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
June 14-15, 2016
Atlanta, Georgia

DRAFT Record of the Proceedings

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DRAFT 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 June 14-15, 2016 at the CDC Corporate Square Campus, Building 8, Conference Room A/B/C, in Atlanta, Georgia.

CHAC is a committee that is chartered under the Federal Advisory Committee Act (FACA) 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 FACA rules and regulations. All sessions of the meeting were open to the public (*Attachment 1: Participants' Directory*).

Opening Session: June 14, 2016

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
Bruce Agins, MD, MPH (New York State Department of Health)	Recipient of federal funding from CDC; recipient of federal funding from HRSA for the Ryan White HIV/ AIDS Program (RWHAP) and a Special Projects of National Significance (SPNS) grant; partner on Project ECHO
Richard Aleshire, MSW, ACSW	Recipient of federal funding from HRSA for RWHAP Part B
Sanjeev Arora, MD, FACP (University of New Mexico Health Sciences Center)	Recipient of federal funding from CDC to focus on hepatitis C virus (HCV) elimination in the country of Georgia; recipient of federal funding from multiple agencies to support Project ECHO; recipient of funding to develop new HCV drugs in clinical trials
Peter Byrd (Peer Educator and Advocate)	No conflicts disclosed
Virginia Caine, MD (Marion County, Indianapolis Public Health Department)	Recipient of federal funding from HRSA for RWHAP Parts A, B and C
Guillermo Chacon (Latino Commission on AIDS)	Recipient of federal funding from CDC for prevention and capacity building activities; recipient of federal funding from HRSA for RWHAP Part A; member of several boards and other advisory committees

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Angelique Croasdale, MA, AND (City of Hartford Department of Health and Human Services)	Recipient of federal funding from HRSA for RWHAP Part A; recipient of federal funding from the U.S. Department of Housing and Urban Development (HUD) for a Housing Opportunities for Persons with AIDS (HOPWA) data integration grant
Carlos del Rio, MD (Rollins School of Public Health Emory University)	Recipient of federal funding from HRSA for a Ryan White Part A Clinic; recipient of federal funding from CDC to conduct research on antimicrobial resistance in gonorrhea
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Recipient of federal funding from HRSA for RWHAP Part B and a SPNS grant; recipient of federal funding from CDC; recipient of federal funding from HUD for a HOPWA grant
Peter Havens, MD, MS (Children's Hospital of Wisconsin)	Recipient of federal funding from HRSA for RWHAP Parts B and D
Jennifer Kates, PhD (Kaiser Family Foundation)	No conflicts disclosed
Amy Leonard, MPH (Legacy Community Health Services)	Recipient of federal funding from CDC for HIV prevention activities; recipient of federal funding from HRSA for RWHAP Parts A, B and C
Jorge Mera, MD[1] (Cherokee Nation Hastings Hospital)	Recipient of federal funding from the Indian Health Service; recipient of federal funding from HRSA for an AIDS Education and Training Center (AETC); recipient of academic funding from Oklahoma University; former member of a Gilead Sciences Advisory Board
Susan Philip, MD, MPH (San Francisco Department of Public Health)	Recipient of federal funding from HRSA for RWHAP Part A; recipient of federal funding from CDC for HIV, STD and viral hepatitis activities
Linda Scruggs, MHS (Ribbon Consulting Group)	No conflicts disclosed

[1]Dr. Mera was absent on day 1 of the meeting, but he disclosed his conflicts during the day 2 roll call.

Dr. Mermin confirmed that the 19 voting members and *ex-officio* members (or their alternates) in attendance constituted a quorum for CHAC to conduct its business on June 14, 2016. He called the proceedings to order at 8:35 a.m. and welcomed the participants to the CHAC meeting.

Dr. Mermin made several announcements regarding changes to CHAC's membership in terms of CDC appointees.

- Mr. Michael Kaplan resigned from CHAC on May 2, 2016 to take a new position with the Melanoma Research Alliance.
- Draft nomination packets were submitted to the CDC Committee Management Office on May 24, 2016 to replace Mr. Kaplan and three CHAC members whose terms will expire on November 30, 2016: Dr. Sanjeev Arora, Dr. Virginia Caine and Mr. Guillermo Chacon.
- The participants were asked to welcome two new CDC-appointed CHAC members to their first meeting. Their biographical sketches were included in the meeting packets.
    - Jorge Mera, MD; Director of Infectious Diseases, Cherokee Nation Hastings Hospital
    - Susan Philip, MD, MPH; Director of the Disease Control and Prevention Branch, Population Health Division, San Francisco Department of Public Health

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

Dr. Cheever also extended her welcome to the participants. She made several announcements regarding changes to CHAC's membership in terms of HRSA appointees.

- The participants were asked to welcome three new HRSA-appointed CHAC members to their first meeting. Their biographical sketches were included in the meeting packets.
    - Richard Aleshire, MSW, ACSW; HIV Client Services Program Manager, Washington State Department of Health
    - Peter Havens, MD, MS, FAAP; Associate Director, Pediatric Intensive Care Unit, Children's Hospital of Wisconsin
    - Linda Scruggs, MHS; Director, Ribbon Consulting Group
- The terms of four CHAC members are scheduled to expire on June 30, 2016: Dr. Bruce Agins, Ms. Angelique Croasdale, Dr. Carlos del Rio and Dr. Jennifer Kates. However, the outgoing members agreed to continue to serve for an additional six months through December 30, 2016 to allow HRSA sufficient time to recruit their replacements. The outgoing members were presented with certificates of appreciation. Dr. Agins attended the meeting remotely and would receive his certificate in the mail. The participants joined Dr. Cheever in applauding the four outgoing members for their outstanding contributions during their tenures on CHAC.

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

Ms. Fukuda asked the participants to join her in welcoming Mr. Peter Byrd to his first in-person meeting as the new CHAC Co-Chair. She also asked the participants to observe a moment of silence to recognize the tragic loss to the lesbian/gay/bisexual/transgender (LGBT) community and the entire American public due to the recent mass shooting in Orlando, Florida.

CDC/NCHHSTP Director's Report

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

Dr. Mermin covered the following topics in his Director's report to CHAC. At the agency level, CDC is continuing to provide leadership for the Zika outbreak response. At this time, 48 countries worldwide are reporting active Zika virus transmission, including 39 countries and territories in the Americas. The complexity of the Zika outbreak response is unprecedented due to the involvement of multiple CDC centers, the need for a broad range of expertise, and an enormous amount of unknown scientific and public health questions.

Several activities are underway or have been completed at CDC to support the Zika outbreak response. The Emergency Operations Center was activated to level 1. On-the-ground support, including education on Zika to healthcare providers (HCPs) and the public, is continuing to be provided to affected areas as new science is developed and new preventive measures are implemented. Travel notices and other travel-related guidance were posted. Diagnostic testing kits were provided to laboratories. Zika prevention kits were created and distributed to affected U.S. territories. A study is being conducted to evaluate the persistence of Zika virus in semen and urine of male residents in the United States due to several documented cases of sexual transmission.

CDC released its "2015 Prevention Status Reports" for all 50 states and the District of Columbia. The reports cover 10 health topics, including HIV, and also provide information on the status of policies that states can use to reduce HIV infection and improve health outcomes for persons living with HIV (PLWH). The information provided to states includes CD4 count and viral load reporting, viral suppression and HIV testing. The reports are used to rank the performance of states in the 10 health topics.

CDC was given responsibility at the federal level to address the opioid epidemic in the United States. CDC will conduct three major activities in its new charge: (1) improve data quality and track trends; (2) strengthen state efforts by scaling up effective public health interventions; and (3) supply HCPs with resources to improve patient safety. In the FY2016 budget, the CDC National Center for Injury Prevention and Control received $70 million to support state overdose prevention programs and ~$5.6 million to improve data collection on illicit opioid overdose deaths. The FY2017 budget proposes an additional $10 million increase to CDC for continued support of state overdose prevention programs.

At the National Center level, NCHHSTP requested $1.13 billion in the proposed FY2017 budget. The request reflects the FY2016 enacted budget for HIV, STD, TB and school health prevention programs and a $5 million increase for viral hepatitis. However, the FY2017 Senate mark that recently was released called for $5 million decreases for both STD and TB and rejected the request for the $5 million increase for viral hepatitis.

Several changes have occurred in NCHHSTP's leadership over the past six months, including the retirement of Ms. Eva Margolies (Associate Director for Program Planning and Policy Coordination) in December 2015 and the upcoming retirement of Dr. Stephanie Zaza (Director of the Division of Adolescent and School Health) in July 2016. Dr. Richard Wolitski was detailed to HHS and is serving as the Acting Director of the Office of HIV/AIDS and Infectious Disease Policy. Dr. Amy Lansky is detailed as the Acting Director of the Office of National AIDS Policy. NCHHSTP also filled a number of key leadership positions: Dr. Michele Owen (Associate Director for Laboratory Science); Dr. Brian Edlin (Chief Medical Officer); and Ms. Sara Zeigler (Associate Director for Planning and Policy).

In April 2016, NCHHSTP released *Program Guidance for Implementing Certain Components of Syringe Services Programs (SSPs), 2016* after HHS released its guidance for jurisdictions to document the need for an SSP based on their actual or potential risk for HIV or HCV outbreaks. In December 2015, Congress provided states and local communities with the option to use federal funds to support certain SSP components, such as staff, supplies, HIV or HCV testing kits and Naloxone. However, the use of federal funds to purchase sterile needles or syringes to inject illegal drugs is still prohibited. CDC is responsible for evaluating applications submitted by state, local or tribal health departments and determining whether their jurisdictions would be eligible to use federal funds for SSP components based on specific local data and evidence.

NCHHSTP recently published a paper on its vulnerability index model that was designed to identify counties in the United States that are at increased risk for an HIV or HCV outbreak among persons who inject drugs (PWID). Most of the at-risk counties identified in the model were in suburban and rural areas, particularly in the Appalachian region. NCHHSTP distributed the paper to all state and local health departments and is closely collaborating with states to identify and respond to a potential outbreak.

NCHHSTP released a beta version of its HIV risk reduction tool. The user-friendly tool provides diverse audiences with structured content to estimate individual risk and HIV prevention messages regarding antiretroviral therapy (ART) and pre-exposure prophylaxis (PrEP).

At the division level, the Division of HIV/AIDS Prevention (DHAP) convened an external peer review panel in March 2016 to obtain advice in three major areas: (1) the use of state and local program data for program monitoring, evaluation and improvement; (2) the use of individual-level surveillance data for improving HIV care outcomes; and (3) the use of molecular surveillance data to maximize HIV prevention efforts by identifying and rapidly responding to HIV outbreaks.

DHAP released *Updated Guidelines for Antiretroviral Post-Exposure Prophylaxis After Sexual Injection Drug Use or Other Non-Occupational Exposure to HIV*. The updated guidelines expand on CDC's 2005 recommendations for medical practitioners. DHAP will hold webinars on the updated guidelines later in 2016 for health departments, HCPs and community-based organizations (CBOs).

The Division of Adolescent and School Health (DASH) recently published "Youth Risk Behavior Surveillance (YRBS)—United States, 2015" in the *Morbidity and Mortality Weekly Report* (*MMWR*). YRBS data showed that many high school students are at increased risk for the leading causes of morbidity and mortality due to certain behaviors: using e-cigarettes (24%), using prescription drugs without a physician's prescription (17%), and texting or emailing while driving in the past 30 days (43%). However, DASH was pleased to report that the prevalence of cigarette use among youth is at its lowest level since the YRBS was initiated in 1991.

DASH compiled YRBS data on HIV risk indicators among youth over the past 25 years. Significant linear decreases were observed in the percentage of high school students who reported HIV-related behaviors from 1991-2015: ever had sexual intercourse, had sexual intercourse with ≥4 persons, and currently sexually active. However, a significant linear decrease also was observed from 2003-2015 among sexually active students who reported using a condom at last sexual intercourse.

DASH recently released two key publications: *Health Education Curriculum Analysis Tool: A Guide for Health Education Teacher Preparation Programs in Institutions of Higher Education* and *Anti-Bullying Policies and Enumeration: An Infobrief for Local Education Agencies*.

The Division of Viral Hepatitis (DVH) recently released the *Annual Report to the Nation on the Status of Cancer, 1975-2012*. The report was published in March 2016 and showed a rapid increase of 72% in the incidence of liver cancer from 2003-2012. Other CDC data have indicated that HCV causes more deaths than all other reportable diseases combined.

DVH released the *2014 Viral Hepatitis Surveillance Report* that showed relative stability in acute hepatitis B virus (HBV) cases, but a dramatic increase in new acute HCV cases from 850 cases in 2010 to 2,194 cases in 2014. Young PWID in rural and suburban areas are the major

contributors to the increase. Current estimates show that ~3.5 million persons are living with chronic HCV in the United States. However, CDC acknowledges that the actual number of acute HCV cases is underreported due to limitations in the current viral hepatitis surveillance system.

DVH deployed its Global Hepatitis Outbreak and Surveillance Technology (GHOST) system in May 2016. The creative software system allows health departments to submit genetic information for rapid identification of viral strains to detect and respond to outbreaks.

The Division of STD Prevention (DSTDP) collected surveillance data that showed increases in reported STD cases from 2013-2014: chlamydia (2.8%), gonorrhea (5.1%), primary and secondary (P&S) syphilis (15.1%), and congenital syphilis (27.5%). The data showed that other than syphilis, increases in STD cases have not been reported since 2006. Young persons and gay/bisexual men were found to be at greatest risk.

DSTDP published a special supplement in the *Journal of Sexually Transmitted Diseases*, "Effective Interventions to Reduce Sexually Transmitted Diseases." The comprehensive supplement includes three overview articles and nine feature articles on a range of STD interventions that will assist programs in selecting the best interventions for their specific needs.

DSTDP will host the 2016 STD Prevention Conference on September 20-23, 2016 in Atlanta. The theme of the conference is "Transcending Barriers: Creating Opportunities." The deadline to submit late-breaker abstracts has been extended to July 1, 2016. Registration for the conference is available on the conference website.

HRSA/HAB Associate Administrator's Report

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

Dr. Cheever covered the following topics in her Associate Administrator's report to CHAC. RWHAP is designed to take a public health approach to provide a comprehensive system of care for all and ensure low-income PLWH receive optimal care and treatment. RWHAP achieves these goals with a five-part framework: service delivery, support for care and treatment policies at both federal and local levels, needs assessments, capacity development and quality improvement.

HAB recently posted the RWHAP Annual Client-Level Data Report on its website with 2010-2014 Ryan White Services Report (RSR) data. By total population, 512,214 persons received at least one RWHAP-funded service in 2014. Of these clients, 96% were PLWH. RHWAP served 48.9%

of all persons in the country with an HIV diagnosis. Racial/ethnic minorities accounted for nearly 75% of RWHAP clients.

By age, PLWH in the 45-54 age group continue to account for the majority of RWHAP clients, while increases were reported in the number of RWHAP clients in the 55-64 and ≥65 age groups from 2010-2014. Because PLWH are living longer, HAB is now focusing on co-morbidities in this older population. By gender, men account for 70.6% of RWHAP clients. By race/ethnicity, African Americans account for 47.2% of RWHAP clients.

By healthcare coverage source, Medicaid covers 33.4% of RWHAP clients, while 25.4% of RWHAP clients are uninsured. Other sources of healthcare coverage among RWHAP clients include Medicare, private employers, private insurance and other plans. By Federal Poverty Level (FPL), the percentage of the total RWHAP population at ≤100 FPL is 64.2%, but the rates are significantly different by gender: 60.7% among males, 72.5% among females, and 79.5% among transgenders.

By health outcomes, retention in care rates among RWHAP clients have remained relatively stable from 82.2% in 2010 to 80.4% in 2014. Viral load suppression rates among RWHAP clients increased from 69.5% in 2010 to 81.4% in 2014. Disparities have persisted in these health outcomes by age, housing status, race/ethnicity and geographic location. The lowest retention in care rates are among RWHAP clients in the 20-24 and 25-29 age groups and those with unstable housing. The highest retention in care rates are among the youngest RWHAP clients in the <13 and 13-14 age groups and the oldest RWHAP clients in the 60-64 and ≥65 age groups.

The lowest viral load suppression rates are among RWHAP clients in the 15-19 and 20-24 age groups, those with unstable housing and transgenders. The highest retention in care rates are among older RWHAP clients in the 55-69, 60-64 and ≥65 age groups as well as Asian and white RWHAP clients. By geographic location, Southern states account for the lowest viral load suppression rates, while low-incidence states account for the highest rates. HAB acknowledges tremendous differences between the RSR dataset and CDC's HIV Care Continuum dataset because its retention in care and viral load suppression denominators are based on RWHAP clients who have presented for care at least once.

HAB will achieve its 2016 priorities through several completed, ongoing and future activities.

Priority 1: Continue to integrate RWHAP with the new healthcare landscape

- RWHAP capacity will be enhanced to engage PLWH in healthcare access. New and existing tools and technical assistance (TA) will be developed and updated for grantees/ providers to enroll PLWH in expanded health insurance plans. The health literacy of grantees/providers and clients will be strengthened to improve their access to and use of the healthcare system.

- The impact of expanded healthcare coverage on RWHAP health outcomes in the context of the Affordable Care Act (ACA) will be analyzed.
- Health economics questions related to the implementation of RWHAP will be addressed. A mathematical model will be created to estimate the cost-effectiveness of RWHAP. Eligible PLWH will be enrolled in expanded health insurance options that are available through Health Insurance Marketplaces.
- RWHAP providers who deliver core medical services will be trained to engage and contract with qualified Health Insurance Marketplace plans. Efforts to enroll clients into health plans will be facilitated as appropriate.
- The Affordable Care Enrollment Technical Assistance Center will be used to strengthen the capacity of RWHAP grantees in providing outreach to and enrolling clients in healthcare coverage, particularly persons of color.
- AIDS Service Organization (ASO) service models will be used to train non-medical ASOs to develop business plans for service delivery to vulnerable populations. Health outcomes will be improved across the HIV Care Continuum.
- Ongoing SPNS Initiatives will continue to be implemented to focus on the integration of RWHAP in the new healthcare landscape: "System-Level Workforce Capacity Building for Integrating HIV Primary Care in Community Healthcare Settings" (August 2014-July 2018) and "Health Information Technology Capacity Building for Monitoring and Improving Health Outcomes Along the HIV Care Continuum Initiative" (September 2014-August 2017).

Priority 2: Implement the updated 2020 National HIV/AIDS Strategy (NHAS) with a specific focus on health disparities and the HIV Care Continuum

- The Secretary Minority AIDS Initiative Fund (SMAIF) will be awarded to increase the use of community health workers (CHWs) to improve access, linkage to and retention in care, particularly among persons of color. CHWs also will be used to strengthen the overall healthcare workforce.
- TA will be provided to RWHAP Part A grantees to strengthen and improve the HIV Care Continuum and affect positive outcomes. The grantees will apply data-driven, evidence-based interventions (EBIs) to enhance health outcomes. The interventions will be scaled up by stimulating action across jurisdictions and partners.
- EBIs along the HIV Care Continuum will be disseminated. RWHAP clinics will be awarded funds to replicate and implement four SPNS Initiatives that have generated proven interventions. These interventions include integrating buprenorphine into primary care in RWHAP clinics; strengthening linkages to and interactions with jails; outreaching to out-of-care PLWH; and reengaging and retaining PLWH in care. AETCs will disseminate models of care and effective practices to RWHAP clinics, Community Health Centers (CHCs), Rural Health Clinics and other primary care sites that manage PLWH.
- Ongoing SPNS Initiatives will continue to be implemented to support the 2020 NHAS: "Culturally Appropriate Interventions of Outreach, Access and Retention Among Latino Populations" (September 2013-August 2018); "Enhancing Engagement and Retention in

Quality HIV Care for Transgender Women of Color Initiative" (September 2012-August 2017; and "Building a Medical Home for Multiply Diagnosed HIV-Positive Homeless Populations" (September 2012-August 2017).

