

**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, 2011
Rockville, Maryland**

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, 2011 and confirmed the presence of quorum on both days of the meeting.)

CHAC Members

Ms. Antigone Hodgins Dempsey, co-Chair
 Dr. Edward Hook III, co-Chair
 Dr. Carol Brosgart
 Dr. Kathleen Clanon
 Dr. William Cunningham
 Dr. Carlos del Rio
 Dr. Perry Halkitis
 Rev. Debra Hickman
 Ms. Regan Hofmann
 Mr. Ernest Hopkins
 Dr. Steven Johnson
 Ms. Maria Lago
 Mr. Kali Lindsey
 Dr. Jeanne Marrazzo
 Dr. Kenneth Mayer
 Dr. André Rawls
 Dr. Britt Rios-Ellis

CHAC Ex-Officio Representatives

Dr. Pradip Akolar
 (Food and Drug Administration)
 Mr. Christopher Bates (Department of
 Health and Human Services,
 Office of HIV/AIDS Policy)
 Dr. Jennifer Crosswell (Agency for
 Healthcare Research and Quality)
 Dr. William Grace
 (National Institutes of Health)
 Dr. Effie George (Centers for Medicare and
 Medicaid Services)
 Dr. Gretchen Stiers (Substance Abuse and
 Mental Health Services Administration)
 Dr. Richard Wild (Alternate, Centers for
 Medicare and Medicaid Services)

CHAC Liaison Member

Mr. Douglas Brooks (Presidential Advisory
 Council on HIV/AIDS)

Designated Federal Officials

Dr. Kevin Fenton,
 NCHHSTP Director, CDC
 Dr. Laura Cheever, HRSA/HAB
 Deputy Associate Administrator

Federal Agency Representatives

Dr. Barbara Aranda-Naranjo
 Dr. Jose Aulay
 Dr. Geoff Beckett
 Dr. Gail Bolan
 Ms. Brittany Bovenizer
 Ms. Kimberly Brown
 Mr. William Bryant
 Dr. Christine Cagle
 Dr. Philippe Chiliade
 Mr. Glenn Clark
 Mr. Gary Cook
 Ms. Corinna Dan
 Dr. Carl Dieffenbach
 Dr. John Douglas, Jr.
 Ms. Teresa Durden
 Ms. Anita Edwards
 Mr. Michael Evanson
 Dr. Margarita Figueroa-Gonzalez
 Ms. Andi Fristedt
 Ms. Shelley Gordon
 Ms. Sonya Gray
 Mr. Lenwood Green
 Dr. Anna Huang
 Ms. Karen Inguoldstad
 Dr. Sarah Linde-Feucht
 Ms. Faye Malitz
 Ms. Karen Mercer
 Dr. Jonathan Mermin
 Mr. Roberto Nolte
 Ms. Diana Travieso Palow
 Ms. Katherine Patterson
 Mr. Harold Phillips
 Ms. Margie Scott-Cseh
 Dr. Rebecca Slifkin
 Dr. Rene Sterling

Mr. Wesley Tahsir-Rodriguez
Ms. Sandra Thurman
Dr. Ronald Valdiserri
Ms. Lynn Wagner
Ms. Viven Walker-Marable
Ms. Terri Webber
Dr. Howell Wechsler
Mr. Steven Young

Members of the Public

Ms. Lynn Barclay
(American Social Health Association)
Mr. Timothy Boyd
(AIDS Healthcare Foundation)
Dr. Lucy Bradley-Springer (University of
Colorado-Denver,
Mountain Plains AETC)
Ms. Sarah Buchanan
(Orasure Technologies, Inc.)

Ms. Kimberly Crump (HIV Medicine
Association)
Ms. Lindsey Dawson (The AIDS Institute)
Ms. Sarah Grigsby-Reiser (Sexuality
Information and Education Council of the
United States)
Ms. Ashley Grosso (American Foundation
for AIDS Research)
Mr. Burke Hays
(National Coalition of STD Directors)
Mr. Ronald Johnson (AIDS United)
Mr. Freddy Pizart (Member of the Public)
Mr. Leo Rennie
(American Psychological Association)
Ms. Allison Rich (AIDS United)
Mr. Carl Schmid (The AIDS Institute)
Mr. Michael Shankle (HealthHIV)
Mr. James Sykes (HealthHIV)
Ms. Bridget Verrette (The AIDS Institute)

ATTACHMENT 2

Glossary of Acronyms

AAALI	Act Against AIDS Leadership Institute
ACA	Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ADAP	AIDS Drug Assistance Program
AETCs	AIDS Education and Training Centers
AHRQ	Agency for Healthcare Research and Quality
AMR	Antimicrobial Resistance
ART	Antiretroviral Treatment
ARV	Antiretroviral
AST	Antibiotic Susceptibility Testing
BHP	Bureau of Health Professions
BPHC	Bureau of Primary Health Care
CBO	Community-Based Organization
CDC	Centers for Disease Control and Prevention
CHAC	CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment
CHCs	Community Health Centers
CHIP	Children's Health Insurance Program
CLSI	Clinical and Laboratory Standards Institute
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare and Medicaid Services
CoAgs	Cooperative Agreement
DASH	Division of Adolescent and School Health
DHAP	Division of HIV/AIDS Prevention
DSS	Division of Service Systems
DSTD	Division of STD Prevention
DVH	Division of Viral Hepatitis
ECHO	Extensions for Community Healthcare Outcomes
ECHPP	Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS
FBOs	Faith-Based Organizations
FDA	Food and Drug Administration
FOAs	Funding Opportunity Announcements
FPL	Federal Poverty Level
FQ	Fluoroquinolones
FQHCs	Federally Qualified Health Centers
GISP	Gonococcal Isolate Surveillance Project
GSAs	Gay-Straight Alliances
HAB	HIV/AIDS Bureau
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HHS	Department of Health and Human Services
HIT	Health Information Technology
HIVMA	HIV Medicine Association
HPV	Human Papillomavirus

HRSA	Health Resources and Services Administration
IDSA	Infectious Disease Society of America
IDUs	Injection Drug Users
IHS	Indian Health Service
IOM	Institute of Medicine
LEAs	Local Education Agencies
LGBT	Lesbian, Gay, Bisexual, Transgender
LGBTQ	Lesbian, Gay, Bisexual, Transgender, Queer
MAI	Minority AIDS Initiative
MICs	Minimum Inhibitory Concentrations
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
MSM	Men Who Have Sex With Men
NAAT	Nucleic Acid Amplification Testing
NASTAD	National Alliance of State and Territorial AIDS Directors
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCQA	National Committee for Quality Assurance
NG	<i>Neisseria gonorrhoeae</i>
NGOs	Non-Governmental Organizations
NHAS	National HIV/AIDS Strategy
NHBS	National HIV Behavioral Surveillance System
NHSC	National Health Service Corps
NIH	National Institutes of Health
NNPTC	National Network of Prevention Training Centers
OASH	Office of the Assistant Secretary for Health
OMB	Office of Management and Budget
PACHA	Presidential Advisory Council on HIV/AIDS
PALs	Program Assistance Letters
PCIPs	Preexisting Condition Insurance Plans
PCMH	Patient-Centered Medical Home
PCMHH	Patient-Centered Medical/Health Home
PCPs	Primary Care Providers
PCSI	Program Collaboration and Service Integration
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PLWHA	Persons Living with HIV/AIDS
PrEP	Pre-exposure Prophylaxis
PWP	Prevention With Positives
QI	Quality Improvement
SAMHSA	Substance Abuse and Mental Health Service Administration
SDH	Social Determinants of Health
SEAs	State Education Agencies
SHP	School Health Profiles
SHPPS	School Health Policies and Practices Study
SOC	Standard of Care
SPNS	Special Projects of National Significance
START	Strategic Timing of Antiretroviral Treatment
TA	Technical Assistance
TAI	The AIDS Institute
UCSF	University of California-San Francisco

UDS	Uniform Data System
USPSTF	U.S. Preventive Services Task Force
VHAP	Viral Hepatitis Action Plan
WHO	World Health Organization
YBMSM	Young Black Men Who Have Sex With Men
YMSM	Young Men Who Have Sex With Men
YRBS	Youth Risk Behavior Survey

**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, 2011
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 the Legacy Hotel and Meeting Centre in Rockville, Maryland on November 15-16, 2011.

Opening Session: November 15, 2011

Kevin Fenton, MD, PhD, FFPH

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

Dr. Fenton conducted a roll call to determine the CHAC voting members, *ex-officio* members and liaison representatives who were in attendance. He asked the voting members to declare any conflicts of interest for the record for themselves and/or their institutions.

- Carol Brosgart, MD: Owner of stock in Gilead Sciences and Tobira Pharmaceuticals
- Debra Hickman: Speaker for Gilead and co-recipient of NIH funding with Johns Hopkins
- Edward Hook III, MD: Recipient of research support from Gen-Probe, Becton Dickinson, Sephia, Siemens, Roche Molecular Systems, CDC and the National Institutes of Health (NIH)

- Steven Johnson, MD: Recipient of research funds and research consulting support from Vive Health, Gilead and Janssen Biotech and federal funding from HRSA and NIH
- Jeanne Marrasso, MD, MPH: Recipient of research support from Gilead, Sephia, CDC and NIH
- Kenneth Mayer, MD: Recipient of unrestricted research and educational grants from Gilead, Bristol-Myers Squibb, Merck, NIH, CDC and HRSA
- Britt Rios-Ellis, PhD: Recipient of funding support from NIH and a member of the Merck Pharmaceutical Latino Advisory Board and Tivo Tech

Dr. Fenton verified that the voting members and *ex-officio* members constituted a quorum for CHAC to conduct its business on November 15, 2011. He called the meeting to order at 8:34 a.m. and welcomed the participants to the meeting.

Dr. Fenton announced that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record. He reminded the CHAC voting members of their responsibility to identify individual potential conflicts of interest and recuse themselves from participating in these matters.

Dr. Fenton announced that the terms of two CHAC members would expire on November 30, 2011: Rev. Debra Hickman and Dr. Edward Hook. However, these members would be allowed to serve up to an additional 180 days if their replacements were not officially appointed. The participants joined Dr. Fenton in applauding the outstanding service of Rev. Hickman and Dr. Hook to CHAC and the broader HIV/STD prevention and treatment community.

Dr. Fenton was pleased to introduce a new non-voting liaison representative, Mr. Douglas Brooks. Mr. Brooks is the Senior Vice President for Community, Health and Public Policy at the Justice Resource Center and serves as CHAC's liaison to the Presidential Advisory Council on HIV/AIDS (PACHA). Mr. Brooks' appointment is in direct response to CHAC's unanimous resolution during the May 2011 meeting to identify a formal liaison to PACHA.

Dr. Fenton noted other changes to CHAC's membership. Dr. Jennifer Croswell is the Medical Officer for the Center for Primary Care, Prevention and Clinical Partnership in the Agency for Healthcare Research and Quality (AHRQ). She was appointed as CHAC's new *ex-officio* member for AHRQ. Dr. Scott Giberson has taken a new position with the Office of the Surgeon General and is no longer serving as the CHAC *ex-officio* member for the Indian Health Service (IHS). Ms. Lisa Neel has been named as an alternate *ex-officio* member for IHS until a permanent replacement for Dr. Giberson has been identified.

Dr. Fenton reminded CHAC of its unanimous resolution during the May 2011 meeting to change its name to the "CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment." In September 2011, the HHS Secretary and CDC Director approved CHAC's

resolution. In October 2011, CHAC's revised charter to change its name and add a formal liaison representative to PACHA was submitted to the CDC Committee Management Office. CDC and HRSA leadership agreed that despite the new name, the well-recognized acronym of "CHAC" would be retained. However, both CDC and HRSA were extremely pleased that CHAC voted to approve the inclusion of "Viral Hepatitis" in its formal name.

Dr. Fenton informed the participants that the meeting agenda was developed with presentations to primarily reflect on three key areas: (1) year 1 progress after the release of the National HIV/AIDS Strategy (NHAS); (2) new advances in HIV prevention and treatment over the past year; and (3) increased awareness and acceptance of two concepts: "HIV prevention as treatment" and "HIV treatment as prevention." Major emerging issues also would be presented during the CHAC meeting (e.g., new strategies focused on national viral hepatitis prevention efforts and the federal response to the urgent threat of gonorrhea antimicrobial resistance).

Laura Cheever, MD

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

Dr. Cheever joined Dr. Fenton in welcoming the participants to the 18th biannual CHAC meeting. For the current meeting, she would serve as the Designated Federal Official for HRSA in the absence of Dr. Deborah Parham Hopson, Associate Administrator of the HRSA HIV/AIDS Bureau (HAB).

Dr. Cheever thanked the participants for taking valuable time from their busy schedules to continue to provide expertise, guidance and creative input to CDC and HRSA on national HIV/STD prevention and treatment efforts. She commended CHAC on its outstanding productivity in 2010-2011, particularly in the context of new directions the members recommended to support NHAS.

Dr. Cheever was pleased to introduce three new CHAC members. She pointed out that detailed biographical sketches of the new members were included in the meeting packets.

- Kathleen Clanon, MD: Director, Division of HIV Services, Alameda County Medical Center (Oakland, California)
- Steven Johnson, MD: Professor of Medicine, Division of Infectious Diseases, University of Colorado School of Medicine
- Britt Rios-Ellis, PhD: Professor of Health Science, Director of the National Council of La Raza/California State University-Long Beach Center for Latino Community Health

Antigone Hodgins Dempsey MEd, CHAC co-Chair

Deputy Director, Knowledge, Transfer and Technical Assistance
HIV/AIDS Lead, Altarum Institute

Ms. Hodgins Dempsey joined her colleagues in welcoming the participants to the meeting. She emphasized that she was honored to serve in her new role as the CHAC co-Chair. In the tradition of Dr. Donna Sweet, the former CHAC co-Chair, she also would facilitate thoughtful discussions to ensure CHAC continues to provide CDC and HRSA with helpful advice and guidance.

Ms. Hodgins Dempsey opened the floor for introductions. The list of participants is appended to the minutes as [Attachment 1](#).

HRSA/HAB Deputy Associate Administrator's Report

Laura Cheever, MD

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

Dr. Cheever covered the following topics in her Deputy Associate Administrator's report to CHAC. The vision and mission of HAB are to (1) provide optimal HIV/AIDS care and treatment to all persons and (2) provide leadership and resources to assure access to and retention in high-quality, integrated care and treatment services for vulnerable persons living with HIV/AIDS (PLWHA) and their families.

HAB data show that each year, the Ryan White HIV/AIDS Program serves >529,000 uninsured and underinsured persons who are affected by HIV/AIDS and their family members. In 2009, the AIDS Drug Assistance Program (ADAP) provided medications to ~194,038 persons (or 1 in 4 persons in the United States who receive antiretroviral (ARV) drugs).

HAB's overarching goal is to over-represent and target services to persons most in need. HAB's 2009 data showed that its reach extended to the most vulnerable populations: uninsured/underinsured persons or those receiving public health benefits (89%), racial minorities (~73%), and women (32%).

HAB maintained its focus on two key areas in FY2011. NHAS activities were continued to better integrate HIV care and treatment into all other parts of HRSA outside of HAB. Efforts were made to continue to prepare for the reauthorization of Ryan White in 2013. In addition to these ongoing activities, HAB also launched a number of new initiatives in FY2011.

The "National Retention in Care Quality Campaign" is a national quality improvement (QI) initiative to improve outcomes in retention in HIV care. HAB designed this effort with a key outcome of building and sustaining a "community of learners" among Ryan White providers. The program includes the development of national measures that grantees will use (e.g., viral suppression, gaps in care for patients out of care >6 months, and retention of new patients). Although the program is voluntary, the membership included 290 providers representing

>334,000 patients as of November 6, 2011. The National Quality Center is managing the program and maintains a website for this initiative at <http://incarecampaign.org>.

HAB and outside contractors are conducting a 2-year “HIV Clinician Workforce Study” to analyze the current HIV workforce in the United States and project future needs. The study population will include physicians, physician assistants and nurse practitioners who prescribe ARV drugs.

The study design will include the use of data by the Centers for Medicare and Medicaid Services (CMS) and industry and a survey to both clinicians and clinical sites. The key outcome of the study is to develop a methodology to measure the HIV workforce on a regular basis. HAB has submitted the study package to the Office of Management and Budget (OMB) for approval.

HAB’s other HIV clinician workforce efforts include increased funding to AIDS Education and Training Centers (AETCs) to conduct new initiatives: (1) expand HIV care in minority communities by building capacity in Community Health Centers (CHCs); (2) develop capacity among healthcare providers who serve American Indian/Alaska Native populations; and (3) implement the U.S.-Mexico Border HIV Clinical Capacity Development Project to fill gaps in the provision of HIV/AIDS care in this region.

HAB funded two new projects to further support workforce development as a part of NHAS. The University of Washington, University of Pittsburgh, and University of California-San Francisco (UCSF) were awarded funds to establish new AETC Tele-Health Training Centers to mentor community-based providers and co-manage HIV infection in their respective geographic areas. HIV training in graduate medical education programs was expanded to include Yale School of Medicine, Family Residency of Boise, Idaho, and State University of New York Research Foundation.

HAB continued to focus on its existing Special Projects of National Significance (SPNS) in FY2011. The focus areas and project periods of these SPNS initiatives are:

- “Enhancement of Linkages to HIV Primary Care in Jail Settings” (2007-2012);
- “Enhancing Access and Retention Into Quality HIV Primary Care for Women of Color” (2009-2013);
- “Hepatitis C Treatment Expansion Initiative” (2010-2014);
- “Systems Linkages and Access to Care for Populations at High Risk of HIV Infection Initiative” (2011-2015); and
- Capacity Building to Develop Standard Electronic Information Data Systems for Ryan White ADAP Programs” (2011-2012).

HAB will fund 3 new SPNS initiatives in FY2012: (1) “Integrated HIV Care, Mental Health and Substance Abuse Treatment for HIV-Positive Homeless Populations;” (2) “Enhancing Access to and Retention in Quality HIV Care for Transgender Women of Color;” and (3) “Health Information Technology (HIT) Capacity Building Initiative for Ryan White HIV/AIDS Program

Providers.” Although HAB set aside \$5 million for SPNS initiatives (or \$100,000 per award), only 17 grantees submitted applications.

HAB funded three new policy studies in FY2011. John Snow, Inc. initiated a study to identify interdisciplinary care models for HIV/AIDS care and treatment among Ryan White grantees. Mathematica Policy research initiated a study to determine the potential impact of the Affordable Care Act (ACA) on the Ryan White Program to inform the 2013 reauthorization. Walter R. McDonald & Associates, Inc. initiated a study on ADAP waiting lists to assess factors that impact ADAP enrollment and management.

In terms of technical assistance (TA), HAB’s planning efforts are underway for its 2012 All-Grantee Meeting that will be held in November 2012. HAB funded five new TA cooperative agreements (CoAgs) in FY2011. The focus areas and grantees of these initiatives are:

- assistance to ADAPs (National Alliance of State and Territorial AIDS Directors (NASTAD));
- improvement of fiscal management systems to decrease dependence on Ryan White grants (HealthHIV);
- assistance to grantees to develop medical home models in preparation of ACA implementation (University of Medicine and Dentistry of New Jersey);
- maintenance of the web-based “Target Center” for HRSA to provide TA to grantees and other public/private entities (UCSF); and
- assistance to grantees to improve data for the purposes of reporting, program evaluation and QI (Cicatelli).

HAB initiated efforts in 2009 to collect client-level data for HIV medical care and medical case management, but significant data quality issues occurred. Since that time, HAB has collected 2010 data across all service categories. After the data are “cleaned” and duplicate information is removed, HAB will begin the analysis process. HAB currently is developing a client-level ADAP Data Reporting System.

HAB will re-compete Part D of the Ryan White Program in FY2012. This effort will be undertaken as a part of NHAS to realign the program to provide more comprehensive and effective healthcare services for women, children and youth living with HIV/AIDS who are in areas of greatest need for services. Beginning in FY2012, all programs that receive Part D funds will be expected to serve women, children and youth.

HAB is continuing to address concerns grantees have raised regarding ADAP. ADAP services include medications, insurance, adherence support and drug treatment monitoring. In accordance with its statute, the ADAP Formulary must contain at least one medication from each class of ARV drugs. However, HAB provides states with flexibility in determining their individual formularies and financial eligibility requirements.

ADAPs are required to re-certify the eligibility of patients every 6 months; use the formula to distribute 95% of funds based on the number of PLWHA in their states for the most recent

calendar year; and set aside 5% of funds for the ADAP supplemental grant. HRSA's \$885 million appropriation for ADAP in FY2011 included a \$50 million increase to assist states with waiting lists and cost containment measures. Federal dollars account for ~50% of the ADAP line item, while state funds account for the remaining 50% (e.g., state matching dollars, Part A and B contributions, rebates and state general revenue funds).

