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 May 20-21, 2008 Atlanta, Georgia

Record of the Proceedings

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ATTACHMENT 1

List of Participants

CHAC Members

Dr. Edward Hook III, Co-Chair Dr. Donna Sweet, Co-Chair Dr. Bruce Agins Ms. Renee Austin Ms. Theresa Devlin Ms. Evelyn Foust Dr. Fernando Garcia Rev. Debra Hickman Mr. Thomas Liberti Mr. Harold Phillips Dr. Lydia Temoshok Dr. Nathan Thielman Ms. Lisa Tiger Dr. Carmen Zorrilla

CHAC Ex-Officio Representatives

Dr. Pradip Akolkar (FDA) Dr. William Grace (NIH) Dr. John Redd Ms. Beverly Watts Davis (SAMHSA)

Designated Federal Officials

Dr. Kevin Fenton (CDC) Dr. Deborah Parham Hopson (HRSA)

HHS, CDC and HRSA Representatives

Ms. Rheta Barnes Mr. Rashed Burgess Dr. Terence Chorba Ms. Janet Cleveland Dr. Samuel Dooley Dr. John Douglas, Jr. Ms. Cindy Getty Ms. Shelley Gordon Ms. Gena Hill Dr. Matthew Hogben Ms. Alexis Kaigler Ms. Cindy Lyles Ms. Eva Margolies Ms. Eva Margolies Ms. Amy Pulver Mr. Raul Romaguera Ms. Margie Scott-Cseh Ms. Jenny Sewell Dr. Madeline Sutton Dr. Stephen Thacker Dr. John Ward Dr. Howell Wechsler

Dr. Richard Wolitski

Guest Presenters and Members of the Public

- Ms. Lynn Barclay (American Social Health Association)
- Mr. Rudy Carn (National Black Gay Men's Advocacy Coalition)
- Mr. Robert Carroll (Northwest AIDS Education and Training Center)
- Ms. Donna Gallagher (New England AIDS Education and Training Center)
- Ms. Felicia Guest (Southeast AIDS Education and Training Center)
- Ms. Coco Jervis (Community HIV/AIDS Mobilization Project)
- Ms. Ann Lefert (National Alliance of State and Territorial AIDS Directors)
- Dr. Melissa Osborn (Emory University)
- Mr. Charles Stephes (AID Atlanta)
- Mr. Darren Webb (OraSure Technologies)

ATTACHMENT 2

Acronyms Used in These Meeting Minutes

AAs	—	African Americans
AAC	—	AIDS Action Council
ADAP	—	AIDS Drug Assistance Program
AETCs	—	AIDS Education and Training Centers
BITCs	—	Behavioral Interventions Training Centers
BSC	—	Board of Scientific Counselors
CBOs		Community-Based Organizations
CCID		Coordinating Center for Infectious Diseases
CDC	—	Centers for Disease Control and Prevention
CHAC	—	CDC/HRSA Advisory Committee on HIV and STD Prevention and
		Treatment
CHCs	—	Community Health Centers
CLTCs	—	Clinical and Laboratory Training Centers
DEBI	—	Diffusion of Effective Behavioral Interventions
DFO	—	Designated Federal Official
DHAP	—	Division of HIV/AIDS Prevention
DSTDP	—	Division of STD Prevention
DVH	—	Division of Viral Hepatitis
4TC	—	4 Training Centers
GAO		Government Accountability Office
GAP		Global AIDS Program
HAB		HIV/AIDS Bureau
HAV		Hepatitis A Virus
HBV		Hepatitis B Virus
HCV		Hepatitis C Virus
HHS		Department of Health and Human Services
HNR	—	Heightened National Response
HPV		Human Papillomavirus
HRSA		Health Resources and Services Administration
HSV		Herpes Simplex Virus
IDUs		Injection Drug Users
MAI		Minority AIDS Initiative
MMWR	—	Morbidity and Mortality Weekly Report
MSM		
NASTAD	—	National Association of State and Territorial AIDS Directors
NCHHSTP		National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NIH		National Institutes of Health
NNPTC	—	National Network of STD/HIV Prevention Training Centers
OWCD	—	Office of Workforce and Career Development
PCSI		Program Collaboration and Service Integration
PEPFAR		President's Emergency Plan for AIDS Relief
POL		Popular Opinion Leader
PSPSTCs		Partner Services and Program Support Training Centers
PTB		Program and Training Branch
SAMHSA		Substance Abuse and Mental Health Service Administration

- SONI
- Severity of Need Index
 Special Projects of National Significance
 Sustained Virologic Response
 "Many Men, Many Voices" SPNS
- SVR
- 3MV
- U.S. Government USG
- Women, Infants, Children and Youth WICY

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 May 20-21, 2008 Atlanta, Georgia

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 J.W. Marriott Buckhead Hotel in Atlanta, Georgia on May 20-21, 2008.

Opening Session

Drs. Edward Hook III and Donna Sweet, co-Chairs of CHAC, called the meeting to order at 8:40 a.m. on May 20, 2008 and welcomed the attendees to the proceedings. The list of participants is appended to the minutes as <u>Attachment 1</u>.

Dr. Hook entertained a motion for CHAC to approve the previous draft meeting minutes. Dr. William Grace, CHAC's *ex-officio* member representing the National Institutes of Health (NIH), turned CHAC's attention to a sentence on page 4 of the minutes: "HRSA should require the inclusion of 10% of the HIV/hepatitis co-infected population in hepatitis C research."

Dr. Grace proposed changing the sentence with the following language: "HRSA should require that 10% of its research samples in studies addressing persons with hepatitis C virus (HCV) be persons with HIV/HCV co-infection."

A motion was properly placed on the floor and seconded by Drs. Agins and Garcia, respectively, to accept the previous meeting minutes with Dr. Grace's proposed change. CHAC **unanimously approved** the "Draft November 15-16, 2007 Meeting Minutes" as amended with no further changes or discussion.

Dr. Kevin Fenton, Director of the CDC National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) and the CHAC Designated Federal Official (DFO) for CDC, reminded the participants that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record.

Dr. Fenton also advised CHAC members to be mindful of potential conflicts of interest identified by the CDC or HRSA Committee Management Office and to recuse themselves from participating in discussions or voting on issues in which they have a real or perceived conflict of interest.

Dr. Fenton announced that the terms of four CHAC members representing CDC would expire in November 2008: Ms. Theresa Devlin, Mr. Aaron Shirley, and Drs. Nathan Thielman and Lydia Temoshok. The outgoing members would be formally recognized for their outstanding service during the next CHAC meeting.

Dr. Deborah Parham Hopson, Associate Administrator of the HRSA HIV/AIDS Bureau (HAB) and the CHAC DFO for HRSA, announced that the terms of five CHAC members representing HRSA would expire in June 2008: Ms. Renee Austin, Mr. Thomas Liberti, and Drs. Fernando Garcia, Dorothy Brewster Lee and Carmen Zorrilla. Dr. Parham Hopson asked the five CHAC members to continue to serve until their replacements had been appointed.

Update by the CHAC Co-Chairs

Dr. Sweet confirmed that CHAC's action items from the November 2007 meeting were given to Drs. Fenton and Parham Hopson to be forwarded to Dr. Julie Gerberding, Director of CDC, and Dr. Elizabeth Duke, Administrator of HRSA.

Dr. Hook pointed out that Drs. Gerberding and Duke jointly signed a letter dated February 26, 2008 in response to a letter from the CHAC Co-Chairs dated August 6, 2007. He highlighted the key points of the response letter.

- CHAC was commended for assisting CDC in its HIV and STD prevention efforts and also for providing guidance in revising and extending the CDC HIV Prevention Strategic Plan Through 2005.
- CHAC's recommendation to support the development of a multi-sectoral national plan for HIV/AIDS in the United States would be conveyed to and discussed with the HHS Secretary.
- CHAC was informed that increases in funding for domestic HIV activities were included in the President's FY'07 and FY'08 budgets and were submitted to Congress.
- CHAC was informed that HRSA would make efforts to develop cost projections for providing adequate prevention, treatment and care services in 2008 and 2009.

Dr. Hook noted that the joint letter by Drs. Gerberding and Duke did not respond to CHAC's repeated recommendation for an integrated and coordinated federal approach to care and management of persons with and at risk for HIV.

Dr. Hook announced that he recently represented CHAC during the CDC Coordinating Center for Infectious Diseases (CCID) Board of Scientific Counselors (BSC) meeting in May 2008. The BSC Workgroup for NCHHSTP focused on integration among HIV/AIDS, viral hepatitis, STDs and TB. Dr. Hook applauded CDC's continued efforts to better integrate these program areas and he asked CHAC to provide input on this activity in the future.

CDC Update

Dr. Fenton reported on CDC's ongoing activities at the agency, coordinating center and national center levels. At the <u>agency level</u>, Dr. Gerberding recently announced a strategic initiative for CDC that aims to make the United States one of the healthiest nations in the world.

To implement the new initiative, CDC, the Association of State and Territorial Health Officials, and the National Association of County and City Health Officials formed a "Healthiest Nation Alliance" in 2007 to emphasize the critical need for the United States to change its fundamental strategic imperative and make more investments to protect health through health promotion, prevention of disease, injuries, disabilities, and preparedness for new threats.

Dr. Gerberding stated that health must be the default choice of all persons and communities for the United States to become one of the healthiest nations in the world. CDC will make efforts to ensure that other nations achieve the same goal. Dr. Gerberding also emphasized that the creation of better values in the U.S. health system is a strategic national imperative to sustain economic success and national security.

CDC's Healthiest Nation Initiative will include at least six key activities. The "vision will be expanded" in collaboration with partners to create a clear and compelling vision that motivates persons and organizations to support a true health system. "Leaders will be empowered" by collaborating with current and new partners to assist in leading and aligning efforts. "Persons will be energized" by creating excitement among individuals and employees.

"Health will be enacted in all policies" by creating opportunities to integrate health issues into social policies, across sectors and at all levels. "Health protection goals will be executed" to achieve greater health impact by focusing on the priorities of CDC's health protection goals portfolio and addressing priorities and needs outlined in CDC's goal action plans. "Health will be evaluated" by defining and measuring health and health value for persons, families, communities, organizations, states and the nation.

CDC formed an internal "Healthiest Nation Coordination Council" to develop, coordinate and implement a cohesive and timely operational plan for accelerating the Healthiest Nation Initiative. CDC will identify a senior coordinator to lead the Coordination Council.

At the <u>coordinating center level</u>, the CCID BSC convened a meeting earlier in May 2008. The BSC Workgroup for NCHHSTP focused on Program Collaboration and Service Integration (PCSI) and made recommendations regarding investments to evaluate the effectiveness of PCSI; operational research to evaluate rapid point-of-service screening tests; and investments to integrate health communications. The workgroup also advised NCHHSTP to explore integrated communication messages of HIV testing for specific subpopulations and validate PCSI through various evaluation strategies, such as a proof of concept trial.

CCID is currently drafting its FY'09 strategic priorities for infectious disease prevention and control. NCHHSTP will have responsibility for two of the ten cross-cutting strategic priorities: (1) reduce health disparities in HIV, viral hepatitis, STDs and TB and (2) eliminate acute hepatitis B virus (HBV) transmission in the United States.

At the <u>national center level</u>, NCHHSTP is continuing to develop priorities for FY'08 to address its strategic imperatives of increasing PCSI, reducing health disparities and maximizing global synergies. NCHHSTP will conduct several activities to achieve its priorities. A PCSI white paper with research priorities will be published. The first integrated surveillance report will be published to provide guidance on the overlap and intersection among HIV, STDs, TB and viral hepatitis in the U.S. population. A PCSI national mobilization plan has been developed and will be implemented from FY'08-FY'10.

