

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION**



**CDC/HRSA Advisory Committee on
HIV and STD Prevention and Treatment
November 2-3, 2009
Bethesda, Maryland**

DRAFT Record of the Proceedings

TABLE OF CONTENTS

	<u>Page</u>
Attachment 1: List of Participants	A1-1
Attachment 2: Acronyms Used in These Meeting Minutes	A2-1
Meeting Minutes	
November 2, 2009	
Opening Session.....	1
HAB Director's Report.....	2
NCHHSTP Director's Report.....	6
Update by the CHAC Workgroup on HIV Care, Treatment and Prevention in the New Millennia	10
Update by the HRSA Bureau of Primary Health Care.....	13
New Leadership Panel Presentation.....	16
Overview by the Global AIDS Coordinator.....	21
November 3, 2009	
Overview of the Role of Surveillance in Informing CDC and HRSA Activities	23
Overview of Biomedical Approaches to HIV Prevention	28
Overview of Health Reform and HIV/STD Prevention and Treatment	32
Update on Federal Adolescent Sexual Health Education Initiatives	35
CHAC Business Session.....	37
Public Comment Session	42
Closing Session	43

ATTACHMENT 1

List of Participants

CHAC Members

Dr. Edward Hook III, Co-Chair
 Dr. Donna Sweet, Co-Chair
 Dr. Bruce Agins
 Dr. Carlos del Rio
 Ms. Antigone Hodgins Dempsey
 Ms. Evelyn Foust
 Rev. Debra Hickman
 Mr. Ernest Hopkins
 Ms. Maria Lago
 Dr. Jeanne Marrazzao
 Dr. Kenneth Mayer
 Mr. Harold Phillips
 Dr. André Rawls

CHAC Ex-Officio Representatives

Dr. Pradip Akolar
 (Food and Drug Administration)
 Ms. Beverly Watts Davis
 (Substance Abuse and Mental Health
 Services Administration)
 Dr. Scott Giberson (Indian Health Service)
 Dr. William Grace
 (National Institutes of Health)
 Dr. David Lanier (Agency for Healthcare
 Research and Quality)

Designated Federal Officials

Dr. Kevin Fenton
 NCHHSTP Director, CDC
 Dr. Deborah Parham Hopson,
 HAB Director, HRSA

Federal Agency Representatives

Mr. Jeffrey Crowley (Director, Office of
 National AIDS Policy & Senior Advisor of
 Disability Policy, White House)
 Ambassador Eric Goosby (Global AIDS
 Coordinator, U.S. State Department of
 Health)
 Dr. Mary Wakefield (HRSA Administrator)
 Mr. Christopher Bates
 Ms. Evonne Bennett-Barnes
 Dr. Laura Cheever
 Mr. Michael Craig
 Dr. John Douglas, Jr.

Ms. Teresa Durden
 Mr. Michael Evanson
 Dr. Margarita Figueroa-Gonzales
 Ms. Shelley Gordon
 Ms. Karen Ingvaldstad
 Ms. Hope King
 Dr. Amy Lansky
 Ms. Darla Lipscomb
 Ms. Alice Litwinowicz
 Ms. Sheila McCarthy
 Ms. Karen Mercer
 Dr. Jonathan Mermin
 Ms. Faye Malitz
 Mr. Douglas Morgan
 Ms. Katherine Patterson
 Ms. Angela Powell
 Ms. Amy Pulver
 Ms. Margie Scott-Cseh
 Mr. Donald Shriber
 Dr. R. J. Simonds
 Ms. Lynn Wegman
 Dr. Howell Wechsler
 Mr. Steven Young

Guest Presenters and Members of the Public

Ms. Deborah Arrindell (American Social
 Health Association)
 Mr. Timothy Boyd (AIDS Healthcare
 Foundation)
 Ms. Donna Crews (AIDS Action)
 Ms. Kimberly Crump (HIV Medicine
 Association)
 Ms. Susan Gorin (National Association of
 School Psychologists)
 Ms. Dana Kuhn (New York State
 Department of Health)
 Ms. Marsha Martin (Get Screened Oakland)
 Ms. Emily McCloskey (The AIDS Institute)
 Ms. Suzanne Miller
 (National Coalition of STD Directors)
 Mr. Carl Schmid (The AIDS Institute)
 Ms. Adelle Simmons
 (World Health Organization)
 Dr. Liza Soloman (Abt Associates)

Ms. Louise Stenberg (The Women's
Collective)

Mr. James Sykes (The AIDS Institute)

ATTACHMENT 2

Acronyms Used in These Meeting Minutes

AA	— African American
ACF	— Administration for Children and Families
ACIP	— Advisory Committee on Immunization Practices
ADAP	— AIDS Drug Assistance Program
AETC	— AIDS Education and Training Center
ARRA	— American Recovery and Reinvestment Act
ART	— Antiretroviral Therapy
ASOs	— AIDS Service Organizations
BHPr	— Bureau of Health Professions
BPHC	— Bureau of Primary Health Care
CBOs	— Community-Based Organizations
CDC	— Centers for Disease Control and Prevention
CHAC	— CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment
CHCs	— Community Health Centers
CMS	— Centers for Medicare and Medicaid Services
DASH	— Division of Adolescent and School Health
DFO	— Designated Federal Official
DHAP	— Division of HIV/AIDS Prevention
DRH	— Division of Reproductive Health
DSTD	— Division of STD Prevention
DVH	— Division of Viral Hepatitis
FDA	— Food and Drug Administration
FPL	— Federal Poverty Level
FQHCs	— Federally Qualified Health Centers
GAO	— U.S. Government Accountability Office
GAP	— Global AIDS Program
GHI	— Global Health Initiative
H1N1	— Novel Influenza A Virus
HAB	— HIV/AIDS Bureau
HBV	— Hepatitis B Virus
HCV	— Hepatitis C Virus
HELP	— Health, Education, Labor and Pensions Committee
HHS	— Department of Health and Human Services
HIT	— Health Information Technology
HRISs	— Human Resource Information Systems
HRSA	— Health Resources and Services Administration
IDUs	— Injection Drug Users
MAI	— Minority AIDS Initiative
MMP	— Medical Monitoring Project
<i>MMWR</i>	— <i>Morbidity and Mortality Weekly Report</i>
MOHs	— Ministries of Health
MSM	— Men Who Have Sex With Men
MTCT	— Mother-To-Child Transmission
NASTAD	— National Alliance of State and Territorial AIDS Directors
NCHSTP	— National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

NCQA	— National Committee for Quality Assurance
NCSD	— National Coalition of STD Directors
NGOs	— Non-Governmental Organizations
OGAC	— Office of the Global AIDS Coordinator
OIG	— Office of Inspector General
ONAP	— Office of National AIDS Policy
OPA AFL	— Office of Population Affairs Adolescent Family Life
PACHA	— President's Advisory Council on HIV/AIDS
PART	— Program Assessment Rating Tool
PCSI	— Program Collaboration and Service Integration
PEPFAR	— President's Emergency Plan for AIDS Relief
PHS	— Public Health Service
PLWHA	— Persons Living with HIV/AIDS
PrEP	— Pre-Exposure Prophylaxis
RWHATMA	— Ryan White HIV/AIDS Treatment Modernization Act
SAMHSA	— Substance Abuse and Mental Health Service Administration
SONI	— Severity of Need Index
SPNS	— Special Projects of National Significance
TPPI	— Teen Pregnancy Prevention Initiative
UDS	— Uniform Data System
USPSTF	— U.S. Preventive Services Task Force
WHO	— World Health Organization

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION**

**CDC/HRSA ADVISORY COMMITTEE ON
HIV AND STD PREVENTION AND TREATMENT
November 2-3, 2009
Bethesda, Maryland**

DRAFT Minutes of the Meeting

The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), and Health Resources and Services Administration (HRSA) convened a meeting of the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment (CHAC). The proceedings were held at the Hyatt Regency Bethesda Hotel in Bethesda, Maryland on November 2-3, 2009.

Opening Session

Dr. Donna Sweet, co-Chair of CHAC, called the meeting to order at 8:32 a.m. on November 2, 2009. She and Dr. Edward Hook III, co-chair of CHAC, welcomed the participants to the proceedings and opened the floor for introductions. The list of participants is appended to the minutes as [Attachment 1](#).

Dr. Kevin Fenton, Director of the CDC National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) and the CHAC Designated Federal Official (DFO) for CDC, reminded the participants that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record. He advised CHAC members to be mindful of potential conflicts of interest identified by the CDC or HRSA Committee Management Office and to recuse themselves from participating in discussions or voting on issues in which they have a real or perceived conflict of interest.

Dr. Fenton informed CHAC that Dr. Jose Esparza, Senior Advisor on HIV Vaccines at the Bill and Melinda Gates Foundation, resigned as a CHAC member effective October 27, 2009. A new CHAC member representing CDC would be identified to replace Dr. Esparza.

HAB Director's Report

Dr. Deborah Parham Hopson is the HAB Director and the CHAC DFO for HRSA. She announced that Dr. Margarita Figueroa-Gonzales was recently appointed as the Director of the Division of Community Based Programs. Dr. Parham Hopson acknowledged Dr. Figueroa-Gonzales and other HAB senior staff members who were in attendance: Shelley Gordon, Faye Malitz, Sheila McCarthy, Douglas Morgan and Steven Young.

Dr. Parham Hopson covered the following areas in her update. HAB released the Group 1 Clinical Performance Measures in April 2007 focusing on antiretroviral therapy (ART) for pregnant women, CD4 T-cell count, highly active ART, medical visits and pneumocystis pneumonia prophylaxis. HAB received ~900 comments on the Group 1 measures.

HAB released the Group 2 Clinical Performance Measures in August 2008 focusing on adherence assessment and counseling, cervical cancer screening, hepatitis B virus (HBV) and hepatitis C virus (HCV) screening, HIV risk counseling, lipid screening, oral examinations, syphilis screening and TB screening.

HAB is finalizing the Group 3 Clinical Performance Measures that are focusing on case management, oral health, AIDS Drugs Assistance Programs (ADAP) and systems measures. HAB is in the early stages of developing the Group 4 Clinical Performance Measures that will focus on pediatrics. Dr. Parham Hopson emphasized that HAB welcomes feedback from CHAC and Ryan White grantees on the clinical performance measures.

HAB is developing a technical assistance tool based on models and key components that have been successful in integrating HCV care into Ryan White Programs. HAB will use 2010 Special Projects of National Significance (SPNS) dollars to release a funding opportunity announcement for Ryan White grantees to incorporate HCV care into HIV primary care. In addition to providing funding and successful models, HAB also will offer technical assistance to help Ryan White grantees in adopting and implementing HCV programs. Dr. Parham Hopson confirmed that she would provide regular updates to CHAC on HAB's ongoing efforts to integrate HCV and HIV care.

HAB recently launched a new SPNS initiative: "Enhancing Access to and Retention in Quality HIV/AIDS Care for Women of Color." The purpose of this project is to test innovative strategies to deliver HIV/AIDS services to women of color. HAB awarded grants totaling \$5 million in FY2009 for this initiative and will award an additional \$25 million over five years. Funds were awarded to 11 urban and rural sites to conduct demonstration projects and another grantee to evaluate the project and provide technical assistance to grantees.

HAB is continuing its efforts to strengthen the HIV clinical workforce. HAB hosted a Steering Committee meeting in 2009 focusing on this issue and posted a summary of the meeting on its website. In the President's 2010 budget, HAB proposed funding for long-term training to

clinicians with an interest in becoming HIV experts and an increase in the AIDS Education and Training Center (AETC) line item.

HAB submitted a study to the HHS Office of HIV/AIDS Policy to quantify the current HIV clinical workforce and project future needs. American Recovery and Reinvestment Act dollars were allocated to several Bureau of Health Professions (BHP) programs to further address workforce issues, including pre-service training to build a pipeline of primary care and HIV/AIDS care providers.

HAB hosted the 12th Annual Ryan White Clinical Conference in Dallas, Texas on October 15-17, 2009 with >400 participants, including Ryan White front-line providers. The conference included interactive workshops, lectures and case consultations with HIV treatment experts. The key conference sessions included drivers of the HIV epidemic in women, the novel influenza A virus (H1N1), medically assisted addiction treatment, strategies to engage adolescents, and challenges of implementing guidelines and recommendations versus the realities of actual practice.

HAB recently implemented the Ryan White HIV/AIDS Program Services Report to enhance its client-level data collection system. Client-level data will help HRSA and funded entities improve their performance in monitoring health outcomes; clearly identify Ryan White clients; allow grantees to better monitor clients who receive specific Ryan White services; and allow HRSA to better describe accomplishments with Ryan White funds. In June 2009, grantees and providers of ambulatory outpatient medical care and medical/non-medical case management completed grantee and provider reports. Due to extensive efforts by grantees, providers, data staff and HAB Project Officers, 89% of 1,536 providers who were required to upload client-level data met the September 15, 2009 deadline.

HAB's next steps in client-level data collection are to follow-up with grantees and providers who had difficulties in submitting their interim data reports by the September 15, 2009 deadline. HAB will continue to build capacity in and offer technical assistance to Parts A, B, C and D Ryan White grantees. HAB awarded 57 SPNS grants in 2009 totaling \$4.4 million to build information technology capacity of grantees. HAB also awarded Community Based Program grants to Parts C and D Ryan White grantees to build capacity in collecting and reporting client-level data.

HAB will provide grantees with feedback on the quality of their interim client-level data reports to facilitate improvements to the year-end reports. HAB will continue to provide technical assistance to grantees and identify strategies to improve the continuous quality improvement system of both HAB and grantees.

HAB completed six major studies in 2009 in response to evaluations conducted by the U.S. Government Accountability Office (GAO) and the HHS Office of Inspector General (OIG). The GAO and OIG evaluations focused on Part D administrative expenses; barriers to program integration in the Minority AIDS Initiative (MAI); procurement mechanisms and procedures in the President's Emergency Plan for AIDS Relief (PEPFAR); the 2009 reauthorization of the Ryan

White HIV/AIDS Program; state compliance with Part B of the ADAP payer of last resort requirement; and the 75%/25% core medical services compliance and waiver process.

