BIOGRAPHICAL SKETCH

NAME: Jeffrey D. Klausner, MD, MPH

eRA COMMONS USER NAME (credential, e.g., agency login): jklausner

POSITION TITLE: Professor of Medicine and Public Health

EDUCATION/TRAINING:

INSTITUTION AND LOCATION	DEGREE (if	Completion Date	FIELD OF STUDY
	applicable)	MM/YYYY	
Cornell University, Ithaca, New York	A.B.	06/1986	Chemistry and Art
Cornell University Medical School, New York, NY	M.D.	06/1991	Medicine
Harvard School of Public Health, Boston, MA	M.P.H.	06/1995	International Health
Centers for Disease Control and Prevention, GA	EIS	06/1997	Epidemiology
University of Washington, Seattle, WA	Fellow	06/1998	Infectious Diseases

Personal Statement

Jeffrey D. Klausner, MD, MPH has conducted syphilis research for over 20 years since serving as CDC EIS Officer with the San Francisco Department of Public Health in 1995. Prof. Klausner is the Senior Editor of the McGraw-Hill textbook Current STD Diagnosis and Management and serves as a policy advisor and technical workgroup member for syphilis prevention and control for the CDC and WHO. As Deputy Health Officer and Director of STD Prevention and Control Services for the San Francisco Department of Health from 1998-2009, Branch Chief of the US CDC HIV and TB Branch in South Africa 2009-2011 and current Professor of Medicine, Infectious Diseases and Epidemiology and Attending Consulting Physician in HIV/AIDS and Infectious Diseases at the David Geffen School of Medicine, Prof. Klausner is recognized as an expert in STI/HIV diagnostics, epidemiology, prevention and treatment. Prof. Klausner has over 400 peer-reviewed publications in STI/HIV research (e.g., Science, NEJM, JAMA, Lancet, Am J. Public Health) and has led or participated in dozens of NIH-, CDC- or industry-funded STI/HIV clinical trials, observational studies and program evaluations.

Building on their NIH-funded capacity-building program to study the epidemiological and biological determinants of syphilis (PI: Caceres, R01 Al099727), Dr. Klausner will act as PI along with Dr. Caceres and directly oversee Aims 1 and 3. As a research collaborator with Dr. Caceres since 1999, Drs. Klausner and Caceres have conducted 2 previous other major NIH-funded studies in Peru: 1) the NIMH Collaborative STD/HIV Prevention Trial (U10 MH61536) and 2) an investigation of the impact of enhanced partner management and community mobilization on STI/HIV incidence (R01 MH078752). Dr. Klausner is currently an active mentor in the NIH UCLA SAPHIR program in Peru (R25 MH087222) and co-investigator in a new study to investigate STI treatment and behavior modification in HIV prevention (R34 MH10527) in MSM in Lima. Dr. Klausner visits Peru quarterly, maintains weekly teleconference calls and oversees the clinical sexual health laboratory at Cayetano Heredia University of Peru. He regularly supports UCLA students, residents and junior faculty as well as pre and post-doctoral students working in Peru in epidemiologic and laboratory science. Finally, he has active collaborations with the US Navy Medical Research Unit in Lima, Peru, and has transferred molecularly-based diagnostic technology to that group to perform surveillance for emerging infections in particular antimicrobial-resistant bacterial sexually transmitted pathogens.

B. Positions and Honors

1991-1994	Intern and Resident, Medicine, NYU-Bellevue Hospital Center, NY
1995-1997	Officer, Epidemic Intelligence Service, Centers for Disease Control, Atlanta, GA
1997-1998	Senior Clinical Fellow, Infectious Diseases, University of Washington, Seattle, WA
1998-2004	Assistant Clinical Professor of Medicine, University of California, San Francisco
1998-2005	Medical Director, San Francisco City Clinic, San Francisco municipal STD Clinic
1998-2009	Director, San Francisco, Department of Public Health, STD Services
2004-2011	Associate Clinical Professor of Medicine, University of California, San Francisco
2009-2012	Member, WHO workgroup HIV and STD prevention for MSM/Transgender persons

2009-2011 2012-Present 2013-Present 2013-Present	Chief, HIV and TB Branch, Centers for Disease Control, South Africa Professor of Medicine, University of California, Los Angeles Professor of Public Health, University of California, Los Angeles Member, WHO workgroup STI Treatment Guidelines
2002	San Francisco Suicide Prevention Community Award
2002	American STD Association, Young Investigator Award
2006	UCSF Association of Clinical Faculty Special Recognition Award
2009	Beyond AIDS Nettie Award
2010	Bay Area's Top Doctors and Dentists Award, Internal Medicine
2010	Clinical Infectious Diseases Award for Outstanding Review
2016	CDC Jack N. Spencer Career Achievement Award

