

Subject of Planned Report: This document summarizes the evidence informing clinical practices for the safe and effective provision of daily oral antiretroviral preexposure prophylaxis (PrEP) to uninfected sexually-active adults to reduce their risk of HIV acquisition.

Purpose of Planned Report: Provide evidence-based guidelines to clinicians and allied providers in clinical settings for the identification of sexually active adults at very high risk of HIV acquisition, prescription of PrEP medication, indicated HIV, STI, and safety laboratory assessments, patient education, medication adherence support, and HIV risk-reduction counseling. These recommendations do not address benefits and risks associated with PrEP-related support services performed by HIV prevention service providers in nonclinical settings or medical providers outside the United States.

Type of Dissemination: Highly Influential Scientific Assessments (HISA)

Timing of Review (including deferrals): March-April 2013

Type of Review (panel, individual or alternative procedure): individual

Opportunities for the Public to Comment (how and when): The recommendations in the guidelines will be presented for discussion at three open webinars in March and April 2013. The webinars will be recorded (audio) to provide a complete and accurate record. A summary of questions and suggestions offered will be posted on this website and shared with the individual peer reviewers listed below. Prior to writing the guidelines, multiple stakeholders (e.g., health departments, clinicians, HIV prevention service providers, technical experts, potential users) provided early input through a series of webinars and an external consultation in May 2011.

Peer Reviewers Provided with Public Comments before the Review: No

Anticipated Number of Reviewers: 6

Primary Disciplines or Expertise: infectious disease epidemiology; prevention, care and treatment of HIV, STD, and viral hepatitis; HIV program planning, HIV/AIDS prevention and care policy; HIV/AIDS guidelines
development and implementation, HIV prevention for MSM, heterosexual women and men, and injection drug users in the US.

**Reviewers Selected by (agency or designated outside organization):** Centers for Disease Control and Prevention (CDC)

**Public Nominations Requested for Reviewers:** No

**Charge to Peer Reviewers:** The documents that you will review are draft “US PHS Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2013: A Clinical Practice Guideline and US PHS Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2013: Clinical Providers’ Supplement” that will be published online at www.AIDSinfo.gov.

We request your expert opinion on:

1. whether any studies on which the recommendations were based were inappropriate as supporting evidence or were misinterpreted,
2. whether there are significant oversights, omissions, or inconsistencies that are critical for the intended audience of clinicians
3. whether the recommendations for the intended audience of clinicians are justified and appropriate.

After we review your comments, they will be posted without attribution along with our responses on this page (add link) at a later date.

**Selected Peer Reviewers**

**Name:** Dr. Charles Gonzalez  
**Academic and Professional Credentials:** MD, Columbia University’s College of Physicians and Surgeons; internal medicine training at NYU-Bellevue Hospital and Infectious Diseases sub-specialty training at Yale University.  
**Position/Job Title:** Associate Medical Director for Science and Policy, Office of the Medical Director, NY State Department of Health/AIDS Institute; Assistant Professor of Medicine, New York University School of Medicine.  
**Organizational Affiliations:** NY State Department of Health AIDS Institute, New York University School of Medicine.  
**Areas of Expertise/Discipline/Relevant Experiences:** Internal medicine and infectious diseases, pharmacology, immunology, clinical trials of medications and vaccines in Hepatitis, STIs and HIV; medical guidelines and policy development on the care and treatments of Hepatitis, STIs and HIV. **Conflict of Interest:**  
**Contact Information:** cjg17@health.state.ny.us ; 212-417-4514

**Name:** Dr. Kenneth Mayer  
**Academic and Professional Credentials:** MD, Northwestern University Medical School; internal medicine residency and Infectious Diseases sub-specialty training at Brigham and Women’s Hospital and Harvard Medical School, Boston, MA  
**Position/Job Title:** Director of HIV Prevention Research, Beth Israel Deaconess Medical Center; Visiting Professor of Medicine, Harvard Medical School; and Medical Research Director, Fenway Community Health Center.  
**Organizational Affiliations:** Harvard Medical School and Fenway Community Health Center  
**Conflict of Interest:**
Name: Dr. Susan Buchbinder
Academic and Professional Credentials: MD, University of California San Francisco, California, 1985, Medicine; Tufts University, 1990, Epidemiology Program
Position/Job Title: Assistant Clinical Professor, Departments of Medicine and Epidemiology/Biostatistics, UCSF; Dr. Buchbinder is an attending physician at San Francisco General Hospital's General Medical Clinic; leads efficacy trials efforts by the NIH's Sexually Transmitted Diseases Clinical Trials Group; she also serves on the NIH AIDS Research Advisory Council and NIH AIDS Vaccine Research Subcommittee.
Organizational Affiliations: San Francisco Department of Public Health and UCSF School of Medicine
Conflict of Interest:
Contact Information: spb@itsa.ucsf.edu; (415) 554-9070

Name: Dr. Kimberly Y. Smith
Academic and Professional Credentials: MD, University of Michigan Medical School; internal medicine residency and infectious disease fellowship, Rush University Medical Center.
Position/Job Title: Associate Professor of Medicine, Section of Infectious Diseases, Rush Presbyterian St. Luke's Medical Center, Chicago, IL
Organizational Affiliations: Rush University Medical Center.
Areas of Expertise/Discipline/Relevant Experiences: HIV infection, sexually transmitted infections, HIV prevention and treatment for women and racial/ethnic minority populations.
Conflict of Interest:
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Name: Dr. Michael A. Kolber
Academic and Professional Credentials: MD, University of Miami School of Medicine; internal medicine residency and infectious disease/immunology fellowship, George Washington University School of Medicine.
Position/Job Title: Professor of Medicine, Director, Comprehensive AIDS Program and Director of Adult HIV Services, University of Miami Miller School of Medicine.
Organizational Affiliations: University of Miami Miller School of Medicine, Miami Dade County STD Clinic Downtown.
Areas of Expertise/Discipline/Relevant Experiences: HIV infection, sexually transmitted infections, HIV prevention and treatment for racial/ethnic minority populations, vaccine research, cellular immunology.
Conflict of Interest:
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Name: Dr. Silvia Cunto-Amesty
Academic and Professional Credentials: MD, Temple University School of Medicine; Family Medicine residency Beth Israel Hospital; MPH, Columbia University, Mailman School of Public Health
Position/Job Title: Assistant Director of Research, Columbia University, Center for Family Medicine; Assistant Professor of Clinical Medicine, Columbia University, College of Physicians and Surgeons; Assistant Professor of Population and Family Health, Mailman School of Public Health
Organizational Affiliations: Columbia University Center for Family Medicine, Mailman School of Public Health, Columbia University, College of Physicians and Surgeons.
Areas of Expertise/Discipline/Relevant Experiences: HIV infection, sexually transmitted infections, HIV prevention and treatment for injection drug users and racial/ethnic minority populations, adolescent medicine, cultural issues in health care, Latino/immigrant access to healthcare.

Conflict of Interest:
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