Track 1: HIV / AIDS   **Venue: Training Center (Room 1)**

1.001

Identifying Individuals at High Risk for Acquiring HIV Infection in Kisumu Kenya: Formative Study and Initiation of a Novel Targeted-Recruitment Incidence Cohort

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Background: HIV prevention trials require high incidence populations, impose intensive study procedures for participants, and demand excellent retention. Studies which do not specifically target individuals likely to acquire HIV ('high-risk') are unlikely to reach these populations and may underestimate HIV burden and transmission. We undertook formative research to determine optimal methods to recruit high-risk study participants for prevention trials in Western Kenya (2007 HIV prevalence 15.3% and then initiated a targeted-recruitment incidence cohort.

Methods: For the formative study, members of high-risk groups were interviewed to identify strategies for recruiting high-risk individuals defined by inconsistent condom use and/or concurrent sex partners. These strategies were then used to guide recruitment for the Kisumu Incidence Cohort Study 3 (KICoS3), which aimed to enroll 625 HIV-uninfected high-risk 15-64 year old Kisumu residents. KICoS3 study activities were performed in locations and at times preferred by participants (late afternoons and nights). Screening procedures included pre-screening, consenting, an extensive behavioral questionnaire, medical evaluation, and HIV testing, simulating the intense requirements of a biomedical intervention trial. KICoS3 incidence and retention data are expected after 12 months of quarterly follow-up.

Results: The formative study identified 4 strategies for mobilization of high-risk individuals: using 1) Link Persons: persons with specific knowledge of target population 2) Peers: co-workers or contemporaries 3) Leaders: group or association leaders and 4) Staff Contact: study staff to directly contact potential participants. Between March and July 2010, KICoS3 pre-screened **2214** and completed screening of **1354** (**51.6%** female) participants using these strategies. HIV prevalence at screening was 27.5%, (13.5% M/ 36.8% F). We enrolled 644 (**51.7%** F) HIV-negative high-risk individuals. Reasons for non-enrollment were HIV+ status (n=340), abnormal labs or concurrent illnesses (n=66) and lack of reported high risk behavior (n=328).

Conclusion: We successfully recruited a population with nearly two-fold higher baseline HIV prevalence than local general population estimates. High-risk individuals can be identified and enrolled into intensive study protocols. Findings will shed light on the local epidemiology of new HIV infections and guide the implementation of future prevention trials.

Keywords: MARPs, risk, Africa, cohort, recruitment, prevention, trials

1.002

NON-BARRIER FAMILY PLANNING (FP) USE AMONG HIV POSITIVE WOMEN ENROLLED IN LUMUMBA HIV CLINIC WITH INTEGRATED FP SERVICES

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Background: Approximately 60% of HIV positive women express an unmet need for family planning (FP) in Kenya. An intervention to integrate free FP into HIV services on site was designed and implemented in 2007.

Methods: Women aged 18-54 years receiving ART or care at Lumumba HIV clinic in Kisumu, Kenya were included in a retrospective cohort analysis. Demographic, clinical and FP data from July 2007 to August 2010 were abstracted from electronic medical records. Multivariate logistic regression was used to assess factors associated with the use of FP, including hormonal methods and the intrauterine device (IUD).

Results: Approximately 4,700 HIV positive women (mean age=33.1 years) were included in this analysis. The prevalence of FP use increased from 36% to 47% from 2007 to 2010 (p<.001). In a multivariate model, odds of use of a non-barrier FP method increased with education level (aOR = 1.35 CI: 1.03 – 1.79 for those with secondary school relative to those with primary school or less) and with calendar year of enrollment into care relative to 2007 (aORs = 2.02, 2.06, 2.21 for years 2008, 2009, 2010 respectively, all p<0.01) and decreased with age (aOR = 0.96 CI: 0.95-0.98 per year). WHO stage and marital status were not associated with FP use.

Conclusion: Integration of FP services into the HIV clinical care setting resulted in a progressive increase in the use of non-barrier FP methods. Further examination of FP clinical and demographic correlates of FP uptake is planned to ensure the continued success of integrated FP/HIV care.

1.003

Prevalence of IRIS in Schistosomiasis/HIV Co-Infected Patients Undergoing Highly Active Antiretroviral Therapy (HAART)

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Background: HIV and schistosomiasis co-infection is common around Lake Victoria region raising the possibility of schistosomiasis-related immune reconstitution inflammatory syndrome (IRIS) in patients undergoing HIV medication. The prevalence of schistosomiasis in this population is nearly 100% with a third of them being HIV positive (HIV+).

Objective: The aim of the study is to investigate the prevalence of schistosomiasis associated IRIS in communities living around Lake Victoria in Rarieda District.

Methods: CD4 cell counts and determination of plasma viral load was performed on baseline and post-treatment samples to assess response to Highly Active Antiretroviral Therapy (HAART). Stool samples from participants were processed by Kato katz technique to diagnose participants with schistosomiasis. Paraziquantel and albendazole were used for treatment of schistosomiasis and other intestinal helminthes respectively. Liver and spleen pathology associated with schistosomiasis were assessed by abdominal ultrasonography.

Results: Up to 1152 persons underwent Voluntary Counseling and Testing for HIV and 551 (47.83 %) of these were HIV positive. . Number enrolled into study after VCT 550 of which 223 were ART naïve at the beginning of the study. Up to 484 were screened for schistosomiasis with 335 of them (69.21%) being positive for *S.mansoni*. The

prevalence of soil transmitted helminthes (STH) in this group was 8.0% and *P.faciparum* parasitaemia was 3.09%. A total of 223 (40.55%) of those consented into study are HIV (ve+) and 67(30.04%) were initiated on HAART. Up to 53 of these (79.10%) are dually infected while 14 (20.90%) are negative for schistosomiasis at recruitment and baseline screening. *S.mansoni* associated IRIS cases have been identified in 9 (13.43%); 6 of these (66.66%) fall into the paradoxical IRIS category while 3 (33.33%) are unmasking schistosomiasis IRIS.

Conclusion: This data shows that Schistsoma-IRIS is prevalent in this setting. Ongoing research is focusing on the epidemiology and management of schistosoma associated IRIS.

1.004

Nevirapine-Associated Hepatotoxicity and Rash are not predicted by a CD4 Cell Count ≥ 250 cells/μL among HIV-infected Pregnant Women in Western Kenya

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Background: Nevirapine-based highly active antiretroviral therapy (HAART) has been associated with an increased risk of rash-associated hepatotoxicity in non-pregnant women with a baseline CD4 cell count (CD4) ≥ 250 cells/ L. Few clinical studies have evaluated its use among HIV-infected pregnant women where it is becoming widely used for the prevention of mother-to-child transmission of HIV.

Methods: We enrolled HIV-infected pregnant women who initiated either nevirapine-based or nelfinavir-based HAART at 34 weeks gestation (Figure 1). Nelfinavir-based HAART was added in the second study period in response to the FDA's advisory on nevirapine. Participants had their serum alanine transferase measured and were evaluated clinically for rash at enrollment, then every 2 weeks until delivery, and then at 2, 6, and 14 weeks, and 6 and 9 months after delivery. In this analysis we identified risk factors for developing severe hepatotoxicity (grade 3 or 4 hepatotoxicity) and rash-associated hepatotoxicity (rash with ≥ grade 2 hepatotoxicity).

Results: HAART was initiated in 522 pregnant HIV-infected women (median age: 23 years, median CD4: 398 cells/μL, median HIV viral load (VL): 33,975 copies/mL). Severe hepatotoxicity occurred in 14 (3%) women and rash-associated hepatotoxicity occurred in 9 (2%) women. In the first analysis (limited to women with CD4 ≥ 250 cells/ L), women who initiated nevirapine had higher rates of severe hepatotoxicity (4.6% vs. 1.0%; p=0.03) and rash-associated hepatotoxicity (4.1% vs. 0%; p=0.003) compared with women who initiated nelfinavir. In the second analysis (limited to women who initiated nevirapine-based HAART), CD4 ≥ 250 cells/ L was not associated with severe hepatotoxicity (adjusted odds ratio [aOR] = 1.6, 95% confidence interval [CI] = 0.4 – 6.0) or rash-associated hepatotoxicity (aOR = 3.2, 95% CI = 0.4 – 26.0) in multivariate analysis. Severe hepatotoxicity was associated with having developed a preceding rash on nevirapine (aOR = 17.3, 95% CI = 5.2 – 58.1) and having a body mass index ≤ 20 kg/m^2 at enrollment (aOR = 6.5, 95% CI = 1.3 – 31.8). No adverse events resulted in fulminant hepatotoxicity or death.