HAB's cost modeling data estimate that beginning in FY2012, ADAP funding will be ~\$12,000 per year for each client. However, HAB is aware that this estimate will significantly vary by state depending on its individual formulary and program costs. Although ADAPs have access to 340b discounted pricing, states and NASTAD have negotiated to obtain further discounts.

As of November 4, 2011, 6,476 persons in 11 states were on ADAP waiting lists. However, this figure represents a decline of ~30% since September 2011. Some states have replaced ADAP waiting lists with cost containment measures (e.g., lowering the Federal Poverty Level (FPL), adding an asset test, reducing formularies, initiating or increasing co-pays, or negotiating lower drug costs). HAB is continuing to closely collaborate with states to assure that patients on ADAP waiting lists have medications through Pharmacy Assistance Programs.

The number of clients served by ADAP has grown by 19% from 2008 to 2010 due to several key factors (e.g., the economic downturn, increased testing and linkages to care, increased prevalence as a result of prolonged survival of patients, and earlier HIV treatment among patients). HAB expects that its ongoing study to assess factors impacting ADAP waiting lists will strengthen knowledge in this area.

The FY2011 Ryan White budget was enacted at a level of ~\$2.3 billion. For the FY2012 budget, HRSA and all other federal agencies are operating under a continuing resolution through November 18, 2011. Of the \$2.3 billion appropriation to the Ryan White Program in FY2012, the top 4 line items were Part B-ADAP (38% or \$885 million); Part A-urban areas (29% or ~\$668 million); Part B-base funding (18% or \$418 million); and Part C-Early Intervention Services (~\$206 million or 9%). The remaining line items in the FY2012 appropriation were Part D-family-centered primary medical care (~\$77 million or 3%); AETCs (~\$35 million or 1%); SPNS initiatives (\$25 million or 1%); and dental services (~\$14 million or 1%).

The ADAP and base budgets have tremendously grown since 1996 due to the increasing importance of ARV drugs, but the budgets for AETCs and dental services have been relative stable since that time. In FY2009, the largest portion of the \$2.15 billion Ryan White budget was spent on medications (39%), medical care (25%), case management (9%), and support services (7%).

HAB's recent staffing changes include Barbara Aranda-Naranjo (Director of the Division of Service Systems (DSS)), Karen Mercer (Acting Deputy Director of DSS), Jose Raphael Morales (Director of the Global HIV/AIDS Program), Tracy Matthews (HAB Clinical Advisor), Marlene Matosky (HAB Nurse Consultant), 22 new Project Officers and 1 administrative staff member.

Dr. Cheever provided additional details on HAB's recent HIV/AIDS treatment and care initiatives in response to CHAC's specific questions. The discussion topics included:

- HAB's collaborations with federal partners to provide direct assistance for housing to HIV-positive homeless persons in the SPNS initiatives;
- gaps in care and problems related to retention in care due to the requirement to re-certify the eligibility of patients every 6 months;
- HAB's plans to link the SPNS adherence initiative to Prevention with Positives (PWP) in clinical settings;
- the concentration of ADAP waiting lists in the Southeastern United States (e.g., 7 of 11 states);
- potential factors that have caused the decline in the number of patients on ADAP waiting lists (e.g., new resources incorporated into formula allocations, changes in cost containment strategies, and changes in patient eligibility levels);
- HRSA's lack of authority to standardize formula allocations in ADAP formularies across states due to explicit language in the Ryan White statute;
- HAB's TA to help grantees prepare for implementation of ACA to minimize disruptions in care and treatment to PLWH;
- the number of patients who dropped out of ADAP and are not on waiting lists due to changes in eligibility requirements and cost containment strategies;
- potential strategies to encourage states to increase their contributions to ADAP;
- complexities related to generic drugs; and
- HAB's efforts to track expenditures for HCV medications within the Ryan White Program and ADAP and the impact of these expenditures on the ADAP budget.

CHAC congratulated HAB on its outstanding record of accomplishment and leadership in HIV care and treatment. The CHAC members made several suggestions for HAB to consider to further improve HIV/AIDS care and treatment to patients.

- HAB should ensure that its survey of clinicians and clinical sites is aligned with the ongoing survey administered by the HIV Medicine Association (HIVMA) and Infectious Disease of Society (IDSA). Training centers provided substantial input into this survey, particularly related to the elements of STD screening in HIV care.
- HAB should expand its graduate medical education programs for HIV training to include viral hepatitis and sexual health components in the curriculum.
- HAB should make strong efforts to allocate sufficient resources for Ryan White clinics to shift to and support a HIT infrastructure and other digital technologies.
- HAB should ensure that Minority AIDS Initiative (MAI) resources are prioritized in the HHS Secretary's discretionary funding of \$50 million to better address health disparities in HIV care and treatment among minority populations.
- HAB's TA activities should help grantees to reconsider existing service models, continue to serve the target population in the future, and strengthen capacity to continue to successfully compete for funding in the future to provide services in the new health reform environment.

- HAB should ensure that its TA is relevant to the provision of services at the local level and the needs of the organization are met. Grantees have raised concerns that HAB's TA is not specific to a Ryan White part.
- HAB should track testing of new Ryan White patients in various venues (e.g., primary care settings, emergency departments or correctional facilities) to measure the impact of CDC's 2006 HIV testing recommendations. HAB should engage the HIV Research Network in this effort.
- As part of the Viral Hepatitis Action Plan (VHAP), HAB should document the success of Ryan White clinics in screening all new HIV patients for hepatitis B/C virus (HBV/HCV); immunizing patients for hepatitis A virus; and retesting patients for HCV, particularly injection drug users (IDUs) and men who have sex with men (MSM).
- HAB should increase its focus on the 850,000 PLWH who are not in care in the United States and develop effective strategies to enroll this population in care in preparation of ACA implementation in 2014.
- HAB should review the sub-study on providers that was conducted as part of the HIV Cost and Services Utilization Study. HAB might be able to use the design, methodology and approach from this nationally representative study to inform the development of its new HIV Clinician Workforce Study.
- HAB should inform HHS of the need to design the Ryan White Reauthorization and ACA Study to obtain direct feedback from PLWH or consumers of HIV services and describe their priorities in the study.
- HAB should improve its TA to grantees in collecting client-level data for HIV medical care and medical case management. Some cities, states and regions appear to gather information that is duplicative and irrelevant in some cases. HAB should clearly communicate its expectations in terms of the collection of client-level data.

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
CHAC Designated Federal Official, CDC

Dr. Fenton covered the following topics in his Director's report to CHAC. At the agency level, the CDC leadership team had two recent personnel changes. Ms. Sherri Berger was appointed as the Chief Operating Officer and Dr. Katherine Lyon Daniel is serving as the Acting Associate Director for Communication.

The FY2011 budget was extremely challenging for CDC. The \$740 million reduction in the budget authority accounted for an 11% decrease compared to the FY2010 funding level. CDC currently is operating under a continuing resolution until November 18, 2011. Due to

uncertainties associated with a continuing resolution, CDC is unable to act on commitments to existing grantees or launch new programmatic initiatives at the beginning of the fiscal year.

For FY2012, the Senate proposal would allocate \$7 billion to CDC. The proposed resources reflect a 2.5% increase (or \$174 million) above the FY2011 funding level. The three key areas of the Senate proposal are highlighted below. The first area is a \$5.77 billion base budget, overall increases for the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) and the National Center for Immunization and Respiratory Diseases, and level funding for the National Center for Emerging and Zoonotic Infectious Diseases.

The second area is \$848 million through the ACA/Prevention and Public Health Fund to support CDC's immunization activities, epidemiology and laboratory capacity, healthcare acquired infections initiatives, and infectious disease screening activities (e.g., viral hepatitis). The third area is the elimination of the block grant.

For FY2012, the House proposal would allocate \$6 billion to CDC. The proposed resources reflect a 13% decrease (or \$863 million) below the FY2011 funding level. The three key areas of the House proposal are highlighted as follows. The first area is the elimination of the Prevention and Public Health Fund. The second area is the return of the block grant with funding of \$100 million.

The third area is decreases to all three infectious disease centers that would be below the FY2011 level. These reductions would range from \$49 million to \$73 million in each center. Both the Senate and House proposals present tremendous challenges for CDC to allocate funding to state and local health departments to provide even the most basic public health services.

CDC released two publications that described the 10 greatest public health achievements for the United States and worldwide. The top 10 U.S. accomplishments are vaccine-preventable diseases, prevention and control of infectious diseases, tobacco control, maternal and infant health, motor vehicle safety, cardiovascular disease prevention, occupational safety, cancer prevention, childhood lead poisoning prevention, and public health prepared and response.

The top 10 global accomplishments are reductions in child mortality, vaccine-preventable disease, access to safe water and sanitation, malaria prevention and control, HIV/AIDS prevention and control, tuberculosis control, control of neglected tropical diseases, tobacco control, increased awareness and response for improving global road safety, and improved preparedness and response to global health threats.

CDC celebrated 50 years of the *Morbidity and Mortality Weekly Report (MMWR)* and the pivotal role of this publication in better understanding both infectious and chronic diseases, describing the public health response in the United States, and publicizing key public health developments at national and global levels. The *MMWR* was responsible for first reporting the unknown

cluster of infections that was later characterized as AIDS and HIV infection. *Public Health Then and Now: Celebrating 50 Years of MMWR at CDC* is available at www.cdc.gov/mmwr.

The CDC Advisory Committee on Immunization Practices (ACIP) approved recommendations during its October 2011 meeting that will have implications on NCHHSTP's activities. For human papillomavirus (HPV), ACIP recommended routine vaccination of males 11-12 years of age with 3 doses of quadrivalent vaccine. The vaccination series can be started at 9 years of age.

ACIP recommended HPV vaccination for males 13-21 years of age who have not been previously vaccinated or who have not completed the 3-dose series. Males 22-26 years of age may be vaccinated. ACIP's recommendations represent a major development for prevention and control of HPV in the United States along with its associated outcomes, particularly anal cancer among MSM. The guidance also addresses concerns regarding gender inequity because the previous vaccine strategy ACIP recommended solely focused on young females.

For HBV, ACIP recommended vaccination of unvaccinated adults <60 years of age with diabetes. ACIP's recommendation of HBV vaccination to unvaccinated adults >60 years of age with diabetes also was approved.

In October 2011, CDC released its new "Framework for Preventing Infectious Diseases: Sustaining the Essentials and Innovating for the Future." CDC developed the framework with three overarching elements.

Element 1 is to strengthen fundamental public health capacity, including infectious disease surveillance, laboratory detection and epidemiologic investigation. The priorities for element 1 are to modernize infectious disease surveillance to drive public health action; expand the role of public health and clinical laboratories in disease control and prevention; improve capacity for epidemiologic investigations and public health response; and advance workforce development and training to sustain and strengthen public health practice.

Element 2 is to identify and implement high-impact public health interventions to reduce infectious diseases. The priorities for element 2 are to identify and validate high-impact tools for disease reduction and use proven tools and interventions to reduce high-burden infectious diseases. The infectious disease issues of special concern for element 2 are antimicrobial resistance, chronic viral hepatitis, food safety, healthcare-associated infections, HIV/AIDS, respiratory infections, safe water, vaccine-preventable diseases, and zoonotic and vector-borne diseases.

Element 3 is to develop and advance policies to prevent, detect and control infectious diseases. The priorities for element 3 are to ensure the availability of sound scientific data to support the development of evidence-based and cost-effective policies and advance policies to improve prevention, detection and control of infectious diseases. NCHHSTP played an integral role with CDC's other infectious disease centers to develop the framework.

Over the next five years, CDC will utilize the framework to increase the focus on and raise the profile of infectious diseases, assure accountability, and make concrete advances in prevention and control of these conditions. The Office of Infectious Diseases Board of Scientific Counselors recently ratified the CDC Infectious Disease Framework during its November 2011 meeting. The framework is available at www.cdc.gov/oid/framwork.html.

At the National Center level, the Division of Adolescent and School Health (DASH) will be formally added to the NCHHSTP organizational structure in FY2012. The new addition will allow NCHHSTP to focus on adolescent and youth programming. Changes in NCHHSTP's leadership include the following appointments: Acting Associate Director for Health Equity (Dr. Ramal Moonesinghe), Associate Director for Science (Dr. Benedict Truman), and Acting Associate Director for Laboratory Science (Dr. Edwin Ades). NCHHSTP is engaged in a recruiting process at this time to permanently fill the acting positions in early 2012.

NCHHSTP made several accomplishments in FY2011 to further advance the prevention and control of infectious diseases. The Division of HIV/AIDS Prevention (DHAP) continued to provide exceptional leadership in the NHAS implementation plan. DHAP released new funding opportunity announcements (FOAs) focused on young MSM (YMSM) and young transgender persons of color. State and local health departments also were funded to conduct HIV prevention activities across the United States.

DHAP hosted the National HIV Prevention Conference in the summer of 2011 with >3,000 participants. The conference provided a forum for the participants to reflect on progress made to date in HIV/AIDS prevention, prepare for the International AIDS Conference in 2012, and determine future directions for HIV/AIDS prevention in the United States. DHAP currently is developing a new FOA for HIV surveillance in collaboration with a diverse group of partners.

The Division of Viral Hepatitis (DVH) began implementation of VHAP. DVH collaborated with the CDC National Center for Immunization and Respiratory Diseases to determine future directions of the Perinatal Hepatitis B Prevention Program and discuss CDC's support to state and local health departments to accelerate efforts to eliminate perinatal HBV transmission in the United States. A detailed update on DVH's recent activities is scheduled on the agenda.

The Division of STD Prevention (DSTDP) is focusing on its reorganization and developing new strategic priorities. DSTDP played an instrumental role in managing several innovative and cross-cutting activities, particularly the formation of the Sexual Health Coalition. NCHHSTP leadership transferred oversight of the Program Collaboration and Service Integration (PCSI) FOA to DSTDP. The 6 PCSI grantees are funded to conduct demonstration projects. A detailed update on DSTDP's recent activities is scheduled on the agenda.

DASH is developing a methodology for an external peer review of adolescent and school health programs that is expected to be conducted in the spring of 2012. The purpose of the peer review will be for external experts to provide guidance on the best approach to integrate DASH into NCHHSTP and harmonize DASH's programs with NCHHSTP's existing programs. The peer review also will provide an opportunity for NCHHSTP to review its portfolio of activities and

identify strategic directions over the next 5-10 years. A detailed update on DASH's recent activities is scheduled on the agenda.

NCHHSTP released its 2010-2015 Strategic Plan in February 2010 to articulate its vision, overarching goals and strategies to guide programs. The six cross-cutting goals of the NCHHSTP Strategic Plan support the disease-specific strategic plans developed by each division. Dr. Fenton highlighted NCHHSTP's key accomplishments in FY2011 for each of the six cross-cutting goals.

For the PCSI goal, NCHHSTP will launch a new Atlas Project in the winter of 2011 that will serve as an interactive and unified platform to improve access to integrated HIV, STD, TB and viral hepatitis data. The project initially will be launched with HIV and STD data, but TB and viral hepatitis data will be added to the platform over time. *Public Health Reports* will issue a call for papers to include in a supplement on social determinants of health (SDH), sexual health and PCSI. NCHHSTP will circulate announcements of the journal supplements to CHAC for the members to broadly distribute to their partners and grantees.

In December 2011, NCHHSTP plans to release *Data Security and Confidentiality Guidelines for HIV/AIDS, Viral Hepatitis, STD and TB Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action*. The guidelines are intended to achieve three major objectives.

Minimum standards will be established to ensure the appropriate collection, storage, sharing and use of data across surveillance and program areas for NCHHSTP. The new guidelines will replace current recommendations for HIV surveillance programs and establish new standards for data sharing and surveillance for viral hepatitis, STD and TB programs. Minimum standards will be established to allow for increased use of HIV surveillance data for public health action.

For the health equity goal, NCHHSTP held a Health Equity Symposium in August 2011 with >300 CDC employees in attendance. The theme of the symposium was "Identifying Root Causes of Health Inequities: Using Data to Monitor and Improve Health." The symposium focused on the use of data to inform and shape public health policy, practice and research. Due to its success, NCHHSTP is exploring the possibility of expanding the symposium to provide an opportunity for grantees and external partners to strengthen their approaches to address SDH and integrate health equity into existing public health activities at the national level.

The World Health Organization (WHO) held the first World Conference on Social Determinants of Health in October 2011 in Rio de Janeiro, Brazil to build support for the implementation of action on SDH. The HHS Secretary played an active role in the conference. Dr. Hazel Dean, Deputy Director of NCHHSTP, was a member of the U.S. Delegation to the conference. NCHHSTP sponsored a supplement to *Public Health Reports* that focused on data systems and their use in addressing SDH. The supplement is available at www.cdc.gov/socialdeterminants.

For the prevention through healthcare goal, NCHHSTP convened the “Prevention Through Healthcare: Enhancing Health Departments’ Preparedness and Response” Consultation in June 2011. The consultation provided a forum for ~100 public health professionals to help CDC identify changes in healthcare delivery that may affect health department activities and propose strategies for health departments to better respond to these changes. NCHHSTP will disseminate more information on prevention through healthcare through its website and print materials to continue the dialogue on ACA and its implications for programs.

For the global health protection and systems strengthening goal, CDC and the Botswana Ministry of Health conducted the TDF2 Study that demonstrated a daily oral dose of ARV drugs can reduce HIV transmission via heterosexual sex. The study showed an overall reduction in risk of ~63% in the cohort of uninfected heterosexual men and women.

A Tuberculosis Trials Consortium study showed that a supervised regimen of once-weekly rifapentine and isoniazid for 3 months was as effective as the standard daily 9-month regimen. The regimen is applicable to countries with low to medium incidence of TB. NCHHSTP is collaborating with the National Institute of Allergy and Infectious Diseases on enrollment and follow-up of persons with HIV and young children 2-12 years of age in the United States, Brazil and Peru.

For the partnerships goal, NCHHSTP collaborated with numerous partners to plan and implement the inaugural World Hepatitis Day on July 28, 2011. NCHHSTP is continuing to build public/private partnerships with the CDC Foundation and the National Viral Hepatitis Action Coalition. NCHHSTP continued to conduct activities to support the “Get Yourself Tested,” “KNOW MORE HEPATITIS,” and “Act Against AIDS” Campaigns.

For the workforce development and capacity building goal, NCHHSTP launched the “Workforce Matters” Blog for employees to discuss workforce development, capacity building and related topics. NCHHSTP added individual career counseling to its workforce development portfolio and hosted 17 fellows and interns during the summer of 2011. The NCHHSTP Strategic Plan is available at www.cdc.gov/nchhstp/publications.

CDC is continuing efforts to harmonize its screening recommendations with those of the U.S. Preventive Services Task Force (USPSTF). USPSTF’s recommendations state that HIV screening criteria are risk-based to a significant degree. CDC’s recommendations state that risk-based criteria are not fundamental to HIV screening. USPSTF’s review of its HIV screening recommendations is underway.

CDC’s criteria for HCV screening recommendations are risk-based. USPSTF does not recommend HCV screening for the general population and notes that evidence is insufficient to recommend HCV screening in high-risk adults. In collaboration with the Agency for Healthcare Research and Quality and external experts, CDC currently is drafting updated HCV screening recommendations with the GRADE methodology. USPSTF also is reviewing its HCV screening recommendations. However, CDC is aware of its limited ability to influence USPSTF because the group is an independent body that operates with statutory autonomy.

In response to CHAC's specific questions, Dr. Fenton and NCHHSTP Division Directors provided additional details on CDC's recent prevention and control activities for infectious diseases. The discussion topics included:

- the possibility of expanding the HPV recommendations to include older age groups;
- USPSTF's inability to consider the provider's perspective in conducting an individual-based risk assessment and providing sensitive care in actual practice;
- USPSTF's tendency to ignore data in some cases (e.g., recent draft recommendations for Pap smear screening that require women to have a history of vaginal intercourse);
- planning efforts by CDC and its federal partners to ensure strong emphasis is placed on the domestic HIV/AIDS epidemic during the International AIDS Conference;
- the possibility of highlighting the Washington Declaration during a special session of the International AIDS Conference;
- strategies to prioritize resource allocations and service integration in jurisdictions with low HIV incidence and high HIV mortality;
- CDC's upcoming release of its analysis of the Gardner study with estimates of the continuum of care and the proportion of Americans with a suppressed viral load stratified by specific categories;
- the capacity and design of the new Atlas Project (e.g., the ability to map differences in HIV incidence and prevalence by racial/ethnic groups and merge relevant data collected by other programs outside of NCHHSTP); and
- CDC's release of provisional guidance on pre-exposure prophylaxis (PrEP) for heterosexuals in the near future and HHS's release of final PrEP guidance in 2012.

CHAC thanked NCHHSTP for its leadership in raising the profile and visibility of SDH and health equity and informing the American public of the strong scientific foundation of these initiatives. Some CHAC members encouraged their colleagues to read and broadly distribute NCHHSTP's supplement in *Public Health Reports* on data systems and their use in addressing SDH.

