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 9-10, 2018 Atlanta, Georgia

Record of the Proceedings

TABLE OF CONTENTS

<u>Page</u>

Minutes of the Meeting	1
Opening Session: May 9, 2018	1
CDC/NCHHSTP Director's Report	3
HRSA HAB Associate Administrator's Report	7
Panel Presentation: CDC's Response to the Opioid Crisis	.16
The Evolving Opioid Epidemic in the United States	.16
HIV, Viral Hepatitis, and STD Consequences of the Opioid Crisis	.17
Panel Presentation: HRSA's Response to the Opioid Crisis	.21
SAMHSA's Role in the HIV Continuum of Care	.28
Panel Presentation: Syringe Services Programs Perspectives and Experiences	.36
Overview of Syringe Services Programs Science and Practice	.37
SSP Perspectives and Experiences: Atlanta, Georgia	.39
SSP Perspectives and Experiences: North Carolina	.40
SSP Perspectives and Experiences: San Francisco, California	.43
Panel Presentation: HIV Transmission Risk in the	
Context of Antiretroviral Use and Viral Suppression	.47
Context of Antiretroviral Use and Viral Suppression	.47
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup CDC's Coordinated Response to Hepatitis A Outbreaks	.47 .51 .54
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup	.47 .51 .54
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup CDC's Coordinated Response to Hepatitis A Outbreaks	.47 .51 .54 .57
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup CDC's Coordinated Response to Hepatitis A Outbreaks Public Comment Period	.47 .51 .54 .57 .61
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup CDC's Coordinated Response to Hepatitis A Outbreaks Public Comment Period CHAC Treatment as Prevention Workgroup Report	.47 .51 .54 .57 .61 .61
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup CDC's Coordinated Response to Hepatitis A Outbreaks Public Comment Period CHAC Treatment as Prevention Workgroup Report Preparation for the CHAC Business Session	.47 .51 .54 .57 .61 .61 .62
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup CDC's Coordinated Response to Hepatitis A Outbreaks Public Comment Period CHAC Treatment as Prevention Workgroup Report Preparation for the CHAC Business Session Opening Session: May 10, 2018	.47 .51 .54 .57 .61 .61 .62 .63
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup CDC's Coordinated Response to Hepatitis A Outbreaks Public Comment Period CHAC Treatment as Prevention Workgroup Report Preparation for the CHAC Business Session Opening Session: May 10, 2018 CHAC School-Aged LGBTQ Youth Health (SALYH) Workgroup Report	.47 .51 .54 .57 .61 .62 .63 .63
Context of Antiretroviral Use and Viral Suppression CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP Update by the HHS Viral Suppression Messaging Workgroup CDC's Coordinated Response to Hepatitis A Outbreaks Public Comment Period CHAC Treatment as Prevention Workgroup Report Preparation for the CHAC Business Session Opening Session: May 10, 2018 CHAC School-Aged LGBTQ Youth Health (SALYH) Workgroup Report CHAC Hepatitis C Workgroup Report	.47 .51 .54 .57 .61 .62 .63 .63 .64

TABLE OF CONTENTS [continued]

<u>Page</u>

Business Item 1: Approval of the Draft CHAC Meeting Minutes	CHAC Business Session	75
Business Item 3: New Resolution by the HCV Workgroup	Business Item 1: Approval of the Draft CHAC Meeting Minutes	75
Business Item 4: Presidential Advisory Council on HIV/AIDS (PACHA)	Business Item 2: New CHAC RWHAP Reauthorization Workgroup	76
Business Item 5: CHAC's Role in the Opioid Crisis 78 Business Item 6: HCV Laboratory Research and Testing 79 Business Item 7: Future Agenda Items 79 Closing Session 81 Attachment 1: Participants' Directory 83	Business Item 3: New Resolution by the HCV Workgroup	76
Business Item 6: HCV Laboratory Research and Testing	Business Item 4: Presidential Advisory Council on HIV/AIDS (PACHA)	77
Business Item 7: Future Agenda Items 79 Closing Session 81 Attachment 1: Participants' Directory 83	Business Item 5: CHAC's Role in the Opioid Crisis	78
Closing Session	Business Item 6: HCV Laboratory Research and Testing	79
Attachment 1: Participants' Directory	Business Item 7: Future Agenda Items	79
	Closing Session	81
Attachment 2: Glossary of Acronyms	Attachment 1: Participants' Directory	83
	Attachment 2: Glossary of Acronyms	85





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

CDC/HRSA ADVISORY COMMITTEE ON HIV, VIRAL HEPATITIS AND STD PREVENTION AND TREATMENT May 9-10, 2018 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 9-10, 2018 at the CDC Corporate Square Campus, Building 8, Conference Room 1-A/B/C, Atlanta, Georgia.

CHAC is formally chartered under the Federal Advisory Committee Act (FACA) to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on state-of-the-art approaches, 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 9, 2018

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 and *ex-officio* members 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 CDC funding and 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 and funding from the National Institutes of Health (NIH); shareholder of pharmaceutical stock with Gilead Sciences	
Marvin Belzer, MD, FACP, FSAM (Children's Hospital Los Angeles)	Recipient of funding from CDC, HRSA, NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA)	
Peter Byrd (Peer Educator/Advocate)	No conflicts disclosed	
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Recipient of CDC and HRSA funding	
Peter Havens, MD, MS (Children's Hospital of Wisconsin)	Recipient of HRSA and NIH funding	
Devin Hursey (U.S. People Living with HIV Caucus)	Recipient of CDC and HRSA funding	
Amy Leonard, MPH (Legacy Community Health Services)	Recipient of CDC and HRSA funding	
Jorge Mera, MD (W.W. Hastings Indian Hospital)	Recipient of CDC and HRSA funding; recipient of a hepatitis C virus (HCV) elimination grant from the Gilead Foundation; recipient of speaker fees from Gilead Sciences	
Michael Saag, MD (University of Alabama at Birmingham (UAB) School of Medicine, UAB Center for AIDS Research)	Recipient of CDC, HRSA, and NIH funding; consultant to Merck, Gilead Sciences, and VIVE	
Bradley Stoner, MD, PhD (Washington University School of Medicine)	Recipient of CDC, HRSA, and NIH funding	
Lynn Taylor, MD, FACP (The Warren Alpert Medical School of Brown University)	Recipient of an RWHAP Part B grant from HRSA	

CONFLICT OF INTEREST DISCLOSURES

Dr. Mermin confirmed that the 17 voting members and *ex-officio* members in attendance (or their alternates) constituted a quorum for CHAC to conduct its business on May 9, 2018. He called the proceedings to order at 8:46 a.m. and welcomed the participants to the first day of the CHAC meeting.