- A consultation on pediatric care will be convened to achieve three major goals: (1) identify assets and existing models of quality pediatric HIV care in specific environments; (2) identify gaps and social determinants of health that affect pregnant women and infants born with HIV; and (3) identify actions for HAB and its federal partners to address existing challenges.
- An ongoing SPNS Initiative, "Use of Social Media to Improve Engagement, Retention and Health Outcomes Along the HIV Care Continuum," will continue to be implemented. The findings from this initiative will be evaluated and disseminated to develop innovative methods to identify, link and retain HIV-positive youth and young adults in care and improve their health outcomes. SPNS Initiatives and AETCs will be used to ensure coordination of HIV training and education to targeted youth and young adults who receive linkage to and retention in care information via social media. The National Evaluation Center will be used to evaluate these social media activities.
- The "Building Futures" contract will be used to support youth living with HIV. The current state of HIV-infected youth 13-24 years of age who receive RWHAP-funded care and treatment will be assessed to better understand current gaps and barriers to care in this population.
- The Center for Engaging Black Men Who Have Sex with Men (MSM) Across the Care Continuum (CEBACC) will continue to be funded to produce solid EBIs or evidence-informed practices for this population. CEBACC's notable achievements to date include developing an inventory of HIV prevention and care models and other resources for black MSM; providing continuing medical and nursing education training courses; creating and disseminating the *HIS Health* training series; and launching the "Well Versed" website for patients and providers.

Priority 3: Augment partnerships

- A strategic plan will be developed to identify and engage HAB's most important partners in other HHS agencies. Most notably, the Substance Abuse and Mental Health Services Administration (SAMHSA) is closely collaborating with HAB to better respond to the opioid epidemic. HAB and CDC released an integrated HIV prevention and care plan in June 2015 that included coordinated guidance to all states on statement of need. HAB and CDC also collaborated in 2015 to provide TA to RWHAP Parts A and B grantees and planning bodies to support activities and strategies for integrated HIV planning across prevention, care and treatment.
- The SMAIF will continue to be awarded to enhance partnerships with RWHAP grantees on several projects.
    - "Building Care and Prevention Capacity: Addressing the HIV Care Continuum in Southern Metropolitan Areas and States" is a project that will provide TA and training to assist Southern jurisdictions in this effort.

- "Jurisdictional Public Health Approach to HCV Diagnosis and Treatment of Co-Infected Persons of Color" is a project that will enhance the infrastructure and capacity of RWHAP Parts A and B grantees to expand HCV testing and treatment. The major objectives of the project are to promote education to providers and patients, offer TA, and make structural improvements to increase access to care and treatment. Recent RSR data estimate that ~100,000 RWHAP clients have HIV/HCV co-infection. HAB's ultimate goal is to allocate the SMAIF and other resources to cure HCV in 100% of RWHAP clients with HIV/HCV co-infection.
- "Partnerships 4 Care" (P4C) is a project that promotes collaboration among the HRSA Bureau of Primary Health Care (BPHC), CHCs, CDC, RWHAP clinics and state health departments to increase capacity for HIV testing, treatment and care.

Priority 4: Advance data utilization to improve health outcomes

- New reports on each eligible metropolitan area and transitional grant area recently were released based on 2014 RSR data.
- A resource allocation tool will be developed to enhance the ability of all RHWAP grantees to prioritize services to maximize clinical outcomes. A mathematical model of the optimal combination of RWHAP services will be created to effectively advance clients through the HIV Care Continuum.
- The RWHAP Annual Client-Level Data (CLD) Report is the first annual publication of national RWHAP CLD collected from the RSR dataset. Efforts will be made in 2016 to expand the availability of and access to RWHAP CLD. The current CLD report includes 2010-2014 RSR data and is now available on the HAB website. The key features of the CLD report include program monitoring and evaluation data; data that are aligned with the updated 2020 NHAS; more mature RSR data for broader use; and health outcome data on the largest cohort of transgenders living with HIV in the United States.
- A retention in care consultation will be convened in June 2016 to assess federal guidelines on the frequency of HIV medical visits. The meeting also will be used as an opportunity to propose revisions to current retention in care performance measures and suggest other factors that should be considered, such as age.
- The SMAIF will be awarded to support a data-driven project, "HIV Care and Housing: Using Data Integration to Improve Health Outcomes Along the HIV Care Continuum." The project will be designed to use information technology to promote integration and coordination of HIV and housing services. A Coordination and Technical Assistance Center will support four demonstration sites to pilot service integration. As a companion activity, a SPNS Initiative will be implemented to improve entry, engagement and retention in care for HIV-positive homeless persons and unstably housed PLWH with mental illness and substance abuse disorders.

Priority 5: Enhance national and international leadership

- The 2016 National Ryan White Conference on HIV Care and Treatment will be held in Washington, DC on August 23-26, 2016. The theme of the conference will be "Forward Momentum: Accelerating Access, Optimizing Care, Transforming Public Health." To date, 2,000 individuals have registered for the conference.
- Global health systems will be strengthened in response to a direct request by the President's Emergency Plan for AIDS Relief (PEPFAR). To support this effort, HAB staff will be deployed to Liberia, Sierra Leone, Democratic Republic of the Congo and South Sudan. HAB will enhance its in-country collaborations with CDC, PEPFAR coordinators and the U.S. Agency for International Development.
- The SMAIF will be awarded to provide training to strengthen the leadership of PLWH in RWHAP, including transgender women of color. Tools will be developed to assist PLWH in participating on planning bodies, care teams, organizations and boards of directors.
- A PLWH leadership consultation was held to achieve three major goals: (1) identify existing strategies that promote public leadership of PLWH; (2) address gaps and barriers to public leadership development of PLWH; and (3) explore strategies to close these gaps.

HRSA's FY2016 Congressional appropriation for RWHAP of ~$2.32 billion included a $4 million increase for Part C grantees to conduct World AIDS Day activities. The Part C budget is now ~$205 million and the other RWHAP parts received relatively stable funding. Part B funding for the AIDS Drug Assistance Program (ADAP) still accounts for 57% of the total RWHAP budget (or ~$900 million).

HAB issued a series of policy clarification notices to address the following issues: clinical quality management, clarifications regarding RWHAP and program income, clarification of the RWHAP policy on services provided to veterans, and RWHAP-eligible persons and allowable uses of funds.

HAB has filled several leadership positions over the past six months: Ms. Heather Hauck (HAB Deputy Associate Administrator); Mr. Michael Goldrosen (Director, Division of State HIV/AIDS Programs); and Dr. Mahyar Mofidi (Director, Division of Community HIV/AIDS Programs).

CHAC DISCUSSION: CDC AND HRSA UPDATES

CHAC discussed the following topics during the question/answer session with Drs. Mermin and Cheever.

- The rationale for the FY2017 Senate mark that called for a $5 million decrease in the STD budget, particularly since the incidence of STDs has markedly increased.
- CDC's rationale for not developing and releasing 2015 Prevention Status Reports for Puerto Rico and the U.S. Virgin Islands.
- The need for communities to activate and deploy their networks to local areas that will be heavily impacted by the Zika virus in the summer of 2016.

- Specific populations that CDC and HRSA should emphasize in HIV prevention and care/ treatment to allocate limited resources in the most efficient and effective manner.
- Coordinated funding opportunities by CDC and HRSA at the federal level (e.g., joint funding opportunity announcements (FOAs) and interagency support) that could be used to encourage states and localities to take a coordinated approach to improve linkage to and retention in care for PLWH.
- Potential reasons for relatively stable retention in care rates versus increased viral load suppression rates (e.g., the provision of more ART prescriptions or variations between clinical and laboratory measures).
- Actions that should be taken at this time to prepare for the smaller pool of graduate students who will apply for infectious disease fellowships and the smaller number of primary care providers (PCPs) who will have expertise in HIV care in the near future.
- HAB's stronger focus on and outreach to two important populations: the broader group of never-in-care PLWH and potential reasons 20% of RWHAP clients discontinue care each year (e.g., a new provider or health insurance coverage, relocation to a different state, incarceration or catastrophic personal issues).
- HAB's ability to monitor health outcomes of PLWH in jurisdictions with limited access to care, such as rural or Southern counties without hospitals, HIV care providers or RWHAP clinics.
- HAB's ongoing study to identify the best models of care to address co-morbidities in the aging PLWH population.
- HAB's approaches to integrate RWHAP into HIV elimination goals and HIV/AIDS healthcare transformation initiatives that New York City and other jurisdictions or states are conducting through leadership and political will.
- HAB's new study that will be designed to identify all necessary components to cure HCV in 100% of RWHAP clients with HIV/HCV co-infection.
- HAB's plans to engage youth peers to serve on care teams as well as to track and monitor retention in care and viral load suppression outcomes of young PLWH.
- HAB's plans to collaborate with SAMHSA to identify and address specific behavioral issues that serve as barriers to PLWH remaining in care over time.
- HAB's strategies to improve the healthcare experience for RWHAP clients by promoting a culture of quality, culturally-competent and welcoming care at both system and provider levels, such as the elimination of discrimination or stigma among RWHAP clinical staff and a simple process for PLWH to contact providers to fill their antiretroviral prescriptions.

The extensive discussion resulted in CHAC making several suggestions in response to the CDC and HRSA updates.

- CDC is to be commended on publishing its recent paper on U.S. counties that are most vulnerable to an HIV or HCV outbreak among PWID. CDC should rerun the analysis at

routine time intervals because local data are critically important in guiding prevention and response efforts in the field.

- HRSA should reconsider its 2016 priority to improve existing retention in care performance measures and identify other potential factors. Retention in care is a complex issue that is extremely difficult to measure. Efforts to collect data for this measure will continue to burden RWHAP grantees. HRSA should direct its focus to more important and meaningful viral load suppression performance measures. CDC's data-to-care activities would be beneficial in providing HRSA with individual-level longitudinal data on viral load suppression. However, the development of long-term performance measures to evaluate retention in care over time would be helpful.
- HRSA should create a model, assessment tool or criteria that would have the ability to predict specific indicators, characteristics or risks of in-care PLWH who are likely to discontinue care in the future. For example, young age would be an excellent predictor in the model. Based on RSR data, RWHAP clients <24 years of age have the highest risk of discontinuing care. CDC should develop a similar assessment tool for prevention that would predict specific factors in newly-diagnosed persons who are not likely to be linked to care in the field. Tailored interventions, individualized case management and other best practices could then be applied to ensure linkage to and retention in care for vulnerable, at-risk populations.
- CHAC should draft resolutions during the Business Session to address HIV treatment and care issues.
    - CHAC should draft a resolution to the HHS Secretary to express its concern regarding plans by the Agency for Healthcare Research and Quality (AHRQ) to defund the HIV Research Network (HIVRN) in FY2016. This decision will result in a tremendous loss to the HIV care community. HIVRN is a valuable resource that collects, analyzes and disseminates timely and relevant data on the delivery of services and care to PLWH.
    - CHAC should go on record regarding the critical need to integrate substance abuse care into HIV care, particularly since substance abuse is a major contributor to low linkage to and retention in care rates for at least 50% of the PLWH population. Emory University recently published a paper that showed much higher linkage to care rates among patients who were enrolled in substance abuse care.
    - CHAC should go on record to emphasize the importance of continuing HIV research and supporting innovation to increase retention in care and viral load suppression rates in the subpopulation of complex, hard-to-reach HIV patients. Most notably, longer-acting antiretroviral drugs that currently are available still will not retain the subpopulation of HIV patients in care who oppose taking daily ART for the remainder of lives. Research to develop HIV drugs that would require an injection once every three or six months would have an enormous impact on increasing retention in care and viral load suppression rates in the subpopulation of complex HIV patients.

Dr. Cheever clarified that CHAC's suggestion to combine CDC and HRSA datasets to obtain individual-level longitudinal data on viral load suppression would not be possible because federal

agencies do not implement the same data collection methodologies. Most notably, RWHAP does not capture personally identified information. As a result, HRSA is continuing to award large grants and provide TA to jurisdictions to build their capacity in gathering these data. HRSA also is continuing its strong partnership with the Centers for Medicare & Medicaid Services (CMS) to collect Medicaid data from states and localities.

PANEL PRESENTATION: ADDRESSING SYPHILIS PREVENTION AND CONTROL IN THE UNITED STATES

A panel of speakers presented overviews of activities that are underway at federal, state and local levels to address syphilis prevention and control in the United States.

Overview of the 2016 Syphilis Summit

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

Advice Requested from CHAC by DSTDP:
1. Are the recommendations from the summit appropriate and specific?
2. What elements are missing from the recommendations?
3. Should CDC take any different actions?
4. Are the goals proposed for the Call to Action appropriate?
5. Should CDC develop a National Strategy instead of a Call to Action for syphilis?
6. What additional agencies, if any, should CDC engage in the development of a Call to Action or National Strategy?
7. Is the Call to Action relevant to state and local programs?
8. What strategies should CDC implement to solicit community input, e.g., webinars, listening sessions at relevant conferences, or events planned in coordination with state STD programs?

Dr. Bolan presented an overview of the 2016 Syphilis Summit. The landscape of STDs in the United States has tremendously changed over the past 25 years. The high rates of reported syphilis cases among men and women in 1990 dramatically declined and reached historically low levels in 2000. Since that time, however, syphilis cases among men and the male-to-female rate ratio have steadily increased.

CDC has been collecting data from 27 states on the gender of sex partners since 2007. MSM have accounted for the highest increase in syphilis cases since 2008, but increases also have been reported for men who only have sex with women (25%) and women (37%). By age and race/ethnicity, young black MSM have accounted for the majority of syphilis cases. The 50% HIV co-infection rate among black MSM in the 20-24 age group is much higher than rates for Hispanic and white MSM in the same age group. However, white MSM in the ≥50 age group have a much higher HIV co-infection rate than the same age group in other racial/ethnic categories.

CDC has been collecting data on adverse outcomes from syphilis due to increasing rates in adults. California and Washington reported 15 cases of ocular syphilis (OS) from December 2014-March 2015. CDC also received passive reports of >200 OS cases from 20 states from April-December 2015. HIV-negative persons, including heterosexual men and women, accounted for a few OS cases, but MSM with HIV co-infection accounted for the vast majority of cases. Several of the OS cases resulted in significant sequelae, including blindness. CDC distributed a clinical advisory on the OS outbreak in April 2015.

CDC conducted an Epi-Aids on 63 OS cases reported by North Carolina in 2014-2015. The OS cases represented a 1.5% prevalence of all 4,234 syphilis cases North Carolina reported over this time period. Males accounted for 94% of the OS cases. Of the 59 male OS cases, 71% reported male sex partners and 56% were HIV co-infected. Patients were identified throughout the state, but no OS patients were identified as sex partners. OS increased by 115% in North Carolina, but all other syphilis cases increased by only 35%. A comparison between OS patients and non-OS patients showed that the majority of OS patients were male, white, ≥40 years of age and HIV co-infected.

The steady rise in P&S syphilis rates among females since 2012 has led to a 27% increase in congenital syphilis (CS) rates. Most health departments have not invested resources in CS because these cases have not been reported for several decades. The number of syphilis cases reported among pregnant women has steadily increased since 2012 as well. CDC estimates that ~20% of pregnant women with syphilis will give birth to an infant with CS.

CDC collected information from case reports on the characteristics of 458 women in the United States in 2014 who gave birth to an infant with CS.

Characteristic		Number (N=458)	Percent
Did not receive prenatal care		100	21.8%
Received prenatal care	No treatment	135	29.5%
	Treated <30 days prior to delivery	78	17.0%
	Non-penicillin therapy	3	0.7%
	Inadequate regimen for stage of pregnancy	13	2.8%

Characteristic		Number (N=458)	Percent
Received prenatal care	Adequate treatment	43	9.4%
	Unknown treatment status	42	9.2%
Unknown prenatal care status		44	9.6%

CDC convened the 2016 Syphilis Summit on January 26-28, 2016 to address the increasing rates in adults and the adverse outcomes associated with syphilis. The multidisciplinary group of ~100 participants represented diverse sectors, including federal agencies, state/local health departments, academia and stakeholder organizations. The summit was organized into five units that were led by a CDC organizer and an external chair from a state/local health department or academia. Key findings and recommendations by the five units are summarized below.

Unit 1: Clinical Management, Diagnostics and Laboratory Issues, Immunology and Vaccines

ISSUES IDENTIFIED

- Laboratory syphilis diagnosis continues to rely on serologic tests rather than direct detection of *Treponema pallidum* (*T. pallidum*). Investments to modernize technologies have been minimal to date.
- Clinical decision-making during syphilis infection remains difficult because of sub-optimal diagnostics.
- Minimal effort has been targeted to vaccine development. Rabbit models are used with unclear comparability to human immunology.

RECOMMENDATIONS

- Develop sensitive molecular diagnostics for the detection of *T. pallidum* infection and patient infectiousness.
- Develop and disseminate guidance from CDC on syphilis serologic tests, including the use of quantitative tests to support clinical decision-making.
- Collect and make available well-characterized specimens with clinical data to facilitate better diagnostics development.
- Scale up syphilis vaccine development.

Unit 2: Heterosexual and Congenital Syphilis

ISSUES IDENTIFIED

- Female and CS rate increases during 2013-2015 were observed in every region and in almost every age and racial/ethnic group.
- The lack of prenatal care, limited timely treatment and co-occurring conditions are some of the factors associated with CS.
- Bridging between MSM and heterosexual networks could play a role in transmission.
- Heterogeneity in CS epidemics across program jurisdictions requires programmatic responses that are tailored to local epidemiology.

- CS is a life-threatening event that should be prioritized as a public health sentinel event. Missed opportunities in the healthcare and public health systems should be identified and addressed.

RECOMMENDATIONS

- Develop separate action plans for CS and MSM syphilis because goals and prevention strategies for these two populations are different.
- Link pregnant women with syphilis to the outcomes of their pregnancies. Document "successes" (e.g., number of CS cases averted) and create a more accurate cascade.
- Conduct cost-effectiveness evaluations of screening and other interventions.
- Provide guidance on prioritizing syphilis cases for case investigations, partner services and other program interventions.
- Provide guidance on a CS surveillance case definition and outbreak response plans.
- Create a renewed sense of urgency around pregnant women with syphilis.

Unit 3: Syphilis Among MSM

ISSUES IDENTIFIED

- The MSM population is quite heterogeneous and their sexual profiles longitudinally change over the lifespan.
- Behavioral interventions and partner services are not effective on a population-based level. The focus needs to be placed on policy and structural interventions, including healthy online communities and new sexual health approaches.
- Screening and timely treatment interventions are under-utilized.
- Condoms are still effective, but new types of condoms and social media approaches are needed to generate renewed interest. CDC's existing HIV/STD prevention messages around condom use are unclear.
- Victimization, social marginalization, homophobia and limited access to gay-friendly services continue to be problematic in many communities.

RECOMMENDATIONS

- Include sex practices and identify MSM on national surveys (e.g., Behavioral Risk Factor Surveillance System (BRFSS) and YRBS) to ensure this population is equitably represented.
- Promote data sharing across programs, including HIV and STD surveillance data, and link epidemiologic data with research funded by the National Institutes of Health. Include other data sources as well: ecological data, community norms, program evaluations, social determinants of health and online sites.
- Develop bold and innovative approaches to increase access to syphilis testing and treatment for MSM, such as new testing technologies (e.g., rapid syphilis tests and home-based tests). Assure the availability of these tests in a variety of settings.

- Build a more holistic, gay-friendly clinical infrastructure that specializes in the sexual health care of MSM and addresses social determinants.
- Identify new approaches to incorporate sexual health history and risk information (including screening and treatment recommendations) into electronic health records and clinical decision support systems. Link these data to public health surveillance.