Panel Presentation: Update on the NHAS Implementation Plan

Ronald Valdiserri, MD, MPH

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

Dr. Valdiserri presented an update on HHS's ongoing activities in the NHAS implementation plan, the 12 Cities Project and VHAP. In terms of NHAS, Mr. Jeff Crowley will be leaving his position as the Director of the Office of National AIDS Policy at the end of December 2011. His departure may have an impact on submitting the report to President Obama on year 1 of the NHAS implementation activities in early 2012. Dr. Valdiserri emphasized that Mr. Crowley has

been an outstanding advocate for HHS, its federal partners and communities with an interest in HIV/AIDS in the United States.

HHS developed a report summarizing all of the efforts across the department in year 1 of the NHAS implementation plan. HHS will make the report available to the public in the near future. The HHS Office of the Assistant Secretary for Health (OASH) has been collaborating with a cross-agency group to develop a detailed inventory of prevention programs for African Americans, including a description of evaluations of these activities. The inventory will be analyzed to identify gaps in evaluation outcomes. HHS plans to submit the inventory to the clearance process before the end of December 2011 and release the report in the first quarter of 2012.

NHAS advised federal agencies to streamline the number of data elements collected by federal HIV/AIDS grantees and also to harmonize measures across agencies to assess program activities. In response to this recommendation, HHS is thoroughly reviewing reporting requirements of HIV grantees in close collaboration with CDC, HRSA and other HHS agencies.

The agencies are developing a proposal that will be presented to the HHS Secretary. The proposal will identify common metrics that all federal HIV/AIDS grantees should collect and outline guiding principles to streamline the data reporting burden (e.g., a decrease in the frequency of collecting some data elements). HHS convened a stakeholder consultation to obtain external input on this effort.

The HHS Secretary traditionally has made MAI discretionary funding of \$52 million available to HHS operating divisions and staff offices to promote activities and programs to address disparities in HIV/AIDS among racial/ethnic minority communities. NHAS specifically recommended that all users of MAI funds improve their utilization of these resources. Concerns have been raised about the need to more appropriately target MAI dollars in terms of geography and the types of supported activities.

HHS obtained extensive input from CDC, HRSA, other federal partners and community leaders on strategies to better use the HHS Secretary's MAI funds. HHS used this feedback to develop an FOA for the first time. HHS operating divisions and staff offices that submit competitive proposals will be required to address 1 of 4 overarching areas: preventing HIV infection in racial/ethnic minorities, improving health outcomes, mobilizing to reduce HIV/AIDS disparities, or developing capacity to achieve the NHAS goals. HHS will set aside a substantial proportion of the \$52 million to conduct a demonstration project. HHS is in the early stages of developing the project and will extensively solicit from federal partners.

HHS is exploring strategies with federal partners and external stakeholders to share information about the distribution of federal HIV/AIDS dollars. Each HHS agency maintains funding data on its individual grantees, but no central location at the HHS level has this information. HHS took initial steps in this effort with the 12 Cities Project in which OASH served as a clearinghouse for funding data submitted by HRSA, IHS, NIH, Substance Abuse and Mental Health Services Administration (SAMHSA), and U.S. Department of Housing and Urban Development. HHS

forwarded the information to CDC to be shared with grantees at the local level, but grantees noted that the funding data were “raw” rather than “cleaned.”

In terms of the 12 Cities Project, this initiative served as a successful first step in addressing the NHAS recommendation for federal agencies to better coordinate their vertical programs that have separate and different funding streams, reporting requirements and planning activities. HHS is funding an external evaluation to determine whether the multitude of federal meetings that were convened to discuss coordination of vertical programs made an impact.

In terms of VHAP, OASH recently hired Ms. Corinna Dan to assist Dr. Valdiserri with this activity. HHS engaged the Department of Veterans Affairs and Bureau of Prisons as important partners in the VHAP implementation plan. A Viral Hepatitis Implementation Group was established with representation from both HHS and non-HHS agencies. The group developed a status report highlighting the progress to date since the release of VHAP. HHS shared the status report with Viral Hepatitis Coordinators and will make the document publicly available in the near future.

During its next meeting, the Viral Hepatitis Implementation Group will discuss the important topic of guidelines. Another workgroup was formed to specifically focus on the development of viral hepatitis educational materials. The initial inventory will include materials produced by federal agencies only and will be publicly available on the website of the CDC National Prevention Information Network at least one month before Viral Hepatitis Testing Day on May 19, 2012. The inventory will include resources targeted to both providers and consumers.

Steven Young, MSPH

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Health Resources and Services Administration

Rene Sterling, PhD, MHA

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Health Resources and Services Administration

Faye Malitz, MS

Director, Division of Science and Policy/HAB
Health Resources and Services Administration

Mr. Young, Ms. Malitz and Dr. Sterling presented an update on HRSA’s ongoing activities in the NHAS implementation plan. As the HAB Associate Administrator, Dr. Deborah Parham Hopson leads a HRSA-wide workgroup for NHAS with all 6 bureaus and many offices. All of HRSA’s proposed activities are aligned with the goals, objectives and actions outlined in the federal NHAS implementation plan and the overall HHS plan to provide a seamless and coordinated approach. The HRSA workgroup holds monthly meetings to determine progress and has initiated discussions on potential new supportive activities in FY2012.

HRSA completed all of its proposed activities outlined in its 2010 NHAS work plan. As of mid-September 2011, HRSA completed or initiated nearly all 50 of its NHAS program activities across 21 objectives and action steps. HRSA's major NHAS achievements in 2010 and 2011 included new collaborations; web-based training for staff, clinicians and grantees; data sharing and TA; and participation in stakeholder meetings. HRSA accomplished its activities despite the inflexibility embedded in existing authorizations and legislative language related to program operations and priorities.

HRSA's policy activities in support of NHAS are highlighted as follows. Language was added to all FOAs stating that program activities should strive to support the three primary NHAS goals and grantees should comply with federally-approved guidelines for HIV prevention and treatment. HRSA supported CMS's release of the State Medicaid Director Waiver Toolkit by providing draft language for the cover letter to Medicaid directors and participating in planning meetings for follow-up training and targeted TA to states and key stakeholders.

The Bureau of Primary Healthcare (BPHC) focused on sustainable integration of HIV into its QI strategy and across the Health Center Program. For the QI goal of developing and enhancing access to care, BPHC strengthened accessibility and availability of services needed by PLWH. For the QI goal of transforming Health Center service delivery, BPHC coordinated and integrated health and support service needs of PLWH (e.g., behavioral health, social services and medication management).

For the QI goal of recruiting, developing and retaining a skilled workforce, BPHC enhanced the ability of primary care providers (PCPs) to manage HIV and recruit specialty providers as appropriate. For the QI goal of coordinating and aligning policies and programs, BPHC will consider the adoption of consensus-driven and established HIV performance measures.

BPHC released two Program Assistance Letters (PALs) to grantees. The 2010-2013 PAL focuses on HIV testing in healthcare settings by reviewing the CDC guidelines and highlighting available resources. The 2011-2016 PAL focuses on HIV care and treatment in CHCs by encouraging integration of HIV into primary care, reviewing guidelines and protocols, and highlighting available resources.

BPHC proposed a number of activities for Primary Care Associations to be involved in the NHAS implementation plan. These groups can receive national CoAgs funds to:

- increase attention to issues impacting the accessibility and quality of services for PLWHA;
- collaborate to increase the visibility and accessibility of opportunities and resources available to CHCs;
- provide training to increase the cultural competency of providers;
- convene CHCs and other providers that serve areas highly impacted by HIV to discuss and implement strategies to increase collaboration and coordination of services for PLWHA;
- participate in local and state planning activities; and

- conduct other activities responsive to the federal NHAS implementation plan.

HAB developed key messages and monitored HAB Project Officers on incorporating NHAS goals into comprehensive planning, work plans and budgets of Ryan White programs. HAB continued to collaborate with Ryan White grantees to focus on MAI planning and service delivery by utilizing strategies that reduce disparities in access and health outcomes. HAB used performance measures, clinical quality measures and documented health outcomes data to assess results and ensure continuous improvement.

HAB is collaborating with CDC to update the PWP guidelines and continued to comply with its statutory requirement to include PLWHA on planning bodies. HAB continued to provide TA to support the training of consumers. Other HRSA advisory committees that could add PLWHA to their memberships are being explored as well. The Bureau of Health Professions (BHP) issued guidance to encourage medical, dental, pharmacy, physician assistant, nurse practitioner, social work and nursing schools to implement curricula that include HIV-specific training.

HRSA's research, dissemination and translation activities in support of NHAS are highlighted as follows. HAB disseminated and translated a SPNS initiative on the integration of buprenorphine for substance abuse treatment in HIV clinical settings. HAB developed a guide on linkages to care based on results and best practices from the "SPNS Engagement and Retention Initiative" and the "CDC Antiretroviral Treatment Access Study." HAB released a new contract to translate SPNS study findings to TA for the Ryan White community.

HAB funded a 2-year HIV Clinician Workforce Study with two major outcomes: (1) estimate the number of PCPs who currently provide medical care to PLWHA in the United States and (2) project the shortage or surplus of the HIV-related primary care workforce into 2015 and beyond. HAB published the *Guide for HIV/AIDS Clinical Care* to describe best practices for clinical management of PLWHA. The topics in the guide address medical care, late diagnosis, and psychological, behavioral and social issues.

HAB was awarded MAI dollars to fund the "Retention and Reengagement Project" to support the integration of HIV primary care, mental health, substance abuse and housing services in Miami, New York and San Juan (Puerto Rico). HAB funded 7 states to conduct the SPNS initiative, "Systems Linkages and Access to Care for Populations at High Risk for HIV Infection."

HAB funded a new pilot project, "Ask, Screen, Intervene," to integrate HIV prevention interventions for positives into Ryan White clinics with a goal of averting new infections. The pilot sites include Baltimore, Chicago, Los Angeles and Miami. Ryan White Part C clinics, AETCs and CDC Prevention Training Centers will be involved with the pilot. HAB funded a study on interdisciplinary care models that could help with shifting tasks and further supporting the HIV workforce.

HRSA's training and TA activities in support of NHAS are highlighted as follows. HAB continued its ongoing involvement in the Federal Training Center Collaborative that was established with 6 National Training Programs to achieve two major outcomes: (1) address the delivery of STD,

HIV, family planning, reproductive health and substance abuse services and (2) train clinicians to provide optimal prevention, care and treatment services.

HAB funded a new pilot project, “Expanding HIV Training into Graduate Medical Education,” to increase the HIV provider workforce. A total of \$450,000 was awarded to 3 grantees to increase access to and improve quality of care and expand existing primary care residency programs to include a focus on HIV.

HAB funded a new demonstration project, “AETC Tele-health Training Centers,” with a total of \$600,000 awarded to 3 grantees. The project targets utilization of tele-health technology in rural Washington State, Idaho, California and West Virginia. The project is designed to achieve three key outcomes: (1) expand access and improve outcomes for hard-to-reach HIV clients receiving care in underserved communities; (2) build capacity of HIV providers and multidisciplinary teams; and (3) provide clinical consultation, training and education.

HAB funded a new CoAg, “AETC National Center for HIV Care in Minority Communities,” to build capacity. HealthHIV was initially awarded \$3 million in the first year of a 3-year project period and will subcontract with the Primary Care Development Corporation and National Association of Community Health Centers in this effort. The initiative is designed to achieve two key outcomes: (1) expand HIV/AIDS care and treatment within highly-impacted communities of color and (2) offer longitudinal capacity building services to Federally Qualified Health Centers (FQHCs) that are not funded by Ryan White using the patient-centered medical home (PCMH) model.

In year 1 of the CoAg, intensive training and TA were provided in five key areas: financial management, clinical management, support services, information technology and infrastructure. The first cohort included 24 CHCs across the United States. Applications for the second cohort for 30 additional CHCs are now available at nchcmc@healthhiv.org.

HAB supported the AETC National Multicultural Center with funding of \$550,000 each year over the 3-year project period to achieve two key outcomes: (1) increase cross-cultural awareness and competence in HIV care and (2) provide training, capacity building and TA to support clinical providers in the field. HAB developed performance measures and launched the “National Retention in+Care Campaign” to increase access to care and reduce disparities.

BPHC hosted the “All-Grantee TA Call” with four CHCs for the health center community to support NHAS by improving HIV/AIDS care. BPHC hosted the “Grantee Enrichment Call” with the Fenway Institute to address public health concerns of the lesbian/gay/bisexual/transgender (LGBT) population. Transcripts, audio archives and other materials from the call are available at <http://bphc.hrsa.gov>.

BPHC added HIV/AIDS resources to its TA website to increase visibility of this issue. BPHC provided its Project Officers with the necessary skills, tools and resources needed to support grantees. These resources included HIV clinical guidelines and protocols as well as activities to enhance performance, improve quality and build capacity.

BPHC Project Officers engaged grantees in meaningful dialogue about HIV service delivery. The topics of these discussions included guidelines and protocols, referral networks in local communities, plans for service delivery expansion, challenges and TA needs, and performance improvement activities.

HRSA provided instructions and information to staff and grantees on the NHAS implementation plan. These topics included:

- an overview of the 12 Cities Project and the “Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS” (ECHPP) Program;
- an overview of NHAS and HIV service delivery targeted to National Health Service Corps (NHSC) clinicians and scholars;
- an overview of NHAS and an HIV resources webcast;
- an overview of the Health Center Planning Grant Program targeted to Ryan White grantees; and
- SHARED II cross-program discussions on critical HIV care and treatment issues within states.

Christine Cagle, PhD

Associate Director, Office of Policy, Planning and Communication/NCHHSTP/DHAP
Centers for Disease Control and Prevention

Dr. Cagle presented an update on CDC’s ongoing activities in the NHAS implementation plan. DHAP’s 2011-2015 Strategic Plan was developed with goals and objectives (e.g., incidence, prevention and care, health equity and organizational excellence) that are closely aligned with NHAS. The DHAP Strategic Plan is available at www.cdc.gov/hiv.

CDC made efforts in several areas to achieve the NHAS vision. Funding and TA were provided to state, local and community HIV prevention programs. HIV surveillance and program monitoring were used to track the epidemic and determine the success of service provision. New behavioral, biomedical and structural HIV prevention interventions were identified and operational implementation was improved.

National media campaigns were launched with targeted messages to educate the American population about the epidemic in general, specific risk groups, and the importance of persons being tested and knowing their status. HIV epidemic and economic modeling was performed to improve decision-making and effectiveness.

CDC conducted several activities to reduce HIV incidence. New FOAs were released for health departments to conduct core prevention activities with demonstrated potential to reduce new HIV infections. Demonstration projects for combination prevention strategies were performed by the Enhanced Comprehensive HIV Prevention Planning (ECHPP) grantees. DHAP will soon post the implementation plans of these grantees on its website. CDC awarded the \$14 million

MSM Testing Initiative for grantees to test and diagnose 3,000 MSM with a focus on African Americans and Latinos and link at least 85% of the HIV-infected cohort to care.

CDC awarded supplemental funds to grantees to collect CD4 and viral load data and improve the capacity of health departments to use geospatial data to monitor and respond to the epidemic at the local level. CDC is continuing to explore the most effective combination of biomedical and behavioral interventions. Research is underway to determine the cost per infection averted, new diagnoses and linkages to care.

CDC conducted several activities to increase access to care. The new health department FOA will be awarded in January 2012 and will prioritize linkages to care. The ECHPP grantees collaborated with federal agencies to facilitate linkages to care.

CDC supported demonstration projects to develop, monitor and evaluate models for using CD4, viral load and other data. The goal of this initiative was to improve the health of PLWH through linkages to and retention in care as well as adherence to appropriate and timely medical care. CDC's Expanded Testing Initiative supported the development of protocols for linking newly diagnosed persons and those reentering care to medical services.

CDC conducted several activities to reduce HIV-related disparities. The new health department FOA, CBO funding, and ECHPP resources were used to emphasize tailored prevention efforts for the epidemic at the local level. Populations disproportionately affected by HIV were targeted. CDC awarded an FOA to increase the number of YMSM and transgender persons of color who are aware of their HIV status and linked to care and prevention services. CDC will allocate \$11 million annually for grantees to reach the target of 3,500 MSM.

CDC published a serosorting statement and updated HIV incidence estimates highlighting the effect of HIV on gay/bisexual men. CDC continued its support of the "Act Against AIDS" social marketing campaigns and expanded the Act Against AIDS Leadership Initiative (AAALI) to include three Latino partner organizations and two SM organizations.

CDC is continuing its efforts to improve coordination with federal partners. CDC serves on federal work groups that were established to implement and monitor NHAS. It collaborates with the Office of the HHS Secretary and other HHS agencies to implement and monitor ECHPP activities; participates on NIH committees and partners with NIH to conduct research, formulate new recommendations and revise existing guidance; collaborates with HRSA on numerous activities (e.g., developing guidance on collecting CD4 and viral load data); and partners with SAMHSA on activities related to service integration and HIV prevention in IDUs.

CDC has planned a number of activities in FY 2012 to further support the NHAS implementation plan. The new health department CoAg will be awarded in January 2012. Recommendations and guidelines will be released for several important areas (e.g., testing in non-clinical settings, PWP, prevention planning, and supplemental testing). The "Testing in Non-Clinical Settings Guidelines" will focus on targeted testing, recruitment and linkage to care and will be published in mid-2012. The "Supplemental Testing Guidelines" will be published in early 2012 with a

focus on new diagnostic algorithms, detection of acute HIV infection, and alternative screening tests to the Western blot.

CDC will revise its HIV testing recommendations for MSM based on National HIV Behavioral Surveillance (NHBS) data that were published in the *MMWR* in June 2011. The current guidance recommends HIV testing at least annually for persons with ongoing risks for exposure to HIV infection, but recent data suggest more frequent testing for MSM. Most notably, 2008 NHBS data reported that sexually active MSM might benefit from more frequent HIV testing. MSM accounted for 64% of all new HIV infections, including 3% among MSM-IDU. Of sexually active MSM, 19% were infected with HIV, but 44% were unaware of their infection. Among MSM with undiagnosed HIV infection, 45% had been tested within the previous 12 months and 29% had been tested within the previous 6 months. The prevalence of undiagnosed HIV was similar among MSM who did and did not report high-risk behaviors (e.g., 7% versus 8%). Moreover, CDC's December 2010 STD Treatment Guidelines recommended STD screening for MSM every 3-6 months.

CDC's Expanded Testing Initiative resulted in 2.8 million tests being performed in the first 3 years of the activity. Of 18,000 persons who were newly diagnosed with HIV, 70% were African American and 12% were Latino. A recently published study showed that large-scale HIV testing programs are effective and cost-saving for the healthcare system. The Expanded Testing Initiative achieved a newly-diagnosed infection rate of 0.7%, averted an estimated 3,381 HIV infections, and yielded a return of \$1.97 for every dollar invested.

CDC's new testing activities include the MSM Testing Initiative, "Take Charge. Take the Test Campaign;" "Testing Makes Us Stronger Campaign" targeted to young black MSM (YBMSM) beginning on November 29, 2011; a study of a rapid testing algorithm; and HIV testing in pharmacy clinics.

CDC is developing a National HIV Prevention Progress Report that will include a dashboard for monitoring progress starting with national reporting and followed by jurisdiction-level reporting. The progress report will examine the alignment between NHAS and 15 indicators outlined in the DHAP Strategic Plan (e.g., HIV incidence and transmission rates, undiagnosed HIV infections, linkages to care, and viral loads). CDC also may describe select contextual factors in the progress report.

Budget constraints (e.g., potential cuts to the CDC budget and continued problems with state funding) are CDC's major barrier to implementing NHAS. The ability to facilitate cross-agency/cross-department collaboration continues to present a key challenge as well.

In response to CHAC's specific questions, the panel of speakers provided additional details on ongoing and planned activities by HHS, HRSA and CDC to support the NHAS implementation plan. The discussion topics included:

- allocation of the NHAS Implementation Fund (or the "1% tap") if the Administration approves these resources;

- the design and methodology that were utilized in the recent study of the Expanded Testing Initiative;
- necessary training and resources public health laboratories will need to implement alternative screening tests to the Western blot and CDC's timeline to roll-out these algorithms;
- continued challenges with cross-department/cross-agency collaboration in the NHAS implementation plan; and
- the critical need to focus on the small percentage of HIV-infected persons who are not in care, are hard to reach due to ancillary issues (e.g., homelessness and substance abuse), and have a profound impact on control of the epidemic.

Dr. Fenton confirmed that he would welcome the opportunity to have offline discussions with Mr. Ernest Hopkins to address his concerns in more detail. During the previous and current CHAC meetings, Mr. Hopkins noted that although CDC expanded AAALI to include two MSM organizations, these groups were not given appropriate training and collaborative opportunities to increase their competency in understanding and interpreting data.

