

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



**Meeting of the
CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis and STD Prevention and Treatment
May 10-11, 2017
Atlanta, Georgia**

Record of the Proceedings

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**CDC/HRSA ADVISORY COMMITTEE ON
HIV, VIRAL HEPATITIS AND STD PREVENTION AND TREATMENT
May 10-11, 2017
Atlanta, Georgia**

Minutes of the Meeting

The U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC). The proceedings were held on May 10-11, 2017 at the CDC Corporate Square Campus, Building 8, Conference Room 1-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 sexually transmitted disease (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: May 10, 2017

RADM 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 (DFO), CDC

Dr. Mermin conducted a roll call to determine the CHAC voting members, *ex-officio* members (or their alternates), 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
Richard Aleshire, MSW, ACSW (Washington State Department of Health)	Recipient of a Ryan White HIV/AIDS Program (RWHAP) Part B grant from HRSA
Jean Anderson, MD (Johns Hopkins Medical Institutions)	Recipient of an RWHAP grant from HRSA; shareholder of pharmaceutical stock with Gilead Sciences
Peter Byrd (Peer Educator and Advocate)	No conflicts disclosed
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Recipient of funding from CDC for HIV prevention and from HRSA, including a RWHAP Part B grant and a Special Projects of National Significance (SPNS) grant
Debra Hauser, MPH (Advocates for Youth)	Recipient of funding from CDC
Peter Havens, MD, MS (Children’s Hospital of Wisconsin)	Recipient of RWHAP Parts B and D grants from HRSA; recipient of funding from the National Institute of Child Health and Human Development
Amy Leonard, MPH (Legacy Community Health Services)	Recipient of funding from CDC for HIV/STD prevention and treatment; recipient of an RWHAP grant from HRSA
Jorge Mera, MD (W.W. Hastings Indian Hospital)	Recipient of funding from the Indian Health Service (IHS), HRSA-funded AIDS Education and Training Center (AETC) Program, and Oklahoma University; advisory board member of Gilead Sciences and AbbVie in 2016
Greg Millett, MPH (amfAR)	Advisory board member of VIVE Initiative
Susan Philip, MD, MPH (San Francisco Department of Public Health)	Recipient of funding from CDC for HIV/STD prevention and treatment; recipient of an RWHAP grant from HRSA
Bradley Stoner, MD, PhD (Washington University School of Medicine)	Recipient of funding from CDC for STD prevention
Lynn Taylor, MD, FACP (The Warren Alpert Medical School of Brown University)	Recipient of an RWHAP grant from HRSA

Dr. Mermin confirmed that the 18 voting members and *ex-officio* members in attendance (or their alternates) constituted a quorum for CHAC to conduct its business on May 10, 2017. He called the proceedings to order at 8:43 a.m. and welcomed the participants to the CHAC meeting.

Dr. Mermin announced that Dr. Leandro Mena submitted his resignation as a new CHAC member on April 20, 2017 due to other commitments. He asked the participants to join him in welcoming three new CHAC members to their first in-person meeting.

- Greg Millet, MPH; Vice President and Director of Public Policy, amfAR
- Bradley Stoner, MD, PhD; Associate Professor of Medicine, Washington University School of Medicine
- Lynn Taylor, MD, FACP; Assistant Professor of Medicine, The Warren Alpert Medical School of Brown University

Laura Cheever, MD, ScM

Associate Administrator, HIV/AIDS Bureau
 Health Resources and Services Administration
 CHAC DFO, HRSA

Dr. Cheever announced that Dr. George Sigounas began his appointment as the new HRSA Administrator on May 1, 2017. She also announced that Ms. Shelley Gordon, the CHAC Committee Management Specialist for HRSA, recently retired after approximately 39 years of public service to the federal government. She asked the participants to join her in commending Ms. Gordon on her outstanding career, particularly her notable list of accomplishments in HIV. She asked the participants to join her in welcoming CDR Holly Berilla, Ms. Gordon's replacement.

Dawn Fukuda, ScM, CHAC Co-Chair

Director, Office of HIV/AIDS
 Massachusetts Department of Public Health

Ms. Fukuda also welcomed the participants to the CHAC meeting. She highlighted the major sessions that would be held during the rich and productive two-day meeting: presentations by CDC and HRSA on emerging topics related to HIV, viral hepatitis, and STD prevention and treatment; updates by the CHAC workgroups; and CHAC's formal approval of resolutions during the Business Session.

CDC/NCHHSTP Director's Report

RADM Jonathan Mermin, MD, MPH

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

Dr. Mermin covered several topics in the CDC/NCHHSTP Director's report to CHAC. At the agency level, CDC has had a change in its leadership. Dr. Anne Schuchat is serving as the Acting Director, while Dr. Patricia Simone is serving as the Acting Principal Deputy Director.

The President's fiscal year (FY) 2018 budget request was released on March 16, 2017. If approved, the budget request will reduce the HHS budget by approximately \$15 billion. Congress expects to release a more detailed budget later in May 2017.

CDC hosted the first "Georgia Day Open House" on April 21, 2017 at its headquarters, the Roybal Campus, in Atlanta. The invited guests and attendees included representatives of state universities, Georgia Congressional offices, the city of Atlanta and other local government officials, the business community, and private organizations. NCHHSTP highlighted its ongoing

activities in the exhibits, presentations, and breakout sessions, including AtlasPlus, advanced molecular detection, the availability of the *STD Treatment Guidelines* for mobile devices, and the response to the Indiana HIV outbreak.

At the CDC center level, NCHHSTP released a *VitalSigns*[™] report on November 29, 2016, “HIV and Injection Drug Use: Syringe Services Programs for HIV Prevention.” The report emphasized three key data points. First, people who inject drugs (PWID) account for 9 percent of HIV diagnoses. Second, syringe services programs (SSPs) lower the risk of HIV. Third, HIV diagnoses have decreased among certain PWID populations, including a 50 percent decline among African American and Hispanic PWID as well as a 28 percent decline among white PWID. However, the data showed that whites have the highest rates of syringe sharing.

NCHHSTP launched [AtlasPlus](#) as an updated and improved version of the previous Atlas tool. The interactive, online mapping application offers several key features to users.

- Ability to search for and map HIV, STD, and TB outcomes (currently updated with 2015 surveillance data) and viral hepatitis outcomes (currently updated with 2014 surveillance data).
- Ability to pinpoint areas of the United States with the greatest disease burden and view other epidemiologic data.
- A mobile-friendly design.
- Improved visuals of CDC’s most recent data by county, state, or U.S. totals.
- A table function that is easier to use.
- Ability to create more maps, charts, and presentation-ready slides.

At the division level, the Division of HIV/AIDS Prevention (DHAP) released recent data that showed an 18 percent decline in the number of estimated HIV infections in the United States (from 45,700 in 2008 to 37,600 in 2014). The data also showed that the reduction of annual HIV infections over this time period prevented 33,200 cases at an estimated cost-savings in medical care of \$14.9 billion.

DHAP also released other datasets. National prevalence data estimated that the population of people living with HIV (PLWH) was more than 1.1 million in 2014. This dataset included all PLWH in the United States who were 13 years of age and older at that time. Moreover, death rates per 1,000 people living with a diagnosed HIV infection were found to greatly vary among states in 2013. The death rates among PLWH reported by states ranged from 2.8-8.3 per 1,000 people (lowest) to 17.8-26.8 per 1,000 people (highest).

The Division of Viral Hepatitis (DVH) released data to demonstrate the disproportionately high rates of hepatitis C virus (HCV) in Appalachia and other rural areas of the country. The National Academies of Science, Engineering, and Medicine, with co-sponsorship by CDC, released *A National Strategy for the Elimination of Hepatitis B and C* on March 28, 2017. The report aims to achieve two key objectives. First, targets are proposed to eliminate the hepatitis B virus (HBV) and HCV as public threats in the United States by 2030. Second, opportunities are identified to prevent HBV/HCV transmission. Specific action steps are recommended to ensure HBV/HCV testing, case management, and linkage to care.

DVH provided leadership to ensure alignment between the National Strategy and CDC’s priorities in five major areas: (1) improve perinatal HBV prevention and adult HPV vaccination;

(2) enhance surveillance and serologic surveys; (3) expand access to HBV and HCV testing; (4) increase screening, vaccination, and treatment in correctional facilities; and (5) expand the availability of and access to SSPs.

DVH was pleased to report a tremendous increase in HCV antibody testing among “baby boomers” (i.e., people in the 1945-1965 birth cohort who account for 75 percent of HCV cases). DVH initiated this effort by identifying the subgroup of baby boomers who had commercial health insurance over the 10-year time period from 2005-2014. DVH’s analysis showed a 136 percent increase in HCV antibody testing among baby boomers, but testing was still found to be remarkably low in this cohort overall. However, HCV antibody testing among baby boomers significantly increased by 91 percent over a short period of time (from 1.7 percent in 2011 to 3.3 percent in 2014). DVH’s position is that the increase likely is due to wide adoption of the CDC and U.S. Preventive Services Task Force (USPSTF) recommendation for baby boomers to obtain one-time HCV testing.

The Division of STD Prevention (DSTDP) is continuing to focus on the alarming increase in national syphilis rates. Based on recent data, primary and secondary syphilis rates rapidly increased by 19 percent in the one-year time period from 2014-2015. Preliminary data in the first six months of 2016 showed a similar trend. Moreover, the increase in congenital syphilis parallels the increase in STD infections among women.

DSTDP celebrated STD Awareness Month in April 2017 with a primary focus on syphilis prevention. DSTDP updated its website with the 2017 theme of the campaign, “Syphilis Strikes Back,” and disseminated multiple resources to partners, providers, and the public. New visuals and messaging on the DSTDP website and social media platforms include key milestones in syphilis and public health posters since the 1940s.

DSTDP released the “[CDC Call to Action on Syphilis: Let’s Work Together to Stem the Tide of Rising Syphilis in the United States](#)” in April 2017. The document calls for the development of new tools to detect and treat syphilis. Most notably, no rapid test is available for syphilis at this time. Moreover, the same medications have been used to treat syphilis for the past 75 years. The Call to Action describes specific action steps for CDC: (1) develop new laboratory guidelines, (2) create a repository of specimens, (3) evaluate new technologies, and (4) develop novel diagnostic tools and improve molecular surveillance capacity.

The Division of Adolescent and School Health (DASH) recently launched its newly designed website. The website features an updated Healthy Youth home page; a new webpage on [teen health services](#); and a new infobrief that advises parents to ensure that their teens have one-on-one discussions with a health care provider.

The Division of Tuberculosis Elimination (DTBE) released provisional data as of February 17, 2017. The number of reported TB cases in the United States decreased from 26,673 cases in 1992 to 9,287 cases in 2016. The new TB cases reported in 2016 reflect the lowest number on record. The current TB case rate of 2.9 cases per 100,000 people also is low, but is not low enough to eliminate TB during this century. Reactivated latent TB infection (LTBI) was found to account for approximately 85 percent of new TB cases. California, Florida, New York, and Texas collectively reported the majority of TB cases (or 52 percent) in the United States from 2012-2016.

DTBE acknowledges that new diagnostics and treatment regimens have the potential to better address the TB epidemic in the United States. A new blood test is now available that diagnoses LTBI more effectively than the standard tuberculin skin test. A new once-weekly, 12-week treatment regimen for LTBI is available as well. Higher adherence, completion, and cure rates are being reported because the new TB regimen is less toxic than current medications. However, DTBE recognizes the need to expand these new developments to non-TB clinical settings, such as primary care and practitioners' offices in communities with a high TB incidence and high LTBI prevalence.

DTBE and its partners published the 2016 American Thoracic Society/Infectious Diseases Society of America (IDSA)/CDC [Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children](#). The guidelines include 23 evidence-based recommendations on the diagnosis of LTBI, pulmonary TB, extrapulmonary TB, and the use of newer tests for diagnosing TB disease and LTBI.

HRSA/HAB Associate Administrator's Report

Laura Cheever, MD, ScM

Associate Administrator, HIV/AIDS Bureau
Health Resources and Services Administration
CHAC DFO, HRSA

Dr. Cheever covered several topics in the HRSA/HAB Associate Administrator's report to CHAC. The vision of HAB is "optimal HIV/AIDS care and treatment for all." The mission of HAB is to "provide leadership and resources to assure access to and retention in high quality, integrated care, and treatment services for vulnerable people living with HIV/AIDS and their families."

RWHAP provides a comprehensive system of HIV primary medical care, medications, and essential support services for low-income PLWH. RWHAP provides care to an estimated 52 percent of PLWH with diagnosed HIV in the United States (over 500,000 people). RWHAP awards grants to states, cities/counties, and local community-based organizations (CBOs). RWHAP recipients determine service delivery and funding priorities based on local needs and planning processes. Based on the payor of last resort statutory provision, RWHAP funds cannot be used for services if another state or federal payer is available.

RWHAP funds are awarded to cities (Part A), states (Part B), CBOs (Part C), and CBOs for women, infants, children, and youth (Part D). These services include medical care, medications, and laboratory services; clinical quality management and improvement; and support services (e.g., case management and medical transportation). RWHAP Part F services include clinician training, dental services, and dental provider training as well as the development of innovative models of care to improve health outcomes and reduce HIV transmission among hard to reach populations. The 83.4 percent of RWHAP clients who had at least one medical visit and a viral load measurement achieved viral suppression in 2015, exceeding the national average of 54.7 percent among those living with diagnosed HIV, some of whom are not in care.

Dr. Cheever described HAB's recent accomplishments and ongoing activities to support its five key priorities in FY2017.

PRIORITY 1: DATA UTILIZATION

HAB established this priority to use data from reporting systems, surveillance, modeling, and other programs, as well as results from evaluation and special project efforts to target, prioritize, and improve policies, programs, and service delivery. HAB collects national RWHAP client-level data through the Ryan White HIV/AIDS Program Services Report (RSR) with a national focus on data for program monitoring and evaluation. The annual publication of RSR data enables access to RWHAP client-level information.

The 2015 Annual Client Level Data Report includes five years of data from 2011-2015 from all 50 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands. All tables in the 2015 Annual Client Level Data Report provide data on all clients served, regardless of the RWHAP funding stream, and are not Part-specific and also does not describe the specific services that were rendered through the AIDS Drug Assistance Program (ADAP).

Other HAB data utilization efforts are our contract to link RSR client-level data over time, link client-level data between the RSR and the ADAP Data Report, and initiate field testing of 4 existing National Quality Forum endorsed HIV electronic clinical quality measures.

The 2015 RWHAP Client-Level Data Report includes several new features. These included the change to “eligible scope” reporting (i.e., all people who are eligible for RWHAP services regardless of the funding source used to pay for the service); the addition of a data table of PLWH served through the program (all other data tables in this report include all clients served by the RWHAP, regardless of serotype); and incorporating data previously reported in the 2014 Supplemental Report on Eligible Metropolitan Areas/Transitional Grant Areas.

HAB has also made a few adjustments to how data are analyzed and displayed, including using a two-step method to more clearly define “gender identity;” changes to the transmission risk categories for transgender clients. For example, “sexual contact” was added as a new classification for transgender clients. Data are now displayed separately by gender.

Select demographic characteristics of clients who were served by RWHAP in 2015 in the United States and three territories are summarized as follows. By the total RWHAP client population, 73 percent are from racial/ethnic minority populations; 65 percent live at or below 100 percent of the Federal Poverty Level; 71.3 percent are male, 27.6 percent are female; and 1.1 percent are transgender.

The RWHAP population served is aging. Notably, clients aged 50 years and older accounted for 42.5 percent of all clients in 2015, which is an increase from 33.6 percent in 2011. By health care coverage, only 20.7 percent of 517,368 RWHAP clients are uninsured; most RWHAP clients have some form of health care coverage. Medicaid (32.8 percent), Medicare (10.4 percent), and multiple coverage sources (10.4 percent) are the top three types of health care coverage for RWHAP clients.

CDC and HRSA used data from the CDC Medical Monitoring Project (MMP) to compare services between PLWH who receive their care from RWHAP providers versus PLWH who do not receive their care at RWHAP funded sites. In all nine of the service categories shown (mental health, substance abuse treatment, dental care, case management, adherence counseling, interpreter services, transportation assistance, nutritionist/dietician, and risk reduction counseling services), more RWHAP providers offered these services than

nonRWHAP-funded facilities, which is, in part due to the system of care created by the RWHAP. Because access to HIV care is seldom the only service needed for PLWH to achieve viral suppression, the co-location of these services may be the reason that the RWHAP has such good outcomes among low-income patients.

MMP data also were used to determine the percentage of virally suppressed clients by health care coverage and RWHAP assistance from 2009-2013. For all four health care coverage types (e.g., private insurance, Medicaid, Medicare, and Medicare plus Medicaid), viral suppression rates were higher with non-RWHAP payers plus RWHAP than with non-RWHAP payers alone, most likely because RWHAP provides the additional services that are needed to help PLWH stay in care and achieve viral suppression.

Data showed that viral suppression rates among clients who were served by RWHAP in the United States and three territories steadily increased from 69.5 percent in 2010 to 83.4 percent in 2015 among patients who had at least one medical visit and one viral load measurement. CDC estimates that 54.7 percent of diagnosed PLWH have achieved viral suppression, although some of these people are not accessing healthcare services. HAB does not expect these improvements to continue without the implementation of new and innovative models. Most notably, persistent disparities still exist in the following populations: people living in the Southeastern states, PLWH in the 13-24 age group, Black/African American clients, and people who are unstably housed. These groups continue to account for the largest disparities in HIV viral suppression rates. [HAB's reports, data, and other resources](#) are available on its updated website.

PRIORITY 2: NATIONAL GOALS TO END THE HIV EPIDEMIC/ PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF (PEPFAR) 3.0

HAB established this priority to maximize expertise and resources across HRSA to operationalize the National Goals and PEPFAR 3.0. To support this priority, HAB is compiling and disseminating evidence-informed practices from successful RWHAP recipients and increasing the focus on RWHAP recipients who provide direct services to achieve the highest impact on RWHAP Parts A-D.

One example is HAB's Secretary's Minority AIDS Initiative Funded (SMAIF) project, called the Center for Engaging Black Men Who Have Sex with Men (MSM) Across the Care Continuum (CEBACC). CEBACC launched the *HIS Health* training series and the "Well Versed" website for patients and providers in the fall of 2016.