Dr. Fenton will continue his Director's site visits to rural states and U.S. territories to focus on the integration of HIV, STD, TB and viral hepatitis. A green paper will be published on reducing health disparities by tracking social determinants of health. Communications with external partners will be strengthened by developing new systems, such as a Director's blog and other electronic mechanisms.

Meta-leadership for prevention will be heightened across federal agencies. The *NCHHSTP* 2020 Strategic Plan will be completed and published by the fall of 2008. Opportunities for strategic partnerships for prevention will be identified. NCHHSTP recently published and posted the *PCSI Consultation Report* on its web site.

In terms of NCHHSTP's senior leadership, Dr. Hazel Dean was recently appointed as the new Deputy Director of NCHHSTP and Dr. Sal Butera was recently appointed as the Associate Director for Laboratory Sciences. Dr. Robert Janssen, former Director of the NCHHSTP Division of HIV/AIDS Prevention (DHAP), recently retired from CDC. Dr. Richard Wolitski and Ms. Janet Cleveland will rotate as acting DHAP Directors for six-month periods. Dr. Fenton will form a search committee with both CDC staff and external colleagues to expedite permanently filling this position.

NCHHSTP has made a number of accomplishments since the November 2007 CHAC meeting. DHAP convened the first Latino/Hispanic consultation in April 2008 with ~110 community leaders and representatives of institutions that serve these populations. The consultation provided a forum for the participants to analyze multiple issues that influence the trajectory of HIV/AIDS among Latinos/Hispanics, including the epidemiology, current evidence-based interventions, social and cultural factors, best prevention practices, and challenges and opportunities.

The consultation played a key role in NCHHSTP's ongoing efforts to develop a more culturally competent approach to prevention with Latino/Hispanic communities in the United States. NCHHSTP looks forward to receiving solid recommendations from the consultation to enhance prevention programs for this population. All states have now adopted confidential and name-based HIV reporting to provide CDC with more complete and consistent data on the HIV epidemic in the United States.

NCHHSTP will sponsor a community mobilization meeting for the "Heightened National Response (HNR) to the HIV/AIDS Crises in the African American (AA) Community." The meeting will provide a forum for partners who have been involved with this activity over the past year to begin planning and developing programs for the HNR over the next two years.

NCHHSTP plans to release the first *Integrated Partner Service Guidelines* by the fall of 2008. The guidelines will have implications for both HIV and STD prevention programs. STD Prevention Training Centers will assess the capacity of programs to implement the guidelines, identify strategies to enhance communication, and provide technical assistance and training.

The NCHHSTP Division of STD Prevention (DSTDP) convened a Chlamydia Immunology Consultation in April 2008 with experts from around the world to discuss the natural history and immune response to chlamydia trachomatis to better inform chlamydia control programs. Recommendations from the consultation will assist DSTDP in further refining its chlamydia screening priorities.

DSTDP held the National STD Prevention Conference in March 2008 to present updates on STD prevention science and programs. The conference received national media coverage, particularly a study that demonstrated one in four females 14-19 years of age in the United States are infected with at least one of the most common STDs: human papillomavirus (HPV), chlamydia, herpes simplex virus (HSV) and trichomoniasis. The study was the first research project to examine the combined national prevalence of common STDs among adolescent females in the United States and provide a clear picture of the overall STD burden in this population.

The NCHHSTP Division of Viral Hepatitis (DVH) collaborated with partners to investigate an HCV outbreak in an endoscopy clinic in Las Vegas, Nevada. DVH determined a genetic link among the cases and identified the source as unsafe injection practices, particularly the reuse of syringes and the use of single-use medication vials with multiple patients.

In response to the outbreak, ~40,000 patients will be notified of their potential exposure to blood-borne pathogens, including HCV, HBV and HIV infection. The initial investigation did not detect any cases of HBV or HIV transmission, but the outbreak emphasized the importance of viral hepatitis surveillance in detecting disease transmission.

On May 30, 2007, the President announced his intention to collaborate with Congress to reauthorize the President's Emergency Plan for AIDS Relief (PEPFAR). The five-year \$30 billion proposal will be an addition to the initial \$15 billion commitment the U.S. government (USG) made in 2003. The ten-year PEPFAR goals are to treat 2.5 million persons; prevent >12 million new HIV infections; and provide care to >12 million persons, including 5 million orphans and vulnerable children.

The new PEPFAR plan will expand current activities; increase efforts to leverage programs that address malaria, TB, child and maternal health, education, clean water, and food and nutrition; and strengthen health systems and sustain outcomes. USG resources and other commitments will be used to strengthen partnerships in countries that are dedicated to fighting the HIV epidemic.

Partnership compacts will be guided by two key principles: (1) increase and combine resources of various partners according to economic capacity to achieve PEPFAR reauthorization goals and (2) implement policies and practices to optimize the effectiveness of resources in key areas. Overall, PEPFAR II will take a more holistic and integrated approach to HIV prevention in PEPFAR countries and place stronger emphasis on partnership compacts. Congress is still considering the reauthorization of PEPFAR at this time.

NCHHSTP's FY'08 enacted budget is nearly \$1 billion and is relatively flat compared to previous years. NCHHSTP allocates 69% of its total budget to domestic HIV prevention activities, 15% to STD prevention programs, 14% to TB prevention and control, and 2% to hepatitis prevention. The Global AIDS Program (GAP) budget increased from \$1.1 billion in FY'07 to >\$1.4 billion in FY'08.

NCHHSTP's proposed FY'09 budget for domestic activities is ~\$1 billion and reflects a decrease of ~\$2.1 million from the FY'08 enacted budget. The proposed FY'09 budget includes the following allocations: (1) \$691 million for HIV prevention (a decrease of ~\$713,000); (2) \$17.5 million for viral hepatitis (a decrease of ~\$78,000); (3) \$151.7 million for STD prevention (a decrease of \$678,000); and (4) \$139.7 million to TB (a decrease of ~\$624,000). The proposed FY'09 budget includes \$118.7 million to GAP for international activities.

Dr. Fenton and the Indian Health Service made a joint site visit to the Navajo and Tohono O'Odham Nations and state and local public health programs in Arizona and New Mexico to explore PCSI activities in these jurisdictions and identify challenges in integrating local programs, particularly in rural parts of the Southwest. The agencies were impressed by creative strategies the programs have developed and implemented to reduce health disparities in Native persons.

NCHHSTP recently published its *FY'07 Annual Report* to highlight accomplishments and provide information on the NCHHSTP budget, priorities and performance indicators. The report is available on the NCHHSTP web site.

Dr. Fenton provided additional details on CDC's ongoing activities in response to specific questions posed by the CHAC members.

- Clinical protocols are being created and implemented in collaboration with host countries to evaluate and monitor the development and spread of antiretroviral resistance in PEPFAR countries and improve the clinical management of patients. PEPFAR countries have identified regional and national networks to assess antiretroviral resistance. However, more efforts are needed to monitor primary acquisition of resistant strains of the virus and systematically evaluate persons who fail on first-line therapy and are placed on second-line therapy. Opportunities are being explored to conduct research and compile data from all PEPFAR countries on specific issues, including the emergence and management of antiretroviral resistance. CDC is leading these efforts, but is partnering with local health systems, universities and governments to conduct antiretroviral resistance research in the PEPFAR countries.
- CDC has strengthened its collaborations with the Substance Abuse and Mental Health Service Administration (SAMHSA) to implement recommendations that were made in 2006 for substance abuse programs to implement HIV testing recommendations. NCHHSTP has convened workgroups with internal colleagues in CDC and external partners in other federal agencies and community-based organizations (CBOs) to support this effort.
- CDC is collaborating with federal partners for HRSA community health centers (CHCs) to implement HIV testing recommendations and play a stronger role in infectious disease prevention. Drs. Fenton and Parham Hopson would attempt to provide CHAC with more details on the activities of CHCs in these areas on the following day.
- CDC is currently reviewing applications that are eligible to receive funding under the Coburn Amendment. Under this grant, funding will be allocated to states and territories that have adopted specific HIV testing policies, such as opt-out testing of pregnant women, universal testing of newborns, and opt-out testing in STD clinics and substance abuse treatment centers. Funding to eligible jurisdictions under this grant will be capped at \$1 million and will be based on specific criteria, such as AIDS case rates, syphilis rates and numbers of new births in each locality. CDC expects to award grants under the Coburn Amendment by the end of May 2008.
- Data from states that have recently adopted confidential and name-based HIV reporting might not be released for three to five years depending on the size of the state. Before data can be included in CDC's national system, a maturation period is required to collect retrospective data from states and assure the operation of each state system. CDC expects to have comprehensive HIV data from all 50 states in five years' time.

CHAC commended CDC on its continued efforts to strengthen program and service integration. Several members made comments and suggestions for CDC to consider in refining its ongoing and future prevention activities.

- Surveillance systems in the United States have not received additional core funding from CDC in more than ten years and are in danger of generating lower-quality data if new investments are not made in this area.
- States, programs and other grantees are extremely challenged in advancing PCSI at the local level due to federal bureaucracies from the CDC Procurement and Grants Office and the HHS Office of Inspector General. Advocacy and education to federal funding and oversight agencies must be strengthened to emphasize the critical need to integrate HIV prevention and care resources. For example, HIV care dollars could be used for screening of both HIV-positive and HIV-negative persons. HIV prevention dollars could be used for syphilis, gonorrhea and chlamydia treatment. HIV prevention or care dollars could be used to increase outreach, particularly in rural Southern states, to re-enroll and maintain HIV-positive persons in care.
- The decrease in NCHHSTP's proposed FY'09 budget and cuts in other federal funding will require states, programs and other grantees to continue to conduct more prevention activities with less resources. Most notably, Medicare payments for primary care are scheduled to be cut by 10.9% beginning on July 1, 2008. Medicare funds a large percentage of HIV care, but the number of primary care providers with a willingness to provide care to Medicare patients will plummet after the 10.9% decrease goes into effect. CHAC should convey a strong message to the HHS agencies of the need to allocate new prevention and care funding rather than shift or divert current dollars.
- The Coburn Amendment grants will result in an unintended consequence of increasing health disparities, particularly in states with fewer resources.
- The Latino/Hispanic consultation did not resolve the disconnect between the expectations of the invited participants and CDC. Most notably, CDC did not appear to recognize the sense of urgency and concern of the HIV/AIDS epidemic in the Latino/ Hispanic community, clearly describe next steps based on outcomes of the consultation, or articulate next steps and future plans to advance this initiative.
- CDC's major HIV testing initiative targeted to AAs most likely will not change behaviors in emergency rooms, CHCs, substance abuse treatment centers and other sites if funding for HIV testing is discontinued. The testing initiative has made an impact on detecting new HIV-positive persons, but capacity to link these individuals to primary care might decrease.
- NCHHSTP should invite new grantees to the upcoming community mobilization meeting for the "HNR to the HIV/AIDS Crises in the AA Community," particularly representatives from ten Southern states who were awarded funding under this initiative.
- DVH should compile and widely distribute lessons learned from the HCV outbreak in the Las Vegas endoscopy clinic to states.
- CDC should strengthen its emphasis on prevention of antiretroviral resistance globally by focusing on issues related to infrastructure, transportation, nutrition, access to care and adherence in PEPFAR countries.

HRSA Update

Dr. Parham Hopson covered the following areas in her update. The Special Projects of National Significance (SPNS) initiative is funded at \$25 million each year to support 10-15 grants in each of the five-year programs. An FY'08 initiative addressed the SPNS mandate to increase the capacity of Ryan White HIV/AIDS Program grantees to report client-level data to the HHS Secretary. Parts A and B grantees will be awarded one-year funding under this initiative. HAB funded two new SPNS initiatives in September 2007: "Enhancing Linkages to HIV Primary Care in Jail Settings" and "Electronic Networks of Care."