C. Contributions to Science

- 1. Pathophysiology and clinical aspects of syphilis: There are 6 million new cases of syphilis annually and a current exponentially growing epidemic of syphilis among men who have sex with men. Since first describing the elimination and re-introduction of syphilis in Seattle-King County in 1999 (*Am J Pub Health*, 1999), I have been one of the leading public health researchers describing clinical manifestations and pathogenesis of the disease and creating and evaluating new interventions to control syphilis and (*AIDS* 2004, *BMC ID* 2013; *STD* 2015). Based on my research and those replicated by others, the US DHHS recommendations for syphilis screening in HIV-infected patients include testing every 3-6 months. Furthermore, based on my prior clinical studies, the CDC STD Guidelines include recommendations for the use of both treponemal and non-treponemal testing in patient presenting symptomatically, in particular with primary stage manifestations. Currently I provide guidance in the frequency and type of STD screening in patients on Pre Exposure Prophylaxis or PrEP for HIV infection. My earlier work describing the frequency and clinical outcomes of patients with azithromycin-resistant syphilis infection resulted in the removal of azithromycin as recommended alternative therapy in patients with syphilis. My published work on the effectiveness of doxycycline treatment provided evidence to maintain doxycycline as a recommended alternative treatment.
 - a. Williams LA, Klausner JD, Whittington WL, Handsfield HH, Celum C, Holmes KK. <u>Elimination and reintroduction of primary and secondary syphilis</u>. Am J Public Health. 1999 Jul;89(7):1093-7. PubMed PMID: 10394323; PubMed Central PMCID: PMC1508824.
 - b. Buchacz K, Patel P, Taylor M, Kerndt PR, Byers RH, Holmberg SD, Klausner JD. <u>Syphilis increases HIV viral load and decreases CD4 cell counts in HIV-infected patients with new syphilis infections.</u> AIDS. 2004 Oct 21; 18(15): 2075-9. PubMed PMID: 15577629.
 - c. Jinno S, Anker B, Kaur P, Bristow CC, Klausner JD. <u>Predictors of serological failure after treatment in HIV-infected patients with early syphilis in the emerging era of universal antiretroviral therapy use</u>. BMC Infect Dis. 2013 Dec 26;13:605. doi: 10.1186/1471-2334-13-605. PubMed PMID: 24369955; PubMed Central PMCID: PMC3877955
 - d. Bolan RK, Beymer MR, Weiss RE, Flynn RP, Leibowitz AA, Klausner JD. <u>Doxycycline prophylaxis to reduce incident syphilis among HIV-infected men who have sex with men who continue to engage in high-risk sex: a randomized, controlled pilot study.</u> Sex Transm Dis. 2015 Feb;42(2):98-103. doi: 10.1097/OLQ.000000000000216. PubMed PMID: 25585069; PubMed Central PMCID: PMC4295649.
- 2. <u>Point-of-care and near care diagnostic testing for STIs</u>: With over 500 million annual curable sexually transmitted infections (STIs) globally, STIs remain a common and preventable means of adverse pregnancy and birth outcomes. Prematurity is the leading cause of under age 5 years mortality and undiagnosed and untreated STIs are one of the most significant causes of prematurity. New diagnostics that are inexpensive, easy-to-use and accurate are urgently needed in low and middle income countries. Since the mid-2000s, I have been researching, developing and evaluation point-of-care diagnostics for HIV, syphilis, chlamydial and gonococcal infections (*CID*, 2008, *Trop Med Int Health* 2009, *PloS One* 2013, *Open Forum ID* 2014). Currently I have STI screening projects in Democratic Republic of Congo, Botswana, South Africa, Haiti and India building upon and extending earlier findings of high-rates of curable STIs in pregnancy associated with adverse pregnancy and birth outcomes including increased rates of mother-to-child transmission of HIV infection. Using those data, I aim to conduct clinical trials demonstrating the impact and cost-benefit of STI screening and treatment in pregnancy in low and middle income country settings.

