



**JOHN E. FOGARTY
INTERNATIONAL
CENTER**

NIH /

Fogarty International
Clinical Research
Scholars Program

Research
Accomplishments

This book contains listings of articles, presentations, posters, and research summaries by the Fogarty International Clinical Research Scholars.

Contents collected and collated by Mili Ferreira, Program Assistant

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FICRS Program Research Accomplishments

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Fogarty International
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Presentations &
Posters

**Fogarty International Clinical Research Scholars
Presentations & Posters Bibliography**

Bangladesh

Botswana

Rossenkhan, Raabya

Rossenkhan R, Ndug'u T, et.al., Receipt of single dose Nevirapine in labor may defer rather than blunt the postpartum breast milk HIV viral load rebound seen after the discontinuation of zidovudine. 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention. Sydney, Australia, July 22-25, 2007.

McDonald, Erin; Rossenkhan, Raabya

Abstract, Evaluation of novel strategies for identification of primary HIV-1C infection in Botswana accepted for presentation at the American Public Health Association annual conference, Boston MA, November 2006 and the AIDS Vaccine Conference 2006, Amsterdam.

Brazil

Marcovici, Peter "Buzz"

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Unger, Alon

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China

Haiti

Horwitz, Russel

Horwitz, R. “Informed Consent: Assessment of Understanding of Experimental HIV Vaccine Trials in Port-au-Prince, Haiti.” PhD Dissertation, University of Illinois in Chicago Joseph P, Schackman BR,

India

Firth, Jacqueline

Water and Diarrheal Disease. The Global Health Council, 2006

Kabeer, Kirti

Kabeer, KK., Koorapati, P., **Singh, S.**, Solomon, S., et.al., “Adherence to Antiretroviral Therapy among Treatment-Experienced Patients at a Community Health Center in Chennai, South India.” “ XVI Internatioanl AIDS Conference Toronto (Poster TUPE0149

Singh, Sonia

Bahrami N, **Singh S.** Causes of glaucoma: Application of epidemiologic concepts and models. 134th Annual Meeting of the American Public Health Association, November 4-8, 2006, Boston, Massachusetts

Subbaraman, Ramnath

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Subbaraman R., Devaleenal B, Cecelia AJ, Selvamuthu P, Yepthomi T, **Narasimhan P.**, Solomon SS, Pradeep A, Mayer KH, Kumarasamy N. Factors Associated with Anemia among HIV-infected Individuals in south India. Poster Presentation. Scientific session for the NIH Fogarty-Ellison Overseas Fellowship in Global Health and Clinical Research Meeting and Interview Day. March 4-6, 2007; Bethesda, MD.

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Subbaraman R, Singh S, Cecelia AJ, Devaleenal B, Yepthomi T, Mayer KH, Kumarasamy N. Resolution of Anemia with use of Highly Active Antiretroviral Therapy among HIV-infected Patients in Southern India [THPE0113]. Poster Presentation. 16th International AIDS Conference; August 13-18, 2006; Toronto, Canada.

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Kinuthia, John

Kinuthia, J., Chung, M., John, F., Richardson, B., Farquhar, C., John-Stewart, G., Kiarie, J., “Uptake of Post pregnancy HIV-1 Testing in MCH Clinic.” XVI International AIDS Conference Toronto (Poster WEPE0379)

Njogu, Norman Kiiru

Evidence Based Strategies in prevention and treatment of Preeclampsia. 9th Feb. 2006, Aga Khan University Hospital.

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Selig, Sara

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Mali

Peru

Blas, Magaly

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Donroe, Joseph

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Russia

Gorlinsky, Alexey

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Kruse, Gina

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South Africa

Bebell, Lisa

Bebell, L., Passmore, J.-A., Williamson, C., Mlisana, K., Iriogbe, I., Abdool Karim, Q., Abdool Karim, S. “Clinical Correlations of Inflammatory Cytokines in the Female Genital Tract during Acute HIV-1 Infection.” XVI International AIDS Conference, August 12-18, 2006. (Oral Presentation)

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Khan, Munira

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Matji, Joan

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Tanzania**Blander, Jeffrey**

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Samuels, Aaron

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Uganda

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Russia

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South Africa

Durban

Pretoria

Tanzania

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Thailand

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Uganda

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Zambia

Fogarty International
Clinical Research
Scholars Program

Research Summary

Bangladesh

Scholars

Begum, Yasmin Ara
Jayasekera, Channa R.
Khan, Ashraful Islam
Nelson, Eric J.

Principle Investigator

Stephen B. Calderwood, MD

Jayasekera, Channa

Mucosal-level anamnestic responses to cholera toxin B subunit in patients in an endemic region

Infection with *Vibrio cholerae*, the causative agent of cholera, is believed to induce long-term protective immunity against future disease in both endemic and non-endemic settings. However, the immunologic mechanisms that confer this protection are insufficiently described.

Circulating antibody against cholera toxin B subunit (CtxB), a primary immunogenic antigen of *V. cholerae*, has not been found to correlate with protection in endemic settings. The toxin coregulated pilus (TCP) a second immunogenic antigen, has not been completely studied to evaluate its role in long-term protection. The vibriocidal antibody response is the best-characterized correlate of protection. However, being a systemic complement-fixing antibody response directed mainly against lipopolysaccharide of a non-invasive pathogen, the vibriocidal antibody is believed to be only a surrogate marker of protective immunity.

It is hypothesized here that long-term protective immunity to cholera is driven by anamnestic responses of B cells, primed at the mucosal surface during initial exposure to *V. cholerae* antigens. Thus, circulating memory B cells may be a better marker of long-term protective immunity than serum antibody titers.

We are studying antigen-specific memory B cells over a 30-day period in ten patients infected with *V. cholerae* O1 at the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B).

Circulating CtxB-specific IgG antibody secreting cells (ASC) are quantified using an enzyme linked immunospot (ELISPOT) assay to determine their kinetics at three time points (acute stage-day 2; early convalescence-day 7; late convalescence-day 30) in the 30 days following symptomatic infection. To quantify memory B cell-derived IgG-ASC during the same period, peripheral blood mononuclear cells are stimulated using an optimized mix of mitogens (pokeweed mitogen, human CpG, and *Staphylococcus aureus*

Cowan) in a 5-6 day culture, and are analyzed by the ELISPOT assay.

Confirmation of the CtxB-specific memory B cell phenotype

(CD19+CD27+IgG+) in fresh and cultured peripheral blood mononuclear cells is made by flow cytometry (FACS). CtxB-specific IgG-ASC population trends are corroborated with the antibody in lymphocyte supernatant

(ALS) assay, a technique to measure mucosa-derived B cell responses.

Anti-CtxB IgG and vibriocidal antibodies are measured using standard procedures.

Botswana

Scholars

Davis, Carl
Hagan, Jose
Kebaabetswe, Lemme
Ketunuti, Melissa
McDonald, Erin C.
Nkwe, David
Rossenkhan, Raabya
Sepako, Enoch

Principle Investigator

Myron Essex, DVM, PhD

McDonald, Erin

Manuscript for publication in development, Development of Recruitment Strategies for an Early and Acute HIV-1C Infection Study in Botswana: Lessons Learned from The Tshedimoso Study.

Davis, Carl

1) Functional characterization of nef alleles from longitudinal samples of patients with primary HIV infection . This is a laboratory-based project conducted at BHP using samples from the Tshedimoso study of acute HIV-1C infection in Botswana. I am interested in seeing whether nef alleles from acute HIV infection are able to downregulate MHC class I molecules from infected cells. I suspect that MHC class I downregulation is only conserved when effective immune selection pressures are present, and therefore it is lost during acute infection. Nef might be a useful marker for determining when an effective cell-mediated immune response begins, letting us better pin down which immune responses drive viral suppression after acute infection. The project involves cloning viral sequences from plasma samples, expressing the nef alleles in cells, and using flow cytometry to see the effect of each allele on MHC class I expression.

2) Analysis of coreceptor expression on T-cells of patients with primary HIV infection in Botswana and correlation with viral load and disease progression. I am reanalyzing data that has been collected in the Tshedimoso study and seeing to what extent variation in CCR5 expression among patients from Botswana influences the viral setpoint. This project basically involves gating flow cytometry data files on the computer and running statistical analyses on the results

Brazil, Fortaleza

Scholars

Eller, Christopher
Kozyak, Benjamin
Lima, Ila Fernanda Nunes
Maciel, Andrêssa L.