HAB is continuing three existing SPNS initiatives: "Integrating Buprenorphine Opioid Abuse Treatment in HIV Primary Care Settings;" Outreach, Care and Prevention to Engage HIV Seropositive Young Men Who Have Sex With Men (MSM) of Color;" and "Innovations in Oral Health Care." HAB is currently developing a comprehensive and structured SPNS initiative to engage and retain HIV-positive women of color in care. Formative research is underway to inform the development of guidance for the initiative that will be implemented in FY'09.

HAB developed the Quality Academy as an online modular learning program on quality improvement in HIV care. The Quality Academy is available on the Internet 24 hours/day-7 days/week at no cost. The 20 Quality Academy tutorials provide guidance on defining quality improvement, understanding the Ryan White Program, clarifying expectations for quality, accessing quality improvement resources, collecting and using performance data, and leading a quality initiative. The Quality Academy is available on the web site of the National Quality Center at <u>www.nationalqualitycenter.org</u>.

HAB released clinical performance measures for input and revised and finalized group 1 of the measures in December 2007 based on 900 comments that stakeholders submitted in April 2007. HAB is currently revising the next set of core measures and will develop new measures for dental and case management services under the AIDS Drug Assistance Program (ADAP). The draft clinical performance measures for ADAP will be released for public comment.

Dr. Parham Hopson reported on HAB's progress in conducting activities under the Ryan White reauthorization. HAB awarded the majority of Ryan White grants in FY'08 and will award additional grants in July-September for Parts A, B, C, D and F: Minority AIDS Initiative (MAI); Early Intervention Services; Women, Infants, Children and Youth (WICY); AIDS Education and Training Centers (AETCs); Dental Services; and SPNS.

HAB is conducting three policy studies to examine legislative changes that resulted from the 2006 reauthorization. The studies are focusing on the impact of reauthorization on core medical services, funding shifts to other jurisdictions, and eligibility determination. The Government Accountability Office (GAO) is currently conducting two studies to (1) evaluate the use of WICY administrative expenses under Part D and (2) assess barriers to program integration of the MAI across all Ryan White grantees. Both of the GAO studies are scheduled to be completed by December 2008.

HAB has improved its technical assistance and communication with grantees. The Technical Assistance Resources, Guidance, Education and Training Center is an online tool that provides examples and other resources to grantees, such as guidance on establishing a better tracking system. Peers are available to provide one-on-one technical assistance to grantees on specific issues. Grantees also can obtain information from HAB by e-mail.

The 2006 reauthorization required Parts A, B and C grantees to spend 75% of funding on 13 core services. However, core services waivers were granted in November 2007 and April 2008 to any jurisdiction that made this request so long as the grantee certified the availability of services to all persons with HIV in the jurisdiction and validated the absence of an ADAP waiting list. HAB plans to improve the waiver process in 2009 by increasing the burden of proof to ensure that all persons with HIV have access to the 13 core services.

HAB launched the severity of need index (SONI) web site on December 1, 2007 and presented SONI to its national partners, Parts A and B grantees, the AIDS Action Subcommittee, and the Domestic Subcommittee of the President's Advisory Council of HIV and AIDS. HAB will describe the SONI data components during the Ryan White All Grantee Meeting in August 2008 and also will finalize and present SONI to Congress later in 2008.

Congress required HAB to use SPNS funds to develop a client-level data system and show that expenditures of Ryan White dollars are matched to services for subpopulations. To fulfill this requirement, HAB presented its draft client-level data system to stakeholders during 12 regional meetings and revised the system based on comments and suggestions that were submitted.

HAB is currently developing a unique patient identification number algorithm and encryption method to assure patient confidentiality and remove duplicate records. HAB completed the vetting process of the draft system with grantees, federal partners and external partners and will implement client-level data collection in January 2009. HAB must report client-level data to Congress by the time Ryan White sunsets on September 30, 2009.

HAB will convene the "4th Annual Ryan White All Grantee Meeting" and "11th Annual Clinical Conference" on August 25-28, 2008 in Washington, DC with seven tracks: access to care, administration and fiscal issues, coordination and linkage, cultural competency, prevention and care continuum, program development, and quality and evaluation data. CHAC will hold a listening session for grantees during the meeting. More information can be obtained on these events at <u>www.ryanwhite2008.com</u>.

HAB is continuing its close collaborations with federal partners, such as HIV testing and the Retention in Care Project with CDC; the Methamphetamine Summit with CDC and SAMHSA; and the 4 Training Center (4TC) partnership with CDC, SAMHSA and the Office of Population Affairs.

Three senior leadership positions are vacant in HAB at this time: Director of the Division of Community-Based Programs; Director of ADAP; and Deputy Director of the Division of Training

and Technical Assistance. Ms. Ruth Roman was recently appointed as the new Director of the Office of Program Support and Ms. Sheila McCarthy was recently appointed as the Policy Director.

The President's FY'09 budget for the Ryan White HIV/AIDS Program of \$2.1 billion and the SPNS budget of \$25 million do not reflect an overall decrease from the FY'08 budget. ADAP in Part B has the largest single budget in the Ryan White Program and was increased from ~\$794.4 million in FY'08 to ~\$815 million in FY'09. Based on 2006 data, 66% of Ryan White dollars were spent on medications and medical care.

HRSA is currently taking actions to prepare for the transition to a new Administration, prepare for the 2009 reauthorization of the Ryan White Program, and conduct a study to identify and analyze issues related to the HIV workforce.

CHAC commended HAB on its extensive outreach to obtain input from grantees and partners on the client-level data system. Several members made comments and suggestions for HRSA to consider in refining its ongoing and future care and treatment activities.

- HAB's requirement for grantees to collect and report client-level data for each patient by
 responding to 142 different data points in three separate databases is not feasible. For
 example, one grantee would need at least two additional case managers to collect clientlevel data from 1,000 patients with this approach. Instead of requiring grantees to spend
 more dollars to hire additional data entry personnel, HAB should develop a process for
 grantees to report client-level data through one unified system. This approach would
 result in cost-savings of Ryan White dollars to both grantees and HRSA.
- The focus of HIV care has shifted to a medical model of new tests and drugs, but the success of grantees in enrolling patients in care by providing nutrition, transportation and other social services should be retained.
- HRSA and CDC should jointly determine whether the successes in providing HIV prevention, care and treatment internationally under PEPFAR could be replicated in the United States under a SPNS initiative. Outstanding data that have been collected in PEPFAR countries could be used to validate both domestic and international models of HIV prevention, care and treatment.
- HRSA and CDC should conduct a formal assessment to determine whether lessons learned from public health leaders who have been deployed to PEPFAR countries overseas could be applied to HIV prevention and care activities in the United States. This approach could result in bi-directional improvement of these services at both global and domestic levels.

Drs. Parham Hopson and Fenton made a number of follow-up remarks in response to CHAC's comments and suggestions on HRSA's care services and collaborative efforts with CDC.

• HAB is aware of the strong concerns that grantees have expressed in collecting and reporting client-level data with 142 different data elements in three separate databases. To address these concerns, HAB is exploring the possibility of phasing in the client-level

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data system to relieve the burden on grantees in collecting these data, ensure that solid data are gathered and reported, and eliminate duplicate records as much as possible.

- CDC is collaborating with HRSA on the Medical Monitoring Project to collect solid data on HIV-positive persons in care across all types of treatment centers. The study is designed with clinical, epidemiological and risk factor indicators for CDC and HRSA to obtain a random sample of HIV-positive persons and better characterize patients based on epidemiological needs and differences by race/ethnicity, gender and other factors.
- CDC hopes that public health leaders who have been deployed to PEPFAR countries overseas and are now returning to the United States will play a key role in strengthening the capacity of the HIV domestic program. CDC also hopes to leverage funds to conduct evaluation studies and compile best practices from PEPFAR.
- HRSA developed a new Partners Initiative to provide funding for smaller organizations to become HIV primary care providing organizations. HRSA is awarding planning grants and distributing CBO best practices to assist these groups in shifting from AIDS service organizations to full-service primary care providing organizations for persons living with HIV.

Panel Presentation on Workforce Training

National Network of STD/HIV Prevention Training Centers (NNPTC). Ms. Rheta Barnes, Chief of the DSTDP Health Professions Training and Education Unit at CDC, explained that the NNPTC is a group of regional training centers with a partnership between an academic institution and a state or local public health department. DSTDP and DHAP jointly fund NNPTC to increase and maintain the skills and knowledge of health professionals in the areas of sexual and reproductive health.

The goals of NNPTC are to address the STD/HIV prevention training needs of public and private sector health professionals throughout the United States and also to develop, deliver and evaluate training activities on the diagnosis, treatment and prevention of STD/HIV. The staff of each PTC includes health professionals with demonstrated expertise in STD/HIV prevention training.

CDC first funded Clinical and Laboratory Training Centers (CLTCs) in 1979 and then established Behavioral Interventions Training Centers (BITCs) and Partner Services and Program Support Training Centers (PSPSTCs) in 1995. In the current 2006-2011 funding cycle, the NNPTC structure includes ten CLTCs, four BITCs and four PSPSTCs. The CLTCs, BITCs and PSPSTCs are all located in the Eastern, Southern, Central and Western quadrants of the United States.

The ten CLTCs provide didactic and experiential training to clinicians in public and private practice on STD diagnostics, treatment and management. The four BITCs provide training to STD/HIV prevention specialists and prevention programs on effective behavioral interventions to decrease STD/HIV risk. The four PSPSTCs provide training to public health workers in STD/

HIV programs in state and local health departments on STD/HIV interviewing, counseling and referral for patients and partners.

Each Clinical PTC is required to provide 130 hours of didactic training and 70 hours of experiential training to at least 75 clinicians. The Clinical PTCs offer the STD Intensive Course over three to five days in a clinical setting to focus on STD treatment and management. Despite level funding since 2000 and a 4% budget cut since 2003, the Clinical PTCs have continued to meet or exceed the minimum training requirements of the CDC cooperative agreement.

During the April 2007-March 2008 project period, the Clinical PTCs convened 752 training events and provided 9,679 hours of didactic or experiential training to 28,227 participants. Of 4,078 course participants who submitted records by profession, 33% were registered nurses, 18% were advanced practice nurses, 13% were physicians, and 10% were physician assistants.

By workplace, 40% of 4,078 course participants worked in state or local health departments, 12% worked in hospitals, and 11% worked in community or non-profit clinics. STD or HIV accounted for most of the work focus areas of the 4,078 course participants, but many students also worked in women's reproductive health, general and family practice, adolescent and student health, corrections, and substance use and addiction. By geographical location, the Clinical PTCs have trained course participants in all 50 states and have increased STD training in the South due to the high prevalence in this region.

DSTDP has developed a number of NNPTC special projects, such as online case studies; a Clinician Symposium to reach more providers through presentations on HIV or STD issues at professional or national meetings; and the "Ask, Screen, Intervene Course" to incorporate HIV prevention into medical care. DSTDP also has involved NNPTC in the 4TC collaboration with training centers in other federal agencies and the PCSI training initiative with other NCHHSTP divisions.

<u>AETCs</u>. Ms. Felicia Guest, of the Southeast AETC at Emory University in Atlanta, explained that the structure of the AETC includes 11 regional centers and four national centers. The overarching function of the AETC is to ensure that each HIV clinician in the United States has a regional telephone number to resolve training needs or other problems.

Of the AETC's 64,500 unduplicated students during the July 2006-June 2007 project period, 32% were registered nurses, advance practice registered nurses or nurse practitioners and 24% were medical doctors or physician assistants. The top five training topics during this project period covered antiretroviral therapy, diagnostic tests and disease progression, adherence, clinical manifestations of HIV, and co-morbidities.