- a. Philip SS, Ahrens K, Shayevich C, de la Roca R, Williams M, Wilson D, Bernstein K, Klausner JD. Evaluation of a new point-of-care serologic assay for herpes simplex virus type 2 infection. Clin Infect Dis. 2008 Nov 15;47(10):e79-82. doi: 10.1086/592696. PubMed PMID: 18840082.
- b. Madhivanan P, Krupp K, Hardin J, Karat C, Klausner JD, Reingold AL. <u>Simple and inexpensive point-of-care tests improve diagnosis of vaginal infections in resource constrained settings</u>. Trop Med Int Health. 2009 Jun;14(6):703-8. doi: 10.1111/j.1365-3156.2009.02274.x. Epub 2009 Apr 20. PubMed PMID: 19392745; PubMed Central PMCID: PMC3625926.
- c. Pilcher CD, Louie B, Facente S, Keating S, Hackett J Jr, Vallari A, Hall C, Dowling T, Busch MP, Klausner JD, Hecht FM, Liska S, Pandori MW. <u>Performance of rapid point-of-care and laboratory tests for acute and established HIV infection in San Francisco</u>. PLoS One. 2013 Dec 12;8(12):e80629. doi: 10.1371/journal.pone.0080629. eCollection 2013. PubMed PMID: 24349007; PubMed Central PMCID: PMC3861178.
- d. Bristow CC, Leon SR, Ramos LB, Vargas SK, Flores JA, Konda KA, Caceres CF, Klausner JD. Laboratory Evaluation of a Dual Rapid Immunodiagnostic Test for HIV and Syphilis Infection. Journal of clinical microbiology. 2014. Epub 2014/11/08. doi: 10.1128/jcm.02763-14. PubMed PMID: 25378568.
- 3. Molecular epidemiology of infectious diseases: The diagnosis, prevention and control of infectious diseases require accurate and timely diagnosis and the easy identification of strains associated with specific exposure or transmission behavior and clinical outcomes. In 2002 I described the use of molecular assays for the diagnosis of pharyngeal gonorrhea (*CID*, 2002) and later the use of molecular assays to describe the clinical epidemiology of proctitis (*CID*, 2004). I went on to show how nucleic acid tests could be used to monitor and measure clinical outcomes of antimicrobial-resistant syphilis (NEJM, 2004) and detect acute HIV infection (*NEJM* 2005). In 2014 based on my work and others, the WHO and CDC recommended the use of nucleic acid amplification tests for the routine detection of extragenital chlamydial and gonococcal infections. I am currently working with the NIH and FDA to develop clinical performance data for the FDA-approval of those test platforms. In addition, given the specter of untreatable multidrug resistant gonorrhea, my work continues with NIH-funded projects developing and clinically validating new molecular assays to detect in real-time drug-resistant gonorrhea in clinical specimens.
 - a. Page-Shafer K, Graves A, Kent C, Balls JE, Zapitz VM, Klausner JD. <u>Increased sensitivity of DNA amplification testing for the detection of pharyngeal gonorrhea in men who have sex with men.</u> Clin Infect Dis. 2002 Jan 15;34(2):173-6. Epub 2001 Dec 7. PubMed PMID: 11740704.
 - b. Klausner JD, Kohn R, Kent C. <u>Etiology of clinical proctitis among men who have sex with men.</u> Clin Infect Dis. 2004 Jan 15;38(2):300-2. Epub 2003 Dec 19. PubMed PMID: 14699467.
 - c. Lukehart SA, Godornes C, Molini BJ, Sonnett P, Hopkins S, Mulcahy F, Engelman J, Mitchell SJ, Rompalo AM, Marra CM, Klausner JD. <u>Macrolide resistance in Treponema pallidum in the United States and Ireland.</u> N Engl J Med. 2004 Jul 8;351(2):154-8. PubMed PMID: 15247355.
 - d. Klausner JD, Grant RM, Kent CK. <u>Detection of acute HIV infections</u>. N Engl J Med. 2005 Aug 11;353(6):631-3; author reply 631-3. PubMed PMID: 16093476.
- 4. <u>Biomedical HIV Prevention</u>: HIV infection continues to be hyper-epidemic in high-risk populations globally with annual incidence rates of 5-10%. Biomedical prevention and combinations thereof—testing, treatment and male circumcision—offer the best opportunity for reducing population-level incidence. From conducting early acceptability studies in various populations to describing the epidemiology of male circumcision in California (*PLoS One* 2007, *STD*, 2011), I have been a leading researcher and advocate informing the evidence base for newborn and adult male circumcision (*Science*, 2008).
 - a. Kojima N, Bristow C, Pollock N, Crouse P, Theodore H, Bonhomme J, Gaston C, Devieu J, J Pape, Klausner, JD. Rapid Training and Implementation of the Pollock Technique, a Safe, Effective Newborn Circumcision Procedure, in a Low-Resource Setting. Global Pediatric Health. Published June 11, 2015, January-December 2015 vol. 2 2333794X15589114. [No PMID]
 - b. Madhivanan P, Krupp K, Kulkarni V, Kulkarni S, Klausner JD. <u>Acceptability of male circumcision for HIV prevention among high-risk men in Pune, India.</u> Sex Transm Dis. 2011 Jun;38(6):571. doi: 10.1097/OLQ.0b013e318219c930. PubMed PMID: 21836398.
 - c. Potts M, Halperin DT, Kirby D, Swidler A, Marseille E, Klausner JD, Hearst N, Wamai RG, Kahn JG, Walsh J. <u>Public health. Reassessing HIV prevention.</u> Science. 2008 May 9;320(5877):749-50. doi: 10.1126/science.1153843. PubMed PMID: 18467575; PubMed Central PMCID: PMC3501984.
 - d. Klausner JD. Newborn circumcision: ensuring universal access. Sex Transm Dis. 2013 Jul;40(7):526-7.

