreeman, R. Owino, C. Huang, K. Gramelspacher, G. Strother, M. Njuguna, F	in at Moi Teaching a	ina Keterrai Hospitai	

	Hagembe, M.				
Start Date:	3/14/2011	Project End Date:	12/1/2012		
Site(s):	MTRH				
Project	Pain assessment is not routinely conducted at Moi Teaching and Referral Hospital (MTRH) in				
Description:	Eldoret, Kenya, and underutilization of analgesics, particularly strong opioids, remains a				
	significant problem. The object	ives of this study are to	assess the prevalence and intensity of		
	pain in patients at MTRH, and t	o describe the utilization	on of pain medications in this setting.		
		•	n hospitalized patients is to develop a		
	_		opulation and of whether that pain is		
			dy, will assess pain in pediatric and		
		· · · · · · · · · · · · · · · · · · ·	pain scales, the Numerical Rating Scale		
			nt patient data such as admission sis, we will describe the prevalence and		
	,		differences in pain levels among		
			in is being adequately treated using the		
	Pain Management Index. We ex	·			
	considerable amount of untrea		· · · · · · · · · · · · · · · · · · ·		
Update:	We have finished all recruitmen	nt and data collection.	We currently analyzing data.		
Project Name:	Awareness Of Breast Cancer, A	mong Men And Wome	n In Western Kenya		
Investigator(s):	Asirwa, C.				
	Busakhala, N.				
	Inui, T.				
	Naanyu, V.				
	Mwangi, A.				
	Strother, M. Loehrer, P				
Start Date:	10/1/2012	Project End	7/1/2014		
	10/1/2012	Date:	7/1/2014		
Site(s):					
Project	The state of the s	-	vareness of breast cancer among men		
Description:			related to their knowledge of risks for		
He data.	breast cancer, signs and sympto				
Update:	Research protocol have been si	ubmitted to IREC/IRB.	We are awaiting approval.		
Project Name:	Biomakers For Vincristine Neur	otoxicity In Kenyan Chi	ildren		
Investigator(s):	Rennebarger, J.				
	Njuguna, F				
Start Date:	6/27/2011	Project End Date:	12/1/2012		
Site(s):	MTRH		<u>'</u>		
Project	We are evaluating biomarkers of	of vincristine toxicity in	any HIV negative child who is		
Description:	receiving vincristine as part of t	heir cancer care. We a	are specifically collecting specimens of		
	blood and saliva to assess the p	harmacokinetics and p	harmacogenetics of vincristine		
	metabolism and toxicity. We are additionally conducting detailed serial neuropathy				
	on subjects enrolled to assess f	or toxicity.			

Update:	We have submitted one abstract to a conference based on the interim analysis. We hope to recruit more clients from July for more data			
	recruit more chents in	on July for more da	ild	
Project Name:	Biomarkers of Vincrist	tine Toxicity in Keny	an Children	
Investigator(s):	Renbarger, J.	, ,		
	Njuguna, F			
	Skiles, J.			
	Olbara, G.			
	Tallam, C.			
Start Date:	6/27/2011	Proje Date:	ct End	3/1/2013
Site(s):	MTRH	<u> </u>		
Project	We are evaluating bio	markers of vincristi	ne toxicity in	any HIV negative child who is
Description:	receiving vincristine a	s part of their cance	er care. We a	are specifically collecting specimens of
		•	-	pharmacogenetics of vincristine
			nally conduti	ng detailed serial neuropathy exams on
	subjects enrolled to a	-		
Update:				ed any significant problems with the
	•	•		and, after interim analysis of data, we
			-	goal accrual of 100 subjects. The data ASCO 2012 national meeting as an
	abstract/poster prese		presenteu at	ASCO 2012 Hational meeting as an
	abstract/poster prese	Titution.		
Project Name:	Building Competencie	s through Bilateral	International	Exchanges-Using Qualitative Methods
.,		_		ost and Visiting Countries in
	Professionalism, Com			_
Investigator(s):	Litzelman, D.			
	Ayaya, S.			
	Umoren,R.			
	Woodward, J.			
	Vreeman, R.			
	Liechty, E.			
	Lorant, D.			
	Stelzner, S. Palmer, M.			
	Riner, M.			
Start Date:	11/27/2009	Proje	ct End	6/30/2013
	11/2//2003	Date:		0,30,2013
Site(s):	Moi University	,		<u> </u>
	Indiana University			
Project	Focus groups to asses	s the impact of resi	dent exchang	ge project on participating residents
Description:		•		Moi University School of Medicine
	· ·			dalgo Health Sciences Campus (UAEH)
	-	•		communication, Systems Based
Lindoto.	Practice, and Practice			
Update:				with the goal of comparing experiences
	between the participa	iting foreign institut	ions.	

Project Name: Investigator(s):	their Acquisition of ACGME Comp Riner, M Palmer, JF Woodward, R and DK Litzelman. 2012 Riley Pedi Causes Of Early Mortality In HIV-II Siika, A Buziba, N. Chumba, D. Ayikukwei, R. Tierney, W. Wools-Kaloustian, K.	etencies through a C Vreeman, S Stelz atric Scholars' Day.		
	Carter, E. J. Yiannoutsos, C.			
Start Date:	7/1/2009	Project End Date:	6/30/2013	
Site(s):	MTRH			
Description:  Update:	<ul> <li>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.</li> <li>The study has two specific aims:</li> <ol> <li>To establish the causes of death by performing detailed pathological autopsies in patients who die in the first 12 months of ART.</li> <li>To develop a verbal autopsy questionnaire that is accurate, specific to HIV infection, and appropriate for identifying causes of death in resource constrained settings.</li> </ol> </ul>			
opuate.	<ul> <li>appropriate for identifying causes of death in resource constrained settings.</li> <li>Study Findings         <ul> <li>Pathological Autopsies: The study has so far conducted a total of three Central Review Board (CRB) to ascertain causes of death (September 2010, July 2011, and April 2012). Causes of death for 223 participants have been ascertained.</li> <li>Verbal Autopsies: The study conducted a total of three CRB) to ascertain causes of death using Verbal Autopsy (September 2010, September 2011, and April 2012). Causes of death for 229 participants have been ascertained.</li> </ul> </li> <li>Training The study sponsored two of its staff namely; Iddah Maulid and Kennedy Kenina to Good Clinical Practice (GCP) training in July 2011.</li> <li>Research Presentations The study submitted an abstract which was accepted for oral presentation in the XIX International AIDS Conference in Washington DC, USA from July 22-27, 2012.</li> </ul>			

Monitoring/ Audit of the study In January 2012 the study underwent a monitoring exercise the recommendations of the audit report are currently being implemented by the study team. **Upcoming events** The study is planning to conduct mid-study review of study findings since it has attained and surpassed 200th autopsy. This is expected at the end of August. Sub- Studies Findings The study has three sub- studies which have been approved by Institutional Review Ethics Committee (IREC). Two are currently running(AST Substudy and Malaria ) while one(DOM Study) has temporarily been halted due to unavailability of funds to run more TB isolates. We are still experiencing challenges in the recruitment process. Moi Challenges Teaching Referral Hospital changed the patient Identification system from the AMRS to a new system which we are unable to link eligible participant to AMPATH unless a referral note from AMPATH is available in the patient chart. We are currently solely relying on participant names which is sometimes unreliable (some registered using proxy names and misspelling of names), and patient referral note in the patient charts. **Project Name:** Cervical Cancer See and Treat: How Best to Follow-Up Investigator(s): Cu-Uvin, S. Omenge, E. Mabeya, H. Washington, S. Itsura, P. **Project End** Start Date: 9/1/2011 6/30/2013 Date: Site(s): **MTRH** Mosoriot Turbo Chulaimbo **Project** This is a cross sectional study involving 660 HIV-infected women attending 4 AMPATH-CCSPP **Description:** (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:** The study has currently recruited a total 158 participants out of possible 168 after 10 were

