

Summary of FACES Affiliated Studies

Integration of HIV care and treatment into MCH in Migori District, Kenya (Researchers: Cohen C., Bukusi E., Turan J., Washington S., Marima R., Penner J., Winestone L.)

This study seeks to determine the most effective way to reach and provide pregnant women with accessible, comprehensive, and high quality HIV care and treatment in Migori District, with implications for other sites in Kenya and sub-Saharan Africa. This study utilizes a prospective cluster randomized design. Twelve FACES-affiliated clinics similar in size, population, and services in Migori district, Kenya that provide ANC will be randomly assigned to receive "integrated ANC, PMTCT & HIV services" (intervention arm) or "non-integrated services" (control arm). This study is funded by the U.S. Centers for Disease Control and Prevention (CDC) as a Public Health Evaluation.

Contact: Janet Turan janet.turan@ucsf.edu

Sub-study: Assessing provider satisfaction with integration of HIV care and treatment into MCH in Migori District, Kenya (Researchers: Cohen C., Bukusi E., Winestone L., Turan J., Washington S., Marima R., Penner J.). This study, conducted within the larger integration trial mentioned above, will examine provider perspectives of HIV care and provider job satisfaction in two service models: "integrated ANC, PMTCT, & HIV services" and "non-integrated HIV services". This study is funded through UCSF discretionary funds and student scholarship funds.

Contact: Lena Winestone lenawine@stanford.edu

Sub-study: Assessing patient satisfaction with integration of HIV Care and treatment into antenatal care in Migori District, Kenya. (Researchers: Bo, V., Cohen C., Bukusi E., Turan J., Washington S.)

This proposed study will function within the clinics randomized in the main study and examine patient satisfaction at the integrated and non-integrated clinics. HIV-positive and HIV-negative pregnant women attending ANC at the 12 clinics in Migori District will be asked to complete a questionnaire. This study is funded by the CDC within the larger integration trial mentioned above and through supplemental student scholarship funding.

Contact: Rachel Smith Rachel.smith@ucsf.edu

The demand for family planning services among HIV-infected individuals receiving care and treatment in Nyanza Province (Researchers: Cohen C., Bukusi E., Grossman D., Newmann S., Shade S.)

This study will help determine how to best meet the family planning needs of HIV-infected women and to provide information for policy makers and program planners that will help them implement high quality services for this population. This study is a cluster-randomized trial comparing the effects of integrating family planning services into HIV care and treatment programs on contraceptive uptake, contraceptive continuation, and unintended pregnancy rates. The study will compare the integration of family planning services into HIV care and treatment versus the standard referral for family planning services outside of HIV care and treatment programs. The study will be conducted in FACES-affiliated clinics in Nyanza Province, Kenya. This study is funded by the Tides Foundation.

Contact: Dan Grossman dgrossman@ibisreproductivehealth.org or Sara Newmann Newmanns@obgyn.ucsf.edu

The effects of HIV/AIDS stigma on use of maternity and HIV services by pregnant women in Kenya (Researchers: Turan J., Holzemer W., Cohen C., Bukusi E., Miller S.)

This study is examining the effects of different types of HIV/AIDS stigma on use of maternity services and HIV services, among pregnant women in Migori and Rongo Districts, Nyanza Province, Kenya through FACES. This is a prospective study among pregnant women using antenatal care clinics and involves structured interviews using PDAs and collection of data from medical records, as well as qualitative in-depth interviews. As of October 2008, over 900 women have been enrolled in the study and participated in interviews at their first antenatal visit. Follow-up interviews during late pregnancy and postpartum with a randomly selected sub-sample of these women began in September 2008. This study is funded by the U.S. National Institute of Mental Health.

Contact: Janet Turan janet.turan@ucsf.edu

A prospective cohort study of the effect of highly anti-retroviral therapy (HAART) on the recurrence of surgically treated High-Grade Cervical Intraepithelial neoplasia in HIV-infected women in Kisumu, Kenya (Researchers: Cohen C., Bukusi E., Huchko M., Marima R., Penner J.)

