

**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 15-16, 2010
Washington, DC**

Record of the Proceedings

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ATTACHMENT 1

List of Participants

(Note: The CDC Designated Federal Official conducted a roll call of the CHAC voting members and the non-voting *ex-officio* members on both November 15 and 16, 2010 and confirmed the presence of quorum on both days of the meeting.)

CHAC Members

Dr. Donna Sweet, Chair
 Dr. Bruce Agins
 Dr. Carlos del Rio
 Ms. Antigone Hodgins Dempsey
 Ms. Regan Hofmann
 Mr. Ernest Hopkins
 Ms. Maria Lago
 Dr. Jeanne Marrazzo
 Dr. Kenneth Mayer
 Mr. Harold Phillips
 Dr. André Rawls
 Ms. Lisa Tiger

CHAC Ex-Officio Representatives

Dr. Pradip Akolar
 (Food and Drug Administration)
 Mr. Christopher Bates (Department of
 Health and Human Services)
 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. Geoff Beckett
 Dr. Stuart Berman
 Dr. Laura Cheever
 Ms. Laura Conn [via conference call]
 Dr. Carolyn Deal
 Dr. John Douglas, Jr.
 Ms. Teresa Durden
 Michael Evanson
 Ms. Shelley Gordon

Dr. Yeal Harris
 Dr. Seiji Hayashi
 Dr. Charlotte Kent
 Dr. Amy Lansky
 Ms. Alice Litwinowicz
 Ms. Faye Malitz
 Dr. Gordon Mansergh
 Ms. Sheila McCarthy
 Dr. Jonathan Mermin
 Mr. Douglas Morgan
 Ms. Amy Pulver
 Ms. Margie Scott-Cseh
 Ms. Adelle Simmons
 Dr. Thomas Tsang
 Dr. Ronald Valdiserri
 Dr. Hillard Weinstock
 Mr. Steven Young

Guest Presenters and Members of the Public

Mr. Chris Aldridge (HealthHIV)
 Ms. Nycal Anthony-Townsend (Alliances for
 Quality Education, Inc.)
 Mr. Nathaniel Baldo (Strategic Health Care)
 Ms. Sarah Buchanan (Orasure)
 Mr. Chris Collins (American Foundation for
 AIDS Research)
 Ms. Donna Crews (AIDS Action)
 Ms. Kimberly Crump
 (HIV Medicine Association)
 Ms. Leslie Erdelack (Association of State
 and Territorial Health Officials)
 Ms. Morgan Ford (Institute of Medicine)
 Dr. Donna Gallagher (New England AIDS
 Education and Training Center)
 Ms. Sarah Grigsby-Reiser (Sexuality
 Information and Education Council of the
 United States)
 Ms. Laura Hanen (National Alliance of
 State and Territorial AIDS Directors)
 Mr. Brian Hujdich (HealthHIV)

Ms. Christine Jamieson
(American Psychological Association)
Ms. Jennifer Kates (Kaiser Family
Foundation)
Ms. Yvonne Knight
(American Dental Education Association)
Ms. Claire Knodell (American Foundation
for AIDS Research)
Ms. Veronique Lozano (Legacy)
Mr. Kali Lindsey (Harlem United Community
AIDS Center, Inc.)
Ms. Emily McCloskey (The AIDS Institute)
Ms. Suzanne Miller
(National Coalition of STD Directors)
Ms. Myla Moss
(American Dental Education Association)

Mr. Carlos Pavuo
(Education Development Center)
Ms. Erin Perucci (Planned Parenthood
Federation of America)
Ms. Kate Petersen (National Association of
County and City Health Officials)
Mr. Carl Schmid (The AIDS Institute)
Mr. Jimmy Schneidewind (AIDS Action)
Ms. Carol Spicer (Institute of Medicine)
Ms. Nicole Stevenson (Alliances for
Quality Education, Inc.)
Mr. Wesley Tahsir-Rodriguez
(National Minority AIDS Council)
Mr. Dan Truesdale (Phillips Sol)
Ms. Andrea Waddle
(HIV Medicine Association)

ATTACHMENT 2

Glossary of Acronyms

ACIP	Advisory Committee on Immunization Practices
ADAP	AIDS Drug Assistance Program
AETC	AIDS Education and Training Center
AHRQ	Agency for Healthcare Research and Quality
ARRA	American Recovery and Reinvestment Act
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
CT	Chlamydia
DASH	Division of Adolescent and School Health
DFO	Designated Federal Official
DHAP	Division of HIV/AIDS Prevention
DSTD	Division of STD Prevention
DVH	Division of Viral Hepatitis
ECHPP	Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS
EHR	Electronic Health Record
FDA	Food and Drug Administration
FOAs	Funding Opportunity Announcements
FPL	Federal Poverty Level
FQ	Fluoroquinolones
FQHCs	Federally Qualified Health Centers
GC	Gonococcal/Gonorrhea
GISP	Gonococcal Isolate Surveillance Project
HAB	HIV/AIDS Bureau
HCCNs	Health Center Controlled Networks
HCV	Hepatitis C Virus
HHS	Department of Health and Human Services
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health Act
HPSAs	Health Professional Shortage Areas
HPV	Human Papillomavirus
HRSA	Health Resources and Services Administration
HSV-2	Herpes Simplex Virus Type 2
HUD	U.S. Department of Housing and Urban Development
IDU	Injection Drug User
IHS	Indian Health Service
IISs	Immunization Information Systems
IOM	Institute of Medicine
MAI	Minority AIDS Initiative
MICs	Minimal Inhibitory Concentrations

MMWR	<i>Morbidity and Mortality Weekly Report</i>
MSAs	Metropolitan Statistical Areas
MSM	Men Who Have Sex With Men
NAAT	Nucleic Acid Amplification Testing
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NHANES	National Health and Nutrition Examination Survey
NHAS	National HIV/AIDS Strategy
NHBS	National HIV Behavioral Surveillance System
NHSC	National Health Service Corps
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
ONAP	Office of National AIDS Policy
ONC	(HHS) Office of the National Coordinator
PACHA	Presidential Advisory Council on HIV/AIDS
PAL	Program Assistance Letter
PCMH	Patient-Centered Medical Home
PCSI	Program Collaboration and Service Integration
PLWHA	Persons Living with HIV/AIDS
PPACA	Patient Protection and Affordable Care Act
PrEP	Pre-exposure Prophylaxis
SAMHSA	Substance Abuse and Mental Health Service Administration
SDH	Social Determinants of Health
SPNS	Special Projects of National Significance
USPSTF	U.S. Preventive Services Task Force
WHO	World Health Organization

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**CDC/HRSA ADVISORY COMMITTEE ON
HIV AND STD PREVENTION AND TREATMENT
November 15-16, 2010
Washington, DC**

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 Omni Shoreham Hotel in Washington, DC on November 15-16, 2010.

Opening Session

Dr. Donna Sweet, Chair of CHAC, called the meeting to order at 8:30 a.m. on November 15, 2010 and welcomed the participants to the proceedings.

Dr. Kevin Fenton is the 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. He conducted a roll call of the CHAC voting members and the non-voting *ex-officio* members to establish a quorum for day 1 of the meeting. He asked the members to declare any conflicts of interest for the record for themselves or their institutions.

- Donna Sweet, MD: HRSA-funded Ryan White grantee and Board member of HealthHIV that is a HRSA grantee.
- Bruce Agins, MD, MPH: HRSA-funded Ryan White grantee.
- Carlos del Rio, MD: HRSA-funded Ryan White grantee and Director of the CDC-funded Gonococcal Isolate Surveillance Project Regional Laboratory in Atlanta, Georgia.
- Antigone Hodgins Dempsey, MEd: CDC contractor.
- Regan Hofmann: Board member of the American Foundation for AIDS Research that receives federal funding.
- Maria Lago, MSW: Association with Nova Southeastern University that receives funding from multiple federal agencies.

- Jeanne Marrazzo, MD, MPH: CDC grantee for STD Training Centers and HRSA-funded Ryan White grantee.
- Kenneth Mayer, MD: CDC and HRSA grantee and recipient of funding from the National Institutes of Health to conduct research.
- Harold Phillips: HRSA contractor.
- Lisa Tiger: Board member of the National Native American AIDS Prevention Center.

After confirming the presence of a quorum, Dr. Fenton reminded the participants that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record. CHAC members should be mindful of potential conflicts of interest identified by the CDC or HRSA Committee Management Office and recuse themselves from participating in discussions or voting on issues for which they had a real or perceived conflict of interest.

Dr. Fenton announced that the terms of three CHAC members representing CDC expired on November 30, 2009: Dr. Edward Hook, Rev. Debra Hickman and Mr. Tishin Jackson. The three outgoing members also served their 180-day extensions that ended on May 30, 2010. CDC submitted waivers to further extend the terms of Dr. Hook and Rev. Hickman for an additional two years.

The terms of Ms. Evelyn Foust and Ms. Regan Hofmann would expire on November 30, 2010. The 180-day extensions of the two outgoing members would end on May 30, 2011, but Ms. Foust resigned from her position as a CHAC member on November 12, 2010 due to a promotion with more demanding duties. CDC submitted a waiver to further extend Ms. Hofmann's term for an additional three years. The HHS White House Liaison is currently considering all of the nomination packages. CDC hopes that by the May 2011 CHAC meeting, the waivers would be approved and a new member would be appointed to replace Ms. Foust.

The list of participants is appended to the minutes as Attachment 1.

HRSA/HAB Associate Administrator's Report

Deborah Parham Hopson, PhD, RN, FAAN

Associate Administrator, HIV/AIDS Bureau
Health Resources and Services Administration
Designated Federal Official, CHAC

Dr. Parham Hopson covered the following areas in her update. The HRSA Maternal and Child Health Bureau held an event in October 2010 to celebrate the 75th anniversary of Title V and its continued commitment to improve the health of women and children in the United States.

At the agency level, HRSA recently hired new staff to fill key leadership positions: Deputy Associate Administrator, Bureau of Clinician Recruitment and Service (Ms. Kimberly Kleine); Director, Office of Special Health Affairs (Dr. Terry Adirim); Director, Office of Health Information

Technology and Quality (Dr. Yael Harris); Special Advisor on Oral Health (Dr. Wendy Mouradian); and three positions in the Office of Policy and Analysis (Dr. Rebecca Slifkin, Director; Mr. Mark Pincus, Director of the Office of Policy and Analysis; and Caroline Cochran, Senior Advisor).

HRSA was named as the lead agency for implementing >50 provisions in the Patient Protection and Affordable Care Act (PPACA). Dr. Parham Hopson summarized four major provisions. To “increase access to primary care,” HRSA will expand access to health care by investing \$11 billion in Community Health Centers (CHCs) over the next five years for the operation, expansion and construction of health centers. HRSA’s accomplishments to date include awarding >\$727 million in PPACA grants to upgrade and expand CHCs. These funds will provide care for an additional 745,000 underserved patients.

To “invest in the healthcare workforce,” HRSA will expand the primary care workforce and the National Health Service Corps (NHSC). HRSA’s accomplishments to date include awarding \$320 million in PPACA grants to strengthen the healthcare workforce. Of this funding, \$253 million in Prevention and Public Health Fund grants will be targeted to improving and expanding the primary care workforce and \$67 million in Health Profession Opportunity grants will be targeted to education, training and supportive services to help low-income persons to enter into and advance healthcare sector careers.

NHSC providers must work in health professional shortage areas (HPSAs), but efforts by the HRSA HIV/AIDS Bureau (HAB) to include HIV in HPSA criteria have been unsuccessful to date. However, the HHS Secretary convened a new committee in July 2010 that is attempting to develop new criteria for HPSAs and medically underserved areas. A Ryan White provider is one of the committee members and is ensuring that persons living with HIV (PLWH) are considered in these discussions.

If HIV is included in HPSA criteria, NHSC providers would be allowed to work in areas that have a high prevalence of HIV. Dr. Parham Hopson confirmed that she would provide CHAC with information on the criteria used to designate an HPSA. However, she cautioned that CHAC would need to take formal action before its next meeting in order to provide input on the committee’s deliberations.

To “support Maternal and Child Health,” HRSA will establish the Maternal, Infant and Early Childhood Home Visiting Program and continue support of the Family-to-Family Program. HRSA’s accomplishments to date include awarding \$88 million in grants to support evidence-based home visiting programs focused on improving the well-being of families with young children. HRSA also awarded \$3.9 million to continue support of Family-to-Family Health Information Centers and non-profit organizations that help families of children and youth with special healthcare needs and professionals who serve these families.

To “broaden access to the 340B Drug Pricing Program,” HRSA will amend the program to add other facilities that will be entitled to discounted drug prices: certain children’s hospitals and freestanding cancer hospitals excluded from the Medicare Prospective Payment System; critical

access and sole community hospitals; and rural referral centers. HRSA's accomplishments to date include ongoing efforts to increase eligibility of discounted medications to ~1,500 additional hospitals and clinics. Press releases on HRSA's activities and accomplishments for PPACA can be viewed at www.hhs.gov/news/press.

HRSA recently released three funding opportunity announcements (FOAs). Grants totaling \$100 million will be awarded for the construction and renovation of school-based health centers. Grants of up to \$335 million will be awarded for existing CHCs across the country to increase access to preventive and primary healthcare services at existing health center sites. Grants totaling \$3.9 million will be awarded to continue support for Family-to-Family Health Center Information Centers.

At the bureau level, HAB provided grantees with information about PPACA and its impact on PLWH/AIDS (PLWHA) and the Ryan White Program. PPACA outlines four provisions that are most relevant to PLWHA. The "access" provision eliminates discrimination based on preexisting medical conditions. The "exchanges" provision provides a competitive marketplace for consumers to easily compare and purchase health insurance plans at one location.

The "affordability" provision provides tax credits for persons who are at 400% of the Federal Poverty Level (FPL) (or a current household income of \$88,200 for a four-member family) when insurance is purchased through the exchange. The "immediate consumer protections" provision eliminates lifetime and annual limits and prohibitions on rescissions and also provides a temporary high-risk pool program for uninsured persons with a preexisting condition. HAB will issue a guidance letter to grantees in the near future to describe specific services that can or cannot be supported with Ryan White dollars under PPACA.

PPACA will result in changes for Medicare and Medicaid populations. For Medicare, cost sharing for recommended preventive services will be eliminated and the Part D coverage gap will be closed by 2020. This change is expected to reduce some of the burden of the AIDS Drug Assistance Program (ADAP) to pay for HIV/AIDS medications for low-income PLWHA. For Medicaid, services will be expanded to more Americans. This expansion will increase access to care for low-income adults up to 133% of the FPL, including many PLWHA.

HAB celebrated 20 years of the Ryan White Program during the All-Grantee Meeting with 2,421 registrants and the 13th Annual Clinical Conference with 651 participants in August 2010. Highlights of the conference are available at www.ryanwhite2010.com. HAB will continue its celebration on World AIDS Day on December 1, 2010.

As of September 30, 2010, HAB awarded the following funding to Ryan White grantees. Part A grantees received \$652 million for primary care and support services, including \$44.8 million for the Minority AIDS Initiative (MAI). Part B grantees received ~\$1.2 billion, including ~\$336.3 million in base funding, ~\$842 million for ADAP and the ADAP Supplemental, ~\$8.4 million for MAI, ~\$17.5 million for the Part B Supplemental, and \$25 for the ADAP RFI. Emergency Community grants will be awarded to 16 states.

Part C grantees received \$191 million for the Early Intervention Services Program. Part D grantees received \$72.5 million. HAB awarded \$3.5 million for two new AIDS Education and Training Center (AETC) National Centers to expand capacity of HIV/AIDS care in minority communities.

HAB will require Parts A and B grantees to monitor their sub-grantees in response to results of an Office of Inspector General evaluation. HAB developed explicit program expectations for grantees to monitor their sub-recipients or subcontractors and issued the draft requirements to grantees for review and comment. The sub-grantee monitoring requirements will become a condition of grant awards beginning in 2011.

HAB is using 2009 Ryan White Services Report data to identify data quality issues and provide technical assistance to grantees and sub-grantees on client-level data. The ADAP Client-Level Data Reporting System is under development. HAB expects ADAP grantees to begin compiling client-level data in April 2012 and issue their first reports to HAB in October 2012.

