

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



**Meeting of the CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis and STD Prevention and Treatment
May 21-22, 2014**

Record of the Proceedings

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**CDC/HRSA ADVISORY COMMITTEE ON HIV,
VIRAL HEPATITIS AND STD PREVENTION AND TREATMENT
May 21-22, 2014
Atlanta, Georgia**

Minutes of the Meeting

The U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC). The proceedings were held on May 21-22, 2014 in Building 8 of CDC's Corporate Square Campus, Conference Room A/B/C, in Atlanta, Georgia.

CHAC is chartered to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on objectives, strategies, policies and priorities for HIV, viral hepatitis and STD prevention and treatment efforts for the nation.

Opening Session: May 21, 2014

Jeanne Mrazzco, MD, MPH, CHAC co-Chair
Professor of Medicine, Harborview Medical Center
University of Washington

Laura Cheever, MD, ScM, Acting CHAC co-Chair
Associate Administrator, HIV/AIDS Bureau
Health Resources and Services Administration
CHAC Designated Federal Officer, HRSA

Jonathan Mermin, MD, MPH
Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer, CDC

Drs. Marrazzo, Mermin and Cheever performed their duties as the CHAC co-Chair and CDC/HRSA Designated Federal Officers (DFOs). Dr. Marrazzo conducted a roll call to determine the CHAC voting members, *ex-officio* members and liaison representative who were attending the meeting either in person or remotely.

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

CONFLICT OF INTEREST DISCLOSURES	
CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Bruce Agins, MD, MPH (New York State Department of Health)	Recipient of multiple CDC and HRSA grants
Sanjeev Arora, MD, FACP (University of New Mexico Health Sciences Center)	Recipient of federal funding from CDC, HRSA, Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare and Medicaid Services (CMS), and Center for Medicare and Medicaid Innovation; principal investigator of multiple clinical trials for new hepatitis C virus (HCV) drug development
Virginia Caine, MD (Marion County, Indianapolis Public Health Department)	Recipient of federal funding from CDC for STD activities and from HRSA for Ryan White; member of the National Medical Association Board that receives federal funding from CDC for HIV activities
Guillermo Chacon (Latino Commission on AIDS)	Recipient of federal funding from CDC for capacity-building services and from the Office of Minority Health for testing and research; member of Community Advisory Boards for Merck and ViiV Healthcare
Tommy Chesbro, HR, CSE (Chesbro Consulting, LLC)	Recipient of a federal contract; member of the National Minority AIDS Council Board of Directors that is a recipient of federal funding
Angelique Croasdale, MA (City of Hartford, Connecticut Department of Health and Human Services)	Recipient of federal funding from CDC and HRSA

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Carlos del Rio, MD (Rollins School of Public Health Emory University)	Recipient of federal funding from CDC, HRSA for a Ryan White Clinic, and the National Institutes of Health (NIH)
Marjorie Hill, PhD (Independent Consulting Services)	No conflicts disclosed
Steven Johnson, MD (University of Colorado School of Medicine)	Recipient of federal funding from HRSA for Ryan White; consultant to Gilead Sciences and ViiV Healthcare
Jennifer Kates, PhD (Kaiser Family Foundation)	No conflicts disclosed
Kali Lindsey (amfAR, The Foundation for AIDS Research)	No conflicts disclosed
Jeanne Marrasso, MD, MPH (University of Washington)	Recipient of federal funding from CDC for HIV, STD and viral hepatitis prevention education; recipient of pharmaceutical funding from Cepheid and Melinta for STD diagnostic studies and treatment trials
Britt Rios-Ellis, PhD (California State University, Long Beach)	Recipient of federal funding from the NIH National Institute on Minority Health and Health Disparities; pharmaceutical funding from Merck for Latino treatment and prevention efforts

The voting members and *ex-officio* members in attendance constituted a quorum for CHAC to conduct its business on May 21, 2014. The proceedings were called to order at 8:45 a.m. Drs. Marrasso, Mermin and Cheever welcomed the participants to day 1 of the 22nd CHAC meeting.

Dr. Mermin described changes to CHAC's membership that have occurred since the November 2013 virtual meeting.

- Ms. Antigone Dempsey accepted a new position at HRSA in April 2014 as the Director of the HAB Division of Policy and Data and could no longer serve as the CHAC co-Chair. The participants congratulated and extended their best wishes to Ms. Dempsey in her new position. Dr. Cheever would serve as the Acting CHAC co-Chair for the current meeting, but efforts are underway to replace Ms. Dempsey.
- Mr. Douglas Brooks accepted a new position as Director of the Office of National AIDS Policy and could no longer serve as the CHAC liaison representative for the Presidential Advisory Council on HIV/AIDS (PACHA). PACHA currently is identifying a new liaison to replace Mr. Brooks.

- Dr. Paul Gaist is a Health Scientist Administrator in the NIH Office of AIDS Research. He has replaced Dr. William Grace as the *ex-officio* member for NIH.
- The terms of four CHAC members would expire on November 30, 2014: Dr. Perry Halkitis, Dr. Marjorie Hill, Dr. Jeanne Marrazzo, and Ms. Regan Hofmann. The *Federal Register* notice that announced the upcoming vacancies in CHAC's membership resulted in nominations of a large, diverse and qualified pool of candidates. The draft nomination packages would be submitted to the CDC Committee Management Office for review at the end of May 2014 as the next step in the HHS approval and clearance process to appoint the new CHAC members.

CDC/NCHHSTP Director's Report

Jonathan Mermin, MD, MPH

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

Dr. Mermin covered the following topics in his Director's report to CHAC. At the agency level, the CDC FY2014 budget includes \$30 million for the CDC National Center for Emerging and Zoonotic Infectious Diseases to establish a new Advanced Molecular Detection (AMD) Program. The AMD Program will target funding and efforts to five major activities.

- Improved pathogen identification and detection
- New diagnostics
- Technical assistance to states to meet their bioinformatics and genomics needs
- Enhanced laboratory information systems
- Prediction, modeling and early recognition of infections

CDC partnered with U.S. government agencies, other nations, international organizations, and public/private stakeholders to launch a "Global Health Security Agenda." The purpose of this initiative is to accelerate progress toward achieving worldwide safety and security related to infectious disease threats and also to promote global health security in three major areas. First, the likelihood of natural, accidental or intentional outbreaks will be prevented and reduced. Second, threats will be detected early to save lives. Third, multi-sectorial coordination and communication will be deployed internationally to ensure a rapid and effective response.

The FY2015 President's budget proposed a \$30 million increase for the "Detect and Protect Against Antibiotic Resistance" initiative. The purpose of this effort is to enhance surveillance and laboratory capacity at national, state and local levels to detect and characterize domestic antibiotic-resistant threats and protect patients from imminent danger. If the initiative is approved in the FY2015 President's budget, investments will be targeted to implementing

proven and evidence-based interventions (EBIs) that have the ability to reduce the emergence and spread of antibiotic-resistant pathogens and improve appropriate antibiotic use.

At the National Center level, CDC's new AMD Program awarded \$917,240 to NCHHSTP to conduct five new AMD projects.

1. Characterization of microbial transmission networks by combining epidemiologic and genetic data
2. Advanced molecular detection of HCV outbreaks
3. Genomic surveillance of *Mycobacterium tuberculosis* in New York City over the 2011-2014 time period
4. Whole-genome sequencing for tuberculosis (TB) outbreak detection and investigations
5. Genomic sequencing of *Neisseria gonorrhoeae* to more effectively respond to the urgent threat of antimicrobial-resistant gonorrhea

NCHHSTP was pleased to announce the appointment of Dr. Stephanie Zaza as the new Director of the Division of Adolescent and School Health. Dr. Zaza's distinguished career at CDC over the past 23 years includes her role as an Epidemic Intelligence Service Officer in 1991 and multiple leadership positions since that time. Dr. Zaza's first update to CHAC was scheduled on the agenda.

Sequester reductions led to the restoration of \$569 million in the FY2014 CDC budget. The FY2015 President's budget requests an increase of ~\$7.4 million to NCHHSTP. If approved, NCHHSTP will allocate the funding increase to two major areas: (1) \$4.4 million to improve HIV surveillance as well as to identify and share HIV prevention best practices and (2) \$3 million to evaluate school health programs.

NCHHSTP implemented a new strategic planning process to identify the best approaches to achieve maximum impact on reducing health disparities, disease incidence, morbidity and mortality for HIV, viral hepatitis, STDs and TB. NCHHSTP held meetings and retreats with staff at the Office of Director, division and branch levels to obtain internal input on the strategic planning process. Key informant interviews also were conducted with partners to obtain external guidance on opportunities and challenges related to HIV, viral hepatitis, STD and TB prevention. After NCHHSTP develops the draft Strategic Plan, the document will be shared and vetted with a broader group of partners and stakeholders.

NCHHSTP launched a new "Prevention Through Health Care" website as an online resource to help leverage changes in the healthcare system at multiple levels: state, local and tribal public health agencies, community-based organizations (CBOs), and other partners. NCHHSTP published success stories and outcomes of demonstration projects related to its Program Collaboration and Service (PCSI) initiative.

A supplement on PCSI was published in the January 2014 edition of *Public Health Reports*. NCHHSTP published the *2013 Annual Report* to highlight its center-wide activities and accomplishments. NCHHSTP updated its “Atlas” with 2012 surveillance data for STDs and TB. All of these resources and publications are available on the CDC.gov/nchhstp website.

NCHHSTP conducted a number of workforce development and capacity building activities. A new seminar series on laboratory science was offered to epidemiologists. A new scientific writing course was held for NCHHSTP scientists. The Coaching and Leadership Initiative was piloted in 2013 with 60 team leaders. NCHHSTP continued to conduct its Ambassador Program to assist new employees during their transition to the workforce.

At the division level, the Division of HIV/AIDS Prevention (DHAP) published its first set of comprehensive clinical guidelines for pre-exposure prophylaxis (PrEP) on May 14, 2014. The guidelines reflect extensive input from an internal CDC workgroup and external guidance from partners, providers, HIV patients and affected communities. DHAP posted its revised HIV case definition on the CDC.gov website in April 2014.

DHAP launched its new “Start Talking. Stop HIV” campaign on May 21, 2014 to encourage gay and bisexual men to openly discuss HIV in their relationships. Dr. Mermin presented fact sheets that were developed for the campaign to emphasize the importance of safe and supportive relationships: “Before the sweet nothings, whisper something that can keep him safe.” “Talk before you play.” “Make conversation before you make out.” DHAP will conduct an evaluation in the future to determine the effectiveness of the campaign.

DHAP awarded new “Capacity Building for High-Impact HIV Prevention” grants in April 2014 to 21 organizations totaling \$23 million. Under the Category B-HIV Testing component of its funding opportunity announcement (FOA), the DHAP grants and guidance will help clinics and health departments to obtain reimbursement for provision of their services.

DHAP released its *2013 National HIV Prevention Progress Report* that highlighted the following outcomes: 62% of HIV targets were exceeded or met; 84% of persons living with HIV (PLWH) know their status; HIV incidence has decreased in heterosexuals, African American women and injection drug users (IDUs); and HIV incidence has increased in men who have sex with men (MSM).

DHAP will soon release its HIV prevention recommendations for adults and adolescents living with HIV in the United States. The guidelines will include several important features. The national goal to decrease HIV incidence by reducing infectiousness and HIV exposure to others will be reinforced. The need to consolidate all federal guidance on “prevention with positives” (PwP) will be emphasized. New, effective and/or under-utilized interventions will be highlighted. The audience will be expanded to include clinicians, non-clinical providers, health departments and HIV planning groups. Additional sections will be added to describe seven new topics.

DHAP's next steps in releasing its HIV prevention recommendations will be to finalize the copy editing and document design, complete the HHS review and clearance process, and publish the guidelines on the CDC.gov website. Links to the guidelines will be posted on a broad range of websites, including the CDC *Morbidity and Mortality Weekly Report (MMWR)*, HRSA, AIDSinfo and other co-sponsor websites.

The Division of Viral Hepatitis (DVH) closely collaborated with the American Association for the Study of Liver Disease (AASLD), Infectious Disease Society of America (IDSA), and the International Antiviral Society-USA in developing a new website (HCVguidelines.org) to provide practitioners who treat HCV-infected patients with the most up-to-date guidance on appropriate care. The website features CDC's published recommendations on HCV testing and linkage to care.

DVH published two *MMWR* articles based on recent viral hepatitis studies. The "Expanding Primary Care Capacity to Treat Hepatitis C Virus Infection Through an Evidence-Based Care Model in Arizona and Utah (2012-2014)" study analyzed the practices of 66 primary care clinicians with training in caring for HCV patients. Most of the clinicians were from rural settings. Over the course of the study, 129 patients received antiviral treatment. The study findings supported the expansion of HCV treatment in primary care settings, particularly since new therapies are far more effective, shorter in duration and much safer than previous treatment.

The "Early Identification and Linkage to Care of Persons with Chronic Hepatitis B Virus Infection: Three U.S. Sites (2012-2014)" study described outcomes of hepatitis B virus (HBV) testing programs in New York City, Minneapolis-St. Paul and San Diego. Of 4,727 persons tested at the three sites, 310 (or 6.6%) were hepatitis B surface antibody-positive. Of 86% of the HBV-positive population that was referred to care, 66% attended their first scheduled medical visit.

The Division of STD Prevention (DSTDP) published an *MMWR* article in March 2014 that updated CDC's 2002 guidelines for laboratory-based screening tests to detect chlamydia and gonorrhea. The new guidelines cover optimal specimen types, the use of specific tests to detect rectal and oropharyngeal infections, and supplemental testing. The guidelines are available on the CDC.gov/std website for use by clinical laboratory directors and staff, clinicians and disease control personnel.

DSTDP will release two new FOAs in the near future. The five-year "National Network of STD Clinical Prevention Training Centers" FOA will be awarded in August 2014 to a maximum of 8 regional and 6 national Centers of Excellence. The grantees will be funded to develop, disseminate and evaluate technical assistance (TA) and training to improve STD care at the individual healthcare clinician, clinical organization and healthcare system levels. The three-year "Community Approaches to Reducing Sexually Transmitted Diseases" FOA will be awarded to advance community wellness, influence sexual health behaviors and practices, and reduce STD disparities.

The Division of Adolescent and School Health (DASH) will publish data from the Youth Risk Behavior Surveillance System in the June 12, 2014 edition of the *MMWR*. DASH will convene the “Expert Panel on School-Based STD Screening Programs” on July 31-August 1, 2014. The expert panel will be charged with achieving five overarching objectives.

- Review published findings on adolescent and school health
- Compare multiple models of school-community partnerships for program implementation
- Consider factors and program characteristics that influence outcomes
- Examine the cost of previous STD Screening Programs
- Identify areas for future research and evaluation

HRSA/HAB Associate Administrator’s Report

Laura Cheever, MD, ScM

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

Dr. Cheever covered the following topics in her Associate Administrator’s report to CHAC. HAB created a framework to describe the future direction of the Ryan White HIV/AIDS Program (RWHAP) in the context of the Affordable Care Act (ACA) and the evolution of the U.S. healthcare system over time.

The framework is based on an overarching goal of achieving “zero new HIV infections” through a comprehensive system of care that incorporates a public health approach. Successful treatment of patient reduces the risk of transmission of HIV by >90, demonstrating the role the RWHAP plays in ending the endemic through improving access to an outcomes of treatment. The RWHAP achieves these goals through service delivery, policy development, assessment, capacity development and quality improvement activities.

HAB has greatly improved the availability and quality of RWHAP data. The time period between refining and disseminating the Ryan White Services Report (RSR) was shortened from 12-18 months to 6-9 months. The AIDS Drug Assistance Program Data Report now reflects a client-level data collection period of an entire calendar year. The time period between refining and disseminating the report was shortened to 3-6 months. State profiles of RWHAP funding now reflect client-level data across states, including viral load outcomes. State data for 2012 will be released by the fall of 2014. HAB data play a critical role in demonstrating the effectiveness of the RWHAP, monitoring grantee activities, and helping grantees to track outcomes and quality in their individual programs.

HAB is applying its data to innovative strategies to improve prevention and care outcomes. The HAB/CDC partnership on HIV Care Continuum initiatives is ongoing to conduct the Care and Prevention in the United States Project, activities supported by the HHS Secretary's Minority AIDS Initiative (MAI) Funding. One Special Projects of National Significance (SPNS) Initiative in 2014 will support clinics utilizing staff differently to improve outcomes along the continuum of care.

A joint HAB/CDC meeting will be held with the National Alliance of State and Territorial AIDS Directors (NASTAD) to discuss opportunities and challenges in surveillance and program data integration and utilization. Findings from the meeting will be used to improve HIV Care Continuum analyses and related activities. Outcomes from the meeting also will benefit the FOA for a new SPNS Initiative that HAB will release in 2014 for states to link their surveillance data and RWHAP health outcomes data.

HAB initiated integrated planning efforts with CDC. HAB and CDC released a joint letter to their grantees to indicate ongoing support for integrated planning and alignment between HRSA's RWHAP Comprehensive Plan/Statewide Coordinated Statement of Needs and CDC's HIV Jurisdictional Prevention Plan. HAB and CDC anticipate releasing integrated planning guidance to their grantees in 2015.

HAB launched a new All Parts HIV Care Continuum Collaborative to improve access to HIV care and increase viral load suppression. RWHAP grantees in Arkansas, Mississippi, Missouri, New Jersey and Ohio were funded to build statewide quality improvement (QI) collaborative teams. This effort aims to achieve three goals: (1) build regional capacity for closing gaps across the HIV Care Continuum to ultimately increase viral load suppression rates for PLWH; (2) align quality management goals across all RWHAP parts to jointly meet legislative quality management mandates; and (3) implement joint QI activities to advance the quality of care for PLWH within a state and seamlessly coordinate services across all RWHAP parts.