This study will assess the effect of Highly Active Antiretroviral Therapy (HAART) on the recurrence of surgically treated High-Grade Cervical Intraepithelial Neoplasia (HGCIN) in HIV-infected women. It is a prospective cohort study of HIV-infected women receiving care at the FACES-supported clinic in Kisumu, Kenya. Women with HGCIN will be followed for two years after their initial surgical excision to determine the effect of HAART on the recurrence of HGCIN after surgical excision. This study is funded through UCSF discretionary funds, including private donations.

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(Discordant Couples) Risk Reduction in HIV serodiscordant couples attempting conception (Researchers: Cohen C., Bukusi E., Brubaker S., Darbes L.)

HIV negative partners in discordant heterosexual relationships are recognized as a high risk group for sexual transmission of HIV in sub-Saharan Africa. Efforts to reduce HIV transmission in this group does not address the concerns of couples who desire children. The goal of this study is to develop a preliminary understanding of the social and cultural context in which these couples are making the decision to conceive, and to explore the hypothetical acceptability of risk reduction strategies for discordant couples attempting conception. Discordant couples of reproductive age who express a general desire to have children in the future will be recruited to participate in structured questionnaire followed by an in-depth interview. Findings will be used to design an investigation to determine the uptake and acceptability of interventions to reduce HIV transmission for HIV discordant couples attempting conception.

Contact: Sara Brubaker sara.brubaker@ucsf.edu

Application of weighted time-series to address bias in evaluation of clinic- and community-level research (Researcher: Shade S.)

The study will use a simulation to develop, test, and apply new analytic methods (weighted time-series) for evaluation the effectiveness of community- and clinic-level interventions. It will then compare results using weighted time-series and conventional methods within the context of a clinic-level intervention, namely at FACES-supported clinics in Kenya. The results of this study will be used to seek funding to test the broader application of these methods in both community- and clinic-level interventions. Application of these methods has the potential to improve evaluation of many community-level interventions, particularly in settings where it is difficult to obtain

individual-level information or to follow individuals in the community over time (e.g. rural or other hard to reach populations). The study is funded through UCSF Center for AIDS Prevention Studies (CAPS) Innovative Grants.

Contact: Starley Shade sshade@php.ucsf.edu

An evaluation of isoniazid preventive therapy (IPT) among HIV-infected children within a family-centered HIV care and treatment program in Kenya (Researchers: Mwacheri C., Dillaugh L., Ongango J., Ombeka V., Penner J.)

This will evaluate the effectiveness of IPT in HIV-infected children to reduce TB incidence, morbidity and mortality. We anticipate that IPT will effectively reduce TB and overall morbidity and mortality in the study population. If this should occur, Kenya NLTP can consider national guidelines for IPT in children. This study is funded through UCSF discretionary funds, including private donations.

Contact: Lisa Dillaugh lisadeebo@gmail.com

International Epidemiologic Databases to Evaluate AIDS (IeDEA) (East Africa Principal Investigator: Yiannoutsos, C.T.)

IeDEA will build regional population-based HIV knowledge and information. IeDEA will pool data from collaborating provider and research networks in East Africa to cost-effectively generate large data sets to address high priority research questions. Data collection, merging, storage, and sharing across sites in the East African Region, will focus on:

- cost-effectiveness of HIV care, treatment, and prevention strategies;
- appropriate guidelines for initiation of first-line therapy for treatment of HIV/AIDS;
- genetic variability of HIV;
- issues related to first-line therapy failure;
- adherence to HIV treatment;
- contextual issues and resource limitations of HIV care delivery in resource-limited settings;
- impact of tuberculosis infection on HIV/AIDS care and treatment in developing world;
- prevention of mother-to-child transmission of HIV

