

BIOGRAPHICAL SKETCH

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NAME: Craig Randall Cohen

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POSITION TITLE: Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
University of California, Los Angeles, CA	None	N/A	Science
University of California, Berkeley, CA	BA	05/1984	Molecular Biology
University of Louisville School of Medicine, KY	MD	05/1990	Medicine
University of Washington School of PH, WA	MPH	06/1997	Epidemiology

A. Personal Statement

I am a Professor in the UCSF Department of Obstetrics, Gynecology & Reproductive Sciences, and co-Director of the University of California Global Health Institute. I conduct clinical and implementation research in HIV/AIDS and reproductive health, including the integration of livelihood and multisectoral interventions to improve health outcomes. In 1994, my colleague Dr. Elizabeth Bukusi at the Kenya Medical Research Institute (KEMRI) and I established the Research Care & Training Program (RCTP), a collaboration with projects in Nairobi and the Nyanza Region of Kenya. In addition to conducting research, the goal of the program is to enhance local capacity to conduct transdisciplinary global health and biomedical research through training and infrastructure development. RCTP employs over 1000 full-time staff in Kenya including epidemiologists, physicians, nurse-counselors, laboratory technologists, field workers, data managers, biostatisticians and administrative staff. I am the Founding Director of the Family AIDS Care & Education Services (FACES: www.faces-kenya.org) since its creation in 2004. FACES is a CDC/PEPFAR-funded HIV/AIDS care and treatment program in the Nyanza Region and Nairobi. FACES serves as an important platform for conducting innovative clinical and implementation research, including the proposed randomized controlled trial (RCT). I have been the PI for a dozen RCTs, including three cluster RCTs conducted in Kenya. Specifically, I was the administrative PI for the recently completed pilot agricultural intervention RCT (1R34MH094215) and the ongoing "Agricultural Intervention for Food Security and HIV health outcomes in Kenya (aka the *Shamba Maisha* Study)" (1R01MH107330) that serves as the basis for this R21 grant application. As a co-investigator of this grant, I have the necessary experience and expertise to support Dr. Weiser and our team of co-investigators, research staff and partner institutions to plan, conduct, and report on the results of the proposed study to understand the impact of the multisectoral agricultural intervention on HIV risk and reproductive health of adolescents in rural Kenya.

My four most relevant publications, related to the *Shamba Maisha* study include:

1. Weiser SD, Hatcher AM, Lemus Hufstедler S, Weke E, Dworkin SL, Bukusi EA, Steinfeld RL, Kodish S, Butler LM, **Cohen CR**. Changes in health and antiretroviral adherence among HIV-infected adults in Kenya: Qualitative longitudinal findings from a multisectoral agricultural and finance intervention. *AIDS & Behavior*, 2016, In press.
2. Jennifer M. Zakaras, Sheri D. Weiser, Abigail M. Hatcher, Elly Weke, Rachel L. Steinfeld, **Craig R. Cohen**, Elizabeth A. Bukusi, Shari L. Dworkin. A Qualitative Investigation of the Impact of a Livelihood Intervention on Gendered Power and Sexual Risk Behaviors Among HIV-Positive Adults in Rural Kenya. *Archives of Sexual Behavior*, 2016, in press.
3. **Craig R. Cohen**, Rachel Steinfeld, Elly Weke, Elizabeth A. Bukusi, Abigail M. Hatcher, Stephen Shiboski, Richard Rheingans, Kate M. Scow, Lisa M. Butler, Phelgona Otieno, Shari L. Dworkin, Sheri D. Weiser. *Shamba Maisha: Pilot agricultural intervention for food security and HIV health outcomes in Kenya: Design, methods, baseline results and process evaluation of a cluster-randomized controlled trial*. SpringerPlus, 2015;4:122. PMID: 25992307.

4. Sheri D Weiser, Elizabeth A Bukusi, Rachel Steinfeld, Edward Frongillo, Elly Weke, Shari Dworkin, Kyle Pusateri, Stephen Shiboski, Kate Scow, Lisa Butler, **Craig R Cohen**. Shamba Maisha: Randomized controlled trial of an agricultural and finance intervention to improve HIV health outcomes in Kenya. AIDS, 2015;29(14):1889-94. PMID: 26214684.