HAB's current technical assistance activities include capacity development for healthcare providers serving American Indian/Alaska Natives, the AETC U.S.-Mexico Border HIV Clinical Capacity Development Project, a new HIV clinician workforce study, an MAI outreach project to recruit young adults into care in the underserved Western Region of Puerto Rico, and the retention of HIV-positive patients in medical care by testing a intervention strategy for HIV clinics.

HAB's new and ongoing Special Projects of National Significance (SPNS) Initiatives include the development of innovative models of care to provide oral health care; enhancement and evaluation of existing health information electronic network systems for PLWHA; enhancement of linkages to HIV primary care in jail settings; capacity building to develop standard electronic data systems; enhancement of access and retention into quality HIV primary care for women of color; and an expansion of hepatitis C treatment at demonstration sites through the Evaluation and Technical Assistance Center.

HAB recently hired new staff for a number of key positions in its divisions and branches: AETC Director (Diana Travieso-Palow); Data Branch Chief (Deborah Isenberg); Deputy Director of the Division of Community-Based Programs (Gary Cook); Western Services Branch Chief (Karen Mercer); ADAP Director (Jose Au Lay); and new project officers.

CHAC thanked Dr. Parham Hopson for presenting a comprehensive update. CHAC engaged Dr. Parham Hopson and other HAB senior leadership in an extensive discussion on the HIV workforce, medical homes for PLWH and technical assistance activities for CHCs. The discussion resulted in the CHAC members making three key suggestions for HAB to consider.

- HAB should establish a policy and develop a strategy to clearly define an "HIV provider" and assure the availability of a capable and competent HIV workforce regardless of the terminology (e.g., HIV specialist or primary care provider). CHAC should engage HAB in an in-depth discussion during the next meeting to explore strategies to increase the

number of Ryan White clinics that qualify as CHCs. With this approach, Ryan White clinics could serve as “health homes” for PLWH and obtain an enhanced rate.

- HAB should provide grantees and sub-grantees (*i.e.*, supportive service providers) with better guidance, more information and concrete examples on actions that need to be taken to create health homes and other types of models of care.
- HAB should provide guidance and technical assistance to Parts A and B grantees regarding their roles and responsibilities in PPACA in terms of collaborating with both clinical care and supportive care providers.

CDC/NCHHSTP Director's Report

Kevin Fenton, MD, PhD, FFPH

Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
Designated Federal Official, CHAC

Dr. Fenton covered the following areas in his update. At the agency level, CDC's new organizational structure is aligned to meet core priorities identified by Dr. Thomas Frieden, Director of CDC. These priorities are to strengthen surveillance and epidemiology; improve capacity and effectiveness in supporting state and local health departments; provide leadership in the areas of health policy and community prevention to further reduce the burden of the leading causes of preventable illness and death; and extend and intensify CDC's activities in global health. Of the 24 senior leadership positions at the Office of Director level, 19 are new-in-post executives who will provide new energy and opportunities to support CDC's mission of prevention, control and elimination of disease, disability and death.

Dr. Frieden also articulated “winnable battles” as high-level priorities for CDC based on four factors. Each area is a leading cause of illness, injury, disability or death or represents enormous societal costs. Evidence-based and scalable interventions currently exist and can be broadly implemented. CDC's efforts can make a difference in terms of incidence or prevalence over time. CDC can obtain results within 1-4 years, but this effort will be difficult.

Based on these criteria, Dr. Frieden's six winnable battles for CDC are healthcare-associated infections, HIV, motor vehicle injuries, teen pregnancy, tobacco, and nutrition, physical activity, obesity and food safety. New infrastructures are being established across CDC to ensure that the ambitious goals are met for the six winnable battles.

The public health community can conduct core activities to help CDC achieve the winnable battles, such as prioritizing these issues at local, state and federal levels; identifying known, effective and scalable interventions; and exploring opportunities to have a large impact on health. Collective and focused efforts in the winnable battles include identifying optimal strategies at all levels across all sectors; leveraging resources and partnerships; communicating successes and challenges; and accelerating efforts to make a measurable impact on health.

The CDC Emergency Operations Center was activated to respond to the Haiti cholera outbreak. As of October 30, 2010, 4,714 cholera cases and 330 deaths were reported. CDC is continuing to assist the Ministry of Health in Haiti and the Pan American Health Organization to establish a National Cholera Surveillance System; provide cholera prevention messages and translate public service announcements; and support laboratory confirmation of suspect cases. CDC will release a report on HIV testing on November 30, 2010 in advance of World's AIDS Day as part of the new *Vital Signs* series. The monthly publication will serve as CDC's call to action on important health topics.

At the National Center level, the NCHHSTP Strategic Plan was released on February 26, 2010. The Strategic Plan articulates a vision, overarching goals and strategies to guide NCHHSTP programs. NCHHSTP's FY2010 accomplishments and FY2011 priority activities for the six cross-cutting goals of the Strategic Plan are highlighted as follows.

Goal 1 is "prevention through health care." In FY2010, NCHHSTP collaborated with HHS to develop the Viral Hepatitis Action Plan in direct response to the 2010 Institute of Medicine (IOM) report on viral hepatitis. The HIV Testing Initiative was expanded in response to CDC's 2006 recommendation to extend and integrate HIV testing more routinely in healthcare settings. HIV testing during pregnancy was included as a measure in the National Committee for Quality Assurance perinatal package. A collaboration was established with the Chlamydia Coalition to expand chlamydia screening in clinical settings and raise awareness among providers.

In FY2011, NCHHSTP will strengthen its existing collaboration with HRSA to address medical home care and the integration of HIV, hepatitis, TB and STD screening in clinical services. Collaborations with critical external stakeholders and partners will be continued to identify priority actions in response to health reform changes. Collaborations with the Centers for Medicare and Medicaid (CMS) will be continued to identify opportunities to access CMS data and improve public health.

Goal 2 is "program collaboration and service integration" (PCSI). In FY2010, NCHHSTP awarded funding to six jurisdictions to implement PCSI pilot projects. Standard PCSI language was developed for incorporation into all of NCHHSTP's future FOAs. The NCHHSTP technical consultation was held to obtain external input on standards and procedures for data security, confidentiality of surveillance systems and data sharing. A nationwide webcast on PCSI was broadcast with participation by >600 individuals. The NCHHSTP Consultation on Sexual Health was held to obtain external input on taking a public health approach to implementing sexual health in the United States with a more holistic framework. Sexual health indicator sets were developed.

In FY2011, NCHHSTP will further integrate PCSI language in all FOAs and contracts. The number of grantees will be increased to 16 if funding permits. An integrated surveillance web portal will be developed to harmonize data across NCHHSTP diseases. The data sharing and confidentiality guidelines will be completed. The first NCHHSTP Sexual Health White Paper will be published. A National Sexual Health Coalition will be launched. A new NCHHSTP HIV/STD

prevention and sexual health framework will be implemented and targeted to men who have sex with men (MSM).

Goal 3 is “health equity promotion.” In FY2010, NCHHSTP published a *Public Health Reports* issue on social determinants of health (SDH) to advise NCHHSTP programs on incorporating an SDH framework into their activities. The first NCHHSTP-wide SDH White Paper was published in October 2010. Analyses were published documenting the disproportionate impact of HIV and syphilis on MSM and HIV in poor urban areas in the United State. The first CDC-wide symposium on homelessness was convened to raise awareness of HIV, STD, TB and hepatitis in this population and explore prevention strategies.

In FY2011, NCHHSTP will develop a health equity research agenda and publish statistical methods for assessing SDH and morbidity. Language on health equity and SDH will be included in all of NCHHSTP’s future FOAs. Health equity activities will be strengthened and aligned between NCHHSTP and its four divisions. Scientific leadership of health equity will be expanded across CDC. Partners will be mobilized on SDH and HIV, hepatitis, TB and STD.

Goal 4 is “global health protection and health systems strengthening.” In FY2010, NCHHSTP supported the new CDC Center for Global Health during the transition to the Division of Global AIDS. A new global TB position was established as a liaison between NCHHSTP and the Center for Global Health. Staff was deployed to the CDC Haitian emergency relief effort. Operational research was conducted in Southeast Asia that changed global policy for HIV/TB screening. The first International Symposium on Hepatitis E was convened in collaboration with global partners. Congenital syphilis was identified as one of CDC’s global winnable battles.

In FY2011, NCHHSTP will strengthen collaborations with the Center for Global Health. Proactive contributions to CDC’s efforts on the Global Health Initiative will be continued. Participation in the U.S.-Mexico Binational Technical Workgroup Infectious Disease will be continued to focus on HIV prevention on both sides of the border.

Goal 5 is “partnerships for prevention.” In FY2010, NCHHSTP continued to build public-private partnerships through collaboration with the CDC Foundation and the National Viral Hepatitis Roundtable. The Viral Hepatitis Action Coalition was expanded. Year 2 of the “Get Yourself Tested, Get Yourself Talking” Campaign will be launched in more jurisdictions. Year 1 evaluation data showed that the social marketing campaign was extremely successful in increasing access to HIV/STD screening and other services.

Activities with the National Chlamydia Coalition will be expanded in collaboration with federal, community and private-sector partners. Coordination on national HIV prevention campaigns will be improved with key strategic partners, such as Kaiser Family Foundation. The Act Against AIDS Leadership Initiative will be expanded to extend the reach of prevention messaging and ensure that organizations serving African American, Latino and MSM populations are partners in prevention.

In FY2011, NCHHSTP will expand its activities with the CDC Foundation, particularly with sexual health and STD screening and on the Viral Hepatitis Action Coalition. A new business plan will be developed for the National Prevention Information Network for the next ten years, including upgrades to the web-based information directory and placement of the network with other available resources.

Goal 6 is “workforce development and capacity building.” In FY2010, NCHHSTP met CDC’s requirements to increase the number of Latino and targeted disabled employees to assure a more diverse workforce. The NCHHSTP Succession Planning Program was initiated to identify critical human resources that will be needed to meet prevention priorities over the next decade. The NCHHSTP Workforce Development, Capacity Building and Succession Planning Advisory Group was developed to provide strategic advice to NCHHSTP on best practices in this area within the federal government and industry. NCHHSTP employee satisfaction benchmarks were established. NCHHSTP summer fellows were mentored.

In FY2011, NCHHSTP will focus on work-life balance by collaborating with the Human Capital Management Office to conduct focus groups with NCHHSTP employees and develop evidence-based interventions on work-life balance. The NCHHSTP Ambassador Program will be created for mid-level staff. Mentoring opportunities will be provided for NCHHSTP leadership. Collaborations will be established with the CDC Office of Diversity to offer the NCHHSTP Diversity for Managers Course. The NCHHSTP Strategic Plan can be viewed in its entirety at www.cdc.gov/nchhstp/publications.

NCHHSTP is operating under a continuing resolution through December 3, 2010 with funds at the FY2010 level. In terms of leadership changes, Dr. Charlotte Kent was named as the Acting Director of the Division of STD Prevention. Dr. Frederick Bloom was named as the NCHHSTP Associate Director for Science.

At the division level, the Division of Viral Hepatitis (DVH) has continued to build public-private partnerships through collaborative efforts with the CDC Foundation and the National Viral Hepatitis Coalition. In FY2010, the Viral Hepatitis Action Coalition grew from four to nine private partners that have made three-year commitments to provide funds for viral hepatitis prevention activities. To date, the partners have pledged \$15 million.

DVH has a lead role in developing the HHS Action Plan in response to the 2010 IOM report, *“Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C.”* Dr. John Ward, Director of DVH, is co-chair of the HHS committee that is developing the action plan. DVH staff members are co-leads on three of six panels that are drafting the plan.

The Division of HIV/AIDS Prevention (DHAP) has been implementing the expanded HIV Testing Initiative for populations disproportionately affected by HIV. The initiative supports expanded HIV testing in clinical settings and aims to make HIV testing more routine. The launch of the initiative in 2007 targeted African Americans, but additional populations were added in FY2010 (e.g., gay and bisexual men of all races, injection drug users (IDU) of all races and Hispanics). DHAP awarded ~\$55 million in FY2010 for the first year of the three-year expanded initiative.

The expanded initiative supports one of the National HIV/AIDS Strategy goals to reduce new infections by increasing the percentage of PLWH who know their serostatus.

The HIV Testing Initiative has been extremely successful. Since 2007, >1.4 million persons have been tested, 10,000 persons have been newly diagnosed with HIV, and the majority of new cases have been linked to care. DHAP will publish a *Vital Signs* report in the *Morbidity and Mortality Weekly Report (MMWR)* in the near future to document the accomplishments of the initiative.

DHAP awarded \$42 million to 133 community-based organizations (CBOs) nationwide in FY2010 to implement effective HIV prevention efforts among populations at highest risk. The program funds were awarded to match the epidemic. Target populations of the grantees include MSM (49%), heterosexual men and women (38%), IDU (5%), African Americans (58%), Latinos (23%), whites (11%), Asian/Pacific Islanders (3%), and Native Americans (1%). DHAP will use the National HIV Prevention Program Monitoring and Evaluation System to monitor the effectiveness of grantees.

The Division of STD Prevention (DSTDP) will release updated STD Treatment Guidelines by the end of 2010 with coverage of the following topics: gonorrhea treatment (e.g., dual therapy for all infections), screening of pregnant women with strengthened language, chlamydia screening of men in expanded venues, including correctional settings, and gonorrhea screening of women with an emphasis on targeted screening.

DTSDP will release its surveillance report later in November 2010 documenting trends in reported cases of chlamydia, gonorrhea and syphilis in the United States. Chlamydia cases reported to CDC increased by 3% between 2008 and 2009. Gonorrhea cases decreased by 10% from 2008 overall, but rates in African American men were 26 times higher than in white men and 17 times higher in African American women than in white women. The National Chlamydia Coalition has grown with 45 partners at this time. DSTDP is continuing to engage state and local medical organizations to identify chlamydia screening champions and physicians to promote chlamydia screening in their communities.

CHAC was impressed by the extensive amount of activities NCHHSTP completed in FY2010 and the multitude of projects planned for FY2011. The members congratulated NCHHSTP on its accomplishments and successes in FY2010.

CHAC advised NCHHSTP to consult with the Joint Commission to explore the possibility of making HIV testing in medical care settings a core measure with quality indicators. Some members were concerned that although CDC called for more HIV testing in healthcare settings in 2006, this recommendation still has not been fully implemented to date.

Panel Presentation: HHS Coordination and Implementation of the National HIV/AIDS Strategy (NHAS)

A panel of speakers presented a series of overviews on the roles of HHS, HRSA and CDC in coordinating the NHAS federal implementation plan.

Ronald Valdiserri, MD, MPH

Deputy Assistant Secretary for Health, Infectious Diseases
Department of Health and Human Services

Dr. Valdiserri described HHS's role in the NHAS implementation plan. The President released the NHAS on July 13, 2010 with a detailed implementation plan that identified responsibilities for three HIV-related goals: reduce new HIV infections, increase access to care and improve health outcomes for PLWH, and reduce HIV-related disparities and health inequities. The fourth overarching goal calls for the federal government to improve coordination of HIV/AIDS activities across programs.

The President issued an Executive Memorandum in conjunction with the NHAS that identified six lead federal agencies with primary responsibility for implementation of the NHAS: HHS, Department of Labor, Department of Justice, Department of Veterans Affairs, Department of Housing and Urban Development (HUD), and Social Security Administration. The Executive Memorandum requires the lead agencies to submit detailed operational plans in 150 days (or by December 9, 2010) to the White House outlining concrete steps to meet their respective NHAS responsibilities.

HHS does not have responsibility for overseeing operational plans developed by the other lead agencies. However, HHS shared its proposed template and process for developing the operational plan for the other lead agencies to use as a technical resource if needed. Although the NHAS did not identify the Department of Education as a "lead federal agency," HHS has outreached to and made extensive efforts to engage this department in the implementation process. HHS initiated the official clearance process for its draft operational plan on November 15, 2010.

The HHS Secretary began the process for developing the HHS operational plan by asking each agency to identify a lead to serve on an HHS-wide workgroup. Drs. Parham Hopson and Fenton are the designated leads for HRSA and CDC, respectively, but other agency-level senior managers are extensively engaged in the NHAS implementation activities. The workgroup of ~45 HHS and agency representatives held a meeting in August 2010 for HHS to describe the proposed process for collecting data and developing the operational plan. CDC detailed Dr. Gordon Mansergh to the HHS Office of the Assistant Secretary for Health to assist in the implementation activities.