For the 75%/25% core medical services, Parts A, B and C grantees are required to spend 75% of their program grant funds in 13 core medical services unless a waiver is granted. OIG's key findings in its evaluation of core medical services are summarized as follows. Most grantees complied with the requirement. Grantee expenditures for core medical services changed little from 2006 to 2007.

The requirement affected support services and administrative processes for some grantees. A higher percentage of Part A grantees (versus Parts B and C) reported that the requirement had a significant impact on support services. OIG also commended HRSA in the core medical services and made several recommendations to improve this area. Core medical services waivers that were granted to Parts A and B grantees have decreased over the past two years from eight in 2007 to one in 2009.

The Ryan White HIV/AIDS Treatment Modernization Act (RWHATMA) of 2006 had a repeal provision for September 30, 2009, but Congress passed a continuing resolution to extend the law through October 31, 2009. A House Subcommittee and a Senate Committee drafted legislation and then reconciled differences between the laws. President Obama signed the Ryan White Treatment Extension Act of 2009 on October 30, 2009 after the legislation was passed with overwhelming bipartisan support in the House and Senate.

The Ryan White Treatment Extension Act of 2009 is effective as if passed on September 30, 2009 and is authorized for four years. The new law also authorizes increased funds for all parts each year. Parts A and B MAI funds will be awarded by formula and synchronized with regular Parts A and B grants. The law extends the exemption for names-based reporting to HRSA and changes eligibility and funds transfer requirements for transitional grant areas.

The percentages of hold harmless provisions for Parts A and B grantees will be 95% in 2010, 100% in 2011, 100% in 2012 and 92.5% in 2013. Unobligated balance provisions have been administratively simplified that will allow HRSA to more rapidly distribute awards to Parts A and B grantees. New language has been included for Part A supplemental funding in which 33% of grant application scores will be based on success in identifying persons with HIV/AIDS who do not know their HIV status and making these persons aware of their status. HAB will closely collaborate with CDC on the new requirement for Part A supplemental funding.

Part D grantees will not be required to use funds for primary care services when payments are available from other sources. HAB will closely collaborate with CDC to ensure that grantees in HRSA, CDC and other federal agencies meet the National HIV/AIDS Testing Goal of performing 5 million tests annually. The new Part G will require grantees to notify CDC of possible exposure to infectious diseases beyond HIV/AIDS. HAB will meet with CDC to carefully review Part G and develop an action plan to implement the new provisions.

HAB will sponsor the 2010 Ryan White All Grantee Meeting and 13th Annual Clinical Conference with a theme of “*Twenty Years of Leadership, A Legacy of Care.*” The conference will be held on August 23-26, 2010 in Washington, DC. The event will focus on clinical updates, technical assistance and implementation of Ryan White reauthorization. HRSA is operating under a continuing resolution through December 18, 2009 because Congress has not yet passed the FY2010 budget.

CHAC was extremely pleased that the Ryan White Treatment Extension Act of 2009 was signed into law and commended HRSA on its tireless efforts in this achievement. CHAC also applauded HAB on its outstanding accomplishment in the Program Assessment Rating Tool (PART) review.

The Office of Management and Budget concluded that HAB has contributed to the decline in the number of new AIDS cases and deaths due to HIV/AIDS and serves women and racial/ethnic minorities in significantly higher proportions than their representation among reported AIDS cases. HAB and only six other programs out of 1,016 programs across the federal government received a PART score of 100% in the area of program results and accountability.

The CHAC members made several suggestions for HAB to consider in implementing the reauthorized Ryan White legislation and continuing its activities to strengthen the HIV/AIDS clinical workforce.

- HAB should use the reauthorized Ryan White legislation to integrate the original intent of MAI and charge planning groups with developing creative strategies to address unmet needs of persons of color with AIDS.
- HAB should increase collaborations with states and cities to collect more solid data on the number of HIV/AIDS tests that are performed annually.
- HAB should collect data from states that currently use preparedness dollars to report infectious diseases to CDC. This approach would avoid duplicating efforts and minimize the burden placed on states in complying with the new Part G requirements.
- HAB should ensure that appropriate linkages to HIV prevention services and care are available because many new cases will be detected as a result of the National HIV/AIDS Testing Goal of performing 5 million tests annually.
- HAB and its federal partners should jointly explore innovative strategies to build the HIV/AIDS clinical workforce. For example, new physicians, nurse practitioners and other providers who receive federal funding could be required to devote a certain amount of time in their careers to caring for HIV/AIDS patients in the United States before working overseas. Moreover, mid-level practitioners make efforts to expand their abilities and opportunities to provide HIV/AIDS care, but boards of nursing, doctor associations and other professional societies in many states and localities frequently serve as barriers to these efforts. HRSA should determine its role in addressing this workforce issue.
- HAB should ensure that all Federally Qualified Health Centers (FQHCs) and Ryan White-funded community-based organizations (CBOs) are included in the new initiative of providing long-term training to clinicians with an interest in becoming HIV experts

NCHHSTP Director's Report

Dr. Fenton covered the following areas in his update. President Obama recently announced that the final rule eliminating the HIV travel ban would be published on November 2, 2009 and become effective on January 1, 2010. The President stated that the elimination of the travel ban would encourage persons to be tested and obtain treatment for HIV, help families to remain together, and save lives.

At the agency level, a new CDC organizational structure was proposed in September 2009 and is expected to become effective on January 1, 2010 pending HHS approval. Under the new organizational structure, Coordinating Centers would be eliminated. A new Center for Global Health and a new Office of Public Health Preparedness and Response would be established. The Global AIDS Program would be transferred from NCHHSTP to the new Center for Global Health.

A Principal Deputy Director and four Deputy Directors would be appointed to report directly to Dr. Thomas Frieden, Director of CDC, from four new offices: the Office of Infectious Diseases; Office of State and Local Support; Office of Surveillance, Epidemiology and Laboratory Services; and Office of Non-Communicable Diseases, Injury and Environmental Health.

Four Associate Directors would be appointed in the areas of programs, science, quality and communications. The National Center for Health Marketing and the National Center for Public Health Informatics would be eliminated and the functions of these operating units would be transferred to new or existing CDC offices. The Organizational Improvement Team is closely collaborating with acting leaders on the implementation of CDC's new organizational design.

CDC is continuing to lead the national response to the H1N1 outbreak. Influenza is perhaps the most unpredictable of all infectious diseases and is a tough enemy. The initial H1N1 outbreak occurred very late in the season and showed remarkable heterogeneity across the United States. H1N1 disproportionately affects young persons, causes widespread illness (some severe or fatal) in most states, and is socially disruptive, particularly for schools. Tens of thousands of healthcare personnel and others are responding worldwide to the outbreak. Influenza season lasts until May.

Widespread H1N1 influenza activity was reported by state and territorial epidemiologists the week ending September 12, 2009 and further spread to most of the country by the week ending October 3, 2009. The current influenza activity is markedly different than the previous year in the week ending October 4, 2008. At that time, most states had no H1N1 influenza activity and no states had widespread H1N1 influenza activity.

At the National Center level, the NCHHSTP Office of Health Disparities was officially renamed as the "Office of Health Equity" on October 1, 2009. The Office was established in June 2003 with a mission to improve the health of populations disproportionately affected by HIV, viral

hepatitis, STDs and TB and to help eliminate health disparities. The new name reflects NCHHSTP's broader focus on eliminating health inequalities within and between populations and health inequities that stem from broader environmental, political and social contexts. To advance its mission, the Office of Health Equity will incorporate and promote a social determinants health approach to achieve health equity.

Efforts are underway to complete the 2010-2015 NCHHSTP Strategic Plan as a consensus document with widespread center-wide input. The Strategic Plan outlines a number of key goals for NCHHSTP: program collaboration and service integration (PCSI), promotion of health equity, global health protection and healthy systems strengthening, partnerships for prevention, and workforce development and capacity building. The Strategic Plan was disseminated to CHAC and other external stakeholders with a three-week deadline for review and comment.

NCHHSTP provided key external stakeholders and program consultants with the first draft of the PCSI white paper that outlines the PCSI strategic vision and framework. The reviewers were asked to give NCHHSTP feedback on the PCSI goals, key measures for monitoring and evaluating new progress, and partnership efforts to advance PCSI efforts at national, state and local levels.

The draft PCSI white paper also was unveiled during the National HIV Prevention Conference in August 2009 and was well received by participants. The Health Communication Science Office staff and PCSI Team jointly gathered stories on successful strategies local and state groups have implemented to encourage PCSI. Public health practitioners across the country from North Carolina to Hawaii were interviewed on camera about their PCSI efforts. The interviews would be packaged as online videos and posted on the PCSI website by the end of 2009.

CDC is currently operating under a continuing resolution through December 18, 2009 that provides funds at FY2009 levels. The President's budget requested an increase of \$53 million for HIV prevention and approximately level funding for viral hepatitis and STD prevention. The House would provide the President's budget for HIV, a \$1.8 million increase for viral hepatitis and the President's budget for STD prevention. The Senate would provide an increase of ~\$19.2 million for HIV, the President's budget for viral hepatitis, and an increase of \$2.25 million for STD prevention.

More than 3,000 persons attended the National HIV Prevention Conference in August 2009. HHS Secretary Kathleen Sebelius, Magic Johnson, Congressional members and leaders in the HIV/AIDS field were among the keynote speakers. The conference included a Town Hall for a National HIV/AIDS Strategy. Feedback on the event has been overwhelmingly positive and was one of CDC's most successful National HIV Prevention Conferences to date. The next conference in 2011 would commemorate the discovery of HIV in the United States 30 years ago in 1981. The 2011 conference would reflect on achievements in HIV prevention over the past three decades and key challenges in advancing the field.

At the division level, the NCHHSTP Division of HIV/AIDS Prevention (DHAP) participated in the HHS HIV Testing Meeting that was held in October 2009 to discuss interagency coordination of

HIV testing activities. CDC reported an 8.7 million increase in the number of persons 13-64 years of age who were tested in 2008 as compared to those tested in 2006 when CDC's new HIV testing recommendations were published. DHAP will initiate strategic planning efforts in FY2010 to prepare for the development of the new 2010-2020 HIV Prevention Strategic Plan. Public comments are being accepted on HIV, hepatitis and all other *Healthy People 2020* objectives at www.healthypeople.gov.

The NCHHSTP Division of Viral Hepatitis (DVH) held a consultation on October 29, 2009 that addressed sexual transmission of HCV among HIV-positive men who have sex with men (MSM). DVH and HRSA would convene a joint meeting on December 10-11, 2009 to focus on the integration of viral hepatitis testing in FQHCs. The Institute of Medicine would release a report on viral hepatitis in January 2010.

DVH would initiate the five-year "Chronic Hepatitis B and C Cohort Study" in early 2010. Chronic disease surveillance data for viral hepatitis were published in *Emerging Infectious Disease* in September 2009. The first report included enhanced surveillance data from six state and county health departments.

Since the Adult HBV Vaccination Initiative was established in November 2007, 56 grantees have joined and enrolled a total of 2,646 venues for adult HBV vaccination. A total of 680,645 HBV vaccine doses were ordered and >448,000 doses have been administered. CDC has been investing \$16-\$20 million per year to purchase HBV vaccine for state and local health departments.

The NCHHSTP Division of STD Prevention (DSTDP) is continuing its focus on infertility prevention. The National Chlamydia Coalition has grown to 59 national organizations. Chlamydia screening will be included as a measure in the Healthcare Effectiveness Data and Information Set as part of the health plan accreditation set that will be implemented in July 2010. Chlamydia screening also is included as a core children's health services quality measure for Medicaid and the Children's Health Insurance Program. Permissibility of expedited partner therapy has grown from ten states in 2006 to 20 states at this time.

CDC initiated collaborations with HRSA and the National Association of Community Health Centers to develop a model to increase chlamydia screening in HRSA-funded community health centers (CHCs). CDC also is partnering with the Centers for Medicare and Medicaid Services (CMS) to pilot the use of collated medical data to monitor the quality of STD care of Medicaid patients. The Partnership for Prevention will convene three roundtables on infertility prevention in 2010.

In October 2009, the Food and Drug Administration (FDA) licensed the bivalent human papillomavirus vaccine for use in females 10-25 years of age and the quadrivalent vaccine for use in males 9-26 years of age. During its October 2009 meeting, the CDC Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination of the bivalent vaccine (Cervarix) for females 11 or 12 years of age and catch-up vaccination with the quadrivalent vaccine for females 13-26 years of age. ACIP recommended permissive vaccination of the

quadrivalent vaccine (Gardasil) for males 9-26 years of age for prevention of genital warts. ACIP voted in favor of including both the bivalent vaccine for females and the quadrivalent vaccine for males in the Vaccine for Children's Program.

DSTDP will convene a series of regional meetings focusing on gonorrhea prevention strategies in FY2010. DSTDP held a meeting to develop an outbreak response plan for cephalosporin-resistant gonorrhea. DSTDP is continuing to respond to the shortage of the recommended prophylaxis for ophthalmia neonatorum (*i.e.*, Erythromycin ophthalmic ointment). The World Health Organization (WHO) STD Diagnostic Initiative is field testing CDC's syphilis rapid test. FDA's decision on the syphilis rapid test is anticipated in the fall of 2010 pending the completion of field testing. DSTDP will convene the National STD Prevention Conference on March 8-11, 2010 in Atlanta, Georgia.

Internal collaboration is underway at CDC to ensure a seamless transition of the Global AIDS Program (GAP) from NCHHSTP to the new Global Health Center. CDC also is taking steps to assure the sustainability of PEPFAR HIV care and treatment programs. In support of this effort, CDC is transitioning ownership of all of its centrally-supported HIV treatment activities to local partners and Ministries of Health (MOHs) over the next four years. CDC is leading the development of advanced costing studies on HIV treatment across PEPFAR countries to identify opportunities to increase the efficiency of utilizing PEPFAR resources and determine the best models of treatment and care.