Dr. Mermin announced the changes in CHAC's membership that have occurred since the previous meeting.

- The terms of three CHAC members will expire on November 30, 2018: Ms. Dawn Fukuda, Ms. Amy Leonard, and Dr. Jorge Mera. Certificates of appreciation will be presented to the three outgoing members in recognition of their service to CHAC, CDC, HRSA, and HHS.
- Dr. Steven Daviss replaced Dr. Melinda Campopiano as the *ex-officio* member for SAMHSA. Dr. Daviss is the Senior Medical Advisor in the Office of the Chief Medical Officer at the SAMHSA Center for Substance Abuse Treatment (CSAT). The participants joined Dr. Mermin in welcoming Dr. Daviss to his first CHAC meeting.
- Dr. Andrey Ostrovsky left his position with the Centers for Medicare & Medicaid Services (CMS) in December 2017. CDC sent a letter to CMS on January 5, 2018, with a request to identify a new *ex-officio* member to replace Dr. Ostrovsky. Dr. Richard Wild is continuing to serve as the alternate *ex-officio* member for CMS.

Dawn Fukuda, ScM, CHAC Co-chair

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

Ms. Fukuda also welcomed the participants to the first day of the CHAC meeting. She announced that Mr. Peter Byrd, the CHAC Co-chair, currently is out of the country. He will attempt to participate remotely at certain times throughout the meeting.

Ms. Fukuda highlighted the agenda items for the first day of the May 2018 CHAC meeting. CHAC primarily will address the impact of the national opioid epidemic on the transmission of HIV, viral hepatitis, and STDs. These agenda items will include two panel presentations: (1) the federal response to the opioid crisis by CDC, HRSA, and SAMHSA and (2) experiences and perspectives by multiple syringe services programs (SSPs) across the country.

CHAC will continue its discussion on the substantial progress that has been made on treatment as prevention (TasP). To guide this discussion, a panel presentation by CDC and the HHS Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) will focus on HIV transmission risk in the context of antiretroviral therapy (ART) use and viral suppression.

CDC/NCHHSTP Director's Report

Jonathan Mermin, MD, MPH (RADM, USPHS)

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

Advice Requested from CHAC by CDC/NCHHSTP:

- 1. What actions can be taken to increase implementation of routine HIV, viral hepatitis, STD, and latent tuberculosis infection (LTBI) screening in healthcare settings, including correctional facilities?
- 2. What would be the most effective policy-level changes to increase access to HCV treatment?
- 3. What are the most effective strategies to support overdose prevention while preventing increases in drug use-associated infectious diseases?

Dr. Mermin covered several topics in the CDC/NCHHSTP Director's report to CHAC. At the agency level, Dr. Robert Redfield was appointed as the new CDC Director in March 2018. Dr. Mermin highlighted the key milestones in Dr. Redfield's distinguished background and career in clinical medicine research and public health, particularly in both domestic and global HIV treatment and research. Dr. Redfield's most frequent quote to CDC staff is "never underestimate the possible."

CDC provided support to the National Governors Association to host a learning laboratory for states on March 15-16, 2018 in Louisville, Kentucky. This event was convened for high-level officials in eight states to explore approaches to decrease the transmission of infectious diseases among people who inject drugs (PWID), including opioids, develop plans, and share successful policies and practices. The eight participating states included teams from Alabama, Arkansas, Delaware, Kentucky, Michigan, Utah, Virginia, and Washington.

At the CDC center level, NCHHSTP recently announced Dr. John Ward's new position with the Task Force for Global Health after serving as the Director of the Division of Viral Hepatitis (DVH) for 13 years. He is still a CDC employee, but his new position will allow him to expand his activities with global virus hepatitis programs. Dr. Mermin asked the participants to join him in recognizing Dr. Ward for his outstanding leadership and contributions to improve domestic and international viral hepatitis efforts during his tenure as the DVH Director. Dr. Paul Weidle will serve as the Acting DVH Director until Dr. Ward's permanent replacement is appointed.

The NCHHSTP Office of Health Equity updated the <u>CDC Correctional Health website</u> with several helpful resources, including recommendations and guidance, scientific reports on correctional health, and a map of state Departments of Corrections and public health departments. The updated website now serves as a "one-stop" resource for correctional staff throughout the country.

NCHHSTP is planning to launch the updated <u>AtlasPlus webpage</u> by the end of May 2018. The key features of the webpage are described below.

- New Social Determinants of Health (SDOH) Indicators
 - \circ Uninsured
 - Less than a high school education
 - o Rural, suburban, or urban residence
 - Below the Federal Poverty Level (FPL)
 - Vacant housing
- New HIV Indicators
 - Linkage to care
 - Receipt of HIV care
 - Viral suppression
 - Estimated HIV incidence
 - Estimated HIV prevalence (diagnosed and undiagnosed)
 - Percent of people with diagnosed HIV infections among all people living with HIV (PLWH) infection

NCHHSTP awarded approximately \$3.8 million to support year 1 of a CoAg, "Accelerating the Prevention and Control of HIV, Viral Hepatitis, STDs, and TB in the U.S.-Affiliated Pacific

Islands." The grant recipients include American Samoa, Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Palau.