HAB's 2012 preliminary RSR data showed that HIV Care Continuum rates were higher in RWHAP than the national average. Of all RWHAP clients who had at least one outpatient ambulatory medical care (OAMC) visit before September 1, 2012, 82% were retained in care (defined as having at least two visits ≥ 90 days apart). Of all RWHAP clients who had at least one OAMC visit and at least one viral load count 75% were virally suppressed (defined as a last viral load test < 200). By risk group, retention in care rates were 82% for MSM, ~80% for black MSM (BMSM), and 74% for young MSM (YMSM) 13-24 years of age. Viral suppression rates were 76% for MSM, ~68% for BMSM, and ~53% for YMSM.

The 2012 preliminary RSR data emphasized the critical need to develop evidence based interventions (EBIs) to improve outcomes in adult and young BMSM. HAB released a cooperative agreement (CoAg) for grantees to compile, distribute and replicate effective models of HIV clinical care and treatment for adult and young BMSM. Year 1 of the CoAg will focus on

building an inventory of existing EBIs for HIV care and prevention. Emphasis will be placed on areas of the nation where epidemiological data support the need for service delivery models.

Grantees will conduct two major activities to achieve the year 1 goals. A TA toolkit and workbook will be developed with effective, best-practice EBIs that can be replicated and implemented across the HIV Care Continuum for BMSM. A web-based TA clearinghouse will be designed and linked to the HAB TARGET Center to assure optimal management of the inventory of TA resources (e.g., models of care, curricula, toolkits and webinars).

Year 2 of the CoAg will focus on identifying and disseminating best practices and effective models of care for adult and young BMSM. Grantees will conduct several activities to achieve the year 2 goals. Comprehensive TA modules will be developed that will include procedural materials to enable providers to replicate and implement best practices and strategies for serving BMSM along the HIV Care Continuum.

Dissemination of effective EBIs, strategies and models of HIV care will aim to increase the capacity, quality and effectiveness of HIV/AIDS service providers to screen, diagnose, link and retain both adult and young BMSM in HIV care. Multiple platforms will be utilized to transfer knowledge and broadly disseminate models, strategies, best practices and all other resources: training manuals, webinars, curricula, and electronic and social media (e.g., Facebook, Twitter and blogs).

To widely increase capacity to deliver services, enhance quality of care and improve health outcomes, dissemination efforts will be targeted to diverse audiences, including HIV/AIDS providers and stakeholders, health departments, Community Health Centers (CHCs), and federally and non-federally funded organizations. HAB expects to award the CoAg for grantees to begin conducting activities on July 1, 2014.

HAB will award a health literacy contract in FY 2014 to improve capacity of grantees to improve health literacy of their patients. This effort is targeted to health departments and CBOs with and without RWHAP funding that provide HIV services to PLWH, particularly adult and young BMSM. The contractors will offer a “train-the-trainer” course to multiple sites and the HAB TARGET Center and also will develop culturally appropriate health literacy materials (e.g., a web-based training manual and curriculum, tip sheets, posters and brochures). A key feature will be to improve health insurance literacy so patients can take full advantage of expanded health care coverage.

HAB will release two new CoAgS that focus on ACA implementation. The goal of CoAg 1 is to increase the capacity of RWHAP core medical providers to initiate contacts with qualified health plans and facilitate enrollment of their clients into these health plans. The goal of CoAg 2 is to assist non-medical AIDS Service Organizations (ASOs) to develop new service models in the rapidly evolving health financing landscape that will support the provision of critical services for

specific vulnerable populations to improve health outcomes through different stages across the HIV Care Continuum.

HAB awarded contracts to conduct three ACA-related studies: (1) “Emerging Issues Related to ACA Implementation and the Future of Ryan White Services: A Snapshot of Outpatient Ambulatory Medical Care;” (2) “Evaluating the Impact of 1115 Medicaid Waivers on the Ryan White HIV/AIDS Program and Its Clients and Providers;” and (3) “Understanding and Monitoring Funding Streams in Ryan White Clinics.” Study 1 is underway. Study 2 will be presented to HAB in May 2014 after the case studies have been completed. Study 3 begun conducting interviews with 130 RWHAP Parts C and D grantees in April 2014. The study will be completed in June 2014.

HAB funded an Affordable Care Enrollment (ACE) TA Center. To inform this new effort, an assessment was performed in the fall of 2013 to determine the needs of grantees in facilitating outreach and enrollment assistance to minority clients who sought private insurance through expansion of Medicaid or in the Marketplace. An enrollment survey also was administered to RWHAP Parts A, B, C and D grantees. Of 231 survey respondents, 31% received resources other than RWHAP funding to support outreach and enrollment efforts and 51% had staff with outreach and enrollment certifications within their organizations.

Because needs of the survey respondents greatly varied by their Medicaid expansion status, insurance exchange type and enrollment capacity, HAB is aware of the need to tailor TA and training based on the specific needs of grantees and providers. Many direct service providers reported their limited experience in and lack of knowledge of new ACA coverage options as well as their challenges in general outreach and enrollment.

Several barriers to care were reported. RWHAP providers reported that their minority clients who historically have faced barriers to accessing care were uncomfortable in enrolling in new ACA coverage options. Clients particularly were concerned about the affordability of plans and the possibility of needing to change providers. Issues were raised regarding the ability to maintain cultural competency in outreach and enrollment efforts to ensure RWHAP clients are retained in care in ACA coverage options.

RWHAP grantees and providers emphasized the need for HAB to provide more local guidance on policies and best practices to improve communication and coordination. Grantees and providers noted that gaps in coordination might have implications for care outcomes of their clients. The ACE TA Center includes numerous resources for grantees. Up-to-date strategies, tools, training, the Needs Assessment Report and other materials can be obtained by subscribing to the ACET TA Center listserve. Questions can be posed directly to the ACE TA Center e-mailbox. New resources and existing tools that are tailored, adapted and translated for RWHAP providers can be viewed on the ACE TA Center of the HAB TARGET Center.

HRSA is continuing to collaborate with CMS and the CMS Center for Consumer Information and Insurance Oversight (CCIIO) on key post-ACA enrollment issues, such as third-party payment monitoring, mail order pharmacies, prior authorization and Essential Community Provider implementation. HAB's post-ACA enrollment activities include responding to frequently asked questions by grantees; co-hosting webinars with CMS on best practices and other topics of relevance to RWHAP; assisting RWHAP grantees to assist clients in applying for and enrolling in healthcare coverage and educating RWHAP patients on the purpose of their health insurance coverage; and assuring RWHAP grantees are "in-network" with qualified health plans and Medicaid Managed Care Organizations.

The FY2014 RWHAP enacted budget totals ~\$2.3 billion with the AIDS Dug Assistance Program accounting for the largest proportion of the appropriations. The FY2015 President's budget proposed level funding for all RWHAP parts except for the consolidation of Parts C and D where a \$4 million increase over FY 2013 for the consolidated budget was proposed. The President's budget recommended the consolidation of Parts C and D to improve the reach of the Women, Infants, Children and Youth program nationally across all Part C and D grantees and to reduce overlap in administrative burden between the two parts.

HAB realigned its leadership and organizational structure in several areas. The Director and Deputy Director of the Division of Policy and Data were appointed. A search is underway to appoint a permanent HIV Education Branch Chief. The Data Management and Analysis Branch reflects the consolidation of two previous branches. The Clinical Unit was relocated to the new Program/Clinical Evaluation and Technical Assistance Branch. The Organizational Development Team was relocated to the Office of Operations and Management. A new branch was added to the Division of Community HIV/AIDS Program.

CHAC discussed the following topics with Drs. Mermin and Cheever on the CDC and HRSA updates.

- The ability of HRSA's health literacy contractors to also provide education and resources to HIV-negative partners of RWHAP's HIV-positive clients, particularly on PrEP and prevention as treatment interventions.
- The exclusion of Latino, Asian and Native American MSM from new CDC and HRSA projects that are targeted to specific HIV risk groups.
- HRSA's efforts to ensure that geographic variations are addressed in the HIV Care Continuum Collaborative.
- HRSA's oversight and leadership to assure retention of a high level of competency for HIV and HCV care when RWHAP clients are required to change their providers in ACA coverage options.
- The need for HRSA to expand RWHAP's extraordinary success in HIV treatment to a much broader infectious disease program that would address PrEP for HIV-negative persons as well as comprehensive care, treatment adherence, drug-drug interactions and retention in care for HBV, HCV and STDs.

The discussion resulted in CHAC making several suggestions for CDC and HRSA leadership to consider in improving their agency-wide activities.

- HRSA should provide leadership in ensuring that HRSA-funded state public health agencies, State Medicaid Directors and Marketplace Insurance Commissioners are extensively engaged in Statewide Coordinated Statement of Needs planning processes. Coordination and collaboration at the state level will be critical in increasing access to health care and improving health outcomes.
- CHAC should set aside time during the Business Session to address two important questions: (1) What is the obligation of HHS, CDC and HRSA to protect the health of the nation in a fair and equitable process? (2) What is CHAC's moral and ethical obligation to provide its expert advice to HHS, CDC and HRSA on combining categorical funding silos to benefit the health of the American public rather than bending to political pressures? The FY2014 budgets reflect Congressional appropriations of ~\$758 million to CDC for HIV/AIDS prevention activities and ~\$2.3 billion to HRSA for RWHAP. The tremendous amount of federal resources that has been targeted to HIV/AIDS prevention and treatment over time was needed to combat this deadly disease and achieve a significant public health impact. However, CDC's viral hepatitis budget of only \$31 million shows that the U.S. government does not view HCV as an urgent public health threat. Based on its surveillance data, CDC reported a >50 increase in new HCV infections over the past five years and potential deaths of 897,000 persons with current HCV treatment rates. As external expert advisors to HHS, CDC and HRSA, CHAC must now take a strong position to emphasize the critical need for more federal funding and efforts to HCV. CHAC's position statement should include future projections on the societal burden of HCV and CMS's cost of paying for new HCV treatments.
- CDC and HRSA should present data to educate Congressional staffers on the need to target more federal resources to HCV morbidity and mortality, but this effort should not result in a reduction of HIV prevention and treatment funding. Most notably, 50,000 new HIV infections are still reported in the United States each year. Moreover, HIV continues to be the leading cause of death in many states, including among African Americans 25-54 years of age in Georgia.
- HRSA's ongoing efforts to improve the collection and dissemination of RWHAP client-level data are commendable, but some CHAC members found HRSA's investments in CAREWare to be "useless." HRSA designed CAREWare as a scalable software system for RWHAP grantees to manage and monitor their HIV clinical and supportive care services to patients and rapidly complete and submit their RSRs. However, CAREWare has not maintained pace with current technology and capabilities of RWHAP providers in delivering HIV care. An Institute of Medicine (IOM) expert committee released the *Monitoring HIV Care in the United States: Indicators and Data Systems* report. The IOM report recommended the CDC Medical Monitoring Project (MMP) database in this effort, but did not even consider the HRSA CAREWare database as a resource. HRSA should take actions to either dramatically modify or entirely eliminate CAREWare because the

database in its current form does not provide information on HIV quality outcomes and new performance measures.

- CDC and HRSA should re-categorize and re-stratify non-IDUs substance use as a “high-risk” group and develop concrete action plans for prevention, treatment adherence and retention in care for this population. Non-IDU of crystal methamphetamines and other illegal substances has dramatically increased in HIV and HCV patient populations. Electronic health records (EHRs) will play a critical role in helping CDC and HRSA to systematically collect non-IDU data.
- CHAC has no time for discussion after the 20-minute ACA presentation. The agenda should be reorganized with sufficient time for CHAC to propose and vote on formal actions in response to important issues that have emerged since ACA was implemented in January 2014.
 - HIV providers have begun to report lower rates of retention in care and viral load suppression in their patients due to much higher co-pays for HIV medications under ACA.
 - ACA explicitly prohibits the denial of insurance coverage based on preexisting conditions. However, some insurance companies are using a “grandfather” clause to retain their pre-ACA restrictions on preexisting conditions and continue to deny coverage to HIV patients. This trend is particularly affecting African Americans and Hispanics with late-stage HIV diagnoses.
 - Some insurance carriers are eliminating HIV providers from their networks due to the perception that these providers will have poor performance outcomes based on ACA requirements.

Drs. Mermin and Cheever responded to CHAC’s comments and concerns regarding the tension between HIV and HCV. CHAC is chartered to advise HHS, CDC and HRSA on objectives, strategies, policies and priorities for HIV, viral hepatitis and STD prevention and treatment efforts for the nation. Decision-making on appropriations is the responsibility of Congress rather than Federal Advisory Committees. HHS, CDC and HRSA must allocate their appropriations as mandated by Congress to achieve the greatest public health impact.

The tremendous amount of federal funding that has been allocated to HIV prevention and treatment over time has resulted in significant public health progress. Prevention resources have decreased the incidence of new HIV infections, while treatment resources have allowed the current HIV-positive population of ~1.2 million persons in the United States to live with rather than die from HIV. The redirection of resources from HIV to HCV could result in unforeseen adverse consequences for public health overall.

Drs. Mermin and Cheever asked CHAC to consider opportunities to make similar progress in HCV by applying HIV lessons learned, building on HIV successes, and leveraging existing systems. For example, CHAC could explore changes in the healthcare systems to advise CDC and HRSA on creating new guidelines, initiating new program activities, or targeting resources to expand HCV prevention and treatment. Most notably, the availability of new all-oral, non-

interferon-based agents for HCV will allow HRSA-funded CHCs and RWHAP grantees to maximize their investments in the treatment of HIV/HCV co-infected patients.

Panel Presentation: Improving Screening and Treatment of Chronic Hepatitis C

CDC and HRSA presented updates on their recent activities to improve screening and treatment of chronic HCV. The updates are set forth below.

Advice Requested from CHAC by DVH and HAB:

1. What existing and new strategies should CDC consider and prioritize to increase the number of persons tested and cured of HCV?
2. What strategies can HRSA implement to address challenges related to screening and providing care to persons with HCV? What approaches can HRSA take to expand access to screening and treatment to persons in most need of these services?
3. What is the potential for new developments in HCV screening and treatment to change the provision of HCV care? Will these new developments give greater opportunities for primary care providers (PCPs) to diagnose and treat HCV?
4. What actions can HRSA take to leverage primary care medical homes, ACA mandates and Accountable Care Organization (ACO) resources to improve access to viral hepatitis screening, care and treatment?
5. What strategies can HRSA implement to streamline viral hepatitis care and treatment in the context of new and simpler regimens?

John Ward, MD

Director, NCHHSTP Division of Viral Hepatitis
Centers for Disease Control and Prevention

Dr. Ward described CDC's strategies to improve the diagnosis, care and treatment of HCV. CDC and the U.S. Preventive Services Task Force (USPSTF) updated their recommendations on HCV testing to assure consistency in three areas. First, a one-time test is recommended for all persons born in 1945-1965 due to the five-fold higher prevalence of HCV in this birth cohort.

Second, HCV testing is recommended for specific risk groups: persons with past or present IDU, persons who received blood transfusions or organ transplants prior to June 1992, persons who were ever on chronic hemodialysis, and persons with a history of incarceration. Third, HCV testing is recommended for persons with medical indications, such as patients with persistent evidence of liver disease and patients with HIV or other important co-morbidities.

Several studies conducted in 2012-2013 demonstrated that the linkage between HCV testing of the 1945-1965 birth cohort and optimal care and treatment of this population would be cost-effective and generate profound health benefits. Full implementation of the CDC and USPSTF HCV testing guidelines would result in a dramatic reduction in liver cancer risks and mortality: a 90% decrease in liver-related mortality, a 70% decrease in hepatocellular carcinoma, a 50% decrease in all-cause mortality, and prevention of >120,000 HCV-related deaths. Multiple studies reported the cost-effectiveness of full implementation of the CDC and USPSTF HCV testing guidelines in the general population (e.g., \$15,700-\$85,300 per quality-adjusted life-year) and also in settings with a low HCV prevalence of $\geq 0.84\%$.

Additional benefits of the linkage between HCV testing and care/treatment will be gained as HCV therapy evolves over time. Most notably, licensure of Sofosbuvir and Simeprevir by the U.S. Food and Drug Administration (FDA) has introduced a new era of all-oral HCV therapy that will result in higher cure rates. Based on clinical trial data, completion rates of >90% were reported because the new drugs eliminated barriers related to the level of disease and specific HCV genotypes.

Despite this progress, efforts are still needed to improve the quality of HCV management in order for patients to benefit from therapy. Of 3.2 million persons living with HCV in the United States, only 50% receive anti-HCV testing. Of persons who are tested, only 38% are linked to care. Of persons in care, only 23% receive follow-up HCV RNA testing. Of persons who receive follow-up testing, only 11% are treated. Of persons who are treated, only 6% achieve a sustained virologic response (SVR) (*i.e.*, cure). These data indicate the ongoing challenge to improve the HCV care continuum to ensure testing achieves the maximum public health benefit of reducing morbidity and mortality.

CDC's public health role in the HCV testing-to-cure continuum at the national level is to provide leadership, resources and support to state and local partners. The 1988 IOM report identified assessment, policy development and assurance as the three overarching goals in any public health framework. Specific activities to achieve the public health goals and inform system management and research also were highlighted in the IOM report: monitor health; diagnose and investigate; inform, educate and empower; mobilize community partnerships; develop policies; enforce laws; link to and provide care; assure a competent workforce; and evaluate outcomes.

CDC is applying the three public health goals as the basis to improve HCV testing, care and treatment. For the "assessment" goal, CDC created a new database to monitor implementation of national HCV testing policies based on data submitted by U.S. commercial laboratories. For example, the number of HCV tests that LabCorp conducted in 2013 increased by ~22% following the release of CDC's guidelines in 2012. CDC's new database also is designed to capture other attributes that will be important for HCV monitoring (e.g., the number of HCV-positive persons nationally, types of providers based on their specialty, and state/local geographic locations of patients and providers based on their zip codes).

CDC is continuing to assist states with standard case surveillance, but many jurisdictions are overwhelmed with and have limited capacity to address the number of new HCV cases. Most notably, >30 states reported a >50% increase in new HCV infections in the 2007-2012 time period. Several studies have described the demographics of persons with new HCV diagnoses: ~70% IDUs, young persons 18-29 years of age with equal distribution between males and females, predominately white persons in non-urban, suburban areas, and previous users of prescription drugs.

