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 20, 2015
Atlanta, Georgia

Record of the Proceedings

TABLE OF CONTENTS

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CDC/HRSA ADVISORY COMMITTEE ON HIV, VIRAL HEPATITIS AND STD PREVENTION AND TREATMENT
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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 20, 2015 at the CDC Corporate Square Campus, Building 8, 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.

Information for the public to attend the CHAC meeting in person or participate remotely via teleconference was published in the *Federal Register* in accordance with Federal Advisory Committee Act (FACA) regulations. All sessions of the meeting were open to the public (*Attachment 1: Participants' Directory*).

Opening Session

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 conducted a roll call to determine the CHAC voting members, *ex-officio* members and liaison representatives who were in attendance. He 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**
Sanjeev Arora, MD, FACP (University of New Mexico Health Sciences Center)	Recipient of federal funding from CDC; recipient of pharmaceutical research contracts from AbbVie and Gilead Sciences for new hepatitis C virus (HCV) drug development
Virginia Caine, MD (Marion County, Indianapolis Public Health Department)	Recipient of federal funding from HRSA for Ryan White; member of the National Medical Association Board of Trustees
Guillermo Chacon (Latino Commission on AIDS)	Recipient of federal funding from CDC; member of Community Advisory Boards for Merck and ViiV Healthcare
Kathleen Clanon, MD (Alameda County, Oakland Medical Center)	No conflicts disclosed
Carlos del Rio, MD (Rollins School of Public Health Emory University)	Recipient of federal funding from CDC and the National Institutes of Health (NIH)
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Recipient of federal funding from CDC and HRSA
Camilla Graham, MD, MPH (Beth Israel Deaconness Medical Center)	Member of the Massachusetts Medicaid Program Drug Utilization Review Board

CONFLICT OF INTEREST DISCLOSURES	
CHAC Voting Member (Institution/Organization)	**Potential Conflict of Interest**
Debra Hauser, MPH (Advocates for Youth)	Recipient of federal funding from CDC; member of the Trojan's Sexual Health Advisory Council
Marjorie Hill, PhD (Consulting Services)	Recipient of federal funding from CDC and HRSA
Steven Johnson, MD (University of Colorado School of Medicine)	Recipient of federal funding from HRSA and NIH; member of the ViiV Healthcare Advisory Board
Michael Kaplan (AIDS United)	Recipient of federal funding from CDC and HRSA; recipient of pharmaceutical funding
Jennifer Kates, PhD (Kaiser Family Foundation)	No conflicts disclosed
Amy Leonard, MPH (Legacy Community Health Services)	Recipient of federal funding from CDC and HRSA

Dr. Mermin confirmed that the voting members and *ex-officio* members in attendance constituted a quorum for CHAC to conduct its business on May 20, 2015. He called the proceedings to order at 8:36 a.m. and welcomed the participants to the CHAC meeting.

Dr. Mermin highlighted the permanent and temporary changes to CHAC's membership in terms of CDC appointees and alternates.

- Ms. Dawn Fukuda's role changed from serving as a CHAC member to replacing Dr. Jeanne Marrazzo as the new CHAC Co-Chair. Dr. Mermin thanked Ms. Fukuda for undertaking this important position.
- The participants joined Dr. Mermin in welcoming four new members to their first CHAC meeting.
    - Camilla Graham, MD, MPH; Co-Director, Viral Hepatitis Center, Division of Infectious Diseases, Beth Israel Deaconness Medical Center
    - Debra Hauser, MPH; President, Advocates for Youth
    - Michael Kaplan; President and Chief Executive Officer, AIDS United
    - Amy Leonard, MPH; Senior Director of Public Health Services, Legacy Community Health Services
- Dr. Marjorie Hill's term expires on November 30, 2015. The participants joined Dr. Mermin in thanking Dr. Hill for her outstanding service as a CHAC member. A draft nomination package was submitted to the CDC Committee Management Office to replace Dr. Hill.
- Dr. Chana Rabiner would serve as the *ex-officio* member for the Substance Abuse and Mental Health Services Administration (SAMHSA) in the absence of Dr. Elinore McCance-Katz.

Kathleen Clanon, MD, CHAC Co-Chair
Medical Director
Alameda County Health Care Services Agency

Dawn Fukuda, ScM, CHAC Co-Chair
Director, Office of HIV/AIDS
Massachusetts Department of Public Health

Dr. Clanon and Ms. Fukuda also welcomed the participants to the meeting. For the benefit of the new members, the Co-Chairs reviewed the charter that formally describes CHAC's overall objectives, scope of activities and duties to improve HIV, viral hepatitis and STD prevention and treatment efforts for the nation. The Co-Chairs explained that meetings are held twice per year to provide CHAC with an opportunity to make recommendations on the future directions of CDC and HRSA programs.

In general, the Co-Chairs emphasized the need for CHAC's guidance to be clearly defined for three specific duties described in the charter: (1) support of healthcare services to persons living with HIV/AIDS (PLWHA); (2) education of health professionals; and (3) support of CDC and HRSA processes to identify and respond to prevention and health service delivery needs.

In particular, the Co-Chairs noted that CHAC would formulate concrete recommendations in three areas during the current meeting: (1) the top priorities of CDC and HRSA in 2016; (2) plans by CDC and HRSA to continue their partnership to integrate prevention and care of HIV, viral hepatitis and STDs; and (3) areas in which CHAC's guidance would be most useful and helpful to the agencies.

The Co-Chairs concluded their opening remarks by asking the four new members to describe their specific areas of expertise that would be contributed to CHAC during their tenures.

- Prevent sexual health morbidity among youth (Ms. Hauser)
- Place more emphasis on the national goal of "Achieving an AIDS-Free Generation" through the National HIV/AIDS Strategy (NHAS) and healthcare reform (Mr. Kaplan)
- Improve the HCV care continuum, particularly access to new drugs (Dr. Graham)
- Strengthen the focus on HIV/STD co-morbidities (Ms. Leonard)

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

Dr. Cheever joined her colleagues in welcoming the participants to the 24th CHAC meeting, particularly the four new members appointed by CDC. She confirmed that similar to previous

meetings, HRSA would continue to solicit CHAC's sound guidance to improve the direction of its treatment programs.

Dr. Cheever announced that the terms of three CHAC members appointed by HRSA would expire on June 30, 2015: Drs. Kathleen Clanon, Steven Johnson and Britt Rios-Ellis. Because their terms have been extended until December 30, 2015, however, the outgoing members would be invited to attend the next meeting. The participants applauded the tremendous contributions of these members as Dr. Cheever presented their letters and certificates of appreciation.

Dr. Cheever made additional announcements regarding CHAC's membership in terms of HRSA appointees. Ms. Antigone Dempsey, the past CHAC Co-Chair and a former member, was formally acknowledged for her excellent service during her tenure. Mr. Tommy Chesbro recently resigned as a CHAC member due to new employment commitments.

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

Advice Requested from CHAC by NCHHSTP:

1. What if any role should the Division of Adolescent and School Health have in addressing the relationship between substance use and risks for HIV, STDs and hepatitis among teens?
2. What are the most effective actions that CDC and the nation should take to address increasing syphilis rates among men who have sex with men (MSM)?

Dr. Mermin covered the following topics in his Director's report to CHAC. At the agency level, CDC's continued leadership in responding to the worldwide ebola crisis has tremendously impacted its operations in terms of staff and resources. As of April 30, 2015, CDC deployed 2,208 staff, including 968 staff to West Africa. These deployments accounted for >40,000 workdays. NCHHSTP staff has accounted for ~230 of CDC's deployments since the fall of 2014, including ~110 staff to West Africa. Other key milestones in CDC's ebola response are highlighted below.

- The Emergency Operations Center supported >3,000 staff from all parts of CDC over the past year to address emerging ebola-related issues.
- The CDC laboratory in Bo, Sierra Leone administered >12,000 ebola tests.
- CDC trained 24,615 health workers in the field in West Africa.

- CDC conducted ebola screening on 180,859 travelers who were leaving Guinea, Liberia and Sierra Leone. State and local health departments have tracked >13,700 of these travelers to date. Of 27 travelers who arrived from West Africa and required medical evaluation, none had ebola. The World Health Organization recently declared Liberia as an "ebola-free" area.
- Of all U.S. hospitals, 55 were approved to treat ebola patients. To date, U.S. hospitals have provided treatment to 11 ebola patients.
- Of all U.S. laboratories, 56 had approved ebola testing capabilities, but only 1 had the capacity to test for the virus prior to the outbreak.
- The CDC National Contact Center, CDC-INFO, provided responses to 35,288 ebola-related questions.

At the National Center level, NCHHSTP published a *Morbidity and Mortality Weekly Report* (*MMWR*) article on its joint investigation with the Indiana State Department of Health regarding a recent outbreak of HCV/HIV co-infection among persons who inject drugs (PWID). Of the small, rural Indiana community of 4,200 persons, ~150 PWID had HIV. Of PWID with HIV, >90% were co-infected with HCV. HCV infections were associated with injections of oxymorphone, while most of the HIV infections were recently acquired. The proportion of PWID with HCV mono-infection is unknown at this time, but is estimated to account for ~60%-70% of this population.

NCHHSTP issued a health advisory in April 2015 to notify all state/local health departments and healthcare providers of the growing HCV epidemic among PWID and the possibility of current or future HIV outbreaks. NCHHSTP data show that injection drug use (IDU) has been the major contributor to the 150% increase in acute HCV cases in the United States in 2000-2013. NCHHSTP asked states to analyze their surveillance data to identify specific geographic areas that are at risk for clusters of HCV/HIV co-infection and report these findings to state and local health departments.

NCHHSTP activities account for ~$1.2 billion of CDC's $7 billion budget request in the FY2016 President's Budget. A $31 million increase was requested for the viral hepatitis budget to stop the HCV epidemic among young persons and reduce mother-to-child transmission of hepatitis B virus (HBV). A $12 million increase was requested for the HIV budget to target persons who are at highest risk for acquiring or transmitting HIV and support the development of integrated statewide plans for prevention, care and treatment.

The organizational structure of the NCHHSTP Office of the Director now includes permanent directors for all five divisions and a new Program and Performance Improvement Office (PPIO). Dr. Richard Wolitski was appointed to lead PPIO to oversee NCHHSTP-wide efforts to enhance efficiency, outcomes and impact. PPIO will be responsible for the following activities.

- Expand capacity for high-impact prevention, particularly through performance indicator reports at national, state and local levels

- Strengthen epidemic and economic modeling, particularly through existing cooperative agreements (CoAgs) with Emory, Harvard and the University of California-San Francisco
- Maximize healthcare system opportunities for prevention and treatment
- Enhance program collaboration and service collaboration across NCHHSTP
- Ensure alignment between funding opportunity announcements (FOAs) and NCHHSTP goals

PPIO will compile and analyze data to monitor NCHHSTP's progress over time. For example, NCHHSTP's National Progress Reports will be used to identify gaps in the actual percentage of PLWH who know their serostatus and the national goal. NCHHSTP's State Progress Reports will be used to compare differences in death rates by state among persons with diagnosed HIV infections. NCHHSTP's Rapid Feedback Reports will be used to compare the six-month performance of grantees. In the Young MSM and Transgender of Color CoAg, for example, grantee performance was evaluated based on three major goals: the number of clients tested for HIV, the percent of HIV-positive clients, and the percent of HIV-positive clients who were linked to medical care.

NCHHSTP enhanced its website for the public to more easily access online resources. Most notably, the National Prevention Information Network (NPIN) (http://npin.cdc.gov) website was redesigned for users to access content from their desktops, tablets and SmartPhones. A new NPIN Social Community was launched. The new GetTested website (https://gettested.cdc.gov) combined the former HIVTest.org and FINDSTDtest.org websites into one resource that is now accessible from any device.

At the division level, the Division of HIV/AIDS Prevention (DHAP) released data to illustrate positive trends in the HIV epidemic in the United States. Based on 2011 data, 86% of PLWH in the United States who knew their status was the highest reported proportion to date. The annual rate of new HIV diagnoses in the United States decreased by 33% in 2002-2011. PWID accounted for ~70% of the reduction, while persons with heterosexual contact accounted for ~35% of the decline. However, HIV rates have increased in young MSM, particularly young MSM of color.

DHAP will release new three-year FOAs up to $185 million, including ~$60 million from the HHS Secretary Minority AIDS Initiative, to support prevention efforts for MSM and transgender persons. Grantees will be required to increase the uptake of pre-exposure prophylaxis (PrEP), apply surveillance data to improve engagement in care, and develop collaborative service networks.

DHAP released estimates of transmission at each stage of HIV care for the first time. The data showed that 9 in 10 HIV infections resulted from persons who did not receive regular care, including individuals with a known HIV diagnosis. The data further documented that persons with viral load counts <200 copies/ml were 94% less likely to transmit HIV than those who did not know

their HIV serostatus. DHAP published and obtained extensive public comments on its new *Prevention with Positive Guidelines* and draft male circumcision recommendations.

The Division of Viral Hepatitis (DVH) published analyses of the cost effectiveness of HCV testing and treatment. The data showed that full implementation of CDC's HCV testing recommendations could avert 320,000 deaths. The data further demonstrated that treating all HCV-infected patients at current market prices rather than delaying care until patients developed severe liver disease would cost <$40,000 per quality-adjusted life-years. DVH provided technical assistance (TA) to Egypt and Georgia due to the high burden of HCV in these countries. DVH implemented testing and linkage to care projects for chronic HBV and HCV.

The Division of STD Prevention (DSTDP) conducted laboratory testing of novel compounds against *Neisseria gonorrhoeae*, including testing to determine the efficacy of a proprietary compound against ciprofloxacin-resistant isolates. DSTDP's application for its *2013 STD Treatment Guidelines* has been downloaded 830,000 times to date. DSTDP plans to issue its *2015 STD Treatment Guidelines* in the near future.

DSTDP provided TA to Detroit to address limited access to quality STD services after the local STD clinic closed. DSTDP collaborated with the CDC-funded STD/HIV Prevention Training Centers (PTCs) to implement provider- and clinic-based interventions to increase STD preventive services for MSM at 31 HIV care clinics in 14 states.

