# 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 10-11, 2011

**Record of the Proceedings** 

# TABLE OF CONTENTS

| Attachment 1: List of Participants | 3 |
|------------------------------------|---|
| Attachment 2: Glossary of Acronyms | 5 |

## Minutes of the Meeting May 10, 2011

| lay 10, 2011   |    |
|--|----|
| Opening Session  | 8  |
| Opening Remarks From Designated Federal Officials                                      | 9  |
| Report from CDC Deputy Director for Infectious Diseases                                | 11 |
| CDC Update Presentation  | 12 |
| HRSA Update Presentation   | 19 |
| Update on National HIV/AIDS Strategy/Implementation and 2012 IAS                       | 25 |
| Progress Report on BPHC Efforts and Strategy to Expand HIV, STD, and Viral Hepatitis   |    |
| Testing, Care, and Reporting Within FQHCs  | 28 |
| Report by CHAC Sexual Health Workgroup, Update on CDC Sexual Health Strategic          |    |
| Activities   | 31 |
| Report by CHAC Viral Hepatitis Workgroup, Update on CDC Hepatitis Prevention Strategic |    |
| Activities   | 37 |
| Update on IOM Studies Related to HIV Testing, Barriers and Linkage to HIV Care         | 40 |
| Wrap-Up of Day One   | 44 |
|  |    |

# May 11, 2011

| Update on CDC's HIV Prevention Portfolio   | .45 |
|--|-----|
| Panel Presentation on CDC's Strategic Priorities and Coordination of Media and Social  |     |
| Marketing Related to HIV, STD, and Viral Hepatitis Prevention                          | .50 |
| Rethinking STD Prevention in a Transformed Health System: Opportunities and Challenges | S   |
|  | .56 |
| Update on Pre-Exposure Prophylaxis (PrEP)  | .62 |
| New Committee Business.  | .65 |
| Public Comment   | .70 |
| Agenda Items and Dates for Next Meeting  | .71 |

## ATTACHMENT 1

#### **List of Participants**

NOTE: The CDC Designated Federal Official conducted a roll call of the CHAC voting members and non-voting *ex officio* members on both May 10 and May 11, 2011. The presence of a quorum was confirmed on both days.

## **CHAC Members**

Dr. Edward Hook, Co-Chair Dr. Donna Sweet, Co-Chair Dr. Bruce Agins Dr. Carol Brosgart Dr. William Cunningham Dr. Carlos del Rio Dr. Perry Halkitis Rev. Debra Hickman Ms. Antigone Hodgins Dempsey Mr. Ernest Hopkins Ms. Maria Lago Mr. Kali Lindsey Dr. Jeanne Marrazzo Dr. Kenneth Mayer Dr. André Rawls Ms. Lisa Tiger

#### CHAC Ex-Officio Representatives

Dr. Christopher Bates (Department of Health and Human Services)

- Dr. William Grace (National Institutes of Health)
- Dr. Gretchen Stiers (Substance Abuse and Mental Health Services Administration)
- Dr. Richard Wild (Centers for Medicare and Medicaid Services)

#### **Designated Federal Officials**

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

#### **Federal Agency Representatives**

Dr. Gail Bolan Dr. Stuart Berman Dr. Fred Bloom Dr. Chris Cagle Dr. John Douglas, Jr. Dr. Gema Dumitru Ms. Teresa Durden Ms. Shelley Gordon Dr. Seiji Hayashi Ms. Paula Jayne Dr. Cynthia Jorgensen Dr. Rima Khabbaz Dr. Amy Lansky Ms. Eva Margolies Dr. Kathleen McDavid Harrison Dr. Mary McFarlane Dr. Jonathan Mermin Ms. Kathy Meyer Ms. Lisa Neel Mr. Kevin O'Connor Ms. Amrita Patel Dr. Monica Ponder Ms. Angela Powell Dr. Raul Romaguera Ms. Susan Robinson Ms. Margie Scott-Cseh Dr. Jill Smith Ms. Sandra Thurman Ms. Abigail Viall Dr. John Ward Dr. Howell Wechsler Ms. Rachel Stern Wynn

### **Guest Presenters and Members of the Public**

Mr. Chris Aldridge (HealthHIV) Ms. Lynn Barclay (ASHA) Mr. Douglas Brooks (Justice Resource Institute) Ms. Jennifer Kates (Kaiser Family Foundation) Mr. Terrance Moore (NASTHD) Mr. Carl Schmid (The AIDS Institute) Mr. Michael Shankle (HealthHIV) Ms. Cathalene Tegham (Georgia AIDS Coalition)

## ATTACHMENT 2

## **Glossary of Acronyms**

| AAA   | Act Against AIDS  |
|-------|---|
| AAALI | Act Against AIDS Leadership Initiative                    |
| AAP   | American Academy of Pediatrics                            |
| AASLD | American Association for the Study of Liver Diseases      |
| ACA   | Affordable Care Act                                       |
| ACP   | American College of Physicians                            |
| ADAP  | AIDS Drug Assistance Program                              |
| AETC  | AIDS Education Training Center                            |
| AHRQ  | Agency for Healthcare Research and Quality                |
| AI    | American Indian   |
| AIDS  | Acquired Immune Deficiency Syndrome                       |
| AN    | Alaska Native   |
| APHA  | American Public Health Association                        |
| ART   | Antiretroviral Therapy                                    |
| ASHA  | American Social Health Association                        |
| ATTC  | Addiction Technology Transfer Center                      |
| BHPR  | Bureau of Health Professions                              |
| BMS   | Bristol-Myers Squibb                                      |
| BOP   | Bureau of Prisons   |
| BPHC  | Bureau of Primary Healthcare                              |
| BSC   | Board of Scientific Counselors                            |
| СВО   | community-based organization                              |
| CCIIO | Center for Consumer Information and Insurance Oversight   |
| CDC   | Centers for Disease Control and Prevention                |
| CGH   | Center for Global Health                                  |
| CHAC  | CDC/HRSA Advisory Committee on HIV and STD Prevention and |
|       | Treatment   |
| CHC   | Community Health Center                                   |
| CIASS | Clinical Assessment for Systems Strengthening             |
| CIHS  | Center for Integrated Health Solutions                    |
| CME   | Continuing Medical Education                              |
| CMS   | Centers for Medicare and Medicaid Services                |
| CR    | Continuing Resolution                                     |
| DASH  | Division of Adolescent and School Health                  |
| DFO   | Designated Federal Official                               |
| DHAP  | Division of HIV/AIDS Prevention                           |
| DIS   | Disease Intervention Specialist                           |
| DOJ   | Department of Justice                                     |
| DOL   | Department of Labor                                       |
| DSMB  | Data and Safety Monitoring Board                          |
| DSTDP | Division of STD Prevention                                |
| DVH   | Division of Viral Hepatitis                               |
| ECHPP | Enhanced Comprehensive HIV Prevention Plan                |
| ED    | Department of Education                                   |
| EIS   | Epidemic Intelligence Service                             |

| EPT     | Expedited Partner Therapy   |
|---------|---|
| FACA    | Federal Advisory Committee Act  |
| FDA     | Food and Drug Administration  |
| FOA     | Funding Opportunity Announcement  |
| FQHC    | Federally-Qualified Health Center   |
| FSMA    | Food Safety Modernization Act   |
| FTC/TDF | Emtricitabine/Tenofovir Disoproxil Fumerate                                       |
| FY      | Fiscal Year   |
| GYT     | Get Yourself Tested   |
| HAB     | HIV/AIDS Bureau   |
| HCV     | Hepatitis C Virus   |
| HAIs    | Healthcare-Associated Infections  |
| HHS     | (United States Department of) Health and Human Services                           |
| HIT     | Health Information Technology   |
| HIV     | Human Immunodeficiency Virus  |
| HPSA    | Health Profession Shortage Area   |
| HPV     | Human Papilloma Virus   |
| HRSA    | Health Resources and Services Administration                                      |
| HUD     | (United States Department of) Housing and Urban Development                       |
| IDSA    | Infectious Disease Society of America   |
| IDU     | Intravenous Drug User   |
| IHS     | Indian Health Service   |
| IOM     | Institute of Medicine   |
| iPrEx   | Preexposure Prophylaxis Initiative, or <i>Iniciativa Profilaxis Preexposicion</i> |
| IT      | information technology  |
| LGB     | Lesbian, Gay, Bisexual  |
| LGBT    | Lesbian, Gay, Bisexual, Transgender   |
| MAI     | Minority AIDS Initiative  |
| MDRGC   | Multi-Drug Resistant Gonorrhea  |
| MEPI    | The Medical Education Partner Initiative  |
| MICs    | Minimum Inhibitory Concentrations   |
| MMWR    | Morbidity and Mortality Weekly Report   |
| MSM     | Men who have Sex with Men   |
| MTV     | Music Television  |
| MUA     | Medically-Underserved Area  |
| NACHC   | National Association of Community Health Centers                                  |
| NASTAD  | National Alliance of State and Territorial AIDS Directors                         |
| NCCDPHP | National Center for Chronic Disease Prevention and Health Promotion               |
| NCEZID  | National Center for Emerging and Zoonotic Infectious Diseases                     |
| NCHHSTP | National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention             |
| NCIRD   | National Center for Immunization and Respiratory Diseases                         |
| NCSD    | National Coalition of STD Directors   |
| NGO     | Non-Governmental Organization   |
| NHAS    | National HIV/AIDS Strategy  |
| NIAID   | National Institute of Allergy and Infectious Diseases                             |
| NIDA    | National Institute on Drug Abuse  |
| NIH     | National Institutes of Health   |
| NPIN    | National Prevention Information Network   |
| NPS     | National Prevention Strategy  |
| INF U   | Inalional Flevenlion Slialeyy   |

| OGAC   | Office of the Global AIDS Coordinator                     |
|--------|---|
| OID    | Office of Infectious Diseases                             |
| OIG    | Office of the Inspector General                           |
| OMB    | Office of Management and Budget                           |
| ОМН    | Office of Minority Health                                 |
| ONAP   | (White House) Office of National AIDS Policy              |
| ONDCP  | Office of National Drug Control Policy                    |
| OPA    | Office of Population Affairs                              |
| OWH    | Office of Women's Health                                  |
| PACHA  | Presidential Advisory Council on HIV/AIDS                 |
| PBRN   | Practice-Based Research Network                           |
| PCIP   | Pre-Existing Conditions Insurance Plans                   |
| РСМН   | Patient-Centered Medical Home                             |
| PCSI   | Program Collaboration and Service Integration             |
| PEPFAR | President's Emergency Plan for AIDS Relief                |
| PHS    | Public Health Service                                     |
| PI     | Principal Investigator                                    |
| PPACA  | Patient Protection and Affordable Care Act                |
| PPFA   | Planned Parenthood Federation of America                  |
| PPHF   | Prevention and Public Health Funds                        |
| PrEP   | Pre-Exposure Prophylaxis                                  |
| PSA    | Public Service Announcement                               |
| RSR    | Ryan White Services Report                                |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SPNS   | Special Projects of National Significance                 |
| SNS    | Strategic National Stockpile                              |
| SSA    | Social Security Administration                            |
| STD    | Sexually Transmitted Disease                              |
| STI    | Sexually Transmitted Infection                            |
| TA     | Technical Assistance                                      |
| ТВ     | Tuberculosis  |
| TrOOP  | True Out of Pocket  |
| UDS    | Uniform Data Set  |
| USPSTF | United States Preventive Services Task Force              |
| VA     | Veterans Administration                                   |
| VOICE  | Vaginal and Oral Interventions to Control the Epidemic    |
| WHO    | World Health Organization                                 |
| WTC    | World Trade Center  |
| YMSM   | Young Men who have Sex with Men                           |
| YRBS   | Youth Risk Behavioral Survey                              |

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

# CDC/HRSA ADVISORY COMMITTEE ON HIV AND STD PREVENTION AND TREATMENT

# May 10 – 11, 2011 Atlanta, GA

# **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 Lowes Atlanta Hotel in Atlanta, Georgia, on May 10 – 11, 2011.

# **Opening Session**

Kevin Fenton, MD, PhD, Director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), and one of two Designated Federal Officials (DFO) for CHAC, called the meeting to order at 8:31 AM on May 10, 2011. He conducted a roll call of the voting CHAC members and the *ex officio* members and established a quorum for Day One of the meeting. He then asked for declarations of conflicts of interest:

- Carol L. Brosgart, MD: Is the Chief Medical Officer for Alios BioPharma, a publicly-held biotech company that works in the area of developing oral therapies for Hepatitis C and respiratory viruses. She sits on the Board of the San Francisco AIDS Foundation and on the Board of Tobira Biosciences, an antiviral company that develops antivirals for human immunodeficiency virus (HIV).
- Edward W. Hook, III, MD: Receives research support from a number of diagnostic test manufacturers for sexually transmitted diseases (STD).
- Jeanne Marrazzo, MD, MPH: Receives research support from at least one diagnostic company for sexually transmitted infections (STI).
- Kenneth H. Mayer, MD: Receives educational research grants from several pharmaceutical companies.
- Donna Sweet, MD: Receives HRSA funds for clinical care, and some pharmaceutical research for clinical and drug research in both HIV and Hepatitis C. She conducts Continuing Medical Education (CME) and develops other educational products for a number of education companies.

Edward W. Hook, III, MD, Co-Chair of CHAC, welcomed new CHAC members. The new members introduced themselves. The list of meeting participants is appended to the minutes as <u>Attachment 1</u>.

Donna Sweet, MD, Co-Chair of CHAC, added her welcome, noting that her CHAC appointment is ending and that her participation on CHAC had been rewarding. She then presented updates on events since the last CHAC meeting and praised the work product of the CHAC.

- Letters including specific "asks" were sent to Mary Wakefield, HRSA Administrator, and Kathleen Sebelius, Secretary of Health and Human Services (HHS).
- A report from the Institute of Medicine (IOM) was released on HIV workforce issues. A number of groups are addressing HIV workforce challenges, and CHAC was among the first groups to engage in this work. Health HIV is the Addiction Technology Transfer Center (ATTC) that was funded to bring AIDS education and care into Community Health Centers (CHC) and Federally Qualified Health Centers (FQHC). Dr. Sweet serves on that Board. Additionally, the American College of Physicians (ACP) Foundation received an unrestricted grant from Bristol-Myers Squibb (BMS) to conduct a three-year HIV workforce initiative. These efforts will lead to workforce growth in hepatitis C. Primary care and internal medicine are critical areas.
- CHAC established the Sexual Health Workgroup and the Viral Hepatitis Workgroup.
- The National HIV/AIDS Strategy (NHAS) includes a declaration that CHAC should work with the Presidential Advisory Council on HIV/AIDS (PACHA). A meeting is scheduled with the group leaders to begin this collaboration.

# **Opening Remarks from Designated Federal Officials**

## Kevin Fenton, MD, PhD

Director, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Centers for Disease Control and Prevention

Dr. Fenton reminded the group that CHAC meetings are open to the public. All comments made during the proceedings are a matter of public record. CHAC members should, therefore, be mindful of potential conflicts of interest identified by CDC or HRSA. Members with such conflicts should recuse themselves from participating in discussions, or voting, on issues for which there may be real or perceived conflict of interest.

He presented an update on CDC's portfolio, priorities, and activities. He encouraged CHAC to provide strategic thinking, advice on implementation, and thoughts regarding how to better engage partners and stakeholders in the effort to control and eliminate infectious diseases. The NHAS has presented a great opportunity for CDC to collaborate with HRSA and other partner HHS agencies. The agencies are building strong collaborations.

On Thursday, HHS will release its first Vital Hepatitis Action Plan. This release is a groundbreaking development for NCHHSTP and for the field working in prevention and control of viral hepatitis. The Plan focuses on a wide variety of stakeholders from across the federal government on viral hepatitis control. The Plan includes concrete action steps as well as roles and responsibilities for federal agencies as they "move the dial" regarding diagnosis, linkage to

care, treatment, and management of viral hepatitis. Dr. Fenton indicated that he looked forward to hearing CHAC's input on how CHAC can uniquely provide support for the success of the Plan; and how CDC and HRSA can strengthen their response to, and implementation of, the Plan.

Dr. Fenton welcomed Dr. Gail Boland, the new Director for the Division of STD Prevention. The CHAC meeting would include reflections on the state of STD prevention, including urgent threats regarding gonococcal antimicrobial resistance, the budget crises faced by state and local jurisdictions, and missed opportunities for integrating and collaborating across portfolios.

Organizational changes continue at CDC. Of particular interest is the integration of the Division of Adolescent and School Health (DASH) into NCHHSTP. Integrating youth programming into NCHHSTP builds upon and adds to the Center's youth prevention work.

During the meeting, Dr. Fenton invited CHAC to weigh in on various challenges facing the Center. The entire federal government is facing a budget crises, and it is important to think critically about their research portfolios. Prioritization issues need to be considered, including what to stop and what to start during these times. Additionally, he requested advice on ways to continue to enhance health impact, even during these difficult budgetary times.

## Deborah Parham Hopson, PhD, RN, FAAN

Associate Administrator HIV/AIDS Bureau Health Resources and Services Administration

Dr. Parham Hopson welcomed the group, particularly noting the new and reappointed members. Three CHAC members leaving the Committee included Ms. Lisa Tiger, Dr. Bruce Agins, and Dr. Donna Sweet. She presented each of them with a certificate of appreciation. New CHAC members have been submitted and approved, including Kathleen Clanon, MD, from California and Steven Johnson, MD, from Colorado, both clinicians in the Ryan White Program; Lenwood Green of Baltimore, Maryland; and Britt Rios Ellis, PhD, of California.

It has been 30 years since HIV was reported in CDC's *Morbidity and Mortality Weekly Report* (*MMWR*). Major events are planned, including the 30-Year anniversary and National HIV Testing Day in June, and the first anniversary of the release of the National HIV/AIDS Strategy in July. Their task is to determine how to meet new challenges with the resources they have while providing care and treatment to those living with HIV/AIDS and continuing to work to end the epidemic. In order to provide access to care and medications, they must know who is living with HIV. At present, they know about half of the people who are living with HIV/AIDS. Some of these people are in care, while others are not. She looked to CHAC for suggestions about how to improve and do things differently, and she thanked the CHAC membership for their time and service.

## **Report from CDC Deputy Director for Infectious Diseases**

#### Rima Khabbaz, MD

CDC Deputy Director for Infectious Diseases Director, Office of Infectious Diseases (OID) Centers for Disease Control and Prevention

On behalf of OID and CDC, Dr. Rima Khabbaz thanked CHAC for its services. She noted that OID provides strategic leadership to CDC's three infectious disease national centers: NCHHSTP, led by Dr. Fenton; the National Center for Immunization and Respiratory Diseases (NCIRD), led by Dr. Anne Schuchat; and the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), led by Dr. Beth Bell.

Dr. Khabbaz began with a report on CDC's FY2011 budget. CDC's current budget reflects a reduction of 11% (\$740 million) below the FY2010 budget. The FY2011 budget includes \$200 million in statutory reductions specified by Congress and an additional \$500 million that CDC had to apply through various programmatic reductions and eliminations. In making these decisions, CDC took into account key agency priorities. A summary of CDC's budget is available at <u>www.cdc.gov</u>.

Dr. Khabbaz next reported on work of the OID Board of Scientific Counselors (BSC). Dr. Edward Hook represents CHAC as the committee's liaison to the OID BSC. At its next meeting, the board will focus on the topic of transitioning infectious disease programs in an era of change and will be asked to provide advice in two areas: 1) ensuring that core infectious disease capacities are sustained during challenging economic times; and 2) identifying opportunities for advancing infectious disease prevention and control through ongoing and anticipated changes in healthcare.

Dr. Khabbaz also announced that OID is working to finalize an infectious disease framework for CDC. OID widely distributed the draft framework in the fall of 2010, solicited broad input from across CDC and from the BSC and other external partners, and revised the document based on input received. OID plans to publish an abbreviated version of the framework, and post the full document on CDC's website.

Among the infectious disease issues of special concern covered in the framework are three that are also identified as part of CDC's "Winnable Battles"—a series of targeted efforts that use known, effective strategies to achieve measurable results against high-burden diseases within a short period of time. For domestic infectious diseases, these efforts include strategies to reduce HIV infections, healthcare-associated infections (HAIs), and foodborne diseases. Dr. Khabbaz stated that she would speak briefly on efforts to reduce HAIs and foodborne diseases but would not cover HIV since Dr. Fenton would be covering CDC's work and progress to implement the National HIV/AIDS strategy in his update.

To advance toward reducing HAIs—which data show are mostly preventable—CDC is closely collaborating with federal and state partners in a variety of activities, including expansion of the agency's National Healthcare Safety Network (NHSN), CDC's primary source for facility-based information on HAIs. Hospitals can access the CDC web-based system at no charge to support

their activities to reduce HAIs. More than 4,000 hospitals are currently using the system. NHSN will also be used to track the progress of the Partnerships for Patients initiative, launched in May 2010 by HHS Secretary Kathleen Sebelius.

In an effort to reduce foodborne diseases, CDC has been directed to conduct two activities as part of the Food Safety Modernization Act (FSMA), signed into law earlier this year. First, CDC is directed to strengthen national and state surveillance for foodborne illnesses through improved efforts to collect, analyze, and share data. Second, CDC is directed to establish five integrated food safety centers of excellence at state health departments to identify and implement best practices in foodborne disease surveillance and serve as resources for public health professionals. As part of these responsibilities, the FSMA calls for the establishment of a working group to make recommendations to the HHS Secretary regarding improvements in surveillance and criteria for the centers of excellence. Plans have begun for establishing this workgroup under the OID BSC.

Dr. Khabbaz concluded her report by thanking CHAC for the opportunity to address the committee and by inviting questions. In response to a question, Dr. Khabbaz clarified that most of CDC's budget lines are considered to be discretionary. Dr. Frieden is considering advice from various sources regarding the FY 2012 budget.

## **CDC Update Presentation**

### Kevin Fenton, MD, PhD

Director, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Centers for Disease Control and Prevention

Dr. Fenton presented major CDC activities and highlights, accomplishments of NCHHSTP, comments on the Strategic Plan, and brief updates from each of the Center's Divisions. Each Division Director would provide more specific presentations on Day Two of the CHAC meeting.

Regarding CDC's budget for FY 2011, Dr. Fenton noted that the overall reductions and rescissions to the budget translate into a cut of about 12% in CDC's programs. These cuts must be taken in the last 5 ½ months of the fiscal year, presenting unique challenges to all CDC programs. The distribution of the cuts is being determined, as Dr. Khabbaz noted, and conclusions about the cuts should be complete by the end of the week.