For the “health policy development” goal, CDC was a major contributor to the updated *HHS Action Plan for the Prevention, Care and Treatment of Viral Hepatitis (2014-2016)* (VHAP). The updated version of VHAP outlines six national priorities for viral hepatitis.

- Educate providers and communities to reduce health disparities
- Improve testing, care and treatment to prevent liver disease and cancer
- Strengthen surveillance to detect viral hepatitis transmission and disease
- Eliminate transmission of vaccine-preventable viral hepatitis
- Reduce viral hepatitis cases associated with drug-use behaviors
- Protect patients and workers from healthcare-associated viral hepatitis

CDC sponsored the development of new joint AASLD/IDSA policies for HCV treatment in the United States that were released in February 2014 (www.hcvguidelines.org) in response to FDA licensure of Sofosbuvir and Simeprevir. The AASLD/IDSA joint policies include guidance on all-oral treatments for HCV genotypes 1, 2 and 3. Other new HCV agents have been filed and are expected to be licensed by FDA by December 2014. However, the cost of the new HCV drugs will be an issue.

For the “assurance” goal, CDC and its federal, state, academia and professional association partners are conducting numerous activities to guide HCV testing and assure linkage to care. Several states used CDC’s recommendations to introduce and/or pass public health legislation to promote HCV testing. Colorado, Connecticut and New York passed laws in 2013-2014 that now require or encourage providers in primary care and in-patient settings to offer HCV testing to all persons in the 1945-1965 birth cohort. Similar HCV testing legislation is pending in California, Illinois, Massachusetts, New Jersey and Pennsylvania. HCV testing legislation was defeated in Florida, Maryland and Oklahoma. The CDC Public Health Law Program is exploring the development of a toolkit to assist states in using the HCV testing recommendations to create model legislation.

CDC is assuring a competent workforce by funding provider training in testing and clinical management of HBV and HCV. An online HCV training course is available on the University of Washington website (<http://hepatitisc.us.edu>). The Primary Care Liver Program was developed by the American College of Physicians and AASLD and is available on the AASLD website (www.aasld.org). Viral hepatitis prevention coordinators are funded to provide training in 48 states and 4 cities.

CDC allocated ~\$1.5 million to the “No More Hepatitis” public education campaign to widely publicize messages on billboards, airport diorama, radio public service announcements and videos. For example, the Times Square Jumbotron featured continuous HCV messages for two weeks in May 2014 to inform the public that HCV is a health threat for persons in the 1945-1965 birth cohort. A cost assessment showed that \$12 of space is donated for each \$1 CDC spends on the campaign.

CDC allocated additional resources that the HHS Secretary awarded from the Prevention and Public Health Fund to conduct HCV testing and linkage to care demonstration projects at CHCs. From October 1, 2012-March 31, 2014, CHCs in seven cities were funded to perform HCV testing and report the following outcomes.

- Total number of persons tested (a range of 1,234 to 6,093 persons)
- Percentage of current infections based on HCV antibody-positive and HCV RNA-positive test results (a range of 3% to 37%)
- Percentage of persons referred to care (a range of 60% to 100%)
- Percentage of persons who attended their appointments (a range of 15% to 100%)

The demonstration projects showed that the most successful CHCs were not required to ensure linkage to care because HCV testing and care occurred in the same facility. In future FOAs, CDC will make strong efforts to replicate the approach in which PCPs will perform HCV testing and provide care in the same setting.

CDC published an *MMWR* article on May 9, 2014 to report outcomes of care models that the Arizona and Utah Project ECHO® sites (Extension for Community Healthcare Outcomes) implemented in 2012-2014. Project ECHO® is a telemedicine-based knowledge network that links PCPs in predominantly rural settings with specialists. Of 66 PCPs who were trained by the Arizona and Utah sites, 93% had no previous experience in HCV care. The provision of antiviral treatment to 46% of HCV-positive patients was more than twice the proportion observed in other CDC studies. These findings demonstrate the utility of the Project ECHO® model in expanding HCV care and treatment capacity.

The CDC Foundation provided support to develop the Viral Hepatitis Action Coalition that has raised \$27 million since 2011 for CDC to conduct numerous viral hepatitis activities, including evaluation projects, policy implementation initiatives, research, development of clinical decision tools, the “No More Hepatitis” campaign, and events for state and local stakeholders.

CDC used a portion of its \$9 million increase in the viral hepatitis budget to release the new “Community-Based Programs to Test and Cure Hepatitis C” FOA. The goal of the new CoAg will be for grantees to build community coalitions that will implement a package of services to strengthen healthcare capacity to diagnose and cure HCV. CDC expects to award a total of \$20 million to three grantees at an average of \$1.5 million annually over the four-year project period.

The deadline to submit applications was May 20, 2014. CDC will announce the award on August 31, 2014.

The FOA outlines specific requirements for grantees. Public health partners, care specialists and PCPs must be included in community coalitions. The package of services that will be developed and implemented must include provider education resources, models of care (e.g., Project ECHO®), physician reminders and other clinical decision tools, performance measures, and registries or other data systems to measure impact.

CDC will use long-term outcome indicators to evaluate progress of the grantees in three areas: (1) an annual increase in anti-HCV testing of $\geq 50\%$ or at least 10,000 persons, whichever is greater; (2) an annual increase of $\geq 50\%$ or at least 2,000 persons, whichever is greater, in the number of persons diagnosed with current HCV infection; and (3) an annual increase of $\geq 50\%$ or at least 2,500 persons, whichever is greater, in the number of HCV-infected persons cured of their infection.

Overall, CDC's strategies to improve HCV testing, care and cure are based on three goals in the public health framework. For the assessment goal, CDC is monitoring and investigating HCV infections nationally. For the health policy development goal, CDC is gathering and evaluating evidence, establishing national priorities to prevent HCV transmission and disease, guiding prevention programs, and mobilizing partnerships. For the assurance goal, CDC is supporting and evaluating programs, assessing policy implementation in the health system, training the workforce, and educating communities. CDC is now shifting its focus to capacity building to ensure that its strategies are successful in improving HCV diagnosis, care and treatment.

Rupali Doshi, MD, MS

Medical Officer, HIV/AIDS Bureau
Health Resources and Services Administration

Dr. Doshi described HRSA's activities to expand access to quality HCV care and treatment. HAB and six other HRSA bureaus and offices contributed to updating VHAP for 2014-2016 and are conducting activities to support the six VHAP priorities identified by the HHS Secretary.

VHAP priority 1 is to educate providers and communities to reduce health disparities. HRSA disseminates educational materials to providers and communities. Support is provided to tele-health programs that target viral hepatitis education among safety net providers in HRSA-funded AIDS Education Training Centers (AETCs). CoAgs were awarded to several CBOs to increase the reach of HRSA's information dissemination and educational activities: Association of Asian Pacific Community Health Organizations, LGBT Health Education Center, National Association of Community Health Centers (NACHC), and National Health Care for the Homeless Council. National Hepatitis Day was widely promoted.

VHAP priority 2 is to improve testing, care and treatment to prevent liver disease and cancer. HRSA promotes adherence to national guidelines for hepatitis screening, treatment and linkage

to care. SPNS Initiatives were awarded to support PCPs in becoming hepatitis treatment providers. Health insurance enrollment is promoted to increase access to viral hepatitis care and treatment.

VHAP priority 3 is to strengthen surveillance to detect viral hepatitis transmission and disease. HRSA promotes reporting of newly-diagnosed viral hepatitis cases to state and local health departments (SHDs and LHDs).

VHAP priority 4 is to eliminate transmission of vaccine-preventable viral hepatitis. HRSA promotes HBV testing among pregnant women and provides appropriate referrals for care and treatment. Compliance with the Advisory Committee on Immunization Practices vaccination recommendations for hepatitis A virus and HBV is promoted.

VHAP priority 5 is to reduce viral hepatitis cases associated with drug-use behaviors. HRSA supports screening, care and treatment of viral hepatitis in opioid treatment and syringe services programs. Linkages with correctional settings are promoted to assure continuity of viral hepatitis care and treatment when newly released persons reenter the community.

VHAP priority 6 is to protect patients and workers from healthcare-associated viral hepatitis. HRSA promotes infection control with safety net providers. Collaborative efforts are undertaken with the Organ Procurement and Transplantation Network (OPTN) to revise existing OPTN policies to assure consistency with CDC guidelines, such as implementation of nucleic acid testing for HCV among organ donors. HBV vaccination among healthcare workers is promoted.

HRSA also is conducting several other HCV care and treatment activities beyond those that are supporting the six VHAP priorities. HRSA is collaborating with CDC on the HHS Secretary's "MAI Funding to Increase HIV Prevention and Care Service Delivery Among Health Centers Serving High Prevalence Jurisdictions." Under this project, health department/Health Center partnerships will be funded in four states to build Health Center capacity to provide prevention, testing, care and treatment to PLWH. The project also will support hepatitis screening and referral to care due to the high level of HIV/HCV co-infection.

HRSA awarded funds to AETCs to support nine demonstration projects at Tele-Health Training Centers. The project is targeted to low-volume healthcare providers who serve PLWH in historically underserved communities. The project aims to expand access to and improve health care for hard-to-reach PLWH in medical care. Key features of the project include clinical consultation, education and training utilizing tele-health technology, and development of an informed support system for trainees. The AETCs were asked to provide additional training to the Tele-health Training Centers to focus on the HIV co-morbidities of HCV and behavioral health.

HRSA awarded the SPNS HCV Treatment Initiative to support demonstration projects at 29 comprehensive HIV clinics. Over the two-year project period, the grantees will implement one

of four models of HCV care for HIV/HCV co-infection: integrated HCV care, designated HCV clinic sessions, HCV care delivery by a PCP with expert backup, or referral to an outside specialist for care.

Preliminary data from the SPNS HCV Treatment Initiative show that of 223 patients who began HCV treatment, 195 (or 87.4%) completed treatment and 99 (or 44.4%) achieved an SVR. A dedicated patient tracker was instrumental in assuring linkage to and retention in care. Ongoing TA through monthly didactic and case-based webinars, site visits and as-needed clinical consultation from the Evaluation and Technical Assistance Center increased the confidence of providers in initiating care.

HRSA's Uniform Data System (UDS) showed increases in the numbers of patients Health Centers served from 2011 to 2012: from 94,605 to 114,881 HIV patients; from 11,108 to 21,890 HBV patients; and from 61,294 to 132,078 HCV patients.

The HRSA Bureau of Primary Health Care's (BPHC) national partners developed several resources and offered numerous trainings on hepatitis-related issues that were targeted to key risk groups, including MSM, homeless persons, the lesbian/gay/bisexual/transgender (LGBT) community, Asians/Pacific Islanders, and CHC and primary care patient populations.

The HRSA Office of Regional Operations is strengthening its strategic regional partnerships to further expand access to quality HCV care and treatment. HRSA's regional offices in Boston, Denver and New York promoted HCV education for PCPs in collaboration with partners, helped to plan the Viral Hepatitis Summit, and participated in the HHS VHAP Stakeholder meeting.

Overall, HRSA will continue to address key challenges to increasing HCV linkage to care and treatment. These issues include the small number of providers with HCV training, the high cost of HCV drugs, the absence of a care system for HCV-positive patients with dedicated funding, and competing priorities for PCPs.

CHAC discussed the following topics with Drs. Ward and Doshi on ongoing activities by CDC and HRSA to improve chronic HCV screening and treatment.

- Concerns expressed by non-Medicaid expansion states in paying for treatment of HCV-positive patients, particularly since the market price for a curative regimen of Sofosbuvir is ~\$84,000 (or ~\$1,000 per pill).
- The failure of New York State legislators to allocate new funding to support training, public information dissemination and other necessary activities for state public health and healthcare providers to implement the new HCV testing law in the field.

CHAC applauded Dr. Ward for his national leadership in elevating the profile of viral hepatitis, advancing the field, and galvanizing strong support for HCV despite tremendous budget

constraints. Several CHAC members made suggestions for CDC and HRSA to consider in improving national HCV screening and treatment efforts.

- HCV screening and treatment should be tied to payment and CMS's Meaningful Use indicators in the healthcare system. Clinics and providers also should be given reports of their performance in these areas on a routine basis. Based on past experiences with HIV quality measures, incentives must be offered in order for PCPs to adhere to and fully implement HCV testing and treatment guidelines.
- The public health model for TB should be replicated for the HCV testing-to-cure continuum, particularly since new drugs have improved the safety and efficacy of HCV therapy. Health departments are responsible for ensuring that TB patients are followed from the time of their diagnosis to achievement of a microbiologically-proven cure.
- Successes, failures and lessons learned over the evolution of the HIV epidemic should be thoroughly reviewed and applied to HCV screening and treatment.
 - The media extensively covered, widely publicized and promoted the success of new antiretroviral (ARV) drugs for “nearly dead” HIV patients. The same level of media coverage should be used to convey personal stories of HCV patients who are completing treatment and being cured with new drugs that are safer and more effective. Similar to HIV, constant media attention could help to increase awareness, visibility and advocacy for HCV testing and treatment at the community level.
 - Cost-effectiveness data and other rigorous evidence were collected to justify the need for more HIV funding at federal and state levels. The same approach should be taken for HCV. Based on CDC data, for example, full implementation of the HCV screening policy for the 1945-1965 birth cohort could result in cost-savings of \$1.5 billion to the healthcare system. Moreover, the difference in healthcare costs between HCV treatment and a liver transplant is large (e.g., \$84,000 versus \$500,000).
 - The original public health strategy of creating “HIV exceptionalism” with distinct screening and care sites and a separate provider workforce has been a mistake in hindsight. CDC's PCSI Initiative and other federal efforts to combine HIV with other infectious and chronic diseases have resulted in minimal and slow progress to date. Public health should not repeat the same mistake with HCV. Ongoing efforts to transition to a more comprehensive and holistic patient-centered medical home (PCMH) model should continue. Full integration of screening and treatment for HIV, HCV, STDs, substance abuse and mental health issues into primary care settings will increase access and obtain evidence base for strong leadership and support for this public health approach. Resources should now be invested to apply the TasP strategy to HCV and rapidly deliver new HCV drugs to persons in need. Healthcare costs associated with complications and long-term follow-up of HCV patients can be avoided if treatment is initiated immediately after acquisition of disease.

Analysis Results: New Coverage for PLWH Due to the Affordable Care Act

Jennifer Kates, PhD

Vice President & Director, Global Health and HIV Policy
Kaiser Family Foundation
CHAC Member & Data Workgroup Chair

Dr. Kates presented the results of a new analysis conducted by the Kaiser Family Foundation (Kaiser) and researchers at the Centers for Disease Control and Prevention (CDC) to estimate the number of PLWH who could gain new coverage under ACA. The ACA will expand insurance coverage for millions of persons in the United States, including PLWH. The expanded coverage will occur in states that have chosen to expand Medicaid and through new Health Insurance Marketplaces available in all states for individuals to purchase coverage, including subsidies for those who are lower incomes. Despite the importance of the ACA for people with HIV, there were no national estimates of the number of people with HIV likely to gain new insurance coverage due to ACA.

Kaiser and CDC undertook an analysis to develop such estimates, and issued a joint report in January 2014, *Assessing the Impact of the Affordable Care Act on Health Insurance Coverage of People with HIV*, to fill this data gap. The study design and methodology are summarized as follows. Data from the CDC MMP were analyzed. MMP is a supplemental HIV surveillance system that produces nationally representative estimates of behavioral and clinical characteristics of HIV-infected adults who receive medical care in the United States. The IOM recommended the use of MMP to monitor the impact of ACA.

The analysis utilized 2009 MMP data of adult PLWH 19-64 years of age who were in care to estimate pre-ACA insurance and income status. The sample size of 4,067 PLWH in care represented an estimated national population of 406,970 PLWH (but did not represent the full population of all people with HIV including those not yet diagnosed or in regular care).

Insurance status was examined by income and whether individuals with HIV received support from the Ryan White HIV/AIDS Program. The number of PLWH who could gain new Medicaid coverage or subsidized coverage through Health Insurance Marketplaces was estimated. The impact of state decisions on Medicaid expansion was described. Key findings of the analysis include the following:

- Insurance coverage of 406,970 non-elderly adult PLWH who were in care in 2009
 - Medicaid: 41%
 - Private insurance: 30%
 - Uninsured: 17%
 - Medicare: 6%

- Other public sources: 5%
- RWHAP support (of those with and without insurance): 4 out of every 10 clients
- Income distribution of 406,970 non-elderly adult PLWH who were in care in 2009
 - <100% of the Federal Poverty Level (FPL): 44%
 - 100%-138% of the FPL: 17%
 - 139%-399% of the FPL: 26%
 - ≥400% of the FPL: 13%
- Income distribution of 69,720 uninsured non-elderly adult PLWH who were in care in 2009
 - <100% of the FPL: 51%
 - 100%-138% of the FPL: 16%
 - 139%-399% of the FPL: 29%
 - ≥400% of the FPL: 4%

Based on the income distribution data, virtually all 69,720 uninsured non-elderly adult PLWH would benefit from new coverage if all states chose Medicaid expansion. At this time, 27 Medicaid expansion states (including the District of Columbia) account for 57% of PLWH, while 24 non-Medicaid expansion states that primarily are in the South account for 43% of PLWH (or >4 out of every 10 PLWH). In the non-Medicaid expansion states, new Medicaid coverage or subsidized coverage through Health Insurance Marketplaces will not be available to 22% of PLWH <100% of the FPL (or 15,460 persons) and 7% of PLWH at 100%-138% of the FPL (or 4,890 persons).

Overall, ~70,000 uninsured PLWH who currently are in care could gain new coverage under ACA, but this estimate would increase to ~200,000 with the inclusion of PLWH who are not yet in care. Decisions by states regarding Medicaid expansion will have significant implications. The number of PLWH who are newly eligible for Medicaid would be reduced by >40% given the number of states that have decided not to move forward with Medicaid expansion at this time.