Principle Investigator

Richard L. Guerrant, MD

Brazil, Salvador

Scholars

Boaventura, Edilane Gouveia Voss
Guimaraes, Luiz Henrique Santos
Marcovici, Peter
Newlove, Tracey
Oliveira, Ricardo Riccio
O'Neal, Seth
Unger, Alon

Principle Investigator

Warren D. Johnson, Jr., MD

China

Scholars

Gao, Xing
Lin, Charles
Liu, Musang
Wong, Susan

Principle Investigator

Myron Cohen, MD

Haiti

Scholars

Bellot, Clovy
Bendix, Peter
Dorsainvil, Dominique
Horwitz, Russell
Louis, Didie Herold

Principle Investigator

Dan Fitzgerald, MD
Warren d. Johnson, Jr., MD

India, Chennai

Scholars

Harshavardhan, Rupa
Houle, Elizabeth
Kabeer, Kirti
Padmanesan, Narashmhan
Pulimi, Sandeep
Sigh, Sonia
Subbaraman, Ramnath
Vallabhaneni, Snigdha

Principle Investigator

Kenneth Mayer, MD

Elizabeth Houle

I have been working primarily on two studies (#1 and #2) this year at YRG Center for AIDS Research and Education (YRG CARE) in Chennai. Both of these projects have involved writing proposals, obtaining IRB approval, data collection, and ultimately analysis. They are currently in the data collection phase. The reproductive desires and intentions study is a cross-sectional questionnaire-based study that looks at reproductiveIn addition, I have worked on a third project (#3) about thrombocytopenia in HIV-infected individuals, which involved secondary data analysis using previously collected data from the YRG CARE natural history database.

1. Reproductive desires, intentions and decision-making among HIV-infected individuals in Chennai, India
2. Adherence to Antiretroviral Therapy among patients participating in a graduated cost recovery program in a tertiary HIV care clinic in South India
3. Profile of HIV-infected individuals with Thrombocytopenia in a resource-limited setting in South India

Subbaraman, Ramnath

Kumarasamy N, **Subbaraman R**, Mayer KH. Antiretroviral Drug Toxicities and Interactions: Prevention, Diagnosis, and Management. In: Diagnosis and Management of HIV/AIDS: A Clinician's Perspective, 2nd edition, Edited by Baveja UK and Rewari BB. (Invited book chapter, forthcoming).

Subbaraman R, Chagatur SK, Mayer KH, Flanigan TP, Kumarasamy N. Adverse effects of highly active antiretroviral therapy in developing countries. *Clinical Infectious Diseases* (Accepted for publication, forthcoming).

Andrews J, **Subbaraman R**. Malnutrition and Tuberculosis: "Consumption" and its Clinical Implications. In: Sharma SK, Mohan A, ed. *Tuberculosis*. 2nd ed. New Delhi, India: Jaypee Brothers Medical Publishers, 2006. (in press)

Subbaraman R. "Generic drugs and the fate of the global AIDS response." *The Hindu* (Chennai). January 29, 2007. Available online at:
<http://www.hindu.com/2007/01/29/stories/2007012904101100.htm>

India, Vellore

Scholars

Ast, Karen
Banda, Kalyan
Finkelman, Andrea S.
Franciosa, Mark
Firth, Jacqueline
Gopal, Srila
Sarkar, Rajiv
Satyhakumar, Krthi

Principle Investigator

Christine Wanke, MD

Sarkar, Rajiv

(1) A community-based case-control study of the factors associated with suicide among elderly in rural south India:

In the year 2000, an estimated 815,000 people died from suicide globally making it the thirteenth leading cause of death worldwide. In Vellore, studies using verbal autopsies have reported one of the highest suicide rates in the world. The average annual suicide rate for the years 1995-99 in the rural areas of Vellore was 95.2 per 100,000. The average annual suicide rate of people aged above 55 years was reported to be 189 per 100,000 (1994-2002), with a male female ratio of 1:0.66.

This community-based exploratory case-control study was undertaken to identify the risk factors for suicide among the elderly population of Kaniyambadi block in Vellore district, Tamil Nadu, India. We selected as cases, 90 individuals aged 50 years and above who were permanent residents of this block and had committed suicide from 1st January 2003 – 31st December 2005, with 177 individuals who had died of causes other than suicide serving as our controls. Controls were frequency matched for year of death (± 1 year) and locality. The next-of-kin of the study subjects were interviewed to collect data on socio-demographic and other risk factors for suicide. A qualitative study (focus group discussion) had been conducted earlier in the same area to identify the locally relevant risk factors.

This study was approved by the CMC Institutional Review Board and the data collection and analysis has been completed. A publication is planned for mid-2007.

(2) Awareness on ethical issues among the participants of a birth cohort in an urban slum in Vellore:

Medical research has made spectacular strides during the past century. With research becoming a global activity, there is renewed concern about possible exploitation of the poor and uneducated subjects by treating them as experimental “guinea pigs”. Research in developing countries brings forth new ethical challenges and dilemmas, especially those related to privacy, autonomy and cultural belief systems. Limited formal education, coupled with the fact that

health-care practitioners are revered by the community, poses further challenges of informed consent and awareness among the study participants.

The aim of this study was to assess the awareness on ethical issues among participants of an ongoing cohort study in diarrheal disease among children. The participants were parents/guardians of children who had been recruited to participate in the Childhood Rotavirus Infection (CRI) study. A total of 452 children were recruited, of which 373 children completed the 3-year intensive follow-up for diarrheal surveillance.

At the end of this follow-up period, parents/guardians of the CRI study children were administered a questionnaire containing questions on the study protocol, the informed consent and other ethical aspects. Questions were also asked to assess the awareness of the responders about the study procedures such as collection of samples. Responders were also asked questions on their decision to participate in the study and what they felt at the end of the study. From this study we hope to understand the ethical complexities of conducting population-based research in a predominantly illiterate population.

In this study I helped design the questionnaire and carry out the survey. We have already completed the data collection and are currently in the process of analyzing the data.

(3) Using Geographic Information System (GIS) to identify spatial and space-time clusters of symptomatic and asymptomatic rotavirus G12 infections in an urban slum in Vellore:

Rotaviruses are the major cause of severe diarrhea in infants and young children worldwide and are estimated to be responsible for 611,000 deaths annually, most of them in poorer countries. As a part of ongoing Childhood Rotavirus Infection (CRI) study, a birth cohort of 452 children was recruited consecutively from March 2002 to August 2003 and intensively followed up for 3 years. Socio-demographic, environmental and health-care related characteristics were collected at baseline, and fecal samples collected every fortnightly. All samples were screened for detection of rotavirus and, if detected, the rotaviral strain genotyped.

This study was undertaken to look for spatio-temporal clustering of G12 rotaviral infection in the community. Between June and September 2005, 14 G12 strains were identified as a part of the routine surveillance, and 8 cases showed significant temporal and space-time clustering.

In this project, I helped carry out the analysis for detection of the space-time cluster of G12 rotaviral infection. The findings had subsequently been published in the Journal of Clinical Microbiology (article attached as PDF).

(4) Investigation of an Hepatitis A outbreak among children under 10 years of age in an urban slum in Vellore using GIS:

An outbreak of symptomatic viral hepatitis in children less than 10 years of age was identified in a semi-urban slum in Vellore, south India, from February to July 2006. There were 26 reported cases with an attack rate of 2.78%, and 10 out of 11 blood samples obtained were positive for anti-HAV IgM. Water samples were tested for microbiological contamination and all showed high presumptive coliform counts ($>180/100$ ml). Spatial analysis using SaTScan software failed to detect any clustering of cases in space.

The outbreak seems to have resulted from local contamination of the water supply system in that area, as there were no reported cases in adjacent areas with different water supply systems.

In this project, I helped in the statistical and spatial analysis of data. The report has been sent to the Indian Journal of Medical Research (manuscript attached as WORD DOCUMENT).

(5) A pilot study to assess groundwater contamination levels in the drinking water sources in rural south India :

Despite repeated efforts by national and international agencies, approximately 1.1 billion people worldwide do not have access to improved sources of water. As a consequence, 2.2 million people in developing countries, mostly children, die every year from lack of safe drinking water, inadequate sanitation and poor hygiene. Studies done in Vellore, both during epidemic and endemic settings, have found persistently high levels of faecal coliforms in drinking water. However, there is lack of data regarding how and where the water supply gets contaminated, whether the contamination in the ground-water itself or whether it occurs while it travels through the water distribution network that are often poorly maintained.