Dr. Fenton emphasized that CDC is interested in making mid-course corrections to ensure messages are appropriately framed, accurate materials are broadly disseminated to AAALI partners at the local level, and data accurately reflect the realities of the epidemic. He made a commitment for CDC and Mr. Hopkins to jointly develop strategies to resolve these issues. Mr. Brooks added that PACHA would welcome the opportunity to be involved in these discussions.

CHAC commended the federal agencies on their extraordinary efforts to advance NHAS. CDC and HRSA were particularly congratulated on their strong collaborative efforts in the NHAS implementation plan, especially in the areas of HIV testing and linkage to care to improve efficiencies in addressing the epidemic.

Because President Obama issued a memorandum that clearly instructed federal departments and agencies to collaborate in the NHAS implementation plan, some CHAC members were surprised CDC reported ongoing challenges in this area. The members proposed two potential suggestions to address this issue.

CHAC and PACHA could issue a formal resolution to HHS to ask the President to reissue a clearer memorandum with a stronger directive for interagency collaboration. CHAC and PACHA could develop a joint position statement with recommendations for the federal departments and agencies to closely collaborate and coordinate efforts in the NHAS implementation plan.

Drs. Fenton and Cheever confirmed that HHS/OASH has provided outstanding leadership in assuring cross-department/cross-agency collaboration and coordination with respect to the NHAS implementation plan. At the interagency level, CDC and HRSA have strengthened their collaborative efforts to be more creative, far-reaching and productive than in the past due to NHAS and the strong commitments of both agencies in achieving a true partnership. At the agency level, HAB has made tremendous progress in leveraging the vast amount of resources

in BPHC and all other parts of HRSA in a meaningful and unique manner to support the NHAS implementation plan.

Dr. Valdiserri agreed with his colleagues that collaboration and coordination within and across federal departments and agencies have greatly increased to support the NHAS implementation plan. Although he also agreed with CHAC's comments on the need for continued improvement in this area, he noted that the federal partners must begin to shift their focus from interagency collaboration to broader and more complex issues of the epidemic. Most notably, the March 2011 Institute of Medicine (IOM) study reported that insufficient capacity and resources exist at provider and systems levels in both the public and private sectors to test all persons for HIV and enroll and retain HIV-positive persons into care and treatment.

During a future meeting, the CHAC members asked the agencies to present the components of their NHAS implementation plans that specifically address HIV-related stigma. Because the CHAC/PACHA HIV Disclosure Workgroup will extensively focus on stigma in its deliberations, this group should be included in the panel presentation.

Overview of the HIV Prevention Trials Network (HPTN) 052 Study

Carl Dieffenbach, PhD

Director, Division of AIDS

National Institute of Allergy and Infectious Disease, National Institutes of Health

Dr. Dieffenbach presented an overview of key findings from the NIH-funded HPTN 052 Study. The 2008 Cohen, *et al.* study described opportunities for preventing HIV infection. Behavioral and structural interventions (e.g., male circumcision and condoms) are targeted to unexposed persons. Vaccines, topical microbicides and PrEP are targeted to exposed persons before and during sexual activity. Vaccines and post-exposure prophylaxis (PEP) are targeted to exposed persons after sexual activity. HIV treatment is targeted to infected persons to reduce infectivity.

The June 10, 2009 edition of the *Journal of the American Medical Association* published the Dieffenbach and Fauci study on universal voluntary testing and treatment for prevention of HIV transmission. The study highlighted major research issues that would require attention in implementing a voluntary "test and treat" or "treatment as prevention" approach.

These research issues include universal testing, relationship of the stage of HIV infection to efficiency of transmission, efficacy of antiretroviral treatment (ART) in preventing HIV transmission, drug resistance, behavioral distribution, benefit to the individual, and societal cost-effectiveness.

In terms of the efficacy of ART in preventing HIV transmission, NIH funded the international HPTN 052 Study, "Treating HIV-Infected People with Antiretrovirals Significantly Reduces Transmission to Heterosexual Partners." The study was designed to achieve three key goals

and objectives: (1) determine whether ARV use by HIV-infected persons could prevent transmission of the virus to their sexual partners; (2) determine the optimal time of initiation of therapy; and (3) evaluate the optimal time for HIV-infected persons to begin taking ART in order to reduce HIV-related illness and death.

The eligibility criteria were HIV-positive persons with CD4 counts of 350-550 cells/ μ L. The cohort included 1,763 serodiscordant couples with a median CD4 count of 436 cells/ μ L at enrollment. Despite strong efforts to enroll MSM, heterosexuals accounted for 97% of the study population. Of HIV-infected partners, 890 were men and 873 were women. The cohort was randomized to immediate ART (e.g., persons with CD4 counts of 350-550 cells/ μ L) or delayed ART (e.g., persons with CD4 counts \leq 250 cells/ μ L or an AIDS-defining condition).

The HPTN 052 Study was conducted in 13 sites in Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, Zimbabwe and the United States. All participants in both arms of the study received counseling on safer sex practices, free condoms, STD treatment, frequent HIV testing, and evaluation and treatment for any complications related to HIV infection. The study was piloted in 2005 and fully implemented in 2007. The study was expected to be completed in 2015, but prematurely ended.

Dr. Dieffenbach summarized the key findings of the HPTN 052 Study that NIH published in May 2011. In terms of prevention, the cohort had 39 total infections. Viral genetics determined that 28 of the infections were linked (27 in the delayed arm and 1 in the immediate arm). Of the 27 infections in the delayed arm, 17 occurred when the CD4 count of the index partner was $>$ 350 cells/ μ L. Of all 28 linked infections, 10 were man-to-woman and 18 were woman-to-man. Of the 7 unlinked infections, 4 were in the delayed arm and 3 were in the immediate arm. Analysis of the remaining 4 infections in the delayed arm found 1 additional linked infection and 3 additional unlinked infections.

Overall, the treatment protocol was quite successful in stopping linked transmission. The rate of preventing transmission was extraordinarily high at 96%. The investigators published two major studies on the sequencing and statistical methodology that was used to determine linkage in the study.

In terms of clinical issues, the 10 deaths in the immediate arm and the 13 deaths in the delayed arm were not statistically significant in terms of treatment. The causes of death included automobile accidents and gunshot fatalities. With the exception of extrapulmonary TB, no significant differences were observed in overall morbidity. Of 20 extrapulmonary TB cases, 17 were in the delayed arm and 3 were in the immediate arm.

Overall, the study showed that immediate ART for HIV-positive persons with CD4 counts of 350-550 cells/ μ L reduced transmission to their uninfected partners by 96% compared to delayed ART for HIV-positive persons with CD4 counts of \leq 250 cells/ μ L. The difference between the two arms accounted for a 27-fold decrease. Immediate ART conferred a clinical benefit to infected partners in the context of extrapulmonary TB.

The next steps in the study are to offer ART to all patients in the delayed arm. The study will be continued for at least one year to analyze the following issues: continued durability of the benefits of prevention to patients in the immediate arm; differences in the benefits of prevention among patients in the delayed arm; and long-term clinical benefits and safety to patients in both arms. In its May 2011 publication, NIH emphasized that the HPTN 052 Study achieved complete and sustained virologic suppression in the immediate treatment arm.

Dr. Dieffenbach provided details on the research issue of benefits to the individual in a voluntary “test and treat” approach. In its June 2009 publication, NIH reported that starting ART earlier would yield better clinical outcomes. An interim review led to the early end of a clinical trial in Haiti. The study reported a 4-fold increased risk of death among 816 patients who deferred ART until CD4 counts dropped below 200 cells/ μ L versus those who initiated ART with CD4 counts of 200-350 cells/ μ L.

NIH is funding the Strategic Timing of Antiretroviral Treatment (START) randomized clinical trial for HIV-infected persons who are ART-naïve and have CD4 counts >500 cells/ μ L. The cohort was randomized to the early ART group (e.g., immediate initiation of ART following randomization) or the deferred ART group (e.g., deferral of ART until the CD4 count dropped to <350 cells/ mm^3 or AIDS developed). The ultimate goal of the START trial is to demonstrate whether starting ART with CD4 counts >500 cells/ μ L is or is not effective.

NIH recognizes that the HPTN 052 Study was successful in patients completing treatment and sustaining virologic suppression due to the controlled environment of a clinical trial. However, the major challenge is applying this success to actual practice in the field in the United States. Most notably, only 21 of 100 HIV-positive persons have their viral loads suppressed. This outcome will not impact HIV transmission on a broad population basis.

NIH and CDC are jointly conducting the HPTN 065 Study in 6 U.S. cities to focus on HIV testing, linkage to care, initiation and continuation of ART in accordance with current guidelines, and viral suppression. The study protocols were designed to address fairly sophisticated issues. For expanded HIV testing, social mobilization will be utilized and universal testing will be offered in emergency departments and to patients upon hospital admission.

For linkage to care, HIV test sites will be randomized to either financial incentives or standard of care (SOC). For PWP, HIV-positive patients will be randomized to care plus SOC or SOC alone. For viral suppression, HIV care sites will be randomized to either financial incentives or SOC. Provider and patient surveys will be administered to obtain knowledge and attitudes regarding ART and financial incentives.

The unique features of the HPTN 065 Study include a strategic and innovative partnership among NIH, CDC, health departments and community providers; engagement of sites outside of the NIH Research Network; use of routinely collected surveillance data; and a combination of methodologies (e.g., community comparisons, site randomization and individual randomization).

The multi-component intervention study includes a biomedical component with testing and ART, a behavioral component with PWP, and a structural component with financial incentives. Enrollment of patients was initiated in March 2011. NIH expects to release results of the study in the first quarter of 2014.

Overall, the NIH-sponsored HPTN clinical trials demonstrate that HIV testing is the entry point for all HIV prevention strategies. ART is the cornerstone of all combination strategies. Approaches to optimize HIV testing and linkage to and retention in care with full virologic suppression of HIV are the bases to judge the success or failure of the “treatment as prevention” concept.

Social science research should be conducted to establish strategies and promote messages where knowledge of HIV status is socially desirable and treatment for HIV infection is socially responsible. Improvements in HIV therapy must continue to be made to enhance safety, tolerability, durability and ease of use.

Therapeutic vaccines that improve the durability of treatment and/or reduce the need for ART could prove to be beneficial. All of the HPTN outcomes are aligned with the 3 NHAS goals to reduce HIV incidence; increase access to care and optimize health outcomes, and reduce HIV-related health disparities.

In response to CHAC’s specific questions, Dr. Dieffenbach provided additional details on the NIH-sponsored HPTN clinical trials for HIV prevention, care and treatment. The discussion topics included:

- the possibility of designing a clinical trial to evaluate the test and treat approach with PrEP or a combination of modalities to identify additive versus synergistic interventions;
- the rationale for including financial incentives as an intervention in the HPTN 065 Study;
- the potential impact of the HPTN 052 Study results (e.g., clinical and transmission benefits for HIV-positive patients with CD4 counts up to 500 cells/ μ L) on the current design of the START clinical trial (e.g., randomization for HIV-positive patients to not receive ART until CD4 counts reach ≥ 350 cells/ μ L);
- potential harm to persons starting ART immediately following their HIV diagnosis (e.g., drug resistance);
- the trend of “efficacy dilution” when applying clinical trial results to actual practice in the field;
- an assessment of STDs, other co-morbidities or behavioral/social factors (e.g., stress, unemployment or homelessness) that potentially amplified viral loads and genital secretions in the HPTN 052 Study cohort;
- translation of the HPTN 052 Study results into “real-world” messages for the general public to (1) empower PLWH to be responsible in taking their medications without shame and (2) change the social acceptability of HIV treatment for both PLWH and the broader society; and

- the need to identify specific behavioral factors that motivated the serodiscordant couples in the HPTN 052 Study to complete treatment and remain in care and broadly disseminate this information to communities.

CHAC commended NIH and its federal partners on their leadership in making advances in combining biomedical, social and structural interventions for HIV prevention and treatment. The members urged NIH to continue conducting and funding HIV prevention and treatment clinical trials.

CHAC noted that scientific data from these studies provide a strong basis to minimize public fear and mistrust regarding HIV treatment, particularly in African American and Latino communities. Clinical trial data also play a significant role in increasing adherence to treatment among PLWH.

Update on ACA Implementation: HRSA Perspective

Rebecca Slifkin, PhD, MHA

Director, Office of Planning, Analysis and Evaluation
Health Resources and Services Administration

Dr. Slifkin presented an update on HRSA's agency-wide perspective of ACA implementation. ACA mandates qualifying health coverage for U.S. citizens and legal residents, but some exceptions apply. Arguments will be presented to the Supreme Court in March 2012 to determine whether the federal government has legal authority to mandate all U.S. citizens to purchase health insurance.

ACA includes Medicaid expansions and creates affordable Health Insurance Exchanges. Estimates show that 40 million persons will gain health insurance coverage by 2014. Coverage also includes >1 million young adults at this time who are allowed to remain on their parents' health insurance until 26 years of age.

Childless adults with incomes at or below 138% of the FPL will be eligible for Medicaid. Many persons who will be newly eligible for Medicaid may be covered through Medicaid managed care plans. Medicaid managed care plans and commercial plans may contract with different providers. The extent to which Exchanges and Medicaid will be aligned will be critical to the continuity, quality and coordination of care that beneficiaries receive. Issues regarding the adequacy of networks and retention of essential community providers also must be addressed.

Persons with incomes above Medicaid and Children's Health Insurance Program (CHIP) thresholds will be allowed to purchase insurance through federal or state Exchanges. Persons with incomes at or below 400% of the FPL will have advance premium tax credits to make Exchange coverage more affordable. HRSA currently is tracking draft rules on the adequacy of networks in accordance with standards established by the HHS Secretary and the inclusion of essential community providers to ensure low-income and vulnerable populations have access.

Insurance companies will not be able to consider preexisting conditions when providing coverage to individuals. ACA helps to make prevention affordable and accessible by requiring new health plans to cover and eliminate cost sharing for preventive services recommended by USPSTF, ACIP, and the Academy of Pediatrics “Bright Futures Guidelines.” ACA also requires insurance companies to cover additional preventive health benefits for women pursuant to HRSA recommendations.

HRSA accepted all of the recommendations for additional preventive health benefits for women in the IOM study that was commissioned by the HHS Office of the Assistant Secretary for Planning and Evaluation. HHS adopted new recommendations for women’s preventive services to fill gaps in current preventive services guidelines (e.g., initiation of HPV testing for women 30 years of age or every 3 years for younger women who are sexually active, annual STD counseling, and annual HIV counseling and screening). However, these testing guidelines can be implemented at the discretion of women and their providers.

ACA has created new opportunities for HRSA to fund health professions training efforts. HHS allocated >\$455 million to support training of new PCPs by 2015. In the Primary Care Residency Expansion Program, 82 programs across the country currently receive funding to train >500 new PCPs. In the Advanced Nursing Education Expansion Program, 26 schools of nursing currently receive funding to train nearly 600 new primary care nurse practitioners and nurse midwives. In the Expansion of Physician Assistants Training Programs, 28 programs currently receive funding to train nearly 600 new physician assistants.

In the Teaching Health Center Graduate Medical Education Program, 11 teaching Health Centers currently receive funding to support community-based training of PCP residents. In the Expanding Residency Slots for Primary Care Program, ACA redistributed and directed unused residency positions for the training of PCPs. Several factors are utilized to prioritize the unused residency positions (e.g., hospitals with a rural training track or hospitals located in a primary care health professional shortage area).

ACA and American Recovery and Reinvestment Act funding transformed the NHSC. The NHSC has helped underserved areas gain access to healthcare services since 1972. NHSC’s presence and strength in the field tremendously grew from 3,601 providers in FY2008 to 10,279 providers in FY2011. In addition to NHSC, two other mechanisms also have increased the distribution of PCPs in the field. ACA allows IHS facilities that only serve tribal members to qualify as NHSC sites. Under the White House Rural Initiative, President Obama announced a pilot project that will include critical access hospitals as eligible NHSC sites.

ACA includes extensive language and provisions to build safety net capacity through Health Centers. Over the past 40 years, Health Centers have delivered comprehensive and high-quality primary health care to patients regardless of their ability to pay for services. Health Centers function as the essential PCP for America’s most vulnerable populations. At this time, >1,100 Health Centers operate 8,100 service delivery sites that provide care to >19 million

patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands and Pacific Basin.

ACA established the Health Center fund that will provide \$11 billion over a 5-year period for the operation, expansion and construction of facilities. The \$11 billion appropriation will target two major areas: (1) \$9.5 billion to support ongoing operations, create new sites in medically underserved areas, and expand preventive and primary healthcare services and (2) \$1.5 billion to support major construction and renovation projects at Health Centers nationwide.

In FY2011, the HRSA Health Center Program announced and awarded >\$1.7 billion in ACA grants (e.g., \$732 million for 144 Health Center Capital Development awards; \$900 million to ongoing Health Center operations; \$30 million to the establishment of 67 new Health Center sites and 129 Health Center planning grants; and \$40 million to the support of QI activities in >900 Health Centers nationwide).

HRSA is aware that research indicates health insurance does not guarantee a usual source of primary care. After Massachusetts passed its health insurance reform legislation, Health Centers in the state reported a 36% increase in patients despite the 22% decrease in the overall percentage of uninsured patients.

The Massachusetts model shows that even with ACA implementation in 2014, uninsured persons will continue to need Health Centers as their source of affordable preventive and primary care. Health insurance reform at the federal level most likely will not cover many services that Health Centers provide to improve the accessibility and quality of care to low-income and vulnerable patients.

HRSA is revisiting its current programs to ensure that new models of care delivery are being supported and providers are being more efficiently used. To support this effort, HRSA will make changes in two of its existing programs in FY2012. In the Advanced Nursing Education Program, applications will be solicited to develop enhanced training in healthcare technology and inter-professional team-based approaches.

Cross-fertilization will be strongly encouraged among professionals to improve the quality of care and increase collaborative relationships in the practice environment. Skills and resources will be provided to prepare nurses to provide health care in a technologically advanced inter-professional environment.

In the Nurse Education Practice, Quality and Retention Program, applications will be solicited that focus on the development of inter-professional practice initiatives. Successful applicants will be required to create clinical practice environments comprised of nursing and at least one other discipline to (1) foster increased communication and shared decision-making among disciplines; (2) promote increased mutual respect and dialogue among diverse healthcare professionals; and (3) create more efficient and integrated practices that lead to high-quality patient-centered outcomes.

In addition to changes to its existing programs, HRSA also will create new programs under ACA to further support new care delivery models. Nurse Managed Health Clinic grants will be awarded to 10 nurse-managed clinics to develop and operate practice arrangements managed by advanced practice nurses who provide primary care and wellness services to underserved and vulnerable populations. The program will complement and extend nurse-managed clinic programs that currently are authorized under the Title VIII Nurse Education, Practice, Quality and Retention Program. HRSA will fund the program for 3 years.

The Personal and Home Care Aide State Training Program will award grants to 6 states to develop, implement and evaluate core competency-based curriculum and certification programs to train and certify qualified personal and home care aides. The grantees will be required to provide a minimum of 75 hours of training. HRSA will fund the program for 3 years.

Under ACA, HRSA will conduct a number of activities through its Patient Centered Medical/Health Home (PCMHH) initiative to encourage and support Health Centers to transform their practices. Health Centers that participate in the PCMHH recognition process will be required to improve the quality of care and outcomes for their patient populations, increase access, and provide care in a cost-effective manner.

BPHC will have primary oversight of the recognition process by covering fees and providing TA resources for practice transformation. HRSA will strongly encourage all Health Centers to participate and take advantage of the opportunity to be formally recognized as a PCMHH under ACA. More information on HRSA's PCMHH initiative is available at www.bphc.hrsa.gov.

The CMS Center for Medicare and Medicaid Innovation (CMMI) will fund 500 Health Centers to serve as PCMHHs. ACA established CMMI with 5-year funding of \$10 billion to help transform Medicare, Medicaid and CHIP through improvements in the healthcare system. CMMI is mandated to fund innovative demonstration projects to ensure better health and health care, improve quality and outcomes, reduce costs for beneficiaries, and ultimately enhance the healthcare system for all Americans.

ACA provided sufficient flexibility and resources to CMMI to rapidly test innovative care and payment models and encourage widespread adoption of practices that deliver better healthcare services at a lower cost. Detailed descriptions of existing CMMI initiatives and new FOAs are available at <http://innovations.cms.gov>.

Laura Cheever, MD

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

Dr. Cheever presented an update on HAB's perspective of ACA implementation in the context of the Ryan White HIV/AIDS Program. In 2011, HAB continued its focus on two ACA provisions that impacted the Ryan White Program. After Preexisting Condition Insurance Plans (PCIPs) became available on July 1, 2010, HAB distributed an informative letter to its grantees in

December 2010 and sponsored a teleconference with advocates and the community at that time. HAB clarified that Ryan White funds could be used to purchase insurance through PCIPs if this approach was cost-effective.