Conclusions: Nevirapine-associated hepatotoxicity occurred in HIV-infected pregnant Kenyan women, but was not predicted by CD4 ≥ 250 cells/μL. Limiting nevirapine use to women with CD4 < 250 cells/μL may reduce treatment options unnecessarily and may not limit the frequency of nevirapine-associated hepatotoxicity events

Category: HIV/AIDS

1.005
Immune Responses to *Cryptosporidium* in HIV Infected Adults Attending Kenyatta National Hospital, Nairobi, Kenya

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Introduction: *Cryptosporidium* causes significant morbidity and mortality in AIDS patients worldwide particularly in developing countries where ART is not widely available or affordable. Across the African continent, the prevalence of cryptosporidiosis in HIV/AIDS patients varies from 8 to 72%. In Kenya, approximately 8% of the adult population lives with HIV/AIDS and *Cryptosporidium* has also been reported as the leading indicator of death among adult HIV/AIDS patients. There is very little information about the molecular epidemiology of Cryptosporidiosis and nothing about immune responses to *Cryptosporidium* in HIV/AIDS infected humans in Kenya. A number of *Cryptosporidium* antigens have been found to induce host immune responses in immunocompetent persons and animals; however their effects in the immunity of immunocompromised individuals are not understood. Glycoprotein 15 (gp15) and Cryptosporidium 23 (cp23) are conserved *Cryptosporidium* antigens that trigger host immune responses and are thus potent agents for vaccine development.
Objective: This study was therefore aimed at evaluating molecular epidemiology and immune responses against *Cryptosporidium* in view of preventing its effect towards immunocompromised persons.
Methods: *Cryptosporidium* species were identified through microscopy, using modified Ziehl-Nielsen method and confirmed by Polymerase Chain Reaction (PCR) and Restriction fragment length polymorphism (RFLP) targeting 18S rRNA to identify species, and *gp40/15* locus to identify subtypes. *Cryptosporidium* antibody and IFN-γ responses were assessed by Enzyme Linked Immunosorbent Assays (ELISA).
Results: In this study *Cryptosporidium* species was found to infect 23% and 28% of symptomatic and asymptomatic persons respectively. The species found were C. *hominis, C. parvum, C. meleagridis, C. muris* and *C. canis*. There was significant difference between asymptomatic and symptomatic patients immune responses levels of serum IgG to Chgp15 (P=0.033) and Cp23 (P=0.007)) and fecal IgA to Chgp15 (P=0.002).
Conclusion: Serum IgG to Chgp15 and Cp23 and fecal IgA to Chgp15 antibodies can offer protective against diarrhea.
Recommendation: The role and possibility of synergistic involvement of other cytokines should also be studied.

1.006
RV 217b: Early Capture HIV Cohort (ECHO): Acute HIV infection in most at risk populations (MARPs) in Kericho

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Background: Events occurring in acute HIV infection critically influence prognosis.

Understanding the nature of host control of viral replication will provide crucial insights to guide

vaccine development. ECHO is a prospective cohort study among high risk adults designed to define incidence, retention in these populations and acquire samples from acutely infected persons prior to the advent of detectable HIV antibody.

Objectives: The purpose of the study is to characterize recruitment and retention, and determine HIV prevalence and incidence in MARPs, and to describe host-virus interactions during early HIV infection.

Methods: HIV uninfected, female sex workers and females considered at high risk for HIV infection based upon a screening questionnaire are enrolling and will be followed for two years. Small blood volumes (SBV) are collected twice a week by finger stick with testing for HIV-1 RNA by the APTIMA Qualitative Assay to detect acute infection. Volunteers are seen every 6 months for larger blood draws to include HIV diagnostics, immunoassays, and host/viral genetics. Volunteers with reactive APTIMA findings are entered into an intensive one-month diagnostic verification phase to establish HIV status definitively. Volunteers with acute HIV infection are followed for an additional five years to correlate clinical outcome with acute events.

Results: To date, 502 volunteers screened and 87% are at high risk by our pre-defined criteria. Baseline HIV prevalence was 31% (131 of 423). SBV collection adherence has been 97% through 3- 12 months of monitoring. Six volunteers have been identified with acute HIV infection, giving a crude incidence of approximately 3.3/100 PYs (95% CI: 0.66-5.94%). All 6 were identified and samples collected prior to advent of detectable HIV antibody (Fiebig I-II).

Conclusion: ECHO has demonstrated that efficient detection of individuals with very early acute HIV infection is feasible in Kenya. This will provide an extremely powerful tool to study host-HIV interactions with direct relevance to HIV vaccine development.

1.007

Effectiveness of PMTCT interventions in reducing Mother to Child Transmission of HIV in Kenya

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Background: Targeted interventions have proven effective in reducing the transmission of HIV from a mother to her unborn child and the infant in developed countries. PMTCT programs are well established in many developing countries. Although it is thought that these programs help reduce transmission of HIV to infants, in Kenya no nationwide study has ever been carried out to support this notion.

Methods: Dried Blood Spots were collected in health facilities from exposed infants and delivered to the KEMRI HIV laboratories by courier. Testing for HIV was done using PCR and dispatched to facilities immediately.

Results: A total of 64,737 children were tested between May 2006 and December 2007. This was approximately 20% of the total demand for tests in infants in Kenya. The overall HIV prevalence was 10.71%, with 10.72% in female infants and 9.92% in male infants. A total of 8,495 (13.12%) mothers said they did not breastfeed while 21,302 (32.91%) mothers admitted they breastfed. Only 8 (0.01%) of the mothers reported mixed feeding. In those who did not breastfed, prevalence was 9.64% (9.25% in males and 10.01% in females). In those who breastfed, HIV prevalence in their infants was 9.52% (9.46% in males and 10.2% in females). For mothers that breastfed and took HAART, HIV prevalence in their infants was 5.76% at the time of testing. For single dose Nevirapine with breastfeeding, the prevalence stood at 10.34%. In mothers who took a combination of Azidothymidine and Nevirapine, and breastfed, the prevalence was intermediate, at 8.02%. Finally, data was analyzed for mothers who did not breastfeed. For those who took HAART, the prevalence was 5.5%. For those who took SDNVP, 10.32%, and for AZT and NVP combined, 7.24%.

Conclusions: Prevention of Mother to child transmission of HIV programs have reduced prevalence of HIV in infants significantly. The prevalence of HIV in female exposed infants

seems to be marginally higher than in males. Preliminary findings suggest that HAART is the most effective therapeutic intervention in HIV

positive mothers with infants regardless of breastfeeding status.

1.008

Improving access to Prevention of Parent to Child Transmission (PPCT) services through mobile outreach antenatal care (ANC) clinics

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Background: In resource-limited settings with high HIV prevalence, mobile outreach clinics may facilitate antenatal care (ANC) service provision for pregnant women. For HIV-positive pregnant women, these clinics may play a critical role in ensuring the Prevention of Parent-to-Child (PPCT) service provision and linkage to HIV care.

Methods: Family AIDS Care and Education Services (FACES), collaborating with 11 government health facilities in Migori, Nyatike, and Rongo districts, utilized community and public health officers to strengthen mobile ANC clinics. Communication materials encouraging pregnant women and their partners to seek ANC services at mobile clinics were developed. Women testing HIV-positive were provided with antiretroviral prophylaxis for PPCT and linked to Community and Clinical Health Assistants (CCHAs) who counseled them on the importance of PPCT and referred them to the nearest health facility for more comprehensive services. The CCHAs conducted home visits if the women did not reach the health facility within two weeks.

Results: From June to August 2010, 831 pregnant women were counseled and tested for HIV at the ANC mobile clinics. Of these women, 117 (14.1%) tested HIV-positive. While 16 of the HIV-positive women revealed that they were already in HIV care, the remaining 101 (86.3%) received PPCT services on site and were referred to a nearby center for comprehensive ANC and HIV care. Of those referred, 95 (94.1%) visited the referral facility within 2 weeks; 5 of the 6 who did not visit were traced at home and subsequently came to the facility. Twenty-one (20.8%) of those referred subsequently enrolled in HIV care within two months.

Conclusion: Combining mobile ANC clinics with community mobilization, referral tools, and tracing efforts is a promising strategy to provide and facilitate linkage to PPCT services. Although fewer than expected HIV-positive women enrolled in HIV care, the mobile clinics did reach women who might not have otherwise enrolled in care. Further exploration of linkage to care for HIV-positive pregnant women is planned.

1.009

Evaluation of drug resistance profiles in a population of drug naïve patients in IRIS state of infection in a cohort study in Western Kenya.

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Background: Since the advent of HIV/AIDS in Kenya in the early 80s, there have been a significant number of deaths related to the pandemic. With this came a rapid rise in number of persons taking antiretroviral medication to manage HIV. Consequently, there has been a rapid access to ARVs in the country. However, as this has

happened, very little monitoring of resistance to ARVs has taken place. There are chances that persons put on ARVs may already be infected with viruses that are resistant to common ARVs in use in Kenya. This study seeks to determine whether carrying out baseline HIV resistance testing is necessary before placing patients on ARVs.