Dr. Fenton presented an organizational chart for CDC, which represented the final results of the agency's reorganization. He reminded CHAC that DASH will move to NCHHSTP.

Dr. Fenton then described major activities at CDC in the last six months, noting that CHAC is kept apprised of these activities through regular email updates.

CDC released its first "CDC Health Disparities and Inequalities Report" in January 2011. The report includes data from across the agency and highlights key health inequities experienced by race, sex, ethnicity, income, education, disability status, and other social characteristics. The report focuses on pervasive inequalities within the United States. Further, the report points out the rudimentary nature of surveillance systems that capture and characterize health inequalities. It calls for greater investment in surveillance, research, and partnerships to provide different perspectives regarding how these inequalities are characterized and addressed.

In March 2011, CDC announced the availability of \$34 million for states and local jurisdictions to participate in the National Public Health Improvement Initiative. The effort to support and improve public health infrastructure at the grassroots level is one of the CDC Director's core commitments. This Initiative provides funding to support states to accelerate public health accreditation readiness activities and to provide additional support for performance management and improvement practices. Further, the Initiative supports developing evidence-based policies and practices at the state level. Information regarding this funding announcement was shared with NCHHSTP's partners to ensure that grantees were able to work with their local public health partners to avail themselves of these resources. Clearly, public health improvement will have tremendous impact for the HIV/AIDS, STD, Viral Hepatitis, and Tuberculosis (TB) Portfolio at the state and local levels.

CDC's *Vital Signs* publications are new from the agency. Since CHAC's last meeting, two *Vital Signs* relevant to CHAC's interests were published. In December 2010, a document on HIV testing confirmed that in 2006, about 40% of Americans aged 18 – 64 reported that they had been tested for HIV. By 2009, the percentage grew to 45%. The document stressed that more needs to be done, and faster, to accelerate HIV testing. In April 2011, a *Vital Signs* publication was released about preventing teen pregnancy. About 4% of all teenage girls give birth each year, and teen births represent about 10% of the four million births in the United States each year. The *Vital Signs* publications have been very successful. They have brought new partners together and have stimulated media interest in core public health issues. The documents have also galvanized partnerships and community actions in these areas. NCHHSTP has the December space in *Vital Signs*, so the Center will continue to share information on important topics through this medium.

The President's FY 2012 budget proposes transferring funds from the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) to NCHHSTP. NCCDPHP, therefore, is making a wide range of changes in its structure, including moving DASH's HIV portfolio to NCHHSTP. The transfer of DASH is intended to improve the coordination between HIV and STD prevention, teen pregnancy, sexual health, and school health, and to align more effectively with NCHHSTP's portfolio. Non-HIV activities in DASH will be housed in a new division within NCCDPHP. The integration will be complete by the end of FY 2011.

DASH is extremely active and has released a number of new publications since CHAC's last meeting, including the following:

- PATHS, Providing Access to HIV testing Through Schools: A Resource Guide for Schools
- Reducing Adolescent Sexual Risk: A Theoretical Guide for Developing and Adapting Curriculum-Based Programs

Like divisions within NCHHSTP, DASH directly funds a variety of non-governmental organizations (NGO). A new funding realm will begin on June 1, 2011. Eleven NGOs are slated to be funded with the following objectives:

- Five NGOs are funded to help state and local education and health agencies support the implementation of more effective school-based policies and programs
- Two NGOs are funded to increase the capacity of juvenile justice and correctional centers, alternative schools, and shelters for homeless and runaway youth

- Two NGOs are funded to increase the capacity of schools and CBOs to reach lesbian, gay, bisexual, and transsexual (LGBT) youth
- One NGO is funded to support school health services
- One NGO is funded to provide training and technical assistance (TA) on implementing evidence-based interventions

DASH has released a number of *MMWR*s. One report, to be published in June 2011, focuses on health behaviors of lesbian, gay, and bisexual (LGB) students. The report is based on data from seven states and six large urban school districts from the 2001 – 2009 Youth Risk Behavioral Survey (YRBS). The study identified differences in health risk behaviors among students identified by sexual identity or the gender of their sexual contacts. Analyzing the data with these two different measurement methods has been important. The data will be released on June 6, 2011, at the first federal LGBT Youth Summit, sponsored by the United States Department of Education (DOE) in collaboration with CDC, the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Justice (DOJ).

Dr. Fenton then offered CHAC specific updates from NCHHSTP. The Center is working toward implementation of six cross-cutting strategic goals. He again welcomed Dr. Gail Bolan, the new Director of the Division of STD Prevention. He also shared the organizational chart for NCHHSTP, emphasizing the strong leadership.

In the FY 2012 Budget, \$1.187 billion is requested for domestic HIV/AIDS, Viral Hepatitis, STDs, and TB at CDC. The request includes increases of approximately \$30.4 million from the PPACA Prevention and Public Health Fund, as well as an increase of \$58.3 million in base appropriations to achieve and implement priority actions under the NHAS Priority actions. The budget request transfers \$40 million from NCCDPHP to NCHHSTP for HIV school health programming, and includes an additional increase of \$6.7 million in STD prevention for a men who have sex with men (MSM) initiative. An additional \$5.2 million is requested to implement IOM recommendations regarding chronic viral hepatitis and associated liver cancer prevention. Dr. Fenton emphasized that the request would undergo negotiations over the next 12 to 18 months. The requests for increases for NCHHSTP are a testament to the quality of the Center's work.

One of the Center's major goals is Prevention Through Healthcare, which focuses on ways to better leverage the healthcare system to advance prevention priorities. To reach this goal, NCHHSTP has continued to develop partnerships with various HHS agencies. One of their most robust partnerships is with HRSA, and they hope to strengthen the integration of health department programs and community health centers. The Center is considering opportunities to examine Beacon community data to better characterize epidemics. Further, the Center seeks to partner with CMS to address quality and coverage of services.

Another major Center goal is to promote Program Collaboration and Service Integration (PCSI). During the last six months, the Center has convened grantee meetings to follow on the allocation of new funding opportunities for six jurisdictions to implement and enhance collaboration and integration activities. Demonstration projects are one means for promoting collaboration and integration. The new resources in the six jurisdictions are beginning to facilitate enhanced planning between infectious disease portfolios, breaking down silos and barriers as well as illustrating new ways to work horizontally across portfolios. Lessons learned and promising practices articulated from this work will benefit the field.

Another PSCI activity is a systematic literature review focusing on the impact and effectiveness of collaboration and integration, allowing for specific consideration of gaps in the research literature. NCHHSTP can prioritize these gaps for future funding to build the evidence base on the effectiveness of collaboration and integration.

To achieve the PCSI goal, recommendations have been finalized regarding revisions to the Security and Confidentiality Guidelines for surveillance programs in NCHHSTP. CHAC has discussed some of the barriers that exist for HIV/STD surveillance systems which prevent the use of surveillance data to inform prevention programs. Further, these barriers prevent the sharing of surveillance data between HIV/AIDS, STDs, viral hepatitis, and TB programs at the local level. CDC will release new recommendations for confidentiality and security standards at the end of 2011. Dr. Fenton hoped that the new recommendations would remove some of the historic barriers to sharing data between programs and using surveillance data for prevention programs.

A third NCHHSTP goal is Health Equity. Dr. Fenton described the Center's accomplishments to characterize the nature of health inequities, focusing on using a social determinants of health approach, and to articulate clear action items for addressing them. The Center's Office of Health Equity has developed language for health equity and social determinants of health. This language is being incorporated into all of the Center's funding announcements to ensure that all funding partners understand the core value of health equity and to specify that clear action steps will be requested from all grantees.

In the Summer of 2011, a social determinants of health guidance document for NCHHSTP surveillance systems will be issued. This guidance will provide recommendations to CDC partners and staff related to how indicators that measure social determinants of health can be considered and incorporated into surveillance systems. The guidance encourages moving away from simply assessing gender, age, and other factors toward a wider spectrum of social determinants of health indicators. This shift will better characterize the burden of disease. Also in the Summer of 2011, the Center will release a 2010 Social Determinants of Health Activities Report. In July 2011, a *Public Health Reports* supplement on social determinants of health and data systems will be issued. The Center is looking at ways to strengthen its surveillance systems to better tell the story of social determinants on the epidemiology of infectious diseases.

NCHHSTP also set a goal of Global Health Protection and Health Systems Strengthening. Some key accomplishments in this area include a collaboration with the Center for Global Health (CGH) to establish a CDC Global TB/AIDS liaison and to strengthen cross-Center and agency-wide global TB control efforts. The Center has worked with the STOP TB Partnership to provide training for healthcare professionals in countries with high TB burden. With the World Health Organization (WHO) and other global partners, NCHHSTP has begun operational research on congenital syphilis. The Center provided an assignee to support the WHO Steering Committee for Global Elimination of Congenital Syphilis. Further, the Center is working with WHO to address the challenge of antimicrobial resistance to *gonorrheae*. Dr. Bolan and others are working to create a strategy to address this problem, as well as to determine the unique role that CDC can play in the effort.

The Center set goals in the area of partnerships, and continues to work closely with the Council of State Government's national conference on the topic of "Reducing Health Disparities in STIs and HIV." A number of communication activities were launched in 2010, and the Center will continue to develop and enhance those activities. The Center continues to build public and

private partnerships, especially those that come about through work with the CDC Foundation and the National Vital Hepatitis Coalition.

NCHHSTP's final goal focuses on workforce development and capacity building. The Center developed Center-specific communications products to encourage staff participation in the 2011 Employees Viewpoint Survey to support staff development. Work is on-going with the CDC Office of Diversity regarding diversity training. NCHHSTP is one of the first Centers in CDC to complete Center-wide training in diversity, diversity management, and leadership. They are proud of this accomplishment. The Center developed incentives for HHS and Presidential initiatives.

Dr. Fenton detailed other Center activities and developments over the last six months. A new Funding Opportunity Announcement (FOA) was released to support the development of a National Coalition to Enhance STD/HIV Prevention through the Promotion of a Holistic Approach to Health and Wellness. This FOA comes from a commitment not to focus solely on the vertical, specialized frame for prevention of HIV, STD, and hepatitis, but to look at opportunities for more holistic approaches. The new FOA will support efforts to improve the health of populations that are disproportionately affected by infectious diseases. The announcement calls for a coalition to maximize the health impact of services, to reduce disease prevalence, and to promote health equity consistent with the NHAS. Applications for the FOA will be accepted through May 31, 2011. Dr. Fenton expected a strong response to the opportunity, and he and the Center staff are excited about the FOA's potential to complement NCHHSTP's disease-specific work. The value of the FOA is modest at the outset, but they hope that funding partners will engage a wide cross-section of national leadership on this holistic approach to prevention, building the portfolio over time to consider the relationship of health and wellness to HIV and STD prevention.

The Annual Report for NCHHSTP for 2010 was released. Highlights of the report include the Center's work in support of the NHAS, marked declines in TB disease incidence in the United States, work to mobilize communities to promote health equity, and work on the Hepatitis Action Plan. A copy of the report is available at <u>http://www.cdc.gov/nchhstp/Publications/index.htm</u>.

Dr. Fenton then presented brief updates on the activities of each of NCHHSTP's Divisions. Activities in the Division of HIV/AIDS include the National HIV Prevention Conference, which will be held August 14 – 17, 2011, in Atlanta, Georgia. The Conference theme is "The Urgency of Now: Reduce Incidence, Improve Access, and Promote Health Equity." It is an excellent time to reflect on accomplishments and to refocus on what needs to be done. The Division of HIV/AIDS Prevention (DHAP) has also engaged in a number of biomedical intervention trials and released data. CDC published interim guidance in January 2011 for use of pre-exposure prophylaxis (PrEP) as an HIV prevention strategy among MSM. DHAP is preparing for the 30<sup>th</sup> commemoration of HIV/AIDS. An online community has been established to reflect on the last 30 years and to visualize the future for HIV/AIDS. Dr. Fenton encouraged CHAC to take part in the online discussions.

The Division of Viral Hepatitis (DVH) is preparing for the upcoming release of the Viral Hepatitis Action Plan. This inter-agency effort has brought together new partners from across HHS to focus on activities in the viral hepatitis portfolio. It is critical to think about what can be achieved by leveraging existing resources in various federal agencies and to be clear about how additional resources should be used and prioritized. Dr. Fenton thanked their federal partners and the Division staff for making the Plan a reality.

The Division of STD Prevention (DSTDP) has released a new FOA. CHAC has been instrumental in helping them re-conceptualize the use of some of the Tuskegee investments that have previously supported bioethics activities. Part of the CHAC Workgroup's recommendation included developing a new FOA to address health disparities in a more comprehensive, inclusive, and participatory way. The new FOA seeks to reduce STD rates by providing Chlamydia and gonorrhea screening, treatment, and partner services to 50% of women in publicly-funded family planning and STD clinics nationwide. Applications were accepted until April 20, 2011. The Division also released an Expedited Partner Therapy (EPT) toolkit in January 2011. It was prepared in collaboration with the Arizona State University College of Law, among other partners.

Dr. Fenton briefly described the "GYT: Get Yourself Tested" campaign, which is delivered in the month of April with a number of external partners, including Planned Parenthood, the Kaiser Family Foundation, and MTV (Music Television). The campaign encourages young people to find an STD testing center by visiting <u>www.findSTDtest.org</u> or by texting their Zip code to 498669. This campaign has shown success not only in raising awareness, but also in demonstrating true change in health-seeking behaviors among young people.

The 2010 STD Treatment Guidelines were released in December 2010. This effort represents an update of the 2006 guidelines. This resource is one of the most-downloaded and referenced documents produced by CDC. NCHHSTP's events for the rest of 2011 include the following:

- The Viral Hepatitis Action Plan will be released on May 12, 2011
- NCHHSTP will host a consultation on "Prevention Through Healthcare: Enhancing Health Departments' Preparedness and Response" on June 20 21, 2011
- The Center continues work on the sexual health White Paper, which is due for publication later in 2011
- New HIV incidence data will be published later in 2011
- The National HIV Prevention Conference will be held in August 2011
- The release of the 2011 STD Laboratory Guidelines is anticipated for the Summer of 2011

CHAC asked for additional details regarding CDC's strategic thinking regarding the changing landscape of HIV prevention. Specifically, data are emerging to suggest that one of the most effective prevention approaches can be to begin treatment earlier. Given this era of constrained resources, and given that CDC funds CBOs that may not be biomedically oriented, there was discussion regarding how to reframe the prevention milieu as antiretrovirals become part of the prevention package.

NCHHSTP is considering ways to adapt its prevention portfolio. DHAP is completing its own Strategic Plan that incorporates the implementation of the NHAS and looks ahead to new tools that are entering the prevention toolkit. They need to move quickly as new trials become available to provide national guidance when it is appropriate to do so. Collaborations are increasing with HRSA and CDC, with CMS and CDC, and across the federal government as well as within state and local jurisdictions. All effective interventions are not equal, and they all should not be brought to scale. Some have more effect with less cost, while others depend on a political context. DHAP realizes the need to work collaboratively and effectively with CBOs and local health departments to understand how to approach new interventions more effectively. Collaborations with other Divisions within the Center, as well as other Centers and Divisions across the agency, are focusing on outcomes. Dr. Fenton emphasized that they look forward to hearing CHAC's advice on these issues.

There was discussion regarding whether the HIV testing algorithm would be simplified, or whether the algorithm would include different elements. Work is on-going with the Association of Public Health Laboratories (APHL) and others in this area regarding how best to change the HIV testing algorithm. New guidance will make it more effective and easier to confirm positive HIV results. There are implications not just within the practice of diagnosis of HIV, but also for surveillance. Dr. Fenton added that they are considering the implications of the availability of over-the-counter or home-based HIV tests. Demonstration projects may need to be established now in order to provide a better understanding of how these kits should be used and implemented. Implications for linkage to care, as well as surveillance systems, must be considered.

CHAC was pleased to see that more funds were proposed in the 2012 budget for the Division of Viral Hepatitis. There was discussion regarding the potential for inter-agency work to examine on-going costs and to predict the increasing costs associated with undiagnosed chronic viral hepatitis, late presentation with end-stage liver disease, and hepatocellular carcinoma. It was noted that CMS is engaged in the issue of healthcare-associated infections.

Dr. Fenton said that the Viral Hepatitis Plan shows resources within the health system that can be better leveraged and coordinated. CMS participated in the development of the Plan and seeks opportunities for improving linkage to care and treatment activities, as well as other support activities for hepatitis. CHAC's voice is important, and engagement with agency leadership has been instrumental in raising awareness of hepatitis and the importance of ongoing investment. He thanked CHAC for their involvement in this work.

CHAC emphasized that decision-makers must be educated regarding how these efforts will save government programs in the future. They need to become more adept at making these economic arguments.

There was discussion regarding whether CDC will reprogram its resources to consider ways to support access to antiretroviral therapy for preventive purposes, given guidelines regarding EPT. Dr. Fenton answered that the dollars currently allotted for prevention represent 4% of the total investment in HIV prevention treatment and care in the United States. As they consider opportunities for expanding treatment as prevention, they should consider the totality of the HIV investments and how to leverage all of them effectively. CDC only recommends EPT for heterosexuals because the approach has only been studied in heterosexuals, and CDC's guidelines are always evidence-based. On an individual basis, however, providers may administer EPT for individuals who are not heterosexual if they assess that it is unlikely that a partner will access care in a timely fashion.

CHAC encouraged that as biomedical advances are implemented in HIV prevention that CDC does not lose sight of behavioral intervention work and the work around how social inequalities place people at risk. Interventions that are largely health system-based could accentuate health inequities, especially for populations or groups that do not engage healthcare services. Conversations on these issues should be held in tandem with conversations about incorporating new prevention interventions.

CDC has not succeeded in providing guidance to communities and institutions regarding which interventions have the most significant impact on the epidemic. Some interventions may be

effective, but they will impact a small number of people, and the cost per infection averted will be in the hundreds of thousands, or millions, of dollars. Many available interventions are costeffective, and guidance is needed regarding their implementation. Further, biomedical interventions have behavioral aspects. These interventions demand an approach to human behavior and an understanding of psychology, both from a social standpoint and on an individual basis.

Major changes in HIV acquisition in the United States have been behavioral, mostly from the community standpoint. Incidence has remained relatively stable, despite increasing prevalence because of slower declines. A third generation of the disease is coming, in which PrEP is available, the potential for a microbicide is on the horizon, and there is an understanding of the use of antiretroviral therapy in addition to condom use and syringe services. All of these approaches must be used effectively.

There was additional discussion regarding linkages to the new CMS initiatives in quality, particularly with provisions in PPACA related to endorsed measures and incentives for meaningful use and quality. Dr. Fenton informed CHAC that NCHHSTP established a leadership focal point to coordinate Center activities on healthcare reform and prevention through healthcare.

## **HRSA Update Presentation**

## **Deborah Parham Hopson, PhD, RN, FAAN** Associate Administrator HIV/AIDS Bureau

Health Resources and Services Administration

Dr. Parham Hopson greeted CHAC and acknowledged Angela Powell, who was present at the meeting from HRSA's Bureau of Primary Healthcare (BPH). She presented CHAC with an update on several topics, first describing staffing changes at the HIV/AIDS Bureau (HAB). Dr. Doug Morgan served as Director of the Division of Service Systems for 13 years and has accepted a new position in HRSA as Deputy Associate Administrator of the Healthcare Systems Bureau. Dr. Morgan's Deputy Director, Captain Hilda Douglas, retired after a 30-year career in the Public Health Service. The search process is underway to fill these vacancies. Harold Phillips was re-hired as a Branch Chief.

Dr. Parham Hopson described the following HAB priorities for 2011:

### Priority #1: Lead the HRSA efforts to implement the National HIV/AIDS Strategy

The NHAS includes 22 Objectives. HRSA has challenged itself with 50 program activities. A major accomplishment in this area is a HRSA/CMS Toolkit Letter, which is in the clearance process. This letter will go to state Medicaid Directors and then to state HIV/AIDS Directors. It will include information about the Ryan White Program and guide HIV/AIDS Directors regarding ways to interact with CMS, including opportunities under the ACA. Parts of HRSA not normally associated with HIV are contributing to these efforts. For instance, they have conducted training for the National Health Service Corps clinicians and for the Bureau of Health Professions grantees. They work closely with CDC on the Enhanced Comprehensive HIV Prevention Plan (ECHPP). Full-time staff at HAB and BPH have been assigned to focus on NHAS activities, building on the momentum and opportunities presented by the Strategy. A number of meetings, consultations, and workgroups have been convened.

### Priority #2: Contribute to science and knowledge about HIV and Ryan White Programs

The *Clinical Guide for HIV/AIDS Clinical Care* is in a "soft launch." A press release and broad announcement will be made in conjunction with the 30<sup>th</sup> anniversary activities. The Guide was written by clinicians in HRSA's grantee community, including CHAC member Dr. Bruce Agins. It can be requested online. Other clinical activities at HRSA include work in hepatitis and collaborative work on the HHS Viral Hepatitis Action Plan. HAB developed a guide for the evaluation and treatment of hepatitis C in adults co-infected with HIV. This guide is also available online.

The HIV Clinician Workforce Study is underway. This study aims to determine who, beyond providers associated with the Ryan White Program, provides HIV care in the United States. Other private providers may receive reimbursement from Medicaid or Medicare, for instance. A recent consultation addressed data sources, including Medicare and Medicaid, but it is time-consuming to assemble and clean those data. An alternative data source from SDI, a national healthcare data warehouse and analytics organization, was identified. The warehouse includes pharmacy and medical claims data from a number of sources, including managed care plans, billing providers, and geographic regions. SDI has sent HRSA data on the number of providers of HIV care per state. HRSA will match this data against other information sources. They want to ensure they capture all providers, not just physicians, so they will include attendees of their clinical meetings. More information and analyses will be presented during the November 2011 CHAC meeting.

Other efforts regarding the HIV clinician workforce include expansion of "HIV Care in Minority Communities: Capacity Building in Community Health Centers." Twenty community centers that do not receive Ryan White funds have been identified. These centers have asked for support to develop capacity to provide HIV/AIDS care. Another initiative is "Capacity Development for American Indian (AI)/Alaska Native (AN) Serving Healthcare Providers." HRSA also supports the AIDS Education and Training Centers (AETC) United States/Mexico Border Initiative.