The Division of Tuberculosis Elimination (DTBE) recently reported the lowest number of TB cases in U.S. history. The 9,412 new TB cases diagnosed in the United States in 2014 represented a 2.2% decrease from 2013. DTBE data from the "iAdhere Study" showed that 78% of U.S. patients who self-administered the three-month, once-weekly isoniazid (INH)/ rifapentine regimen (3HP) completed therapy.

DTBE found that the 3HP regimen resulted in more cost-savings and a much higher completion rate than the current nine-month INH regimen. Due to the success of the 3HP regimen, DTBE will provide TA to the ongoing multi-state outbreak of INH-resistant TB among homeless persons and also will explore the possibility of strengthening its focus on latent TB infection in the United States.

The Division of Adolescent and School Health (DASH) recently released the *Youth Risk Behavior Surveillance Report, United States 2013*. DASH developed a new web-based system to measure and evaluate the performance of its funded programs. DASH released the first cost-benefit study of school nursing services that estimated a $98 million net benefit to the Massachusetts program. DASH is continuing to develop two major resources: indicators at national, state and grantee levels to monitor progress and an *MMWR Surveillance Summary on Sexual Minority Youth*.

CHAC discussed the following topics with Dr. Mermin in follow-up to the NCHHSTP Director's report.

- The critical need for CDC to continue to address HIV and other public health needs in the field during its global ebola response.
- Additional geographic locations outside of Indiana with a high prevalence of HCV/HIV co-infection among PWID. For example, the HCV/HIV outbreak in Indiana underscores the urgent need to take stronger public health actions to address the heroin epidemic in the metropolitan Washington, DC area in terms of enrolling persons in treatment and preventing overdoses.
- Indiana's limited ability to respond to CDC's recommendations on HIV/HCV co-infection due to the lack of drug treatment programs and other resources.

CHAC made several suggestions in response to Dr. Mermin's request for input.

Question 1: *DASH's role in addressing the relationship between substance use and risks for HIV, STDs and hepatitis among teens*

- DASH should acknowledge that substance abuse played a large role in the outbreak of HCV/HIV co-infection in Indiana. The lack of clear national policies and limited federal investments to increase PWID access to syringe exchange programs (SEPs) contributed to the outbreak.
- DASH proposes to address the relationship between substance use and risks for HIV, STDs and hepatitis among teens, but its existing expertise and resources should be brought to bear to more strongly focus on youth sexual health. Compared to substance use among teens, for example, communities would be less likely to endorse, adopt and support youth sexual health activities. Moreover, an additional focus on substance use would minimize the importance of the youth sexual health goal as a top priority. The $31 million DASH budget is small, but provides the only opportunity in the federal government to specifically address sexual health and sex education of youth. If resources permit, however, DASH should explore the relationship among youth sex education, substance use, and substance use morbidity related to the prevention of HIV, STDs and hepatitis.
- DASH should compile and thoroughly review lessons learned, experiences and best practices from health departments and national organizations before undertaking its new proposed role to address the relationship between substance use and risks for HIV, STDs and hepatitis among teens. For example, the New York City Department of Health and Mental Hygiene has served as a national leader in removing bureaucratic silos to address public health issues in a non-traditional and holistic manner, such as HIV, STDs and mental health problems.
- DASH should partner with a diverse group of entities (e.g., the Boys and Girls Clubs of America) to provide youth with accurate sexual health information.

Question 2: *Effective interventions for CDC and its partners to reduce increasing syphilis rates among MSM*

- CDC and its partners should aggressively target education, information and support to clinicians who still are reluctant to address the needs of MSM, including routine HIV and STD testing. "Unwilling" clinicians should be provided with clear and compelling data. For example, the incidence of syphilis is dramatically increasing in the United States. MSM account for >80% of syphilis infections, while HIV-positive MSM account for >50%. CDC should acknowledge that creative strategies outside of traditional disease intervention specialists (DIS) will be needed in this effort.
- CDC and its partners should explore the possibility of replicating the Boston model. For example, persons who present with syphilis symptoms in Boston healthcare settings automatically are tested for HCV due to the high rate of co-infection. CDC and its partners should develop a screening protocol to automatically test for HIV, other STDs and HCV when MSM present with syphilis symptoms.
- CDC and its partners should create a streamlined and standardized process for health departments and private providers to ensure a seamless transition to treatment when MSM and their partners present with syphilis symptoms. Treatment of syphilis typically is prioritized only during outbreaks and based on the patient's risk.
- CDC and its partners should use the syphilis epidemic among MSM as an opportunity to more widely implement and institutionalize the treatment as prevention strategy.

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

Advice Requested from CHAC by HAB:

1. What are CHAC's recommendations to ensure that HAB's ongoing and future HIV/AIDS care and treatment programs are well represented in the updated NHAS?
2. What are CHAC's recommendations to HAB to improve HIV health outcomes in youth? Of all age groups, for example, young persons 19-24 years of age have the lowest viral suppression rate of ~59%.
3. What are CHAC's recommendations to HAB to identify critical areas of need, determine gaps in evidence, and better demonstrate program effectiveness across the HIV Care Continuum to inform RWHAP reauthorization in the future?

Dr. Cheever covered the following topics in her Associate Administrator's report to CHAC. HAB created a framework to guide 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 RWHAP framework is based on an overarching goal of achieving "zero new HIV infections" through comprehensive care systems and a public health approach. HAB focuses on several key components to achieve this goal, including service delivery, policy at federal, state and local levels, needs assessments to identify and fill gaps, capacity development, and quality improvement of HIV care systems for all PLWH in the United States.

HAB currently is focusing on achieving its FY2015 priorities. Support will be provided to the updated NHAS with particular emphasis on the greatest health disparities and the HIV Care Continuum. Data utilization will be further advanced to improve health outcomes. RWHAP will continue to be integrated into the changing healthcare landscape with an increased focus on community-based engagement and evaluations of the healthcare needs of RWHAP clients during the transition to an ACA environment. HAB's national leadership and internal operations will continue to be enhanced and improved.

HAB highlighted key findings from the 2013 Ryan White Service Report (RSR). The data showed that 524,675 clients received at least one RWHAP-funded service in 2013. Of 505,887 clients who were HIV-positive, 216,326 (or 42.8%) were diagnosed with AIDS and 313,952 (or 59.8%) received at least one outpatient ambulatory medical care (OAMC) visit. RWHAP has an extensive and profound reach. Most notably, CDC's 2012 data estimated that RWHAP served 931,449 persons diagnosed with HIV (or 56% of the total HIV-positive population in the United States).

By age, persons 35-54 years of age accounted for 55.2% of RWHAP clients. By race/ethnicity, minority populations accounted for 71.2% of RWHAP clients. By gender, males accounted for 70.6% and females accounted for 28.4% of RWHAP clients. By risk, MSM (45%) and heterosexual contact (39%) accounted for the most common risk factors.

Other demographics of RWHAP clients include some form of health care coverage (72.1%); below 100% of the Federal Poverty Level (FPL) (67.6%); and stable housing (83.3%). The 2012 and 2013 RSRs showed no significant differences in payer sources of RWHAP clients between the two years. No insurance (28%), Medicaid (26%), private insurance (12%) and Medicare (9%) were still the top four payer sources in 2013. The RWHAP budget of ~$2.3 billion has remained relatively stable since FY2013.

In terms of health outcomes, CDC's 2011 national surveillance data showed that 30% of all PLWH were virally suppressed. HAB's 2010-2013 RSR data showed that the percent of RWHAP HIV-positive clients who were retained in care remained stable at ~81% over this time, while the percent of clients who achieved viral load suppression increased from 69.5% to 78.6%.

Differences in health outcomes between national data and RSR client-level data are due to definitions. "Retained in care" is defined as RWHAP clients who had at least one OAMC visit before September 1 of the measurement year and at least 2 OAMC visits ≥90 days apart. "Viral suppression" is defined as RWHAP clients who had at least one OAMC visit, at least one viral load count, and a last viral load test in the year of <200 copies/ml.

By race/ethnicity, RSR data showed decreases in retention in care rates in all groups in 2010-2013 and increases in viral suppression rates in all groups with the exception of Native Hawaiians. HAB's analyses demonstrate that gaps are being closed, but disparities continue to persist in some groups. The lowest viral suppression rates were observed in African Americans and multi-racial persons (by race/ethnicity); Southern states (by geographic location); and young persons 19-24 years of age (by age).

The role of RWHAP in ACA is to fund a system of care that benefits all PLWH and provide a safety net for PLWH with little or no income. The RWHAP safety net includes the provision of services to PLWH who might be ineligible for other forms of assistance; provision of coverage for necessary services that might not be covered by other types of insurance; and provision of an entry to medical care and assistance in enrolling in other more comprehensive coverage.

HAB contracted Abt Associates to conduct a study to determine the impact of ACA on RWHAP, particularly in ambulatory medical settings. Preliminary findings of the study are highlighted as follows. The number of uninsured clients decreased in all study sites, but reductions were less in non-Medicaid expansion sites. Non-Medicaid expansion sites believed their clients have not significantly benefited from ACA. Health and insurance literacy was poor for both providers and clients. Managed care organizations and qualified health plan providers might not have the necessary expertise to provide HIV care. Efforts to coordinate activities between RWHAP providers and new providers were challenging.

The level and intensity of services varied by client type. For example, a 30-minute visit was typical for stable and established clients, while a 2- to 4-hour visit was required for new or complex clients. However, longer visits are not fully reimbursed by insurance. Insured clients most frequently relied on RWHAP for mental health, medical/non-medical case management and transportation services. Some sites had limited experience with third-party billing and were required to adopt complex billing processes, acquire new billing systems and hire new staff, (e.g., case managers, benefits counselors and coordinators, resource specialists and billing specialists).

HRSA is extensively involved in HHS's new Healthcare Delivery System Reform. The initiative focuses on the provision of better care at a lower cost by improving incentives to providers, care delivery and dissemination of information. HAB is exploring strategies to apply each of the three focus areas to RWHAP.

For incentives, HAB is conducting a study to determine the feasibility of awarding RWHAP Part A supplemental funds based on performance. For care delivery, HAB will continue to provide national leadership in integrating and coordinating RWHAP clinical care services. HAB also will compile its lessons learned, experiences and best practices in this area to assist other groups in improving their delivery of care. For information dissemination, HAB will continue to provide RWHAP grantees with Meaningful Use quality measures for their clinical sites.

HAB will convene two technical expert panels in 2015 to obtain external input and guidance on the consolidation of RWHAP Parts C and D. The charge of the expert panels will be four-fold: (1) describe the unique needs of women and youth living with HIV; (2) identify existing models of care and gaps; (2) describe barriers to care for these populations, particularly in the context of trauma, adherence to treatment and viral suppression; and (4) identify key strategies and innovative tactics to better serve the needs of women and youth clients.

HAB is partnering with the National Institute of Mental Health and the National Institute of Allergy and Infectious Diseases (NIAID) to examine the impact of sexual violence and other forms of trauma on risk factors for HIV among women and youth and their ability to access services. To support this effort, HAB and NIH are analyzing data on trauma-informed care and its capacity to improve outcomes in medical settings. HAB and NIH will convene an expert meeting in June 2015 to apply these findings to RWHAP and initiate the development of a new research agenda.

HAB has or will soon award four contracts in 2015: (1) "Strengthening the HIV Continuum of Care: Future Role of RWHAP Part A Jurisdictions;" (2) "Evaluation Methods to Award RWHAP Part C Funds;" (3) "RWHAP Outcomes Within the Context of the Affordable Care Act;" and (4) "Building Futures: Supporting Youth Living with HIV." HAB grantees are continuing to conduct five Special Projects of National Significance (SPNS) that focus on the integration of HIV primary care in Community Health Centers (CHCs), health information technology capacity building, HIV interventions for Hispanic populations, medical homes for HIV-positive homeless populations, and HIV care for transgender women of color.

HAB will award two new SPNS Initiatives in September 2015. The "Use of Social Media to Improve Engagement, Retention and Health Outcomes Along the HIV Care Continuum" will be specifically targeted to youth. The "Dissemination of Evidence-Informed Interventions to Improve Health Outcomes Along the HIV Care Continuum" will provide grantees with incentives to implement innovative, evidence-based approaches in this area.

HAB re-competed the Regional AIDS Education and Training Center (AETC) FOA to increase the size and strengthen the skills of the HIV clinical workforce and improve outcomes along the HIV Care Continuum. The AETCs will focus on training novice and low-volume HIV providers to provide high-quality HIV care and assist current HIV providers in practice transformation to improve health outcomes. HAB also re-competed the National Resource Center FOA to achieve four major goals: coordinate the development and dissemination of national HIV curricula;

support TA activities of HAB and all AETCs; serve as a central repository for materials developed by AETCs; and convene TA training sessions.

HAB contributed extensive resources to respond to the recent HIV outbreak in Indiana. A Part A grantee provided care to newly identified clients upon referral. Part B grantees in Indiana and Kentucky coordinated response efforts across their states. A Part C clinic and other clinics in Kentucky provided early intervention services and care. CHCs in the area were engaged in the response as well. HAB learned several important lessons during the investigation, such as the critical need for a solid infrastructure, high-quality surveillance and a rapid response. HAB also learned that HIV-related stigma and barriers have persisted at the local level.

HAB is continuing its planning efforts for the 25th anniversary of the Ryan White CARE Act (RWCA) on August 18, 2015. HAB will implement a multifaceted approach to commemorate the anniversary with numerous events at federal, state and local levels throughout the fall of 2015. Most notably, RWHAP's comprehensive public health approach to care and treatment will be featured and its success in serving PLWH along the HIV Care Continuum will be showcased. RWHAP's future plans, particularly aggressive outreach to youth, young MSM and young women of color, will be highlighted. RWHAP's important role in a post-ACA environment will be described.