AETC training promotes an abundant, experienced and qualified HIV workforce by enhancing morale, listening to providers, and increasing their sense of value. AETCs offer longitudinal training sequences for intense capacity building and support. AETCs also provide training at low or no cost, pay for travel costs of certain high-priority students, conduct onsite training at Ryan White clinics to reach students at a lower cost, make special efforts to train minority and

minority serving providers, and attempt to expand the HIV skills of primary care providers in various settings.

AETCs provide training to experienced providers on specific topics, such as care for caregivers, strategies to combat compassion fatigue, management of grief and loss, burnout prevention, approaches to negotiate limits with patients who have chaotic lifestyles, and updated clinical guidelines and issues.

AETCs recognize that certain difficulties related to the HIV workforce cannot be solved with training. For example, compensation to clinicians in the public sector is not competitive with providers in the private sector due to years of flat funding in Ryan White programs and cost-reimbursement inequities in HIV clinics and organizations. Healthcare professionals often select specialty and subspecialty care over primary care. The limited teaching role of AETCs in health professions schools minimize their influence in increasing the interest of students in the HIV field.

Flat funding also causes barriers to training. Management is reluctant to release personnel to attend training courses due to inadequate staff. Leveraging dollars to pay for travel expenses and registration costs for staff to attend training courses is difficult. Low morale can diminish interest in learning new knowledge and skills.

CDC Office of Workforce and Career Development (OWCD). Dr. Stephen Thacker of OWCD explained that the public health workforce lost 50,000 workers between 1980 and 2000. Within the next five years, 25% of CDC workers and 50% of workers in some state health agencies will be eligible to retire. By 2020, 250,000 more public health workers will be needed to replenish the loss to the public health workforce.

OWCD acknowledges that three key questions must be answered to address the workforce crises. First, what jobs and skills are critical to success? Second, what strategies can be implemented to ensure that these jobs and skills are available when needed? Third, what approaches can be taken to optimize the public health workforce? Workforce planning will help to ensure that organizations have the right talent in the right jobs at the right time.

The mission of OWCD is to improve health outcomes by ensuring a competent and sustainable workforce through excellence and innovation in workforce and career development. OWCD conducts a number of activities and functions to fulfill its mission. The use of evidence-based practices is assured. A strategic human capital plan for CDC was developed and implemented. Leadership development programs are strengthened. "Pipeline" programs are implemented and evaluated from middle school through undergraduate school to increase the interest of students in public health and science. The quality and scope of CDC University is enhanced.

The key components of CDC's Strategic Human Capital Management Plan are summarized as follows. The Plan is aligned with HHS, the Office of Personnel Management, and the Office of Management and Budget. The Plan is linked to CDC's performance goals and objectives. CDC's human capital management strategies are consolidated within the plan. The Plan

emphasizes data collection and analysis. Accountability is promoted by assigning responsibility to initiative champions. The Plan provides a road map to guide CDC's human capital management through 2010.

The framework of the Plan includes roles and responsibilities, performance management for results, leadership and knowledge management, talent management, data analysis, and implementation and accountability. CDC's human capital objectives from 2008-2010 are to (1) ensure effective human capital planning; (2) improve recruitment, retention and outreach; (3) improve the career development of employees through CDC University; (4) improve leadership development; and (5) improve human resources processes.

OWCD provides the following training courses to CCID's HIV/STD staff in the field: project management, scientific writing, technical report writing, community health development and capacity building, and SAS training. OWCD also places fellows in HIV/STD positions through the Epidemic Intelligence Service, Prevention Effectiveness Fellowship Program, and Public Health Informatics Fellowship Program. With funding provided by Pfizer, *The CDC Experience* is a one-year fellowship in applied epidemiology for medical students. The program is designed to increase the pool of physicians with a population health perspective. These programs have been effective in retaining fellows in public health.

OWCD recruits ~200 fellows to work in the field of public health each year. These recruitment efforts bring new disciplines such as informatics and economics into public health; and explore the development of new programs to recruit fellows into current and emerging fields such as nanotechnology and genomics.

Overall, the integration of HIV/STD into workforce development will require joint efforts to expand the recruitment of professionals with an interest in HIV/STD. A coordinated approach will allow HIV/STD training to be incorporated into workforce development curricula and provide fellows to participate in field investigations.

The CHAC members made a number of comments and suggestions on the HIV/STD workforce training crisis.

- Professional societies and credentialing organizations have created higher standards for providers to qualify as HIV specialists due to the increasing complexity of administering antiretroviral therapy. However, more rigorous and stringent requirements will limit the number of providers who can qualify as HIV specialists.
- AETCs should provide more one-on-one HIV/AIDS training to nurses, health educators and physicians in public health departments.
- Efforts to replenish the workforce for HIV care must address the lack of physicians, nurses, physician assistants and other providers who are available at this time to develop HIV expertise and skills in the new generation of students. A model of HIV care should be created and integrated into a general primary care model to reshape and target clinical training initiatives to medical students, residents and nursing students.

- CHAC should formulate recommendations to direct the focus of current programs toward building HIV skills and capacity in a new generation of primary care providers.
- CHAC should explore the possibility of issuing a formal statement on using abstinenceonly dollars to strengthen the public health workforce.
- CDC should explore the possibility of re-offering the Public Health Advisor Program to provide states with a workforce of experts in HIV, syphilis and other diseases at the local level.
- CDC should assign staff to closely collaborate with North Carolina and other states that now have PEPFAR graduates. This approach would allow states to use the expertise of PEPFAR graduates in developing direct patient models and conducting other activities.
- CDC, HRSA and other parts of the public health sector at federal and state levels should take leadership in convening professional groups to address the HIV/STD workforce issue from a public health perspective.
- Efforts should be made to reuse high-quality and highly trained public health experts to work part-time in HIV care.

Dr. Fenton made a number of remarks in response to some of CHAC's suggestions and comments. CDC is currently making efforts to reinvent, revitalize and reestablish the Public Health Advisor Program. An intervention was successfully piloted in Florida in 2007 to introduce persons to public health programming at a beginner's level. Dr. Gerberding has made a commitment to expand the pilot over time, but new resources will be required.

Dr. Fenton and other NCHHSTP leadership will attend the NNPTC Conference in June 2008 to discuss strategies on integrating training program curricula, cross-fertilizing training for HIV, STD, TB and hepatitis, and developing integration training modules as interventions.

Overview of HCV Prevention, Surveillance, Treatment and Care Issues

Dr. John Ward, Director of DVH, reported that remarkable prevention successes in decreasing the number of new acute HCV cases have been achieved in the United States since 1992. Several factors contributed to this progress, including the implementation of prevention measures; development of antibody tests to screen the blood supply and prevent transmission of HCV; and behavior change, syringe exchange programs for injection drug users (IDUs) and other interventions to prevent transmission in various settings.

A number of challenges related to HCV have not been addressed to date. Of the large chronically infected population of 3.2-4.2 million persons, ~60% are unaware of their infection and many have behavioral risks that place other individuals at risk for HCV transmission. Of chronic HCV-infected persons, 5%-20% progress to cirrhosis, cancer or chronic liver disease and 35%-80% have a sustained response to treatment.

HCV is the most common cause of chronic liver disease and liver transplantation in the United States. HCV represents a health disparity, particularly for the AA population. Barriers limit

access to HCV care and treatment. HIV accelerates HCV disease. Of HIV-positive persons, 11%-34% have HCV. HCV is a major cause of death, but HIV and HCV therapy can improve survival.

Although the number of case reports has decreased over time, 50% of 19,000 HCV cases reported in 2006 were among IDUs. Of new IDUs, studies suggest approximately 15% acquire HCV each year. These data show that in addition to clean syringes, other HCV interventions are also needed to protect IDUs, prevent sexual transmission particularly among HIV-positive MSM, and to limit blood exposures in healthcare and other settings.

DVH conducts a number of activities to achieve its four strategic imperatives for viral hepatitis prevention. To protect vulnerable populations from infection, DVH promotes hepatitis A and hepatitis B vaccination, and education and risk reduction counseling to risk populations to facilitate behavior change and avoid transmission, and training to improve infection control practices. Since 1998, >30 HBV and HCV outbreaks have occurred in various settings throughout the United States resulting in transmission to >400 patients.

DVH's epidemiologic and laboratory investigation of an HCV outbreak among endoscopy patients in Nevada in 2007 showed that at least six persons have been infected with HCV to date. The investigation and response are underway, but 40,000 patients have been notified to obtain HIV, HBV and HCV testing.

DVH provides information, education and outreach to IDUs to improve knowledge of HCV, methods of protection, and the benefits of vaccination, screening and care. DVH conducts these activities in communities, jails and syringe exchange programs through social marketing, peer education and video-based education approaches. DVH's "Project Knowledge" has resulted in tremendous improvement in knowledge of HCV prevention and care and retention of knowledge among ~100 IDUs over a 12-week period.

To prevent disease from chronic HBV and HCV, DVH promotes identification, counseling and testing of persons at risk and medical management of infected persons. A 2002 study showed that 51% of 199 anti-HCV-positive persons were unaware of their infection. Of 101 persons who were aware of their infection, only 7% had been tested for HCV because of a risk factor. DVH published recommendations on routine HCV testing in the United States based on increased risk for infection.

In addition to releasing its National Hepatitis C Prevention Strategy, DVH is also making efforts to bring rapid HCV testing to the market to facilitate point-of-care testing and better integrate HCV and HIV testing. Data from CDC's HIV Outpatient Study showed that only 9.5% of 189 persons who died from HIV/HCV co-infection had evidence of any HCV treatment before death.

DVH's role in improving screening and care for chronic HCV is to evaluate rapid HCV tests, develop demonstration projects for public health settings, analyze alternatives for risk-based HCV screening by examining age-based approaches or birth cohort screening in clinical

settings, gather data on healthcare access and outcome, and build model prevention and referral programs.

To build surveillance systems to guide prevention efforts, 36 states have made chronic HBV and HCV nationally notifiable diseases. These regulations allow DVH to collect data from states to better describe the magnitude of the epidemic. However, DVH continues to be challenged by limited resources, passive reporting in many states, and incomplete case reports that lack data on risk factors and race/ethnicity.

DVH is assisting states in developing chronic viral hepatitis surveillance systems and registries with performance standards to improve surveillance for HIV/HCV co-infection, monitor HCV-related cancer and deaths, prepare systems to monitor anti-viral resistance, support acute surveillance to identify outbreaks, and guide prevention efforts.

To strengthen prevention capacity through program development, policy development and PCSI activities, DVH awarded funds to 49 states and six cities to support Adult Viral Hepatitis Prevention Coordinators. DVH conducted and published operational research regarding the integration of viral hepatitis prevention services. The study showed that clients readily accepted integrated services and acceptance of HIV testing increased when HCV testing was offered.

DVH is taking advantage of several opportunities within PCSI to further advance integration. Of 23 HIV testing sites that were funded to conduct viral hepatitis testing, 13 requested funds to support HIV/HCV testing. HIV/HCV registry matching is being piloted at three sites and data sharing standards are being developed across HIV, STD and viral hepatitis surveillance programs. Curricula and other training efforts are being integrated in viral hepatitis, STD and AIDS training centers. DVH commissioned the Institute of Medicine to conduct an independent review of its viral hepatitis activities.

Dr. Melissa Osborn, of the Emory University Division of Infectious Diseases, described a variety of issues and challenges related to HCV treatment. Hospital data collected from Spain showed that liver disease was the leading cause of death in HIV patients in 2000. The pathway for patients to achieve a sustained virologic response (SVR) to HCV treatment includes screening to identify HCV-positive persons, appropriate referral to a hepatitis C specialist, an interest in treatment, access to a viable payer source, capacity to undergo HCV therapy based on the absence of liver disease or co-morbidities, and the ability to begin and complete therapy.