	inelligible at time of presentation to the clinic 6 months post cryotherapy. Eight were pregnant, 1 refused while the other was inelligible due to age (above the age bracket under inclusion criteria). Dr. Peter Itsura got IRB approval for inclusion as a Co-Investigator. The other amendment saw Chulaimbo Sub-District hospital included as a study center making study sites to 4. The study has put forward another amendment to increase the transport reimbursement to participants. All but 8 participants have received their HPV results which is now run at AMPATH reference laboratory. The main challenge experienced in the last 6 months has been low numbers getting cryotherapy treatment due to the elligibility for the same. The CCSP has currently accrued 447 cryotherapies done which the study will seek to recruit 6 months after the cryotherapy date.			
Project Name:			falciparum Malaria levels in AMPATH and	
Investigator(s):	Non- AMPATH COBES centres in Western Kenya by Taylor, K. Kwena, A. Mcdowell, A. M. Mining, S. Wakhisi, J.			
Start Date:	8/1/2011	Project End Date:	8/1/2013	
Site(s):	Mosoriot Turbo Burnt Forest Amukura Naitiri Chulaimbo Nambale			
Project Description:	Protein Energy Malnutrition and malaria are global as well as a national problems in Kenya. Some AMPATH sites are also used annually by Moi University College of Health sciences students for their community diagnosis work. The project therefore aims to look at malnutrition and malaria in COBES (AMPATH) and NON-AMPATH sites and compare the levels malnutrition and malaria to ascertain the impact of AMPATH in the community.			
Update:	Preliminary results show that stunting, wasting and underweight appear to be lower in AMPATH centres when compared to non-AMPATH centres. Only results from 2 AMPATH centres (Mosoriot and Chulaimbo) were available for the analysis. Further data collection and analysis is hoped to be carried out in the next quarter in more centres to confirm the results and suggest possible reasons for the trends. The results reported here do not include <i>P. Falciparum</i> levels.			
Project Name:	Computerized Counseli Kenya)	ing to Promote Positive Prev	ention and HIV Health in Kenya (CARE+	
Investigator(s):	Kurth, A. Siika, A Sidle, J. Ayuku, D. Baliddawa, J. Fortenberry, J.D.			

	Magla Kalawatiana K				
	Wools-Kaloustian, K.				
Start Date:	Braithwaite, S.				
	8/14/2009	Project End Date:	6/30/2013		
Site(s):	MTRH				
	Burnt Forest				
Project	Specific Aims:				
Description:	•	·	erized counseling intervention (CARE+		
	Kenya) for use in western		urban and up to 25 rural 50		
			ess to Health (AMPATH®) to understand		
		_	focus groups (n~16) to assess positive		
			liefs about patient computer use and		
	training needs.	chec support practices, be	mers about patient compater ase and		
	_	v intervention content; tra	nslate and record audio files into local		
	_	•	Ith' (prevention, disclosure, ART		
	adherence, reproductive h	nealth, etc.).			
	2.1.C. Conduct iterative so	oftware usability testing wi	th 10 urban and 10 rural patients (n=20)		
			sessment to establish psychometric		
	performance of measures.				
	2.2 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 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 (DALY) 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.		. 2		
Update:	Achievements:				
			ent, we have only two participants who		
		•	e for Burnt forest study site.		
			n IREC to add biostatistician from		
		~	are familiar with the AMPATH system		
	including its OpenMRS	electronic health record a	nd other databases seek services. There		

expertises are highly relevant in supporting onsite support of data capture, troubleshooting, cleaning, merging, management, and analyses., use of questionnaires form for cost analysis, IREC Amendment Form, Cost Analysis Form for Patients, Amended Reviewer Guideline Form, Participants exit interview forms and Pill count survey to further enhance data collection methods for the study

- 3. SUPPORT VISITS: Care+ (Plus) Spanish Coordinator John Lizcano came to Kenya on Junet 4th for one week to oversee the CARE Plus Kenya team during the exit of study participants in Module1.
- 4. QA/QC One of the study investigators, Joyce Baliddawa, has been submitting weekly Quality Assurance (QA) for the RCT procedures and documentation to Principal Investigators
- 5. RECRUITMENT: We have had tremendous success in recruitment of study participants in module1 study site but a slower rate in Burnt Forest due to planting season the first quarter of year 2012.
- 6. DATA COLLECTION: We are currently using RCT appointment log, RCT recruitment script, RCT consent form, RCT participants tracking form, and RCT ID Number labels (that is being used on participants' paperwork and appointment and incentive logs). This helps us in ensuring we track our participants as they come on their monthly follow-up visits. All the data at the end of each day is stored electronically into the study database and uploaded on a weekly basis to NYU secure site while we another copy is stored to an external and password protected hard drive.
- 7. PSYCHOLOGICAL FINDINGS: Some of the psychological findings we have documented for Module1 and Burnt forest since recruitment began were as follows

Depression - Module1= 4 Burnt Forest= 3

Intimate Partner Violence (IPVs) - Module1= 62
 Burnt Forest= 32

• Suicidal thoughts - Module1= 20 Burnt Forest= 3

All participants were referred to AMPATH Psychosocial department for further intervention purposes by the study protocol (including assessment with Psychiatry), especially for those with potentially suicidal thoughts.

- 8. LAB TESTING All Module1 lab results have been filed to the respective participant's files and another copy into their regular AMPATH file. All those with Trichomonas Vaginalis results turning positive, we recall them for further care. We have test result and treatment guideline sheets for reporting test results and suggested treatment back to the clinics. All viral Load results that come back and copies/ml is >5000, Trichomonas, GC or CT is Positive we post the result into the patient file for further treatment
- 9. STANDARD OPERATING PROCEDURES All SOPs were developed, revised and approved by the study team.
- 10. COMMUNICATIONS The study team has kept abreast with the study activities on a weekly basis via Skype conference calls. The study coordinator and NYUCN research scientists have provided weekly reports and study updates to the study team.
- 11. ECAP: We have seen a reduction of breakages of the eCAP bottles by participants as compared to year 2011. We attributed this to continuous education by study staff to the participants.
- 12. PERSONNEL Phlebotomist at Burnt Forest was brought on board to the study since he is well trained on the procedures we anticipate to carry out. Although this required extensive time, approval was obtained from AMPATH Program Managers Office, on 20th November 2011 and the Phlebotomist started working with the project on 23rd November 2011 to date.

Plans: RECRUITMENT/RETENTION: We finalized recruitment of participants for module1 study site beginning of February 2012 while for Burnt Forest, we were though by May 2012. Based on this timeline, we expect to have last follow-up visits by the end of 2012 and February 2013.

### Challenges:

- 1. REPETITION OF BASELINE OBSERVATIONS: Due to incomplete sessions at the baseline, we have recalled participants in Burnt Forest to complete the sessions to enable them proceed ahead to follow-up sessions
- 2. CARE+ APPLICATION PROGRAM: We've had also to reschedule participants for follow up visits due to small computer bugs in the CARE tool but that was sorted out by the software programming company in Seattle.

Publications: Several scientific presentations have been made:

- 1. 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
- 2. 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. User-centered Design for Mobile Health Intervention Content in a Low-Income Setting. NIH mHealth Summit, Washington DC, November 2010.
- 3. Kurth A, Kitani T. Information & communication technologies for HIV: Sustainability. Panel lead, Collaborative Group Meeting, Nairobi Kenya January 2010. The time motion subs-study data have been analyzed and a manuscript has been submited. The CARE+ Kenya study team would like to thank AMPATH for their ongoing support and the opportunity to report our progress.