HAB will devote a track to the Ryan White anniversary during the U.S. Conference on AIDS (USCA) on September 10-13, 2015. The HAB track will include 16 sessions covering four major themes: celebrating the 25th anniversary, linking persons to care, improving health outcomes, and addressing health disparities. HAB will convene an all-grantee meeting in FY2016 for HAB and the RWHAP grantees to share lessons learned and disseminate best practices.

HAB appointed Branch Chiefs and Division Directors to permanently fill leadership positions in the Division of Metropolitan HIV/AIDS Programs, Division of State HIV/AIDS Programs, Division of Policy and Data, Division of HIV/AIDS Training and Capacity Development, and Office of Operations and Management. HAB appointed new RWHAP Project Officers as well.

CHAC made several suggestions in response to the HAB Associate Administrator's report.

- HAB should consider the possibility of presenting a session on strategies to reduce HIV-related stigma in its upcoming USCA track.
- HAB should develop and widely disseminate a report to document its lessons learned, best practices and success in retaining 81% of RWHAP HIV-positive clients in care. A report describing these approaches would be extremely helpful to HIV care and treatment programs in the field.
- HAB should extensively engage and educate health departments, legislators and health commissions that drive state policy on the major contribution of RWHAP in improving the national delivery of HIV care over the past 25 years.

- HAB should explore the possibility of including a new indicator in the RSR dataset to monitor the relationship between the age at which minorities enter the healthcare system and delayed HIV diagnoses in these populations. This indicator could be extremely useful in earlier identification and initiation of treatment in these populations to disrupt HIV transmission.
- HAB should collect and publish data to illustrate differences in ACA benefits and health outcomes of HIV patients in Medicaid expansion versus non-Medicaid expansion states.
- HAB should create a map of the United States to pinpoint locations of existing HIV providers; identify local primary care providers who can be trained in this capacity; and apply the food desert model to determine geographic areas of the country that should be designated as "HIV care deserts." The map will be particularly helpful in rural areas of the country, but in the interim, local efforts are underway to fill this data gap. For example, the Marion County, Indianapolis Public Health Department recently allocated $1 million to a Federally Qualified Health Center (FQHC) network to build the knowledge and capacity of providers to care for HIV patients.
- HAB should collect targeted data to support the proposed consolidation of RWHAP Parts C and D. Several women and youth advocacy organizations have expressed concern that the consolidation will dilute the specific focus of Part D on women and youth. For example, HAB should analyze RSR data to document differences in health outcomes between HIV-positive youth who do and do not receive RWHAP services.
- HAB should create a process to reverse the adverse consequences related to tiered pricing of HIV drugs. In Colorado, for example, this approach has led to problems with insurance plans and resulted in unintended discrimination against a chronic disease.
- HAB established "zero new HIV infections" as the overarching goal for the RWHAP framework, but this goal focuses on prevention and is not aligned with the original intent and purpose of RWHAP to provide care to PLWH. HAB should integrate "optimal health outcomes of PLWH" into the RWHAP goal.

The federal agencies made several remarks in follow-up to CHAC's discussion. Dr. Cheever confirmed that if Congress approves the consolidation of RWHAP Parts C and D, the specific focus on women, children and youth in Part D will be retained.

Dr. Cheever explained that HRSA will continue its interagency partnership with the Centers for Medicare and Medicaid Services (CMS), particularly if an ACA proposed rule is released in 2016. In the interim, CMS has been notified of the critical need to reverse the unintended outcomes resulting from tiered pricing of drugs for HIV and other chronic diseases. Dr. Richard Wild, the alternate *ex-officio* member for CMS, added that the Center for Consumer Information and Insurance Oversight announced its plans to more rigorously scrutinize insurance plans in 2016.

Dr. Clanon concluded the session by noting that CHAC would need to revisit the three questions posed by Dr. Cheever and provide guidance in response to her request for input. During the follow-up discussion, Ms. Fukuda asked CHAC to also consider and provide feedback on common

themes of the CDC and HRSA updates: populations with the greatest need, disparities issues, health outcomes from both HIV prevention and treatment perspectives, and strategies to accomplish public health aims.

PANEL PRESENTATION: THE ROLE OF STD CLINICS IN PREP IMPLEMENTATION

Gail Bolan, MD
Director, Division of STD Prevention
Centers for Disease Control and Prevention

Advice Requested from CHAC by DSTDP:

1. What steps can be taken to fill gaps for uninsured and underinsured clients who are interested in taking PrEP? What are the differences in PrEP uptake between Medicaid and non-Medicaid expansion states? Can RWHAP be leveraged to provide clinical and/or non-clinical case management PrEP-related services to priority populations? Can HRSA change funding restrictions to allow PrEP support and TA?
2. What actions can CDC and HRSA take to ensure equitable access to PrEP, while preventing exacerbation of racial disparities in HIV? For example, the differential implementation of PrEP in Medicaid versus non-Medicaid expansion states and in privately versus publicly funded medical settings has the potential to worsen disparities.
3. What strategies can be applied to coordinate current resources and build operational capacity to deliver PrEP in STD clinics? Most notably, STD/HIV PTCs have clinical and scientific expertise, but not necessarily operational experience. Moreover, capacity building assistance (CBA) and TA providers need more skills to offer guidance on operational issues.
4. Can CDC negotiate with Gilead Sciences on behalf of state and local health departments? For example, can the requirement be eliminated for clinical sites only to dispense monthly refills? What is an effective approach for CDC to help STD clinics in non-Medicaid expansion states minimize their dependence on and direct negotiation with the Gilead Sciences Patient Assistance Program?
5. What is the best data source for CDC to monitor population-based PrEP uptake (e.g., the CDC National HIV Laboratory Surveillance System; baseline HIV RNA test results of patients submitted by their medical providers; or data submitted by state surveillance programs)?

Dr. Bolan was pleased to introduce a panel of guest speakers who would present a series of overviews on the role of STD clinics in PrEP implementation in the field. The presentations are outlined below.

U.S. PrEP Demonstration Project

Stephanie Cohen, MD, MPH
City Clinic Medical Director, San Francisco Department of Public Health
Assistant Clinical Professor at the University of California, San Francisco

Dr. Cohen presented an overview of the U.S. PrEP demonstration project. San Francisco data documented decreases in the number of new HIV diagnoses, the number of HIV-related deaths and the prevalence of HIV from 2006 to 2013. San Francisco has served as a national leader in PrEP-related randomized controlled trials (RCTs) and other activities over the past 10 years. In this role, San Francisco formed a multi-agency consortium to scale-up PrEP uptake and launched the "Getting to Zero" initiative to expand access to PrEP and improve outcomes along the HIV Care Continuum through rapid initiation of antiretroviral therapy and enhanced retention in care.

San Francisco led the NIAID-funded, multi-site and open-label PrEP demonstration project that was targeted to MSM and transgender women who have sex with men. The demonstration sites included two STD clinics and a CHC in San Francisco, Miami and Washington, DC. The study was designed to determine key outcomes of the cohort: PrEP uptake, adherence to and retention in care, sexual behaviors and STDs, side effects and toxicities of treatment, drug resistance in seroconverters, and staff and space needed to effectively deliver PrEP in clinical settings. The study was launched in September 2012 and final visits were completed in February 2015.
Eligible persons for the PrEP study included HIV-negative MSM and transgender women who have sex with men and are at risk for HIV infection. For purposes of the study, "risk" was defined as one or more of the following behaviors within the past 12 months: condom-less anal sex with ≥2 partners; ≥2 episodes of anal sex with an HIV-positive partner; and positive syphilis, rectal gonorrhea or chlamydia test results. Other eligibility criteria also were established for the cohort: ≥18 years of age, fluent in English or Spanish, normal renal function, HBV-negative, and no medical contraindications.

The demonstration sites provided the cohort with a 30-day supply of Truvada® during the enrollment/screening process at weeks 1-2 and then conducted follow-up at weeks 4, 12, 24, 36 and 48 weeks. A final visit was completed 4 weeks after the cohort discontinued use of Truvada®. Over the course of the study, the demonstration sites screened the cohort for HIV, kidney function, HBV and STDs, including urethral, rectal and pharyngeal gonorrhea and chlamydia.

The demonstration sites pre-screened a total of 1,069 persons. Of the pre-screened cohort, 364 persons declined PrEP, 148 persons were ineligible for the study, and 557 persons enrolled or an overall uptake of 60% among potentially eligible clients. After controlling for the three sites in the multi-variable analysis, the potential for enrolling in the study was greatest among persons with prior awareness of PrEP, higher levels of self-reported risks and self-referrals to the study.

The demonstration sites noted that a substantial proportion of pre-screened persons who provided sexual behavior data, but declined participation in the study actually needed PrEP due to their risk for HIV acquisition. Of 346 pre-screened non-participants, for example, 62% reported condom-less, receptive anal sex in the past 3 months. Of 276 pre-screened non-participants, 27% reported ≥5 condom-less anal sex partners in the past 12 months. Of 276 pre-screened non-participants, 43% reported positive rectal gonorrhea/chlamydia or syphilis test results in the past 12 months.

The demonstration sites observed that PrEP uptake did not vary by age, educational level, HIV risk perception, race/ethnicity or target population (e.g., MSM or transgender women). However, black MSM (BMSM) and transgender women were underrepresented in the study due to their reluctance to self-refer. The demonstration sites also collected anecdotal data from the cohort.

Main reason for enrolling in the study

- Self-protection against HIV
- The need to help the community and advance the fight against the HIV epidemic
- Self-protection against an HIV-positive partner
- Increased safety of having sex without condoms (~5% only)

Major factors for declining enrollment in the study

- Insufficient time to participate in the study
- Concerns about PrEP side effects
- No risk for HIV based on self-perceptions
- The need for more time to consider enrollment in the study

The demonstration sites collectively documented an extremely high PrEP adherence rate of ~80% during weeks 4-48 of the study. Stable housing was found to be a strong protective factor in PrEP adherence. However, lower drug levels were observed by site (Miami) and race/ ethnicity (African Americans).

The demonstration sites noted key changes in the cohort's risk behaviors while on PrEP. From initial screening to week 48, decreases over the prior three months were observed in the number of anal sex partners (~11 to ~9); the number of receptive anal sex episodes (~15 to ~12); and the number of receptive anal sex episodes with a condom (6 to ~3). Over the same period of time, no changes in behaviors over the prior three months were observed in the number of receptive anal sex episodes without a condom (9) and the percent of the cohort that reported any condom-less receptive anal sex (~66%).

The demonstration sites gathered extensive STD data. Of the entire cohort, ~27% had gonorrhea, chlamydia or early syphilis at baseline and ~53% had at least one STD episode during follow-up. The cohort's high STD incidence did not increase over time, but its re-infection rate was significant. Of 77 participants with rectal gonorrhea or chlamydia at baseline, for example, ~60%

were re-infected during follow-up. Of 33 participants with urethral gonorrhea or chlamydia at baseline, ~24% were re-infected during follow-up. Of 60 participants with pharyngeal gonorrhea or chlamydia at baseline, 25% were re-infected during follow-up.

The demonstration sites collected a wealth of HIV data. Of the entire cohort, three participants initially were found to have acute HIV infections at enrollment (all three had negative fourth generation Ab/Ag tests, but positive HIV viral loads). Seroconversions were documented in two participants who had dried blood spot levels equal to <2 doses of Truvada® per week.

The demonstration sites analyzed the data to document the HIV/STD incidence of the cohort: HIV incidence of 0.43/per 100 person-years; gonorrhea incidence of ~43/per 100 person-years; chlamydia incidence of ~48/per 100 person-years; and syphilis incidence of ~12/per 100 person-years. The HIV incidence of the cohort was found to be extraordinarily low based on the high level of sexual risk. Moreover, studies with similar cohorts have reported a much higher HIV incidence of 3.9, 4.2 or 8.9/per 100 person-years.

The San Francisco and Miami demonstration sites administered a follow-up survey 4-6 months after the study was completed to determine the ability of the cohort to continue to access PrEP. Of 174 participants across the two sites, 85% were interested in participating in a PrEP post-study. Of the sub-sample, ~51% had discussed PrEP with a provider and ~43% had completed a PrEP post-study. The sub-sample highlighted the cost of Truvada®, lack of access to knowledgeable PrEP providers and no insurance as the top three barriers to continuing PrEP after the study.

The demonstration sites learned several critical lessons during the study. The demand for and interest in PrEP were high in multiple populations across various clinical settings. PrEP retention and adherence rates were solid overall, but differences were observed by site, race/ ethnicity and sexual risk category. The delivery of PrEP was found to be feasible in STD clinical settings, but complex navigation and access issues that widely vary at the local level should be addressed.

The San Francisco Department of Public Health capitalized on its success in the demonstration project to incorporate PrEP navigation services into the San Francisco City Clinic (SFCC). A full-time program coordinator and counselor as well as a half-time nurse practitioner were hired to provide PrEP education and counseling. Depending on whether clients are insured, uninsured or have barriers, education is provided on navigating health systems and accessing PrEP at medical homes; linkages are made to providers with knowledge of PrEP; and other types of assistance are given as needed.

Of 450 clients who have received SFCC's PrEP navigation services since May 2014, >120 have been given PrEP; 36% previously received non-occupational post-exposure prophylaxis (nPEP) at SFCC; ~41% had a history of syphilis, rectal gonorrhea or chlamydia in the prior year; 43% had

insurance; and 95% were uninsured and enrolled in either a medication assistance program or a health insurance plan.

SFCC is aware of both the advantages and disadvantages of STD clinics playing a major role in PrEP implementation. On the one hand, STD clinics are ideal sites for the delivery of PrEP. STD clinics serve clients who are at elevated risk for HIV infection. Moreover, STD clinical staff includes clinicians and counselors who have skills and expertise in taking a sexual history, providing risk reduction counseling, and linking HIV-positive clients to care. Staff experience in linkage and navigation can be applied to PrEP.

On the other hand, the integration of PrEP into routine sexual health service at STD clinics is associated with several barriers. STD clinics are accustomed to providing episodic care and might not have existing systems to conduct longitudinal follow-up. Moreover, STD clinics are unlikely to offer creatinine monitoring as part of routine services. STD clinical staff might be uncomfortable explaining the risks and side effects of Truvada® and/or providing adherence counseling, particularly if nPEP is not a part of services. Other staff might have a conflict in offering PrEP, while delivering routine STD or family planning health education messages.