This is a pilot project to assess ground-water contamination levels in the Kaniyambadi block in Vellore district, Tamil Nadu, India, and to correlate it with distance traveled by groundwater from source, i.e. the hills at the far end of this block. A total of 60 borewells (30 from near the foothills and 30 further down the block) will be selected. Water samples obtained from these borewells will be tested for presumptive coliform counts, using the most probable number technique. These samples will be obtained at three different time points: in summer (April-May), during rainy season (September-October) and during winter (December-January). Difference in the microbiological contamination of water between the samples collected from near the foothills and those further down as well as seasonal variations, if any will be assessed.

This study has been approved by the CMC Institutional Review Board. The data collection is expected to begin in April 2007.

Kenya

Scholars

Beard, Jessica
Kinuthia, John
Mungai, Anne
Ndegwa, Serah Wanjiru
Njogu, Norman Kiiri
Page, Cameron
Reddy, Ashok
Selig, Sara

Principle Investigator

Carey Farquhar, MD, MPH
King Holmes, MD, PhD

Jessica Beard

Abstract as it was presented at the KOGS (Kenya Obstetric and Gynaecology Society conference) in February of 2007

Elective cesarean section for PMTCT: utilization and decision making among HIV-infected mothers in Nairobi, Kenya

Beard JH,^{1,2} Ndegwa, SW,¹ Farquhar C,^{1,4} Ong'ech JO,^{1,3} Govedi F,⁶ Kiarie JN^{1,3}

¹University of Nairobi, Obstetrics and Gynecology Department, ²Yale University School of Medicine, ³Kenyatta National, Hospital, Obstetrics and Gynecology Department, ⁴University of Washington, ⁵University of Nairobi, Pediatrics Department, ⁶Pumwani Maternity Hospital,

Introduction:

Elective cesarean section (ECS) is a well-established, highly effective intervention for prevention of mother-to-child transmission of HIV (PMTCT). In accordance with WHO guidelines for PMTCT in resource-poor settings, ECS is offered but not recommended to antenatal HIV infected mothers attending clinic at Pumwani Maternity Hospital (PMH), the largest maternity hospital in East Africa. Although elective cesarean section has been deemed generally inappropriate in the developing world due to limited access, cost, and potential for increased postpartum complications, data suggests that cesarean section is more widely available in Kenya than in other African nations, and ECS for PMTCT may be as safe as ECS for other indications, even in resource-poor settings. Thus, elective cesarean section may be a potentially useful yet under-exploited PMTCT tool at PMH. Of note, use of this intervention at PMH has never been studied and no data exists on mode of delivery decisions in this population (or other similar populations).

Objectives:

To describe the decision making regarding mode of delivery among HIV positive women at PMH
Specific objectives

- 1: To determine utilization of ECS for PMTCT at PMH
- 2: To determine HIV infected women's knowledge and attitudes regarding ECS for PMTCT
- 3: To compare HIV positive women's planned and actual modes of delivery
- 4: To determine correlates of mode of delivery decisions

Methods:

As part of the evaluation of Pumwani's PMTCT Program, 246 post-partum HIV positive women at PMH will be surveyed using a structured questionnaire. Utilization of ECS for PMTCT at PMH will be described and mode of delivery decision making among HIV positive women will be characterized in an effort identify actual and potential patient barriers to implementation of ECS for PMTCT and PMH.

Preliminary Conclusions:

Preliminary data illustrates that ECS, though generally acceptable in this population, is not a widely utilized PMTCT intervention at PMH. Limited education, lack of basic delivery planning and cost of the procedure represent important patient barriers to acceptance of this mode of delivery. Data collection is currently ongoing.

Reddy, Ashok

Chung M, Reddy A, Kimani C. Sakr S et.al., “Rapid HAART Scale-up Associated with Improved Medical Outcomes in Kenya”

Early on during the Fogarty Fellowship I worked on developing proposals to analyzing the retrospective data collected at the Hope Center for Infectious disease. I filed human subject and IRB applications to the University of Washington and University of Nairobi. In addition I developed skills using SPSS to clean and analyze data collected. If accepted to the IDSA conference in October, I will be participating in developing a poster.

Serah Wanjiru Ndegwa

Research Topic:

To determine the appropriateness of the infant feeding choices made by HIV seropositive mothers in Pumwani Maternity Hospital.

Background:

Sub Saharan Africa has been plagued with HIV/AIDS. Interventions to prevent Mother-to-Child transmission of HIV/AIDS are rapidly expanding in hope to halt progression of the disease. The weakest link in this fight continues to be infant feeding. Mothers are often unable to determine the best mode of feeding their children. Counsellors are often, overworked inadequately informed and unable to assess the real home situation of the mothers. The use of local simple tools would be of value in assisting both mother and counsellor choose the appropriate infant feeding option.

Objectives: To determine the appropriateness of the infant feeding choices made by HIV seropositive mothers in Pumwani Maternity Hospital in relation to the AFASS guidelines (acceptable, feasible, affordable, sustainable and safe). To determine the utility of a standardized tool in determining the appropriateness of infant feeding choice. Study Design: A descriptive cross-sectional study. Study Site: The study will be carried out in the postnatal PMTCT clinics at Pumwani Maternity Hospital. Study Subjects: The eligible population will be HIV infected women who have infants between 2-3 months of age. Data collection and analysis: Still in progress.

Mali

Scholars

Assadou, Mahamadoun Hamady
Conard, Craig J.
Coulibaly, Drissa
Nixon, Jason

Principle Investigator

Christopher V. Plowe, MD, MPH

Hamady, Assadou Mahamadoun (Maiga)

Double-blind, randomized, controlled, phase 1 study of the safety and immunogenicity of ama1-c1/alhydrogel® vaccine for plasmodium falciparum malaria, in semi-immune adults in doneguebougou, Mali (ongoing study before fellowship clinical research activities on site)

Randomized, controlled, phase 1/2 study of the safety and immunogenicity of ama1-c1/alhydrogel® vaccine for plasmodium falciparum malaria in children in donéguébougou and bancoumana, Mali

Peru (JHU)

Scholars

Bowman, Natalie
DeLea, Suzanne
Donroe, Joseph Anthony
Gerson, Galdos
Griffen, Anne M.
Herrera, Phabiola
Lanfranco, Julio
Reddy, Krishna
Sherman, Jonathan
Soto, Giselle
Tapia, Martin
Walker, Paul

Krishna Reddy

Primary project: Detection of Tuberculosis in Patients with HIV.

I am investigating the utility of MODS, a new technique (developed in Peru) for diagnosing tuberculosis, in ruling out TB in patients with HIV before they receive isoniazid preventive therapy. Active TB must be ruled out before patients receive preventive therapy, and currently this is done by clinical exam, chest radiography, and smear stain and Lowenstein-Jensen or Ogawa culture of 2-3 sputum specimens. We believe that MODS will be more sensitive and more rapid than the current rule-out scheme in detecting active TB, and that it will be more cost-effective. I am coordinating this multicenter study, in which sputum specimens are obtained from patients at various hospitals and analyzed by MODS in our research laboratory. Results are then compared to those of the current rule-out scheme.

Secondary project: I have written a review chapter of pediatric and maternal tuberculosis, to be published in a book on international maternal and child health.

Sherman, Jonathan

Sherman J., "Epidemiological study on MDR TB treatment outcome in Peru" Tropical Medicine and Hygiene Young Investigator Competition, November 2006 [Presentation]

My biggest project is a diagnostic tool that we developed using vital stains for the prediction of TB quantitative cultures in hours after sputum samples. This work is done (data-wise) but will not be written and sent out until this Winter or even next Spring

Soto, Giselle

Kawai V, Soto G, Gilman RH, Bautista CT, Caviedes L, Huaroto L, Ticona E, Ortiz J, Tovar M, Chavez V, Rodriguez E, Moran A, Goswami R, Chaisson RE, Evans CA. "TB mortality, drug resistance in patients with and without AIDS, Peru." [Submitted to International Journal of TB and Lung Disease.]

Moore DAJ, Mendoza D, Gilman RH, Hollm Delgado MG, Guerra J, Caviedes L, Vargas D, Ticona E, Ortiz J, Soto G, Serpa J, and the Tuberculosis Working Group in Perú. "MODS – a rapid, reliable diagnostic for MDR TB suitable for resource-poor settings." [In press JCM.]