Of ~4,500 HIV-positive patients who were followed by the Grady Hospital Infectious Disease Program in 2006, 20% were HCV-positive. Of ~50 patients who were treated from 2004 to the present, only five achieved an SVR. Of 16 patients who were referred for therapy from September 2007 to the present, only four were candidates for treatment and only one has started treatment at this time. Uncontrolled HIV, psychiatric issues, ongoing substance abuse and cirrhosis of the liver were the key reasons patients did not receive HCV treatment.

Of 1,300 HIV patients who are currently being followed by Emory Crawford Long Hospital, 13% are co-infected with HCV. Since January 2005, 55 patients have been treated for either HCV

only or HIV/HCV co-infection. An SVR was achieved by only 13.6% of 22 co-infected patients and 30.3% of 33 mono-infected patients. The remaining patients had relapses, were not responsive to treatment or did not tolerate therapy.

Four fibrosis stages are used to assess liver disease and determine when to begin treatment. Stage 1 or 2 is the optimum time to offer treatment and prevent progression to cirrhosis. Stage 3 patients have bridging fibrosis or severe inflammation and have a risk of >90% of developing cirrhosis in ten years. A liver biopsy is the gold standard to assess liver disease, predict prognosis, evaluate steatosis to determine fibrosis progression, and eliminate other liver diseases.

Because biopsy is invasive, expensive and associated with death and other complications, better methods are needed to assess liver disease. Biomarkers, fibrosis scores and radiographic methods have been evaluated, but none of these technologies have been shown to be as predictive as biopsy. Pegylated interferon plus ribavirin is the current standard therapy for HCV. Treatment is administered for 24-72 weeks depending on the patient's genotype and is associated with a number of side effects, such as influenza-like symptoms, myalgias, leukopenia, anemia, fatigue, cognitive dysfunction, depression and irritability.

HCV treatment studies measure four responses. The rapid virologic response is undetectable HCV RNA at week 4 of treatment. The early virologic response is an undetectable or a log decrease of >2 in HCV RNA at week 12 of treatment. The potential for an SVR is only 1%-2% if patients do not respond at this stage. The end-of-treatment response is undetectable HCV RNA at week 24 or 48. The SVR is undetectable HCV RNA six months after completion of therapy.

The current standard therapy for HCV is only effective in 50% of mono-infected patients overall. The response rate is only 45% in mono-infected patients with genotype 1 and ~80% in patients with genotypes 2 and 3. The response rate is ~65% in HIV/HCV co-infected patients with genotypes 2 and 3 and only 14%-30% in co-infected patients with genotype 1.

The most significant predictors of an SVR include non-genotype 1, age <40 years, body weight <75 kg, low baseline HCV viral load, absence of bridging fibrosis or cirrhosis, and maintenance of full-dose therapy throughout treatment, particularly ribavirin. Clinical trial data collected in 2006 showed that AAs had lower SVR rates and worse adherence to therapy compared to whites.

A study showed that 99% of patients with an SVR remained RNA-negative after a mean of four years. Because the impact of an SVR on the development of cirrhosis, decompensation or risk for liver cancer is unknown, more research is needed to fill these data gaps. Population-based studies should be conducted to identify the number of HCV-positive patients who are not in care, analyze reasons for non-treatment, and determine the number of patients who were ever assessed for treatment among those who died from cirrhosis.

Resources should be allocated to turn non-candidates for treatment into candidates. For example, more support should be provided to substance abuse and mental health programs

and stronger efforts should be made to control HIV and other co-morbidities. Non-invasive methods should be developed to determine liver histology, facilitate earlier assessment and intervention, and promote repeated evaluations for change.

Treatment data should be collected and treatment should be evaluated in addition to HCV screening. More data should be gathered to determine the best models for HCV treatment, such as multidisciplinary approaches, directly observed therapy, training to providers, and access to psychiatric services and other supportive care during therapy.

Studies should be conducted to identify and change the reasons for disparate responses for treatment, particularly to document differences in treatment between AAs and whites, within racial groups, and HIV versus non-HIV patients. Interventions should be targeted to prevent liver mortality in persons who are not candidates for treatment, including hepatitis A virus (HAV) and HBV vaccination and alcohol cessation counseling.

Long-term studies should be conducted to analyze solid outcomes in SVR versus non-SVR patients in the context of cirrhosis, end-stage liver disease events and hepatocellular carcinoma. Registries of HCV-positive patients should be established to link treatment histories to mortality data and estimate the number of deaths that would have been prevented with earlier interventions.

CHAC made a number of suggestions for CDC and HRSA to consider in ongoing efforts to address HCV prevention, surveillance, treatment and care issues.

- CDC and HRSA should provide states with cost benefit analyses to demonstrate the cost effectiveness of investing in hepatitis prevention and treatment. States could use the data to show that these investments could result in tremendous cost savings to Medicare programs due to decreased liver transplantation.
- CDC should conduct a demonstration project to gather data on the cost of hepatitis prevention at the local level, including additional resources that would be needed to train the workforce.
- DVH and DHAP should jointly collect robust data on the proportion of HIV-positive patients who are screened for HCV and identify quality improvement strategies to increase this population.
- DVH should include "prevention for HCV-positive persons" as an additional strategic imperative for viral hepatitis prevention. This new strategy should be designed to identify HCV-positive persons and target interventions to educate, change behavior and prevent transmission in this population.
- DVH should identify key prevention partners to generate strong advocacy for HCV among consumers, professionals and other stakeholders. DVH could use its Viral Hepatitis Roundtable as a forum to convene community advocates.
- CDC should compile and widely distribute lessons learned and best practices from HIV prevention to the hepatitis community.

Overview of the DSTDP Extramural Research Portfolio Review

Dr. John Douglas, Jr., Director of DSTDP, explained that CDC requires external reviews of its intramural research programs every five years. However, DSTDP was last reviewed in 1999 and the STD Laboratory was reviewed in 2003 prior to its consolidation with DSTDP. Due to this gap in time, the most recent extramural research portfolio review covered DSTDP's intramural, extramural and laboratory research.

A panel of 26 reviewers was divided into five groups to evaluate DSTDP and its four branches in three areas: (1) the overall portfolio in terms of DSTDP's epidemiology, surveillance, behavioral interventions, health services and laboratory research; (2) the coverage, focus, quality, program relevance and potential public health impact of the research portfolio; and (3) gaps, redundancies and weaknesses in the research portfolio or research quality. The review panel was also charged with recommending mechanisms for continuous evaluation and quality improvement of DSTDP's research.

The review panel made a number of overarching comments. DSTDP is the world's preeminent STD prevention organization and has highly qualified experts in the areas of theory and programmatic application of STD prevention strategies. DSTDP's sense of mission is directly derived from the dedication of staff to the prevention of STD-related morbidity. The effectiveness of DSTDP's tangible products is enhanced by crucial intangible factors, including leadership, role models, and maintenance of the political visibility of STD prevention programs and outcomes. Numerous challenges have recently eroded DSTDP's current and potential success in prevention research.

The review panel's Division-wide recommendations in six major areas are summarized as follows. <u>One</u>, DSTDP should develop research priorities and agendas. DSTDP's research and activities focus on the prevention of STI-related infertility, adverse outcomes of pregnancy, cancers and HIV transmission. These goals provide an effective framework, but are too broad to serve as research priorities. DSTDP typically develops research agendas through a reactive process in response to available funding and has poorly integrated research planning with program planning.

DSTDP should develop research priorities that emphasize practical programmatic outcomes at least every five years. Annual research agendas should integrate research priorities with budget and personnel resources, but should not be linked to the annual budget process. The existing research portfolio should be modified to assure alignment with current priorities. Files of unfunded proposals should be maintained and systematically reviewed for future consideration. Measures should be implemented to enhance branch autonomy in research planning.

<u>Two</u>, DSTDP's decision-making processes should determine research planning. DSTDP's process to consider and select proposed projects is not clear. Clear decision-making principles and processes, fairness in both reality and perception, and feedback when research proposals

are not adopted are essential. Formal criteria should be established for developing and selecting research proposals.

Clear and bidirectional communication channels for research agenda decisions should be created. Written feedback should be provided to scientists when potentially promising proposals are not adopted. New research proposals should be solicited no more than twice per year and not linked to the budget. Prioritized files of projects to be funded should be maintained when new or unanticipated resources are identified. Multi-year projects should be included in the research agenda.

<u>Three</u>, DSTDP should strengthen the interface between research and program implementation. The translation of prevention research to operational interventions is impaired by inadequate bidirectional collaboration between branches, particularly between the Program and Training Branch (PTB) and four analytic branches. Mechanisms should be established to assure programmatic input in research priorities and agendas and vice versa.

Cross-disciplinary expertise in PTB and the analytic branches should be enhanced, including scientific training of PTB personnel and development of programmatic expertise in research scientists. The majority of projects proposed for inclusion in a research agenda should be hypothesis-driven. Program personnel should be encouraged to take primary responsibility for research proposals.

<u>Four</u>, DSTDP should address issues related to culture, communication and collaboration across branches and disciplines. Longstanding cultural divides have resulted in impediments to communication and collaboration between branches and across disciplines and also have caused inefficiencies, redundancies and gaps. The divide between PTB and the analytic branches is particularly profound.

Clear expectations and procedures should be established to assure inter-group communication and collaboration in designing and conducting research. Rewards for successful inter-branch and cross-disciplinary collaboration should be developed and staff should be held accountable for meeting these expectations. Assuring the implementation of other key recommendations is a central strategy to ensure interdisciplinary collaboration. For example, unlinking research agenda development from the budget will enhance opportunities for thoughtful collaboration.

<u>Five</u>, DSTDP should prioritize professional support and career development of its scientists. With the exception of EIS trainees who are assigned to DSTDP, sub-optimal evaluation of professional performance and the absence of professional accountability have impaired morale, productivity and retention. Mechanisms and procedures should be established to assure systematic mentoring and career development.

Performance goals and standards should be developed beyond the enumeration of publications. Accountability measures should be created, including standards for interdisciplinary coordination and programmatic impact of research. Scientists should be encouraged to seek expanded training opportunities and supported in these endeavors. <u>Six</u>, DSTDP should initiate a long-term planning process. The formal portfolio review was limited to DSTDP's research programs, but many of the panel's recommendations should be applied to non-research programs to maximize the success of STD prevention. DSTDP's administrative organization should be evaluated and alternative structures should be considered.

The distribution of resources to and within DSTDP should be critically assessed, including an evaluation to determine whether the balance of resources between research and program activities is optimal at this time. The "program" scope should be broadened and incorporated into all aspects of STD prevention planning. The broader program scope should include activities of HRSA and other federal healthcare agencies, representatives of practitioners and non-governmental organizations.

Overall, DSTDP found the panel's recommendations to be constructive and consistent with its own observations. DSTDP's position is that the recommendations can serve as a catalyst for a clearer focus on its challenges. DSTDP is currently making efforts in a number of areas to respond to the panel's recommendations.

In response to the panel's recommendations on research priorities, agendas and planning, DSTDP will complete its 2007-2008 strategic planning process in July 2008 and initiate new annual project planning processes for both research and non-research activities. DSTDP's strategic planning process is intended to be both comprehensive and efficient to take advantage of previous strategic plans and review processes.

DSTDP's new Strategic Plan will communicate its priorities to both internal and external STD prevention stakeholders and provide a framework to guide decision-making for the research agenda and the allocation of both human and financial resources. The Strategic Plan will clearly outline DSTDP's vision, mission, goals, objectives and strategies over a five-year time frame. DSTDP will review the Strategic Plan each year and make revisions as necessary.