Dr. Valdiserri highlighted key sections in the current draft of the HHS operational plan. Activities each HHS agency will conduct to achieve the NHAS goals are based on direct feedback from

agency leadership and information collected online. A detailed HIV/AIDS budget is outlined across HHS agencies, including CDC and HRSA discretionary programs and CMS entitlement funding for persons who receive services for HIV/AIDS.

A description is provided on the HHS “12 City Project” that will play an important role for HHS agencies to meet the NHAS goals. This innovative effort will support a cross-agency response and a comprehensive approach to cross-categorical and cross-program planning in 12 U.S. metropolitan statistical areas (MSAs) that are most heavily impacted by HIV/AIDS.

CDC recently awarded grants to these 12 MSAs under the “Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS” (ECHPP) Program to enhance HIV prevention planning. However, other HHS agencies (e.g., HRSA, CMS, Substance Abuse and Mental Health Administration (SAMHSA), Indian Health Service (IHS), and National Institutes of Health (NIH)) are collaborating with CDC in a joint effort to actively explore strategies to build on this platform. HHS hopes that lessons learned and outcomes from ECHPP could be more broadly applied in the future to other areas beyond the 12 CDC-funded MSAs.

The NHAS documents the important role of the HHS Office of the Secretary in improving coordination of domestic HIV/AIDS activities within HHS, across all HHS agencies, and throughout the federal government. To meet this charge, HHS will engage the lead agencies on a more formal basis beginning in 2011 to focus on specific outcomes and identify activities with the highest priority. For example, the NHAS emphasizes the need for PLWHA to have access to housing and other necessary support services. HHS would need to closely coordinate HIV/AIDS activities with HUD to meet this objective.

Dr. Valdiserri highlighted two HHS responsibilities in the NHAS implementation plan that are particularly relevant to CHAC. First, HHS was asked to obtain input from CDC, HRSA, SAMHSA, HUD and other federal agencies on their current policies and formulas that are used to allocate federal HIV/AIDS resources. HHS will convene an initial meeting with the agencies on November 29, 2010 to discuss these issues and begin determining whether changes are needed in existing policies or formulas for allocation of federal HIV/AIDS resources.

Second, HHS will convene a consultation in the first quarter of 2011 with leadership of gay, lesbian, bisexual and transgender communities and other national organizations to explore strategies for the federal government to more productively collaborate with these groups and reengage leadership.

Dr. Valdiserri concluded his overview with overarching remarks on HHS’s role in the NHAS implementation plan. The HHS operational plan does not provide substantial details on activities that each agency will conduct in the NHAS implementation plan. Instead, each HHS agency is developing an agency-specific work plan or strategy. HHS and the other lead agencies have made a commitment to update and refine their operational plans on an annual basis in the short-term with a more focused approach and additional details.

In terms of the timeline, the HHS operational plan will not be publicly available on December 9, 2010 because the White House will need time for review and comment. However, HHS has made a strong commitment to broadly share its operational plan with CHAC and other stakeholders at some point in January 2011.

HHS is attempting to identify resources at this time to rigorously evaluate successes or failures of its agencies in the NHAS implementation plan, but this effort will be extremely challenging. Most notably, the HHS agencies with key roles in the NHAS implementation plan collectively account for domestic HIV/AIDS resources of ~\$19 billion each year. Independent of the NHAS, Dr. Valdiserri encouraged CHAC and other stakeholders to continue to communicate with the HHS Office of the Secretary about unmet needs and potential funding sources for HIV/AIDS prevention and treatment.

Deborah Parham Hopson, PhD, RN, FAAN

Associate Administrator, HIV/AIDS Bureau
Health Resources and Services Administration
Designated Federal Official, CHAC

Dr. Parham Hopson described HRSA's role in the NHAS implementation plan. HHS was appointed as the HRSA lead for the NHAS implementation plan, but an internal workgroup was established with representation by other HRSA bureaus and offices as well. The workgroup's initial step was to identify all of HRSA's responsibilities outlined in the NHAS implementation plan that need to be completed in 2010 and 2011. The workgroup then matched the list of HRSA's responsibilities with its current resources.

Dr. Parham Hopson explained that the vast majority of HRSA's planned activities for the NHAS implementation plan have not been officially cleared and could not be disclosed at this time. However, she highlighted three ongoing activities that could be publicly shared. For the NHAS goal to reduce new HIV infections, the Bureau of Primary Health Care (BPHC) issued a Program Assistance Letter (PAL) to its grantees describing HRSA's expectations for CHCs to provide HIV testing. Moreover, HRSA is extensively engaged in and fully supportive of the CDC ECHPP Program. For the NHAS goal to increase access to care, HRSA is developing a culturally competent HIV workforce by funding the National Multicultural Center through the AETC Program.

Dr. Parham Hopson concluded her overview by noting that CHAC is specifically named in the NHAS implementation plan. The NHAS goal of reducing HIV-related health disparities outlines three specific steps to achieve this goal: (1) reduce HIV-related mortality in communities at high risk for HIV infection; (2) adopt community-level approaches to reduce HIV infection in high-risk communities; and (3) reduce stigma and discrimination against PLWH.

The third step includes a sub-activity to promote public health approaches to HIV prevention and care. For this sub-activity, CHAC has been tasked with soliciting public input and making recommendations for normalizing and promoting individuals' safe and voluntary disclosure of their HIV status by the end of 2011. HRSA will publish CHAC's recommendations. In order for

HRSA to submit CHAC's recommendations to the clearance process in November 2011 to meet the December 2011 deadline, Dr. Parham Hopson advised CHAC to begin exploring strategies to solicit public input at this time.

Kevin Fenton, MD, PhD, FFPH

Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
Designated Federal Official, CHAC

Dr. Fenton described CDC's role in the NHAS implementation plan. CDC is closely collaborating with the White House Office of National AIDS Policy (ONAP) to conduct several activities in support of the NHAS implementation plan. In addition to playing a lead role in the development of the HHS operational plan, CDC also is creating an agency-specific work plan to support the NHAS implementation plan. CDC established an agency-wide NHAS Coordination Workgroup with broad representation by National Centers and divisions outside of NCHHSTP for this effort.

CDC has a number of ongoing projects that are directly aligned with the NHAS goals. For the NHAS goal to reduce HIV incidence, CDC received ~\$30 million to accelerate implementation of the NHAS recommendations. CDC awarded \$11.6 million of these funds for ECHPP to be conducted in 12 MSAs: Chicago, District of Columbia, Florida, Georgia, Houston, Los Angeles, Maryland, New York City, Philadelphia, Puerto Rico, San Francisco and Texas.

CDC is investing >\$50 million per year to expand and scale-up its HIV Testing Initiative. CDC allocated new resources to align activities by CBOs with the NHAS goals. The new resources to CBOs are being used to deliver evidence-based interventions and conduct HIV prevention projects targeted to young MSM of color and young transgenders of color. CDC will continue to fund 65 health departments to conduct HIV prevention activities. CDC will apply lessons learned as well as best and promising practices from the 12 ECHPP grantees when the HIV prevention FOA for health departments is re-competed in FY2012.

For the NHAS goal to increase access to care, CDC will use lessons learned, successful models and best practices from the 12 ECHPP grantees, the new CBO awardees and the expanded HIV Testing Initiative to improve linkages to care. CDC is partnering with HRSA on a multi-year evaluation of interventions delivered by six clinics to increase the number of HIV-positive clients who present for their appointments.

For the NHAS goal to reduce HIV-related disparities, CDC used new resources from the Prevention and Public Health Fund to invest in new approaches to modernize existing HIV surveillance systems and improve the collection and analysis of data on community viral loads and CD4 counts at the national level.

CDC developed and published a white paper with its strategic vision to incorporate SDH into prevention programming across all NCHHSTP divisions and operating units. CDC is using its

Act Against AIDS Leadership Initiative to conduct research to better characterize epidemics among gay men or localities in the United States with high rates of HIV or poverty.

For the overarching NHAS goal to improve federal coordination of HIV activities, CDC is participating on several HHS-wide workgroups for the NHAS implementation plan and also is extensively engaged in the HHS 12 Cities Project. CDC is partnering with NIH to conduct operational research on HIV prevention and develop the next generation of studies in this area. CDC is continuing its collaborative efforts with HRSA to advance HIV testing and prevention services in CHCs.

Dr. Fenton concluded his overview by highlighting activities CDC is currently conducting outside of NCHHSTP to support the NHAS goals. Most notably, the Division of Adolescent and School Health (DASH) drafted new school health guidelines to prevent HIV, other STDs and teen pregnancy. The guidelines will respond to the NHAS directive for CDC to explore strategies to ensure that school-based health education provides scientifically sound information about HIV. An expert panel is currently reviewing the draft school health guidelines.

DASH is developing toolkits for state, localities and school boards to implement age-appropriate HIV education programs. DASH expects to release a compendium of effective school-based interventions to guide this activity in January 2011. A number of school districts currently use DASH's Health Education Curriculum Analysis Tool to assure that a critical and standardized approach is taken to include HIV and sexual health content in health education curricula.

DASH is updating its existing HIV/STD prevention language for incorporation into the School Health Index. This Self-Assessment and Planning Guide is utilized by thousands of schools across the country. The School Health Index with DASH's updated HIV/STD prevention language is expected to be released in March 2011.

CHAC commended HHS, CDC and HRSA on their collective and individual efforts to date in coordinating the NHAS implementation plan. CHAC was particularly pleased that in response to its previous recommendation and the NHAS goal to reduce new HIV infections, HRSA issued the PAL to advise CHCs to expand HIV testing. CHAC applauded HRSA for developing the PAL with detailed information on the purpose, background, rationale, technical assistance and other resources for CHCs to expand HIV testing.

The CHAC members made a key suggestion for HHS to consider in the NHAS implementation plan. HHS should ensure that the final version of its operational plan strongly encourages extensive involvement by federal agencies with no solid collaborative history with HHS (e.g., CMS, Department of Justice, Department of Education, Department of Veterans Affairs, and Social Security Administration).

The CHAC members noted that participation of these "non-traditional" agencies would be essential to HIV/AIDS strategic planning for the NHAS goals at state and local levels. For example, substantial changes in disability determinations planned by the Social Security Administration will greatly impact a large proportion of the PLWHA population.

The CHAC members also proposed three action steps to respond to its NHAS charge to promote public health approaches to HIV prevention and care.

- CHAC and the Presidential Advisory Council on HIV/AIDS (PACHA) should coordinate a joint effort to respond to tasks in the NHAS implementation plan that are similar or redundant between the two groups. As an action item, Dr. Sweet confirmed that she would contact the PACHA Chair to initiate the joint effort and solicit volunteers from the CHAC membership to support this activity.
- CHAC should administer a survey to a large number of PLWH to respond to its NHAS charge to solicit public input on normalizing and promoting individuals' safe and voluntary disclosure of their HIV status. Ms. Regan Hofmann is the CHAC liaison to *POZ Magazine* and POZ.com. As an action item, she offered the resources of POZ to administer this large-scale survey.
- CHAC should send a letter to the HHS Secretary to emphasize the critical need to extend Prevention and Public Health Fund dollars allocated for 2010 NHAS activities to 2011 and thereafter.

Status Report on the CHAC Realignment Program Review Workgroup

Kevin Fenton, MD, PhD, FFPH

Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
Designated Federal Official, CHAC

Dr. Fenton reminded CHAC that CDC convened a conference call on July 29, 2010 for CHAC to vote on recommendations the Realignment Program Review Workgroup made during its meeting on July 8, 2010. The conference call was open to the public. The voting members who participated on the conference call unanimously ratified the Workgroup's draft report, but CDC subsequently learned that CHAC was not operating with a quorum and could not take formal action. Because CHAC had a quorum during the current meeting, Dr. Fenton announced that he would highlight the Workgroup's recommendations and call for a formal vote of the report.

In 1997, President Clinton issued an apology on behalf of the nation for the U.S. Public Health Service Tuskegee Study of Untreated Syphilis in the Negro Male. President Clinton committed to provide Tuskegee University with funds to establish the Center for Bioethics Research and Healthcare.

CDC awarded cooperative agreement funds of \$2 million annually to Tuskegee University to support the Bioethics Center. The last funding cycle of the 12-year cooperative agreement ended in FY2009, but CDC awarded a one-year extension to Tuskegee University of \$1.6 million in FY2010. CDC determined that continued funding for this initiative would need to be

competed because no Congressional language exists to justify eligibility status to a single grantee.

CHAC unanimously approved the establishment of a new workgroup during the May 2010 meeting with the following charge: (1) identify future opportunities to accelerate impact in health disparities through programs, policy, research and public health ethics; (2) provide guidance to CDC regarding the potential use of realigned funding; and (3) articulate key principles in the areas of program, policy and research to be considered in the development of a new FOA for use of the realigned resources.

During the consultation, the Workgroup made the following recommendations in response to four questions posed by CDC.

Question 1: What criteria should be used to realign funds? The Workgroup advised CDC to use the following criteria:

- Significance and impact of the proposed projects in reducing disparities.
- Innovation and novel methods to implement a comprehensive sexual health framework that values the diversity of sexual expression.
- An innovative and significant STD Prevention Plan highlighting established partnerships.
- Engagement of disproportionately affected communities.
- Accountability of STD grantees to integrate prevention, treatment and care into their programs.

Question 2: How should these funds be directed to accelerate the impact on STD disparities? The Workgroup advised CDC to target funding to the following areas: multifaceted intervention strategies, evaluation, innovation, a priority focus on service and policy interventions, health communications and media development, direct funding to CBOs, engagement of CHCs, a commitment to health equity and public health ethics, community-based participatory research, compilation and dissemination of “best practices,” and provision for multi-year project periods.

Question 3: How should CDC ensure that the principles of public health ethics inform and guide efforts to reduce STD disparities? The Workgroup advised CDC to take the following actions: require grantees to develop public health ethics plans; require grantees to incorporate the “Principles of the Ethical Practice of Public Health” into their activities; evaluate public health ethics efforts; and include public health ethics criteria in the FOA.

Question 4: What institutional or organizational partnerships should be developed to effectively implement strategies to reduce STD disparities among racial/ethnic minority groups? The Workgroup advised CDC to take the following actions: award institutions with credibility with affected communities and populations; target the majority of support to CBOs; make efforts to address human sexuality and sexual health, require grantees to establish Community Advisory Boards; ensure that eligible applicants for the FOA are diverse; and emphasize partnerships.

Dr. Fenton confirmed that CDC would use the guiding principles articulated by the Workgroup to develop the new FOA. Dr. Sweet chaired the Workgroup and added that the key themes of the consultation focused on partnerships, promotion of a sexual health framework, integration and innovation.

A motion was properly placed on the floor and seconded by Drs. Carlos del Rio and Bruce Agins, respectively, for CHAC to ratify the Workgroup recommendations. **CHAC unanimously approved the motion.**

Overview of the IOM Report: HIV Screening and Access to Care

Jennifer Kates, MA, MPH

Vice President and Director, HIV Policy
Kaiser Family Foundation

Ms. Kates provided an overview of the IOM Report, “HIV Screening and Access to Care: Exploring Barriers and Facilitators to Expanded HIV Testing.” The IOM is an independent health arm of the National Academy of Sciences that provides unbiased and authoritative advice to decision-makers and the public. ONAP commissioned the IOM to evaluate barriers and facilitators to expanded HIV screening and access to care. The IOM report was designed to inform the NHAS implementation plan.

The IOM Committee of 15 experts held three public workshops with diverse audiences to obtain input, searched the literature to collect data, and produced three reports. The IOM Committee reviewed 2006 data on the estimated percentage of undiagnosed HIV/AIDS cases by race/ethnicity and 2010 data on the percentage of AIDS diagnoses <12 months after an HIV diagnosis by race/ethnicity.

The IOM Committee was given a statement of task to address three questions. What is the extent to which federal, state and private health insurance policies pose a barrier to expanded HIV testing? What federal and state policies and private insurance policies and practices inhibit entry into clinical care for individuals who test positive for HIV or inhibit the provision of continuous and sustained clinical care for HIV-positive persons? What is the current capacity of the healthcare system to administer a greater number of HIV tests and accommodate new HIV diagnoses?

The focus areas of the three workshops were identifying facilitators and barriers to HIV testing (April 2010); exploring facilitators and barriers to HIV/AIDS care (June 2010); and determining the capacity of the healthcare system to identify and provide care for PLWHA (September 2010). Ms. Kates highlighted the IOM Committee’s key findings and conclusions from the first workshop in April 2010.