Project Name:	Descriptive Analysis of Patients Seen in an Emergency Department in Western Kenya		
Investigator(s):	House, D.		
	Nyabera, L. S.		
	Ongaro, N.		
	Kurt, Y.		
Start Date:	1/1/2011	Project End	6/30/2012
		Date:	
Site(s):	MTRH		
Project	Descriptive analysis of all patients	presenting to the A	ccident & Emergency Department over
Description:	2011. Data includes demographic	s, diagnoses, disposit	tion. The data will allow for
	assessment of needs for the depa	rtment.	
Update:	Data collection is complete. We are now analyzing data and writing manuscript.		
_			
Project Name:	Diabetes Mellitus And Glucose In	tolerance In HIV Pation	ents In Western Kenya
Investigator(s):	Carter, E. J.		
	Kirui, N.		
	Kamano, J.		
	Diero, L.		

	Chege, P.		
	Pastakia, S.		
	Gardner, A.		
1	Mwangi, A.		
Start Date:	9/3/2012	Project End	8/31/2015
Otart Bate.	3/3/2012	Date:	8/31/2013
Site(s):	MTRH		
	Webuye Hospital		
Project Description:	intolerance, and HIV among HIV propose that HIV and ART use in among HIV patients in Western k	positive patients in \ creases the risk of di Kenya.	abetes mellitus and glucose intolerance
Update:	The study protocol has been dev	eloped and will be s	ubmitted for ethics approval.
Project Name:	Drug Resistance In HIV Infected ( Transmission In Western Kenya:I		e Of Prevention Of Mother To Child al Number;000457
Investigator(s):	Kantor, R.		
	Nyandiko, W.		
	Vreeman, R.		
	Songok, J.		
	Diero, L.		
	Kosgei, R		
0, 10,	Ayaya, S.	TB : /E :	0.100.100.10
Start Date:	5/3/2011	Project End Date:	9/30/2012
Site(s):	MTRH		
	Turbo		
	Kitale		
Project	The project seeks to determine t	he proportion of chi	ldren becoming HIV infected despite
Description:	interventions of pMTCT, and the	type, if any of antire	troviral drug resistance in those
			.The project was approved by IREC on
	30th October,2009.Continuing IF	REC approvals were g	given on 3rd January,2011 and 10th
	Aprill ,2012 subsequently. Our re	ecruitment has been	slow due to few children becoming
	positive. This is as a result of a vik	rant pMTCT prograi	m within AMPATH. We have so far
	enrolled a total of 11 patients sir	ice we commenced	the study.11 have consented and none
	has withdrawn.		
Update:	A total of three(3) patients have	been enrolled since	1st January,2012. Three(3) patients
•	have consented and none have v	vithdrawn.The recru	itment has been slow due to the same
	reason stated above.		
Project Name:	EARNEST: A Randomised Control	led Trial To Evaluate	Options For Second-Line Therapy In
-	Patients Failing A First-Line 2NRT	T+ NNRTI Regimen Ir	n Africa. (Version 3.0, Dated 06
	September 2010).	-	
Investigator(s):	Wools-Kaloustian, K.		
• ( )	Siika, A		
	Kwobah, C		

Start Date:	2/9/2011	Project End Date:	12/31/2014
Site(s):	MTRH		
Project Description:	1200 patients will be included who NNRTI-based regimen continuous treatment failure defined by modi  New WHO Stage 4 event (with	o are HIV-infected ad ly for a total period o ified WHO 2010 crite n CD4 < 200 cells/mm fall to pre-treatment	of at least 12 months, and developed ria as one of the following: a3 and viral load (VL) > 400 copies/ml) baseline or below, or CD4 < 200
	plus 2 new NRTIs) in achieving	(an integrase inhibito ggood HIV disease co non-inferior to stand	a first-line NRTI and NNRTI- or) is superior to standard of care (bPI entrol at 96 weeks after randomisation dard of care in achieving good HIV
Update:	The study closed to accrual in April 2011. Participants have completed one year on study and will be followed up for two more years. Two participants have since died and one withdrew consent. The other 49 active participants are doing well on study.		
Project Name:	Engagement In Care Among HIV-Infected Patients In Resource Limited Settings: A Protocol For Assessing The Magnitude Of And Reasons For Failure To Engage In Care Among HIV-Infected Patients In The East Africa International Epidemiologic Databases To Evaluate AIDS (IeDEA) Consortium		
Investigator(s):	Geng, E. Ayuo, P. Diero, L. Yiannoutsos, C. Wools-Kaloustian, K		
Start Date:	Braitstein, P. 6/1/2011	Project End Date:	7/31/2012
Site(s):	MTRH Burnt Forest Webuye Hospital		
Project Description:	Plan for AIDS Relief (PEPFAR)-function engaging HIV-infected patients to Failures of engagement in the form (FTR) may well represent the bigg services. Attempting to understart 25% of patients who start ART are their originating clinic by two years are eligible but who have not yet.	ded sites in Africa mo initiate ART followed m of failure to initiate est limitation to the e and FTI and FTR brings lost to follow-up (i.e ss, and this percentag started ART. For ART-	By consistent retention in care. ART (FTI) and failure to retain in care effectiveness of PEFPAR-funded ART a critical barrier into focus: in Africa,

systematically under ascertained, rendering the observed magnitude and impact of delays uninterruptable. For patients already on ART, losses to follow-up have been regarded as synonymous with disengagement from care. Yet emerging data suggests many 'lost' patients have simply started accessing care at newer sites as ART services decentralized. Furthermore, many lost patients have died, and unless these deaths are accounted for, existing estimates of outcomes and the effect of FTI and FTR are incomplete. Without generalizable and efficient strategies to manage the impact of losses to follow-up (i.e., unknown outcomes), the task of intelligently evaluating FTI and FTR is at a standstill. At a prototypical ART delivery site in Mbarara, Uganda, we have used a sampling-based approach to understand the effect of losses to follow-up on our clinic population's experience over time. We now propose to implement this approach at 11 sites in 3 countries in the East Africa leDEA consortium in order to further understand the magnitude and determinants of FTI and FTR as well as the effects of FTR and FTI on survival and finally how to improve engagement in care for HIV-infected patients in Africa. Specifically, this process involves:

- 1. enumerating an underlying cohort of patients from which engagement in care and loss to follow-up will be assessed
- 2. identifying patients who become lost to follow-up
- 3. identifying a representative sample of patients in whom outcomes obtained through contact in the community will be used to generalize to all lost patients
- 4. ascertaining outcomes in this sample through patient contact in the community.

## **Update:**

The Lost to follow-up (LTFU) project ran to completion end May 2012. The purpose of this project was to identify reasons for LTFU and outcomes of patients who became LTFU within the AMPATH program. The project was being undertaken at 3 AMPATH clinics, namely; MTRH, Webuye, and Burnt Forest. LTFU was defined for the purposes of this project as any patient who had initially been registered at AMPATH HIV care services but had not returned for a period of 3 months or more since their last (missed) return to care visit date. A random sample of 1157 patients defined as LTFU January 2009-June 2011 was generated and this represented approximately 18% of patients LTFU within the study sites during this time period.

Data is maintained in an online system QUESGEN, where all data was entered and maintained centrally for AMPATH sites. Patient names and IDs are blinded, except for the parent organization, hence the use of de-identified data.

Results from reviewing the charts found that 89% of patients were truly LTFU. 100% records have been entered to the electronic online databases system. In approximately 73% of tracking attempts either the patient or an informant has been found to date. Currently data analysis is in progress.

Presentations and publications:

- 1. A preliminary report was presented to the AMPATH program management in February 2012.
- 2. Accepted poster presentation: Ochieng D, Choge I, Rotich E, Ochieng V, Maritim B, Bernheimer I, Geng E, Kimiayo S, Mamlin J, Ndege S, Naanyu V, Ayuo P, Diero L, Braitstein P. Evaluating outcomes of patients lost to follow-up in a large comprehensive care treatment program in western Kenya.19th International AIDS conference, Washington D.C, 22-27 July, 2012.

