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 applicable) | Completion DateMM/YYYY | FIELD OF STUDY |
| --- | --- | --- | --- |
| Cornell University, Ithaca, New York | A.B. | 06/1986 | Chemistry & Art History |
| 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

I have conducted research and implementation science in infectious disease epidemiology, prevention, diagnosis and control for over 25 years with a specific interest in sexual and reproductive health and in the prevention of preterm delivery and neonatal morbidity and mortality. I have multiple NIH-funded projects past and present studying interventions and pathobiologic mechanisms of preterm delivery and low birthweight infants. I recently published a review of an international meeting I convened on the role of STIs in pregnancy and prevention and research challenges (*STD Journal*, 2020)

I have over 550 peer-reviewed publications in public health, disease prevention and STI/HIV research (e.g., in *Science, NEJM, JAMA, Lancet, Am J. Public Health*). I have led or participated in dozens of NIH-, CDC- or industry-funded STI/HIV clinical trials, observational studies and program evaluations. I am the Senior Editor of the McGraw-Hill textbook *Current STD Diagnosis and Management.*  I serve as a policy advisor and technical workgroup member for HIV and STI prevention and treatment for the CDC and WHO.

For this project, I will provide medical leadership and expertise in study methods, implementation, data collection, analysis and interpretation.

B. Positions and Honors

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| --- | --- |
| 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 |
| 2004-20112009-20122009-2011 | Associate Clinical Professor of Medicine, University of California, San FranciscoMember, WHO workgroup HIV and STD prevention for MSM/Transgender personsChief, HIV and TB Branch, Centers for Disease Control, South Africa |
| 2012-Present2013-Present2013-Present | Professor of Medicine, University of California, Los AngelesProfessor of Public Health, University of California, Los AngelesMember, WHO workgroup STI Treatment Guidelines |
| 2002200220062009201020102016 | San Francisco Suicide Prevention Community AwardAmerican STD Association, Young Investigator Award UCSF Association of Clinical Faculty Special Recognition AwardBeyond AIDS Nettie HIV Prevention AwardBay Area’s Top Doctors and Dentists Award, Internal Medicine*Clinical Infectious Diseases* Award for Outstanding ReviewCDC Jack N. Spencer Career Achievement Award |

C. Contributions to Science

1. Internet, social media and HIV/STD prevention: Networks of interconnected persons are critical to the introduction and spread of infectious diseases, especially 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. I have helped the Internet and social media become the *sine qua non* opportunity for sexual health research, health education and interventions to reach high risk groups regarding sexual and reproductive health.

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

2. Biomedical HIV Prevention: 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 PrEP—offer the best opportunity for reducing population-level incidence. From conducting early acceptability studies in various populations to implementing telePrEP and describing the epidemiology of PrEP use associated with STIs, I have been a leading researcher and advocate informing the evidence base for biomedical HIV prevention with PrEP.

1. Liu AY, Kittredge PV, Vittinghoff E, Raymond HF, Ahrens K, Matheson T, Hecht J, Klausner JD, Buchbinder SP. Limited knowledge and use of HIV post- and pre-exposure prophylaxis among gay and bisexual men. J Acquir Immune Defic Syndr. 2008 Feb 1;47(2):241-7. PubMed PMID: 18340656. PubMed Central ID not available.
2. Scott HM, Klausner JD. Sexually transmitted infections and PrEP: challenges and opportunities among men who have sex with men in the US. AIDS Res Ther. 2016 Jan 19;13:5. PubMed PMID: 26793265; PubMed Central PMCID: PMC4719214.
3. Refugio ON, Kimble MM, Silva CL, Lykens JE, Bannister C, Klausner JD. PrEPTECH: A Telehealth-Based Initiation Program for HIV Pre-exposure Prophylaxis in Young Men of Color Who Have Sex With Men. A Pilot Study of Feasibility. J Acquir Immune Defic Syndr. 2019 Jan 1;80(1):40-45. PubMed PMID: 30272632; PubMed Central PMCID: PMC6291368.
4. Wong KYK, Stafylis C, Klausner JD. Telemedicine: a solution to disparities in human immunodeficiency virus prevention and pre-exposure prophylaxis uptake, and a framework to scalability and equity. *Mhealth*.2020;6:21.2020 Apr 5. doi:10.21037/mhealth.2019.12.06. PMCID: PMC7138949

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.

1. Page-Shafer K, Graves A, Kent C, Balls JE, Zapitz VM, Klausner JD. Increased sensitivity of DNA amplification testing for the detection of pharyngeal gonorrhea in men who have sex with men. Clin Infect Dis. 2002 Jan 15;34(2):173-6. Epub 2001 Dec 7. PubMed PMID: 11740704.
2. Klausner JD, Kohn R, Kent C. Etiology of clinical proctitis among men who have sex with men. Clin Infect Dis. 2004 Jan 15;38(2):300-2. Epub 2003 Dec 19. PubMed PMID: 14699467.
3. Lukehart SA, Godornes C, Molini BJ, Sonnett P, Hopkins S, Mulcahy F, Engelman J, Mitchell SJ, Rompalo AM, Marra CM, Klausner JD. Macrolide resistance in Treponema pallidum in the United States and Ireland. N Engl J Med. 2004 Jul 8;351(2):154-8. PubMed PMID: 15247355.
4. Klausner JD, Grant RM, Kent CK. Detection of acute HIV infections. N Engl J Med. 2005 Aug 11;353(6):631-3; author reply 631-3. PubMed PMID: 16093476.