Overall, STD programs can play a critical role in supporting PrEP uptake and implementation. PrEP can be directly delivered to clients. A directory of local PrEP resources can be developed, including a PrEP provider list as well as options and gaps in local health insurance plans. PrEP can be initiated or referrals can be made for clients who are at elevated risk for HIV and are identified through STD surveillance and partner services. Capacity in administering PrEP can be built for both clinical and non-clinical providers.

SFCC acknowledges the need for more data because the impact of PrEP on STD prevention is unknown at this time. San Francisco data collected in 2002-2013 showed that even before the availability of PrEP, the number of early syphilis and gonorrhea cases continued to grow. The average number of male sex partners in the past three months reported by MSM patients who presented to SFCC also increased from ~5 in 2007 to ~6 in 2013. Survey responses showed a decrease in the percent of HIV-negative MSM who always used condoms during anal sex and an increase in this same population of condom-less sex with $\geq$6 partners. Similar trends were observed in San Francisco MSM based on National HIV Behavioral Surveillance (NHBS) data.

SFCC convened a series of focus groups to share STD data with and obtain input from MSM. Because many MSM do not view STDs as a major priority, SFCC created a multi-tiered approach to discuss STD prevention with its clients in a PrEP environment. Clients are extensively engaged in a dialogue regarding their sexual health goals. Emphasis is placed on the fact that the high efficacy of PrEP in HIV prevention does not protect against other STDs, including HCV. Quarterly STD screening is recommended for clients on PrEP. Other drivers of risk are addressed (e.g., substance use and mental health issues).

SFCC learned several lessons in its initial efforts to determine the impact of PrEP on STD prevention. Definitions of "safe sex" and "unprotected sex" are evolving among MSM. Condom use rates declined and STD rates increased prior to the availability of PrEP. PrEP offers opportunities for synergies in prevention, particularly in the context of providing care to a new population of MSM that previously did not seek sexual health services. New strategies and innovative STD prevention tools are needed to motivate clients in this area.

Dr. Cohen concluded her overview by asking CDC and HRSA to consider six recommendations to enhance PrEP implementation.

- Provide quarterly STD screening, including extra-genital screening, to persons on PrEP.
- Integrate new PrEP training sessions into existing training courses for Partner Services Programs and HIV test counselors.
- Provide TA to support implementation of third-party billing for PrEP in STD clinics.
- Support PrEP capacity building and education for clinicians.
- Develop innovative STD prevention strategies due to the continued growth of syphilis, gonorrhea and chlamydia rates.
- Add STD screening to NHBS.

Practical Considerations for Integrating PrEP into Public Health STD Programs

Julie Dombrowski, MD, MPH
Medical Director
Public Health-Seattle and King County STD Clinic

Dr. Dombrowski described practical issues that should be considered to integrate PrEP into public health STD programs. Even in the current ACA environment, STD clinics will continue to play a critical role in HIV prevention, including PrEP implementation. Most notably, HIV is an extremely concentrated epidemic that most heavily affects the small and stigmatized MSM population. General primary care is not adequate to provide high-quality HIV/STD prevention and care, including PrEP. STD clinics are the single largest source of new HIV diagnoses and provide care to substantial uninsured patient populations.

The Washington State Medicaid Program included coverage for PrEP with no restrictions. However, Seattle and King County's (SKC) preliminary calculations showed that MSM who might be eligible for or interested in PrEP would account for 32% of the state's $21 million Medicaid drug budget. As a result, SKC was required to prioritize PrEP delivery.

SKC reviewed several data sources to stratify risk in MSM. The 2009 Menza, *et al.* study assigned a risk score to four specific behaviors in the past year to predict the acquisition of HIV in MSM: methamphetamine or amyl nitrate use (11 points), bacterial STD (4 points), $\geq$10 sex partners (3

points), and condom-less anal sex with an HIV-positive partner or a partner with an unknown status (1 point). SKC agreed that MSM with any of the four risk factors should be tested for HIV more frequently and would be candidates for PrEP.

SKC refined the 2009 risk identification strategy with more recent data in 2014 by examining STDs by pathogen and anatomic site in its HIV-negative STD cases. The updated analysis showed that based on the highest incidence of specific STDs, SKC's priority populations for PrEP should be MSM with rectal gonorrhea (4.1/100 person-years) and early syphilis (2.8/100 person-years).

SKC emphasized that prioritization is a local approach. Several studies documented other populations that should be prioritized for PrEP in local areas based on their annual incidence of HIV: MSM with early syphilis in the SKC STD Clinic (2.8/100 person-years); BMSM in six cities of the HIV Prevention Trial Network 061 Study (3.0/100 person-years); BMSM 18-24 years of age in Atlanta (10.9/100 person-years); and BMSM 13-29 years of age at the Crossroads Clinic in Mississippi ($\geq$11/100 person-years).

SKC developed guidelines to deliver PrEP in an STD clinical setting. Highest priority is given to populations for which PrEP is recommended: MSM with rectal gonorrhea and syphilis, MSM who exchange sex for drugs or money, MSM who actively use methamphetamines and have anal sex, and persons with an HIV-positive partner. Persons outside of the high-risk group who are interested in taking PrEP are referred to SKC's organizational partners and private providers.

SKC administers the PrEP program with DIS staff, nine mid-level providers and clinicians. Because the original model of scheduling appointments for PrEP initiation failed due to the high rate of patient no-shows, SKC now conducts PrEP intake at the time of the patient's STD treatment, provides counseling, and collects blood samples for baseline laboratory tests. SKC conducts follow-up one month after the initial visit and every three months thereafter. Computer-assisted self-interviews are used to monitor variables of interest, such as sexual risk, changes in sexual risk due to PrEP, and sharing of PrEP medication. The Washington PrEP Drug Assistance Program played a critical role in eliminating cost-related barriers to PrEP uptake.

SKC learned that public health is prohibited from billing insurance above the direct cost of medications. As a result, SKC partnered with two HIV specialty pharmacies. SKC does not have sufficient data at this time to report on PrEP adherence and retention of its patients, but methamphetamine users throughout the city have not been engaged to date.

SKC's 1993-2014 data show that compared to women and men who have sex with women, MSM now account for >50% of all visits to the STD Clinic. However, PrEP highlights a new source of tension for STD clinics. As a safety net provider, STD clinics provide walk-in care to symptomatic and uninsured persons without primary care, particularly men. This role typically focuses on heterosexuals with gonorrhea and chlamydia. As a disease controller, STD clinics prioritize HIV and syphilis in MSM and other high-risk groups

SKC identified several resources that are available to address PrEP operational challenges and build the capacity of STD clinics to deliver PrEP. CDC-funded PTCs provide outstanding clinical and scientific expertise, but their operational skills and resources are limited. CDC-funded DIS Training Centers should be used to strengthen DIS skills in delivering PrEP in clinical settings and through population-based STD partner services.

The CDC-funded CBA Program is changing its traditional focus from offering behavioral interventions to community-based organizations (CBOs) to providing operational assistance to health departments and STD clinics. AETCs are another excellent resource, but are prohibited from using their HRSA funds to provide PrEP education, training and TA.

SKC met with several health departments over the past year to gather input from STD clinics in the field on HIV/STD prevention services. SKC found tremendous disparities in access to PrEP between Medicaid and non-Medicaid expansion states. In non-Medicaid expansion states, for example, programs are not focusing on implementing PrEP due to their enormous difficulties in paying for HIV testing of young, uninsured gay men. Creative programs are available, but are heavily dependent on the Gilead Sciences Patient Assistance Program.

SKC explored several approaches to overcome these barriers for STD clinics. Access to PrEP should be addressed in the context of numerous competing priorities. Guidance and TA on operational issues should be expanded and improved. For example, STD clinics that still require face-to-face interviews to discuss test results do not provide the best care to patients or appropriately use limited medical resources. DIS training should be updated, particularly to replace outdated models for partner services and syphilis investigations.

Analytic capacity should be improved in local health departments. Data sharing between states and local jurisdictions should be required or encouraged. A platform should be available to connect and mentor STD clinic medical directors across the country on an ongoing basis. Collaborations between health departments and academic institutions should be promoted.

SKC's site visits resulted in the identification of a number of key action steps. To build the foundation, state Medicaid programs and private insurance companies should continue to cover PrEP. Additional funding opportunities for PrEP should be created in non-Medicaid expansion states. Policies should be developed to ensure equity for public and private medical providers who prescribe PrEP.

To build programs, operational capacity to deliver PrEP in STD clinics should be enhanced through coordinated efforts by CDC and HRSA TA and CBA programs. State and local health departments should be given extensive TA to develop and implement PrEP prioritization guidelines based on their individual priority populations. Guidance should be developed for health departments to monitor PrEP uptake.

PrEP Implementation Activities in Chicago and New York City

Tarek Mikati, MD, MPH
Senior Medical Director
New York City Department of Health and Mental Hygiene

Dr. Mikati presented an overview of the Lakeview Specialty Clinic (LVSC) and Howard Brown Health Center (HBHC) PrEP Implementation Pilot Project in Chicago. He also provided a status report on PrEP implementation in New York City (NYC). The Chicago Department of Public Health (CDPH) focused on three key issues after the U.S. Public Health Service released the first comprehensive clinical practice guidelines for PrEP in May 2014: (1) whether most STD clinic patients are PrEP candidates; (2) specific subpopulations that should be prioritized for PrEP in STD clinics; and (3) strategies to implement PrEP in STD clinics with limited resources.

In terms of priority populations, LVSC acknowledged that MSM account for 1,350 patient visits of all 5,500 visits each year (or 60% of all MSM-STD visits to CDPH). Demographics of the LVSC MSM patient population are highlighted as follows: <30 years of age (58%), racial/ethnic minorities (67%), foreign-born (22%), and uninsured (62%). LVSC provides STD diagnosis and treatment, HIV/acute HIV screening, and referrals as needed.

LVSC's STD data showed that in April-July 2014, MSM rectal GC positivity rate was 18% and MSM rectal CT positivity rate was 19%. Behavioral risk factors were noted in 76 MSM who tested positive for rectal STDs:

- HIV-positive (22%)
- New HIV diagnosis (5%)
- Multiple sexual partners in the past three months (82%)
- Receptive anal intercourse in the past three months (83%)
- Inconsistent condom use during anal receptive sex (83%)
- History of previous STDs (70%)
- Drug use during sex (45%)

LVSC considered three options to implement PrEP in an STD clinical setting. Option 1 was a passive referral module in which PrEP educational brochures would be distributed to STD clinic patients. Option 2 was an active referral module in which high-risk patients would be linked to HBHC. Option 3 was onsite administration of PrEP at LVSC. LVSC selected option 2 because active referral to HBHC could be implemented in a much shorter period of time than onsite delivery of PrEP at LVSC. Option 2 also was more likely to link patients to PrEP than passive referral and generate cost-savings in LVSC's resource-limited setting.

LVSC selected HBHC as the partner PrEP clinic due to its role as one of the nation's largest lesbian/gay/bisexual/transgender organizations. HBHC provides mental health, primary care, outreach, and walk-in STD/HIV testing services. Moreover, the demographics of HBHC patients are similar to those of LVSC patients: HIV-positive (31%), racial/ethnic minorities (44%), and <100 FPL (17%).

The HBHC PrEP Coordinator reduces barriers to PrEP by helping patients to assess coverage on their health insurance plans, linking uninsured patients to ACA navigators, and ensuring that patients complete their follow-up primary care visits. Although 25% of the patient population is uninsured, the HBHC PrEP Program is continuing to grow with >250 patients at this time.

LVSC reviewed its STD data over a four-month period to identify and prioritize candidates who would be actively referred to HBHC. From April to July 2014, LVSC's high-risk patients included 183 HIV-negative MSM with rectal gonorrhea and/or chlamydia; 30 HIV-negative MSM with early syphilis; and 60 HIV-negative partners of patients newly diagnosed with HIV.

Of 1,350 LVSC patients who are at risk for HIV each year, 276 were identified as PrEP candidates. The PrEP delivery cascade includes identification of high-risk patients, PrEP counseling and education on active referral, linkage to the HBHC PrEP Program, treatment initiation, retention in the PrEP program, and achievement and maintenance of medication adherence. For patients who give consent, LVSC developed a protocol for clinicians, DIS staff and the PrEP Coordinator to facilitate active referral, linkage to and retention in the HBHC PrEP Program. For patients who do not give consent, an educational brochure and information on the HBHC PrEP Program are distributed. LVSC also educates providers on counseling and offering PrEP to high-risk populations.

Of 52 LVSC patients that consented to active referral to the HBHC PrEP Program, 52 were MSM, 49 were ≤35 years of age, and 36 were racial/ethnic minorities. Risk behaviors of the 52 patients were documented:

- Anal receptive intercourse within the past year (44)
- Early syphilis (15)
- Rectal chlamydia (6)
- Rectal gonorrhea (6)
- Partner to a newly diagnosed HIV patient (3)
- Combination of syphilis/rectal STI's (21)
- STD history (38)
- Inconsistent condom use (33)
- Sex while impaired due to alcohol or drugs (35)
- Drug use within the past three months (25)

LVSC recently collected data on outcomes of the 52 patients who were actively referred to the HBHC PrEP Program. From September 17, 2014 to April 4, 2015, only 27 of the 52 patients responded to the PrEP Coordinator. Of this cohort, 19 patients were linked to the HBHC PrEP Program and 18 initiated treatment.

The LVSC/HBHC collaboration was successful in several areas. The active referral pilot project was launched with only three months of planning. In terms of allocating programmatic resources, HBHC greatly benefited from LVSC providing an estimate of the number of PrEP candidates who would be actively referred. LVSC clinical providers strongly endorsed the PrEP implementation pilot project at the outset. Most patients were enthusiastic about PrEP education and also were receptive to both active and passive referrals. High-risk patients now have knowledge of sources to access PrEP. PrEP was initiated within two weeks for undocumented immigrants who were at high risk for HIV.