Peru (UW)

Scholars

Alva López, Isaac Efraín
Blas, Magaly
Chow, Felicia
Hsieh, Evelyn
Khan, Cristina T.
Martínez Esteban, Peggy
Mejía, Carolina
Núñez Cabrera, Mirtha
Rager, Christina
Rozas LaTorre, Marizabel

Khan, Christina Tara

I. Determinants of morbidity and mortality following cervical cancer treatment in Peru

Study type: retrospective multivariate survival analysis

Study location: Instituto Nacional de Enfermedades Neoplásicas (INEN), Lima

Data source: patient charts

Description of topic: Cervical cancer is the second leading cause of cancer morbidity and mortality worldwide in females but holds first place in many low-resource nations such as Peru. Access to screening and care by skilled providers is lacking in many regions, most notably in the provinces and rural areas, with the resulting majority of cases reported at first diagnosis in advanced stages (IIB-IV). The Instituto Nacional de Enfermedades Neoplásicas (National Institute for Neoplastic Diseases, INEN) in Lima, Peru is the main reference center in Peru for cancer and thus treats the bulk of cervical and other malignancies from around the nation. To date, there have been no studies examining outcomes and prognostic factors following treatment for all stages of cervical cancer at INEN.

Description of research activities: See abstract

Notes: This is a site that is not connected with my overseas post but one that I encountered through outside connections (my sister worked at the National Cancer Institute with a Peruvian gynecologic oncologist who worked at INEN before joining NCI). It has actually been the most supportive of the sites I have worked at in Lima. The study is one I designed after first spending over two months in an informal rotation in the Department of Gynecologic Oncology in INEN. Upon learning that they have not reviewed basic M&M stats for all stages of cervical cancer and with input from the attending physicians, I designed a database to be used for collection of clinical data from over 1300 patients who entered INEN for treatment of cervical cancer in the year 2001 (to allow for calculation of 5-year survival rates). Please see attached abstract submission for further information. The project abstract has been accepted and will be presented at the *Disparities in Surgical Care: Access to Outcomes* Conference in Boston on May 18, 2007 (the first annual symposium of the Center of Surgery and Public Health of Brigham & Women's Hospital:

<http://www.brighamandwomens.org/CenterforSurgeryandPublicHealth/default.aspx>).

II. Violence against sex workers in Peru: Implications for sexual and reproductive health

Study type: mixed methods (qualitative/quantitative)

Study location: Centro de Salud Alberto Barton/brothels/bars/street, Callao; brothels/bars/street, Cuzco

Data source: focus groups/survey

Description of topic: Gender-based violence (GBV) does not obey the normally protective effects of education, wealth, and other indicators of economic development; all over the world women are victimized in crimes perpetrated because of gender. Women who pertain to marginalized groups such as sex workers are at even greater risk for GBV and related health concerns. A recent multi-site study by the WHO showed that Peru has among the highest rates of physical and sexual violence against women of the countries studied. To date there have been no studies on GBV in the female sex worker population in Peru, nor are there any disseminated screening questionnaires on violence validated specifically for sex worker populations around the world.

Description of research activities: This is a mixed methods study with focus groups and surveys to better understand violence in this population and how it relates to sexual and reproductive health. This project will add a qualitative component to an existing study of sexual health that Joe Zunt has conducted in this population for the past 10 years and that has received additional funds for HPV testing for the next few years of research. We have a team of social workers who will help conduct the project through our work at the Centro de Salud Alberto Barton in Callao and through health services contacts from another study in Cuzco, Peru. The first phase of research will consist of focus groups with both brothel and street-based sex workers, which will inform the construction of a screening questionnaire on violence to be used with these populations. In a subsequent phase of the study, we will incorporate these questions in the larger (existing) survey to assess prevalence rates of physical, psychological, sexual, and childhood violence and their relationships to sexual behaviours and STIs.

Notes: This study is currently under IRB review.

III. Cost-effective analysis of a community randomized trial of STI prevention

Study type: cost-effective analysis

Study location: Universidad Peruana Cayetano Heredia, Lima

Data source: PREVEN trial data

Description of topic: Innovative methods are needed to measure population-level impact of HIV vaccines, STD and HIV treatment and other HIV preventive interventions on STD/HIV incidence in developing countries with nascent or concentrated HIV epidemics. PREVEN is an urban community randomized trial of STI prevention conducted by researchers from the University of Washington and the Universidad Peruana Cayetano Heredia and implemented between the years of 2003-2006 in 20+ cities in Peru. The three main interventions included in PREVEN were: pharmacy provider trainings for improved STD syndromic management, female sex worker mobile team treatment and outreach, and men-who-have-sex-with-men mobile team treatment and outreach. A cost-effective analysis (CEA) of these three interventions is necessary to measure population-level impact and planning for future large-scale implementation.

Description of research activities: Discussion about the CEA for the PREVEN interventions began in the fall of 2007. As part of the CEA team, I work with an economist, the accountant for the PREVEN project, and my Peruvian Fogarty foreign fellow (Issac Alva) on the tasks involved in a CEA. More than anything else, Issac and I serve as “los manos” (the hands of the team) as we are new to the field of CEA and are just learning the terminology and the process. Our tasks involve collecting data from the three interventions and the study personnel to aid in the cost analysis. We will also be visiting some of the study sites in the ensuing months to collect local cost data. Needless to say, we are learning a lot about a type of study that is a very important consideration in planning for global health interventions.

Notes: This study is expected to continue through June 2007.

IV. Sexual and reproductive health education intervention in Puente Piedra, Peru

Study type: mixed method intervention with prospective longitudinal survey evaluation

Study location: Primary/secondary school in Puente Piedra, Lima

Data source: surveys

Description of topic: The 2000 National Health and Demographic Survey in Peru showed that on average, 13% of female adolescents 15-19 years old nationwide are already mothers or are pregnant. The statistics are more striking in regions of extreme poverty like the Cono Norte of Lima, which has been described as the world's fourth largest slum. In a country where approximately 80% of the population describes itself as Roman Catholic, there are myriad institutional, social, cultural, and ideological barriers to the implementation of sexual education programs in public schools. Puente Piedra, one of the cities in the Cono Norte region, is the site of a school-based intervention on sexual and reproductive health to be implemented in April – November 2007. This interactive program takes a three-pronged approach to education, which includes engaging teachers on curriculum development and administration, parents/community leaders on community measures to help reduce STIs, and students on peer education techniques to help disseminate knowledge about sexual and reproductive health.

Description of research activities: The principal investigator of this study is a physician-sexologist (and possibly future Fogarty foreign fellow!) with considerable experience working on STI/HIV prevention in a variety of special population groups (adolescents, men-who-have-sex-with-men (MSM), etc.). Given my prior experience with evaluation of school-based programs, he has requested my help with the evaluation component of the intervention, which will include longitudinal surveys with all three stakeholder populations (teachers, students, parents/community members) along with supervision throughout the intervention.

Notes: This study is about to begin and will run through at least the end of 2007.

V. Epidemiology of HIV and other STIs in Guyana

Study type: clinical surveillance and genotyping

Study location: U.S. Navy Research Medical Center Detachment (NMRCDC), Callao; Guyana Ministry of Health, Georgetown, Guyana

Data source: clinical laboratory data, surveys

Description of topic: Guyana has the highest rates of HIV prevalence in South America and is second only to Haiti in the Western hemisphere. Although the early epidemic was characterized by high rates among commercial sex workers (prevalence estimates in small-scale studies ranging from 26-45%), between the years of 2001 and 2005, the epidemic began to take on a generalized form, with a UNAIDS prevalence estimate in the adult population of 2.5% at the end of 2004. In high-risk groups, recent reports have documented HIV prevalence of 30.6% among CSWs and 21% among MSM. The main challenge to HIV/AIDS programs in Guyana is a lack of adequate resources and data.

Description of research activities: I have prepared a literature review and protocol for a prospective study of HIV/STI surveillance and HIV genotyping in Georgetown, Guyana based on resources available through NMRCDC for infectious disease surveillance in the region. My role, if this project gets underway, will be to help with coordination of the project between Peru and Guyana, survey design, and data analysis and manuscript preparation.

Notes: This is a project that I designed based on NMRCDC's interest in conducting HIV surveillance in Guyana, a country the NMRCDC HIV group has not worked in previously, and on my own interest in assisting with the HIV epidemic in Guyana, my parents' home country. We have made contacts in the Guyana Ministry of Health but have not yet discussed logistics or implementation of the protocol.

Martínez, Peggy

Will present a poster in the meeting of the American Academy of Neurology in Boston, on may 1st. This is a small research about Bell`palsy. Here you have the abstract.

In February 2007, presented a project about children HIV (+) and polyneuropathy at the Instituto Nacional Del Niño, Lima Peru. I am waiting for the local ethics committee approval.