HAB awarded a SPNS grant, "Dissemination of Evidence-Informed Interventions to Improve Health Outcomes Along the HIV Care Continuum." The grant recipients will develop four evidence-informed care and treatment interventions for linkage and retention based on four evidence informed interventions: the SPNS linkage in jail settings, SPNS buprenorphine initiatives, SPNS targeted outreach to underserved populations, and as well as a SMAIF funded reengagement and retention initiatives.

A new SPNS evidence-informed intervention initiative also will be used to improve health outcomes among PLWH by targeting activities to four key areas: (1) improving HIV health outcomes for transgender women; (2) improving HIV health outcomes for black MSM (BMSM); (3) integrating behavioral health and primary medical care for PLWH; and (4) identifying and addressing trauma among PLWH.

HAB awarded a cooperative agreement (CoAg) to strengthen and improve the HIV care continuum within RWHAP Part A jurisdictions. The CoAg is targeted to RWHAP recipients to support the development of collaborative partnerships and relationships among multiple sources of HIV prevention and care planning, service provision, and state/local resources for improving outcomes along the HIV care continuum. The RWHAP recipients formed learning collaboratives based on five topic domains: data access and coordination; identification and implementation of target interventions; identification and implementation of evidence-based/-informed interventions; linkages to care; and health care implementation changes to HIV care systems.

HAB's other investments in FY2016-2017 to support the National Goals/PEPFAR 3.0 priority are set forth below.

- SMAIF-funded initiative, "Building Care and Prevention Capacity: Addressing the HIV Care Continuum in Southern Metropolitan Areas." The project aims to increase capacity to improve health outcomes for minority MSM, youth, cisgender and transgender women, and PWID.
- RWHAP Part A Planning Council and Transitional Grant Area Planning Body Technical Assistance CoAg.
- An evaluation study, "Building Futures: Supporting Youth Living with HIV." The study aims to identify barriers and best practices to support youth living with HIV to access RWHAP-funded services.
- An evaluation study, "Assessing Client Factors with Detectable Viral Load." The study aims to identify differences between PLWH who are and are not virally suppressed.
- "Models of Care" study. The study aims to evaluate the impact of different models of HIV care.

PRIORITY 3: LEADERSHIP

HAB established this priority to enhance and lead national and international HIV care and treatment through evidence-informed innovations, policy development, health workforce development and program implementation.

HAB convened a diverse PLWH Leadership Expert Panel to discuss leadership qualities and explore strategies to cultivate leaders. Based on the outcomes of this initiative, HAB used SMAIF funds to develop and release a competitive funding opportunity announcement (FOA). The CoAg was awarded to the National Minority AIDS Council (NMAC) to offer leadership training to PLWH of color throughout the country. However, NMAC will place special emphasis on supporting increased engagement of transgender women of color living with HIV in leadership opportunities and also to support national leadership training.

HAB awarded SMAIF funds to improve access to care using community health workers (CHWs) to improve linkage and retention in HIV care. This initiative aims to increase the use of CHWs to strengthen the health care workforce and improve access to health care and health outcomes for racial and ethnic minority PLWH.

HAB obtained endorsement from the National Quality Forum on its existing HIV measures, including those for retention, viral suppression, and antiretroviral prescriptions. In addition, three HIV measures were endorsed as electronic clinical quality measures. HAB redesigned its infrastructure to enhance its quality capacity by providing direct technical assistance (TA) at the individual RWHAP recipient level. The RWHAP Implementation Center for HIV Clinical Quality

Improvement is exploring strategies to help RWHAP recipients and subrecipients identify and measure gaps in clinical processes and health outcomes, implement improvements, and assess the impact of improvement projects.

HAB leveraged PEPFAR support to launch the “Resilient and Responsive Health Systems” initiative in the Democratic Republic of Congo, Liberia, Sierra Leone, and South Sudan. The aims of this initiative are three-fold: (1) support the implementation of country-specific national health strategies and recovery plans to respond to emerging epidemics; (2) prevent, manage, and control HIV and other diseases; and (3) improve population health outcomes.

PRIORITY 4: PARTNERSHIPS

HAB established this priority to enhance and develop strategic domestic and international partnerships internally and externally. HRSA supports the HIV Health Improvement Affinity Group (HHIAG) along with CDC and the Centers for Medicare & Medicaid Services (CMS). The purpose of the HHIAG is to support state collaborations between public health and Medicaid programs to improve sustained HIV viral suppression rates among Medicaid and Children’s Health Insurance Program enrollees who are living with HIV. There are 19 states that participate in this affinity group.

HAB awarded a three-year cooperative agreement to JSI Research and Training Institute to provide TA to RWHAP Parts A and B recipients and their planning bodies to support integrated HIV planning implementation. The guidance document specifically focuses on activities related to submissions for the CDC/HRSA Integrated HIV Prevention and Care Plan. The funding is intended to encourage a streamlined approach to HIV planning and promote effective local and state decision-making to develop systems of prevention and care.

HAB is integrating HIV care and housing data to improve health outcomes along the HIV care continuum. This initiative aims to use information technology to promote integration and coordination of HIV and housing services to improve entry, engagement, and retention in care for homeless and unstably housed PLWH with mental illness and substance use disorders. RSR data show that compared to RWHAP clients with temporary and unstable housing in the United States and three territories, those with stable housing consistently achieved significantly higher viral suppression rates from 2010- 2015.

PRIORITY 5: INTEGRATION

HAB established this priority to integrate HIV prevention, care, and treatment in an evolving health care environment. For example, HAB is attempting to better understand the successes, barriers, and costs related to HCV treatment among PLWH who receive RWHAP services to increase the focus on curing HCV in the RWHAP client population. To support this effort, HAB launched a SMAIF-funded initiative, “Jurisdictional Approach to Curing Hepatitis C Among HIV/HCV Co-Infected People of Color.”

HAB awarded funding to three RWHAP Part A jurisdictions and two RWHAP Part B jurisdictions to increase HCV screening, care, and treatment systems for HIV/HCV co-infected people of color. HAB also expanded the scope of work for and awarded additional funding to the National Clinician Resource Center to create training materials to educate clinicians on screening and treatment of HIV/HCV co-infection.

CHAC DISCUSSION: CDC/NCHHSTP DIRECTOR AND HRSA/HAB ASSOCIATE ADMINISTRATOR REPORTS

The CHAC members discussed the following topics with Dr. Mermin, Dr. Cheever, and other CDC/NCHHSTP and HRSA/HAB leadership during the question/answer session.

- CDC's response to several disturbing developments: the tremendous \$500 million cut to the DSTDP budget in FY2017; the ongoing syphilis epidemic in the United States; the closure of STD clinics in multiple states; and the weak infrastructure of limited personnel and overall capacity for state/local health departments to adequately deliver STD public health services to communities.
- Strategies for CDC and HRSA to target limited federal resources to more efficiently address HIV, HCV, and STDs in the same geographic locations and risk populations.
- CDC's ongoing efforts to vigorously integrate sexual health into primary care settings, particularly to address the reemergence of syphilis in the United States.
- Plans at the federal level to launch creative initiatives, scale-up successful youth-specific programs, and replicate effective community-based models to increase HIV viral suppression rates in young PLWH:
 - CDC's new FOA to address youth who are at risk and/or living with HIV (e.g., young MSM [YMSM] and transgender youth of color).
 - Ongoing efforts by CDC and HRSA to enhance access to and increase the availability of "safe spaces" and "youth-friendly" environments for young people who need confidential HIV/STD prevention and treatment, sexual health, and other services.
- Specific factors that contributed to the significant 18 percent decline in the HIV incidence from 2008-2014.
- CDC's new priority and targeted activities to focus on factors that are playing a key role in the surprising increases in the rates of syphilis among women and congenital syphilis, such as the national opioid epidemic or individual substance use disorder among pregnant women.
- HRSA's development of contingency plans to account for the potential increase in PLWH who might re-enroll in RWHAP clinics if the insurance markets shift.
- Opportunities for CDC to apply the experiences, lessons learned, and successes of its ongoing TB elimination activities to the HIV, HCV, and STD epidemics.
- HRSA's ongoing data collection efforts and collaboration with CDC to eliminate barriers to using STD screening as a quality indicator in HIV care that is provided by RWHAP recipients.

The question/answer session led to the CHAC members providing guidance to CDC/NCHHSTP and HRSA/HAB leadership on the following four topics.

- CDC's recent data show that the number of estimated HIV infections in the United States decreased from 45,700 in 2008 to 37,600 in 2014. This dataset was presented in an abstract, but CDC should widely publicize the significant 18 percent decline in the HIV incidence as a tremendous public health success over the past six years. For example, several HIV training programs and educators are still using the outdated dataset of approximately 52,000 HIV infections. CDC also should update its website to ensure that diverse audiences have access to the most recent HIV incidence data. Moreover, CDC should present various stratifications of the new data, such as HIV incidence by age and

race/ethnicity, to assist grant recipients in targeting their state and local public health programs.

- Some RWHAP recipients increasingly are providing HIV services only and referring clients to primary care physicians in other settings. Unless HRSA links HIV primary care funding to rigorous performance criteria, additional RWHAP recipients likely will discontinue these services in the future, particularly since the RWHAP client population is aging and resources are continuing to diminish.
- HRSA should implement a strategic approach in its ongoing efforts to cure HCV in the RWHAP client population that is living with HIV/HCV co-infection. Several indicators potentially could be used to measure the performance of RWHAP recipients in this area: perform annual HCV antibody testing with reflexive RNA confirmative testing; retest MSM with HIV/HCV co-infection to determine their HCV reinfection rates; and provide HCV treatment to 1 percent more of RWHAP clients than those who were treated in the previous year.
- HRSA should use its new evaluation study, “Assessing Client Factors with Detectable Viral Loads,” as an opportunity to pinpoint specific changes in the RWHAP health care system and the overall client population. For example, HRSA can apply the study findings to identify key differences in viral suppression rates and other medical outcomes among RWHAP clients who have received continuous services over time, RWHAP clients with disruptions in their services, and new RWHAP clients.
- CDC, HRSA, and their federal partners should develop, disseminate, and utilize uniform definitions that clearly distinguish between “youth” and “young people” in the context of HIV, viral hepatitis, and STD prevention and treatment service delivery. For example, federal agencies are continuing to characterize and place youth and young people in inconsistent categories, such as under 18, 13-24, 18-24, and 25-34 years of age.

HIV Transmission Risk in the Context of Antiretroviral Therapy (ART) Use and Viral Suppression

David Purcell, PhD, JD

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Dr. Purcell presented an overview of the science on the HIV prevention benefits of ART and the implications of the science for HIV prevention messages. ART is a powerful medicine to treat and prevent HIV infection. ART greatly improves the health of PLWH and decreases HIV transmission. Several components are required to fully leverage the benefits of this biomedical intervention: (1) provide clear, science-based messages on the prevention benefits of ART (along with caveats and necessary conditions); (2) tailor messages to a variety of audiences; and (3) communicate about the effectiveness of ART in the context of other HIV prevention tools.

Because consumers communicate about ART to make sexual decisions, many dating applications, particularly those for MSM, have options to share their HIV status and the use of ART or pre-exposure prophylaxis (PrEP). ART options often include reporting an undetectable viral load (UVL). In the 2016 Newcomb, *et al.* study with a cohort of approximately 700 MSM, 67 percent of HIV-negative MSM and 90 percent of HIV-positive MSM reported that an HIV-positive partner had reported a UVL load on a dating application. Several MSM reported engaging in condom-less anal sex based on this disclosure. Qualitative data showed that some men reported the use of biomedical matching tools to provide added protection, particularly in the cases of two HIV-positive men with UVLs or an HIV-positive man with a UVL and an HIV-negative man on PrEP.

CDC implemented multiple approaches to broadly communicate the HIV prevention benefits of ART. CDC reviewed the literature on the prevention benefits of ART as part of releasing the beta version of its HIV Risk Reduction Tool (HRRT) during the National HIV Prevention Conference in December 2015. CDC cited the 2011 Cohen, *et al.* study that reported a 96 percent reduction in HIV transmission for people who are waiting to take ART. CDC featured three key messages on its website and in the HRRT: “ART greatly reduces the change of transmitting HIV.” “If taken the right way every day, both ART and PrEP can dramatically reduce the changes that someone will get HIV.” “Adding prevention options can further reduce your risk.” New science in 2016 led CDC to review the science in preparation of updating its 2015 prevention messages.

Other ART communication initiatives include the rollout of the “U=U” campaign (i.e., “undetectable equals untransmissible”) by the Prevention Access Campaign in 2016. Based on the new science, the term “negligible risk” of sexual transmission of HIV has been adopted by multiple stakeholder groups as a tagline of the campaign.

Similar to CDC’s agency-level efforts in 2015, several HHS agencies initiated a department-level process in 2017 to review the science and develop updated HIV prevention messages. The Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) is leading this initiative with extensive participation by CDC, HRSA, the National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA). The literature review that CDC conducted in 2015 has now been integrated into the broader HHS process.

CDC’s activities in 2015 were designed to provide diverse audiences with clear, concise, and accurate answers to six complex questions on the HIV prevention benefits of ART.

- What are the comparable protective benefits of ART, no ART, and ART with viral suppression?
- What is the time to viral suppression on ART and viral rebound when stopping ART?
- What is the additional benefit of durable or sustained viral suppression versus viral suppression at the last visit?
- What is the best terminology for communication purposes: “viral suppression” or “UVL?”
- When do small variations in viral load matter for HIV transmission?
- What factors affect variations in HIV viral load? What is the importance of STDs to these variations?

CDC reviewed and gathered evidence from several sources as the first step in communicating the HIV prevention benefits of ART. The 2011 Cohen, *et al.* study was designed as an interim

analysis of the HIV Prevention Trials Network (HPTN) 052 trial. The randomized controlled trial (RCT) examined the protective benefits of early ART versus delayed ART. A cohort of 1,763 mostly heterosexual, serodiscordant couples was followed for 1.7 years on average.

The evidence showed high ART usage among the early ART group and a viral suppression rate of 89 percent at three months after ART initiation. The key findings included one linked infection in the early ART arm and 27 linked infections in the delayed ART arm. The study estimated the effectiveness of ART at 96 percent because the intention-to-treat analysis only included verified cases of HIV linked to the study participants. However, 1,100 unlinked cases were included in the study. Based on these solid results, the RCT was ended and study participants in both arms were offered ART.

The interpretation challenges of the 2011 Cohen, *et al.* study included a design of “early” versus “late” uptake that did not allow for an analysis between participants who were on and off ART. High adherence via pill count and viral suppression in the early treatment arm were more representative of a trial of optimal ART use rather than early versus late uptake. The PrEP trials showed that high uptake of an intervention in the treatment arm is not always observed in RCTs. However, the high uptake in the ART trial was understandable in light of the existing guidance for ART usage only in people with CD4 counts of 250 or less. The high condom use of 93 percent that was reported among couples likely contributed to the observed reduction in HIV transmission risk.

The 2016 Cohen, *et al.* study was designed as a final analysis of the HPTN 052 trial. All participants in both the immediate and delayed arms were offered ART at the end of the RCT, but the design was changed from an RCT to a modified observational study. A cohort of 1,763 serodiscordant couples was followed for a median of 5.5 years. ART effectiveness was estimated at 93 percent.

Of all participants in the delayed arm, 96 percent were taking ART by the end of the study and 86 percent were taking ART at the one-year follow-up. Of the 78 infections reported, none were genetically linked transmission when the HIV-positive partner achieved viral suppression of less than 400 copies per mL at the prior visit. ART effectiveness was re-estimated at 100 percent, but this finding was not reported in the study. The confidence intervals for the effectiveness of ART and the transmission rate estimates were not reported in the study and could not be calculated from the reported data.

The 2016 Cohen, *et al.* study further reported that nearly all of the 78 partner infections were among PLWH who had not achieved viral suppression due to various factors, such as not being on ART, not yet virally suppressed, treatment failure, or drug resistance. Genetic linkages in six cases could not be determined due to an inability to amplify HIV RNA. These six cases were excluded from all analyses. Linked infections could not be definitively ruled out for the six cases, but the 2017 Eshleman study concluded that an epidemiologic investigation strongly suggested most of the cases were not linked. The six cases likely are not linked infections, but this finding cannot be confirmed with certainty.

The 2016 Rodger, *et al.* study followed 1,166 serodiscordant couples for a median of 1.3 years while the HIV-positive partner was treated with ART. Of the entire cohort, 62 percent were heterosexual and 38 percent were MSM. In a total of 1,238 couple-years of follow-up, no genetically linked transmissions were observed in the following situations: (1) the HIV-positive

partner achieved viral suppression of less than 200 copies per mL; (2) the couples engaged in condom-less sex acts (or more than 58,000 in total); and (3) the use of PrEP or post-exposure prophylaxis (PEP) was not reported.

The transmission rate was estimated at 0 percent per 100 couple-years with an upper confidence interval of 0.3. The transmission rate remained at 0 percent for all partner types and behaviors. The upper 95 percent confidence limits varied by couple type and behavior due to difference amounts of behaviors reported during follow-up.

The upper 95 percent confidence limit for the transmission rate of 0 percent was less than 1 percent per couple-year of follow-up for all types of HIV-negative partners when all sex acts were combined: heterosexual women (0.97), heterosexual men (0.88), and MSM (0.84). The highest upper 95 percent confidence limits for the transmission rate of 0 percent were for anal sex: receptive anal sex with ejaculation among heterosexual women (12.71), insertive anal sex among heterosexual men (7.85), and receptive anal sex with ejaculation among MSM (2.7).

The 2015 Grulich, *et al.* abstract was designed as a pre-planned interim analysis of the “Opposites Attract” study. The observational cohort included 234 serodiscordant MSM couples from three countries. The abstract did not report any linked transmissions in any of the 5,905 condom-less anal sex acts. The authors expect to publish the final results in July 2017.

CDC reviewed two studies that described variations in viral suppression over time among PLWH in care. The 2016 Marks, *et al.* study included a cohort of 10,942 clinic patients who had a baseline HIV viral load and one or more other HIV viral loads in 2012-2013. With the single HIV viral load measure, 75 percent of participants were virally suppressed at the first measure and 83 percent of participants were virally suppressed at the last measure. With multiple HIV viral load measures, 66 percent of participants were virally suppressed at all times, 25 percent of participants were virally suppressed at some times, 9 percent of participants never achieved viral suppression.