Question 1: What are current federal and state laws, private health coverage policies or other policies that impede HIV testing? The IOM Committee found state informed consent and pretest counseling laws to be less of a barrier, but changes or inconsistencies in policies might be a source of confusion for providers. State regulations about providers who can perform HIV testing might restrict testing capacity and limit the number of venues that can offer testing.

Discordant federal guidelines and recommendations between CDC and the U.S. Preventive Services Task Force (USPSTF) might limit insurance coverage of routine testing. Barriers to adequate reimbursement for HIV testing vary by payers and settings (e.g., cost sharing under private insurance or Medicaid differences by state). State and local regulations and institutional laboratory policies might inhibit the use of rapid HIV tests in clinical settings.

Correctional policies (e.g., compromising confidentiality) and criminalization laws might inhibit access to testing. Provider barriers include limited education and training, constraints on practice environments, and lack of necessary resources to incorporate routine HIV testing into practices. Stigma and discrimination are major barriers to HIV testing and have received minimal attention in programs. Culturally-sensitive programs and policies are needed aimed at the medical community and the public that raise awareness about HIV and HIV-related risks and provide social support.

Question 2: What effective HIV testing methods or policies should be implemented by federal, state or local agencies, federal programs, or private insurance companies that can be used to reach populations with high HIV prevalence or high prevalence of undiagnosed HIV infection? The IOM Committee determined that correctional settings provide an excellent public health opportunity for HIV testing. Successful models can be broadly replicated with appropriate resources and leadership. Efforts to increase HIV testing highlight the need to better assess and improve the effectiveness of laws and institutions in addressing HIV discrimination.

Several strategies show promise for increasing identification of PLWH: rapid HIV testing, including community settings, partner notification, social network strategies, integration of HIV testing with other services, and HIV/AIDS campaigns. A number of strategies might help to promote HIV testing by providers, such as the establishment of standards of care and quality metrics; provider education and training related to cultural competency and communication with patients about risk behaviors; and administrative strategies to help streamline counseling and testing in busy practice environments.

Question 3: What has been the impact of opt-out HIV testing? The Committee found that available studies suggest routine opt-out HIV testing could facilitate HIV testing by reducing some administrative barriers to testing experienced by clinicians. Bodies considering adoption of opt-out HIV testing should weigh the ethical advantages and disadvantages of opt-out testing that have been identified by ethicists and advocates. Further research is needed on opt-out HIV testing.

The IOM Committee's key messages across the three questions are summarized as follows. Expanded HIV testing would help reduce the number of persons who are unaware of their HIV

status, facilitate access to earlier care and better outcomes, and reduce HIV transmission. Several laws, policies and procedures might impact expanded HIV testing.

The absence of programs and policies to support clinical education and training are barriers to expanded testing. Evidence-based approaches that are available to facilitate HIV testing should be considered for expanded testing. Before expanding testing, consideration should be given to whether persons who test positive for HIV can obtain timely access to care. The barriers to expanded HIV testing were not prioritized, but the IOM Committee agreed that the behavior of providers was the most significant challenge in this area.

The IOM submitted the report from the April 2010 workshop on facilitators and barriers to HIV testing to the White House. The report from the June 2010 workshop on facilitators and barriers to HIV/AIDS care is currently undergoing the IOM review and clearance process and is expected to be released in January 2011. The report from the September 2010 workshop on the capacity of the healthcare system to identify and provide care for PLWHA is expected to be released in March 2011. Key discussion topics covered during this workshop included:

- The impact of healthcare reform on public health and the clinical infrastructure.
- Current capacity for HIV testing and treatment.
- Capacity of the healthcare system to increase the provision of HIV testing.
- The current and future HIV workforce.
- HIV training and existing gaps in this area.
- Models of HIV/AIDS care delivery.
- Healthcare workforce training issues, including implications of the cultural competence and experience of providers on HIV testing and care.

Ms. Kates encouraged CHAC to visit the IOM website at www.iom.edu to obtain more detailed information, including the workshop agendas and presentations, report summaries and the IOM Committee membership. The IOM will publish a synthesis of all three workshop reports in a peer-reviewed journal for broader dissemination of the Committee's findings and conclusions. The White House has commissioned another IOM study to identify and make recommendations on existing data gaps in expanding HIV testing.

CHAC extensively discussed and agreed that the behavior of providers has continued to impede efforts to expand HIV testing in healthcare settings. CHAC expressed a strong interest in reviewing all three of the IOM Committee reports and making formal recommendations to the HHS Secretary on expanding HIV testing. Several members emphasized the need for CHAC's formal action because the IOM Committee was charged with summarizing input from the workshops and compiling data from the literature, but was not asked to make recommendations to ONAP.

CHAC advised the IOM to leverage media resources to widely publicize the release of the two remaining reports. CHAC also raised the possibility of CDC collaborating with professional societies to distribute HIV prevention materials in the offices of private providers. Materials in

these settings could help to normalize and raise awareness of the need for HIV testing among both patients and providers.

Dr. Fenton agreed that massive behavioral change of providers is a critical need to expand HIV testing. The stigma associated with HIV testing continues to prevent providers from routinely offering the test to their patients. Dr. Fenton was interested in having a discussion with CHAC at a future meeting about best practices in other fields that have been successful in changing the behavior of providers.

In the interim of this discussion, Dr. Sweet noted that colonoscopy and mammogram rates dramatically increased when television programs and commercials informed the American public to ask their physicians for these tests. A national public awareness campaign with public service announcements or advertisements could be launched to empower the American public to demand an HIV test during their routine healthcare visits.

CHAC Business Session 1

Kevin Fenton, MD, PhD, FFPH

Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
Designated Federal Official, CHAC

Dr. Fenton presented a proposal for the creation of a new CHAC Workgroup on Viral Hepatitis. The workgroup's overarching charge would be to advise CDC and HRSA during a strategic planning process to respond to the "HHS Action Plan for the Prevention and Treatment of Viral Hepatitis."

The Action Plan outlines a number of recommendations for programs supported by CDC and HRSA to increase viral hepatitis prevention and treatment. The workgroup would convene meetings two or three times per year, but the chair would determine its entire length. Dr. Fenton pointed out that a document was included in the meeting packets describing the background, purpose, and proposed membership of the workgroup, including CHAC members and external subject-matter experts.

A motion was properly placed on the floor and seconded by Dr. Donna Sweet and Ms. Maria Lago, respectively, for CHAC to establish a Viral Hepatitis Workgroup. **CHAC unanimously approved the motion.** Drs. Carlos del Rio, Kenneth Mayer, Donna Sweet and Ms. Regan Hofmann will represent CHAC on the workgroup.

Dr. Fenton presented a proposal for the creation of a new CHAC Workgroup on Sexual Health. The workgroup's overarching charge would be to advise CDC on the development and implementation of a new Sexual Health activities and assist in the development of the White Paper on this matter.

The workgroup would be asked to address several critical issues to fulfill its charge, such as the best strategies for CDC to provide national leadership in a sexual health initiative, policy actions to take in this area, indicators to assess progress over time, strategic partnerships, and priorities of CDC and partner organizations. The workgroup would convene meetings two or three times per year for a two-year period. Dr. Fenton noted that a document was included in the meeting packets describing the rationale, goal, objectives, activities and timeline of the new workgroup.

A motion was properly placed on the floor and seconded by Drs. Donna Sweet and André Rawls, respectively, for CHAC to establish a Sexual Health Workgroup. **CHAC unanimously approved the motion.** Drs. Jeanne Marrazzo, André Rawls, Mr. Ernest Hopkins and Ms. Maria Lago will represent CHAC on the workgroup.

Overview of Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS (ECHPP)

Jonathan Mermin, MD, MPH

Director, Division of HIV/AIDS Prevention, NCHHSTP
Centers for Disease Control and Prevention

Dr. Mermin presented an overview of ECHPP. The purpose of ECHPP funding is to support the development and implementation of enhanced comprehensive HIV prevention plans in 12 MSAs with the greatest number of AIDS cases and directly link these activities to achieving the NHAS goals. The 12 MSAs represent 44% of the national AIDS epidemic. The major goals of ECHPP are aligned with the NHAS goals: reduce HIV incidence; increase access to care and improve health outcomes among PLWH by assuring retention in and adherence to care; and reduce HIV-related disparities using community viral load among MSM, African Americans and Latinos as a metric to monitor success in this goal.

In Phase 1 of ECHPP, CDC awarded \$11.6 million in September 2010 and convened the first grantee meeting in November 2010. After CDC holds additional grantee meetings, the grantees will submit draft and final versions of their enhanced HIV plans in February-March 2011 for implementation in March 2011. The one-year project period will be for the 12 grantees to focus on enhanced HIV plan development and implementation. In Phase 2, CDC will award funding in a competitive process to 4-8 grantees from Phase 1 over a two-year project process. The grantees will implement a "Help to the Top" framework to take further action on implementation of the enhanced HIV plans.

CDC established two key objectives for ECHPP. New concepts and planning strategies will be brought to bear to align HIV prevention-related activities in jurisdictions with the NHAS. To achieve this objective, grantees will maximize the impact on HIV incidence; identify and address gaps in the scope and reach of prevention activities among priority populations; and enhance coordination among prevention, care and treatment.

An optimal combination of activities will be implemented to maximally reduce new infections. To achieve this objective, grantees will prioritize the most effective biomedical, behavioral, community and structural interventions and assure that interventions and investments targeted to populations and communities match the level of risk.

CDC identified three types of interventions for grantees to achieve the second objective: "required," "recommended for consideration," and "innovative local concepts." The required and recommended interventions included in the enhanced plans all have an evidence base, do not assume a particular level of funding for each activity, and have funding at an appropriate scale for the particular jurisdiction.

Criteria for the required interventions include implementation of CDC guidelines for routine opt-out HIV testing in healthcare settings and targeted HIV testing in non-healthcare settings; comprehensive prevention with positives; condom distribution prioritized to HIV-infected persons and those at highest risk for acquiring HIV infection; post-exposure prophylaxis in non-healthcare settings for populations at greatest risk; and efforts to maximize existing structures, policies and regulations to optimize HIV prevention, care and treatment.

The ten interventions recommended for consideration include a variety of evidence-based strategies: condom distribution, communication or social marketing campaigns, clinic-wide or provider-delivered evidence-based prevention interventions, community interventions, linkages to and provision of services for social factors impacting HIV incidence, integrated hepatitis, TB and STD testing and partner services, behavioral risk screening followed by effective individual or group interventions, surveillance data to prioritize counseling and partner services, brief alcohol screening and interventions, and community mobilization. CDC plans to add circumcision as an additional recommended intervention after its guidelines on this issue are officially cleared and released.

CDC is currently finalizing a detailed evaluation plan for ECHPP, but has already awarded a \$3 million contract to conduct a supplemental evaluation of ongoing activities in the 12 funded MSAs. With the process indicators, CDC will evaluate grantees on their budget allocations, program costs and programmatic activities (e.g., numbers and characteristics of persons served, numbers of condoms distributed, and numbers of HIV tests performed).

With the outcome indicators, CDC will evaluate grantees on two types of survey data: (1) community venue-based surveys to PLWH, high-risk negative persons, IDU, high-risk heterosexuals, and MSM using the CDC National HIV Behavioral Surveillance System (NHBS) and (2) clinic-based surveys to PLWH, IDU, high-risk heterosexuals and MSM. With the impact indicators, CDC will evaluate grantees on their surveillance data of HIV incidence, diagnoses, late diagnoses, CD4 counts and viral loads.

HHS is coordinating cross-agency collaboration and cooperation of ECHPP through the NHAS Implementation Workgroup and the ECHPP Steering Committee with representation by CDC, CMS, HRSA, IHS, SAMHSA and NIH. These agencies are providing guidance to their grantees

to facilitate communication and coordination between the ECHPP grantees and existing CBOs, planning bodies, states and CHCs to strengthen linkages between prevention and care.

Overall, the 12 grantees will be required to develop an enhanced plan and leverage resources across agencies; select and target resources for maximum impact on the epidemic; and provide interventions at an appropriate scale. More intensive interventions will be reserved for areas or persons at highest risk. Less intensive interventions typically will be less costly and have a broader reach, but with a less significant impact.

CHAC commended CDC for rapidly awarding the ECHPP funds for faster implementation of this exciting new initiative in the field. CHAC was particularly pleased that other HHS agencies beyond HRSA are extensively engaged in ECHPP to enhance linkages between prevention and care.

After an extensive discussion with CDC and HRSA on payment or reimbursement for linkage to care, the CHAC members made two key suggestions for CDC to consider prior to the full implementation of ECHPP in March 2011.

- CDC should solicit public comment and external expertise on the use of community viral load as an impact indicator and the actual steps involved with meeting this metric. For example, the community viral load could be the same if one individual has an extensive number of copies and 99 persons are suppressed versus 100 persons with the same number of copies. CDC also should develop a meaningful “correction factor” to account for unknown viral loads of persons who are not captured in surveillance systems. CDC will need “real numbers” of community viral loads to accurately measure the success of grantees in this indicator.
- CDC should revise the required intervention of comprehensive prevention with positives to include HIV testing and counseling of partners or couples. Recent data show that persons in stable relationships, including both MSM and heterosexuals, account for a significant portion of HIV transmission.

Update on the CDC Pre-exposure Prophylaxis (PrEP) Implementation Plan

Amy Lansky, PhD, MPH

Deputy Director, Surveillance, Epidemiology and Laboratory Science, DHAP, NCHHSTP
Centers for Disease Control and Prevention

Dr. Lansky presented an update on CDC’s proposed implementation plan for PrEP with MSM. The NIH/Gates Foundation iPrEX Trial is a double-blind randomized controlled trial with a daily dose of Truvada (*i.e.*, tenofovir plus emtricitabine) or a placebo. The study is the only efficacy trial of PrEP among MSM and includes a cohort of 2,500 HIV-uninfected MSM at 11 sites in six countries. Results from the trial are expected in the fourth quarter of 2010.

CDC sponsored a safety study of daily oral PrEP among MSM in Atlanta, Boston and San Francisco that showed no significant biomedical safety issues between the tenofovir and placebo arms. The Adolescent Trials Network safety and acceptability study in young MSM in Chicago is underway.

In addition to MSM, daily oral PrEP trials also are underway with other populations. CDC sponsors a PrEP efficacy trial with IDU in Thailand and expects to release results in 2012. Multiple PrEP efficacy trials with heterosexuals in various sites in Africa are underway. Results from these studies are expected in 2012-2013.

CDC is preparing for rapid implementation of PrEP based on several factors. The iPrEX Trial may demonstrate the efficacy of PrEP. Using ARV for preventing mother-to-child transmission of HIV is similar to PrEP, and has been proven effective. Non-human primate and safety studies of PrEP have shown promising results as well. New HIV infections continue to increase among MSM in the United States. The medication is widely available for HIV treatment and can be immediately used “off-label” for PrEP.

The risk for misuse of PrEP is substantial if evidence-based guidance and support for appropriate use are not available. Serious concerns have been raised about the potential for PrEP to lead to “less inhibition” or more “risk compensation” (e.g., the elimination of condom use or other preventive measures). Leadership by HHS, CDC and other agencies will be critical when the PrEP results are released.

Several studies have been conducted with NHBS data documenting the demand for PrEP among MSM. The 2009 Al-Tayyib, *et al.* study reported that among MSM in Denver, 87% were willing to take PrEP daily to protect themselves from HIV based on 75% efficacy and 73% were willing to take PrEP daily based on 50% efficacy. The 2009 Mimiaga, *et al.* study reported that among MSM in Boston, 74% were willing to use PrEP in the future and 89% were willing to take PrEP for all unprotected anal sex. The 2010 Barash and Golden study reported that among MSM in Seattle, 44% would take PrEP daily if the regimen helped to prevent HIV.

CDC unpublished data and the 2010 Smith, *et al.* study were used to determine attitudes toward the provision of PrEP. The HealthStyles survey to consumers reported that with 75% efficacy, 81% of respondents would recommend PrEP to a friend or family member at high risk for HIV, 47% would support PrEP for MSM, 70% would support PrEP for discordant couples, and 68% would support public funding of PrEP for persons who could not afford the regimen. The DocStyles survey to providers reported that with 75% efficacy, 88% of physicians and nurses would prescribe PrEP to at least one risk population, 68% would prescribe PrEP to MSM, 78% would prescribe PrEP to discordant couples, and 61% would support public funding of PrEP.