Objectives: The objectives of this study were to determine the presence of HIV drug resistance mutations in a cohort of IRIS patients who are drug naïve, the circulating subtypes of HIV and common mutations in the cohort that may contribute to HIV-1 subtype evolution.

Methodology: Plasma samples were collected from patients at IRIS stage of HIV-1 infection enrolled in a cohort study at baseline before being put on ARV medication. Viral RNA was extracted, amplified and sequenced using the Trugene system. Portions of the protease and reverse transcriptase genes about 1000bp in size were successfully sequenced and analyzed.

Results: Fifty samples were successfully analyzed. The analysis indicated that 78% (39 patients) had no HIV drug resistance mutations while 12 % (11) had mutations that conferred resistance to one or more common drugs used to manage HIV/AIDS. Most of the infecting viruses were HIV-1 subtype A-1.

Conclusions and Recommendations: The study indicated a significant number of patients had mutations conferring resistance to ARVs. These findings indicate that it may be important to carry out baseline resistance testing. The downside to this is that resistance testing is a very expensive test.

1.010

Motivation to join and 'stay' in a vaginal microbicide trial in Kisumu: Participants' perceptions

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Background: A variety of reasons may motivate healthy, HIV-negative, reproductive-age women to join and continue participating in phase I/II vaginal microbicide trials. Such trials are often carried out in settings where the general reproductive health care of the women falls short of recommended standards of care. A research clinic offering comprehensive reproductive health care services such as contraceptive services, HIV testing, STI management and risk-reduction counseling as part of the vaginal microbicide trials is potentially women-friendly and may provide some of the reasons motivating women to join and continue participating in these trials.

Objective: To describe the reasons motivating women to enroll and continue participating in a phase I/II vaginal microbicide gel study in Kisumu, Kenya in 2010.

Methodology: Twenty-nine women were enrolled in a multisite phase I/II vaginal microbicide gel study at Kar Geno centre in Kisumu, Kenya in 2010. These women were interviewed at enrolment visit and responded to a question asking about the reasons that encouraged them to join the study; data were captured in a questionnaire. A follow-up questionnaire at visit 5 was administered to each of the 29 participants in which they responded to questions regarding what they liked about taking part in the study.

Results: All 29 enrolled participants responded to the questions evaluating their reasons for joining the study and the things they liked about their study participation. Most participants (65.5 %) cited "feeling like they are helping to solve the HIV/AIDS problem" as the most important reason for joining the study. Also cited were STI testing and treatment (6.7%), to know one's HIV status (6.9 %) and other reasons (20.7 %) chief among which was friendly research centre staff. Of the 29 enrolled participants interviewed regarding the things they liked most about their study participation, 48.1% cited getting to know their HIV status, 24.1 % getting to see a doctor regularly, 13.8 % feeling like they are helping solve the HIV/AIDS problem, 3.4 % STI testing and treatment and 3.4% regular counseling (3.4%). Nearly 7% of the women interviewed cited other aspects of study participation that they enjoyed, with the commonest one being friendly research centre staff. The main limitation of the study is that these data were obtained through a questionnaire administered by research staff members and could have thus been influenced by social desirability bias.

Conclusions: The greatest motivating factor for enrolling in the trial was the perception that one was helping to solve the HIV/AIDS problem. Provision of reproductive health care services such

as HIV testing and other health care services namely health check-ups and STI treatment may have motivated the women to continue participating in the study.

1.011
HIV-1 genetic diversity and naturally occurring polymorphisms in HIV-1 Kenyan isolates Integrase gene: Implications for integrase inhibitors.

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Background: Little is known about the extent and predictors of polymorphisms potentially influencing the susceptibility to HIV integrase inhibitors (INIs).
Objectives: To determine the extent of drug resistance mutations in HIV-1 positive antiretroviral naive and those on treatment prior to Intergrase inhibitors intervention.
Methods: HIV-1 positive plasma samples were collected from forty nine (49) subjects: (**30**) drug naive and (**19**) treated with ARV, within Nairobi cohort (18 males and 35 females) consenting patients between April and December 2009. The viral RNA from plasma samples were extracted using Qiagen® RNA isolation kit and intergrase (IN) gene was amplified by nested PCR. The amplified products were analysed by gel electrophoresis and visualized under UV light. The successfully amplified products were then labeled with a sequence dye in sequence PCR reaction using the Big Dye® sequence terminator kit (Applied Biosystem®) and the products purified by use of Qiagen purification kit before directly sequenced using an automated ABI 310 sequencer (Applied Biosystem, Foster City CA). In the IN gene (288bp) of the virus was sequenced.
Results: From the partial pol- intergrase sequences the phylogenetic analysis revealed: A1 (38.8%), D (20.4%), A (2%), C (18.4%), AICD (2%), A2D (2%), BG (2%), 02_AG (4%) and URF (6%). The higher levels of unique and circulating recombinant forms detected suggested a possible viral mixing within Nairobi populations. Two (2) % of the study subjects were detected with integrase mutation at position T97A that is associated with reduced susceptibility. This occurred in patients infected with predominant HIV-1 subtype A1. Therefore, drug reduced susceptibility prevalence of 2% prevalence against raltegravir was detected. In addition, 22.4% of the study subjects were found to harbour viral strains with other mutations that are not associated with any intergrase drug resistance. This suggested a possible evolution of the virus due immune and other class of antiretroviral pressure. This study showed that the new class of intergrase inhitors was eligible to be used in among the rest of cocktail of HAART in treatment of HIV cases.

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1.012
Impact of home based counseling and testing for HIV on care-seeking and disease incidence in rural western Kenya

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Category: HIV/AIDS

Background: In rural Africa, most individuals living with HIV do not know their HIV status and therefore are not accessing timely care.
Objective: We examine the impact of home based counseling and testing (HBCT) for HIV on care-seeking and disease incidence in rural western Kenya.
Methodology: In 2008, we offered HIV HBCT to a population under surveillance for infectious diseases in Asembo, rural western Kenya. We linked HIV test results to morbidity data routinely collected by field workers through home visits. We analyzed healthcare seeking and incidence rates of acute lower respiratory tract infection (ALRI), acute febrile illness (AFI) and diarrhea among HIV infected and HIV uninfected individuals before and after HBCT using chi-square tests and rates. Rate ratios were calculated using Poisson regression.
Results: Among 6366 first-time HIV testers ≥ 13yrs of age, 698 (10.9%) were HIV-infected. HIV prevalence was highest among individuals aged 35–49 years at 22.1%. Compared with the HIV-

uninfected, HIV-infected persons had higher incidences of ALRI (RR 3.14, 95% CI 1.90-5.20), AFI (RR 1.36, 95%CI 1.27 – 1.45) and diarrhea (RR 1.77, 95%CI 1.58 – 1.98). At home follow-up visits 1 month after HBCT, 46.1% of infected persons had begun HIV care at nearby clinics of whom 89.9% had started CTX prophylaxis and 16.6% ART. Following HBCT, care-seeking at health facilities increased among HIV-infected persons for ALRI (35.8% before versus 45.5% after) and AFI (30.5% before versus 39.6% after). No change in care-seeking for diarrhea occurred. The incidence rate ratios - post to pre-HBCT for ALRI was RR 0.66 (95% CI 0.28-1.58), AFI was RR 0.84 (95% CI 0.77-0.91), and diarrhea RR 0.85 (95% CI 0.73-0.98).
Conclusion: There was more illness among those HIV-infected than HIV-uninfected. However, after learning of their status through HBCT, care-seeking at health facilities increased among HIV-infected persons and the reported disease incidence decreased.

1.013
Early Infant Diagnosis-The KEMRI/WRP CRC Laboratories Experience
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Background: Early Infant Diagnosis (EID) is a nationwide program for diagnosis of HIV in infants born to HIV positive mothers. Currently, there are four EID testing centers in Kenya involved in this program and the KEMRI/WRP Laboratory is one such lab.
Objective: To determine the prevalence of HIV-1 in infants in Rift Valley region, as well as the challenges within the EID program and its future prospects.
Methods: Data on all tests done at the KEMRI/WRP CRC laboratory received from sites in the Rift valley in the year 2010 was analyzed. The percentage of HIV positive and HIV negative infants was then tabulated. Bar graphs and pie charts were generated to represent the results.
Results: 5110 samples were analyzed in the year 2010. The second half of the year experienced an increased number of samples analyzed with 3312 infant samples, compared to 1798 samples

analyzed for first half of 2010. Of the 5110 infant samples analyzed, 637 (12.5%) were HIV positive while 4483 (87.5%) were HIV negative.
The major challenges identified in the EID program in this region included use of manual testing methods in the laboratory that increased the turnaround time, stigmatization of those infected, communication challenges with facilities sending in samples for diagnosis, use of outdated request forms for ordering tests and use of expired filter papers to collect Dried Blood Spots.
Conclusions/Recommendations: There was high prevalence of HIV-1 infection in the tested infants for the year 2010. We recommend an increase in number of testing sites to reduce the distance covered to deliver samples and test results and to "take services closer to the people" in line with Vision 2030. There is need for automation using the Cobas Taqman Ampliprep platform and sensitization of communities to reduce stigma.