Moreover, most PLWH with incomes <100% of the FPL in non-expansion states will not be eligible to obtain subsidized coverage through Health Insurance Marketplaces because they fall into the “coverage gap”. The implementation of ACA has not diminished the critical role of RWHAP in covering services for PLWH, particularly those in non-Medicaid expansion states and those with new or existing coverage who will need additional services due to out-of-pocket costs. Kaiser and CDC are exploring the possibility of conducting additional analyses in the future due to the expansion of MMP, but CHAC’s input on approaches to strategically and effectively disseminate the report to key target audiences would be welcome.

CHAC pointed out that it was interested in identifying recommendations that could be provided to states about the best way to use RWHAP resources in the current ACA environment. Such recommendations would need to be state-specific; national guidelines would not be useful in

this regard. The CHAC agreed to revisit this issue at a future meeting to discuss ways to assist HRSA in developing state-specific guidance, especially in states that are not expanding Medicaid.

Panel Presentation: Innovative HIV Prevention Approaches for MSM and Other At-Risk LGBT Populations

A panel of speakers presented a series of overviews on innovative HIV prevention approaches that are being implemented for MSM and other at-risk LGBT populations. The overviews are set forth below.

Advice Requested from CHAC by NCHHSTP:

1. What are the best strategies to identify MSM who are eligible for and at greatest need of PrEP?
2. What are the optimal settings to provide PrEP to MSM (e.g., HIV providers, STD clinics or MSM-focused clinics)?
3. What steps can CDC take to encourage providers at specific sites to offer PrEP to eligible MSM?
4. Due to the importance of STDs in facilitating HIV transmission and acquisition, what strategies can CDC implement to reduce syphilis and gonorrhea rates among MSM, particularly among MSM who use TasP and PrEP to prevent HIV?
5. What are the best models to increase syphilis and gonorrhea screening among MSM?
6. Due to limited funding, should CDC's efforts to improve sexual health and HIV/STD prevention education be generalized for all students or focused on youth at a disproportionate risk (e.g., LGBT youth and YMSM)?
7. What are the top 2 activities that schools should prioritize to create a safe and supportive environment for LGBT youth and YMSM?
8. What are reasonable expectations of sexual health services provided by School-Based Health Clinics (SBHCs) or school nurses for all youth, including LGBT youth and YMSM?

Amy Lansky, PhD, MPH

Deputy Director for Surveillance, Epidemiology and Laboratory Sciences
Division of HIV/AIDS Prevention, NCHHSTP
Centers for Disease Control and Prevention

Dr. Lansky presented an overview of CDC's *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2014 Guidelines* that were released on May 14, 2014. The guidelines are for clinicians and provided recommendations on prescribing PrEP.

The PrEP guidelines include several overarching recommendations. Daily oral PrEP with Truvada® is recommended as one prevention option for sexually active MSM, sexually active heterosexual men and women, and IDUs at substantial risk for HIV infection. In addition, the

use of PrEP during conception and pregnancy should be discussed with HIV-discordant couples wanting to become pregnant. The use of PrEP should be carefully weighed for adolescent minors. Acute or established HIV infection and renal compromise should be excluded prior to initiation and regular use of PrEP. Medication adherence and risk reduction practices should be supported throughout the use of PrEP.

For this presentation, Dr. Lansky highlighted specific recommendations for MSM. Daily oral PrEP with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) is recommended as one HIV prevention option for sexually active MSM who are at substantial risk of HIV acquisition. This guidance is based on evidence from the iPreX PrEP clinical trial which demonstrated the safety and efficacy of PrEP in MSM, particularly when medication adherence was high.

Indications for PrEP use among MSM include risks such as having an HIV-positive sexual partner, recent bacterial STD, high number of sex partners, history of inconsistent or no condom use, or commercial sex work. Indications for PrEP use among heterosexual men and women are include having an HIV-positive sexual partner, recent bacterial STD, high number of sex partners, history of inconsistent or no condom use, commercial sex work, or location in a high-prevalence area or network. Indications for PrEP use among IDUs include having an HIV-positive drug-injecting sexual partner; sharing of drug injection equipment; and recent drug treatment, but continued IDU.

The PrEP guidelines include several resources that will be useful to providers. Examples of risk assessment questions and tools are provided in the guidelines. The PrEP guidelines include specific recommendations for adolescents. Clinicians who are considering providing PrEP to a minor should be aware of local laws, regulations and policies that may apply. Because none of the completed PrEP clinical trials included persons <18 years of age, clinicians are urged to carefully consider three important issues: (1) the lack of data on the safety and efficacy of PrEP taken by persons <18 years of age; (2) the possibility of bone or other toxicities among youth who are still growing; and (3) available safety evidence when Truvada® is used as a treatment regimen for HIV-infected youth.

The PrEP guidelines include a supplement for clinical providers with patient fact sheets on PrEP, Truvada® and acute HIV infection and PrEP. Materials for providers include a patient/provider checklist; information on PrEP during conception, pregnancy and breastfeeding; an HIV incidence risk index for MSM; billing codes; potential PrEP practice quality measures; and supplemental counseling information.

The PrEP clinical trials raised several issues that will be critical to implementation. Safety monitoring will continue to be important in actual practice in the field. Healthcare providers who are not HIV specialists will need extensive education on administering PrEP in the following areas: discussing the benefits and risks of PrEP with patients; initiating and monitoring PrEP to minimize toxicity and maximize effectiveness; discussing and supporting adherence and risk reduction strategies; and managing HIV infection if the disease is acquired.

In response to FDA's post-marketing requirements regarding further study of adherence to PrEP, CDC, the CDC Foundation and Gilead Sciences established a public/private partnership to launch the "Sustainable Health Center Implementation PrEP Pilot" (SHIPP) Study. This is a pilot study of PrEP implementation in community health centers (CHCs). The SHIPP sites are located in underserved communities with high rates of HIV infection: Chicago, Houston, Newark and Philadelphia. SHIPP was designed as a health services observational cohort. CHCs to collect de-identified data from medical records and evaluate prescribing practices, patient outcomes and service costs for all patients who receive PrEP. The SHIPP Medication Adherence Sub-Study collects dried blood spots to measure drug levels, and provides adherence aids to patients with sub-optimal adherence. CDC will fund the "Context Matters" study in the SHIPP communities to assess attitudes and knowledge about PrEP among clinicians, key stakeholders and laypersons.

PrEP costs can be addressed in several ways. The average retail pharmacy price for a one-month supply of Truvada® is \$1,400, but payment of the full price is rare. Price reductions have been negotiated. Most private employers, school-based insurance carriers, Medicaid and other public insurers cover PrEP medication and care. PrEP drug and co-pay assistance programs are available. PrEP is offered to persons with low incomes or no insurance coverage at no charge.

One study by Rawlings, *et al.* (2013) estimated early PrEP uptake using U.S. retail pharmacy claims data. The dataset was estimated to represent 55% of PrEP prescriptions in the United States. PrEP prescribers in ~700 cities across 49 states included family practice and internal medicine physicians (31%), nurse practitioners, physician assistants or other non-physicians (17%), emergency medicine physicians (14%), and infectious disease physicians (12%). The study reported an 8.5-fold increase in the number of PrEP prescriptions from 150 in 2011 to 1,274 in 2012. Women accounted for 48% of prescriptions and persons <25 years of age accounted for 14% of prescriptions.

CDC is also focusing on the next generation of PrEP because adherence to a daily pill is challenging. Most notably, new modalities of PrEP that do not require daily dosing currently are being developed, such as long-acting injectables, vaginal rings and rectal microbicide gels for use around the time of sex.

CDC also is engaging multiple groups with an important role in the implementation of PrEP. HIV prevention programs are encouraged to integrate PrEP education into their existing activities. Advocates are needed to raise awareness of PrEP among persons at substantial risk of acquiring HIV. Providers can increase awareness and uptake of PrEP, while clinical professional associations have a role to educate providers and share experiences on the provision of PrEP in the field.

Susan Philip, MD, MPH

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Clinical Assistant Professor of Medicine
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Dr. Philip presented an overview of STD prevention in MSM in the era of PrEP and HIV TasP. San Francisco can be used as a test case to demonstrate the divergence between HIV and STD prevention strategies. SFDPH surveillance data from 2006 to 2013 showed an increase in the number of living HIV cases from 14,441 to 15,867; a decrease in the number of new HIV diagnoses from 515 to 332; and a decrease in the number of HIV deaths from 327 to 164. The estimated incidence of new HIV infections has remained fairly stable from 498 in 2007 to 437 in 2011.

MSM and MSM-IDUs account for 86% of all new HIV diagnoses in San Francisco, but new HIV diagnoses have declined or are fairly stable in MSM and all other risk groups. Unlike HIV, however, STD rates are not declining in MSM. Compared to other men and women, MSM have disproportionately high rates of gonorrhea that have steadily increased since 2009. MSM also account for an overwhelming 90% of early syphilis rates. Of MSM with syphilis, 60% are HIV-positive.

Historical data on gonorrhea cases in San Francisco from 1955 to 2013 showed that behavior changes among MSM due to HIV prevention strategies in the 1980s-1990s had a secondary, profound impact on reducing gonorrhea rates. SFDPH utilizes its data reported to the CDC National HIV Behavioral Surveillance System (NHBS) to address issues related to discordance and disparities between HIV and STD prevention. NHBS is a time-, location- and sampling-based survey that is conducted every three years with standardized questionnaires. Blood samples are drawn as well to diagnose and estimate the incidence of HIV.

NHBS data showed that the prevalence of HIV-positive test results among MSM in San Francisco remained fairly stable at 23% from 2004 to 2011. Estimates of HIV incidence among MSM decreased overall during the same time period, but self-reports of HIV positivity markedly increased. Rates of unrecognized HIV infection among MSM dramatically decreased to ~7.5% in 2011. The proportion of HIV-positive MSM in San Francisco who do not know their status is estimated to be 6.3%.

SFDPH's routine HIV surveillance data currently show that persons are now being tested more frequently and have more accurate knowledge of their status than in the past. Median CD4 counts at the time of diagnosis among persons with new HIV diagnoses in San Francisco increased from 364 in 2007 to 434 in 2011.

SFDPH's recent HIV care indicators show better outcomes than national estimates. Compared to the national estimate of linkage to care of 77%, the proportion of persons in San Francisco who were linked to care within 3 months of a new HIV diagnosis increased from 84% in 2010 to 89% in 2012. Compared to the national estimate of viral suppression of 25%-28%, the proportion of persons in San Francisco who were virally suppressed within 12 months of a new HIV diagnosis increased from 56% in 2010 to 68% in 2012.

SFDPH reviewed its 2007-2011 data to identify trends in CD4 counts at the initiation of ART stratified by CD4 counts at the time of diagnosis among persons with new HIV diagnoses. Among 1,203 persons who initiated ART, the median CD4 counts remained the same at 91 in the <200 group and only slightly increased from 270 to 275 in the 200-350 group. However, the median CD4 counts dramatically increased from 352 to 420 in the 351-500 group and from 531 to 656 in the >500 group.

SFDPH's 2004-2010 data showed that early initiation of ART resulted in a marked decrease in the median time in months between HIV diagnosis and virologic suppression among persons diagnosed with HIV. San Francisco used these data to become the first city in 2010 to recommend that providers universally offer ART to all patients diagnosed with HIV regardless of their CD4 count.

Despite its tremendous progress over time in linking PLWH to care and increasing viral load suppression, SFDPH still has not resolved the disparity between HIV and STD prevention because risk behaviors have not changed (e.g., multiple partners, substance abuse and an increase in self-reported gonorrhea). CDC's inclusion of STD testing in the next NHBS-MSM cycle would be extraordinarily useful to states and localities, but SFDPH already has initiated efforts to maximize sexual health services for MSM.

San Francisco is one of three sites that received funding from the National Institute of Allergy and Infectious Diseases to conduct an open-label PrEP demonstration project in 600 MSM and transgender women. The demonstration project was launched in September 2012 with several focus areas: PrEP uptake, adherence and persistence; PrEP side effects, toxicities and resistance in seroconverters; sexual behaviors; and necessary staff and space for successful delivery of PrEP in STD clinics.

SFDPH has proposed several strategies to respond to the steady increase in STD rates among MSM. First, high-quality, culturally-responsive clinical and disease investigation services (DIS) and the provision of sexual health information should be continued. For example, the "Healthy San Francisco Program" was established in 2007 to provide documented and undocumented low-income residents with a primary care home.

The Municipal STD Clinic in San Francisco provides services to ~19,000 patients per year with MSM accounting for 48% of all patient visits. Magnet is a Gay Men's Health Center in San Francisco that has increased its capacity to perform gonorrhea, syphilis and chlamydia testing.

These two sites diagnose and report 48% of all primary and secondary syphilis cases in San Francisco. Adverse public health impacts should be carefully considered before STD clinics or community-based sexual health services for MSM are eliminated in states and localities.

Second, resources should be targeted to optimizing screening and clinical management of STDs and HIV through clinical providers, including a focus on PwP; collecting accurate data on the sexual orientation and gender of sex partners; issuing standing orders for self-collected screening; and offering consultation or referral for complex cases.

Third, MSM should be extensively engaged to discuss their priorities and propose collaborative opportunities with public health. Strategies to achieve this goal include street intercept surveys, focus groups, consultation with CDC, academic ethnographers and other social scientists, and a Gay Men's Health Summit. Fourth, SFDPH has reorganized its Population Health Division to support a broader and more holistic sexual health framework that addresses both HIV and STDs.

Stephanie Zaza, MD, MPH, CAPT USPHS

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

DASH is one of five divisions of NCHHSTP and includes three branches in its organizational structure. The School-Based Surveillance Branch focuses on all aspects of risky adolescent behavior and coordinated school health. The branch achieves this goal with the Youth Risk Behavior Surveillance System (YRBS), School Health Profiles, and School Health Policies and Practices Study (SHPPS).

YRBS Coordinators in health departments and state/local education agencies (SEAs/LEAs) recently voted to include two critically important sexual minority questions on national and core YRBS surveys. The release of YRBS data in 2015 will include the first nationally representative data on self-reported sex-of-sex contacts and sexual orientation of youth.

The Research Application and Evaluation Branch conducts the following activities: (1) primary and secondary research, research synthesis, and evaluation studies of risk factors, protective factors and interventions for adolescent sexual behaviors; (2) development and dissemination of practical tools and research-based guidance; and (3) provision of evaluation technical assistance (TA) to grantees. The Program Development and Services Branch oversees the DASH grant program, including grants management and TA for grantees.

DASH is the only CDC program that directly funds SEAs/LEAs rather than health departments. DASH's national leadership and expertise in adolescent school health, strong relationships with schools, and relocation to NCHHSTP allow CDC to address the complex epidemic of HIV, syphilis and rectal gonorrhea in YMSM, particularly YMSM of color.

DASH awarded the 2013-2018 cooperative agreement (CoAg) to SEAs/LEAs to implement interventions for HIV and STD prevention in schools and conduct school-based surveillance programs. DASH also funds a small number of non-governmental organizations to provide TA to grantees. The funded SEAs will conduct statewide activities and target intensive TA and other efforts to 15 selected LEAs in the state. The funded LEAs will target activities to 20 schools in their respective districts. DHAP allocated additional funding for three LEAs in Broward County, FL, Los Angeles and San Francisco to conduct a new initiative focused on YMSM.

The DASH CoAg supports a multi-component program that emphasizes several key risk and protective factors for HIV, STD and pregnancy prevention among teens. These components include exemplary sexual health education for all students; targeted programs for youth at disproportionate risk; teen friendly school-based or school-linked sexual health services; safe and supportive environments that address bullying and harassment and emphasize school connectedness and family engagement; and educational attainment.

Dr. Zaza presented data from two sources to illustrate the role of schools as a venue for HIV and STD prevention among youth. The 2012 SHPPS survey included self-reported data from a nationally representative sample of school districts and a census of SEAs. The 2012 School Health Profiles included self-reported data from representative samples of secondary schools in each state.

For HIV/STD prevention education, the percentage of districts that required teaching about HIV and STD prevention was fairly high in middle and high schools with a range of ~73% to ~82%. During the two years before the 2012 SHPPS survey was conducted, ~88% of states and ~49% of districts funded or offered professional development to staff that taught health education on HIV prevention. The high proportion of states (86%) and low proportion of districts (~48%) were similar for the professional development of staff that taught health education on STD prevention.

States reported a wide range of percentages of their secondary schools that provided HIV/STD prevention education in the following areas:

- Percentage of secondary schools that taught 12 key HIV, STD and pregnancy prevention topics in a required course during grades 6-8 (range: 11%-5%)
- Percentage of secondary schools that taught 9 key HIV, STD and pregnancy prevention topics in a required course during grades 9-12 (range: 30%-96%)
- Percentage of secondary schools that taught 4 key topics related to condom use in a required course during grades 9-12 (range: 0%-85%)
- Percentage of secondary schools in which the lead health education teacher received professional development on 6 key HIV prevention topics during the 2 years before the School Health Profiles survey were conducted (range: 4%-33%)

The percentage of school districts that adopted practices or policies on sexual health services was extremely low.

Policy or Practice	Percentage of Districts	
	HIV	STD
Adopted a policy for schools to provide HIV counseling, testing and referral or STD identification, treatment or referral	15.0%	15.2%
Adopted a policy for schools to provide HIV or STD prevention in one-on-one or small-group sessions	39.5%	36.7%
Adopted a policy for middle or high schools to make condoms available to students	1.9%	
Had arrangements with any organization or healthcare professional to provide HIV or STD prevention at other sites not on school property	7.4%	7.6%
Adopted a policy for schools to provide services specifically for gay, lesbian or bisexual students	9.3%	

The percentage of districts that funded or offered HIV professional development to school nurses dramatically declined from 2000 to 2012: from ~45% to ~25% for HIV prevention and from 25% to ~14% for HIV counseling, testing and referral. Striking disparities were reported between the percentage of states and districts that provided or offered STD professional development to school nurses during the 2 years before the release of the 2012 SHPPS survey: 64% of states versus ~18% of districts for STD identification, treatment or referral and ~73% of states versus ~25% for STD prevention.

