

Centers for Disease Control and Prevention (CDC) Atlanta GA 30329-4027

Peer Review Plan for Updated Recommendations for Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States – 2016

Title: Updated Recommendations for Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States - 2016 **Subject of Planned Report:** This document summarizes updated recommendations for use of antiretroviral postexposure prophylaxis after nonoccupational exposures to HIV in the United States.

Purpose of Planned Report: Provide healthcare providers in the United States with updated recommendations on the use of antiretroviral non-occupational postexposure prophylaxis (nPEP) and other aspects of the management of individuals with isolated exposure outside of healthcare settings, to blood, genital secretions, or other potentially infectious body fluids that might contain human immunodeficiency virus (HIV)

Type of Dissemination: Influential Scientific Information (ISI)

Timing of Review (including deferrals): 10/14/14 – 12/2/15 (peer review)

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

Opportunities for the Public to Comment (how and when): Public engagement was obtained from members of the public through participation in webinars presenting the key recommendations of draft guidelines on 11/14/14 and 11/17/14. A summary of comments received and our responses will be posted to the DHAP OMB website. The draft guidelines will be revised to incorporate feedback received from these sources.

Peer Reviewers Provided with Public Comments before the Review: Yes **Anticipated Number of Reviewers:** 5 to 6

Primary Disciplines or Expertise: HIV medicine specialists (adult and pediatric), sexual abuse and injection drug use experts, HIV/AIDS prevention and policy

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

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: The document that you will review is a guideline entitled "Updated Recommendations for Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States – 2016". 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 the recommendations are justified by the science reported and appropriate for clinical use

At a later time, CDC will publicly post any comments you make without attribution. Our response to your comments can be found on this page (http://www.cdc.gov/hiv/policies/planning.html)

Reviewers

Judith Aberg, MD, FIDSA, FACP

Academic and Professional Credentials: MD, FIDSA, FACP Current Position Title: Chief, Division of Infectious Diseases Organizational Affiliation: Icahn School of Medicine at Mount Sinai, New York, NY Areas of Expertise, Discipline, Relevant Experiences: Internal medicine, clinical infectious diseases, HIV/AIDS research, participated in the development of national, state and local guidelines regarding HIV prevention and treatment and contributor to New York State nPEP Guidelines

Stephen M. Arpadi, MD, MS

Academic and Professional Credentials: MD, MS

Current Position Title: Professor of Pediatrics, Professor of Epidemiology

Organizational Affiliation: Columbia College of Physicians and Surgeons, Gertrude H. Sergievsky Center, New York, NY; Columbia University Mailman School of Public Health, International Center for AIDS Care and Treatment Programs

Areas of Expertise, Discipline, Relevant Experiences: Pediatrics, Epidemiology, clinical care and research in area of prevention of mother-to-child HIV transmission, pediatric HIV, long-term morbidities related to early-life infection with HIV, including growth failure, alteration in bone mass density, dyslipidemias, and lipodystrophy. Member, UNICEF and World Health Organization Inter-Agency Task Teams on Children and HIV and AIDS, Technical Advisor for Pediatric HIV care and treatment programs and prevention of mother to child transmission of HIV(PMTCT)initiatives; peer reviewer for New York State pediatric nPEP guidelines.

Allison H. Bartlett, MD, MS

Academic and Professional Credentials: MD, MS

Current Position Title: Assistant Professor of Pediatrics; Associate Medical Director, Infection Control Program; Pediatric Associate, Antimicrobial Stewardship Program

Organizational Affiliation: The University of Chicago Medicine, Comer Children's Hospital, Chicago, IL

Areas of Expertise, Discipline, Relevant Experiences: Pediatrics, Pediatric Infectious Diseases, medical management of acute and chronic infectious diseases, Director of pediatric nPEP program.

Betty Dong, PharmD

Academic and Professional Credentials: PharmD, FCCP, FASHP, AAHIVP Current Position Title: Professor of Clinical Pharmacy, Adjunct Professor of Clinical Pharmacy and Family and Community Medicine Organizational Affiliation: University of California, San Francisco, School of Pharmacy; University of California, San Francisco, School of Medicine, San Francisco, California.

Areas of Expertise, Discipline, Relevant Experiences: Pharmacy consultant for UCSF's national Clinicians' Consultation Center on treatment and prevention of HIV, HBV, and HCV infection in adults, children, and during pregnancy. Provides pharmacy care for patients with HIV and patient education, and medication and side effect monitoring. She has performed research on pharmacogenomics, pharmacy practice, pharmacokinetics, pharmacodynamics, and HIV and HCV therapy. Member of HIV/AIDS Editorial Board for the Annals of Pharmacotherapy. Associated with the International Training and Education Centers for HIV (ITECH) to assist countries in antiretroviral implementation and support capacity building.

José Eguía, M.D.

Academic and Professional Credentials: MD

Current Position Title: Consultant in Infectious Diseases and Director of Infection Control (St. Mary's Medical Center), Associate Physician (University of California San Francisco, Clinical Consultation Center)

Organizational Affiliation: St. Mary's Medical Center, and University of California, San Francisco (Clinician Consultation Center, Division of Family & Community Medicine) in San Francisco, CA Areas of Expertise, Discipline, Relevant Experiences: Internal medicine, Infectious Diseases, provides expert consultation and education to UCSF's national Clinical Consultation Center callers and online service users on HIV management and bloodborne pathogen exposure management; specifically consults for the PEPline and HIV Warmline.

John Schneider, MD, MPH

Academic and Professional Credentials: MD, MPH

Current Position Title: Assistant Professor of Medicine and Epidemiology, Director of Global Health Programs

Organizational Affiliation: University of Chicago Medicine, Departments of Medicine and Health Studies, Chicago Children's Hospital, Section of Infectious Diseases and Global Health University of Chicago

Areas of Expertise, Discipline, Relevant Experiences: Infectious diseases, HIV prevention and treatment, LGBT health, research in the use of social networks among men who have sex with men in relation to HIV prevention.

Antonio Urbina, MD

Academic and Professional Credentials: MD

Current Position Title: Medical Director, HIV/AIDS Education and Training Organizational Affiliation: Spencer Cox Center for Health, Mt. Sinai Hospital Areas of Expertise, Discipline, Relevant Experiences: Internal medicine, Infectious Diseases, HIV/AIDS Medicine, Principal Investigator for Clinical Education Initiative HIV/Hepatitis C Center for Excellence from the New York State Department of Health AIDS Institute, Executive Producer of Pep411.com to educate men who have sex with men and health care providers about nPEP as an HIV prevention strategy, including resources and guidelines.

Additional elements to be added to the public posting as they become available

Peer Reviewers' Comments CDC/ATSDR's Response to Reviewers' Comments The Guidelines (Influential Scientific Information)