NCHHSTP created a map to illustrate the vulnerable counties and jurisdictions that are experiencing or are at risk of HCV or HIV outbreaks. NCHHSTP combined two of its datasets to develop the map. First, the September 2015 dataset described the top 220 counties in 26 states that are most vulnerable to rapid dissemination of HCV or HIV outbreaks among PWID. Second, the February 2018 dataset described the jurisdictions that are determined to be experiencing or at risk of significant increases in HCV infections or HIV outbreaks due to injection drug use (IDU). States that fall in the second category have applied to CDC for a determination of need that will allow federal funds to be used to support SSPs. The two datasets in the map showed that areas in 44 states and Puerto Rico are experiencing or are at risk for HCV/HIV increases or outbreaks.

At the division level, DVH published the <u>Viral Hepatitis Surveillance Report-2016</u> in April 2018. The data showed that the number of reported hepatitis A virus (HAV) cases increased by 44 percent due to two large outbreaks associated with foods. Moreover, the number of reported HCV cases increased by 22 percent from the previous year. However, the number of reported hepatitis B virus (HBV) cases decreased by five percent from 2015. DVH acknowledges that the national opioid epidemic is the primary driver of the increases in viral hepatitis cases.

DVH has been providing assistance to health departments in Kentucky, Michigan, California, Indiana, and Utah since March 2017 to combat the spread of HAV outbreaks. Homeless people, close contacts, PWID, and people who use non-injection drugs accounted for the vast majority of the outbreaks. To date, more than 2,100 cases and 49 deaths have been reported by the five states. DVH's assistance to the health departments includes providing epidemiology and laboratory support, testing more than 1,000 specimens, and supporting vaccine policy development and supply.

DVH published an article in the January 12, 2018, edition of the *Morbidity and Mortality Weekly Report* (*MMWR*), "<u>Prevention of Hepatitis B Virus Infection in the United States:</u> <u>Recommendations of the Advisory Committee on Immunization Practices</u>." The guidelines recommend universal HBV vaccination within 24 hours of birth for stable infants; further testing of hepatitis B surface antigen-positive pregnant women; and vaccination of people with chronic liver disease. A new two-dose HBV vaccine also is recommended in the guidelines.

DVH published the Zibbell, *et al.* study in January 2018 that reported an association between increased HCV infections and increased admissions for opioid injections. The study analyzed CDC's hepatitis surveillance data and data collected by SAMHSA on admissions to substance use disorder (SUD) treatment facilities. The CDC and SAMHSA data showed that during the dramatic rise of HCV and opioid injections among White Americans from 2004-2014, HCV rates increased by 300 percent and admissions to treatment facilities for opioid injections increased by 134 percent.

The Division of HIV/AIDS Prevention (DHAP) published the 2018 Singh, *et al.* study that reported a decline in the estimated HIV incidence in the United States from 2008-2015. The decrease from 45,200 HIV infections in 2008 to 38,500 HIV infections in 2015 represented an overall reduction of 14.8 percent. With the exception of men who have sex with men (MSM), decreases were reported for all transmission groups from 2008-2015: heterosexual contact (6.3

percent decline per year); IDU (10.7 percent decline per year); and male-to-male sexual contact and IDU (4.3 percent decline per year).

The HIV incidence among MSM was relatively stable (from 26,700 infections in 2008 and 26,200 infections in 2015). The 2.7 percent decline per year among White MSM accounted for the relatively stable rates from 2008-2015. However, the HIV incidence increased 3.1 percent per year among Latino MSM (from 6,300 infections in 2008 to 7,900 infections in 2015). The overall HIV incidence among Black MSM (BMSM) was stable at approximately 10,000 infections per year, but young BMSM under 25 years of age were the most disproportionately affected group. DHAP has awarded new CDC funding and is partnering with community-based organizations (CBOs) to decrease HIV infection rates nationally in young BMSM, BMSM in the 25-34 age group, and Latino MSM.

DHAP updated its "HIV Treatment as Prevention" webpage with a technical fact sheet and the latest data on HIV transmission. The <u>TasP webpage</u> presents evidence to demonstrate the effectiveness of ART and viral suppression in preventing the sexual transmission of HIV.

DHAP awarded \$400 million in January 2018 to state, local, and territorial health departments to conduct integrated HIV surveillance and prevention activities. The cooperative agreement (CoAg), "Integrated HIV Surveillance and Prevention Programs for Health Departments," is intended to promote more efficient, coordinated, and data-driven prevention efforts. Over the five-year project period, the recipients will be expected to focus on the following priority areas of the CoAg: knowledge of HIV status, viral suppression, pre-exposure prophylaxis (PrEP), cluster investigations, community-level prevention, and outbreak response.

DHAP presented the 2018 Smith paper during the March 2018 Conference on Retroviruses and Opportunistic Infections (CROI) to demonstrate the benefits of PrEP to Americans. The paper reported that an estimated 1.1 million Americans potentially could benefit from PrEP due to their high HIV risk, but commercial pharmacies have filled only 90,000 PrEP prescriptions to date. The paper also documented racial disparities in the uptake of PrEP in two key populations. For example, PrEP potentially could benefit 44 percent of African Americans (approximately 500,000 people) and 25 percent of Latinos (nearly 300,000 people). To date, however, PrEP has been prescribed for only 1 percent of African Americans (7,000 people) and only 3 percent of Latinos (7,600) people.

DHAP collaborated with DVH to release a new publication in March 2018, <u>Managing HIV and</u> <u>Hepatitis C Outbreaks Among People Who Inject Drugs: A Guide for State and Local Health</u> <u>Departments</u>. The guide is intended to assist health departments in responding to HIV and/or HCV outbreaks among PWID.

The Division of STD Prevention (DSTDP) celebrated STD Awareness Month in April 2018 to increase STD prevention, diagnoses, and linkages to treatment. The theme of the 2018 event, "Treat Me Right," focused on strengthening the patient/provider relationship. Patients were encouraged to ask questions, present for testing, access treatment, and take control of their sexual health. Providers were encouraged to build trust with their patients, take a thorough sexual history, and reassure their patients of the confidentiality of all information that is provided. The messages and other prevention resources that DSTDP developed for STD Awareness Month are available on <u>CDC's STD Awareness Month website</u>.