The 2016 Crepaz, *et al.* study included a cohort of 238,000 patients in 17 states that reported complete HIV viral load data. The participants had at least one HIV viral load in 2011 and two or more HIV viral loads in 2012-2013. Of all participants, 62 percent achieved durable viral suppression across all measurements and 38 percent had a high HIV viral load burden with significant time above 200, 1,500, or 10,000 copies per mL.

CDC’s comprehensive literature review showed that three peer-reviewed studies and one abstract reported no linked infections from sexual behavior over extensive follow-up and numerous condom-less sex acts. The longitudinal data showed that even among PLWH in consistent care, viral suppression is not universally maintained. However, most PLWH who are in consistent care are virally suppressed.

The study findings led CDC to focus on three key questions to determine the implications of the science for HIV prevention messages: (1) How should communicators share ART information? (2) What caveats are important to provide? (3) Do caveats affect the receipt of messages and eventual behaviors? To effectively communicate the HIV prevention benefits of ART, CDC released a beta version of the HRRT in December 2015 and will launch version 1.0 of the HRRT later in 2017.

The major design features of the HRRT include comprehensive messages on a variety of topics; variables to tailor and personalize content by gender, HIV status, and gender of sex partners; both high-level and in-depth critical information and resources; and interactive tools to engage users with risk information. The CDC website includes numeric tables to support the HRRT. The estimates and supporting science are presented in three sections: HIV risk behaviors per act risk, effective HIV prevention strategies, and factors that increase HIV risk.

The CDC website provides detailed information on several effective HIV prevention strategies: ART for PLWH, daily use of PrEP for HIV-uninfected people, male condom use, serosorting for HIV-negative people, and circumcision. The CDC website also provides detailed information on the following factors that increase HIV risk: ulcerative STD infection of HIV-negative people or HIV-positive sex partners and acute infection of a sex or injection-sharing partner.

Dr. Purcell presented images of the comprehensive messages highlighted in the HRRT; the “Know the HIV Risk” calculator for users to estimate their individual risk and/or the risk of their partners based on specific factors that are entered into the HRRT; and the ART effectiveness table. The CDC website emphasizes that the data in the tables will be updated as the science evolves.

CDC concluded that the new science is playing a key role in the delivery of updated HIV prevention messages. CDC and the majority of other HHS agencies cite the 2011 Cohen, *et al.* study that reported a 96 percent reduction in HIV transmission for people who are waiting to take ART. The underlying message of the study is that “ART greatly reduces the risk of sexual transmission of HIV.”

Community groups, national organizations, and several health departments also have embraced the new science and HIV prevention messages, such as “U=U” (i.e., “undetectable equals untransmissible”) and “negligible risk” of sexual transmission of HIV with viral suppression. Moreover, the following message is featured on the website of the Prevention Access Campaign: “People living with HIV can feel confident that if they have an undetectable viral load and take their medications properly, they will not pass on HIV to sexual partners.” The underlying message of all of these communication campaigns is that “ART with viral suppression is 100 percent effective.”

The HHS agencies will make changes in their ongoing process to review the new science, develop and disseminate updated HIV prevention messages, and address key challenges in several categories. In terms of science and communication challenges, some domains lack clear science, such as transmission risks from breastfeeding or injections when PLWH take ART or are virally suppressed. A new strategy is needed to translate and effectively apply population-level messages at the individual level. Different messages likely will need to be crafted for various audiences, such as scientists and the broader public health workforce; clinicians, nurses, and allied health professionals; and consumers and the general public. A new approach is needed to integrate messages across multiple prevention options, such as CDC’s recommendations in the current version of the HRRT.

In terms of user implementation challenges, ART use is not under the control of HIV-uninfected people who might lack knowledge in this area. Similar to other prevention strategies, male condom use is not necessarily under the control of the receptive partner. The partner’s HIV status might be unknown for people who are attempting to serosort. The extent to which a

person should rely on statements regarding the serostatus or HIV viral load of another individual is uncertain. “Current” HIV status or viral load status has not been clearly defined to assist HIV-uninfected people in making informed decisions.

In terms of content/language challenges, some segments of the general public likely will not understand the current HIV prevention messages, such as “greatly reduced risk,” “negligible risk,” or “no transmission if virally suppressed.” The HHS agencies are considering several plain-language alternatives. Simpler terminology to describe “risk” could include “nearly zero,” “close to zero,” “extremely low,” or “almost no risk.” Simpler terminology to describe “effectiveness” could include “nearly 100 percent,” “close to 100 percent,” and “almost 100 percent.” OHAIDP has asked the HHS agencies to update their respective websites to promote department-wide consistency and uniformity in the use of “viral suppression,” “undetectable,” and other terminology.

In terms of topical challenges, the comprehensive list of potential topics to cover in HIV prevention messages needs to be streamlined. The HHS agencies are considering a number of options: the time to viral suppression when starting ART; the importance of adherence over time; the time to HIV viral load rebound if ART use is stopped; drug resistance and other treatment failures; and the effects of STDs or other viral complications.

The next steps in the HHS process will be for OHAIDP to lead a federal meeting in July 2017 for the four HHS agencies to coordinate their understanding of the science and discuss HIV prevention messages for multiple audiences. However, other opportunities will be made available to extensively engage community members. The major outcome of this process will be the development of a unified set of HIV prevention messages across HHS to share the important science in a clear, concise, and accurate manner.

CHAC DISCUSSION: HIV TRANSMISSION RISK IN THE CONTEXT OF ART USE AND VIRAL SUPPRESSION

The CHAC members commended CDC on its extremely deliberate and thoughtful process of reviewing the science before crafting and delivering HIV prevention messages to multiple audiences. The CHAC members also thanked OHAIDP and the four HHS agencies for developing a process that will engage community members. The CHAC members asked CDC and its federal partners to consider the following issues during the upcoming HHS meeting in July 2017.

- The U=U Campaign and other current messages that do not discuss the use of PrEP are disempowering HIV-negative people from protecting themselves against HIV-positive partners who might not be adhering to ART. However, the new HIV prevention messages should be designed to avoid the unintended consequence of stigmatizing HIV-positive partners.
- Viral suppression is not necessarily a sustained state. Most notably, a breakthrough HIV infection has the potential to re-stigmatize an entire group of virally suppressed PLWH and cause harm to important policy changes that have been made over time.
- Other important issues should be considered as potential topics to cover in the HIV prevention messages: (1) “risk” in the context of casual versus long-term partners; (2) the potential capacity to criminalize genetically linked HIV infections; and (3) disclosure. For example, recent anecdotal data show that large segments of PLWH with UVLs do not feel the need to disclose their HIV status to their sexual partners.

- A decision should be made on whether HIV prevention messages should be updated for the clinical audience. For example, the current standard of care calls for HIV viral load testing of PLWH once per year. However, annual HIV viral load testing might need to be more frequent for HIV-positive subgroups that are engaging in unprotected anal intercourse.
- The science should be thoroughly reviewed and a separate set of HIV prevention messages should be developed regarding the effect of STDs, particularly syphilis in MSM, on the risk of HIV transmission in PLWH with UVLs. Most notably, the “undetectable equals untransmissible” message does not apply to syphilis or HCV.
- The HHS agencies should develop tools and other resources (e.g., downloadable slide sets and infographics) to assist their external partners in widely disseminating the new HIV prevention messages to policymakers, communities, and other stakeholder groups.
- The CHAC members should explore the possibility of forming a new Treatment as Prevention (TasP) Workgroup. The workgroup could provide ongoing guidance to the HHS agencies to ensure that the science and HIV prevention messages will have “real world” application.

Drs. Purcell and Mermin thanked the CHAC members for their extremely helpful feedback. They confirmed that CDC would convey CHAC’s input to its federal partners during the HHS meeting in July 2017. Dr. Gail Bolan, Director of DSTDP, also confirmed that she would be engaged in this effort to improve harmonization between CDC’s HIV and STD prevention messages based on the new science.

In response to Dr. Cheever’s request, Dr. Purcell confirmed that he would provide her with references to several studies. These data show that PLWH in care have reported their lack of knowledge regarding the ability of ART to protect against sexual transmission of HIV.

Monitoring PrEP Use in the United States

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Advice Requested from CHAC by DHAP:

1. Should DHAP establish a limited number of sentinel jurisdictions in high-incidence geographic areas for the purpose of monitoring PrEP uptake, persistence in care, and outcomes using both electronic medical record (EMR) data from clinical care sites and billing data from public and private insurers?
2. Should DHAP develop an active surveillance system for HIV infections that occur among PrEP users to assess specific reasons for PrEP failure (e.g., non-adherence, intermittent use, frequency of atypical HIV test responses, or the presence or absence of resistant mutations)?

Dr. Smith covered several topics in her update to CHAC on PrEP utilization in the United States. CDC and its federal partners are exploring three potential approaches to monitor PrEP use and have clearly articulated the advantages and disadvantages of each option.

Option 1 involves the collection of PrEP utilization data from user and provider surveys, including the National HIV Behavioral Surveillance Survey (NHBS), DocStyles, MMP, and web

samples. However, these surveys often are not representative of the entire population of PrEP users or providers and typically are not released in a timely manner. For example, NHBS is released on a three-year cycle, while web samples are periodically released.

Option 2 involves the collection of PrEP utilization data from insurance billing databases. State Medicaid/Medicare data are fairly timely and complete overall, but national Medicaid/Medicare data from CMS generally are incomplete and untimely. For example, CMS needs three to four years, on average, to complete the entire process of gathering, analyzing, and cleaning Medicaid data for all 50 states for the national database. Moreover, data from commercial sources that currently are used by CDC, such as Marketscan, are only representative of large employer-sponsored insurance plans. However, this data source provides no race/ethnicity data.

Option 3 involves the collection of PrEP utilization data from pharmacy databases that are linked to insurance claims, such as Symphony Health or IMS Health. These datasets are expensive to access, but the data are timely and more complete, include extensive race/ethnicity information, and describe geographic granularities. For analyses of insurance and pharmacy databases, CDC designed the following five-step algorithm to estimate the use of Truvada for PrEP.

- Use drug codes to identify the entire population of people who were prescribed Truvada.
- Use diagnostic codes to exclude people who were prescribed Truvada based on a diagnosis of HIV or HBV.
- Use the remaining subgroup to identify the number of people who were prescribed PrEP or PEP.
- Exclude people from the remaining subgroup who were prescribed Truvada for 30 days or less as likely PEP users.
- For those remaining, provide an estimate of people who likely were prescribed Truvada for PrEP.

CDC applied its algorithm to Marketscan to estimate PrEP utilization. Based on 2014 Marketscan data, 9,375 commercially insured people in the United States (or 9,137 men and 238 women) were prescribed Truvada for PrEP in 2014. Based on its recent analysis of preliminary 2015 Marketscan data, CDC observed a three-fold increase in PrEP prescriptions to commercially insured people (or approximately 30,000 people in total).

Because Marketscan data are readily accessible, CDC and the National Goals currently are using this dataset as a performance indicator to measure PrEP uptake. Most notably, the 2014 Marketscan dataset was used to establish baseline PrEP utilization (or 9,375 people) and calculate a 500 percent increase for the 2020 target (or 56,250 people).

Based on 2012-2015 Symphony Health pharmacy data for an analysis conducted by Gilead Sciences, the manufacturer of Truvada, and the use of an algorithm that was similar to CDC's, the number of unique individuals who started PrEP by quarter increased from 1,671 people in the fourth quarter of 2012 to 14,000 people in the fourth quarter of 2015. By gender, men overwhelmingly accounted for the rapid increase in PrEP uptake from 2014-2015. By race/ethnicity, African Americans accounted for 44 percent of new HIV infections in 2015, but only 10 percent of people who initiated PrEP in 2015. Hispanics accounted for 23 percent of new HIV infections in 2015, but only 12 percent of people who initiated PrEP in 2015.

CDC's next steps in monitoring PrEP utilization will particularly focus on closing gaps in existing disparities. PrEP utilization data on additional populations is being collected from other public and private health care systems, such as IHS, U.S. Department of Veterans Affairs (VA), U.S. Department of Defense, and large, closed networks (e.g., Kaiser Permanente and United Healthcare). PrEP utilization by patients in these systems are usually not included in billing and insurance databases. Efforts are underway to establish a collaboration to share these data.

Based on 2015 data, 1.2 million people are estimated to have indications for PrEP nationally. However, more in-depth analyses will be conducted to assess PrEP coverage based on the denominators of states and local jurisdictions. PrEP uptake and coverage levels also will be monitored in populations and geographic locations with the highest rates of new HIV infections.

Dr. Smith presented images of the online "PrEP Locator: Find Your Provider" tool that was developed by Emory University as a resource to monitor access to PrEP care. Based on the zip code that is entered into the tool, users are given the addresses and specific number of miles to their nearest PrEP provider, a map of the location of the facility, and information on whether uninsured people can obtain care from the provider. Emory is upgrading the tool to identify "PrEP deserts" throughout the United States.

CDC will monitor the persistence in and quality of PrEP care based on various service delivery models, sites, and populations. For example, the 2016 Chan, *et al.* study reported limited persistence in PrEP care among high-risk MSM in three primary care settings over time. CDC also will monitor and compare the impact of PrEP utilization on new HIV diagnoses in locations and populations in which usage and coverage are and are not increasing.

The 2017 Nwokolo study reported a 40 percent decline in new HIV infections among MSM who increasingly accessed PrEP at the Dean Street Clinic in London from January 2015-December 2016. During the time period of increased access to PrEP from 2006-2015, San Francisco reported a reduction in new HIV infections among white MSM (WMSM) and no change in new HIV diagnoses among BMSM among whom PrEP utilization is low.

CHAC DISCUSSION: MONITORING PREP USE IN THE UNITED STATES

The CHAC members discussed the following topics with Dr. Smith, CDC/NCHHSTP, and HRSA/ HAB leadership during the question/answer session.

- Potential strategies for CDC to collect data on insurance coverage rates of PrEP from public payers (e.g., Medicaid and Medicare) to better address disparities in access to health care.
- CDC's plans to broadly disseminate its five-step algorithm in the future as a resource for states, localities, and communities to estimate the use of Truvada for PrEP in large health services databases.
- The correlation between increased PrEP uptake and regions of the country that have launched advertising or marketing campaigns.
- Limitations and opportunities in HRSA's legislative mandate to award funds to RWHAP recipients and Community Health Centers (CHCs) to pay for PrEP services.
- Key challenges for CDC to resolve to develop and maintain a PrEP surveillance system, such as cost, the frequency of collecting data, other sources to gather sentinel state data, and potential partners.

- Potential indicators (e.g., recurrent STDs or sociodemographic factors) to identify major disparities between the current group of insured PrEP recipients and uninsured, high-risk people who have a greater need for PrEP.
- CDC's collaborative efforts with primary care providers, CBOs that serve at-risk groups, and CHCs to reduce stigma associated with PrEP utilization and increase access to and uptake of PrEP.
- CDC's data collection and monitoring efforts in two specific areas: (1) PrEP utilization through the Gilead Patient Assistance Programs and (2) PrEP access, utilization, and efficacy among young people under 18 years of age.

The question/answer session led to the CHAC members providing the following guidance to DHAP on monitoring PrEP use in the United States.

- CDC should explore the possibility of adapting existing models to strengthen workforce capacity to deliver PrEP services in clinical settings.
 - The experiences, lessons learned, and success of Project ECHO (Extension for Community Healthcare Outcomes) should be replicated to increase PrEP access and utilization. Project ECHO has been extremely successful in providing training and expertise to decrease HCV rates and deliver opioid addiction treatment. Moreover, PrEP is one of the four Project ECHO training sessions that currently is offered to primary care physicians.
 - The Cherokee Nation launched a pilot project to overcome barriers to initiating and maintaining PrEP utilization in rural areas with a limited number of providers. Training is provided to clinicians to detect clients who might need PrEP and also to clinical pharmacists to ensure that clients continue their PrEP regimens.
 - The Washington State Department of Health partnered with a local pharmacy to offer PrEP to hard-to-reach populations. The pharmacy serves as a “one-stop” resource for all of the necessary steps that are involved in delivering PrEP services, such as writing the prescription, conducting follow-up, and performing laboratory testing of STDs. A large pharmacy chain is considering the possibility of scaling-up PrEP delivery in locations nationally where their pharmacies operate onsite clinics.
- A 2015 dataset estimated that 1.2 million people have indications for PrEP nationally. Because women account for approximately 50 percent of this population, CDC should launch more aggressive outreach efforts to increase PrEP utilization among high-risk women, such as women in discordant relationships and women who have heterosexual risk factors. Title X Family Planning Clinics and STD clinics would serve as optimal settings to identify high-risk women who are PrEP candidates.

Vulnerable Youth at Risk for HIV, STDs, Hepatitis, and Other Health Outcomes

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Centers for Disease Control and Prevention

Advice Requested from CHAC by DASH and DHAP:

1. How can DASH make progress in enhancing common protective factors for sexual risk, substance use, violence, and mental health given the current challenges in resources and the availability of interventions?
2. Are new strategies available for DHAP to utilize the education system, healthcare system, or media to reach and influence YMSM in a non-stigmatizing manner to improve their linkages to testing and preventive health care at earlier ages?
3. How can DHAP better address the broad range of social, structural, and psychosocial issues that prevent YMSM, particularly YMSM of color, from accessing and successfully utilizing PrEP (and other prevention services) or keep young PLWH from consistently engaging in care? What services can be brought to bear? Can DHAP bridge silos in care to provide more comprehensive services for youth?

Dr. Ethier presented 2005-2015 data from the Youth Risk Behavioral Survey (YRBS) to provide an update to CHAC on vulnerable youth who are at risk for HIV, STDs, hepatitis and other health outcomes. All sexual risk behaviors declined from 2005-2015, including condom use, among five categories of youth: youth who have ever had sex, currently sexually active youth, youth who had sex before 13 years of age, youth who had four or more sexual partners, and youth who used a condom at last sexual intercourse. DASH defines “youth” as people under 18 years of age.