4. Online, point-of-care and near care diagnostic testing for STIs: 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.

1. 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.
2. Madhivanan P, Krupp K, Hardin J, Karat C, Klausner JD, Reingold AL. Simple and inexpensive point-of-care tests improve diagnosis of vaginal infections in resource constrained settings. 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.
3. 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. Performance of rapid point-of-care and laboratory tests for acute and established HIV infection in San Francisco. PLoS One. 2013 Dec 12;8(12):e80629. doi: 10.1371/journal.pone.0080629. eCollection 2013. PubMed PMID: 24349007; PubMed Central PMCID: PMC3861178.
4. 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.

5. 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.

1. Williams LA, Klausner JD, Whittington WL, Handsfield HH, Celum C, Holmes KK. Elimination and reintroduction of primary and secondary syphilis. Am J Public Health. 1999 Jul;89(7):1093-7. PubMed PMID: 10394323; PubMed Central PMCID: PMC1508824.
2. Buchacz K, Patel P, Taylor M, Kerndt PR, Byers RH, Holmberg SD, Klausner JD. Syphilis increases HIV viral load and decreases CD4 cell counts in HIV-infected patients with new syphilis infections. AIDS. 2004 Oct 21; 18(15): 2075-9. PubMed PMID: 15577629.
3. Jinno S, Anker B, Kaur P, Bristow CC, Klausner JD. Predictors of serological failure after treatment in HIV-infected patients with early syphilis in the emerging era of universal antiretroviral therapy use. BMC Infect Dis. 2013 Dec 26;13:605. doi: 10.1186/1471-2334-13-605. PubMed PMID: 24369955; PubMed Central PMCID: PMC3877955
4. Bolan RK, Beymer MR, Weiss RE, Flynn RP, Leibowitz AA, Klausner JD. 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. Sex Transm Dis. 2015 Feb;42(2):98-103. doi: 10.1097/OLQ.0000000000000216. PubMed PMID: 25585069; PubMed Central PMCID: PMC4295649.

**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-R01AI155217 PI: Klausner 07/13/2020-06/30/2025

Title: Clinical trial comparing the effectiveness of cefixime versus penicillin G for treatment of early syphilis

Role: PI

Goal: Study the efficacy of cefixime for treatment of early syphilis

NIH-NICHD-R21HD100821 PIs: Klausner and Morroni 02/22/2020-01/31/2022

Title: The diagnosis and treatment of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in pregnant women to prevent adverse neonatal consequences

Role: PI

Goal: Study outcomes and cost-effectiveness of STI screening in pregnancy

NIH-NIAID-R01AI149339 PIs: Klausner and Medina-Marino 01/07/2020-12/31/2024

Title: Clinical Study of STI Screening to Prevent Adverse Birth and Newborn Outcomes

Role: PI

Goal: Study implementation and outcomes of etiologic STD screening in pregnancy

NIH-NIAID-R44AI143012 PI: Schoolnik 03/22/2019-02/29/2021

Title: Development of preclinical and preanalytical evaluation of a rapid point-of-care NAAT device to determine ciprofloxacin sensitivity of gonococci in urogenital samples
Role: Co-investigator
Goal: Develop preliminary performance estimates of new point-of-care device

NIH-NIAID-R01AI139265 PI: Klausner and Caceres 09/01/2018-08/31/2022

Title: Syphilis immunology and biology to improve clinical management and vaccine design

Role: Principal Investigator
Goal: Describe new immune correlates of seroprotection against syphilis

NIH-NIDA-2UG1DA040309 PI: Marsch 06/01/2018-11/30/2020

Title: Using Social Media to Deliver HIV Self-Testing Kits and Link to Online PrEP Services
Role: Principal Investigator of NIDA Clinical Trial Network sub-study
Goal: Determine effectiveness of various Internet platforms for promoting HIV self-testing and PrEP uptake

NIH-NIMH-R01MH114891 PI: Wray 12/01/2017-10/31/2022

Title: Mobile health platform for providing real-time follow-up after home-based HIV self-testing
Role: Co-Investigator for Los Angeles site

Goal: Evaluate impact of electronic home-based HIV self-test

NIH-NICHD-U19HD089886 PI: Rotheram-Borus 09/30/2016-05/31/2021
Title: A Comprehensive Community-Based Strategy to Optimize the HIV Prevention and Treatment Continuum for Youth at HIV Risk, Acutely Infected and with Established HIV Infection
Role: Co-investigator
Goals: Reduce HIV/STIs among adolescents

Recently Completed Research Support

NIH-NIAID-SBSS-DMID-NIHAI201112 PI: Klausner 09/15/2013-07/28/2020

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-HHSN272201300014I PI: Klausner 07/15/2016-03/31/2020

Title: Clinical Validation of a Molecular Test for Ciprofloxacin-Susceptibility in *Neisseria Gonorrhoeae*

Role: Principal Investigator responsible for clinical trial

Goal: Measure efficacy of molecular laboratory assay to predict treatment outcomes

NIH-NIAID-1R21AI117256-01A1 PI: Klausner 04/01/2016-03/30/2019
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-NICHD-R21HD084274-01 PI: Klausner 09/01/2015-08/31/2018
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 PIs: Chambers and Fowler 11/01/2014-10/31/2018
Title: Performance of Nucleic Acid Amplification Tests for the Detection of NG and CT (pNAAT)
Role: Protocol Chair
Goal: Measure clinical performance of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* assays

CDC-200-2013-N15562 PI: Montoya 09/01/2013-08/31/2017

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