DSTDP recently released an updated version of <u>Syphilis: A Provider's Guide to Treatment and</u> <u>Prevention</u>. The purpose of the pocket guide is to disseminate information to physicians and other healthcare providers on the diagnosis, treatment, and prevention of syphilis. New syphilis infections in heterosexual men and women as well as new cases of congenital syphilis are increasingly being reported to CDC.

The Division of Adolescent and School Health (DASH) announced a new Notice of Funding Opportunity (NOFO), "Promoting Adolescent Health Through School-Based HIV Prevention," that will award approximately \$17 million per year over the five-year project period. The funding will be targeted to education agencies at state, local, and territorial levels as well as tribal governments. The recipients will be expected to conduct activities in several areas to improve adolescent health: school-based surveillance, HIV and STD prevention, capacity building, and technical assistance (TA).

The Division of Tuberculosis Elimination (DTBE) published an article in the March 23, 2018 edition of the *MMWR* that showed the number of reported tuberculosis (TB) cases in the United States from 1982-2017. Based on DTBE's provisional TB surveillance data, the slight decline to 9,093 cases in 2017 represents the lowest TB case count on record. Despite this progress, however, interim targets have not been achieved to meet the national TB elimination goal.

DTBE is conducting economic analyses and increasing the dissemination of information to advance progress toward reaching TB elimination. Most notably, CDC's updated guidelines on the 3HP regimen (i.e., a once-weekly dose of Isoniazid/Rifapentine for three months) will soon be released. The guidelines will recommend the use of 3HP by self-administered therapy. The use of new modalities will be promoted to administer TB treatment, such as electronic directly observed therapy via video calls with patients or other electronic methods. The shift from the use of tuberculin skin tests to interferon gamma release assays for TB testing and diagnosis is being encouraged. Efforts are underway at DTBE and in health departments to decrease the time of LTBI treatment and further reduce the toxicity associated with therapy.

HRSA HAB Associate Administrator's Report

Laura Cheever, MD, ScM Associate Administrator, HRSA HIV/AIDS Bureau CHAC DFO, HRSA

Advice Requested from CHAC by HRSA HAB:

- 1. What are the tools or other resources that jurisdictions need from HAB to advance toward ending the HIV epidemic?
- 2. What are the best practices or changes that HAB should consider to further reduce the burden in the AIDS Drug Assistance Program (ADAP) six-month recertification (i.e., client eligibility) process?

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."

HAB is continuing to conduct activities to support jurisdictions in their efforts to end the HIV epidemic. Tools are currently available to achieve this goal, but HAB acknowledges the need to refocus existing resources. HAB's ongoing activities and recent accomplishments to advance toward ending the HIV epidemic are highlighted below.

HAB will host the 2018 National Ryan White Conference (NRWC) on HIV Care and Treatment from December 11-14, 2018, at the Gaylord National Harbor Hotel and Convention Center in Oxon Hill, Maryland. The theme of the event is "Catalyzing Success: Advancing Innovation. Leveraging Data. Ending the HIV Epidemic." The 2018 NRWC will include six tracks:

- Increasing Access, Engagement, and Retention in HIV Care and Treatment
- Data Utilization
- Leveraging Innovative Practices to Improve Outcomes and Address Emerging Priorities
- Clinical Quality Management and Quality Improvement
- RWHAP Planning and Resource Allocation: Collaborative Partnerships and Community Engagement
- RWHAP Fiscal and Grant Management Boot Camp

The NRWC 2018 Clinical Conference will be held from December 9-11, 2018. Because accommodations for the 2018 NRWC will be expanded, the participants will include RWHAP Parts A, B, C, D, and F recipients and subrecipients as well as PLWH who serve on Planning Councils. The 2018 <u>NRWC website</u> is open at this time for people to complete the online registration process and/or submit an abstract.

HAB collaborated with the HRSA Office of Federal Assistance Management and a contractor to establish a five-year project period for RWHAP Part B recipients. HAB initiated this change in fiscal year (FY) 2015 based on requests by the recipients. The current five-year project period replaces the one-year competing cycle that HAB had implemented for the past 27 years.

The five-year project period significantly reduces the application burden for state health departments. Most notably, HAB eliminated the 100-page annual application and reduced the information that recipients are required to submit. Instead of completing 12 key components in the full application, recipients are now required to complete seven key components in the non-competing application in years 2-5.

In addition to conducting its burden reduction activities at the bureau level, HAB also is supporting HRSA's agency-wide commitment to reduce the burden on recipients and patients. A request for information regarding potential areas for burden reduction has been issued. HAB has asked for input on changes to HRSA to reduce the burden in three RWHAP components: the Core Medical Services Waiver, Ryan White HIV/AIDS Program Services Report data, and the ADAP six-month recertification process to validate the eligibility of clients. Responses to HRSA's request for input can be submitted at the <u>HRSA website</u>.

HAB created the RWHAP Part C funding methodology to facilitate a rational distribution of limited funding, including "right-sizing" funding based on the number of clients served. The funding methodology resulted in 10 new service areas, more than 50 percent in the South, expanding the delivery of RWHAP services to these new areas. The proportions of the funding methodology are based on the following objective factors:

- 70 percent of funding (Base Funding): This proportion of funding reflects the minimum baseline amount per service area and is augmented by the number of clients served.
- 30 percent of funding (Demographics): This proportion of funding reflects the percentage of a population in a service area that is disproportionately impacted by the HIV epidemic resulting in significant disparities in health outcomes and uninsured populations.
- Additional funding (-Presence of RWHAP Part A Resources): RWHAP Part C service areas outside of RHWAP Part A jurisdictions will receive additional funding.

HAB implemented the RWHAP Part C funding methodology for the first time in FY2018 with specific caveats. The service areas will receive no more than a 25 percent increase or a 10 percent decrease.