59th Annual Meeting of the American Academy of Neurology **Abstract Number:** 953145 **Presenting Author** Peggy Martinez, MD **Department/Institution:** Instituto Nacional de Ciencias Neurologicas **Address:** Av. Canaval y Moreyra 777, San Isidro **City/State/Zip/Country:** Lima, Peru **Phone:** 511-2249615 **Fax:** **E-mail:** carolme2@hotmail.com

Topic: Peripheral Nerve: Clinical

Presentation format: Poster

Status: Neither

Case Report: No

Did this study incorporate the usage of animal material in any way? No

Muscular Dystrophy Integrated Neuroscience session: No

Ataxias Integrated Neuroscience session: No

Small Fiber Neuropathy Integrated Neuroscience session: No

Functional Imaging Integrated Neuroscience session: No

Frontotemporal Dementia Integrated Neuroscience session: No

Acute Stroke Therapy Beyond Thrombolysis: Hypothermia and Neuroprotection Integrated Neuroscience session: No

Future of Neuroscience Conference: Therapies for Genetic Disorders: No

Unlabeled Use of Products Disclosure: There is no unlabeled use to disclose.

Has the work described in this abstract been previously published and/or presented? No

Title: Clinical and Electrophysiological Characteristics of Bell's Palsy at the Instituto Nacional de Ciencias Neurologicas (INCN), Lima, Peru.

Peggy Martinez, Lima Peru, Hugo Garcia, Lima Peru, Silvia Montano, Lima Peru, Joe Zunt, Seattle United States and Luis Crovetto, Lima Peru.

Objective: Describe the clinical and electrophysiological characteristics of patients with Bell's Palsy.

Background: Bell's Palsy is a frequent reason for patient visits to INCN

Design/Methods: Neurophysiological records and clinical histories of 900 patients with possible Bell's Palsy examined in the Department of Neurophysiology between June 2005 and May 2006 were reviewed. Of 422 patients with Bell's Palsy, the following information was collected: past medical history, symptoms, clinical grading according to House and Brackmann, neurological and electrophysiological evaluation (compound muscle action potential [CMAP] and electromyography) and treatment received.

Results: 193 of 422 (54.3%) patients were women. Mean age was 44.4 years (SD 15.63). Past medical history was notable for: hypertension in 49 (11.6%), diabetes mellitus in 21 (4.98%) and prior episode of facial palsy in 56 (13.3%). 232 (54.98%) had right-sided palsy, 341 (80.8%) pain, 262 (62%) dysgeusia and 59 (13%) hyperacusia. 26% of patients had severe axonotmesis. Increasing severity of axonotmesis was associated with prior history of diabetes mellitus ($p=0.01$), vitamin treatment ($p=0.006$) and age >60 years ($p<0.001$). Lesser severity of axonotmesis was associated with use of corticosteroids ($p<0.001$). Multivariate linear regression demonstrated that higher CMAP values were associated with use of corticosteroids (Coef. 11.65, CI: 7.20, 16.09; $p<0.001$) and lower CMAP values were associated with prior history of hypertension (Coef. -9.06 IC: -16.41, -1.69, $p=0.016$) and age >60 years (Coef. -7.12; CI -12.93, -1.30; $p=0.016$).

Conclusions/Relevance: Age greater than 60 years and lack of treatment with corticosteroids are associated with greater severity of axonotmesis and lower amplitude of CMAP.

Study supported by (if applicable): Fogarty/Ellison Fellowship Program

Hsieh, Evelyn

Hsieh E, Zunt JR, Montano SM, Quijano E, Solari V. Migration and Sexually Transmitted Infections Among Ecuadorian Commercial Sex Workers in Lima, Peru. *Sex Trans Diseases* (submitted).

Alva, Isaac

Alva IE, Blas MM, García, PJ, Cabello R, Kimball AM, Holmes KK. Risks and benefits of internet use among people living with HIV/AIDS in a resource-constrained setting. *Rev Panamericana Salud Pub.* (in press)

Blas MM, Canchihuaman FA, Alva IE, Hawes SE. Pregnancy outcomes in women infected with *Chlamydia trachomatis*: a population-based cohort study in Washington State. *Sex Trans Infect.* 2007 (in press).

Blas, Magaly

Alva IE, Blas MM, García, PJ, Cabello R, Kimball AM, Holmes KK. Risks and benefits of internet use among people living with HIV/AIDS in a resource-constrained setting. *Rev Panamericana Salud Pub.* (in press)

Chow, Felicia

Chow F, Garcia HH. Helminthic Diseases: Taeniasis and cysticercosis. In *Encyclopedia of Public Health*, ed. K. Heggenhougen. Elsevier, Amsterdam. In press.

Mejia, Carolina

PhD Thesis

Geographic mobility and the association with sexually transmitted infections and HIV among female sex workers in Peru. Sex Trans Infections.

What Are the Major Mobility Patterns and Push and Pull Factors for in Female Sex Workers in Peru?
International Migration Review.

Mobile Female Sex Workers' Perceptions of Sociocultural Factors, Work Conditions and Risk Behaviors Increasing their Vulnerability to Sexually Transmitted Infections. Qual Report

Russia

Scholars

Davidson, AuTumn
Gorlinsky, Alexey
Kruse, Gina
Tolstov, Yanis

AuTumn Davidson

I have been working on two research projects. *In the first, Sexual Risk Behavior and STIs in St. Petersburg's IDUs*, I am using data previously collected through the Russian arm of Sexual Acquisition and Transmission of HIV-Cooperative Agreement Program (SATH-CAP) study. I am comparing the sexual risk behavior, the impact of knowledge of partner HIV serostatus on this behavior, and STI prevalence in female to male injection drug users. The objective of this work is to gain a better understanding of gender-specific sexual behavior, patterns of STIs among this marginalized population, and to evaluate whether these factors are influenced by the knowledge of sexual partner serostatus. I hope that the results of this work will be used to assist in the development of effective reproductive health education programs targeted toward drug users, and to monitor behavioral and epidemiological trends in order to evaluate the impact of future prevention efforts.

In my second project, *Serostatus Disclosure and Attitudes Toward Partner Notification policies*, I am working to examine serostatus disclosure practices among the city's HIV- infected patients. I have developed a survey and will be administering them to patients seeking care at St. Petersburg's AIDS Center. The aim of this study will be a) to assess the degree to which HIV-infected individuals are disclosing their positive serostatus to injecting and sexual partners, b) to evaluate differences in disclosure patterns between sex and drug partners, c) to understand the extent to which patients currently receive disclosure counseling by health care practitioners, and d) to understand the general attitudes of HIV-infected patients towards the potential implementation of a partner notification policy. To date, little is known regarding current serostatus disclosure practices among this population, and no HIV partner notification program currently exists in the Russian Federation. The results of this project will provide useful information for policy makers as they develop new models of disease control within a society whose HIV epidemic currently ranks among the worst in Europe.

Kruse, Gina

Kruse G, Shaboltas A, Toussova O, Hoffman I, Kozlov AP. "Psychostimulant use and risk-taking behaviors among heterosexual injection drug users in St. Petersburg, Russia." (In press: AIDS, Cancer and Public Health, a Russian journal edited by The Biomedical Centre. Abstract has been submitted elsewhere and manuscript in preparation for peer reviewed journal.)

South Africa, Durban

Scholars

Babell, Lisa
Edwards, David
Hudspeth, James
Khan, Munira
Johnson, Daniel
Moodley, Terrence
Naidoo, Kogieleum
Vivek Naranbhai
Ntsele, Sibusiso
Sibeko, Sengeziwe
Wiseman, Richard

Vivek Naranbhai

I started as a CAPRISA research placement in 2005 concurrent with the initiation of medical school. My work has been focused on epidemiology/public health and initially I worked on issues regarding ART provision. My current interests reflect this continued activity and new endeavors in basic science and prevention science.

1. AIDS Treatment

Mortality

Mortality in HIV treatment facilities is a key indicator of outcomes. Understanding the factors predisposing to and ameliorating mortality in patients receiving ART in resource-constrained settings informs the programmatic delivery of ART. Our studies in this area commenced prior to the award of the Fogarty-Ellison fellowship, and a final manuscript submission is in underway. The manuscript describes predictors of and rates of mortality at the Vulindlela CAPRISA AIDS Treatment facility.