CDPH is taking several actions to expand the LVSC/HBHC PrEP implementation pilot project. PrEP training is planned to be provided to DIS staff at all STD clinics in terms of offering counseling and actively referring all patients with rectal STDs who were empirically treated at the first visit. Partnerships were established in February 2015 with two STD clinics and the University of Chicago to implement the active referral process. BMSM account for the vast majority of patients at these sites. Efforts are underway to engage other PrEP clinics in Chicago that have expressed an interest in collaborating with STD clinics on utilizing the active referral module.

Dr. Mikati described the current status of PrEP implementation in NYC. The NYC Department of Health and Mental Hygiene includes a large network of eight STD clinics that provide confidential, walk-in services six days per week to persons $\geq$12 years of age regardless of their insurance or immigration status. NYC STD clinics collectively account for ~80,000 patient visits per year. Populations with a low socioeconomic status (SES) and racial/ethnic minorities account for the vast majority of patient visits.

The percent of patient visits to NYC STD clinics by MSM and transgenders increased from 14% in 2010 to 23% in 2014. Of 8,747 MSM who presented to NYC STD clinics in 2014 and tested negative for HIV, 40% were symptomatic and had a medical visit, 54% had an HIV or STD screening visit, 5% had an HIV visit only, 61% were <30 years of age, and 61% were racial/ ethnic minorities.

NYC STD clinicians currently are identifying potential PrEP candidates and providing passive referrals. Patients are given a three-day starter PEP regimen and are actively referred to PrEP after completion of the regimen. NYC STD clinics are planning to develop a statewide system to screen and identify PrEP candidates. The New York program will be similar to the Chicago active referral module and will most heavily focus on the priority population of MSM with bacterial STDs. Navigators in STD clinics will actively refer candidates to New York PrEP programs, provide PrEP

and adherence counseling, and offer linkages to primary care services. Candidates will be offered a one-month PrEP starter regimen before being referred to primary care.

Several important lessons have been learned in implementing PrEP in large urban cities. Regardless of whether STD clinics implement PrEP onsite or utilize the active referral module, HIV prevention navigators will be needed to enroll patients in insurance plans, increase adherence and expand access to medications. STD clinics also will need billing expertise and training to provide PrEP onsite or offer linkages to offsite PrEP services.

CDC-funded STD/HIV PTCs should provide extensive training and widely disseminate curricula on HIV prevention, diagnosis and medication use. Many STD clinicians have no HIV experience and are not comfortable in providing counseling to their patients in these areas. The role of DIS staff should be expanded as well to provide counseling and implement PrEP. Surveillance data on MSM with positive syphilis and rectal STD test results should be collected from health departments to outreach to, provide counseling and improve linkages to PrEP services in this high-risk population.

CHAC emphasized the need for an extensive discussion to begin formulating guidance to HHS, CDC and HRSA on the role of STD clinics in implementing PrEP. CHAC's resolution should address gaps in financing and reimbursement of PrEP, the need to clearly define PrEP as "prevention" or "treatment," and necessary funding to support PrEP coordinators and patient navigators. In the interim of approving a formal resolution, CHAC made two key suggestions for the agencies to consider.

First, innovative STD prevention strategies should be developed. Most notably, STD rates are continuing to increase in MSM, but a large proportion of this population does not view STDs as a major priority or a risk factor for HIV acquisition. Potential approaches to consider include PrEP for STDs; non-traditional collaborations to deliver interventions directly to venues where MSM meet sex partners; and extensive engagement of MSM in initial planning efforts to obtain input on the most effective STD messaging and strategies for this population.

Second, STD clinics should review their demographic data to determine the percentage of young MSM 18-24 years of age who do not have a primary care provider or medical home. These data could play an important role in identifying and delivering PrEP to high-risk young BMSM who are outside of the healthcare system.

PANEL PRESENTATION: NEW HCV INFECTIONS AMONG PERSONS WHO INJECT DRUGS

John Ward, MD
Director, Division of Viral Hepatitis
Centers for Disease Control and Prevention

Advice Requested from CHAC by DVH:
1. What strategies can be implemented to strengthen HCV surveillance, testing and linkage to preventive services, including HCV treatment?
2. What approaches can be taken to encourage state and local health departments to perform assessments and initiate efforts to avert ongoing HCV transmission and HIV outbreaks in their individual jurisdictions?
3. What is the role of HCV testing and surveillance activities in identifying priority populations for HIV detection and response?

Dr. Ward was pleased to introduce a panel of speakers who would present a series of overviews on the prevention, detection and response to new HCV infections among PWID. The presentations are outlined below.

Indiana HIV Outbreak Among Persons Who Inject Drugs

John Brooks, MD
Medical Epidemiologist, Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Dr. Brooks presented an overview of the Indiana HIV outbreak among PWID. Scott County, Indiana is a rural community that diagnosed three new HIV infections in late 2014. Of the three new cases, two shared a needle-injection partner. Contact tracing identified an additional eight new HIV infections for a total of 11 cases. Interviews with community residents showed high IDU rates of analgesic extended-release oxymorphone (commercially sold as OPANA® ER). Prior to this event, Scott County historically had reported <5 new HIV infections annually.

On March 17, 2015, the Indiana State Department of Health requested CDC assistance in the form of an Epi-Aid to identify and characterize the extent of HIV infection in the community and implement interventions to control the epidemic. As of May 19, 2015, 155 new HIV infections were diagnosed in Scott County. Compared with all 92 counties in Indiana, Scott County ranked extremely low in a variety of health and social indicators prior to the epidemic.

A recent *MMWR* article described the demographics of 135 of the 155 new HIV cases. The age range of the cases was 19-56 years with a median age of 32 years. Non-Hispanic whites accounted for 55% of the cases. Of 112 interviews conducted to date, 108 persons reported IDU with OPANA® ER, heroin or methamphetamines. A small subpopulation of women was identified

as commercial sex workers. A large proportion of the cohort was poor, unemployed, uninsured and had low educational attainment.

Interviews with 108 persons who reported IDU showed that IDU is a multi-generational activity in the community. Some households reported sharing drugs or injection equipment in three generations of one family. The reported number of injections ranged from 4-15 per day, while the reported number of injection partners ranged from 1-6 per injection event. The unprecedented frequency of the number of daily injections was due to the short half-life of OPANA® ER.

New HIV infections began to be diagnosed in Scott County in mid-November 2014, rapidly increased after January 2015, and peaked in mid-April 2015. A sharp decline in the number of new HIV infections has been observed over the past month. Assuming all infections wee among Scott County adult residents 18-65 years of age, the estimated-HIV prevalence based on 155 new infections in Scott County at 1.1%.

CDC also focused on the high prevalence of HCV in Scott County. A large convenience sample of specimens was tested in "high-risk" persons who were defined as those with an injection equipment sharing partner or a sexual partner of the case patient. HIV/HCV co-infection was found to be ~30% in this cohort, while HCV mono-infection was found to be 30%-40% in the general population of high-risk persons. These data emphasize the importance of implementing CDC's recommendations to provide HCV testing to all HIV-positive persons.

Molecular analyses were performed on 97 HIV specimens. Of these, 98% showed no evidence of antiretroviral-resistant mutations and 95% cluster around a single phylogenetic pattern ("Cluster 1"). Recency testing indicated that most HIV infections were acquired in past six months prior to specimen collection, supporting the hypothesis that after HIV was introduced into the PWID community, infection spread rapidly. Regarding HCV infection, of ~200 HCV isolates analyzed to date, ~50% of strains were grouped into three clusters: one cluster of genotype 1A and two clusters of genotype 3A. Cases of multi-strain infection were observed, including an individual who was affected by three different strains.

CDC's analyses showed that HCV has been repeatedly introduced into Scott County over many years.

CDC's extensive contact tracing work included efforts to locate all contacts, particularly those who were reported to share injections or were high-risk sexual partners. CDC has located 79% of all contacts to date and conducted HIV testing: HIV prevalence is highest among in priority contacts with injection sharing or high-risk sexual partners (44%) and lower in non-priority or social contacts (7%).

Several factors have slowed CDC's and state's ability to locate the remaining 101 contacts and conduct HIV testing, including inaccurate contact information, relocation and death. At this time,

only four persons have been identified as new contacts and need to be investigated. CDC also has asked its local partners to systematically locate hard-to-reach contacts or those who previously refused testing and enroll these persons in care.

CDC and its partners launched a number of new interventions to control the epidemic. Indiana developed a simple "one-stop shop" resource to enroll uninsured cases in ACA health insurance plans. HRSA provided resources to expand HIV/HCV care in Scott County. CDC hosted webinars, broadcast radio announcements and conducted other activities to widely disseminate prevention information to the community, including low-literacy fact sheets.

CDC collaborated with state partners to implement an emergency SEP, but the moratorium on methadone provision is still in effect in Indiana. The emergency SEP dispenses new syringes and retrieves used syringes from an IDU population of ~169 persons in Scott County. At this time, ~10 syringes per person are distributed daily. However, CDC estimates that the total IDU population in the community could include as many as 500 persons.

Several state organizations are continuing to raise awareness of the benefits of medication-assisted therapy. There is an effort to train and accredit providers in prescribing Suboxone®. A local health care provider was recently designated as an FQHC. Emphasis on HCV is increasing due to its higher prevalence than HIV in Scott County. Most notably, non-medical, community-wide approaches are being considered to eliminate HCV infections.

State and local partners have rapidly offered treatment to and coordinated care for 156 persons diagnosed with new HIV infections in Scott County. Of this cohort, 44% have been engaged in care and 21% have initiated antiretroviral therapy. CDC intends to collect extensive data on PrEP uptake in this cohort in the near future; two high-risk persons in Scott County already have initiated PrEP. Indiana appears to have been the first state in the nation to develop and target an HIV prevention campaign specifically to truck drivers. This effort was undertaken due to the large numbers of commercial sex workers who conduct their business at truck stops across the country.

To identify outbreaks as early as possible, CDC recommends that at-risk communities implement routine HIV testing in jails, at addiction service organizations that offer substance abuse counseling and mental health services, and at emergency departments (EDs).

In Scott County, current loans ae to create protocols for HIV-infected and non-HIV-infected persons to ensure that high-risk individuals are systematically tested and educated on an ongoing basis. Efforts will be made to establish a new PrEP program and a permanent SEP. Long-term solutions will be identified to better characterize the HIV/HCV co-infected population and expand the public health infrastructure.

HCV Infection Among Persons Who Inject Drugs

Eyasu Teshale, MD
Epidemiologist, Division of Viral Hepatitis
Centers for Disease Control and Prevention

Dr. Teshale presented an overview of HCV infection among PWID. Several studies have documented the burden of HCV among PWID. In this population, the HCV prevalence ranges from 30%-70% and the HCV incidence ranges from 5-42/100 person-years. HCV infection is acquired early in the course of injection, while HCV prevalence increases with years of injection. High-risk injection practices are extremely prevalent.
To prevent morbidity, HCV infection is managed by performing polymerase chain reaction and assessing all HCV-positive persons for genotype, HBV/HIV co-infection and stage of liver disease. Efforts are made to reduce alcohol use or other behaviors and administer vaccination. Persons with HIV/HBV co-infection and moderate to severe liver disease are prioritized for HCV therapy. Initial drug costs are considered high, but therapy is cost-effective. Actual drug costs are 23% lower with Medicaid coverage and 46% lower with the Gilead Sciences Patient Assistance Program. For PLWH, HIV control is initiated prior to the start of HCV therapy. An appropriate HIV regimen is selected to minimize drug-drug interactions.

National surveillance data showed that the decline in the number of reported cases of acute HCV in 2000-2003 remained stable until 2010. However, a ~2.5-fold increase was observed in the number of HCV cases from 850 in 2010 to 2,138 in 2013. With the exception of the 0-19 year age group, acute HCV rates decreased in all age groups in 2000-2002 and remained fairly stable until 2010.

Persons <40 years of age accounted for the largest increases in acute HCV rates from 2010 to 2013: from 0.75 to 2.01/100,000 in the 20-29 year age group and from 0.60 to 1.36/100,000 in the 30-39 year age group. In 2013, the 20-29 year age group accounted for the highest acute HCV rate (2.01/100,000), while the $\geq$60 year age group accounted for the lowest acute HCV rate (0.10/100,000).

The 2014 Suryprasad, *et al.* study reported that non-urban settings accounted for the largest increase in HCV incidence from 2006-2011, but the absolute increase was highest in rural settings. Young PWID were the major contributors to the increase in HCV incidence in non-urban settings.

CDC and its state/local public health partners have investigated multiple HCV outbreaks in young PWID since 2008. The outbreaks occurred in white populations in rural and suburban areas: Erie and Courtland Counties (New York), Massachusetts, Wisconsin, Indiana and Virginia. An HCV outbreak also was reported in Native Americans in the Northern Plains. The common denominator in all seven outbreaks was the misuse of prescription opioids followed by early initiation of IDU.

Of 34 states that reported acute HCV cases in young persons in both 2006 and 2012, 30 states reported increased rates with 15 of these states reporting increases >200%. Of all cases reported, 50% were in persons <30 years of age. Based on 2013 surveillance data, 29,000 new HCV infections were estimated and accounted for a 150% increase since 2010. Of 39 states, 24 (or 62%) reported increases in case counts with 12 of these states accounting for 66% of cases. The demographics of these cases included a high rate of IDU (61%), similar rates by gender (0.8 male and 0.7 female), the highest rate by age in the 20-29 year age group (2.01), and the highest rates by race/ethnicity (Native Americans 1.7 and whites 0.82).

The investigation of the Scott County, Indiana outbreak showed that the number of acute HCV cases increased by 548% in 2010-2013. The HCV incidence in Scott County of 2.7/100,000 is the third highest rate in the nation. Prior to the outbreak, Scott County accounted for only 2 (or 1.1%) of all 175 HCV cases reported in 2013 and only 5 (or 1.2%) of all 396 HCV cases reported for the entire state of Indiana in 2010-2013. The Indiana public health laboratory only conducted HCV antibody testing as part of the outbreak response and did not perform HCV RNA testing on antibody-positive samples to detect current infection. Based on Medicaid criteria, HCV treatment is indicated for chronic HCV patients with stage 2 fibrosis, HIV or AIDS co-infection, or post-liver transplant.