Unit 4: Syphilis in Program Jurisdictions

ISSUES IDENTIFIED

- Separate, population-specific approaches to MSM and heterosexual syphilis prevention and control are needed due to differences between the two groups.
- The role of disease intervention specialists (DISs) is changing. DISs are not only conducting partner services, but also are involved in treatment verification, PrEP, linkage to care and other services. The DIS workforce is burdened and continually asked to undertake additional efforts with no clear guidance on prioritizing these activities.
- STD programs should consider strategies to leverage HIV goals for STD care, integrate STD and HIV agendas and goals, and advance toward the development of a sexual health framework.
- Better coordination is needed across specific components of local STD programs (e.g., linking field services, epidemiology, surveillance and laboratory) as well as within the greater scientific community (e.g., basic scientists, social scientists, epidemiologists and clinicians).

RECOMMENDATIONS

- Develop a population-specific approach to syphilis and target effective interventions that can be brought to scale.
- Develop practice standards for and demonstrate the cost-effectiveness of DIS partner services and linkage to care efforts that could be used to make a business case model on the need for DIS services.
- Integrate STD and HIV surveillance and field services with health departments to facilitate case reviews, linkage to care and treatment.
- Evaluate outcomes (e.g., number of cases and adverse health outcomes averted), assess the cost of current interventions, and prioritize existing funds.
- Examine existing partnerships and explore strategies to integrate syphilis prevention and care into existing prevention and care models, including HIV prevention and care, prenatal care, family planning, Federally Qualified Health Centers (FQHCs) and other settings.
- Develop the next generation of syphilis and STD experts.

Unit 5: Practical Considerations for Implementing a New Syphilis Action Plan

ISSUES IDENTIFIED

- Strategies that only focus on syphilis might not resonate with providers, communities affected by syphilis or partner organizations.

- Separate goals, strategies and partnerships should be established for each population. A primary prevention approach should be taken to address CS; syphilis and unplanned pregnancies in women of reproductive age; and screening and timely treatment of pregnant women with syphilis. A secondary prevention approach should be taken to address MSM syphilis with a focus on preventing adverse outcomes (e.g., OS and neurosyphilis) and supporting comprehensive healthcare systems to better serve the general MSM population.
- The operation of the public health infrastructure needs to shift. Greater analytic capacity is needed to more effectively use STD, HIV and other clinical data. More organizational integration is needed at the local level (e.g., STD and HIV surveillance and field services). More collaboration is needed between STD programs and healthcare systems to improve clinical preventive services for syphilis.

RECOMMENDATIONS

- Develop a new "Syphilis Call to Action" that is high-level, short, marketable, realistic and focused.
- Engage partners and local communities before the Call to Action is finalized.
- Ensure that the final Call to Action has strong support to help local programs use this product to galvanize their activities as appropriate for their local contexts.
- Prioritize partnerships and strategies for MSM syphilis with HIV. Prioritize partnerships and strategies for congenital/female syphilis with maternal and child health.
- Leverage other broader efforts that have more resources and share similar goals as a promising pathway for action.

Dr. Bolan announced that CDC's next steps will be to release the comprehensive report from the summit in its entirety. A *Call to Action: Priorities for Syphilis Prevention in the United States* will be developed. The action plan will be structured with three two-page goals: eliminate CS in the United States; prevent adverse outcomes of syphilis among MSM in the United States; and galvanize and invigorate research and development. A townhall discussion will be convened on September 20, 2016 during the STD Prevention Conference. The recommendations and findings from the summit will be used to produce a research agenda and publish a special supplement in the *Journal of Sexually Transmitted Diseases*.

A Local Perspective: Syphilis in Rhode Island

Thomas Bertrand, MPH, MA
Chief, Office of HIV/AIDS, Viral Hepatitis, STDs and Tuberculosis
Rhode Island Department of Health

Mr. Bertrand described Rhode Island's experiences and lessons learned in its ongoing syphilis prevention efforts among MSM. Rhode Island is the 43rd largest state in the country and has a population of slightly more than 1 million individuals. The state covers 37 cities and towns. The racial composition of Rhode Island includes whites (85.1%), African Americans (7.7%), Asians (2.9%), and American Indian/Alaska Natives (0.6%). The ethnicity of Rhode Island includes non-Hispanics (87.6%) and Hispanics (12.4%).

Rhode Island's national rankings include number 1 for the percentage of its MSM population (6%) and number 2 for its insurance coverage rate (97%). The Rhode Island Department of Health (RIDOH) serves as both a state and local health department. Funding for RIDOH's HIV, STD and viral hepatitis programs have decreased by 44% from 2011-2016.

RIDOH data showed a dramatic increase in the number of syphilis cases among gay/bisexual men from 14 cases in 2005 to 80 cases in 2014. Preliminary RIDOH data show that this trend is continuing based on 20 syphilis cases reported in the first quarter of 2015 versus 40 syphilis cases reported in the first quarter of 2016. The demographic breakdown of the 80 MSM syphilis cases RIDOH reported in 2014 is summarized below.

By Age
- MSM 20-29 years of age 34%
- MSM 30-39 years of age 30%
- MSM ≥40 years of age 26%

By Race/Ethnicity
- White MSM 73%
- Hispanic MSM 11%
- Black MSM 8%
- Other MSM 8%

By HIV Status
- HIV-negative MSM 67%
- HIV-positive MSM 33%

In addition to syphilis, RIDOH also is extremely concerned about its lack of progress in other sexual health issues among MSM. MSM in Rhode Island had the poorest HIV Care Continuum outcomes compared to all other populations in the state. The number of new HIV cases among gay/bisexual men has increased from 45 cases in 2005 to 56 cases in 2014. The number of new gonorrhea cases among gay/bisexual men has increased from 34 cases in 2006 to 132 cases in 2014.

RIDOH has been making strong efforts to clearly distinguish between "equality" (equal funding allocated to all populations) and health equity (more funding allocated to populations with greater

health disparities). For example, a marginal increase was reported in the low syphilis case rate among heterosexual males in Rhode Island from 1.0/100,000 in 2010 to 3.3/100,000 in 2014. Among MSM in Rhode Island over the same period of time, the syphilis case rate dramatically increased from 255.4/100,000 in 2010 to 381.3/100,000 in 2014.

RIDOH identified several actions that should be taken to achieve health equity and address sexual health issues in MSM. Public health funding and investments should be distributed in proportion to the disease burden. Existing case reports should be redesigned with new fields on the mode of transmission and gender of sex partners. New sexual orientation questions should be included in the BRFSS and YRBS. New data should be gathered to estimate the MSM population and determine incidence rates. The traditional characterization of MSM as a "hard-to-reach" population is an offensive, blaming and inaccurate label that should be eliminated. The provider community should make strong efforts to simplify hard-to-reach services.

RIDOH launched several initiatives to listen to and respond to personal health priorities in the MSM community. A survey was administered in 2012 to 106 gay men who expressed an interest in increasing their knowledge of specific health and wellness topics.

- Assistance in locating a gay-friendly physician 92%
- General gay men's health issues 85%
- HIV/STD testing services 78%
- Oral sex 78%
- Anal sex 77%
- Health relationships 74%

RIDOH developed, launched and targeted a website, Men2MenRI, to "guys who like guys." The non-judgmental and holistic website has the "look and feel" of Rhode Island. The website includes content-driven input from gay men and local information, but does not feature sexual images. The web pages include "Play Safe" (sex, drugs and you); "Find a Doctor" (get health facts); and "Get Connected" (the Rhode Island scene). Mr. Bertrand presented a series of slides with screen shots of the web pages.

RIDOH collected Google analytic data that showed from May 2013-June 2016, the website was used by 10,189 users in 12,671 total sessions at an average of 12 sessions per day. The page views have totaled 36,275 to date. The most popular web pages have been Find a Doctor (6,716 visits); Community Calendar (1,086 visits); Get Connected (858 visits); HIV Risk Quiz (781 visits); and Ask Dr. Phil Chan (658 visits). RIDOH found the website to be extremely cost-effective at a price of $5,000.

RIDOH took a number of public health actions to target syphilis prevention to venues and in formats that are friendly to MSM. A new "Sexual Health Information for Gay Men" web page was posted on the RIDOH website with helpful resources. Planning activities were conducted in

preparation of launching a new MSM syphilis campaign. Provocative images were gathered from previous campaigns by other local health departments and national organizations. A focus group was conducted to obtain feedback from academia and MSM patients in STD clinics. RIDOH was advised to not push condoms and design the campaign to be fun, eye-catching, treatable and simple.

Mr. Bertrand presented a series of slides to illustrate posters from other campaigns and the clear, succinct slogan in RIDOH's new MSM syphilis campaign: "Syphilis is up in Rhode Island. It's Easily Cured. Get Tested." Marketing of the campaign was expensive and cost RIDOH $20,000 for two months of advertising through various websites, Smartphone applications and local gay media markets. The campaign received 206 page views per day on the RIDOH website for the two-month period on average; resulted in a 125% increase in visits to the Men2MenRI website; and led to an 80% increase in the number of STD patients who identified the RIDOH website as their referral source.

RIDOH estimated that ~20% of gay/bisexual men living in Rhode Island visited the website after seeing the campaign poster. Over 95% of users accessed the campaign via cell phone. These successful outcomes indicated that launching an online public health campaign on "hook-up" sites might be an effective approach in prompting MSM to access STD clinical services and local web-based sexual health information. Overall, the campaign represented RIDOH's commitment to building an infrastructure and delivering services that are dedicated to improving MSM health.

RIDOH administered a survey in June-July 2015 to obtain input directly from MSM on issues related to access to care and comprehensive clinical services. Of 199 respondents, 69% had anal sex in the past 12 months; 57% did not always use condoms; 85% had a regular physician; 34% had not "come out" to their physicians; and 25% had never received HIV or STD testing from their physicians. Of the 80 MSM syphilis cases Rhode Island reported in 2014, non-private physicians reported 65% and private physicians reported 35%. The Miriam HIV Immunology Center and the Miriam Hospital STD Clinic accounted for 62% of MSM syphilis cases reported by non-private physicians in 2014.

RIDOH conducted an STD study from August 2014-April 2015 on extragenital site testing of gonorrhea and chlamydia among 266 MSM. The study found 40 cases at the rectal site, 28 cases at the oral site, and only 8 cases at the genital site. The study concluded that genital testing only at STD clinics in Rhode Island would have missed 87% of these cases. The study also reinforced the critical need for comprehensive clinical care for MSM. As of June 2016, PrEP has been prescribed to 200 persons in Rhode Island with MSM accounting for 91% of these prescriptions.

RIDOH's decision to embed DIS into the Miriam Hospital STD Clinic had a significant impact on partner services for MSM based on outcomes of 58 index patients pre-DIS and 87 index patients post-DIS. These improvements included the percent of index patients interviewed (from 76% to

92%); the percent of index patients who named at least one partner (from 76% to 85%); and at least one partner treated per index case (from 12% to 20%).

RIDOH has identified several components that will be necessary to fully redesign partner services: inclusion of DIS to provide client-centered services; hook-up applications and other Internet-based partner services; rapid syphilis testing; active support of self-referrals; and a web page dedicated to partner services on all health department websites.

RIDOH developed a framework to guide its future public health directions in syphilis prevention and sexual health services for MSM. The focus will not be exclusively placed on changes in sexual behavior. Client-centered interventions will be prioritized to increase access to primary/ specialty care and partner services. Comprehensive clinical care will be promoted and biomedical interventions will be advanced. Internet-based prevention efforts will be researched, supported and expanded. The goal of achieving health equity for MSM will be embraced. Mr. Bertrand thanked RIDOH's national and regional partners for their extraordinary role in assisting Rhode Island to launch syphilis prevention efforts for MSM.

CHAC DISCUSSION: SYPHILIS PREVENTION AND CONTROL

CHAC discussed the following topics during the question/answer session with Dr. Bolan and Mr. Bertrand.

- Efforts at the federal level to integrate case reviews of CS, infant mortality and HIV.
- Current collaboration between DSTDP and the HRSA Maternal and Child Health Block Grant Program.
- DSTDP's ongoing collaborations with internal and external partners to collect data from other sources to improve STD surveillance.
    - DHAP: Analyzing STD screening rates in the CDC Medical Monitoring Project.
    - DHAP: Piloting a project to perform syphilis testing in the field with vaginal and rectal swabs as part of the National HIV Behavioral Survey.
    - HAB: Measuring and implementing continuous quality improvement programming to scale up syphilis screening in Ryan White clinics.
    - HAB: Tracking the annual syphilis screening measure in RSR client-level data.
    - BPHC: Reviewing a Project ECHO (Extension for Community Healthcare Outcomes) model to include more LGBT-friendly services, increase HIV testing in FQHCs for persons with acute STDs, and offer PrEP to HIV-negative persons with STDs in these settings.
- The possibility of leveraging the existing Project ECHO model for HCV to address the comprehensive needs of patients (e.g., HIV, STDs and substance abuse disorders) in a holistic manner.
- DSTDP's focus on emerging issues, particularly meningococcal urethritis as the source of STDs in young, heterosexual men.

- Ongoing efforts to resolve insurance coverage and reimbursement issues when STD testing is performed at multiple sites on the same patient.
- Specific reasons MSM do not disclose their sexual orientation to their providers based on the Kaiser Family Foundation's representative survey of self-identified gay/bisexual men in 2014.

Ms. Fukuda confirmed that during the Business Session on the following day, CHAC would revisit the eight questions posed by DSTDP. In the interim, several CHAC members addressed question 5 and suggested key issues that DSTDP should consider in developing a new Syphilis Call to Action.

- A section should be included to describe the significant impact of illicit drug use on the increase in syphilis cases at the local level. For example, illicit drug use was reported by >33% of syphilis patients in Indianapolis in 2015.
- Clear messaging should be included to clarify and emphasize the role of PrEP: "Syphilis rates began to rise long before PrEP was available on the market. PrEP is not the cause of the ongoing syphilis epidemic. PrEP has generated a larger population that is now presenting for HIV testing. Increased HIV testing for PrEP has resulted in the diagnoses of more syphilis cases than in the past."
- A new recommendation should be included for public health to replicate the tailored, patient-centered model in STD clinical settings to inform data-to-action and data-to-impact approaches.

Update on the CDC Medical Monitoring Project (MMP)

Joseph (Buzz) Prejean, PhD
Chief, Behavioral and Clinical Surveillance Branch
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Dr. Prejean presented an update on the MMP. The 2009-2014 MMP cycles only focused on PLWH who were known to be in care. However, a 2012 report by the Institute of Medicine (now the National Academy of Medicine (NAM)) recommended that the MMP population of inference be expanded to include all diagnosed PLWH. To respond to this recommendation, CDC designed and tested new methods in a sampling pilot project of all eligible HIV-diagnosed patients from HIV case surveillance.

CDC collected data over the three project years of July 2012-May 2015 for the sampling pilot. Existing MMP project areas were used to select the five pilot sites: Los Angeles County, Mississippi, New York City, San Francisco and Washington. Both standard MMP surveillance

and data collection for the sampling pilot were conducted. The sampling strategy and data collection methods were refined over the three-year project period. During the third year of pilot data collection (2014) 1,010 PLWH were sampled. The pilot sites located 664 PLWH (or 66%).

The pilot sites used a diverse group of data sources to locate participants for the sampling pilot. The ability of these data sources to provide accurate information greatly varied.

Database	Provision of Accurate Information
HIV Care Facility	51%
eHARS (Enhanced HIV/AIDS Reporting System)	46%
NYC HepWeb	28%
People Search Engines, e.g., Lexis-Nexis	16%
Auxiliary HIV Databases	11%
Social Services Databases	11%
Ryan White Administrative Database	10%
STD or Partner Services Databases	8%
Other HIV Case Surveillance	6%
Internet Searches, e.g., Google	3%
ADAP Lists	2%
Facebook	<1%

Of the 664 PLWH the pilot sites located in 2014 for the sampling pilot, 87% resided in the MMP project area of their sample. Of this sub-sample, 70% were interviewed and the remaining 30% refused, were ineligible or did not participate for other reasons (such as death). Of the 13% of PLWH who did not reside in the MMP project area of their sample, 27% were interviewed and the remaining 73% refused, were ineligible or did not participate for other reasons. Because the response rate in the pilot jurisdictions was comparable to standard MMP surveillance and the sampling pilot, CDC was confident that the new sampling method could be scaled up for MMP.

The sampling pilot was designed to capture the out-of-care population, and the pilot was successful in that regard. Interviews were conducted with 9 PLWH who had never been in care and 80 PLWH who had discontinued care based on a definition of “no medical care visit in the past six months.” Linkage to care services were provided to all 89 out-of-care PLWH.

CDC reached several conclusions based on the findings of the sampling pilot. Efforts to locate PLWH were more difficult and time consuming because the participants were sampled from case surveillance data rather than from clinics. Most notably, health departments reported that ~40% more staff time was required to implement the new sampling method. Response rates to interviews in the sampling pilot and overall MMP were similar. Outcomes of the sampling pilot suggested that MMP has the capacity to capture out-of-care PLWH. The sampling pilot indicated

that data can be linked to the National HIV Surveillance System (NHSS) to improve case surveillance data completeness.

In 2015, CDC redesigned MMP to be representative of all diagnosed PLWH who are both in and out of care. The current status of MMP since CDC implemented the new sampling method in 2015 is summarized as follows. In terms of progress, MMP was adjusted to sample from NHSS. All data collection and data entry for the new MMP sampling method will be completed on June 15, 2016. MMP's two-stage design includes sampling from all 50 states, the District of Columbia and Puerto Rico in Stage 1. This sample is drawn based on the size of the population of persons living with AIDS in 2002. An analysis of 2012 HIV diagnosis data found that the distribution of states fell into bands of low, moderate, and high morbidity consistent with the distribution of AIDS cases in 2002.

Persons within each MMP project area who meet the following criteria on the sampling date are included in Stage 2: present in NHSS, meets the HIV surveillance case definition, alive, $\geq$18 years of age, and most recently reported address in NHSS also in the MMP project area. As of June 2, 2016, CDC has nearly reached its goals for the 2015 MMP data collection cycle. Of the total sample of 9,700 PLWH, 3,694 interviews were conducted (goal of 3,743 interviews), 3,456 medical records were abstracted (no applicable goal); and an initial response rate of 39.5% was achieved among eligible persons (goal of a 40% response rate). Over the next four years, CDC will increase its target rate by two percentage points each year until the previous MMP response rate is reached.

In terms of challenges, the inability or lack of interest of some staff to adapt to the new method of recruiting potential participants led to changes in MMP personnel. Interviewing experience and other skill sets are required to locate out-of-care and out-of-jurisdiction PLWH. Additional methods are being developed to contact and recruit PLWH across surveillance jurisdictional boundaries. However, close collaboration with DISs has been extremely valuable in helping MMP project area staff to locate PLWH.

State and local health departments are continuing to be encouraged to gain access to both public and commercial databases to locate information on a broader scale. Capacity is continuing to be built among staff in the MMP project areas, such as training to use people-search engines and effective strategies to approach PLWH with no assistance from their providers. MMP project area staff is beginning to cautiously use social media and technology to confirm the location of PLWH.

In terms of opportunities, MMP now has the capacity to produce care utilization measures: (1) the percent of persons living with diagnosed HIV infection who received HIV medical care during the previous 12 and 24 months and (2) the percent of persons living with diagnosed HIV Infection who were retained in HIV care (based on two care indicators at least 90 days apart during the same calendar year) during the previous 12 and 24 months. Both interview and medical record data will be used to measure the care indicators: encounter with an HIV care provider, viral load

or CD4 test result, HIV resistance test or tropism assay result, self-reported adherence to ART, and PCP or MAC prophylaxis.

In terms of next steps, MMP data will be closed out, reconciled and weighted. CDC anticipates completing this process in six to eight months and releasing the first surveillance report with the new MMP sampling method in the summer of 2017.