States reported extremely low percentages of their secondary schools that provided students with direct access or referrals to healthcare providers for 7 sexual health services. However, states reported a higher percentage of their secondary schools that taught students to access valid and reliable health information, products or services related to HIV, other STDs and pregnancy in a required course.

For safe and supportive environments, states reported an extremely low percentage (median <25%) of their secondary schools with a Gay/Straight Alliance or similar club. A similarly low percentage was reported for secondary schools in which families and/or community members of students helped to develop or implement HIV, STD or teen pregnancy prevention policies and programs. Across states, the median percentage of secondary schools that provided curricula or supplementary materials and engaged in 5 practices related to LGBT/questioning youth was <25%:

1. Identify safe spaces for LGBT youth to receive support from administrators, teachers or other school staff
2. Prohibit harassment based on a student's perceived or actual sexual orientation or gender identity

3. Encourage staff to attend professional development on safe and supportive school environments for all students regardless of their sexual orientation or gender identity
4. Facilitate access to providers outside of school property who have experience in providing health services, including HIV/STD testing and counseling, to LGBT youth
5. Facilitate access to providers outside of school property who have experience in providing social and psychological services to LGBT youth

CHAC discussed the following topics with the panel on innovative HIV and STD prevention approaches that are being implemented for MSM and other at-risk LGBT populations.

- The need to correct inaccurate data in the Rawlings study that reported emergency medicine physicians accounted for only 14% of PrEP prescriptions.
- The decision-making process, expertise and evidence involved in addressing the use of PrEP during pregnancy in the guidelines without supporting data from clinical trials.
- The need to provide HIV prevention programs with better STD facility- and community-level screening data.
- The small sample size and limited data that did not allow transgender persons to be specifically addressed in the PrEP guidelines.
- Concerns regarding the absence of CDC-funded SEAs in Alabama, Georgia and South Carolina due to the high burden of HIV and STD morbidity in these states.
- The lack of communication, minimal coordination and overall disconnect between funded SEAs and health departments despite the CDC CoAg requirement for these two entities to enter into a formal, written memorandum of understanding.
- Efforts to minimize stigma associated with teaching topics related to condom use in high schools.
- The possibility of forming a new high-level federal task force led by HHS and the U.S. Department of Education to fully integrate health and education.
- The possibility of school districts implementing a peer-based model in which educators with optimal performance in teaching HIV/STD prevention topics in schools would share their experiences and lessons learned with peers.

The discussion resulted in CHAC responding to some of the questions posed by the panel and providing specific guidance to CDC on PrEP implementation.

Responses to the Panel Questions

- *Question 1:* CDC should coordinate its efforts with innovative, non-traditional social engagement networks and other initiatives to better identify and reach the high-risk population of MSM that currently is not accessing HIV prevention and treatment services. For example, CDC should sponsor a series of listening sessions with MSM in informal settings. If CDC solicits input in non-traditional settings that are comfortable and familiar to MSM (e.g., outside of government-sponsored meetings and surveys), more accurate self-reported information likely will be provided on the MSM population in greatest need of PrEP.

- *Question 2:* STD clinics are the optimal setting for providing PrEP to MSM. CDC should advise STD clinics to prescribe PrEP to all MSM who receive a positive STD test result due to their higher risk of acquiring HIV. Expanded roles of STD clinics should be to screen, offer treatment or provide referrals for both IDUs/non-IDUs and promote HCV testing of MSM due to the increase in sexually-transmitted HCV infections in this group. However, CHAC acknowledged the challenge in implementing this recommendation due to the severe reduction or entire elimination of STD clinics in several states.
- *Question 3:* Creative strategies will be needed to assure uptake of PrEP among eligible MSM in primary care settings.
 - A network of local PrEP referral services should be established because PCPs with no history of prescribing ARV drugs will not be comfortable in prescribing Truvada® for eligible MSM. In this model, PCPs would document the risk and HIV status of MSM and then refer these patients to local providers in the PrEP referral network.
 - The successful Project ECHO® model for HCV should be replicated for the provision of PrEP to eligible MSM. With this approach, each primary care practice would designate a physician or nurse as the “PrEP expert.” The success of Project ECHO® as a TA, training and knowledge transfer network, particularly its innovation in tele-health, also should be adapted for the provision of PrEP.
- *Question 5:* Numerous training activities, TA modules and other resources to change provider behaviors and practices related to screening have been unsuccessful overall. As a result, more emphasis should be placed on the current model of STD self-testing. Clients can visit an HIV/STD clinic at any time without an appointment to provide urine and take their rectal and throat swabs using poster instructions in a bathroom. Clients are then given instructions on obtaining a syphilis serology from the laboratory.
- *Question 6:* Professional development of health education teachers and school nurses will not be sufficient to increase HIV/STD prevention and sexual health education in schools due to limited funding. Instead, schools should identify respected and credible external champions who have solid relationships and a history of collaboration with schools and communities to galvanize support for teaching these topics in schools. Examples of external champions include former school gym teachers, coaches and guidance counselors, LGBT organizations, and local partners.

PrEP Implementation

- PrEP implementation activities should convey messages to the public that strongly emphasize the need for continued use of condoms. Based on SFPHD surveillance data, for example, HIV rates in MSM likely will continue to decline with ART, TasP and PrEP, but STD rates in this group will continue to steadily increase because condom-less sex, multiple partners and other risk behaviors have not changed. The CDC guidelines clearly state that PrEP does not protect against other STDs and condom use can increase the efficacy of PrEP. However, these messages should be widely publicized in other formats for communities and laypersons who will not read the guidelines. Moreover, condom use messages will be particularly important for YMSM <18 years of age because PrEP most likely will not be a practical or feasible option for this population.

- Poverty and no insurance coverage are the top two risk factors that deter HIV prevention and treatment, but the employed and insured “worried well” population likely will account for the greatest uptake of PrEP. The following actions should be taken during PrEP implementation to address this issue.
 - CDC should urge all groups with a role in PrEP implementation (e.g., HIV prevention programs, providers, advocates and national organizations) to widely publicize the availability of programs that will offer PrEP to low-income and uninsured persons at no charge.
 - The four groups CDC has identified for PrEP implementation will play an important role, but these traditional partners will not substantially increase access to HIV prevention and treatment services for populations at highest risk. As a result, ACA enrollment and PrEP implementation activities should simultaneously occur in non-traditional settings with primarily poor and uninsured populations: (1) state/local programs serving General Assistance recipients and new applicants; (2) programs serving adults and adolescents recently released from correctional institutions, including the juvenile justice system; and (3) programs serving homeless persons, including homeless adolescent sex workers. Coordinated efforts with non-traditional programs will strengthen the ability of PrEP to serve as a broad public health intervention and better control the HIV epidemic.
- Providers should be given clear guidance on limiting each prescription of PrEP to a one-month supply. The need to refill prescriptions each month will greatly increase patient/provider interactions. Providers can use the monthly visits as an opportunity to routinely conduct HIV testing and discuss risk behaviors with their patients, particularly MSM.
- The CDC guidelines include several tools that will be extremely helpful to providers in implementing PrEP in clinical practice. However, the implementation activities also should include model guidance on adapting the PrEP tools for individual clinical settings and local needs.

Panel Presentation: HIV and HCV Among IDUs and the Prescription Drug Overdose Epidemic

A panel of CDC representatives presented data to illustrate drug user health in the context of HIV and HCV among IDUs and the prescription drug overdose epidemic. The presentations are set forth below.

Advice Requested from CHAC by CDC and HRSA:

1. What steps can CDC and HRSA take to more holistically and better address drug user health issues?
2. What strategies can CDC implement to better integrate its activities for the drug user population (e.g., HIV, HCV and prescription drug overdose)?
3. What steps can CDC and HRSA take to increase collaboration with other federal agencies,

particularly the Substance Abuse and Mental Health Administration (SAMHSA), National Institute on Drug Abuse, and the White House Office of National Drug Control Policy?

4. What steps can CDC and HRSA take to support health departments and providers in offering integrated services for drug users?
5. What steps can CDC and HRSA take to leverage ACA-related changes in healthcare coverage to improve access to and quality of prevention, care and treatment services?

Amy Lansky, PhD, MPH

Deputy Director for Surveillance, Epidemiology and Laboratory Sciences
Division of HIV/AIDS Prevention, NCHHSTP
Centers for Disease Control and Prevention

Dr. Lansky presented data on HIV infection among persons who inject drugs and described CDC's prevention strategies for this population. CDC surveillance data showed a peak in AIDS diagnoses among IDUs in the mid-1990s, and has continued to decrease over time. In 2011, male, female and MSM IDUs accounted for 11% of HIV diagnoses. The percentage of IDU-related cases that were male injection drug users generally increased with increasing age, while the percentage of diagnoses that were males with HIV infection attributed to male-to-male sexual contact and injection drug use increased with increasing age until the 20-24 age group, for which percentages then decreased with increasing age. African American IDUs accounted for the majority of new HIV diagnoses among IDUs in the Northeast, Midwest and South, but disparities also were observed between white and Hispanic IDUs. Meta-analysis combined data from four national surveys to estimate the proportion of persons >13 years of age in the United States with any IDU history and found that persons who inject drugs comprised 2.6% of the US population (approximately 6.6 million persons).

CDC gathers data through the National HIV Behavioral Surveillance System (NHBS) on MSM, IDUs and heterosexuals at increased risk of HIV infection each year on a rotational basis (or data collection for each group every three years). NHBS monitors the prevalence and trends in HIV-related behaviors (e.g., sex and drug use), HIV testing, HIV infection, and use of prevention services. The second NHBS-IDU cycle in 2009 captured data on 10,090 IDUs in 20 cities. Key findings from this dataset are highlighted below.

The percentage of IDUs who engaged in HIV-associated behaviors was high: engaged in condomless vaginal sex (64%), had multiple sex partners (46%), shared syringes (34%), shared other injection drug equipment (58%). The proportion receiving HIV testing in the past year (49%), and who participated in behavioral interventions (19%) was fairly low.

The prevalence of HIV infection among persons in NHBS-IDU was 9%. By age, the HIV prevalence was 4% in younger IDUs 18-29 years of age and ~10% in older IDUs >30 years of age. Compared to older IDUs, younger IDUs were at higher risk for receptive syringe sharing based on several independent factors: binge drinking in the past 30 days, daily IDU in the past

12 months, attainment of syringes from unreliable sources in the past 12 months, and unprotected sex in the past 12 months. These data from NHBS-IDU demonstrate the need to consider younger IDUs as a new generation of an at-risk HIV population. Younger IDUs have a lower HIV prevalence, but their sexual and IDU behaviors greatly increase the risk of HIV infection. Continued efforts are needed to strengthen and target HIV prevention activities to young IDUs.

CDC has implemented a number of HIV prevention strategies for IDUs. Guidelines were published in the *MMWR* in November 2012 on integrated prevention services for HIV, viral hepatitis, STDs and TB for IDUs. The guidelines recommended specific public health strategies for this population: substance use prevention and treatment, outreach programs, drug use and infectious disease risk assessments, screening and diagnosis for infections, vaccination, prevention of mother-to-child transmission, risk reduction interventions, partner services, referrals and linkage to care, treatment for infectious diseases, and integrated services.

In addition to implementing these strategies, CDC also produces fact sheets on topics that are relevant to the U.S. IDU population, such as HIV/substance use and HIV risk among adult sex workers. The CDC.gov/idu website was archived in 2005, but plans are underway to revise and update this resource later in 2014. CDC reviewed its existing evidence-based interventions to determine those that would be the most cost-effective, high-impact, relevant and scalable—while only one has a specific component for IDUs (Community Promise), others would be relevant for IDUs who are HIV-positive, MSM, or female.

CDC's 2014 PrEP guidelines recommend PrEP for HIV-uninfected persons who had injected illicit drugs within the past 6 months and shared equipment or had been in drug treatment within the past 6 months. The guidelines emphasize that the FDA labeling indication for Truvada® as PrEP is only for preventing sexual transmission, but many IDUs also meet these criteria.

Jon Zibbell, PhD

Health Scientist & Medical Anthropologist
Division of Viral Hepatitis, NCHHSTP
Centers for Disease Control and Prevention

Dr. Zibbell presented national data on HCV infection among persons who inject drugs (PWID). In the general population, 4.1 million persons are HCV antibody-infected, with 75% living with chronic infection (3.2 million) and 45%-85% unaware of their infection. HCV is the most common bloodborne infection in the United States and is the leading cause of liver transplants and liver cancer. Hepatocellular carcinoma is the fastest rising cause of cancer-related deaths with HCV-related deaths doubling to >17,000 per year in 1999-2007.

Liver disease is the second leading cause of death for PLWH/AIDS and HIV hastens the progression of HCV-related liver disease. HCV prevalence is 5.3 times higher in persons born

between 1945-1965 (3.29%) compared to other age groups (0.55%), and this age cohort accounts for 81% of adult chronic HCV infections and 73% of HCV-associated mortality.

Injection drug use (IDU) is the principal 'motor' of HCV incidence. HCV antibody prevalence among PWID is between 30%-70%, depending on frequency and duration of use, and incidence rates among PWID are 16%-42% annually. Young PWID (18-29 years of age) have lower anti-HCV prevalence between 10-30%. Of 4.5 million persons with HIV/HCV co-infection globally, the United States accounts for 25% of HIV/HCV co-infection, while China, Vietnam, Ukraine and other countries account for 80% of large IDU-related epidemics. Recent data show that HCV mortality (3.2 million HCV-infected persons) now surpasses HIV mortality (1.2 million HIV-infected persons).

CDC published its recommended testing sequence for identifying current HCV infection in 2013. Because 15%-20% of persons who are exposed to HCV will clear the virus, follow-up RNA testing is recommended for persons with an HCV antibody-positive test result to determine whether chronic infection is present. No further action is recommended for persons with a non-reactive HCV antibody test result who are not engaging in risk behaviors. Follow-up testing is recommended for persons engaging in risk factors. Linkage to care and treatment are recommended if current HCV infection is detected.

Of 3.2 million persons currently living with chronic HCV in the United States, 50% receive anti-HCV testing, 38% are linked to care, 23% receive follow-up, HCV RNA testing, 11% are treated, and 6% are cured. In other words, only 6% of the 3.2 million persons chronically infected are cured. Advances in all-oral, non-interferon-based agents are expected to greatly improve the HCV test, care and cure continuum. Most notably, SVRs of 96%-98% for HCV genotype 1 have been reported with the new drugs.

Studies are underway to determine the feasibility of replicating HIV Treatment as Prevention (TasP) for HCV, particularly to reduce overall incidence and prevalence among PWID. Martin, et al. have modeled the effects of scaling-up of treatment for PWID based on 10-80/1,000 populations annually and baseline chronic HCV prevalence at 25%, 50% and 65%. The results showed significant reductions in HCV infection among PWID over a span of 15 years.

CDC published *MMWR* articles on the increase in new injection-related HCV infections among persons <30 years of age reported by Massachusetts, New York State and Wisconsin. However, CDC also has received similar reports from 15 additional states. The demographics of HCV incidence have changed since the 1990s. Males, minorities, urban residents and persons 40-49 years of age previously accounted for the majority of anti-HCV prevalence. Current HCV cases primarily involve males and females equally, predominantly white persons, non-urban, suburban or rural residents, and young PWID 18-29 years of age, many of whom report antecedent prescription opioid analgesics (POA) misuse.

States reporting significant increases in HCV infections among young persons were virtually the same as those with the largest amount of opioid analgesics prescribed per 10,000 persons: Alabama, Arkansas, Florida, Kentucky, Oklahoma, Oregon, Tennessee, Virginia, Washington and West Virginia. CDC recently investigated and published results of an HCV cluster outbreak among young persons in New York State (Zibbell et al 2014, *American Journal of Public Health*, in press). Young persons who reported injecting POA only were 5 times more likely to be HCV-infected than those who inject drugs other than POA. Similar results were reported in two additional papers (Havens 2012; Bruneau 2011). Kentucky reported an increase in poly-drug overdoses among young persons that included a mixture of opioids, benzodiazepines and other drugs.

In response to this emerging epidemic, states are implementing stricter prescribing policies to reduce the availability of prescription opioids. Based on Washington State's experience, however, enforcement of a more stringent prescription opioid policy can lead to unintended consequence such as increased heroin use.

Traditional HIV prevention strategies with proven success among PWID have not been as effective in their replication for HCV prevention among this population. However, several studies in the literature have reported reductions in HCV of up to 80% among PWID with a combination of readily available, low-threshold opioid agonist therapy (e.g., methadone and/or buprenorphine) and Syringe Access Programs. These combination prevention strategies were found to reduce the overall HCV/HIV incidence and risky injection behaviors (e.g. injection equipment sharing) among PWID.

Brian Manns, PharmD

Pharmacist

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Dr. Manns presented national data to illustrate the prescription drug overdose epidemic. Prescription drug overdose deaths have nearly quadrupled from 1999 to 2010. Prior research has suggested methadone accounts for the vast majority of these deaths. Of ~30,000 unintentional drug overdose deaths in 2010, 16,651 involved prescription opioid pain relievers. Dual use of prescription opiates and benzodiazepines accounted for 75% of these deaths.

Each opioid overdose death in 2010 was associated with 15 admissions to substance abuse treatment facilities, 26 emergency department visits, 115 persons who reported substance abuse or dependence, and 733 non-medical users. Persons 45-49 are at highest risk of drug overdose deaths. The rise in opioid deaths has paralleled the increase in opioid sales and admissions to substance abuse treatment facilities.

At the state level, Utah collected data on the characteristics of 254 unintentional opioid pain reliever overdose deaths that occurred in 2008-2009: history of pain (~89%), history of

hospitalization for substance abuse (~80%), history of illicit drug use (~61%), mental illness diagnosed by a provider (~56%), and use of an opioid pain reliever for reasons other than pain (~30%).

At the national level, the National Survey on Drug Use and Health reported ~12 million non-medical users of prescription opioids in 2012. A steady rise in heroin abuse and dependence has been observed with the increase in opioid sales and overdose deaths. Increased heroin use is perhaps a consequence of the prescription opioid epidemic. Heroin use and misuse of prescription opioids in the past year were reported in 7 out of 10 persons. Among dual users of both heroin and prescription opioids in the past year, misuse of prescription opioids occurred first in 3 out of 4 persons.