Alcohol use significantly declined from 2005-2015 in four categories of youth: youth who ever used alcohol, youth who drank before 13 years of age, youth who currently use alcohol, and youth who participated in binge drinking behavior. Mixed trends were observed in the use of other substances among youth from 2005-2015. Marijuana, heroin, and injection drug use (IDU) did not significantly change. Cocaine, methamphetamine, and prescription drug use declined. With the exception of marijuana, the use of these substances is extremely low among high school students.

Mixed trends also were observed in interpersonal and sexual violence from 2005-2015, including youth who were threatened at school and youth who were involved in a physical fight at school. However, increases were observed in youth who were bullied, forced to have sex, or missed school due to feeling unsafe. Suicide risk increased from 2005-2015 based on the proportion of youth who reported seriously considering suicide, attempting suicide, planning suicide, or attempting suicide resulting in injury.

The 2005-2015 YRBS data showed that DASH has made progress in sexual risk behaviors, alcohol use, and violence at school among youth. DASH recognizes the need to increase its focus on specific factors that have contributed to the decline in condom use, the mixed results in substance use and sexual violence, and alarming suicide risks among youth.

DASH performed a behavioral clustering analysis to target youth who are at highest risk and intervene earlier. DASH collected 2015 YRBS data to obtain a nationally representative sample of 15,506 high school students. More “extreme” behaviors and experiences among youth were included in the analysis: no condom use or four or more sexual partners; IDU, illicit drug use, or non-medical prescription drug use; bullying and sexual/dating violence; and past suicide attempt.

The behavioral clustering analysis showed that the top three risk behaviors were bullying, non-medical prescription drug use, and no condom use. Most youth had none or a few risk

behaviors, but the 14 percent of high school students with three or more risk behaviors was significant. Youth who experienced four or more risk behaviors were more likely to be in higher grades than in lower grades; identify as lesbian, gay, or bisexual; have poorer grades (i.e., C's, D's, and F's); and report sexual risk clusters with drug use and drug use clusters with violence and suicide. However, any combination of three or more risk behaviors was possible.

The behavioral clustering analysis emphasized the need for DASH to broaden its focus beyond sexual risk behaviors to address the needs of youth who are at highest risk in a more holistic manner. As a result, DASH is conducting activities to prevent risk and promote health among youth. To support these efforts, DASH identified common socio-environmental risk and protective factors that are important for youth in terms of primary prevention of HIV and other health outcomes, including sexual risk, substance use, violence, and suicide. These risk and protective factors include:

- Intra-personal factors (adverse childhood events)
- Parental factors (parental support, engagement, monitoring, and communication)
- School factors (school involvement and connectedness)
- Community factors (available services and supports)
- Social determinants

Overall, DASH is leveraging opportunities for vulnerable youth who are at risk for HIV, STDs, hepatitis, and other health outcomes. DASH currently funds 18 state and 17 local education agencies to address environmental approaches in schools. Several school-based programs have made a commitment to address very high-risk youth, particularly the lesbian/gay/bisexual/transgender/questioning (LGBTQ) youth population. DASH also is making efforts to address a key challenge. Most notably, some of the most influential protections, such as parental monitoring and school connectedness, do not have available intervention strategies with rigorous evaluation results and approaches for wide implementation.

HIV in Youth: Prevention Needs and Challenges

Linda Koenig, PhD

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Centers for Disease Control and Prevention

Dr. Koenig covered several topics in her update to CHAC on the prevention needs and challenges of young PLWH. Health disparities are exaggerated among young PLWH. Young people, aged 13-24, accounted for 22 percent of the 39,393 new HIV infections that were diagnosed in 2015. (People aged 25-34 accounted for 33 percent.) Males accounted for a larger proportion of new diagnoses among those in the 13-19 age group (85 percent) and in the 20-24 age group (89 percent) than in the 25 year and older group (79 percent).

YMSM accounted for the majority of new HIV diagnoses among male adolescents and young adults in 2015. Male-to-male sexual contact accounted for 93 percent of HIV transmission in the 13-19 age group and 91.5 percent in the 20-24 age group. Male-to-male sexual contact plus IDU accounted for 2.9 percent of HIV transmission in the 13-19 age group and 3.3 percent in the 20-24 age group.

The 2016 Wejnert, *et al.* study analyzed NHBS data collected from 20 U.S. cities and reported increased disparities in the HIV prevalence between BMSM and WMSM from 2008-2014, particularly among YMSM. More recent data show that HIV disparities among MSM by race and age are persisting. In the 13-24 age group, BMSM accounted for 54 percent of new HIV diagnoses among MSM in 2015, while WMSM accounted for 16 percent of new HIV diagnoses in 2015. In the 24 year and older age group, BMSM and WMSM both accounted for 33 percent of new HIV diagnoses in 2015.

A 6 percent increase in new HIV diagnoses was reported for YMSM in the 13-24 age group from 2010-2014. However, an 18 percent decline in the estimated HIV incidence was reported among YMSM in the 13-24 age group from 2008-2014. This may seem inconsistent. However, DHAP acknowledges that the inconsistency between the increase in new HIV diagnoses and the decrease in HIV incidence may be due to an increase in testing and case finding. Additional HIV testing programs and initiatives have been launched over the past five years that specifically target YMSM. Data indicating a decrease in the proportion of MSM ages 13-24 living with undiagnosed infection – from approximately 70 percent in 2008 to just over 50 percent in 2014 – provide support for this explanation.

Young people are also not receiving all the health and prevention benefits of HIV treatment that they could be receiving. Of the total population of 1.1 million PLWH in the United States, 15 percent are estimated to be undiagnosed. By risk category, 17.3 percent of MSM have undiagnosed HIV infections (the risk category with the largest percentage of undiagnosed people). By age and risk category, over 50 percent of MSM in the 13-24 age group had undiagnosed HIV infections, the age group of MSM with the largest proportion of undiagnosed infections.

Based on data collected from 32 states and the District of Columbia in 2014, young PLWH in the 13-24 age group had the lowest rate (67.5 percent) of linkage to HIV medical care within one month after diagnosis compared to PLWH in all other age groups. The retention in HIV medical care rate (54.9 percent) among young PLWH in the 13-24 age group was relatively similar to the rates of PLWH in all other age groups. However, the viral suppression rate (43.7 percent) among young PLWH in the 13-24 age group was lower than the rates of PLWH in all other age groups.

DHAP is aware that important issues in three major categories must be addressed to prevent new HIV infections among youth and engage YMSM, particularly YMSM of color, as consumers of HIV testing and prevention services at an earlier age. First, HIV testing rates among YMSM are extremely low. YRBS data were collected from 26 states and district high schools to determine HIV testing rates among sexually experienced MSM. The analysis showed that from 2005-2013, only 26.6 percent of this population had ever been tested for HIV and only 30.2 percent had ever been tested for an STD. Of the same population, only 29.4 percent had ever been tested for HIV among those who reported no condom use at last intercourse.

The NIH-funded Adolescent Trials Network (ATN) evaluated the benefits of targeted HIV testing across 12 Adolescent Medicine Trial Units in high prevalence cities. Compared to routine or universal screening in clinical settings, the study found that targeted testing achieved three key outcomes: (1) reached fewer people, but more MSM and MSM of color; (2) yielded a higher rate of newly diagnosed PLWH; and (3) resulted in higher rates of linkage to other prevention services, including PrEP, for HIV-negative men.

Second, PrEP uptake among YMSM, particularly YMSM in the younger age groups and MSM of color, is limited. Significant barriers among YMSM have been reported by local jurisdictions, including access to and the cost of PrEP, confidentiality issues, and stigma. Moreover, other needs of YMSM likely will take precedence over the initiation of PrEP, such as social and structural needs (housing, food instability, and safety) and psychosocial co-morbidities (mental health conditions and substance use disorder).

Findings from a recent ATN trial showed that due to their vulnerabilities and developmental issues, YMSM, particularly YBMSM, will need more support for adherence to a PrEP regimen. A demonstration project recently reported the benefits of addressing YMSM of color within community networks and introducing PrEP within comprehensive health and prevention services.

Third, only a small subgroup of young PLWH is benefiting from treatment. The co-morbidities that affect PrEP uptake are the same as those that impact young PLWH. This disparity is complicated by the complex and fragmented HIV testing and care system. In an effort to bridge HIV testing and care for youth, CDC, HRSA, and NIH launched a cross-agency demonstration project. The collaborative sites included CDC-funded health departments, HRSA-funded RWHAP Part D clinics, and NIH/ATN-funded treatment centers.

Specially trained linkage coordinators were engaged to increase linkage to care among young people with a new HIV diagnosis. Community-based coalitions also were engaged to address structural barriers of young PLWH at the local level. The Fortenberry, *et al.* paper on the cross-agency demonstration project is available in print:

[JAMA Pediatr.](https://doi.org/10.1001/jamapediatrics.2017.0454) 2017 Jul 1;171(7):687-693. doi: 10.1001/jamapediatrics.2017.0454).

CHAC DISCUSSION: DASH AND DHAP UPDATES ON YOUTH

The CHAC members thanked Drs. Ethier and Koenig for their comprehensive and extremely informative presentations. The CHAC members were impressed by CDC's ongoing efforts to place emphasis on issues beyond sexual risk behaviors to address the needs of vulnerable youth who are at highest risk in a more holistic manner. The CHAC members particularly commended CDC on its two initiatives in this regard.

- DASH's behavioral clustering analysis to identify common socio-environmental risk and protective factors that are important for youth.
- DHAP's cross-agency demonstration project with HRSA and NIH to bridge HIV testing and care for youth, including the focus on major structural barriers for young PLWH.

Due to time constraints, Ms. Fukuda tabled CHAC's further discussion on this agenda item. However, she noted that the CHAC School-Aged LGBTQ Youth Health Workgroup likely is addressing issues to respond to the specific requests for advice by DASH and DHAP.

Recommendations for Providing Quality STD Clinical Services

Gail Bolan, MD

Director, Division of STD Prevention
Centers for Disease Control and Prevention

Advice Requested from CHAC by DSTDP:

1. Is the strength of the recommendations below appropriate (e.g., “should” versus “could”)?
 - PrEP for HIV risk assessment and counseling and referral/linkage services should be available for basic STD care?
 - PrEP for HIV risk assessment and counseling services should be available for specialized STD care?
 - PrEP and non-occupational PEP (nPEP) for HIV could be provided onsite for basic STD care?
 - PrEP and nPEP for HIV should be provided onsite for specialized STD care?
2. Are the recommended screening and laboratory services appropriate for both levels of care (specifically cervical cancer screening and HIV viral load testing)?
3. Is the recommended treatment for STD-related infections appropriate for both levels of care (specifically treatment for syphilis, trichomoniasis, and provider-applied regimens for genital warts)?
4. Is “basic” an appropriate terminology for the minimal level of services?

Dr. Bolan described the background and DSTDP’s rationale for developing new quality STD clinical services recommendations. The CDC *STD Treatment Guidelines* serve as the premiere resource for the medical community to diagnose and treat STDs. However, DSTDP recognized the need to prepare national guidance on optimal services for the provision of quality STD care by providers who offer basic or specialized STD care. The new recommendations will serve as a companion document to the *STD Treatment Guidelines*, but with an emphasis on clinical operations. DSTDP used the April 2014 recommendations by CDC and the Office of Population Affairs, “Providing Quality Family Planning Services,” as a model in this effort.

DSTDP established two definitions to describe the levels of care. “Basic” STD care is the delivery in primary care, such as Federally Qualified Health Centers (FQHCs), HIV care settings, and family planning clinics of recommended risk assessment, screening, and treatment of people identified with asymptomatic infection, as well as the diagnosis and treatment of patients with common symptomatic infections. Most of the patients seen in these settings are seeking primary care services. “Specialized” STD care is the delivery in STD specialty clinics of more comprehensive, confidential STD clinical services, including same-day diagnostic and treatment services. Patients seen in these clinics are specifically seeking STD services because of STD-related symptoms, their partner’s diagnosis of an STD, or concerns about an STD.

The recommendations are appropriate for implementation in multiple provider settings: family planning, HIV care, primary care, pediatric, family medicine, OB/GYN, prenatal, adolescent health, school-based health center, corrections, FQHC, and STD/sexual health clinic. A “strong” recommendation involves support for providing a service or against providing a service. The wording includes “recommend/should” or “recommend against/would not.” With “strong” language, all or nearly all informed providers would select the recommended course of action.

A “weak” (or conditional, discretionary, or qualified) recommendation involves support for providing a service or against providing a service. The wording includes “may/could” or “may not/would not.” With “weak” language, most informed providers would select the recommended course of action, but a substantial number of providers would not.

Dr. Bolan concluded her portion of the presentation by emphasizing that DSTDP would welcome CHAC's input in response to its request for advice on the four key questions outlined above and any other input on the recommendations presented.

Roxanne Barrow, MD, MPH

Medical Epidemiologist, DSTDP
Centers for Disease Control and Prevention

Dr. Barrow described DSTDP's process to develop the recommendations for quality STD clinical services. The CDC *STD Treatment Guidelines* were thoroughly reviewed to identify specific clinical services to include in the recommendations. A literature review was conducted to determine the current landscape of STD clinical service delivery, followed by a modified Delphi process to rate whether each clinical service should be available at the specified level of care. A technical meeting was convened to obtain individual external input from a diverse group of health care providers.

A Basic STD Care Workgroup with nine members and a Specialized STD Care Workgroup with nine members were formed to individually rate whether specific clinical services should be available based on their respective STD level of care. All 18 members, across both workgroups, individually rated whether a clinical service should be offered based on scale that ranged from 1 ("disagree") to 9 ("agree"). An association with quality of care was a major factor in the rating scheme, but feasibility also was considered.

The ratings from each workgroup were classified into three categories. A median rating of 7-9, with no disagreement, was required to consider a STD clinical service for the given level of care as "appropriate." A median rating of 1-3, with no disagreement, was required to consider a STD clinical service for the given level of care as "inappropriate." A median rating of 4-6, or any median with disagreement, was required to consider a STD clinical service for the given level of care as "uncertain."

The draft recommendations that are set forth below reflect guidance on what should be available for both basic and specialized STD care for each clinical service offered. However, the recommendations do not mean that all patients should receive the service. These decisions are determined by the provider and patient based on the patient's medical history and concerns along with evidence-based clinical guidelines and clinical standards of care. The full set of draft recommendations includes guidance on other services that should be available for specialized STD care for each clinical service offered to distinguish STD clinics from primary care settings.

Sexual History and Physical Examination

- A physical examination, including external genital examination for patients with STD-related symptoms or concerns, should be available as a basic and specialized STD care service.
- A pelvic examination should be available as a basic and specialized STD care service.

Prevention

- The following prevention services should be available as a basic and specialized STD service:
 - Onsite HBV vaccination
 - Onsite human papillomavirus vaccination

- Brief, single STD/HIV prevention counseling (up to 30 minutes)
- PrEP and nPEP risk assessment, education, and referral/linkage

Screening

- Screening and assessment for the following should be available as a basic and specialized STD care service:
 - Gonorrhea
 - Chlamydia
 - Syphilis
 - HBV
 - HCV
 - HIV
 - Cervical cancer

Partner Services

- The following partner services should be available as a basic and specialized STD service:
 - Guidance regarding notification and care of sex partners
 - Expedited partner therapy (where legal)

Evaluation of STD-Related Conditions

- Evaluation (including an STD history and physical examination) for the following STD-related conditions should be available as a basic and specialized STD service:
 - Genital ulcer disease
 - Male urethritis syndrome
 - Vaginal discharge syndrome
 - Pelvic inflammatory disease
 - Genital warts
 - Ectoparasitic infections

Laboratory Tests: At the time of the patient visit

- The following general services should be available as a basic and specialized STD care service at the time of the patient visit.
 - Phlebotomy
 - Finger-stick
 - Genital swab collection
 - Extragenital swab collection
 - Urine collection
 - Self-collected genital and extragenital specimens
- The following tests should be available as a basic and specialized STD care service with results available during the patient visit:
 - pH paper
 - Urine dipstick
 - Thermometer

Laboratory Tests: Clinical

- The following tests should be available through a clinical laboratory as a basic and specialized STD care service:

- Urogenital nucleic acid amplification test (NAAT) for gonorrhea and chlamydia
- Extragenital (pharynx or rectum) NAAT for gonorrhea and chlamydia
- Test for trichomonas
- Gram stain or methylene blue stains
- Quantitative non-treponemal serologic test for syphilis
- Treponemal serologic test for syphilis
- Herpes simplex virus (HSV) viral culture or polymerase chain reaction
- HSV type-specific serology
- HIV test using a strategy to detect acute infection
- HIV viral load
- Oncogenic HPV NAAT with Pap smear

Treatments for STD-Related Infections: Onsite

- Treatments for the following STDs should be available onsite as a basic and specialized STD care service:
 - Chlamydia (including expedited partner therapy)
 - Chlamydia-related cervicitis
 - Nongonococcal urethritis
 - Chlamydia-related proctitis

Treatments for STD-Related Infections: Prescription

- All recommended STD treatments should be available by prescription as a basic and specialized STD care service:
 - Herpes
 - Trichomonas
 - Bacterial vaginosis
 - Vulvovaginal candidiasis
 - Urinary tract infection
 - Patient-applied regimens for genital warts

CHAC DISCUSSION: RECOMMENDATIONS FOR PROVIDING QUALITY STD CLINICAL SERVICES

The CHAC members provided guidance in two major categories in response to DSTDP's request for advice.

Content/Wording Guidance

- Include urgent care centers and emergency departments (EDs) as additional provider settings for symptomatic people.
- Reconsider “should” for vaccination, anoscopy, and colposcopy. These clinical services are “aspirational” rather than feasible in STD clinics and other resource-limited settings. Moreover, some STD clinics are likely to oppose a “should” recommendation for these services, particularly since federal funding for STD clinical services has been cut in most jurisdictions.
- Change “could” to “should” for onsite condom provision as a basic service (prevention).
- Change “should” to “could” for bacterial vaginosis as a specialized service (onsite treatment).
- Relocate “pregnancy test,” as a specialized service, from a clinical laboratory test to an onsite laboratory test.