Of 299 patients in Scott County who were tested for both HIV and HCV, HIV/HCV co-infection was diagnosed in 79 patients (or 26%). Among 185 high-risk patients who reported IDU, however, 96% were diagnosed with HIV/HCV co-infection. The CDC laboratory genotyped 214 HCV strains as part of the Scott County investigation and found that 67% were 1A strains and 22% were 3A strains. Genotyping also found three clusters of endemic HCV strains, but HIV co-infection was not detected in the 3A cluster. Of 106 specimens that were tested for quasi-species, 12 were infected with >1 strain and 14 clusters of transmission with 2-8 members each were identified. Expanded sampling is expected to detect more transmission clusters. Moreover, the collection of additional data will guide prevention interventions.

CDC made several recommendations to prevent further HCV-related morbidity and mortality in Scott County. All HCV-infected persons should be referred to care and treatment. Therapy should be prioritized and guided by recommendations from clinical experts. PWID should not be denied treatment due to their drug addiction. Studies have documented comparable adherence rates between PWID and other risk groups as well as low re-infection rates in this population. Clinical settings should be given assistance in implementing strategies to promote adherence to therapy. Data should be collected on adherence and treatment outcomes with direct-acting antiviral drugs.

CDC proposed a number of activities to improve prevention of HCV transmission in Scott County. Studies of social networks of HCV transmission will be completed. Drug treatment and harm reduction strategies will be scaled-up. Case management will be prioritized based on the study

findings. Modeling will be conducted to determine the impact of cured PWID on HCV prevalence and incidence. The potential of establishing an HCV cure and prevent infrastructure will be assessed, including clinical capacity to treat a target number of PWID, ancillary prevention services and drug availability. A protocol will be developed for a demonstration project with prevention and elimination targets. Required services will be integrated and scaled-up, including drug treatment, harm reduction, HCV treatment and PrEP for HIV.

SAMHSA data showed dramatic increases in regional drug injection trends among persons <30 years of age in Kentucky, Tennessee, Virginia and West Virginia. In addition to reviewing data from its federal partners, CDC also estimates HCV incidence based on indirect data. These sources include real-time commercial laboratory data, HCV test results, genotypes, provider and patient characteristics, prescription data, overdoses and deaths, drug treatment data, law enforcement data and liver transplantation data.

Several studies have documented the effectiveness of multi-component interventions in preventing HCV transmission among PWID. In meta-analyses of single interventions, the evidence only supported drug treatment. Readily available and low-threshold opioid agonist treatment with methadone and/or buprenorphine plus SEPs have been demonstrated to reduce syringe sharing, lower injecting risk, and reduce the incidence of HIV and HCV (e.g., up to 80% in a U.K. cohort and three-fold in a New York cohort).

The 2011 Martin, *et al.* study was the first modeling study that indicated HCV therapy might be used to reduce HCV prevalence among PWID. The study projected that annual treatment of 10 HCV infections/1,000 IDU could achieve a sustained virologic response of 62.5%. The relative benefits in reducing HCV prevalence would be highest among low-prevalence populations. The *European Association for the Study of Liver Disease 2015 Report* documented that HCV re-infection after treatment-induced viral clearance is the major concern in treating active or recent IDU. However, a number of studies conducted in the era of peg interferon therapy consistently reported an HCV re-infection rate of 2%-4%.

CDC is either funding or collaborating with partners on research projects to cure or prevent HCV in PWID. The “Reduce Hepatitis Infections by Treatment and Integrated Prevention Services” longitudinal study is designed to integrate HCV detection, prevention, care and treatment among young, non-urban PWID. The University of New Mexico and University of Cincinnati were awarded funds to conduct the study in 2014-2018. The “Model of HCV Cure and Prevention in the United States” is an RCT that is based on HCV epidemiology and drug use. RTI and the University of Bristol in the United Kingdom were the grantees and will release the study results in 2016.

The “Patient-Centered Models of HCV Care for PWID” is an RCT that is designed to compare the effectiveness between directly-observed treatment and patient navigators in achieving a sustained virologic response, increasing treatment adherence and reducing HCV re-infection.

The multi-site study is being conducted in eight U.S. cities and will include 1,000 PWID recruited from diverse venues, including CBOs, FQHCs, SEPs and methadone maintenance treatment programs. HCV treatment will be co-located in drug treatment and community health settings.

CDC will include language in its FY2016 FOA to improve the prevention of HCV transmission. HCV capacity will be strengthened for all states to monitor drug use and other transmission risks, detect new infections and coordinate prevention activities. Testing, surveillance and prevention capacity will be expanded in states and tribal areas that report large increases in new HCV infections. The adoption of viral hepatitis education, testing and prevention will be promoted in drug treatment programs, correctional settings and other priority settings. HCV surveillance and prevention activities will be enhanced through partnerships and additional prevention research.

Overall, HCV is readily transmissible among PWID. Most states are reporting increases in HCV infections with young persons <30 years of age in suburban areas accounting for the largest increases. Surveillance needs to be improved to detect recent HCV infections, determine risk factors, and identify gaps in access to care and treatment. Opioid substitution therapy and SEPs have been documented to reduce HCV transmission. A new HCV cure and prevention strategy might reduce both the prevalence and incidence of HCV infection.

Massachusetts Response to HCV Infection Among Young PersonsHsons Who Inject Drugs

Daniel Church, MPH
Viral Hepatitis Prevention Coordinator, Bureau of Infectious Disease
Massachusetts Department of Public Health

Mr. Church presented an overview of the Massachusetts response to the public health crisis of HCV among young PWID. Massachusetts is one of the few states that has developed a robust surveillance system for HCV. However, data are only maintained on persons who present to a clinician for HCV testing. Clinical laboratories electronically report HCV test results to the Massachusetts Department of Public Health (MDPH). MDPH distributes case report forms to clinicians for new patients.

MDPH designed the Massachusetts Virtual Epidemiologic Network (MAVEN) as an integrated and highly automated surveillance system. The key features of MAVEN include the same interface for multiple users, sharing of real-time data, data standards, quality control, case investigation and management, outbreak-cluster management, and analysis and evaluation.

MDPH established several case definitions for HCV infection. A “confirmed acute” case is based on a positive HCV antibody test result confirmed by supplemental assay, symptoms (e.g., elevated alanine aminotransferase levels), ruling out of other acute hepatitis infections, and

documented seroconversion within six months (optional). A “confirmed non-acute” case is based on a positive HCV antibody test result confirmed by supplemental assay. A “probable non-acute” case is based on a positive HCV antibody test result.

MDPH began reporting HCV cases in 1992. Since that time, 120,781 confirmed HCV cases and 32,049 HIV cases have been reported. However, an additional 7,000-10,000 new HCV infections have been reported each year since 2002 due to the combination of confirmed and probable cases. The 2011 Onofrey, *et al.* study reported that the age distribution of newly confirmed HCV cases in Massachusetts dramatically changed from the 1945-1965 birth cohort in 2002 to a larger population of younger persons in 2009. Males account for ~66% of HCV infections in older populations, while females account for ~50% of HCV infections in younger populations. This trend has led to a substantial number of cases of mother-to-child transmission of HCV.

MDPH analyzed the demographics of 2,331 HCV infections that were reported in 2013 among persons 15-29 years of age. The HCV burden by gender was 52% males, 47% females, and 1% transgenders or unknown gender. The HCV burden by race was 57% whites, 35% unknown, 5% other, and 3% blacks. The HCV burden by ethnicity was 58% unknown, 37% non-Hispanics, and 4% Hispanics. However, MDPH acknowledges the challenges in relying on reports from clinicians to gather demographic data.

MDPH conducted enhanced surveillance in 2012 to determine injection equipment sharing practices among 41 persons 18-25 years of age who ever reported any IDU.

- Ever used syringes previously used by another injector (71%)
- Ever divided drugs using a needle (59%)
- Ever used a cooker, bottle cap or spoon previously used by another injector (71%)
- Ever used cotton previously used by another injector (68%)
- Ever used rinse water previously used by another injector (61%)
- Knowledge of locations to access clean needles (76%)

MDPH reported a marked increase in the number of unintentional or undetermined opioid-related deaths in Massachusetts from 2002-2014. Of persons who were admitted for substance abuse treatment in Massachusetts in FY2012, 42,904 reported IDU in the prior year. Of this IDU population, 68% were male, 85% were white, 11% were Hispanic, and the mean age was 31 years. Of the 85% of the IDU population that reported heroin as their primary drug, 27% reported other opiate use in the past year.

MDPH reported a significant decrease in the number of HIV/HCV co-infections among persons <30 years of age in Massachusetts from 2004-2013. Of 3,797 cases of HIV/HCV co-infection in Massachusetts at this time, persons in the <30 year and 30-34 year age groups collectively account for only 129 (or 3%) of these cases. The percentage is small compared to other age

groups, but the current number of HIV/HCV co-infected cases in persons <35 years of age is still higher than in the past.

MDPH implemented a number of strategies to respond to the public health crisis of HCV among young PWID in Massachusetts. HCV services were fully integrated into all HIV prevention and screening programs. MDPH predicts that this new approach will result in a substantial increase in HCV tests from ~8,000 to ~60,000 annually. The ARCHITECT® fourth-generation HIV test was integrated into HCV antibody testing to improve the capacity of MDPH Office of HIV/AIDS (OHA)-funded programs to detect acute HIV cases.
Funding was allocated to five SEPs in Massachusetts. Pharmacy access to sterile syringes is available to persons >18 years of age. A naloxone distribution program was piloted. An inter-bureau workgroup was established to enhance the focus on drug user health, explore effective solutions and replicate model programs. OHA-funded programs offer HIV testing at 75 locations in 27 cities or towns across the state during various hours. OHA-funded programs include ~275 staff with expertise to use both rapid and conventional sample collection methods.

Despite MDPH's robust response, HCV cases among young PWID continue to increase each year in Massachusetts. The growing prevalence of HIV/HCV co-infection in this population has raised concerns regarding the potential for increased transmission rates. OHA-funded programs have detected only 10 acute HIV cases since 2012, but none since February 2014. The federal investment in HIV prevention among PWID has sharply declined.

MDPH has made a significant statewide investment in addressing HCV in young PWID, but infections in this population are at alarmingly high levels and are continuing to increase. A similar trend in HIV infections is likely to occur. An enhanced federal response is urgently needed, including model programs, community and provider education, and additional resources for disease surveillance, prevention research, testing and linkage to care. Multiple federal agencies should implement a comprehensive approach based on recommendations in the HHS Viral Hepatitis Action Plan. HCV treatment as prevention should be evaluated as well.

CHAC discussed the following topics with the panel of speakers on new HCV infections in PWID.

- CDC's existing infrastructure or capacity to conduct enhanced HCV surveillance to detect high-risk communities in advance of an epidemic.
- CHAC's advice to the federal agencies to prioritize the HCV epidemic as a public health emergency and allocate sufficient resources for surveillance, prevention research, and implementation of comprehensive programs and policies to achieve the ultimate goal of an HCV cure.
- Efforts by CDC and its partners to identify the source of widespread use of OPANA® ER in Scott County, Indiana (e.g., prescribing patterns of local ED physicians, local drug overdose data, and Prescription Drug Monitoring Program data).
- The possibility of expanding existing surveillance systems to capture additional data:

- ICD-9 codes of medical emergencies, such as osteomyelitis and endocarditis, to engage healthcare professionals in HCV linkage to care.
- Specific drugs involved in HCV-related overdoses and deaths.

- The current capacity of STD clinics to perform HCV testing, particularly in high-risk populations.

Ms. Fukuda closed the session by confirming that CHAC would review the HHS Viral Hepatitis Action Plan as a starting point in formulating concrete guidance to the federal agencies. Based on the panel presentation, CHAC's follow-up discussion and upcoming recommendations drafted by the HCV Workgroup, she pointed out that CHAC's formal resolution would emphasize the following issues.

- A sense of urgency will be conveyed to address HCV with a national call to action. State and local data will be cited to justify this effort. For example, Scott County, Indiana is a rural community with a small population of 4,200 persons. However, data from the Scott County outbreak investigation showed that the number of acute HCV cases substantially increased by 548% in only three years from 2010-2013.
- The critical need for high-quality and solid capacity in HCV surveillance, epidemiology, DIS, and public health expertise and rapid follow-up in all states will be underscored.
- The importance of integrating HCV into behavioral health and addiction programs to determine the vulnerability of certain populations in acquiring HIV/HCV co-infection will be highlighted.
- Tremendous opportunities for CDC and HRSA to provide a collaborative response to achieve the greatest impact on HCV will be described.

Update by the Hepatitis C Virus Workgroup

Sanjeev Arora, MD, FACP
Professor, Department of Internal Medicine
University of New Mexico Health Sciences Center
CHAC Member & Workgroup Chair

Dr. Arora covered the following topics in his update to CHAC on the workgroup's recent activities. The workgroup drafted two recommendations and provided justification to support its proposed guidance.

> **Recommendation 1:** CDC and HRSA should provide guidance and instruct provider education and CBA grantees to incorporate learning objectives into their curricula regarding testing and treatment for persons with HCV mono-infection and HCV/HIV co-infection. CHAC recommends that CDC and HRSA collaborate in providing grantees

with materials to assist in integrating HCV education into their existing HIV educational curricula.

The workgroup provided the following justification to support recommendation 1 to integrate HCV into provider education and CBA efforts. Current estimates show that 2.7 persons have HCV in the United States, but as many as 50% of these individuals have not been diagnosed to date. The total cost of treating HCV is $6.5 billion, but the burden on the U.S. healthcare system is continuing to grow.
CDC estimates that as many as 897,000 HCV-related deaths might occur based on current rates of treatment. Effective methods of testing and treating HCV are now available and could significantly reduce costs in the future. Education and training for healthcare workers to provide care to persons who are infected with or at risk for HCV are required to disseminate evolving recommendations.