B. Positions and Honors

Positions:

- 1994-1996 Visiting Lecturer, WHO Collaborative Center for AIDS and STD Research, University of Nairobi, Kenya.
- 1995-1996 Administrative Director, Owen House Counselling Centre for HIV Positive Adults, Nairobi, Kenya.
- 1997-1999 Acting Instructor, Department of Obstetrics & Gynecology, University of Washington.
- 1997-Present Visiting Lecturer, Department of Obstetrics & Gynecology, University of Nairobi, Kenya.
- 1997-Present Visiting Senior Scientist, Center for Respiratory Disease Research, Kenya Medical Research Institute
- 1998-2003 Core Faculty, International AIDS Research Training Program, University of Washington
- 1999-2003 Acting Assistant Professor, Department of Obstetrics & Gynecology, University of Washington
- 2003-2009 Associate Adjunct Professor, Department of Obstetrics & Gynecology, University of California San Francisco
- 2004-Present Fellowship Director, Reproductive Infectious Disease Fellowship, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California San Francisco
- 2009-Present Professor in-Residence, Department of Obstetrics & Gynecology, UCSF
- 2010-2016 Co-Director, UC Global Health Institute Center of Expertise in Women's Health & Empowerment
- 2016-Present Co-Director, UC Global Health Institute

Honors:

- 1987 Dr. Calhoun Prize in Physiology
- 1989 Who's Who of American College Students
- 1989 Alpha Omega Alpha Honors Society
- 2010 Nominated, Mentor of the Year, AIDS Research Institute, UCSF
- 2012 Mentor of the Year, Clinical Translational Research student training program, UCSF
- 2014 Distinguished Mentor of the Year (Professor), UCSF

C. Contribution to Science

Complete List of Published Work in UCSF Profiles:

<http://www.ncbi.nlm.nih.gov/sites/myncbi/craig.cohen.1/bibliography/47174962/public/?sort=date&direction=ascending>

I am a Professor in the UCSF Department of Obstetrics, Gynecology & Reproductive Sciences, and co-Director of the University of California Global Health Institute. I conduct clinical and implementation research in HIV/AIDS and reproductive health, including the integration of livelihood and multisectoral interventions to improve health outcomes. In 1994, my colleague Dr. Elizabeth Bukusi at the Kenya Medical Research Institute (KEMRI) and I established the Research Care & Training Program (RCTP), a collaboration with projects in Nairobi and the Nyanza Region of Kenya. In addition to conducting research, the goal of the program is to enhance local capacity to conduct transdisciplinary global health and biomedical research through training and infrastructure development. RCTP employs over 1000 full-time staff in Kenya including epidemiologists, physicians, nurse-counselors, laboratory technologists, field workers, data managers, biostatisticians and administrative staff. I am the Founding Director of the Family AIDS Care & Education Services (FACES: www.faces-kenya.org) since its creation in 2004. FACES is a CDC/PEPFAR-funded HIV/AIDS care and treatment program in the Nyanza Region of Kenya. FACES serves as an important platform for conducting innovative clinical and implementation research, including the proposed randomized controlled trial (RCT). I have been the PI for over a dozen RCTs, including three cluster RCTs conducted in Kenya. Specifically, I serve as the administrative PI for the completed pilot agricultural intervention RCT (1R34MH094215), and the ongoing **Agricultural Intervention for Food Security and HIV health outcomes in Kenya** RCT (which serves as the foundation study for this R21 grant application). As the administrative PI for this grant, and in partnership with Dr. Weiser, I have the necessary experience and expertise to lead our team of co-investigators, research staff and partner institutions to plan, conduct, and report on the results of the proposed cluster RCT.