- Include additional language for HCV screening, as both basic and specialized services, to strongly emphasize the need for clinicians to also perform confirmatory RNA viral load or reflexive RNA testing.
- Reconsider “could” for trichomoniasis as both basic and specialized services (screening and onsite laboratory test). Previous data have indicated that trichomoniasis is a risk factor for HIV transmission.
- Reconsider “should” for rapid HIV point-of-care testing as a specialized onsite laboratory test service. For example, Massachusetts only supports fourth-generation HIV testing via blood draw to detect acute infections and properly screen potential PrEP candidates. Massachusetts no longer recommends rapid HIV testing.
- Include a new “could” or “should” recommendation to address perinatal care of STDs, particularly perinatal HCV transmission and congenital syphilis services.

Overarching Guidance

- The terminology should be changed from “basic” to “core” STD care throughout the recommendations. Clients might misinterpret “basic” to mean the provision of sub-optimal or a lower level of care.
- CDC should establish tertiary STD clinics as Centers of Excellence to provide clinical care, research, teaching, and training. CDC should review the HIV model in this effort.
- HRSA should launch a demonstration project with a sample of RWHAP recipients that currently are funded to provide clinical services. HRSA and CDC could use the findings from the project to measure adherence to the recommendations for quality STD clinical services and determine whether the guidelines can be successfully implemented in these settings.
- The HRSA Maternal and Child Health Bureau (MCHB) should be represented at all future CHAC meetings to address perinatal issues in the context of HIV, HCV, and STDs.
- CHAC should establish a new STD Workgroup to provide ongoing guidance as DSTDP revises and refines the recommendations.

Dr. Bolan thanked the CHAC members for contributing their valuable expertise. She clarified that the guidelines will serve as “tools” rather than “rules” because CDC has no regulatory authority to mandate adherence or implementation. After DSTDP applies CHAC’s input to revise and refine the content of the quality STD clinical services recommendations, she expressed an interest in taking action on three of CHAC’s overarching suggestions.

- First, a demonstration project would be extremely helpful to test, model, and evaluate whether the recommendations are feasible to implement based on the resources of clinical practices in the field. DSTDP and HAB leadership would discuss the possibility of piloting the project in RWHAP clinical settings.
- Second, based on the evaluation and modeling outcomes, DSTDP would determine whether funding is available to establish a Center of Excellence for the quality STD clinical services recommendations.
- Third, DSTDP would welcome ongoing input from a new CHAC STD Workgroup to ensure that the guidelines are in compliance with FACA rules and regulations. If CHAC votes to approve the formation of a new STD Workgroup, DSTDP would provide TA as needed.

Dr. Cheever added that “required” activities and services provided by RWHAP recipients are limited to those outlined in HRSA’s Congressional statute. HAB ensures that the language in its FOAs is well aligned with the legislation. Similar to Dr. Bolan, however, she also was in favor of conducting a demonstration project of the recommendations for quality STD clinical services with RWHAP recipients that already receive funding to provide clinical services.

Ms. Fukuda exercised the co-chair’s prerogative and announced changes to the published agenda. The DSTDP presentation/CHAC discussion was scheduled for 50 minutes, but this agenda item required more time. As a result, the update by the CHAC Viral Hepatitis Workgroup would be rescheduled for the following day. However, she confirmed that this one-hour agenda item would not be shortened. Although the second day of the meeting does not include a public comment period, she also confirmed that members of the public who registered to provide comments to CHAC on viral hepatitis activities would be heard.

Preparation for the CHAC Business Session

Dawn Fukuda, ScM, CHAC Co-Chair

Director, Office of HIV/AIDS

Massachusetts Department of Public Health

Ms. Fukuda presented a high-level summary of the overviews and updates by CDC and HRSA on the first day of the CHAC meeting. Based on her notes, three issues were raised during the panel discussions that might warrant CHAC’s further consideration and/or formal action during the Business Session on the following day. The three business items are highlighted below.

1. CDC emphasized the need for clear and accurate messaging to diverse audiences on the risk of HIV transmission in the context of ART use and viral suppression.
2. Ms. Leonard proposed the formation of a new CHAC TasP Workgroup. The workgroup could be charged with drafting action plans and providing ongoing guidance to OHAIDP, CDC, HRSA, NIH, and SAMHSA (collectively, the 2017 HHS interagency process) to ensure that the science on the HIV prevention benefits of ART and the updated HIV prevention messages will have “real world” application. The workgroup also could inform the HHS interagency process by framing HIV prevention messages for diverse audiences, including providers, the specialized group of HIV prevention and care clinicians, and communities.
3. Dr. Philip proposed the establishment of a new CHAC STD Workgroup to provide ongoing guidance as DSTDP revises and refines its draft recommendations on quality STD clinical services.

Ms. Antigone Dempsey, Director of the HRSA/HAB Division of Policy and Data, provided follow-up remarks on business item 2. She clarified that in addition to the upcoming federal meeting in July 2017, OHAIDP and the four HHS agencies also are engaging in offline discussions on a rapid, ongoing basis. Although the formation of a new workgroup is quicker and less formal than the establishment of a new FACA committee or subcommittee, certain steps are still required, such as appointing members from the parent committee to chair and serve on the workgroup, clearly defining a charge, and scheduling regular teleconference meetings.

Because the formation of a new TasP Workgroup likely will not meet the timelines of the 2017 HHS interagency process, Ms. Dempsey proposed an alternate strategy in which CDC would

report on the key outcomes of the July 2017 HHS meeting during the October 2017 CHAC meeting. In addition to the extensive feedback that CHAC provided to CDC during the current meeting, individual members are still free to submit comments to Drs. Cheever and Mermin, as the CHAC DFOs, for consideration by OHAIDP and the four HHS agencies.

In response to Ms. Dempsey's clarifying remarks, Ms. Leonard withdrew her proposal for CHAC to establish a new TasP Workgroup. Instead, she agreed to reach out to her CHAC colleagues, on an informal, ad hoc basis, to determine their interest in drafting and submitting guidance on key TasP issues, particularly the HIV prevention benefits of ART. She would immediately undertake this effort to ensure that the guidance was submitted to OHAIDP and the four HHS agencies to consider prior to the upcoming federal meeting in July 2017.

Ms. Fukuda advised Ms. Leonard to contact Ms. Margie Scott-Cseh (CDC) and CDR Berilla (HRSA), the CHAC Committee Management Specialists, to obtain assistance in distributing an email invitation to the entire CHAC membership and scheduling a follow-up teleconference within the next two weeks.

Dr. Mera questioned whether CHAC is authorized to provide formal guidance to CDC and HRSA on issues beyond HIV, viral hepatitis, and STDs. He was particularly concerned about CDC's current data that show reactivated LTBI accounts for approximately 85 percent of new TB cases. Dr. Mermin explained that the Advisory Council for the Elimination of Tuberculosis is a separate FACA committee with a mission and charter to advise HHS and CDC on all matters related to TB elimination in the United States. However, he made a commitment to continue reporting up-to-date TB and LTBI data during his NCHHSTP Director's updates to CHAC.

Dr. Stoner questioned whether CHAC should draft and submit formal guidance to CDC on the integration of EMRs. Because EMR systems are proprietary, the companies charge a fee to include additional fields (e.g., country of origin and sexual history). Dr. Mermin confirmed that CDC currently is exploring opportunities to centralize EMR systems and prioritize the most important fields to add. He would present an update to CHAC as progress is made on this issue.

Public Comment Period

David Harvey, MSW, ACC

Executive Director

National Coalition of STD Directors (NCSD)

Mr. Harvey was pleased that CHAC planned to call for a vote to establish a new STD Workgroup. CDC's recent data show a decline in the number of HIV infections in the United States, but an alarming increase in syphilis rates among MSM nationally. NCSD recognizes the need for effective messaging and improved coordination with communities to respond to the syphilis epidemic.

Mr. Harvey reported that NCSD is continuing to discuss concerns regarding the severe shortage of STD resources nationally. If approved, he asked the STD Workgroup to explore strategies to pool limited resources, such as strengthening coordination between HIV and STD resources at the local level. He also proposed other topics for the workgroup to consider in its deliberations:

- Use the lessons learned, existing infrastructure, capacity, and public health success of the “Reducing Perinatal HIV Transmission” initiative as a model to combat congenital syphilis.
- Review the series of new public service announcements by the “Building Healthy Online Communities” consortium as a model to develop consistent HIV/STD prevention messaging on PrEP and condom use.
- Formulate guidance on youth-specific issues, enhanced provider education, and improved linkages to CHCs.

With no further discussion or business brought before CHAC, Ms. Fukuda recessed the meeting at 4:30 p.m. on May 10, 2017.

Opening Session: May 11, 2017

RADM Jonathan Mermin, MD, MPH

Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC DFO, 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 the first day of the meeting.

Dr. Mermin confirmed that the 18 voting members and *ex-officio* members in attendance (or their alternates) constituted a quorum for CHAC to conduct its business on May 11, 2017. He reconvened the proceedings at 8:40 a.m. and welcomed the participants to the second day of the CHAC meeting.

Dawn Fukuda, ScM, CHAC Co-Chair

Director, Office of HIV/AIDS
Massachusetts Department of Public Health

Ms. Fukuda also welcomed the participants to the second day of the CHAC meeting. On behalf of CHAC, she thanked the CDC and HRSA speakers for their extremely informative presentations on the previous day on HIV and STD prevention and treatment activities for adults and youth. She reported that the second day of the CHAC meeting would focus on HBV/HCV prevention and treatment, the CHAC workgroup reports, and the Business Session.

A National Strategy for the Elimination of Hepatitis B and C

Gillian Buckley, PhD, MPH

Staff Officer

National Academies of Science, Engineering, and Medicine

Advice Requested from CHAC by CDC and HRSA:

1. What different actions should CDC and HRSA take to respond to and ultimately eliminate viral hepatitis in the United States (e.g., successful models, partnerships, policy changes, program priorities, training, and outreach education)?
2. What are the best strategies for CDC to engage non-federal stakeholders in HBV and HCV elimination efforts?

Dr. Buckley presented an overview of the National Strategy for the Elimination of Hepatitis B and C. CDC and its co-sponsors gave the National Academies study committee a two-part charge. Phase 1 of the charge focused on determining the feasibility of eliminating HBV and HCV from the United States. The study committee concluded that HBV and HCV could be eliminated as public health threats in the United States, but this goal likely would not be achieved without attention to serious systematic barriers. The National Academies released *Eliminating the Public Health Problem of Hepatitis B and C in the United States: Phase One Report* on April 11, 2016.

Phase 2 of the charge focused on recommending an approach, with concrete action steps, to eliminate viral hepatitis from the United States. The National Academies released *A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report* on March 28, 2017.

The study committee began phase 2 of its work by documenting the public health significance of viral hepatitis. Chronic HBV and HCV infections affect three to five times more Americans than HIV. The incidence is 10 times higher worldwide. Viral hepatitis kills more people worldwide each year than HIV, road traffic injuries, or diabetes. Despite its ranking as the seventh leading cause of death in the world, viral hepatitis consumes less than 1 percent of the NIH research budget.

About 1.3 million Americans have chronic hepatitis B and 2.7 million Americans have hepatitis C. HBV and HCV infections account for approximately 80 percent of liver cancer worldwide. Chronic hepatitis B increases the odds of liver cancer 50 to 100 times; hepatitis C increases the odds 15 to 20 times. Viral hepatitis drove the 38 percent increase in liver cancer in the United States between 2002 and 2012.

The burden of viral hepatitis does not have to be so serious. There is an effective vaccine for hepatitis B; new treatments can cure the vast majority of hepatitis C patients. Treatment for hepatitis C is expensive, but is still cost-effective compared to the alternatives. The elimination of hepatitis B and C as public health problems is possible in the United States and would avert approximately 90,000 deaths by 2030. The National Strategy serves as a roadmap to achieve this goal.

The World Health Assembly passed a resolution in 2016 to eliminate viral hepatitis by 2030. The member states are developing national viral hepatitis elimination strategies, but the United States was one of the first countries to release its roadmap. The World Health Organization

(WHO) asked all countries to consider and include five strategic directions in their national strategies: information for focused action, interventions for impact, delivering for equity, financing for sustainability, and research.

The study committee commissioned models to estimate the numeric targets for viral hepatitis elimination. Based on these models, they concluded that a 50 percent reduction in mortality from chronic HBV is possible in the United States by 2030 and would avert over 60,000 deaths. The following actions are required to achieve this goal: diagnose 90 percent of chronic HBV cases; link 90 percent of diagnosed cases to care; and treat 80 percent of cases with treatment indications. The same levels of diagnosis, care, and treatment will reduce new cases of HBV-related hepatocellular carcinoma by approximately 33 percent and new cases of HBV-related cirrhosis by approximately 45 percent. As demonstrated in Alaska Natives, the elimination of HBV infection in neonates and young children under 5 years of age is possible.

A 90 percent reduction in hepatitis C incidence, relative to the 2015 incidence carried forward, is possible in the United States by 2030. Meeting this goal depends on treatment with no restrictions on severity of disease and a consistent ability to diagnose new cases as prevalence decreases. The same levels of diagnosis and treatment will reduce mortality from HCV in 2030 by 65 percent, relative to the 2015 level, and avert 28,800 deaths by 2030. The following number of cases would need to be diagnosed to meet the HCV targets: at least 110,000 cases per year until 2020; nearly 89,000 cases per year from 2020-2024; and over 70,000 cases per year from 2025-2030.

The study committee structured the report around WHO's five key areas. Their recommendations follow.

CENTRAL COORDINATING OFFICE

The elimination of viral hepatitis is a complex effort that will require coordinated action from various federal and state government agencies and extensive cooperation from the private sector. The leadership of a single office would help to ensure efficient and harmonious work.

- *Recommendation:* The highest level of the federal government should oversee a coordinated effort to manage viral hepatitis elimination.

This office might, for example, be modeled after the White House Office of National AIDS Policy.

STRATEGIC DIRECTION 1: INFORMATION FOR FOCUSED ACTION

Many state and local health departments are not in a position to measure hepatitis disease burden. Integrated, highly-automated electronic surveillance systems could go far toward more accurate understanding of the viral hepatitis disease burden.

- *Recommendation:* CDC, in partnership with state and local health departments, should support standard hepatitis case-finding measures, follow-up, monitoring, and linkage to care of all viral hepatitis cases reported through public health surveillance. CDC should work with the National Cancer Institute to attach viral etiology to reports of liver cancer in its periodic national reports on cancer.

Research in high-risk populations promotes better understanding of the epidemiology of viral hepatitis. This research can help clarify the true incidence and prevalence of HBV and HCV infection.

- *Recommendation:* CDC should support cross-sectional and cohort studies to measure HBV and HCV infection incidence and prevalence in high-risk populations.

The Department of Justice surveys of inmates in jails and prisons is a promising tool that might be adapted to include hepatitis research.

STRATEGIC DIRECTION 2: INTERVENTIONS

HBV is a vaccine-preventable disease, but only about 25 percent of adults over 19 years of age are fully immunized.

- *Recommendation:* States should expand access to adult hepatitis B vaccination, removing barriers to immunization in pharmacies and other easily accessible settings.

Expanding vaccination in pharmacies and other convenient venues might help reach more adults, as it has with seasonal influenza vaccination.

Early testing viral load analysis can help to determine the best course of treatment for HBsAg-positive pregnant women, balancing the risk of hepatitis flare against the risk of mother-to-child transmission.

- *Recommendation:* CDC, the American Association for the Study of Liver Diseases (AASLD), the American College of Obstetricians and Gynecologists, and the Infectious Diseases Society of America (IDSA) should recommend that all HBsAg-positive pregnant women have early prenatal HBV DNA and liver enzyme tests to evaluate whether antiviral therapy is indicated for prophylaxis to eliminate mother-to-child transmission or for treatment of chronic active hepatitis.

People who inject drugs account for about 75 percent of new HCV infections. The most effective way to prevent hepatitis C in this population is to combine strategies that improve injection safety with those that treat the underlying addiction.

- *Recommendation:* States and federal agencies should expand access to syringe exchange and opioid agonist therapy in accessible venues.

Pharmacies and mobile syringe exchange are both promising settings to expand syringe exchange, especially in rural and suburban areas.

Increased screening for viral hepatitis would identify more cases, but screening can place a burden on providers and on the health system.

- *Recommendation:* CDC should work with states to identify settings appropriate for enhanced viral hepatitis testing based on an expected prevalence.

A reduction in cirrhosis and a return to normal liver function are two major benefits of curing hepatitis C. Treating everyone with hepatitis C, regardless of their disease stage, would avert

considerable suffering. This approach also would protect society by reducing the population reservoir for infection.

- *Recommendation:* Public and private health plans should remove restrictions that are not medically indicated and offer direct-acting antivirals to all chronic hepatitis C patients.

STRATEGIC DIRECTION 3: SERVICE DELIVERY

There are gaps between the practice of medicine as recommended by experts and real life. The National Committee for Quality Assurance (NCQA) is charged with closing these gaps. To this end, they manage the HEDIS indicators (officially, the Health Effectiveness Data and Information Set). HEDIS commands special attention from providers and health plan managers. The inclusion of viral hepatitis indicators in HEDIS would increase attention to these essential services.

- *Recommendation:* NCQA should establish measures to monitor compliance with viral hepatitis screening guidelines and hepatitis B vaccine birth dose coverage and include the new measures in HEDIS.

The need to be treated by specialists is a major barrier to hepatitis care, especially for people in rural and underserved areas.

- *Recommendation:* AASLD and IDSA should partner with primary care providers and their professional organizations to build capacity to treat hepatitis B and hepatitis C in primary care. The program should set up referral systems for medically complex patients.

The people most affected by viral hepatitis can be the hardest to reach. Patients with serious health problems, including those with behavioral health problems, need more support services.

- *Recommendation:* HHS should work with states to build a comprehensive system of care and support for special populations with hepatitis B and C on the same scale of the Ryan White system.

Incarcerated people bear a disproportionate burden of viral hepatitis. Jails and prisons are an ideal setting to vaccinate against hepatitis B and cure hepatitis C.

- *Recommendation:* The criminal justice system should screen, vaccinate, and treat hepatitis B and C in correctional facilities according to national clinical practice guidelines.

STRATEGIC DIRECTION 4: FINANCING

HCV elimination in the United States depends on treating at least 260,000 patients per year with direct-acting antivirals, but none of these drugs will come off patent before 2029 (or one year before the target viral hepatitis elimination date of 2030). Delaying mass treatment until cheaper generic versions of these drugs are available would result in tens of thousands of deaths and billions of dollars in wasted medical costs.