Two new FOAs will be released soon. One will focus on telehealth training, and the other will expand HIV training in graduate medical education programs. The telehealth training will examine how to use telehealth to expand access to and improve healthcare and health outcomes for underserved populations, particularly those living in rural areas. The technology

will be used for clinical consultations and other education and training available through the AETCs. The FOA responds to a directive in the NHAS which instructs HRSA to consider opportunities to foster residency training with a focus on HIV management and care at community health centers. HAB is collaborating with the Bureau of Health Professions (BHPR) on this FOA. Efforts in expanding HIV care in community health centers in minority communities, developing capacity for AI/AN providers, and AETC capacity development on the United States/Mexico border are funded by Minority AIDS Initiative (MAI) dollars. Because of uncertainties in the budget, the fate of these projects in 2012 is uncertain. The Clinician Workforce Study and the two new FOAs are funded by the Ryan White Program, so they will continue to completion.

Discussed previously with CHAC, the Ryan White Services Report (RSR) is comprised of clientlevel data that were collected for the first time in 2009, but these data were not of high-quality. Given that HAB identified the quality issues and provided technical assistance to grantees, the data from 2010 are of higher-quality. The data are being cleaned, and analysis will begin near the end of 2011. When the analysis is complete, data will be available about the number of people who receive care via the Ryan White Program. The client-level reporting was developed a piece at a time. The next report will be the AIDS Drug Assistance Program (ADAP) report. The tool will be complete and data collection will begin in 2012.

Several new Special Projects of National Significance (SPNS) Initiatives are planned for FY 2011. One exciting initiative focuses on systems linkages. HRSA aims to link programs more effectively so their populations can get into care and remain in care. Another initiative is the Hepatitis C Treatment Expansion. The first cohort was funded in 2010, and a second cohort is funded in 2011. As part of the 2006 reauthorization, HRSA is required to provide funding for capacity-building to move toward electronic health records and improvement of electronic data systems. In 2011, the focus of this work has been ADAP.

In response to an Office of the Inspector General (OIG) finding, HAB developed more specific program expectations for its grantees to monitor their sub-grantees or sub-grantees. This work primarily focuses on Part A, funds allocated to cities, and Part B, funds allocated to states. HAB always expected that grantees would monitor sub-grantees activities and expenditures; however, monitoring methods differed across grantees. The monitoring expectations can be viewed at <a href="http://hab.hrsa/gov/manage/granteebasics.htm">http://hab.hrsa/gov/manage/granteebasics.htm</a>. Effective in FY 2011, following these guidelines is a condition of receiving grant monies. The United States Government Accountability Office (GAO) asked four questions as follow-up to the OIG report:

- How does HRSA monitor grantees and sub-grantees providing Ryan White care services to individuals with HIV?
- How does HRSA monitor funds after they have been awarded?
- What steps has HRSA taken to prevent and detect waste, fraud, and abuse of federal resources?
- To what extent has HRSA put in place corrective actions against grantees and subgrantees found to have misused funds and to deter additional improper expenditures?

In 2010, the Ryan White budget was \$2.3 billion. The first of seven continuing resolutions (CR) was passed in October 2010. Some grant were awarded at that time. On April 15, 2011, the final CR for the remainder of FY 2011 was passed by Congress and signed by the President. From April 15 through April 29, HRSA developed an Operating Plan to allocate its funds. The Plan was submitted to HHS on April 29, and from April 29 through May 15, HHS will continue to

negotiate and modify budgets from each HHS agency. For this reason, they will not know their budgets until the negotiations are complete. After the budgets are finalized, the Office of Management and Budget (OMB) allocates an apportionment to HHS, which distributes an allotment to HRSA, which gives allowances to its Bureaus. All grant awards must be made by September 30, 2011.

Under earlier CRs, HAB made partial awards. These partial awards were calculated based on 2010 award amounts. Part A grantees received partial awards on March 1, and Part B grantees received partial awards on April 1. Because of the large number of Part C grantees, there are three start dates in this category: January 1, April 1, and July 1. The 232 grantees with start dates of January 1 and April 1 received partial awards. If funds are received in time, the grantees with July 1 start dates can receive their full awards. Otherwise, partial awards will be allocated. The same conditions apply to Part F grantees with July 1 start dates. Partial awards put pressure on HRSA's grants office to revise all of the grants that are partially awarded. Part D, Dental, and SPNS grantees have a start date of August 1, so they should receive their full awards. Because it is not yet possible to compare FY 2011 to FY 2012, Dr. Parham Hopson presented a breakdown of the President's proposed budget for 2012, which may not reflect the actual award. ADAP has an increase in the 2012 request.

The ADAP program pays for medication, insurance, adherence support, and drug treatment monitoring. Of the ADAP funds, 95% are distributed according to a formula based on the number of living HIV/AIDS cases in a state in the most recent calendar year as reported by CDC. Five percent of ADAP funds are set aside for a supplemental grant. In 2010, \$835 million was originally appropriated for ADAP. An additional \$25 million was awarded in July to assist states that had waiting lists and other cost containment measures in place. Other sources of funding for ADAP include state matches, part A/B contributions, and state general revenue funds. Federal ADAP funds represent about 50 percent of a state's ADAP funding. ADAP may be allocated approximately \$885 million for FY 2011. This amount includes \$50 million to assist states with waiting lists and cost containment measures. HAB is determining how to distribute that \$50 million. The formulas that dictate how ADAP funds are distributed do not apply to the \$50 million, so they will be able to target the funds where they are most needed.

The number of people eligible for ADAP grew 18% from 2008 to 2009. This growth is likely fueled by the economic downturn, increased HIV testing, prolonged survival and increased prevalence, and earlier HIV treatment. These factors all put pressure on the ADAP program. CHAC can learn more about these issues on Dr. Parham Hopson's blog at <u>www.AIDS.gov</u>. As of May 3, 2011, over 7700 people are on waiting lists for ADAP in 11 states. This number is the highest it has been in the history of the program. Other states have cost containment measures in place, such as lowering the federal poverty level, adding an asset test, reducing formularies, initiating or increasing co-pays, and negotiating lower drug costs. People who are waiting for ADAP are not necessarily waiting for medication. Those on the list are identified by the Ryan White Program, and HRSA works to ensure that they have access to medications, largely through the Pharmacy Assistance Programs.

PPACA impacts ADAP in two ways. Most of the areas in which PPACA will impact people living with HIV/AIDS will take effect in 2014. However, on January 1, 2011, ADAP began counting toward True Out of Pocket (TrOOP) Expenses for Medicare. This change helps people "in the donut hole" obtain coverage from Medicare Part D. Additionally, Pre-Existing Conditions Insurance Plans (PCIP) serve as a bridge between now and 2014. HRSA has worked with CMS and the Center for Consumer Information and Insurance Oversight (CCIIO) to ensure that ADAP can pay premiums.

Dr. Parham Hopson described ways that HAB provides technical assistance to their grantees. A new TA Cooperative Agreement focuses on ADAP; data and reporting; fiscal management; HIV/AIDS medical homes; and the TARGET Center, which is the TA Center. During their grantee meeting last year, HAB asked the grantees to name the areas in which they most needed TA. Based on that information, they created the above priorities. TA is available in other areas as well. A National Technical Assistance Contract operates separately from these Cooperative Agreements, and that Contract helps provide TA to grantees in any area in which they express need. HAB continues to host Webinars, which help keep grantees up-to-date on new developments. Initial planning has begun for the All-Grantee Meeting in December 2012, near World AIDS Day. With respect to Patient-Centered Medical Homes (PCMH), HAB is educating its staff regarding PCMHs. HAB is also determining how PCMHs might apply to Ryan White programs. On-going collaboration with BPHC has expanded HIV care within FQHCs. Many of these FQHCs are adopting the PCMH model.

#### Priority Area #4: Maintain Global HIV Programs

Regarding HAB's global work, the Medical Education Partner Initiative (MEPI) is a new, joint effort funded by the President's Emergency Plan for AIDS Relief (PEPFAR) that is led by the Office of the Global AIDS Coordinator (OGAC). HRSA works with NIH to fund medical schools in Africa so that the schools can train more physicians to become providers of HIV care. There are three major points in the continuum of health workforce capacity development: Entry in the Workforce, Workforce Management and Performance, and Exit from the Workforce.

MEPI focuses on the first area. Strengthening the medical school includes providing support for faculty and assisting with research. In addition to funding the medical schools, MEPI funds a Coordinating Center to provide TA and help collect data. That Center is at George Washington Medical School in Washington, DC. MEPI operates under several principles. Any PEPFAR-related work focuses on sustainability. The country should "own the strategy." To this end, the medical schools in Africa are directly funded. The work should be relevant to country- and community-level needs, and should be innovative.

The Clinical Assessment for Systems Strengthening (CIASS) work continues. CIASS strengthens the programs that provide clinical care and treatment for people with HIV in PEPFAR countries. This assessment tool is based on domestic work with the Primary Care Assessment Tool and on community health centers' work with their Primary Care Effectiveness Reviews. CIASS is a self-assessment, but TA is provided to help countries determine how to maximize their resources, avoid duplication, assure financial stability, and assure program compliance.

CHAC thanked Dr. Parham Hopson for addressing the issues that were raised in previous CHAC meetings.

Regarding the workforce issues, CHAC noted that states can contribute valuable information that may not be in national data sets. Dr. Parham Hopson agreed, noting that state data from SDI will be sent first to the State AIDS Director for his or her review and comment.

CHAC emphasized the importance of monitoring standards, but commented that these activities will involve the redeployment of staff into activities that will take them away from other, more traditional public health activities. CHAC should be aware of the potential impact of these changes.

It was suggested that CHAC consider a potential role for HRSA and CDC to work together to influence medical school curricula regarding HIV.

Regarding workforce issues, there was discussion of the apparent lack of interest among HIV residents and fellows in working domestically. It is "fashionable" to work overseas, and there is a shortage of domestic HIV providers. It was suggested that PEPFAR and other funding agencies, such as CDC and OGAC, tailor domestic work into their efforts.

CHAC asked for information regarding a movement toward making HIV clinics "underserved areas" through workforce initiatives. Dr. Parham Hopson replied that one of CHAC's new members is the HIV representative on the Negotiated Rulemaking Committee that is assessing medically-underserved area (MUA) and health profession shortage area (HPSA) designations.

Dr. Sweet reminded CHAC that the letters she sent to Secretary Sibelius and Dr. Wakefield on behalf of CHAC asked that they strongly support HIV as a workforce area in HPSA, MUA, and other areas.

There was discussion regarding designating a segment of the National Health Services Corps for underserved diseases. It was observed that while HIV/AIDS material can be taught in the medical school curriculum, medical students with an interest in public health or in community service would truly be affected if there was a way to repay the cost of medical training.

In terms of HRSA's thinking regarding early access to treatment and/or maintenance of care, Dr. Parham Hopson reported that HRSA has had Prevention with Positives on-going for some time and will continue its commitment to this initiative. Treatment largely comes through ADAP. Ryan White grantees follow the Public Health Service (PHS) treatment guidelines. As more people join ADAP as a result of success in testing and early treatment, and as ADAP is already stressed due to a shortage of providers and other challenges, more challenges are presented.

It was stated that as ADAP takes steps to decrease its waiting lists, dropouts occur and people do not receive the care they need. There are tradeoffs associated with linkage to care systems, including frustration with paperwork and the need to be re-certified every six months. CHAC felt that it was critical to work with the ACA. Every time cost containment measures are implemented, patients are impacted as they try to "do more with less."

There was discussion of a recent report from the state of Florida, which suggested that ADAP "was not the payer of last resort" for many people in the program. There was question regarding whether client-level data will reflect the extent to which those who access ADAP are also accessing primary care through Ryan White and other means. PPACA will continue to break down silos, and prevention modalities will become opportunities for reimbursement for prevention and care providers. Dr. Parham Hopson explained that the Florida report included challenges identified in a HRSA site report. One of the issues was that some individuals in ADAP were using the program when they had other sources of funding, and the site visit report recommended that Ryan White dollars should be used when there are no other resources. The RSR will use unique identifiers and will be able to tell which individuals accessed which services in the Ryan White program.

CHAC asked for guidance and clarity regarding the PCIPs and the extent to which Ryan White funds can pay for deductibles and copays. Dr. Parham Hopson agreed to research this issue and provide an answer at a later time.

## Update on National HIV/AIDS Strategy/Implementation and 2012 IAS

#### Christopher H. Bates, MPH

Executive Director, Presidential Advisory Council on HIV/AIDS Director, Office of HIV and Infectious Disease Policy Department of Health and Human Services

As Dr. Helene Gayle, PACHA Chair, was not able to attend the meeting, Christopher Bates presented an update on implementation of the NHAS. He reported that PACHA was rechartered in 2009 and is re-chartered every two years. The Council has 25 members, including the Chair, and four subcommittees. PACHA is charged to "provide advice, information, and recommendations to the Secretary regarding programs and policies to promote effective prevention and cure of HIV disease and AIDS. The function of the Council shall be solely advisory in nature."

The NHAS implementation plan includes a few items specific to PACHA. For instance, PACHA is expected to conduct general monitoring of the implementation of the Strategy. Further, PACHA provides either its own report, or feeds into other reports that are developed by the government, to inform the public about accomplishments and challenges associated with the NHAS, as well as whether redirection is needed. PACHA has been assigned to consider the roles of disclosure, stigma, and discrimination.

PACHA uses the vehicle of resolutions to move its recommendations to the Secretary and to the White House. ADAP has experienced challenges. There is a need for additional resources, and perhaps repositioning in some states. PACHA supports an increase of \$126 million to help eliminate the waiting list. Another PACHA resolution supports balancing the United States Prevention Services Task Force (USPSTF) recommendations regarding HIV testing and the recommendations in CDC Guidance. The approaches are different regarding routine testing, and PACHA has asked USPSTF to revisit its recommendations.

In PACHA's first year, the group focused on the full landscape of activities and programs within HHS and across the federal government. After July 2010, when the NHAS and Implementation Plan were released, PACHA focused its efforts. The group has been engaged in operational discussions with different entities of the government that the NHAS identifies as lead agencies. The Council has also considered the criminalization of HIV disease, the routinization of HIV testing and referral, the impact of the ACA on HIV, addressing stigma and discrimination, harmonizing data systems across HHS, and a structured method of monitoring the NHAS implementation.

CHAC asked about representation on PACHA from African American HIV-positive women and from the Hispanic population. Mr. Bates answered that two names are being vetted by the White House to replace a person who stepped down from PACHA. Both candidates are HIV-positive African American women. Five members of PACHA are Hispanic and represent the Hispanic perspective.

CHAC asked for more information regarding the manner in which federal agencies and departments other than HHS are responding to the NHAS. Mr. Bates replied that the White House released an Executive Statement about the operational plans of HHS and other lead agencies on February 14, 2011. All of the operational plans can be accessed on www.AIDS.gov. The plans are available on individual agency websites as well.

Mr. Bates then described implementation of the NHAS. When the NHAS and Implementation Plan were released, the President also released a memo identifying HHS, particularly the Assistant Secretary of Health, Dr. Howard Koh, to serve as the lead coordinating entity for HIV and AIDS services and activities.

In terms of the elements of the NHAS Implementation Plan, all HHS offices and agencies with an AIDS portfolio meet quarterly. Currently, about 26 different offices and agencies participate in these meetings, and their newest addition has been the Office of Adolescent Health, which is under the Office of the Assistant Secretary for Health. In this meeting, the entities share data about their various activities. They also discuss where they can link, partner, and coordinate.

The Federal Leads Group includes the different departments that have HIV portfolios or roles in HIV/AIDS work, including the following:

- DOJ: The Office of Civil Rights does work in HIV-related discrimination, and the Bureau of Prisons (BOP) has a large HIV program that works with other Departments and HHS.
- DOL: Just had a large cross-governmental meeting on issues related to HIV and the labor force in the United States, including laws and opportunities for employment for those with an HIV/AIDS disability.
- VA
- SSA: Many people rely solely on SSA for income.
- Housing and Urban Development (HUD): Housing opportunities for persons with AIDS is a focus, but if people are low-income or have disabilities, then they are eligible for multiple HUD programs.
- Department of Education (DOE): Thus far, DOE has not had an active role, but they have a role to play because of their training programs for people with disabilities and opportunities in public education.

Discussions across Departments related to housing have been very powerful, and they are moving aggressively toward creating language and definitions that will help conversations about the integration of work related to those with HIV and their housing needs.

Part of PACHA's charge is to reconsider how funds are used. Funds for the Office of HIV and Infectious Disease Policy come from the MAI Fund. There are two tiers of MAI funding. One tier consists of dollars that Congress assigns directly to specific agencies for HIV programs and activities. The Secretary's budget includes the second tier of MAI funds. This \$53 million is provided for informative and other activities related to areas and points of interest to the Secretary. Administration of those funds takes place in the Office of HIV and Infectious Disease Policy under the leadership of Dr. Howard Koh. For the first time this year, the Office carved out funds to support two new initiatives: CDC's ECHPP, on which the 12 Cities Project has piggybacked; and in support of the NHAS. Given the uncertainty surrounding the 2012 budget, they are engaging in discussions with internal colleagues and external partners in order to gain perspective on how to use the dollars they do receive. They have met with OMB to discuss how funds have been used in the past and how they might be used differently in the future.

Additionally, they recently conducted a Congressional briefing with 13 different members of Congress and their staff to address the direction of the MAI Program.

A recent LGBT Consultation was mandated through the NHAS, the aim of which was to reengage segments of the LGBT community that are no longer engaged in health promotion activities. These activities are important, given the impact that this epidemic has had on gay men and MSM. Many issues emerged in the two-day meeting, and they extracted salient issues to share with colleagues and other areas of the department. A workgroup has been created to assess LGBT issues and how to utilize opportunities for health promotion through existing relationships between the Department and LGBT organizations, as well as through new relationships that can be built.

In July 2011, a consultation will be held with persons living with HIV/AIDS to help determine ways in which people infected with HIV can play a leadership role in prevention work across the country. The faith-based community has also been an important partner in HIV prevention for some time through the active Faith Community Initiative. The White House Office of Faith-Based and Community Initiatives and the HHS Office of Faith-Based and Community Affairs work in collaboration with the Office of HIV and Infectious Disease Policy. Their first large project as a group is a focus on faith communities and HIV testing for HIV Testing Day.

The 12 Cities Project builds on CDC's work with the ECHPP program. The project takes advantage of opportunities to coordinate across HHS Departments such as SAMHSA, HRSA, the Office of Population Affairs (OPA), the Office of Minority Health (OMH), the Office of Women's Health (OWH), and others. The VA has expressed an interest in participating. They hope that city plans will reflect a larger "cast of characters" into a coordinated system in order to help people access and navigate systems and stay in care. The 12 Cities Project assists communities in building seamless systems to move people through social services and health services programs. The 12 cities in the Project represent 44% of the epidemic, which is why CDC selected the cities. In building on the ECHPP Program, the 12 Cities Project aims to provide complete mapping of federally-funded HIV/AIDS resources; share data across vertical HHS HIV/AIDS programs to better inform local planning; identify and address local barriers to coordination across HHS grantees; and develop common measures and evaluation strategies. The direction for the 12 Cities Project was established by Secretary Sebelius, who has been very involved in the work. PACHA felt that it would be helpful to have a liaison to CHAC, and for CHAC to have a liaison to PACHA, to coordinate their efforts under the NHAS concerning disclosure.

There was discussion regarding the role of women and the Office on Women's Health (OWH) in the NHAS. OWH has held its own consultations on the NHAS and has provided recommendations for inclusion in the Operational Plan.

CHAC commented on the specific and bold goals in the NHAS for increasing rates of viral load suppression and improving retention and care and asked about the next steps for strategies that will focus on these goals. A PACHA Workgroup has been established to respond to the Secretary's demand for metrics. The Workgroup has had its first meeting, and they plan to work with CDC, HAB, BPHC at HRSA, and others as appropriate.

There was discussion pertaining to the requested one percent tap on federal HIV spending to support implementation of the NHAS. The funds will probably not be used everywhere across the country, but will focus on the opportunities created by the 12 Cities Project and ECHPP. Those initiatives are the foundation to collect lessons learned and to guide the rest of the

country in positioning prevention, care, and treatment programs and services in relationship to other partner agencies.

The Office of HIV and Infectious Disease Policy is working with CDC and other HHS partners regarding the Hepatitis Plan and its implementation, for which they will serve as lead. More details will be presented during the next CHAC meeting, and more discussion will be possible at that time.

CHAC requested a future presentation on the 12 Cities initiatives and best practices. Time is needed for implementation before outcomes can be reported. Launch is anticipated in Fall 2011.

## Progress Report on BPHC Efforts and Strategy to Expand HIV, STD and Viral Hepatitis Testing, Care and Reporting Within FQHCs

## **Seiji Hayashi, MD, MPH** Chief Medical Officer Bureau of Primary Health Care Health Resources and Services Administration

Dr. Seiji Hayashi described events impacting the Federally Qualified Health Center Program. The FQHCs provide treatment and care for HIV/AIDS and a number of other diseases and conditions. He acknowledged the work of Angela Powell and Renee Sterling and their contributions to HIV/AIDS efforts in BPHC, and shared greetings to CHAC from Dr. Wakefield and from Jim McCray, Director of BPHC.

Pertaining to the context for HRSA-supported health centers, the complete 2010 Uniform Data Set (UDS) data were not available. Some health centers reported late, but care has been provided to over 19 million individuals in the Health Centers across the United States. 1100 organizations and over 8100 sites are included in this data. The number of patients being served is increasing, with 8.8 million served in 2009. Additionally, the Centers cared for over one million homeless individuals and over 800,000 migrant and seasonal farmworkers. Of their patients, 92% are below the 200% poverty level. Health Centers cared for over 100,000 HIV positive individuals, which represents 10% of the total number of HIV positive individuals in the United States. Health Centers treated 73,000 individuals primarily for other STDs. The UDS reports primary diagnoses, not secondary or tertiary diagnoses, so this number is likely to be an under-representation of the actual number of people who were treated. Over one million patients were seen in Health Centers primarily for addiction services. That number is high, but it is still likely an under-representation.

At the CHAC meeting six months ago, it was reported that PPACA would provide the Health Centers with \$11 billion over the next five years. At that time, they hoped to double the number of patients served to reach a number close to 40 million. This goal will not be achieved if the trajectory established with FY 2011 funding persists. Through PPACA, the FY 2011 appropriation was \$1 billion, in addition to the discretionary appropriation of \$2.2 billion. The Health Center Program appropriations were cut by \$600 million, so they have about \$400 million in additional funds. However, over the past two years, the Recovery Act allowed for funding of a great deal of expansion, especially for services for the uninsured. About three-quarters of the \$400 million addition is committed to continuing services for those new axis points as well as to continuing services for the newly uninsured. The number of newly uninsured is between two and three million, and approximately four million new patients have been seen in the Health Centers over the last two years.