Dr. George Sigounas, the Administrator of HRSA, encouraged all HRSA bureaus to more widely promote their programs. HAB responded to this request by publishing the following papers in peer-reviewed journals in 2017.

- "For Many Served by the Ryan White HIV/AIDS Program, Disparities in Viral Suppression Decreased, 2010-2014." *Health Affairs* (2017)
- "Using Systems of Care and a Public Health Approach to Achieve Zero Perinatal HIV Transmissions." *JAMA Pediatrics* (2017)
- "Implementation of an Integrated Approach to the National HIV/AIDS Strategy for Improving Human Immunodeficiency Virus Care for Youths." *JAMA Pediatrics* (2017)
- "The Transgender Women of Color Initiative: Implementing and Evaluating Innovative Interventions to Enhance Engagement and Retention in HIV Care." *American Journal of Public Health* (February 2017)

HAB is continuing to focus on and invest in advancing data utilization to improve health outcomes for RWHAP clients. To support this effort, HAB currently is assessing the implementation of two new resources. First, internal and external data dashboards will be developed for HAB project officers, RWHAP recipients, and stakeholders to more easily access, use, and measure RWHAP client, service, and outcome data. Second, a benchmarking methodology will be developed to enable comparisons of client outcome data.

HAB's future plans to further improve data utilization include consideration of awarding a small amount of funding based on "quality bonus points" accumulated by RWHAP recipients. This would require a legislative change to implement in Parts A and B. The HRSA Bureau of Primary Health Care (BPHC) has successfully implemented this incentive for its high-performing recipients as well as those that have made significant improvements.

HAB is continuing to collaborate with its federal partners on messaging around decreased transmission risk in the setting of an undetectable viral load (known in the HIV advocacy community as the U=U campaign (i.e., "Undetectable equals Untransmittable"). OHAIDP is providing leadership for this effort at HHS. CDC issued the following message to clearly explain the meaning of an undetectable viral load (UVL): "People living with HIV who take HIV medications daily as prescribed and achieve and then maintain an undetectable viral load for at least six months have **effectively no risk** of sexually transmitting the virus to an HIV-negative partner."

HAB is aware that CDC's language represents a paradigm shift because the messaging could have an immensely positive impact on the self-stigma of PLWH, their dignity, and self-actualization across the lifespan. The messaging also could have a positive impact on PLWH in terms of their linkage to care, retention in care, and ultimately, HIV viral suppression. However, HAB's current interest is in the delivery of consistent and uniform messaging among the HHS agencies. To inform this effort in the context of RWHAP, clinicians at the RWHAP clinical Conference in 2017 were polled. The polling showed that 82 percent of providers are routinely educating their patients with UVLs for a prolonged period about negligible risk to transmit HIV infection.

HRSA's full-year appropriation for RWHAP in FY2018 is approximately \$2.3 billion. Compared to the RWHAP appropriations in FY2016 and FY2017, the FY2018 appropriation reflects maintained funding. The bulk of the FY2018 RWHAP appropriation (85 percent) is allocated to Part A (approximately \$656 million or 28 percent to heavily impacted cities with more than 70 percent of HIV cases); Part B-Base (approximately \$1.3 million to states); and Part B-ADAP (\$900 million for medication).

The RWHAP appropriations history from FY1991-FY2018 demonstrates fairly level funding over a significant period of time. The maintained funding in the setting of health care inflation poses challenges over time.

There are two notable additions to the RWHAP-specific section of the FY2019 Congressional Justification. First, HAB expressed strong support for collaborating with Congressional staff on RWHAP reauthorization. As a part of this process, HHS recommends (1) shifting the distribution of RWHAP Parts A and B supplemental resources to a data-driven methodology and (2) simplifying, modernizing, and standardizing certain statutory requirements and definitions for consistency across the program. Second, HHS acknowledged a commitment for CDC and HRSA to continue to work together to accelerate the elimination of perinatal HIV transmission in the United States.

HAB posted a call for nominations of four new HRSA-appointed CHAC members in a recent *Federal Register* notice. The seated CHAC members were asked to view and share the notice and follow the instructions to submit the names of appropriate candidates.

ANNOUNCEMENT: HRSA is seeking four qualified candidates to be considered for CHAC membership!

Please spread the word to those you feel would be qualified.

By May 30, interested parties must submit the following to <u>CHACAdvisoryComm@</u> <u>hrsa.gov</u>: 1) nominee's name and affiliation, basis for nomination (experience, education, positions, etc.), and confirmation of interest in membership; 2) nominee's address, telephone number, and email; and 3) current CV.

Visit the <u>Federal Register website</u> for additional details.

Those with questions may email <u>CHACAdvisoryComm@hrsa.gov</u> or call CDR Holly Berilla at 301-443- 9965.

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

Dr. Cheever provided additional details on the following topic in response to a specific question by the CHAC members. CHAC asked HRSA HAB how staff can engage with Congress during a reauthorization. Dr. Cheever noted that HRSA HAB can provide technical assistance to Congress if requested.

CHAC GUIDANCE

The CHAC members provided extensive input in response to the CDC and HRSA updates, including some of the specific questions posed by Drs. Mermin and Cheever.