- *Recommendation:* The federal government, on behalf of HHS, should purchase the rights to a direct-acting antiviral for use in neglected market segments, such as

Medicaid, the Indian Health Service, and prisons. This could be done through the licensing or assigning of a patent in a voluntary transaction with an innovator pharmaceutical company.

STRATEGIC DIRECTION 5: RESEARCH

The elimination of viral hepatitis cannot be achieved without better attention to research gaps. Existing gaps in mechanistic research include curative therapy for chronic HBV infection and an HCV vaccine. Existing gaps in implementation research include stigma alleviation, health among incarcerated people, and a clear understanding of drug users.

Dr. Buckley thanked CDC and their partners for serving as study sponsors. She particularly acknowledged Dr. Ward and the DVH staff for their support of the study.

CDC's Role in the Elimination of Hepatitis B and C

John Ward, MD

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

Advice Requested from CHAC by DVH:

1. What should be DVH's initial steps to begin using the National Strategy?
2. What are the most promising recommendations for increasing attention to greater prevention capacity?
3. Which of the National Strategy recommendations warrant increased attention from CDC in the context of the DVH 2016-2020 Strategic Plan?
4. What approaches should DVH implement to broaden awareness of and commitment for interventions that prevent viral hepatitis and other bloodborne pathogens among people with substance use disorder?

Dr. Ward described CDC's role in the elimination of HBV and HCV as public health threats in the United States. At the global level, WHO introduced the concept of viral hepatitis elimination in 2010; subsequently released three viral hepatitis resolutions; and asked WHO to take more action regarding prevention, program development, and the establishment of HBV/HCV elimination targets.

WHO drafted the targets in response to WHA's request. WHA formally endorsed the WHO global elimination targets for viral hepatitis. Other global policy statements, such as the Sustainable Development Goals and the UNAIDS Political Declaration on HIV and AIDS, have recognized viral hepatitis as a global public health problem and proposed interventions to reduce this burden.

The WHO Global Health Sector Strategy on Viral Hepatitis (2016-2021) include the following incidence and mortality targets:

- Reduction in new cases of chronic HBV and HCV infections (30 percent decrease by 2020 and 90 percent decrease by 2030)
- Reduction from 6 to 10 million cases of chronic infection in 2015 to 900,000 infections by 2030

- Reduction in deaths from chronic HBV and HCV (10 percent decrease by 2020 and 65 percent decrease by 2030)
- Reduction from 1.4 million annual deaths in 2015 to less than 500,000 deaths by 2030.

WHO also established indicators to measure performance in implementing interventions to reach the global viral hepatitis targets.

At the domestic level, approaches in the United States to prevent and eliminate viral hepatitis transmission and disease have included the publication of national reports, action plans, and strategic plans since 2010 by the (former) Institute of Medicine, HHS, CDC/DVH, and the National Academies. Another major development over this period of time was an increase in the DVH budget to approximately \$34 million.

CDC developed an interagency agreement with several partners to commission the National Academies to release *Eliminating the Public Health Problem of Hepatitis B and C in the United States: Phase One Report* in April 2016 and *A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report* in March 2017. The National Strategy includes HBV and HCV elimination goals to be reached by 2030 and recommends 13 actions to achieve these goals in five major categories: vaccination of vulnerable populations; prevention of HCV among PWID; access to testing, care, and treatment; surveillance and strategic data analysis; and national coordination of elimination efforts.

The 2030 targets to eliminate the public health threat of viral hepatitis in the United States include a 50 percent reduction in HBV mortality; a reduction to zero in the HBV incidence of children under five years of age; a 65 percent reduction in HCV mortality; and a 90 percent reduction in HCV incidence. CDC's role in achieving some of the National Strategy recommendations is described below.

Recommendation: *All HBsAg-positive pregnant women should have early prenatal HBV DNA and liver enzyme tests to guide antiviral prophylaxis.*

The publication of new recommendations by the CDC Advisory Committee on Immunization Practices (ACIP) will include language on HBV DNA testing of HBsAg-positive mothers. The CDC Perinatal HBV Prevention Coordinator Program will provide assistance in implementing this recommendation.

Recommendation: *States should expand access to adult HBV vaccination by removing barriers to free immunization in pharmacies and other easily accessible settings.*

The HBV vaccination coverage rate is only 32 percent in people over 19 years of age. CDC currently is responding to ACIP's request to develop new HBV vaccination strategies for adults.

Recommendation: *States and federal agencies should expand access to syringe exchange and opioid agonist therapy in accessible venues.*

Acute HCV cases have been increasing since 2010. CDC's most recent data show that 33,900 new HCV infections were reported in 2015. The national opioid epidemic accounted for the majority of these cases. Syringe exchange and opioid agonist therapy are the cornerstones of viral hepatitis elimination and can reduce HCV transmission by 70 percent. As of early 2017, 270 SSPs were in operation, but approximately 2,200 additional SSPs are needed to ensure adequate geographic access. Moreover, only 20 percent of people 15-29 years of age who

have HCV live within 10 miles of an SSP. In early 2017, CDC gave approval to 29 state and county grant recipients to redirect their CoAg funds to support SSPs.

Recommendation: *NCQA should establish and include new measures in HEDIS to monitor compliance with viral hepatitis screening guidelines and coverage of the HBV vaccine birth dose.*

CDC and states collaborate to identify settings that are appropriate for enhanced viral hepatitis testing, such as EDs and drug treatment facilities. Based on the outcomes of its demonstration projects, CDC published effective evidence-based interventions that expand access to HCV testing, care, and cure. These strategies include testing policies, provider education, clinical decision tools, reflex RNA testing, performance indicators, case management, and co-localization of HCV and primary care. CDC awarded approximately \$90,000 per year to 50 grant recipients to implement these interventions in 46 states and four localities.

CDC is continuing to prioritize screening, vaccinating, and treating HBV and HCV in correctional facilities according to national clinical practice guidelines. Correctional facility data from 2012-2015 showed that of 4,784 people incarcerated in federal facilities, 16 percent were anti-HCV-positive. Of 97,897 people incarcerated in state facilities, 12-17 percent were anti-HCV-positive (based on routine screening), while 15-48 percent were anti-HCV-positive (based on risk-based screening). The high cost of medications frequently is cited as a major barrier to decreasing the high rates of HCV infection in correctional facilities. CDC currently is updating its guidance on HCV prevention, care, and treatment in correctional facilities.

The United States is on track to achieve the WHO goal of eliminating HCV mortality. Over a four-quarter period in 2015-2016, approximately 250,000 people were treated for HCV. Based on several data sources, the number of people with HCV who were treated decreased by 26 percent in 2016 and is expected to decline by 31 percent in 2017. People living with HCV who are waiting on the availability of safe, highly effective oral treatments account for a proportion of these decreases. CDC acknowledges the need to expand HCV testing and linkage to care, particularly in marginalized populations.

Recommendation: *Public and private health plans should remove restrictions that are not medically indicated and offer DAAs to all chronic HCV patients.*

In 2014, state Medicaid programs limited access to HCV therapy based on fibrosis score, provider type, and sobriety criteria. Several major developments have occurred since that time. CMS issued a cautionary letter to state Medicaid programs. The cost of HCV medications has been decreasing. Lawsuits filed in Washington and other states have provided patients with greater access to HCV therapy.

The three new HCV medications that will be released in 2017 and 2018 will be extremely affordable and beneficial to the health system. The price range of approximately \$30,000 to \$45,000 for an eight- or 12-week regimen is highly cost-effective and cost-saving. The VA negotiated an even lower price of \$17,000 per patient treated. However, stigma associated with the HCV population remains a major concern.

Recommendation: *CDC should support cross-sectional and cohort studies to measure the incidence and prevalence of HBV and HCV infections in high-risk populations.*

CDC recently awarded funding to 14 states with a high HBV or HCV incidence in May 2017 to conduct core surveillance, locate acute cases, and develop and maintain case registries. The

grant recipients account for more than 70 percent of all new HBV and HCV infections in the country. CDC will use NHBS and other surveys on high-risk populations as opportunities to integrate new fields regarding HBV and HCV. However, a significant increase in capacity is needed to fully meet this recommendation.

Recommendation: *The federal government, on behalf of HHS, should purchase the rights to a DAA for use in neglected market segments, such as Medicaid, IHS, and prisons.*

The National Academies study committee recommended a voluntary transaction between the federal government and a patent holder. The options include licensing (revocable rights to a patent); assignment (permanent transfer of a patent); or authorization of rights in the least lucrative market segments.

At this time, 700,000 people are eligible for treatment in state Medicaid programs and correctional facilities at an average cost of \$40,000 per treatment. Based on the current eligible population, \$10 billion would be needed over the next 12 years to treat 240,000 people living with HCV. The value of the current market segment is \$6.5 billion, but companies can expect different segments of the market.

Negotiations to license or purchase a patent will lower the cost of dominant medications on the market. Based on drug manufacturing costs of \$200, the product cost would be \$140 million. Based on this scenario, the purchasing costs would be \$2 billion for the patent, \$70 million for federal drug purchases, and \$70 million for state drug purchases. This scenario would result in an increase of 460,000 people receiving HCV treatment. The National Strategy proposed CDC, HRSA, or Treasury as the lead negotiating agency. In the interim, bulk purchasing and other strategies should be pursued, such as five-state bulk purchasing pools.

The National Strategy presents a rare opportunity for advocacy by enlightening the national vision of potential progress with sufficient commitment and resources; endorsing existing viral hepatitis prevention priorities; elevating CDC's activities as part of a national effort; engaging new partners in elimination; and evaluating progress toward achieving HBV and HCV elimination goals.

The CDC Foundation convened the [Viral Hepatitis Elimination Summit](#) in April 2017 with 135 in-person attendees and an additional 540 participants in 14 countries via webcast. The key topics presented during the summit are highlighted below.

- State elimination models to reach the 2030 targets: California, Louisiana, Ohio, New York, and Washington
- HBV vaccination of high-risk adults
- HCV prevention in rural and urban areas
- Programs with best practices (e.g., the Cherokee Nation HCV Elimination Program and the Kaiser Mid-Atlantic program)
- State and local HBV and HCV elimination plans and programs: Louisiana, New Mexico, New York, and San Francisco
- Low-cost medications, testing incentives, and other features of the Australia health system HCV program
- Special populations: veterans, African migrants, dialysis patients, and people living with HIV/HCV co-infection

In May 2016, DVH released its 2016-2020 Strategic Plan, *Bringing Together Science and Public Health Practice for the Elimination of Viral Hepatitis*. The four strategic imperatives are to (1) assure vulnerable populations are vaccinated to prevent viral hepatitis; (2) assure early detection and response to stop transmission of HBV and HCV; (3) assure people living with HBV and HCV are identified and linked to recommended care and treatment services; and (4) act globally to prevent, detect, and control viral hepatitis. DVH currently is using the National Strategy recommendations as a guide to update its Strategic Plan. The revised document will be distributed to CHAC and other stakeholders for review and comment.

Overall, the National Strategy eliminates all reasons that previously have been used to disregard HBV and HCV. Existing barriers demonstrate that viral hepatitis is not adequately prioritized in the United States. However, the National Strategy can serve as a vehicle for change at this time. The United States should not be late to or play a halfhearted role in the global viral hepatitis elimination effort because the National Strategy intends to hasten elimination in both domestically and globally.

Hepatitis C Elimination in the Context of RWHAP

Laura Cheever, MD, ScM

Associate Administrator, HIV/AIDS Bureau
Health Resources and Services Administration
CHAC DFO, HRSA

Advice Requested from CHAC by HAB:

1. What different actions should HAB take to increase HCV cure rates in the context of

Dr. Cheever described HCV elimination in the context of RWHAP. RWHAP takes a public health approach to provide a comprehensive system of care for all and ensure that PLWH receive optimal care and treatment. The RWHAP framework includes five major components to achieve these goals: service delivery; care and treatment policies at federal, state, and local levels; needs assessments to identify and fill gaps; capacity development to maintain a strong infrastructure; and quality improvement of HIV care systems for all PLWH in the United States.

HAB's position is that HCV can be cured in RWHAP settings due to various models of care for HCV treatment offered to HIV/HCV co-infected clients. These models include culturally competent care; primary care services delivered by experts; integrated care with and without a designated HCV clinic internally; the use of expert consultation for severe complications; and co-located care with specialists who manage treatment at RWHAP clinical sites. Moreover, RWHAP has a long history of providing HIV treatment and patient-centered care to homeless people, PWID, and other marginalized populations.

HAB is attempting to better understand the successes, barriers, and costs related to HCV treatment among PLWH who receive RWHAP services to increase the focus on curing HCV in the RWHAP client population. To support this effort, HAB launched a SMAIF-funded initiative, "Jurisdictional Approach to Curing Hepatitis C Among HIV/HCV Co-Infected People of Color." HAB awarded funding to three RWHAP Part A jurisdictions: Hartford, Connecticut; New York City, New York; and Philadelphia, Pennsylvania. HAB also awarded funding to the National

Alliance of State and Territorial AIDS Directors to serve as a TA provider to two RWHAP Part B sub-recipients in Louisiana and North Carolina.

The RWHAP recipients and sub-recipients will aim to achieve two key objectives in this initiative. First, jurisdiction-level capacity will be increased to provide comprehensive screening, care, and treatment of HCV among HIV/HCV co-infected people of color. Second, the number of HIV/HCV co-infected people of color who are diagnosed, treated, and cured of HCV infection will be increased. HAB is pleased to report that the current HCV screening rate in RWHAP jurisdictions is over 95 percent.

HAB's ongoing and future activities to support the jurisdictional approach to address HIV/HCV co-infected people of color are described below.

- The AETCs were awarded funds to support provider training and develop a robust HIV/HCV co-infection curriculum. The curriculum serves as a tremendous resource to offer HCV training to providers. The curriculum will be disseminated to the CHAC members and other key stakeholders in the field.
- An FOA will be released in FY2017 to fund two additional jurisdictions, but a broader group of partners will be engaged, such as RWHAP clinics, health departments, CHCs, and SAMHSA-funded sites.
- The evaluation outcomes and overall success of the initiative will be analyzed to determine whether the project should be scaled-up to reach a wider population of HIV/HCV co-infected people of color.
- A study is underway to determine the actual number of RWHAP clients living with HCV who are being treated and cured.
- A contract will be awarded that will focus on the development of new tools to help RWHAP recipients to systematically ascertain HCV treatment and cure rates in their client populations.
- FY2016 SMAIF funds were awarded to support an Evaluation and Technical Assistance Center for a three-year period.

CHAC DISCUSSION: PANEL PRESENTATION ON THE ELIMINATION OF HBV AND HCV AS PUBLIC HEALTH THREATS IN THE UNITED STATES

The CHAC members commended the National Academies, CDC, and HRSA on their leadership in awarding funds, conducting activities, performing research, and providing other support to make progress toward achieving the national goal of eliminating viral hepatitis in the United States. The CHAC members discussed the following topics with Drs. Buckley, Ward, and Cheever during the question/answer session.

- Alignment between the National Strategy and the HHS National Viral Hepatitis Action Plan (2017-2020).
- Removal of alcohol use, drug use, and all other non-medically indicated restrictions that serve as barriers to chronic HCV patients receiving DAAs, particularly among Medicaid beneficiaries.
- The need to launch an aggressive national effort to encourage Congress to remove all non-medically indicated restrictions for viral hepatitis treatment in all state Medicaid programs.

- Political will, strong advocacy, and other components that are needed to prioritize an effective viral hepatitis elimination infrastructure in public health, particularly since HBV is a vaccine-preventable disease and HCV is a curable disease.
- Lawsuits filed against state Medicaid programs for refusing treatment to hepatitis patients based on their fibrosis levels.
- Potential strategies to increase awareness and implementation of the National Strategy in state health departments.
- New approaches to change the “top-secret” nature involved with pricing of viral hepatitis medications and make this information more transparent.
- DVH’s plans to review lessons learned and experiences of other elimination campaigns, such as syphilis.
- Potential factors for the low HBV vaccination coverage rate of only 32 percent in people over 19 years of age.
- Specific factors that are contributing to the lack of uptake of medications on the ADAP formulary by co-infected HIV/HCV clients in RWHAP clinical settings.

The question/answer session led to the CHAC members providing guidance to CDC and HRSA on the following topics regarding their ongoing activities to eliminate HBV and HCV as public health threats in the United States.

- CDC and HRSA should commission the National Academies study committee to conduct an HCV cost-effectiveness study. For example, DAAs for the treatment of HCV are inaccurately characterized as “extremely expensive,” but the actual cost of these medications per patient treated is approximately \$30,000 with rebates. Moreover, Medicaid is continuing to pay for other medications that are much more expensive than DAAs, such as a one-year ART regimen for PLWH, a one-year regimen of cholesterol lowering medications, and proton pump inhibitors for people with gastrointestinal diseases.
- CDC should encourage the National Academies study committee to expand the “intervention” recommendation to promote legal, over-the-counter access to syringes in pharmacies in all states.
- CDC and HRSA should leverage opportunities to raise awareness of and support for the National Strategy at the highest level of government. These opportunities include (1) the high visibility of and new public health resources that are being allocated to the national opioid epidemic and (2) existing public health models to replicate and launch new viral hepatitis communication/storytelling campaigns. For example, storytelling campaigns for other diseases of public health significance from the personal perspectives of patients, parents, children, and partners have been extremely effective in the past. Some of the most compelling storytelling campaigns have played a major role in the shift from apathy to empathy to drive changes in public health policies and funding decisions. Moreover, pharmaceutical companies are sponsoring all of the HCV television commercials that are being aired at this time. The tremendous advertising investment by pharmaceutical companies does not showcase public health’s leadership role in funding viral hepatitis elimination efforts.