5. Internet, social media and HIV/STD prevention: Networks of interconnected persons are critical to the introduction and spread of infectious diseases, in particular those transmitted through sexual activity. In 2000 I described the first outbreak of syphilis related to men meeting partners in an Internet chat room (JAMA, 2000) and went on to develop and evaluate Internet-based interventions for disease control (AIDS Care, 2004; STD 2005; PloS Med 2008). In 2004, I started "AskDrK.org," at the time one of the most popular sites for up-to-date and clear sexual health information for adolescents and sexual minorities. The Internet and social media have since become the *sine qua non* opportunity for health education and interventions to reach high risk groups regarding sexual and reproductive health.

- a. Klausner JD, Wolf W, Fischer-Ponce L, Zolt I, Katz MH. <u>Tracing a syphilis outbreak through cyberspace</u>. JAMA. 2000 Jul 26;284(4):447-9. PubMed PMID: 10904507.
- b. Klausner JD, Levine DK, Kent CK. <u>Internet-based site-specific interventions for syphilis prevention among gay and bisexual men.</u> AIDS Care. 2004 Nov;16(8):964-70. PubMed PMID: 15511728.
- c. McFarlane M, Kachur R, Klausner JD, Roland E, Cohen M. <u>Internet-based health promotion and disease control in the 8 cities: successes, barriers, and future plans.</u> Sex Transm Dis. 2005 Oct;32(10 Suppl):S60-4. Review. PubMed PMID: 16205295.
- d. Levine D, Woodruff AJ, Mocello AR, Lebrija J, Klausner JD. <u>inSPOT: the first online STD partner notification system using electronic postcards.</u> PLoS Med. 2008 Oct 21;5(10):e213. doi: 10.1371/journal.pmed.0050213. PubMed PMID: 18942887; PubMed Central PMCID: PMC2570420.

Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/jeffrey.klausner.1/bibliography/47475064/public/

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

NIH/NIAID. 1R01AI099727 PI: Caceres 07/2012-06/2017

Title: Syphilis: Translating technology to understand a neglected epidemic

Role: Co-director of project responsible for overall implementation with specific emphasis on

biologic measures, data quality and interpretation of findings.

Goal: Increase research capacity in Lima, Peru, through studying syphilis in high-risk men

NIH-NIAID-SBSS-DMID-NIHAI201112 PI: Klausner 07/2013-06/2020

Title: Sexually Transmitted Infection Clinical Trials Group, 2013-2020 Role: Principal Investigator responsible for study network implementation

Goal: Implement clinical prevention and treatment trials in STIs

NIH-NIAID-1R21AI117256-01A1 PI: Klausner 04/2016-03/2018

Title: Reducing Excess Broad-Spectrum Antibiotic Use in Gonorrhea Role: Principal Investigator responsible for overall study implementation

Goal: Evaluate a novel approach to controlling the spread of drug-resistant N. gonorrhoeae

NIH-NIAID-5R21AI109005-02 PI: Klausner 08/2014-03/2017

Title: Controlling Drug Resistant Gonorrhea with Real-Time PCR Susceptibility Testing