#### **Project Name:**

Enhancing Infant Feeding Options for HIV Infected Mothers

Investigator(s):	Wools-Kaloustian, K		
invoorigator (o):	Nyandiko, W.		
	Bucher, S.		
	•		
	Musick, B.		
	Nyunya, B.		
	Yiannoutsos, C.		
Start Date:	1/10/2006	Project End Date:	12/1/2012
Site(s):	Burnt Forest Chulaimbo		
Project		is to determine if question	naire administered within the clinic can
Description:	1	·	
Description.	•		hould be encouraged to breastfeed and
			eir infants. In addition this study will
	- I	y some women choose to n	nix breast feeding with other types of
	foods.		
Update:	Data analysis is in progres	ss. Manuscript is partially di	rafted.
Project Name:	Evaluating Handheld Clini	ical Decision Support Tools	To Improve Community-Based Delivery
	Of Reproductive And Pedi	• •	
Investigator(s):	Christoffersen-Deb, A.	idente meditir Services	
investigator(s).	Chemwolo, B.		
	Fazen, L.		
	•		
011 D-1-	Ruhl, L.	Donate at Food	40/04/0040
Start Date:	6/1/2011	Project End Date:	12/31/2012
Site(s):	Mosoriot		
Project	Given recent price reduct	ions in smartphones and an	extensive telecommunications
Description:	infrastructure in Rift Valle	ey, mobile devices represent	t a potential solution for improving the
		•	an help CHWs organize and prioritize
	1 .	•	, and have the capacity to display IEC
	•		ges and video. We suggest that
			ecord system with CDS algorithms may
			nable the delivery of patient-centered
	forms and IEC material.	or manaricia devices and er	nusic the delivery of patient centered
Update:		as been done. Software tes	ting isbeing conducted before training
opuate.	all the participant and off		ting isbeing conducted before training
	all the participant and on	icially folling out.	
Project Name:	Evaluation Of A Compreh-	encive Strategy To Measure	Pediatric Adherence To Antiretroviral
Project Name.	•	ensive strategy to ivieasure	Pediatric Adrierence To Antiretroviral
I	Therapy (CAMP Study)		
Investigator(s):	Vreeman, R.		
	Nyandiko, W.		
	Inui, T.		
	Wanzhu, T.		
	Ayaya, S.		
	Downs, S.		
	Carroll, A.		

	Marrero, D.			
	Blaschke, T.			
	Arpadi, S.			
	•			
Ctart Data:	Bell, D.	Drainat End	2/20/2014	
Start Date:	9/11/2009	Project End Date:	2/28/2014	
Site(s):	MTRH			
	Turbo			
	Webuye Hospital			
	Kitale			
Project	The objectives of this project	are to develop and test	t a reliable, valid instrument to	
Description:	measure pediatric ART adhere	nce for children ages 0	to 14 years in western Kenya and to	
	evaluate which administration	strategy yields the mos	st accurate information about	
	children's ART adherence. We	e will pursue the follow	ing four specific aims:	
	Aim 1: Develop a reliable,	, valid comprehensive j	pediatric ART adherence	
	measurement questionnai	re (CAMP - Compreher	nsive ART Measure for Pediatrics);	
			n of the pediatric ART adherence	
	•		rence screening measure in busy	
	clinical care environments		,	
			ition feasibility, and clinical utility of	
			cal care system in western Kenya;	
			measurement tool in a clinic-based	
	care setting compared to a			
Update:				
	We have received funding for Aims 1, 2 and 3 via K23 career development to Rachel Vreeman via NIH-NIMH. IRB and IREC approvals secured. Approved IRB/IREC accrual target is			
		• •	cipants from urban and rural clinics to	
	develop and modify the questi	·	•	
	·	•	cients (with 10 withdrawals). All	
	-	· ·	is is being done. With funding from a	
			e 4 of the project; recruiting patients	
		· · · · · · · · · · · · · · · · · · ·	aluating the adherence measurement	
			_	
	in a home-based vs. clinic-based care setting. 41 children were enrolled and completed the study. The participants were randomized to have 10 home-based adherence evaluation. We			
	had 20 patients recruited in Turbo and 20 patients recruited in MTRH clinic site. We have			
	had only 1 withdrawal. We started the phase 5 of the project and have already enrolled a			
	-	•	bo sites. Eleven of these participants	
	· ·	•	group and the remaining 54 are in the	
	clinic only group.	a into the nome enime g	roup and the remaining 54 are in the	
	cinic ciniy gi cap.			
Project Name:	Health Facility Incentives To In	nprove Adherence To M	Malaria Diagnostic Test Results	
Investigator(s):	O'Meara, W. P.			
	Menya, D.			
	Armstrong, J.			
	Manji, I.			
Start Date:	4/1/2012	Project End	3/31/2014	
		Date:		
Site(s):				

Project Description:	of malaria. In some areas, mala malaria transmission declines, However, these fevers continu diagnostic testing. In a typical in patients are prescribed an anti microscopy or rapid diagnostic negative test are nonetheless in children can lead to serious condrug resistance. In addition to financial strain on the government sustainable financial incentive are treated inappropriately with targeted at the health facility the clinical protocols. Eighteen run randomly allocated to one of the technical training in diagnosis of linked to prescription practices non-malaria fevers. The practice diagnostic will be compared be secondary outcomes will include centers, use of alternative treatof antimalarial drugs. This pro-	a greater fraction of per to be treated as mala ural health facility in kindle malarial when no diagonescribed antimalarial assequences for the particle for th	some exciting reductions in the burden we dropped by more than 90%. As ediatric fevers are from other causes. aria, often despite the availability of Kenya, more than 90% of febrile nostic tests are available. Even when able, between 50-80% of patients with a ls. Inappropriately treated fevers in tient and can accelerate the spread of eruse of antimalarials also puts a is project aims to test an innovative, a number of non-malarial fevers that We will test a financial incentive eves adherence to diagnostic results and estern Kenya will be enrolled and coare the effectiveness of clinical and 1) to training plus financial incentives diagnosis and treatment of malaria and alarials to patients with a negative nd without the incentive structure. If if it is in collaboration with Kenya's Division of tion, if successful, will be actively
Project Name: Investigator(s):	Important Co-Morbidity In Pati Carter, E.J. Kirui, N. Kamano, J. Pastakia, S. D. Cheng, S. Manuthu, E. Chege, P. Gardner, A. Mwangi, A. Enarson, D. A. Reid, A. J.	ents With Diabetes Mo	ellitus In Three Clinics In Western Kenya
Start Date:	9/1/2010	Project End Date:	2/29/2012
Site(s):	MTRH Webuye Hospital Kitale	Date.	
Project Description:	This was a retrospective study history of TB, HIV infection and	tobacco smoking in th	
Update:	The study was completed. The	manuscript is being w	ritten.