Anemia

In analyses of factors influencing mortality, we found a strong relationship between significant anemia and death. Similar findings have been reported from across Sub-Saharan Africa and elsewhere. This study aims to delve deeper into understanding the types, etiologies and pathogenesis of anemia in HIV and the impact of ART on anemia through epidemiologic analysis of patients who are received ART. This work may be combined with work already done by others in CAPRISA endeavoring to understand anemia in acute HIV infection. Data-analysis is underway.

2. Alcohol and HIV

South Africa has a per capita alcohol consumption that is amongst the highest in the world. It also experiences a mature but growing HIV epidemic, driven to some extent by continued adolescent HIV acquisition. There have been numerous studies describing the influence of alcohol and other substance-abuse on HIV acquisition. Our concerns in this area are the biology of alcohol and HIV, and designing STI/HIV specific behavioral interventions for male adolescents in a community tavern context. Our studies in this arena are at a preliminary stage.

3. Cochrane Systematic Review

I shall be participating in a review group which will be compiling a Cochrane Systematic Review of the evidence regarding **behavioral interventions for preventing HIV in street and young children**. The South African Cochrane Centre is the hosting institute for South African reviewers and will be mentoring us through this process during 2007.

4. NK cells in HIV infection

Based on a genetic epidemiologic observation of the correlation between particular HLA allotypes (HLA Bw4) and Natural Killer Cell receptor (KIR3DS1) and superior outcomes in chronic , my laboratory based study is in the laboratory of the Human Pathogenesis Program. This study forms a component of the Natural Killer cell focus area of Dr William Carr (Partners HealthCare). These studies are attempting to define the biology of HIV-1 in the interaction between the potential ligand HLA-Bw4 and KIR3DS1. I shall be initiating labwork in mid-April and the completion of this work is expected by November.

James Hudspeth

1) Substudy of the SAPIT Trial on TB/HIV cotreatment

The SAPIT trial is an RCT investigating the impact of starting ART at various points relative to TB therapy, namely during intensive phase treatment, after intensive phase treatment, and after completion of therapy. This is done with an eye towards a better understanding of whether the toxicities of concurrent TB therapy and ART outweigh the benefits of immune reactivation during a TB episode, a question that currently has no answer. My substudy reviews the initial responses to therapy in a set of patients started on ART during the intensive phase of their TB therapy, looking to how things have gone to date in these patients. Possibly publishable or abstract, remains to be seen.

2) Value of Adding Streptomycin to the Retreatment Regimen of Patients with Recurrent TB

Retrospective chart review analyzing responses to therapy in patients who received the WHO recommended retreatment regimen of streptomycin, pyrazinamide, ethambutol, rifampicin, and isoniazide in the intensive phase vs. those not receiving a streptomycin-containing regimen. Two cohorts selected from clinic records. Paper in progress at the moment.

Bebell, Lisa

Bebell, L., Passmore, J.-A., Williamson, C., Mlisana, K., Iriogbe, I., Abdool Karim, Q., and Abdool Karim, S. "Inflammatory Cytokines in the Female Genital Tract during Acute HIV-1 Infection." (To be submitted June 2006) Working Manuscript

South Africa, Pretoria

Scholars

Feucht, Ute
Hoehnen, Sarah
Kinzer, Michael
Matji, Joan
Wiseman, Vanessa

Feucht, Ute

The medical and social characteristics of HIV-infected children seen at the paediatric immunology clinic at Kalafong hospital after the start of the antiretroviral treatment programme on the 1st of April 2004 (U Feucht, M Kinzer, M Kruger)

Audit of the response to antiretroviral therapy in therapy-naïve HIV-infected children at Kalafong hospital. (U Feucht, H Bapela, C Hosking, M Kruger)

Severe adverse events in children started on antiretroviral therapy at Kalafong hospital. (U Feucht, C Gallup, V Wolfman, C Nyasulu, S Hoehnen, M Kruger)

The socio-economic profile and support structures of HIV infected and HIV exposed children cared for at Kalafong hospital, Pretoria (U Feucht, N Mkhondo, M Kruger, B Jeffrey, B Forsyth)

Food as medicine and medicine as food: Antiretroviral Therapy and Nutritional Supplementation in a Cohort of HIV-Infected Children in South Africa. (M Kinzer, M Kruger, U Feucht, B Forsyth)

Improving the diagnosis of HIV in children born to HIV infected mothers (V Wolfman, B Jeffrey, B Forsyth, A Puren, U Feucht, M Kruger)

Effects Of Food Insecurity on Growth of Children Born to HIV Infected Mothers (V Wolfman; U Feucht, M Kruger)

Cardiac involvement in newly diagnosed HIV infected children and the effect of HAART on cardiac disease (N du Plessis, U Feucht, R Ahmed, F Takawira, M Kruger)

Assessing neurodevelopment in HIV infected children under the age of three years at Kalafong Hospital (S Hoehnen, U Feucht, E Honey, H Bapela, Paediatric Occupational Therapy Department Kalafong Hospital, B Forsyth, M Kruger)

Matji, Joan

Matji J, Wolfman V., "Missed opportunities in the prevention of mother to child transmission of HIV/AIDS in 4 clinics in Pretoria, South Africa" Written in collaboration with the South African Fogarty Fellow, Joan Matji, results from this study are currently being analyzed, an abstract will be submitted for the South African National pediatric Congress in September 2006, and we intend to submit a paper for publication.

"Evaluating the diagnosis of HIV in children born to HIV-infected mothers" An abstract of preliminary results from this study will be submitted for a poster presentation at the South African National pediatric Congress in September 2006, and final results are intended to be submitted for publication.

Factors affecting the growth and health of children born to HIV-infected mothers – working title

Tanzania

Scholars

Acosta, Anna Marie
Blander, Jeffrey
Drain, Paul
Furaha, August
Makubi, Abel
Mwiru, Ramadhani

Acosta, Anna

1. Predictors of gestational hypertensive disorders and gestational diabetes in a population of HIV negative Tanzanian women This research is a secondary analysis of data derived from a study which examined the effects of prenatal multivitamin supplementation on the primary outcomes of fetal loss, low birth weight, and preterm birth in a population of HIV negative Tanzanian women. Although there are a number of potential causes of gestational hypertensive disorders and gestational diabetes, little is known about the specific associations in this population of sub-Saharan women. In addition to investigating the predictors for gestational hypertension and diabetes, we will also explore the effect of multivitamin supplementation on the incidence of gestational hypertension, as some previous studies have found that specific micronutrient supplementation has reduced the incidence of this disorder.

2. C-reactive protein as a predictor for adverse birth outcomes in a HIV negative population This proposal describes an evaluation of C-reactive protein (CRP) as a predictor for adverse birth events in a pregnant HIV negative population. This research will be an adjunct to a larger, completed study which examined the effects of multivitamin supplementation on the primary outcomes of fetal loss, low birth weight, and preterm birth. In addition to investigating CRP as a predictor for outcomes such as preterm birth and low birth weight, we will also examine the effect of multivitamins on CRP levels during pregnancy and postpartum time periods. These results may indicate a mechanism by which multivitamins influence outcomes through reduced inflammation. Furthermore, if CRP levels are found to be associated with pregnancy complications and adverse birth outcomes, it may be used as an inexpensive diagnostic predictor for this population.

Ramadhani Stephano Mwiru

Title # 1: Acute respiratory illness in a cohort of children 1-18 months old in Dar es Salaam, Tanzania.

One of my research topics is on acute respiratory illnesses (ARI) in a cohort of children 1-18 months old in Dar es Salaam, Tanzania; acute respiratory illnesses are major cause of morbidity and mortality in children in Tanzania and other developing countries and they contribute significantly to pediatric care costs. Intervention strategies including vaccination and early recognition and treatment of ARI have been designed to reduce the morbidity and mortality. It is thus very important to regularly evaluate the trend of these illnesses. The specific research objectives are to determine the incidence and risk factors for acute respiratory illnesses in this cohort of children. I will use data collected as part of an extension of a double-blind placebo-controlled trial of multivitamins supplementation in HIV negative women and adverse pregnancy outcome. Data collection was done by following up the breastfeeding women and their infants once per month to the study clinic until 18 months post delivery. During each visit, women were asked questions regarding their babies' health during the previous month and general physical exam was done on the babies.

Title # 2: The experience of Pediatric Treatment of HIV/AIDS in Dar es Salaam, Tanzania.