DSTDP drafted three new STD prevention goals in April 2008: (1) strengthen STD prevention capacity and infrastructure, (2) reduce STD-related health disparities, and (3) address effects of social and economic determinants and costs of STD. External partners are currently reviewing DSTDP's draft goals and objectives. DSTDP branches, workgroups and units will use the draft goals and objectives to develop strategies.

To guide the FY'09 project planning process, DSTDP leadership used specific criteria to identify and prioritize six draft goals and objectives: produce a comprehensive framework to reduce disparities; monitor and respond to antibiotic-resistant gonorrhea; reduce gonorrhea in AAs; reduce HSV-associated HIV transmission; increase chlamydia screening of women; increase treatment of men with gonorrhea and chlamydia; and reduce gonorrhea incidence among women. For the FY'09 planning process, each branch was allowed to develop up to two single or multiyear projects that corresponded to the top six objectives. Although branch staff assumed leadership in generating ideas, collaboration with other branches was heavily weighted by 10%. DSTDP leadership prioritized and voted on 11 proposed projects and will determine the top ranking projects that will be developed in FY'09 funding announcements.

In response to the panel's recommendations on the research/program interface, DSTDP is enhancing bidirectional collaboration by assuring programmatic input into research priorities and agendas and strengthening translation of prevention research to operational interventions. DSTDP's Syphilis Elimination, Performance Measures, Partner Services, HPV Vaccine, Infertility Prevention, and Disparities Workgroups are also conducting a number of activities to improve the research/program interaction.

DSTDP will soon release its new Comprehensive STD Prevention Program Services grant with a five-year project period. Grantees will be encouraged to develop projects that emphasize DSTDP's priorities, including expanded chlamydia screening, partner services, a stronger focus on health disparities, use of local data to target syphilis elimination efforts, improved monitoring and evaluation, innovative ideas to assess screening and partner services coverage, and PCSI.

DSTDP is partnering with the Canadian National Center for Infectious Diseases to close the gap between STD prevention science and program implementation and actively encourage sciencebased programs and program-relevant research. Products from this initiative will include additional meetings, publications and information exchange networks to facilitate dissemination.

DSTDP's other efforts to enhance the research/program interface include program collaboration on research priorities and agendas; incorporation of staff input into the selection of projects; inclusion of feedback on research in program announcements and activities; and increased interaction between DSTDP program and research staff through syphilis elimination discussion groups, reverse site visits, the National STD Prevention Conference, the Program Science Meeting, and discussions on the programmatic implications of chlamydia immunobiology.

In response to the panel's recommendations on interdisciplinary coordination, collaboration and communication, DSTDP will strengthen the role of its six workgroups and create clear expectations regarding inter-group collaboration in developing priorities. DSTDP also will provide incentives for collaboration, strengthen routine inter-branch and branch-workgroup communications, and complete an organizational assessment.

DSTDP established an interagency agreement in 2007 for the Office of Personnel Management to evaluate its organizational climate, employee satisfaction, leadership competencies, and skills needed to enact change. This effort will assist DSTDP in recruiting and retaining a highquality workforce, leveraging employee talents, ensuring effective leadership, and enhancing Division-wide communication and collaboration. A preliminary report of the organizational assessment was drafted based on interviews with leadership and focus groups with employees. A quantitative survey will be administered to all DSTDP staff beginning in June 2008. Action planning training will be launched in June 2008. In response to the panel's recommendations on professional support and career development of scientists, DSTDP is currently evaluating approaches to create and launch a mentoring program for all levels of staff and a variety of domains by the end of 2008. CDC is modifying its agencywide performance appraisal system to have a stronger focus on performance expectations and standards. Interdisciplinary collaboration will be increasingly emphasized through workgroups and project funding criteria. Expanded training is being encouraged through leadership training opportunities and individual development plans.

In response to the panel's recommendations on long-term planning, DSTDP will complete and annually review its new five-year Strategic Plan. DSTDP will coordinate its vertical Strategic Plan with horizontal planning at higher levels, such as NCHHSTP priorities and the CDC goals management process. DSTDP will consider strategies to re-allocate its budget, but this effort will be difficult due to decreased program infrastructure resources. Most notably, DSTDP's budget has been cut by ~22% based on current inflation-adjusted dollars and its field staff has decreased to 176 personnel.

DSTDP will continue its efforts to maximize research translation through better collaboration with programs beyond health departments. DSTDP is collaborating with the Partnership for Prevention to increase annual chlamydia screening to 40% in sexually active women <25 years of age. Under this partnership, a *Chlamydia Screening Implementation Guide* will be developed and the National Coalition for Chlamydia Screening will be established with multiple organizations. DSTDP also will leverage external partnerships to make additional progress in STD disparities.

CHAC commended DSTDP for developing thoughtful and comprehensive responses to the panel's recommendations on the STD prevention research portfolio. Several CHAC members made comments and suggestions for DSTDP to consider in its ongoing strategic planning process.

- DSTDP should ensure that its STD prevention research and activities are culturally appropriate for populations in small, rural and indigenous communities.
- DSTDP and DHAP should facilitate joint site visits with HIV and STD Project Officers to determine the actual feasibility and effectiveness of HIV/STD integration at the local level.
- DSTDP should encourage STD grantees to report HIV incidence data to CDC and DHAP should urge HIV grantees to provide CDC with STD incidence data.
- CDC and HRSA should make stronger efforts to promote integrated HIV/STD training in AETCs and STD Prevention Training Centers.
- CDC, HRSA, NIH and SAMHSA should jointly fund a demonstration project to determine the feasibility of integrating prevention and treatment of HIV, STD, hepatitis, substance abuse and mental health across federal agencies.

Update on the Ryan White Reauthorization Workgroup

Dr. Hook reminded CHAC of its consensus recommendation to reestablish the workgroup. He asked CHAC to provide input in two major areas: (1) key topics and issues for the workgroup to propose for inclusion in the reauthorized legislation and (2) the composition of the workgroup with current and former CHAC members, outside experts or other partners.

Because the Ryan White legislation is scheduled to be reauthorized in September 2009, Dr. Hook pointed out that the workgroup would need to present its recommendations to CHAC for a discussion and formal vote during the November 2008 meeting.

CHAC made several comments and suggestions related to the potential charge, focus and composition of the Ryan White Reauthorization Workgroup.

- The workgroup should strongly recommend the need for the reauthorized bill to emphasize the best interests and needs of HIV/AIDS patients through advocacy.
- The workgroup should recommend only minor changes to the reauthorized bill at this time. The workgroup should advise HRSA to conduct or commission a study over the next four years to determine the outcomes of the previous reauthorization on the current HIV/AIDS care and treatment system and identify changes that will be needed in the future to meet the emerging needs of the aging HIV population.
- The workgroup should recommend including language in the reauthorized bill for Ryan White grantees to provide other services that are critically important to HIV/AIDS clients, such as STD screening and referrals to substance abuse clinics, mental health programs and chronic disease clinicians. The workgroup should solicit input from SAMHSA block grantees and other constituents in this effort.
- The workgroup should convene representatives from major HIV/AIDS organizations across the country to resolve differences in various reauthorization recommendations. This approach would allow CHAC and other groups to present a unified rather than a divided voice to the new Administration and demonstrate strong support from HRSA, CDC, SAMHSA, other federal agencies and communities.
- The workgroup should analyze and focus on policy issues and priorities for HIV prevention, treatment and care that are important to the Presidential candidates.
- Due to time and resource constraints, the workgroup should not hold public hearings across the country with patients, CBOs and other groups to discuss changes to the reauthorized bill. Instead, the workgroup should implement a top-down approach to propose language to the reauthorized bill and obtain external feedback through less expensive mechanisms. For example, the workgroup could gather and thoroughly review input on the reauthorized bill submitted to HRSA by Ryan White grantees.
- The workgroup should take leadership in unifying various perspectives and consolidating common themes for the reauthorized bill, such as interagency PCSI activities and emerging needs of the aging HIV population.

Drs. Hook and Sweet described the immediate next steps for the Ryan White Reauthorization Workgroup. CHAC members should inform Drs. Hook and Sweet of their interest in serving on the workgroup. The members also should submit names of advocacy organizations that would support the workgroup's proposed language for the reauthorized bill, such as groups representing social workers, case managers, clinicians, substance abuse programs and mental health providers.

With no further discussion or business brought before CHAC, Dr. Hook recessed the meeting at 5:00 p.m. on May 20, 2008.

Update on CDC's Activities to Eliminate Health Disparities

Dr. Hook reconvened the CHAC meeting at 8:37 a.m. on May 21, 2008 and yielded the floor to the first presenter.

Dr. Madeline Sutton is the Acting Associate Director for the HNR at CDC. She explained that DHAP developed the HNR because AAs, particularly young MSM, are disproportionately affected by the HIV epidemic. AAs comprise ~13% of the U.S. population, but accounted for 49% of new HIV diagnoses in 2006 based on data from 33 states. Data collected in 2006 also showed that AA adult and adolescent males and females had much higher HIV/AIDS case rates than other racial/ethnic groups.

DHAP officially launched the HNR in March 2007 with well-recognized leaders in the AA community to expand the reach of prevention services; increase opportunities for diagnosing and treating HIV; develop new and effective prevention interventions; and mobilize broader community action. DHAP's major activities and new approaches to stop the HIV/AIDS epidemic are summarized below.

The "Take Charge, Take the Test" campaign was targeted to single AA women 18-34 years of age who made <\$30,000 per year, had some college education or less, and had unprotected sex with men. The campaign focused on education to increase awareness of HIV/AIDS, describe different mechanisms of transmission and encourage testing. The campaign was piloted in specific areas of Cleveland and Philadelphia with high AIDS rates and resulted in increased HIV testing among AA women. DHAP is currently evaluating the successful campaign and intends to expand the pilot to the national level.

HIV tests are primarily available in emergency departments, CHCs, STD clinics, correctional health facilities and other clinical settings. To increase this coverage, Congress appropriated \$45 million for CDC to conduct an HIV testing initiative. DHAP allocated \$35 million to health departments to increase HIV testing for populations that are disproportionately affected by HIV, particularly AAs who are unaware of their HIV status. DHAP targeted the remaining \$10 million to support training, capacity building, social marketing, program evaluation and technical assistance in high-prevalence areas.

DHAP held a partnership meeting in March 2007 with >80 AA leaders to mobilize a broader community response to HIV/AIDS in the AA community. DHAP and its partners are conducting a number of activities to support the "Mobilizing African American Communities to ACT! Against AIDS" campaign. For example, efforts are being made to break the silence and increase awareness of HIV/AIDS among friends, families and coworkers. Communication messages are being delivered in places where AAs live, work, play and worship. Testing is being promoted to lead to early diagnosis and treatment of HIV/AIDS.

Of 113 HNR Launch Leaders who made commitments during the March 2007 meeting, 85% have completed or are completing their commitments at this time. Of 162 total commitments that external partners have made since the March 2007 HNR meeting, 90% have been completed or are currently being completed.

Other HNR activities include Lyfe Jennings' recording of the "AIDS It's Real" single and the broadcast of his "Rap-It-Up" public service announcement on Black Entertainment Television. Dr. Ronald Mason, President of Jackson State University, led the development of a campus-wide HIV/AIDS awareness and prevention agenda. He also sent a letter to presidents of 53 Historically Black Colleges and Universities to discuss the importance of the education sector being involved in HIV prevention.

Tom Joyner partnered with DHAP to outreach to HIV providers and CHCs through the "Take a Loved One to the Doctor Day" campaign on his nationally syndicated radio program. Darian "Big Tigger" Morgan is a TV and radio personality who hosts the Street Corner Foundation's Annual Celebrity Classic Basketball Game and the motorcycle "Ride for Life" campaign to promote HIV/AIDS awareness. These events feature rapid HIV testing and distribution of outreach information on HNR leaders.