CDC is implementing a three-prong approach at the state level to address the prescription drug overdose epidemic nationally. First, the quality of data is being improved to better protect public health. Trends are being tracked to monitor the epidemic. For example, CDC-funded states have launched Prescription Drug Monitoring Programs to determine the frequency in which prescriptions are written, identify specific locations that fill prescriptions, and communicate with other states regarding prescribing and dispensing patterns.

Second, state efforts are being supported to customize and target prevention resources. For example, North Carolina launched Project Lazarus as a community-based overdose prevention and opioid safety initiative. Third, healthcare providers are given data, tools and guidance to enhance patient safety, inform evidence-based decision-making and improve population health. For example, state Prescription Drug Monitoring Programs are being integrated into EHRs.

CHAC discussed the following topics with the panel on drug user health in the context of HIV and HCV.

- New activities by CDC and its federal partners (e.g., the development and dissemination of implementation toolkits, EHR modules and other resources) to increase the capacity and confidence of PCPs in treating opiate dependence in primary care settings.
- The need to incorporate and prioritize drug user health and other public health issues into CMS ACOs.
- The need to create new policies and provide education at both physician and community levels to broadly improve drug user health nationally.

Preparation for the CHAC Business Session

Jeanne Marrazzo, MD, MPH, CHAC co-Chair
 Professor of Medicine, Harborview Medical Center
 University of Washington

Dr. Marrazzo moderated a discussion for CHAC to consider issues from the updates and panel presentations on day 1 that would warrant formal action during the Business Session on the following day. She noted that the meeting packets included a guidance document to assist the CHAC members in drafting resolutions and recommendations.

Champions	Topic	Basis for Resolution/Recommendation
Dr. Steven Johnson (Lead) Dr. Sanjeev Arora Dr. Virginia Caine Mr. Guillermo Chacon Dr. Britt Rios-Ellis	HIV/HCV Testing	<ul style="list-style-type: none"> • CHAC endorses the importance of performance measures for HIV and HCV testing. • CHAC recommends that HIV and HCV testing be given higher priority in ACOs and the healthcare system through Meaningful Use indicators or performance measures. • CHAC recommends that CDC and HRSA explore strategies to expedite the process of integrating performance measures for HIV and HCV testing into EHR systems. • CHAC recognizes the relevance of clinical decision tools and emphasizes the need to increase the linkage between HIV/HCV screening and care.
Mr. Guillermo Chacon (Lead) Dr. Elinore McCance-Katz	Prescription Drug Overdose Epidemic	<ul style="list-style-type: none"> • CHAC is extremely concerned about the alarming epidemic of prescription opioid and heroin overdoses that has emerged in the United States. • CHAC calls for a proactive response to this crisis to prevent exposure to other diseases (e.g., HIV and HCV) in vulnerable populations.

Champions	Topic	Basis for Resolution/Recommendation
Dr. Sanjeev Arora-Lead Dr. Bruce Agins Dr. Kathleen Clanon Dr. Jeanne Marrazzo	National HCV Program	<ul style="list-style-type: none"> • CHAC recommends support for an external evaluation to be conducted to determine the cost of establishing a robust National HCV Program. • If funding is not sufficient to support a National HCV Program, CHAC recommends that HRSA encourage all Federally Qualified Health Centers (FQHCs) to incorporate an electronic reminder into EHRs to conduct HCV screening of the 1945-1965 birth cohort. • CHAC recommends that a legislative review be conducted of existing statutes to identify areas in which CDC and HRSA can enhance collaboration to improve HCV screening, treatment and care. • CHAC recommends that CDC and HRSA provide their funded SHDs/LHDs with clear guidance on federal expectations regarding HCV screening and treatment. • CHAC supports the reestablishment of its Viral Hepatitis Workgroup to closely work with CDC and HRSA on addressing all issues in the HCV resolution.
Dr. Kathleen Clanon (Lead) Ms. Angelique Croasdale	Adolescent Health	<ul style="list-style-type: none"> • CHAC recommends that CDC issue formal guidelines for SBHCs and school nurses to implement the 7 EBIs for sexual health services to all youth, including LGBT youth and YMSM.
Dr. Jeanne Marrazzo	PrEP Implementation	<ul style="list-style-type: none"> • CHAC recognizes the significance and value of the PrEP Guidelines due to their high level of detail and quality for clinicians. • CHAC welcomes and supports subsequent activities and data to understand challenges to implementation and targeting of PrEP to populations in most need. • CHAC recommends that CDC and HRSA

Champions	Topic	Basis for Resolution/Recommendation
		require their grantees to “vigorously pursue” the use of PrEP in appropriate populations, including groups in most need of HCV screening and treatment. <ul style="list-style-type: none"> • CHAC recommends that CDC present regular updates on results of the PrEP demonstration projects to facilitate its ongoing assessment on implementation.

Public Comment Session

Carole Treston, RN, MPH
 Chief Nursing Officer
 Association of Nurses in AIDS Care (ANAC)

Ms. Treston made the following comments for CHAC’s consideration. ANAC recently released a position statement and soon will issue a letter to *The New York Times* to support CDC’s PrEP Guidelines in general and emphasize the important role of nurses in implementation of PrEP in particular.

ANAC has proposed a collaborative project with State Nurses Associations and nursing departments in large hospital systems in three cities to provide continuing education on HCV care. If funded, the project will strengthen the capacity of the nursing workforce overall, more extensively engage nurses in HCV testing, reduce stigma related to HCV in primary care settings, and encourage HIV/AIDS nurses to provide more holistic care in HCV and other areas.

Ms. Treston advised CHAC to emphasize the important role of nurses in its guidance to CDC and HRSA on implementation of prevention and treatment activities. CHAC also should ensure that nurses are represented on its workgroups and teleconferences to discuss these issues. Most notably, nurses ultimately will be responsible for implementing expanded HCV screening and treatment guidelines in the field and providing ongoing counseling and support to PrEP patients.

Carl Schmid
 Deputy Executive Director
 The AIDS Institute (TAI)

Mr. Schmid made the following comments for CHAC's consideration. TAI identified several new opportunities for reimbursement of HCV testing. The new USPSTF Grade B recommendation will impact coverage for HCV screening by private insurers, Medicaid and Medicare as a result of ACA. Beginning in June 2014, Medicaid expansion states and private insurance plans both inside and outside of Health Insurance Marketplaces must cover HCV testing for high-risk individuals and the 1945-1965 birth cohort.

The decision to cover HCV testing in non-Medicaid expansion states will remain at the discretion of the individual state. For example, California, New York and Texas cover routine HCV screening, while Florida covers medically necessary HCV testing. CMS will soon finalize Medicare coverage determinations for HCV screening to assure consistency with the USPSTF Grade B recommendation. To provide the public with detailed information on these new opportunities, TAI recently released a coverage guide for HCV screening in conjunction with National Hepatitis Testing Day on May 19, 2014.

TAI recognizes that tremendous progress has been made in policy development for coverage of HIV and HCV preventive services, but existing gaps still need to be addressed in Medicaid coverage at the state level and Medicare coverage of routine HIV testing. These policies must now be widely implemented to cover HIV and HCV testing as billable services. TAI is pleased that additional resources were allocated in CDC's FY2014 and FY2015 budgets to expand HIV and HCV preventive services. These funds will dramatically increase testing and link more persons to care.

With no further discussion or business brought before CHAC, Dr. Cheever recessed the meeting at 4:54 p.m. on May 21, 2014.

Opening Session: May 22, 2014

Jeanne Marrazzo, MD, MPH, CHAC co-Chair
Professor of Medicine, Harborview Medical Center
University of Washington

Dr. Marrazzo conducted a roll call to determine the CHAC voting members, *ex-officio* members and liaison representatives who were attending the meeting either in person or remotely. None of the CHAC voting members publicly disclosed any individual or institutional conflicts of interest for the record that were new or different than those declared on day 1 of the meeting.

Dr. Marrazzo confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for CHAC to conduct its business on May 22, 2014. She called the proceedings to order at 8:32 a.m. and welcomed the participants to day 2 of the CHAC meeting.

Dr. Marrazzo reviewed the day 2 agenda and highlighted six recommendations/resolutions that would be proposed during the Business Session for CHAC's consideration, deliberation and formal vote. However, she clarified that the CHAC members were free to propose additional recommendations/resolutions based on the day 2 presentations.

Dr. Bruce Agins, a CHAC member, commended Dr. Cheever for her outstanding efforts in formally engaging CMS in CHAC's deliberations. He noted that the expertise and input by Drs. Stephen Cha and Richard Wild, the primary and alternate *ex-officio* members for CMS, have been particularly helpful for CHAC to provide more informed guidance to CDC and HRSA on ACA-related issues.

Update by the CHAC Integration Workgroup

Bruce Agins, MD, MPH

Medical Director, AIDS Institute
New York State Department of Health
CHAC Member & Workgroup co-Chair

Kali Lindsey

Deputy Director, Public Policy
amfAR, The Foundation for AIDS Research
CHAC Member & Workgroup co-Chair

William Garrett

Program Associate, AIDS Institute
New York State Department of Health

The workgroup covered the following topics in the update on its recent activities. The workgroup extensively discussed the tremendous variation among groups in their use, meaning and interpretation of "integration." As a result, the workgroup acknowledged the need to clearly define "integration" for CHAC's purposes.

In response to CHAC's previous advice, the workgroup developed a new "Integration Matrix" to illustrate various types of service integration. The matrix will be regularly updated to serve as a living document in two major areas: (1) a repository of evidence and detailed information on specific types of integration and (2) a resource from which to extract common themes, describe challenges, and identify potential integration opportunities.

INTEGRATION MATRIX

Integration Types:

- Disease-specific integration: HIV, HCV, STDs, Mental Health, Substance Abuse [purple boxes]
- Integration in primary care: CHCs/FQHCs, PCMHs [blue boxes]
- Integration of public health with medicine [green boxes]

Matrix Key:

Axes = Services

X axis: Integration of _____

Y axis: Integration into _____

Relevant information in each link:

- Facility type with integrated services
- Research and policy papers
- Funding opportunities

		Infectious Diseases (Clinical)				Primary Care	ID (PH)	Behavioral Health		Women's Health	Family Planning
		HIV	VH	STDs	TB			Mental Health	Substance Abuse		
Infectious Diseases (Clinical)	HIV					HIV into PC			HIV into Substance Abuse		
	Viral Hepatitis	Hepatitis into HIV				Viral Hepatitis into PC			Viral Hepatitis into Substance Abuse		
	STDs	STDs into HIV				STDs into PC			STDs into Substance Abuse		
	TB	TB into HIV				TB into PC			TB into Substance Abuse		
Primary Care		Primary Care into HIV						Primary Care into Behavioral Health			
Infectious Diseases (Public Health)		Public Health into HIV				ID PH into PC	PH into PC		Public Health into Substance Abuse		
Behavioral Health	Mental Health	Mental Health into HIV	Mental health into non-HIV clinical Infectious Diseases			Behavioral Health into PC			Mental Health into Substance Abuse		
	Substance Abuse	Substance Abuse into HIV									

	Infectious Diseases (Clinical)				Primary Care	ID (PH)	Behavioral Health		Women's Health	Family Planning
	HIV	VH	STDs	TB			Mental Health	Substance Abuse		
Women's Health	Women's Health into HIV				Women's Health into PC					
Family Planning	Family Planning into HIV				Family Planning into PC					

The workgroup conducted an exhaustive literature review to identify and compile federal and national evidence-based integration guidance, policies and initiatives in an inventory to support the Integration Matrix.

Source	Resource
REPORTS AND GUIDANCE ON INTEGRATION	
IOM	"Primary Care and Public Health: Exploring Integration to Improve Population Health," 2012
CDC	"Prevention of HIV/AIDS, Viral Hepatitis, STDs, and TB Through Health Care," 2014 www.cdc.gov/nchhstp/PreventionThroughHealthCare
CDC, de Beaumont Foundation, Duke University Department of Community and Family Medicine	"Public Health and Primary Care Together: A Practical Playbook," 2013, https://practicalplaybook.org
HRSA	"Public Health: Five Priorities," 2012 www.hrsa.gov/publichealth
CDC, NACHC, Association of State and Territorial Health Officials (ASTHO), National Association of County and City Health Officials, National Coalition of STD Directors (NCSD)	"CDC National Partners Collaborative on Public Health and Primary Care Integration for STD Prevention," August 2013 Meeting Report
ASTHO, IOM, CDC, HRSA, United Health Foundation	"Primary Care and Public Health Integration Strategic Map: 2012-2014"
ASTHO	"Integration of Public Health and Primary Care: A Practical Look at Using Integration to Better Prevent and Treat Sexually Transmitted Diseases," 2013
ASTHO	"Infectious Disease Integration of Primary Care and Public Health," December 2012

Source	Resource
NATIONAL INTEGRATION POLICIES AND INITIATIVES	
CDC	PCSI Initiative
SAMHSA & HRSA	SAMHSA-HRSA Center for Integrated Health Solutions (behavioral health and primary care)
HRSA & U.S. Department of Veterans Affairs	Reports from RWHAP and VA Hospitals on lessons learned from integrated models
The AHRQ Academy	Integrating Behavioral Health and Primary Care
NASTAD	Integration of HCV into HIV guidance; exploration of HIV/HCV in CHC/health department collaborations
NACHC	Quality of HIV, HCV, behavioral health, sexual health and LGBT health in CHCs and the clinical workforce

The workgroup is using the Integration Matrix and inventory of integration resources as the bases to determine its next steps. However, the workgroup welcomes CHAC's advice in two areas to further refine its future direction.

Questions 1a/1b: What should be CHAC's specific areas of focus in terms of integration? What strategies should be implemented for integration to occur? To address questions 1a/1b, the workgroup abstracted common implementation strategies across the three major types of integration: disease-specific integration, integration in primary care, and integration of public health with medicine. The workgroup will apply findings from questions 1a/1b to advise CHAC on providing CDC and HRSA with informed guidance on integrated care and services.

The workgroup agreed that 7 integration components would be needed to address questions 1a/1b. Integration component 1 is a teamwork approach with a collaborative, multidisciplinary medical team. The composition of the medical team should reflect the clinical needs of the patient population. Formal partnership agreements should be established to clearly delineate the core roles and responsibilities of all medical team members. The medical team should include a combination of the following types of providers:

- PCPs
- Nurses
- Behavioral health providers (e.g., psychologists, psychiatrists and substance abuse counselors)
- Infectious disease practitioners (e.g., HIV, HCV and STD providers)
- Health department partners
- Social workers
- Community health workers
- Care coordinators, care managers and patient navigators

Integration component 2 is a strong workforce with enhanced capacity for HIV, other infectious diseases and behavioral health. Access to expertise should be increased to improve the competency of providers and promote the delivery of evidence-based treatment in primary care settings. Task-shifting should be considered as an option in building the integration workforce.

Integration component 3 is strong leadership that will create and institutionalize a culture of integration, leverage resources to support integration, and articulate a vision and goal to improve integration outcomes. Integration component 4 is models of service integration that will provide co-located services, a full continuum of services within the medical team, virtual onsite coaching with access to expertise to for capacity building, and a consultation network.

Integration component 5 is resources that will pay for all services within an integrated system of care; leverage joint resources to achieve patient-centered goals in primary care, behavioral health and other settings; and offer reimbursement options for primary care and behavioral health reported in the literature:

- Fully capitated payment (e.g., an established amount per enrolled person)
- Case-rate payment (e.g., reimbursement based on the expected cost for clinically-defined episodes of care) that would augment fee-for-service payments
- Fee-for-service
- Pay-for-performance
- Shared savings models

Integration component 6 is information systems that will be designed to perform the following functions: capture and report data related to integrated models of care, consolidate EHR data, provide clinical decision support tools, maintain registries, collect longitudinal data, use public health data to inform clinical priorities and decision-making, and share data platforms (e.g., Health Information Exchanges and Regional Health Information Organizations).

Integration component 7 is the application and use of data to achieve three major outcomes. Internal assessments of the quality of care will be performed to ensure the provision of evidence-based treatment, measure clinical outcomes, and solicit patient experiences to inform QI. Provider- and program-level outcomes will be examined on a routine basis. Integrated models will be evaluated to make a business case for this effort.

The workgroup identified several challenges to implementing the 7 integration components: limited resources; inadequate workforce capacity; insufficient evidence (particularly in primary care settings); competing priorities; minimal support to build competency; bureaucratic silos and standalone academic divisions; the absence of available leadership; and lack of information systems to capture integrated services.

Question 2: What are best approaches for CHAC to formulate specific recommendations to support service integration utilizing the 7 integration components? The workgroup's next steps will be to focus on addressing this question.

CHAC made several suggestions in response to the workgroup's request for input on its next steps and future direction.

- Emphasis should be placed on developing indicators to measure integration.
- Additional models should be included in the Integration Matrix.
 - Integrated public health surveillance systems are extremely beneficial in targeting resources due to their capacity to identify gaps in service delivery for certain populations in specific geographic areas.
 - Project ECHO® has been enormously successful in integrating outreach and TA for HCV.
- CHAC's focus should be directed to three important components in the Integration Matrix: HIV, viral hepatitis and STDs into primary care. Efforts should be made to determine the evidence base for successful integration of prevention and treatment of these three infections to support both public health and personal health outcomes in primary care settings. However, other CHAC members emphasized the important need to also focus on integrating behavioral health into primary care. Most notably, the lack of trained mental health professionals is one of the top five indicators for poor outcomes in substance abuse disorders. Mental health support also is instrumental in providing HIV care.
- Future research on integrated services should be conducted from the perspective of patients. These findings should be included in any new integration guidance, policies and initiatives to ensure that the needs of patients are met.
- An analysis should be performed to identify federal funding streams, opportunities and other resources for integration that would have the highest potential for broad implementation at state and local levels. Most barriers to integration occur in states and localities.
- CHAC's formal resolution or recommendation on integration should be linked to the President's Executive Order on the HIV Care Continuum Initiative. This effort focuses on the need to improve integration of care and services for PLWH in order to maximize the public health impact across the Care Continuum. A clear linkage between CHAC's formal resolution/recommendation and the President's Executive Order would play an important role in minimizing barriers to integration among state and local providers.