For the second ACA provision, HAB informed grantees that ADAP would count toward “true out-of-pocket expenses” for Medicare. States currently are calculating cost-savings as a result of the ACA provision. In the past, ADAP covered eligible patients that fell into the Medicare Part D “donut hole” and Part D would then assume costs.

HAB is positioning Ryan White grantees to anticipate changes in the healthcare environment when ACA is fully implemented in 2014. Most notably, Ryan White delivery systems will be maintained and enhanced to function as medical homes and continue to provide a high level of care to patients. HAB released a CoAg in 2011 to build capacity for Ryan White grantees to qualify as medical homes. Ryan White grantees are partnering with existing Health Centers or are taking steps to become new Health Centers themselves. BPHC awarded planning grants to 6 HIV-based organizations to become Health Centers in 2011.

Several activities are underway both within and outside of HAB to improve HIV care capacity in primary care. AETCs were funded to build capacity in minority communities. BPHC issued 2 PALs to Health Centers to reinforce the need to follow federal guidelines on HIV testing and care/ treatment. BPHC awarded CoAg funds to the Fenway Institute to increase LGBT cultural competence in Health Centers. BPHC partnered with SAMHSA to increase behavioral health capacity within Health Centers. All parts of HRSA are making efforts to build the primary care workforce.

To better understand the impact of ACA implementation, HRSA closely collaborated with CMS to examine the rollout of state plans. HRSA supported CMS’s release of its “State Medicaid Director Waiver Toolkit” by providing training and TA. HRSA thoroughly reviewed expanded insurance laws in Massachusetts and other states to increase knowledge of the impact of ACA implementation at the federal level on the Ryan White Program. HRSA funded 2 studies in FY2011 to assess and attempt to fill anticipated gaps in care in the Ryan White Program after ACA is fully implemented in 2014.

Overall, the Ryan White Program is designed to fill gaps that were identified through local needs assessments. After ACA is fully implemented in 2014, the Ryan White Program will continue to fill important gaps in state Medicaid programs (e.g., limitations by some Medicaid programs on the number of prescriptions allowed per month; limited coverage of oral health and substance abuse treatment services; support services to link clients to care; and training of providers through AETCs).

In response to CHAC’s specific questions, Drs. Slifkin and Cheever provided additional details on HRSA’s ongoing and future activities as part of ACA implementation. The discussion topics included:

- the ability of state and local Ryan White grantees to maintain flexibility in their funding allocations under ACA;
- the critical role of the Ryan White Program in serving as an essential component of the care system and creating unique programs in many settings;
- actions HRSA will take to resolve problems related to the lack of access and poor continuity of HIV care to eligible patients, particularly in counties that have taken a “regional” approach with centralized providers;
- HRSA’s TA to ensure small- to medium-sized Ryan White community-based providers can continue to provide high-quality care to patients in a more technologically-based environment that will require electronic medical records, new billing systems, licensure, linkage to primary care, and new staffing skill sets;
- HRSA’s discussions with the insurance industry to ensure costs to patients are not raised under ACA;
- the role of essential benefits in ACA for HIV, HCV and substance abuse;
- federal subsidies of up to 400% of the FPL that will be available to persons who opt-out of purchasing health insurance under ACA;
- the role of AIDS Service Organizations in developing creative models to address anticipated gaps in ACA;
- ACA health coverage for families with “mixed” documentation status (e.g., a documented mother, undocumented father, and both documented/undocumented children); and
- the need to expand NHSC to specifically meet HIV and hepatitis needs in the United States.

Dr. Cheever confirmed that in response to CHAC’s request, she would invite Ms. Rebecca Spitzgo, Associate Administrator of the Bureau of Clinician Recruitment and Service & Director of NHSC, to a future meeting to present an overview of NHSC.

CHAC advised HRSA to engage POZ and other advocacy organizations to rapidly disseminate information to help Ryan White providers in shifting to an ACA environment. For example, HRSA should develop a one-page document with contact information that clearly and succinctly articulates the roles, responsibilities and potential decisions of Congress, federal agencies, and agencies at state and local levels in ACA. The advocacy organizations could then widely publicize and broadly distribute the HRSA document to communities across the country.

During a future meeting, Dr. Fenton was interested in CHAC engaging in a comprehensive and meaningful discussion to provide guidance in response to two key questions: (1) What strategies can federal agencies implement to take advantage of the existing transformative moment in the U.S. response to the HIV epidemic? (2) What efforts can federal agencies make to shift from existing mental models of current delivery systems, Congressional restrictions and funding constraints to identify new strategies, innovative approaches and bold targets to truly scale-up ARV treatment in the United States?

Dr. Fenton posed these questions for CHAC's future discussion because 30 years after the start of the HIV epidemic, only 250,000-300,000 persons are virally suppressed out of a total of 1.2 million HIV-infected Americans. He emphasized the critical need for innovative approaches to change these outcomes over the next 3-5 years. He asked CHAC to focus its future discussion on different strategies to provide training, creative approaches to deliver HIV care in the United States, and mechanisms to apply lessons learned from overseas countries in using new clinical delivery models to scale-up ARV treatment.

Panel Presentation: Update on the CDC and HRSA Viral Hepatitis Prevention Activities

Geoff Beckett, PA-C, MPH

Chief, DVH Prevention Branch
Centers for Disease Control and Prevention

Mr. Beckett presented an update on CDC's viral hepatitis prevention activities in support of VHAP. HHS developed VHAP in response to several years of activities. The January 2010 IOM report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, reflected extensive work by federal, state and local governments, CBOs and patient advocates. A Congressional hearing was held on "Viral Hepatitis: The Silent Epidemic." Trust for America's Health developed and released a report, *HBV and HCV: America's Hidden Epidemic*. The White House began to formally observe World Hepatitis Day.

CDC uses VHAP as a guide to inform the development and implementation of its viral hepatitis prevention activities. The overarching VHAP goals are to:

- educate providers, affected communities, policymakers and the general public to reduce health disparities;
- improve testing, care and treatment to prevent liver disease and cancer;
- strengthen surveillance to detect viral hepatitis transmission and disease;
- eliminate transmission of vaccine-preventable viral hepatitis;
- reduce viral hepatitis cases caused by drug-use behaviors; and
- protect patients and workers from healthcare-associated viral hepatitis.

VHAP describes implementation strategies to achieve these goals (e.g., realize opportunities within reformed health systems; build collaborative opportunities within HHS and across the U.S. government; incorporate new HIT standards; integrate viral hepatitis into existing plans and programs, including HIV and immunization programs; expand the capacity of state and local public health programs; and establish a research agenda).

Mr. Beckett highlighted CDC's ongoing and future activities to achieve the 6 VHAP goals. To "educate providers, affected communities, policymakers and the general public to reduce health disparities," CDC will build a U.S. healthcare workforce that will be prepared to prevent, diagnose and treat hepatitis.

In collaboration with federal partners, colleagues and grantees, CDC will create educational curricula; develop professional education programs; prepare and disseminate materials to HHS-sponsored programs; and distribute guidelines to professional societies. Communities that experience health disparities will be educated on viral hepatitis.

Culturally-appropriate awareness campaigns will be developed and launched. Support will be provided to CBOs. Public awareness will be raised for National Viral Hepatitis Day on May 19 and World Hepatitis Day on July 28. CDC launched the “KNOW MORE HEPATITIS” Campaign to provide education on viral hepatitis to healthcare providers, persons at risk for chronic HBV and HCV, and the general public.

To “improve testing, care and treatment to prevent liver disease and cancer,” CDC will identify persons early in the course of their disease. Federal policies for testing and linkage to care will be revised. In this effort, CDC will consider its existing recommendations for HCV testing of persons born in 1945-1965. Care standards for clinical prevention programs (e.g., HIV, STD and Ryan White Programs) will be integrated. Infected persons will be linked and referred to care and treatment.

In collaboration with HRSA, CDC will develop and implement care models; replicate and disseminate models to expand capacity in primary care settings; and create databases for testing and care referral services in both clinical and health department settings. The “Extensions for Community Healthcare Outcomes” (ECHO) Model will be modified to more strongly emphasize public health and linkages to health departments.

CDC’s rationale for focusing on HCV infection among persons born in 1945-1965 is three-fold. Of this birth cohort, 45%-85% of HCV-infected persons are unidentified. The cohort has a higher HCV prevalence compared to the general population (e.g., 3.29% versus 0.55%). The cohort represents 81% of HCV infections. Cost-effectiveness studies estimate that the costs for treating this cohort are \$28,74 per HCV case and \$15,700-\$35,700 per quality-adjusted life year. The impact of HCV testing in this cohort is comparable to other successful interventions (e.g., colorectal screening, influenza immunization for persons ≥ 50 years of age, cervical and breast cancer screening, and chlamydia screening).

CDC initiated research on the 1945-1965 birth cohort to assess the effects of screening and treatment on HCV infection against the standard of care (e.g., risk-based screening). The study population was persons born in 1945-1965 who were unaware of their HCV status. The study intervention was screening and care (e.g., response and workup as needed). The comparison group received no screening (e.g., the standard of care or risk-based screening). Any outcomes that were important to the patient were examined.

Based on the research findings, CDC recommended one-time testing of adults born in 1945-1965 for HCV infection as a routine part of care (strong recommendation with moderate quality of evidence). CDC noted that antibody reactivities reflex to HCV RNA for infection. The recommended services included vaccination, prevention counseling, alcohol counseling, linkage to care, medical evaluation, and therapy as appropriate. CDC will finalize and release the draft

recommendation in 2012 after the public comment period and internal clearance process are completed.

To “strengthen surveillance to detect viral hepatitis transmission and disease,” CDC will collaborate with federal partners to build state and local surveillance systems. Assistance will be provided to all states to collect core data for reporting to CDC. Surveillance capacity will be built in Centers of Excellence. Case detection from electronic medical records will be automated. Data will be collected from non-traditional sources (e.g., clinical data sets).

The provision of preventive and care services will be monitored by collecting data to evaluate quality; creating data-sharing agreements across federal agencies; and providing data to support state and local case registries. Research will be conducted on electronic reporting systems and the development of assays.

To “eliminate transmission of vaccine-preventable viral hepatitis,” CDC will conduct activities to support elimination of perinatal transmission of HBV. Interagency efforts will be made to achieve high vaccination coverage of vulnerable adults. Strategies will be identified to support vaccination in the era of health reform. A care standard for prevention and clinical programs will be integrated at the federal level.

To “reduce viral hepatitis cases caused by drug-use behaviors,” CDC will collaborate with federal partners to ensure that IDUs have access to viral hepatitis prevention in conjunction with drug treatment and HIV prevention programs. Community resources will be mobilized to prevent viral hepatitis. IDUs will be provided with access to care and substance abuse treatment. A network will be built with PCPs who are trained to provide prevention and care services for IDUs. Continuity of care will be provided to inmates who are released back into communities. Health Centers will strengthen their partnerships with Community Reentry Programs.

A study was published in the *MMWR* in 2011 that described the age distribution of confirmed HCV cases in Massachusetts in 2002-2009. The state reported 1,925 HCV cases among persons 15-24 years of age in 2007-2009. The cases were equally distributed between males and females by gender, but whites accounted for the majority of cases by race/ethnicity. Of all cases, 72% were past or current IDUs and 84% had injected drugs in the past 12 months. Other states reported similar increases in HCV rates among adolescents and young adults.

To “protect patients and workers from healthcare-associated viral hepatitis,” CDC will reduce hepatitis transmission associated with the misuse of devices and drugs. Educational campaigns to promote safe use will be expanded. Capacity for outbreak response will be strengthened. Transmission associated with blood, organ and tissues will be reduced by sharing data on adverse events and updating policies for HCV nucleic acid amplification testing (NAAT) of donors. Occupational transmission will be reduced by increasing HBV vaccination of healthcare workers. Research will be conducted to evaluate strategies to promote safe use of devices and drugs.

In addition to its viral hepatitis activities to meet the VHAP goals, CDC also launched new surveillance and epidemiologic initiatives in 2011 in support of the VHAP implementation plan. A supplement was added to NHBS to administer a survey on HBV and HCV in Chicago, the District of Columbia, Louisiana and New York. California, Florida, Michigan, Ohio and Wisconsin were funded to improve viral hepatitis surveillance.

Florida, Massachusetts, Michigan, Minnesota, Ohio, Philadelphia and Wisconsin were funded to investigate HCV infection among adolescents and young adults. The National Surveillance Report was revised with more data on viral hepatitis outbreaks, chronic disease and mortality. Guidelines were developed on community HBV screening, vaccination, and linkage to care and treatment among foreign-born persons residing in the United States. The HCV Testing Guidelines were revised. Viral hepatitis surveillance was enhanced at 9 sites and Viral Hepatitis Prevention Coordinators were placed at 55 sites.

In 2013, CDC will release a combined viral hepatitis surveillance/prevention FOA to state and local health departments to conduct both core and enhanced activities. The objectives of the FOA will be to implement CDC-related actions to support VHAP, increase capacity and program effectiveness, improve accountability to demonstrate program success, improve TA, and enhance responses to feedback. The *HCV Counseling and Testing Manual* CDC developed will continue to be tested in the field.

Sarah Linde-Feucht, MD

CAPT, U.S. Public Health Service
Chief Public Health Officer
Health Resources and Services Administration

Dr. Linde-Feucht presented an update on HRSA's viral hepatitis prevention activities in support of VHAP. HRSA's mission is to improve health and achieve health equity through access to quality services, a skilled workforce and innovative programs. HRSA fulfills its mission through its programs: Ryan White HIV/AIDS Program, Health Center Program, Maternal and Child Health Programs, NHSC, Workforce Training Programs, Rural Health Care Program, Federal Organ Procurement System Program, Poison Control Centers, and 340B Low-Cost Drug Program.

HRSA allocates its ~\$9 billion budget to 80 grant programs to strengthen the safety net for vulnerable populations across the country. HRSA established 5 public health priorities to guide its programmatic activities:

- achieve health equity and improve outcomes;
- link and integrate public health and primary care;
- strengthen research and evaluation, assure the availability of data, and support health information exchange;
- assure a strong public health and primary care workforce; and
- increase collaboration and alignment of programs within HRSA and among its partners.

VHAP describes goals, strategies and action items for each of the 6 topic areas. For example, topic area 1 is to educate providers, affected communities, policymakers and the general public to reduce health disparities. The 2 goals for topic area 1 are to (1) build a U.S. healthcare workforce that will be prepared to prevent, diagnose and treat hepatitis and (2) decrease health disparities by educating communities about the benefits of viral hepatitis prevention, care and treatment.

The 3 strategies for topic area 1 are to (1) develop an educational curriculum for viral hepatitis prevention, care and treatment to be used by multiple disciplines of health professionals; (2) integrate a viral hepatitis component into curricula of all HHS healthcare provider training programs; and (3) collaborate with professional, medical and other organizations to build a workforce with capacity to provide viral hepatitis prevention, care and treatment.

The action items for each VHAP topic area identify federal agencies that will serve as leads or co-leads for the activity. HRSA was named as the lead or co-lead for 5 VHAP action items:

- assess medical and health education materials and programs and draft plans to improve quality and distribution;
- leverage ACA resources to support workforce development and the development of curricula;
- train all healthcare providers in HHS-sponsored clinical programs to deliver vaccination, early detection, testing, management of alcohol and other co-factors, and treatment services;
- fully integrate curricula into provider training programs; and
- collaborate with academic institutions and educational organizations.

HRSA's viral hepatitis resources are described in detail at <http://careacttarget.org>. These resources include the *Guide for Evaluation and Treatment of Hepatitis C in Adults Co-Infected with HIV*; *Guide for HIV/AIDS Clinical Care* with chapters on HBV and HCV; a document on integrating HCV treatment in Ryan White Clinics; and *Hepatitis C Clinical Management Manual*. The website of the AETC National Resource Center also maintains several training materials on viral hepatitis. HRSA used SPNS dollars to fund projects across the country to evaluate the effectiveness of interventions to deliver HCV treatment to HIV-positive persons and share best practice models with Ryan White grantees and HIV medical providers.

The New Mexico and Mountain Plans AETCs are using the ECHO Model to link academic health centers, healthcare providers, and underserved or vulnerable populations through the use of technology. The ECHO Model was designed to focus on complex chronic diseases, but the New Mexico AETC began its initiative with HCV.

The PrimaryCareforAll.org Training Site is an online community for HRSA-funded NHSC providers. The site provides education, networking and free continuing medical education. A training course was added to the site, "New Developments in the Diagnosis and Treatment of Hepatitis C Virus." In the future, HRSA plans to open the training site to providers beyond NHSC.

HRSA funds a number of programs and initiatives to disseminate education, provide training and conduct surveillance to advance the detection, prevention and treatment of viral hepatitis. These resources include Public Health Training Centers, Area Health Education Centers, state Rural Health Offices and Clinics, critical access hospitals, and tele-health activities to increase the use of technology in rural areas of the country.

HRSA changed its Uniform Data System (UDS) in 2010 to add data elements for HBV and HCV and capture the number of patients, number of visits and number of tests completed. The system maintains data that are collected annually from Section 330-funded Health Centers. HRSA uses the data to review and assure compliance with legislative and regulatory requirements, improve the performance and operations of Health Centers, and report programmatic accomplishments.

In response to CHAC's specific questions, Mr. Beckett and Dr. Linde-Feucht provided additional details on the CDC and HRSA viral hepatitis activities. The discussion topics included:

- recent data that showed HCV has been the cause of more deaths than HIV or HBV each year since 2008;
- funding and resources CDC needs to establish a chronic viral hepatitis surveillance system to document the number of cases at the national level that are diagnosed late each year, better characterize the epidemiology of HBV and HCV, and guide public health action;
- the potential of integrating HIV and hepatitis treatment into one center due to the similar nature of adherence, drug interactions, and toxicity and virologic monitoring between the two diseases;
- the possibility of establishing a new "Hepatitis Medicine Association" through a collaboration among HIVMA, IDSA, Ryan White Program, and American Association for the Study of Liver Diseases that would serve as a focused programmatic approach to strengthen the viral hepatitis workforce, provide training and assure quality of care;
- the lack of capacity in Ryan White clinics for providers to treat patients who are co-infected with HCV; and
- CDC's ongoing efforts to integrate Meaningful Use indicators for HBV and HCV into electronic medical records.

Dr. Fenton confirmed that during a future meeting, CDC would present an overview of its internal efforts in developing models for a viral hepatitis surveillance system and the potential cost of the system.

Update by the CHAC Sexual Health Workgroup

John Douglas, Jr., MD

Chief Medical Officer, NCHHSTP
Centers for Disease Control and Prevention

Dr. Douglas presented an update on the workgroup's activities since the May 2011 CHAC meeting. The workgroup is making efforts to integrate the determinants of sexual health into broader social, community, personal and individual contexts. The sexual health determinants are closely aligned with the core mission and priorities of the Sexual Health Framework that uses health promotion to complement disease control and prevention. The focus on sexual disease control and prevention contextualizes issues, addresses sexuality as an intrinsic component of health, takes a syndemic approach, focuses on relationships, and emphasizes wellness.

In June 2011, CDC released a meeting report entitled *A Public Health Approach for Advancing Sexual Health in the United States: Rationale and Options for Implementation*. The report serves as a compilation of key outcomes and recommendations from the Sexual Health Consultation that CDC held in April 2010. The participants strongly endorsed the broad, contextual, positive, inclusive and empowering Sexual Health Framework. The participants also noted that the framework provided an opportunity to communicate, normalize and de-stigmatize sexual health, leverage partners, and facilitate synergy with other health approaches.

The workgroup is using the following recommendations outlined in the report to guide its activities. CDC should develop a definition of "sexual health" and a white paper. Key objectives should be created and aligned with national sexual health indicators. Communications research should be conducted to determine the appropriate tone, metaphors and messages for greatest acceptance within public health audiences and the broader population.

Consideration should be given to establishing a national coalition of partners, including faith-based organizations (FBOs). Collaborations should be established with national, state and local programs and providers to identify strategies for a sexual health framework to enhance the activities of these groups.

ACA authorized the release of the 2011 U.S. National Prevention Strategy in June 2011. The vision of the strategy is for departments and governments to collaborate to improve health and quality of life by shifting from a narrow focus on sickness and disease to a broader prevention and wellness approach.

The strategy primarily focuses on 4 areas: health and safe community environments, preventive clinical and community efforts, empowered individuals, and elimination of health disparities. Reproduction/sexual health is one of the 7 target priorities identified in the strategy along with tobacco-free living, prevention of other drug abuse and excessive alcohol use, healthy eating, active living, injury and violence-free living, and mental and emotional well-being.

In June 2011, the first population-based data on health risk behaviors of sexual minority youth were published in the *MMWR*. The publication was based on Youth Risk Behavior Survey (YRBS) data collected from 7 states and 6 cities. The publication reported increased health risk behaviors (e.g., injury, violence, suicide, tobacco, alcohol and drugs, sexual behavior, diet and physical activity) among LGB youth.