A number of studies have been conducted to estimate the number of potential MSM PrEP users in the United States. The 2010 Xu, *et al.*, study used 2001-2006 National Health and Nutrition Examination Survey (NHANES) data to show that 1.8 million men 18-59 years of age reported sex with a man in the prior year and self-identified as gay. Of the study population, 47% reported >2 male sex partners in the past year and 83% did not test positive for HIV.

The 2010 Reece, *et al.* study used National Survey of Sexual Health and Behavior data to report that 39% of gay men did not use condoms during their most recent sexual event. CDC unpublished data estimate that potential MSM candidates for PrEP would be ~275,000 uninfected gay men with >2 male sex partners in the past year and no condom use at the last occurrence of anal sex. Moreover, CDC has developed and is currently validating a screening tool to define “high-risk” populations for PrEP.

The 2010 Supervie, *et al.* study presented impact models to document the percent reduction in new HIV infections among MSM in San Francisco with the implementation of PrEP over the next ten years. With 50% efficacy of PrEP, the percent change in HIV incidence would decrease by 30% with 50% coverage and by 50% with 80% coverage. Risk behaviors would substantially impact the effectiveness of PrEP. The percent change in HIV incidence would decrease by 30% with a 30% increase in new partners per year and a 50% reduction in condom use. The percent change in HIV incidence would increase by 5% with an 80% increase in new partners per year and an 80% reduction in condom use.

Several studies have shown that PrEP is most cost-effective in high-risk populations, but CDC is aware of its high cost. Most notably, the Truvada regimen that is being assessed in the iPrEX Trial is expensive and would cost \$5,000-\$7,000 per year if taken daily.

CDC has conducted several activities to date to prepare for PrEP implementation. In 2007-2008, DHAP convened a cross-branch workgroup and began obtaining external input through stakeholder consultations and expert meetings. In 2009, DHAP initiated studies to address specific needs for PrEP implementation, established workgroups to develop guidelines, and prepared for a possible stop of trials for interim analyses.

In 2010, DHAP intensified its discussions of options for PrEP implementation with stakeholders, HHS agency partners and other parts of CDC and also prepared a formal implementation plan. The federal partners that have played a critical role over the past three years in assisting CDC in the development of the PrEP guidelines and implementation plan include CMS, HRSA, SAMHSA and the Food and Drug Administration (FDA).

The external workgroups have provided input on PrEP to CDC in the areas of clinical care, clinic-based counseling, integration of PrEP with other prevention services, IDU, MSM, women, adolescents, and African American, Hispanic and other heterosexual men at risk. CDC held additional conference calls to obtain external input on the use of PrEP in transgenders. CDC established 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 intends to immediately communicate results of the PrEP trials to physicians and partners, but will not fund PrEP medications or clinical care. CDC's PrEP implementation plan for MSM will cover activities in multiple areas, including guidance, technical assistance and training,

monitoring and evaluation, implementation research, policy, communications and stakeholder engagement.

CDC will release different implementation plans depending on results of the PrEP efficacy trials and the availability of funding. With <30% efficacy, CDC will issue guidance against the use of PrEP. With $\geq 30\%$ efficacy, CDC will recommend “core functions” that are covered in base funding and require no additional resources for PrEP, such as release of the U.S. Public Health Service guidelines, guidance to health departments on the use of HIV prevention funds for PrEP, general information to the public, ongoing policy activities, cost and impact modeling, and use of existing surveillance systems for monitoring.

With 30%-79% efficacy, CDC will recommend the core functions plus additional activities that would require new funding, such as communications and training for clinical and non-clinical providers, demonstration projects among MSM, health communications efforts for MSM, and research on PrEP implementation.

With $\geq 80\%$ efficacy, CDC will recommend the core functions, activities requiring new funding in the 30%-79% efficacy plan, and additional activities with new funding, such as planning grants to local jurisdictions, additional monitoring and evaluation, and additional implementation research. Additional information on CDC’s PrEP implementation plan and results of the efficacy trials can be obtained at www.cdc.gov/hiv/prep.

CHAC commended CDC on taking proactive actions for the implementation of PrEP before the trial results are released. CHAC also applauded CDC for its leadership with the HHS agencies and its transparent efforts to engage a diverse group of stakeholders and communities at every level of the PrEP implementation planning process.

CHAC extensively discussed three major concerns that CDC needs to address prior to full implementation: the potential for less inhibition/more risk compensation with PrEP, the high cost of PrEP, and an ethical issue with PrEP. The CHAC members noted that PrEP is not a live-saving regimen, but 3,500 patients who need antiretroviral therapy to stay alive were on ADAP waiting lists in October 2010.

The CHAC members made four key suggestions for CDC to consider in its ongoing activities to refine and finalize the PrEP implementation plan.

- CDC should increase its emphasis on effectiveness research at this time to ensure a mechanism is available to track and monitor actual utilization and effectiveness of PrEP in communities. For example, the Boston study showed that side effects and the cost of PrEP would play important roles in the willingness of MSM to use the regimen. These two factors would have serious implications on the high percentage of MSM in the Boston study who reported their willingness to take PrEP daily based on its efficacy. CDC must take these and other factors into account when estimating the “demand” for PrEP among MSM at the community level.

- CDC should extensively engage BPHC in the PrEP implementation planning process at the same level as HAB because HRSA awards healthcare prevention dollars to CHCs.
- CDC's guidance should strongly emphasize to PLWH that 100% adherence to daily PrEP plus condom use and other measures in a comprehensive prevention program are the best approaches to preventing transmission of HIV. This clarification will be critical because HIV-positive persons could begin to "share drugs" with their HIV-negative partners who would have no other access to PrEP.
- CDC should use results from the recent Centre for the AIDS Program of Research in South Africa Trial to publicize the benefits of PrEP for STDs other than HIV. The trial showed that PrEP reduced the acquisition of genital herpes simplex virus 2 (HSV-2) in women by 50%. CDC could use these findings to identify HSV-2 research priorities, determine potential public health interventions for HSV-2, and inform the development of a new "Herpes Prevention and Control Program."

With no further discussion or business brought before CHAC, Dr. Sweet recessed the meeting at 5:00 p.m. on November 15, 2010.

Overview of NIH STD Prevention and Treatment Research

Dr. Sweet reconvened the CHAC meeting at 8:31 a.m. on November 16, 2010 and yielded the floor to Dr. Fenton to perform his duties as one of the CHAC DFOs.

Dr. Fenton conducted a roll call of the CHAC voting members and the non-voting *ex-officio* members to establish a quorum for day 2 of the meeting. None of the CHAC voting members disclosed any new conflicts of interest from day 1 of the meeting.

After confirming the presence of a quorum, Dr. Fenton reminded the CHAC members of their responsibility to identify potential conflicts of interest and recuse themselves from participating in discussions or voting on issues in which they have a real or perceived conflict at all times during the public meeting. Dr. Fenton yielded the floor to the first presenter.

Carolyn Deal, PhD

STD Branch Chief, Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Dr. Deal highlighted STD prevention and treatment research that is underway in the NIH National Institute of Allergy and Infectious Diseases (NIAID). NIH conducts basic research, develops medical interventions, and creates a research infrastructure. In addition to NIH, other parts of HHS also have a mission to conduct STD prevention and treatment research. CDC performs STD surveillance and detection, develops guidance for vaccine use, and maintains vaccine stockpiles. FDA is a regulatory agency that approves the licensure of vaccines. The National Vaccine Program Office is responsible for HHS-wide coordination of vaccines.

NIAID has a long history in addressing gonococcal (GC) antibiotic resistance in the United States. These approaches include the promotion of rational use of antimicrobials, infection control and surveillance, but NIAID's primary focus in this area is on biomedical research. NIAID's antimicrobial research portfolio is directed toward microbial pathogenesis, research resources, mechanisms of resistance, immunology, diagnosis and rapid detection, drugs and novel therapies, vaccines and preventive strategies, genetics and genomics, and biochemistry.

As new antibiotics have been introduced in the United States, resistance to GC antimicrobial agents subsequently has developed over time. This trend led CDC to suspend recommending fluoroquinolones (FQ) for routine use of GC treatment in 2007 and resulted in only one recommended GC antibiotic. Moreover, the broader international STD community expressed concern regarding limited capacity to treat a GC "super-bug."

NIAID published its "GC Antimicrobial Resistance Research Agenda" in 2008 with three key components to address this issue. Component 1 is basic research that involves the generation and testing of novel scientific concepts. NIAID's basic research activities in this area are highlighted as follows.

Research on infectious disease pathogenesis focuses on biofilm formation, iron acquisition and type IV secretion system. Research on mechanisms of antimicrobial resistance focuses on chromosomal-mediated resistance and the MtrCDE efflux pump that has the potential to lead to the development of novel therapeutic agents. Research on identifying and characterizing novel vaccine targets focuses on transferring binding protein and paraglobosyl lipooligosaccharides.

Component 2 is translational research and product development that involve the use of accumulated knowledge to create drugs, diagnostics and vaccines. NIAID's research activities in this area are highlighted as follows. Annual partnership initiatives have been sponsored since 2000 to translate milestones and findings from basic research to actual practice. NIAID's Northeastern and Southeastern STI Cooperative Research Centers were funded to examine GC mechanisms and treatment strategies.

The "Partnerships for the Development of New Therapeutic Classes for Select Viral and Bacterial Pathogens" FOA was announced in FY2010 to engage industry in funding new drugs. In response to the FOA, applications were submitted for the development of new GC, *Clostridium difficile* and hepatitis B therapeutic agents. Comprehensive pre-clinical services will be delivered to fill gaps and reduce risks through mouse models of GC infection, *in vitro* testing and vaccine services in the future.

Component 3 is clinical research that involves rigorous safety and efficacy testing of candidate products and practices. NIAID's research activities in this area are highlighted as follows. The STI Clinical Trials Group is focusing on new uses of GC treatment with older drug combinations (e.g., azithromycin/gentamycin and azithromycin/gemifloxacin). Small Business Innovation Grants were awarded to apply research findings to evaluate new GC diagnostics, more rapidly diagnose GC infections, and identify low-resource settings that need point-of-care diagnostics.

The NIAID Phase I Unit is evaluating the safety, pharmacokinetics and pharmacodynamics of delafloxacin that is currently licensed as an antibiotic for intravenous use. Delafloxacin is being assessed as a new generation FQ to determine its oral bioavailability as an STD treatment option. The NIAID Vaccine Treatment and Evaluation Units are conducting Phases I and II clinical trials of vaccine and therapeutic agents for future evaluation of these drugs in actual clinical settings.

Overall, NIH serves academia, patients and advocacy groups, the general public, professional societies, industry, physicians and other health professionals, voluntary organizations, and federal partners. Most notably, NIAID is continuing to closely collaborate with and obtain safety and efficacy data from CDC on GC antibiotics. NIAID and CDC are currently cosponsoring a clinical trial to determine new uses for older drug combinations.

Overview of CDC's Priorities for Gonorrhea Antibiotic Resistance Management

Hillard Weinstock, MD, MPH

Medical Epidemiologist & Surveillance and Special Studies Team Lead
Division of STD Prevention, NCHHSTP
Centers for Disease Control and Prevention

Dr. Weinstock highlighted program and research priorities that CDC has identified for managing antibiotic-resistant GC in the United States. GC accounts for an estimated burden of >700,000 U.S. cases annually and is the second most commonly reportable notifiable disease after chlamydia. GC may cause pelvic inflammatory disease, infertility or chronic pelvic pain and has been associated with increased risk for HIV transmission and acquisition. Prompt and effective diagnosis and treatment of GC are critical to limit disease and prevent transmission.

Antimicrobial resistance complicates the treatment of GC. Several classes of antibiotics that traditionally were recommended from 1940-2000 (e.g., sulfonamides, tetracyclines, penicillins and fluoroquinolones (FQ)) are no longer sufficiently effective in treating GC. Since 2007, CDC has recommended cephalosporins as the only class of antibiotics for GC treatment. CDC's 2010 STD Treatment Guidelines are in press and recommend 250 mg of ceftriaxone intramuscularly in a single dose or 400 mg of cefixime orally in a single dose if the first option is not feasible (as well as co-treatment for chlamydia).

CDC's response to the management of antibiotic-resistant GC is focusing on three key areas. For surveillance, CDC is conducting susceptibility monitoring. For program activities, CDC has implemented GC prevention and control interventions, is developing a U.S. outbreak response plan, and is collaborating with the World Health Organization (WHO) and other international partners. For research, CDC is studying the mechanisms of cephalosporin resistance, evaluating GC treatment failures, and assessing alternative treatment regimens in partnership with NIAID.

CDC established the Gonococcal Isolate Surveillance Project (GISP) in 1986 to perform surveillance of GC antimicrobial resistance. This national sentinel surveillance system monitors trends in antimicrobial susceptibilities of GC and establishes a rational basis for the selection of antimicrobial treatment of GC infections. The GISP sentinel sites and regional laboratories cover 29 sites in the United States.

GISP maintains >20 years of trend data and provides sentinel surveillance in sites of all regions of the country with over-sampling of Hawaii and the West Coast to detect the importation of resistant GC cases. CDC implements GISP in close collaboration with state and local public health authorities and STD clinics. GISP co-investigators are GC subject-matter experts.

GISP data showed a dramatic increase in FQ resistance from 1990-2007. GISP first documented the emergence of FQ resistance in Hawaii, then in California and among men who have sex with men, and finally in the remainder of the United States. CDC withdrew its recommendation of FQ for GC treatment for any population in 2007.

Early factors associated with acquisition of FQ resistance included residence in or a history of recent travel to Asia or the Pacific Islands, Asian or White race, heterosexual transmission, or MSM transmission in the United States. Several reports from Japan, Hong Kong, Australia, Europe and the United States have now documented decreased susceptibility of cephalosporins to gonorrhea.

A 2007 Hong Kong report documented four treatment failures with cefixime. Data have shown slight increases over time in the MICs to injectable ceftriaxone for GC among GISP isolates from 2005-2009. The same data set also showed that the MICs to oral cefixime for GC increase between 2005 and 2009. The Western part of the country and MSM accounted for the vast majority of the higher MICs.

CDC has implemented a broad programmatic response to enhance GC prevention and control activities to reduce the size of at-risk populations. A series of meetings was convened in each HHS region in 2008-2010 to discuss the epidemiology of GC, apply lessons learned from peers and develop realistic action plans. A consultation was held on a cephalosporin-resistant GC outbreak response plan in September 2009. The development of the plan is underway.

Funding was awarded to sites in California, Hawaii, New York State and Washington State to develop local GC response plans to inform CDC's national response plan. An *MMWR* report will be published in the near future to increase awareness of the threat of cephalosporin-resistant GC. An international collaboration was established with WHO and WHO Collaborating Centers on the Gonococcal Regional Antimicrobial Susceptibility Programme.

WHO and CDC hosted a joint consultation in Manila in April 2010 with representation by microbiologists and epidemiologists from >17 countries to share country and agency data and experiences of monitoring for emergence of cephalosporin resistance. Differences in testing methods, definitions of "susceptibility" and "resistance," and various areas for collaboration were

extensively discussed during the consultation. WHO will develop a web-based system for international partners to continue to share GC data and experiences.

CDC is aware of several challenges in addressing its program priorities for managing antibiotic-resistant GC in the United States. Information is limited on “break point” MICs to define “resistance” to cephalosporins. A mechanism has not been developed to date to systematically monitor cephalosporin treatment failures.

Routine culture and antimicrobial susceptibility capacity is diminishing due to wider use of nucleic acid amplification testing (NAATs) by public health and private laboratories. In public health laboratories along, the percent of tests for GC that are culture decreased from 18% in 2000 to 5% in 2007.

In terms of its research priorities, CDC is attempting to better understand the mechanisms of cephalosporin resistance, evaluate the feasibility of monitoring for GC treatment failures, and assess the efficacy of alternative drug regimens. CDC and the NIH STI Clinical Trials Group are collaborating on a randomized clinical trial to determine the efficacy of two dual drug regimens (e.g., azithromycin/gentamycin and azithromycin/gemifloxacin) for uncomplicated urogenital GC infection treatment.

The trial is designed to independently assess each arm. The overarching aim of the trial is to evaluate the use of dual drug regimens where emerging GC cephalosporin resistance or severe allergy to cephalosporins may be a problem. The rationale for dual therapy is based on three major factors. The expected efficacy of the few available single-drug options is modest. Dual therapy might provide greater efficacy by controlling the emergence of resistant strains. Few new drugs are expected to be introduced to the market in the near future.