DHAP will convene its annual HNR Partnership meeting on May 29-30, 2008 to report on activities that have been conducted over the past year, describe future initiatives and next steps with HNR, and explore strategies to increase HIV/AIDS awareness and prevention within the AA community. DHAP will also use the meeting to demonstrate its sustained leadership, progress and commitment toward preventing HIV/AIDS in the AA community and assure partners of CDC's continued support of AA communities that are mobilizing to sustain action against HIV/AIDS.

Dr. Wolitski described CDC's response to HIV/AIDS in AA MSM. Data collected in 25 states from 1994-2006 showed stable or decreased HIV/AIDS cases among adults and adolescents in every transmission category with the exception of MSM. HIV/AIDS diagnoses have increased in MSM of all racial/ethnic groups since 1999, but these increases are most prevalent in AA and white MSM. Data collected in 33 states from 2001-2006 showed striking increases in new HIV diagnosis in AA MSM 13-24 years of age.

CDC's response to the HIV/AIDS epidemic in AA MSM includes four major components. To "expand and strengthen prevention programs," CDC supports 100 projects for AA MSM, 68

projects for young AA MSM, and 47 projects for AA transgenders. One of these initiatives is a five-year project with annual funding of \$9.7 million to implement interventions for young men of color and young transgenders of color. Of all grantees, >50% provide services to young AA MSM. The project supports the provision of effective prevention services to high-risk men and their partners; HIV testing in medical and community settings; and demonstration projects of HIV prevention interventions developed at the local level.

CDC is providing support to the National Association of State and Territorial AIDS Directors (NASTAD) to disseminate information, assess best practices, and encourage state health departments to address the needs of AA MSM. Under this initiative, NASTAD held a technical assistance meeting in February 2007 with 14 health departments; administered a survey to its membership to identify activities that are underway in health departments to address HIV/AIDS among AA MSM; and issued briefs on the epidemic in this population.

To "disseminate evidence-based interventions," CDC continues to fund its Diffusion of Effective Behavioral Interventions (DEBI) Program to distribute efficacious HIV interventions nationwide through training, technical assistance and other capacity-building activities. The DEBI Program is implemented during multi-day training sessions by 21 capacity-building assistance providers, four regional Prevention Training Centers, the Behavioral and Social Science Volunteers Program, CDC project officers and capacity-building experts, and state health department project officers and contractors. The DEBI Program currently supports 14 interventions, but 11 additional interventions are being prepared for dissemination over the next year.

DEBIs for MSM include (1) community outreach, discussion groups and social marketing for young MSM with the Mpowerment Intervention; (2) group interventions for HIV-positive men and women to promote disclosure and reduce risk behavior with the Healthy Relationships Intervention; and (3) engagement of and training to key opinion leaders to change risk social behaviors with the Popular Opinion Leader (POL) Intervention.

The "Many Men, Many Voices" (3MV) Intervention was originally targeted and tested in white MSM, but has been adapted to meet the specific cultural needs of AA MSM. The small group intervention includes seven sessions focusing on the enhancement of self-esteem related to racial identity and sexual behavior; HIV/STD risk education and sensitization; development of personal risk reduction strategies; behavioral and partner communication skills training; and social support and relapse prevention.

To date, >128 agencies and 335 individuals have been trained to deliver the 3MV Intervention. CDC, academic partners and a CBO serving AA MSM recently conducted an evaluation study in which 343 persons were randomized to either a 3MV Intervention group or a wait-list control group. Follow-up data collected at three and six months post-intervention showed a retention rate of >85%. CDC is currently analyzing the evaluation outcomes and hopes to release the data later in 2008.

The D-Up! Intervention was culturally adapted from the POL Intervention and is currently being packaged for inclusion in the DEBI Program. The tailored intervention for AA MSM includes

conversations regarding racism, homophobia, bisexuality, poverty and religion; a condom demonstration; and campaign materials to increase visibility of the intervention and trigger dialogue. During the pilot of the adapted intervention in North Carolina, 226 opinion leaders were trained.

Pilot data showed significant reductions in risk behavior in three North Carolina communities, including decreases in unprotected insertive or receptive anal intercourse. Most notably, a 44% reduction was observed in rates of unprotected receptive anal intercourse from baseline to 12-month follow-up and a 40% reduction was seen in the number of sex partners. To expand implementation of the D-Up! Intervention, CDC has dedicated funds to support training and technical assistance to capacity-building assistance providers and >200 CBOs serving AA MSM.

To "support research to develop new interventions," CDC documents risks to AA MSM through its Young Men's Survey and National HIV Behavioral Surveillance System. CDC also supports projects to better understand the rationale for disparities and develop and evaluate strategies to address these disparities.

The Brothers y Hermanos Study was designed to examine demographic, structural and socioeconomic factors associated with HIV risk behavior and HIV infection in AA and Latino MSM. The study was conducted at four sites in Los Angeles, New York City and Philadelphia with 2,236 MSM. The study was completed in 2006 and is being prepared for numerous publications.

CDC is devoting resources to develop new interventions for AA MSM. The Latino and AA Men's Project is testing four new interventions that were specifically designed for AA MSM: a computer-based intervention, a social network-based intervention, a culturally tailored group intervention focused on contextual risk, and a small-group intervention emphasizing reconstruction of the social environment. CDC is currently conducting testing to determine whether the Community Promise and Mpowerment Interventions can be adapted for AA MSM.

To "promote and improve the efficiency of HIV testing," CDC is conducting a four-site study to evaluate the relative ability of testing strategies to identify undiagnosed HIV infection in AA MSM. The HIV testing strategies that are being assessed in the study include alternative venue testing outside of medical clinics, social networks, and partner counseling and referral services. (PCRS). During the study, >5,000 AA MSM will be tested.

The HIV testing strategies will be compared to determine the number and percent of newly identified positive persons, the cost for each new infection identified, and the number of newly identified positive persons who are linked to medical and prevention services. The project will end in August 2009.

CDC is continuing to promote traditional HIV testing by developing communication materials and creating a new campaign for AA gay and bisexual men. DHAP allocated \$1 million of FY'07 dollars to the campaign to reach this population through the Internet and other electronic channels. Local health departments and CBOs will be able to adapt campaign materials to specifically target local needs.

In addition to its comprehensive response to the HIV/AIDS epidemic in AA MSM, CDC will conduct additional activities in the future. CDC will distribute new information through various mechanisms to raise awareness of the epidemic within the professional community and guide the field. A fact sheet, web page and publications will focus on HIV/AIDS trends among AA and other MSM and HIV/AIDS in the AA community.

CDC and NIH are collaborating to develop a multi-site study focusing on AA MSM through the HIV Prevention Trials Network. CDC and the National Black Gay Men's Advocacy Coalition are engaging in an ongoing dialogue to increase involvement and mobilization of the HNR. DHAP established an MSM Executive Committee in May 2007 to improve CDC's response to the HIV epidemic in AA MSM. The committee recently submitted recommendations on this issue to DHAP for review. CDC will perform a broader assessment of HIV prevention efforts for MSM in all racial/ethnic groups.

CHAC commended CDC for continuing to provide leadership to eliminate health disparities. CHAC was particularly impressed with the scope and magnitude of the HNR activities that have been conducted over the past year. Several members made comments and suggestions for CDC to consider in strengthening its health disparities projects and initiatives.

- CDC should conduct a study to determine whether the inclusion of STD screening in HIV prevention efforts for AA MSM would increase the impact of these initiatives.
- CDC should engage SAMHSA as a formal partner in the HNR due to the success of its activities to eliminate health disparities. For example, >128,000 college students were educated on HIV or received HIV testing under SAMHSA's peer-to-peer college initiative. SAMHSA also recently received new funding from HHS to develop MSM curricula.
- CDC and SAMHSA should jointly explore strategies to incorporate culturally adapted prevention interventions for AA MSM into drug treatment programs and mental health centers. This approach would be particularly effective in providing HIV/STD information to AA MSM who were recently released from correctional facilities.
- CDC and NIH should conduct thoughtful research to identify specific domains, structural issues and determinants of health disparities beyond behavior, such as genetics, early childhood development, social circumstances, environment, mental health issues, co-morbidities, and barriers to accessing healthcare systems.
- CDC should engage a broader group of partners in its HIV prevention efforts to reach young AA MSM 13-24 years of age, particularly the educational sector, parents, juvenile detention centers, and alcohol and substance abuse counseling programs.
- CDC should be mindful of important cultural differences while adapting interventions for AA MSM. For example, AA men typically do not seek care from health departments. As a result, interventions from these venues would not be particularly effective in reaching AA MSM.

- CDC should ensure that its interventions for AA MSM do not have an unintended consequence of dividing the broader AA community. Most notably, the HIV/AIDS epidemic in AA MSM has a significant impact on HIV rates in AA women and heterosexual men. CBOs that serve other subgroups of the AA population should not be placed in a position of competing with AA MSM-serving organizations.
- CDC should compile and widely distribute a comprehensive "mobilization" list to states to increase HIV/STD testing and expand the reach of the HNR at regional, state and local levels. The mobilization list should include AA newspapers, churches and radio stations.

Update on CDC's Recommendations for STD/HIV Partner Services

Dr. Samuel Dooley, of CDC, explained that CDC developed and integrated new guidance for STD/HIV partner services due to the poor uptake of partner services for HIV, gonorrhea and chlamydia. For example, a survey showed that only ~33% of index patients were interviewed for HIV partner services. Moreover, CDC's two separate guidelines and training courses for HIV and STD partner services have resulted in duplication, gaps, discrepancies, confusion in the field, and fragmentation of services.

With the new integrated guidelines, CDC intends to emphasize the importance of integrating STD/HIV partner services as a public health strategy, improve and integrate services at the client level, achieve economies of scale to improve coverage, and address new issues and methods that have emerged since the previous guidelines.

CDC took several steps to develop the new integrated partner services guidelines. DHAP and DSTDP established an inter-division workgroup to gather input from end-users, stakeholders and subject matter experts. An extensive literature review was conducted and listening groups were convened at national conferences.

State laws were reviewed to better understand the legal issues associated with partner services. Site visits were made to eight programs to obtain a field perspective on issues and concerns related to partner services. Focus groups were held with members of affected communities, program managers, front-line staff, CBO staff and clinicians in the private sector. A consultation was convened in November 2006 to obtain input on the draft partner services guidelines.

A steering committee was established to oversee the revision process and seven workgroups were created to revise different parts of the guidelines. CDC and outside experts served on the steering committee and the seven workgroups. Another literature review was conducted and the draft guidelines underwent a major revision. The second draft was sent to >170 reviewers for evaluation and comment. Additional revisions were made based on input from >80 reviewers. The final draft of the partner services guidelines was cleared and submitted to the *Morbidity and Mortality Weekly Report (MMWR)* for publication.

The background section of the guidelines discusses the goals, principles, benefits and concerns of partner services. The section on index patients provides guidance on identifying, prioritizing, interviewing, counseling, treating and referring patients. The section on partners gives guidance on prioritizing, notifying, counseling, testing, treating, providing linkages to care, and referring partners. This section also emphasizes the need to screen for HIV and other STDs and provide hepatitis screening and vaccination if appropriate.

The section on special populations covers youth, incarcerated persons, immigrants and migrants. Strategies are described for enhancing partner services through core areas, social networks and the Internet. Other sections of the guidelines cover legal and ethical issues associated with partner services, PCSI, monitoring and evaluation, and staff development and support.