1.014

Assessing Various Strategies that Motivate Couples for CHCT Service in Kisumu: Lessons Learnt.

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Introduction:
Meeting participant accrual goals in clinical trials is a core aspect of any research study. Multi-site trials may engage diverse communities – rural, urban, resource limited, unstable, and those with diverse historical and cultural backgrounds. It is important to consider community dynamics and local social, economic and environmental conditions when developing recruitment strategies. Therefore one strategy may not be sufficient or necessarily appropriate for all contexts.

Methods: The Pre Exposure Prophylaxis (PrEP) study in Kisumu had a target to recruit 600 discordant couples over a two year period. We explored various mobilisation strategies employed y to assess what motivated couples to seek HIV testing. These strategies included but were not limited to Couple Ambassadors , Accelerated Mobilzation, Radio/media, Signage, Partner Referrals through the VCT Centres . We tracked referral sources of couples seen at various VCT sites within Kisumu. Couples presenting for testing identified the mobilisation strategy that motivated them to make the decision to access couple testing and counseling services using an interviewer administered questionnaire t.o couples at the respective VCT sites.

Results: A total of 387 couples were interviewed. The couples identified several options of information. The media (Radio and Television) was identified as an information source for 45.0% of the couples, while health care providers were identified by 4.0% . Written information sources were also reported as follows: Signposts by 14.3% couples and pamphlets/leaflets/fliers by 11.6% couples. Accelerated mobilization, was reported by 13.7% while social events by 12.0%. Faith based organizations was reported by 4.1%, with friends informing 15.6% of couples. Information sources including NGOs, CBOs, family member other than partner, peer educators, school functions, work place and influence agent networks were reported by less than 5% of respondents across gender.

Conclusion: All the mobilization strategies that were employed contributed to the increased uptake of CHCT within Kisumu District. The media proved to be the best source of information strategy for the couples who were seen at VCT sites.

1.015

Family Model of HIV Care and Treatment – Building on Family Strengths

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Background: Nyanza Province, Kenya, had the highest HIV prevalence in the country at 14.9% in 2007, while the national HIV prevalence was 7.1%. Only 16% of HIV-infected adults in the country accurately knew their HIV status. The family model of care was examined to determine its viability to broaden testing access, HIV case identification, and to facilitate HIV positive family member enrollment.

Methods: A Family Information Table (FIT) tool was developed to assess HIV-infected index patients and family member linkages. A retrospective study of 5,802 adult HIV patients seen between Sep. 2007 and Sep. 2009 at Lumumba Health Centre in Kisumu was conducted. A 5% random sample of index patient FITs were examined to assess family reach. Additionally, electronic medical record (EMR) enrollment data from 2,569 adults and 792 children were examined for referral source and immunological status. FIT and EMR data were not linked. Descriptive FIT and EMR data were analyzed in SPSS and SAS, respectively. Fisher's Exact test was used for proportions compared and Kruskall Wallis for medians.

Results: FIT data indicated that for each HIV-infected index patient approximately 2.5 family members at risk were identified and about 1.5 family members were tested. Among adults aged 15 years and older, 68% (n=168) were tested and among children aged 0-14 years, 57% (n=269) were tested. EMR data revealed that 68% (n=542) of pediatric enrollment was through family member referrals. Patients entering care through family member referrals had a higher median CD4 count than voluntary counseling and testing patient referrals: for adults aged 15 years and older the median CD4 count was 311 vs. 229 (p=0.07), and for children aged 6-14 years the median CD4 count was 421 vs. 310 (p=0.08). These results were marginally statistically significant and suggestive of an association.

Conclusions: The family model of care is a feasible approach to broaden HIV case detection and service reach, and to facilitate early enrollment. Results suggest that persons tested through family model are diagnosed at an earlier stage of infection. Further efforts are needed to increase family testing.

1.016

Concomitant use of ARVs and herbal medicine in Western Province - Kenya

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Background: Risks and benefits of concomitant use of herbal medicine and ARVs have been claimed but there is no epidemiological or biomedical data to support such claims. HIV Treatment programmes lack pharmacovigillace system or collaboration with biomedical research organizations to detect adverse drug reactions or beneficial effects. The use of herbal medication has increased due to encouragement of community participation in HIV and AIDS care. Cultivation of herbal medicines and regular use is common among communities of PLWHA. The composition of the herbs used are not known nor their performance with ARVs. Health workers are expected to monitor and advice clients on HIV disease and medications but the information about herbal medicines are often not disclosed at the clinics.

Study Objective: The objective of the study was to establish the incidences of concomitant use of herbal medicine and ARVs, to identify the factors associated with disclosure to health workers, reasons for herbal medications and effects on users.

Methodology: Data was collected from 120 clients attending major CCC at Webuye, Bungoma, Teso (Kocholia), Busia , Mumias and Vihiga District hospitals. The clients were selected through convenient sampling and requested to respond to self administered questionnaire comprising 21 questions.

Results: The results showed that prevalence of herbal medicine use was at 54.2% among patients taking ARVs and 37 medicinal plants were identified. Reasons for taking herbal medicine were varied but were grouped into 4 categories; 0.8% used it to boost immunity, 1.7% took it because of side effects of ARVs, 7.5% took herbs for reasons not related to HIV. The majority, 11.7% took herbal medicine because of opportunistic infections. Only 12.3% discussed herbal use with health workers. Reasons cited for lacks of disclosure were; failure of health workers to ask about herbal medication, lack of knowledge about the importance of disclosure, fear of health workers and communication barrier. Higher percentage of those with post secondary education and above 49 years of age disclosed their herbal

medication to health workers compared to younger clients and lower education. Of the 70 who made general comments about herbal medicine 24% felt that herbal medicine should be available at medical facilities, 18% expressed need for research, 17% said they were useful and another 17% commented that they were harmful. Another 6% expressed doubt about the use of herbal medicine. Of the 120 clients who responded to the questionnaires, 23 testified about their experiences with concomitant use of ARV and herbal medicine. Out of 23, beneficial effect was reported by 12 but 11 reported adverse effect or no benefits.

Conclusion: The study concluded that lack of specific inquiry about herbal medicine, lack of supportive relationship between health workers and clients plus lack of awareness was the major causes of non-disclosure. There were both beneficial and adverse experiences with concomitant use of herbal medicine and ARVs.

Recommendations: Collaboration with biomedical research institutes to investigate performance of ARVs with herbal medicines, particularly those used regularly by the clients. Better provision of medication counseling by health workers.

1.017

Gene Expression analysis of HIV Resistant Female sex workers show a lowered immune activation state and high expression of type 2 diabetes markers
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Design of effective vaccines against the human immunodeficiency virus (HIV-1) continues to present formidable challenges. However, individuals who are exposed HIV-1 but do not get infected may reveal correlates of protection that may inform on effective vaccine design. To identify novel biomarkers for HIV resistance including pathways that may be critical in anti-HIV vaccine design, we carried out a gene expression analysis on blood samples obtained from HIV-1 resistant (HIV-R) sex workers in Nairobi and compared their profiles to HIV susceptible negative controls. Whole blood samples were collected from 43 HIV-R and a similar number of HIV negative controls. Total RNA was extracted and hybridized to the affymetrix HUG 133 Plus 2.0 micro arrays (Affymetrix, Santa Clara CA). More than 2,274 probe sets were differentially expressed in the HIV resistant women as compared to the control group (fold change ≥ 1.3; p value ≤ 0.0001, FDR <0.05) . Unsupervised hierarchical clustering of the differentially expressed genes readily distinguished HIV-R from susceptible controls. Pathway analysis revealed a majority of the impacted pathways (13 of 15, 87%) were significantly down expressed. The most down expressed pathways were glycolysis/gluconeogenesis, insulin signalling, and T-cell receptor pathway. The most up expressed gene, was Dipeptidyl peptidase 4, a multifunctional enzyme associated with type 2 diabetes. We infer that the hallmark of HIV resistance is down regulation of genes in key signaling pathways that HIV depends on for infection probably through mechanism similar to evolution of type 2 diabetes.