CHAC DISCUSSION: CDC MEDICAL MONITORING PROJECT
CHAC discussed the following topics during the question/answer session with Dr. Prejean.

- The unique contributions of MMP to other CDC and HRSA datasets, particularly its provision of the most recent and accurate data on viral load suppression in the United States.
- CDC's proposed qualitative study among MMP participants to identify common vulnerabilities in the out-of-care PLWH population that serve as barriers to linking to and reengaging in care.
- CDC's plans to use MMP to focus on the complex PLWH population that continually moves in and out of care.

In response to Dr. Williamson's question, Dr. Prejean confirmed that CDC has plans in the near future to collect MMP interview data on reasons the sub-sample of PLWH has never been in care. In the interim, he asked Dr. Williamson to email him at nzp1@cdc.gov to obtain links to or information on CDC's previous "Never in Care" project.

Overview of the Division of Adolescent and School Health Strategic Imperative on Confidentiality and Sexual Health Services

Lisa Barrios, DrPH, ScM
Chief, Research Application and Evaluation Branch
Division of Adolescent and School Health
Centers for Disease Control and Prevention

Advice Requested from CHAC by DASH:
1. What are the major issues for teen confidentiality and sexual health services?
2. What additional tools do schools need to better address this issue?
3. What additional tools do clinicians need?
4. What actions can clinicians take to support schools in building confidentiality protections?
5. What additional research should be conducted to address confidentiality as a barrier to teen sexual health?

Dr. Barrios presented an overview of DASH's strategic imperative to address confidentiality protections for teens to increase their use of sexual health services. DASH's vision of *Healthy Teens, Successful Futures* focuses on providing teens with healthy and safe environments as well as knowledge and skills to ensure their success as adults. DASH's mission is to promote environments where teens can gain fundamental knowledge and skills, establish healthy behaviors for a lifetime, connect to health services, and avoid becoming pregnant or infected with HIV or STDs.

DASH takes several actions to promote its vision and fulfill its mission. DASH's core business model is based on organizational excellence, visibility, strategies, funding awards to state/local education agencies (SEAs/LEAs), and management of surveillance systems (e.g., School Health Profiles (Profiles) and YRBS). DASH conducts a number of activities to support its four strategic imperatives.

- *Strategic Imperative 1:* Scale up sexual education nationally to assure teens have access to information and skills development.

- *Strategic Imperative 2:* Address confidentiality protections for teens to increase their use of sexual health services.

- *Strategic Imperative 3:* Expand the evidence base regarding sexual and gender minority health to develop methods that decrease risk and increase protective factors.

- *Strategic Imperative 4:* Integrate substance use prevention in HIV/STD prevention efforts for teens.

Dr. Barrios explained that her overview would focus on DASH's ongoing efforts to support Strategic Imperative 2 and CHAC's advice to improve this area. DASH acknowledges that teens need to use more sexual health services. Most notably, young persons 13-24 years of age account for 25% of all new HIV infections in the United States. Of the 20 million new STDs reported each year, nearly 50% are among young persons 15-24 years of age.

DASH recently released 2015 YRBS data that were collected from a survey of U.S. high school students: 41% reported ever having had sex; 43% of sexually active students did not use a condom at last sexual intercourse; and ~90% had never been tested for HIV. Although teens are engaging in behaviors that increase their risk, only 38% of adolescents had a preventive care visit in the previous 12 months and <33% of providers routinely discuss sensitive sexual health topics during these visits.

DASH is aware of the critical need for schools to improve their performance in providing or referring teens to sexual health services. Data show that <50% of schools have a full-time nurse on staff. Moreover, the vast majority of school nurses are responsible for multiple sites. Based

on 2008 data, one school nurse served 1,151 students on average. The 2014 School Health Policies and Practices Study (SHPPS) reported that only 2.3% of middle schools and only 7.2% of high schools made condoms available to students.

The percentage of middle/high schools that provides HIV prevention services in one-on-one or small group sessions and HIV counseling, testing and referral services in either onsite or offsite settings is extremely low. School-based health services, counseling, psychological or social services staff is used to offer onsite HIV prevention services in only 30.2% of schools and onsite HIV counseling, testing and referral in only 27.5% of schools. Arrangements with organizations or professionals are used to offer offsite HIV prevention services to students by only 29.1% of schools and offsite HIV counseling, testing and referral to students by only 13.4% of schools.

Of all 2,315 School-Based Health Centers (SBHCs) in the country that were surveyed in 2014, ~1,300 (or ~60%) served middle/high school students. Services delivered by the SBHCs included pregnancy testing (80.2%), abstinence counseling (83.3%), STD diagnosis and treatment (69.5%), and Pap tests (45.3%). The survey also showed that 50.2% of SBHCs were prohibited from dispensing contraceptives due to laws, regulations or policies by the state, SBHC sponsor, individual school or school district. An earlier survey in 2010 reported similar findings in the percent of SBHCs that were prohibited from conducting HIV or STD testing.

DASH launched multiple efforts to increase access to and use of sexual health services among teens. Funding was awarded to 19 SEAs and LEAs to provide sexual health services or create and strengthen existing referral systems. SHPPS and Profiles data were used to assess national, state and local policies and practices. YRBS data were used to monitor trends in teen HIV testing. Key sexual health services were recommended before and after the onset of sexual activity among teens: human papillomavirus vaccination, anticipatory guidance, condom availability, HIV/STD testing and treatment, contraceptive services, health counseling and pregnancy testing.

DASH created resources and also awarded funding to partner organizations to develop and disseminate a variety of tools.

- A referral system toolkit and resource guide for establishing partnerships
- Adaptation and wide dissemination of the “Get Yourself Tested” (GYT) campaign for STDs, but with the addition of a new HIV testing component for teens
- Adaptation and wide dissemination of the “Testing Makes Us Stronger” campaign for teens
- Policy guidance and an infobrief to educate and help schools better understand the Family Educational Rights and Privacy Act (FERPA), Health Insurance Portability and Accountability Act (HIPAA), and Medicaid Free Care Act (MFCA)

DASH has identified several barriers to access and use of sexual health services among teens: lack of awareness of these services among teens and their parents; limited availability of and minimal funding to support sexual health services in communities and referral systems in schools;

weak parental support of sexual health services for teens; a low number of "teen-friendly" or "teen-welcoming" service providers; the cost of sexual health services that teens cannot afford; and confidentiality concerns.

DASH is aware that threats to the confidentiality of teens are well documented in the literature. Service providers and referral organizations often have no knowledge of laws in their individual states that permit teen consent or require parental notification and consent to deliver sensitive services. FERPA and HIPPA laws that govern privacy issues at the federal level continue to be associated with a tremendous amount of confusion and uncertainty regarding the rights of parents to review the medical/educational records of their minor children.

Teens expect and have a right to receive confidential sexual health services, but an insurance coverage summary, billing record or explanation of benefits (EOB) form typically is sent to parents as the policyholder of the teen's health plan. Providers have limited competency in offering confidential teen-friendly services, while school staff has minimal skills in confidentially referring teens to external sexual health services. Teens with no access to public or private transportation are particularly challenged in obtaining confidential sexual health services.

DASH's ongoing efforts to address confidentiality protections for teen sexual health services are highlighted as follows. A generic technical package is being created that will include strategies and resources for SEAs/LEAs to resolve confidentiality issues for teens to access and use sexual health services. Several efforts are underway at DASH to support the development of this template.

- Engaging a diverse group of partners to identify necessary resources
- Expanding and adapting the current guidance for DASH grantees
- Expanding the current content on the DASH website
- Identifying new tools and resources for future development
- Developing guidance to adapt and disseminate a teen-focused model of the GYT campaign
- Creating infobriefs to clarify specific issues to different audiences:
    - An explanation to parents on the importance of allowing their teens to be alone with providers
    - An explanation to SEAs/LEAs on the role of MFCA in allowing schools to bill for sexual health services delivered to students
    - An explanation to schools and clinicians on FERPA and HIPAA policy issues

Research and research synthesis activities are being implemented to inform the development of resources in the future. Efforts to support this initiative include conducting modeling studies and analyzing and publishing data from YRBS, SHPPS and the National Survey of Family Growth on a number of indicators (e.g., provider counseling during sexual and reproductive health visits, parent/adolescent communications, and provider/adolescent communications). Sexual health

services to teens will be assessed with an applied evaluation design to inform the development of future programs.

CHAC DISCUSSION: DASH STRATEGIC IMPERATIVE

CHAC discussed the following topics during the question/answer session with Dr. Barrios.

- DASH's efforts to build partnerships between schools and health service providers at the local level.
- Best practices and lessons learned in urban or rural areas that can be replicated and shared with SEAs/LEAs, such as SBHCs with linkages to nearby FQHCs, hospitals or providers.

CHAC provided the following feedback in response to DASH's request for advice.

Question 1: Major confidentiality issues

- DASH should solicit independent expertise from ethicists to address the tension between the rights of teens to receive confidential sexual health services versus the rights of parents to have access to the medical/educational records of their minor children.

Question 2: Additional tools for schools

- DASH should compile and provide schools in each state with a list of teen-friendly referral services. This resource would be particularly helpful to Texas and other conservative states that oppose the delivery of school-based sexual health services to teens.

Question 3: Additional tools for clinicians

- DASH should provide leadership and facilitate partnerships between various groups that prioritize adolescent health issues. For example, alignment of the common interest in EOB issues among DASH, DHAP and DSTDP at the federal level would be extremely helpful to the National Coalition of STD Directors and other stakeholder organizations that are involved in policy and advocacy efforts at the state level. Federal support for stakeholder organizations to resolve EOB issues at the state level likely would encourage clinicians to provide confidential sexual health services to teens at the local level.

Question 5: Research needs to address confidentiality

- The illegal use of prescription drugs among teens is an ongoing public health problem that is continuing to rise. Because school nurses are legally required to maintain and dispense medications assigned to individual students only, Naloxone cannot be kept on school property to reverse an opioid overdose in the general school population. DASH should conduct research, in consultation with the CDC Public Health Law Program, to determine whether existing state laws, regulations or policies that prohibit the use of Naloxone on school property can be overturned.

- DASH should invest research dollars in the development of innovative models. For example, DASH should pilot a partnership project for local unified school districts and LEAs to coordinate, align and jointly conduct creative projects to improve the health of teens in jurisdictions throughout the country.
- DASH should develop and pilot Smartphone applications to determine the effectiveness of this technology in delivering sexual health services to teens nationally.
- DASH plans to develop an infobrief to explain FERPA and HIPAA policy issues to schools and clinicians. However, DASH should first administer a survey to determine the current level of knowledge of these laws among school officials and clinicians in their individual states.

Update by the CHAC Data Workgroup

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

Advice Requested from CHAC by the Data Workgroup:
1. What are the major gaps or areas that need increased emphasis related to the use of molecular surveillance data for HIV prevention at state and local levels?
2. What logistical, legal and ethical issues should CDC address to facilitate state and local use of molecular surveillance data for HIV prevention?

Dr. Kates reminded CHAC that the Data Workgroup was formed to conduct two major tasks: (1) evaluate emerging data to inform the implementation of ACA and (2) collaborate with CDC and HRSA to explore different strategies to analyze their data to inform policy and practice. During its most recent teleconference meeting, the workgroup asked CDC to make a presentation on molecular HIV surveillance (MHS) data to increase CHAC's understanding and knowledge of this dataset. Although MHS primarily focuses on prevention, the data also can play an important role in improving linkage to care.

Dr. Kates explained that Dr. Hernandez's presentation would serve as the workgroup's update to CHAC.

Angela Hernandez, MD, MPH
Acting Chief, HIV Incidence and Case Surveillance Branch
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Dr. Hernandez presented an overview on the use of MHS data to maximize HIV prevention efforts. NHSS is the primary source for monitoring HIV infection in all 50 states, the District of Columbia and six U.S.-dependent areas. NHSS sites have regulatory authority and confidential protections to collect and report data on persons with diagnosed HIV infection. CDC uses surveillance data to monitor trends, target prevention efforts, plan services, allocate resources and develop policies.

MHS is a component of NHSS and is designed to collect HIV nucleotide sequence data generated as part of HIV care and drug-resistance testing that is recommended for all persons at entry into care. MHS data currently are collected in 27 HIV surveillance jurisdictions. The primary functions of MHS are to assess drug resistance, monitor the genetic diversity of HIV, and describe HIV transmission patterns by identifying clusters, potential outbreaks and the growth of clusters.

The ability to explain patterns of HIV transmission and identify growing clusters provides opportunities to target public health interventions to specific characteristics of the cluster, such as geographic, risk or clinical factors. Clusters of persons with early HIV infection indicate recent transmission and should be prioritized for investigation and action. The identification of active HIV transmission is a key component to focusing prevention efforts.

Transmission network analysis methods expand the use of HIV surveillance data to identify, investigate and intervene recent HIV transmission events that are important in improving health outcomes and preventing transmission. The identification of growing clusters of active transmission can help target interventions to interrupt transmission. This approach views every HIV transmission as a sentinel event that requires rapid and complete investigation and action.

Transmission network analysis methods are utilized to compare nucleotide sequences to determine a potential relationship and infer a direct or indirect epidemiologic link. However, directionality cannot be inferred. This approach is taken because HIV mutates and evolves over time. Moreover, infection in PLWH whose viral strains are genetically similar might be more closely related in transmission.

Surveillance data are used to determine active transmission, identify potential outbreaks, and translate findings into local prevention activities. A “network” is defined as a group of persons with diagnosed HIV infection who are in care and have genetically similar HIV strains and sequences that have been reported. The network represents a subset of an underlying sexual risk network that also could include other groups: persons with diagnosed HIV infection who are in care and do not have a sequence; persons with diagnosed HIV infection who are not in care, persons with undiagnosed infection; or HIV-negative persons who are at risk for acquiring HIV.

The identification of transmission clusters plays an important role in targeting preventing efforts. Some rapidly growing clusters represent outbreaks that require rapid and complete investigation and action. The identification of key characteristics of the underlying transmission network can guide intervention efforts. An analysis of existing data or the collection of new data from diverse sources can identify factors associated with transmission.

Various interventions can be implemented to interrupt transmission: identifying undiagnosed cases through partner services, linking out-of-care PLWH to care, referring HIV-negative persons who are at risk for acquiring HIV to PrEP services, and conducting other cluster-specific interventions. Cluster data can be a powerful tool to target interventions with known efficacy, such as engagement in care, HIV testing and PrEP.

The analysis, visualization and interpretation of data present both challenges and opportunities. National and local datasets are extremely large. Some state and local health departments are not familiar with molecular data and need substantial support and training in the analysis and interpretation of cluster data. The CDC Advanced Molecular Detection Initiative currently is funding the development of systems to build, filter and visualize transmission networks. The new systems include Secure HIV-TRACE and the Microbial Transmission Networks Analytics Platform.

Laws and policies that require rigorous protection of HIV surveillance data have improved protection and reduced concerns regarding the misuse of data. Ethical issues have been raised regarding the potential use or misinterpretation of phylogenetic and transmission network data. The data could be subject to a subpoena in some jurisdictions because laws related to the criminalization of HIV transmission vary across states.

Numerous complexities are associated with interstate data sharing. Despite the challenges in the potential uses of HIV surveillance data, CDC is aware of tremendous opportunities to use these data for prevention planning and public health intervention. CDC also is planning to convene a consultation in the near future to focus on state laws that criminalize HIV transmission.

State and local health departments are soliciting guidance from CDC in several areas to improve their capacity to respond to growing clusters.

- Who should have access to cluster data? What protections should be included?
- How should clusters be prioritized for additional evaluation and investigation?
- What types of investigations are needed?
- What specific clusters and types of clusters should trigger additional prevention efforts?
- What are the legal and ethical implications of these activities?

In addition to providing guidance to states and localities, CDC also is advancing the science to develop evidence-based approaches at this time. To support this effort, CDC is reviewing experiences and models from other groups that also use molecular data to identify outbreaks (e.g., molecular tuberculosis (TB) data, foodborne illness data from PulseNet and the British Columbia MHS dataset).

Current approaches that are implemented by surveillance staff need to enhance the collection and use of MHS data for action. Most notably, a shift must be made from the traditional monitoring

approach to a rapid response strategy because timeliness is much more critical than in the past. Because MHS does not cover the entire United States, CDC is exploring the possibility of expanding the coverage area beyond the 27 current HIV surveillance jurisdictions, including particularly vulnerable areas. The ability to specify clusters that are most likely to represent active transmission will be important in the future direction of MHS. As a result, CDC is considering the possibility of expanding the collection and timeliness of additional data elements to identify specific infections that are acute or early.

Overall, the current use of molecular surveillance data for HIV prevention represents an exciting time with numerous challenges and tremendous opportunities. The ability to address these challenges will be critical to achieving advancements caused by the widespread availability of sequence data and new analytic tools. Dr. Hernandez concluded her overview by presenting a slide with simulated data to illustrate transmission clusters.

CHAC DISCUSSION: MOLECULAR HIV SURVEILLANCE DATA

CHAC discussed the following topics during the question/answer session with Dr. Hernandez.

- The ability of MHS to perform viral load suppression, drug resistance and HIV drug testing to determine whether PLWH are actually taking medications.
- Strategies to translate important MHS data into interventions at the network level to change the epidemiology of HIV and stop transmission.
- Workforce capacity, ethics and other issues related to DISs continuing investigations to pursue networks.
- CDC's TA to help localities overlay MHS data with other local datasets (e.g., syphilis data and social networks developed by partner services).
- Existing models of rapid response teams in health departments (e.g., TB and foodborne illness) that can be replicated for an HIV rapid response with MHS data.
- Successful efforts in HIV prevention and care integration, such as British Columbia's tremendous progress in fully linking HIV prevention and care data and the longstanding CDC/HRSA partnership to deliver PrEP as treatment and treatment as prevention.
- The need to translate and clearly distinguish between epidemiologic and service-based language (e.g., an "outbreak" versus a "cluster") for direct services staff that will use MHS data for a response in the field.
- Current data gaps in local jurisdictions that are extremely problematic for state health departments, such as incomplete electronic laboratory reports with no CD4 or viral load data and the limited number of DISs/field epidemiologists to reengage out-of-care PLWH in care.
- Ongoing efforts to make public health services a billable service under ACA.

Dr. Hernandez described several MHS-related activities CDC currently is conducting or planning to implement in the near future that directly respond to some of CHAC's questions and comments.

- CDC is improving the capacity of states to electronically collect and report sequences to the national surveillance system. For example, CDC is partnering with the University of San Diego to develop analytic tools for states to meet CDC's rigorous security, protection and confidentiality standards for HIV surveillance data.
- CDC is developing new analytic tools for localities that are expected to significantly reduce time delays in the overall MHS data reporting process: states reporting data to CDC; CDC testing the data, constructing networks and producing quarterly datasets; and CDC reporting MHS data back to states.
- CDC participated in initial calls with surveillance and prevention teams in states that recently were identified as having rapidly growing clusters. These calls also were used to explain the purpose, function and use of MHS data. The next cycle of calls will focus on the need for states to expand and link MHS data to partner services, co-morbidity data, clinical data and other health department datasets. The states highlighted several challenges in expanding and linking MHS data to other datasets, such as workforce and policy issues. For example, a policy in one state prohibits interviews with unnamed HIV-positive persons.

The discussion resulted in CHAC making two key suggestions for CDC to consider in its ongoing efforts to enhance and expand the use of MHS data. First, CDC should advance to the proof of concept phase to demonstrate the feasibility and effectiveness of implementing MHS at the local level to intervene networks. Second, CDC should coordinate with HAB at this time to use MHS to identify PLWH who need to be linked to or reengaged in care.

Preparation for the CHAC Business Session

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

Ms. Fukuda described the purpose of this session for the benefit of the new members. CHAC devotes time at the end of the meeting on day 1 for individual members (*i.e.*, "champions") to propose draft resolutions that will be placed for a formal vote during the Business Session on day 2. Draft resolutions proposed by champions are not required to be a certain length or cited with references. Based on CHAC's discussion and formal approval, the draft resolution will be revised, finalized and included in a letter to the HHS Secretary.