CDC is strengthening overseas laboratory systems. On July 27, 2009, GAP provided support to 120 host government laboratory personnel, health experts and policymakers from 12 African countries to launch a WHO accreditation program in Kigali, Rwanda for laboratory quality improvement of the continent's medical laboratories. GAP established a new Health Systems Strengthening and Program Integration Team at CDC Headquarters. Dr. Jordan Tappero is leading the new team to enhance service delivery, the health workforce, laboratory networks, information systems, and leadership and governance in the host countries.

GAP is supporting a partnership among MOH officials in Kenya, Zimbabwe and Nigeria to help develop human resource information systems (HRISs). Zimbabwe and Nigeria officials conducted a site visit to see the CDC-supported HRIS in Kenya. MOH officials in Kenya who were involved in the development of the national HRIS over the past seven years are now serving as technical assistance providers to Nigeria and Zimbabwe MOH officials.

CHAC thanked Dr. Fenton for providing an extremely informative update on CDC's recent prevention activities. Several members made suggestions for CDC to consider in refining these efforts.

- CDC and HRSA should give consideration to inviting a Department of Defense representative to serve as an *ex-officio* member on CHAC. The U.S. Armed Forces represent a huge population of persons who are at risk for HIV/STDs. Moreover, the Veterans Administration Medical Center is the single largest provider of care in the United States for persons with chronic HCV.

- CDC should place more emphasis on the resurgence of syphilis across the country, particularly among MSM and in the South, to reinvigorate interest in the prevention of STDs and other infectious diseases among Congress, appropriators and external partners.
- CDC should take a proactive rather than a reactive approach to consistently notify states of the shortage of Erythromycin ophthalmic ointment.
- CDC and HRSA should take leadership in emphasizing that the virtual elimination of funding for HIV/STD prevention in state and local Medicaid programs is unacceptable.
- CDC should develop guidelines to monitor home HIV testing. These guidelines should describe protective factors for women who might become victims of domestic violence based on a positive result; include recommendations for persons who might become severely depressed after receiving a positive result; and outline methods to ensure rigorous surveillance and appropriate linkages to primary care and treatment for persons with a positive result at home. CDC also should conduct a cost-effectiveness study to determine whether low-income persons would be able to afford home HIV tests. CDC should engage CBOs and AIDS service organizations (ASOs) in piloting and field testing the home HIV testing guidelines.
- CDC should increase its HIV prevention efforts to more effectively reach Hispanic men and hold state, local and community-based grantees accountable to these activities. For example, CDC has not posted HIV prevention and testing messages on websites targeted to Hispanic MSM.
- CDC and HRSA should develop joint educational initiatives to enhance the capacity and skills of HIV care providers in diagnosing and managing STDs.

Update by the CHAC Workgroup on HIV Care, Treatment and Prevention in the New Millennia

Dr. Bruce Agins is a CHAC member and co-chair of the workgroup. He reported on the workgroup's activities over the past six months. The objective of the workgroup is to develop a formal policy statement with recommendations for HIV care and service delivery within healthcare reform. After CHAC's unanimous agreement to establish the workgroup during the May 2009 meeting, the workgroup held a planning call in June 2009 to develop a scope of work and convened three additional conference calls in August, September and October 2009. During the first conference call, the workgroup raised the possibility of forming a separate subgroup to specifically focus on the future of healthcare reform and its impact on HIV services.

The workgroup administered a survey to CHAC members to guide the development of a medical home background paper and bibliography. These documents and other materials were distributed to CHAC for review. Key findings of the workgroup's literature review are highlighted as follows. The medical home model is a centerpiece of healthcare reform and represents an expansion of the primary care model, chronic care model and dimensions of quality articulated in *Crossing the Quality Chasm*. The literature also emphasizes that health information

technology (HIT) should be a cornerstone of the medical home model in providing coordinated and comprehensive care to individuals.

Numerous demonstration projects have been successfully implemented through the Patient-Centered Primary Care Collaborative. The American Academy of Pediatrics initially developed the medical home concept in 1967 to address the care of special needs children. The definition of the “medical home” is that every individual should have a personal medical home offering a “basket of acute, chronic and preventive services” with the following core elements: a personal physician to provide continuous and comprehensive care, physician-directed medical practice, whole-person orientation to care, coordinated and integrated care, emphasis on quality and safety, enhanced access to care, and a payment system reflecting the added value of the medical home.

The National Committee for Quality Assurance (NCQA) developed criteria for accrediting medical homes based on nine standards with three levels and “must-pass” elements for each level. HIT is a central element, but is not required in the first tier. Progression is expected through the tiers and higher levels of the medical home correlate with higher levels of reimbursement. A growing body of evidence demonstrates that the medical home model can achieve improvements in quality and reductions in costs.

The purpose of the workgroup administering the survey to CHAC was to begin identifying issues for the policy statement and determine the most important aspects of a medical home in the context of HIV care. The CHAC members were asked to respond to the following question in the survey: In your opinion, what are the three most important elements related to HIV care that should be incorporated into regulations and standards for medical homes?

The workgroup acknowledged that current Ryan White-supported programs offer programmatic features of the medical home. However, specific concerns have been expressed about adequate support for linkages to community services, mental health/substance abuse services, and continuous prevention interventions for persons living with HIV/AIDS (PLWHA). General concerns also have been raised regarding coordination of subspecialty care and support for primary care workforce development.

The workgroup’s next steps will be to discuss its future activities with CHAC during the current meeting; schedule additional expert calls; determine the role of HIV care in recently proposed healthcare reform legislation; and establish a deadline to complete the policy statement based on the timing of advocacy and upcoming legislation. The workgroup’s expert calls will be with Massachusetts regarding its experience with health reform in the context of the medical home model and the North Carolina Medicaid Program regarding its current public health issues in the context of the medical home model.

Ms. Dana Kuhn, of the New York State Department of Health, is a workgroup member. She summarized responses from 14 of 17 CHAC members who completed the survey. Based on the workgroup’s ranking system, HIV specialty care, mental health services and prevention were CHAC’s three most important elements that should be included in the medical home model in

the context of HIV care. Other elements that CHAC identified from most to least important were patient-centered care, comprehensive care, case management, social services (excluding mental health and substance abuse services), treatment and cultural competency.

Several CHAC members provided additional comments on the survey. The respondents noted that one size of a medical home model would not fit all. Concerns were expressed about an overabundance of regulation. The respondents also commented on the need to address equity issues and include transportation and outreach in a medical home. The respondents further pointed out that Ryan White programs are already medical homes and should be included in the legislation. The respondents conveyed that patients have complained about insensitive care resulting in dropping out of care.

CHAC was extremely impressed with the workgroup's productivity in conducting numerous activities in only six months, particularly the comprehensive literature review, administration of the survey and development of the bibliography and background paper. Several members made suggestions for the workgroup to consider in its ongoing efforts to develop the policy statement.

- The policy statement should emphasize two key issues. State and local public health departments must play a role in the medical home model because HIV care is designed to protect the health of the public. Efforts must be made to prevent further budget cuts to state Medicaid programs across the country.
- The following actions should be taken to integrate prevention into the medical home model. The policy statement should recommend the inclusion of prevention in NCQA's criteria for evaluating and accrediting medical homes. Successful Ryan White programs that have fully and effectively embraced prevention should be promoted as models of best practices. These data could be gathered from HRSA's previous SPNS initiative on prevention with HIV-positive persons.
- The medical home should emphasize the importance of the client's self-management of the disease over their life span through individual knowledge, advocacy and other personal strengths.
- The workgroup should consult with CDC and HRSA to extensively engage and obtain input from other agencies that play a significant role in enrolling and maintaining persons in care.
- The workgroup should continue to gather feedback from external partners to clearly articulate key differences between medical homes in the policy statement.

Dr. Fenton offered CDC's support to the workgroup in filling data gaps related to models of best or promising practices for integrating prevention into medical homes. In terms of the timeline to draft the policy statement, he advised the workgroup co-chairs to raise this issue during the healthcare reform presentation on the following day.

Update by the HRSA Bureau of Primary Health Care (BPHC)

Ms. Angela Powell is the Director of the Western Division of BPHC. She explained that the mission of BPHC is to improve the health of the nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent and quality primary healthcare services.

BPHC's focus areas include public health care and public health leadership; performance improvement through outreach and quality of care, health outcomes and disparities, and financial viability and costs; and program requirements focusing on needs, services, management and finance, and governance. BPHC grantees also must comply with other requirements, such as accessibility of care with no regard to the client's ability to pay and accessible locations and hours of operation for CHCs. Moreover, users must represent 51% of the membership of CHC Community Boards.

Data collected from the Uniform Data System (UDS) showed that of 17.1 million (or 1 in 18) clients served by CHCs in 2008, 92% (or 1 in 6) were 200% below the Federal Poverty Level (FPL); 70% (or 1 in 3) were 100% below the FPL; 38% (or 1 in 7) were uninsured; 934,000 were homeless; 834,000 were migrants or seasonal farmworkers; and 157,000 were public housing residents. In 2008, 67 million patient visits were made to 1,087 BPHC grantees at >7,500 service sites. Of all BPHC grantees, 50% are rural. Of >113,000 staff employed in CHCs in communities across the country, 8,400 are physicians and 5,100 are nurse practitioners, physician assistants and certified nurse midwives.

UDS data showed that ~500,000 CHC clients received HIV/STD testing in 2007 with ~9% of this population being tested more than once. In 2008, ~600,000 CHC clients received HIV/STD testing with ~8% of this population being tested more than once. Preliminary UDS data for 2008 showed that 86,816 CHC clients, both symptomatic and asymptomatic, had HIV or AIDS as their primary diagnosis. Syphilis and other STDs were the primary diagnoses for 69,489 CHC clients. Symptomatic and asymptomatic HIV clients accounted for 391,246 medical encounters in CHCs in 2008, while clients with syphilis and other STDs accounted for 112,556 medical encounters.

Of 1,080 BPHC grantees that submitted UDS data in 2008, 160 (or 15%) received Ryan White Part C funding. Of ~17.1 million clients served by CHCs, 86,816 (or 0.5%) had a principal diagnosis of HIV or AIDS. BPHC grantees not receiving Ryan White Part C funding saw 28,009 clients whose principal diagnosis was HIV or AIDS.

Legislation was signed on February 17, 2009 allocating \$2 billion to HRSA in American Recovery and Reinvestment Act (ARRA) funding. To improve healthcare services, HRSA used ARRA dollars to fund 126 new access points for CHCs and meet the increased demand for services due to a new population of recently uninsured persons and state and city budget cuts. To modernize CHCs, HRSA used ARRA dollars to fund construction, repair and renovation of CHCs in the Capital Improvement Program as well as equipment and HIT systems in the Facility

Investment Program. BPHC is exploring the possibility of establishing “teaching” CHCs in which health center staff would receive extensive training and education on providing primary care.

Ms. Powell provided additional details on the CHCs in response to CHAC’s specific questions and comments. BPHC acknowledges the need to provide stronger guidance and leadership to CHCs and emphasize that routine testing must be a part of the standard of care for clients. BPHC also recognizes the need to improve its performance in collecting data on the number of HIV-positive clients who receive care in CHCs and the funding streams that are utilized to provide both HIV-specific and primary care.

Dr. Fenton noted a tremendous missed opportunity in CHCs. HIV testing in CHCs represents only 5% or less of the current proportion of client visits each year. In response to Dr. Fenton’s comment, Ms. Powell described several options other than reimbursement that could play a significant role in scaling-up HIV testing coverage in CHCs.

CHC providers should be urged to use each medical encounter to discuss HIV testing with clients. HRSA and CDC must take joint leadership in urging CHCs to include HIV testing as a routine part of care regardless of the payer. BPHC should administer a survey to CHCs to identify technical assistance, education, training or other resources beyond reimbursement that would be needed to scale-up HIV testing.

Ms. Powell confirmed that BPHC is collaborating with HHS colleagues to examine the role of CHCs in the medical home (healthcare home) legislation. BPHC views HIV prevention and care as integral parts of the healthcare home.

Ms. Powell announced that similar to other HRSA bureaus, BPHC also is addressing workforce issues in primary care. BPHC and BHPPr are using ARRA dollars to scale-up the National Health Services Corps Scholarship and Loan Repayment Programs. This initiative repays education loans after students graduate and work in CHCs for a period of time. BPHC is collaborating with academic institutions and medical school associations to establish fellowships and residencies in CHCs for medical school students.

Ms. Powell conveyed that BPHC would administer a survey to CHC providers to identify specific training needs and the best format for training to increase participation (*i.e.*, webcasts, technical assistance meetings at the local level or all-grantee meetings).

Mr. Steven Young is the Director of the HAB Division of Training and Technical Assistance. In response to Dr. Fenton’s question, he described two of BPHC’s best practices of effective interventions that were scaled-up in CHCs. Non-Ryan White-funded CHCs were the focal point of the MAI-funded project, “Supporting Networks of HIV Care.” The CHCs received tremendous ongoing support, technical assistance and funding to build capacity in HIV care and treatment.

Routine HIV testing was piloted in 21 CHCs in the Southeast. Data from the pilot project were published and demonstrated actions that were taken for CHCs to redesign their workflow

process, establish leadership, significantly increase the number of clients who were tested for HIV, and provide care or make referrals to Ryan White programs for clients who tested positive.

Ms. Beverly Watts Davis is the CHAC *ex-officio* member for the Substance Abuse and Mental Health Services Administration (SAMHSA). She emphasized the critical need for combined resources and a centralized data reporting system in HHS because CDC, HRSA and SAMHSA are serving the same populations.

CDC, HRSA and SAMHSA grantees also should be required to implement a social determinants of health approach to provide HIV, STD, TB and hepatitis prevention and care services and address substance abuse and mental health issues. The inclusion of these issues as a routine part of comprehensive care also would play a significant role in reducing stigma. Ms. Watts Davis strongly supported convening an interagency meeting to begin developing guiding principles and an action plan to implement this approach.

Ms. Watts Davis announced that SAMHSA is currently leveraging funds to convene a “Policy Academy” with leadership from key state agencies to develop an integrated care plan. She raised the possibility of CHAC members attending the Policy Academy. She concluded that the HHS agencies could report its preliminary joint efforts during the next CHAC meeting.