The other significant change in the funding landscape for HRSA-funded Health Centers concerns Medicaid cuts in some states for some services. Because of the unemployment rate, numbers of uninsured individuals have increased. Additionally, Health Centers report that the community-based philanthropy on which they rely in many areas, such as wraparound services, has declined or disappeared. The fact that Health Centers were able to see more patients under these circumstances is a surprise.

There was vibrant discussion during the last CHAC meeting. The BPHC took that opportunity to think about where HIV/AIDS fit into their work. The Bureau's mission is primary healthcare, and the leadership has discussed how HIV/AIDS relates to tobacco, obesity, hepatitis, diabetes, hypertension, and cancer, which are all disparity areas with high prevalence. It is possible to make inroads into diabetes, hypertension, and cancer, especially concerning disparities. If they do not work on HIV/AIDS, then who will? At BPHC, they discussed whether the Health Centers could contribute meaningfully to the efforts, and if so, then how they would go about that work. BPHC decided that HIV/AIDS is a priority. At BPHC, they asked several questions about their work in HIV/AIDS:

- How do the Centers do testing?
- How do the Centers track testing?
- How do the Centers provide care when many are unprepared to provide specialty care?
- How can BPHC create, facilitate, and monitor partnerships?

Regarding screening, BPHC reviewed the USPSTF Guidelines and the CDC Guidelines. The CDC Guidelines are more comprehensive, and BPHC published a program assistance letter advocating for the CDC Guidelines for testing. They convened a national call on the topic as well, in which few objections were heard. Many Health Centers were already doing the testing and following the Guidelines, especially in the 12 cities of ECHPP. Testing is not being done in many rural communities, however, and even some Centers in urban communities are not testing. CDC has provided assistance in this area, especially around the ECHIPP program. The NHAS has helped BPHC align its messaging and create partnerships. Surprisingly, treatment is less controversial than testing. Guidelines for treatment are clear, and a program assistance letter has been drafted with the support of CDC, NIH, IHS, SAMHSA, and others. The letter will be announced and published in June 2011.

Beyond these issues, BPHC assessed its internal structure to determine whether its project officers were knowledgeable about HIV/AIDS. Some were, and others were not, he said, so they developed capacity within BPHC to help project officers work with their grantees, especially those in the 12 cities of ECHIPP, regarding HIV/AIDS. An HIV Workgroup was created within BPHC. They have convened a number of times, and they are working internally to train staff on HIV/AIDS. Further, the Bureau is considering combining, integrating, and leveraging many of its activities. They are not funded specifically for HIV, but they have discussed integrating behavioral health to impact HIV and other issues.

HRSA and SAMHSA have entered into a Cooperative Agreement and have launched the Center for Integrated Health Solutions (CIHS). This Center focuses on integrating behavioral health and primary healthcare bi-directionally. The Center also takes an endemic approach, thinking about how to leverage resources.

BPHC has met with the National Alliance of State and Territorial AIDS Directors (NASTAD), the Ryan White Clinicians' group, Hepatitis Coordinators, and state Medicaid Directors. They have a great deal underway, and Dr. Hayashi will report results from this momentum at CHAC's next meeting.

It was noted that a great deal of expertise can be found in the FQHCs, and it was suggested that CHCs that are already doing HIV care and testing could be incentivized to share their information and expertise with other CHCs.

CHAC asked about progress in measuring the implementation of routine HIV testing in the Health Center environment. Dr. Hayashi replied that the guidelines used vary across Health Centers. BPHC is determining how to capture and measure the testing. He welcomed ideas and guidance from those who were tracking implementation of the CDC Guidelines.

CHAC asked for an update regarding BPHC's approach to the fiscal challenges that CHCs face and the impact that those challenges may have on the Centers' decision to engage in HIV care. Dr. Hayashi agreed that the fiscal challenges, which are barriers to providing HIV care at CHCs, have not changed. It is important to help CHCs understand that whether they know it or not, they are seeing people with HIV/AIDS. By knowing, they can still care for those people even if they do not have an HIV specialist, as there are many primary care needs in this population. BPHC encourages the Centers to determine what they can do with the resources they have, and then to determine what they cannot do, and where they need help. Then, they can align incentives and work with federal, state, and local partners to fill those gaps. He felt that the message was resonating with the Centers.

There was discussion regarding why testing is harder to implement than treatment. There is concern in the field regarding reimbursement for activities that are not endorsed by USPSTF. Treatment guidelines are straightforward and include an algorithm, so there is less controversy.

CHAC asked whether the BPHC Workgroup was considering HIV education, including stigma and discrimination. In general, BPHC addresses cultural competence and health disparities in a broad, primary care context. Dr. Hayashi said that he would raise the specific issue of HIV/AIDS stigma to the BPHC Workgroup.

There was discussion regarding efforts to integrate primary care and behavioral healthcare in the Health Centers, especially whether those efforts explicitly include substance abuse awareness and treatment as well as mental illness. BPHC has been working on the question of providing patient-centered addiction care in FQHCs. The Office of National Drug Control Policy (ONDCP) has worked to bring federal partners together around addiction and substance abuse.

Dr. Fenton recalled that at the November 2010 meeting, CHAC recommended that the BPHC think strategically about its vision for change. He wondered whether the Bureau had considered developing an HIV or an HIV/Hepatitis Strategy to set bold targets for change and could hold accountable, or inspire, that change within Health Centers.

Dr. Fenton was pleased to see the real change pertaining to HIV that was demonstrated in Dr. Hayashi's presentation. This change is a testament to leadership. He asked about BPHC's high-level commitments in the Viral Hepatitis Plan. Dr. Hayashi answered that BPHC will follow the NHAS and the HHS Implementation Plan. The Viral Hepatitis Plan includes specific goals and objectives for the Health Centers. To address those goals, BPHC has begun conducting surveillance for hepatitis B and hepatitis C prevalence and testing.

CHAC suggested that BPHC conduct round tables that include CHCs that want to implement routine screening for HIV, human papillomavirus (HPV), and Hepatitis C virus (HCV), bringing those Centers together with Centers who have already implemented this testing.

Angela Powell, MPH, Director, Southwest Division, BPHC, HRSA, reported that the National Association of Community Health Centers (NACHC) sponsors an HIV/AIDS Behavioral Health Subcommittee. BPHC has worked with them and with HAB to bring Centers together in such a manner. The Health Centers are in a spectrum of readiness. It may be a goal for some to include pamphlets in their waiting rooms, while other Centers are already providing advanced primary care for HIV clients. BPHC works to leverage expertise and existing partnerships across that spectrum, hoping to move Centers along the spectrum. Internally, BPHC is working with its staff so that their project officers know the right questions to ask as they monitor grantees and help them progress. The BPHC shares CHAC's sense of urgency, and they are working systematically and critically to address the spectrum of staff and spectrum of Health Centers to reach their goals and activities in the NHAS.

BPHC funds the Health Center Control Networks, some of which have data warehousing capabilities. Oregon Community Health Information Network, Alliance of Chicago, and Health Choice Network of Miami are the three largest networks. They include over 40 organizations and hundreds of sites. These networks can pull out data on HIV/AIDS to the detail of individual encounters.

The Community Health Applied Research Network, a new Practice-Based Research Network (PBRN), is funded by HRSA. Fenway, and its included networks, is developing a PBRN using electronic health records to conduct HIV/AIDS-specific research in Health Centers. BPHC is encouraging research as well as data collection. The infrastructure should be complete in the next few years.

## Report by CHAC Sexual Health Workgroup Update on CDC Sexual Health Strategic Activities

#### Edward W. Hook, III, MD

Co-Chair, CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment Director, Division of Infectious Diseases Department of Medicine University of Alabama at Birmingham

Dr. Hook reported on the CHAC Sexual Health Workgroup. The Workgroup came about as a result of discussions and meetings with CDC. Those discussions and meetings led to a number of events, including the recommendation that CHAC form a Sexual Health Workgroup. The Sexual Health Workgroup includes the following members of CHAC: Edward Hook, III, MD;

Ernest C. Hopkins; Maria Lago, MSW; Jeanne Marrazzo, MD, MPH; and Andre Rawls, JD, PhD. Other individuals who were invited to join, or volunteered to join, the Workgroup include: Lynn Barclay, American Social Health Association (ASHA); Eli Coleman, University of Minnesota; William Smith, National Coalition of STD Directors (NCSD); and Christian Thrasher, Morehouse University

Dr. Fenton engaged the help of Dr. John Douglas and others, so CDC participation has increased. Sexual health issues are not new. In fact, WHO developed a carefully-worded and inclusive definition of sexual health. About a year ago, CDC convened a meeting on sexual health. This meeting served as an opportunity to evaluate and to increase the inclusiveness of the agency's efforts related to sexual health. The report from that meeting is forthcoming. A recurring theme during the meeting was, "What is CDC's definition of sexual health, and is it sufficient and adequate?" It was concluded that CDC needed its own definition of sexual health, in part because the WHO definition focuses on populations, communities, and organizations. CDC's definition should be dedicated and directed toward CDC's mission, which is public health and disease prevention. CDC's definition needed to be inclusive of community and individual perspectives, but ultimately it needed to convey a public health-related message.

Many meetings and discussions took place regarding CDC's definition. The WHO definition of sexual health states that sexual health is "not merely the absence of disease." That phrasing is not sufficient, because it may imply that persons with HIV, HPV, or herpes may not be able to be sexually healthy and pursue sexually healthy activities. CHAC believes that those persons can be sexually healthy. Participants in the meeting also discussed whether "pleasure" and / or "spirituality" belong in the definition of sexual health. Sexuality has a spiritual element, but including "spirituality" could be alienating and have other effects.

Speaking from a personal perspective, Dr. Hook noted that for all of the progress that has been made in control and prevention of STDs, including HIV, it has not been adequate or sufficient. Sexual health efforts have their genesis in the belief that after nearly a century of providing health education messages that use disease-oriented messages that implicitly place blame and lead to stigma, the time has come to change the messaging. Personally, Dr. Hook felt that promoting health, safety, and well-being means that there is no one to blame. This approach is appealing and provides a "big tent" with room for people with different attitudes and approaches.

The CHAC Sexual Health Workgroup has created the following Sexual Health Definition:

"Sexual health is a state of wellbeing in relation to sexuality across the lifespan that involves physical, emotional, mental, social, and spiritual dimensions. Sexual health is an inextricable element of human health and is based on a positive, equitable, and respectful approach to sexuality, relationships, and reproduction, that is free of coercion, fear, discrimination, stigma, shame, and violence. It includes the ability to understand the benefits, risks, and responsibilities of sexual behavior; the prevention of disease and other adverse outcomes; and the possibility of fulfilling sexual relationships. Sexual health is impacted by socioeconomic and cultural contexts–including policies, practices, and services–that support healthy outcomes for individuals and their communities."

Dr. Hook pointed out that the definition had undergone hours of crafting and discussion. The definition addresses sexual health as a state of well-being. Sexual health relates to sexuality and goes across the lifespan. It is not limited to one group, and it begins before individuals become sexually active. It involves many dimensions and is an inextricable element of human health. As such, sexual health is positive and involves a respectful approach to sexuality,

relationships, and reproduction. This definition moves away from issues of coercion, fear, discrimination, stigma, shame, and violence. Further, sexual health includes the ability to understand the benefits, risks, and responsibilities of all sexual behavior. Prevention of disease and other adverse outcomes is desirable. This definition acknowledges that sexual health is impacted by a number of external forces such as socioeconomic and cultural contexts. Of importance to CHAC are external forces such as policies, practices, and services that are provided to support healthy outcomes for individuals and their communities.

This definition has both individual and relationship contributors. It acknowledges the importance of safe and fulfilling relationships, as well as the importance and diversity of individual values and acting consistently. The importance of honest communications and trust, as opposed to blame, is the foundation for respectful relationships. Making safe decisions about reproduction and sexual activity is important. Sexual health involves both personal and partner protection from adverse outcomes. Personal responsibility is assumed in the definition. All of these elements are worth promoting from a public health perspective. This definition also addresses community and societal contributors to sexual health, including the acceptance of sexuality as a normative, healthy part of a person's life; and respect for the diversity of sexual values and beliefs that should be free of stigma and discrimination from others. Access to medically accurate and developmentally appropriate services throughout and over the lifespan is emphasized in this definition of sexual health. These elements are important for a public health message about sexual health. Finally, the definition addresses policies, social structures, and physical environments which provide resources for communities and individuals to sustain and protect sexual health. These elements are also important for a public health message.

The CHAC Sexual Health Workgroup has made important contributions to the definition of sexual health, and Dr. Hook expressed hope that they would continue to provide input and participate as this initiative moves forward. There are opportunities to discuss expanding these initiatives to HRSA and HRSA-related activities. Sexual health is a unifying theme that can be useful for primary care providers across the nation. Perhaps the CHAC Sexual Health Workgroup can create recommendations for strategies to engage HHS leadership. Now is the time to think about how to translate theory into practice, thinking about how they can change the disease-oriented framework to a health-oriented framework. For example, CDC's STD/HIV Training Centers might choose to review all of CDC's STD education materials to make sure they are not promoting a disease, blame-worthy approach, but rather a consistent health-promoting message.

The CHAC Sexual Health Workgroup planned to meet at the conclusion of the CHAC meeting, and Dr. Hook welcomed other members of CHAC to join them.

#### John M. Douglas, Jr., MD

Chief Medical Officer National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Dr. John Douglas reminded CHAC that he had presented to them one year ago. CDC has been working on a variety of sexual health topics for the last three years, after leadership from external partners, including Dr. Hook, urged CDC to focus on sexual health. Dr. Douglas presented CHAC and *ex officio* members with *A Public Health Approach for Advancing Sexual Health in the United States: Rationale and Options for Implementation, Final Meeting Report.* They have a great deal of work ahead of them, and the work begins with the definition of sexual health.

Since meeting with CHAC one year ago, NCHHSTP has been challenged to describe how sexual health fits into a larger relationship, community, and societal construct. Dr. Douglas shared a conceptual framework for Determinants of Sexual Health and a Logic Model, noting that it will serve as an organizing principle within the forthcoming White Paper. They have created short- and medium-term outcomes toward the following four long-term objectives: 1) Increase knowledge of, communication about, and healthy and respectful attitudes regarding sexual health; 2) Increase use of educational, programmatic, and clinical services that promote sexual health; 3) Increase healthy, responsible, and respectful sexual behaviors and relationships free of coercion; and 4) Decrease adverse health outcomes, including HIV/STDs, viral hepatitis, unintended pregnancies, and sexual violence.

Dr. Douglas discussed the Center's policy priorities, thanking CHAC members and external experts who assisted with the work. They were gratified to see that sexual health is being articulated in a number of important national policy documents. Responsible sexual behavior has been endorsed as a leading indicator for Healthy People 2020, as it was for Healthy People 2010. The NHAS explicitly endorses the importance of linking HIV prevention to a public health approach to sexual health that includes HIV prevention as one of its components.

The National Prevention Council is developing a new National Prevention Strategy (NPS) policy framework. This pan-governmental and cross-departmental effort looks for health in all sectors. The effort was authorized by PPACA. Its vision is to work together to improve health and quality of life by moving the nation from a focus on sickness and disease to one based on prevention and wellness. The Report is nearly final. A draft version was posted on the Internet for review by an Advisory Committee at the beginning of April 2011. The current draft focuses the NPS on four pillars, including healthy communities, preventive clinical and community efforts, empowered individuals, and elimination of health disparities. The NPS also includes six focused content priority areas, including tobacco-free living, preventing alcohol and other drug abuse, healthy eating, active living, mental and emotional wellbeing, and sexual health. "Sexual health" may be modified to "sexual and reproductive health." The April draft NPS document stated that:

- Healthy sexual and reproductive knowledge, practices, and health care play a critical role in people reaching their potential;
- Safe and responsible sexual practices are critical in reducing sexual violence and the spread of HIV, viral hepatitis, and STI;
- Planning and having a healthy pregnancy is vital to health of the newborn baby and the mother;
- Teen pregnancy and childbearing can impact educational attainment, employment, and financial stability, both immediately and in the long term.

The NPS made a number of recommendations that the Center will build on for its work and in the White Paper:

- Provide effective sexual health education for youth;
- Empower people to make healthy choices regarding receiving services;
- Enhance early detection of HIV, viral hepatitis, STIs and linkage to care; and
- Increase utilization of preconception and prenatal care.

CDC has articulated the value of sexual health within funding opportunities. One of these opportunities is "HIV Prevention for Young MSM and Transgender Persons of Color." This FOA cites the NHAS as a grounding document for the importance of sexual health and includes a definition of sexual health as one of its guiding values.

In terms of communications, it is hoped that the *Final Meeting Report* will bring attention to their work. Susan Robinson, Director of Health Communications at NCHHSTP, is developing a project to reach out to stakeholders across the political spectrum to determine the most effective way to communicate sexual health using messages, words, and metaphors that engage stakeholders and bring about positive reactions. The final products from this effort will inform the Center's work as well as the work of their partners, since one of the project deliverables is a set of training materials and a final report to serve as a guide for communicating about sexual health effectively.

A meeting was convened by Christian Thrasher, a member of the CHAC Sexual Health Workgroup, in December 2010. The five meeting participants had worked with Dr. David Satcher on his National Consensus Process. Following his "Call to Action for Sexual Health" in 2001, Dr. Satcher reached out to politically disparate individuals and organizations to find common ground. Where they could not find common ground, they strove to define the terms of their disagreement. The participants reviewed the Green Paper and provided feedback. Strengths included the paper's holistic approach and its foundation in CDC's core credentials of trusted data, which should never "be left behind." The reviewers also felt that the paper was not as liberal as expected, but also was not as conservative as it should be. The reviewers also noted a weakness in that the paper suffered from a lack of clarity as to whether a sexual health framework replaces or complements CDC's core values of disease control and prevention. That is, the effort should be explained in terms of health promotion and as a complement to CDC's mission, which is disease control, and it must be clearly explained why the agency is moving toward health promotion. If the rationales are not articulated, then CDC may lose credibility.

NCHHSTP is also working on approaches to compare trans-national approaches to sexual health, examining how various nations have developed their strategies and messaging. They are reviewing existing national surveys and developing a set of indicators. They envision a special journal issue addressing sexual health to be released in 2012, and they are creating an array of presentations and symposia at scientific meetings.

Dr. Douglas directed CHAC's attention to a report on teen pregnancy in *Vital Signs*. The news in the report was partly good, as the overall rate of teen pregnancy in the United States dropped 37% from 1999 – 2009. However, they have a long way to go, as teen pregnancy rates in the United States are still high compared to other nations.

The Center is interested in elevating the importance of health, health promotion, and in particular sexual health for MSM. To that end, they have developed a Center-wide Sexual Health Strategic Framework with the goal of improving the health of all gay and other MSM in the United States by promoting health equity and reducing HIV, STD, and viral hepatitis transmission. The framework will guide the nature, priorities, and content of the Center's programs. It will also facilitate communication with partners, as well as identify and allow for leveraging opportunities with other government entities. The framework is based on 17 key strategies organized around the following three core areas: 1) Engagement: proactively and consistently engaging gay communities and other MSM and strategic partners; 2 ) Expansion of effective programs; and 3) Evaluation: improving data collection and analysis to understand whether the engagement and expansion of prevention is really working.

During the CHAC meeting one year ago, it was recommended that a coalition of partners interested in the framework of sexual health would be valuable to CDC and other government entities. Such a coalition was discussed at CDC, and an FOA was released at the end of March 2011 titled "National Coalition to Enhance STD/HIV Prevention through Promotion of a Holistic Approach to Health and Wellness." This single award of \$325,000 will create partnerships to address sexual health considerations for the priority populations of the general population and two key sub-populations: adolescents and young adults and MSM. Dr. Douglas thanked the CHAC Workgroup members who are not CDC staff, as well as CDC staff, for their hard work.

The CHAC members of the Sexual Health Workgroup shared their thoughts. They observed redundancy, such as similar data collected in various surveillance systems and similar interventions to pursue similar outcomes. The sexual health issue is appealing as it provides a unifying theme and celebrates common messages. There was excitement that a sexual health framework could pave the way toward curriculum, training, education, and practice changes.

Dr. Fenton offered his gratitude to the Workgroup members, and was pleased with the inclusion of "spirituality." The definition will proceed higher within CDC and HHS, stimulating discussions about what is meant by sexual health. With the definition in hand, their next steps are to determine what to change, and how to change it. CHAC will be engaged in discussions about the behaviors that will be changed at the state and local health department levels as well as at grantee and community levels. He asked CHAC for advice regarding the White Paper on sexual health. NCHHSTP has produced a series of White Papers that serve as policy documents to set a strategic vision and articulate key actions for jurisdictions to incorporate. He asked CHAC what CDC should include in a White Paper that will serve as a public statement to the nation on sexual health.

CHAC felt that there would be better medical involvement in sexual health if medical providers understood that sexual health is not solely public health's role.

CHAC discussed the approach to sex in the United States. Although sexual images and messages abound, sex is not normally discussed. Rather than talking about diseases that impact sex, they should talk about sex. Medical students and residents often do not understand that they have to talk about sex and ask people about their sexual behaviors in order to help them. Many providers, even HIV providers who may be more comfortable talking about sex, want simple guidance on what to do and how to do it. It was suggested that the White Paper recommend products that can easily be integrated into the clinical setting.

CHAC agreed with including "spirituality" in the sexual health definition.

CHAC suggested engaging pharmaceutical companies in messaging efforts, as they create many of the materials made available in providers' waiting rooms. Direct consumer advertising was also discussed.

It was recommended to bring the sexual health definition to a practical level by including the voices of young people. It is important to include emotional well-being and aspects of self-esteem.

There was discussion about the Prism Awards, which were started by the National Institute on Drug Abuse (NIDA). NIDA worked with Hollywood to give awards for accurate portrayals of drug abuse in entertainment. A similar program could recognize portrayals of sexual health.

Dr. Fenton thanked CHAC for their comments and creative thinking, and requested that they continue thinking about this challenging work. As they expand the circle of leaders who learn about this initiative, they are met with some reticence regarding next steps and implementation. CHAC's voice is important as they move forward. CHAC can talk about the initiative with their stakeholders and discover ways that the sexual health work can enhance HIV and STD prevention activities at the state and local levels.