1.019

Moving towards Evidence-based HIV Prevention Behavioural Interventions for Kenya
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Background: Although there has been a plethora of prevention work in Kenya, to date there have been few packaged, standardized, national interventions for specific target populations.
Objective: Kenya's National AIDS and STD Control Program along with United States Government agencies implementing the President's Emergency Plan for AIDS Relief (PEPFAR) and implementing partners are developing a four pronged approach to move evidence-based behavioral interventions (EBIs) from research to practice.

Methods: The first prong is development of a tool that can be used to systematically assess HIV prevention behavioral interventions currently used in Kenya to determine if they include characteristics found in effective programs and cover conventional health education standards. The second prong will identify Kenyan HIV prevention behavioral interventions developed and rigorously evaluated with demonstrated efficacy for translation into user friendly packages for wide spread dissemination. The third prong will focus on further development of a systematic adaptation process to ensure EBIs developed in other countries are appropriate for specific target audiences (e.g., youth, most at risk populations, rural, urban) and repackage these adapted EBIs for scale-up. All EBIs will be integrated into combination prevention programs that include biomedical interventions (e.g., male circumcision) and structural interventions (e.g., micro-enterprise, stigma reduction). The forth prong will focus on operational research to improve the functioning and effectiveness of EBIs.

Results: Currently the initiative has begun to scale up four evidence-based interventions: Prevention with Positives, the Families Matter Program, and Healthy Choices I and II. Preparations have begun to adapt and package a number of other interventions.

Conclusion/recommendation: The initiative will ensure that the large investment in behavioral prevention research is translated into improving practice. Further, it will allow partners to fulfill Next Generation Indicators required by PEPFAR. Finally, it allows better resource utilization on interventions that work and is an important piece of combination prevention.

1.018

Daily Monitored Adherence: Optimizing Adherence in a Vaginal Microbicide Study in Kisumu, Kenya

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Background: Optimization of adherence within HIV prevention studies especially in the context of microbicide studies continues to pose an enormous challenge. Adherence to investigational product is critical in any trial as it is crucial to the determination of the product effectiveness and builds on the understanding of the safety of the product. Although various approaches are currently being employed to optimize adherence in microbicide trials none has been proven to be fully effective.

Objective: To monitor and enhance adherence in the ongoing International Partnership for Microbicides (IPM) sponsored phase I/II vaginal microbicide gel studies a method designated as Daily Monitored Adherence (DMA) is in use. DMA borrows heavily from the Daily Observed Therapy (DOTs) used to administer and enhance adherence to medication for multi-drug resistant tuberculosis on a daily basis. Similarly, in the DMA method, trained study staff members monitor adherence through the daily collection of used applicators. As one of the IPM research centre sites based in Kisumu, Kenya, we sought to implement the DMA model during the conduct of the trial and assess its feasibility in our set up.

Methodology: We started off by mapping what are now termed 'DMA communities' that is densely populated estates within the environs of the research centre, which have approximately a 14-minute-walk diameter. Within these DMA communities a central location hereby termed as a 'drop off centre' was identified that could serve as a point where participants could drop off their used applicators. Participants were then recruited from these DMA communities to join the trial upon meeting the eligibility criteria. Once enrolled into the study, the participants could return their applicators by either having an outreach worker visit their homes on a daily basis excluding public holidays and weekends or the participants could drop off their applicator to an outreach worker stationed at the drop off centre.

Lessons Learnt: Two out of the six DMA communities mapped were utilized in recruiting all participants for the trial. 55% of participants opted for the drop off centre and 45% for home visits and all were followed up successfully. Of the screened out

participants, none cited the use of the DMA design in the study as a reason for unwillingness to participate. One main advantage of this method is that the daily contact with a study staff member provides an opportunity for the participants to report any adverse events or social harms in a timely manner. This model requires an extensive preparatory phase including exhaustive community engagement work within the DMA communities so as to optimize recruitment within these communities. Male partner involvement is imperative to the success of this model due to the daily contact with the participants. Well trained and dedicated staff is required so as to efficiently implement the model on a day to day basis. Finally, securing of a central location within the DMA community to serve as a drop off centre for the duration of the study was a challenge more so because we were targeting already well established communities.

Conclusions: The DMA design is potentially a suitable method for optimizing adherence in microbicide trials, However, sufficient preparatory groundwork and monitoring should be incorporated into the trials to ensure success.

Track 1: HIV / AIDS	Venue: Training Center (Foyer)

1.020

Factors Associated with Early Uptake of HIV Care and Treatment Services after Testing HIV-Positive during Home-Based Testing and Counseling in Rural Western Kenya

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Background: The extent to which individuals who test HIV-positive during home-based HIV testing and counseling (HBTC) access care and treatment services remains unclear. We describe characteristics associated with seeking HIV care serviceswithin six months of diagnosis among HIV-positive persons identified through HBTC.

Methods: Trained counsellors offered HBTC to all adult residents of the KEMRI/CDC Health and Demographic Surveillance System areas (HDSS. Identified HIV-infected residents were referred to nearby care and treatment clinics. Two to 6 months after HBTC, peer educators contacted all consenting HIV-positive residents in their home and administered a brief questionnaire. A multivariable logistic regression model adjusted for age, gender, marital status, and village was used to identify predictors of HIV clinic attendance.

Results: Overall, 10,585 (83%) of the 12,746 HDSS residents approached by a counsellor accepted HBTC; 1,140(11%) were HIV-positive and peer educators interviewed 752 (70%). 60% of HIV-positive residents tested as individuals, 22% as a family, and 18% as a couple. 36%had disclosed their status to a spouse/partner and 41%reported being currently enrolled in HIV care. Factors significantly associated with care enrolment includedbeing female (AOR:1.1, 95%CI:1.0-1.2), having disclosed (AOR:1.2, 95%CI:1.1-1.3), and reporting current health status as fair/poor (AOR:1.3, 95%CI:1.2-1.4). Participants who tested as a couple or family were more likely to disclose (AOR:1.5, 95%CI:1.4-1.6) and to enrol in care (AOR:1.2, 95%CI:1.1-1.3) than participants testing as individuals. The main reason for not seeking care was still feeling strong (19%).

Conclusions: HBTCwas well-received by the community and increased individuals' and families' knowledge of HIV status. Future HBTC activities should target men and continue to encourage individuals to test as couples or families to facilitate disclosure and subsequent enrollment into care. Given that earlylinkage of HIV-positive individuals into prevention, care and treatment services reduces morbidity, mortality and HIV transmission risk to sex partner(s),HBTCcounsellors should emphasize the importance of early care among asymptomatic persons.

1.021

Disproportionate HIV and HSV-2 Prevalence and Incidence among Women and Adolescent Girls in Western Kenya: Preparation for Female-Centred Prevention Trials

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Background: HIV and Herpes Simplex Virus type 2 (HSV-2) disproportionately affect young women in sub-Saharan Africa. Recent success with a vaginal microbicide active against HIV and HSV-2 reinforces the need to establish high HIV/HSV-2 incidence female cohorts for urgent and important studies of female-centred prevention strategies. We analyzed HIV prevalence and incidence and HSV-2 prevalence by gender in HIV incidence cohort studies conducted in western Kenya from 2007-2009.

Methods: HIV uninfected, sexually active non-pregnant residents of Kisumu were eligible to participate. Enrolment of two target populations was carried out sequentially: 1) adults 18–34 years old and 2) adolescent boys and girls 16-17 years old. At screening and quarterly visits over 12 months, demographic, sexual and other behavioural data were collected using audio-computer-assisted self interview. In addition, medical evaluations and testing for HIV, HSV-2, other sexually transmitted infections and pregnancy (for females) were performed.

Results: Median age was 22 for adults and 16 for adolescents. HIV and HSV-2 results are presented in the table below:

(Author posted a table……..)

1.022

Inter-study Variation In Peripheral Blood Mononuclear Cell (PBMC) Yields: A Comparative Approach

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KEMRI / WALTER REED PROJECT, KERICHO

Background: The study of PBMCs is finding increasing applicability in the study of vaccines, autoimmune disorders among others. Studies have been conducted at KEMRI/WRP Kericho to isolate PBMCs for use in studying the response of the human body to vaccines, ARVs and evolution of HIV. Questions remain concerning the variation in PBMC cell yields between studies and over time; information which could find relevance in assays such as proliferation, cytotoxicity and cytokine production assays.
Objectives: To compare PBMC cell yield trends for different studies over time with the aim of proving or disproving the hypothesis that PBMC cell yields vary from study to study and over time.