CHAC thanked Ms. Powell for attending the meeting and presenting data on the CHCs. The members agreed with Dr. Fenton’s suggestion for Ms. Powell’s update to serve as the first in a series of regular updates by BPHC during CHAC meetings. CHAC could use this agenda item to explore strategies to develop joint programming in the HHS agencies and strengthen data collection in the CHCs.

In response to Ms. Powell’s request for input, a number of CHAC members made suggestions for BPHC to consider in the areas of education and training to CHCs and increased HIV/STD testing in CHCs.

- BPHC should offer incentives and develop other creative strategies to change provider attitudes and behaviors in terms of routinizing testing in CHCs that do not receive Ryan White funding.
- BPHC should extensively engage Ryan White clinics if new teaching CHCs are formed. Ryan White clinics could play an instrumental role in educating CHCs on a broad range of topics, including cultural competence in HIV/STD testing and care; sexual, gender and minority issues; and substance abuse and mental health issues.
- BPHC should provide data during the next update to CHAC on the number of CHCs that receive Ryan White funding in Parts A and B.
- BPHC should encourage all CHCs to consult with AETCs and STD/HIV Prevention Training Centers in their respective states or regions to obtain education and training on evolving strategies for HIV/STD prevention.
- BPHC should establish and enforce a quality measure in which 100% of clients with syphilis and other STDs as their primary diagnosis in CHCs would know their HIV status or receive an HIV test.

- BPHC should take advantage of current technologies and replicate best practices to train providers onsite at CHCs. For example, the Seattle STD Training Center has established regional model clinics to provide onsite training, build skills and discuss current challenges with clinical staff. The Joint Commission has an exceptional record of busy clinicians completing mandatory training to provide good quality care to patients.

At the conclusion of the discussion, several members were in favor of CHAC adopting a formal resolution. CHAC's official statement would urge BPHC to monitor the performance of grantees in providing routine HIV testing as a part of good quality health care in CHCs. Dr. Sweet confirmed that the members would have an opportunity to propose motions for a formal vote during the CHAC business session on the following day.

New Leadership Panel Presentation

Dr. Mary Wakefield, Administrator of HRSA; Mr. Jeffrey Crowley, Director of the Office of National AIDS Policy (ONAP) and Senior Advisor of Disability Policy; and Dr. Fenton (on behalf of Dr. Thomas Frieden, Director of CDC, who was unable to attend the CHAC meeting due to a scheduling conflict) served on a new leadership panel to describe the priorities, challenges and strategic directions of their respective agencies. The prepared remarks of the new leadership panel are summarized below.

HRSA. Dr. Wakefield expressed her appreciation to and pride of HRSA staff, particularly the tireless efforts of Dr. Parham Hopson and her staff at HAB, in facilitating the passage of the Ryan White reauthorization. She also thanked CDC and HRSA's other federal partners, White House staff and external stakeholders for participating in a collaborative and coordinated effort on the Ryan White legislation. HHS Secretary Sebelius has stated that all HHS operating units must take every opportunity to collaborate and cooperate in aligning resources, maximizing efficiencies, minimizing silos within and outside of HHS, and leveraging partnerships.

HRSA received \$2 billion in ARRA funding to reinvigorate primary care across the United States. HRSA is allocating the ARRA funds to achieve the following goals: (1) enhance existing capacity of CHCs in providing primary care; (2) construct, renovate and modernize new and existing CHC sites and equipment; (3) expand CHC staff, services and hours of operation to meet increased demand as a result of a new population of uninsured persons; (4) improve health professions training through loan repayments, scholarships and academic programs; and (5) double the size of the National Health Service Corps with ~3,300 additional physicians, nurse practitioners, dentists and other professionals who will be deployed to medically underserved areas in exchange for HRSA repaying their student loans.

Dr. Wakefield established three priorities for HRSA to ensure that all expectations are met in terms of its existing appropriated programs, management of the new ARRA funds and upcoming health reform legislation. Priority 1 is stronger collaboration and cooperation across all HRSA bureaus and with grantees, external partners and stakeholders to improve efficiency

and productivity. Internal collaborations are being leveraged with BPHC, BHP and the Maternal and Child Health Bureau.

For external collaboration, Dr. Wakefield met with >100 outside organizations within the first two months after she assumed her position as the HRSA Administrator on March 10, 2009. She obtained valuable feedback from external stakeholders on potential strategies HRSA could implement to be more transparent and engage a broader sector of the public.

Priority 2 is performance improvement at all levels to ensure that HRSA makes a strong contribution to health care in America, particularly after the enactment of health reform. All HRSA programs and grantees will be engaged in performance improvement efforts. HRSA will strengthen data collection; place more emphasis on evaluating and testing the effectiveness and impact of its activities on health care in the United States; quantitatively track actual outcomes; and utilize existing data to guide programmatic improvements.

All HRSA bureaus are extensively involved in efforts to promote quality care. Most notably, HAB launched a capacity building initiative to assist Ryan White grantees in complying with the new requirement for client-level data reporting. Since September 2008, HAB's capacity building initiative has helped 17 grantees to purchase or enhance HIT systems that are capable of meeting the new client-level data reporting requirement. HRSA recently awarded additional grants to build the capacity of other grantees in reporting client-level data.

Efforts are underway to transition HAB grantees from the old aggregate data collection system to the new Ryan White HIV/AIDS Services Report. HAB is addressing several significant challenges related to the transition (*i.e.*, hardware, software, training and unique data security requirements for PLWH). The new reporting system is designed with several innovative functions for grantees. Service utilization patterns can be reviewed to determine whether the allocation of resources is effectively meeting the needs of clients. Service linkages can be improved to follow-up on referrals and adherence to treatment plans among clients.

Priority 3 is HRSA's new approach to public health with a shift from a primary focus on treatment of acute conditions to broader emphasis on disease prevention and healthier living at both individual and community levels. HRSA is currently reviewing its existing programs and policies from a public health perspective and closely collaborating with partners and constituents to promote prevention and health in populations served by HRSA programs. HRSA also is thoroughly evaluating its current organizational structure. For example, the responsibilities of HRSA's ten regional offices traditionally have been limited to reviewing the performance of grantees. Under the new organizational structure, the regional offices will have a much broader role in all of HRSA's programmatic activities.

CDC. Dr. Fenton conveyed that Dr. Frieden brought a new vision to CDC immediately after he assumed his position in June 2009. Dr. Frieden clearly articulated his key focus areas: (1) collection of solid data and evidence to improve effectiveness; (2) wise use of investments and policy levers to maximize health impact and achieve programmatic excellence at federal, state and local levels; (3) better accountability of grantees in spending federal dollars; (4) enhanced

collaboration across federal agencies; (5) stronger support to state and local health departments; and (6) a prominent role for CDC's prevention activities in health reform and the future of health care in the United States.

Dr. Frieden's key focus areas are evident in the strategic directions he established for CDC: strengthen abilities in surveillance and epidemiology; improve capacity to support state and local health departments; provide public health leadership in global health, health reform and other health policies; better address the leading causes of death and disability; and enhance efficiency of day-to-day functioning in terms of personnel and procurements to achieve cost savings. Additional details on CDC's strategic directions are outlined below.

Dr. Frieden approved the establishment of CDC's new Office of Surveillance, Epidemiology and Laboratory Services. He emphasized that solid surveillance and epidemiology capacity is the foundation of effective public health programming. He further noted that laboratory science is a core public health component and a key line of defense in protecting the public from diseases and environmental health hazards. With this new office, CDC will provide national leadership in surveillance, epidemiology and laboratory support; offer training and technical assistance in these areas to state and local health department partners; leverage opportunities with HIT investments to strengthen surveillance and epidemiology; and elevate the agency-wide profile of laboratory science.

Dr. Frieden approved the establishment of CDC's new Office of State and Local Support with the following functions. A CDC-wide system of performance and accountability will be developed and regularly monitored. Capacity in state and local public health agencies will be expanded and strengthened. Guidance, strategic direction and oversight will be provided to state and local public health agencies in expenditures of CDC investments. Guidance and strategic direction will be provided for recruitment, development and management of CDC field staff. Leadership of public health policy and practice will be shared. Health and public health IT implementation will be supported.

Dr. Frieden approved the establishment of CDC's new Center for Global Health to enhance the current PEPFAR platform and build on previous investments in HIV globally to address other infectious and non-infectious diseases, environmental conditions, injuries and chronic diseases. CDC will apply lessons learned in its global HIV activities over the past decade to expand its global portfolio to include these other areas. CDC will be an active participant in and contributor to PEPFAR II and the President's Global Health Initiative.

Dr. Frieden prioritized CDC's leadership and response to H1N1 in four key areas. Clinical, epidemiologic and laboratory surveillance will be strengthened because these components are critical to the H1N1 response. Support to states and localities will be improved because the federal H1N1 response will succeed or fail based on state and local actions. Global activities will be enhanced because H1N1 patterns overseas will play a key role in U.S. decision-making. Policy effectiveness will be improved because the resolution of important policies will depend on a strong H1N1 response. CDC also will focus on reducing illness, death and economic dislocation due to H1N1.

ONAP. Mr. Crowley emphasized that ONAP greatly appreciates and relies on the outstanding leadership of Drs. Fenton and Frieden in CDC and Drs. Parham Hopson and Wakefield in HRSA. With respect to HRSA, the Ryan White HIV/AIDS Program will continue to play a critical role after comprehensive health reform legislation is passed. The enactment of the Ryan White Treatment Extension Act in October 2009 was a tremendous accomplishment for HRSA in ensuring the continuation of this program.

With respect to CDC, President Obama most likely would not have eliminated the HIV travel ban without CDC's remarkable leadership and commitment. Due to CDC's efforts to provide education and raise awareness on this issue at the national level, >19,500 of 20,000 comments submitted supported the elimination of the HIV travel ban.

ONAP is continuing to conduct activities to support the development of the National HIV/AIDS Strategy. The ninth HIV/AIDS community discussion was recently held and the remaining five community discussions will be completed in mid-December 2009. A Federal HIV/AIDS Interagency Workgroup will be convened with key White House Offices, all operating units of HHS and other parts of the federal government to address a variety of issues for PLWHA such as housing, low-income/poverty issues, and legal and regulatory affairs.

ONAP issued a "Call to Action" on the National Strategy and will collect input through November 13, 2009 at www.whitehouse.gov/onap. A series of meetings will be held at the White House with a diverse group of ~25-30 research experts, community members and others to obtain additional feedback on the National Strategy. The participants will be asked to specifically provide input on issues related to women and HIV. Dr. Helene Gayle, former Director of the CDC National Center for HIV, STD and TB Prevention, was appointed as the new chair of the Presidential Advisory Council on HIV/AIDS (PACHA).

ONAP's community discussions across the country emphasized the need for the National Strategy to prioritize and clarify issues related to certain populations, such as African American (AA) and Hispanic MSM, gay and bisexual men in all racial/ethnic groups, women, and transgender males and females. For example, AA women have a 15 times greater chance of acquiring HIV than white women. Gay and bisexual men only account for 2%-3% of the population, but represent >50% of new HIV infections.

Transgenders are frustrated about their inaccurate classification as "MSM." Asians, Native Americans and Pacific Islanders feel marginalized due to their historical population classification of "other." The community discussions emphasized the need for ONAP to ensure that the National Strategy addresses the tremendous needs of populations at significant risk for HIV.

ONAP also heard a multitude of comments on service issues during the community discussions. The participants emphasized the need for the federal government to increase investments in housing and other support services for PLWHA, such as transportation and vocational rehabilitation.

Other key suggestions participants made during the community discussions were for the federal government to scale-up prevention interventions, particularly to reduce HIV-related health disparities; initiate broader and more extensive engagement with the faith community; improve integration within HHS and across the federal government; and streamline the process for organizations to submit grant applications and report data to multiple HHS agencies for the same populations.

ONAP's next steps in the development of the National Strategy are outlined as follows. A broad range of stakeholders will be engaged to ensure that the National Strategy effectively addresses issues related to young persons and HIV, stigma, and housing and other support services for PLWHA. A contractor was hired to synthesize input from the community discussions and feedback submitted on the website. Common themes from the public comments will be released in January 2010.

PACHA will issue formal recommendations on the draft National Strategy and a public comment period will be announced to solicit input from a wider group of external stakeholders, including CHAC. ONAP and the Federal HIV/AIDS Interagency Workgroup will prioritize activities for the National Strategy that are consistent with the President's three goals for domestic HIV: reduce HIV incidence, enroll all PLWH into care to improve their health outcomes, and reduce HIV-related health disparities.

CHAC commended the new leadership panel on establishing solid priorities and strategic directions to improve their respective agencies. CHAC thanked Dr. Wakefield for her leadership in greatly improving the HRSA/community and HRSA/Congressional relationships with more transparency. CHAC applauded Mr. Crowley for his tremendous leadership in taking swift actions to develop the National HIV/AIDS Strategy with minimal staff. CHAC also thanked Dr. Fenton for providing his insightful perspectives and observations on Dr. Frieden's new direction for CDC. The members looked forward to meeting Dr. Frieden during the first CHAC meeting in 2010.

For the benefit of the new leadership panel, the CHAC members reiterated several suggestions proposed earlier in the meeting that should be considered for inclusion in the National HIV/AIDS Strategy or the future activities of the agencies:

- A coordinated multi-agency effort to provide HIV/AIDS, STD, TB, viral hepatitis, mental health and substance abuse prevention, treatment and care as part of comprehensive care to the "whole person."
- Immediate scale-up of HIV/STD testing in CHCs.
- A significant increase in investments at the federal level for HIV/STD prevention.
- Promotion of Ryan White clinics as excellent models of medical care homes.
- Strategies to address the severe workforce shortage in HIV, primary care and public health.
- Cross-training of primary care providers in CHCs.

The CHAC members also made additional suggestions and comments for the new leadership panel to consider in shaping the future direction of their respective agencies.