My second topic is on Pediatrics Treatment of HIV/AIDS in Dar es Salaam. This will be a retrospective cohort study in which case records of HIV positive pediatric patients (≤ 15 years of age) attending HIV/AIDS clinic between January 2006 and December 2006 at Muhimbili National Hospital in Dar es Salaam, Tanzania, will be identified and reviewed. Specific objectives for this study are to evaluate the availability of ARVs (including pediatric doses and formulations) to the HIV/AIDS patients eligible for treatment and also to evaluate the treatment outcomes in terms of clinical, immunological and

virological responses. To my knowledge, the experience of treatment and treatment outcomes of the pediatric HIV/AIDS cases has not been explored in Tanzania; I hope that the results of this study will help in the whole process of continuously improving the management of pediatric HIV/AIDS

Drain, Paul

Drain, PK., Baeten JM., Overbaugh J., et al. "Low Serum Albumin and the Acute Phase Response Predict Low Serum Selenium in HIV-1 Infected Women." *BioMed Central Infectious Diseases* May 2006, 6:85.

Drain, PK., Primack, P., Hunt, D., Fawzi, W., Holmes, K., Gardner, P., "Global Health in Medical Education: A Call for More Training and Opportunities." (Submitted to the *Journal of the American Medical Association*.)

Drain, PK., Smith, JS., Hughes, JP., Halperin, DT., Holmes, KK., "Correlates of National HIV Seroprevalence: An Ecologic Analysis of 122 Developing Countries." *JAIDS*, 35(4):407-420, April 1, 2004.

Drain, PK., Shepard, C., Alter, M., Hughes, JP., Holmes, K., "Transmission of Hepatitis C by Needlestick Injury: A Meta-analysis." (Not yet submitted.)

Drain, PK., Huffman, S., Pirtle, S., *Caring for the World: A Guidebook to Global Health & Medicine.* (Currently in discussion with several publishers.)

Drain, PK., Kupka, R., Mugusi, F., Fawzi, W., "Micronutrients among HIV-Infected Individual taking Highly Active Antiretroviral Therapy (HAART)." (Submitted to the *American Journal of Clinical Nutrition*.)

Drain, PK., Kupka, R., Msamanga, GI., Urassa, W., Mugusi, F., Fawzi, W., "C-Reactive Protein Independently Predicts HIV Disease Progression and Mortality among Women and Children in a Resource-Poor Setting." (Will be submitted to *J AIDS*.)

Drain, PK., Petraro, P., Kim, S., Mugusi, F., Fawzi, W., "Anthropometric Changes after Highly-Active Antiretroviral Therapy (HAART) Initiation among HIV-Infected Adults in a Developing Country." (Will be submitted to *Clinical Infectious Diseases*.)

Thailand

Scholars

Hyder, Joseph
Lee, Benjamin
Nord, Jo E.
Phiyaraj, Phunlerd
Prmsarn, Parichat
Sakkhachornphop, Supachai
Samuels, Aaron
Utaipat, Utaiwan
Wansom, Tanyaporn
Wongtrakul, Jeerang

Ben Lee

1. Metabolic side effects of HAART in HIV+ Thai Children. We are conducting a sub-study within a longitudinal cohort study of children on HAART, doing laboratory assessment of a small selection of laboratory parameters to analyze the metabolic side effect profile of HAART in this population.
2. Behavior and mental health among perinatally-HIV-infected Thai adolescents. We are conducting quantitative surveys among HIV+ Thai adolescents to assess behavior, mental health, and psychosocial adjustment.
3. Outcomes among IDU in Northern Thailand. I am helping analyze a small portion of certain behavioral outcomes data for a large HPTN study among IDU here in northern Thailand.

Wansom, Tanyaporn

- 1) Chart review comparing cryptococcal infection in HIV vs non-HIV infected patients
- 2) Demographic characteristics of women receiving abortions at a private clinic in N. Thailand
- 3) Quality of Life among HIV+ patients taking ARV
- 4) Antibiotic resistance patterns and protocols for antibiotic use in the ICU setting for patients with hospital-acquired pneumonia

Utaiwan, Utaipat

Topic of Research

I am a researcher, base at the Research Institute for Health Sciences, Chiang Mai University (CMU) in Thailand. I consider myself as a translational research scientist, working in 2 fields; HIV and HPV infection. Because HIV/AIDS has been the focus interest of our research institute since an early epidemic of AIDS problem in Thailand, this allows me to get involve in HIV research. Collaborate with a leading scientist/lecturer from the Microbiology department, Faculty of Medicine, I study the virus isolates from the primary infections in a cohort with heterosexual contact, the main route of HIV transmission in Thailand. With further phenotypic characterization of the isolates, we are able to study the relationship between virus factor(s), and host-related factors with the clinical outcome. We also continue to do basic research with these clinical isolates in the infection experiment to better understand the pathogenesis of the viruses that may explain disease development.

My recent expertise is in HPV/cervical cancer research that I gained through my PhD training at the Johns Hopkins Bloomberg School of Public Health in Baltimore. With support from my mentors and the HPV interesting group in the CMU campus, I currently established the HPV research laboratory that we are able to detect and genotyping the virus from clinical specimens. To provide the information for the public health with regard to the currently available HPV vaccine, our first priority is placed on the collection of the prevalence data of HPV infection, particularly, the high-risk types associated with cervical cancer in our population.

Hyder, Joe

Beyrer C, Kawichai S, Hyder J A. Patterns of HIV and Syphilis in Northern Thailand 1998-2001. (paper to submitted Int J STD AIDS)

Hyder J A, Rungruengthanakit K, Beyrer C, et al. Detection of recent HIV infection among injection drug users in northern Thailand. In preparation

Piyaraj, Phunlerd

Piyaraj P., Rangsin R., Sirisanthana T., Sirisopana N., Short O, Nelson K.E. "The Natural History of HIV-1 Subtype E Infections in Young Men in Thailand" [submitted for publication]

Rangsin R., Piyaraj P., Sirisanthana T., Sirisopana N., Short O., Nelson K.E "HIV Incidence among Young Thai Men 10-12 years after Discharge from the Royal Thai Army" [submitted for publication]

Sakkhachornphop, Supachai

Hirunpetcharat C, Wipasa J, Sakkhachornphop S, Nitkumhan T, Zheng YZ, Pichyangkul S, Krieg AM, Walsh DS, Heppner DG, and Good MF. CpG oligonucleotide enhances immunity blood-stage malaria infection in mice parenterally immunized with a yeast-expressed 19 kDa carboxyl-terminal fragment of Plasmodium yoelii merozoite surface protein-1 (MSP1 19) formulated in oil-based Montanides. Vaccine 2003; 21: 2923-32.

Tovanabutra S, Beyrer C, Sakkhachornphop S, et al. The Changing Molecular Epidemiology of HIV-1 Among Northern Thai Drug Users, 1999 to 2002. AIDS Res Hum Retroviruses 2004; 20 :Number 5 : Issue date May 2004

Samuels, Aaron

Beyrer C, Mullany L, Richards A, Samuels A, Suwanvanichkij, Lee, Franck. Responding to AIDS, TB, Malaria and Emerging Infectious Diseases in Burma: Dilemmas of Policy and Practice. March 2006. Report can be found at The Center for Public Health and Human Rights, Johns Hopkins Bloomberg School of Public Health, website: <http://www.jhsph.edu/burma>. An abridged version has been accepted for publication by the peer reviewed journal Public Library of Science, Medicine.

Uganda

Scholars

Akuete, Kwei
Baker, Bonnie
Dickman, Katherine
Luman, Kyle
Meya, David B.
Nakiyingi, Lydia
Namukwaya, Elizabeth
Simo, Sekeganda Luzige
Schwartz, Jeremy

Katherine Dickman

1. Tuberculosis treatment failure in Kampala, Uganda: incidence and mechanisms. This project aims to describe the incidence of and risk factors for TB treatment failure in Kampala, as well as to determine whether exogenous reinfection with new Mycobacterium tuberculosis strains occurs during treatment to produce disease that mimics treatment failure. Treatment failure cases were identified retrospectively from among adults with pulmonary TB enrolled in cohort studies conducted from 1993 to present. Using a case-cohort design, cases will be compared to control subjects, adults with pulmonary TB who were treated and cured. Potential risk factors include demographic, clinical, radiological, and mycobacterial factors. DNA fingerprinting using restriction fragment length polymorphism (RFLP) analysis will be done on sputum isolates from baseline and time of treatment failure to determine whether reinfection with new strains had occurred. If RFLP patterns of isolates from baseline and time of failure are identical, we will assume that the patient is infected with the same strain. If RFLP patterns of duplicate isolates from baseline and time of failure are different, we will assume that the patient was exogenously reinfected with a new strain during treatment.