- CDC and HRSA should advise the National Academies study committee to review the 21st Century Cures Act that was signed into law in December 2016 to determine whether the National Strategy could benefit from this language. The purpose of the legislation is to advance health care innovation for the 21st century by providing resources to researchers to develop the next generation of cures and treatment.
- The National Academies study committee concluded that jails and prisons are “ideal” settings to provide HBV vaccination and treat HCV. CDC and HRSA should encourage the study committee to revise this language or add a disclaimer. Most notably, numerous state and local correctional facilities contract for-profit companies to provide medical care to their incarcerated populations. However, several states and localities have reported that these companies provide sub-optimal HCV, HIV, STD, and TB medical services that are much lower than the recommended standard of care.
- HRSA should determine the legal issues involved with RWHAP clinicians prescribing syringes, particularly in states and localities where people cannot legally obtain access to syringes for prevention.
- CDC should review the Cherokee Nation model that specifically focuses on linking hard-to-reach populations to HBV/HCV prevention, treatment, and care services. The interventions in this model that potentially could be scaled-up include community outreach programs and the implementation of directly-observed therapy.
- CDC should explore strategies to strengthen political will and overcome other barriers to expanding opiate substitution treatment (OST) programs. Incentives at both system and individual provider levels could serve as a potential option in this regard because OST can be administered without a specialist.

Dr. Mermin commended the National Academies on producing the comprehensive, thoughtful, and outstanding Phase Two Report. He made two key suggestions on the National Strategy from a public health perspective. First, the study committee should review the modeling data to determine whether the HCV mortality target should be revised. Most notably, the HCV target of averting a total of 28,800 deaths by 2030 appears to be extremely low, particularly since the current HCV mortality rate is approximately 20,000 deaths per year.

Second, the study committee should revise its research recommendations to address ethical issues. The current language does not mention giving intensive interventions to cohorts that would be followed in research projects. As a public health agency, for example, CDC would be required to offer access to SSPs, linkage to curative therapy, HBV vaccination, or other interventions to monitor and follow a cohort of PWID in a study.

Development of Guidance for Perinatal HCV Testing and Prevention

CDR Sarah Schillie, MD, MPH, MBA
 Division of Viral Hepatitis
 Centers for Disease Control and Prevention

Dr. Schillie reported that CDC asked the CHAC Viral Hepatitis Workgroup to consider perinatal HCV testing and prevention. She presented preliminary data to assist the workgroup in fulfilling its charge. She explained that her presentation would serve as an overview of the same preliminary data to the entire CHAC membership.

A 2.9-fold increase in the number of acute HCV cases has been reported over the past five years (or from 850 cases in 2010 to 2,436 cases in 2015). However, 33,900 acute HCV cases actually were reported in 2015 when adjusting for under-ascertainment and under-reporting. By risk factor, PWID accounted for 80 percent of the reports. By geographic location, 10 states accounted for the highest incidence of acute HCV: Indiana, Kentucky, Maine, Massachusetts, Montana, New Jersey, New Mexico, North Carolina, Tennessee, and West Virginia.

By age, people 20-39 years of age, including women of childbearing age (WCBA), accounted for the largest increase in HCV cases. By gender, the increase in HCV rates was similar among males (0.8 per 100,000 people) and females (0.7 per 100,000 people). The 2017 Ly, *et al.* study reported the characteristics of HCV-infected WCBA from 2006-2014. The cohort included 171,801 women with past or current acute HCV infection. The demographics of the cohort are highlighted below.

Age

- 15-30 years of age (47 percent)
- 31-44 years of age (53 percent)

IDU

- Yes (5.4 percent)
- No (2.7 percent)
- Missing/unknown data (91.9 percent)

Geographic Location

- Midwest (27.5 percent)
- Northeast (30.1 percent)
- South (29.6 percent)
- West (12.8 percent)

Race/Ethnicity

- Non-Hispanic white (23.6 percent)
- Non-Hispanic black (1.9 percent)
- Asian/Pacific Islander (0.5 percent)
- American Indian/Alaskan Native (1.3 percent)
- Hispanic (3 percent)
- Non-Hispanic/other (3.2 percent)
- Missing/unknown data (66.5 percent)

The number of WCBA with past or present acute HCV infection doubled from 15,550 cases in 2006 to 31,039 cases in 2014. Based on the application of a laboratory-derived infection rate to annual live births from 2011-2014, an estimated 29,000 HCV-infected women give birth to 1,700 HCV-infected infants each year.

Dr. Schillie presented a map of the United States to illustrate geographic variations in the number of births to HCV-infected mothers in 2015 nationally. She also presented a map of Tennessee to illustrate geographic variations in the number of births to HCV-infected mothers in 2014 among 95 counties in the state. Appalachian counties in Eastern Tennessee reported the highest rates of births to HCV-infected mothers.

Kentucky also reported tremendous disparities. The proportion of births to HCV-infected mothers in 2014 was 1 in 63 births in Kentucky versus 1 in 308 births in the United States. The data from Kentucky, Tennessee, and other states with a high incidence of HCV emphasize the need for enhanced surveillance to identify high-risk populations and specific geographic areas.

Commercial laboratory data show that the HCV testing rate in 2015 was 7.6 percent among WCBA 15-44 years of age (or approximately 1.9 million women). This rate reflects a 25 percent from 2011. Moreover, the HCV testing rate in 2015 was 0.50 percent among children under 5 years of age (or approximately 15,373 children). This rate reflects a 7 percent from 2011.

The 2017 Epstein, *et al.* study reported on a cohort of 879 unique mother-infant pairs who were seen at Boston Medical Center for opioid use disorder during pregnancy from 2006-2015. Of all 879 women, 84.6 percent were assessed for HCV during pregnancy, 29.7 percent were viremic, and 41 percent of RNA-positive mothers were linked to care. Of 404 infants 18 months of age and older who were followed in the study, 67.6 percent were given HCV diagnostic testing and 44.6 percent completed diagnostic testing. Five children (or 2.7 percent of those who completed testing) were diagnosed with HCV and linked to care.

Several studies published in 2014-2016 estimated that perinatal HCV transmission occurs in 5.8 percent of infants born to HCV-infected, HIV-negative mothers. These studies found that HCV transmission increases with three major risk factors: maternal HIV co-infection, high maternal viral load, and prolonged rupture of membranes more than six hours. Another set of studies published in 2005-2012 documented HCV rates in infants. Based on HCV RNA testing, up to 20 percent of infants 2-6 months of age with an identified virus spontaneously cleared their infections by 5-7 years of age.

HCV antibody testing can be performed on infants beginning at 18 months of age because passively acquired maternal antibody might be detected in infants younger than this age group. Infants with negative HCV antibody at 18 months of age are not HCV-infected and need no further testing. This population includes approximately 95 percent of infants who are born to HCV-infected mothers. However, studies emphasize the need for further testing, linkage to care, virologic monitoring, and follow-up for RNA-positive infants 2-6 months of age.

HCV can be cured in more than 90 percent of people with daily administration of DAAs for eight to 12 weeks. However, the safety and efficacy of this regimen have not been established during pregnancy. The SOVALDI® package insert includes the following disclaimer: “No adequate human data are available to establish whether or not SOVALDI® poses a risk to pregnancy outcomes.” Moreover, Ledipasvir/Sofosbuvir is an effective and well-tolerated treatment for children 6-11 years of age with chronic HCV.

Other data show that HCV treatment before pregnancy is optimal to prevent infant infection and maternal disease progression. However, challenges regarding Medicaid treatment restrictions in drug treatment programs are a priority for programs in California and several other states.

Because CDC is not a regulatory agency, existing collaborations with AASLD, IDSA, and other partners are leveraged to develop and implement HCV treatment recommendations during pregnancy.

To date, no registries have been developed for the use of HCV medications during pregnancy. However, any event involving drug therapy that includes ribavirin can be reported to the Ribavirin Pregnancy Registry. Moreover, any event involving women with HIV/HCV co-infection who take an HIV antiretroviral medication during pregnancy can be reported to the Antiretroviral Pregnancy Registry.

The existing USPSTF risk-based HCV testing recommendations apply to pregnant women: IDU, pre-1992 blood transfusion, long-term hemodialysis, birth to an HCV-infected mother, incarceration, intranasal drug use, an unregulated tattoo, and other percutaneous exposures (e.g., exposures to health care workers or exposures from surgery before the implementation of universal precautions). In addition to USPSTF, other agencies and organizations also have published risk-based recommendations: CDC, WHO, AASLD, IDSA, American College of Gastroenterology, American Academy of Family Physicians, American Academy of Pediatrics, and North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition.

The recommendations for testing people born during 1945-1965 are based on an anti-HCV prevalence of 3.25 percent. Risk-based recommendations apply to pregnant women and their infants. However, specific testing algorithms are needed to clarify and harmonize infant testing recommendations.

The Council of State and Territorial Epidemiologists (CSTE) proposed a perinatal HCV case definition for surveillance. The laboratory criteria include the following language: HCV RNA-positive for infants 2-36 months of age; or HCV genotype test results for infants 2-36 months of age; or HCV antigen test results for infants 2-36 months of age. The epidemiologic linkage calls for maternal infection with HCV, if known, of any duration. CSTE's proposed perinatal HCV case definition also provides additional guidance. Test results at earlier ages than those specified should not be reported. Test results at later infant ages than those specified should be reported under the 2015 Acute and Chronic HCV Infection case classification and not as perinatal HCV infection.

Several operational considerations should be addressed to implement risk screening and HCV testing for pregnant women. Women with HCV infection should be identified. Risk-based testing or similar algorithms should be utilized to determine the population of WCBA, including those who receive family planning services. Referrals to appropriate medical care should be provided, including post-pregnancy HCV treatment in consultation with a clinician. Children who need HCV testing should be identified.

Infants born to HCV-infected mothers should be tested. HCV antibody testing should be performed to identify uninfected infants (or a total of approximately 95 percent) at 18 months of age. This testing protocol is the least expensive, but might be affected by loss of follow-up of these infants. HCV RNA testing should be performed to determine the negative likelihood ratio, such as a one-test strategy at 8 weeks of age or a two-test strategy at 8 weeks and 4-6 months of age. Testing at 2 months of age might presumptively exclude infection for surveillance purposes. Testing at 2 months of age followed by HCV antibody testing at 12-18 months of age might definitively exclude infection for clinical care purposes.

Clear recommendations should be developed for a testing algorithm to identify the 95 percent of infants who will not need additional follow-up and the 5 percent of infants with HCV infection who will need follow-up. A system should be established to link the mother's prenatal information to postnatal infant care. A case management system that provides access to information on pregnant women with HCV potentially could allow linkage to care and ensure follow-up of infants. However, the case management system will require collaboration between public health and community care providers.

Update by the CHAC Viral Hepatitis Workgroup

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Dr. Havens reported that CDC asked the CHAC Viral Hepatitis Workgroup to draft guidance on perinatal HCV testing and prevention due to the dramatic change in epidemiology. The increase in the number of younger people and women with HCV infection demands a change in the existing public health testing recommendations. To broaden treatment strategies nationally, the focus might be placed on decreasing the risk of HCV infection to infants.

A recently published paper showed that the phenomenal effectiveness of treatment of pregnant women with HIV has nearly eliminated mother-to-child transmission of infection in the United States. The workgroup's position is that the inability to replicate and apply this model to pregnant women with HCV is a public health failure. Moreover, the current population of 1,700 infants with HCV infection, based on a transmission rate of 5 percent, is higher than the number of infants with HIV infection at the peak of epidemic. Although the simple and straightforward strategy of treating WCBA will prevent HCV in infants, a strong commitment must be made at the federal level to provide treatment as soon as a diagnosis is made.

Dr. Anderson reported that in addition to addressing perinatal transmission of HCV, the Viral Hepatitis Workgroup also extensively discussed the identification, testing, and management of HCV in pregnancy. The workgroup reviewed numerous concerns and data gaps that the clinical community has raised regarding HCV treatment in pregnancy:

- Maternal morbidity and mortality related of HCV during pregnancy
- Adverse pregnancy outcomes related to HCV
- Safety and efficacy of new DAAs
- Toxicity of existing medications
- Teratogenic effects of medications
- Administration of prophylaxis to and treatment of young children
- No medications approved by the U.S. Food and Drug Administration for use in children under 6 years of age

The workgroup emphasized that none of the HCV medications have been proven to be unsafe in pregnancy. For example, AZT (Category C grade) is given to pregnant women with HIV, while HCV medications (Category B or C grade) are not given to pregnant women. The workgroup proposed the development of a registry for the use of HCV medications during pregnancy to report and monitor any adverse event.

Dr. Havens pointed out that the Viral Hepatitis Workgroup distributed its provisional report to CHAC for review and comment, "Prevention of Perinatally Acquired Hepatitis C Virus Infection in the United States." He clarified that the full seven-page report includes key questions from CDC and HRSA to CHAC; the workgroup's provisional action steps and recommendations for perinatal HCV testing; background information/rationale for the recommendations; and references/ guidelines (pending). He requested CHAC's input on the workgroup's provisional action steps, recommendations, and issues for consideration that are outlined below.

Provisional Action Steps

- CHAC should convene a larger workgroup, including specialists from the liver diseases research and care community, and clinicians/specialists in obstetrics, pediatrics, and family medicine to consider and provide advice on recommendations for HCV testing of women of childbearing age, including pregnant women and women who are planning to become pregnant, and HCV-exposed and at-risk infants. The recommendations should be aligned with those for HCV care and treatment of these populations.
- CDC should publish interim guidance regarding HCV testing of women of childbearing age; pregnant women and those who are planning to become pregnant; and infants born to women with HCV.
- CDC should consider the use of epidemiologic data, other information to target interventions to key risk populations, and studies in the interim guidance, including cost-effectiveness analyses of the recommendations.
- CDC and HRSA should establish programs to assure appropriate testing, linkage to care, and treatment of women and their infants (e.g., health navigators and medical case managers).
- CDC should fund Hepatitis C Surveillance Programs in all states.
- CDC should ensure that states with the highest incidence of HCV are prioritized for resources for HCV surveillance and treatment.
- CDC and HRSA should establish a pregnancy registry to capture data on the safety of HCV treatment during pregnancy.
- CDC should support increased funding for clinical trials on the use of DAAs in pregnancy and young children.

Provisional Perinatal HCV Testing Recommendations

1. Women of childbearing age should be screened based on a history of risk factors for HCV infection, specifically injection drug use.
 - *Consider:* Risk-based, prevalence-based, or universal screening
2. Pregnant women should be screened based on a history of risk factors for HCV infection, specifically injection drug use.
 - *Consider:* Risk-based, prevalence-based, or universal screening

3. Infants born to women with identified HCV should have antibody testing at 18 months of age. Infants with positive results should be further evaluated with HCV RNA testing to confirm infection.
 - *Consider:* Viral RNA testing at 2-6 months of age with later testing at 18 months of age
4. Infants born to women with a history of injection drug use, but no maternal HCV testing prior to delivery, or infants with neonatal abstinence syndrome should be screened with HCV antibody testing to identify HCV exposure. Further testing is not needed if such testing is negative. Testing is recommended if HCV antibody screening is positive (see Recommendation 3).
 - *Consider:* Only test infants whose mothers have tested positive for HCV
5. Linkage to care for infected women and their infants is an important part of any testing program.

CHAC DISCUSSION: UPDATE BY THE VIRAL HEPATITIS WORKGROUP

The CHAC members provided extensive feedback in response to the workgroup's request for input on its provisional report to prevent perinatally acquired HCV infection in the United States.

- The provisional report recommends three potential options for HCV testing of WCBA and pregnant women. The perspectives and insights of the CHAC members on these three approaches are described below.
 - Risk-based screening of perinatally acquired HCV infection will not be an effective strategy due to stigma. For example, women are not likely to report IDU during pregnancy due to fears of losing custody of their children and/or other punitive measures.
 - Universal screening was found to play an important role in reducing stigma of pregnant women with HIV. Based on experiences and lessons learned, wide-scale implementation of universal screening is likely to be successful in increasing HCV testing rates among WCBA. However, additional research is needed to support the development of new national guidelines on perinatally acquired HCV infection. In the interim, CDC could target interventions to specific areas of the United States with the highest incidence of births to HCV-infected mothers to decrease morbidity and mortality. A "targeted" universal screening approach potentially could identify the highest number of pregnant women with HCV in the country and offer post-delivery treatment to both mothers and their infants
 - Prevalence-based screening of perinatally acquired HCV infection should be recommended to CDC as the optimal approach. CDC should be advised to conduct a cost-benefit analysis to support this recommendation.
- The recommendations should be revised to clearly articulate differences between the treatment of pregnant women for HCV versus HIV/other STDs. Unlike HIV/other STDs, for example, pregnant women with HCV can be refused treatment based on their fibrosis scores or use of alcohol/illicit drugs.

- Increased access to family planning services among WCBA should serve as a cornerstone of the recommendations. This guidance would place much more emphasis on perinatal HCV prevention, such as contraception.
- The terminology in the provisional report should be changed from “women of childbearing age” to “women of childbearing potential.” The new language would be more inclusive of LGBTQ women of childbearing age who become pregnant through methods other than traditional sexual intercourse with men.

Dr. Mermin thanked the Viral Hepatitis Workgroup for producing its comprehensive and thoughtful provisional report to prevent perinatally acquired HCV infection in the United States. Before CDC could respond to the overarching action step of publishing interim guidelines, however, he emphasized the need for additional research on HCV screening in pregnancy in the context of harms, benefits, and key data gaps.

Dr. Mermin added that new data also would help CDC to respond to CHAC’s recommendation to conduct a cost-benefit analysis of prevalence-based HCV screening in pregnancy. He noted that a meta-analysis with specific GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) criteria would serve as an extremely useful data source in this effort.

Dr. Mermin highlighted several research questions, scientific issues, and considerations for screening and testing of HCV during pregnancy that CDC and its partners would need to address prior to the development of interim guidelines on perinatally acquired HCV: stigma, universal screening/opt-out testing, expansion of existing testing guidelines, one-time screening of women of childbearing potential, and universal screening of all pregnant women.

Dr. Havens thanked the CHAC members and Dr. Mermin for their extremely helpful comments on the provisional report. He, Dr. Anderson, and Ms. Fukuda summarized the Viral Hepatitis Workgroup’s next steps based on the discussion.