Ms. Fukuda moderated CHAC's review of the presentations, updates and key discussion topics on day 1 that might warrant formal action during the Business Session on the following day.

DRAFT RESOLUTION 1

Drs. del Rio and Kates served as champions of a draft resolution to express CHAC's concern regarding AHRQ's plans to defund HIVRN in FY2016.

> The CHAC expresses concern that the Agency for Healthcare Research and Quality (AHRQ) plans to defund the HIV Research Network (HIVRN) in FY2016. Established in 2000, the HIVRN is comprised of 18 clinical research sites collecting data on more than 25,000 children, adolescents and adults with HIV for more than 15 years. It provides an irreplaceable longitudinal data set that has been instrumental in tracking data on health outcomes, service utilization and care and treatment costs for HIV-infected patients. It is routinely used by federal agencies, including the Centers for Disease Control and Prevention, Health Resources and Services Administration, and White House Office of National AIDS Policy, as well as non-governmental organizations to help assess resource allocation, implementation of treatment guidelines, performance along the HIV care continuum, the role of the Ryan White HIV/AIDS Program and other health financing mechanisms, and challenges and opportunities remaining in HIV care and treatment. It is a unique and invaluable resource in the fight against HIV. The CHAC urges the Secretary to work with AHRQ to restore the $1.6 million required to sustain this critical and unique national HIV clinical database.

CHAC proposed the following revisions to the draft resolution.

- Consult with Dr. Cheever on the most appropriate language to frame sentence 1.
- Change sentence 2 as follows: "…the HIVRN is a unique dataset comprised of…".
- Change sentence 4 as follows: "Because HIVRN is the only source of national cost data, it is routinely used by federal agencies…".
- Include new language to emphasize the need for continuous, sustained funding of HIVRN rather than one-time support. Change sentence 6 as follows: "…sustain this critical and unique national HIV clinical database and to ensure continued funding by including HIVRN in future budget requests."

Dr. Mermin noted for the record that none of the voting CHAC members are associated with or receive funding from HIVRN.

DRAFT RESOLUTION 2

Dr. Caine expressed an interest in CHAC drafting a resolution to address the limited number of HCPs in the current workforce who have the necessary expertise, knowledge and skills to deliver HIV/AIDS and HCV care and provide sexual health services. Based on CHAC's extensive discussion, however, the focus on workforce capacity development was expanded to include the

provision of care by the broader infectious disease (ID) workforce in medically underserved areas of the country. CHAC proposed multiple issues that should be considered for inclusion in draft resolution 2.

- The major crisis in recruiting young medical and nursing students to begin their careers in ID. For example, 117 of the 335 ID fellowships that currently are available have not been filled to date.
- A recommendation for the federal agencies to commission NAM to conduct a workforce capacity development study to identify specific reasons for the shrinking ID workforce, such as reimbursement issues or medical/nursing school debt.
- The need to recruit and build the capacity of minority medical and nursing students in the ID field.
- The need to preserve subspecialties, such as pediatric HIV care, and retrain these providers to deliver HCV care to broader geographic areas through tele-medicine, centralized clinics or electronic technologies.
- The need for innovative approaches to deliver HIV/HCV care to medically underserved areas (*i.e.*, "HIV/HCV care deserts") that are at most risk of an outbreak.
- The need to leverage SAMHSA's expertise, capacity and resources in drug addiction and mental health to target communities at risk for an HIV outbreak due to illicit drug use.
- Adoption of the ECHO Act that was introduced in the Senate and called for the use of the Project ECHO model to reduce disparities in underserved, complex patients with co-morbidities (e.g., HIV, HCV and substance use disorders).
- The need for PCPs to incorporate sexual health services into their routine practices.
- A request for the HHS Secretary to recommend short-, intermediate- and long-term strategies to build U.S. capacity in ID responses, including HIV, HCV, STDs, Ebola and Zika.

Ms. Fukuda led CHAC in a summary of the next steps to formulate draft resolution 2.

- The resolution will be framed in two parts or as two standalone resolutions to address workforce capacity in the broader ID field (including Ebola and Zika) to meet the needs of persons living with HIV and HCV and those who are at risk of or acquire STDs.
- The following points will be raised in the context of developing a strategy:
    - Describe systems of care and the geographic distribution of HCPs that might allow for the delivery of subspecialty services to medically underserved areas.
    - Identify HIV/HCV care deserts based on their at-risk populations and/or geographic locations.
    - Utilize existing assessments, such as CDC's vulnerability index, to help identify medically underserved areas in the country that are particularly vulnerable to HIV or HCV outbreaks.
    - Coordinate these assessments with SAMHSA's analyses of substance use patterns across the country.

- The following points will be raised in the context of implementing the strategy:
  - Increase ID workforce capacity to serve persons in HIV/HCV care deserts through creative mechanisms: electronic technologies, Project ECHO and tele-medicine initiatives.
- The following CHAC members will serve as champions in crafting specific parts of draft resolution 2: Mr. Byrd, Dr. Caine, Dr. del Rio, Ms. Fukuda and Dr. Havens.

Dr. Arora announced for the record that he is the founder and director of Project ECHO at the University of New Mexico. Because draft resolution 2 proposes the use of Project ECHO as a model for service delivery to HIV/HCV care deserts, he would recuse himself from further discussing and voting on this issue.

Public Comment Session

Ms. Fukuda opened for the floor for public comments; no participants responded.

With no further discussion or business brought before CHAC, Ms. Fukuda recessed the meeting at 4:03 p.m. on June 14, 2016.

Opening Session: June 15, 2016

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.

Dr. Mermin 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. None of the CHAC voting members publicly disclosed any individual or institutional conflicts of interest for the record that were new or different than those declared on day 1 of the meeting.

Dr. Mermin confirmed that the 20 voting members and *ex-officio* members (or their alternates) in attendance constituted a quorum for CHAC to conduct its business on June 15, 2016. He reconvened the proceedings at 8:30 a.m. and welcomed the participants to day 2 of the meeting.

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

Ms. Fukuda also welcomed the participants to day 2 of the CHAC meeting. She revisited CHAC's preparation for the Business Session on the previous day because the different types of advice and guidance that CHAC provides to the federal agencies were not clearly articulated. A "resolution" is CHAC's formal position on a specific issue that directly relates to HIV, viral hepatitis, and STD prevention and treatment efforts by CDC and HRSA. CHAC resolutions are included in letters to the HHS Secretary.

A "recommendation" is CHAC's advice to the agencies to take action. Recommendations are provided to CDC and HRSA programs through Drs. Mermin and Cheever. Historically, CHAC has placed much more emphasis on developing resolutions for the HHS Secretary than formulating recommendations in response to specific guidance requested by CDC and HRSA. Ms. Fukuda confirmed that during the current and future meetings, she and Mr. Byrd would set aside time to ensure CHAC provides recommendations to address questions posed by the federal agencies.

Ms. Fukuda concluded her opening remarks by summarizing the day 1 presentations, updates and discussions on HIV/STD prevention, treatment and care. She announced that day 2 would be devoted to a series of presentations on viral hepatitis and the CHAC Business Session.

PANEL PRESENTATION: PREVENTION OF HIV AND VIRAL HEPATITIS AMONG PWID

A panel of NCHHSTP staff presented a series of overviews on CDC's ongoing efforts for the prevention of HIV and viral hepatitis among PWID.

Overview of the CDC Vulnerability Assessment Model

John Brooks, MD
Epidemiology Research Team Lead, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Advice Requested from CHAC by NCHHSTP:

1. What steps can HIV and viral hepatitis programs take to best coordinate with opioid overdose prevention and behavioral health programs to decrease infections, drug use and their associated personal, social and health consequences?
2. What promising strategies can be implemented to address barriers to HIV and viral hepatitis testing in different care settings (e.g., substance abuse treatment programs, emergency departments (EDs), FQHCs or correctional facilities) among PWID?
3. What policies facilitate prevention for PWID?
4. What is CHAC's advice to CDC and HRSA on prioritizing the recommendations given in response to questions 1-3 to maximize prevention impact?

Dr. Brooks presented an overview of a model that CDC developed to identify vulnerability to rapid transmission of HIV/HCV infection among PWID at the county level. Beginning in late 2014, an outbreak of HIV infection rapidly spread among a network of PWID in the small rural community of Austin (Scott County), Indiana. As of February 1, 2016, 188 HIV infections have been diagnosed. Of these diagnosed cases, >90% are co-infected with HCV. Rapid recognition of the outbreak and implementation of intensive control efforts prevented new infections and limited the geographic spread.

Because other jurisdictions might be at risk for an event similar to the Indiana outbreak, CDC performed an analysis to identify counties in the United States that are particularly vulnerable to rapid transmission of HIV/HCV infection among PWID. CDC designed the analysis with a two-step approach.

In step 1 of the analysis, the Poisson regression model was used to identify variables associated with unsterile injection drug use (IDU). Acute HCV infection was used as a proxy for this outcome of interest due to limited data on the national prevalence of unsterile IDU. Data from 2012 or later were collected to identify variables that were plausibly or known to be associated with IDU. The data sources were required to be ≥90% complete and nationally available at the county level.

Of 15 variables that met the inclusion criteria for the analysis, six were identified with the ability to reliably predict acute HCV infection in a county.

- Percent non-Hispanic white population
- Drug overdose deaths per 100,000 persons
- Per capita income
- Percent unemployed population
- Prescription opioid sales per 10,000 persons
- Buprenorphine prescribing capacity by waiver per 10,000 persons

In step 2 of the analysis, the six variables were calculated to develop a "vulnerability score" and rank all 3,143 counties in the United States by their individual scores to identify those with the greatest potential vulnerability. Dr. Brooks presented a map to illustrate the 220 counties with the

highest vulnerability scores. The map showed that 56% of the top-ranking counties were located in the Appalachian core region (e.g., Kentucky, Tennessee and West Virginia). However, residence in an area identified as vulnerable does not indicate a risk of HIV or HCV infection for all residents because the analysis was limited to PWID.

CDC is aware that some limitations of the analysis will serve as barriers to interpreting the data at the local level. Inclusion criteria for indicators excluded several factors that are highly associated with IDU, such as calls to emergency medical services and ED visits for drug overdoses and Prescription Drug Monitoring Program data. Vulnerability to rapid transmission of HIV or HCV is dependent on the prevalence of infection and IDU behaviors in the region. For example, a region with low HIV prevalence might be at lower risk for rapid transmission than a region with high HIV prevalence. The number of times individuals inject drugs per day might increase their risk for acquisition of HIV or HCV.

Dr. Brooks presented a map to illustrate the estimated rates of persons living with diagnosed HIV infection per 10,000 population who were in and around each vulnerable county as of the end of 2012. Despite its ranking of counties that are most vulnerable to rapid transmission of HIV/HCV infection among PWID, CDC is encouraging all communities in the country to thoroughly review their local data due to the national epidemic of prescription opioid and heroin overdoses.

Dr. Brooks highlighted the key recommendations in the paper that CDC recently published on its vulnerability assessment model.

- Determine if unsterile IDU is occurring
  - Identify and monitor available data sources that might indicate IDU
  - Improve surveillance for acute HCV infection

- Enhance testing for HIV and HCV infections
  - Take steps to improve detection of IDU and a possible HIV outbreak in settings where encounters with PWID are most likely: providers of services for persons with substance use disorder, jails/prisons, EDs and in-patient settings

- Prepare an action plan with concrete steps to respond to a potential HIV outbreak
  - Have knowledge of HIV, HCV and injection drug treatment landscapes in the county in advance of an outbreak

In addition to CDC's development and publication of its vulnerability assessment model, the Indiana outbreak also resulted in other outcomes at the federal level. Most notably, Congress changed the law on January 16, 2016 and now permits the use of federal funds to support certain SSP components. However, the use of federal funds to purchase sterile needles or syringes to inject illegal drugs is still prohibited.

To be eligible for federal funds, health departments must consult with CDC to demonstrate the need for an SSP based on evidence that the jurisdiction is experiencing or is at risk for a significant increase in HCV infections or an HIV outbreak due to IDU. Health departments can apply to any HHS agency to request federal funds to support local SSPs, but CDC has responsibility for the "determination of need" process.

Jurisdictions that are experiencing increases can demonstrate need by providing CDC with data to document increases in HBV, HCV or HIV infections. Evidence to document that IDU is the cause of increased infections in the jurisdiction should include data on the transmission category, epidemiologic surveys, or social/ethnographic community data.

Jurisdictions that are risk for, but not yet experiencing increased infections can demonstrate need by providing CDC with data from multiple sources, particularly local data when available. The data should be triangulated with evidence to show that the increase in drug use is likely associated with IDU and is placing the community at risk for increased infections.

CDC has provided health departments with extensive guidance to document the need for SSPs in both categories of jurisdictions.

- Both categories of jurisdictions should provide CDC with the following data elements: outcomes, data sources and geographic area; beginning and ending year of and number/rate of cases in the assessment period; and the percent increase in cases during the assessment period. "Outcomes" can include increases in acute HCV cases (jurisdictions experiencing increased infections) and increases in IDU based on treatment admissions to publicly-funded programs, heroin-related arrests or drug overdose deaths (jurisdictions at risk for increased infections).

- Jurisdictions at risk for increased infections should use a variety of data sources to demonstrate a direct or indirect association between increased infections and unsterile IDU: prevalence of IDU; uptake of SSP services; substance use disorder treatment admissions related to IDU; drug-related crime statistics; drug-related overdose mortality data; and ED or other medical care related to substance use.

- Both categories of jurisdictions should use CDC's example of a narrative to synthesize their data and other evidence collected.

Dr. Brooks announced that a new website would be launched on CDC.gov in the near future. The website would be regularly updated to identify jurisdictions that CDC approves to receive federal funds for SSPs.

Overview of CDC's Guidance for Syringe Services Program Implementation

Renata Ellington, MSEd, MCHES, CCHP
Associate Deputy Director for Prevention Programs, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Ms. Ellington presented an overview of CDC's 2016 guidance for programs to implement certain SSP components. The HHS guidance that was released on March 29, 2016 on the AIDS.gov website is applicable to all HHS-funded recipients. The CDC guidance that was released on April 29, 2016 on the CDC.gov website is applicable to all eligible CDC grantees. The AIDS.gov and CDC.gov websites include a number of resources, such as slides and transcripts from CDC's archived webinars on determination of need, a mailbox to submit questions directly to the SSP Coordinator, and additional guidance from HRSA and SAMHSA.

The Consolidated Appropriations Act of 2016 modified the prohibition on the use of federal funds to support SSPs. The guidance released by HHS and CDC is in accordance with the revised legislation. The CDC guidance provides grantees with extensive details in the following areas for jurisdictions with an approved determination of need: the use of CDC funds to support specific SSP activities; the use of relevant CDC cooperative agreements (CoAgs) to support SSPs; and the process to redirect existing resources to implement new or expand existing SSPs.

CDC funds cannot be used to supplant or replace state or other non-federal funding sources that currently support local SSP activities. Requests by grantees to redirect resources to different emergent activities are subject to CDC approval. The modified legislation applies to CDC-funded programs beginning in FY2016, but will continue in future years unless otherwise noted.

The HHS guidance outlines several guiding principles regarding the use of federal funds to support SSPs. Adherence is required to federal, state and local laws or regulations related to SSPs and SSP services. Variations in state and local laws might impact the ability of HHS-funded recipients to implement SSPs. Recipients should coordinate with and make efforts to obtain cooperation from local law enforcement officials in the implementation of SSPs.

Recipients should ensure that SSPs supported with federal funds provide referrals and linkages to HIV, viral hepatitis and substance use disorder prevention, care and treatment services as appropriate. Recipients should minimize duplicative efforts by coordinating and collaborating with other local agencies, providers and organizations in their jurisdictions that also play a role in implementing comprehensive prevention programs. SSPs are subject to the terms and conditions incorporated or referenced in the recipient's federal funding. Recipients can only redirect existing federal funds to establish a new or expand an existing SSP with prior approval from the respective HHS agency.

A two-step process has been developed for recipients to apply to redirect federal funds to support SSPs. Step 1 is the determination of need process in which state, local, tribal and/or territorial health departments consult with CDC and provide evidence to document the need for an SSP in a jurisdiction. Step 2 is the application process in which health departments and other HHS-funded recipients solicit approval from the respective funding agency to redirect funds to support SSP activities. HHS agencies (e.g., CDC, HRSA and SAMSHA) have created their individual guidance for the application process.

Recipients cannot redirect federal funds to purchase needles, syringes or other devices used to inject illegal drugs, but federal funds can be redirected for the following SSP components:

- Staff
- Supplies (e.g., alcohol pads, sterile water and cotton)
- HIV and viral hepatitis testing kits
- Syringe disposal services
- Navigation services to facilitate linkage to care
- Provision of Naloxone to reverse drug overdoses
- Communication, outreach and educational materials
- Condoms
- Planning and evaluation activities

CDC approved two CoAgs for grantees to redirect funds to support SSPs. The "Comprehensive HIV Prevention Programs for Health Departments" CoAg funds 61 health departments in all 50 states, the District of Columbia, 8 directly-funded cities, Puerto Rico and the Virgin Islands. The CoAg supports the implementation of high-impact, comprehensive HIV prevention programs to achieve maximum impact on reducing new HIV infections. The CoAg also enhances the capacity of public health departments to increase HIV testing, refer and link HIV-positive persons to medical care and other essential services, and increase program monitoring and accountability.

The "Reduce Hepatitis Infections by Treatment and Integrated Prevention Services Among Non-Urban Young Persons Who Inject Drugs" CoAg funds two sites to develop and implement an integrated approach for the detection, prevention, care and treatment of HCV infection in this population. Funding for the three-year CoAg was awarded in September 2014 and will end on September 29, 2017.

DHAP and DVH are coordinating efforts to provide TA to grantees in submitting determination of need requests and redirecting CDC funds from the two CoAgs to support SSPs. DHAP and DVH will continue their collaboration to provide ongoing TA and capacity building assistance over time as grantees develop, implement and monitor their SSPs.

CDC's next steps will be to develop standardized SSP language for inclusion in future FOAs. All requests received by eligible grantees to redirect their FY2016 funds to support SSP activities will

be tracked. The review and approval process for these requests will be coordinated across DHAP and DVH. SSP activities supported by CDC funds will be analyzed to determine their impact.

Overview of Viral Hepatitis in Persons Who Inject Drugs

Alice Asher, PhD, RN
Division of Viral Hepatitis
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Centers for Disease Control and Prevention

Dr. Asher presented a two-part overview. In part 1, she described DVH's response to the viral hepatitis epidemic in PWID. DVH observed several changes in HCV incidence in the United States in 2014:

- An approximate 2.6-fold increase in the number of reported acute HCV cases
- 30,500 new HCV infections estimated in 2014
- 76% of HCV cases reported by 16 states
- HCV rates by risk factor: IDU (68%)
- HCV rates by gender: males (0.8%) and females (0.7%)
- HCV rates by age: young adults 20-29 years of age (2.2%)
- HCV rates by race: American Indians (1.32%) and non-Hispanic whites (0.84%)

DVH also observed a marked increase in IDU among adolescents and young adults in rural and suburban areas of the country that typically began with the abuse of oral prescription opioids. The 2015 Zibbell, *et al.* study reported a sharp rise from 2006-2012 in IDU and substance treatment program admissions for opioids and heroin among young adults <30 years of age in the Appalachian region: Kentucky, Tennessee, Virginia and West Virginia.

The key components of the DVH response are highlighted as follows. The 2016-2020 DVH Strategic Plan includes two objectives that are directly related to the viral hepatitis epidemic among PWID: (1) reduce HBV and HCV transmission associated with drug use and (2) increase access to testing, care and treatment services for persons at risk for or living with viral hepatitis.