CDC and HRSA should issue a guidance document because many of their provider education and CBA grantees only focus on grant requirements. At this time, only a few grantees integrate HCV education into HIV training that is provided. If CDC and HRSA issue guidance, more grantees are likely to provide HCV education that will address both HCV mono-infected and HCV/HIV co-infected populations.

Recommendation 2: CDC and HRSA should support collaborations with clinical care experts, community representatives and other stakeholders to develop HCV testing, care and treatment guidelines endorsed by the federal government. The new guidelines should build on existing guidance by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). The new guidelines should be created in collaboration with IDSA and AASLD to prevent duplicative efforts. CHAC recommends that the new guidelines be created with the GRADE-based framework used by the U.S. Preventive Services Task Force (USPSTF) to develop preventive health recommendations.

The workgroup provided the following justification to support recommendation 2 for the federal government to issue and endorse HCV treatment guidelines. Patients face enormous difficulties in accessing expensive HCV treatment. Providers and staff are inundated and demoralized by the constant barrage of denials from managed care companies. Most payers ignore the current guidelines due to their belief that the recommendations are biased and were developed by AASLD/IDSA members who receive pharmaceutical funds or have other conflicts of interest.

The current guidelines are extremely stringent and their interpretation or implementation greatly varies among payers. Payer policies and practices in interpreting the current guidelines have led to tremendous health inequities across the country based on whether patients have high or low SES. Medicaid patients are denied HCV care most of the time. The AASLD/IDSA guidelines are based on expert opinion rather than the rigorous GRADE-based framework that USPSTF and

CDC use to develop preventive health recommendations. The HIV model indicates that federally endorsed guidelines are helpful, but calculations for HCV treatment might be different due to the much higher cost of medications.

Government guidelines will provide one standard of care and improve access to HCV treatment throughout the country. The guidelines should cover the following topics.

- Assessment of awareness of HCV
- HCV testing
- Evaluation of HCV patients
- Patient selection for HCV treatment
- Culturally responsive HCV care
- HCV treatment regimens with doses and durations
- Patient follow-up during HCV treatment
- Long-term follow-up of HCV patients

The time and expense associated with developing new HCV treatment guidelines might be the contributing factors for NIH declining to undertake this effort. As a result, the workgroup is interested in applying lessons learned from the Federal Advisory Committee that developed HIV treatment guidelines to create new HCV treatment guidelines. To date, the workgroup has been unable to identify any other entity in the federal government that has a focus on HCV treatment.

The pros and cons of CHAC's role in developing new federal HCV treatment guidelines are summarized as follows. On the one hand, an urgent public health issue would be addressed. On the other hand, CHAC has no resources to support an elaborate and resource-intensive process that is required to develop a new set of guidelines. Moreover, CHAC might not have sufficient prominence in the medical payer community to influence or change reimbursement practices. The development of new HCV treatment guidelines might be outside of the scope of CHAC's charter.

Dr. Arora concluded his update by directing CHAC's attention to two draft letters that were included in the meeting packets. The workgroup agreed to draft two letters because one letter with backgrounds and rationales for both recommendations would be too lengthy. Based on CHAC's formal approval, the Co-Chairs would sign and submit both letters to Dr. Thomas Frieden, Director of CDC, and Mr. Jim Macrae, Acting Administrator of HRSA.

CHAC Business Session

Kathleen Clanon, MD, CHAC Co-Chair

Medical Director
Alameda County Health Care Services Agency

Dawn Fukuda, ScM, CHAC Co-Chair
Director, Office of HIV/AIDS
Massachusetts Department of Public Health

Dr. Clanon and Ms. Fukuda opened the business session and called for CHAC's review, discussion and/or formal action on several topics. For the benefit of the new members, Ms. Fukuda reviewed the guidelines for CHAC to issue formal recommendations and resolutions to the HHS Secretary, CDC Director and HRSA Administrator.

Topic 1: HIV in Youth Populations

Ms. Fukuda asked CHAC to review the two-part resolution that was drafted to address HIV in youth populations.

Part 1: *Enhanced data collection to inform a strategic response to HIV in youth populations*

CHAC recommends that CDC and HRSA define a methodology to collect key data points about youth to (1) help triage and target responses to facilitate access to prevention and care for the most at-risk populations of adolescents and young adults in the United States and (2) complete a thorough review of policies to identify barriers to effective uptake of interventions in both traditional and crisis situations. Insufficient access to timely and relevant data regarding the health, vulnerability and risk experience of youth hampers the ability to design responsive programs and justify the investment of federal resources.

CHAC recommends that the HHS Secretary develop a plan to collect and disseminate a set of key data indicators on youth in a timely manner to support the implementation of effective, evidence-based approaches. Persons <24 years of age represent an increasing proportion of new HIV infections in the United States and accounted for 22% of new HIV infections in 2012. Young men who have sex with men (MSM), particularly young Black and Latino MSM, are disproportionately impacted by HIV. It is also noteworthy that persons living with HIV (PLWH) 19-24 years of age have the lowest rates of viral suppression in the nation.

CHAC encourages CDC and HRSA, in collaboration with behavioral scientists and health economists, to develop a methodology to collect key data on the health status of youth 13-24 years of age in the United States across HIV, STD and viral hepatitis indicators

and include behavioral health issues (e.g., substance use status, experience of violence/victimization, and incarceration/detention). These data also should utilize a consistent set of measurements related to both vulnerability and resiliency. As a component of this effort, the federal agencies should use these data analyses to assign priority status to particular subgroups of the youth population and selectively fund and require enhanced investments and service responses tailored to meet the needs of these youth.

The proposed acuity framework should consider environmental, behavioral and psychosocial factors; be applied to intentionally target resources to maximize program effectiveness and fiscal efficiency; and engage youth populations as advisors in the planning process. Populations identified for priority attention include young MSM of color, homeless youth, corrections-involved youth, sex trafficked youth, and young persons who use injection drugs.

Part 2: *Expand direct care intervention services for the highest risk youth populations*

Ryan White medical case management approaches have been proven to be effective in supporting HIV-positive individuals who face psychosocial challenges to remain engaged and retained in care and achieve viral suppression. These successful models can be expanded and extended to serve subgroups of youth identified as particularly vulnerable to experience HIV exposure or infection; prevent new HIV, STD and viral hepatitis infections in youth; and promote sexual health into adulthood.

CHAC recommends that CDC and HRSA develop frameworks to respond to the most at-risk youth and build resilience through increased protective factors, including the Youth Ambassador Program.

CHAC recommends that CDC and HRSA assess the feasibility of expanding medical case management services to reach youth who might be vulnerable to HIV, hepatitis C, and STDs, including HIV-negative sexual and drug injection partners of HIV-positive individuals. This approach might reach large numbers of at-risk youth who currently are engaged in HIV prevention services, but are not eligible for Ryan White care.

CHAC recommends that through the scope of the Integration Workgroup, members develop recommendations for review by CHAC, CDC and HRSA to improve quality for those accessing services in school-based, community-based, and traditional clinical environments. As a component of this effort, in the context of the substantially disproportionate impact of HIV infection among young men who have sex with men, notably young Black and Latino MSM, CDC and HRSA should assess the feasibility, acceptability and projected impact (inclusive of cost-effectiveness) of expanding access to PrEP in this population in both medical and community-based settings.

Co-Chair's call for a vote	Motion properly made by Dr. Sanjeev Arora for CHAC to formally adopt the two-part resolution related to HIV in youth populations with CHAC's proposed revisions Motion seconded by Mr. Guillermo Chacon
Outcome of vote	**Motion unanimously passed by 14 CHAC voting members**
Next steps	The Co-Chairs will revise the two-part resolution based on CHAC's feedback: (1) incorporate new language to acknowledge CDC's robust Youth Risk Behavior Surveillance data and (2) include "youth in the Child Welfare System" and "youth of incarcerated parents" as additional special populations. The Co-Chairs will submit the final two-part resolution to the HHS Secretary, CDC Director and HRSA Administrator for consideration and action.

Ms. Fukuda explained that the two-part resolution to address HIV in youth populations was drafted well in advance of the May 2015 meeting. As a result, the resolution did not capture specific advice that CDC and HRSA requested from CHAC in their current presentations.

- The potential role of DASH in addressing the relationship between substance use and risks for HIV, STDs and hepatitis among teens.
- Effective actions for CDC and the nation to take in addressing increasing syphilis rates among MSM, including youth in general and sexual minority youth in particular.
- Strategies to increase PrEP uptake in high-risk youth.
- Approaches to decrease HCV transmission among young PWID.
- Methods for HAB to improve HIV health outcomes in youth, particularly since young persons 19-24 years of age have the lowest viral suppression rate of all age groups.
- A process to facilitate a seamless consolidation of RWHAP Parts C and D, while ensuring that resources remain focused on women, children and youth.

Ms. Fukuda clarified that CHAC could form a new Youth Workgroup to address both prevention and care issues across HIV, STDs and viral hepatitis. The new workgroup would be charged with focusing on these additional youth-related topics and formulating recommendations for CHAC's consideration and formal action. She reminded the members that CHAC currently has three workgroups: the HCV, Ryan White Reauthorization and Data Workgroups.
CHAC proposed several topics that should be addressed if a vote is taken to approve the establishment of a new Youth Workgroup.

- A portion of RWHAP medical case management and other support services should be devoted to the specific HIV care and treatment needs of youth.

- A comprehensive inventory of activities conducted by SAMHSA and other federal agencies that are targeted to substance abuse among youth should be developed. The inventory would help DASH to avoid duplicating ongoing federal efforts, identify areas of synergy with federal partners, and target funding to priority issues.
- Interventions that have been successful in high rates of treatment adherence and retention in care for youth with diabetes should be compiled. These strategies potentially could be replicated for youth with HIV.
- Consideration should be given to dividing the youth age group of 13-24 years into two distinct groups: youth 13-18 and 19-24 years of age. Youth in these two age groups have tremendous differences in terms of their development and interventions that will be effective.
- Guidance should be provided to ensure that the updated NHAS for 2016-2020 reflects the HIV needs of youth.

Topic 2: HCV Workgroup Recommendation 1

CHAC provided feedback in two areas on recommendation 1 proposed by the HCV Workgroup. First, some CHAC members found recommendation 1 to be problematic. CDC and HRSA are being asked to provide their grantees with guidance and materials to integrate HCV education into existing HIV educational curricula, but no new funding would be allocated for this task.

Second, other CHAC members believed recommendation 1 could be implemented by compiling case studies to illustrate situations in which grantees successfully augmented their funding to conduct additional activities. These models could serve as examples for TA and CBA grantees to incorporate HCV education into HIV training. For example, MDPH and other state health departments receive CDC funding to include HCV testing in their HIV prevention activities.

Co-Chair's call for a vote	Motion properly made by Dr. Britt Rios-Ellis for CHAC to formally approve recommendation 1. CDC and HRSA will provide their grantees with guidance and materials to integrate HCV education into existing HIV educational curricula. Motion seconded by Dr. Virginia Caine
Outcome of vote	**Motion unanimously passed by 14 CHAC voting members**
Next steps	The workgroup will revise recommendation 1 based on CHAC's feedback to compile case studies of situations in which grantees successfully augmented their funding to conduct additional activities. The Co-Chairs will send letter 1

	with revised recommendation 1 to the CDC Director and HRSA Acting Administrator for consideration and action.

Topic 3: HCV Workgroup Recommendation 2

Drs. Ward and Mermin described several practical issues for CHAC to consider before taking a formal vote on recommendation 2. DVH would welcome the opportunity to be fully engaged in developing new HCV treatment guidelines because CDC's involvement likely would strengthen the credibility and increase implementation of the recommendations in the field.

In the interim of Congress approving CDC's request for a $31 million increase in the FY2016 viral hepatitis budget; however, if this is not appropriated, DVH would need to devote its existing resources to this effort. In addition to DVH establishing a structure that would support a high-quality, independent and objective guideline development process, DVH also would need to dedicate ongoing resources to sustain the recommendations over time with routine updates as new data are generated and new HCV drugs are introduced to the market. Moreover, DVH would need to consider the unintended consequence of the new HCV treatment guidelines supplanting existing AASLD/ IDSA guidance.

Dr. Graham reminded CHAC of her role as a new member to improve the HCV care continuum, particularly access to new drugs. In general, she agreed that recommendation 2 is critically important. However, she believed that CDC's release of new HCV treatment guidelines would have little impact in the field. However, even if the guidelines are developed with more rigorous science, the GRADE-based framework and CDC's strong public health leadership, payers will still create excuses or identify "loopholes" to continue to deny coverage of expensive HCV treatment.

Dr. Graham clarified that unlike HIV, the vulnerable population of HCV patients virtually has no strong advocates or outspoken champions. The continued ability of payers to ration HCV care and treatment has been unprecedented in the U.S. healthcare system to date. Instead of submitting recommendation 2 to CDC and HRSA leadership, she urged CHAC to issue a compelling position statement to emphasize that the practices and policies of payers in terms of denying coverage of HCV treatment are inexcusable, illegal and would no longer be tolerated.

Dr. Graham conveyed that the workgroup's request for CHAC to formally approve and submit recommendation 2 to CDC and HRSA leadership also might result in unintended harm. Most notably, the guidance does not capture three new HCV drugs that the U.S. Food and Drug Administration is scheduled to approve in 2015 and early 2016. CHAC's outdated guidance would be at least one year behind the availability of these new drugs.

CHAC considered the practical issues Drs. Ward and Mermin described from the perspective of a federal agency as well as the operational issues Dr. Graham highlighted from the perspective of a viral hepatitis clinician in the field. The members proposed a revision based on this input.

CHAC should elevate the prominence and urgency of recommendation 2 by submitting letter 2 to the HHS Secretary rather than to CDC and HRSA leadership. CHAC should ask the HHS Secretary to convene an independent panel to develop new guidelines that will address the realities and challenges of HCV screening, care and treatment for patients and providers. The panel should include representation by clinical care experts, community representatives, HCV patients and federal partners (e.g., CDC, HRSA, NIH and SAMHSA).