- The workgroup was pleased that CHAC’s discussion resulted in Drs. Jorge Mera and Lynn Taylor volunteering to serve as new members.
- The workgroup will change the terminology throughout the provisional report from “women of childbearing age” to “women of childbearing potential.”
- The workgroup will reframe and broaden the responses to the six questions posed by CDC and HRSA, such as testing women of childbearing potential and infants as well as collecting necessary data to more fully inform these discussions. The workgroup also will solicit guidance from CDC and HRSA to streamline their original list of six questions and identify the most important key questions or specific work product that should serve as the basis of its amended charge. For example, the workgroup’s streamlined charge could focus on the (1) development of recommendations on “targeted” universal screening in areas of the United States with the highest incidence of births to HCV-infected mothers while new research is underway; (2) development of recommendations on prevalence-based screening of HCV in pregnancy; or (3) development of a new registry for the use of HCV medications during pregnancy to report and monitor adverse events to mothers and their infants.
- The workgroup will consult with CDC and HRSA to expand its membership to include representation by a broader group of external clinicians, specialists, and other key

experts to better address and provide guidance on perinatally acquired HCV, including screening and research needs in this population. CDC will provide staff to support the workgroup meetings as needed (e.g., take notes, draft new iterations of the provisional report, and provide other TA).

- The workgroup will hold its next teleconference meeting in June 2017. CDC and HRSA will be in attendance to provide technical expertise. The workgroup will use this opportunity to refine and clarify its provisional report in preparation of presenting the revised recommendations to CHAC for review, discussion, and a formal vote. For example, the workgroup's revised recommendations on the prevention of perinatally acquired HCV in the United States might be for CDC and HRSA to "gather more data" or "develop and disseminate interim guidelines during the collection of additional data."
- The workgroup will revise the provisional report based on the feedback provided during the current CHAC meeting. Most notably, a new "Research Needs" section will be included to address the input from the CHAC members and Dr. Mermin regarding existing data gaps in HCV testing in pregnancy. The revised provisional report will be distributed to CHAC prior to the October 2017 meeting.

Update by the CHAC School-Aged LGBTQ Youth Health Workgroup

Debra Hauser, MPH

President

Advocates for Youth

CHAC Member and Workgroup Chair

Ms. Hauser reported that CHAC voted to approve the establishment of a new Youth Workgroup during the November 2016 meeting. During its first teleconference meeting, however, the members reached agreement on a broader, more inclusive name, "School-Aged LGBTQ Youth Health Workgroup." The workgroup was formed in response to CDC's 2015 YRBS data that showed extremely high rates of risk factors and disparities among LGB youth.

Ms. Hauser was pleased to announce that each of the workgroup's teleconference meetings has resulted in a high rate of participation by approximately 23 attendees, including representation by governmental agencies and national non-governmental organizations with a specific mission to serve LGBTQ youth. In addition to expanding its name, she noted that the workgroup also refined its charge to focus on the two key goals described below.

Increase awareness of and widely disseminate CDC's 2015 YRBS data

- The workgroup collaborated with CDC on several activities to complete this goal. A postcard with links to helpful resources for young people was distributed, including LGBTQ youth. A form letter was sent to numerous national organizations, health care systems, educational systems, and large after-school programs with a request to incorporate CDC's 2015 YRBS data into their newsletters and other communication materials. CDC leadership and staff graciously contributed their time and expertise to serve as keynote speakers for important youth-related conferences that the workgroup recommended over the past few months. CDC communicated key data points from the sample of young people who were included in the 2015 YRBS dataset: 60 percent reported severe depression; 40 percent reported suicide ideation; and 30 percent reported at least one suicide attempt.

Identify promising practices, gaps, and research

- The workgroup is continuing to explore existing models and potential opportunities to help agencies, organizations, health care systems, and after-school programs improve the health, well-being, and connectedness of LGBTQ youth. The workgroup is collecting recent data from CDC to achieve this goal. The major product of this effort will be the development and dissemination of a blueprint or compendium for LGBTQ youth. The document will be designed to describe effective approaches and interventions to guide the strategic planning activities of external organizations and also to inform CDC's decision-making process. The workgroup is collaborating with partners to convene a two-day summit in June 2017 as an initial effort in developing the blueprint/compendium. The first day of the summit will be open to the public, while the second day will be limited to researchers and other experts by invitation only. The invited experts will be asked to propose guidance on the current knowledge, existing data gaps, effective strategies, and evidence-based/evidence-informed practices to improve the health, well-being, and connectedness of LGBTQ youth in their families, schools, after-school programs, and health care settings. The workgroup will present the research findings and other key outcomes of the summit during the October 2017 CHAC meeting. The workgroup's report will highlight evidence-based approaches that CHAC should prioritize in its recommendations to CDC and practical interventions with a demonstrated track record of success in the field.

Ms. Hauser read a poem that she retrieved from the Tumblr website from a student. The poem calls for traditional institutions (e.g., the public health, medical, and educational communities) to consider the strong cultural, social, and environmental factors that young people currently face on a daily basis.

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.

Business Item 1: Approval of the November 2016 Draft CHAC Meeting Minutes

A motion was properly placed on the floor by Dr. Peter Havens and seconded by Dr. Jorge Mera for CHAC to approve the previous meeting minutes.

CHAC unanimously approved the Draft November 16-17, 2016 Meeting Minutes with no changes or further discussion.

Business Item 2: Establishment of a New CHAC STD Workgroup

Ms. Fukuda entertained a motion for CHAC to take formal action on the suggestion that was made on the previous day to establish a new STD Workgroup.

Action	Description
Co-Chair's call for a	Dr. Susan Philip properly placed a motion on the floor for CHAC to establish a new STD Workgroup to provide ongoing guidance as DSTDP revises and refines its draft recommendations on quality STD clinical services. Dr. Bradley Stone seconded the motion.
Outcome of vote	The motion was unanimously passed by 12 CHAC voting members.
Next steps	<ul style="list-style-type: none"> • STD Workgroup Membership: Susan Philip (chair); Jean Anderson, Peter Byrd, Peter Havens, and Bradley Stoner (members) • The new STD Workgroup chair will convene interim teleconferences before the October 2017 CHAC meeting to formalize its charge, including key specific tasks that the CHAC members proposed as a starting point: <ul style="list-style-type: none"> ➢ Identify and recruit non-CHAC members, as needed, to serve as external STD subject-matter experts on the workgroup. ➢ Provide recommendations to CHAC on the proposed provision of quality STD clinical preventive services by types of STD services that should be offered at both basic and specialty levels for CHAC's vote during the October 2017 meeting. ➢ Weigh in on CDC's existing process to update the STD Treatment Guidelines. ➢ Consider systems level interventions (e.g., express visits and pharmacy services), as necessary, to improve STD prevention, screening/testing, care, and treatment in both primary and subspecialty care settings. ➢ Engage HRSA/MCHB staff to leverage Title V expertise. • Dr. Cheever will follow-up on the suggestion by Dr. Havens to secure representation by Title V staff from HRSA/MCHB at the fall 2017 CHAC meeting. He made this suggestion to ensure that the new STD Workgroup and the broader CHAC membership obtain ongoing expertise from MCHB on HIV, HCV, and STDs in the context of perinatal transmission, including congenital syphilis.

Business Item 3: Future Agenda Items

Ms. Fukuda opened the floor for the CHAC members to propose topics to place on future agendas.

Presenter	Agenda Item
CDC/DSTDP HRSA/MCHB	Update on congenital syphilis, including the most recent data, state-of-the art prevention efforts, and the federal response to the increase in congenital syphilis rates by CDC and HRSA.
Dr. Susan Philip, Chair	Update by the STD Workgroup chair to prepare CHAC for its formal vote on DSTDP's revised quality STD clinical services recommendations.
Dr. Peter Havens, Co-Chair Dr. Jean Anderson, Co-Chair	Update by the Viral Hepatitis Workgroup on its revised provisional report to prevent perinatally acquired HCV infection in the United States.
Mr. Peter Byrd, Chair	<p>Update by the CHAC HIV and Aging Workgroup:</p> <ul style="list-style-type: none"> • Mr. Byrd will continue consulting with CDR Berilla to better understand the requirements of a FACA workgroup and develop an overall framework. After he completes his "orientation process" with CDR Berilla over the next two weeks, he will reach out to the CHAC members who agreed to serve on the workgroup: Richard Aleshire, Jean Anderson, Amy Leonard, and Richard Haverkate (IHS <i>ex-officio</i> member). • The workgroup will convene an interim teleconference to refine its charge, identify specific tasks, and draft a progress report. • The workgroup will consider Ms. Fukuda's advice during its deliberations regarding the need to be mindful of the key points that were raised during the November 2016 CHAC meeting. Most notably, people who are 50 years of age and older account for well over 50 percent of the PLWH population in the United States at this time.

Presenter	Agenda Item
CHAC Membership	<p>Discussion on HCV care and treatment in RWHAP clinical settings:</p> <ul style="list-style-type: none"> • The major barriers for HCV patients include limited access to drugs and decreased clinical capacity to provide screening, care, and treatment. However, the excellent RWHAP model cannot be used to respond to these needs because the current legislation does not cover clients with mono-HCV infection. CHAC's discussion should focus on its role and/or influence to change the RWHAP requirements or develop an entirely new system that would permit the care and treatment of clients with mono-HCV infection in RWHAP clinical settings. • Ms. Dempsey clarified that CHAC's suggestion to change the existing language on the care and treatment of mono-infected HCV patients in RWHAP clinical settings would require Congressional action. CHAC's charter to provide recommendations and advice to the HHS Secretary and CDC/HRSA leadership does not extend to Congress. However, CHAC's discussion and guidance on this issue would be extremely helpful to the federal agencies. • Based on Ms. Dempsey's clarification, CHAC agreed to focus its discussion on two major topics: (1) potential options to address infrastructure needs in the context of delivering HCV prevention, care, and treatment services in the United States and (2) models other than RWHAP to consider in this effort. • Dr. Andrey Ostrovky (CMS <i>ex-officio</i> member) or his proxy (Dr. Richard Wild) will be asked to provide remarks during CHAC's discussion regarding CMS's role in ensuring that viral hepatitis patients have access to DAAs nationally. CHAC also will ask CMS to explore the possibility of replicating the HHIAG to establish a new HCV Health Improvement Affinity Group.

Public Comment Period

Thelma King Thiel
 Chair, Liver Health Initiative

Ms. Thiel read the following statement into the public record. (*Editor's note:* Ms. Thiel's public comments are captured in the minutes with no editorial or content changes.)

"I am Thelma King Thiel, a mom who lost my precious son Dean to cirrhosis at age 4, I have spent the last 47 years promoting prevention of hepatitis and teaching liver wellness

to tens of thousands of healthcare providers, teachers, serving as the CEO of the American Liver Foundation and the Hepatitis Foundation International and currently the Liver Health Initiative.

Last month I conducted two workshops on the Prevention of Hepatitis for SAMHSA grantees who are tasked with counseling hepatitis patients. Acknowledging that they were unaware of the important role their liver plays, the grantees were delighted to learn new techniques and to receive liver education teaching tools to share with their clients.

When I showed our Emmy award winning DVD called *Give Your Liver a Break* to another group, the administrator was so impressed with the content of the DVD he planned to provide a copy to 30 community grantees.

However, that NEVER happened. Liver information was not scientifically approved for their programs.

Having trained over 3500 SAMHSA's grantees, I offered to help CSAP integrate liver information in their programs. They thanked me . . . and explained that they were **limited in what they are allowed to include in their programs**. However, they asked me to do a presentation at their upcoming National Prevention Conference.

Unfortunately . . . upon review of the first draft of the National Academy of Science (NAS) Strategies for Eliminating Viral Hepatitis, I was very concerned that it failed to include Primary Prevention or liver information to prevent hepatitis. I shared my concerns with the NAS committee and provided them with two national research reports that identified scientific evidence that providing liver health information to high risk cohorts, including IDUs and homeless children in Baltimore, reduced risk behaviors and improved immunization rates.

Concerned that this was not sufficient evidence, the Liver Health Initiative mounted an international awareness campaign to enlist support for the inclusion of liver information and primary prevention in the NAS report.

The AASLD, ACG, and many others representing over 30,000 health professionals expressed the urgency to include liver health education in the upcoming NAS Strategy. They recommend providing liver information to children in schools, especially Head Start Programs, all government and military agencies. In addition, they added their support of efforts to expand the dialogue beyond hepatitis to address the many other liver related diseases including drug and alcohol abuse and obesity, etc.

Tragically, the final NAS report failed to respond to their plea. Without NAS's stamp of approval SAMHSA, CDC, HRSA, HHS and other agencies will continue to spend billions on programs that have an enormous gap in valuable lifesaving information on liver wellness.

The American Public needs the NAS to give these organizations the GREEN LIGHT to include Life Saving liver information in their programs.

Your decision being made today can save precious lives and healthcare dollars, provided liver health education is included as an essential component of primary prevention.”

Closing Session

Ms. Fukuda thanked the CHAC members for continuing to contribute their valuable time and expertise to assist CDC and HRSA in refining their outstanding portfolios of HIV, viral hepatitis, and STD prevention and treatment activities. She also thanked the CDC and HRSA leadership and staff for their ongoing and tremendous support to CHAC.

The next CHAC meeting will be a HRSA-focused meeting that will be held in October 2017 in Rockville, Maryland. The meeting also will be open to members of the public via webinar and teleconference. HRSA committee management staff will poll the CHAC members to confirm the specific date.

CHAC Co-CHAIRS' CERTIFICATION

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

Peter W. Byrd, Co-Chair (Date)
CDC/HRSA Advisory Committee on HIV,
Viral Hepatitis and STD Prevention and
Treatment

H. Dawn Fukuda, ScM, Co-Chair (Date)
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
Mr. Richard Aleshire
Dr. Jean Anderson
Ms. Debra Hauser
Dr. Peter Havens
Ms. Amy Leonard
Dr. Jorge Mera
Mr. Greg Millett
Dr. Susan Philip
Dr. Bradley Stoner
Dr. Lynn Taylor

CHAC Member Absent

Ms. Linda Scruggs

CHAC Ex-Officio Members Present

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

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

Mr. Richard Haverkate
Indian Health Service

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
(Alternate for Dr. Andrey Ostrovsky)
Centers for Medicare & Medicaid Services

CHAC Ex-Officio Members Absent

Dr. Melinda Campopiano
Substance Abuse and Mental Health
Services Administration

Dr. Andrey Ostrovsky
Centers for Medicare & Medicaid Services

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 Attendees

Dr. Roxanne Barrow
CDR Holly Berilla
Ms. Sara Bingham
Dr. Gail Bolan
Dr. Kate Buchacz
Ms. Lara Bull
Ms. Lizeth Camacho
Dr. Hazel Dean
Ms. Hanna Demeke

Ms. Antigone Dempsey
Dr. Patricia Dietz
Ms. Diane Dlouhy
Dr. Brian Edlin
Ms. Loni Elmore
Dr. Kathleen Ethier
Dr. Jennifer Fuld
Mr. Brian Katzowitz
Dr. Linda Koenig
Dr. Eugene McCray
Dr. John Moore
Ms. Diana Padron
Dr. David Purcell
Ms. Margie Scott-Cseh
Dr. Dawn Smith
CAPT Nicole Smith
Ms. Salina Smith
Dr. Judith Steinberg
Dr. John Ward
Ms. Rachel Wingard
Ms. Sharon Wong
Ms. Sara Zeigler

**Guest Presenters/
Members of the Public**

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

Ms. Jessica Frasure
National Coalition of STD Directors

Mr. David Harvey
National Coalition of STD Directors

Mr. Carl Schmid
The AIDS Institute

Ms. Thelma King Thiel
Liver Health Initiative

Mr. Michael Weir
National Alliance of State and Territorial
AIDS Directors

Mr. Joey Wynn
Empower U Community Health Center



Attachment 2: Glossary of Acronyms

Acronym	Full Name
ACIP	Advisory Committee on Immunization Practices
ADAP	AIDS Drug Assistance Program
AETC	AIDS Education and Training Center
ART	Antiretroviral Therapy
ATN	Adolescent Trials Network
BMSM	Black Men Who Have Sex With Men
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
CMS	Centers for Medicare & Medicaid Services
CoAg	Cooperative Agreement
CSTE	Council of State and Territorial Epidemiologists
DAAs	Direct-Acting Antivirals
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DHAP	Division of HIV/AIDS Prevention
DSTD	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DVH	Division of Viral Hepatitis
EDs	Emergency Departments
EMR	Electronic Medical Record
FACA	Federal Advisory Committee Act
FOA	Funding Opportunity Announcement
FQHCs	Federally Qualified Health Centers
FY	Fiscal Year
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation

Acronym	Full Name
HAB	HIV/AIDS Bureau
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HEDIS	Health Effectiveness Data and Information Set
HHIAG	HIV Health Improvement Affinity Group
HHS	U.S. Department of Health and Human Services
HPTN	HIV Prevention Trials Network
HRRT	HIV Risk Reduction Tool
HRSA	Health Resources and Services Administration
HSV	Herpes Simplex Virus
IDSA	Infectious Diseases Society of America
IDU	Injection Drug Use
IHS	Indian Health Service
LGBTQ	Lesbian/Gay/Bisexual/Transgender/Questioning
LTBI	Latent TB Infection
MCHB	Maternal and Child Health Bureau
MMP	Medical Monitoring Project
MSM	Men Who Have Sex With Men
NAAT	Nucleic Acid Amplification Test
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCQA	National Committee for Quality Assurance
NCSD	National Coalition of STD Directors
NHBS	National HIV Behavioral Surveillance Survey
NIH	National Institutes of Health
NMAC	National Minority AIDS Council
NPEP	Non-Occupational Post-Exposure Prophylaxis
OHAIDP	Office of HIV/AIDS and Infectious Disease Policy
OST	Opiate Substitution Treatment
PEP	Post-Exposure Prophylaxis
PLWH	People Living with HIV
PrEP	Pre-Exposure Prophylaxis
Project ECHO	Extension for Community Healthcare Outcomes
PWID	People Who Inject Drugs
RCT	Randomized Controlled Trial
RSR	Ryan White HIV/AIDS Program Services Report
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SMAIF	Secretary's Minority AIDS Initiative Fund
SPNS	Special Projects of National Significance
SSPs	Syringe Services Programs

Acronym	Full Name
STD	Sexually Transmitted Disease
TA	Technical Assistance
TasP	Treatment as Prevention
USPSTF	U.S. Preventive Services Task Force
UVL	Undetectable Viral Load
VA	U.S. Department of Veterans Affairs
WCBA	Women of Childbearing Age
WHA	World Health Assembly
WHO	World Health Organization
WMSM	White Men Who Have Sex With Men
YMSM	Young Men Who Have Sex With Men
YRBS	Youth Risk Behavioral Survey