Materials and methods: One individual participant from a mixed age population was sampled randomly from each of the three studies, i.e. a vaccine study Retro Virology (RV 172), an acute HIV infection study (RV 217) and an Immune Reconstitution Inflammatory Syndrome Study (RV 246). Each participant was used as a data point for their respective study. Their PBMC cell yield data was compiled retrospectively at all protocol defined time points between 2009 and 2010. PBMC cell yield for each sample in the three studies was calculated as PBMC value obtained from ACT5DIFF count $* 10^6$ / Volume of blood. Data was tabulated and graphed to depict variation trends of PBMC cell yields.

Results: RV 217 and RV 172 exhibited most and least erratic PBMC cell yield respectively. % Variation was computed as (Highest PBMC yield - Lowest PBMC yield) /Lowest PBMC yield * 100%. RV 172 and RV 217 had lowest and highest % variation of 93.4% and 11076.4% respectively. RV 246 had a 363.7% variation. The significance level of the differences was 90%. The confidence levels were 4.09, 4.33 and 7.21 for RV 172, RV 246 and RV217 respectively.

Conclusions and Recommendations: Cell yields vary between studies and over time**.** The Acute HIV infection study showed greatest cell yield variation with a sharp spike in PBMC cell yield observed at the point of acute HIV infection. The IRIS study showed less variation in PBMC cell yields due to immunocompromised status of the volunteer. The Vaccine study showed least variation in PBMC cell yield with a slight increase in PBMC cell yield at the point of immunological response to the vaccine. Institutions conducting Clinical Trials should take note of immune status of study participants as indicated by PBMC cell yields in order to evaluate the level of pathogen specific immunity and immune priming on PBMCs. Although PBMC assays cost more and are more complex to perform than CBCs, their role in gauging a patient's immune status should not be understated. Therefore, there is need to conduct further studies to establish the effectiveness of conducting stand alone PBMC assays compared to conventional Complete Blood Counts.

1.023
Genetic Diversity of HIV-1 in Busia; a crossing border point of Western Kenya

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Background: HIV-1 displays extensive genetic diversity globally and different genetic subtypes with mosaic recombinants have continued to emerge in different geographic locations. They spread from person to person and country-to-country posing difficulties in diagnoses and influenced HIV-1 mediated pathogenesis among the infected populations.

Objective: To investigate the prevalence of HIV-1 subtypes along the western border of Kenya, blood samples were collected from 75 HIV-infected individuals in Busia, a business town located on the border close to Uganda, and analyzed.

Methodology: Polymerase chain reaction, sequencing and phylogenetic analysis of HIV-1 partial *protease* was done.

Results: The majority of strains analyzed were of subtype A1 (39/75) followed by D (21/75), C (5/75) and G (5/75) with possible recombinants of AC and AD. Other prevalent subtypes included, A2 (2/75) and B (1/75).

Conclusion & recommendations: These data highlight the presence of stable strains of HIV-1 (A1, C and D) in this commercial town. However, there is need for continuous monitoring of emerging subtypes/recombinants since this town is a gateway to central Africa where all reported HIV subtypes are known to exist. This will serve to advice on effective testing methodologies and regimens should those infected seek treatment

1.024
Prevalence of IRIS in Schistosomiasis/HIV Co-Infected Patients Undergoing Highly Active Antiretroviral Therapy (HAART)

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Category: HIV/AIDS

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Background: HIV and schistosomiasis co-infection is common around Lake Victoria region raising the possibility of schistosomiasis-related immune reconstitution inflammatory syndrome (IRIS) in patients undergoing HIV medication. The prevalence of schistosomiasis in this population is nearly 100% with a third of them being HIV positive (HIV+).

Objective: The aim of the study is to investigate the prevalence of schistosomiasis associated IRIS in communities living around Lake Victoria in Rarieda District.

Methods: CD4 cell counts and determination of plasma viral load was performed on baseline and post-treatment samples to assess response to Highly Active Antiretroviral Therapy (HAART). Stool samples from participants were processed by Kato katz technique to diagnose participants with scistosomiasis. Paraziquantel and albendazole were used for treatment of schistosomiasis and other intestinal helminthes respectively. Liver and spleen pathology associated with schistosomiasis were assessed by abdominal ultrasonography.

Results: Up to 1152 persons underwent Voluntary Counseling and Testing for HIV and 551 (47.83 %) of these were HIV positive. This prevalence is high but may not be an accurate representative of the general HIV prevalence in this community since mobilization was biased for high risk groups. Number enrolled into study after VCT 550 of which 223 were ART naïve at the beginning of the study. Up to 484 were screened for schistosomiasis with 335 of them (69.21%) being positive for *S.mansoni*. The prevalence of soil transmitted helminthes (STH) in this group was 8.0% and *P.faciparum* parasitaemia was 3.09%. A total of 223 (40.55%) of those consented into study are HIV (ve+) and 67(30.04%) were initiated on HAART. Up to 53 of these (79.10%) are dually infected while 14 (20.90%) are negative for schistosomiasis at recruitment and baseline screening. *S.mansoni* associated IRIS cases have been identified in 9 (13.43%); 6 of these (66.66%) fall into the paradoxical IRIS category while 3 (33.33%) are unmasking schistosomiasis IRIS.

Conclusions: This data shows that Schistsoma-IRIS is prevalent in this setting. Ongoing research is focusing on the epidemiology and management of schistosoma associated IRIS.

1.025
Quality indicators for Peripheral blood mononuclear cells used for Research Purposes

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KEMRI / WALTER REED PROJECT, KERICHO, KENYA[1,]

Background: The use of peripheral blood mononuclear cells (PBMCs) for immunologic studies in HIV (Human Immunodeficiency Virus) Research has been on the increase. This is mainly because of the search for a HIV Vaccine. The viability and yields of pre-cryopreservation cells are critical to the success and accuracy of immunological assays. The utilization of these cells is impacted greatly by PBMC quality indicators namely cell yield and viability. Their cellular functionality can be predicted prior to freezing of cells.

Objective: Determination and analysis of the cell yield and viability ranges of PBMCs isolated.

Materials and Methods: Whole blood samples collected from uninfected adult volunteers were processed using ficol hypaque separation and frozen within 4 hours of collection. An enumeration and analysis of expected cell yield per milliliter of usable whole blood obtained from the coulter counter and viability derived from trypan blue exclusion method. The data was limited to samples processed between April 2006 and August 2007.

Results: The Mean cell yield obtained for the 17 months was 1.03×10^6 cells/ml of blood and a mean viability obtained was 96%.The minimum viability and the minimum cell yield was 93% (was observed in December 2006,April 2007 and August 2007) and 0.87×10^6 cells/ml (observed in December 2006) respectively. The maximum viability and cell yield obtained was 99% (May 2006 and

September 2006) and 1.42×10^6 cells/ml (August 2007) respectively.

Conclusion and recommendations: The cell yields and viability from viable PBMCs will vary depending on the following factors; circulating mononuclear cells at the time of blood draw, adequate harvesting of cell interface, cell losses during blood washes and extended processing time which is defined as

time taken between collection and freezing. Based on these observations, PBMC isolation programs should monitor the viabilities and cell yields for variance. This poses challenges including the availability of adequate equipment and technical proficiency. There is need for the development of cell yield reference ranges for various populations.

1.026

Comparison of two visit reminder strategies to ensure retention of participants in an HIV prevention preparedness research study in Kisumu, Kenya: Preliminary Analysis

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Background: Retention of participants in longitudinal research studies is important for the success of the research studies and the validity of the research findings. Most intervention trials require 95% or better retention. Implementing and evaluating visit reminder strategies can be a valuable component of conducting longitudinal research studies.

Methods: Participants enrolled in two HIV incidence cohort studies in urban Kisumu, Kenya (one of adults and one of adolescents) were randomized to receive the standard pre-visit reminder (phone call) or to receive the enhanced pre-visit reminder (home visit) in order to optimize attendance at study visits. Data from the two cohort studies were combined for analysis. A multivariable logistic regression model was used to identify factors

associated with completing all study visits compared to missing any visits.

Results: Overall, participant retention was 90.4%. Type of pre-visit reminder (phone call vs. home visit) was not associated with whether participants completed all study visits. The only factor significantly associated with completing all study visits was sex; females had lower odds (AOR=0.38, CI=0.26, 0.58) than males.

Conclusion: In this analysis, home visits to remind participants of upcoming study visits were not more effective than phone call reminders. In addition, the findings suggest that females may have specific, unmet needs which hinder their retention in longitudinal studies. Future work will include qualitative assessment of retention issues for females, and development of new retention interventions.

Key words: recruitment, recruitment and retention strategies

1.027

Screening to enroll participants for a HIV incidence study in preparation for a vaginal microbicides study among sexually active adult women living within in Suba district Kenya

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Introduction: Trials to determine the safety and efficacy of microbicides require the participants who meet specific eligibility

criterion. For enrollment into a phase III female microbicide preparatory trial estimating HIV incidence, women had to be between 18-40

years, not breastfeeding, sexually active, on a stable form of contraceptive, and testing negative for both H IV and pregnancy.