Luman, Kyle

The Effect of Exposure to Environmental Mycobacteria on the Immune Response to Mycobacteria tuberculosis in Kampala, Uganda. This is in the final analysis phase and the write-up has been started. Hopefully, this will be presented at a conference and published.

Namukwaya, Elizabeth

predictors and risk factors of treatment failure among patients on anti-tb treatment in mulago hospital.

Zambia

Scholars

Aparicio (Grey), Sylvia Susana
Goldman, Jason
Kapembwa, Kenneth C.
Megazzini, Karen
Mweenba, Aggrey
Nyirenda, Christopher
Phaendler, Krista
Sinkala, Edford
Zachary, Dalilia

Nyirenda, Christopher

RESEARCH TOPIC

Refeeding Syndrome as a cause of early mortality in HIV/AIDS patients initiating Antiretroviral Therapy(ART) in Zambia

Christopher Nyirenda,(Registrar, Department of Internal Medicine,University Teaching Hospital,Lusaka,Zambia)-Fogarty-Ellison fellow-2006

Mentor: Douglas C Heimburger,(Professor, Department of Nutritional Sciences,University of Alabama at Birmingham,USA)

This research topic describes refeeding syndrome as a possible nutritional cause for early ART mortality in severely wasted HIV/AIDS patients initiating antiretroviral therapy in Zambia. The study involves a follow up of enrolled subjects for 12weeks (6visits) at which clinical-nutritional review and drawing of serum samples for electrolytes and nutrients are conducted.

It is an ongoing pilot project at Chawama Clinic, a University of Alabama's Centre for Infectious Disease Research in Zambia (CIDRZ) supported site for HIV care.

The study is specifically looking at a cohort of ART-naïve Zambians who are starting ART and who exhibit major risk factors for early ART mortality(defined as CD4+ count<50 cells/ul or BMI<16kg/m²), with the Aims:

1. To determine whether refeeding syndrome occurs, and estimate its incidence

Refeeding syndrome being defined as serum phosphorus<0.65mmol/l at any time in the the first 90days of ART.

2. To determine whether persons who develop refeeding syndrome are at higher risk of early ART mortality than persons who do not develop refeeding syndrome.

Study Rationale

Initiation of antiretroviral therapy in HIV patients can improve appetite, potentially resulting in increased food intake and nutrient absorption that exceeds the body's ability to meet the high phosphorus demands of carbohydrate metabolism. The resulting hypophosphatemia could lead to adverse outcomes, including cardiopulmonary decomensation and death. Refeeding syndrome has been described in subjects with severe cachexia of any cause who experience sudden increases in nutrient intake due to improved food supply or therapeutic feeding. Hypophosphatemia is essential to the development of refeeding syndrome. However a broad range of interrelated metabolic derangements involving potassium, magnesium, glucose and vitamins can also occur. Refeeding syndrome can cause multiple organ complications and may include weakness, muscle paralysis, cardiorespiratory failure with pulmonary or peripheral oedema, WBC dysfunction and long term effects such as osteomalacia.

Kapembwa, Kenneth

Working on HIV and Hepatitis B and C co-infection in patients about to commence on HAART.

Title: Hepatitis B and C viral co-infection in HIV infected patients enrolled in the antiretroviral treatment program at the University Teaching Hospital in Lusaka, Zambia.

The study is being done to look at the prevalence of Hepatitis B and C in HIV infected patients as currently, there is no regard to this aspect of HIV during therapy. The importance of this study is mainly for optimal choice of anti-retroviral therapy as some ARV drugs can worsen the outcome in co-infected patients whereas other ARV drugs can improve the outcome. Findings of this study may have a bearing on the necessity of routine testing for hepatitis B and C in HIV patients about to commence on HAART.

Goldman, Jason

Viral Load Study:

Title: Comparison of two strategies of HIV viral load monitoring to improve AIDS survival in Lusaka, Zambia

PI: M. Saag, MD; IoR: J. Stringer, MD

Funding agency: NIH

Type: Prospective, cluster-randomized trial

Progress: Activation- Dec-06, 730 patients enrolled as of Mar-07

Jason's role: Study Coordinator- data collection

Despite its key role in HIV care in the developed world, the utility of routine viral load in low-resource settings like Zambia is a subject of debate. In particular, it remains uncertain whether the limited resources for care are best spent on viral load monitoring or on the purchase of therapy for more patients. Central to these discussions are the yet unknown long-term benefits and cost-effectiveness of HIV viral load monitoring in these settings. It is possible that, in settings with high prevalence of opportunistic infections and limited repertoires of antiretroviral agents, the benefits of viral load testing may not be as striking or cost-effective when compared to the United States or Europe.

This trial will compare patients presenting to community clinics randomized to one of two arms:

- Routine monitoring: viral load tests at baseline, and routine intervals after initiation of ART
- Discretionary monitoring: viral load test only for suspicion of treatment failure based on clinical or immunologic criteria

By comparing the overall survival, indicators of clinical disease progression, and virologic resistance, we hope to determine potential survival benefits of viral load monitoring in a resource-poor setting, as well as provide urgently needed information on feasibility, acceptability, and cost-effectiveness. A total of 12 community clinics in the Lusaka District Health Management Board will be randomized, each clinic enrolling 150 patients.

Adherence and Viral Load:

Title: Simple assessments of adherence to antiretroviral therapy predict virologic failure in HIV infected patients in Lusaka, Zambia.

Mentors: B. Chi, MD, J. Stringer, MD

Funding agency: PEPFAR/EGPAF

Type: Retrospective data analysis

Progress: Abstract submitted- IAS Conference, 2007

Jason's role: Corresponding Author- study design, data collection, data analysis, manuscript preparation

Please see submitted abstract attached.

HBV & HIV Co-infection:

Title: Hepatitis B and C viral co-infection in HIV infected patients enrolled in the antiretroviral treatment program at the University Teaching Hospital in Lusaka, Zambia.

Mentors: B. Chi, MD, S. Lakhi, MD

Collaborator: Kenneth Kapembwa, MD

Funding agency: Fogarty Fellowship

Type: Cross-sectional prevalence study

Progress: Ethics approval process. Activation expected- Apr-07

Jason's role: Secondary author- study design, data collection, data analysis, manuscript preparation

Co-infection with HIV and hepatitis B virus occurs frequently in Zambia, a high HBV prevalence area with most patients becoming chronic HBV carriers in childhood. Drug induced hepatotoxicity as a result of antiretroviral therapy depends on the drug classes or agents used as well as on pre-existing liver dysfunction. Certain ART agents used in the treatment of HIV have activity against HBV, while others are hepatotoxic. In Zambia, there is no routine testing for hepatitis B and/or C virus in HIV infected patients who are about to commence ART, and hence directed therapy is not possible. This cross-sectional study will assess the prevalence of hepatitis B and C viruses in ART naïve, HIV-infected individuals, and determine prevalence of liver dysfunction in co-infected patients. A questionnaire will also assess predictors of hepatitis B or C and HIV co-infection.

Treatment Failure:

Title: Assessment of WHO guidelines on immunologic criteria for diagnosis of antiretroviral treatment failure in HIV-infected patients on ART.

Mentors: S. Reid, MD, R. Cantrell, B. Chi, MD, J. Stringer, MD

Funding agency: PEPFAR/EGPAF

Type: Cross-sectional study

Progress: Activated- Dec-06.

Jason's role: Study design, data collection.

In low-resource settings, patient decisions on ART failure and switch to second-line therapy is often based on clinical and immunologic data alone without virologic confirmation of failure. This preliminary study with cross-sectional design seeks to roughly evaluate the test characteristics of the 2006 WHO ART guidelines for immunologic treatment failure definitions in predicting virologic failure.

Cryptococcal IRIS:

Title: Immune reconstitution inflammatory syndrome in HIV-infected patients with prior cryptococcal meningitis.

Mentors: P. Pappas MD, C. Wilson MD, B. Chi, MD, J. Stringer, MD

Collaborator: Kenneth Kapembwa, MD

Progress: Concept

Jason's role: Study design

Immune reconstitution inflammatory syndrome (IRIS) is the paradoxical worsening of preexisting infectious processes following initiation of ART, due to newly acquired immune response to pathogen to which the immune system was previously anergic. Patients with pre-existing cryptococcal infections are particularly susceptible after initiation of ART to a syndrome which is usually self-limited, though sometimes severe and occasionally fatal. This trial will assess the optimal timing for initiation of ART following diagnosis of and treatment for cryptococcal meningitis