During its meeting on the previous day, the workgroup reviewed a summary by CDC staff which aligned the 4 Sexual Health Framework objectives with national indicators to inform the further development of the white paper. For the objective to increase knowledge, communication and healthy/respectful attitudes regarding sexual health, the 4 potential indicators would focus on knowledge, communication and attitudes. For the objective to increase the use of high-quality, coordinated and integrated educational, programmatic and clinical services that promote sexual health, the 7 potential indicators would focus on both division-level and cross-cutting activities.

For the objective to increase healthy, responsible and respectful sexual behaviors and relationships, the 5 potential indicators would focus on behaviors and relationships. For the objective to decrease adverse health outcomes, including HIV/STD, viral hepatitis, unintended pregnancy and sexual violence, the 6 potential indicators would focus on division-level activities.

Dr. Douglas highlighted specific activities CDC and the workgroup have conducted to respond to the recommendations that were made during the April 2010 Sexual Health Consultation. In September 2011, CDC awarded funds to the Partnership for Prevention to form the new “National Coalition to Enhance STD/HIV Prevention Through Promotion of a Holistic Approach to Health and Wellness.”

The coalition will target activities to its key audiences of adolescents, the general population and MSM and will collaborate with numerous non-governmental organizations (NGOs) to reach these populations (e.g., health plans, schools, FBOs, federal agencies, developmental agencies, professional organizations, private industry and the media).

CDC launched the “Coordinated Communication Project” to develop a framework for coordinated and synergistic messages for key stakeholders; engage stakeholders in the creation of a framework and messages; and develop a plan to increase the frequency, reach and effect of sexual health messages. Formative research for the project showed that sexual health messages will be more compelling and effective depending on the specific audience. As a result, CDC tailored and tested sexual health messages for a “more moderate/conservative” audience, a “more liberal” audience, a general audience, youth and policymakers.

CDC and the workgroup thoroughly reviewed drafts of the sexual health white paper in August and September 2011. The comments currently are being reviewed to plan next steps in this effort. CDC issued a call for papers on sexual health that will be published in a special issue of *Public Health Reports* in March or April 2013. The deadline to submit manuscripts is March 1, 2012.

Papers selected for publication in the special issue must focus on a wellness-based framework to promote prevention approaches. The priority topics include:

- the role of SDH in sexual health;
- implications of sexual health study results across the lifespan and for special populations (e.g., adolescents, LGBT persons, persons in midlife and older adults);
- strategies and best practices for advancing sexual health that should be prioritized in efforts to produce the greatest impact in the prevention of HIV, STD, viral hepatitis, unintended pregnancy and sexual violence;
- studies focusing on developing and identifying key metrics to better measure and monitor sexual health;
- analyses to support the design, implementation and evaluation of policies, services and interventions that improve sexual health;
- strategies to enhance healthcare provider training and communication to policymakers and the general public about sexual health; and
- evidence to determine the impact of partnerships and collaborative efforts to advance sexual health.

The workgroup held extensive discussions on provider training with HRSA and the National Network of Prevention Training Centers (NNPTC). NNPTC provides clinical training, behavioral training and partner services training. Opportunities to promote sexual health were highlighted during the annual NNPTC meeting in October 2011 and in a follow-up call with the NNPTC Strategic Response Committee in November 2011.

The workgroup currently is considering 3 issues to strengthen provider training in sexual health: (1) review, modify and compile existing training materials and curricula into an inventory to incorporate a sexual health framework and messages; (2) develop and test new curricula and training materials focused on healthy sexuality and relationships; and (3) explore the creation of curricula for new audiences (e.g., health department public policy officers who communicate with the media).

During its biweekly teleconferences and face-to-face meeting on November 14, 2011, the workgroup has discussed HRSA's potential areas of focus on sexual health, the sexual health white paper, and a consultation with faith-based leaders. The workgroup developed a briefing document outlining potential sexual health opportunities for HRSA. HRSA's provider training activities should focus on healthcare providers, AETCs, outreach workers, case managers and peer training.

HRSA's provider communication efforts should include guidance documents, toolkits and sessions during regional grantee meetings. HRSA's other activities should include patient education, demonstration projects using existing indicators to assess outcomes following implementation of these efforts, and opportunities to promote sexual health within HRSA and its partners.

For the consultation with faith-based leaders, the workgroup emphasized the importance of creating sustainable interactions and dialogue over time. The possibility was raised of forming a small steering group of clergy to obtain a broad spectrum of perspectives and discuss possible approaches. The workgroup reinforced the need to link this effort with the National Sexual Health Coalition. CDC identified FY2010 funds to support and convene the faith-based consultation within the next year.

In response to CHAC's specific questions, Dr. Douglas provided additional details on recent activities by the Sexual Health Workgroup. The discussion topics included:

- CDC's efforts to track structural determinants of behavior in surveillance systems, national probability surveys and other tools to guide future policy;
- the need for federal and state governments to establish non-traditional partnerships with Internet dating and pornographic sites to better understand sexual behaviors of young adults/adolescents, educate this group with accurate sexual health information, and promote prevention messages during STD outbreaks;
- existing gaps in national sexual health indicators, particularly those related to lifespan issues;
- the need for CDC and Hollywood, Health and Society to collaborate in promoting the use of condoms in cable programming;
- the need to strengthen collaborative efforts with school-based clinics; and
- the need to integrate the anti-bullying movement into the Sexual Health Framework.

CHAC thanked Dr. Douglas for leading the national effort to raise the profile and importance of sexual health. The CHAC members made two key comments for the workgroup to consider and discuss during its upcoming teleconferences.

- A clear distinction should be made in the Sexual Health Framework between "MSM" and "gay" or "bisexual" men. The generic term of "MSM" denies gay men their identity and place in society, inappropriately encompasses their entire being, and does not account for the role of sexual identity in risk behaviors. The workgroup should have an in-depth discussion on shifting to the more inclusive term of "gay, bisexual and other MSM."
- The word "virginity" should be redefined because the vast majority of youth believes that virginity only applies to vaginal intercourse and "oral sex" is not actually sex.

With no further discussion or business brought before CHAC, Dr. Hook recessed the meeting at 5:30 p.m. on November 15, 2011.

Opening Session: November 16, 2011

Kevin Fenton, MD, PhD, FFPH

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

Dr. Fenton conducted a roll call to determine the CHAC voting members, *ex-officio* members and liaison representatives who were in attendance. He asked the voting members to declare any conflicts of interest for the record for themselves and/or their institutions.

- Carol Brosgart, MD: Owner of stock in Gilead Sciences and Tobira Pharmaceuticals
- Debra Hickman: Speaker for Gilead and co-recipient of NIH funding with Johns Hopkins
- Edward Hook III, MD: Recipient of research support from Gen-Probe, Becton Dickinson, Sephia, Siemens, Roche Molecular Systems, CDC and NIH
- Steven Johnson, MD: Recipient of research funds and research consulting support from Vive Health, Gilead and Janssen Biotech and federal funding from HRSA and NIH
- Jeanne Marrazzo, MD, MPH: Recipient of research support from Gilead, Sephia, CDC and NIH
- Kenneth Mayer, MD: Recipient of unrestricted research and educational grants from Gilead, Bristol-Myers Squibb, Merck, NIH, CDC and HRSA
- Carlos del Rio, MD: Recipient of funding from CDC and NIH

Dr. Fenton verified that the voting members and *ex-officio* members constituted a quorum for CHAC to conduct its business on November 16, 2011. He reconvened the meeting at 8:32 a.m. and welcomed the participants to day 2 of the meeting.

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. He reminded the CHAC voting members of their responsibility to identify individual potential conflicts of interest and recuse themselves from participating in these matters.

Antigone Hodgins Dempsey MEd, CHAC co-Chair

Deputy Director, Knowledge, Transfer and Technical Assistance
HIV/AIDS Lead, Altarum Institute

Ms. Hodgins Dempsey joined Dr. Fenton in welcoming the participants to day 2 of the meeting. She reviewed the agenda items presented on day 1 of the meeting and highlighted the updates that would be presented on day 2. She reminded CHAC that the upcoming business session would be used for the membership to propose and vote on formal resolutions for action by CDC and HRSA.

Edward Hook III, MD, CHAC co-Chair
Director, Division of Infectious Diseases
University of Alabama at Birmingham

To make the most efficient use of time, Dr. Hook asked the CHAC members to write their proposed resolutions in advance of the business session and inform the co-Chairs of their intention to propose official recommendations. He noted that the proposed resolutions must be developed with clear and concise language in order for CHAC to formally vote on these issues and for CDC and HRSA to take action.

Update by the HRSA Bureau of Primary Health Care

Rene Sterling, PhD, MHA
Senior Advisor, Southwest Division/Bureau of Primary Healthcare
Health Resources and Services Administration

Dr. Sterling presented an update on BPHC's programmatic, HIV and viral hepatitis activities. The mission of the Health Center Program is to improve the health of the nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally-competent and quality primary healthcare services.

BPHC's 4 Primary Care Divisions have responsibility for monitoring Health Centers, while its 5 offices have various roles to support Health Center activities. BPHC formed a new HIV/AIDS Workgroup with staff representing all of its divisions and offices. The workgroup holds monthly meetings to discuss the development and implementation of various HIV/AIDS activities.

HRSA's UDS data showed that of 19.5 million patients Health Centers served in 2010, 93% were below 200% of the FPL, 62% were racial/ethnic minorities, 38% were uninsured, ~1 million were homeless, 863,000 were migrants or seasonal farmworkers, and 173,000 were residents of public housing. The Health Center Program includes 1,124 grantees at >8,100 service sites. In 2010, 77 million patient visits were made to Health Centers. The Health Center workforce of >131,000 staff includes 9,592 physicians and 6,362 nurse practitioners, physician assistants and certified nurse-midwives.

Health Centers serve a higher proportion of low-income, minority and uninsured patients than clinics for the general population. Health Centers have had tremendous growth from 2008 to 2010 (e.g., 13.7% growth in the number of patients, 8.5% growth in the number of sites, and 16.5% growth in the number of jobs).

For HIV/STD, Health Centers performed 781,750 HIV tests (e.g., a 13% increase from 2009) and provided services to 90,559 PLWHA and 59,158 patients with syphilis or other STDs. For preventive health screening, Health Centers performed ~1.8 million Pap tests and provided contraceptive management services to ~1.1 million patients. For viral hepatitis, Health Centers

provided services to 58,594 HCV patients, 12,333 HBV patients, 256,133 patients who received HBV testing, and 162,320 patients who received HCV testing.

For mental health issues, Health Centers provided services to 726,779 patients with depression or mood disorder and 397,541 patients with anxiety or post-traumatic stress disorder (e.g., a 12% increase from 2009). For substance use, Health Centers provided services to 110,031 patients for tobacco use (e.g., a 20% increase from 2009), 97,913 patients for substance use, and 73,082 patients for alcohol abuse.

Of all 1,124 Health Center Program grantees, 223 are located in the 12 Cities of the country with the highest incidence of HIV. Health Centers in these jurisdictions accounted for 41.6% of patients who received HIV testing, 42.1% of HIV tests conducted, ~51% of patients with an HIV diagnosis, and 51.3% of patient visits for an HIV diagnosis.

BPHC currently is integrating HIV, STD and hepatitis into Health Center Program initiatives; collaborating with its sister agencies and key stakeholders; clarifying and strengthening policy in partnership with HAB and CDC; and providing and supporting opportunities for TA. In terms of integration, BPHC is increasing access to care and improving health outcomes for patients through its QI Strategy.

To achieve this goal, BPHC is developing and enhancing access to care; recruiting, developing and retaining a skilled workforce; coordinating and aligning policies and programs; and transforming Health Center service delivery through 4 major mechanisms: Meaningful Use indicators, data and HIT, the PCMH model, patient safety and risk management, and local health systems integration.

BPHC is promoting PCMH national recognition and encouraging all Health Centers to become a PCMH. The PCMH model serves as a comprehensive and integrative approach in providing quality care for PLWHA and improving the quality of care through enhanced access, planning, management and monitoring of patient care. The National Committee for Quality Assurance (NCQA) establishes PCMH standards.

BPHC awarded 1-year supplemental grants totaling \$25 million to 904 Health Centers to cover the costs associated with obtaining NCQA-PCMH recognition. BPHC and CMS awarded 3-year grants to 500 Health Centers to participate in the FQHC Advanced Primary Care Practice demonstration project with a focus on services provided to Medicare beneficiaries. This project will be used to evaluate the effectiveness of the PCMH model in improving care, promoting health and reducing the cost of care.

BPHC is increasing the integration of Health Center service delivery into local systems by improving access to care and coordination of services as well as by developing and maintaining partnerships with various providers (e.g., local health departments, CDC and SAMHSA grantees, teaching Health Centers and support service providers). BPHC is using NASTAD and Adult Viral Hepatitis Prevention Coordinators to further facilitate partnerships in Health Centers.

BPHC's local partners include the Minnesota Association of Community Health Centers and the Illinois Primary Care Association. BPHC's recent activities with these local partners include (1) participating in a one-day summit with Ryan White grantees and Health Centers to discuss opportunities for increased collaboration and (2) conducting a demonstration project regarding implementation of routine HIV testing in medical settings, including 6 CHCs.

BPHC serves on several interagency groups to increase collaboration with its federal partners (e.g., HHS Viral Hepatitis Strategy Committee, HHS NHAS Implementation Committee, CDC ECHPP Implementation and Evaluation Workgroups, and 2012 AIDS Interagency Domestic Workgroup).

BPHC also is collaborating with HAB and CDC to incorporate language into MAI FOAs for Health Centers to compete for funding to improve hepatitis service delivery. To further promote collaboration, BPHC made presentations during several key events in 2011 (e.g., the VHAP Press Conference, White House World Hepatitis Day, and *NHAS Implementation Dialogues: Building Capacity Within the HIV Workforce*).

In terms of policy, BPHC requested OMB clearance to track all reported diagnoses rather than primary diagnoses only to improve data reporting and accuracy. BPHC is participating in the HHS-wide effort to identify and streamline metrics to inform the development and incorporation of HIV-specific performance measures into primary care services.

BPHC is drafting communications materials to all Health Center Program grantees regarding the HCV Treatment Guidelines that will be posted on its website. BPHC issued a 2010-2013 PAL regarding HIV testing in healthcare settings that reminded grantees to review CDC's guidelines and highlighted available resources. BPHC issued a 2011-2016 PAL regarding HIV care and treatment in Health Centers to encourage grantees to integrate HIV testing into primary care, review existing guidelines and protocols, and take advantage of available resources.

In terms of TA, BPHC is collaborating with the HRSA Center for Integrated Health Solutions and SAMHSA to host two TA webinars focusing on (1) viral hepatitis and behavioral health and (2) substance abuse and screening, brief intervention, and referral to treatment. BPHC awarded CoAg funds to Fenway Institute's National Training and Technical Assistance Center for LGBT Health.

The CoAg funds are intended for Health Centers to recruit experts in LGBT health to lead seminars and provide consultation; develop curricula specifically addressing the LGBT population; and closely collaborate with state Primary Care Associations to maximize the geographic reach of the project. Transcripts, audio archives and other materials from the "Grantee Enrichment Call" that BPHC hosted in October 2011 to begin addressing the public health concerns of the LGBT population are available at <http://bphc.hrsa.gov>.

BPHC awarded funds to the Association of Asian Pacific Community Health Organizations to implement various training and disseminate information regarding hepatitis and HIV in Health Centers. BPHC continued its longstanding partnership with the National Association of

Community Health Centers by awarding funds to develop routine HIV screening program resources, support service delivery to LGBT patients, and enhance the Health Center workforce.

In response to CHAC's specific questions, Dr. Sterling provided additional details on BPHC's recent activities. The discussion topics included:

- BPHC's efforts to collect data from Health Centers to track the number of HIV patients who are co-infected with HBV and HCV versus the number of patients who are mono-infected with HBV and HCV;
- the extent to which BPHC partners with the Migrant Clinicians Network;
- the breakdown of the increase of Health Center patients who are treated for mental health issues (e.g., by geography, HIV-positive status or other factors);
- BPHC's process in developing and prioritizing performance measures;
- BPHC's efforts to resolve problems regarding the practice of some Health Centers to refer patients to health departments for STD testing; and
- BPHC's process to assess "poor performance" of Health Centers and resolve problems in its QI Strategy.

Dr. Fenton raised the possibility of CDC partnering with BPHC to use its new HIV/AIDS Workgroup to begin developing a sexual health package of services for implementation by Health Centers. To support this effort, BPHC's existing mechanisms (e.g., PALs and TA) could be used to market sexual health services to Health Centers.

CHAC commended BPHC on its extraordinary progress and growth over a relatively short period of time in strengthening partnerships and collaborative efforts to position Health Centers to better address HIV, STD and viral hepatitis. The CHAC members made several comments and suggestions to assist BPHC in further enhancing its collaborative efforts.

- BPHC should more effectively and fully use the HRSA-funded Community Health Applied Research Network to track QI in sentinel surveillance and other existing activities.
- BPHC should separate its data to clearly distinguish between the number of PLWHA who are served by Health Centers versus those who are served by Ryan White-funded clinics. BPHC should distribute these de-aggregated data to CHAC for review.
- BPHC should collaborate with HAB, CDC and other federal partners to identify and implement effective strategies to scale-up HIV testing in Health Centers, particularly in a health reform environment. Potential approaches in this effort include offering incentives or instituting punitive measures; developing bold and innovative targets; gathering and providing Health Centers with information on reimbursement for HIV testing by state; and promoting cost-sharing for local Health Centers and Ryan White grantees to co-manage patients and offer HIV, STD and viral hepatitis testing.
- BPHC should consider the following indicators in its ongoing efforts to develop and incorporate performance measures into primary care services:
 - routine HIV testing of specific age groups;

- HBV testing of foreign-born persons, their children and/or sexual partners;
- HCV testing;
- the proportion of patients diagnosed with HIV who had an undetectable viral load in the past year;
- service utilization based on the rates of and reasons for hospitalization; and
- mortality.

Update by the CDC Division of Adolescent and School Health

Howell Wechsler, EdD, MPH

Director, Division of Adolescent and School Health/NCHHSTP
Centers for Disease Control and Prevention

Dr. Wechsler covered the following topics in his update to CHAC on DASH's recent activities. Unlike other parts of CDC that primarily collaborate with state and local health departments, DASH's major partners are state education agencies (SEAs), local education agencies (LEAs) and national education organizations. DASH established these partnerships because school-based initiatives can significantly contribute to the prevention of HIV, STD and teen pregnancy.

In its 2010 publication, the Task Force on Community Preventive Services recommended group-based and comprehensive sexual risk reduction, including school-based efforts, based on sufficient evidence of effectiveness in two areas: (1) increasing the use of protection against pregnancy and STDs and (2) reducing engagement in any sexual activity, frequency of sexual activity, number of partners, frequency of unprotected sexual activity, and incidence of self-reported or clinically documented STDs.

DASH serves as the primary federal unit that gathers and disseminates evidence-based information to document the strong linkage between health risk behaviors and academic achievement. DASH has widely distributed YRBS data, fact sheets and other materials to demonstrate this correlation. Most notably, 2009 YRBS data showed a negative association between the percentage of U.S. high school students who engaged in sexual intercourse and the grades students typically received in their coursework. The same trend was observed based on the number of sexual partners students had during their lives.

Dr. Wechsler highlighted DASH's key activities to support its 4 prevention strategies. Strategy 1 is to collect and disseminate data. DASH has oversight of three surveillance systems to gather, review, report and maintain data on youth health risk behaviors and school policies and practices to address youth health risk behaviors. DASH initiated YRBS in 1991 as a biannual survey of students in grades 9-12. YRBS provides nationally representative data and also representative data for states and localities; in 2009, 47 states, 23 cities, 4 territories and 2 tribes participated in YRBS.

YRBS assesses a number of risk behaviors (e.g., injury and violence-related events, tobacco use, alcohol/other drug use, diet, physical activity and sexual behaviors). The sexual behavior component of YRBS gathers data from students in the following areas:

- ever had sex;
- had sex before 13 years of age;
- had sex with ≥ 4 partners;
- currently are sexually active;
- use condoms/contraception;
- used alcohol or other drugs before the last sexual encounter; and
- ever received an HIV test.

YRBS data showed a significant decrease in the percentage of high school students who ever had sexual intercourse from 1991-2009 and a substantial increase in condom use in this population from 1991-2003, but progress in these behaviors has remained flat over the past few years. The “Youth Online System” is available on the CDC website for users to analyze national, state and local YRBS data. This resource can be used to quickly produce graphs and compare trends in behaviors among subgroups of students at national, state, and city levels.