DVH developed the GHOST system to better understand and detect IDU, phylogenetic relationships and transmission practices within social networks. DVH's use of the GHOST system in the 2015 Indiana outbreak investigation found 23 social network clusters. A major cluster involving 130 persons included 50 individuals with mixed genotypes as well as multiple introductions of HCV and super-infections.

DVH's joint modeling study with the University of Bristol reported the impact and efficacy of specific prevention interventions, such as scaling up SSPs alone or in combination with opioid substance treatment programs and scaling up HCV treatment for PWID. The study showed that increased coverage of large-scale prevention interventions could reduce new HCV infections by as much as 70%. DVH's surveillance data showed that increases in acute HBV infections from 2006-2013 occurred in the same populations and regions of the country as HCV.

DVH is applying the GHOST system and other advanced laboratory and epidemiologic techniques to assist with outbreak investigations in Tennessee and other areas of the country with disproportionately high rates of HCV. DVH is sponsoring a study for two sites to develop methods to improve the detection of HBV-/HCV-infected young persons and increase referrals to care and treatment in this population. DVH is conducting another study to identify the best strategies to treat and cure viral hepatitis in PWID and avoid reinfection in this population. DVH is enhancing HCV surveillance among pregnant women and newborns.

DVH is conducting a number of SSP-related activities. DVH is serving on the SSP Guidance Workgroup that CDC formed to assist state and local health departments in establishing a determination of need and provide TA to local jurisdictions in implementing SSPs. DVH will host several training events, including an Appalachian regional meeting for viral hepatitis prevention coordinators in July 2016 and webinars for state prevention staff. A local planning grant was awarded to Virginia to provide resources to address the epidemic.

DVH has proposed several features to include in a new SSP communication contract: partnership with an experienced non-governmental organization; assessment of education, communication and policy needs; and development of TA resources to support local efforts. DVH is more widely publicizing and communicating IDU-related risks to the public, such as materials related to needles found in community settings. DVH plans to update its website with a stronger focus on PWID. DVH will apply findings from the 2016 Van Handel study that reported the impact of SSP clusters on HCV infection rates among PWID.

Dr. Asher described an SSP model of care for PWID in part 2 of her overview. San Francisco implemented a comprehensive approach to ensure that PWID have access to viral hepatitis prevention, care and treatment services. The strategy includes regular HCV testing; rapid linkage to care and treatment; and access to substance abuse treatment, risk reduction counseling and sterile injection equipment.

Characteristics of the young adult PWID population in San Francisco include homelessness (70%), HIV-positive (7%), HCV-positive (45%), HBV-positive (21%), history of incarceration (85%), travel outside of San Francisco (62%), witness to a drug overdose (73%), and past heroin overdose (22%). Based on recent data, ~5,000 young persons <30 years of age are estimated to be homeless in San Francisco at this time.

IDU risk behaviors among young persons tremendously vary by demographic subgroup. Females are more likely than males to initiate IDU earlier and share syringes or other ancillary injecting equipment. The highest HCV seroconversion rates are among young PWID who are 22 years of age on average, white, heroin users or poly-substance users.

San Francisco launched a comprehensive needle exchange program (NEP) and adopted a citywide harm reduction philosophy early in the HIV epidemic. At this time, four NEPs in San Francisco operate seven days per week and provide services to ~75% of the total population of ~15,000 PWID in the city. The San Francisco Needle Exchange (SFNE) offered a range of services to PWID during its physical co-location with Homeless Youth Alliance San Francisco. During that time, SFNE outreach workers served >200 unique PWID each week and made ~12,000 contacts each year through delivery of the following services.

- Drop-in center (food, movies, bathroom/shower, case management and respite from the streets)
- Mental health services through one-on-one counseling with a social worker and a psychiatrist who was able to prescribe and dispense medications
- Specialty groups and workshops: the arts, LGBTQ support, men's issues, women's issues and games
- Street-based outreach
- Medical care: wound care, lice or scabies treatment, pregnancy testing, substance use treatment referrals, hepatitis A virus and HBV vaccination, and primary care referrals
- Incentives for monthly HIV and HCV testing
- Naloxone distribution
- Syringe access and safe disposal, ancillary injecting equipment, crack pipes, condoms and lube
- Biweekly community cleanups to remove discarded needles

San Francisco's partnership with the Drug Overdose Prevention Education Project in 2003 served as the country's first Naloxone distribution program that was sanctioned by a public health department. The partnership resulted in 2,500 PWID, their family members and friends being prescribed or trained in the administration of Naloxone from 2010-2013. The 2015 Rowe study reported key outcomes among these 2,500 individuals: 1,592 previously witnessed an overdose; 702 experienced overdose reversals; 95.7% of Naloxone recipients were known to have survived; and <1% reported serious adverse effects.

SFNE conducted extensive outreach to overcome local barriers to and ensure the success of its NEP. SFNE outreach workers established a regular street presence in venues where PWID congregated to initiate conversations and distribute supplies. Enrolled SFNE participants were trained as secondary recruiters to refer new participants and provide PWID with clean syringes, needles and other equipment when needed. SFNE staff closely collaborated with SSPs,

community clinics and other agencies that also serve PWID to increase the reach of education provided to the community.

SFNE outreach workers leveraged their existing relationships and closely collaborated with street-based health providers and staff at homeless drop-in sites to obtain direct referrals. SFNE outreach workers posted flyers at multiple venues where PWID were likely to congregate: single-room occupancy hotels, clinics, popular street locations, SSPs, alleys, parks, public bathrooms, shelters and bars. SFNE sustained a reliable presence over time by maintaining the same hours of operation 365 days per year with no holiday closures.

In addition to outreach, SFNE also implemented a comprehensive approach to provide retention in care, follow-up and case management services to all participants. An extensive seven-page form was used to collect detailed contact information from PWID, including their physical and email addresses, phone numbers, social media accounts, and three family/close personal contacts. During the intake process, PWID were asked to pinpoint their regular street locations, identify social services programs that are routinely accessed, allow SFNE staff as Facebook friends, and permit their photographs to be taken. SFNE maintained these data in a secure encrypted database.

SFNE sent reminders of medical care, court or other types of appointments to all participants via street contacts, cell phone/email messages, text messages, home visits or social media messages. SFNE used contact information on the intake form and made calls to jails and hospitals to locate and reengage non-responsive participants. SFNE staff with access to jails regularly visited incarcerated participants to facilitate reengagement in care and confirm continued provision of resources upon their release. The medical examiner's office also was contacted to verify that participants had not died since their last contact with SFNE.

Dr. Asher announced that SFNE closed its physical location in December 2014 as a result of opposition from the community. Due to significant public health support, however, SFNE is still delivering the same services from a mobile van. The provision of services from a mobile van has increased visibility and nearly tripled the number of persons who present to SFNE each week. However, the disadvantages of outreach from a mobile van include a sub-optimal site for medical care and the relocation of NEP services from a physical location to the street.

Dr. Asher concluded her overview by presenting a series of photographs of camps of homeless youth in Golden Gate Park; single-room occupancy hotels that rent rooms from 1-30 nights; and outreach workers providing care to PWID on the street.

CHAC DISCUSSION: HIV/HCV PREVENTION AMONG PWID

CHAC discussed the following topics during the question/answer session with the panel of NCHHSTP staff.

- CDC's plans to routinely rerun the vulnerability index analysis (e.g., every two years) as the top-ranking jurisdictions continue to submit updated local data over time.
- CDC's ongoing efforts to improve viral hepatitis surveillance at the national level to ensure that states and localities have the ability to report both their acute HCV and chronic HCV cases.
- CDC's consultation or collaboration with the SAMHSA Block Grant Program in developing guidance for state grantees to redirect federal funds from the two CoAgs to support SSPs.
- CDC's direct communications and other follow-up activities with the top 220 counties in the vulnerability index.
- Plans by CDC, HRSA and SAMHSA to translate the vulnerability index data into actual systems of prevention and care to address HIV, HCV and IDU in the most vulnerable jurisdictions.
- HRSA's successes, experiences and lessons learned from its systems-level approach, in collaboration with SAMHSA, to incorporate buprenorphine prescribing practices into primary care in Ryan White clinics.
- The urgent need to target interventions for the prescription opioid/heroin epidemic to school-age children and significantly improve access to drug treatment among adults through an HHS-wide partnership.
- The ability to use RWHAP and CHC funds from HRSA to provide HIV and HCV care, treatment and other services to the top-ranking counties identified in the CDC vulnerability index.
- Support for or best practices of successful relationships between behavioral health treatment programs and harm reduction programs in the same jurisdiction.
- SAMHSA's extensive training and outreach to states to resolve reimbursement, stigma and other issues related to poor buprenorphine prescribing practices among providers.
- SAMHSA's new three-year "Medication-Assisted Treatment (MAT) Prescription Drug and Opioid Addiction" grant program that awards funding to states to conduct innovative approaches, such as the provision of MAT in jails.
- The ability to replicate the SFNE model in FQHCs.
- The need for state agencies to establish close partnerships in redirecting their federal funds to support SSPs.

CHAC applauded the tremendous accomplishment of Congress changing the law that now allows the use of federal funds to support SSP components. The extensive discussion resulted in CHAC making several suggestions for the federal agencies to consider in their ongoing efforts to address HIV and viral hepatitis among PWID.

- CDC should address perceived discrepancies between actual data and the vulnerability index by providing states and localities with a clear explanation of the methods that were used in the analysis. For example, the disproportionately high rates of opioid overdoses and HCV among young PWID in Massachusetts are well documented. However, no county in the state was included in the vulnerability index. CDC should clarify that its

inclusion criteria for the analysis was based on population sizes per 100,000 or 10,000 persons. Counties in Massachusetts and other states that were excluded from the vulnerability index likely would be included if CDC used smaller population sizes (e.g., per 1,000 or 500 persons).

- CDC should compile lessons learned and experiences from the Indiana outbreak to develop and disseminate "rapid linkage to care best practices" to all jurisdictions in the United States. CDC should design the document to highlight and propose strategies to resolve structural and administrative barriers to care.
- CDC should include acute HCV as an indicator in its national viral hepatitis surveillance system. CDC used acute HCV as a proxy for unsterile IDU in its vulnerability analysis, but state health departments have no capacity to conduct contact tracing for acute HCV at this time.
- CDC, HRSA and SAMHSA should jointly conduct an economic modeling study to estimate the potential costs states will incur in providing prevention, treatment and care services to address the combined IDU/HCV epidemic in their individual communities. The study should be designed to illustrate the cost-effectiveness of prevention versus the societal burden of taking no action to lower the incidence of IDU/HCV.
- HRSA should host a webinar or issue guidance to RWHAP grantees on redirecting their Early Intervention Services funds for the CDC determination of need process.
- Congress proposed a $1.1 billion appropriation to respond to the opioid epidemic. CHAC should discuss a strategy to educate Congressional staff on the need to allocate a portion of the proposed appropriation to implement and scale up cost-effective interventions at the national level to prevent the transmission of blood-borne viruses (e.g., HIV, HBV and HCV).
- SFNE closed the physical location of its NEP due to limited community support. The federal agencies should provide their grantees with potential approaches to overcome strong opposition to SSPs by the community or local law enforcement:
    - Present local policymakers with rigorous data on the positive impact of SSPs
    - Identify a champion or advocate for the SSP from the law enforcement community at the local level
    - Create relationships through police/public meetings and other community events
    - Recruit staff that will be devoted to delivering unique, street-based outreach and services to society's most vulnerable and marginalized populations
    - Obtain endorsement by addressing the needs of the community
- CDC and HRSA should provide their grantees with successful models of SSPs that are co-located in FQHCs (e.g., Boom! Health in the Bronx and Housing Works in New York City).
- CDC should develop and widely disseminate a best practices document to states on successes, experiences and lessons learned in the field in implementing SSPs and other harm reduction activities. The document would be extremely helpful to programs in urban, suburban and rural areas.

PANEL PRESENTATION: CURRENT STATUS OF AND HHS'S ROLE IN HBV AND HCV ELIMINATION IN THE UNITED STATES

A panel of speakers presented a series of overviews regarding the current status of and HHS's role in establishing goals to eliminate HBV and HCV as a public health threat in the United States.

Overview of the National Academies HBV and HCV Elimination Phase 1 Report

Vincent Lo Re III, MD, MSCE
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Dr. Lo Re presented the National Academies *National Strategy for the Elimination of Hepatitis B and C in the United States: Phase 1 Report*. HBV and HCV are major public health threats in the United States. Current data estimate that >5 millions Americans are infected with chronic HBV and HCV, but most of these persons are unaware of their infection. Viral hepatitis mortality rates have continued to rise and now exceed 20,000 deaths per year. Recent data show that deaths attributable to chronic HCV now exceed mortality rates for 60 other nationally notifiable infectious conditions, including HIV.

CDC has continued to emphasize the critical need for increased attention to the viral hepatitis epidemic. Most notably, highly efficacious, well-tolerated and all-oral direct-acting antivirals (DAAs) for chronic HCV were introduced in 2014 with a 95% cure rate. Although emerging HBV therapies are in the pipeline, the existing HBV vaccine is still highly efficacious and provides ≥95% protection. A new study will be published in July 2016 and will demonstrate that >90% of persons maintained immunity 30 years after HBV vaccination.

The rising mortality rates and new, emerging tools generated a major call to action on viral hepatitis. At the global level, the World Health Assembly (WHA) launched a global response to HBV and HCV in 2014 that called for a 90% decrease in incidence and a 60% reduction in mortality by 2030. WHA formally approved this resolution in May 2016. At the U.S. level, HHS developed the National Viral Hepatitis Action Plan (VHAP), "Combating the Silent Epidemic of Viral Hepatitis," as a comprehensive, coordinated public health plan with specific goals to reduce the national burden and achieve HBV/HCV elimination in the United States.

To advance toward elimination, CDC and its partners solicited external input from the National Academies on HBV/HCV elimination goals. An independent scientific committee was convened with 17 subject-matter experts (SMEs) who have extensive experience in multiple disciplines:

viral hepatitis, virology and transplant surgery; epidemiology, public health and community action; primary care, substance abuse and corrections; and health education and research.

The committee's overall charge was to rigorously examine HBV/HCV scientific and policy issues related to diagnosis, linkage to/retention in care, prevention, treatment and control. No federal employees served on the committee to avoid conflict. DVH and the HHS Office of Minority Health co-sponsored the two phases of the committee's tasks.

Phase I Tasks (Completed)

- Conduct an up-to-date literature review on the following topics: HBV/HCV epidemiology; HBV/HCV diagnosis, screening, linkage to care and treatment; and HBV/HCV prevention and control
- Determine if HBV/HCV elimination is feasible in the United States
- Identify barriers to elimination and critical success factors
- Prepare a report of findings (submitted on April 1, 2016)

Phase II Tasks (Initiated on June 8, 2016)

- Determine numerical goals for viral hepatitis reduction and elimination
- Identify key stakeholders and their responsibilities to achieve elimination goals
- Formulate a plan to overcome barriers to elimination
- Prepare a report of findings (scheduled for submission in early 2017)

Dr. Lo Re highlighted the key outcomes of the committee's Phase I tasks. Meetings on HBV and HCV elimination were held in November and December 2015. Both meetings included presentations from SMEs in the field, panel discussions and committee deliberations.

Presentations for the HBV Elimination Meeting

- HBV epidemiology and natural history
- Gaps in HBV monitoring and screening
- Logistics of community HBV screening
- Obstacles to HBV elimination
- Management of HBV infection
- HBV reactivation, immunology and virology

Presentations for the HCV Elimination Meeting

- HCV epidemiology and natural history
- HCV screening and management
- Treatment of chronic HCV
- Cost-effectiveness of DAA therapy
- Price of and access to DAA therapy
- National infrastructure for HCV

- HCV elimination among PWID
- Outreach to HCV patients in correctional settings

The committee thoroughly reviewed and discussed the 1998 Dowdle study as a starting point to reach agreement on standard definitions. "Disease control" was defined as a decrease in the incidence and prevalence of infection and sequelae. The committee recognized that ongoing disease control measures might be required. "Elimination" was defined as the cessation of HBV/HCV transmission and complete prevention of their undesirable manifestations (e.g., liver cancer and advanced liver disease). "Eradication" was defined as a decrease in the incidence of infection and disease to zero.

The committee used the smallpox eradication campaign as the gold standard in exploring the feasibility of HBV/HCV elimination in the United States. The successful factors of this effort included a recognizable clinical presentation of smallpox, no silent transmission of disease, lack of chronic infection, no non-human reservoir, and availability of a highly effective vaccine. However, the committee acknowledged that many of the successful factors for the smallpox eradication campaign could not be applied to HBV/HCV elimination. Most notably, both HBV and HCV are endemic abroad. The importation of HBV cases into the United States enhances disease transmission.

Acute and chronic HCV typically are asymptomatic. The HBV vaccine is effective, but vaccination is not universal. Modeling studies have shown that even with universal HBV vaccination, the disease would not be eradicated for two generations. A curative therapy for chronic HBV and a vaccine for HCV have not been developed to date. The cost of DAAs for HCV limits access to these drugs.

The committee reached several conclusions regarding HBV/HCV control and elimination in the United States. HBV/HCV control is feasible in the short-term. HBV/HCV elimination as a public health problem is feasible, but will require more time, considerable public and political will, resources and attention to existing barriers to elimination. The committee defined a "public health problem" as a disease that is a major threat to the health of communities by virtue of its transmission or need for attention due to morbidity and mortality.

The committee's assessment of steps to eliminate chronic HBV as a public health problem is summarized below.

Major barriers to HBV elimination

- HBV surveillance is limited and under-funded. Active surveillance is needed to evaluate whether elimination goals are being achieved, but CDC only funds seven jurisdictions to conduct HBV surveillance at this time.
- HBV screening, diagnosis and linkage to care are inadequate. Current data estimate that only ~33% of persons with chronic HBV are aware of their infection. Stigma is a major

barrier to high-risk patients seeking screening and care. Immigrants, refugees and other foreign-born adults who import HBV into the United States are difficult to reach. Programs should be tailored to specifically address HBV screening, diagnosis and linkage to care in foreign-born populations.
- Existing capacity to track HBV vaccination across jurisdictions is extremely weak. Vaccine registries should be developed to share data across jurisdictions.

Steps to end HBV transmission
- Childhood HBV vaccination rates should be improved. Current data show that only 72% of infants receive HBV vaccine within three days of birth.
- Stronger efforts should be made to identify, diagnose and provide linkage to care services to populations that are at high risk for HBV. Enhanced targeting to these groups should include routine HBV vaccination in STD clinics and correctional settings.
- HBV vaccination programs should be supported in endemic countries, particularly Asia and sub-Saharan Africa, to reduce the importation of cases into the United States.
- HBV-positive pregnant women should be identified, linked to care and treated as early as possible. However, SMEs and consensus-based guidelines should be consulted in the management, care and treatment of HBV-positive pregnant women.
- Universal HBV vaccination should be considered.

Steps to reduce morbidity and mortality attributable to chronic HBV
- The pool of providers with solid training in chronic HBV management should be increased to improve monitoring of the disease from both serologic and virologic perspectives; track the need for and adherence to treatment among patients; and identify, avoid and modify key risk factors that progress to end-stage liver disease and HBV-associated hepatocellular carcinoma.
- Awareness of and research in HBV reactivation should be enhanced, including HBV screening and antiviral prophylaxis.
- The development and testing of HBV therapies that eliminate cccDNA should be promoted.

The committee's assessment of steps to eliminate chronic HCV as a public health problem is summarized below.

Major barriers to HCV elimination
- HCV surveillance is limited and under-funded.
- HCV screening, diagnosis and linkage to care are inadequate. Current data estimate that ~50% of persons with chronic HCV are undiagnosed and unaware of their infection. PWID account for most infections, but are less likely to be tested. CDC data show that persons in the 1945-1965 birth cohort account for 75% of HCV cases. Stigma is a major barrier to high-risk patients seeking screening and care.