NCHHSTP Question 1: Increased Routine Screening

- Drs. Saag and Stoner pointed out that providers have the ability to link newly diagnosed HIV cases to systems of care through RWHAP. However, an "RWHAP-like" model is not available for providers in STD clinics or other settings to facilitate linkages to treatment and care for newly diagnosed HCV cases. Australia's commitment to address HCV as a public health issue rather than a medical issue potentially could be replicated in the United States to increase the implementation of routine HIV, viral hepatitis, and STD screening. Most notably, the Australian government paid approximately \$800 million to a pharmaceutical company to ensure that HCV patients had access to medications for a period of three to four years. This initiative motivated providers to perform screening, facilitate linkages to treatment, and cure HCV infections with no out-of-pocket medication costs to patients. CDC should explore potential strategies to replicate the Australian model in the United States to increase HCV screening in healthcare settings and correctional facilities. For example, CDC's first step should be to partner with states to create an "RWHAP-like" fund, develop a feasible approach, and collaborate with pharmaceutical companies to deliver HCV medications to patients. Moreover, the successful promotion, adoption, and implementation of HIV TasP could help to widely publicize "HCV treatment as cure."
- Dr. Mera announced that the Cherokee Nation implemented "laboratory-triggered" screening for any test ordered for a patient. The decision to exclude an opt-out component played a critical role in increasing the screening rates of patients by 300 percent. The Cherokee Nation's position is that the ability of patients to opt-out of screening should be eliminated to make meaningful progress in the diagnosis and treatment of HIV and HCV. To date, none of the Cherokee Nation patients who were unaware of laboratory-triggered screening and informed of a positive test result voiced opposition at the time of their diagnosis. He advised CDC to review the Cherokee Nation's laboratory-triggered screening model for potential replication and implementation nationally.
- Dr. Mera encouraged CDC and its federal partners to resolve two key issues to increase routine screening in healthcare settings and correctional facilities.
 - The national opioid crisis has led to increased HCV rates in young people, but Medicaid reimbursement for HCV screening based on age rather than risk is a major barrier to testing this population. For example, Medicaid reimburses HCV screening costs for "baby boomers" (i.e., people in the 1945-1965 birth cohort who account for a significant proportion of HCV cases). However, Medicaid does not reimburse HCV screening costs for people who meet certain risk factors that are identified by their providers, but are younger than the 1945-1965 birth cohort.

- Electronic health record (EHR) reminders have played an important role in the past in terms of increasing screening rates. However, newer technologies that are more innovative and smarter should be standardized for national implementation.
- Dr. Anderson highlighted two key opportunities for CDC to increase routine infectious disease screening. First, pregnant women in care are tested for various infections and conditions. CDC should leverage this opportunity to establish new collaborations and ensure that pregnant women in these settings are routinely screened for HIV, viral hepatitis, and STDs. Second, women of reproductive age who are at risk for infections and are screened might have negative test results. However, CDC should leverage this opportunity to promote routine screening of the sexual partners of these women and facilitate linkages to care and treatment for partners with positive test results.

NCHHSTP Question 2: Increased Access to HCV Treatment

 Dr. Mera reported that the Cherokee Nation has found telehealth to be an excellent option to expand HCV treatment options in its communities. For example, Project ECHO (Extension for Community Healthcare Outcomes) has allowed providers to treat a much larger population of HCV patients. Moreover, local pharmacies are using PrEP to successfully treat HCV patients in Cherokee Nation communities.

HAB Question 2: ADAP Six-Month Recertification Process

 Dr. Havens urged HAB to eliminate the six-month recertification process that is used to validate the eligibility of RWHAP clients for ADAP. During the 2018 NRWC in December 2018, HAB should convene a session for states with successful ADAP recertification models to describe their best practices, experiences, and lessons learned that potentially could be adopted by other states.

RWHAP Reauthorization

- Dr. Saag expressed strong support for CHAC to form a new workgroup that would be charged with proposing language on RWHAP reauthorization to submit to HRSA/HAB for consideration.
- Dr. Havens encouraged HAB to propose an expansion of RWHAP in the reauthorization language to also address HCV care and treatment.
- Dr. Anderson noted the high rate of comorbidities in RWHAP clients, such as depression, violence, or other trauma. However, screening of these factors in the RWHAP client population has been poor and inconsistent to date. She advised HAB to address trauma-informed care in its proposed language on RWHAP reauthorization.
- Mr. Aleshire commended Dr. Cheever for her leadership at HAB in reducing the burden on RWHAP recipients, particularly the replacement of the previous one-year competing cycle with the current five-year project period. He encouraged HAB to continue its efforts to eliminate other restrictions or requirements to increase opportunities for recipients to provide care and treatment to their clients. He pointed out that RWHAP currently reaches 90 percent of PLWH, but additional barriers will need to be removed for recipients to have more freedom to allocate their funds and reach the remaining 10 percent of the PLWH population.

Other CHAC Guidance

- Dr. Stoner found CDC's U=U messaging to be "perfect" for HIV, but he emphasized the important need to maintain the focus on addressing the increased rates of other STDs, particularly syphilis.
- Dr. Taylor made several comments and suggestions for CDC and HRSA to consider in their ongoing prevention and treatment efforts.
 - HAB should broadly promote HIV care in the context of basic, fundamental primary health care, particularly in the aging HIV population. She asked HAB to consider the possibility of adding HIV in primary care as a funding requirement for recipients.
 - Some IDU-related HIV outbreaks that are occurring in jurisdictions across the country are not being captured in surveillance systems. CDC should take a proactive rather than a reactive approach in this regard by prioritizing the integration of HIV prevention and surveillance and specifically targeting PWID.
 - OCDC funding is awarded to recipients (e.g., health departments, correctional systems, and needle exchange programs) based on the number of HCV antibody tests performed. However, CDC's data consistently show that more than 50 percent of HCV reactive antibody tests in the United States are never followed up with a confirmatory diagnostic test. She asked CDC to consider the possibility of linking funding to the performance of recipients in conducting reflexive confirmatory viral load testing for HCV. For example, recipients that continue to conduct HCV antibody testing only would have funding implications.
 - CDC should widely promote the use of point-of-care fingerstick testing for HCV to close diagnostic gaps. Efforts are underway in several states and multiple countries to approve a standardized, inexpensive platform to diagnose HCV with fingerstick testing. This platform will play a significant role in improving the HCV cascade from diagnosis to cure.
- Dr. Belzer returned to CDC's data that showed increased HIV infection rates in young Black and Latino MSM. To improve outreach to and interactions with young populations with low rates of engagement in care, he advised CDC and HRSA to make better use of telehealth technology. For example, cell phones would be an effective mechanism to send text message reminders regarding upcoming testing appointments and/or prescription refills.
- Dr. Mera agreed with Dr. Taylor's comments regarding the need to improve the HCV cascade from diagnosis to cure. He encouraged CDC and HRSA to consider replicating the Cherokee Nation's HCV model program for national scale-up. He emphasized that the Cherokee Nation has achieved a great deal of success in improving HCV outcomes in its patient population: screening rates of nearly 90 percent, engagement in care rates of 75 percent, and cure rates of 90 percent. The Cherokee Nation's HCV model program includes key staff positions to address all stages in the HCV cascade:
 - Nurses rather than physicians to order HCV screening that is prompted by EHR reminders;
 - Dedicated staff (i.e., navigators) to guide patients with a positive HCV test result through diagnosis and follow-up;
 - Case managers to procure medications and monitor patients during HCV care and treatment, particularly those with IDU and/or mental health comorbidities; and
 - Community health workers (CHWs) to evaluate and validate the treatment outcomes of patients, including those who are homeless.