- a. **Cohen CR**, Sinei S, Reilly M, Bukusi E, Eschenbach D, Holmes KK, Ndinya-Achola JO, Bwayo J, Grieco V, Stamm W, Karanja J, Kreiss J. Effect of human immunodeficiency virus type 1 infection upon acute salpingitis: a laparoscopic study. *J Infect Dis*. 1998 Nov;178(5):1352-8. PMID: 9780255.
 - b. Bukusi EA, **Cohen CR**, Stevens CE, Sinei S, Reilly M, Grieco V, Eschenbach DA, Holmes KK, Bwayo J, Ndinya-Achola JO, Kreiss J. Effects of human immunodeficiency virus 1 infection on microbial origins of pelvic inflammatory disease and on efficacy of ambulatory oral therapy. *Am J Obstet Gynecol*. 1999 Dec;181(6):1374-81. PMID: 10601915.
 - c. **Cohen CR**, Manhart LE, Bukusi EA, Astete S, Brunham RC, Holmes KK, Sinei SK, Bwayo JJ, Totten PA. Association between *Mycoplasma genitalium* and acute endometritis. *Lancet*. 2002 Mar 2;359(9308):765-6. PMID: 11888591.
2. In more recent years my work has focused on development of technologies to prevent HIV and other reproductive tract infections. I completed a phase 1 microbicide trial of VivaGel® with sites in Kisumu, Kenya and San Francisco. As an ancillary study, I showed that young, health, STI-free women (aged 18-24) in Kisumu had a greater number and proportion of activated CD4 T-cells in the endocervix than similar women in San Francisco. This finding is important because it provides evidence that young women in sub-Saharan Africa, a group at very high risk of HIV infection in the region, may biologically be more susceptible to HIV acquisition than young women in the US. I served as the primary investigator for all of these studies.
 - a. **Cohen CR**, Moscicki A, Scott ME, Ma Y, Shiboski S, Bukusi E, Daud I, Rebbapragada A, Brown J, Kaul R. Increased Levels of Immune Activation in the Genital Tract of Healthy Young Women from sub-Saharan Africa. *AIDS*, 2010;24:2069-2074. PMID: 20588163.
 - b. Mosckicki A, Kaul R, Yifei MA, Scott ME, Daud I, Bukusi EA, Shiboski S, Rebbapragada A, Huibner S, **Craig R. Cohen**. Measurement of mucosal biomarkers in a phase 1 trial of intravaginal 3% SPL 7013 gel (VivaGel®) to assess expanded safety. *JAIDS*, 2011, Nov 7. PMID: 22067666 PMCID: PMC3261360.
 - c. **Cohen CR**, Plummer FA, Mugo N, Maclean I, Shen C, Bukusi EA, Irungu E, Sinei S, Bwayo J, Brunham RC. Increased interleukin-10 in the the endocervical secretions of women with non-ulcerative sexually transmitted diseases: a mechanism for enhanced HIV-1 transmission? *AIDS*. 1999 Feb 25;13(3):327-32. PMID: 10199222.
 3. I was the first person to describe the association between bacterial vaginosis (BV) and HIV. My work in this area has continued in two related areas. Starting in 2004 I forged a relationship with Osel Inc., a company which is developing bacterial probiotics. The company has two major products under investigation including *Lactobacillus crispatus* CTV-05 (LACTIN-V) and a genitally modified product, *Lactobacillus jensenii* 1666 (MucoCept) which produces the potent antiviral compound cyanovirin-N. I led as PI a dose-ranging phase 1 and phase 2a trial of LACTIN-V. These studies determined that the product was well tolerated, safe, and had good colonization rates in women treated with antibiotics for BV. A request for a task-order from the NIH was recently requested through the STAR STI CTG for me to lead a phase 2b trial of LACTIN-V to prevent recurrence of BV. In addition, I have been working closely with Osel to plan the clinical development of MucoCept, which has the potential to prevent BV and HIV. In November 2014, I submitted as PI a U19 grant to NIAID which included four projects and three cores. Lastly, I published a manuscript in PLOS Medicine (site-PI of Partners' HSV-2 study) in July 2012 that included over 2,200 female HIV-positive/male HIV-negative discordant couples. This study found a three-fold increased risk of female-to-male HIV transmission in women with BV in comparison to women with normal vaginal flora. Thus, this study demonstrated the potential of the human genital microbiota to prevent reproductive tract infections including HIV.
 - a. **Cohen CR**, Duerr A, Pruthithada N, Ruggao S, Hillier S, Garcia P, Nelson K. Bacterial vaginosis and HIV seroprevalence among female commercial sex workers in Chang Mai, Thailand. *AIDS*. 1995 Sep;9(9):1093-7. PMID: 8527084.
 - b. Hemmerling A, Harrison W, Schroeder A, Park J, Korn A, Shiboski S, **Cohen CR**. Phase 1 Dose-ranging Safety Trial Testing *Lactobacillus crispatus* CTV-05 (LACTIN-V) for the Prevention of Bacterial Vaginosis. *Sex Transm Dis*. 2009 Sep;36(9):564-9. PMID: 19543144.
 - c. Hemmerling A, Harrison W, Schroeder A, Park J, Korn A, Shiboski S, Foster-Rosales A, **Cohen CR**. Phase 2a Study Assessing Colonization Efficiency, Safety and Acceptability of *Lactobacillus crispatus* CTV-05 (LACTIN-V) in Women with Bacterial Vaginosis. *Sex Trans Dis*, 2010, Jul 16. PMID: 20644497.