Key features of the partner services guidelines are summarized as follows. The guidelines specifically focus on HIV, syphilis, gonorrhea and chlamydial infection. The "PCRS" terminology in the previous guidelines was changed to "partner services" in the new guidelines to include other STDs in addition to HIV. Because program managers are the target audience, the guidelines focus on program design and management rather than operational details.

A comprehensive description is given on the background and rationale for partner services. The guidelines are based on a health department model of partner services due to the lack of data on the effectiveness of partner services in CBOs. Direct involvement with health departments in partner notification is strongly emphasized due to the demonstrated success of this approach. Active linkages to care and prevention services are highlighted. Collaborations within health departments are noted to improve the integration of services at the client level.

The need for data security is emphasized due to recommendations on using surveillance and disease reporting systems to identify index patients. Specific data security principles and standards are listed in an appendix. Program monitoring and quality improvement of partner services is encouraged. Collaborations with providers, CBOs, community planning groups and other external partners are described to support the development and implementation of partner services within the community. Common goals, frameworks and strategies for partner services are highlighted, but the guidelines are designed to be flexible and tailored when necessary.

Examples are given for situations when partner services should be tailored. For example, all newly diagnosed cases of early syphilis and HIV should be interviewed. Surveillance and disease reporting systems should be used to identify persons with newly diagnosed or reported infection. The use of individual-level data should be strongly considered if appropriate security and confidentiality procedures have been established. Partner services should be offered to all newly diagnosed cases of gonorrhea if resources permit or alternative strategies should be used. Alternative strategies should be implemented for newly diagnosed cases of chlamydial infection.

The guidelines describe a model of a tailored approach for partner services. For example, a program might interview all HIV, early syphilis and repeat gonorrhea cases. Providers would be

used for partner notification of early syphilis and repeat gonorrhea cases, while providers or contract referral would be used for partner notification of HIV cases.

The program would notify partners of HIV and early syphilis cases to confirm their notification, evaluation and appropriate medical management. Field delivered-therapy might be used to notify partners of repeat gonorrhea cases. Self-referral and patient-delivered partner therapy might be used to notify partners of new gonorrhea and all chlamydia infection cases.

Dr. Matthew Hogben, of CDC, explained that implementation of the guidelines is designed to motivate and support substantial changes in STD and HIV programs in the context of partner services via dissemination of information, training and capacity building. In the dissemination plan, CDC will publish the guidelines in the *MMWR* before the end of 2008 and also distribute the guidelines through *MMWR* mailings, a "Dear Colleague" letter, presentations at conferences, editorials, postings on the Internet, operational guidelines and technical assistance documents.

In the implementation plan, 15 DSTDP and DHAP staff members will oversee a nine-step theoretical framework for training and capacity building. The implementation plan will focus on CDC's activities to support uptake of the HIV/STD partner services guidelines. However, focus group participants and public health advisors will provide CDC with ongoing external input throughout the implementation phase.

CDC will emphasize three essential components in the implementation plan: (1) reorganization of resources in conjunction with consultation of sites; (2) quality standards, quality improvement and quality assurance of the implementation plan; and (3) standards and measures to evaluate the fidelity of the implementation plan.

In the training and capacity-building plan, CDC will develop and distribute an operational guideline, toolkits, an integrated curriculum and a training plan. DSTDP and DHAP will make joint site visits to provide technical assistance to individual programs and develop specific implementation plans for various sites. Slide sets will be created for program consultants and project officers. Agency- or program-wide updates to the partner services guidelines will be made periodically.

To assess the capacity of programs in providing partner services, CDC will examine barriers for organizations and individuals, training and technical assistance needs, and potential challenges. Programs will be encouraged to provide CDC with continuous input and recommendations to inform the process of tailoring and updating the guidelines.

CHAC commended CDC on its innovative approach to developing integrated guidelines for STD/HIV partner services. However, several members were concerned about the potential for "push-back" in the field due to vast differences in the capacity of disease intervention specialists providing partner services. The CHAC members made a number of comments and suggestions for CDC to consider in addressing this issue.

- CDC should aggressively and widely launch an educational campaign to inform health departments and communities of the need for and benefits of partner notification. CDC also should use this effort to overcome traditional barriers to providing partner services.
- CDC should partner with SAMHSA to link STD/HIV partner services to mental health or psychosocial counseling referrals. For example, notification to partners could potentially result in violence or index patients might not be emotionally equipped to inform their partners of an HIV or STD diagnosis.
- CDC should take leadership in clarifying the most appropriate allocation of resources and identifying different strategies for HIV/STD partner services.

CHAC Business Session

Dr. Hook pointed out that each CHAC meeting typically results in the members proposing at least 20-30 action items. From an advocacy level, he realized that the numerous action items reflected CHAC's strong passion, commitment and dedication to HIV/STD prevention and treatment.

From an administrative level, he acknowledged that this approach has not allowed the agencies to provide a solid response to the action items or CHAC to effectively address the issues at future meetings. To resolve this dilemma, Drs. Hook and Sweet would attempt to streamline and consolidate CHAC's proposed action items before submitting the suggestions to CDC and HRSA.

Drs. Hook and Sweet led CHAC in a review of action items and agenda items that were raised over the course of the meeting and during the business session.

Action Items:

- HRSA Bureaus other than HAB should regularly attend CHAC meetings and have much more involvement in CDC's integrated activities. For example, CHCs have a significant role in CDC's HIV/STD partner services. In the interim, PowerPoint slides presented at meetings and CHAC minutes should be shared with all HRSA Bureau Directors.
- The Executive Director of the Association of Community Health Centers should be invited to attend the next CHAC meeting as an observer and listen to a presentation by the HRSA Bureau of Primary Health Care.
- Drs. Fenton and Parham Hopson will have an offline discussion to identify strategies to formalize HRSA's presence at CHAC meetings with Bureaus other than HAB. In this effort, the DFOs will remind colleagues that CHAC is chartered to provide guidance to "HRSA" at the agency level and not solely to "HAB" at the Bureau level.

Agenda Items:

• Update on the Ryan White Reauthorization Workgroup. The following CHAC members volunteered to serve: Ms. Renee Austin, Ms. Evelyn Foust, Rev. Debra Hickman, Mr.

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Harold Phillips, and Drs. Edward Hook, Donna Sweet, Lydia Temoshok and Carmen Zorrilla.

- Update on HAB's three policy studies on the impact of the 2006 reauthorization on core medical services, funding shifts and eligibility determination.
- Update on the impact of integration activities, workforce issues and training on CHCs, HIV/STD clinicians, lay counselors and other providers.
- Update on the effectiveness of routine HIV testing, opt-out testing at the state level, and efforts to link patients to adequate care.
- Update on HRSA's client-level data system.
- Presentation by the HRSA Bureau of Primary Health Care focusing on three specific topics: (1) the number of CHCs providing care to HIV patients; (2) the number of CHCs that have established counseling and testing policies; and (3) an updated map with geographical locations of all CHCs in the United States.
- Overview on integrated HIV/STD prevention and care programs and other public health efforts targeted to the reentry of incarcerated persons in the community.
- Update on acute infections, including testing algorithms for HIV in the United States and changes in laboratory science.
- Presentation of solid data from key experts at domestic and PEPFAR sites in three areas: (1) the epidemiology of antiretroviral drug resistance in drug-naïve HIV-infected persons; (2) the current status of interventions to enhance adherence and potentially prevent development of drug resistance; and (3) and the efficacy of these interventions on the prevention of drug resistance.
- Presentation on the long-term effects of antiretroviral drug regimens to guide the development of language for the reauthorized Ryan White legislation.
- Presentation on methods to modernize surveillance for HIV/AIDS, strategies to integrate HIV/AIDS surveillance with STD and hepatitis program activities, and approaches to improve the timeliness of surveillance reports.
- Presentation on the interface between mental health services and HIV/STD issues, including risk issues and comprehensive and synergistic care.
- Update on integrated HIV/STD services in the context of stigma and health disparities.
- Update on HRSA's program collaborations with CDC, SAMHSA and other federal partners to provide case management.
- CHAC discussion to formulate solid recommendations on advancing integration issues at the operational level.
- CHAC discussion on the possibility of HRSA funding partner notification services for HIV cases.
- CHAC discussion on the Congressional requirement for grantees to lose Ryan White dollars in perpetuity if obligated funding is not spent.
- Presentation by clinicians in the field on policy issues associated with an integrated HIV/ AIDS, STD, viral hepatitis and TB model and the feasibility of translating an integrated model into actual practice.

Dr. Sweet concluded the business session by clarifying that votes could not be taken on any formal motions or recommendations because CHAC was operating without a quorum.

However, she confirmed that suggestions individual CHAC members made over the course of the meeting and during the business session would be captured in the minutes and considered.

Public Comment Session

Mr. Ronald Johnson is the Deputy Executive Director of AIDS Action Council (AAC). He made the following public comments for the record. AAC commends CHAC for focusing on the next reauthorization of the Ryan White legislation. AAC and several other national organizations are collaborating through the Ryan White CARE Act Reauthorization Workgroup of the Federal AIDS Advocacy Partnership to unify a reauthorization agenda. National Executive Directors recently reaffirmed the workgroup as the primary mechanism to develop a set of principles and positions to guide collective community advocacy on Ryan White reauthorization.

A number of national organizations are beginning to agree on the need for small changes to the reauthorized bill and a broader scope of "HIV care" due to the current debate on healthcare reform. Because AAC and other organizations have joined the Call for Action for a National AIDS Strategy in the United States, a major restructure of the Ryan White legislation should take this effort into consideration.

AAC's position is that the Ryan White legislation should be continued while efforts are made to develop a National AIDS Strategy and achieve healthcare reform. The workgroup would welcome the opportunity to make a presentation to CHAC during its next meeting.

Ms. Ann Lefert is the Associate Director of Government Relations at NASTAD. She made the following public comments for the record. At this time, >50% of AIDS directors have responsibility for viral hepatitis and are leading the effort in the nation's fight against viral hepatitis with insufficient resources.

CHAC should advise the federal agencies to convene a cross-departmental Viral Hepatitis Workgroup to discuss the need for the government to scale-up its response to viral hepatitis. Most notably, more resources are needed to provide hepatitis education and outreach, additional HAV and HBV vaccine to high-risk adults, safe injection programs and surveillance. Funding is also needed to strengthen the HAV and HBV vaccine infrastructure, enhance chronic HBV and HCV surveillance systems, and integrate rapid testing into existing state structures.

CHAC should advise the federal agencies to partner with and provide solid data to grassroots and other community organizations to increase advocacy for hepatitis. These groups include the National Viral Hepatitis Roundtable, Hepatitis B Coalition, Hepatitis C Appropriations Partnership, and Hepatitis C Advocates United.

In terms of HIV prevention, NASTAD agrees with Dr. Gerberding's recent statement on the inadequate investment in this area for the AA community. NASTAD hopes Dr. Gerberding's

comments will help to raise awareness of the epidemic in the United States and increase critical programmatic funding.

In terms of the new Administration, a number of community organizations are compiling policy papers and other documents for submission to transition teams and agency heads. The documents will outline top priorities for the first 100 days of the new Administration in the areas of leadership; sufficient funding levels for the FY'10 budget; prevention, care and treatment; Medicare and Medicaid; Ryan White regulations; and substance abuse, mental health and corrections.

Closing Session

CHAC applauded Ms. Margie Scott-Cseh and Ms. Shelley Gordon, CHAC's Committee Management Specialists at CDC and HRSA, respectively, for their diligent efforts in planning and organizing the meeting. The next meeting would be held on either November 17-18 or November 20-21, 2008 in Washington, DC. CDC and HRSA would poll the CHAC members by e-mail to determine a specific date.

With no further discussion or business brought before CHAC, Dr. Hook adjourned the meeting at 11:30 a.m. on May 21, 2008.

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

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

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

Date

Date

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