Overall, multiple efforts are ongoing to address the probable emergence of cephalosporin-resistant GC. Many challenges are associated with these efforts from program, surveillance and research perspectives. Additional data on alternative therapeutic regimens are a critical need.

Overview of Non-Genital Chlamydia and Gonorrhea Screening of MSM

Charlotte Kent, PhD

Acting Director, Division of STD Prevention, NCHHSTP
Centers for Disease Control and Prevention

Dr. Kent presented an overview of missed opportunities for non-genital chlamydia (CT) and GC screening of MSM. MSM historically have been a population with early emergence of GC-resistant infections and a disproportionate burden of GC infection. Infection occurs at multiple anatomic sites depending upon sexual exposures. The San Francisco STD Clinic collected

data in 2008 that showed the prevalence of STDs among MSM was ~2.8% for early syphilis, 10.2% for GC and 8.8% for CT.

CDC published CT and GC screening and diagnostic testing guidelines for MSM in 2002, 2006 and 2010. CDC recommended annual rectal GC and CT screening for MSM who had receptive anal sex; annual urethral screening for GC and CT among sexually active MSM; and annual pharyngeal GC screening for MSM with receptive oral-genital exposure. The guidelines further recommended screening regardless of reported condom use for anal sex and screening every 3-6 months for MSM at highest risk.

The 2002 guidelines recommended the use of culture as the diagnostic test for GC and CT screening, but the 2009 Schachter study showed that NAAT was far superior to culture. The study documented that NAAT had the capacity to detect at least two times more rectal and pharyngeal GC and CT infections. FDA is not likely to clear non-genital NAAT because these tests are a niche market and manufacturers most likely would not achieve a return on their investments in studies. However, alternatives are available to overcome this barrier.

Laboratories can verify non-genital NAAT to meet regulations of the Clinical Laboratory Improvement Amendments. Laboratories can request specimens from CDC's specimen bank for verification of non-genital NAAT. Many private and public health laboratories have non-genital NAAT available. Validated self-collected rectal specimens are a well-accepted modality in many jurisdictions. The San Francisco Department of Public Health released instructions for individuals to self-collect rectal swabs.

The 2010 Bernstein study used 2003-2005 data from the San Francisco STD Clinic to document the association between HIV seroconversion and the number of prior rectal infections. Local health department data showed that the prevalence of rectal infections in 2009 was ~8% for rectal CT and ~6% for rectal GC in Los Angeles based on >9,000 tests. The prevalence of rectal CT was similar in San Francisco based on >10,000 tests, but lower for rectal GC. The prevalence of rectal infections was higher in the Philadelphia STD Clinic. The prevalence of rectal CT was high in New York City STD Clinics with NAAT.

Data collected from a San Francisco STD Clinic in 2009 showed that compared to HIV-uninfected men, the relative risk among HIV-infected men was 1.7 times greater for acquiring rectal CT and 1.8 times greater for acquiring rectal GC. However, the majority of rectal infections were among HIV-negative men (54%) compared to HIV-positive men (32%). These data showed that HIV-negative men are at high risk for future acquisition of HIV.

The 2005 Kent, *et al.* study reported the prevalence of pharyngeal CT and GC among gay and bisexual men seen in two clinical settings in San Francisco in 2003. The prevalence of pharyngeal CT was <2% in both settings, but the prevalence of pharyngeal GC was 7.8% and 9.4% in the two settings.

The San Francisco Department of Health collected 2008-2009 data from a local clinic on the proportion of CT and GC infections among asymptomatic MSM who would be identified and

missed by different screening algorithms. The data showed that 14.3% of GC and CT infections would be identified with urethral screening only, but 91.4% of GC and CT infections would be identified with both rectal and pharyngeal screening and only 8.6% of GC and CT infections would be missed if urethral screening was omitted. These data show that the pharynx and rectum are the major sites of CT and GC infections.

The 2005 Kent, *et al.* study used 2003 San Francisco data to determine the proportion of rectal CT infections that would not be identified if only GC testing was performed among gay and bisexual men. The study showed that culture would miss ~50% of GC infections and elimination of CT testing would miss ~81% of rectal CT infections. These data emphasize the importance of rectal screening for both CT and GC. The San Francisco Department of Health collected 2005-2009 data that showed the number of rectal CT and GC infections reported among men was much higher than syphilis.

CDC is developing a coding guide in collaboration with numerous partners to address barriers to rectal screening and non-genital NAAT screening. The lack of guidance on appropriate billing codes has been identified as a major challenge to screening. After the coding guide is released in the spring of 2011, CDC will develop a comprehensive guide by patient populations (e.g., MSM, IDU and high-risk adolescents).

Overall, CDC has recommended non-genital screening for MSM since 2002. The burden of non-genital infections among MSM is substantial, particularly GC infections. Routine screening is not widely available in ~50% of metropolitan areas with the greatest burden of HIV/AIDS. CDC has identified several opportunities and benefits to expanding non-genital screening among MSM, such as preventing HIV, improving the sexual health of MSM, and controlling GC among MSM to diminish the impact of the emergence of resistant infections.

Dr. Kent requested CHAC's input on three key questions to assist CDC in improving and expanding non-genital CT and GC screening of MSM. How should CDC frame the importance of rectal and pharyngeal screening for practitioners (e.g., messages directed toward GC control, MSM sexual health or HIV prevention)? What are major issues related to the feasibility, acceptability and barriers to proactive screening? What are CHAC's recommendations to CDC regarding relevant program, research and policy advances?

CHAC thanked the panel of NIH and CDC speakers for presenting comprehensive and informative overviews of ongoing and future efforts to strengthen the national strategic response to STD prevention research. The CHAC members made several suggestions in response to Dr. Kent's specific request for input on three questions.

- **Question 1:** CDC should target training and education to physicians to reduce the stigma of rectal and pharyngeal screening for the detection of STDs in populations other than MSM, such as women and youth. For example, CDC proposed "MSM sexual health" as a potential strategy to frame the importance of rectal and pharyngeal screening for practitioners. CDC should expand this proposed strategy to include providers who serve HIV-infected youth, women and other sexually active persons.

- **Question 2:** CDC can take several steps to address issues related to the feasibility, acceptability and barriers to proactive screening: (1) widely release the coding guide to address barriers to rectal screening and non-genital NAAT screening; (2) distribute information to the general public and provide extensive training to providers to increase advocacy for and understanding of the necessity of STD screening; and (3) implement strategies to include STD screening in mainstream health care as part of health maintenance for the general population.
- **Question 3:** CDC should establish a formal network with HRSA, particularly BPHC, to engage CHCs, Migrant Health Centers, Rural Health Centers, HIV programs and AETCs in STD screening and education. The HRSA partnership will be critical in translating STD prevention research into actual clinical practice, educating primary care providers on STD screening and management, and widely disseminating information on the latest advances in STD prevention research in HRSA-funded settings.
- CDC should collaborate with CBOs, outreach organizations and mobile testing sites that deliver HIV prevention interventions to bathhouses, gay bars and similar venues at the local level. Existing outreach networks for HIV prevention could be used to distribute information on STD screening and sexual health issues to young and healthy persons or high-risk individuals who do not routinely present to healthcare providers. These opportunities also could be used to gather input on reasons that sexually active persons engaging in oral or anal sex do not present for STD screening. Collaborative efforts with local outreach groups will be important in raising awareness of the critical need for screening of STDs that are equally important as and more prevalent than HIV.
- CDC should use its existing network of GISP regional laboratories and sentinel sites as a resource to support the public health infrastructure of testing antibiotic resistant-GC specimens.
- CDC should consider other strategies to address relevant program, research and policy advances: wide distribution of the coding guide; continued education to the public and providers; practical approaches for laboratories (e.g., LabCorp and Quest) to validate self-collected rectal specimens to eliminate this burden from providers; and monitoring of STD screening with performance indicators (e.g., medical homes or Physician Quality Reporting Initiative measures).

Update on the USPSTF HIV Screening Recommendations

David Lanier, MD

Associate Director, Center for Primary Care Prevention and Clinical Partnerships
Agency for Healthcare Research and Quality

Dr. Lanier presented on update on the USPSTF HIV screening recommendations. USPSTF is a 16-member panel of non-federal representatives with expertise in primary care, prevention, research methods and behavioral health. USPSTF is supported by, but is an independent body from the Agency for Healthcare Research and Quality (AHRQ). USPSTF recommendations are evidence-based and rely on explicit and published review methods. USPSTF obtains scientific

support from the academic Evidence-Based Practice Center and engages partners from federal agencies and primary care professional associations.

The USPSTF methodology in developing recommendations for preventive services focuses on four key areas. Questions and outcomes of interest that might be age- and risk factor-specific are defined. Relevant evidence on the benefits and harms of the preventive service under review is systematically retrieved and evaluated. The balance between benefits and harms is determined. Guidance is linked to judgments made about the net benefit of the preventive service. USPSTF used its established analytic framework to make recommendations on HIV screening of adolescents and adults.

After a recommendation is linked to net benefits and harms, USPSTF assigns a letter grade to document the magnitude of the net benefit. "Grade A" preventive services have substantial benefits and minimal harm. "Grade B" preventive services have moderate benefits. "Grade C" preventive services have a small benefit that clinicians should discuss with their patients. "Grade D" preventive services are not recommended because their benefits are either zero or would have a negative impact. An "I Statement" is assigned to preventive services with insufficient evidence.

The 2005 USPSTF recommendations on HIV screening are summarized as follows. All adolescents and adults at increased risk for HIV infection should be screened (Grade A). This recommendation included all patients seen in high-prevalence settings (e.g., STD clinics, TB clinics or MSAs with HIV prevalence $\geq 1\%$). All pregnant women should be screened for HIV (Grade A).

No recommendation was made for or against routine screening of HIV among adolescents and adults not at increased risk for HIV infection (Grade C). In making this recommendation in 2005, USPSTF assumed that every individual who was tested for HIV would be required to receive pre-test counseling and give written consent. USPSTF did not consider an opt-out approach. USPSTF found inadequate evidence that knowledge of HIV seropositivity would result in a decrease of risky behaviors.

The rationale for the USPSTF Grade C recommendation for screening individuals without recognized risk factors was based on three key factors. The benefits of HIV screening of average-risk persons in terms of appropriate treatment and monitoring would be the same as if the risk factors were recognized. Harms of the actual HIV screening test would be no different than the accuracy of testing. Harms included opportunity costs of screening a large number of patients with low discovery rates. An outcomes analysis was performed that indicated 11,018 average-risk patients would need to be screened to prevent one clinical progression of disease or death over three years compared to screening 28.6 high-risk patients to achieve the same outcomes.

In September 2006, CDC recommended HIV screening of all individuals 13-64 years of age regardless of recognized risk factors. The CDC recommendation assumed use of the opt-out approach without pre-test counseling. CDC considered research published subsequent to

USPSTF completing its systematic evidence report. In November 2006, USPSTF assessed the new research and reaffirmed its Grade C recommendation for HIV screening among adults and adolescents not at increased risk for HIV.

USPSTF plans to update its 2006 HIV screening recommendations in 2011 to ensure consistency of guidance between two HHS agencies. AHRQ strongly encourages investigators and others to submit evidence for USPSTF to consider subject to quality assessments. Leaders of the HIV Medicine Association have already submitted articles that relate to questions and issues USPSTF will consider in the upcoming review.

Update on HIV/STD Prevention and Care in Federally Qualified Health Centers

Seiji Hayashi, MD, MPH

Chief Medical Officer, Bureau of Primary Health Care
Health Resources and Services Administration

Dr. Hayashi presented an update on HIV/STD prevention and care in HRSA-funded Federally Qualified Health Centers (FQHCs). The 1,131 FQHCs are located at >7,900 service sites across the United States with rural communities accounting for 50% of sites. FQHCs are non-profit and independent CBOs that are funded by, but are not controlled by HRSA. Section 330 funding from HRSA accounts for ~20% of the overall budgets of FQHCs. Federal funding allowed FQHCs to serve nearly 18.8 million patients in 2010 or a total of 73.8 million patient visits.

Of FQHC patients, 92% are at or below 200% of the FPL, 38% are uninsured, 63% are racial/ethnic minorities, >1 million are homeless, 865,000 are migrant or seasonal farmworkers, and 165,000 are public housing residents. Of 123,000 FQHC staff, >9,100 are physicians and >5,700 are nurse practitioners, physician assistants and certified nurse midwives. HIV and STD are important health issues in FQHCs, but are far less of a priority than well-child examinations, upper respiratory infections, hypertension, diabetes, heart disease, alcoholism and depression.

PPACA will provide \$11 billion over the next five years for the operation, expansion and construction of FQHCs throughout the nation. The FQHC base budget was \$2.2 billion in FY2009-FY2010, but will increase to \$5.6 billion at the end of the five-year PPACA funding. Of \$11 billion in new PPACA funding, \$9.5 billion is targeted to the creation of new FQHC sites in medically underserved areas and the expansion of preventive and primary healthcare services in existing FQHC sites, including oral health, behavioral health, vision services, pharmacy services or enabling services. The remaining \$1.5 billion in new PPACA funding will support major construction and renovation projects at FQHCs nationwide.

The national presence of FQHCs follows population density, but HRSA is making efforts to expand services, increase access and reach populations in areas without an FQHC. The Southwest and Southeast account for the vast majority of populations below 200% of the FPL

served by FQHCs. The new PPACA funding will enable FQHCs to nearly double the number of patients seen.

BPHC has created a quality improvement strategy framework with several components to place FQHCs in communities with most need and assure high-quality care. Collaborative efforts are underway at regional and local levels to transform FQHCs to patient-centered medical homes and coordinate services with health departments, emergency departments, laboratories, and other primary care and specialty services.

Steps are being taken to align quality improvement policies, programs and measures among HRSA (e.g., FQHCs and Ryan White Programs), CDC, CMS and the HHS Office of the National Coordinator (ONC) for Health Information Technology (HIT). Strong emphasis is being placed on filling gaps in the existing primary care and specialty care workforce by recruiting and retaining highly-skilled providers in FQHCs and leveraging outside resources. The turnover rate of FQHC staff is ~6%-8%.

Data were collected from the Uniform Data System in 2009 documenting the HIV/STD burden in FQHCs. Of 691,000 patients who received HIV tests, 25,691 had asymptomatic HIV, 69,281 had symptomatic HIV, and 73,330 had syphilis or other STDs. However, HRSA recognizes that the HIV/STD burden in FQHCs is grossly underestimated because primary diagnoses were used to collect data.

The 1992 Singer study defined “syndemics” as two or more afflictions synergistically interacting and contributing to excess burden of disease in a population. For example, indicators of health, socioeconomic factors and social issues (e.g., substance abuse, violence and poverty) play a strong role in worsening HIV and other disease entities.

BPHC is taking a diverse approach to addressing HIV/STD in FQHCs. Efforts are underway to ensure that FQHCs adhere to recommendations outlined in the NHAS, HHS Action Plan for Viral Hepatitis Prevention and Care, and other national strategies and initiatives. Additional partnerships are being established with internal and external stakeholders. Support is being provided for the use of evidence-based guidelines and practices, such as the HAB PAL to expand HIV testing in FQHCs. An infrastructure for access to high-quality care is being supported that includes patient-centered medical and health homes, adoption of HIT and Meaningful Use, and workforce development.

Overview of Efforts to Harmonize CDC and USPSTF Screening Recommendations

Stuart Berman, MD, ScM

Senior Advisor to the Director of NCHHSTP
Centers for Disease Control and Prevention

Dr. Berman reported on the current status and future possibilities of harmonizing the CDC and USPSTF screening recommendations for HIV, STD, human papillomavirus (HPV) and hepatitis C virus (HCV). In 2005 and 2007, USPSTF recommended HIV screening of all adolescents and adults with at least one risk factor and screening of all patients who receive health care in high-prevalence or high-risk clinical settings with HIV prevalence $\geq 1\%$ (Grade A). In 2006, CDC recommended HIV screening of all adolescents and adults at increased risk and screening of patients 13-64 years of age in settings with undiagnosed HIV prevalence $\geq 0.1\%$.

USPSTF's updated 2007 recommendations recognized that a risk factor assessment could identify persons at increased risk of infection, but targeted screening would miss a significant number of infected persons with unidentified or unreported risk factors. A risk factor assessment also would impede efforts to achieve the NHAS objective to increase the percentage of PLWH who know their serostatus from 79% to 90% (or 948,000 to ~1 million persons) by 2015.