Once local and international IRB approvals are obtained, FACES will share HIV data with IeDEA. This study is supported by NIH through Indiana University. **Contact: Jayne Kulzer** jkulzer@globalhealth.ucsf.edu

FACES Study Partner for Patients in Need of HIV Care and Treatment Referral and Services

(PrEP) Parallel Comparison of Tenofovir and Emtricitabine/tenofovir Pre-Exposure Prophylaxis to Prevent HIV-1 Acquisition within HIV-1 Discordant Couples (Researchers: Celum C., Baeten J., Lingappa J., McElrath J., Magaret A., Cohen C, Bukusi E.)

This study addresses the need for novel strategies to prevent HIV-transmission within discordant couples. UCSF-KEMRI is one of eight sites in this multi-site trial that is funded by the Gates Foundation and coordinated by the University of Washington. The sites are in Kenya and Uganda; the UCSF-KEMRI site is in Kisumu, Kenya. It is a multi-site, 3-arm, placebo-controlled, double-blind, proof-of-concept, Phase III safety and efficacy trial that is examining the effects of taking once-daily pre-exposure prophylaxis (PrEP) on HIV acquisition within discordant couples. Pre-exposure prophylaxis involves HIV-1 uninfected individuals at high risk for contracting HIV-1 taking antiretroviral medications

(PrEP) to maintain blood and genital drug levels to prevent HIV-1 acquisition. The Kisumu site will enroll up to 800 HIV-1 discordant couples. The HIV-1 infected partner will be randomly assigned to one of three study arms: 1) TDF, 2) FTC/TDF, or 3) placebo. Accrual and follow-up will continue for a total of approximately 48 months, with 12 additional months of follow-up to complete all follow-up procedures. This study hypothesizes that PrEP will decrease HIV-1 acquisition among HIV-uninfected individuals within HIV discordant couples, if found to be safe and efficacious.

Contact: Jayne Kulzer jkulzer@globalhealth.ucsf.edu

Fertility Desires and Family Planning among HIV-Infected Couples in Nyanza Province, Kenya (Researchers: Newmann, S., Harrington E., Kwena, Z., Ochieng, J., Onono, M., Bukusi E., Oudia, S., Cohen C., Grossman, D.) This study will explore decision-making and relationship power around fertility and family planning among HIV-affected couples and community leaders in Nyanza Province, Kenya. This is a qualitative, hypothesis-generating research project which will involve in-depth, open-ended interviews with couples who present to HIV clinics for care, couples from high prevalence HIV communities, and with individual community leaders. The study is funded by the Hellman Foundation and by the Center for AIDS Research at UCSF. Contact: Sara Newmann newmanns@obgyn.ucsf.edu

Formative Research for the Adaptation of an Intervention of HIV/AIDS Service Providers on Gender-Based Violence in Rural Nyanza Province

Researchers: Turan JM, Bukusi E, Doolan K, Onono M, Otieno V, Romito P.

Preliminary data from pregnant women in rural Kenya indicate that fear of violence from a male partner is an important reason why some women refuse HIV testing, and that pregnant women who test HIV-positive or refuse testing may be more likely to be victims of violence. In response to these findings, we aim to develop an intervention on gender-based violence (GBV) for health workers who provide HIV-related services to pregnant women in this setting. First, in order to gain in-depth contextual understanding of gender-based violence, we will conduct focus groups and in-depth interviews with pregnant women, men, and a variety of service providers (health, law enforcement, education, women's groups, and village leadership) in rural Nyanza Province, Kenya. We will use the knowledge gained to develop a GBV intervention for health workers, taking advantage of existing Kenyan GBV training programs. Finally, we will conduct a preliminary pilot of the adapted intervention to assess feasibility and acceptability. The results of this pilot study will form the basis for future research on a larger scale to examine the impact of addressing GBV on prevention of HIV/AIDS.