DASH used YRBS data to publish the landmark *Health Behaviors of Sexual Minority Students Report* in the *MMWR*. The report reflected a compilation of 2001-2009 data from 7 states and 6 large urban school districts and identified differences in 76 health risk behaviors among subgroups of students who were defined by their sexual identity and gender of sexual contacts. The report documented that sexual minority youth were at significantly higher risk for behaviors related to violence, suicide, alcohol/other drug use, tobacco use, unsafe weight and sexual health.

DASH conducts the School Health Policies and Practices Study (SHPPS) every 6 years at the national level. These data are aligned with several *Healthy People* objectives. For example, DASH used SHPPS data to determine the percentage of secondary schools in which school health services staff provided HIV counseling, testing and referral as well as identification or treatment of STD. From 2000 to 2006, SHPPS data showed a substantial increase in the percentage of secondary schools providing HIV services (e.g., 12% to 39%) and basically no increase in STD services (e.g., 22% to 23%).

DASH administers the School Health Profiles (SHP) survey every 2 years and collects data from states, territories, tribes and large urban school districts in this effort. The survey measures several key issues, including sexual health education topics taught, provision of education to parents and families, professional development offered to and received by sexual education teachers, health services offered in schools, and policies established to protect the rights and confidentiality of HIV-infected staff and students.

SHP data showed that in 2010, a median of 43% of secondary schools (a range of 13%-66%) taught 11 key HIV, STD and pregnancy prevention topics in a required course in grades 6-8. These topics included:

- differences between HIV and AIDS;
- how HIV and STDs are diagnosed, transmitted and treated;
- health consequences of HIV, STDs and pregnancy;
- benefits of abstinence;
- how to prevent HIV, STDs and pregnancy;
- how to access valid and reliable information, products and services;
- influences of media, family, and social and cultural norms;
- communication and negotiation skills;
- goal-setting and decision-making skills; and
- compassion for PLWHA.

Strategy 2 is to conduct research and evaluation studies. DASH's research studies have assessed the impact of (1) parent education activities to complement sexual health education curricula for students; (2) a condom availability program; (3) policies designed to decrease bullying and harassment among LGBT students; and (4) curricula and STD screening programs on economic outcomes. In the near future, DASH-funded researchers will publish results of a study comparing two curricula with similar designs but different frameworks: one focused on sexual risk avoidance and the other focused on sexual risk reduction.

Strategy 3 is to disseminate evidence-based guidance. DASH is currently developing *School Health Guidelines to Prevent HIV, Other STDs and Pregnancy and Promote Sexual Health*. Published tools include: *School Health Index: A Self-Assessment and Planning Guide*; and the *"Health Education Curriculum Analysis Tool."*

Strategy 4 is to provide funding and TA. DASH awards funding to 72 education agencies at state, local, tribal and territorial levels to build capacity of schools and other institutions. These funds are intended to foster the delivery of high-quality and evidence-based sexual health education; increase access to contraception and sexual health services among youth, including HIV and STD testing; establish supportive environments for LGBT youth; and enhance youth resilience through positive youth development and family education. DASH also funds 14 national NGOs to assist programs in areas with the highest burden of HIV, STD and teen pregnancy.

Grantees use DASH funding to collect and disseminate data; guide policy development and implementation; advocate for evidence-based sexual health curricula; provide professional development, consultation and TA to teachers and other school staff on evidence-based interventions; and collaborate with health departments and other groups to integrate HIV, STD and pregnancy prevention efforts.

In addition to mainstream schools, education agencies also are required to focus efforts on youth at greatest risk by targeting activities to juvenile justice centers, shelters for runaway for homeless youth, alternative schools and foster care programs. DASH is continuing to make strong efforts to promote evidence-based sexual health education and encourage programs to emphasize two guiding principles to youth. First, sexual abstinence is the only strategy that is

100% effective in preventing HIV infection, STDs and pregnancy. Second, young persons who engage in sexual intercourse must limit their number of sexual partners and consistently and correctly use condoms.

DASH has taken several actions to inform the adoption, facilitation and implementation of new policies. For example, DASH played an integral role in providing Mississippi with scientific expertise and professional development to pass new legislation. Mississippi passed a bill in 2011 requiring each local school board to adopt a sex education policy by June 30, 2012. Moreover, all schools in the state must teach a sex education curriculum that is either “abstinence-only” or “abstinence-plus.” The Mississippi Department of Education must approve the curriculum of each school district and establish a protocol for all districts to provide continuity in teaching the approved curriculum.

To promote HIV and STD testing, DASH has developed fact sheets: *HIV Testing Among Adolescents* and supported the development of a manual, *Providing Access to HIV Testing Through Schools: A Resource Guide for Schools*. In 2010, 41 of 65 DASH-funded SEAs and LEAs conducted activities to promote HIV and STD testing and increase the capacity of school districts and schools to reach youth who were at a disproportionate risk for HIV.

DASH-funded local initiatives included facilitating ongoing testing programs in collaboration with health departments; developing resource guides to link students to community-based testing services; providing professional development to school nurses on referring students to community-based testing services; and promoting special testing events. To promote World AIDS Day, for example, Memphis City School students 17-19 years of age who were tested for HIV at no charge were offered free tickets to a hip-hop concert. Orange County, Florida also promoted HIV and STD testing through its Teen Xpress Mobile Healthcare Unit.

DASH is continuing its efforts to establish supportive environments for LGBT youth. Of DASH grantees, ~50% of SEAs and nearly all LEAs implement activities to address the needs of this population by, for example, providing professional development to district and school staff; ensuring health curricula are inclusive of and relevant to LGBT youth; helping schools to establish Gay-Straight Alliances (GSAs); and linking schools to CBOs that have experience in providing health and mental health services to LGBT youth.

Models of DASH-funded efforts to establish supportive environments for LGBT youth across the country include (1) Michigan’s training program and complementary manual, *A Silent Crisis: Creating Safe Schools for Sexual Minority Youth*; (2) Philadelphia’s training program for all teachers and staff, *Fostering Knowledge About and Respect for LGBT Youth*; and (3) numerous activities in Los Angeles (e.g., including a sexual orientation chapter in its health textbook, providing anti-bias training to all teachers, and supporting 50 active GSAs).

DASH recently launched a new YMSM project in which NGOs will collaborate with LEAs and ECHPP partners to target the following activities to YMSM 13-19 years of age: evidence-based interventions, social media/social marketing, referrals to HIV and other STD testing, counseling and treatment, and policies to support health and mental health care. DASH’s partners in the

new YMSM project include Advocates for Youth, National Association of School Nurses, National Assembly on School-Based Health Care, and LEAs in New York City, Philadelphia and San Francisco. Depending on its success, DASH hopes to expand the project to other ECHPP sites in the future.

DASH has been making strong efforts to enhance youth resilience through positive youth development. DASH collaborated with internal CDC partners to publish two key documents: (1) *A Review of Positive Youth Development Programs that Promote Adolescent Sexual and Reproductive Health* and (2) *School Connectedness: Strategies for Increasing Protective Factors Among Youth*.

DASH funds 14 NGOs to increase capacity of education and health agencies; enhance capacity of juvenile justice centers, correctional centers, alternative schools, and shelters for homeless and runaway youth; strengthen capacity of schools and CBOs to reach LGBT youth; increase capacity of schools to provide effective school health services; and provide training and TA on evidence-based interventions.

DASH's TA to grantees has yielded positive results. For example, the percentage of secondary schools in Newark, New Jersey that taught all of the essential topics for an HIV prevention education program in grades 9-12 increased from 47% in 2008 to 92% in 2010. The percentage of secondary schools in South Carolina that taught key topics related to condoms increased from 50% in 2008 to 65% in 2010.

Condom use during last sexual intercourse significantly increased from 57% in 2007 to 65% in 2009 among sexually active students who were surveyed as part of YRBS at a San Diego, California high school.

DASH is continuing its longstanding and close partnerships with the U.S. Department of Education, HHS Office of Adolescent Health's Teenage Pregnancy Prevention Program, and HHS Administration for Children and Families' Personal Responsibility Education Program and abstinence education program.

In response to CHAC's specific questions, Dr. Wechsler provided additional details on DASH's recent activities. The discussion topics included:

- the relationship between states that reported same-sex behaviors and states with the highest HIV and STD morbidity in the country;
- potential reasons for virtually no increase in the identification and treatment of STDs from 2000 to 2006;
- DASH's activities in and focus on vaccine-preventable STDs (e.g., viral hepatitis and HPV);
- DASH's efforts to train teachers to feel more comfortable discussing sex with their students; and
- YRBS data on unwanted sexual advances and sexual abuse among school-age youth.

CHAC made several suggestions for DASH to consider in refining its existing activities and implementing its new initiatives.

- DASH should explore the possibility of using a recent IOM report that strongly recommended the inclusion of questions regarding sexual orientation and gender identity in national probability surveys. DASH should determine whether the addition of these types of questions in national surveys could increase funding of adolescent and school health initiatives.
- DASH and DHAP should collaborate to overlay HIV incidence rates of young gay, bisexual and other MSM with states that provide sex education in schools to determine correlation in these areas.
- DASH should include questions regarding alcohol/drug use in its new YMSM project.
- DASH should explore creative strategies to train GSA members in administering national sexual health surveys to their peers in high school. This training opportunity could provide GSA members with future career options.
- DASH should establish a partnership with U.S. Immigration and Customs Enforcement to improve its ability to reach and survey adolescents whose parents are undocumented.
- DASH should consider the possibility of collaborating with the American Academy of Pediatrics to offer sexual health courses to elementary school students.
- DASH and DVH should closely collaborate to focus on the risk of HCV acquisition in adolescents/young adults due to the use of prescription opiates.
- With its relocation to NCHHSTP, DASH should become more actively engaged in NCHHSTP's longstanding partnership with NIH.
- DASH should engage HRSA in dialogue to explore the possibility of partnering with FQHCs to scale-up school-based Health Centers in the United States.

Update by the Presidential Advisory Council on HIV/AIDS

Douglas Brooks, MSW

Senior Vice President, Community, Health and Public Policy

Justice Resource Center

CHAC Liaison Representative, Presidential Advisory Council on HIV/AIDS

Mr. Brooks covered the following topics in his update to CHAC on PACHA's activities since the May 2011 meeting. In August 2011, PACHA submitted a letter to President Obama to thank him for his leadership in HIV/AIDS, provide an update on PACHA's activities, and propose future directions for the Administration in the context of HIV/AIDS. In its letter, PACHA advised the Administration to:

- support full access to testing, care and prevention services;
- identify optimal resource allocations for evidence-based prevention strategies;

- transform expensive reporting requirements to a strategic management dashboard to reduce the burden on health departments;
- support the transfer of authority for the Strategy Implementation Fund;
- address HIV-related health disparities in the United States (e.g., stigma, discrimination and criminalization); and
- more strongly emphasize the domestic/global interface of the HIV/AIDS epidemic.

PACHA issued a formal resolution to the HHS Secretary highlighting the following points. The HHS Secretary should convene a high-level summit with both governmental and non-governmental stakeholders to discuss the HIV epidemic and its impact on YBMSM. An HHS-wide task force should be created and charged with developing a comprehensive plan to address all aspects of the epidemic among YBMSM.

The HHS Secretary should ensure that HIV prevention, care and treatment funding distribution methodologies are aligned with the epidemic to adequately support the needs of populations disproportionately impacted by HIV, including YBMSM. The HHS Secretary should ensure that knowledge gained from SDH studies are integrated into all interventions to help reduce health inequalities.

NIH should develop and issue a high-priority research plan by March 31, 2012 to address HIV among YBMSM. The research plan should be designed to evaluate the potential benefits of biomedical interventions (e.g., PrEP and treatment as prevention) and the use of novel technologies and other strategies to engage YBMSM in care, treatment and combination prevention strategies.

HRSA and CMS should require all physicians who practice at publicly-funded institutions or receive public reimbursement for the delivery of healthcare services to undergo continuing medical education and certification where available in HIV testing, care and treatment.

PACHA concluded its resolution to the HHS Secretary by noting that NHAS envisions a nation where HIV infections are rare and all persons in need of care would be granted care without exception. PACHA further pointed out that the provision of prevention, care, treatment and all social services should be culturally structured and of high quality to BMSM at all stages of life and serve as a key milestone to ending the HIV epidemic in the United States.

The theme of World AIDS Day on December 1, 2011 will be “Getting To Zero.” PACHA issued a formal statement on World AIDS Day highlighting the following points. The President should make a bold announcement during the event about using science to begin ending the AIDS pandemic and reinforce the nation’s commitment to this goal. Based on research establishing that AIDS treatment also is HIV prevention, the President should make a commitment to scale-up AIDS treatment to cover 6 million persons by 2013 along with other evidence-based and combination prevention interventions through the President’s Emergency Plan for AIDS Relief (PEPFAR).

Donor and affected countries should accept the challenge of increasing their investments in the response to HIV/AIDS and joining the United States in stronger efforts to scale-up high-impact activities (e.g., condom distribution and access to ART) to greatly reduce new infections and deaths. The President should pledge to make advancements in ending the AIDS epidemic in the United States by (1) continuing to implement NHAS with a commitment of resources for HIV prevention, care and treatment to meet the NHAS targets and (2) forcefully defending ACA, including the federal commitment to the Medicaid Program, with its potential to greatly enhance HIV prevention and treatment.

The President should make a bold commitment to defend global health budgets in debt negotiations and appropriations in FY2012 and beyond. This commitment should be targeted to budgets for PEPFAR; the Administration's multi-year Global Fund to Fight AIDS, Tuberculosis and Malaria; and domestic HIV research, prevention, care and housing programs. The President should call for new investments in research along with public health-driven research and development incentive mechanisms and policies to make new tools and technologies available to help end the AIDS crisis.

PACHA's ongoing activities include the establishment of the new Metrics Workgroup and the joint PACHA/CHAC HIV Disclosure Workgroup. The Disclosure Workgroup set an ambitious goal to develop and present recommendations during the 2012 World AIDS Conference. The White House has selected a candidate to replace Dr. Helene Gayle, the former PACHA Chair, and expects to make an announcement over the next two weeks.

In response to CHAC's specific questions, Mr. Brooks provided additional details on PACHA's recent activities. The discussion topics included:

- the need to apply global lessons learned and best practices from PEPFAR to the U.S. epidemic;
- collaborative opportunities between PACHA and CHAC to advance the Sexual Health Framework by calling for other agencies to be engaged in this effort beyond CDC; and
- the need for new and innovative strategies to scale-up the treatment as prevention public health approach.

CHAC was extremely pleased about recent efforts to improve the synergy and coordination between the two advisory bodies, particularly the appointments of Mr. Brooks and Ms. Hodgins Dempsey as liaison representatives and the establishment of the joint PACHA/CHAC HIV Disclosure Workgroup. CHAC also fully supported PACHA's resolutions that emphasized the critical need to scale-up efforts in the United States to end the domestic HIV/AIDS epidemic.

CHAC made several suggestions and comments to further strengthen joint efforts between the two advisory bodies.

- PACHA and CHAC should issue a joint resolution for the federal agencies to conduct modeling to determine the actual costs and investment that will be needed to end the domestic HIV/AIDS epidemic.

- PACHA and CHAC should form a new joint “Treatment as Prevention” Workgroup.
- After CDC finalizes and presents the Sexual Health White Paper to CHAC for formal approval, the document also should be presented to PACHA for its formal endorsement.
- PACHA and CHAC should explore creative strategies to mobilize and empower communities to interact with leadership and policymakers at federal and state levels and strongly advocate for the domestic HIV/AIDS epidemic in a much broader manner than in the past.

Update by the CDC Division of STD Prevention

Gail Bolan, MD

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

Dr. Bolan covered the following topics in her update to CHAC on DSTDP’s recent activities. DSTDP has been responding to the urgent threat of gonorrhea antimicrobial resistance (AMR). *Neisseria gonorrhoeae* (NG) is an organism that has demonstrated its capacity to progressively develop AMR to all drugs used to treat gonorrhea (e.g., sulfonamides, penicillins, tetracyclines and fluoroquinolones (FQ)). AMR undermines treatment success, facilitates HIV transmission and heightens the risk of complications.

The 1979 Perine, *et al.* study reported on the global distribution of reported penicillin-producing NG cases in 1976-1979. Hawaii and Guam both reported >20 cases over this period of time. The emergence of FQ-resistant NG in the United States in 1984-2008 affected Hawaii, California and MSM. In 2007, CDC recommended against further use of FQ to treat gonorrhea.

Gonorrhea rates were the lowest in U.S. history in 2009, but >300,000 cases still are reported each year with African Americans accounting for 70% of cases. These data reflect the greatest health disparity in public health. CDC released its STD Treatment Guidelines in December 2010. For the treatment of uncomplicated gonococcal infections of the cervix, urethra and rectum, the guidelines recommended 250 mg of ceftriaxone in a single intramuscular dose (or 400 mg of oral ceftriaxone if the injectable form was not available) plus 1 g of oral azithromycin or 100 mg of doxycycline twice daily for 7 days.

The Clinical and Laboratory Standards Institute (CLSI) established antimicrobial susceptibility criteria for gonorrhea in 2010. Resistant thresholds were determined for penicillin, tetracycline, ciprofloxacin and spectinomycin. Because the resistant threshold for cephalosporins is unknown, CDC recommends azithromycin for patients who are allergic to this class of drugs. However, CLSLI has not defined susceptibility or resistance breakpoints for this drug.

At the global level, trends in cephalosporin susceptibility for gonorrhea have been reported in Japan, Hawaii, Australia, Europe Norway, Sweden, United Kingdom, China and Austria in 2000-

2011. At the domestic level, CDC developed the Gonococcal Isolate Surveillance Project (GISP) in 1987 to monitor trends in NG antibiotic susceptibility.

At this time, 29 STD clinics participate in GISP by providing urethral NG isolates obtained from the first 25 symptomatic men seen each month. Regional laboratories conduct initial susceptibility testing, while CDC performs confirmatory testing of elevated minimum inhibitory concentrations (MICs). CDC awards \$5,000 annually to each GISP site, but the funding level has not increased since 1987.

CDC published a study in the July 8, 2011 edition of the *MMWR* that calculated the proportion of NG isolates with elevated MICs to cefixime and ceftriaxone in 2000-2010. By date, 1.7% of isolates had elevated MICs to cefixime ≥ 0.25 $\mu\text{g/ml}$ in the first 6 months of 2007. By region, 3.6% of isolates in the West had elevated MICs to cefixime ≥ 0.25 $\mu\text{g/ml}$ in 2011. By sexual partner, 4.7% of isolates from MSM had elevated MICs to cefixime ≥ 0.25 $\mu\text{g/ml}$ in 2011. Based on consolidated 2010 and 2011 data, MSM in the Western part of the country already are above the 5% threshold that is used to switch to another drug. However, no other drug is available.

Shifts in the distribution of elevated MICs to ceftriaxone in 2006-2011 were not as significant as those for cefixime. Although only 0.5% of isolates had elevated MICs to ceftriaxone ≥ 0.125 $\mu\text{g/ml}$ in 2011, this small trend is still of concern because ceftriaxone is the best drug for gonorrhea treatment that is currently available.

The current GISP alert breakpoint for azithromycin susceptibility for gonorrhea is an MIC of ≥ 2 $\mu\text{g/ml}$. In 2005-2011, 132 isolates had values above this breakpoint. No clear trend has been observed in azithromycin susceptibility, but the Western part of the country and MSM tend to account for higher MICs. A study published in the *MMWR* reported 9 cases from MSM in the West with MICs to azithromycin of 8-16 $\mu\text{g/ml}$. Hawaii recently reported a case involving a heterosexual male with an MIC $\geq 1,024$ $\mu\text{g/ml}$. CDC currently is investigating a case of possible azithromycin treatment failure in Oregon.

CDC reviewed antimicrobial susceptibility of gonorrhea isolates to elevated MICs to cefixime in 2010-2011. The analysis showed that only 23% of the strains were susceptible to penicillin, tetracycline or FQ, 99% of the strains were susceptible to azithromycin, and 100% of the strains were susceptible to spectinomycin.

CDC recognized a number of challenges in its response to the urgent threat of cephalosporin-resistant gonorrhea. Awareness of the problem is extremely low among providers and patients. Alternative treatment options that are known to be effective are lacking. STD control resources have significantly declined. CDC's STD screening guidelines are not routinely followed in HIV, primary care and other care settings.

Timely and sensitive AMR surveillance for gonorrhea is lacking due to limitations in GISP, the absence of clear laboratory criteria for resistance, a decline in laboratory capacity for culture and antibiotic susceptibility testing (AST), and limited screening at non-genital anatomic sites. The likelihood of preventing and controlling resistance is low.

The 2008 Spellberg, *et al.* study reported that the Food and Drug Administration (FDA) only approved 4 antibacterial agents in 2003-2007. A study highlighted the drivers of change for the declining STD public health infrastructure. The study reported that in 2008-2009, 69% of state and STD programs experienced funding cuts and reduced services in disease investigation services (40%), laboratory services (37%), clinical care and screening services (32%), and HIV tests or HBV vaccination (32%).