The difference in the USPSTF and CDC HIV screening recommendations has implications for reimbursement and messages delivered to the general public. For example, the CDC "Take Control of Your Health. Get Tested" campaign recommends HIV screening at least once for all persons 13-64 years as part of routine health care and annual or more frequent testing for persons at high risk (e.g., gay and bisexual men, IDU or persons with multiple sexual partners).

USPSTF will consider a number of relevant issues during its review of HIV screening in 2011. HIV screening would be cost-effective with undiagnosed HIV prevalence of 0.1%-0.2%, particularly with the recommended initiation of antiretroviral therapy at CD4 counts < 500 or higher. Earlier treatment would result in beneficial outcomes sooner.

USPSTF's original assessment focused on outcomes at three years, but a longer interval should be considered. USPSTF can now review additional data that were not previously available on the ability of antiretroviral therapy to reduce HIV transmission. Several recent studies have documented the acceptance of routine HIV testing by providers and patients.

In terms of STD screening at non-genital sites, CDC published STD Treatment Guidelines in 2002, 2006 and 2010. The 2002 and 2006 guidelines were based on preliminary data and recommended culture as the diagnostic test for STD screening, frequent screening of persons at highest risk, and screening regardless of reported condom use. The 2006 guidelines included a new recommendation for providers to use culture or a test cleared by FDA or locally verified in accordance with applicable statutes. The 2010 guidelines do not have the "based on preliminary data" language and include a revised recommendation to use NAAT for STD testing.

CDC identified an explicit rationale for screening at non-genital sites in an effort to achieve concordance with the USPSTF screening recommendations. In this exercise, CDC took the USPSTF approach by reviewing evidence to link the performance of screening to improved outcomes. CDC acknowledged the lack of outcome data to document the benefits of screening and prevention of infection, but the evidence showed that screening was a solid objective marker to identify persons at risk.

In terms of HPV vaccination of males, the CDC Advisory Committee for Immunization Practices (ACIP) recommended HPV vaccination of females in June 2006. In October 2009, ACIP recommended HPV vaccination of females with use of the FDA-licensed bivalent vaccine and made a permissive recommendation for HPV vaccination of males with the quadrivalent vaccine.

The quadrivalent HPV vaccine was licensed for males 9-26 years of age for HPV types 6/11-related genital warts. The ACIP guidance stated that the quadrivalent HPV vaccine could be given to males 9-26 years of age to prevent acquisition of genital warts, but this language was not included in the routine immunization schedule. However, the language was included in the Vaccines for Children Program to enable providers to vaccinate eligible males 9-18 years of age.

Recent data on the quadrivalent HPV vaccine were presented during the October 2010 ACIP meeting documenting high efficacy against persistent infection in males and prevention of vaccine type-related anal pre-cancers (AIN 2/3); a strong safety profile in males; and high acceptability among providers with 36% of pediatricians giving the HPV vaccine to males.

Cost-effectiveness data also were presented during the October 2010 ACIP meeting showing that HPV vaccination of MSM appeared to be cost-effective. However, the data showed that the cost-effectiveness of providing HPV vaccination to all males depended on coverage in females. FDA will review Merck's supplemental Biologics License Application of the quadrivalent HPV vaccine for males for anal cancer indication on November 17, 2010.

ACIP will discuss various options regarding HPV vaccination of males during future meetings, such as routine HPV vaccination of males, use of the existing recommendations for HPV vaccination of MSM, and retention of the current permissive recommendations with or without new language on HPV vaccination of MSM.

In terms of HCV screening, CDC's 1998 guidelines recommended testing to persons with the following risk factors: history of injecting illegal drugs, receipt of clotting factors made before 1987, receipt of blood or organs before July 1992, history of chronic hemodialysis treatment, evidence of liver disease, infants born to HCV-infected mothers, or HIV infection. In 2004, USPSTF found insufficient evidence to recommend for or against routine screening of HCV infection in adults at high risk for infection (I Statement).

The difference between the CDC and USPSTF recommendations has important implications. The 2005-2006 NHANES survey showed that 2.8 million persons in primary care had HCV. A minimal number of these persons will be identified prior to serious disease without screening. The failure to implement interventions will result in 1.5 million cirrhosis cases and ~900,000 HCV deaths.

HCV therapy is improving with shorter duration and more efficacy. Screening and treatment are important components in the HHS Action Plan for Viral Hepatitis Prevention and Care. USPSTF is current exploring the possibility of revisiting its 2004 recommendations on HCV screening with

the CDC Division of Viral Hepatitis, but the outcome of these discussions are unknown at this time.

CHAC thanked the panel of AHRQ, HRSA and CDC speakers for presenting comprehensive and informative overviews of ongoing and future efforts to harmonize the CDC and USPSTF screening recommendations. CHAC engaged the HHS agencies in an extensive discussion on the following topics:

1. The failure of FQHCs to fully implement HIV testing despite CDC's long history of widely disseminating solid, rigorous and excellent data in support of screening.
2. The failure of USPSTF to consider the disproportionate burden of HIV in racial, ethnic and sexual minorities in formulating its HIV screening recommendations.
3. The critical need for a clearly defined strategy with concrete action steps for BPHC to ensure that FQHCs effectively provide basic HIV care and leverage resources to increase access to offsite HIV expertise when needed.
4. The important need for a public discourse to explore innovative strategies to move beyond HIV testing, particularly since a large percentage of PLWH in the United States are diagnosed with AIDS rather than HIV in a short time before dying.

CHAC's extensive discussion with the HHS agencies resulted in the members making three key suggestions to refine efforts to harmonize the CDC and USPSTF recommendations on routine HIV screening and expand HIV testing in FQHCs.

- USPSTF should gather published data to support an evidence-based recommendation addressing HIV screening-related stigma at individual, system and provider levels and including HIV testing as a part of routine care.
- BPHC should urge FQHCs to deliver "good public health services" by including sexual health as part of the overall health of their patients. In this paradigm, FQHCs should acknowledge the health profile of their populations. For example, 63% of FQHC patients are racial/ethnic minorities and would greatly benefit from HIV testing.
- BPHC should consider implementing a mandatory process in which FQHCs would use their local data and community health profiles to opt-in or opt-out of HIV screening based on whether the percentage of their HIV-positive patient populations was high or low, respectively. BPHC should partner with CDC to identify communities where FQHCs should use an opt-in or opt-out approach for HIV screening. A mandatory opt-in or opt-out process would minimize the burden or discomfort of providers in assessing patients to administer HIV testing.

Based on the discussion, Dr. Fenton was aware of CHAC's frustration with the dissonance and conflict between the USPSTF and CDC HIV screening recommendations and messaging. He also acknowledged CHAC's concern that CDC's HIV screening recommendations still have not been fully implemented in FQHCs to date.

Dr. Fenton commended BPHC on issuing the PAL to FQHC grantees to emphasize the need for expanded HIV testing. However, he encouraged BPHC to clearly articulate its vision and

strategy to increase the 691,000 HIV tests that FQHCs perform each year to more closely match the demand of the annual FQHC population of 18.8 million patients.

Dr. Fenton offered CDC's technical assistance and expertise in two areas to address CHAC's concerns: (1) gather published data to inform USPSTF's process of making evidence-based recommendations on HIV screening in the upcoming 2011 review and (2) assist BPHC in making concrete changes to improve HIV prevention and care in FQHCs.

Dr. Fenton reiterated CDC's continued commitment to assist HAB, BPHC and other parts of HRSA in identifying opportunities for change, reaching the critically important goal of prevention through health care, and leveraging existing assets in the healthcare system to advance prevention priorities.

Overview of Meaningful Use and Patient-Centered Medical Homes (PCMH)

Thomas Tsang, MD, MPH

Medical Director, Meaningful Use and Quality

Office of the National Coordinator for Health Information Technology

Department of Health and Human Services

Dr. Tsang presented an overview of Meaningful Use and the PCMH model. Of the current U.S. population, 125 million persons live with ≥ 1 chronic illnesses, disabilities or functional limitations. Of the current \$2.4 trillion healthcare budget in the United States, 80% is spent on the management of chronic diseases. The 2007 Commonwealth Study reported that patients with a medical home had better outcomes. National health expenditures currently account for ~17% of the gross national product.

These figures emphasize the critical need to improve management of patients with chronic illnesses (e.g., HIV, hepatitis B, diabetes and congestive heart failure) and identify efficiencies in the existing healthcare system to deliver better care, reduce inefficiencies, decrease waste and promote enhanced coordination of care.

The 2001 IOM Report on Quality described six domains of patient care: safety, efficacy, patient-centered, timeliness, efficiency and equitable. These domains are well represented in the PCMH model. Multiple professional societies have defined "PCMH" as a model of care in which each patient has an ongoing relationship with a personal physician who leads a team that takes collective responsibility for patient care. PCMH emphasizes enhanced care through open scheduling, expanded hours and communication between patients, physicians and staff.

PCMHs have been in existence since the 1970s as pediatric homes. Improvement in chronic care coordination is needed because >60% of Medicare beneficiaries have ≥ 3 chronic diseases at this time. North Carolina and other states have initiated PCMH models and reported improved quality and savings that exceeded \$100 million per year. Minnesota enacted

legislation in 2007 for Medicaid enrollees and began to recognize care coordination standards in July 2010. Washington State implemented public/private efforts in 2010 to launch PCMH pilot projects for Medicaid in conjunction with chronic care management. New Hampshire launched a multi-payer pilot project and shifted its existing disease management budget.

The Picker Institute characterized the attributes of patient-centered care as respect for the patient's values, preferences and expressed needs; information and education; access to care; emotional support to relieve fear and anxiety; involvement of family and friends; continuity and secure transition between healthcare settings; physician comfort; and coordination of services.

PPACA outlines health home services through three grant programs: a Medicaid demonstration project, community health teams, and the AHRQ Primary Care Extension Program. These initiatives will focus on comprehensive care management; care coordination and health promotion; comprehensive transitional care, including appropriate follow-up from inpatient to other settings; patient and family support; referral to community and social support services; and use of HIT to link services if feasible and appropriate.

The National Committee for Quality Assurance has developed Physician Practice Connections-PCMH standards across nine domains: access and communication, patient tracking and registry function, care management, patient self-management support, electronic prescribing, test tracking, referral tracking, performance reporting and improvement, and advanced electronic communications. Based on these attributes, FQHCs will not require an extensive amount of additional effort and resources to become PCMHs. The vast majority of services FQHCs currently provide already are consistent with the PCMH concept.

Evidence suggests that PCMHs lead to improved outcomes, better patient satisfaction, system savings, and recognition of the value of primary care and care management services. A critical need exists to shift from acute care to ambulatory chronic care. Primary care will be critical in the payment reform environment with risk-sharing and bundling of inpatient services.

In terms of Meaningful Use, HHS published the Final Rule to offer incentives to providers and hospitals to meaningfully adopt technology. Meaningful Use providers will receive \$44,000 under the Medicare Program and \$63,750 under the Medicaid Program. Meaningful Use hospitals will receive $\geq$ \$2 million depending on their discharges.

In Stage 1 in 2011-2012, eligible providers must report 20 of 25 Meaningful Use objectives and hospitals must report 19-24 of 24 Meaningful Use objectives. The reporting period is 90 days for the first year and one year subsequently. The Stage 1 Meaningful Use core set is mandatory, but five objectives in the menu set can be deferred. All of the Meaningful Use measures along with their descriptions can be reviewed on the ONC and CMS websites.

Overview of the Real Meaning of Meaningful Use

Yael Harris, PhD, MHS

Director, Office of Health Information Technology and Quality
Health Resources and Services Administration

Dr. Harris described the real meaning of Meaningful Use. Efforts were initiated in the 1980s for providers to improve quality by obtaining a baseline, tracking performance over time and making refinements. CMS began to offer incentives in early 2000 (e.g., pay for performance, quality indicators and reporting measures) to motivate providers to track their performance, measure their quality improvement efforts and identify opportunities for improvement. Technology was proposed to improve quality, but providers must properly and systematically use this tool for maximum effectiveness.

An electronic health record (EHR) is the cornerstone of the PCMH model. The purpose of EHRs is to improve and better coordinate care and align several forces, including comparative effectiveness research, medical product safety issues, clinical research, chronic care management, public health improvements, care coordination, performance measurement and improvement, engagement of patients, and transformation of care delivery.

Meaningful Use criteria become a focal point across initiatives that previously were disparate, such as PCMH, accountable care organizations, state and regional chronic care programs, personal health record platforms with real-time access, payer disease and care management, and regional health information organizations. Meaningful Use is a trajectory that begins with data capture and sharing, moves to advanced clinical processes, and ends with improved outcomes. HRSA has established a goal for 100% of FQHCs to be Meaningful Users by 2015.

Several Meaningful Use objectives have been established, including computerized physician order entry, interaction checking, electronic prescribing, medication reconciliation, information exchange, patient access, eligibility and claims, population condition management, and privacy and security.

HRSA has made HIT investments in a number of areas to improve quality, such as Health Center Controlled Networks (HCCNs), the Capital Improvement Program, rural health, telehealth, IT for PLWHA, newborn screening, the HIT workforce, HIT innovations, and the HIT Adoption Toolbox. To support the Capital Improvement Program, HRSA awarded American Recovery and Reinvestment Act (ARRA) dollars totaling ~\$182 million (or 584 grants) to existing FQHC grantees for capital improvement and employment opportunities in underserved communities. HIT projects under this initiative included the enhancement or purchase of new EHR systems.

To support HCCNs, HRSA awarded grants to FQHCs for the creation, development and operation of safety net provider networks through the enhancement of health center operations, including HIT. HRSA has funded ~60 HCCNs since 2007 for a total of \$164 million. Of the

FQHCs involved in a funded HCCN, ~50% have successfully implemented an EHR. HRSA funded 14 grantees for planning, 73 grantees for EHR implementation and quality improvement, 44 grantees for innovation, and 11 grantees for both EHR and innovations.

HRSA made a number of HIT investments specifically related to HIV/AIDS in 2008-2010. The SPNS Electronic Networks of Care included 21 awards for a total of ~\$8.9 million. The grantees are conducting HIT demonstration projects for PLWHA in underserved communities. HRSA awarded additional funds for technical assistance and evaluation of these grants.

The IT Capacity Building Grant included 101 awards for a total of \$9.4 million. The grantees are purchasing systems to collect and report patient data and also are evaluating and documenting their processes to demonstrate proven outcomes. The Capacity Building Early Intervention Services Grants included 14 awards for a total of \$942,000. HRSA requires all EHR or EHR modules purchased with Capacity Building Program funds to meet Meaningful Use certification requirements.

CAREWare is a free and scalable software tool for managing and monitoring HIV clinical and supportive care. Providers are able to import selected data from their certified EHRs into CAREWare. The tool provides a mechanism for contract monitoring at city and state levels. Grantees can use CAREWare to monitor activities of their providers. HAB invested ~\$500,000 in CAREWare. By the end of 2012, HRSA will have provided \$800,000 in technical assistance for grantees to use EHR systems to alter or meet HAB's client-level data requirements.

Overall, HRSA conducts several activities to inform grantees of its Meaningful Use activities and the availability of HIT funding. HRSA uses a listserve of all grantees to publicize monthly webinars. The webinars, Meaningful Use and quality improvement toolkits, a readiness assessment tool and other resources are available to grantees at www.HRSA.gov/healthIT. The proposed HRSA budget includes a request to fund the development of EHR toolkits specific to the needs of populations that each bureau serves.

Overview of Electronic Health Records in Meaningful Use and Public Health

Laura Conn, MPH

Associate Director for Science, Public Health Informatics and Technology Program Office
Office of Surveillance, Epidemiology and Laboratory Services
Centers for Disease Control and Prevention

Ms. Conn presented an overview of EHRs in Meaningful Use and public health. The Health Information Technology for Economic and Clinical Health Act (HITECH) was enacted in February 2009 as part of ARRA. HITECH provided HHS with authority to establish programs to improve health care quality, safety and efficiency through the promotion of HIT, including EHRs and private and secure electronic health information exchange. The public health HITECH

Programs were awarded at \$30 million to link immunization information systems to EHRs and facilitate electronic reporting of notifiable conditions to public health agencies.