- d. **Cohen CR**, Lingappa JR, Baeten JM, Ngayo MO, Spiegel CA, Hong T, Donnell D, Celum C, Kapiga S, Delany S, Bukusi EA, for the Partners in Prevention HSV/HIV Transmission Study Team. Bacterial vaginosis associated with increased risk of female-to-male HIV-1 transmission: a prospective cohort analysis among African couples. *PLoS Medicine*, 2012, PMID: 22745608 PMCID: PMC3383741.
4. I am the PI/founding director of Family AIDS Care and Education Services (FACES: www.faces-kenya.org), and President's Emergency Plan for AIDS Relief (PEPFAR)-funded program focused on HIV care, treatment and prevention in western Kenya. FACES, initiated in 2005, now provides HIV care and treatment services to over 138,000 persons at 77 health care facilities. In addition, FACES serves as the foundation for a growing number of clinical and implementation research studies (including EA leDEA), most of which focus on the intersection of HIV and reproductive health. FACES is a major innovator of HIV care and treatment in Kenya, with impact on HIV care, treatment and prevention throughout sub-Saharan Africa. In addition, through FACES we have trained over 200 students, residents and fellows, both Kenyan and from UCSF and other US institutions. I am the Director/PI of several training programs, including the GloCal Health Fellowship (Fogarty International Center), Reproductive Infectious Disease Fellowship, and Student Training and Education Program (STEP).
- Lewis-Kulzer JA, Marima R, Penner JA, Oyaro P, Oyanga A, Shade SB, Blat CC, Nyabiage L, Mwachari C, Muttai H, Bukusi EA, **Cohen CR**. Family model of HIV care and treatment - building on family strengths. *J International AIDS Society*, 2012. doi:10.1186/1758-2652-15-8.
 - Dillabaugh L, Kulzer JL, Owuor K, Ndege V, Oyanga A, Ngugi E, Shade S, Bukusi EA and **Cohen CR**. Towards elimination of mother-to-child transmission of HIV: the impact of a rapid results initiative in Nyanza Province, Kenya. *AIDS Research and Treatment*, 2012, PMID: 22548155 PMCID: PMC3324880.
 - Cohen CR**, Steinfeld R, Weke E, Bukusi EA, Hatcher AM, Shiboski S, Rheingans R, Scow KM, Butler LM, Otieno P, Dworkin SL, Weiser SD. *Shamba Maisha*: Pilot agricultural intervention for food security and HIV health outcomes in Kenya: Design, methods, baseline results and process evaluation of a cluster-randomized controlled trial. Springer Plus, in press, 2015.
 - Turan JM, Onono M, Steinfeld RL, Shade SB, Owuor K, Washington S, Bukusi EA, Ackers ML, Kioko J, Interis E, **Cohen CR**. Effects of antenatal care and HIV treatment integration on elements of the PMTCT cascade: Results from a cluster-randomized controlled trial in Kenya. *JAIDS*, in press, 2015.
5. I have been the PI of two related cluster randomized controlled trials. The first evaluated the impact of the integration of family planning services in to HIV clinics, and the second studied the impact of the integration of HIV care and treatment in to the maternal child health clinics for HIV-infected pregnant women and their newborns. We recently published results from the family planning and HIV service integration which found a >70% increase in the use of more effective contraception among women enrolled at intervention vs. control facilities. These data were presented to the Office of the Global AIDS Campaign in DC, and in part led to the inclusion of "integration" as one of the 21 PEPFAR indicators. Following this work, I was asked by the Bill & Melinda Gates Foundation to support the Kenyan Ministry of Health to develop a Sexual & Reproductive Health/HIV integration toolkit to aid the expansion of integrated services in the country.
- Tao A, Onono M, Baum S, Grossman D, Steinfeld R, **Cohen CR**, Bukusi EA, Newmann S. Providers' perspectives on male involvement in family planning in the context of an RCT evaluating integrating family planning into HIV care in Nyanza, Kenya. *AIDS Care*, 2014, PMID: 25329436.
 - Grossman D, Onono M, Newmann SJ, Blat C, Bukusi EA, Shade SB, Steinfeld R, **Cohen CR**. Integration of family planning services into HIV care and treatment in Kenya: a cluster-randomized trial. *AIDS*, 2013, PMID: 24088687.
 - Shade SB, Kevany S, Onono M, Ochieng G, Steinfeld R, Grossman D, Newmann S, Blat C, Bukusi EA, **Cohen CR**. Cost, cost-efficiency and cost-effectiveness of integrated family planning and HIV services. *AIDS*, 2013, PMID: 2408868
 - Newmann S, Grossman D, Blatt C, Onono M, Bukusi E, Shade S, **Cohen CR**. Does integrating family planning into HIV care and treatment impact intention to use contraception? Patient perspectives from HIV-infected individuals from Nyanza Province, Kenya. *Intl J Obstet Gynecol*, 2013, PMID: 24008310.