Role: Principal Investigator responsible for overall study implementation

Goal: Investigate use of real-time PCR to determine antimicrobial susceptibility of gonorrhea infections

CDC-200-2013-N15562 PI: Montoya 09/2013-06/2017

Title: A Waiting Room-Delivered Video to Enhance ART Care Continuum for HIV-Positive Minority Persons

Role: Co-investigator for video development and evaluation

Goal: Develop and evaluate a brief video to increase clinic retention in high-risk HIV-infected patients

NIH-NICHD-R21HD084274-01 PI: Klausner 9/2015-8/2017

Title: Pilot Study of STI Screening and Treatment for PMTCT, South Africa

Role: Principal Investigator responsible for overall study implementation

Goal: Evaluate the impact of STI point-of-care screening and treatment on birth and newborn outcomes

NIH-NIAID-UM1AI104681 Pls: Chambers and Fowler 11/2014-10/2018

Title: Antibiotic Resistance Leadership Group

Role: Co-investigator/ Protocol Chair of Extra-genital CT/NG study

Goal: Evaluate various approaches to addressing antibiotic resistant infections

NIH-NIAID-R21AI120838 PI: Shin 08/2015-7/2017

Title: Utility of Deep Sequencing for Detecting Heteroresistant MTB Infections among HIV infected Persons

Role: Co-investigator assisting with study design and epidemiologic analysis

Goal: Determine the frequency and impact of multiple MTB infections

NIH-NIDA-1U01DA036926-01A1 PI: Kipke 08/2015-08/2019

Title: Young men of color who have sex with men cohort study

Role: Co-investigator responsible for STI assessments and biospecimen management

Goal: Determine and describe interventions to reduce HIV risk in young men

Recently Completed Research Support

NIH/NIAID. 1R01AI097045 PI: Zetola 09/2011-08/2016

Title: Molecular epidemiology of TB in low and high HIV prevalence settings, Botswana.

Role: Consultant responsible for assisting in intervention development, study design, outcome

assessment, and interpretation of findings.

Goal: Understand the transmission of TB in different epidemiologic settings

CDC-200-2013-N15562 PI: Montoya 09/2013-06/2016

Title: A Video to Enhance ART Care Continuum for HIV-Positive Minority Persons

Role: Co-investigator for video development and evaluation

Goal: Develop and evaluate a video to increase clinic retention in HIV-infected patients

NIH-NIAID-1R21AI109005-01A PI: Klausner 08/2014-07/2016

Title: Controlling Drug Resistant Gonorrhea with Real-Time PCR Susceptibility Testing

Role: Principal Investigator responsible for overall study implementation

Goal: Develop and evaluate a new molecular assay for gonorrhea resistance on treatment

NSF-1549003 PI: Chiu 01/2016-06/2016

Title: Point-of-care enhanced lateral flow assay for *Chlamydia trachomatis*

Role: Co-investigator in Chlamydia trachomatis test development

Goal: Develop and evaluate a new point-of-care tests for Chlamydia trachomatis

NIH-NIMH-1R21HD076685-01A1 PI: DeVieux 07/2013-06/2015

Title: An innovative video/ SMS intervention for newborn medical male circumcision Role: Co-investigator helping with study design, measurement and evaluation

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Goal: Evaluate a brief video on demand for newborn circumcision

NIH/NIAID AI28697 UCLA CFAR sub-award PI: Klausner 11/2012-11/2014

Title: Parental decision-making for HIV prevention, Haiti

Role: Principal Investigator responsible for ensuring study implementation and completion

Goal: Identify facilitators for newborn health intervention acceptance

NIH/NIDA 3R01DA030234-Suppl PI: Fisher 08/2013-07/2014

Title: Behavioral Science Aspects of rapid test acceptance

Role: Co-investigator responsible for study design, implementation and analysis

Goal: Determine the performance of rapid dual HIV and syphilis tests

NIH/NIMH 5P30MH058107 PI: Rotherham 08/2013-7/2014

Title: CFAR supplement using technology to address HIV/AIDS

Role: Co-investigator responsible for intervention development and study design

Goal: Develop new interventions to increase HIV testing among high-risk men in Los Angeles

NIH-Fogarty Center-D71 PI: Caceres 07/2013-06/2014

Title: Planning a Strategic HIV Population Science Training Program at UPCH in Peru

Role: Co-investigator responsible for proposal development

Goal: Develop and submit a proposal for an HIV science training center