# Report by CHAC Viral Hepatitis Workgroup Update on CDC Hepatitis Prevention Strategic Activities

## Carlos del Rio, MD

Professor and Chair, Hubert Department of Global Health Rollins School of Public Health Emory University

Dr. del Rio explained that the *HHS Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis* was soon to be released. After the Plan's release, plans will need to be created to implement it. He provided background information about the CHAC Viral Hepatitis Workgroup. CHAC serves as a forum to address the recommendations assigned to CDC and HRSA in the Plan. However, CHAC lacks representation from viral hepatitis subject matter experts and community representatives that work in hepatitis: CHAC primarily includes people with expertise in HIV and STDs. People who are not members of CHAC can belong to the Workgroup on Viral Hepatitis. The Workgroup will review the progress and implementation of proposed actions and present its conclusions to the CHAC. CHAC members Dr. Carlos del Rio, Dr. Kenneth Mayer, and Dr. Donna Sweet have expressed interest in participating in the Workgroup. They have held one conference call and suggested other non-CHAC persons who could be invited to join the Workgroup. Dr. del Rio invited CHAC would make additional suggestions for Workgroup membership.

#### John Ward, MD

Director, Viral Hepatitis Program National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Dr. Ward shared highlights of the Viral Hepatitis Action Plan that are relevant to CDC and HRSA. The Plan is the product of a process that began several years ago to revisit prevention, care, and treatment policies for viral hepatitis. The effort began as a result of an IOM report on hepatitis and liver cancer that outlined a number of deficiencies in the approach to viral hepatitis. The scope of the problem is large, as 3.5 - 5.3 million people live with viral hepatitis, and most persons do not know their status. The IOM report identified issues with low levels of awareness throughout society, including clinical and public health care providers. The report also noted missed opportunities in prevention, education, immunization, testing, counseling, and referral for care, as well as the capacity to deliver appropriate care. The IOM report was followed by a variety of policy statements and Congressional hearings.

Dr. Ward expressed appreciation that Dr. Koh took on the task of creating the Action Plan. He convened a Workgroup in January 2010, and expert panels were subsequently convened to consider different aspects of viral hepatitis prevention, care, and treatment. The panels met periodically, and public meetings were held in June 2010 and November 2010.

The Action Plan recognizes opportunities within the reformed health system. PPACA was passed and became law during the time that the Plan was developed. The Plan also recognizes changes in technology, health information technology (IT), health information, management in surveillance and quality assurance, and integration. Despite challenges in the budget, there are capacity needs for viral hepatitis. The Plan sets out a research agenda to improve prevention efforts and calls for partner development in a variety of ways.

The Plan is broken into six areas: Public and provider education; strategies to improve testing and referral for care and treatment to prevent liver disease and cancer; strengthening public health surveillance; eliminating transmission of vaccine-preventable hepatitis; reducing viral hepatitis caused by drug use behaviors; and protecting patients and workers from healthcare-associated viral hepatitis.

In the area of "public and provider education," the goal is to build a healthcare workforce that is prepared to deliver viral hepatitis prevention and care services and to treat those who are infected. This issue also applies to HIV. The Plan calls for the development of an educational curriculum that can be tailored to different healthcare and public health providers. Large health disparities are related to hepatitis, and many communities have low levels of knowledge regarding what to do about the problem. A national campaign is needed to raise awareness. CDC and HRSA are given equal responsibility in this area.

The second chapter of the Plan recognizes the large proportion of the viral hepatitis population that is unaware of their infection. They are, therefore, not in care or treatment and are potentially transmitting hepatitis B and hepatitis C virus to others. The Plan calls for revising and aligning federal policies to ensure they are understandable to providers. Further, care models should be developed and implemented to help persons make the transition from testing to care and treatment. The models should be disseminated to expand capacity in different settings, and databases of testing, care, and referral services should be created to make it easier for persons to receive care. CDC has a significant role in working with federal policies, and HRSA has been tasked with developing care models.

Surveillance is a public health function, so CDC will play a significant role in the third area. CDC will help states build systems that provide a minimum set of data to detect the burden of disease and outbreaks and are able to respond to emerging trends. Other systems, including serosurveys, are needed to monitor health disparities at the national, sub-national, and community level. The systems will also accomplish the assurance function of public health, monitoring how well recommended preventive care and treatment services are being delivered, as well as their impact.

Regarding the transmission of vaccine-preventable hepatitis, many challenges in vaccine delivery relate to cost and provider delivery of vaccination, especially for adults. The Plan includes a list of opportunities to achieve the national goal of eliminating mother-to-child transmission of hepatitis B. The Plan also looks for opportunities within PPACA, since adult vaccinations are already Category A prevention services under the USPSTF. The Plan calls for research to develop new vaccines for other types of viral hepatitis.

Drug users are the only risk population that has its own chapter in the Action Plan, Dr. Ward explained, because they are at risk for multiple forms of hepatitis, and there are multiple opportunities for integration in substance abuse treatment and in HIV prevention and treatment programs. This chapter of the Plan also addresses correctional health and how to improve services within corrections as well as how to improve services for persons making the transition from corrections back into the community, where they are at risk of transmission to others and where they need to continue their own treatment.

Lastly, the Plan lays out a number of strategies to reduce healthcare-associated hepatitis. There is already a detailed plan for healthcare-associated infections prevention at the HHS level. The Action Plan looks for specific opportunities for viral hepatitis within that larger plan.

The Plan has health goals of increasing the proportion of persons with hepatitis B who are aware of their status. Similar goals are set for persons with hepatitis C. Many, if not most, of the persons living with these two chronic infections are currently unaware of their status. Another goal focuses on reducing the incidence of hepatitis C, and another goal focuses on eliminating mother-to-child transmission.

The Action Plan will be released on May 12, 2011. A Congressional briefing will take place in the morning, and the public release will occur in the afternoon. Dr. Ron Valdiserri will be tasked with developing an implementation plan for the Action Plan. Dr. Ward hoped that Dr. Valdiserri could provide CHAC with information about implementation at the HHS level at a future CHAC meeting.

CHAC asked whether CDC or HRSA was interacting with the VA, given that VA hospitals represent one of the largest care providers in the nation. There are concerns about the expense of drug therapies. The VA participated in the development of the Action Plan and is listed as a co-partner with other HHS agencies. The VA has one of the most well-developed hepatitis C programs and recommends very expanded, if not universal, screening. A conference in June 2011 will be hosted by CDC and the American Association for the Study of Liver Diseases (AASLD) to bring together the VA, HRSA, CMS, AHRQ, and NIH to discuss how to improve screening and referral for care. The VA will be part of the discussion of care models.

CHAC discussed questions about the sexual transmission of hepatitis C, which is clearly sexually transmitted among MSM, although not as obviously as hepatitis B in heterosexual populations. Resistance among providers to address hepatitis may be associated with discomfort with the population, with the disease itself, and with the drugs. These issues reinforce the need for educational programs for clinicians. Treatment can clear the virus, so they can share hopeful as well as factual messages.

CHAC discussed the Plan's recognition of some of the genetic factors that result in lower treatment response for African Americans. The Plan calls for more research and treatment development to overcome that barrier. Overall care can be improved, and positive changes in co-factors such as HIV infection and alcohol use can contribute to improvement in long-term outcomes.

CHAC discussed the Plan's support for community-based organizations (CBO) and access to specialty care. Specialty care is a challenge, because there are not enough hepatologists, and primary care providers will have to provide treatment. Different care models exist, including tertiary care providers acting in a consultative role and telemedicine models. New imaging tools may make biopsy less necessary. In the Action Plan, community-based organizations are tasked to help establish relationships in communities of need, improve education, deliver screening, and refer people as needed.

Additional discussion focused on the possibility of an approach of cancer screening, as opposed to screening for a sexually transmitted disease or a disease transmitted by needle practice. Progress in hepatitis B and hepatitis C may help de-stigmatize HIV, HPV, and HCV. CDC recommends screening for chronic viral infections.

## Update on IOM Studies Related to HIV Testing, Barriers and Linkage to HIV Care

#### Jennifer Kates, MA, MPA

Vice President and Director of Global Health and HIV Policy Kaiser Family Foundation IOM Committee Member

Ms. Kates thanked CHAC for inviting her to present the results of the IOM's Committee on HIV Screening and Access to Care. She reminded them about the preliminary presentation she delivered to CHAC on this topic. The IOM Committee process was multi-staged and involved three different reports. At the time of her previous presentation, only one of those reports had been released. All three reports have now been released and are available online, as are the presentations and documents provided to the Committee as part of the process.

This study was commissioned by the White House Office of National AIDS Policy (ONAP) as part of the NHAS effort. It was commissioned to evaluate barriers and facilitators to expanded HIV screening and access to care and the capacity of the healthcare workforce to provide care to more people with HIV. The Committee was asked a number of questions designed to inform the development and implementation of the NHAS. The Committee was aware of a number of challenges, including the percentage of those unaware of their HIV status and the percentage of late HIV diagnoses.

The Committee was given several goals and challenges:

- Consider expanding HIV testing to identify undiagnosed HIV-positive individuals;
- Link and retain those who are diagnosed with HIV to care; and
- Accommodate the growing number of persons living with HIV who require care, even as the HIV workforce is decreasing relative to need.

Ms. Kates shared the Committee's Statement of Task, adding that IOM Committees do not deviate from their Statements of Task:

- What is the extent to which federal, state, and private health insurance policies pose a barrier to expanded HIV testing?
- What federal and state policies and private insurance policies/practices inhibit entry into clinical care for individuals who test HIV-positive or inhibit the provision of continuous and sustained clinical care for HIV-positive persons?
- What is the current capacity of the health care system to administer a greater number of HIV tests and to accommodate new HIV diagnoses?

The process of answering these questions included convening a Committee of 15 experts. The Committee planned and conducted three public workshops and gathered data to produce three reports. ONAP asked the Committee not to produce recommendations, but to provide a summary of the collected information. Ms. Kates said that the recommendation process can be lengthy. She acknowledged the members of the Committee and the IOM Project Staff.

The workshops were divided into three areas, and the Committee identified people and experts to invite to the workshops. Input from the broader community was also solicited. The three areas, which are discussed in detail in the three reports, are: 1) Identifying Facilitators and Barriers to HIV Testing; 2) Exploring Facilitators and Barriers to HIV/AIDS Care; and 3) Capacity of the Healthcare System to Identify and Provide Care for Individuals with HIV/AIDS.

The barriers to expanding HIV testing include:

- Discordant federal HIV testing guidelines and recommendations between the CDC and the USPSTF. Ms. Kates noted that more attention is being given to this issue;
- State informed consent and pre-test counseling laws;
- State regulations on who can perform HIV testing;
- Inconsistent coverage and reimbursement policies have an effect on willingness to test;
- Inadequate provider training in HIV testing and counseling;
- HIV stigma and discrimination at all levels; and
- Lack of access to quality care.

With those barriers in mind, the Committee considered facilitators to expanded HIV testing. These facilitators include:

- Explore implementation of routine opt-out testing: there are many challenges associated with this approach;
- Make state laws and regulations more consistent; Increase provider education and training;
- Increase funding to implement and maintain testing programs;
- Include HIV testing in standards of care and quality metrics;
- Integrate HIV testing with provision of other services;
- Promote testing using media and social marketing strategies;
- Increase the use of rapid testing and use in non-medical settings; and
- Ensure that all community health centers provide HIV testing. Since discussions at this workshop, additional dialogue has taken place at the BPHC.

While many of these barriers and facilitators are not new, the Committee felt it was important to identify these issues for ONAP.

The second workshop focused on barriers to HIV/AIDS care:

- Fragmentation of coverage and multiple funding sources: this continues to be a challenge that will probably not go away easily, but healthcare reform may address this issue;
- Restricted access to HIV-experienced providers;
- Anticipated decrease in the number of HIV-experienced providers relative to the number of individuals needing care;
- Inconsistent provider reimbursement policies for HIV care;
- Categorical funding that does not necessarily "meet people where they are," and gaps in coverage for care services; and
- Eligibility criteria for coverage that are not uniform across the country.

Several facilitators of access to HIV/AIDS care were identified:

- Bring eligibility criteria for public and private coverage in line with HHS guidelines for initiating antiretroviral therapy (ART);
- Sufficiently fund ADAP and other programs to eliminate waitlists;
- Include HIV providers in health plan networks;
- Create consistent and fair provider reimbursement policies;
- Provide flexible funding to cover gaps in care to meet people where they are; and
- Harmonize data collection and reporting requirements.

Ms. Kates encouraged CHAC to read the report and review the presentations from the third workshop. A number of HIV providers and provider organizations spoke to the Committee about the challenges of the workplace for HIV providers and about how capacity can be increased. A number of points emerged from this workshop:

- Use of task shifting, co-management, and care coordination models (e.g., integrated delivery systems) to maximize the capacity of the current HIV care workforce. Additionally, concern was expressed that the number of providers going into HIV has decreased over time as the population with HIV has increased;
- Provision of incentives (e.g., loan repayment/forgiveness, adequate and stable financial support to clinics serving HIV patients) to attract and retain health care professionals in HIV care;
- Reform of medical, nursing, and other health professional curricula to increase opportunities for training in outpatient settings, where most HIV care now takes place. The Committee discussed the "changing landscape of HIV treatment," with a shift from in- to out-patient and a shift from acute care to chronic care; and
- Use of interdisciplinary care teams in the provision of HIV care to improve job satisfaction and retention of current HIV care providers.

ONAP also asked the Committee to identify the populations that face additional barriers to HIV testing and access to care, including individuals within the correctional system; immigrants, in particular undocumented immigrants; individuals with mental illness and substance abusers; individuals who are homeless or unstably housed; and individuals over age 50, who are often not thought to be at risk for HIV.

Because PPACA passed after the Committee began its work, they felt that they should address the Act. Several experts spoke to the Committee regarding potential changes as a result of PPACA. They considered increased access to Medicaid and private insurance, which will certainly benefit people with HIV. Concern was raised regarding the Ryan White Program and what will happen to the benefits provided by Ryan White that are not provided elsewhere. There are provisions in the Act designed to support the training and placement of 16,000 new primary care providers over the next five years.

Ms. Kates then discussed next steps for the reports. Ultimately, sharing the findings depends on ONAP. They are interested in sharing the findings, but they are also working to implement the NHAS. She felt that it was important to find opportunities to share the reports and to stimulate dialogue about them, and invited CHAC to share their dissemination ideas.

Throughout the process, the lack of nationally representative data regarding where, and from whom, HIV positive individuals receive care was identified as a gap. It is not possible to understand changes without understanding a baseline. Different data sources exist, but they tend to include small, non-representative samples. One representative study was conducted, but it is nearly 15 years old. The Committee felt that the lack of data hampers policy decisions. In part because of the lack of data, ONAP commissioned a new study from IOM to look at data systems for monitoring HIV care. Ms. Kates will serve on this Committee. They are assessing available data systems to capture information about HIV care, and they have been asked to provide recommendations about the most critical data and indicators needed to gauge the impact not just of the NHAS, but also of the ACA. The Committee will also consider whether it is feasible to have nationally representative data. If not, the Committee will consider other options. Two meetings have taken place so far, and more are planned. Many of the meetings have a public component. They have already learned that some available data are not being mined.

The Study is posted on the IOM site, and the Committee members are available to discuss the reports or to make presentations in other venues: <u>http://www.iom.edu/Activities/PublicHealth/</u><u>HIVScreeningCare.aspx</u> She recognized that some of the information in the reports is not new, but she hoped that it will be important for the information to come from the IOM. The next step will be to share the information to appropriate places. All of the many identified barriers/ need to be addressed, but she felt that the provider-level barrier emerged consistently in their deliberations. Questions included how to reach providers and train them, how to equip providers with the tools that they need to be comfortable to administer HIV tests and provide screening and care, and retention issues. Individuals need to be motivated to get care, but they have moved beyond the individual model to structural barriers.

CHAC thanked Ms. Kates for her review of the reports.

Kaiser Family Foundation has not identified a strategy for sharing the information in the reports. Kaiser supported the public briefing with IOM and the White House. Ms. Kates said that she would take the question back to Kaiser, adding that Kaiser could potentially provide media coverage around the issues.

There was discussion of cost as a barrier to testing. The concern was reflected in reimbursement challenges, both in the cost to patient and to the provision and care system. One of the identified barriers was that reimbursement is not just for the literal test, but for all of the attendant activities associated with the test.

CHAC asked for clarification regarding why ONAP did not ask the Committee for recommendations and whether the impetus for the reports was a need for guidance and information to assist in implementation of the NHAS. Ms. Kates could not speak for why the decision was made not to ask for recommendations. IOM has multiple models for its studies, one of which is the workshop model without recommendations. This model holds workshops with experts to compile information with some analysis and to share that information. CHAC felt that this tactic was appropriate, as recommendations take a great deal of time to create.

There was discussion regarding why policies and recommendations sometimes do not translate into practice. The Committee addressed the importance of including metrics in standard measurement systems, as opposed to a reporting requirement based in a grant.

It is not clear how ONAP plans to further disseminate the IOM report. It has been suggested that ONAP host a Webinar with federal colleagues. There was discussion regarding whether it would be helpful for CHAC to make a recommendation regarding further dissemination. As CHAC makes recommendations to the heads of CDC and HRSA, it was decided that such a recommendation would not be appropriate. Dr. Fenton suggested that he and Dr. Parham Hopson reach out to ONAP at one of the meetings of the NHAS Implementation Group of leaders from across HHS. They should learn about ONAP's plans before implementing their own strategies.

# Wrap-Up of Day One

Dr. Hook asked CHAC members to review their calendars and indicate their availability for dates for the November 2011 CHAC meeting in Washington, DC. He noted the timing of the American Public Health Association (APHA) and US AIDS meetings. The 14<sup>th</sup> and 15<sup>th</sup> of November were raised as possible dates.

Dr. Sweet asked CHAC to review and approve the minutes from the November 2010 meeting. A motion was properly placed on the floor and seconded. **CHAC unanimously approved the meeting minutes from November 2010**.

Dr. Fenton summarized the day's proceedings. He asked for advice from CHAC regarding moving from theory into action, especially on sexual health. He looked forward to hearing thoughts from CHAC regarding strengthening the viral hepatitis portfolio and how CHAC can strengthen that work in the future. CHAC has historically focused on HIV and STDs, and he hoped for their leadership in viral hepatitis prevention. He also hoped for additional feedback from CHAC regarding a dissemination plan for the IOM report. CHAC should be as specific as possible in its recommendations so the agencies can respond to the recommendations and provide feedback on their progress.

Dr. Sweet hoped that CHAC was pleased with their Workgroup activities, as two Workgroups have provided substantial reports. With that, Dr. Sweet recessed the meeting at 4:37 pm on May 10, 2011.

# **Update on CDC's HIV Prevention Portfolio**

Dr. Hook reconvened the CHAC meeting at 8:37 am on May 11, 2011. Dr. Fenton greeted the group and conducted a roll call of CHAC members and non-voting *ex officio* members. A quorum was present, and no new conflicts of interest were disclosed. He reminded them that CHAC meetings are open to the public, and all comments made during the proceedings are a matter of public record. CHAC members and associate members should be mindful of potential conflicts of interest identified by CDC or HRSA Management Committee Offices and should recuse themselves from participating in discussions or voting on issues for which there are real or perceived conflicts of interest.

#### Jonathan Mermin, MD, MPH

Director, HIV/AIDS Prevention Program National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Dr. Mermin presented CHAC with updates regarding CDC's HIV Prevention Portfolio. He acknowledged those who were involved in helping DHAP design a new Strategic Plan. This effort has been on-going for approximately two years, and it is reaching its final stages. The purpose of the effort was to create a division-specific framework for achieving high-impact prevention, redesigning their activities to have a greater effect on the HIV epidemic. To make these changes, they looked internally as well as at external partnerships. Further, the Plan prioritizes the allocation of prevention resources.

In 2009, an external peer review was conducted, focusing on surveillance research and HIV prevention. More than 200 staff and external stakeholders have been involved in this activity. The penultimate draft of the Strategic Plan is under review and will be completed soon. One of the major outcomes of creating a Strategic Plan is the process itself. Reflecting on their work and whether they are having a major effect has influenced collaborations within DHAP as well as changed their focus areas. The NHAS and the NCHHSTP Strategic Plan served as guides for the Division Plan.

The first goal in the Plan relates to HIV incidence, and it aligns with NHAS goals. The objectives, which are also major indicators for success, are to reduce the annual number of HIV infections by 25%; increase the percentage of people with HIV who know their status to 90%; increase early diagnosis (that is, at a stage earlier than AIDS) by 25%; decrease the rate of perinatal HIV cases by 25%; reduce the proportion of MSM who report unprotected anal intercourse during last sex with partners of discordant or unknown HIV status by 25%, and reduce the proportion of intravenous drug users (IDU) who report risky sexual or drug-using behavior by 25%.

The second goal of the Plan relates to prevention and care. This goal is aligned with the NHAS goal of quality and access to care, but includes a focus on prevention aspects. Their chief goal is prevention with positives as well as to focus on negatives not acquiring HIV. The objectives for this goal are to reduce HIV transmission rate by 30%; increase the percentage of persons diagnosed with HIV linked to clinical care to 85%; increase by 10% the proportion of persons with HIV in care whose most recent viral load was undetectable; and reduce by 33% persons

with HIV in care who report unprotected anal or vaginal intercourse during the last 12 months with partners of discordant or unknown HIV status.

The third goal relates to health disparities. The first indicator matches the NHAS, and the objectives are to increase the proportion of HIV-diagnosed gay and bisexual men, African Americans, and Latinos with undetectable viral load by 20%; reduce the disparity in HIV incidence for MSM compared with other adults in the United States by 25%; and ensure the percentage of persons diagnosed with HIV with a CD4 count within three months of HIV diagnosis is 75% or greater for all racial and ethnic groups.

There was a great deal of discussion in DHAP regarding how to view health disparities and how to make a difference in them, and Dr. Mermin welcomed thoughts from CHAC on this topic.

The fourth goal of the Plan relates to organizational excellence, or "doing a better and more efficient job" with the resources they have. The objectives of this goal are that each year, all branches and operating units will complete at least 80% of their work plan activities; each year, all branches and operating units will adhere to 80% of administrative and extramural processing deadlines; and by 2015, DHAP will have improved its rating on the HHS Annual Employee Viewpoint Survey.