Under HITECH, eligible health care professionals and hospitals can qualify for Medicare and Medicaid incentive payments after adopting and using certified EHR technology to achieve specified objectives. Federal agencies released two EHR and Meaningful Use regulations. CMS issued the Incentive Program for EHRs Final Rule to define minimum requirements and objectives that providers must meet through use of certified EHR technology in order to qualify for incentive payments. ONC issued Standards and Certification Criteria for EHRs to identify standards, technical capabilities and criteria required for certified EHR technology to ensure that eligible healthcare professionals and hospitals adopt systems with capacity to perform the required functions.

The “Meaningful Use” definition is based on five health outcome policy priorities: improve quality, safety and efficiency and reduce health disparities; engage patients and families in their personal health development; improve care coordination; improve population and public health; and ensure adequate privacy and security protection for personal health information.

Meaningful Use plays an important role in public health. Bilateral communication with healthcare providers will be increased. Interoperable data will be provided for reuse inside public health. Eligible providers and hospitals will emphasize Meaningful Use over public health requests. Eligible providers, hospitals and their vendors will send and receive data using the ONC published standards. A shift will be made toward prevention-oriented health reform with quality measures. Public health information systems will be challenged in preparing for Meaningful Use. Existing partners will need to change to new standards. New partners will need to be integrated. Adjustments will be needed to meet higher workflow demands for data.

Stage 1 of Meaningful Use has three public health objectives that must be achieved in 2011-2012. Objective 1 is electronic submission of data to immunization information systems (IISs) to enhance interoperability of EHRs and IIS, improve integration and product support for EHR-IIS interoperability, and strengthen clinical decision support tools. HITECH dollars and CDC funding support 20 Section 317 state grantees.

Objective 2 is electronic submission of reportable laboratory results to public health. Awards were made to ten CDC Epidemiology and Laboratory Capacity grantees for infrastructure and interoperability support for public health laboratories. Funding was awarded to the Association of Public Health Laboratories to provide technical assistance to public health laboratories for implementation. An FOA is pending that will provide standard and reusable solutions for hospital laboratories to submit reportable laboratory results to public health. All of the laboratory activities will be aligned with laboratory interoperability and enterprise architecture solutions.

Objective 3 is syndromic surveillance. In FY2010, CDC used BioSense Program dollars to fund a number of professional associations to collaboratively define core EHR data requirements for syndromic surveillance, develop standards and create implementation specifications. The Meaningful Use Workgroup that was established for this effort includes representation by the

International Society for Disease Surveillance, National Association of City and County Health Officials, Association of State and Territorial Health Officials, and CDC. The workgroup's recommendations are being publicly vetted at this time and will be finalized in early 2011.

Meaningful Use will impact state and local health departments. Collaboration of clinical and public health care will be improved at local and state levels by implementing electronic reporting in public health and improving patient-centric preventive care quality measures. Meaningful Use will determine the readiness of state public health agencies for bi-directional communication with clinical care providers. However, state and local partners will need help in implementing standardized data elements and messaging guides for data exchange of Meaningful Use public health measures.

The inclusion of public health objectives in the next stages of Meaningful Use has been resisted, but a number of public health activities are underway at CDC to advance Meaningful Use to the next level. CDC established an internal Meaningful Use Advisory Committee to obtain input on public health priorities for Stages 2-3. CDC and other public health representatives gave testimony to workgroups of the HIT Policy and Standards Committee.

CDC's relationships with CMS and ONC in Meaningful Use are ongoing. CDC is determining the existing capacity of state and local health departments to accept electronic data from EHRs. CDC and seven public health organizations that serve on the Joint Public Health Informatics Committee are developing a public health framework and roadmap for Meaningful Use over the next few years. CDC is identifying technical support that public health will need for Meaningful Use.

National coordination is needed to address workforce shortages and enhance capacity for >50 state and territorial jurisdictions to take similar actions across different program areas in a short period of time. Changes to public health systems typically involve data used by many programs. The traditional "not invented here" approach and slow consensus will frustrate the White House, ONC, the healthcare community and vendor stakeholders.

ONC and CMS intend to propose two additional stages through future rulemaking to expand the Stage 1 Meaningful Use criteria in 2013 and beyond. Stage 2 would expand the Stage 1 criteria in the areas of disease management, clinical decision support, medication management support for patient access to their health information, transitions in care, quality measurement and research, and bi-directional communication with public health agencies. Information exchange will be a critical part of care coordination and the infrastructure is expected to support greater requirements for using health information exchanges in Stage 2.

Stage 3 would focus on achieving improvements in quality, safety and efficiency and providing decision support for national high priority conditions, patient access to self-management tools, access to comprehensive patient data, and improvement of population health outcomes.

Several concepts have been proposed to develop Meaningful Use criteria for Stages 2 and 3, such as whether the EHR is the most appropriate tool to address the sensitivity of HIT and

whether standards and technologies are available for HIT readiness. Other proposed criteria include continuation of the Stage 1 trajectory; a reduction in the burden of morbidity and mortality by filling existing gaps and promoting winnable battles; a reduction in the work burden; clinical sensitivity in terms of whether clinical change can impact prevention; alignment with information sharing laws that respect jurisdictional regulations; and public health system readiness.

CHAC thanked the panel of ONC, HRSA and CDC speakers for presenting comprehensive and informative overviews of ongoing and future efforts to widely implement the PCMH model and incorporate Meaningful Use in both healthcare and public health settings. The CHAC members made two key suggestions for the HHS agencies to consider in advancing the PCMH model and Meaningful Use to the next level.

- During the May 2010 meeting, CHAC unanimously approved core principles of HIV care and service delivery that should be included in the health reform legislative agenda. The HHS agencies should ensure that CHAC's recommendations are included in discussions of the PCMH model for Medicaid and Medicare populations.
- The HHS agencies should use results of an NIH-funded pilot project to include patient empowerment, education and transparency of medical records as key components of Meaningful Use. In the innovative project, FQHC providers in HIV and primary care settings give consent for patients to review their entire medical records online, including notes by clinicians and laboratory results. The HHS agencies could use these findings to determine behavioral changes among patients in requesting additional services or correcting their medical records.

Public Comment Session

Carl Schmid

Deputy Executive Director, The AIDS Institute

Mr. Schmid urged CHAC to ask HRSA to present its expectations and estimates of the projected status of ADAP as of March 31, 2011 and over the next two years until health reform is implemented. At this time, 3,800 persons in nine states are on ADAP waiting lists. An additional \$25 million in emergency federal funding was allocated to ADAP, but the number of persons on waiting lists still increased four-fold in only six months.

Enrollment in ADAP continues to grow due to the number of new infections, increased testing programs, longer life spans, and the loss of health insurance as a result of the economic recession. At the national level, the average increase of 1,554 new ADAP clients per month (or 18,000 new clients per year) in FY2008 was unprecedented. At the state level, Florida has >2,000 persons on its ADAP waiting list and enrolls 450 new clients each month.

Increased enrollment in ADAP and dramatic state budget cuts have occurred at the same time. Budget cuts have forced states to reduce drug formularies, decrease eligibility and dis-enroll beneficiaries. Policymakers must be informed of the magnitude of the ADAP problem to adjust budgets, explore other funding streams and identify other solutions.

CDC and HRSA should now update estimates that previously were presented to CHAC on the number of persons who would test positive as a result of expanded testing and the impact of expanded testing on care and treatment, particularly in the Ryan White Program. The updated data would be helpful in identifying increases in ADAP enrollment and corresponding budget estimates. The updated data also would play an important role in fulfilling the goals of the Ryan White Program to offer care and treatment to low-income PLWHA in the United States.

Chris Collins

Vice President and Director of Public Policy, American Foundation for AIDS Research

Mr. Collins encouraged CHAC to issue a formal statement to the Administration and HHS Secretary to award additional dollars and implement policies to maximize the impact and effectiveness of the NHAS and ECHPP. The HIV/AIDS community strongly supports ECHPP because this initiative could be a successful strategy in both the NHAS and reform of the overall public health system. Most notably, two key objectives of ECHPP are to expand the reach of services and coordinate HHS agencies in linking prevention with treatment and care.

CDC recently released results of a survey in 21 urban settings that showed 71% of young African American MSM living with HIV had no knowledge of their status. These data emphasize the critical need to change the healthcare delivery system and scale-up interventions to reach the most at-risk populations. The evaluation component of ECHPP will be essential in compiling and applying lessons learned from similar surveys and projects in the future.

New resources will be required in FY2012 for programs to scale-up ECHPP best practices, but several approaches can be taken in the interim. Resources allocated to programs that will not achieve population-level impact should be redirected to initiatives with the capacity to meet this goal. Existing funding streams should be thoroughly reviewed to ensure dollars are matched to the epidemic.

Local entities should be given flexibility to more easily integrate federal and state resources. Opportunities in health reform should be leveraged (e.g., Community Transformation Grants and new FQHC funding) to target resources to the 12 ECHPP grantees and other jurisdictions to scale-up evidence-based interventions to meet the NHAS goals. Overall, the NHAS and ECHPP provide significant opportunities to make a huge impact.

CHAC Business Session 2

Dr. Sweet opened the floor for the members to propose motions or reach agreement on issues that would require CHAC's formal action.

ISSUE 1: Dr. Sweet entertained a motion for CHAC to approve the previous meeting minutes. A motion was properly placed on the floor and seconded by Drs. André Rawls and Bruce Agins, respectively, for CHAC to adopt the previous meeting minutes. **CHAC unanimously approved the Draft May 11-12, 2010 Meeting Minutes with no changes or further discussion.**

ISSUE 2: Dr. Sweet noted that CHAC would need to formalize two action items raised on the previous day. First, Dr. Sweet would contact the PACHA Chair to initiate a joint effort to respond to tasks in the NHAS implementation plan that are similar between CHAC and PACHA. Second, Ms. Regan Hofmann would use the resources of POZ to administer a large-scale survey to assist CHAC in fulfilling its NHAS charge of soliciting public input on normalizing and promoting individuals' safe and voluntary disclosure of their HIV status.

A motion was properly placed on the floor and seconded by Dr. André Rawls and Mr. Ernest Hopkins, respectively, for CHAC to formalize the two action items. **CHAC unanimously approved the motion.** Ms. Antigone Hodgins Dempsey, Ms. Regan Hofmann, Mr. Ernest Hopkins and Mr. Harold Phillips would serve on an ad hoc group to support this activity.

ISSUE 3: A motion was properly placed on the floor and seconded by Mr. Ernest Hopkins and Dr. André Rawls, respectively, for Dr. Sweet to write a letter to HRSA expressing CHAC's strong support of including HIV care in health professional shortage area criteria. The letter would be addressed to Dr. Mary Wakefield, Administrator of HRSA, with a copy to Mr. Andy Jordan, Director of the HRSA Office of Shortage Designation. **CHAC unanimously approved the motion.**

ISSUE 4: A motion was properly placed on the floor and seconded by Mr. Ernest Hopkins and Dr. André Rawls, respectively, for Dr. Sweet to write a letter to the HHS Secretary expressing CHAC's strong support for the continuation of Prevention and Public Health Fund dollars to CDC in FY2011 and an increase of these resources in FY2012. **CHAC unanimously approved the motion.**

ISSUE 5: The following motion was properly placed on the floor and seconded by Dr. Carlos del Rio and Mr. Harold Phillips, respectively. CHAC recommends that the IOM use the news media to widely publicize the release of the three reports on HIV screening and access to care to translate the conclusions and findings of the IOM Committee into practice and assure accountability. **CHAC unanimously approved the motion.**

ISSUE 6: A motion was properly placed on the floor and seconded by Dr. André Rawls and Mr. Harold Phillips, respectively, for Dr. Sweet to write a letter to Dr. Mary Wakefield, Administrator of HRSA, emphasizing the following key points. CHAC appreciated BPHC's presentation during

the November 2010 meeting. CHAC was pleased that BPHC sent a Public Assistance Letter to its grantees with guidance on implementing CDC's revised HIV testing recommendations in healthcare settings, but more action is needed.

CHAC recommended that each CHC develop a strategic work plan outlining their strategies or approaches to:

- routinize HIV, STD and viral hepatitis testing;
- collect baseline data on testing and establish measurable targets and outcomes;
- address the NHAS goals;
- address testing-related stigma among providers; and
- scale-up HIV, STD and viral hepatitis testing, care and treatment nationally.

CHAC made several specific requests to support its formal motion.

- During the next meeting, BPHC should provide a progress report on the development of the CHC strategic work plans to expand HIV, STD and viral hepatitis testing and care.
- BPHC should categorize its data by Ryan White-funded and non-Ryan White-funded programs.
- BPHC should present preliminary data by the two new AETCs that were awarded funds to expand capacity of HIV/AIDS care in minority communities.
- BPHC should inform CHAC of specific leaders who will be tasked with assuring actual changes and progress in CHCs and overseeing accountability of CHCs to their strategic work plans.

CHAC unanimously approved the motion. The CHAC members agreed to e-mail Dr. Sweet with other potential points to emphasize in the letter to Dr. Wakefield. Dr. Sweet confirmed that she would circulate the draft to CHAC for review and comment before forwarding the final letter to the CDC and HRSA DFOs for submission to Dr. Wakefield.

ISSUE 7: CHAC recommended that Dr. Sweet write a letter to the HHS Secretary to emphasize the need to add routine HIV screening as a preventive service to be covered under PPACA. The letter should cite CDC's recent data as supporting evidence and convey a sense of urgency in light of the upcoming USPSTF review of HIV screening in 2011. **CHAC generally agreed on this action item.**

Dr. Sweet led CHAC in a review of presentations, overviews or updates that were proposed as future agenda items.

CDC and HRSA

- Presentation on previous models in which HIV, STD and viral hepatitis research was translated into actual practice.
- Update on the NHAS federal implementation plan.

- Status reports by Drs. Fenton and Parham Hopson on a strategy to disseminate to decision-makers the core principles and recommendations of the PCMH model that were previously approved by CHAC and ensure HIV, STD and public health issues are included in these discussions.
- Progress reports by Drs. Fenton and Parham Hopson on updating previous estimates of the number of persons who would test positive as a result of expanded testing and the impact of expanded testing on care and treatment with a focus on the Ryan White Program.
- Update on activities or campaigns to interact with the media, utilize social marketing and engage non-traditional partners followed by a discussion with CHAC to highlight gaps and identify areas of improvement in these areas.

CDC

- Update on new HIV testing algorithms and technologies.
- Update on the “HHS Action Plan for the Prevention and Treatment of Viral Hepatitis.”
- Update on the NCHHSTP Sexual Health White Paper and next steps in this initiative.
- Update on the NCHHSTP Social Determinants of Health White Paper.

HRSA

- Presentation by BPHC and the National Association of Community Health Centers.
- Update on HIV healthcare workforce issues.
- Progress report on the development of the CHC strategic work plans to expand HIV, STD and viral hepatitis testing and care.
- Update on the PCMH model, including actions taken by Ryan White providers to transition to medical homes and BPHC’s strategy with concrete action steps to ensure that FQHCs effectively provide solid and basic HIV care and access to expertise.

Other Agenda Items

- CMS: CMS leadership panel presentation on agency-wide strategies and programs for HIV.
- IHS: Overview of the impact of systems changes, policy changes and provider training on universal HIV testing in IHS clinics as well as rapid testing conducted by AETCs on Indian reservations and in other rural areas.
- CHAC: Status reports by the Viral Hepatitis Workgroup, the Sexual Health Workgroup, and the CHAC/PACHA ad hoc NHAS group.
- CHAC: Discussion on potentially effective strategies (e.g., Physician Quality Reporting Initiative measures and other incentives) to influence practitioners to change testing-related behaviors. The discussion should include a review of best practices and lessons learned with a broad group of practitioners both inside and outside of the HIV, STD, hepatitis and sexual health fields.
- Invited Speaker: Update by Jennifer Kates, an IOM Committee member, on the three IOM studies: (1) identifying facilitators and barriers to HIV testing; (2) exploring facilitators and barriers to HIV/AIDS care; and (3) capacity of the healthcare system to

identify and provide care for individuals with HIV/AIDS. Dr. Fenton will invite Dr. Valdiserri to a future CHAC meeting to listen to and provide input on this presentation.

Closing Session

The next CHAC meeting would be held on May 10-11, 2011 in Atlanta, Georgia. With no further discussion or business brought before CHAC, Dr. Sweet adjourned the meeting at 2:36 p.m. on November 16, 2010.

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

Date

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