In 2008-2009, state and local governments enacted salary freezes and/or reductions (69%), furloughs and/or shutdown days (50%), and layoffs (28%). From 2005 to 2009, the number of STD program disease intervention specialists in state and local health departments decreased by 21% and the number of categorical STD clinics in state and local health departments decreased by 10%.

Dr. Bolan highlighted CDC's ongoing and planned activities to respond to the threat of cephalosporin-resistant gonorrhea. To raise awareness of the problem, CDC hosted a session on AMR during World Health Day, published data in the *MMWR* and other venues, distributed "Dear Colleague" letters, collaborated with WHO to mention NG in its large media effort to combat AMR, and highlighted gonorrhea as a concern in the World Health Day Media Fact Sheet.

In 2012, CDC will host webinars, hold public health grand rounds on resistant gonorrhea, publish a *Vitalsigns* Report, and strengthen outreach to the media. Concerns regarding the gonorrhea "superbug" have been extensively covered by print and television media in Canada, Japan and the United States.

To scale-up education on gonorrhea prevention to both providers and patients, CDC is reinforcing the need to screen for asymptomatic gonorrhea in younger women and MSM at sites of exposure according to CDC guidelines. CDC also is reminding providers to correctly diagnose symptomatic gonorrhea, provide timely treatment according to the recommended gonorrhea regimen, ensure sexual partners of patients are tested and treated, promote correct and consistent use of condoms, and link patients to risk reduction counseling. Patients are being educated on the need to seek care for symptoms and return to their providers if symptoms recur after treatment or do not resolve.

CDC is closely collaborating with WHO on its Gonorrhea Antimicrobial Susceptibility Project to develop a global strategic response plan and enhance laboratory sentinel surveillance. CDC is exploring the possibility of changing its 2010 gonorrhea treatment guidelines by removing oral cefixime as a recommended regimen. CDC will hold a follow-up meeting with the GISP Principal Investigators later in November 2011.

CDC is collaborating with partners to expand local and regional laboratory capacity for gonorrhea by developing better transport media and improving performance in extra-genital NAAT and AST/culture testing. Efforts are underway for CMS and health plans to reimburse for

both gonorrhea NAAT and culture testing when suspected treatment failure cases are evaluated.

CDC is collaborating with several partners to identify promising new treatment regimens for gonorrhea. NIH and CDC are conducting the Dual Therapy Clinical Trial to identify new combination options. NIH is mining the Department of Defense stockpile to identify possible new agents. IDSA added gonorrhea as a “qualifying pathogen” in its incentives legislation. CDC, FDA, NIH, industry and the Transatlantic Task Force on Antimicrobial Resistance are attempting to identify solutions to improve the antibacterial drug pipeline through task forces, incentives, and changes in existing infrastructures and regulations.

CDC developed the “U.S. Cephalosporin-Resistant Gonorrhea Response Plan” to provide extensive guidance in 3 major areas. For surveillance, CDC awarded funds to 5 GISP sites to add AST/culture testing to measure MICs at non-genital anatomic sites of gay/other MSM. Resistance may emerge in this population, particularly in the throat. The response plan also provides a working case definition of “cephalosporin-resistant gonorrhea.”

To improve surveillance, the response plan advises clinicians to report suspected treatment failures. Laboratories should report isolates with MICs ≥ 0.25 - 05 . $\mu\text{g/ml}$ for cefixime and ≥ 0.125 - 0.25 $\mu\text{g/ml}$ for ceftriaxone. Local surveillance capacity should be enhanced by maintaining or establishing the ability for AST/culture testing, reviewing duplicate case reports, and strengthening local sentinel site surveillance, including test-of-cure.

For clinical management of suspected cases, clinicians should maintain vigilance for treatment failures and conduct AST/culture testing if a suspected case is lower than the test-of-cure threshold. The response plan recommends the use of NAAT one week following treatment. Clinicians should immediately report cases to CDC and the local health department.

For cefixime treatment failures, the patient should be given 250 mg of intramuscular ceftriaxone and 2 g of oral azithromycin. For ceftriaxone treatment failures, an STD infectious disease expert should be consulted. Test-of-cure should be determined through AST/culture testing after the patient is retreated. Follow-up of partners should be assured, including culture testing and treatment according to treatment of the index case.

For public health management of suspected cases, vigilance should be maintained for treatment failures. A disease intervention specialist should initiate an investigation of suspected cases and the patient’s sexual partners and extended socio-sexual network as appropriate. CDC should be immediately notified.

Gonorrhea control and prevention efforts should be targeted and enhanced through screening and treatment with CDC’s recommended gonorrhea regimen, provision of partner services, and promotion of correct and consistent condom use. Case management should be prioritized with existing resources by discontinuing high-cost/low-impact STD prevention interventions.

Overall, cephalosporin-resistant gonorrhea is likely to occur in the United States, but significant challenges exist to respond to this threat. Efforts should be targeted to decreasing gonorrhea morbidity and developing an appropriate infrastructure to detect treatment failures and resistant strains; slow their spread and limit their complications; and increase the antimicrobial pipeline. Success in rebuilding the defense against gonorrhea will depend on a collaborative and collective effort through public/private partnerships.

In response to CHAC's specific questions, Dr. Bolan provided additional details on CDC's response to gonorrhea AMR. The discussion topics included:

- the possibility of administering a higher dose of ceftriaxone to overcome resistance;
- the need to prioritize the provision of solid educational tools to STD clinics due to their limited capacity and resources to administer parenteral therapy;
- the need for innovative strategies, structural interventions and systems approaches for providers to more easily screen men who are at increased risk for gonorrhea, particularly gay/other MSM;
- the need to launch a national campaign to educate and empower gay/other MSM to ask their providers for a gonorrhea test;
- development of a comprehensive and holistic package of services to simultaneously address the disproportionate burden of both HIV and gonorrhea in gay/other MSM;
- mechanisms to develop and distribute accurate, "non-hysterical" messages along with clear recommendations to both social and traditional media regarding the gonorrhea "superbug;"
- the need to prioritize rapid diagnostic tests to provide more tools for clinics to diagnose and treat STDs in a timelier fashion; and
- the need for federal agencies to establish strong partnerships with the pharmaceutical industry and biotechnology companies to increase their involvement, investment, interest and incentives (e.g., venture grants) in developing new AMR therapies of public health importance.

CHAC made a number of comments and suggestions for CDC, its federal partners and external groups to consider in the ongoing effort to respond to the urgent threat of gonorrhea AMR.

- The data Dr. Bolan presented regarding the urgent threat of gonorrhea AMR should be appropriately packaged and presented to diverse audiences for broader distribution and education. These groups include the Labor-HHS Appropriations Committee, Kaiser Family Foundation Media Task Foundation, National Black Gay Men's Advocacy Coalition, health reporters, community health workers, patient navigators, *USA Today*, cable news programs, and traditional/social media. Wide dissemination of these data most likely would have an impact on shifting "relatively regular" use of condoms among gay/other MSM to "consistent" use. The package of data should (1) clearly explain that most gonococcal infections of both the throat and rectum are asymptomatic and (2) describe complications and adverse health effects from untreated gonorrhea, particularly in HIV-positive persons. The federal agencies should sponsor a roundtable with these

groups in Washington, DC as an initial step in educating the media and traditional/non-traditional organizations.

- POZ and other social media outlets should explore the possibility of launching a campaign for PLWH and gay/other MSM to “grade” the performance of their healthcare providers, particularly in terms of testing that is offered during visits.
- CDC’s routine practice of releasing its STD Treatment Guidelines every 4 years is outdated. CDC should post more up-to-date and real-time STD data on its website each year.

Public Comment Session

Carl Schmid

Deputy Executive Director, The AIDS Institute

Mr. Schmid made the following comments for CHAC’s consideration. ACA’s transformation of HIV care, treatment and prevention will impact CDC, HRSA and other federal agencies. CDC’s primary focus is on preventing disease and various payers can reimburse certain preventive services under ACA. This important element of health reform can be very helpful in the prevention of HIV and other diseases.

CDC is undertaking both internal and external efforts to take advantage of new ACA authorities. Most notably, CDC held a consultation with external partners and is continuing its important dialogue with advocates, grantees and other groups on strategies to best implement the preventive components of ACA.

The primary purpose of preventive services is to expand access to health care and treatment, including HIV services. At this time, >500,000 low-income persons depend on the Ryan White Program for their care and nearly 200,000 persons rely on ADAP for lifesaving medications. A dependable system of care has been established with specialized providers, case workers, administrative staff and facilities. PLWH continue to rely on this system to receive HIV care and treatment.

Health reform will drastically change the existing system. Most Ryan White clients will access care and treatment services through Medicaid, while others will purchase health insurance through Exchanges. Most health reform changes will not occur until 2014, but some elements have already been implemented. Planning efforts are well underway to test the new system for persons with HIV and other conditions.

Mr. Schmid noted that The AIDS Institute (TAI) is concerned about the lack of dialogue and planning between HRSA and its external partners. Although HRSA’s studies and modeling activities are important, ongoing dialogues is a more critical need. TAI recommends that HAB form a small workgroup in which internal staff and external partners would collaborate to ensure seamless implementation of ACA to meet the needs of PLWH.

Formal implementation of ACA is scheduled for 2014, but several components of this effort are currently underway (e.g., the development of essential health benefits). In light of the current environment of limited resources, collaboration will play a significant role in planning for both ACA implementation in 2014 and reauthorization of the Ryan White Care Act in 2013; conducting new research on the effectiveness of treatment as HIV prevention; and continuing to conduct activities in support of NHAS.

Health reform can serve as a tremendous transformational moment, but the entire system of care for PLWH can be dismantled if appropriate actions are not taken. Significant changes will need to occur to navigate through this difficult process, address the great deal of angst in the public, and respond to the urgent need for leadership. Collaboration and coordination will be needed to fill voids in these areas.

CHAC Business Session

Antigone Hodgins Dempsey MEd, CHAC co-Chair

Deputy Director, Knowledge, Transfer and Technical Assistance
HIV/AIDS Lead, Altarum Institute

Edward Hook III, MD, CHAC co-Chair

Director, Division of Infectious Diseases
University of Alabama at Birmingham

Ms. Hodgins Dempsey and Dr. Hook opened the business session and called for CHAC's review, discussion or formal action on the following topics.

ISSUE 1: Ms. Hodgins Dempsey entertained a motion for CHAC to approve the previous meeting minutes. A motion was properly placed on the floor and seconded by Dr. André Rawls and Rev. Debra Hickman, respectively, for CHAC to approve the previous meeting minutes. **CHAC unanimously adopted the Draft May 10-11, 2011 Meeting Minutes with no changes or further discussion.**

ISSUE 2: The following motion was properly placed on the floor and seconded by Drs. Kenneth Mayer and Carol Brosgart, respectively.

CHAC recommends the formation of a new workgroup with representation by CHAC, PACHA, CDC, HRSA and NIH to review the evidence on how treatment as prevention can be optimized in the United States. The workgroup's review of the evidence should include efforts to increase testing, engage at-risk persons in care, retain persons in care, strengthen PWP activities, and determine optimal PrEP utilization. The workgroup's charge should include considering innovative models and strategies to increase treatment that have been successfully implemented outside the United States (e.g.,

nurse-based models in Africa). To fulfill its charge, the workgroup should listen to focused presentations in between CHAC meetings, identify impediments in existing initiatives to address these goals, and make recommendations for presentation to the full CHAC membership. The workgroup's major deliverable should be the development of an evidence-based position paper with clearly defined objectives, goals, activities and timelines to the federal agencies to reduce the number of new HIV transmissions. After CHAC's formal ratification, the position paper should be submitted to the HHS Secretary, CDC Director and HRSA Administrator for action. **CHAC unanimously approved the resolution.**

ISSUE 3: The following motion was properly placed on the floor and seconded by Drs. Steven Johnson and Kathleen Clanon, respectively.

CHAC recommends that CDC and HRSA establish a new interagency workgroup to provide nimble and ongoing guidance. CDC and HRSA should provide increased TA to current HIV care organizations, including HRSA-funded Ryan White Programs, to ensure a seamless transition to care in anticipation of ACA implementation. This effort should result in the development and dissemination of a template or tool with a step-wise approach for CDC-/HRSA-funded CBOs to prepare for ACA implementation. The TA activities should cover PCP designation; principal care provider designation (e.g., providers without a formal PCP designation, but who have an interest in continuing primary HIV care); PCMH designation; and FQHC designation. AETCs should be engaged in this interagency effort to provide TA to the field at the local level. The interagency workgroup should review chronic disease models in its activities.

CHAC approved the resolution by a majority vote with 1 abstention (Mr. Ernest Hopkins). Agreement was reached for CDC and HRSA to convene a conference call with a subgroup of CHAC members, PACHA members and outside experts to refine the language of this resolution in order to provide more concrete guidance to CDC and HRSA before the new interagency workgroup is established and formally charged.

ISSUE 4: The following motion was properly placed on the floor and seconded by Drs. Carol Brosgart and André Rawls, respectively.

BPHC should collaborate with HAB, CDC, CMS and other federal partners to ensure CDC's HIV, HBV and HCV screening recommendations are used to create relevant performance measures for use in FQHCs, federally-funded sites and programs, and CBOs that also provide HIV, HBV and HCV testing. **CHAC unanimously approved the resolution.**

ISSUE 5: The following motion was properly placed on the floor and seconded by Dr. Jeanne Marrazzo and Mr. Ernest Hopkins, respectively.

CHAC strongly endorses the ongoing activities of the Sexual Health Workgroup. CHAC recommends continued escalation or scale-up of the sexual health activities, specifically

with a focus on developing and implementing packages of interventions for appropriate populations and settings as well as indicators for application across the lifespan. The interventions and indicators should be designed to provide optimal sexual health care, normalize the dialogue around sexual health, and measure the impact of the Sexual Health Plan. The recommendation acknowledges that additional PCPs and federally-funded Health Centers will assume more responsibility for HIV/STD-related care in the future. **CHAC unanimously approved the resolution.**

ISSUE 6: The following motion was properly placed on the floor and seconded by Mr. Ernest Hopkins and Rev. Debra Hickman, respectively.

CHAC agrees to collaborate with PACHA in communicating the progress and activities of the Sexual Health Workgroup to the HHS Secretary, CDC Director and HRSA Administrator. CHAC recommends that HHS, CDC and HRSA leadership support and disseminate messages regarding the importance of a public health approach to advance sexual health in the United States. **CHAC unanimously approved the resolution.**

ISSUE 7: Ms. Hodgins Dempsey led CHAC in a review of future action items.

- CHAC's mission, purpose, meeting outcomes and other activities should be much more widely publicized, particularly among communities and other relevant external bodies that would benefit from this information. CHAC agreed that 3 actions should be taken in this effort.
 - All PowerPoint slide sets and background materials that are presented or made available during meetings will be available on the CDC and HRSA websites for CHAC members to disseminate to their respective organizations and constituents.
 - A summary of the CHAC business session (e.g., consensus recommendations, action items and future agenda items) will be circulated for the members to use as talking points with their respective organizations and constituents.
 - A 1-hour conference call will be convened to discuss using blogs, tweets and other media/technology to raise the profile of CHAC meetings and critically consider additional options to increase public engagement. The conference call participants will include the CHAC Designated Federal Officials (Kevin Fenton and Deborah Parham Hopson or her replacement); CHAC co-Chairs (Antigone Hodgins Dempsey and Edward Hook or his replacement); and CHAC members (Debra Hickman or her replacement, Regan Hofmann, Ernest Hopkins and André Rawls).
- CDC and HRSA should explore 3 research priorities suggested by CHAC:
 - a study on the impact of HIV/AIDS on undocumented immigrants and families with mixed documentation status;
 - a study on the potential of using community health workers (*promotores*) to recruit persons from underserved populations to participate in PEP, PrEP and microbicide trials; and
 - the development of bold targets and a review of existing training and service delivery modules that would achieve maximum viral suppression.

Agreement was reached that as part of its charge, the new “Treatment as Prevention” Workgroup would explore and discuss strategies to implement CHAC’s 3 suggested research priorities.

ISSUE 8: Ms. Hodgins Dempsey opened the floor for CHAC to propose changes to improve the format and organizational structure of future CHAC meetings.

- The Public Comment Session should be held on day 1 rather than on day 2 of the meeting.
- The floor should be opened for CHAC members to place formal motions on the floor after each presentation rather than at the end of the meeting on day 2. The business session on day 2 of the meeting should be reserved for CHAC to propose any additional resolutions.
- The number of presentations should be decreased and the content of presentations should be shortened. For topics that do not require formal action by CHAC, information should be distributed to the members in advance of meetings for review. For topics that will require formal action by CHAC, presentations made during meetings should be limited to key points to allow for more discussion. Each presentation should end with specific questions or take-home messages for CHAC to discuss, formulate guidance, and provide expertise and support as an advisory body. The speakers should structure and focus their presentations on the diverse scientific backgrounds and community interests of the CHAC members.
- CHAC members should be assigned as primary reviewers of presentations that will be made during meetings based on their individual backgrounds, interests and areas of expertise. During meetings, the primary reviewers should lead CHAC’s discussions on gaps, unmet needs and other key areas of the presentations.
- CHAC meetings should be restructured to have a more equal balance between presentations from science-based and community-based perspectives. To achieve this goal, CHAC should be represented by more community-based members. The meeting agendas should include more presentations by community members and external experts outside of CDC and HRSA to enrich discussions and provide more diverse perspectives.
- A process should be developed for workgroups to report back to CHAC in a timelier and more structured manner. For example, summaries of workgroup conference calls/ meetings and background materials used by the workgroup should be distributed in advance of meetings to facilitate CHAC’s actions, ratification and decision-making.

ISSUE 9: Ms. Hodgins Dempsey led CHAC in a review of presentations, overviews or updates that were proposed as future agenda items.

CDC

- Presentation on the increasing number of sexually-acquired HCV cases, including current knowledge and effective prevention interventions.
- Presentation by the NCHHSTP-PCSI Team on models and systems with demonstrated success in integrating sexual health, HIV and STD.

HRSA

- Presentation on TA that will be provided to federally-funded clinics on HBV and HCV screening, surveillance, diagnosis and treatment in collaboration with CDC.
- Overview of NHSC by Ms. Rebecca Spitzgo, Associate Administrator of the Bureau of Clinician Recruitment and Service & Director of NHSC.

Interagency/External Presenters

- Panel presentation on expanded HBV and HCV testing as part of VHAP. The following topics should be covered in the panel presentation:
 - IDU rates in different parts of the country and their relationship to prescription opiate use;
 - late diagnosis of chronic hepatitis;
 - overview by HRSA/United Network for Organ Sharing on liver transplants and the proportion of these cases due to HBV and HCV;
 - current HBV and HCV trends;
 - the proportion of patients diagnosed after presenting with end-stage liver disease;
 - overview of CDC's internal efforts in developing models for a viral hepatitis surveillance system and the potential cost of the system; and
 - overview by the National Cancer Institute's Surveillance, Epidemiology and End Results Program on hepatocellular carcinoma.
- Overview of a "real-world" model in implementing retention in care activities in the field.
- Presentation on the new HIV testing modality that will be approved in December 2011, including training and certification CDC, HRSA and the pharmaceutical industry will require of various jurisdictions.
- Presentation on HIV/HCV and the relationship of these diseases with domestic violence across genders and sexuality.
- Presentation on the relationship between STDs and post-traumatic stress disorder among military personnel returning from combat.
- Presentation by SAMHSA on its ongoing capacity building, training and TA activities related to ACA implementation.
- Update on the CDC and HRSA NHAS implementation plans that specifically address HIV-related stigma. (The PACHA/CHAC HIV Disclosure Workgroup should be included in this panel presentation.)
- Presentation by Paul Volberding, chair of the IOM Committee on HIV Care Data Systems. (The IOM Committee will release a report in February or March 2012 on using data systems to monitor and measure HIV care.)

Closing Session

Dr. Hook emphasized that he was privileged and honored to serve on CHAC as both a member and co-Chair. He encouraged the members to continue their important and outstanding efforts to improve HIV/STD prevention and treatment in the United States. Rev. Hickman thanked CDC and HRSA for providing her with an opportunity to serve on CHAC. She had no doubt that CHAC would continue to conduct excellent activities in the future.

The next CHAC meeting will be held on May 8-9, 2011 or May 15-16, 2011 in Atlanta, Georgia. The CHAC Committee Management Specialist will poll the members via e-mail to confirm the date.

With no further discussion or business brought before CHAC, Ms. Hodgins Dempsey adjourned the meeting at 3:08 p.m. on November 16, 2011.

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

Date

Antigone Hodgins Dempsey, MEd, Co-Chair
CDC/HRSA Advisory Committee on
HIV and STD Prevention and Treatment

Date

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