- CDC should make every effort to ensure that its current reorganization avoids the mistakes of the “Futures Initiative.” This process paralyzed, demoralized and hampered CDC’s progress for a long period of time. The Futures Initiative was initiated in June 2003, but some of CDC’s state and local partners still have not fully recovered from the previous reorganization.
- HRSA leadership should develop and implement strategies to increase involvement in HIV/AIDS prevention and treatment by bureaus other than HAB.
- HRSA should encourage its HAB and BPHC grantees to enhance prevention services by offering clients STD treatment, partner services or ART at an earlier stage to decrease the transmission of HIV from PLWH to others.
- ONAP should develop a “national PEPFAR” program at the highest level of the White House to target the same level of energy, commitment, dedication and funding to the domestic HIV/AIDS epidemic as was given to the global epidemic.
- ONAP should broadly focus on sexual health in the National Strategy to effectively address the population issues that were raised during the community discussions. This approach could help to routinize HIV/STD screening; normalize conversations on general sexual, homosexual and other behaviors that are highly stigmatized; and provide evidence-based interventions to train clinicians in feeling more at ease in discussing “uncomfortable” sexual issues with their patients.
- ONAP should reactivate the large body of faith-based organizations that was assembled in 2007 to provide additional input on the National Strategy.
- ONAP should consider the possibility of expanding the National Strategy to include STDs.
- The National Strategy and other future activities proposed by CDC and HRSA, particularly new data collection requirements, should not be mandated with no additional funding to grantees.

Overview by the U.S. Global AIDS Coordinator

Ambassador Eric Goosby is the U.S. Global AIDS Coordinator at the U.S. Department of State. He commended HRSA on the fourth reauthorization of the Ryan White Care Act and CDC on the elimination of the HIV travel ban. He reported that the Office of the Global AIDS Coordinator (OGAC) is currently reviewing the extraordinary global response to HIV/AIDS by PEPFAR programs, particularly the significant scale-up of ART in sub-Saharan Africa from ~50,000 to 2.1 million persons as well as prevention efforts targeted to the general population overseas.

PEPFAR programs have made a concerted effort to target resources to the HIV/AIDS epidemic through the delivery of prevention interventions and care and treatment services. PEPFAR programs also are positioned for affected persons who use HIV/AIDS prevention and treatment

services in overseas communities to engage in dialogue and provide input to decision-makers to guide improvements.

The initial emergency response to HIV/AIDS by PEPFAR programs was designed to ensure that urgent or emergent needs were met and services would be sustained in countries over time. However, discussions are underway to shift PEPFAR from an emergency response to a sustained and permanent response based on previous prevention efforts and care and treatment services. In this transition, services will be moved to a public setting and incorporated into MOHs and governments whenever possible.

For MOHs or governments that are unwilling or unable to participate in this effort, non-governmental organizations (NGOs) will be engaged to assure the continuum of care and services in HIV/AIDS prevention and treatment is completed. Technical assistance strategies will be developed and implemented based on discussions with country leadership regarding their existing abilities and limitations.

The technical assistance strategies and ongoing mentoring will enable and facilitate increased involvement of country leadership and ownership of these management roles. A special strategy will be produced to address the absence of senior and mid-level managers in certain countries to manage clinics and hospitals and use budgets as strategic planning tools. The PEPFAR programs have learned a valuable lesson from the Ryan White HIV/AIDS Program regarding the important need for proximity in planning and policy-making.

The President and Secretary of State have announced their commitment to developing the \$63 million Global Health Initiative (GHI) over a six-year period. GHI will be based on an expansion of the current platforms of PEPFAR, TB, malaria and development programs within the U.S. Agency for International Development. GHI will initially focus on women and their children and partners with the addition of family planning, reproductive health, maternal and child health, well-baby care and immunization services.

GHI will be designed as a centralized resource for primary care services overseas for chronic and progressive diseases, such as hypertension, diabetes and coronary artery disease. GHI will serve as a highly functional system of care and will reflect a more comprehensive response to global health issues. Governments in the current PEPFAR countries have expressed strong support and endorsement of GHI. Planning efforts are ongoing to clarify certain details of GHI, particularly the process to identify and select countries for implementation of activities.

The President's commitment to advance PEPFAR programs and continue to provide prevention, care and treatment services overseas in the current economic downturn has required OGAC to identify areas of efficiency to assure a rational and non-duplicative approach to HIV/AIDS care. In terms of prevention, OGAC is exploring strategies to strengthen and target prevention interventions to the known demographics of various epidemics in countries. For HIV, for example, prevention interventions will be matched to locations where recent seroconversions have been occurring.

To support a rigorous evidence-based approach, the prevention interventions and their impact will be documented and data will be collected for broader implementation to other populations in the future. OGAC and country teams will take aggressive actions over the next few months to compile a package of prevention interventions for groups with overlapping health issues, but the initial focus will be placed on high-risk populations.

To support the needs assessment, OGAC, MOHs and in-country health workers will engage in discussions regarding the development and dissemination of appropriate conduits for prevention messaging, testing, effective strategies and services. Anthropologic interviews will be conducted to better understand the social networks and identify specific locations of high-risk populations overseas (*i.e.*, injection drug users (IDUs), sex workers, MSM and transgenders). Peer-based outreach efforts will be implemented to create “safe spaces” for high-risk persons to access needed HIV/AIDS prevention and treatment services overseas.

CHAC thanked Ambassador Goosby for providing an informative presentation on activities that will be conducted in PEPFAR II and plans to develop GHI. The CHAC members made three key suggestions for OGAC to consider in refining these initiatives.

- OGAC should ensure that strong capacity is built and the healthcare infrastructure of providers at all levels is adequately developed in shifting PEPFAR from an emergency response to a sustained and permanent response.
- OGAC should provide solid leadership in assuring that the countries tremendously scale-up HIV/AIDS prevention in PEPFAR II. The first cycle of PEPFAR heavily focused on HIV/AIDS treatment and paid minimal attention to prevention.
- OGAC should partner with SAMHSA in its ongoing initiative with the Department of State to ensure that mental health and substance abuse issues are included in PEPFAR II and GHI. SAMHSA is allocating funds to communities overseas to change the global health infrastructure and address social determinants that cause environmental risk factors.

With no further discussion or business brought before CHAC, Dr. Sweet recessed the meeting at 5:15 p.m. on November 2, 2009.

Overview of the Role of Surveillance in Informing CDC and HRSA Activities

Dr. Sweet reconvened the CHAC meeting at 8:31 a.m. on November 3, 2009 and yielded the floor to the first presenters.

CDC. Dr. Amy Lansky is the Deputy Director for Surveillance, Epidemiology and Laboratory Science at DHAP. She reported that DHAP oversees multiple HIV surveillance systems. The Case Surveillance System collects core data from all 50 states and U.S. territories and provides data for DHAP’s *Annual Surveillance Report*. This system also collects incidence data that allow DHAP to monitor new HIV infections. The Variant, Atypical and Resistant HIV System

allows DHAP to monitor drug resistance and HIV subtypes. The National HIV Behavioral Surveillance System monitors behaviors among HIV-negative persons at risk.

The Medical Monitoring Project (MMP) is a nationally representative sample of HIV-infected persons in care. DHAP uses MMP as an HIV prevention tool to collect data on behaviors and clinical outcomes of HIV-positive persons; describe characteristics and behaviors of persons at high risk for transmitting HIV infection; determine the extent to which HIV prevention services and programs reach HIV-infected persons; and determine whether HIV-positive persons receive ART early in the course of their infection. The Core Surveillance System and MMP cover the broadest spectrum of DHAP's HIV surveillance systems.

DHAP provides HIV surveillance data to several external partners, including HRSA for funding allocations of the Ryan White HIV/AIDS Program, SAMHSA, Congress, private organizations, and the Housing Opportunities for Persons with AIDS Program sponsored by the U.S. Department of Housing and Urban Development. CDC and HRSA use surveillance data to jointly publish the annual *HIV/AIDS Surveillance Supplemental Report*. To assist HRSA in allocating funds to Ryan White Part B grantees, the report shows the number of PLWH without AIDS and AIDS cases for each state.

DHAP uses surveillance data for priority setting and planning of the resource allocation model, funding opportunity announcements to determine eligibility, and strategic planning to identify priority populations. DHAP also uses surveillance data for national monitoring and evaluation, the creation of sampling frames for other studies, and modeling and projections of data.

DHAP strives to have data available 12 months after the surveillance period ends. Dr. Lansky provided an example based on core surveillance. The core surveillance period ends on December 31. Grantees need time to close out their datasets and transfer data to DHAP, as cases continue to be reported after the surveillance period ends. Thus, DHAP creates a dataset as of June 30, then processes the data, writes the surveillance report, obtains CDC clearance, and, ideally, makes the report available by December 31 of the year following the surveillance period.

During the external peer review of DHAP earlier in 2009, the panel recognized the increased complexity greater volume of data reported to CDC surveillance systems. DHAP is taking two key actions to improve its timeliness in producing surveillance reports. Systems are being developed with more standardized and automated features that will improve procedures and require less time to complete data processing. Consideration is being given to releasing preliminary or interim reports for some data from some surveillance systems.

DHAP also is implementing strategies to improve and increase the use of surveillance data for program planning. Technical assistance is routinely provided to local areas to increase the use of their individual data for local planning. DHAP's technical assistance includes analysis programs, templates of data tables, telephone calls, site visits, conferences, workshops, and release of the "Capacity Building for Epidemiology and Program Activities" Cooperative Agreement.

DHAP is implementing strategies to compile and make data from various surveillance systems easier to understand. DHAP distributed *HIV Prevention in the United States: At a Critical Crossroads* during the National HIV Prevention Conference in August 2009. The report provides a succinct overview of the current status of the HIV epidemic. DHAP provides HIV incidence data to the public through its "State of the Epidemic" interactive web-based tool. DHAP disseminates fact sheets on the HIV epidemic among MSM and other specific groups.

The NCHHSTP Surveillance Workgroup is charged with coordinating different surveillance systems. To fulfill its charge, the workgroup produces the *Annual Disease Profile* with up-to-date information on HIV, hepatitis, STDs and TB in both the general population and specific groups. The workgroup also is developing security and confidentiality guidelines to improve NCHHSTP's capacity in sharing data and integrating various data systems.

Overall, DHAP's multiple surveillance systems monitor various aspects of the HIV epidemic. Both CDC and HRSA use surveillance data to inform prevention planning. DHAP will continue to develop and implement strategies to address challenges related to the timeliness of its surveillance reports and synthesis of data for better understanding. All of DHAP's surveillance reports are available on the CDC website.

HRSA. Ms. Faye Malitz is the Director of the Division of Science and Policy at HAB. She reported that HAB uses surveillance data to meet legislative requirements in several areas. For program eligibility, HAB uses surveillance data to determine the eligibility of Ryan White grantees for Part A funding. "Eligible metropolitan areas" are defined as those with >2,000 cumulative AIDS cases for the most recent period of five calendar years. "Transitional grant areas" are defined as those with 1,000-1,999 cumulative AIDS cases for the most recent period of five calendar years.

The Ryan White legislation also contains language regarding the number of cumulative cases an area needs to continue its eligibility status for Part A funding. HAB uses surveillance data to determine the eligibility of Ryan White grantees for Part B funding. "Emerging communities" are defined as those with 500-999 cumulative AIDS cases.

For program funding, HAB uses surveillance data to develop a distribution factor based on the number of living HIV/AIDS cases. Parts A and B formula funding is determined by the ratio of living cases of HIV/AIDS in eligible areas to the sum of living cases of HIV/AIDS cases across all eligible areas. The current prevalence of HIV/AIDS and demonstrated need are used to distribute supplemental funding under Parts A and B. Examples of surveillance-based factors that are used to assess demonstrated need include:

- An increasing need for HIV/AIDS-related services, including relative rates of increase in the number of living cases of HIV/AIDS;
- Relative rates of increase in the number of living cases of HIV/AIDS within new or emerging subpopulations;
- The current prevalence of HIV/AIDS;

- The impact of co-morbid factors, including co-occurring conditions or conditions the HHS Secretary has determined to be relevant (*i.e.*, high rates of STDs, hepatitis, TB, substance use and severe mental illness); and
- The prevalence of persons who were released from federal, state or local prisons during the preceding three years and had HIV/AIDS on the date of their release.

HAB uses surveillance data to meet other legislative requirements. In Part A, funding is prioritized for women, infants, children and youth. In Part B, minimum awards are allocated to low incidence areas. In Part C, funding preferences are given to grantees based on a number of factors, such as the number of HIV/AIDS cases; the rate of increase in HIV/AIDS cases; the number of STD, TB and drug abuse cases and the number of persons co-infected with HIV/AIDS and HBV or HCV; and the rate of increase in each of these factors.

HRSA grantees use surveillance data to estimate unmet needs for care. RWHATMA required Parts A and B grantees and planning bodies to determine the number of persons in their service areas who knew their HIV-positive status, but were not receiving regular HIV-related primary medical care. Grantees conduct a three-step process to estimate unmet need for care in their service areas.

First, an estimate is made of the number of persons in each Part A or Part B service area who know their HIV-positive status, but are not receiving HIV-related medical care. Second, service needs and barriers to care are assessed for these persons, including their identities and places of residence. Third, unmet need is addressed by using unmet need data for decision-making and then locating and helping these persons enroll into care.

In addition to legislative requirements, HAB also uses surveillance data to set performance targets and report these goals to Congress and others. For example, HAB set a performance goal of 5 percentage points above CDC's national AIDS prevalence data for the proportion of women served by Ryan White-funded programs. HAB exceeded this target in 2007 because 33% of women were served by Ryan White-funded programs compared to 23% of CDC's national AIDS prevalence data.

HAB established a performance goal of 5 percentage points above CDC's national AIDS prevalence data for the proportion of racial/ethnic minorities served by Ryan White-funded programs. HAB exceeded this target in 2007 because 72% of racial/ethnic minorities were served by Ryan White-funded programs compared to 64.1% of CDC's national AIDS prevalence data.

HAB uses surveillance data to inform the development of new SPNS initiatives. For example, surveillance data showed that women account for >25% of all new HIV/AIDS diagnoses. Women of color bear a disproportionate burden of HIV disease. AA and Latina women represent only 24% of all women in the United States, but account for 82% of the total AIDS diagnoses. HAB applied these surveillance data to launch a new SPNS initiative: "Enhancing Access to and Retention in Quality HIV/AIDS Care for Women of Color."