Methods: Participants were referred from VCT Centre's, MCH clinics, dispensaries and local community based organizations. Prescreening was conducted to ascertain basic eligibility. Those eligible then underwent an informed consent process and were assigned a screening number. A behavioral questionnaire was administered, detailed medical examination, contraceptive counseling, HIV counseling and blood drawn for HIV serology and urine provided for pregnancy testing.

Results: To attain the sample size of 300 HIV negative, sexually active women on a stable contraceptive, a total of 528 women referred to the research Centre. Of the 528 women referred, 121 (23%) were pre-screened and found ineligible while 112 (21%) were screened

out during the screening process. Of the 121 women prescreened out, 35 (6.6%) were on HAART, 3 (0.6%) were breast feeding, 14 (2.6%) were not sexually active, 27 (5.1%) had no valid age verification documents, while 42 (7.9%) were not on a stable contraceptive.

During the screening procedures, those ineligible for enrollment were 106(21%); the majority 56, (10.6%) tested HIV seropositive, 7 (1.3%) had a positive pregnancy test while 30 (5.7%) requested additional time to decide if they wanted to participate. .

Conclusion: Suba district has a high HIV prevalence reflected by those ineligible due to HAART treatment or testing HIV positive during screening. . The lack of use of effective contraceptive and lack of valid age verification documents were a second reason for the screening failure.

1.028

Factors Impacting on the Quality of Life of HIV and AIDS Female Patients in Korogocho Slums - Kenya

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Introduction: Since HIV/AIDS was reported in Kenya the country has been and continues to be impacted negatively in all sectors. Despite Government's initiatives, patients continue to succumb to this condition.

Objective: To assess the factors that impact on the QoL among HIV/AIDS female patients in Korogocho Slums.

Methodology: This was an exploratory study conducted in Korogocho slum. Quality of Life was evaluated using several items which employed a Likert-type five-point scale. These items were distributed in four domains: Physical health and level of independence; Psychological well being; Social relationships and environment. The domain scores scaled in a positive direction – higher scores denoted higher quality of life and vice versa. Structured interviews were used to collect quantitative data while in-depth interviews were used to collect qualitative data.

Results: A total of 100 female patients were interviewed. Only 31% reported that they were restricted by physical pain to go about their business. As high as 70% of the respondents reported that they did not get enough support from relatives and friends. Eighty percent reported that they were not satisfied with their sex life and 37% reported that the environment they lived in was unhealthy. There was an element of sharing drugs and practicing unprotected sex as reported in the qualitative data. Generally 53% of the respondents reported low QoL.

Conclusion/Recommendations: The Government's intervention programs aim at improving the QoL of HIV/AIDS patients however this research reported a low quality of life of 53% among the respondents. It is recommended that HIV/AIDS programmes should be tailored to suit slum environment so as to improve the quality of life.

1.029

A cross-sectional survey of natural immunity against Hepatitis B virus infections among HIV discordant heterosexual couples in Kisumu, Kenya

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Background: HIV and hepatitis B virus (HBV) share modes of transmission. HIV infected people are thought to be at increased risk of HBV acquisition, chronic HBV infection and HBV disease progression. Moreover, chronic HBV infection may pose a challenge among HIV infected individuals' eligible for antiretroviral therapy, increasing the risk of rapid HIV–disease progression. Therefore, early prevention of HBV infection by vaccinating HIV infected people is recommended. However, the current general practice on determining eligibility for anti-HBV vaccination in Kenya involves establishing active HBV infection status by testing for the presence of HBV surface antigen (HBsAg) and rarely testing for presence of antibody to HBsAg (anti-HBs). Thus individuals testing negative for HBsAg are considered eligible for anti-HBV vaccination irrespective of their anti-HBs status. We sought to determine the prevalence of HBV infection and natural immunity against HBV infection, and further to evaluate immune response following HBV vaccination among HIV discordant couples. Here, we characterize baseline HBV infections and natural immunity against HBV in this population.

Objective: The main objective of this study was to evaluate the prevalence of HBV infections and natural immunity against HBV infections.

Methods: Nine hundred and forty nine HIV discordant heterosexual couples (1898 subjects) were screened for eligibility into a randomized trial on HIV pre-exposure prophylaxis among HIV discordant couples. None of these participants reported a history of anti-HBV vaccination. Among other tests, HBV surface antigen (HBsAg) and anti-HBs status were established as part of trial's inclusion eligibility determination. CD4 count was also performed for HIV infected potential subjects. Ethical approval for the trial was sought through KEMRI Ethical Review Committee.

Results: Of 949 HIV positive subjects, 34.7% (329) were men thus women were more likely to be the HIV positive spouse in these HIV discordant relationships (P<0.001). HBVsAg was detected in 99 (60 men and 39 women) of 1898 subjects tested, resulting in an overall HBV prevalence of 5.2%, with men being more likely to be HBV infected compared to women (P<0.05). Of the 1898 subjects tested for anti-HBs, 758 (40%) were immune to HBV, with men being more likely to possess natural protective antibodies against HBV compared to women (P<0.05). This indicates that men are more predisposed to HBV infections and subsequent development of natural immunity against HBV compared to women. Among HIV infected subjects, those with a CD4 count >250 cells/ml of blood were more likely to possess immunity against HBV compared to those with a CD4 count <250 cells/ml of blood (P<0.001). However, HIV status was not associated with either HBV infection (P=0.302) or immunity against HBV (P = 0.512).

Conclusions: Introducing anti-HBs testing in routine HBV screening for determining anti-HBV vaccination eligibility could be cost-effective, because about 40% of individuals who would otherwise be vaccinated will be deemed ineligible for anti-HBV vaccination by the anti-HBs test.

Recommendation: Strengthen the anti-HBV vaccination eligibility determination algorithm from:
Screening for HBsAg only then vaccinating those negative for HBsAg; To First screening out those positive for anti-HBs, then screening out those positive for HBsAg and finally vaccinating those negative for both anti-HBs and HBsAg.

1.030

Limitations of Indian Ink Preparation for the Diagnosis of Cryptoccocal Meningitis (CM) in Cerebrospinal Fluid (CSF) Samples from HIV-infected Patients in Western Kenya

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Background: Cryptococcal Meningitis is the most common central nervous system complication of Acquired Immune Deficiency Syndrome (AIDS) worldwide accounting for up to 30% of deaths in the developing world. Diagnosis of CM is difficult due to: presence of few organisms, degenerated cells in CSF, oil or air droplets in slide preparations. In Sub-Saharan Africa, the quickest and most feasible way to diagnose CM is by Indian ink preparation on the CSF as culture-based diagnosis takes weeks. This study aimed at determining the sensitivity/specificity of Indian ink preparation compared to the Cryptococcal Antigen serological test.

Materials and methods: The Clinical Research Center (CRC) laboratory received 262 CSF samples from March 2009 to December 2010. All samples were subjected to Indian ink preparation for determination of presence or absence of capsules and qualitative Cryptococcal antigen testing (CraG). Optical density values for samples using the CraG test were read spectrophotometrically and color visualization interpreted.

Results: Fifty one (51/262) samples were CraG positive of which only 36 (70%) were also positive in India ink. Sensitivity and specificity of Indian ink examination were 70.5% and 100%, respectively. The sensitivity and specificity for CraG test were 100% and 93.4%, respectively. Therefore, CraG test proved more sensitive than Indian ink.

Conclusion/Recommendation: Indian ink test has less sensitivity than CraG test for the diagnosis of CM. False negative results from misinterpreted Indian ink preparations cause misdiagnosis, contributing to delayed treatment and increased morbidity and mortality rates. Based on our findings, we propose that the CraG test be adopted in all laboratories due to its superior sensitivity. Additionally CraG test can be interpreted using the visual method or reading the OD of samples using a spectrophotometer as opposed to potential microscopy error when using Indian ink. Other specimens such as serum can also be used for the CraG testing.

1.031

Determination of the relationship between the total lymphocyte counts (TLC) and CD4 counts in HIV positive patients

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Background: Understanding the TLC-CD4 count relationships could aide design of predictive instruments for making clinical decisions during ART, especially in underserved resource-poor settings. The burden of HIV patient in resource poor countries is extensive and large portion rely on accessing treatment in areas that cannot run CD4.

Objective: To determine the relationship between the total lymphocyte counts (TLC) and CD4 counts in HIV positive patients.

Methodology: This was a retrospective

sampling method which utilized the data available in KEMRI/Walter Reed Laboratory. A total of 200 results were sampled from the archives in KEMRI/Walter Reed Laboratory. The results reviewed were for samples collected and analyzed using the FACS Calibur and Coulter Counter for CD4 and Total lymphocyte counts respectively.