- DAAs are cost-effective, but are given to only 10% of chronic HCV patients due to costs, restrictions and denials from insurers. The prevalence of HCV in correctional settings is estimated to be 10- to 15-fold higher than in the general population, but correctional facilities have limited capacity to test and treat HCV. Increased access to HCV curative therapies will be critical to elimination.
- HCV is not a public health priority in terms of the level of visibility and research funding devoted to this disease.

Steps to end HCV transmission

- Additional research is needed to facilitate the development of an HCV vaccine.
- Primary prevention is a critical component to ending HCV transmission. Harm reduction services should include NEPs/SSPs, opioid substitution therapy, and substance abuse prevention and counseling. Harm reduction programs that have been developed for urban jurisdictions should be adapted for use in rural, less densely populated areas.
- DAA treatment should be expanded to include HIV-positive persons, incarcerated persons and PWID.
- HCV reinfection rates after cure with DAA therapy should be decreased, particularly among PWID and MSM. However, additional research is needed to determine risk factors for reinfection and develop and test interventions to reduce reinfection.

Steps to eliminate chronic HCV

- HCV screening, diagnosis, and linkage to/retention in care should be improved. More candidates for DAA therapy should be identified.
- Access to DAA therapies should be increased due to their $\geq$90% efficacy rate in chronic HCV patients.
- Adherence to DAAs and factors for non-adherence should be evaluated.
- Understanding of resistance to DAAs should be strengthened to achieve a better impact of HCV treatment.

Steps to reduce morbidity and mortality attributable to chronic HCV

- The number of patients treated for chronic HCV and cured should be increased to prevent disease transmission and associated sequelae (e.g., cirrhosis, end-stage liver disease, extra-hepatic complications, hepatocellular carcinoma and death).
- The pool of providers with solid training in chronic HCV management should be increased to avoid and modify key risk factors that progress to liver disease.
- Research on anti-fibrotic therapies should be promoted.

Update on the 2017-2020 National Viral Hepatitis Action Plan

Richard Wolitski, PhD
Acting Director, Office of HIV/AIDS and Infectious Disease Policy
U.S. Department of Health and Human Services

Advice Requested from CHAC by HHS:

1. What are the most important actions to take to achieve the following goals?
   - Reduce new HBV and HCV infections among infants, adolescents and adults
   - Screen and diagnose more persons with HBV and/or HCV infection
   - Increase access to viral hepatitis care and treatment
   - Improve viral hepatitis data and surveillance
2. Should the federal government implement different strategies to respond to and ultimately eliminate viral hepatitis in the United States? To respond to this question, CHAC members should describe their lessons learned in the field, successful models, partnerships, policy changes, program priorities, training, and outreach/education.
3. What approaches should be conducted to best engage non-federal stakeholders?

Dr. Wolitski described HHS's ongoing efforts to update the 2017-2020 VHAP. The major challenges related to HBV/HCV include large populations that are estimated at 850,000 persons living with HBV and 3.5 million persons living with HCV. The number of reported acute HCV cases increased by 250% from 2010-2014, while the number of reported acute HBV cases increased by 5% from 2012-2013. Prescription opioid addiction is driving increases in heroin use and HBV, HCV and HIV infections. Of all persons with HCV, only 9% are cured. Current data show that more persons are dying from HCV than all other 60 nationally notifiable infectious disease combined, including HIV.

HHS is coordinating efforts with its federal partners to respond to the threat of viral hepatitis in the United States by updating the current VHAP that ends in December 2016. The Viral Hepatitis Implementation Group (VHIG) includes representation by 21 federal departments and agencies, including the White House, HHS, HUD, U.S. Department of Veterans Affairs, and U.S. Department of Justice.

VHIG has been convening meetings to provide input on the updated 2017-2020 VHAP and secure commitments from the U.S. government to take action at the federal level with existing resources. During its strategic planning meeting in March 2016, VHIG proposed three strategic goals for the 2017-2020 VHAP to ensure alignment with the updated 2020 NHAS: (1) prevent new viral hepatitis infections; (2) reduce deaths and improve the health of persons living with viral hepatitis; and (3) decrease viral hepatitis health disparities.

HHS acknowledges that achievement of the national VHAP goals will require action and response beyond the federal government. The critical role, active involvement and innovation of state, local and non-governmental stakeholders and partners in implementing VHAP in the field are emphasized. HHS has been holding a series of stakeholder engagement events and leveraging existing opportunities (e.g., the current CHAC meeting) to obtain input from non-federal partners and key stakeholders in both public and private sectors across the country.

The National Academies committee is scheduled to release its Phase 2 report on HBV/HCV elimination in the United States in early 2017, but HHS has made a commitment to release the 2017-2020 VHAP by October 2016. HHS recognizes the importance of having a complete and updated plan before the new Administration takes office. However, HHS intends to reexamine the 2017-2020 VHAP after the release of the National Academies Phase 2 report in 2017. HHS also is exploring the possibility of launching a new website for state/local governments, CBOs and national organizations to publicly declare their individual commitments to achieving the VHAP goals.

Dr. Wolitski announced that CHAC as a whole and/or individual members are free to email him (Richard.Wolitski@hhs.gov) if time is not available during the meeting to respond to the three questions posed by HHS. He clarified that CHAC also is welcome to submit a formal resolution for consideration. He confirmed that VHIG would discuss and consider CHAC's input in its ongoing efforts to update the 2017-2020 VHAP. Because the 2017-2020 VHAP is scheduled for release in October 2016, he asked individual members to submit their feedback within the next two weeks and CHAC to submit its formal comments within the next 2-4 weeks.

Overview of CDC's Role in HBV/HCV Elimination

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

Advice Requested from CHAC by DVH:

1. What activities should CDC and HRSA jointly conduct to help advance progress on HBV/HCV elimination?
2. What public health infrastructure should be considered as critical when considering HBV/HCV elimination goals?
3. What HIV expertise, programmatic experience and infrastructure can serve as the basis to expand access to HBV prevention services?
4. What collaborative strategies should CDC and HRSA undertake to jointly support HBV/HCV elimination in the United States?

5. What approaches can be taken to obtain broader leadership and commitment to HBV/HCV elimination efforts in the United States?

Dr. Ward described CDC's role in the development and implementation of plans to eliminate HBV/HCV as public health threats. CDC is the sole supporter of the World Health Organization (WHO) Global Hepatitis Program. WHA introduced the concept of HBV/HCV elimination in 2010; subsequently released three viral hepatitis resolutions; and directed WHO to take more action regarding prevention, program development and the establishment of HBV/HCV elimination targets.

WHO responded to the WHA resolutions by conducting modeling studies, convening expert panels, and holding meetings in every region of the world to discuss the feasibility of the potential targets. WHO presented the findings of these efforts to WHA in May 2016. WHA's approval of global elimination targets for viral hepatitis led UNAIDS to include two viral hepatitis strategies in its political declaration on HIV/AIDS in 2016.

WHO's global targets to eliminate HBV/HCV as public health threats are a reduction in new cases of chronic HBV/HCV infection (30% decrease by 2020 and 90% decrease by 2030) and a reduction in deaths from chronic HBV/HCV (10% decrease by 2020 and 65% decrease by 2030). CDC's modeling studies showed that if these goals are reached, the 6-10 million infections in 2015 would decrease to 900,000 infections by 2030 and the 1.4 million deaths in 2015 would decrease to <500,000 deaths by 2030. WHO also described programmatic improvements that would need to occur to achieve the health outcome targets, such as vaccination, prevention of mother-to-child transmission, harm reduction and safe injection services, testing and linkage to treatment.

CDC's role in HBV/HCV elimination at the global level includes implementation of the National HCV Elimination Demonstration Project in the country of Georgia in collaboration with partners. The comprehensive elimination plan is supported by a strong political commitment due to the tremendous burden of HCV in the country. Of ~4 million persons in the population, ~5% are HCV RNA-positive. By demographic group, 1 out of every 5 men 40-49 years of age in Georgia is HCV RNA-positive.

CDC maintains an in-country office in Georgia and provided leadership in several areas of the demonstration project, including elimination planning, laboratory quality assessment, policy development, program evaluation, capacity building, and facilitation of a public/private partnership with Gilead Sciences to provide up to 20,000 treatment courses per year at no charge. From May-October 2015, 3,722 persons initiated treatment. Georgia established its HCV elimination targets as 90% diagnosed, 95% treated and 95% cured by 2020.

CDC's role in HBV/HCV elimination at the U.S. level includes the development of a proposal and scope of work, creation of an interagency agreement, and identification of co-sponsors to support independent activities conducted by the National Academies committee. The co-sponsors include

CDC/DVH, HHS Office of Minority Health, National Viral Hepatitis Roundtable, American Association for the Study of Liver Disease, and Infectious Diseases Society of America. HHS and CDC have released several U.S. strategies and plans to prevent viral hepatitis transmission and disease since 2010.

In May 2016, DVH released its 2016-2020 Strategic Plan, *Bringing Together Science and Public Health Practice for the Elimination of Viral Hepatitis*, with a vision, mission, three overarching goals and four strategic imperatives with objectives.

Vision
- Eliminate viral hepatitis in the United States and worldwide

Mission
- Bring together science and public health practice to eliminate viral hepatitis

Goals
- Decrease the incidence and prevalence of viral hepatitis
- Decrease morbidity and mortality from viral hepatitis
- Reduce viral hepatitis-related health disparities

Strategic Imperatives
- Assure vulnerable populations are vaccinated to prevent viral hepatitis
- Assure early detection and response to stop HBV/HCV transmission
- Assure persons living with HBV/HCV are identified and linked to recommended care and treatment services
- Act globally to prevent, direct and control viral hepatitis

Examples of CDC's role in implementing national HBV/HCV elimination plans are highlighted as follows. For policy development, CDC is updating Advisory Committee on Immunization Practices policies to guide vaccine-based strategies for HBV elimination. Testing and treatment policies are being updated in response to strategic information. For assurance, the birth dose coverage of HBV vaccine is being improved with accreditation measures. Access to recommended testing, care and treatment is being enhanced with clinical decision tools. Assistance is being provided to develop interventions to prevent HBV/HCV transmission. For prevention research, social networks of PWID with HBV or HCV are being investigated. Strategies are being explored to reduce barriers to the recommended services.

CDC recently reviewed its metrics to determine progress toward reaching the HBV/HCV elimination targets. In terms of HBV vaccination coverage, the current birth dose coverage rate of 74% in newborns 0-3 days of age does not meet the 85% target. The current HBV vaccination rate of 93% in infants 19-35 months of age exceeds the 85% target. The current HBV vaccination rate of 25% is extremely poor in adults $\geq$19 years of age. In terms of state performance, several

states still have not decreased HBV/HCV incidence by 60% to reach the Healthy People 2020 goals.

In terms of assuring persons living with HBV/HCV are identified and linked to recommended care and treatment services, none of the four 2020 targets for morbidity have been achieved as of 2014: increase the number of persons who are aware of their HCV or HBV status; increase HBV testing of Asian/Pacific Islanders; and increase HCV testing of the 1945-1965 birth cohort. The two 2020 targets to reduce HBV and HCV mortality have been achieved as of 2014.

CDC acknowledges the critical need for additional data and enhanced surveillance systems to better monitor progress toward potential elimination targets in the following areas: the burden of disease at state and local levels; access to and utilization of testing, care and treatment services to document rates of HCV cure and reinfection; preventive services for PWID (e.g., the number of SSPs per PWID in jurisdictions); and progress in reducing health disparities by race/ethnicity, socioeconomic status, incarceration and geographic location.

A coalition of professionals in public health, clinical care and academic medicine launched an HCV elimination program in October 2015 in the Cherokee Nation in Oklahoma with a strong commitment by tribal leadership. Of the small population of 314,000 persons in the defined coverage area of 14 counties, 95% receive care from Cherokee Health Services. The number of HCV infections in the target population is estimated at ~5,000. HCV prevalence and mortality rates in American Indian populations are twice as high as rates in the general population.

Emerging testing, care and cure programs were implemented. Routine testing was initiated in the 1945-1965 birth cohort and eventually was expanded to include all persons >20 years of age who receive care from Cherokee Nation Health Services. Of 715 HCV antibody-positive persons who presented to Cherokee Nation Health Services from October 2012-July 2015, 488 received RNA testing, 388 were RNA-positive, 223 initiated treatment, 201 completed treatment, and 180 achieved a sustained virologic response.

The 2016 *MMWR* publication, “Identification and Clinical Management of Persons with Chronic HCV Infection in the Cherokee Nation (2012-2015),” currently is being translated into the Cherokee language for distribution to local tribes. The Principal Chief issued a strong statement regarding the need to entirely eliminate HCV from the Cherokee Nation population. The Cherokee Nation established its HCV elimination goals as 85% diagnosed and 85% cured of HCV by 2020.

Overall, CDC’s role in HBV/HCV elimination is to support elimination planning efforts; improve vaccine-based strategies to eliminate HBV transmission; strengthen detection, investigation and response to prevent new HBV/HCV infections; accelerate the adoption of HBV/HCV testing and treatment as routine services in diverse settings; develop model elimination projects; and revise existing data systems to monitor progress national elimination targets.

CHAC DISCUSSION: HBV/HCV ELIMINATION

CHAC devoted its discussion to responding to the HHS questions posed by Dr. Wolitski and the DVH questions posed by Dr. Ward.

CHAC DELIBERATIONS ON THE HBV/HCV ELIMINATION QUESTIONS

HHS QUESTIONS BY DR. WOLITSKI: 2017-2020 VHAP

Question	CHAC Response
Q1: Most important actions to take	• The current workforce of trained and experienced viral hepatitis providers is extremely limited. For example, only infectious disease physicians and gastroenterologists are permitted to treat HCV patients in the state of Indiana. The goal of increasing HBV/HCV testing, treatment and care will not be achieved unless the larger pool of PCPs is trained in viral hepatitis. • Current awareness and testing initiatives at the community level are extremely weak because the public does not perceive HBV/HCV as public health threats. CDC should scale up screening at the national level, particularly since ~67% of persons are unaware of their HBV infection and ~50% of persons are unaware of their HCV infection. • CDC should provide programs and CHWs with guidance and TA on identifying and targeting HBV/HCV testing to high-risk groups in the field, particularly PWID. • CDC's rationale for recommending HCV testing of the 1945-1965 birth cohort without including other high-risk groups is unclear. For example, minority populations with limited or no access to health care typically are diagnosed with HCV at late stages of the disease (e.g., cirrhosis or liver cancer). HCV treatment would not benefit persons with late-stage diagnoses.

Question	CHAC Response
Q2: Different strategies by the federal government	• The Federal Bureau of Prisons (FBOP) should allocate a portion of its budget to pay for directly-observed short-course therapy with DAAs for all HCV-positive incarcerated persons. Correctional facilities are the best settings to ensure adherence to HCV treatment due to their "captive" populations. Payment of HCV treatment by FBOP would ensure that the same standard of care is provided to all incarcerated persons in the country. However, innovative non-federal payment models also should be considered due to the history of private, for-profit companies providing sub-optimal, low-quality HIV and HCV medical services to incarcerated persons. For example, Illinois now contracts with an academic institution to provide HIV and HCV care to all incarcerated persons in the state via tele-medicine technology. • Federal agencies should develop and launch an "ADAP-like" program nationally. For example, the new "Hepatitis Drug Assistance Program" would ensure that uninsured and under-insured persons with HCV have access to DAAs. However, other CHAC members noted that with additional funding, the current ADAP infrastructure would be sufficient to provide medication assistance to cure HCV-positive/HIV-negative persons. Some ADAPs have added HCV drugs to their formularies, but an extremely small percentage of HIV-positive clients have initiated treatment to be cured of HCV. The National Alliance of State and Territorial AIDS Directors recently conducted a survey to determine factors for the low uptake of HCV treatment among HIV-positive ADAP clients.
Q3: Engagement of non-federal stakeholders	• Communities should launch a collective call to action to inform local elected officials and policymakers that the current cure for HCV is one of the most significant public health successes. Grassroots efforts could play a critical role in increasing support and funding of viral hepatitis elimination goals. • Stakeholders should take an active role in widely publicizing the success of the Cherokee Nation HCV elimination program. Grassroots efforts could lead to replicating this model in other local jurisdictions throughout the country.

DVH QUESTIONS BY DR. WARD: CDC'S ROLE IN HBV/HCV ELIMINATION

Question	CHAC Response
Q2: Critical public health infrastructure for HBV/HCV elimination	• CDC should closely collaborate with professional associations to improve HCV surveillance. Chronic HCV should be made a nationally reportable condition and these data should be routinely collected from all states and local jurisdictions. Enhanced surveillance of both HBV and HCV should be a major priority at CDC.
Q4: CDC/HRSA collaboration in HBV/HCV elimination	• Collaborative strategies for CDC and HRSA to support HBV/HCV elimination in the United States should explicitly include Puerto Rico, the U.S Virgin Islands and other U.S. territories. The burden of HCV in these areas is tremendous.
Q5: Broader leadership and commitment to HBV/HCV elimination	• CDC should perform economic modeling to illustrate and compare costs between HCV treatment versus treatment of significant sequelae at late-stage diagnosis, such as cirrhosis and organ transplantation. Ethicists should be extensively involved in economic modeling to inform treatment decision-making (e.g., reinfected patients who require additional expensive treatment versus patients who have never received treatment).

Dr. Mermin made several remarks in response to the panel presentation. The new terminology of "elimination as a public health threat" that is referenced in current strategic plans and goals is unclear and not well defined. Discussions on elimination might be better served at this time by focusing on a vision rather than a strategic plan with a concrete mission. For example, HBV is included in both U.S. and global elimination goals, but HBV cannot be "eliminated" without a cure. Moreover, elimination plans and goals do not address disparities among existing resources, the percentage of the population diagnosed with HBV/HCV, and the current scope and capacity of programs.

Dr. Ward thanked Dr. Mermin for his insightful comments. He clarified that a precedent already has been established in creating elimination goals for diseases with no curative therapies or highly-effective vaccines. However, these regiments are available for hepatitis. The inclusion of HBV in elimination goals with no cure is intended to galvanize political commitment, leverage resources and generate planning efforts at this time for the future.

Update by the CHAC Viral Hepatitis Workgroup

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

Dr. Arora presented background information and other data to support the workgroup's five draft recommendations that would be presented during the Business Session for CHAC to take formal action. Current data estimate that 3.5 million persons in the United States are living with HCV and 30,000 new HCV infections occur each year, but most of these individuals are unaware of their infection.

The HCV epidemic disproportionately impacts the 1945-1965 birth cohort. HCV causes liver disease and liver cancer and is the leading cause of liver transplantation. HCV mortality now exceeds deaths from all other nationally reportable diseases. The HCV lifetime mortality rate is 25%-40%, but expanded access to treatment will reduce HCV-related healthcare expenditures over the long-term.

All-oral HCV regimens have cure rates that exceed 90%. On June 28, 2016, one pill per day will be available for all genotypes. HCV treatment costs have been steadily decreasing over time. HCV treatment of PWID can reduce disease transmission and generate a reduction in the prevalence of disease. Adoption of a test and treat strategy as a comprehensive intervention has the potential to reduce incidence, particularly with MAT and in SSPs. Expanded access to HCV treatment will avert >320,000 deaths.

The workgroup's five draft recommendations and supporting information are outlined below.

1. *Provide increased funding (through additional resources and/or flexibility with existing federal awards) for HCV surveillance, prevention, linkage to care, treatment, and medical case management programs.*

    - The United States should ensure that each state has core capacities to scale up the collection of HCV surveillance data.
    - Timely and accurate surveillance is essential to directly responding to data-driven HCV programs.
    - Increased funding is needed to sustain viral hepatitis coordinators in jurisdictions and ensure technological and epidemiological capabilities are available to monitor the HCV epidemic at the local level.