Contact: Janet.Turan@ucsf.edu

Enhancement of clinical research and data analysis skills for the analysis of the effects of women's HIV/AIDS knowledge, attitudes and testing status on their infant feeding intentions and practices – Kenya

Trainee: Maricianah Onono, MB.ChB

Instructor: Janet M. Turan, PhD, MPH

Breastfeeding continues to pose a significant risk of HIV transmission to infants born to HIV-infected mothers, accounting for 200,000 infants sero-converting per year in low-resource settings. Myriad social, cultural and economic factors, including knowledge of HIV/AIDS and HIV status, could affect the extent to which women adhere to the recommended practice of exclusive breastfeeding. Very little research has examined the effects of knowledge of HIV/AIDS and HIV testing status on infant feeding intentions in the antenatal period and followed women to ascertain actual

practices postnatally. To address these gaps in the literature, Dr. Maricianah Onono will examine the effects of HIV/AIDS knowledge, attitudes and testing status on infant feeding intentions and actual postnatal practices in a cohort of pregnant women in Nyanza Province, Kenya. During the training period, Dr. Onono will work with her mentors to supervise data collection and management, conduct the analyses regarding infant feeding, and prepare manuscripts. Her support from this grant and the time spent at UCSF will enhance Dr. Onono's clinical research expertise, including analytical and scientific writing skills, and will lead to the design of future studies to be conducted at the KEMRI-UCSF Program research sites in Kenya.

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The HIV Neurology in Kenya (THINK) Dementia Study (Researchers: Meyer, A, Kwasa, J, Cettomai, D, Birbeck, G, Bukusi, E, Cohen, C, Vickrey, B, Price, R)

This study will validate a diagnostic tool for use by non-physician health care providers to diagnose HIV associated dementia. This is a cross sectional study which will involve the validating the diagnostic tools against a structured history, neurological exam, neuropsychological testing and imaging with computed tomography. Subjects will be recruited from a random sample of sites throughout Nyanza province. This study was funded by the American Academy of Neurology Foundation (AANF) and the Fogarty International Clinical Research Fellowship (FICRF) of the National Institutes of Health. Contact: Ana-Claire Meyer meyerac@sfgh.ucsf.edu

Substudy: **THINK Neuropathy** (Researchers: Cettomai, D, Kwasa, J, Birbeck, G, Bukusi, E, Cohen, C, Vickrey, B, Price, R, Meyer, A)

This study will validate a diagnostic tool for use by non-physician health care providers and quantitative sensory testing protocols to diagnose HIV associated peripheral neuropathy and to determine its severity. This is a cross-sectional study using the sample from the parent study which will validate the listed modalities against a clinical neurological exam. This study was funded by Doris Duke International Clinical Research Fellowship, AANF and FICRF. Contact: Deanna Cettomai deanna@jhmi.edu

Substudy: **THINK Adherence** (Researchers: Kwasa, J, Cettomai, D, Bukusi, E, Cohen, C, Vickrey, B, Price, R, Meyer, A)

This cross-sectional survey using the sample from the parent study will explore caregiver support as a mediator of adherence among cognitively impaired persons with HIV. This study was funded by AANF and FICRF. Contact: Judith Kwasa jkwasa@yahoo.com

Substudy: **THINK Norms** (Researchers: Meyer, A, Kwasa, J, Birbeck, G, Bukusi, E, Cohen, C, Vickrey, B, Price, R)

This study will perform neuropsychological tests on HIV negative persons to develop Kenyan norms. A convenience sample of subjects will be recruited in Kisumu. This study is funded by AANF and FICRF. Contact: Ana-Claire Meyer meyerac@sfgh.ucsf.edu

Substudy: **THINK Training** (Researchers: Meyer, A, Kwasa, J, Cettomai, D, Birbeck, G, Bukusi, E, Cohen, C, Vickrey, B, Price, R)

This study will assess provider knowledge and capacity to care for neurological complications of HIV before and after a training module.
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