HAB uses surveillance data to guide the development of other SPNS initiatives, special projects and formative research. These activities include (1) the 2004-2009 SPNS initiative: "Outreach, Care and Prevention to Engage HIV Seropositive Young MSM of Color;" (2) the 2007-2011 SPNS initiative: "Enhancing Linkages to Primary Care and Services in Jail Settings;" (3) a new special project: "Response to the HIV/AIDS Epidemic Among Hispanics and Latinos: Best Practices from Ryan White HIV/AIDS Program Grantees;" and (4) a new formative research project: "Promoting Linkages to HIV Care for Newly Diagnosed HIV-Positive Persons in Racial/Ethnic Minority Communities Disproportionately Impacted by HIV/AIDS."

HAB will continue to use surveillance data in the future to inform the development of the proposed severity of need index (SONI). The direct components of SONI include the number of living HIV and AIDS cases reported to CDC, while the indirect components include measures of need (*i.e.*, prevalence, poverty and AIDS death rates). However, HAB's further development of SONI will depend on more direction and guidance from Congress. The Ryan White Treatment Extension Act of 2009 signed by the President in October 2009 had no specific language on SONI. Surveillance data also will help HAB to collect more detailed data from grantees in the client-level data reporting system to guide improvements of community programs.

The CHAC members made several suggestions for CDC and HRSA to consider in refining their respective surveillance systems to better inform HIV/STD prevention and treatment.

- CDC should replicate the HRSA model in which states would be awarded points or credit for submitting surveillance data on HIV, STD and hepatitis morbidity from the field.
- HRSA should expand its surveillance systems to collect more solid data that would describe actual outcomes of clients served by Ryan White clinics, such as CD4 counts upon entry into care; the percentage of clients with viral loads <400 and diagnoses of STDs and hepatitis; the median age of clients served in clinics; and the percentage of clients diagnosed with HIV who were linked to care.
- HRSA's further development of SONI should include an additional component focusing on the distribution of co-morbidities related to mental health and substance abuse. An external peer review panel raised strong concerns that SONI was limited in its ability to adequately capture these factors.
- HRSA should ensure that planning bodies, particularly for Parts A and B grantees, are included in initiatives to build capacity in collecting, using and reporting data. Client-level and surveillance data play a major role in helping planning bodies to make decisions, improve the effectiveness of services and increase community outreach.
- CDC and HRSA should jointly hold regional meetings to teach states to appropriately and effectively use surveillance data. Surveillance, AIDS and STD directors at the state level should be required to attend the regional meetings.
- CDC and HRSA should develop and implement strategies to address inadequate surveillance staff and insufficient budgets that many states have in complying with federal data reporting requirements.

Overview of Biomedical Approaches to HIV Prevention

CDC. Dr. Jonathan Mermin is the Director of DHAP at CDC. He presented data on pre-exposure prophylaxis (PrEP) of HIV infection. New biomedical HIV prevention interventions are needed due to the severe HIV epidemic in the United States. Data show that 56,000 new HIV infections occur annually and ~1.1 million persons are currently living with HIV. Lifetime HIV treatment costs are currently estimated at \$355,000 per person, but are continuing to increase because persons are living longer due to more effective treatment. New interventions and new strategies to more effectively use existing HIV prevention interventions are needed.

PrEP for HIV prevention is based on the concept that ART will protect high-risk HIV-negative persons from HIV infection. PrEP prevents the establishment of permanent HIV infection, but is a theoretical concept at this time due to the absence of efficacy data from human studies. However, the biomedical community has established a precedent for PrEP based on malaria prophylaxis, trimethoprim-sulfamethoxazole prophylaxis and antibiotic prophylaxis in intensive care units.

Supporting evidence showed that the use of ART in HIV-infected women and newborns reduced the risk of mother-to-child transmission (MTCT) of HIV from 25% to <2%. The use of ART following needlesticks and accidental exposure to HIV-infected blood was found to be associated with a reduction of ~80% in the risk of HIV infection. Animal studies demonstrated that ART blocks infection in monkeys with repeated exposures to an HIV-like virus.

PrEP has several positive features if clinical trials prove its efficacy and solid implementation. Opportunities will be available to provide periodic risk reduction counseling and HIV testing on an ongoing basis and improve linkages to preventive care. Both women and men can use PrEP without negotiation with a partner. PrEP is not dependent on anticipating risk events and might be effective for more than one type of exposure, such as sexual transmission and drug use. PrEP can be discontinued during periods of low risk for HIV. PrEP drugs are currently licensed by FDA and are available for rapid implementation at this time.

In human clinical trials of PrEP antiretroviral medications, tenofovir, emtricitabine and a combination of both drugs were administered. Both drugs suppress the replication of HIV by interfering with the reverse transcriptase enzyme of HIV. The advantages of these drugs include a long half-life, once-daily dosing, and favorable safety and drug resistance profile. Other PrEP drugs, drug combinations, regimens and routes are being studied at this time.

CDC conducted studies on the use of ART as PrEP in monkeys. The study showed that as the control monkeys had rectal exposures to simian HIV, the number of uninfected monkeys rapidly decreased over time. However, high daily doses of tenofovir, emtricitabine or a combined regimen virtually prevented infection to simian HIV among the monkeys.

In terms of human research, the 2006 study on male circumcision has been the only successful study on HIV biomedical prevention interventions. Other HIV biomedical prevention research

showed no efficacy or actually harmed participants. These studies focused on the female diaphragm, microbicides, the role of male circumcision in HIV-infected persons in preventing infections in partners, acyclovir prophylaxis to prevent the recurrence of herpes simplex 2 in HIV transmission or acquisition, and HIV vaccines. CDC and other federal agencies are currently sponsoring PrEP studies in West Africa, Bangkok and Botswana focusing on a number of populations, including women, MSM, IDUs, heterosexuals and discordant couples.

CDC acknowledges the need to answer two critical questions before implementing PrEP. First, what should be the role of PrEP within a comprehensive national and local HIV prevention strategy? Second, what should be the role of each HHS agency in PrEP program activities? Although some of the ongoing PrEP studies are expected to generate a fair amount of data in 2010, CDC identified several reasons to support planning efforts before these results become available. PrEP prescriptions will begin to be given to patients as soon as a successful trial is announced. Time will be needed to effectively plan and consider the viewpoints, needs and concerns of multiple stakeholders. Interim analyses might terminate efficacy studies.

The rapid timeline of implementing prevention interventions for MTCT of AIDS in 1993-1994 can be used as a model to further support early planning efforts for PrEP. The interim analysis of studies on the prevention of MTCT of AIDS was released in December 1993. Research results were announced in February 1994. The Public Health Service (PHS) convened a workgroup in June 1994 and published guidelines for the field in August 1994. FDA approved label indications for drugs in August 1994.

A number of planning activities for PrEP are underway at CDC. A multidisciplinary workgroup was established to focus on implementation planning. An Intranet website was developed and external facing pages might be added in the future. Conversations have been held with other HHS agencies to coordinate activities related to PrEP implementation. Dialogue was initiated and maintained with a wide range of stakeholders to raise awareness regarding the timeline for trial results, develop collaborations, and obtain input on major implementation issues. Current and future budgets have been proposed for implementation planning activities.

To obtain external input on PrEP, CDC established workgroups focusing on clinical care, clinic-based counseling, integration of PrEP with other prevention services, IDUs, MSM, women, adolescents, and AA, Hispanic and other heterosexual men at risk. External stakeholders recently asked CDC to form an additional workgroup to specifically focus on the use of PrEP in transgenders.

CDC convened expert panels to formulate recommendations on several key issues related to PrEP, including financing and reimbursement, public health ethics, a monitoring and evaluation framework, conception in discordant couples, use of network science, legal and regulatory issues, and insurers and employers.

CDC will take a number of actions to issue guidance on PrEP following any successful trials. A "Dear Colleague" letter will be distributed to an extensive list of partners within the next few days. A "Notice to Readers" will be published in the *Morbidity and Mortality Weekly Report*

(*MMWR*) within the three months in collaboration with a PHS Workgroup. PHS guidelines will be published as *MMWR Recommendations and Reports* within six to nine months. Program implementation guidelines will be published within 12 months.

Potential users of PrEP could include HIV-uninfected persons with: (1) an HIV-infected sexual partner, (2) frequent changes in partners or concurrency, (3) partners at high risk for infection, such as IDUs, and (4) other evidence of risk (*i.e.*, frequent STDs or unintended pregnancies). Other potential users of PrEP would include HIV-discordant couples with an interest in conceiving and persons at risk for HIV who are unable to consistently use other prevention modalities.

Potential PrEP providers would include primary care clinicians, HIV care providers, allied CBOs or ASOs, pharmacies and nursing education programs. Primary care providers of PrEP potentially would include routine clinical HIV test providers; providers at STD, family planning and OB/GYN clinics; providers at community and rural health centers; and providers serving MSM and IDUs.

CDC's planning efforts for PrEP include a strong focus on preventing disparities. Effective provision of PrEP by the public sector will be critical due to the high incidence of HIV in AAs, Hispanics and MSM. These populations often are uninsured or under-insured; have disparities in treatment access; and typically rely on health departments, STD, family planning or community health clinics for health care. However, these factors might change with healthcare reform.

The annual PrEP program cost for Truvada would be \$6,570 per year based on a cost of \$18 per dose for 340B pricing. If 50 persons are treated to prevent one incident infection (based on 2% HIV incidence and 100% efficacy) and 10% of 56,000 infections are prevented each year, a \$1.8 billion investment would be needed for PrEP based on treating 275,000 persons at a cost of \$6,570 per year.

Additional costs would be incurred for recruitment, counseling, laboratories, provider time, and monitoring and evaluation. Data have shown a huge variation in the cost-effectiveness of PrEP ranging from \$50,000 to \$142,000 per quality-adjusted life year. The 2008 Paltiel, *et al.* study demonstrated that PrEP would be much more cost-effective if the annual HIV incidence in the population is high and the cost of drugs is much less.

CDC acknowledges the need to develop an evaluation framework to measure availability and coverage by assessing recruitment, usage and retention of PrEP in persons at high risk for HIV acquisition; inappropriate delivery and use; and sources of reimbursement and financial coverage. An evaluation framework also is needed to measure HIV incidence and risk behaviors while persons are on PrEP, medication adherence, and the delivery cost of PrEP programs.

Representative samples need to be characterized to define local and national estimates to add to existing data collection systems, identify external data sources and determine targeted

surveillance needs. Several existing data sources could be tailored to monitor the use of PrEP. For example, current surveillance databases at CDC, CMS, SAMHSA, the Agency for Healthcare Research and Quality, Veterans Administration, and state and local health departments could be modified to collect valuable data on the use of PrEP in a number of populations, such as persons newly diagnosed with HIV or other STDs, IDUs, MSM and heterosexuals. Existing surveillance databases also could be revised to collect data on other aspects of PrEP, such as sexual risk behaviors, HIV testing, intercurrent diagnoses, adverse events and outpatient services.

CDC is currently building a solid foundation for implementation of PrEP based on advance planning, inclusive decision-making, thoughtful implementation and financing, and monitoring, evaluation and surveillance. Implementation research is being conducted to develop cost-effectiveness and program cost models; assess attitudes and requirements among providers and users; design pre-testing tools; and develop communication strategies and materials. External technical experts are being engaged to develop potential financing strategies, create a monitoring and evaluation framework, and assess issues for special populations. Planning efforts are underway to launch PrEP demonstration projects in high-incidence/low-resource sites. Strategies are being developed for programs to deliver PrEP.

HRSA. Dr. Laura Cheever is the Deputy Associate Administrator of HAB. She described challenges to PrEP from a disease management perspective based on input HRSA has received from communities and other external stakeholders. HRSA is extremely excited about PrEP as a new modality to prevent HIV infection, but strong concerns have been raised about the absence of solid efficacy data in humans. The U.S. government is supporting expensive PrEP clinical trials with a study population of ~20,000 persons who might be exposed to an intervention with no proven effectiveness.

Other concerns that constituents conveyed to HRSA about PrEP are summarized as follows. The PrEP clinical trials exclude certain groups, such as patients with renal and kidney diseases, pregnant and breastfeeding women, and persons with untreated STDs. Data on the efficacy of implementing PrEP in these populations will be instrumental in informing actual clinical practice. Clinical trials to date have not documented a significant amount of risk from PrEP, but actual risks are unknown if high-risk persons begin to adopt PrEP in place of preventive measures with demonstrated success.

The 2008 Paltiel, *et al.* study did not find PrEP to be cost-effective, but outcomes based on a reduction in HIV transmission were not considered in the study. As a result, the cost-effectiveness of PrEP is still uncertain. Many persons who are at greatest risk for HIV and would serve as the best candidates for PrEP do not self-identify as “high risk” and change risky behaviors.

Data show that populations with the most disproportionate burden of HIV (*i.e.*, AA heterosexual women and MSM of color) typically engage in less risky behaviors than their white counterparts, but have a considerably higher risk for acquiring HIV due to various structural factors and other

issues. Strategies have not been developed to effectively target PrEP to persons at highest risk for HIV, but who have less risky behaviors than other groups.

The heavy emphasis on and strong investment in PrEP by the U.S. government appear to reflect a biomedical approach to eliminating the HIV epidemic. This strategy might result in a decreased focus and less finite resources targeted to behavioral approaches or structural interventions with proven effectiveness in reducing risks for HIV and other STDs in populations with tremendous disparities. Many populations at greatest risk for HIV (*i.e.*, young MSM of color, IDUs and AA women) currently have limited access to medical care. Investments in PrEP targeted to primary care would not capture these populations.

The CHAC members made a number of suggestions for CDC and HRSA to consider in the ongoing planning efforts related to the implementation of PrEP.