- DISs and other field-based epidemiologists contribute to service response by reengaging out-of-care HCV-positive persons.
- The failure to deploy systems-level capacity to address the care and treatment needs of persons living with HCV infection and protect the health of the public from a growing HCV epidemic will result in substantial increases in morbidity and mortality.

2. *Integrate HCV and HIV prevention and care programs to leverage federal, state and local direct care program capacities and infrastructures when practicable and feasible.*

    - The existing HIV and STD prevention and care infrastructure and expanded health insurance coverage can be leveraged to increase access to HCV prevention and treatment services.
    - New treatments are highly effective in curing HCV infection. Direct-care, intensive and short-term interventions likely will enable more persons to be served than in the current HIV care system that requires long-term engagement.

3. *Develop enhanced public health support initiatives, including surveillance and direct care services, for counties that are identified as vulnerable to the transmission of HCV and outbreaks of HIV among PWID.*

    - Results of CDC's recent HIV outbreak vulnerability assessment and HBV/HCV incidence data should be utilized to ensure at-risk states have the capacity to mount a data-driven response.
    - The urgency to address the impact of HCV infection has not been emphasized, particularly among PWID <30 years of age.
    - Increased funding should be allocated to CDC to provide TA to states to respond to increases in new HCV infections.
    - HRSA should leverage the capacity of AETCs to deliver training and TA in the context of HCV care and treatment.

4. *Utilize the National Academies elimination targets framework for the development of an HCV action plan, including population-specific targets and plans with attention to health disparities by race/ethnicity, age and injection drug use experience.*

    - CDC should apply the National Academies framework of HBV/HCV elimination targets to its domestic action planning efforts.
    - CDC should establish population-specific targets, including treatment goals for the 1945-1965 birth cohort, young PWID and persons with HIV co-infection.
    - New prevention efforts and treatment modalities historically have disproportionately benefited groups with greater resources and exacerbated health disparities.

5. *Develop an HCV elimination project in a state or local jurisdiction that is modeled after P4C demonstration projects, the Cherokee Nation program or other data-to-care (data-to-impact) initiatives.*

- An HCV elimination project should be developed to:
    - demonstrate the value of HCV elimination on overall healthcare expenditures;
    - document a commitment to the WHO goal to advance toward HCV elimination;
    - expand and apply lessons learned from P4C demonstration projects; and
    - provide research findings to demonstrate best practices for HCV testing, care and treatment as well as cost-savings from a targeted elimination program.

CHAC Business Session

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

Ms. Fukuda opened the Business Session and called for CHAC's review, discussion and/or formal action on several topics.

TOPIC 1: DRAFT CHAC MEETING MINUTES

A motion was properly placed on the floor by Dr. Sanjeev Arora and seconded by Mr. Guillermo Chacon for CHAC to approve the past two sets of meeting minutes.

CHAC unanimously adopted the draft November 4-5, 2015 and the draft February 3, 2016 Meeting Minutes with no changes or further discussion.

TOPIC 2: AMENDED HIV RESEARCH NETWORK RESOLUTION

Dr. Kates presented the amended HIVRN resolution that she and Dr. del Rio revised in response to CHAC's comments and suggestions on the previous day.

> CHAC expresses concern that the Agency for Healthcare Research and Quality (AHRQ) plans to defund the HIV Research Network (HIVRN) in FY2016. Established in 2000, HIVRN is a unique dataset comprised of 18 clinical research sites that has collected data

on more than 25,000 children, adolescents and adults with HIV for more than 15 years. In addition to HIVRN providing an irreplaceable longitudinal data set tracking HIV-related health care outcomes, it is the only source of U.S. domestic data that tracks resource utilization and care and treatment costs for HIV-infected patients.

Because HIVRN is the only source of national cost data, it is routinely used by federal agencies (including the Centers for Disease Control and Prevention, Health Resources and Services Administration, and White House Office of National AIDS Policy) and non-governmental organizations to help assess resource allocation, implementation of treatment guidelines, performance along the HIV care continuum, the role of the Ryan White HIV/AIDS Program and other health financing mechanisms, and challenges and opportunities remaining in HIV care and treatment. HIVRN is a unique and invaluable resource in the fight against HIV.

CHAC urges the Secretary of the U.S. Department of Health and Human Services to work with AHRQ to restore the $1.6 million required to sustain this critical and unique national HIV clinical database and to ensure continued funding by including HIVRN in future budget requests.

Action	Description
Co-Chair's call for a vote	Motion properly made by Dr. Sanjeev Arora for CHAC to accept the amended HIVRN resolution Motion seconded by Ms. Linda Scruggs
Outcome of vote	**Motion unanimously passed by 15 CHAC voting members**
Next steps	The CHAC Co-Chairs will draft a letter with the finalized resolution to the HHS Secretary with copies to the CDC Director and HRSA Administrator. Because HIVRN funding is scheduled to end in FY2016, the CHAC Co-Chairs will send the letter as quickly as possible.

TOPIC 3: SYPHILIS PREVENTION AND CONTROL IN THE UNITED STATES

Dr. Bolan acknowledged that CHAC would not have sufficient time during the remainder of the Business Session to address all eight questions DSTDP posed on the previous day. As a result, she asked CHAC to focus on only one of the eight questions that requires formal action at this time: "Should CDC develop a National Strategy instead of a Call to Action for syphilis?"

Dr. Bolan made several clarifying remarks to guide CHAC's discussion. A "call to action" is a brief document (generally six pages maximum) that succinctly describes the problem, brings attention

to relevant issues, and specifies the roles and responsibilities of key stakeholders (e.g., health departments, providers, academia and communities). A "national strategy" is a longer, more extensive document that outlines goals, objectives, strategies and action steps. National strategies have been developed for HIV, viral hepatitis and TB.

Ms. Fukuda proposed the following recommendation based on CHAC's extensive discussion on the advantages and disadvantages of CDC developing a call to action versus a national strategy for syphilis.

> CHAC recommends that CDC develop and implement a Syphilis Call to Action with the following components:
>
> - Deliver technical assistance to jurisdictions
> - Provide strong support for implementing and scaling up data-to-impact approaches
> - Clearly articulate the urgent need to address the resurgence of syphilis in the United States
> - Replicate aggressive syphilis response efforts, such as those conducted by the Marion County (Indianapolis) Public Health Department, that have been successful in decreasing syphilis rates at the local level
> - Emphasize the development of strategies for populations with a disproportionate impact (e.g., congenital syphilis and MSM)

Action	Description
Outcome of vote	**No formal vote taken; consensus agreement by CHAC to endorse the recommendation**
Next steps	• The CHAC Co-Chairs will draft a letter with the recommendation to the CDC Director for DSTDP to take action. • DSTDP will present the draft Syphilis Call to Action to CHAC for review and comment during the November 2016 meeting. DSTDP expects to finalize and begin implementing the Call to Action in January 2017. • CHAC members, particularly those who are state/local health department officials, will email their individual comments to Margie Scott-Cseh (zkr7@cdc.gov) on the remaining seven questions for distribution to DSTDP. DSTDP will consider CHAC's input in its ongoing efforts to develop the Syphilis Call to Action.

TOPIC 4: VIRAL HEPATITIS WORKGROUP'S DRAFT PROPOSED RESOLUTION

Ms. Fukuda noted that a written version of the Viral Hepatitis Workgroup's full three-page draft proposed HCV resolution was included in the meeting packets. However, she announced that the remaining time in the Business Session was insufficient for CHAC to fully discuss, vet and formally vote on all components. She opened the floor for CHAC's brief, interim comments.

CHAC commended the workgroup on its outstanding efforts in drafting a comprehensive resolution that covers all aspects of HCV, including prevention, testing, treatment and elimination. However, several members were concerned about tabling the formal vote because the next meeting would be held after HHS released the 2017-2020 VHAP in October 2016 and CHAC's input would not be considered.

Ms. Fukuda suggested an approach to address CHAC's concern. First, CHAC would provide high-level, overarching comments. Second, the draft proposed HCV resolution would be revised based on CHAC's input and a shorter, more condensed version would be emailed to Dr. Wolitski immediately after the meeting as CHAC's formal response to the 2017-2020 VHAP. Third, CHAC would agree on a process to formally approve the draft proposed HCV resolution at a later time.

CHAC agreed with Ms. Fukuda's proposed approach, engaged in a discussion and suggested several revisions to the draft proposed HCV resolution. Based on this feedback, Ms. Fukuda entertained a motion for CHAC to approve emailing the following draft proposed resolution to Dr. Wolitski.

1. **Provide increased funding (through additional resources and/or flexibility with existing federal awards) for HCV surveillance, prevention, linkage to care, treatment, and medical case management programs.**

   Given the number of individuals impacted by hepatitis C virus (HCV), it is of utmost importance that the United States ensures every state and territory has the core capacities necessary to scale up the collection of HCV surveillance data and other epidemiologic information to guide and evaluate HCV testing and treatment. Notably, all states must maintain robust surveillance to monitor HCV incidence, prevalence and mortality. Timely and accurate surveillance is essential to direct responsive HCV programming that is data-driven. CDC should increase funding to the Division of Viral Hepatitis to sustain Viral Hepatitis Coordinator positions at the jurisdictional level; ensure technological capacities are available to monitor the local HCV epidemic; and ensure sufficient epidemiologic capacity exists in health department programs to perform HCV surveillance and monitoring.

2. **Integrate HCV and HIV prevention and care programs to leverage federal, state and local direct care program capacities and infrastructures when practicable and feasible.**

CDC and HRSA should allow for flexibility in existing federally-funded HIV and STD prevention and care programs to administer HCV risk assessment, testing services, and linkage to care and treatment in medical and community-based settings. Existing HIV and STD infrastructures can be readily deployed to deliver HCV services. Additional investments in the system would be required to sufficiently integrate HCV prevention, care and treatment. Due to the strength of the existing foundation, however, any new investments would need to be highly efficient and readily deployed to direct care interventions in a manner that is scalable.

3. **Develop enhanced public health support initiatives, including surveillance and direct care services, for counties that are identified as vulnerable to the transmission of HCV and outbreaks of HIV among persons who inject drugs (PWID).**

CDC should update the HIV outbreak vulnerability assessment and utilize these results with incidence data from HCV and HBV surveillance to ensure that states with at-risk counties are prioritized. The priority counties should have adequate funding to perform HCV surveillance and also should be provided with capacity-building initiatives and technical assistance to achieve a data-driven public health response to HCV. HRSA could deploy the capacity of AIDS Education and Training Centers to deliver training and technical assistance for HCV care and treatment to clinicians who serve both HIV/HCV co-infected and HCV mono-infected patients.

4. **Utilize the National Academy of Medicine (formerly the Institute of Medicine) elimination targets framework for the development of the 2017-2020 VHAP, including population-specific targets and plans with attention to health disparities by race/ethnicity, age and injection drug use experience.**

CDC should establish population-specific targets and treatment goals to maximize health equity in specific populations: the birth cohort, young PWID, all PWID, persons with HIV co-infection, racial/ethnic minorities, and marginalized populations (e.g., incarcerated persons and persons residing in rural areas with limited access to health services). New prevention and treatment opportunities at the outset historically have disproportionately benefited groups with greater resources and can serve to exacerbate health disparities. An approach of creating and monitoring population-specific targets will create greater accountability. These targets should be tracked along with other progress indicators.

5. **Develop an HCV elimination project in a state or local jurisdiction that is modeled after the Partnership for Care, an ongoing HCV elimination project by the Cherokee Nation, and other data-to-care (data-to-impact) initiatives.**

CDC and HRSA should implement an HCV elimination pilot project in at least one state or local community to demonstrate the feasibility of this model, document the value of eliminating HCV on overall healthcare expenditures, and further reinforce the U.S. commitment to the World Health Organization's guidelines to achieve HCV elimination.

Action	Description
Co-Chair's call for a vote	Motion properly made by Dr. Peter Havens to email the draft proposed HCV resolution, as amended, to Dr. Wolitski Motion seconded by Mr. Peter Byrd
Outcome of vote	**Motion unanimously passed by 15 CHAC voting members**
Next steps	The CHAC Co-Chairs will email the draft proposed HCV resolution, as amended, to Dr. Wolitski. Drs. Mermin, Ward and Cheever as well as the CHAC members will be copied on the email.

In terms of part 3 of Ms. Fukuda's approach, CHAC did not agree on a process to formally vote to approve the draft proposed HCV resolution. However, the members suggested several options in this regard.

- The Co-Chairs and Committee Management Specialists (Ms. Shelley Gordon and Ms. Margie Scott-Cseh) will either schedule an interim conference call before the next meeting or place the draft proposed HCV resolution on the November 2016 meeting agenda to allow CHAC to engage in more detailed discussion, propose additional revisions and take a formal vote.
- The Co-Chairs will not draft and send a letter with the final approved resolution to the HHS Secretary. Instead, the final resolution will be emailed to CDC and HRSA officials to take immediate action at the federal level: Drs. Cheever, Mermin, Ward and Wolitski. Several CHAC members emphasized the need for Dr. Richard Wild, the alternate *ex-officio* member for CMS, to be engaged in these discussions or designate another CMS official.
- The CHAC members will use the written version of the draft proposed HCV resolution to review and submit additional comments. CDC and HRSA staff will circulate an email for CHAC members to submit their votes electronically. (*Editor's note:* This option can only be implemented if FACA-chartered committees are allowed to vote electronically.)

Closing Session

The next CHAC meeting will be a HRSA-focused virtual meeting that will be held on November 16-17, 2016.

With no further discussion or business brought before CHAC, Ms. Fukuda adjourned the meeting at 2:00 p.m. on June 15, 2016.

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

_____
Date

_____
Peter Byrd, 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

Mr. Peter Byrd, Co-Chair
Ms. Dawn Fukuda, Co-Chair
Dr. Bruce Agins
Mr. Richard Aleshire
Dr. Sanjeev Arora
Dr. Virginia Caine
Mr. Guillermo Chacon
Ms. Angelique Croasdale
Dr. Carlos del Rio
Dr. Peter Havens
Dr. Jennifer Kates
Ms. Amy Leonard
Dr. Jorge Mera
Dr. Susan Philip
Ms. Linda Scruggs

CHAC Member Absent

Ms. Debra Hauser

CHAC *Ex-Officio* Members Present

Dr. Melinda Campopiano
Substance Abuse and Mental Health Services 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. Lisa Kaplowitz
(Alternate for Dr. Melinda Campopiano)
Substance Abuse and Mental Health Services Administration

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

Dr. Richard Wild
Centers for Medicare & Medicaid Services

CHAC *Ex-Officio* Members Absent

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

Ms. Lisa Neel
Indian Health Service

CHAC Liaison Representative Present

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. Alice Asher
Dr. Lisa Barrios
Dr. Stuart Berman
Dr. Gail Bolan
Dr. John Brooks
Ms. Antigone Dempsey
Ms. Patty Dietz
Ms. Gala Edwards
Ms. Renata Ellington
Ms. Lori Elmore
Dr. Thomas Gift
Ms. Shelley Gordon
DeKeely Hartsfield, Esq.
Dr. Angela Hernandez
Mr. Reid Hogan-Yarbro
Dr. Matthew Hogben
Mr. Brian Katzowitz
Ms. Niki Keiser
Ms. Ellen Kersh
Ms. Amelia Khalil
Ms. Jennifer Ludovic
Dr. Eugene McCray
Dr. Ann O'Leary
Dr. Michele Owen
Ms. Rebecca Polinsky
Dr. Joseph (Buzz) Prejean
Dr. Raul Romaguera
LCDR Alyson Rose-Wood
Ms. Candace Rosen
Ms. Margie Scott-Cseh
Ms. Nora Spencer-Loveall
Mr. Thom Sukalac
Ms. Michelle Van Handel
Ms. Abigail Viall
Dr. John Ward
Dr. Richard Wolitski
Dr. Stephanie Zaza
Ms. Sara Zeigler

Members of the Public

Mr. Thomas Bertrand
Rhode Island Department of Health

Dr. Gillian Buckley
The National Academies of Sciences, Engineering and Medicine

Ms. Isabelle Leonaitis
Member of the Public

Dr. Vincent Lo Re III
University of Pennsylvania

Mr. Carl Schmid
The AIDS Institute

Attachment 2: Glossary of Acronyms

Acronym	Full Name
ACA	Affordable Care Act
ADAP	AIDS Drug Assistance Program
AETCs	AIDS Education and Training Centers
AHRQ	Agency for Healthcare Research and Quality
ART	Antiretroviral Therapy
ASO	AIDS Service Organization
BPHC	Bureau of Primary Health Care
BRFSS	Behavioral Risk Factor Surveillance System
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CEBACC	Center for Engaging Black Men Who Have Sex With Men Across the Care Continuum
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHCs	Community Health Centers
CHWs	Community Health Workers
CLD	Client-Level Data
CMS	Centers for Medicare & Medicaid Services
CoAg	Cooperative Agreement
CS	Congenital Syphilis
DAAs	Direct-Acting Antivirals
DASH	Division of Adolescent and School Health
DHAP	Division of HIV/AIDS Prevention
DISs	Disease Intervention Specialists
DSTDP	Division of STD Prevention
DVH	Division of Viral Hepatitis

Acronym	Full Name
EBIs	Evidence-Based Interventions
EDs	Emergency Departments
eHARS	Enhanced HIV/AIDS Reporting System
EOB	Explanation of Benefits
FACA	Federal Advisory Committee Act
FBOP	Federal Bureau of Prisons
FERPA	Family Educational Rights and Privacy Act
FOAs	Funding Opportunity Announcements
FPL	Federal Poverty Level
FQHCs	Federally Qualified Health Centers
GHOST	Global Hepatitis Outbreak and Surveillance Technology
GYT	"Get Yourself Tested"
HAB	HIV/AIDS Bureau
HBV	Hepatitis B Virus
HCPs	Healthcare Providers
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIVRN	HIV Research Network
HOPWA	Housing Opportunities for Persons with AIDS
HRSA	Health Resources and Services Administration
HUD	U.S. Department of Housing and Urban Development
ID	Infectious Disease
IDU	Injection Drug Use
LEAs	Local Education Agencies
LGBT	Lesbian/Gay/Bisexual Transgender
MAT	Medication-Assisted Treatment
MFCA	Medicaid Free Care Act
MHS	Molecular HIV Surveillance
MMP	Medical Monitoring Project
MMWR	*Morbidity and Mortality Weekly Report*
MSM	Men Who Have Sex With Men
NAM	National Academy of Medicine
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NEP	Needle Exchange Program

Acronym	Full Name
NHAS	National HIV/AIDS Strategy
NHSS	National HIV Surveillance System
OS	Ocular Syphilis
P&S	Primary and Secondary (Syphilis)
P4C	Partnerships 4 Care
PCPs	Primary Care Physicians/Providers
PEPFAR	President's Emergency Plan for AIDS Relief
PLWH	Persons Living with HIV
PrEP	Pre-Exposure Prophylaxis
Profiles	School Health Profiles
Project ECHO	Project Extension for Community Healthcare Outcomes
PWID	Persons Who Inject Drugs
RIDOH	Rhode Island Department of Health
RSR	Ryan White Services Report
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SBHCs	School-Based Health Centers
SEAs	State Education Agencies
SFNE	San Francisco Needle Exchange
SHPPS	School Health Policies and Practices
SMAIF	Secretary's Minority AIDS Initiative Fund
SMEs	Subject-Matter Experts
SPNS	Special Projects of National Significance
SSPs	Syringe Services Programs
T. pallidum	*Treponema pallidum*
TA	Technical Assistance
TB	Tuberculosis
VHAP	Viral Hepatitis Action Plan
VHIG	Viral Hepatitis Implementation Group
WHA	World Health Assembly
WHO	World Health Organization
YRBS	Youth Risk Behavior Surveillance/Survey