Project Name:	Increasing Animal Source Foods i	n Diets of HIV-Infecte	d Kenyan Women and Their Children	
Investigator(s):	Ernst, J.			
	Ettyang, G.			
	Neumann, C.			
	Nyandiko, W. ;			
	Siika, A			
Start Date:	10/1/2006	Project End	7/31/2012	
		Date:		
Site(s):	MTRH			
	Turbo			
	Soy			
	Mautuma			
Project	The study is a three arm random	ized, blinded and cont	trolled nutrition intervention trial that	
Description:	tests the effect of iso-caloric bisc	uit supplements of m	eat, soy or wheat protein added to the	
	diets of drug naive HIV-infected	Kenyan women and th	neir children-8 years and younger and	
	who live in the Turbo environs ar	nd who receive care a	t one of the AMPATH clinics (Turbo,	
	Soy, Mautuma, and MTRH. The v	vomen are of reprodu	ctive age and at enrollment WHO	
	stage I or II. The biscuits are prov	ided five days a week	(Monday to Friday) to subject mother	
	and child, using directly observed	d therapy (DOT) for 18	months. The outcome variables	
	include estimates of lean and fat	mass, quality of life, s	strength measures, biochemical	
	indicators of nutritional status, ir	ndicators of immune f	unction, measures of inflammation,	
	nutrient intake, food security, me	easures of growth and	development in children and	
	activities of daily living.			
Update:	Post follow up assessments at 24	months were done for	or the subjects.	
	Oral Presentations:			
	1. Ernst, Judith - Field Nutrition Research in Rural Kenya. Presented study design to			
	doctoral students in the India	ana University School	of Public Health, Global Health Class,	
	2 February, 2012.			
	2. Ernst, Judith - Field Nutrition	Research in Rural Ker	nya. Presented study design to	
	doctoral students in the India	ana University School	of Public Health, Epidemiology	
	Seminar, 30 May, 2012.			
	Poster Presentation/Abstract:			
	1. Hand grip strength and body	•	·	
	, ,	•	a, C. Neumann. Experimental Biology,	
	Abstract # 4101, April 23, 20	12, San Diego, Califorr	nia.	
Project Name:	Indiana University-Moi University	Academic Research	Ethics Partnership	
Investigator(s):	Meslin, M. E.			
	Ayuku, D			
	Were, E.	T=		
Start Date:	5/31/2008	Project End	5/31/2012	
0:(-(-)		Date:		
Site(s):	MTRH			
	Moi University			

# Project Description:

The Indiana University-Moi University Academic Research Ethics Partnership(IU-Moi AREP) 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. IU-Moi AREP is a curriculum development and training initiative that builds on longlasting partnerships and collaborations in East Africa. IU-AREP has developed two Masters' degree programs:one at Indiana University-Purdue University Indianapolis and one at Moi University in Eldoret, Kenya. These graduate programs have common overlapping components, joint advisory committes, shared dissemination plans and harmonized evaluation strategies. Both programs include a curriculum involving required core courses, electives and a practicum experience, part of which is taken at the counterpart university. Besides, each IU-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:**

From January 29-31 IU-Moi AREP, in collaboration with University of Manitoba and the University of Nairobi, facilitated the International Infectious Disease and Global Health Training Program in which TaSkR faculty(i.e Prof.Edwin Were, Prof.David Ayuku, Dr. Rose Ayikukwei, Prof. Eunice Kamaara, Prof. Naomi Shitemi, Dr. Eric Meslin, Dr. Ross Upshur and Dr. Jeremy Sugarman) took part in teaching a Research Ethics Course as part of the training.TaSkR IV: The fourth annual event took place between February 1 st to 3rd at the Noble Conference Centre in Eldoret, Kenya. A total of 80 participants attended the workshop, where Dr. Ross Upshur from University of Toronto and Dr. Jeremy Sugarman from John Hopkins University were part of the TaSkR faculty. Invited guests who graced the workshop included Prof. Wenceslaus Kilama and Dr. Ramadhani A. Noor, both from AMANET and Prof. Kirana Bhatt from National Council for Science and Technology. The workshop followed the two and half day fromat used in previous years. Mock Thesis and Proposal Presentation: On 4th and 5th April masters students in International Health Research Ethics were scheduled to make presentation of their thesis proposals. This event was meant to bring together all the Masters students with their supervisors in order to assess the progress of each student's research/proposal. All the 7 second year and 10 first year students made the presentations. Short-course: Second short course on International Health Research Ethics was held for three weeks running from April 10-30 and 30 participants were trained. This course, just like the previous one, was intended to build capacity in the area of International Research Ethics in order to maintain the ethical and scientific quality of research protocols developed by local and international scientists. The course content focused on responsible design and conduct of scientific research. It covered the same topics as the previous short course except for two courses namely Research Methods and Community Engagement in Research, which were not included previously.

## **Project Name:**

International epidemiologic Databases to Evaluate AIDS (IeDEA)

## Investigator(s):

Yiannoutsos, C.

Ayaya, S.

Wools-Kaloustian, K.

Otieno, J.

Somi, R. G.

Swai, R.

Ngonyani, K.

Lyamuya, R.

Mtiro, B. H.

	T		
	Sidle, J.		
	Braitstein, P.		
	Martin, J.		
	Bangsberg, D.		
	Glidden, D.		
	Deeks, S.		
	Hunt, P.		
	Diero, L.		
	1		
	Nash, D.		
	Abrams, E.		
	Batya, E.		
Start Date:	6/20/2006	Project End Date:	7/31/2016
Site(s):	All Sites		
Project	IEDEA(International epidemiologic	Databases to Evaluat	e AIDS) Initiative This initiative will
Description:			n and harmonization of data and the
	establishment of an international		
			by single cohorts. High quality data
	1	•	, , ,
		•	This initiative provides a means to
			ol the collected data—thus providing
	a cost effective means of generati		= :
	questions. Combination of data co	llected under various	protocols is frequently very difficult
	and not as efficient as the collection	on of pre-determined	and standardized data elements. By
	developing a pro-active mechanisi	m for the collection of	key variables, this initiative will
	enhance the quality cost effective		•
Update:	As of August 31, 2011, IeDEA had		
	(AMRS) of which 96,299 were fem	•	
	(Alvins) of which 50,255 were rem	aic and 55,420 were	maic.
	Descriptor y Descriptor y approvale	مامورة مغمام مرموما مربوط	and manifestational Community requires my
			nd maintained. Separate regulatory
	approval has been obtained and maintained at participating sites for the Retention in care		
			estigator from each institution sits
	on the Executive Committee which	h continues to meet e	very two months in order to address
	administrative issues within the co	onsortium.	
	Over the past year the functions o	f the consortium have	e been divided between three
	different cores (The Scientific Dev		
	·	•	based and an East-African-based co-
	1		
	chair. The Core Chairs meet at reg		
		-	ed of senior investigators within the
	consortium and meets on alternat		_
	with prioritizing projects, from a s	• •	
	within the consortium. The Data C	Core is composed of th	ne regional data managers and meets
	every other week in order to discu	iss issues related to th	ne development of site-level master
			ial concept proposals The Statistics
			outsos and Glidden along with Drs.
			_
	Maya Petersen, Ann Mwangi and		
			nggang Yu at University of Wisconsin
	Medical School and Drs. Judith Lol	k and Ronald Bosch at	the Harvard School of Public Health.

Members of the group meet (via phone, e-mail or in person) on an ad hoc basis to address specific analyses.