Drs. Clanon and Ward summarized key points from CHAC's discussion that should be emphasized in letter 2. The federal government's guiding principle should be that all persons in America deserve the best health care regardless of their geographic location or SES. The federal government is obligated to advocate for its poorest residents and ensure that HCV treatment is equitably provided regardless of risk factors or SES.

Current Medicaid reimbursement policies are extremely restrictive, tremendously vary among payers, and do not comply with AASLD/IDSA guidelines for HCV treatment. Payer policies and practices have resulted in enormous disparities among patients who desperately need HCV care. The federal government can build on the existing AASLD/IDSA infrastructure to develop guidelines and establish benchmarks to measure the quality of HCV care and treatment in the United States. Based on the recent outbreak of HCV/HIV co-infection among PWID in Scott County, Indiana and the extremely high prevalence of HCV in Massachusetts, CDC should strengthen its national HCV surveillance capacity.

Co-Chair's call for a vote	Motion properly made by Dr. Virginia Caine for CHAC to formally approve recommendation 2. CDC and HRSA will collaborate with their federal partners and external experts to develop new HCV treatment guidelines. Motion seconded by Mr. Guillermo Chacon
Outcome of vote	**Motion passed by a majority vote of 13 CHAC voting members and 1 abstention (Graham)**
Next steps	The workgroup will revise recommendation 2 based on the extensive feedback provided during the discussion. New language will be added to emphasize health inequities and disparities in HCV treatment based on SES and risk factors. The Co-Chairs will send letter 2 with revised recommendation 2 to the HHS Secretary for consideration and action.

Dr. Clanon charged the workgroup with responding to the specific advice that CDC requested from CHAC during the panel presentation on new HCV infections among PWID. Dr. Arora confirmed that the workgroup would undertake the expanded charge. He announced that the

workgroup welcomes participation by other members and external experts due to CHAC's stronger focus on HCV. He clarified that his institution, the University of New Mexico Health Sciences Center, coordinates, supports and convenes workgroup meetings via video conference. The workgroup intends to hold two additional meetings before the November 2015 CHAC meeting.

Topic 4: DVH's National Leadership in Viral Hepatitis

Dr. Arora asked CHAC to formally approve a resolution to commend DVH on its extraordinary accomplishments and national leadership in viral hepatitis with a small budget of $30 million. Most notably, DVH widely publicized the important need for HCV screening of the 1945-1965 birth cohort and also collected extensive surveillance data on HCV mortality. CHAC's formal adoption of the resolution would demonstrate its strong support for Congress to approve CDC's request for a $31 million increase in the FY2016 DVH budget. The additional resources would allow DVH to advance and improve the response to the national HCV epidemic.

Co-Chair's call for a vote	Motion properly made by Dr. Camilla Graham for CHAC to formally approve the resolution Motion seconded by Mr. Guillermo Chacon
Outcome of vote	**Motion unanimously passed by 14 CHAC voting members**
Next steps	The HCV Workgroup, including Dr. Graham as a new review and comment. However, new language will be added for DVH to increase its focus on HBV.

Topic 5: CHAC's Recognition of the 25th Anniversary of the Ryan White CARE Act

Mr. Chacon asked CHAC to review the resolution that was drafted to formally recognize the 25th anniversary of RWCA.

> Considering that on August 18, 1990, the Ryan White CARE Act (RWCA) was enacted by Congress to address the alarming impact of the HIV/AIDS epidemic in the United States and Territories;
>
> Considering that RWCA was named in memory of the courage and tenacity of a young man and his family's brave stand in the face of outrageous discrimination; and that Ryan

White services continue to address racial, ethnic, sexual orientation, and class barriers that impede our desired goal;

Considering that over the years, RWCA developed the most comprehensive model of care to provide treatment and other critical services to the most vulnerable and underserved populations impacted by the HIV/AIDS epidemic;

Considering that RWCA is a model that welcomes and affirms the active participation of persons living with HIV in the policy, implementation and evaluation of program design and delivery;

Considering the tremendous impact on the quality of life and life-saving treatment and support services, RWCA has become a model of addressing an epidemic among low-income and underserved communities throughout the nation and U.S. Territories;

Considering that recent RWCA data show that persons receiving care and services under this program have higher levels of retention in care and viral suppression than the general population of persons living with HIV;

Considering the treatment model developed by RWCA programs underscoring and meeting the training needs of providers to increase their delivery of these critical services to those most in need;

Resolve that CHAC recognizes each individual who contributed to developing this steadfast, groundbreaking and comprehensive model of care in addressing treatment and other critical services related to HIV in our communities across the United States and Territories;

Resolve that CHAC calls for proactive commemoration activities to begin in the summer of 2015 and continue throughout the fall at federal, state and local levels to highlight the contributions and accomplishments of RWCA.

CHAC calls for all institutions, community-based organizations, and persons living with HIV/AIDS to celebrate improvements in patient care and treatment through person-centered and holistic care to better address the evolving needs of those living with HIV/AIDS.

CHAC calls on all federal agencies and community partners to protect the effective services of RWCA as a testament to catalyze health equity and as a model of responsiveness to the HIV/AIDS epidemic in a rapidly changing healthcare environment.

CHAC took no action on the proposed resolution. Dr. Jennifer Kates, the Data Workgroup Chair, confirmed that the workgroup would discuss the feasibility of identifying data on the notable accomplishments, key gaps and unmet needs of RWCA over the past 25 years. Based on CHAC's feedback, the workgroup would focus on the following areas to support the resolution: health equity and disparities, inequitable allocation of resources by geographic location and population, and limited HCV surveillance capacity.

Topic 6: CHAC Meeting Schedule

Dr. Cheever reminded the members that on the following day, CHAC would hold its first joint meeting with the Presidential Advisory Council on HIV/AIDS (PACHA) to specifically provide input on the updated NHAS. She was aware that several members expressed concern regarding CHAC's inability to complete all of its business items in a one-day rather than a two-day meeting.

To address this issue, Dr. Cheever explained that CHAC could convene a teleconference before the November 2015 meeting to complete any unresolved business items. However, all FACA regulations would apply in terms of announcing the teleconference in the *Federal Register*, operating with a quorum of the CHAC membership, and calling for public comment. She confirmed that CDC and HRSA would contact the CHAC members to determine their availability to participate in the teleconference in either July or August 2015.

Topic 7: PrEP Implementation in STD Clinics

Dr. Cheever provided clarification on one presentation that noted AETCs are prohibited from using their HRSA funds to deliver PrEP education, training and TA. She explained that RWHAP legislation requires AETCs to target prevention activities to high-risk populations. As a result, AETCs are allowed to conduct PrEP-related activities.

Due to the joint meeting with PACHA on the following day, Dr. Clanon conveyed that CHAC would not have sufficient time during the remainder of the current meeting to draft, review, discuss and take a formal vote on a new resolution regarding PrEP implementation in STD clinics. CHAC agreed with her suggestion to form a new short-term workgroup with one charge to address a series of concrete, targeted questions.

Action Step	Establish a new short-term PrEP Workgroup
Workgroup Membership	Dr. Jennifer Kates, Dr. Virginia Caine Mr. Guillermo Chacon Dr. Kathleen Clanon (Temporary Lead)

Workgroup Charge	Mr. Michael Kaplan Ms. Amy Leonard
	Draft a resolution in response to specific questions: • Are STD clinics the most appropriate, useful or effective setting to deliver PrEP? • Should CDC update the *2014 STD Treatment Guidelines* with a risk profile for PrEP candidates? • What is the role of electronic medical decision support in defining and identifying PrEP candidates? • What guidance should CHAC provide to CDC and HRSA regarding PrEP financing and reimbursement?

Topic 8: Agenda Items

Dr. Clanon 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**
Guest Speakers	Overview by health departments with low, medium and high HIV incidence that made presentations during the HIV testing trends meeting in Washington, DC
CHAC Membership	Formal vote on the resolution to recognize the 25th anniversary of the Ryan White Care Act (interim teleconference before November 2015)
CDC and HRSA	Update on high-impact prevention activities
CHAC Membership	Formal vote on the resolution to support CDC's request for a $31 million increase in the DVH budget (interim teleconference before November 2015)
CHAC Membership	Formal vote on the resolution by the new PrEP Workgroup
HRSA (Laura Cheever)	Overview of key findings from the two technical expert panels that HAB will convene on women and youth living with HIV

Closing Session

The next CHAC meeting would be HRSA-focused and convened as a webinar on November 4-5 or 18-19, 2015. HRSA will poll the CHAC members via e-mail to determine their availability.

With no further discussion or business brought before CHAC, Dr. Clanon adjourned the meeting at 5:05 p.m. on May 20, 2015.

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

_____ _____

Date

Kathleen Clanon, MD, Co-Chair
CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

_____ _____

Date

Dawn Fukuda, ScM, Co-Chair
CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

ATTACHMENT 1: *Participants' Directory*

CHAC Members Present

Dr. Kathleen Clanon, Co-Chair
Ms. Dawn Fukuda, Co-Chair
Dr. Sanjeev Arora
Dr. Virginia Caine
Mr. Guillermo Chacon
Dr. Carlos del Rio
Dr. Camilla Graham
Ms. Debra Hauser
Dr. Marjorie Hill
Dr. Steven Johnson
Mr. Michael Kaplan
Dr. Jennifer Kates
Ms. Amy Leonard
Dr. Britt Rios-Ellis

CHAC Members Absent

Dr. Bruce Agins
Ms. Angelique Croasdale

CHAC *Ex-Officio* Members Present

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

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

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. Chana Rabiner
(Alternate for 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. Elinore McCance-Katz
Substance Abuse and Mental Health Services Administration

Ms. Lisa Neel
Indian Health Service

CHAC Liaison Representative

Dr. Mildred Williamson
Presidential Advisory Council on HIV/AIDS

CHAC Designated Federal Officers

Dr. Laura Cheever
HRSA/HAB Associate Administrator

Dr. Jonathan Mermin
CDC/NCHHSTP Director

Federal Agency Representatives

Dr. Lisa Barrios
Dr. Kyle Bernstein
Dr. Gail Bolan
Dr. John Brooks
Dr. Chris Cagle
Dr. Hazel Dean
Ms. Antigone Dempsey
Ms. Teresa Durden
Dr. Thomas Gift
Ms. Shelley Gordon
Dr. Matthew Hogben
Dr. Jill Huppert
Mr. David Johnson
Mr. Dan Lentine
Ms. Jennifer Ludovic
Dr. Mary McFarlane
Mr. John Milberg
Dr. John Moore
Mr. Kevin O'Connor
Ms. Lydia Poromon
Dr. David Purcell
Ms. Angel Ortiz Ricard
Dr. Raul Romaguera
Ms. Margie Scott-Cseh
Dr. Eyasu Teshale
Dr. John Ward
Dr. Richard Wolitski
Dr. Claudia Vellozzi
Dr. Stephanie Zaza

Members of the Public

Dr. Chanza Baytop
Abt Associates

Mr. Daniel Church
Massachusetts Department of Public Health

Dr. Stephanie Cohen
San Francisco Department of Public Health

Dr. Julie Dombrowski
University of Washington; Public Health-Seattle and King County STD Clinic

Mr. Kenyon Farrow
Treatment Action Group

Dr. Cynthia Klein
Abt Associates

Dr. Tarek Mikati
New York City Department of Health and Mental Hygiene

Mr. Carl Schmid
The AIDS Institute

Ms. Patricia Shifflett
Abt Associates

Mr. William Smith
National Coalition of STD Directors

Ms. Gretchen Weiss
National Association of County and City Health Officials

ATTACHMENT 2: *Glossary of Acronyms*

3HP	Three-Month, Once-Weekly Isoniazid/Rifapentine Regimen
AASLD	American Association for the Study of Liver Diseases
ACA	Affordable Care Act
AETC	AIDS Education and Training Center
BMSM	Black Men Who Have Sex With Men
CBA	Capacity Building Assistance
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CDPH	Chicago Department of Public Health
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CMS	Centers for Medicare and Medicaid Services
CoAgs	Cooperative Agreements
DASH	Division of Adolescent and School Health
DHAP	Division of HIV/AIDS Prevention
DIS	Disease Intervention Specialists/Services
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
EDs	Emergency Departments
FOAs	Funding Opportunity Announcements
FPL	Federal Poverty Level
FQHC	Federally Qualified Health Center
HAB	HIV/AIDS Bureau
HBHC	Howard Brown Health Center
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	Injection Drug Use
INH	Isoniazid
LVSC	Lakeview Specialty Clinic
MAVEN	Massachusetts Virtual Epidemiologic Network
MDPH	Massachusetts Department of Public Health
MMWR	*Morbidity and Mortality Weekly Report*
MSM	Men Who Have Sex With Men
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NHAS	National HIV/AIDS Strategy
NHBS	National HIV Behavioral Surveillance
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
nPEP	Non-Occupational Post-Exposure Prophylaxis
NPIN	National Prevention Information Network
NYC	New York City
OAMC	Outpatient Ambulatory Medical Care
OHA	Office of HIV/AIDS
OPANA® ER	Extended-Release Oxymorphone
PACHA	Presidential Advisory Council on HIV/AIDS
PEP	Post-Exposure Prophylaxis
PLWH; PLWHA	Persons Living with HIV; Persons Living with HIV/AIDS
PPIO	Program and Performance Improvement Office
PrEP	Pre-Exposure Prophylaxis
PTCs	Prevention Training Centers
PWID	Persons Who Inject Drugs
RCTs	Randomized Controlled Trials
RSR	Ryan White Service Report
RWCA	Ryan White CARE Act
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SEPs	Syringe Exchange Programs
SES	Socioeconomic Status
SFCC	San Francisco City Clinic
SKC	Seattle and King County
SPNS	Special Projects of National Significance
TA	Technical Assistance
USCA	U.S. Conference on AIDS
USPSTF	U.S. Preventive Services Task Force