• Mr. Hursey asked CDC to reframe its viral suppression messaging to more strongly focus on harm reduction, such as improved access to HIV screening and PrEP.

CDC/NCHHSTP and HRSA/HAB leadership made several remarks in follow-up to CHAC's discussion.

- In response to the comments by Drs. Saag and Stoner, Dr. Mermin clarified that CDC would be unable to "partner with states" to replicate the Australian model in the United States by creating an "RWHAP-like" fund. However, he confirmed that CDC potentially could facilitate linkages between interested states and HCV experts in the field.
- Dr. Mermin responded to Dr. Taylor's comments regarding the inability of surveillance systems to capture IDU-related HIV outbreaks in all jurisdictions of the country. He explained that after the large IDU-related HIV outbreak in Scott County, Indiana in 2015, CDC and health departments across the country thoroughly analyzed epidemiologic data to identify HIV outbreaks among PWID in other jurisdictions. These analyses found no other large HIV outbreaks, but CDC currently is investigating a small cluster of HIV cases related to IDU in one state. CDC has made improvements in surveillance to ensure that its outbreak detection and response capacity is as robust as possible. Most notably, DHAP is now awarding funds to all of its HIV prevention recipients to report pulse sequences to the CDC National HIV Surveillance System in addition to viral loads and CD4 counts. The ability of pulse sequences to detect drug resistance prior to the initiation of ART or changes in ART is enhancing CDC's capacity to identify and rapidly respond to clusters of HIV cases.
- Dr. Mermin responded to Dr. Taylor's comments regarding CDC's funding awards to recipients based on the number of HCV antibody tests performed. He clarified that in addition to the number of tests performed, DVH's current performance measures for its recipients also include indicators for the number of people diagnosed and the outcomes of newly diagnosed viral hepatitis cases.
- Dr. Mermin responded to Dr. Taylor's comments regarding the need to close gaps between testing and diagnosis. CDC acknowledges that the inability to widely implement routine screening has served as a barrier to diagnosing NCHHSTP's infections of interest. CDC is now considering innovative methods to address this issue. For example, EHR systems could be preprogrammed to automatically screen for HIV, viral hepatitis, and LTBI when an "at-risk" patient's blood is drawn to screen for cholesterol, diabetes, hypertension, or other chronic conditions. EHR systems can play an important role in promoting widespread diagnoses by eliminating the need for individual clinicians to make screening decisions.
- In response to Dr. Belzer's comments, Dr. Cheever confirmed that HAB has launched several telehealth initiatives. For example, AIDS Education and Training Centers (AETCs) have utilized the Project ECHO model to amplify its HIV expertise in jurisdictions with limited access to care. Moreover, all of the AETCs have incorporated telehealth components into their activities to build the capacity and expertise of clinicians in underserved areas. Dr. Cheever asked the CHAC members to provide input to HAB to inform its ongoing efforts to further support and utilize telehealth.

- In response to the comments by Dr. Havens, Dr. Cheever noted that the Trust for America's Health and other policy experts have extensively analyzed the possibility of expanding RWHAP to include culturally competent care and treatment for HBV and HCV, particularly in immigrant populations. However, it would require statutory changes to allow such activity.
- In response to Dr. Anderson's comments, Dr. Cheever confirmed that HAB has a strong
 interest in implementing evidence-based and evidence-informed interventions to deliver
 trauma-informed care to PLWH. To support this effort, HAB is collaborating with the NIH
 National Institute of Mental Health to address post-traumatic stress disorder, avoidance
 coping mechanisms, and other factors that impact HIV care. HAB also is reviewing the
 existing literature on the role of trauma-informed care in improving substance abuse
 treatment outcomes. However, no evidence-based or evidence-informed interventions
 have been published to date on the delivery of trauma-informed care in the context of
 HIV specific medical care. To fill this data gap, HAB is funding a pilot project for a
 sample of RWHAP clinics to determine whether the implementation of trauma-informed
 care interventions with the strongest evidence can improve health outcomes in PLWH.
- Dr. Daviss described potential collaborative opportunities for the federal partners to address the third CDC/NCHHSTP question related to drug use-associated infectious disease prevention.
 - Medication-assisted treatment (MAT) (e.g., buprenorphine, long-acting naltrexone, or methadone) is the most effective strategy to prevent increases in drug use-associated infectious diseases, reduce IDU, and save lives from overdose deaths. The federal partners should provide national leadership in ensuring that Naloxone is widely available in and easily accessible to communities across the country. For example, SAMHSA and HRSA leadership recently met to discuss the need for RWHAP providers to obtain buprenorphine waivers to prescribe this drug. However, RWHAP providers are not required to obtain waivers to prescribe naltrexone. SAMHSA is continuing its analysis to identify and target outreach to RWHAP providers and clinics that do not have buprenorphine waivers.
 - SAMHSA data show that 10 percent of people who survive drug overdoses in emergency departments (EDs) are likely to die from a subsequent overdose within one year. To advance the collection of drug use-associated morbidity data for surveillance systems, routine screening of HIV and HCV should be performed for people who survive drug overdoses in EDs. CDC should develop and disseminate clear guidance for ED physicians to screen for infectious diseases in drug overdose cases and make referrals to treatment and care for patients with positive test results. To advance the collection of drug use-associated mortality data for surveillance systems, CDC should develop and disseminate guidance for medical examiners and coroners to perform HIV and HCV testing on patients who died from drug overdoses during the autopsy or death investigation.