Their next steps are to refine action steps and work plans and to work within NCHHSTP to complete the Strategic Plan. Dr. Mermin hoped for clearance and publication to the DHAP website soon. They will continue implementation and monitor and evaluate progress.

He then presented CHAC with an update on the expanded HIV initiative. The first three years of the initiative are complete. Approximately 2.7 million tests were conducted. The majority of participants, 62%, were African Americans. Hispanic/Latino participants were 15%. The focus of the initiative was areas of disproportionate impact. More than 28,000 HIV positive persons were identified, and about 17,500 were newly diagnosed. A proportion of those who are diagnosed with HIV during screening activities had previously been diagnosed, but they had fallen out of care. These screening activities present an opportunity to re-link those individuals to prevention and care services. At a minimum, 75% of new positives were linked to care. It is difficult to obtain good data on the linking activities. They believe that a greater proportion of positive individuals were actually linked to care. Rates of linkage to care were higher when people were tested in clinical settings as opposed to non-clinical settings. Many more hospitals and clinics are providing routine screening, but the rates are not at the level they should be. Few outlets are testing in the inpatient setting, although this setting is efficient and were reimbursement is likely to be easily obtained. This initiative highlights a national effort to increase routine HIV screening across a variety of clinical venues. Times have changed, and routine screening is more accepted now. The importance of knowing status is a priority for positive individuals as well as for those in discordant couples. The newly-diagnosed infection rate, on average, was .7%. It is estimated that 3,381 HIV infections were averted and that a return of \$1.97 was achieved for every dollar invested. This program provides evidence for large-scale HIV testing programs in general.

A new cycle of funding began in September 2010. This cycle expands the program focus to include MSM and IDU populations. Although there is overlap among the populations, African Americans, Latinos, MSM, and IDU represent over 90% of the people with HIV in the nation. Focusing solely on a race and ethnicity framework would not have addressed the highly impacted IDU and MSM groups. Additionally, the new funding cycle requires that 70% of testing activities occur in a healthcare setting, where the previous cycle required 80% to occur in a

healthcare setting. This change allows for venue-based, response-driven, and social network testing, which can be productive, particularly for MSM and IDU populations. \$56 million was awarded to 30 health department jurisdictions to expand and capitalize upon successes of the program. \$3.9 million was awarded to 18 health department jurisdictions to improve and enhance linkage to care and to establish best practices to ensure greater than 75% linkage to care.

An FOA has been released on young men who have sex with men (YMSM) and transgender persons of color. This FOA is a renewal of a cooperative agreement, with a change in focus. The five-year agreement supports 25 organizations to provide effective HIV prevention services to young men of color who have sex with men and to young transgender persons of color and their partners. The award is approximately \$9 million per year. The program requires not only that all recipients conduct HIV testing, but also that the HIV testing positivity rate is 4%. Another requirement is associated with the number of people tested. The positivity rate was calculated based on data from a variety of other programs and surveillance activities. The National HIV Behavioral Surveillance System has shown an 8% newly-diagnosed positivity rate. A 4% positivity rate allows for variance, but is a challenge for many of these organizations that have historically not had such high rates. The rate encourages recipients to focus on diagnosing individuals, linking them to appropriate services, and re-engaging and retaining individuals. A section of the FOA focuses on finding individuals who know they have HIV and ensuring they are getting appropriate treatment, care, and prevention services, including links to behavioral interventions, substance abuse, and other services for persons with and without HIV. The FOA will move the program toward more effectiveness in preventing HIV infection and toward engaging CBOs into the healthcare setting, developing strong partnerships.

Dr. Mermin noted that a recent study of the pre-exposure prophylaxis showed efficacy of daily Truvada in reducing acquisition of HIV in MSM. Recently, the FEM-PrEP study, which took place among women, was stopped by the Data and Safety Monitoring Board (DSMB) for futility. Details would be provided on the PrEP study in a subsequent presentation, and he looked forward to discussions not only on scientific issues, but from program and policy perspectives, to determine how to help people without doing harm.

He then turned to ECHPP, or the "12 Cities" Program. Final plans from health departments were submitted to CDC on March 15, 2011. The plans have been reviewed by CDC staff and partners from other HHS agencies. Phase Two planning requirements focus on updating the current plan, implementing experience, incorporating new science or data from the literature as well as from experience in the jurisdictions, and new aspects of the Health Department FOA. HHS is leading cross-agency discussions, and new funding activities from other agencies are all related to maximizing impact in these 12 jurisdictions. Although the effort has been complex and sometimes time-consuming, bringing the agencies together to think about the entire portfolio of HIV activities has been helpful and a way for leaders and staff of the agencies to work together.

The new Health Department FOA could change, as it has not been issued yet. It is likely to be issued in late June 2011. The funding distribution will be determined by the unadjusted number of people diagnosed and reported to be living with HIV in 2008. DHAP has anticipated this change. The previous metric of AIDS cases means that if people are treated early with ART and AIDS is prevented, then there is essentially a "penalty." There are imperfections associated with using the metric of people living with HIV, but there is support from constituencies to use that metric. The FOA includes a base minimum floor so that every jurisdiction will have at least some resources to be able to maintain an HIV prevention program. Currently, they plan for

funding changes to take place over three years, with 50% of the change in the first year, 75% in the second year, and 100% in the third year. This will allow for an alignment within three years without devastating programs by implementing all changes in one year. The Expanded Testing Program will be incorporated as a separate category within the FOA. Programmatically, they will learn from the successes and difficulties with ECHPP.

DHAP is working on guidelines and recommendations in several areas. Male circumcision guidelines will be available for public comment soon. Male circumcision has been shown in three randomized trials to reduce female-to-male transmission of HIV and multiple other STDs. Limited information is available for MSM, however. The American Academy of Pediatrics (AAP) is updating recommendations as well. There is an urge to provide information while respecting autonomy. Prevention with Positives guidelines are being created in collaboration with HRSA and several other organizations, including the HIV Medical Association. A successful consultation took place in April 2011. They are adopting a modular approach to these guidelines: rather than waiting for the guidelines to be completed, which could take two years, they will release sections of the guidelines as they are ready. These guidelines will lead to additional programs related to Prevention with Positives. The Interim HIV Testing Guidance is progressing and is linked to efforts to revise guidance related to confirmatory testing. The Syringe Services Program Guidance for partners is going through the clearance process and should be completed soon.

Upcoming events associated with the 30<sup>th</sup> Anniversary of the recognition of HIV/AIDS. Multiple lectures will commemorate the event, and the National HIV Prevention Conference will take place in August 2011: <u>http://www.2011nhpc.org/</u>

CHAC thanked Dr. Mermin for the presentation.

There was concern regarding the success of testing, consistent adherence to care, and keeping people in care. The link between diagnosis and connecting to prevention services is a major area of collaboration for CDC and HRSA. Prevention with Positives incorporates a conceptual framework that views prevention and care as the same activity. Helping people get services, whether they need substance abuse, mental health, prevention, or treatment services, is one continuum of a holistic approach to HIV prevention and treatment.

It was noted that there has been an increase in infection rates for African American and Latino women. Behaviors are not being addressed. Another research area of concern was the behaviors of men of color who were incarcerated who return to the community. Dr. Mermin assured CHAC that these issues are part of the DHAP portfolio.

There was discussion regarding Goal A of the DHAP Strategic Plan, which includes reducing the proportion of MSM who report unprotected anal intercourse. The Goal seems to be to reduce the rate at which negative men engage in unprotected anal intercourse with positive or status-unknown men. It was not clear why the goal was framed that way, as opposed to a goal of reducing the rate of unprotected anal intercourse in general. Dr. Mermin replied that there have been recent changes in some populations of gay and bisexual men who have begun using their own and their partners HIV status for determining use of condoms - called seroadaptation. DHAP focused this indicator on the risk behavior that directly correlates with HIV transmission or acquisition to obtain an assessment that incorporates knowledge of true status into the outcome of interest. CHAC was concerned that the stated goal focuses on negative men not having unprotected anal intercourse with HIV positive men and hoped that they could encourage HIV-negative men not to have unprotected anal intercourse at all.

It was suggested that DHAP examine the HIV Strategic Plan for 2001 – 2005 goals and learn lessons from why those goals were not achieved. Dr. Mermin agreed that the indicators were ambitious. Strategic Plans need to strike a balance between aspiration and practicality. Many of the new objectives are in NHAS, and they cannot be less aspirational than the NHAS. CHAC reviewed the 2001 – 2005 Strategic Plan and evaluated the reasons why the Plan failed. This evaluation factored into the design of the extension of the 2005 Plan and of the new Plan.

CHAC encouraged DHAP to make difficult decisions. If they determine that an activity that they have undertaken for years is not productive, then the activity should not be funded.

Dr. Fenton addressed the issue of unprotected anal intercourse. CDC struggles with its position on this issue. With the increase of prevalence of serosorting, seroadaptation and strategic positioning, CDC is grappling with public health messaging. He felt that CHAC should weigh in on CDC's direction with these issues.

There was extensive discussion regarding the AAP statement on male circumcision. A population of young minority men who have not been circumcised is being built in the United States. Because of a previous statement from AAP, Medicaid and most insurance plans do not pay for circumcision. Dr. Mermin believed that the AAP recommendations will be aligned with CDC's new recommendations. The issue is political, as there is sound data to show that it prevents HIV acquisition among heterosexuals. CDC is in a position of needing to share information while respecting the autonomy of adults to make decisions for themselves and for their children. He believes that the guidelines from the AAP and CDC will come to the right balance, but the next step is careful and thoughtful implementation. CHAC noted that CDC and HRSA can speak loudly on this issue with the benefit of data. Analyses have shown infant male circumcision to be cost-saving to the healthcare system. It is also the only proven intervention with lifelong effect. Their task is to frame the intervention in public health and clinical settings for individuals.

CHAC suggested that DHAP consider how to offer incentives to different agencies and organizations in the field that may not traditionally work together, such as primary healthcare institutions and CBOs.

There was discussion regarding the 4% positivity rate and the rigorous nature of the YMSM announcement. Concerns were being voiced from CBOs that are currently at 2% or 3% positivity rates, and they are worried that they will not be able to achieve the required four percent rate. CBOs should receive training and TA. DHAP is conscious of these issues, and they anticipate working with all CBOs and Health Departments to make the changes as effective as possible, as there are many program examples with newly diagnosed rates as high or higher than 4%.

There was discussion regarding base minimum floor for the new Health Department FOA which was based on inductively looking at the necessary resources to implement a program, and then calculating funding based on experience with jurisdictions. This internal formula was developed under the assumption that there would be changes in programmatic requirements. The "floor" is a small amount to ensure every jurisdiction has a program.

There was discussion concerning coordination among the various funding sources for ECHPP. Leaders of HHS agencies in the 12 Cities Project meet regularly in person and via telephone. Additionally, an Implementation and Monitoring Subcommittee works to ensure coordination. Resources are coordinated at the federal as well as the local level.

CHAC discussed budgetary challenges at the state and local health department levels. These issues affect all HHS agencies.

## Panel Presentation on CDC Strategic Priorities and Coordination of Media and Social Marketing Related to HIV, STD, and Viral Hepatitis Prevention

A panel of speakers addressed the coordination of media and social marketing related to NCHHSTP activities. This presentation was in response to a direct request from CHAC.

#### Susan Robinson, MS

Associate Director for Communication Science National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Ms. Robinson began the panel presentation by describing NCHHSTP's major communication priorities, which are the NHAS and its Implementation and Operational Plans and the HHS Action Plan for Viral Hepatitis. The IOM Report called for educational activities in this area, and the Center has responded. Additionally, CDC has identified HIV prevention as a "winnable battle." The Director has issued a number of directives associated with the winnable battles, including a social media plan. Finally, the strategic objectives in the NCHHSTP Strategic Plan inform their communication activities. Each Division has program priorities, and the communication efforts align with them as well. These priorities, combined with input from communities, keep them focused.

Coordination of all of the Center's work is critical to communication. PCSI is an important activity, and a monthly meeting is held with division leaders and key staff. During these meetings, they share resources and report their activities. Sometimes, research activities are associated with a media campaign and can inform other campaigns. Quarterly, a National Prevention Information Network (NPIN) Advisory Committee, comprised of individuals from each Division, meets. In response to emerging technology and issues, a Workgroup has been formed for the HIV Testing Database.

The Health Communications Science Office works across the Center Divisions to map out campaign coverage by objectives, audiences, and timing. They coordinate with HHS for approval for the campaigns as well as to cross-clear and promote related agency campaigns. To consider campaigns, the Office reviews the objectives of each campaign and assess partner campaigns. Their goal is to maximize every dollar for HIV, both within the agency and other federal agencies, and outside the agency with partners. They also look for overlaps and synergies across Divisions.

### Jill Smith

Campaign Manager, Act Against AIDS Division of HIV/AIDS Prevention National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Ms. Smith presented an overview of the *Act Against AIDS* (*AAA*) campaign, which was launched in 2009 with the White House and HHS. The campaign's goal is to refocus attention on the domestic HIV epidemic. They set out to build a "brand" or framework under which many HIV prevention campaigns can operate. These campaigns include prevention, testing, health literacy, and education. Partnerships and strategic alliances carry messages and extend the reach of the campaign while providing credibility as messages are heard from different organizations. The NHAS was released after the launch of *AAA*, but the campaign is aligned with the National Strategy.

The overarching goal of the campaign is to support the reduction of HIV incidence in the United States through effective, evidence-based communication, marketing and education campaigns. Their key objectives are to increase information-seeking behaviors, knowledge and awareness about HIV; and increase targeted behavior change in this environment. The campaign has established a national campaign and brand and has reached about two billion media impressions. Media impressions are one metric that assesses the campaign's reach. These impressions include traditional media stories, billboard advertisements, bus and transit advertising, and more. Partnerships help carry the campaign's message. The *Act Against AIDS* Leadership Initiative (AAALI) has been a major player in their work, and the Black AIDS Media Partnership worked with the Kaiser Family Foundation to launch the "Greater than AIDS Campaign," which doubles the number of media impressions of *AAA* alone. The Kaiser Family Foundation has also worked with the GYT campaign in STD prevention, and this work has helped in sharing information and evaluation metrics and contributed to partnerships with external organizations.

The campaign has a number of media partnerships. Clear Channel, for example, has donated advertising space. This year, the campaign has pushed its materials to partners and state health departments. These materials include messages that have been tested with target audiences. Some materials are available online. Target audiences include physicians and providers who are encouraged to include HIV screening in their practice as standard of care, and black MSM. Co-branding has been effective. The Virginia Department of Health co-branded with *AAA* with the "9 ½ Minutes" campaign.

To evaluate their work, they assess exposures and impressions. Media impressions have grown over time through broadcast Public Service Announcements (PSA), which show strong return for investment. Other metrics include attendance at events. More than 600,000 people have attended events, mostly through the AAALI. About \$10 million of media has been donated. The National Medical Association donated space on the Jumbo-Tron in Times Square, for instance. One of the campaign's goals is to increase information-seeking behavior, so they track website hits. A social media presence will launch this year, and the website will be redesigned. Many of the campaigns are designed to run concurrently. To encourage providers to make HIV screening part of their standard of care, they presented at the American College of Physicians regional meeting. Physicians' intent to screen in their practice was measured before and after the presentation. Before the presentation, 47% of the attendees indicated an intention to include HIV screening in their practice. After the presentation, 93% of attendees indicated that intention.

Through formative research and materials testing, they have learned that CDC is seen as a trusted source of information. They also learned that CDC and HHS logos do not detract from advertising receptivity. Recognition of the <u>www.HIVtest.org</u> resource is low, but they are addressing this issue through their black MSM campaign. AAALI is an effective dissemination tool. AAALI was expanded to include organizations that serve MSM as well as Hispanic and Latino populations.

Ms. Smith presented the portfolio of campaigns for 2011. The NHAS calls for more targeted and prioritized efforts. Much of *AAA* campaigns are "general population interventions," including the "9 ½ Minutes" campaign. *AAA* is creating campaigns for more targeted audiences, such as community-level interventions to reach communities by ethnicity and geography. Several campaigns focus on prevention with high-risk HIV-negative populations, and "Prevention is Care" focuses on Prevention with Positives. This campaign has been targeted to physicians and will expand to consumers in 2011. Most of their resources focus on community-level campaigns.

### Mary McFarlane, PhD

Division of STD Prevention National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Dr. McFarlane updated CHAC on GYT: Get Yourself Tested. This campaign intentionally does not specify a specific disease, and uses the same language that youth use (e.g., abbreviated, text-message-style communication). GYT is a partnership with MTV, the Kaiser Family Foundation, and Planned Parenthood Federation of America. Most adolescents spend at least some amount of time watching MTV. The brand is different from when the network launched, and it is the number one media brand among youth aged 18 – 29.

The objectives of the GYT campaign are to present testing in a context that is familiar and relatable to young people. The campaign appears on MTV, on mobile phones, and on the Internet so that it exists where young people spend time. Testing is encouraged as an act of pride and something that young, fun, successful people do. The campaign connects viewers to testing centers in their area using an online testing locator. These behaviors are measurable actions, so they can assess results at the end of the campaign. Another goal of the campaign is to encourage young people to use the GYT acronym and to spread the word about the campaign, promoting open dialogue about STDs.

Negotiating across various groups and partners can be challenging, but partnerships are critical. Part of the effort of GYT is to get people to clinics for testing, but the clinics must be ready for people when they present. Therefore, resources are available for providers. They can connect to CDC's training about STD prevention, the testing and treatment guidelines, basics about STD facts as well as details about specific diseases, and assessment tools to determine whether the GYT campaign increased their clientele or the number of cases identified. CDC provides all of these resources to prepare providers so that when individuals come to a clinic, they should have a good experience. The website includes common misconceptions that young people have about STDs, and what young people want. No matter the results of the test, young people want to know that they are still okay. Young people do not want to be labeled "wrong." The testing should be confidential. Young people want to feel good about being tested, rather than to feel bad that they need a test. Many young people assume that they are being tested for every STD, which is not the case.

Another part of GYT is a connection with the Take Action Tour, a group of socially conscious musicians who tour the country. This year, their charity is Sex, Etc. GYT is co-promoted at these concerts. The promotion efforts include mobile testing vans, information distribution, and testing for band members, the tour manager, and other personnel. Young people who come to the concerts see that testing is normal, easy, and cool. GYT also works with the "Greater than AIDS" campaign. Kaiser Family Foundation and MTV are both involved in that effort as well. A different set of concert tours will promote testing for HIV in coordination with National HIV Testing Day.

The GYT staff collects and evaluates data in a number of ways. The Porter-Novelli YouthStyles and TRU surveys are national media surveys that ask people if they have heard of the GYT campaign, if they watch MTV, if they go to the website, and more. A post-campaign implementation survey is conducted with GYT partners to hear their feedback. Many web metrics indicate the popularity of their websites. One of the drawbacks to Web metrics is the lack of a baseline or comparison, she noted. Additionally, Planned Parenthood Federation gathers data from each of their clinics during the month of April, which is STD Awareness Month, to determine testing progress. Testing in sentinel PPFA clinics in April 2010 was 70% higher than testing in April 2008, according to these data. Planned Parenthood does local promotions and adaptations of GYT. Data from the Infertility Prevention Project are also available, and qualitative data are gathered from social networking, kit distribution, and other feedback. Those data are used to improve the campaign. The key aspect of this campaign has been the ability to push it out through professional societies and organizations such as the AAP, the National Assembly of School-Based Health Centers, and other groups that have implemented GYT in schools and CBOs.

#### Cynthia Jorgensen, DrPH

Lead, Education and Training Division of Viral Hepatitis National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Dr. Jorgensen presented the proposed National Viral Hepatitis Education Campaign: "Know More Hepatitis," reporting that 4.5 million Americans are infected with chronic viral hepatitis, and 85,000 new infections are identified each year. 15,000 deaths occur each year due to chronic viral hepatitis, and it is a leading cause of liver cancer and liver transplants. About one year ago, IOM issued a report on hepatitis, and the HHS Strategic Plan for Viral Hepatitis is about to be released. The IOM report indicated that many providers lack basic knowledge about viral hepatitis, and public awareness about viral hepatitis is low. These points will also emerge in the HHS Strategic Plan. Both the IOM and HHS have recommended that CDC and various HHS agencies launch a national education campaign.

CDC plans a three-pronged educational campaign targeting the general population, who are largely unaware of the disease; healthcare providers, especially those who do not screen at-risk patients and who are uncomfortable regarding care, treatment, and referral of patients; and at-risk populations among whom awareness is low.

The national campaign's goal is to decrease the burden of viral hepatitis in the United States. The phased approach begins by raising general awareness, engaging media, opinion leaders, policymakers, and the public to reinforce that this issue affects millions of Americans. The first phase will change perceptions of the disease. Dr. Jorgensen likened the need to educate the general population and providers about viral hepatitis to the education work regarding HIV/AIDS in the 1980's and early 1990's. Providers should encourage assessment and appropriate follow-up with their patients. Early intervention will save lives. New treatments are expected to be approved that will make a dramatic difference in the disease. The campaign strategies will be implemented in three phases that build on one another. Multimedia approaches will be tailored to each phase. It is critical to reach providers before reaching out to consumers. Because hepatitis includes different diseases that affect different populations, multiple campaigns will target the groups at risk for each. The Division hopes for sufficient funding to supplement its activities with Community Mobilization Grants. Depending on resources, strategies will be tested in pilot cities.

The first phase is on-going and builds awareness about the disease. It focuses on opinion leaders, policymakers, and the media. The first phase also seeks to support action. The second phase focuses on healthcare providers, encouraging them to interact with their clients and patients about hepatitis B and hepatitis C. This phase encourages appropriate care and treatment and will educate providers about existing guidelines. CDC expects to release new, expanded guidelines on hepatitis C in 2012. Through grantees, this phase will also build capacity to screen, refer, and treat. With this phased approach, they will create spheres of influence that interact with each other. A supportive population will understand the disease and decrease stigma. Opinion leaders, policymakers, and community partners will support healthcare providers. Healthcare providers need to interact with patients at risk. The community mobilization will create a supportive environment for encouraging treatment and for working with those who are infected. Multiple communication channels are proposed. These channels can interact and mutually reinforce each other. Most of the funding for this campaign comes from the CDC Foundation, which raises money through public partnerships. The Division of Vital Hepatitis is very small, and their resources are limited.