- Information should be systematically gathered on experiences with the use of PrEP in communities and private practice. The data collection effort should include reviews of the 2007 Liu, *et al.* and 2008 Brown University studies published in the *Journal of Infectious Diseases*; a survey administered to MSM in San Francisco in which one individual used antiretroviral medications as PrEP; and the “End of Condoms?” article featured in the September 24, 2009 edition of *The Daily Beast*. Additional data on the uptake of PrEP most likely would be presented during the February 2010 Conference on Retroviruses and Opportunistic Infections.
- Consideration should be given to establishing a threshold incidence to recommend PrEP.
- The implementation of PrEP should be used as an opportunity to reenergize the concept of highly-active prevention interventions in which PrEP would be only one component in a broader prevention package with various modalities. The prevention package also should include an assessment of the client’s risk for STDs, mental health and substance abuse.
- Measures should be developed to only provide PrEP in rigorously controlled environments with intensive and intermittent testing, ongoing monitoring and referral as needed.
- Research should be conducted to determine the role of PrEP in emergency departments for both female and male rape victims. Data from this research could be extremely valuable in determining the effectiveness of PrEP.

Overview of Health Reform and HIV/STD Prevention and Treatment

Mr. Donald Shriber is the Acting Associate Director for Policy and Mr. Michael Craig is a Public Health Analyst in the CDC Washington, DC Office. They provided an overview of health reform and its potential implications on HIV/STD prevention and treatment. Health reform is intended to address two major programs in the American healthcare system. The first problem is that 47 million Americans lack health insurance and millions more are under-insured and exposed to

huge medical bills. Potential solutions to this problem include reforming and restructuring the health insurance market through exchanges and regulation; requiring employers to provide and individuals to have health insurance; and offering subsidies to help low-income families purchase health insurance.

The second problem is rapidly growing healthcare costs, even for insured persons, with no real improvement in health status. Obesity and other conditions threaten to further increase healthcare costs. Potential solutions to this problem include making Medicare and Medicaid more efficient; generating an evidence base to demonstrate effective strategies and expose wasteful spending; and “bending the curve” over the long term by creating incentives for efficient and high-quality care.

Two committees have jurisdiction for health reform in the Senate. The Health, Education, Labor and Pensions Committee (HELP) and the Finance Committee passed bills in July and October 2009, respectively. However, leadership must resolve the liberal bill by the HELP Committee and the moderate bill by the Finance Committee. Three committees have jurisdiction for health reform in the House. The Ways and Means, Energy and Commerce, and Education and Labor Committees jointly developed one “Tri-Committee” bill. All three committees passed their bills in July 2009, but differences still need to be reconciled before bringing the bill to the floor.

The next steps in the health reform process are for leadership in each chamber to craft and bring a bill to the floor and structure a debate through the amendment process. The House and Senate would debate and vote on the bills. The Conference Committee would negotiate differences that are expected to be substantial. Significant political obstacles remain, but most observers still expect some sort of health reform bill to pass by the end of 2009.

Several controversial topics are associated with health reform. The Exchange is a regulated market through which individuals and small businesses could purchase coverage from private companies. The Exchange would allow for pooling of many smaller groups and “apples-to-apples” comparisons. Debates still remain regarding state, regional and national structures of the Exchange, the level of regulatory power for the Exchange, and the extent to which insurance companies could vary premiums in the Exchange.

Tax credit subsidies would be offered to low-income persons who purchase insurance on the Exchange. Debates still remain on the amounts of these subsidies. The public option is a “Medicare-like” government run plan that would compete with private insurance companies on the Exchange. Individuals could choose to purchase insurance from the public option or private insurance. Multiple variations of the public option have been proposed. The Senate Finance Committee has proposed taxing “Cadillac Plans,” particularly expensive insurance plans.

Health reform potentially would impact CDC in several areas. CDC might gain new grants and funding of \$2-\$10 billion each year. CDC might be given new high-priority authority to oversee calorie labels at chain restaurants, the collection of better health data, a “health in all policies” program, and mandatory reporting of healthcare-associated infections. Stronger public health institutions are expected to be built within and across the federal government. Major reforms

(i.e., vaccines recommended by ACIP and cancer screening or other services recommended by the U.S. Preventive Services Task Force (USPSTF)) would give more individuals access to preventive services.

The Senate and House bills include major and stable funding sources for prevention activities. The Senate HELP Committee bill proposes \$30 billion over five years and \$10 billion per year after 2014, but this bill has not identified specific allocations. The House Tri-Committee bill proposes \$15.2 billion over five years with the following allocations to CDC: \$150 million to conduct Task Force activities, \$1.75 billion to enhance CDC's internal infrastructure, \$5.4 billion to strengthen external infrastructures of states, \$1 billion to implement prevention research grants, and \$7 billion to implement community intervention grants.

The \$7 billion in community intervention grants most likely would fund infectious and chronic disease programs and other interventions that meet the high standards of the CDC *Guide to Community Preventive Services*. The final health reform bill is not expected to fund prevention activities at quite the proposed levels, but a significant investment as much as \$2 billion per year is likely.

The House bill proposes allocations of funds for new and exciting approaches that would be mandatory rather than just authorized. Truly transformative grants would facilitate a shift from disease-specific funding to holistic state and local support. Both the Senate and House invest hundreds of millions of dollars in broadening the public health workforce through an expansion of the Epidemic Intelligence Service Program, the development of new programs for loan repayment, and a new Public Health Service Corps.

CDC's new authority under health reform might include requiring all chain restaurants to place calorie information on their menus; developing a mandatory system to track healthcare-associated infections that would be administered by CDC; assessing health impacts of federal building projects; and taking steps to coordinate and improve data collection and surveillance by creating "Key National Health Indicators." These provisions could be more comprehensive.

Both the Senate and House authorize and fund activities conducted by USPSTF and the Community Preventive Services Task Force. The Senate and House also have called for the creation of a National Prevention Strategy. The Task Force activities and National Prevention Strategy could affirm the importance of certain prevention priorities.

Reforms have been proposed for Medicare and Medicaid payments to increase reimbursement for primary care. Private insurers, Medicare and Medicaid would cover preventive services, including vaccines recommended by ACIP and services recommended by USPSTF, without cost-sharing. With these reforms, vaccines and preventive screening would become available to nearly every American at no charge.

Other provisions in the health reform legislation that are relevant to HIV/STD prevention and treatment are summarized as follows. The Early HIV Treatment Act in the Senate bill would provide Medicaid eligibility to HIV-positive persons who are not yet disabled. Significant

expansion of FQHCs in both the House and Senate bills would broaden access to care and treatment to low-income persons. Teen pregnancy and STD prevention provisions would be managed by CDC (House bill) or the Administration for Children and Families (ACF) (Senate bill).

CHAC thanked Mr. Shriber and Mr. Craig for the comprehensive presentation on health reform legislation and its potential implications for HIV/STD prevention and treatment. Several CHAC members expressed concerns regarding the heavy emphasis on chronic diseases in health reform and the minimal attention given to infectious diseases. The CHAC members made several suggestions to elevate the role of HIV/STD prevention and treatment in health reform.

- Strong advocacy efforts should be launched to avoid waiting for USPSTF to issue recommendations on public health interventions or services with proven effectiveness. For example, USPSTF did not recommend perinatal prophylaxis until ten years after experts in the field collected data and created guidelines to demonstrate effectiveness. The lives of thousands of infants would have been lost if the HIV community had waited to administer perinatal prophylaxis until after the release of USPSTF guidance. Moreover, USPSTF still scores routine HIV testing with a Grade C recommendation.
- Consideration should be given to urging USPSTF to evaluate services with a clear benefit to the clinical status of the individual and strong evidence of effectiveness from a public health perspective, such as partner therapy for chlamydia and gonorrhea. An approach in which USPSTF would assess personal benefits would help to cover services for 280 million uninsured persons.
- CDC should explore the possibility of elevating the profile in the *Community Guide* of infections that have less personal health benefit, but could be construed as “community prevention” (*i.e.*, notification to partners of HIV-infected persons or syphilis reinfection driven by community transmission).
- Advocacy efforts should be launched to ensure representation of HIV/STD prevention experts on USPSTF.

Dr. Sweet confirmed that the members would have an opportunity to propose formal motions related to health reform during the business session.

Update on Federal Adolescent Sexual Health Education Initiatives

Dr. Howell Wechsler is the Director of the CDC Division of Adolescent and School Health (DASH). He explained that DASH supports efforts to reduce risks for HIV, other STDs and teen pregnancy among youth. DASH funds education agencies in 49 states, the District of Columbia, 16 large urban school districts, six territories and one tribal government to improve school policies, curricula and instruction. DASH also funds 13 NGOs to build the capacity of schools and CBOs to implement effective policies and programs.

The Division of Reproductive Health (DRH) builds capacity of local organizations to implement science-based approaches to prevent teen pregnancy. DRH funds state coalitions and regional training centers to provide support to local organizations, including health clinics, CBOs and other youth-serving organizations. DRH also funds three NGOs to disseminate lessons learned and science-based information to organizations that serve youth.

The CDC Workgroup on Adolescent Sexual and Reproductive Health published a comprehensive compendium in the *MMWR* that compiled data from 2002-2007 on sexual and reproductive health of persons 10-24 years of age in the United States. The compendium addressed current levels of risk behaviors and health outcomes; disparities by gender, age, race/ethnicity and geographic region; and trends over time. The workgroup used several databases across CDC to develop the compendium, including the National Vital Statistics System, Youth Risk Behavior Survey, National Health and Nutrition Examination Survey, National Survey of Family Growth, HIV/AIDS Reporting System, and National Electronic Injury Surveillance System.

DASH's HIV, STD and teen pregnancy prevention activities were funded at ~\$40 million in FY2009, but the House and Senate Appropriations Committees did not endorse an increase in the FY2010 budget. These activities have received flat funding since 1990. DRH's teen pregnancy prevention activities were funded at \$10.7 million in FY2009. The Senate Appropriations Committee did not endorse an increase for these activities in FY2010, but the House Appropriations Committee endorsed the FY2010 President's budget proposal that called for a \$5.1 million increase. DRH would use the new funding to increase the number of state coalitions from nine to 17.

The ACF Community-Based Abstinence Education Program was funded at \$94 million in FY2009. The House and Senate Appropriations Committees endorsed the FY2010 President's budget proposal that called for the elimination of funding for this program. The State Abstinence Education Program was funded at \$50 million in FY2009. The House Appropriations Committee endorsed the FY2010 President's budget proposal that called for elimination of funding for this program, but the Senate Finance Committee endorsed continued funding of \$50 million for the program as part of health reform legislation.

The President's FY2010 budget proposal would redirect funding from community-based and state abstinence programs to community grants under the new Teen Pregnancy Prevention Initiative (TPPI). Under TPPI, \$110 million would be appropriated to ACF to award competitive grants to CBOs and faith-based organizations to develop evidence-based interventions that provide medically accurate and age-appropriate resources to reduce risks for pregnancy and STDs. The TPPI legislative language focuses on education rather than provision of contraceptive services as an intervention to promote teen pregnancy prevention.

The TPPI budget would be broken down into three major categories: (1) \geq \$75 million for the development of curriculum-based models shown through rigorous evaluation to be effective in reducing teen pregnancy, delaying sexual activity, or improving contraception use without increase sexual activity; (2) \geq \$25 million to support demonstration projects to develop and

evaluate innovative approaches; and (3) \$4.5 million for evaluation plus funding to support communications between parents and children to discuss teen pregnancy through an interactive website.

Other components of TPPI would include \$50 million to ACF to allocate funding to states to support evidence-based teen pregnancy prevention. The Office of Population Affairs Adolescent Family Life (OPA AFL) Demonstration and Research Program previously allocated \$13.1 million for projects focusing on abstinence education. In the President's FY2010 budget proposal, this funding would focus on evidence-based teen pregnancy prevention. Title X Family Planning Programs that serve both teens and adults would receive a \$10 million increase for a total budget of \$317 million. Medicaid family planning eligibility would be expanded. CDC/DRH would receive an increase of \$5.1 million.

The reduction in teen pregnancy and teen birth rates for 14 consecutive years from 1991-2005 was a tremendous public health success. However, the stronger emphasis on teen pregnancy prevention at the federal level at this time is due to an increase in U.S. birth rates per 1,000 females 15-19 years of age since 2005. Moreover, the United States has one of the poorest records of teen birth rates compared to all other industrialized nations.

Congressional action on TPPI to date is summarized as follows. The House Appropriations Committee endorsed the FY2010 President's budget proposals of \$110 million for ACF community grants and \$13.1 million for OPA AFL teen pregnancy prevention activities. The Senate Appropriations Committee endorsed similar funding for community grants, but recommended that the HHS Office of Adolescent Health rather than ACF manage this initiative. The Senate rejected the \$13.1 proposed funding for OPA AFL teen pregnancy prevention activities.

The House, Energy and Commerce Committee approved \$50 million for states to develop evidence-based programs for the reduction of teen pregnancy or STDs, but recommended that CDC rather than ACF manage this initiative. The Senate Finance Committee approved \$75 million for ACF to fund states to deliver personal responsibility education on various topics, such as healthy relationships, financial literacy, decision-making, pregnancy prevention and HIV/STD awareness. The Senate Finance Committee also approved \$50 million for ACF to fund states to develop and deliver abstinence education.

Dr. Wechsler concluded that the outcomes of the funding proposals would not be known until Congress approves the FY2010 budget. However, several activities are underway at ACF because the \$110 million appropriation for community grants is expected to be approved. ACF is preparing a funding opportunity announcement, making efforts to develop a registry of evidence-based and effective teen pregnancy prevention initiatives, and taking steps to create a rigorous national evaluation of its teen pregnancy activities.

Dr. Wechsler was pleased to announce that ACF has embraced CDC as a full and equal partner in the development of all these new efforts. Although the community grants would focus on teen

pregnancy prevention, CDC would use this opportunity to ensure that ACF's new programs and guidance also produce positive results in the reduction of adolescent risks for HIV/STD.

The CHAC members made three key suggestions for federal agencies to consider in allocating new FY2010 dollars for adolescent sexual health education initiatives.