Panel Presentation: Perspectives from the Field on Public Health/Primary Care Integration

A panel of guest speakers described perspectives from the field regarding state and local collaboration to prevent HIV, STDs and viral hepatitis. The overviews are set forth below.

Advice Requested from CHAC by the Guest Speakers:

1. What steps can CHAC take to influence primary care, Medicaid and other systems at state

and local levels?

2. What strategies can CDC implement to raise the profile of infectious disease prevention among Medicaid directors, Primary Care Associations (PCAs), and other key providers and payers at state and local levels?
3. What data are needed to demonstrate that HIV, STD and viral hepatitis prevention meet the triple aims of healthcare: improving the care experience, lowering cost and improving population health?
4. What creative models are being utilized? What actions are needed to compile and share these models?

John Auerbach, MBA

Distinguished Professor of Practice and Director
Institute on Urban Health Research and Practice (the Institute)
Northeastern University

Mr. Auerbach described ongoing efforts in the field to reexamine the roles of SHDs/LHDs. CDC awarded a grant to the Institute to conduct research to better understand efforts to integrate STD public health services into primary care settings due to ACA-related changes and SHD/LHD budget cuts. The project was designed to identify challenges, opportunities, successes and lessons related to integration; determine assistance that would be needed to support future integration efforts; and build resources to support this initiative.

The Institute and its partners initiated the project by conducting interviews in 10 states with 5 local health directors, 7 state health commissioners, 5 state PCA leaders, and 4 CHC leaders. The project sites were selected to reflect national diversity in terms of geographic areas, demographics, population density and Medicaid expansion policies. The project was conducted prior to ACA implementation in January 2014.

Key findings of the research are highlighted as follows. Public health currently provides a range of STD activities (DIS, epidemiology, outbreak response, laboratory services, assurance of direct or indirect access to services, and limited primary prevention) some of which are likely to continue and others of which may be reduced as health care insurance coverage is expanded. In particular there is potential to shift the provision of some direct STD clinical services to primary care sites as a result of the ACA.

Currently public health agencies often offer a limited range of clustered clinical services such as ST screening and treatment, TB screening and treatment, reproductive health and Women, Infants and Children (WIC) Programs. Billing was found to be the exception rather than the rule in these settings. Public health was found to operate CHCs or FQHCs in limited instances.

Integration, collaboration and coordination between public health and primary care exist but is limited and uneven throughout the country. However, SHDs/LHDs across the country expressed a great deal of interest in advancing integration with primary care where possible.

With the implementation of the ACA and the expansion of health insurance coverage, an alternative model might replace the current one. It might include the use of DIS and epidemiology to assist primary care and the increased likelihood that primary care sites, particularly CHCs, would more frequently and regularly treat STDs.

Challenges and opportunities were identified. The ACA will continue to change health care in America, particularly with the addition of a large newly-insured populations. At this time, 27 states (including the District of Columbia) have expanded Medicaid, 19 states chose not to expand Medicaid, and 5 states are continuing to debate the issue. ACA enrollment of large uninsured populations in Medicaid expansion states likely will have a significant impact on STD services.

The impact in non-Medicaid expansion states is unclear. The number of persons who obtained insurance through non-Medicaid providers is unknown at this time. Moreover, persons who obtained insurance might not be current STD patients in public health clinics. Public health is not always aware of or involved in changes related to insurance expansion. Insurance coverage might not lead to changes in care sites. Assumptions about impact might be incorrect.

Resource-related issues due to SHD/LHD budget cuts were identified. An NCSO study reported that severe budget cuts to STD programs would affect the national public health infrastructure. SHD/LHD budget cuts also had implications beyond STD Programs, such as Title X, Women's Health and Family Planning Programs that provide STD screening. Budget cuts might reduce services and flexibility, while other issues might absorb limited resources that are needed for planning purposes to address future changes. Issues that appear to be unrelated might lead to reduced funding for STDs.

Wide variation was noted in the availability of primary care sites. In some cases, locations of FQHCs did not match geographic areas of the country with the highest STD burden. Geographic disparities are important because decisions on integration could be made based on the inaccurate assumption that primary care options are widely available for STD patients. Inequitable access to primary care could leave segments of the population without options because unlike CHCs, not all PCPs offer comprehensive care.

STD-related stigma and discrimination among state and local providers were noted. For some populations (e.g., teens) and in some geographic areas (e.g., small towns and rural areas), persons might avoid primary care settings or other settings that require an insurance card due to the persistent stigma of STDs.

Patients who fear discrimination based on race/ethnicity, poverty, sexual orientation or other factors might conclude that public health-run STD clinics are the only safe, supportive and comfortable clinical provider site due to their commitment to anonymity and confidentiality. The same populations that fear stigma and discrimination have an elevated risk for STDs and HIV,

but might avoid care. Moreover, these populations might be less likely to be insured even in an ACA environment.

Because state and local STD services are often linked to and housed with other services, including family planning, immunization and WIC services, the loss of STD services due to integration into primary care could result in an unintended consequence of adversely impacting the ability of the clinic to provide other services.

The need for clinical expertise was emphasized. Concerns were raised that primary care practices may not have sufficient expertise to treat complex STD-related cases. Initial skill-building is needed for clinicians in training, while advanced clinical skills are needed for practicing physicians. Public health STD expertise needs to be retained for referrals.

Key integration needs and next steps were highlighted. Information and TA are needed in establishing reimbursement systems, changing policies on explanation of benefits, and using health information technology. Best practices need to be identified based on experiences and lessons learned from SHDs/LHDs that have successfully integrated services in the field. TA is needed in piloting new integration models. A continuum with 6 levels of integration for STD services (e.g., isolation, mutual awareness, cooperation, collaboration, partnership and full merger) may be helpful for SHDs/LHDs in determining their progress in integration.

Kathy McNamara, RN

Assistant Director of Clinical Affairs
National Association of Community Health Centers

Ms. McNamara described ongoing efforts in the field to reframe public health and primary care integration. The mission of NACHC is to promote the provision of high-quality, comprehensive and affordable health care that is coordinated, culturally competent and community-directed for all medically underserved persons. The 9,500 Health Centers collectively serve 23 million patients annually.

The National Health Center Quality movement has tremendously evolved from a focus on accountability and quality control in the 1980s to the requirement for all CHCs to become recognized PCMHs by 2016. The components to achieve population-based health must be strategic, structural, cultural and technical. Emphasis is now being placed on developing and testing cost measures.

Of the entire Health Center budget, Medicaid accounts for 38% and BPHC accounts for 16%. HRSA's 2012 UDS data showed much larger numbers of Health Center patient visits than numbers of patients. The numbers of patient visits were 571,696 for symptomatic and asymptomatic HIV, 18,480 for TB, 143,146 for syphilis and other STDs, 48,080 for HBV, and 303,713 for HCV. The numbers of patients were 114,881 for symptomatic and asymptomatic HIV, 9,755 for TB, 95,500 for syphilis and other STDs, 21,890 for HBV, and 132,078 for HCV.

NACHC's position is that health reform should emphasize transformation of both primary care and public health by managing population health over time and across all settings, strongly focusing on performance measure and improvement, documenting costs, and generating improved savings and quality. NACHC aims to strengthen the patient- and community-centered primary care health home through public health, community and primary care collaboration. These efforts are designed to maximize impact and avoid duplicity.

The health home and transformation framework is built on population health and a reduction of disparities; patient, family and community engagement; and high value based on superior cost and quality outcomes. To change systems of care, health funders are accountable to the four guiding principles of the Safety Net Medical Home Initiative: establish the foundation, build relationships, change care delivery and reduce barriers to care.

At this time, ~47% of Health Centers have achieved PCMH recognition by a national accrediting body and 37 and 106 Quality Improvement Coaches are National Committee for Quality Assurance PCMH Certified Content Experts. Integrated Health Center Teams are now matched to their target populations, including Enhanced PCMH Teams, Mental Health High Intensity Teams, Intensive Outpatient Clinics, and Children with Special Health Needs Clinics.

PCMHs provide clinical support to Expanded Care Teams based on the complexities of patients: Examples of expanded teams include: 23 navigators to support tiers 3 and 4 patients for care management; 3 pediatric nurses to support tiers 3 and 4 children for care management; 3 clinical pharmacists to support tiers 3 and 4 adults for medical management and transition; and 5 behavioral health consultants for behavioral health integrated care. Community Health Teams inside Health Centers include nurse coordinators, social workers, nutrition specialists, community health workers, Medicaid care coordinators and public health specialists.

NACHC convened an expert consultation to obtain input on developing its 2014-2015 framework. The advisory group described the components that should be included in NACHC's framework for clinical/service integration and education: a solid infrastructure, learning opportunities, measures, analytics and business outcomes.

NACHC is applying its integration and education framework to implement innovation models. The "clinical decision support" intervention is focusing on chlamydia to align QI and information technology to specific measures at the patient level. The "partnership" intervention is focusing on HIV in collaboration with non-Ryan White Health Centers, Ryan White Programs and PCAs. The "community partnership" intervention is focusing on chlamydia as a prototype for rapid QI of STDs.

Lynda Meade, MPA

Director of Clinical Services

Michigan Primary Care Association

Ms. Meade described Michigan's experience with integration in the cities of Detroit and Benton Harbor. The mission of Michigan PCA is to promote, support and develop comprehensive, accessible and affordable community-based healthcare services to all Michigan residents. Michigan PCA closely collaborates with Health Centers on advocacy, policy, clinical support and other issues. Across the state, 39 Health Centers provide care to >600,000 residents at >230 delivery sites.

Michigan built its foundation of integration with Health Centers, public health, Michigan PCA, Michigan Quality Improvement Network and community partners. Michigan PCA also conducts activities in close collaboration with formal and informal advisory groups that have diverse, knowledgeable and trusted members who are committed to service and increased access. These components have been instrumental in addressing high HIV rates in Benton Harbor and extremely high rates of chlamydia in Detroit among young persons <30 years of age: 37% in the 15-19 age group, 40% in the 20-24 age group, and 11% in the 25-29 age group.

Michigan's state and local partners include Health Centers, ASOs, SHD/LHDs, a once-weekly community infectious disease clinic sponsored by a hospital, PLWH/AIDS, Michigan PCA and AETCs. Michigan PCA will soon implement a rapid-cycle model for outbreak management of STDs. In the project, 75% of sexually active women 15-25 years of age will be screened. Evidence-based treatment will be provided to at least 95% of women with positive test results. A new relationship will be built with a community that has served this population. Partnerships will be created and sustained over time with the public health infrastructure.

Activities to change the package aggregation will be completed in 3 weeks: compile evidence-based guidelines and protocols, confirm measures, convene expert faculty and partners, and develop the change package. Validation will be completed in 1 week. The "ramp-up" phase will be completed in 8 weeks: provide education to Health Centers, implement reporting, convene weekly calls in weeks 1-2 and transition to biweekly calls thereafter, and conduct aggressive outreach. The accelerated action period will be completed in 12 weeks: convene weekly calls to all teams, engage faculty and hold open calls with external stakeholders. A shared web-based reporting system will be used to distribute sample policies, describe measures and regularly report key outcomes before, during and after the project.

A partnership with Michigan PCA is beneficial due to its shared mission as well as diverse experiences and perspectives of staff. Moreover, Health Centers are progressive and serve the same populations as public health. Efforts must be targeted to populations in most need in order to change the health status and rates. Based on Michigan PCA's experience, five important concepts should be applied to inform integration efforts:

- Identify common goals and create a vision of the meaning of "success" to clients and partners
- Allow local partners to resolve issues and process improvement

- Value and consider all perspectives and needs
- Consider sustainability and financing at the outset
- Prepare for change and new strategies to provide services and address needs in PCMHs

CHAC applauded the panel for their exciting activities and tremendous efforts to advance public health/primary care integration in the field. The following topics were raised during the discussion.

- The decision-making process for Health Centers to undertake and prioritize new responsibilities, such as primary care integration, with no additional resources.
- The ability of the Safety Net Medical Home Initiative to address barriers to care in the hard-to-reach populations of migrants and homeless persons.
- Efforts to adapt and incorporate integrated public health surveillance systems and measures into Health Centers.
- The need to increase the use of community health workers in integration efforts due to their demonstrated success in reducing stigma related to HIV and STD testing.

Update by the CHAC Ryan White Reauthorization Workgroup

Kathleen Clanon, MD

Director, Division of HIV Services
Alameda County Medical Center
CHAC Member & Workgroup Chair

Dr. Clanon covered the following topics in her update on the workgroup's recent activities. The workgroup's original charge in May 2012 was to develop and present recommendations to CHAC regarding reauthorization of RWHAP that would reflect the evolving care needs in the context of ACA implementation. Despite the expiration of its authorizing statute in September 2013, HRSA is implementing the RWHAP through continued appropriation for the program. No definite plans have been announced for RWHAP reauthorization at this time.

The workgroup convened a teleconference meeting in December 2013 and is now soliciting CHAC's input in two areas. First, the workgroup's current charge should be suspended until clear plans are announced that actions will be taken on RWHAP reauthorization. Second, consideration should be given to charging the workgroup with new tasks:

- Advise CDC and HRSA on the contribution of RWHAP to progress on the National HIV/AIDS Strategy, particularly goal 4 that emphasizes the need for collaboration among federal agencies

- Advise HRSA on RWHAP's progress in meeting basic ACA goals (e.g., uninterrupted access to insurance, care and medications for low-income PLWH)
- Advise HRSA on the best use of RWHAP as part of the national investment in achieving the goal of "zero new cases"

In response to the workgroup's request for input, Dr. Cheever proposed two areas that would be particularly helpful for HRSA to obtain external advice and guidance on RWHAP. First, programmatic areas in RWHAP that need to be modified to respond to changes in the health environment as a result of ACA should be regularly monitored and evaluated. Second, input should be provided on RWHAP data that HRSA should routinely gather and analyze to inform reauthorization in the future. Because reauthorization is not planned at this time, Dr. Cheever also advised the workgroup to change its name to reflect broader RWHAP issues beyond reauthorization.

CHAC also responded to the workgroup's request for input. The members emphasized the need to maintain the workgroup, but with a more focused charge that would be more responsive to the needs of CDC and HRSA. Prevention, care and treatment resources that are allocated by CDC and HRSA are instrumental in sustaining the healthcare infrastructure, particularly as efforts are now being made to enhance public health/primary care integration. CHAC should continue to provide CDC and HRSA with evidence-based policy guidance.

Based on this feedback, Dr. Clanon announced that the next steps would be for the newly expanded "Ryan White Workgroup" to focus on the tasks proposed by Dr. Cheever and the CHAC members. The workgroup would refine its charge based on these tasks and present an update at the next CHAC meeting.

CHAC Business Session

Jeanne Marrasso, MD, MPH, CHAC co-Chair

Professor of Medicine, Harborview Medical Center
University of Washington

Dr. Marrasso opened the business session and called for CHAC's review, discussion and/or formal action on the following topics.¹

Topic 1: Draft CHAC Meeting Minutes

¹*Editor's Note:* The minutes reflect the recommendations/resolutions that CHAC revised and finalized immediately after the May 2014 meeting, but formally approved as drafts during the meeting.

A motion was properly placed on the floor by Dr. Jeanne Marrazzo and seconded by Mr. Kali Lindsey for CHAC to approve the previous meeting minutes.

CHAC unanimously adopted the Draft November 13-14, 2013 Meeting Minutes with no changes or further discussion.

Topic 2: National HCV Program

Dr. Marrazzo presented the National HCV Program recommendation for CHAC's consideration, deliberation and formal action.

As summarized in the HHS National Viral Hepatitis Action Plan (VHAP), the hepatitis C virus (HCV) epidemic is causing increased morbidity and mortality in the United States, including an alarming trend in new HCV infections in young persons who inject drugs. New treatments offer the hope of controlling the epidemic and saving hundreds of thousands of lives. Lessons learned from the successful Ryan White Program will be invaluable as the nation develops a response to the HCV epidemic and should serve as a model to maximize access to care and treatment services.

Current resource levels invested in the viral hepatitis response are insufficient to combat the challenge of HCV and to carry out VHAP. Until such funding is identified, HRSA and CDC (acting within the constraints of existing statutes) should collaborate and leverage existing HIV and STD resources to develop a national program for awareness, screening, surveillance, linkage to care and cure of HCV. Therefore:

- CHAC recommends that CDC commission or request an independent assessment of cost issues that currently limit access to HCV treatment, with specific attention to target reductions in cost of newer agents.
- Because some state laws require HIV screening as part of some healthcare activities and some have extended this to HCV, CHAC recommends that CDC share "best practices" in this area of public health policy in order to strengthen momentum for expanded screening.
- CHAC recommends that CDC and HRSA conduct a legislative review to determine what additional HCV activities can be performed by CDC and HRSA under existing statutes.
- CHAC recommends that new programmatic guidance be developed to give to Federally Qualified Health Centers and Ryan White grantees regarding HCV screening, care and treatment for persons with HCV and HIV/HCV co-infection.

- CHAC recommends that data regarding performance on HCV screening and linkage to treatment be prioritized for collection, analysis and feedback to funded programs and for project officer discussions with grantees.
- CHAC recommends the development of standardized performance measures and data elements for HCV surveillance and corresponding funding support for epidemiologic capacity at the state health department level.

Co-Chair's call for a vote	Motion properly made by Dr. Sanjeev Arora for CHAC to adopt the National HCV Program recommendation Motion seconded by Mr. Guillermo Chacon
Outcome of vote	Motion unanimously passed by 13 CHAC voting members
Next steps	Dr. Marrazzo will convey CHAC's formal recommendation in a letter to the HHS Secretary, CDC Director and HRSA Administrator.

Topic 3: HIV and HCV Testing

Dr. Johnson presented the HIV/HCV Testing resolution for CHAC's consideration, deliberation and formal action.