Potential campaign messages in Phase One include: Millions of Americans are living with hepatitis - many don't know it; hepatitis is a leading cause of liver cancer; and early intervention can save lives. Phase Two focuses on healthcare providers, and formative research has begun to learn what they know about CDC guidelines and screening patients at risk. In Phase Three, separate campaigns are planned for hepatitis B and hepatitis C. The hepatitis B campaign messages include: One in 12 Asian-Americans has hepatitis B; protect your loved ones; and new treatments are helping people live longer, healthier lives. CDC is considering the efficacy and effectiveness of screening birth-year cohort for hepatitis C, primarily "baby boomers." The hepatitis C campaign will likely target baby boomers, but the campaign content will depend on CDC's guidelines. Should an age cohort approach be adopted, messages may include: One in 30 Baby Boomers has hepatitis C; three of every four people with this disease may not know they are infected; if you are at risk, get tested; and treatment can eliminate the virus. They are creating campaign strategies and materials which will be revised over the coming year, and they are conducting formative research. The campaign will roll out in concert with CDC's release of the new, expanded guidelines for hepatitis C. They will primarily focus on hepatitis C, pending the availability of funds to address hepatitis B. Phase Two will take place before they reach out to populations at risk.

#### Susan Robinson, MS

Associate Director for Communication Science National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Ms. Robinson said that the NHAS includes an objective stating that CDC shall initiate an inventory of all education and social marketing campaigns related to HIV/AIDS, STIs, substance abuse, and related campaigns. This work has begun, and a Resource Guide is being created for NPIN. This Guide will be searchable and will include general as well as targeted campaigns. The Tobacco Division created a media resource guide, and she hoped to improve on that model. For instance, this Resource Guide will include a "Strength of Evidence Index." The goal is to make sure more effective resources are available. The Guide will start with federal campaigns, but will include community-generated activities. The criteria will be internally and externally reviewed.

CHAC thanked the panel for the presentations.

CHAC asked for more information regarding efforts to reach the Hispanic community. Ms. Smith replied that a new Hispanic campaign has been funded for *AAA* this year. The campaign is currently under development. Members of the Hispanic population will provide input through the AAALI. She invited recommendations and input from CHAC in this process.

CHAC suggested that people may need to be educated on what the age cohort "baby boomers" means. It was clarified that "baby boomers" are birth year 1945 – 1963. Age cohort sorting may be the best way to approach testing with general practitioners, as they are not likely to do strong risk assessment. Dr. Jorgensen said that formative research was beginning with physicians regarding how best to communicate about the age cohort. Communication will be challenging because the age will shift from year to year. The research will assess how physicians respond to and interpret an age cohort or various terms, including "baby boomer."

Stigma continues to be an issue for AIDS and for hepatitis. There was discussion regarding directly targeting stigma in campaigns. The theme of stigma is woven throughout their campaigns. Each Division tests its messages. Health messages are presented with "gain frame" or "loss frame," and consultations have included behavioral scientists and communication scientists to do literature reviews around framing issues.

There was discussion regarding HRSA's role among individuals who are HIV-positive and their linkage to care, adherence to care, and retention in care and treatment. One of the target audiences for these campaigns might be the FQHCs and other primary care sites that are administered through HRSA. Dr. Fenton added that they had not yet discussed opportunities across agencies for expanding and integrating messaging and focusing on collaboration.

There was discussion regarding integrated communication campaigns and opportunities either for communicating around the idea of sexual health, or by combining messages on HIV and STDs. There is some evidence that HIV and other STIs can be messaged together in certain communities. There is also evidence that those conditions are thought of separately: HIV/AIDS is deadly, where other STIs are "nuisances." The frame for these issues is critical. Given resource constraints and an interest in the positive frame of "sexual health" as a wellness effort, future construction and testing of combined messaging in certain populations was anticipated.

There was discussion of youth decision-making regarding sex, which tends to focus on pregnancy. They are working with that concept to build ideas of sexual health and disease prevention into pregnancy concerns. Dr. Fenton said that the addition of DASH to NCHHSTP provides an excellent opportunity to look at the issue of integrating messages. Their campaigns are thinking horizontally as well as within disease frames.

CHAC suggested that instead of "stigma," they might talk about "normalization." Stigma is part of the "loss frame" orientation that they hope to move away from.

Interest was expressed in other, less traditional social media that are used by younger people. Dr. McFarlane replied that MTV is an ideal partner, and they have partnered with CDC in creative ways.

Dr. Sweet reminded CHAC and meeting attendees about the public comment period, inviting those interested in providing public comment to sign up on the sheet at the registration table.

## Rethinking STD Prevention in a Transformed Health System: Opportunities and Challenges

#### Gail Bolan, MD

Director, Division of STD Prevention National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Dr. Bolan shared with CHAC opportunities and challenges associated with STD prevention in the changing healthcare landscape. She began by offering background on the history of STD prevention in the United States. In 1938, the Surgeon General published *Shadow on the Land*, an initiation of syphilis prevention and control. In 1972, an expanded gonorrhea screening program for women in the United States was initiated. The 1980's saw the initiation of HIV and hepatitis B prevention and control. In 1993, Congress authorized the National Infertility Prevention Program, which focused on Chlamydia prevention. The National Syphilis Elimination Effort was launched in 1999, and the HPV vaccine was licensed in 2006.

The approach to STD prevention and control in the United States has not changed a great deal since the 1930s. The approach includes health education and health promotion, and the main strategy is to identify and treat infected individuals, through screening programs of asymptomatic individuals, STD clinics for symptomatic individuals, and health department partner notification and treatments. Most interventions are individually based, and they have primarily been the public sector's responsibility. For many years, the focus was on the STD clinic and through Disease Intervention Specialist (DIS) staff who are trained in field investigation and contact tracing.

The Division has had a number of strategic plans. The most recent Plan was developed in 2008. The goals focused on preventing a variety of STI-related complications, strengthening STD prevention capacity and infrastructure, reducing health disparities, and addressing the effects of social and economic determinants an costs of STDs and associated complications.

Appropriations for STD prevention in the United States may change when budget cuts are announced. \$153.9 million is appropriated for STD prevention. The majority of resources, 71%, go to state and local health departments for STD prevention programs. Of the total resources, 22% stay within CDC for a variety of activities and support in surveillance, programs, and other CDC costs. Three percent of the resources are devoted to the STD/HIV Prevention Training Center networks. Three percent of the resources support partnerships. The Research and Evaluation budget accounts for one percent of the total appropriation, or \$1.8 million. In these resource-challenged times, in addition to considering how changes in the healthcare system will affect STD prevention, they also need to think critically and prioritize the interventions that have the greatest impact and are the most cost-effective.

One area of programmatic emphasis is the Infertility Prevention Project, which provides screening for Chlamydia and gonorrhea to low-income women. The Project began with a focus on STD clinics and family planning clinics, and some programs have expanded to school-based health centers and juvenile detention facilities. The Syphilis Elimination Program was a response to longstanding health disparities and historically low levels of infection to reduce syphilis below levels compatible with ongoing domestic transmission. Other areas of emphasis include PCSI and reducing health disparities.

It is important to rethink STD prevention. A number of changes will occur in health systems in the next few years, and it is important to be prepared to move forward. There are opportunities to leverage prevention efforts through the new healthcare system as it evolves. They also need to rethink STD prevention due to declining public health infrastructure and competing priorities at the state and local levels. Most health departments focus on chronic diseases more than infectious diseases, and it has been difficult for STD programs to have visibility and not to suffer disproportionate cuts at the state and local levels.

Dr. Bolan described possible changes in STD prevention efforts due to the ACA. The proportion of people with insurance coverage should increase. Additionally, if evidence-based services have an A or B rating from the USPSTF, the services will be provided with no cost-sharing to the patient. Chlamydia and gonorrhea screening for young women have high ratings and should be offered to women 25 years of age and under. Also, large resources will expand the CHC network. Those centers will be the primary providers of services for the most vulnerable STD populations. Further, Medicaid will expand, and children can stay on their parents' health insurance until age 26. Finally, investments will be made in health IT, an area where public health has lagged. Investments are being made in electronic medical records and meaningful use of data. Improvements are needed in public health to reach the level of healthcare delivery systems.

Another driver of change in STD prevention is the declining STD public health infrastructure. In 2008 – 2009, 69% of state and local STD programs experienced some kind of funding cuts. Many programs saw salary freezes or staff reductions, and a number of states are using furloughs and shutdown days as a way to reduce costs. Of state and local programs, 28% laid of staff. The core workforce of DIS staff has declined by 21% from 1999 – 2009. DIS plays many parts in public health, and they are the "front lines" of public health, but most of them reside in STD programs. Additionally, there has been an erosion of categorical STD specialty clinics. There has been a 10% drop in the number of these clinics in the United States. A variety of other services have also been reduced, including laboratory services, the number of screening tests performed, the number of hepatitis vaccinations, the number of HIV tests, and in HPV vaccinations. The public health infrastructure is challenged, and STD prevention cannot

work as they have worked in the past. This changing healthcare environment and evolving healthcare system presents two major opportunities.

"Prevention Through Healthcare" is a major initiative. This model is essentially a PCSI model in which clients, especially those with multiple issues, receive comprehensive, holistic services. There are opportunities here to scale up STD prevention services beyond the STD clinic through the healthcare delivery system and without requiring additional funds from STD prevention programs. The Infertility Prevention Project is a model that did a similar activity through family planning clinics. STD prevention programs now need to focus on FQHCs, other community health centers, and school-based health centers. These venues are ways to reach at-risk STD populations, the majority of which have asymptomatic infections and who will only know they are infected if a provider tests them. The quality of STD prevention services can be enhanced. The Medicaid expansion presents opportunities as well. Medicaid has changed its philosophy, remarked Dr. Bolan, and moved toward improving quality of care and cost of care. The number of at-risk individuals who are covered will expand, and CMS and HRSA can help improve access to quality STD prevention services.

Opportunities also exist in the Health Information Technology (HIT) systems that have been built by the healthcare system. Traditional public health surveillance has relied on the healthcare delivery system. This approach has eroded public health surveillance, and there are new opportunities on the horizon. Dr. Bolan hoped that healthcare service partners would recognize that healthcare services research and public health surveillance have a great deal in common, including shared interests, data sources, methodologies, and evaluation. Quality of care measures can serve as the basis for some population health measures, she added. These systems represent new avenues. The traditional approach has been through case-based notifiable disease reporting for STDs. New models for surveillance will emerge, and there will be new ways for public health to assist the healthcare system in assessing and ensuring that quality STD prevention services are being provided. If they are not provided, then public health can design quality initiatives to improve those metrics. Electronic health records will allow for a comprehensive, longitudinal data set with well-defined patient populations. These robust data will inform surveillance activities as well as assessment and assurance. Ultimately, changes in the healthcare system present the opportunity to expand leverage and to reach more individuals at risk and in need of STD prevention.

Changes in the healthcare system also bring challenges. Dr. Bolan emphasized that "coverage does not equal access." One of public health's roles will be to do more in the area of assessment and assurance, defining the needed "safety net" services. Public health will likely still work in these "safety net" areas. STD programs will also play a role in assessing the coverage and quality of STD prevention services provided by FQHCs and other community health centers. They are already seeing obstacles in areas that have closed STD clinics. Screening for asymptomatic individuals can probably be done outside the STD clinic, but these clinics have necessary specialty services such as syphilis management. Many primary care providers are not knowledgeable about syphilis management, especially in HIV-infected patients. Additionally, two conditions require injectable medications to treat patients: syphilis and gonorrhea. Most private practice settings do not have these injectable medications available. Pharmacies could be part of the "expanded medical home" to serve as locations for timely medical treatment.

STD programs will need to assess the extent to which the "essential community providers" can provide adequate care. If adequate care is not being provided, then STD programs will need to offer training and technical assistance. The "safety net" needs will be variable because "one size does not fit all." STD programs will have to determine how to get reimbursed for the "safety net" services as well. Clinics will either need to bill, or become part of the medical home or FQHC. This change represents a paradigm shift for many clinics. One of the reasons people access STD specialty or categorical clinics is for expert care and because of confidentiality. Many state laws protect confidentiality in STD clinics, but the laws do not apply to a primary care setting. Maintaining patient confidentiality will be a priority as healthcare delivery systems change.

STD programs need to advance their technology. The decentralized, federalized approach has led to varying electronic capacity of public health surveillance systems at the state and local levels. Many of the categorical systems do not communicate and are not integrated. Relationships, responsibilities, and roles will need to be revisited. There are concerns about maintaining privacy and confidentiality in public health surveillance systems, and as the systems get larger, these issues can be more challenging.

Dr. Bolan also mentioned the challenge of ensuring that STD program staff are "fit for purpose" as the programs move toward assessment, assurance, and policy development. With less service delivery and more surveillance and assessment, the disease control investigator role will change. "Safety net" and field investigation services will still be needed, but these individuals will have different roles, such as reaching out to providers or collecting data in the field. Surveillance staff are fairly limited in many STD programs, and a number of programs do not have an epidemiologist. Retraining and growth are needed to meet the current needs of assessment and assurance.

In addition to enhancing surveillance activities, programmatic impacts are needed to measure effects when programs are cut or interventions change. Partnerships and collaborations need to be built between STD programs and the healthcare providers in the community that serve atrisk populations. Some STD programs have built collaborative relationships, while others are less familiar with the private sector and in FQHCs. STD programs can bring guidance, guidelines, tools, best practices, training, and TA to the table. Further, there is a robust network of STD/HIV Prevention Training Centers with expertise that can help improve practice in the private sector.

Dr. Bolan turned from "systems approaches" to "infrastructure approaches," reiterating that STD specialty clinics may need to bill or become part of the medical home or part of a FQHC. STD expert clinicians should be viewed as part of the essential provider network. Reimbursement mechanisms should be established while maintaining patient confidentiality. Electronic reporting should be upgraded, and STD clinics need to move toward electronic health records. In order to promote health equity and reduce health disparities, work is needed in areas other than the healthcare delivery system. Other approaches include community mobilization, policy intervention, economic educational interventions, promoting science on disparities, and more.

In terms of emerging issues in STD prevention, the Syphilis Elimination Effort has not eliminated syphilis. This situation presents a dilemma regarding whether they should continue to pursue syphilis elimination when they do not have the tools that they thought they had. When the Effort was launched, the disease was mainly found among heterosexual African Americans in the United States who had little access to care. Demonstration projects have shown that if access

to care is increased, partner services improve and syphilis can be reduced in a given population. More recently, the epidemic has shifted to MSM and many anonymous partners. It is difficult to use the best tool for syphilis control, partner notification, in this population, so they have not been successful in decreasing the burden of syphilis among MSM. Dr. Bolan felt that they should rethink their goals and interventions, and that perhaps targeted approaches would be helpful. The global elimination of congenital syphilis is a CDC Winnable Battle, which suggests that NCHHSTP might focus on congenital syphilis. In years past, congenital syphilis was not on the elimination list because STD programs do not have control over prenatal care. With changes in healthcare systems and additional programs, there is a platform for work. Then, the MSM priorities could focus on the burden of STDs in that population and on STDs as a risk marker for HIV prevention.

In terms of multi-drug resistant gonorrhea (MDRGC), a sentinel surveillance system monitors resistance in symptomatic men who come to selected STD clinic sites around the United States. Those cultures are sent to regional laboratories for susceptibility testing. This system has been used over the years to monitor susceptibility and to change treatment as the organism became less susceptible to recommended regimens. They are now using the last class of antibiotic to treat gonorrhea: cephalosporins. There are concerning trends in an increase of minimum inhibitory concentrations (MICs) to Cefixime. Overall in 2010, 1.5% of isolates are showing increasing MICs to Cefixime. Of concern is the geographic distribution, as rates are higher in the western regions of the United States, a pattern that has emerged in the past with gonococcal resistance. The same trend emerged with fluoroquinolone resistance, which showed emerging resistance first among MSM before spreading to heterosexual populations. In West Coast MSM, the proportion is up to 6%. CDC has always recommended that if the threshold of susceptibility is above 5%, then the antibiotic should be changed. The question in this case is: Change to what antibiotic? They are also monitoring MICs to Ceftriaxone, the injectable form of cephalosporins, the best drug to treat gonorrhea. Decreased susceptibility to Ceftriaxone is beginning. When fluoroquinolone resistant gonorrhea was a problem in 2007, an article in The New York Times had a large impact on provider behavior. The trends in 2007 appear to repeat today.

In summary, Dr. Bolan said that the Division will work with state and local programs on Prevention Through Healthcare. STD programs are likely to spend more time on assessment, assurance, and policy development in the future, and less time delivering direct services, as the healthcare system will provide more service delivery of STD prevention, except for the "safety net services." Clear priorities must be set, because they cannot do everything they need to do with the resources they have. She reminded them that the more they can think holistically with combined prevention approaches, the more successful they will be.

CHAC asked whether the Division had worked formally with the National Association of Community Health Centers. Dr. Bolan replied that the Division has not yet worked with the network on a national level. Structural work will take place at the federal, regional, and local levels as they determine how to establish routine screening and to maintain quality in busy primary care settings.

CHAC noted that the USPSTF recommendations for Chlamydia screening are a helpful tool. A similar tool could be used for routine screening for STDs, particularly among MSM and HIV-infected populations. Most USPSTF guidelines are based on the general population, but there are few recommendations on targeted populations. Further, USPSTF's definition of "prevention" is narrow. The evidence base must be built so it is understood by the USPSTF. It takes time to

build an evidence base, though, so their challenge is to advance the field while working within the system to move the evidence portfolio forward.

It was observed that most doctors and nurses have little training in basic STD management.

CHAC discussed MDRGC's emerging resistance to cephalosporin. There is reluctance on behalf of the pharmaceutical industry to engage in antibiotic development because the work is difficult and expensive. An arm of NIH will be more involved in drug development. Engaging higher levels of NIH would help with this challenging work, and CHAC's recommendations in this area would be helpful. Dr. Bolan suggested that CHAC could assist in this matter via connections with the Infectious Disease Society of America (IDSA) or other organizations.

There was extensive discussion regarding lessons that could be learned from Massachusetts' system of healthcare access and its impact on STDs. Medicaid systems vary by states, and in states with poor systems, STD patients could "fall through the cracks." It is important to put data systems in place to do better measurement and to educate policymakers. It may be too early to evaluate the experience in Massachusetts.

Additional discussion focused on the workforce issue. As HIV providers focus on early identification and testing, there is an obvious connection to doing both STI and HIV testing. This idea leads to the AETCs and integration of training and service initiatives. CDC and HRSA could collaborate on this effort.

Concern was expressed that if STD treatment categorically moves to FQHCs, CHCs, and local doctors' offices, they will not be prepared. Most general physicians count on public health to do this work and are not current with STD treatment and prevention. Concerns included increased resistance, increased incidence, and increased spread. They should not assume that PPACA will take care of STD patients.

There was discussion of CDC's plans for providing care for the percentage of uninsured who will not be covered by PPACA. This group appears to be disproportionately contributing to HIV/STD morbidity and mortality. Dr. Bolan noted that currently, federal grants cannot be used for clinical services. Most of the clinical services have been provided with state and local dollars. With the budget shortfalls at state and local levels, cuts have taken place. They must prioritize and determine which activities really work and which activities may need to be discontinued. They should consider innovative strategies. For instance, some clinics are doing "express visits" in which patients never see a clinician. They should also share best practices around the country. Some states have done extensive work with Expedited Partner Therapy. Their first step will be to put data systems in place to understand consequences.

CHAC noted that individuals who are insured may choose to go to STD clinics for treatment for confidentiality, to acquire expert care, and for other reasons. While there was approval for the idea of integrating STD care into primary care and for upgrading training, integration will not be the answer for everyone. Stigma has not gone away, and a safe haven with knowledgeable people must be provided. It is important to define what the clinics do, because they can be "invisible" to funders. It is also important to advocate for areas where the clinics need to be. The clinics also provide opportunities for research and training for residents.

Dr. Fenton closed the session by remarking that the STD Division is thinking about the structure, nature, and form of its work in an evolved health system. The TB Division is going through the same process. These older programs need to think about new opportunities. Later

in 2011, a consultation will be held regarding the role of health departments and how that role is changing in the era of health reform. They are also examining how surveillance needs to change. There are opportunities for CHAC to have a stronger voice in these conversations. He heard CHAC comment on the importance of "safety net services," and NCHHSTP needs to do internal work on that issue. CHAC's voice will help to clarify the roles of these programs and to clarify their strategic redirection.

Dr. Sweet reminded CHAC that after lunch, the business session would take place. That session would be CHAC's opportunity to make recommendations to CDC and HRSA and their leaders. She encouraged CHAC members to write their thoughts down.

# Update on Pre-Exposure Prophylaxis (PrEP)

### Amy Lansky, PhD, MPH

Deputy Director for Surveillance, Epidemiology, and Laboratory Science Division of HIV/AIDS Prevention National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Centers for Disease Control and Prevention

Reminding the group that she had addressed them in November 2010, Dr. Lansky described events that had taken place in the interim and offered an update on CDC's PrEP implementation activities among MSM

The iPrEx results were released at the end of November 2010, and an HHS PrEP Workgroup was convened immediately thereafter. This Workgroup includes CDC, NIH, two Bureaus of HRSA, CMS, and the Food and Drug Administration (FDA). The group has met periodically since then. CDC released Interim Guidance in the *MMWR Weekly* in January 011, and a technical experts meeting was held in February 2011. CDC also convened an Implementation Symposium in February. The iPrEx trial included 2499 participants who reported male sex at birth, and 29 participants were transgender women. Participants ranged in age from 18 – 67 years old, and they reported high-risk behaviors for HIV acquisition in the past six months. Study sites included South America, the United States, South Africa, and Thailand. The overall result in a modified intent to treat analysis was 44% efficacy. Further analyses looked at adherence measured through self-report, pill count, and pill dispensing. Higher levels of efficacy with greater adherence were found. Analyses also examined whether drug levels were detected. In those persons where drugs were conducted, higher efficacy was found. The results were exciting for HIV prevention.

CDC's interim guidance in the *MMWR* included several key recommendations, including the following:

- Before initiating PrEP, it is important to document that the potential recipient is HIV negative and also at risk.
- Screening for hepatitis B and STDs is recommended before initiating PrEP.
- The PrEP regimen is one pill daily, with a 90-day supply. Participants are seen regularly, and risk reduction and adherence counseling is provided.

- Follow-up for PrEP should occur every two to three months and should include another HIV test, counseling, and checking for STI symptoms.
- In cases where PrEP may be stopped, it should be confirmed that the participant is HIV
  negative, and the participant should be linked to other risk reduction services. If PrEP is
  stopped due to HIV infection, then the participant should be checked for resistance and
  linked to care.