- Grantees of the teen pregnancy prevention community grants should be required to develop memoranda of understanding or demonstrate a formal collaborative relationship with state HIV and STD programs.
- States that receive funding to develop evidence-based programs for the reduction of teen pregnancy or STDs should be required to include culturally-specific and culturally-competent components.
- CDC and ACF should develop formal interagency agreements with other federal agencies that fund adolescent sexual health education initiatives. For example, the federal Safe Schools and Healthy Students Program would soon allocate \$3-\$9 million to various school districts to create safe environments and reduce risks for violence, mental health issues and other social problems among adolescents. Although HHS is one of the federal funding agencies along with the Department of Justice and Department of Education, this initiative does not address responsible sexual behaviors or HIV/STD awareness among adolescents.

CHAC Business Session

Dr. Sweet entertained a motion for CHAC to approve the previous meeting minutes. A motion was properly placed on the floor and seconded by Mr. Hopkins and Dr. Agins, respectively, for CHAC to adopt the previous meeting minutes. CHAC **unanimously approved** the "Draft May 18-19, 2009 Meeting Minutes" with no changes or further discussion.

Dr. Sweet led CHAC in a review of future agenda items that were raised over the course of the meeting. The members proposed placing presentations, overviews or updates of the following topics on future agendas:

1. **CDC:** Presentation on strategies to scale-up the test and treat initiative, including a review of the evidence base on linkages to care and use of different diagnostic assays to estimate HIV incidence and prevalence. As part of this presentation, CHAC requested that Dr. Bernard Branson, Associate Director for Laboratory Diagnostics in DHAP, present data on surveillance techniques, point-of-care tests, home HIV testing, and other new testing modalities. CHAC also raised the possibility of CDC and HRSA identifying and funding an organization to model or pilot a test to treat initiative.
2. **CDC:** Presentation by GAP to guide the development of CHAC's recommendations on synergies between domestic and global HIV/AIDS programs.

3. **CDC:** Remarks by Dr. Frieden on CDC's new organizational structure, priorities, challenges and strategic directions.
4. **CDC:** Update on CDC's prevention activities for syphilis and other STDs in HIV-infected persons, including the role of the *2010 STD Treatment Guidelines* in the prevention and management of STDs in HIV-infected persons.
5. **CDC:** Status report by the CDC Hispanic/Latino Executive Committee Workgroup in developing recommendations on improving HIV prevention activities for this population in the "ACT Against AIDS Campaign." Status report on implementation of the campaign in all communities to date.
6. **CDC:** Presentation on missed opportunities for HIV prevention in multiple settings (*i.e.*, emergency departments and correctional settings).
7. **CDC:** Update on the incidence of HCV co-morbidity in HIV-infected persons.
8. **CDC:** Update on new and improved HIV prevention methods.
9. **CDC:** Update on expedited partner treatment.
10. **CDC:** Overview of actions taken in response to feedback submitted on the NCHHSTP Strategic Plan.
11. **HRSA:** Facilitated discussion with CHAC on whether regional model centers could be developed to provide training to CHC staff.
12. **HRSA:** Preliminary results from the collection of client-level data.
13. **HRSA:** Update on the current status of state ADAPs.
14. **HRSA:** Results of and lessons learned from the Young MSM of Color SPNS Initiative.
15. **CDC/HRSA:** Presentation on the availability of CDC's STD surveillance and outcome data to CHCs to determine institutional rates of STD screening.
16. **CDC/HRSA:** Update on recent developments in health reform related to HIV/STD prevention and treatment.
17. **HHS Agencies:** Status report on outcomes of the interagency meeting with CDC, HRSA and SAMHSA to discuss coordinated strategies and collaborative opportunities to maximize HIV testing dollars.
18. **HHS Agencies:** Status report by the Federal Interagency Workgroup on the National HIV/AIDS Strategy.

19. **Guest Speaker:** Representative from Massachusetts to describe the state's public health experience in health reform.
20. **Guest Speakers:** Presentation by CMS, the National Alliance of State and Territorial AIDS Directors (NASTAD), and the National Coalition of STD Directors (NCSD) on the current state of and budget cuts in state Medicaid programs and the impact of these funding decreases on HIV.
21. **Recurring Agenda Items:** Updates by BPHC, the CHAC Workgroup on HIV Care, Treatment and Prevention in the New Millennium, and CDC/HRSA on HIV/STD workforce issues.

Dr. Sweet opened the floor for the members to propose motions that would require CHAC's formal action.

ISSUE 1: The following motion was properly placed on the floor and seconded by Dr. Agins and Ms. Foust, respectively. CHAC should develop core principles related to HIV care and service delivery that should be recommended as part of the health reform legislative agenda. The core principles should be designed to achieve three key outcomes. The core principles should frame Ryan White clinics as medical home models that can be used for the purpose of health reform advocacy. The core principles should be incorporated into the National HIV/AIDS Strategy. The core principles should emphasize the inclusion of HIV prevention, testing and treatment as a standard of good quality care in CHCs. **CHAC unanimously approved the motion.**

Dr. Sweet described the next steps to advance the approved motion. Ms. Kuhn would develop and distribute an electronic version of the core principles to the CHAC members for review. CHAC would convene a conference call prior to the next meeting to provide comments on the core principles in preparation of submitting the document to CDC and HRSA.

ISSUE 2: The following motion was properly placed on the floor and seconded by Dr. Hook and Rev. Hickman, respectively. CHAC recommends that CDC, HRSA and SAMHSA jointly convene a "Policy Academy" (*i.e.*, regional meetings) to provide clients with comprehensive HIV/STD, mental health and substance abuse prevention and management services at CDC-funded, HRSA-funded and SAMHSA-funded sites. This activity should be designed to reach out to primary care sites, family planning clinics, and HIV and STD sites and explore opportunities to maximize evidence-based STD and viral hepatitis interventions. The Policy Academy should include constituents in three important groups: (1) CDC, HRSA and SAMHSA at the federal level; (2) state agency directors and other decision-makers for HIV/AIDS, alcohol, drug abuse and mental health issues at the state level; and (3) CHAC members and other external stakeholders. **CHAC unanimously approved the motion.**

Dr. Fenton described next steps to advance the approved motion. CDC, HRSA and SAMHSA would jointly develop the overarching goals, key objectives and methodology of the regional

meetings and present a progress report to CHAC during a conference call prior to the next meeting.

ISSUE 3: The following motion was properly placed on the floor and seconded by Mr. Phillips and Mr. Hopkins, respectively. CHAC advises HRSA to require all grantees that provide primary medical care to routinely offer HIV/STD testing and prevention as a part of good quality health care. HRSA should monitor grantees on their ability to provide HIV/STD testing and prevention services. HRSA should identify the needs of grantees (*i.e.*, training, funding or technical assistance) in implementing CDC-recommended prevention interventions for HIV/STD screening. CHAC requests an annual report from HRSA on the progress of grantees in this area. **CHAC unanimously approved the motion.**

ISSUE 4: The following motion was properly placed on the floor and seconded by Ms. Foust and Rev. Hickman, respectively. CHAC recommends that Drs. Sweet and Hook send a letter to Dr. Frieden (CDC), Dr. Wakefield (HRSA), and Mr. Crowley (ONAP) to thank them for the continued opportunity to provide external advice and guidance to CDC and HRSA. The letter also should express CHAC's appreciation for the continued outstanding leadership of Drs. Fenton and Parham Hopson. The letter should further highlight CHAC's key products and accomplishments in the past and emphasize CHAC's future role and viability in the National HIV/AIDS Strategy. **CHAC unanimously approved the motion.**

ISSUE 5: The following motion was properly placed on the floor and seconded by Mr. Phillips and Mr. Hopkins, respectively. CHAC recommends that HRSA and other federal agencies return to the original intent of the MAI and use the new Ryan White legislation to remind grantees of the overarching purpose of the MAI; encourage grantees to reexamine surveillance data, and develop effective initiatives to provide access to and retain minority populations in care. **CHAC unanimously approved the motion.**

ISSUE 6: The following motion was properly placed on the floor by Mr. Hopkins. HRSA should conduct a special study to determine the impact of the 75%/25% core medical services requirement on the ability of HIV-positive persons to access Ryan White supportive services. HRSA should design the special study to determine whether a significant number of the population that should be served is not being served because the preferred gateway for clients to access services through Ryan White supportive services is becoming less available at the local level. **Mr. Hopkins withdrew the motion due to the absence of a second and pending further action.**

Mr. Hopkins would gather more anecdotal information and case studies to clarify and further support his request for the HRSA special study. If HRSA is successful in its \$10 million proposal for ARRA funding to support research of Ryan White and other community-based programs, Dr. Parham Hopkins confirmed that she would encourage CHAC and other external stakeholders to propose comparative effective research projects.

ISSUE 7: The following motion was properly placed on the floor by Ms. Foust. CDC and HRSA should jointly administer a survey to states in partnership with NASTAD, NCSD and the

Association of State and Territorial Health Officials to determine the impact of state funding cuts on ADAP and HIV/STD prevention at this time. CDC and HRSA should present the survey results to CHAC on a conference call prior to the next meeting. **Ms. Foust withdrew the motion due to the absence of a second.**

Although the motion was withdrawn, Dr. Fenton described next steps to respond to Ms. Foust's request. CDC and HRSA would undertake a rapid assessment process to quickly identify and review data from surveys that have been administered to the field regarding the impact of state funding cuts on ADAP and HIV/STD prevention.

CDC and HRSA would consult with NASTAD and NCSO to determine when the next survey results would be available for presentation to CHAC. CDC and HRSA would convene a conference call with CHAC prior to the next meeting to report the outcomes of their discussions with NASTAD and NCSO. Dr. Fenton pointed out that this approach would ensure CDC and HRSA do not duplicate ongoing efforts in the field.

ISSUE 8: Drs. Sweet and Hook would send a letter to Dr. Frieden emphasizing the following points. CHAC commends the close collaboration between CDC and HRSA on PrEP and encourages the continuation and expansion of this partnership to include other federal agencies. CHAC urges CDC and HRSA to convene an independent ethics committee with representation by community members to oversee the implementation of PrEP strategies at the outset. CHAC is enthusiastic about the promise of PrEP, but expresses ongoing concerns about this biomedical intervention. CHAC strongly encourages CDC and HRSA to proceed with caution in implementing PrEP. **CHAC generally agreed with this action item.**

Dr. Mermin described next steps to support this action item. He would provide CHAC with the membership of the PHS Workgroup that was established to oversee PrEP issues. He also would provide CHAC with the memberships of external workgroups that were formed to give guidance on ethical issues, clinical care, clinic-based counseling, integration of PrEP with other prevention services, IDUs, MSM, women, adolescents, as well as AA, Hispanics and other heterosexual men at risk.

ISSUE 9: The following suggestion was proposed by Dr. Hook. The CHAC members should individually provide comments on the NCHHSTP Strategic Plan as soon as possible. **CHAC generally agreed with this action item.**

Dr. Sweet closed the business session by asking CHAC to consider the best process to provide CDC and HRSA with more solid and focused advice on no more than five topics during the next meeting. These topics should be important and relevant to communities in most need of HIV/STD prevention and treatment services.

Dr. Sweet was concerned that the multitude of agenda items, formal resolutions and action items CHAC raises during each meeting would dilute the ability of CDC and HRSA to take concrete actions or effectively respond. She raised the possibility of convening a strategic

planning conference call prior to the next meeting for CHAC to explore approaches to provide CDC and HRSA with clearer and more streamlined guidance in the future.

Public Comment Session

Ms. Suzanne Miller is the Health Policy Manager of the National Coalition of STD Directors (NCSD). She reported that NCSD administered a national survey in September 2009 to its membership of STD directors in state, local and territorial public health departments. The overarching purpose of the survey was for NCSD to assess the current state of the public health program infrastructure on STD prevention and control.

NCSD designed the survey to obtain input in six major areas: funding cuts to public health STD programs; reductions to national STD program capacity; reductions in the STD program workforce; the impact of funding cuts on clinic closures and reductions in STD services in communities across the country; reductions in services in response to dwindling resources; and contributions of STD programs to the nation's public health readiness.

The 85% response rate to the NCSD survey represented program directors from 64 of 75 public health departments in 48 states and the nation's largest metropolitan regions. Of all STD programs that responded to the survey, 69% experienced salary freezes or funding cuts; 50% experienced furloughs of staff or government shutdown days; and 27% experienced staff layoffs in 2008-2009. From 1999-2009, the size of the STD program workforce was reduced by 12%; the number of disease intervention specialists was decreased by 20%; and staff vacancies were reported in 63% of STD programs.

From 2008-2009, 39 clinics in the United States (*i.e.*, categorical STD clinics, family planning clinics, CHCs, and school-based clinics supported by state and local health departments) stopped providing essential STD services. The number of clinics that receive state and local categorical funding for STDs declined in the last decade by >10%. The survey further showed that 69% of STD programs directly participated in H1N1 influenza outbreak activities in the spring of 2009 and 73% of STD programs anticipated being involved in the H1N1 response during the 2009-2010 influenza season.

Overall, the survey demonstrated that federal, state and local funding cuts are severely hampering the ability of STD programs to retain an adequate workforce and maintain pace with the increasing demand for STD testing and treatment services. These funding cuts are particularly challenging in light of the current demand for a public health response to H1N1 and increasing STD rates. NCSD plans to administer a follow-up survey to its membership within the next two months and would welcome the opportunity to present the new survey results during the next CHAC meeting.

Closing Session

CHAC applauded Ms. Margie Scott-Cseh and Ms. Shelley Gordon, CHAC's Committee Management Specialists at CDC and HRSA, respectively, for their tremendous efforts in planning and organizing the meeting and providing excellent administrative support. CHAC also thanked Drs. Fenton and Parham Hopson for continuing to provide outstanding leadership and informing CHAC of important developments in CDC and HRSA HIV/STD prevention and treatment activities.

The next CHAC meeting would be held on either May 11-12 or 18-19, 2010 in Atlanta, Georgia. Ms. Scott-Cseh and Ms. Gordon would poll the members by e-mail to confirm the date of the next meeting.

With no further discussion or business brought before CHAC, Dr. Sweet adjourned the meeting at 2:24 p.m. on November 3, 2009.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

Edward W. Hook III, M.D., Co-Chair
CDC/HRSA Advisory Committee on
HIV and STD Prevention and Treatment

Date

Donna Sweet, M.D., Co-Chair
CDC/HRSA Advisory Committee on
HIV and STD Prevention and Treatment