Testing for HIV and HCV is routinely recommended in adults, including by CDC and the U.S. Preventive Services Task Force. However, currently 1 in 6 HIV-infected persons and 1 in 2 HCV-infected persons are unaware of their diagnosis.

CHAC recommends that CDC and HRSA work to enhance adherence to these testing guidelines through their work with their directly-funded clinical programs and through collaborations with other federal agencies, such as the Centers for Medicare and Medicaid Services. Incorporation of routine HIV and HCV testing into Meaningful Use requirements, core quality measures, reminders in electronic health records, and pay-for-performance programs may enhance provider adherence to these guidelines and increase the proportion of patients living with these infections who are diagnosed and linked to care.

Co-Chair's call for a vote	Motion properly made by Dr. Steven Johnson for CHAC to adopt the HIV and HCV testing resolution Motion seconded by Dr. Sanjeev Arora
Outcome of vote	Motion unanimously passed by 13 CHAC voting members

	members
Next steps	Dr. Marrazzo will convey CHAC's formal resolution in a letter to the CDC Director and HRSA Administrator.

Topic 4: Adolescent Health

Dr. Clanon presented the Adolescent Health recommendation for CHAC's consideration, deliberation and formal action.

CHAC endorses the CDC Division of Adolescent and School Health's (DASH) list of sexual health services for youth as reasonable with proven effectiveness.

CHAC recommends that CDC issue formal guidelines for these services to be provided by school nurses or in School-Based Health Clinics for all youth, including LGBT youth and young men who have sex with men. The DASH list of sexual health services for youth includes:

1. HIV counseling and testing
2. STD testing and treatment
3. Pregnancy testing
4. Provision of condoms
5. Provision of contraception other than condoms (e.g., birth control pill and long-acting reversible contraception)
6. Prenatal care
7. Human papillomavirus vaccine administration

In instances where these services cannot be accessed or administered by a school nurse or at a School-Based Health Clinic, referrals should be made to an established teen-friendly health clinic in the community.

Co-Chair's Call for a vote	Motion properly made by Mr. Guillermo Chacon for CHAC to adopt the adolescent health recommendation Motion seconded by Dr. Bruce Agins
Outcome of vote	Motion unanimously passed by 13 CHAC voting members
Next steps	Dr. Marrazzo will convey CHAC's formal resolution in a letter to the CDC Director.

Topic 5: PrEP Implementation

Dr. Marrazzo presented the PrEP Implementation resolution for CHAC's consideration, deliberation and formal action.

CHAC congratulates CDC on the recent release of the *Preexposure Prophylaxis (PrEP) for the Prevention of HIV Infection in the United States-2014 Guidelines*. While PrEP represents a promising new addition to the HIV prevention toolkit, uptake of PrEP utilization at a national level remains low.

CHAC recommends that CDC provide periodic updates on key implementation metrics, including data derived from ongoing demonstration projects, to inform its approach and consideration of the following activities and related recommendations:

- Methods to target and deliver PrEP to individuals and populations in urgent need
- Methods to enhance access to PrEP (including delivery in HIV care clinics, primary care settings, and capacity-building and clinical training support efforts for prescribers)
- Methods to measure and address cost and health insurance coverage concerns, including cost-sharing obligations that may present a barrier to receipt of PrEP
- Methods to measure the impact of PrEP on the incidence of sexually-transmitted diseases (STDs) other than HIV and changes in sexual and drug-injection behaviors that may increase risks for HIV/STD and viral hepatitis exposure or infection.

Co-Chair's Call for a vote	Motion properly made by Dr. Marjorie Hill for CHAC to adopt the PrEP implementation resolution Motion seconded by Mr. Kali Lindsey
Outcome of vote	Motion unanimously passed by 13 CHAC voting members
Next steps	Dr. Marrazzo will convey CHAC's formal resolution in a letter to the CDC Director.

Topic 6: Prescription Drug Overdose Epidemic

Dr. Marrazzo presented the Prescription Drug Overdose Epidemic resolution for CHAC's consideration, deliberation and formal action.

CHAC is concerned about the alarming epidemic of opioid overdoses in the United States.

Considering the alarming increases in deaths associated with overdoses of prescription opioid analgesics and heroin;

Considering the risks to those prescribed opioids with concomitant use of other licit or illicit drugs or alcohol that may result in overdose related to drug-drug interactions;

Considering the social and behavioral connections between opioid use and injection, and risk for exposure to or acquisition of HIV, sexually-transmitted diseases and viral hepatitis;

Considering those risks, morbidity and mortality could be reduced by making education and training on the signs and symptoms of opioid overdose and use of naloxone widely available through federal guidance to states and communities and by increasing access to treatment for opioid use disorders, including the use of pharmacotherapies that are FDA-approved in combination with psychosocial therapies;

Considering these treatment options for opioid use disorders can be available in primary care settings or in specialized substance abuse treatment programs underscoring the need for training of providers to increase the delivery of these services to those in need;

Be it resolved that CHAC calls for proactive program initiatives in response to the opioid overdose epidemic to avoid more deaths or potential exposure to hepatitis B, hepatitis C, or HIV in vulnerable individuals and populations across the United States and U.S. territories.

CHAC calls for improvements to patient safety through person-centered and holistic care to better address drug user health needs, access to medical care, communicable disease screening and treatment, and substance abuse treatment services, and to improve their well-being.

CHAC calls on all federal agencies working in this area to increase collaboration to improve integrated health services for drug users in the nation.

Co-Chair's Call for a vote	Motion properly made by Dr. Jeanne Marrazzo for CHAC to
Outcome of vote	Motion unanimously passed by 13 CHAC voting

Next steps	Dr. Marrazzo will convey CHAC's formal resolution in a letter to the HHS Secretary, CDC Director and HRSA Administrator.
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Topic 7: STD Prevention Among MSM

Dr. Marrazzo presented the STD Prevention Among MSM resolution for CHAC's consideration, deliberation and formal action.

CHAC is concerned about the sustained increase in bacterial STDs among MSM. CHAC recommends that efforts to enhance the detection and treatment of these infections, including support for extragenital testing for chlamydia and gonorrhea, be prioritized.

Co-Chair's Call for a vote	Motion properly made by Mr. Guillermo Chacon for CHAC to adopt the STD prevention among MSM resolution Motion seconded by Ms. Angelique Croasdale
Outcome of vote	Motion unanimously passed by 13 CHAC voting members
Next steps	Dr. Marrazzo will convey CHAC's formal resolution in a letter to the CDC Director.

Topic 8: New Agenda Items

Dr. Marrazzo moderated CHAC's discussion, review and summary of new agenda items that were raised over the course of the meeting.

NEW AGENDA ITEMS	
Presenter(s)	Topic
CMS/CCIIO	<p>Overview of HIV-relevant services covered under ACA, e.g.:</p> <ul style="list-style-type: none"> • Screening and outreach • Provision of specific ARV drugs • Coverage of PrEP • ACA performance measures to reduce health disparities • Efforts by private Health Insurance Exchanges to address the unintended consequence of higher co-pays for HIV medications
HRSA	<p>Update on ACA-related issues:</p> <ul style="list-style-type: none"> • Integration efforts in an ACA environment • ACA-related problems reported to date by RWHAP grantees that are affecting HIV care
HRSA	Overview of the Ryan White HIV Workforce Study
CDC, HRSA & CMS	<p>Extensive update on HCV screening and treatment:</p> <ul style="list-style-type: none"> • CDC/HRSA: Overview of an interagency, collaborative plan to implement the six VHAP activities the HHS Secretary prioritized for 2014-2016 • CDC/HRSA: Overview of existing resources and new opportunities for HCV screening and treatment, particularly with the availability of new drugs • CDC: <ul style="list-style-type: none"> ○ New studies and activities that specifically will be targeted to the new high-risk HCV population (e.g., young, white persons 18-29 years of age in suburban areas with a history of prescription drug use) ○ Efforts to redesign existing data systems to better characterize and monitor the epidemiology and treatment outcomes of the high-risk HCV population and deliver effective harm-reduction interventions (e.g., syringe exchange and drug treatment programs) ○ DVH's progress on including new variables in NHBS to capture data on MSM, non-IDUs and other populations at high risk for HCV • HRSA: Progress on requesting all FQHCs to incorporate an electronic reminder into EHRs to conduct HCV screening of the 1945-1965 birth cohort • CMS: HCV performance measures and cost estimates to establish

NEW AGENDA ITEMS	
Presenter(s)	Topic
	a new National Hepatitis C Program, including the lowest cost of drugs that would achieve the greatest public health impact
CDC & HRSA	Overview of ongoing tele-medicine projects that support expanded outreach and improvement in HIV, HCV and STD prevention and care
CDC & SAMHSA	Update on drug user health after additional substance use data are presented during an upcoming summit
CDC & Guest Speakers	Overview of both anecdotal and evidence-based PrEP experiences in the field, particularly PrEP prescriptions and insurance coverage for high-risk groups: <ul style="list-style-type: none"> • Results of the New York State PrEP project that is being piloted at six sites and targeted to diverse populations, including LGBT, Asians/Pacific Islanders, African Americans and adolescents

Topic 9: Action Items

Dr. Marrazzo led CHAC in a review of the action items that were raised over the course of the meeting.

NEW ACTION ITEMS	
Responsibility	Action Step
CDC (John Ward)	Distribute information and links to CHAC on the “National Summit to Improve Access to HCV Testing, Treatment and Cure” webcast that CDC will host on June 17-18, 2014
CHAC (Bruce Agins)	Identify a guest speaker to report the results of the New York State PrEP pilot project
CHAC (Bruce Agins & Kali Lindsey)	Draft a resolution on integration, as the Integration Workgroup co-Chairs, for CHAC’s consideration, deliberation and formal action during the next meeting

NEW ACTION ITEMS	
Responsibility	Action Step
CHAC co-Chair	Reestablish the Viral Hepatitis Workgroup with new members: <ul style="list-style-type: none"> • Dr. Sanjeev Arora (Chair) • Mr. Guillermo Chacon • Dr. Britt Rios-Ellis
CHAC co-Chair & DFOs	Distribute an e-mail to confirm the membership of the Data Workgroup, in addition to Dr. Jennifer Kates
HRSA (Kristen Mangold)	Participate on the first teleconference of the reestablished Viral Hepatitis Workgroup and present the parts of the RWHAP legislation that pertain to HCV
CHAC Members	Ongoing discussion to revisit whether the Sexual Health Workgroup should be reestablished

Closing Session

Dr. Marrazzo thanked the CHAC members for their continued commitment and dedication to improve HIV, viral hepatitis and STD prevention and treatment for the nation. She noted that the informative presentations by CDC, HRSA and the guest speakers resulted in an extremely productive meeting. Drs. Mermin and Cheever also thanked the CHAC members for providing tremendously helpful advice to guide the CDC and HRSA prevention and treatment programs.

The next CHAC meeting would be HRSA-focused and virtually convened on November 19-20, 2014. With no further discussion or business brought before CHAC, Dr. Marrazzo adjourned the meeting at 12:54 p.m. on May 22, 2014.

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

Date

Jeanne Marrazzo, MD, MPH, Co-Chair
CDC/HRSA Advisory Committee on HIV,
Viral Hepatitis and STD Prevention and
Treatment



Participants' Directory

CHAC Members Present

Dr. Laura Cheever, Acting co-Chair
Dr. Jeanne Marrasso, co-Chair
Dr. Bruce Agins
Dr. Sanjeev Arora
Dr. Virginia Caine
Mr. Guillermo Chacon
Mr. Tommy Chesbro
Dr. Kathleen Clanon
Ms. Angelique Croasdale
Dr. Carlos del Rio
Dr. Marjorie Hill
Dr. Steven Johnson
Dr. Jennifer Kates
Mr. Kali Lindsey
Dr. Britt Rios-Ellis

CHAC Members Absent

Ms. Dawn Fukuda
Dr. Perry Halkitis
Ms. Regan Hofmann

CHAC Ex-Officio Members Present

Dr. Pradip Akolkar
U.S. Food and Drug Administration

Ms. Kaye Hayes
Office of HIV/AIDS and Infectious Disease
Policy, U.S. Department of Health and
Human Services

Dr. Iris Mabry-Hernandez
Agency for Healthcare Research and
Quality

Dr. Elinore McCance-Katz
Substance Abuse and Mental Health
Services Administration

Dr. Richard Wild
(Alternate for Dr. Stephen Cha)
Centers for Medicare and Medicaid
Services

CHAC Ex-Officio Members Absent

Dr. Stephen Cha
Centers for Medicare and Medicaid
Services

Dr. Paul Gaist
Office of AIDS Research
National Institutes of Health

Ms. Lisa Neel
Indian Health Service

CHAC Designated Federal Officers

Dr. Laura Cheever
HRSA/HAB Associate Administrator

Dr. Jonathan Mermin
CDC/NCHHSTP Director

Federal Agency Representatives

Ms. Carmen Ashley
Dr. Stuart Berman
Dr. Gail Bolan
Ms. Heather Bradley
Dr. Kenneth Castro
Dr. Hazel Dean
Ms. Elizabeth DiNenno
Dr. Rupali Doshi
Dr. Wayne Duffus
Ms. Teresa Durden
Ms. Lori Elmore
Ms. Norma Harris
Ms. Jill Huppert
Dr. Kathy Irwin
Ms. Tracy Ingraham
Dr. Amy Lansky
Mr. Dan Lentine
Ms. Kristen Mangold
Dr. Brian Manns
Mr. John Moore
Mr. Kevin O'Connor
Mr. Terry Parker
Mr. Alan Penrod
Ms. Lydia Poromon
Mr. William Potts-Datema
Ms. Amy Pulver
Ms. Susan Robinson
Mr. Raul Romaguera
Ms. Margie Scott-Cseh
Dr. Salaam Semaan
Ms. Abigail Viall
Dr. John Ward
Ms. Yescenia Wilkins
Mr. Erik Williams
Dr. Stephanie Zaza
Dr. Jon Zibbell

Members of the Public

Mr. John Auerbach
Institute on Urban Health Research and
Practice, Northeastern University

Mr. William Garrett
AIDS Institute, New York State Department
of Health

Ms. Marisol Martinez
AbbVie

Ms. Kathy McNamara
National Association of Community Health
Centers

Ms. Lynda Meade
Michigan Primary Care Association

Dr. Susan Philip
San Francisco Department of Public Health

Mr. Boris Renjifo
AbbVie

Mr. Carl Schmid
The AIDS Institute

Mr. William Smith
National Coalition of STD Directors

Ms. Marissa Tonelli
HealthHIV

Ms. Carole Treston
Association of Nurses in AIDS Care



Glossary of Acronyms

AASLD	American Association for the Study of Liver Diseases
ACA	Affordable Care Act
ACE	Affordable Care Enrollment
ACO	Accountable Care Organization
AETCs	AIDS Education and Training Centers
AHRQ	Agency for Healthcare Research and Quality
AMD	Advanced Molecular Detection
ANAC	Association of Nurses in AIDS Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASOs	AIDS Service Organizations
ASTHO	Association of State and Territorial Health Officials
BMSM	Black Men Who Have Sex With Men
BPHC	Bureau of Primary Health Care
CBOs	Community-Based Organizations
CCIO	Center for Consumer Information and Insurance Oversight
CDC	Centers for Disease Control and Prevention
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHCs	Community Health Centers
CMS	Centers for Medicare and Medicaid Services
CoAg	Cooperative Agreement
DASH	Division of Adolescent and School Health
DFOs	Designated Federal Officers
DHAP	Division of HIV/AIDS Prevention
DIS	Disease Investigation Services
DSTDP	Division of STD Prevention
DVH	Division of Viral Hepatitis
EBIs	Evidence-Based Interventions
EHRs	Electronic Health Records

FDA	U.S. Food and Drug Administration
FOA	Funding Opportunity Announcement
FPL	Federal Poverty Level
FQHCs	Federally Qualified Health Centers
HAB	HIV/AIDS Bureau
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
IDSA	Infectious Diseases Society of America
IDU; IDUs	Injection Drug Use; Injection Drug Users
IOM	Institute of Medicine
KFF	Kaiser Family Foundation
LEAs	Local Education Agencies
LGBT	Lesbian/Gay/Bisexual/Transgender
LHDs	Local Health Departments
MAI	Minority AIDS Initiative
MMP	Medical Monitoring Project
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
MSM	Men Who Have Sex With Men
NACHC	National Association of Community Health Centers
NASTAD	National Alliance of State and Territorial AIDS Directors
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCSD	National Coalition of STD Directors
NHBS	National HIV Behavioral Surveillance System
NIH	National Institutes of Health
OAMC	Outpatient Ambulatory Medical Care
OPTN	Organ Procurement and Transplantation Network
PACHA	Presidential Advisory Council on HIV/AIDS
PCAs	Primary Care Associations
PCMH	Patient-Centered Medical Home
PCPs	Primary Care Providers
PCSI	Program Collaboration and Service Integration
PLWH	Persons Living with HIV
POA	Prescription Opioid Analgesic
PrEP	Pre-Exposure Prophylaxis
Project ECHO®	Extension for Community Healthcare Outcomes
PWID	Persons Who Inject Drugs
PwP	Prevention with Positives
QI	Quality Improvement

RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Service Administration
SBHCs	School-Based Health Clinics
SEAs	State Education Agencies
SFDPH	San Francisco Department of Public Health
SHDs	State Health Departments
SHIPP	Sustainable Health Center Implementation PrEP Pilot
SHPPS	School Health Policies and Practices Study
SPNS	Special Projects of National Significance
STDs	Sexually-Transmitted Diseases
SVR	Sustained Virologic Response
TA	Technical Assistance
TAI	The AIDS Institute
TasP	Treatment as Prevention
TB	Tuberculosis
TDF/FTC	Tenofovir Disoproxil Fumarate/Emtricitabine
The Institute	Institute on Urban Health Research and Practice
UDS	Uniform Data System
USPSTF	U.S. Preventive Services Task Force
VHAP	Viral Hepatitis Action Plan
WIC	Women, Infants and Children
YMSM	Young Men Who Have Sex With Men
YRBS	Youth Risk Behavior Surveillance System