As part of an on-going series of technical expert series meetings to gather input on various issues related to PrEP, a meeting in February included representatives from insurance companies and benefits managers in private industry. Dr. Lansky said that the main take-home message from that meeting is that if PHS guidelines support PrEP, then many insurers are likely to cover it. This concept is important to remember as guidelines are developed. Other issues that were discussed in that meeting included the need to look at program costs under different funding scenarios and through different delivery systems. Additionally, it is important to understand issues that are specific to coverage decisions made by public insurers. Medicaid is a state-based system, so issues related to coverage at that level should be discussed.

The PrEP Implementation Symposium in February 2011 included a broad range of participants representing researchers, care providers, CBOs, policy advocates, and other stakeholders. Key messages from this Symposium include:

- The importance of adherence, especially in the move from a clinical trial setting to a "real world" setting;
- Awareness and education, making those who might benefit from PrEP aware of its existence and providing education about guidelines and when PrEP is applicable;
- The idea of "bridging" and the prevention strategies that might come before or after PrEP, and the concept that PrEP is not a lifelong strategy; and
- The impact of PrEP at the population level, its role in combination prevention, and the use of data to target PrEP activities.

The FEM-PrEP Project was a PrEP trial among heterosexual women. A regularly-scheduled interim review was conducted by an independent data monitoring committee. The committee found that the FEM-PrEP trial could not demonstrate efficacy, even if it continued to its originally planned conclusion. Therefore, the FEM-PrEP trial was stopped in April 2011. It cannot be definitively determined whether the drug combination works or does not work. In response to the stoppage of the trial, CDC released statements to caution against women using PrEP at this time due to uncertainty regarding its efficacy. The statement reiterated that daily PrEP with oral Emtricitabine/Tenofovir Disoproxil Fumerate (FTC/TDF) has only been shown to be effective for HIV prevention among MSM.

Some of the information from FEM-PrEP will be the subject of further analyses. That information has to do with pregnancy among the participants and the role of hormonal contraceptive. The women participating in FEM-PrEP were required to be on effective contraception, with 66% using injectables and 30% using oral contraceptives. The overall pregnancy rate in the study was9%. The highest pregnancy rates were among those using oral contraceptives. Further, pregnancy rates were higher among women who were randomized to the Truvada arm versus the placebo arm of the study. This area merits additional exploration and analysis to look at possible drug interactions, the role that adherence might play in the findings, or a combination of those factors. FEM-PrEP also engendered a look at data from the iPrEx study among transgender women. At the recent consultation, the Principal Investigator

(PI) for iPrEx presented preliminary data from the small population of transgender women. iPrEx classified transgender women as persons who identified themselves as female, but also stratified by whether the participants were using hormones. There was no evidence of efficacy for PrEP in this population. While this sample is small, additional analyses and considerations of these issues will take place.

A consultation was held in May 2011 to gather input to move forward with the PHS guidelines. The objective of the consultation was to hear comments on the proposed content for those guidelines. Many issues were discussed, such as the clinical counseling that might be required, adherence and risk reduction counseling, and the fact that the guidelines are specifically to MSM. The consultation included participants from academic institutions, state and local public health, CBOs, other HHS agencies, and national organizations. In terms of the major areas of the CDC PrEP Implementation Plan for MSM, the MSM Strategy will focus on guidance and policy; communications and stakeholder engagement; technical assistance and training; monitoring and evaluation; implementation science; and program Integration.

Pertaining to the update on the daily oral PrEP trials, the iPrEX trial was completed in 2010. The study among IDU in Thailand is expected to have results in 2012. Partners PrEP and Vaginal and Oral Interventions to Control the Epidemic (VOICE) are expected to continue through 2013: VOICE had an interim analysis and will progress. The FEM-PrEP trial was stopped. The CDC 4323 safety trial among MSM presented results in the summer of 2010. Results from CDC's safety trial in Botswana should be released later in 2011.

CHAC agreed that demonstration projects are needed to understand how PrEP will work outside the clinical trial setting. Coordination is taking place through the HHS Workgroup.

CHAC noted that some insurance plans cover Tanofivir or Truvada because they are approved drugs for HIV. Insurance plans will probably cover PrEP, except perhaps in systems with formularies. Problems will arise for people who do not have insurance, and pressure will increase on state-funded programs and ADAP.

There was discussion regarding FEM-PrEP. The 9% pregnancy rate may not have been due to drug-drug interactions, but to a lack of adherence. Dr. Lansky said that the analyses for FEM-PrEP are on-going, and issues around adherence and drug levels are being considered. The findings were surprising, and the results with oral contraceptives were not consistent with previous studies.

CHAC asked for clarification regarding the idea that PrEP is not a lifelong strategy. Dr. Lansky said that in the PrEP Implementation Consultation, many people felt that PrEP should be a timelimited strategy. Individuals come in and out of risk periods in their lives, and thought should be given to who is on the drug and to the strategies that come before and after PrEP. There was concern that the message might be misinterpreted.

There was discussion regarding addressing the social and emotional lives of people who take PrEP as a way to prevent HIV. People who are HIV positive may avoid taking their medication because it is a reminder that they are positive. There could be a parallel for persons taking PrEP, who may not take their drugs because the drugs are a reminder that they are at risk for HIV. These issues need to be explored. In the iPrEx study, one of the most common adverse events was serious depression. Mental health issues and the framing of counseling will be an important part of PrEP.

CHAC expressed concern regarding the potential for racial and ethnic disparities in PrEP. Since there has been little study of PrEP in the United States, and because the disparities in the United States are different from other countries, it will be important to examine the possibility for disparities and learn ways to diminish them when PrEP is disseminated more widely.

It was observed that new information and data are emerging quickly in this area, and CDC will need to disseminate information and guidelines to allow for this new information. CDC's intent is to design the guidelines so they can be updated as needed, and as more information becomes available. Part of CDC's role in this challenging time is to be vigilant and to ensure that their messages are as clear as possible, given the state of the science.

CHAC discussed the 90-day supply of medications provided by PrEP. Some members felt that more follow-up was needed. Concerns of adherence and possible diversion were raised. It was noted that the National Consumer League is doing a yearlong public service plan for medication adherence.

Dr. Fenton thanked Dr. Lansky. This field is moving rapidly, and new results will likely be available for CHAC's next meeting. CDC will release statements and guidance in the coming weeks. CHAC will be copied on these releases, and he hoped for CHAC's input and comments. The area of biomedical interventions is critically important for CDC, and the agency will look at its prevention portfolio, the prevention mix, and implementation. Because the field is moving rapidly, flexibility from CDC and CHAC will be needed. As data on specific groups and information from trials is released, CDC has to make pronouncements on implications for other groups. This situation is a wonderful challenge in terms of how far they can go to make assumptions about other risk groups based on one randomized trial. A positive result in one trial does not necessitate trials in each group to prove the effectiveness of that biomedical intervention, as they do not have the time or resources to do so. These public health ethics issues must be discussed, and he hoped that they would discuss these issues at every CHAC meeting.

## New Committee Business

Dr. Sweet dismissed the group for lunch at 12:28 pm. At 1:40 pm, Dr. Sweet established a quorum and began the next session of the CHAC meeting.

### Update on CHAC/PACHA Ad Hoc NHAS Workgroup Efforts Douglas Brooks, MSW

President's Advisory Council on HIV/AIDS

Mr. Brooks reminded CHAC that Dr. Helene Gayle, PACHA Chair, suggested establishing a PACHA liaison to CHAC. They also hope for a CHAC liaison to PACHA. The NHAS includes a goal of reducing HIV health-related disparities. Step Three, "reducing stigma and discrimination against people living with HIV," includes an action of "promoting public health approaches to prevention and care." PACHA and CHAC are both tasked with developing recommendations for safe and voluntary HIV disclosure. HRSA will publish CHAC's recommendations, and PACHA will present its recommendations to the Secretary. Mr. Brooks is leading this effort at PACHA. It makes sense for CHAC and PACHA to work together to avoid duplicating effort and to produce a useful set of recommendations for those living with HIV and for those not living with HIV.

A meeting was convened in March 2011 of people who have an interest in this topic and who have some expertise. There was representation from a variety of organizations and government entities, as well as ONAP. Mr. Brooks had an individual meeting with a representative from ONAP to get clarity on what the recommendations should be. He learned that the set of recommendations should be helpful and should take into consideration all of the different facilitators and barriers to HIV disclosure. The recommendations should also encourage dialogue, which links to CHAC's discussions on sexual health. The framework of social determinants of health should also inform the development of the recommendations. Other issues to consider include the criminalization of HIV. Some states, for instance, may protect STD clinics, but criminalize HIV. There are opportunities to address these points.

Mr. Brooks asked CHAC if there was interest in working with PACHA to develop these recommendations. Since PACHA has created a Working Group, he suggested that CHAC assign representatives to that group. He was open to feedback and suggestions from CHAC.

Dr. Hook anticipated that CHAC would be enthusiastic about this opportunity. He invited Mr. Brooks to CHAC's next meeting in November 2011. Regarding liaisons, he asked Dr. Fenton to explore whether Mr. Brooks could be invited to be an *ex officio* member of CHAC. He commented that providing a CHAC liaison to PACHA will be a matter of deciding who "gets to be the liaison."

Dr. Fenton addressed the formal liaison between PACHA and CHAC. To comply with federal rules, CHAC should ratify the decision to create a liaison to PACHA. Next, CHAC will nominate a liaison to PACHA from its ranks. Then, the most efficient course of action would be to invite representatives from CHAC to join the PACHA Workgroup. CHAC needs a mechanism for providing feedback to their liaison.

A motion was properly placed on the floor and seconded by Mr. Kali Lindsey and Dr. Carol Brosgart, respectively, for CHAC to ratify the creation of the liaison relationship between PACHA and CHAC. In the absence of additional discussion, **CHAC unanimously approved the motion.** 

There was discussion regarding the intended outcome of the proposed work around disclosure. One of the positive outcomes of the recommendations will be to normalize HIV. The action item under which this deliverable falls focuses on lessening stigma and discrimination, as well as preventing new infections and promoting care and treatment. Another element of this work addresses interacting with state legislatures. The recommendations should not only be "a set of bullet points," but could include a White Paper or document that encompasses the barriers and facilitators to HIV disclosure with a set of recommendations that could be enacted on state levels and at the national level.

CHAC extensively discussed criminalization of HIV. A reauthorization of the Ryan White Care Act required recipients of Ryan White money to pass laws on willful transmission, which is different from HIV criminalization. Every state has a law that in some way prohibits willful transmission. Those laws can be used for criminalization of HIV. The restrictiveness of the laws vary by individual states. Even among CHAC, there is room for clarification and understanding of these issues. It was suggested that Mr. Brooks be included on the agenda for CHAC's November meeting for a more formal presentation.

Dr. Fenton asked about the intended audience for the guidance. Mr. Brooks replied that the audience has not been determined. The Implementation Plan instructs them to "make recommendations for people to safely and voluntarily disclose their HIV status." Initially, he assumed the audience was people with HIV. ONAP representatives and the Workgroup felt it was important to provide recommendations for people who are not living with HIV regarding disclosing their status. This aspect of the work fits into the sexual health framework.

CHAC thanked Mr. Brooks for his attendance and looked forward to his continuing participation. An email would be sent to CHAC members to collect the names of those who would be interested in serving as a PACHA liaison. Dr. Fenton and Dr. Parham Hopson would then select the liaison for PACHA and representatives to the NHAS Workgroup.

Mr. Brooks added that December 31, 2011, is the deadline for this deliverable.

## **Recommendations**

ISSUE 1: The following motion was properly placed on the floor and seconded by Dr. Edward Hook and Dr. Andre Rawls, respectively. The CHAC recommends that CDC and HRSA actively assume a leadership role in informing the public about the scientifically proven, lifelong potential health benefits of male circumcision for prevention of HIV and other STDs. **CHAC generally approved this motion.** 

CHAC discussed whether any studies in the United States showed efficacy for male circumcision for prevention of HIV and other STDs. United States studies have shown efficacy for HPV and other STDs, but not HIV.

ISSUE 2: CHAC discussed the issue of working with USPSTF's recommendations for routine HIV screening. The CDC guidelines include routine screening for high-risk populations in highrisk settings. CHAC discussed whether CHAC should recommend that CDC provide a clear definition for "high-risk populations" and for "high-risk settings" and whether CDC should provide implementation guidance to be disseminated to states to implement routine screening and to expand access and uptake of screening in high-risk settings and with high-risk populations. It was noted that the 2006 guidelines seek to routinize screening and to move away from designations such as "high-risk" settings or individuals, moving toward screening all Americans between the ages of 13 and 64. USPSTF is reviewing its recommendations now. Some CHAC members felt that defining high-risk settings and populations would provide an opportunity to expand routine HIV screening, but others felt that being sexually active is being at some risk and that the terms should not be redefined. Community-based models still use the term "highrisk." Medicare provides coverage to anyone who asks for the test. The need to prioritize routine HIV screening is different from the need to define "high-risk." Dr. Fenton suggested that CHAC wait for the new USPSTF recommendations before acting on this issue. There was discussion regarding whether CHAC or CDC has a liaison to USPSTF. Dr. Fenton clarified that CDC has a liaison to USPSTF. CDC's Office of the Director is assisting with the reconciliation of HIV testing guidelines. No action was taken.

ISSUE 3: The following motion was properly placed on the floor and seconded by Dr. Carlos del Rio and Dr. Edward Hook (amended); and Dr. Carol Brosgart and Mr. Ernest Hopkins (amended), respectively. CHAC requests, in anticipation of implementation of ACA, that CDC/HRSA work to develop a comprehensive plan to continue and/or improve HIV, STD, and hepatitis surveillance, prevention, and clinical management services for the portion of the population not covered by ACA services.

There was discussion regarding clarification of whether the motion asks for improvement in services or surveillance. The motion was intended to be broad. It was noted that people not covered by ACA services may disproportionately contribute to community disease morbidity. There was discussion regarding the potential "safety net services" provided by STD clinics. There was additional discussion regarding whether the motion should include the term "case management." **CHAC unanimously approved the motion.** 

ISSUE 4: A motion was properly placed on the floor and seconded by Reverend Hickman and Dr. Carlos del Rio, respectively, recommending that CDC conduct a consultation with community-based organizations (CBO) relative to CBO roles regarding the restructuring of HIV, STD, and hepatitis prevention activities as the ACA is implemented. **CHAC unanimously approved the motion.** 

There was discussion regarding whether consultations should be held with the superintendents of schools in the "12 Cities" Project. These consultations could move the sexual health conversation forward and allow for engagement with the schools and parents, removing stigma and addressing issues related to sex. Dr. Fenton noted that as DASH joins NCHHSTP, a review of the Center's programming will take place. That consultation will look at strategy and how to enhance school health, given HIV prevention goals, and will incorporate the issues raised. Representatives from CHAC will be invited to participate in the consultation.

ISSUE 5: A motion was properly placed on the floor and seconded by Reverend Hickman and Dr. William Cunningham, respectively, recommending that CDC conduct a consultation with faith-based groups to address the sexual health initiative and their role in rolling out that initiative and in promoting a national dialogue to promote sexual health. **CHAC generally approved the motion.** 

ISSUE 6: A motion was properly placed on the floor and seconded by Dr. Jeanne Marrazzo and Dr. William Cunningham, respectively, requesting that CDC/HRSA work to prioritize *neisseria gonorrhoeae* as an agent of great concern with regard to the public health impact of emerging antimicrobial resistance, and to actively encourage closer collaborations with HHS agencies, such as NIH, as well as partnerships with other external partners, such as IDSA and NIAID, that are working to address such threats to health and prioritize funding for the development and investigation of alternative agents. **CHAC unanimously approved the motion.** 

There was discussion regarding broadening the request to include other STDs and to call for additional research opportunities.

ISSUE 7: A motion was properly placed on the floor and seconded by Dr. Bruce Agins and Dr. Edward Hook, respectively, recognizing Donna Sweet, MD, and her commitment, service, and leadership of the CHAC. **CHAC unanimously approved the motion.** 

Dr. Fenton expressed thanks to Dr. Sweet for her leadership of CHAC on behalf of his federal colleagues.

ISSUE 8: A motion was properly placed on the floor by Dr. William Cunningham and Dr. Hook, and seconded by Dr. del Rio, calling for CDC's affirmation of continuing CHAC contributions to consultations related to PrEP and other biomedical interventions for HIV prevention. **CHAC unanimously approved the motion.** 

ISSUE 9: A motion was properly placed on the floor by Dr. William Cunningham and Mr. Ernest Hopkins, respectively, for CHAC to recommend additional studies relating to the spectrum of disparities and barriers to care that impact the rollout of PrEP and other biomedical interventions. **CHAC unanimously approved the motion.** 

CHAC discussed the intended and unintended consequences of the PrEP rollout, including whether to recommend conducting studies to examine the potential for racial/ethnic disparities in the dissemination of PrEP, or whether to create a working group within CHAC to examine these issues. CHAC also discussed whether a longer presentation on these issues should be included as part of the November 2011 meeting. It was suggested that CHAC have a role in evaluating the messages that are sent to providers and at-risk communities and in monitoring uptake and barriers to PrEP. Other issues discussed included understanding the role of insurance coverage for the cost of medications and a range of factors influencing access to care, adherence to medications, and/or disparities in care. HRSA should have an important role in this work. The Division of HIV Prevention has an active consultation process, and members of CHAC participate in the consultations.

ISSUE 10: A motion was properly placed on the floor and seconded by Dr. Perry Halkitis and Dr. Ken Mayer, respectively, that CHAC recommend that HRSA and CDC summarize the scientific evidence on the potential benefits of routine anal Pap smears for MSM in general, and HIV-positive MSM specifically, and, if the evidence merits, make recommendations on the implementation of routine screening; or, if insufficient evidence exists, work toward the development of funding opportunities to support studies to build this knowledge base. **CHAC unanimously approved the motion.** 

It was noted that the HIV treatment guidelines include specific recommendations. Good guidance is not available for at-risk, HIV-uninfected individuals, particularly MSM.

ISSUE 11: A motion was properly placed on the floor and seconded by Dr. Carol Brosgart and Dr. William Cunningham, respectively, recommending to change the name of the committee to the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment. **CHAC generally approved the motion.** 

This change would recognize the Viral Hepatitis Action Plan. It was noted that the group would still be called "CHAC."

ISSUE 12: A motion was properly placed on the floor and seconded by Dr. Carol Brosgart and Mr. Ernest Hopkins, respectively, recommending that CDC report to CHAC regarding the harmonization of recommendations for screening for chronic viral infections. This harmonization could reduce stigma and increase uptake for HIV, HPV, and HCV. **CHAC generally approved the motion.** 

# **Public Comment**

At 2:58 pm, Dr. Hook invited comments from the public.

### **Carl Schmid**

Deputy Executive Director The AIDS Institute

Mr. Carl Schmid recommended that CHAC not hold public comment at the end of its meetings in order to ensure proper time for discussion. At the last two CHAC meetings, The AIDS Institute addressed CHAC regarding the growing crisis in ADAP. One year ago, the wait list was approximately 1000 people. In November 2010, the wait list was over 3800. Now, the wait list is nearly 8000 in 11 states. The following is the verbatim statement provided to CHAC:

This situation is growing worse each and every day. And, we know that wait lists do not tell the complete story. What is happening more and more now is that states are closing enrollment or changing their eligibility requirements, and in the process removing people from the program. In both these instances, people will not appear on waiting lists because they are no longer eligible for ADAP. However, they still need to receive their medications. Florida went so far as to remove 6000 patients from their ADAP for six weeks. During that time, patients received their medications through a drug company-sponsored foundation. The cost of the donated drugs was over \$23 million.

ADAP enrollment continues to climb. HRSA reports that between FY '08 and FY '09, 30,252 additional people were enrolled into ADAP for a total of 205,446 people, or about one in four people with HIV who are in care today. Despite this unprecedented growth in demand, funding to the program, particularly from the federal side, has not kept up. NASTAD reports that state funding actually increased by \$150 million last year for a total of \$346 million. Pharmaceutical company rebates grew to over \$522 million. Federal funding now accounts for less than half of all ADAP spending.

While it is far from enough, we are pleased the Congress, even while they cut discretionary spending by \$40 billion, did approve a nearly \$50 million increase this year to ADAP. Half of that amount is a continuation of the \$25 million in emergency funding that was added mid-year, so the real increase is less than \$25 million in new money going to the state, or enough for about 2200 people. NASTAD estimates that the true need is an increase of approximately \$400 million. The President has proposed an increase of almost \$55 million. What are we going to do to ensure people with HIV/AIDS in the United States are receiving their medications for the next couple of years until health reform is implemented?

At your last meeting, you asked HRSA to provide you with what the estimated future needs for ADAP. We felt knowing this information will help policymakers know the magnitude of the problem to help them make decisions and plan accordingly. Unfortunately, I have not heard at this meeting that these estimates have been forwarded to you. We ask you to keep the ADAP crisis at the top of your agenda and to continue to urge the Obama Administration to address this situation. Asking states to lower eligibility requirements, which HRSA is now doing, is not an answer. People need to receive their medications. Currently, we are letting them down, and we are concerned we have just seen the beginning of the crisis. Thank you very much.

# Agenda Items and Dates for Next Meeting

Dr. Hook announced that the next CHAC meeting would take place on November 15-16, 2011and that an email confirmation would be sent. The following topics were discussed as agenda items for future CHAC meetings:

## <u>CDC</u>

- A presentation on women and HIV, relative to PrEP and surveillance.
- Updates on the progress of consultations held by the Division of Adolescent and School Health (DASH), which will integrate topics of sexual health.
- Additional presentations on PrEP, including how CHAC can continue to have input.

## <u>HRSA</u>

- A report from the Bureau of Primary Healthcare regarding progress on their efforts to scale up screening for HIV, STDs, and hepatitis in Health Centers is a standard agenda item. More detail is requested regarding the metrics used to measure the testing at community health centers.
- An update of current issues with ADAP, future needs, and issues of integration based on future CDC work. A request was made to receive an update before the next CHAC meeting.
- An update on the progress and status of the report to Congress regarding a transition plan for medical services and pharmaceuticals for Ryan White clients in anticipation of ACA. If the report has already been transmitted, then a briefing is requested.

## Other Agenda Items

- Invited Speaker: Updates from PACHA on its work and collaboration with CHAC.
- Information on the issue of CHAC workgroups, including their role and structure.

With no further discussion or business brought before CHAC, Dr. Hook adjourned the meeting at 3:07 pm on May 11, 2011.

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

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

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

Date

Date