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
- '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 study ended

#### **Publications:**

- Geng EH, Hunt PW, Diero LO, Kimaiyo S, Somi GR, Okong P, Bangsberg DR, Bwana MB, Cohen CR, Otieno JA, Wabwire D, Elul B, Nash D, Easterbrook PJ, Braitstein P, Musick BS, Martin JN, Yiannoutsos CT, Wools-Kaloustian K. Trends in the clinical characteristics of HIV-infected patients initiating antiretroviral therapy in Kenya, Uganda and Tanzania between 2002 and 2009. J Int AIDS Soc. 2011 Sep 28;14:46. http://www.ncbi.nlm.nih.gov/pubmed/21955541
- 2. BraithWaite R S, Nucifora A K. Yiannoutsos C T, Musick B, Kimiayo S, Diero L, Bacon C M, and Wools-Kaloustian K. Alternative Antiretroviral monitoring strategies for HIV-infected patients in East Africa: Opportunities to save lives? Journal of International AIDS Society 2011, 14:38.
- 3. Ochieng-Ooko V, Ochieng D, Sidle J, Holdsworth M, Wools-Kaloustian K, Siika A, Yiannoutsos C, Owiti M, Kimaiyo S, Braitstein P. Gender and Losses to Follow up From a Large HIV Treatment Program in Western Kenya. Bulletin of the WHO (In press)

#### Abstracts:

- Ochieng D, Choge I, Rotich E, Ochieng V, Maritim B, Bernheimer I, Geng E, Kimiayo S, Mamlin J, Ndege S, Naanyu V, Ayuo P, Diero L, Braitstein P. Evaluating outcomes of patients lost to follow-up in a large comprehensive care treatment program in western Kenya.19th International AIDS conference, Washington D.C, 22-27 July, 2012.
- Yiannoutsos T C, Musick S B, Siika A, Sang E, Kosgei R, Kimiayo S, Wools-Kaloustian K: Assessment of a task-shifting strategy among stable patients receiving HIV care in resource-limited settings: A framework for program evaluation. (an AMPATH only analysis). 16th International Workshop on HIV Observational Databases abstract ## 16\_117; Athens, Greece, 29-31 March 2012
- 3. Mann M, Diero L, Kemboi E, Mambo F, DeLong A, Injera W, Schreier L, Wools-Kaloustian A, Buziba N, Kantor. Unplanned Antiretroviral treatment Interruptions Induced by the Kenyan Post-Election Crisis are Associated with HIV Virologic Failure. Poster #1157, at the 19th Conference on Retroviruses and Opportunistic

Infections, Seatle, March 3-8th 2012. 4. Martin J, Wenger W, Busakhala N, Buziba N, Mwebesa B, Muyindike W, Mbabazi R, Amerson E, Yiannoutsos C, Musick B, LeBoit P, McCalmont T, Ruben B, Maurer T, and Wools-Kaloustian K. Prospective evaluation of the impact of potent antiretroviral therapy on the incidence of Kaposi's sarcoma in East Africa: Findings from the International Epidemiologic Databases to Evaluate AIDS (IeDEA) Consortium. 19th Conference on Retroviruses and Opportunistic Infections, Seatle, March 3-8th 2012. 5. Holmes B. C, Elul B, Padian N, Wools-Kaloustian K, Musick S B, Diero L, Kambugu A, Cohen C, Williams C, Goosby E and Yiannoutsos T C for the the East African IeDEA Regional Consortium. Impact of increasing proportion of pregnant women accessing HIV care in PEPFAR-supported East African HIV care and treatment programs. 19th Conference on Retroviruses and Opportunistic Infections, Seatle, March 3-8th 2012. 6. Tsai J, Sharp G, Silverberg M, Bhatia K, Buziba N, Nash D for the International epidemiologic Databases to Evaluate AIDS (IeDEA) Collaboration. An assessment of the capacity to screen, diagnose and treat cancers in HIV care programs in low-, middle- and high-income regions. 6th IAS conference on HIV pathogenesis, treatment and prevention, Rome, 17-20 July 2011. Papers in Final Draft Form or Submitted to Journal's for Publication 1. Leroy V, Malateste K, Rabie H, Lumbiganon P, Ayaya S, Dicko F, Davies MA, Kirimina A, Wools-Kaloustian K, Addi Aka E, Phiri E, Linda A, Yiannoutsos TC, Signate`-Sy H, Dabis F for the IeDEA Pediatric multiregional collaboration. 18-monthly mortality and loss-tofollow-up in antiretroviral treated Children in Asia and Africa. PMEDICINE-D-11-0195R1 (submitted July 2011). 2. 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. (revising draft) 3. Billngton H, Buchner S, Nyandiko W, Otieno Nyunya B, Musick B, Yiannoutsos 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. 4. Carter EJ, Diero L, Siika Am, Kimaiyo S, Gardner A, 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, 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. (Comments received from reviewers, being revised for submission)

Project Name:	Levels Of Breast Cancer Awareness Among Women Volunteering For Breast Cancer		
	Screening In Western Kenya		
Investigator(s):	Inui, T.		
	Busakhala, N.		
	Asirwa, C		
	Njiru, E.		
	Naanyu, V.		
	Mwangi, A.		

	Loehrer, P		
	Strother, M.		
Start Date:	10/1/2012	Project End Date:	6/1/2012
Site(s):		,	
Project Description:	The general purpose of this study is to measure women's knowledge on breast cancer and. In addition, the study will determine how perceptions (attitudes) affect the decisions women make about going to be screened for breast cancer. The study will also determine the presence of factors that increase a Woman's chances of developing breast cancer. In addition, the study will find out whether women with breast cancer are treated according to standard guidelines. In order to achieve these objectives, we will administer questionnaires to study participants, do fine needle aspiration cytology and get stain breast specimens after		
	for one year.	na progesterone receptors. We	e will also follow up these participants
Update:		has been submitted to IREC/IR	B for approval.
Project Name:	Low Risk Express Care		
Investigator(s):	'		
Start Date:	11/1/2009	Project End Date:	12/1/2012
Site(s):		·	
Project Description:	An assessment of the i model into the clinics.	impact on patient outcomes of	introducing the low risk express care
Update:	Data analysis is being r	revised.	
Project Name: Investigator(s):	Modified Directly Observed Antiretroviral Therapy (M-DART): An Intensive, Nurse-Directed, Home-Centered, Treatment Strategy To Reduce Mortality And Loss To Follow-Up In High-Risk HIV-Infected Patients Initiating Antiretroviral Therapy  Siika, A  Wools-Kaloustian, K Murage, W. T.		
	Thirumurthy, H.		
	Goodrich, S.		
Start Date:	8/1/2011	Project End Date:	11/1/2013
Site(s):	Chulaimbo Kitale Busia Port Victoria Khunyangu		
Project Description:	M-DART Study is a ran modified directly obse of care in patients with reduce both mortality initiated. In addition t	rved antiretroviral (ART) treatrent HIV/AIDS in Port Victoria and and the number of patients look these important objective out	g the effectiveness of a home-based ment strategy to clinic-based standard Khunyangu, Kenya. The aim is to st to follow-up after ART therapy is atcomes, it also seeks to find out if M- r patients and help to diminish HIV

Update:	The study expanded to new sites and satellite clinics in order to boost its enrollment numbers. The new sites include Busia, Kitale, and Chulaimbo. The satellite clinics include Sio Port, Mukhobola, Bumala A and B. The study was audited by an external auditor in mid January, 2012. The recommendations have since been implemented. The study got approval		
	from IREC and IRB for continuing rapprovals from IREC for protocol v		
Project Name:	1		DEA: Improving Kaposi's Sarcoma and coma Incidence in Western Kenya.
Investigator(s):	Wools-Kaloustian, K Diero, L.		
	Busakhala, N.		
	Jeff, M.		
	Toby, M		
	Loehrer, P.		
	Strother, M.		
	Czader, M.		
	Leboit, P.		
	McCalmont, T.		
	Asirwa, C Yiannoutsos, C.		
	Buziba, N.		
Start Date:	8/1/2008	Project End	7/31/2016
	0, 1, 2000	Date:	7,51,2010
Site(s):	All Sites		
Project			lignancy justify a standard of care in
Description:	1		assessment of the epidemiology of
	_ , ,		gnosis. This study will help validate
	local pathology for the diagnosis o		
	are techniques, like many patholo		g and immunohistochemistry which
		-, -	s a major determinant in diagnostic
	1	, -	uation of diagnostic skills are routine
	1		producibility between pathologists.
	The present effort will facilitate sin		
	reliability of a biopsy-based diagno	osis of Kaposi's sarcon	na and lymphoma at the selected
	sites.		
Update:	Punch Biopsies are continually been done at the Oncology clinic, AMPATH Centre. Visiting		
	clinicians continue to go to the On		
	Webuye. Currently clinicians have	been trained at Nam	bale, Busia, and Bumala A.
Project Name:	Patient-Reported Outcomes of Ca	ncer Care in Eldoret K	/enva
Investigator(s):	Hess, L.	ilcer care ili Liuoret, N	Cerrya
invostigator(s).	Naanyu, V.		
	Asirwa, C.		
Start Date:	10/14/2010	Project End Date:	9/1/2012