D. Research Support

Ongoing Research Support

Cohen, Craig R.

1R01MH107330-01 (PIs: Cohen, Weiser) 5/7/15 - 4/30/17

NIH/NIMH

Agricultural Intervention for Food Security and HIV health outcomes in Kenya

The study aim is to determine the impact of a multisectoral agricultural intervention among HIV- infected farmers on ART on HIV clinical outcomes.

U01AI099959 (PI: Havlir) 8/1/12 - 6/30/17

NIH/NIAID

Adult AIDS Clinical Trials Unit (ACTG)

Sustainable East Africa Research in Community Health (SEARCH)

SEARCH is a community cluster randomized trial in Uganda and Kenya of widespread early community wide antiretroviral therapy (ART), where primary endpoints will include both community health and community economic status.

Role: Co-Investigator

1R25TW009343-01 (PIs: Cohen, Strathdee) 4/04/12 – 6/30/17

NIH – Fogarty

University of California Global Health Institute Program for Fellows and Scholars:

This project will train pre-doctoral scholars and post-doctoral fellows from UC San Francisco, UC San Diego, UC Los Angeles, UC Davis and 21 international collaborating institutions from low- and middle-income countries in a wide range of pressing and emerging global health issues.

GH001947 (PI: Cohen) 9/30/16 - 9/29/21

Centers for Disease Control (CDC)

Supporting the Implementation and Expansion of High Quality, Sustainable and Comprehensive HIV Prevention, Care and Treatment Programs in the Western Region and Turkana County of the Republic of Kenya under the President's Emergency Plan for AIDS Relief (PEPFAR) (Family AIDS Care and Education Services)

This project will expand comprehensive, integrated HIV services and strengthen local healthcare systems to reduce HIV incidence, morbidity, and mortality in Kisumu County, Kenya. The primary objectives are to expand primary prevention efforts; strengthen comprehensive HIV prevention, care, and treatment service delivery; and build local Government of Kenya HIV service and system capacity.

U01AI23082 (PI: Cohen) 8/6/15 - 7/31/17

NIAID

PRECLINICAL DEVELOPMENT OF MUCOCEPT

The overall goal of the Integrated Pre-Clinical & Clinical Program for HIV Microbicides and Biomedical Prevention (IPCP)-MucoCept is to advance the development of *Lactobacillus jensenii* 1153-1666 as a recombinant live biotherapeutic product (rLBP), leading to the testing of MucoCept in a Phase 1 clinical trial following the completion of this IPCP

CRB-SSS-S-15-004544 (Cohen: Sub-PI) 8/6/15 - 7/31/17

Social & Scientific Systems, Inc. Prime Sponsor: NIH (HHSN272201300014I)

Phase II-b Randomized Double-Blind Placebo-Controlled Trial of *Lactobacillus crispatus* CTV-05 (LACTIN-V) to Prevent the Recurrence of Bacterial Vaginosis

The primary objective is to estimate the efficacy of repeated doses of LACTIN-V in preventing BV recurrence.

3R25TW009343 (Cohen: PI) 7/1/12 – 6/30/17

FIC

University Of California Global Health Institute Program For Fellows And Scholars (GloCal Health Fellowship)

This program supports year-long global health fellowships to advanced doctoral and professional students, US post-doctoral fellows and post-doctoral fellows from 27 partner institutions in low- and middle-income countries.