Results: Correlation obtained between CD4 and TLC was r=0.568.

The TLC cut off points has a major impact in predicting CD4 cell count. The use of TLC of

≤2000 cells/mm3 maximized the number of respondents with CD4 less than 200 cell/mm^3, but included many others who had CD4 counts above 200 cells/mm3. As the TLC decrease to 1000 cells/mm^3, the number of respondents with CD4 less than 200 cell/mm^3 decreases, but a greater percentage of persons with CD4 cells count of <200 cells/mm^3 are not identified.

Conclusion and Recommendations: Total lymphocyte count did not correlate strongly with CD4 cell count and the Total lymphocyte count was not a surrogate for CD4 cell count. It is an imperfect predictor of CD4 count. Further studies need to be done to establish the relationship between TLC and CD4 count so that this can be used as a surrogate maker of CD4 as suggested by World Health Organization.

1.032

THE UTILITY OF USING THE APTIMA HIV-1 QUALITATIVE ASSAY FOR THE DIAGNOSIS OF HIV

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Background: Most HIV diagnostic tests rely on the presence of antibodies in body fluids for the detection of HIV. Where acute infection has to be detected, these tests are not sensitive enough because of the window period. Detection of acute HIV infections is important in studying the immunological, virological and clinical changes occurring from the onset of a new infection. APTIMA HIV-1 qualitative assay has the ability to detect early infection.

Objectives: To determine the utility of using APTIMA in detection of early HIV infection and compare it to other diagnostic assays i.e. Western Blot and ELISA in diagnosis of acute infections. It was hypothesized that APTIMA is a better as a standalone assay in the detection of early HIV infection than Western blot and ELISA.

Methods: 36 samples were collected from suspected and HIV infected cases and were analyzed for 9 different time points 4 day interval, over a period of 4 weeks. Whole blood was collected in small volumes of 600µl, span to separate plasma. The plasma was subjected to APTIMA, ELISA and Western blot.

Results: Out of 36, 8.3% were already known reactive cases of which all were nonreactive for Aptima Assay but turned reactive on both ELISA and Western blot. Of 91.7% from suspected HIV-1 infected cases, all were reactive for Aptima but only 18.2% were reactive for both ELISA and Western blot. The 18.2% were reactive for Aptima 4 days after exposure and after 3 and about 4 weeks for ELISA and Western blot respectively.

Conclusions and Recommendations: APTIMA can be a vital diagnostic test for HIV-1 early infection but cannot be used as a standalone assay in the detection of acute HIV infection cases. ELISA and Western Blot assays need to be coupled with APTIMA to monitor and in studying acute HIV infection.

1.033

Impact of Public Health Education in HIV/AIDS on Behaviour Change: Western Kenya Experience.

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Background: Africa experiences approximately 80% of deaths annually due to HIV / AIDS and 70% new infections. In Kenya, about 830 deaths occur daily. The national prevalence is reducing from 7.0 % in 2009, while in Western Kenya (study site), it

varies between 10 – 23%. Both Non-Governmental Organisations (NGOs) and the Government are actively involved in HIV/AIDS awareness campaign and advocacy for prevention and control.

Objective: The purpose of this study was to establish community understanding of HIV/AIDS and the impact of these on condom use and VCT operations in selected sites.

Methodology: This was a community-based survey conducted in eight study sites. Study population comprised randomly selected males and females, aged twelve years and above. Oral interviews were done on consenting subjects. Data entry was done using EPIINFO and analysed by SPSS / PC+.

Results: These indicated 174(38.2%) males and 282(61.8%) females aged 14 – 95 years (mean age 35, Std. Err. 0.738, median age 30). Most (95.5%) had low socio-economic status and were married (71.8%); majority (62.8%) had attained primary education and had moderate knowledge (66.6%) on HIV / AIDS. Chi-square tests done showed literacy level influenced knowledge on HIV/AIDS ($P < 0.001$). Sex had influence on condom use and knowledge on HIV/AIDS ($p < 0.001$) and re-marriages ($P = 0.015$). Literacy level ($P=0.048$) influenced VCT attendance and knowledge on HIV/AIDS ($P < 0.001$) had greater influence, while sex ($P = 0.700$) had no significance impact.

Conclusion/Recommendation: Proper understanding of HID/AIDS through continued and intensive education is likely to increase better understanding of HIV/ AIDS, thus, enhancing positive behaviour change. This may lead to a more effective management and control program.

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1.034

Cost benefit Analysis of recruitment strategies during accrual process in one of the Partners PrEP site in Kisumu Kenya

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Introduction: Recruitment of potential participants into a clinical trial takes a big effort and may be challenging and costly. Due to anticipated changes in regulatory standards, competition for discordant couples by various organizations recruiting from the same population or strategies of low yield and exploring new areas of operations, clinical trials focus on developing strategies that would reduce these costs. Partners PrEP developed multiple strategies to bring discordant couples for screening and enrollment into the study. We did a cost benefit analysis to compare the costs verses the yield per strategy.

Methods: The outreach team developed strategies which were used to realize Kisumu PrEP site goal of enrolling between 600-800 discordant couples. The methods employed included HIV testing of couples at the voluntary counseling and testing sites; Home based counseling and testing, using couple ambassador model, Radio talk shows, couples referring couples (peer s); Those who tested as individuals were requested to bring in their partners to test together; phone calls and physical tracings were made to former HSV2/HIV cohort that met PrEP eligibility criteria, faith based organizations, Accelerated mobilization, support groups and social events were also used. All the above mentioned methods were to identify a discordant couple, thereafter on arrival at the trial clinic they were prescreened out to determine obvious parameters that would make them ineligible e.g WHO stage 4. Potential couple then underwent a screening process to exclude those who did not meet the eligibility criteria. Some strategies run throughout the recruitment period while some ran for some months. All these were done in both urban and rural set ups in Kisumu town and its environs and a few districts in Nyanza, the cost of every activity was tabulated using baysern approach. And this varied depending on recruitment strategies.

Results: During distinct recruitment period from August 2007 to October 2010, A total of

2060 discordant couples were referred to the clinic. Of these 979(47.5%) were referred from Vct collaboration by health care providers, 355(17.2%) by couple ambassadors, HBCT 301(14.6%), Partner arousal 123(6.4%) 82(4%) by other methods. The average cost per couple enrolled from VCT was ($20.1) almost equivalent to couple ambassadors of ($19.1), HBCT referral cost per couple is ($6.7) a figure 3 times more than the above two methods while partner arousal cost ($8.7)

Conclusion: Comparing the cost to the number of referrals, VCT is the best strategy to employ especially if we have a short time for recruitment. HBCT is the least costly but referral numbers were much smaller compared to VCT and Couple Ambassador Strategies. All the other methods and Partner arousal had low yield. Due to time limit in recruitment there is need to combine all the strategies.

1.035

Community Preparation for a Microbicides Trial: Microbicides Awareness Creation in Kisumu, Kenya

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Background: Microbicides are a new concept in the community, and it is therefore important to create a general awareness. We present the steps taken to create microbicide awareness as part of the preparatory phase for a Phase I/II microbicide trial being conducted in Kisumu, Kenya.

Objective: The main objective was to prepare the community for the microbicide study since it was a new concept. We also wanted to know which mobilization technique would be ideal for our recruitment area and population and whether it would be possible to involve men in the whole process.

Methods: We used a three-pronged approach to conduct microbicide awareness education. 1) Through mapping we identified existing organized groups in the community and invited their leaders to attend educational sessions. These leaders were charged with the responsibility of disseminating the information to their groups. 2) We took note of public events in the community such as the International Candlelight Memorial, Chief Barazas, Agricultural Show and World AIDS Day. During these events, we gave speeches, issued brochures, and engaged in one-on-one discussions with attendees. 3) We also conducted door-to-door microbicides education where we had one-on-one discussions with adults in households in potential recruitment areas.

Results: We realized from frequently asked questions that the community's knowledge of microbicides was limited, and thus continuing education was needed. Due to diverse levels of knowledge, discussions had to be tailored according to specific needs of the audience. There was fear among women on the mode of application of microbicides, and we reassured them that they will be taught how to use it. In as much as women felt that their male sexual partners should also be involved in the education, most of their male partners felt that their role was insignificant.

Conclusions: One-on-one education is productive because of assurance of confidentiality and availability of time for discussion. Since men play an important role in their female partner's reproductive health decision making, there is a need to clearly define their role as we develop protocols on female microbicides. Microbicide awareness education should be conducted prior to upcoming microbicide trials to prepare the community and clear myths. The value of this education will be apparent during recruitment for the upcoming microbicide