Site(s):	MTRH		
Project	This project is designed to valid	late and subsequently	implement a standardized
Description:	1	·	physical and psychosocial well-being
	·	• •	t. First, the instrument will be tested
	1	-	n a two-phase study. Second, it will be
	implemented into standard dat	•	•
	1 '	•	of cancer patients in Eldoret will help us
	-		g cancer patients and will help guide
	future strategies to improve co		
Update:	Accrual to this study is ongoing. The only barrier has been lack of return for subsequent		
	chemotherapy, thus the inabili	ty to obtain all needed	follow up assessments. We will have
	to continue to enroll additional	participants to reach	our goal of 120 patients with complete
	assessments for the validation	portion of the study.	
Project Name:	Post-Crisis Evaluation		
Investigator(s):	Goodrich, S.		
	Wools-Kaloustian, K.		
	Some, H.		
	Wachira, J.		
	Owino, R.		
	Braitstein, P.		
	Sidle, J.		
	Chesoli, C.		
	Gichunge, C.		
	Komen, F.		
	Obiero, C.		
	Sitienei, J.		
	Sang, E.		
	Siika, A.		
	Kimaiyo, S.		
	Mamlin, J.		
	Ndege, S.		
Start Date:	1/1/2009	Project End Date:	12/1/2012
Site(s):			
Project	Retrospective look at how AMI	PATH dealt with the po	st Election violence, including a look at
Description:	how soon patients returned to	clinic and a case study	of how the Burnt Forest Clinic dealt
	with the Crisis.		
Update:	Manuscript being draft and will be circulated to the co-authors in the next 2-3 weeks.		
Project Name:	Quinolone Use by Patients with Kenya	n Tuberculosis in a Larg	ge HIV Treatment Program in Western
Investigator(s):	Gardner, A.		
3(3)-	Siika, A.		
	Carter, E. J.		
	Pastakia, S.		
	Diero, L.		
	,		

	Cohon T				
	Cohen, T				
	Musick, B.				
	Simiyu, G.				
	Koech, J.				
Start Date:	1/12/2009	Project End Date:	12/1/2012		
Site(s):	MTRH				
Project	Retrospective analysis of p	pharmacy and AMRS data	to characterize the extent and		
Description:	indications for use of fluor implications for TB control		ents in AMPATH and understand the		
Update:	Abstract presented at Inte Data set completed. Analy		B and Lung Disease Annual Conference. gress.		
Project Name:	REACH Informatics COE. For	ogarty grant			
Investigator(s):	Biondich, P.				
	Siika, A.				
	Braitstein, P.				
	Diero, L.				
	Sidle, J.				
	Downs, S.				
	Hogan, J.				
	Kroenke, K.				
	Mamlin, B.				
	Meslin, E.				
	Nyandiko, W.				
	O'Meara, W. P.				
	Palakal, M.				
	Rotich, J.				
	Shen, C.				
	Vreeman, R.				
	Were, M.				
	Wools-Kaloustian, K				
	Yiannoutsos, C.				
Start Date:	6/1/2009	Project End Date:	6/30/2014		
Site(s):					
Project	The project is a collaboration between Indiana and Moi Universities and the global				
Description:	leadership of the Regenstr	rief 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 didactic and mentored practicum training				
	programs.	-	-		
Update:		1st Fellowship student is t	finalizing his second year of study at		
-		·	ip program by August. The 2nd and 3rd		
		_	y at Indiana and will begin their 2nd year		
	•	-	h is focused on patient matching and		

	·	•	te was accepted into the program and
	will begin his studies on 2nd July	2012 at Indiana Unive	ersty.
	Short courses update:		
	·	ning on Reporting was	s held between 16th and 20th January
	_		ty of the from Kenya, Tanzania and
	Rwanda.	o emonea with majori	ty of the from Kenya, ranzama ana
		training was held on ?	7th -9th February and attended by 18
	·	-	CChange, Centre for Health Solutions,
	CDC, AMPATH and Meridian Hospital.		
	3. Data Management on Da	ita Quality and Assura	nce was held on 25th -29th June and
	attended by 14 participa	nts from MOH Kenya,	MSF France and Holland in Kenya and
	South Sudan, KEMRI DnE	i and AMPATH.	
	Challenges: Some expected train	nings programs failed t	to kick off due to low number of
	_		venues to allow frequent training
	sessions.		
Project Name:	Renal Study		
Investigator(s):	Wyatt, C.		
	Owino Ong'or, W.		
	Abuya, J.		
	Wools-Kaloustian, K	T	1
Start Date:	12/10/2007	Project End Date:	12/10/2012
Site(s):	MTRH		
Project		ormance of equations	to estimate kidney functions to a
Description:		·	a disappearance of iohexol in HIV-
	infected adults		
Update:	The study is closed to enrollment	and followup, and re	mains open for data analysis and
		•	rently under review by co-authors for
	submission to a peer-reviewed jo	ournal.	
Project Name:	Screening for Cervical Cancer in I	HIV-Positive Kenyan W	omen: The Role of Human
Investigates/a)	Papillomavirus Typing		
Investigator(s):	Dainty, E.		
	Omenge, O. Walmer, D.		
Start Date:	10/11/2011	Project End	6/30/2012
Start Date.	10/11/2011	Date:	0,30,2012
Site(s):	MTRH; Mosoriot; Turbo		
Project		on of demographic dat	a as well as cervical swab specimens
Description:	• •	- ·	•
i –	for HPV genotyping from women with HIV who receive cervical cancer screening through the AMPATH supported program.		
	AMPATH supported program.	All specimens are collected and undergoing processing. Once processing is complete, data	
Update:		undergoing processing	c. Once processing is complete, data
Update:		undergoing processing	. Once processing is complete, data

Project Name:	TB Reach			
Investigator(s):	Carter, E. J.			
	Buziba, N.			
	Injera, W.			
Start Date:	10/1/2011	Project End Date:	12/31/2012	
Site(s):	We have 200 sites (from dispensal	ries to the Referral Ho	spital) spread across three	
	Provinces- North Rift ( excluding T	urkana), Western, and	d North Nyaanza	
Project	Kenya remains 13th on the list of t	the top 22 countries o	f the world affected by TB. The	
Description:	Academic Model Providing Access to Healthcare (AMPATH)- Moi University School of			
	Medicine (MUSOM) and Moi Teaching and Referral Hospital (MTRH) are institutions situated			
	in Eldoret that provide care to the western half of the country. The AMPATH-MUSOM-MTRH			
	partnership has worked in active T	B case finding for ove	r 5 years and has established a TB	
	culture facility. In this application, we will address the barriers of poverty, limited access to			
	diagnostic facilities due to distance, and stigma. Our intensified case finding activities will			
	revolve around four activities: 1.) Establishment of 150 intensified case finding sites utilizing			
	our present cough monitor program; 2.) Provision of TB culture for patients served by our			
	present cough monitor program who are smear negative to improve access to diagnosis for			
	this category of individuals; 3.) Provision of GeneXpert for patients served by our present			
	cough monitor program who are smear negative who live in areas too distant from our			
	culture facility to be served in activity #2; and 4.) Institution of a chest radiograph package			
	(chest radiograph and transport fees) for children under 5 years of age who live in			
	·	households of smear positive individuals. With these four interventions, we propose to		
	diagnose 4122 additional cases of Tuberculosis in our area and bring them into care with a			
111	completion of therapy rate of 85%.			
Update:			montitors were hired and trained as	
	well as 12 new field coordinators. Three Genexpert labs were established ( Busia,			
	Chulaimbo, Kabernet). Sputum transport system to the MLR built presently consists of 19			
	sites.			
	AIM 1: Quarter 1: 10,169 suspects had a positive questionnaire and were screened with			
	sputa microscopy with 1,228 diagnosed with smear positive TB. Quarter 2: 12,114			
	suspects had a positive questionnaire and were screened with sputa microscopy with			
	1.586 diagnosed with smear positive TB.			
	AIM 2: By the end of Quarter 2, 15 sites were recuited and over 125 cultures for smear negative TR suspects had been profromed.			
	negative TB suspects had been profromed.			
	AIM 3: All three labs were established with over 150 Genexpert tests perfromed on smear negative nations. In both arm 2 and 3, approximately 12-14% of the smear			
	smear negative patients. In both arm 2 and 3, approximately 12-14% of the smear negative patients are confirmed as TB.			
	AIM 4: Not yet insitituted in quarter 2.			
	Anvi 4. Not yet misititutueu mi	quarter 2.		
Project Name:	The III Simon Cancer Center (IIISC	C) AMPATH-Oncology	Institute (AOI): An Exemplar of Care	
i roject Hame.	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			
Investigator(s):	Inui, T.	paration based neset	aren Environment for 103ce	
	Busakhala, N.			
	Asirwa, C.			
	Omenge, O.			
Start Date:	7/1/2011	Project End	6/30/2014	
Ctart Date.	,, <u>,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, </u>	. rojout End	0,00,2017	

	Date:				
Site(s):	MTRH; Mosoriot; Turbo; Webuye Hospital				
Project	Kenya, like much of the developing world, is rapidly undergoing an 'epidemiologic transition'				
Description:	from a health scene dominated by infectious diseases to one in which the major causes				
	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				
Undoto	a federally designated Comprehensive Care Center.				
Update:	1. Naftali Busakhala will characterize the awareness, beliefs, attitudes and behaviors of				
	women coming to AMPATH's clinician breast exam screening as volunteers, comparing these beliefs to those of a community-based sample of women. He will also characterize				
	the yield of the AMPATH screening program, the kinds of cancers detected, and the				
	quality of care achievable in Western Kenya at present, with comparison against an				
	international standard of care.				
	2. Chite Asirwa will similarly characterize the awareness, beliefs, attitudes and behaviors of				
	this community-based sample of women, comparing their beliefs to those of their				
	husbands, often a key influence on behavior in traditional societies. Taken together				
	these two studies should reveal a great deal about how to influence women's behaviors				
	and encourage participation in the only breast cancer screening program available				
	presently - clinician examination. We'd love to have mammography!				
	3. Both of these studies with use the BCAM (Breast Cancer Awareness Measure), a survey				
	tool developed in Great Britain. We have worked carefully through the standard BCAM				
	to sort questions into theoretically sound domains, using the Health Belief Model as a				
	framework. Violet Naanyu will be conducting field testing and focus groups to do a				
	culturally appropriate KiSwahili version.				
	These protocols are being submitted for IREC and Oncology Working Group review.				
Project Name:	The Prevalence of Markers of Atherosclerosis Among Adult Patients with Congestive Cardiac				
	(heart) Failure				
Investigator(s):	Velazquez, E.				
	Kimaiyo, S.				
	Bloomfield, G.				
	Carter, E. J.				
	Maghasi, M				

	Akwanalo, C			
	Hogan, J.			
Start Date:	5/24/2011	Project End Date:	6/30/2012	
Site(s):	MTRH	<u> </u>		
Project	Using a case-control re	search design in a Kenyan popu	lation with heart failure, this project	
Description:	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:	IREC and NHLBI approvements for the 2012. Consistent with the enrollment protocol to enrolled participants. Notes that the enrolled participants are the enrolled participants. To day includes 14 newly enrolled participants.	val of the amendments were obt his study. Participant recruitmen our most recent amendment ap o include four new blood tests. T We are also contacting previousl te over 41 patients have underg	his will be performed on all newly ly enrolled participants to have three one a complete enrollment which participants. We recruited a new	
Project Name:	The Provalence Of Pho	umatic Heart Disease In Wester	n Kenya: An Echocardiographic Study	
Investigator(s):	Corey, R. Kimaiyo, S. Holland, T. Koech, M. Carter, E.J.			
Start Date:	12/2/2010	Project End Date:	7/31/2012	
Site(s):	MTRH	= 3353	-1	
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			
Update:	rheumatic heart diseas  The study is ongoing and the past 6 months.		nent is ongoing and has accelerated in	

Project Name:	The relationship of Indoor Air Pollution (IAP) Exposure to Isolated Right Heart Failure (IRHF)		
	in Women in Western Kenya		
Investigator(s):	Carter, E.J.		
	Kimaiyo, S.		
	Sherman, C.		
	Anstrom, K.		
	Hogan, J.		
	Lagat, D.		
	Diero, L.		
Start Date:	12/10/2010	Project End Date:	5/30/2012
Site(s):	Kaptagat		
Project	Several studies have shown that is	solated right heart fa	ailure (IRHF) is more prominent in
Description:	African women than in those living	g in resource rich na	itions. Its prognosis is thought to be
	worse among African women rela	tive to similar patier	nts from the richer economies given
	their general lack of access to hea	Ith care and often la	ate presentation of disease. COPD is the
	leading cause of IRHF in resource	rich nations. It rema	ins unclear whether this relationship
	exists in African women. COPD re	emains the 7th leadi	ng 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, esp	ecially in the sub-Sa	haran 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 wom	en.	
Update:	The Indoor Air Pollution study beg	gan its active enrollm	nent in November 2010. We have
	screened 395 patients to date and	l enrolled 98 particip	pants. We have completed all home
	visits for 94 participants and had 4	1 patients who were	lost to follow-up. We are finalizing
	data entry for this study. The study team has also submitted an abstract for this study to the		
	American Thoracic Society for the	May 2012 conferen	ce. The abstract was accepted as a
	poster presentation at the conference and was presented at the ATS Conference in San		
	Francisco during the month of Ma	y 2012. We are curr	ently working on the manuscript.
Project Name:	Understanding the Social and Structural Processes of AIDS-Related Stigma and		
	Discrimination in Burnt Forest, Ke	nya.	
Investigator(s):	Pfeiffer, E.		
	Maithya,H.		
	Naanyu, V.		
	Dickerson-Putman, J.		
	Inui, T.		
	Pescosolido, B.		
	Phillips, S.		

	Sidle, J.		
Start Date:	10/18/2011	Project End Date:	5/1/2013
Site(s):	Burnt Forest		
Project Description:	Using intensive ethnographic methods in the community of Burnt Forest, Kenya, the primary goal of this PhD dissertation research is to identify the social and structural roots of AIDS-related stigma and discrimination. In order to understand these factors, this study has three primary objectives:  (1) To investigate the impact that enacted and felt stigma has had on the lived experiences of individuals who are living with HIV and using antiretroviral therapies; (2) To explore public stigma;		
	(3) To examine the everyday HIV/AIDS discourses and practices associated with the disease in Burnt Forest.		
Update:	Using intensive ethnographic methods, PhD student, Elizabeth Pfeiffer conducted dissertation research between the months of October 2011 - April 2012. She will also be returning to Kenya to collect additional data during the months of July and August 2012. In May 2012, Ms. Pfeiffer presented a poster of some preliminary results of this research at the National Clinical and Translational Sciences Predoctoral Programs Meeting (required by her funding) in Rochester, MN. During the 2012/2013 academic year, Elizabeth Pfeiffer will analyze the data collected and write her dissertation in Indiana with the support of an Indiana University, Bloomington College of Arts and Sciences Dissertation Year Fellowship.		

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