Panel Presentation: CDC's Response to the Opioid Crisis

CAPT Paul Weidle, PharmD

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

Dr. Weidle moderated a panel presentation for a series of speakers to highlight CDC's response to the opioid crisis. He introduced the panel of CDC speakers and opened the floor for their presentations.

The Evolving Opioid Epidemic in the United States

Grant Baldwin, PhD, MPH

Director, Division of Unintentional Injury Prevention (DUIP) Centers for Disease Control and Prevention

Advice Requested from CHAC by CDC/DUIP:

- 1. How can individuals who have experienced an opioid overdose be connected with HIV and viral hepatitis programs in addition to substance use treatment?
- 2. What are some HIV/viral hepatitis linkage to care models that would also be effective in the SUD space?

Dr. Baldwin presented an overview of the evolving opioid epidemic in the United States from a public health perspective. All states have reported increases in their county-level drug overdose mortality rates from 2000-2016, but Appalachian and Southwestern states have had a disproportionate impact. The 2017 Dowell, *et al.* study reported that opioid-involved poisoning has decreased U.S. life expectancy by over two months from 2000-2015. Based on these data, all infants who are born in the United States in 2015 will live 800,000 fewer years of life. If the trend of opioid-related deaths continues for infants who were born in 2017, a decrease in U.S. life expectancy for three consecutive years will occur for the first time in the United States since the 1918 influenza pandemic.

Recent data show that six key factors have caused the U.S. opioid epidemic: (1) the designation of "pain" as the fifth vital sign; (2) an underappreciation of the addictive potential of prescription opioids; (3) aggressive marketing of prescription opioids to clinicians; (4) clinicians who operated "pill mills" and profited from overprescribing; (5) sophisticated actions of drug traffickers to open new heroin markets; and (6) the potency and ease of making, trafficking, and profiting from illicit fentanyl and its analogs.

Since 1999, over 350,000 people in the United States have died from overdoses from either prescription or illicit drugs. The opioid epidemic involves three waves that are overlapping and entangled, but distinct. First, prescription opioids (e.g., natural/semi-synthetic opioids and methadone) have caused overdose deaths in nearly 200,000 people since 1999. Second, illicit opioids (e.g., heroin) have resulted in a four-fold increase in the overdose death rate since 2010 and caused 15,000 deaths in 2016 alone. Third, other opioids (e.g., illicit fentanyl and synthetic opioids, excluding methadone) have resulted in a 6.5-fold increase in the overdose death rate since 2013 and caused nearly 20,000 deaths in 2016 alone.

DUIP published an *MMWR* article in March 2018, "Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants: United States 2015-2016." The article reported that in one year, cocaine-related mortality increased by 52 percent and psychostimulant-related mortality increased by 33 percent. Compared to 9,700 deaths related to cocaine or psychostimulants in 2014, these drugs caused nearly 18,000 deaths in 2016.

CDC's surveillance data showed variations across states in the trend of fatal drug overdoses from 2010-2016. A total of 47 states reported increases in their drug overdose mortality rate over this six-year time period. West Virginia had the highest absolute rate in both 2010 and 2016. The District of Columbia and New Hampshire had the largest absolute rate increases (over 25 deaths per 100,000 people). Connecticut, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, and Vermont moved up over 20 spots in the ranking of states for fatal drug overdoses.

DUIP published a CDC *VitalSigns*[™] report in the *MMWR* in March 2018 that showed increases in ED visits related to opioid overdoses in all regions and most states for both males and females in nearly all age groups. EDs in 52 areas across 45 states reported a 30 percent increase in opioid overdoses from July 2016 through September 2017. Over this same time period, EDs in the Midwestern region reported a 70 percent increase in opioid overdoses. Compared to EDs in rural areas, the 54 percent increase in opioid overdoses was much larger in EDs in urban areas/ large cities.

SAMHSA data showed that 11.8 million Americans (or 4.4 percent of the total U.S. population over 12 years of age) misused opioids in 2016: 11.5 million misusers of prescription opioids, 948,000 misusers of heroin, and 640,000 misusers of both prescription opioids and heroin. Of 2.1 million Americans who had opioid use disorder (OUD) in 2016, only 1 in 5 received specialty addiction treatment. Of this group, only 37 percent received MAT.

The 2017 Guy, *et al.* study reported that the amount of opioids prescribed increased three-fold (from 180 morphine milligram equivalents (MME) per person in 1999 to 640 MME per person in 2015) and varied six-fold across U.S. counties in 2015. However, these data represent a decline in the amount of opioids prescribed from the peak of 782 MME per person in 2010.

HIV, Viral Hepatitis, and STD Consequences of the Opioid Crisis

John Brooks, MD

Senior Medical Advisor, DHAP Centers for Disease Control and Prevention

Advice Requested from CHAC by CDC/NCHHSTP:

1. What are CHAC's recommendations on different actions that NCHHSTP should take to control the further resurgence of HIV and ongoing spread of HCV and HBV among PWID?

Dr. Brooks described DHAP's response to the opioid crisis in the context of HIV. The Peters, *et al.* study reported the HIV outbreak among PWID that occurred in Scott County, Indiana in 2015. A single strain of HIV rapidly spread within a dense network of PWID who were injecting OPANA® ER. The U.S. Food and Drug Administration (FDA) removed this prescription opioid from the U.S. market in 2017 due to its public health risk. As of April 1, 2018, 225 HIV infections

have been diagnosed in Scott County. Scott County is ranked 92nd in several health and social indicators among all 92 counties in the state of Indiana.

CDC and health departments across the country thoroughly analyzed epidemiologic data to identify HIV outbreaks among PWID in other jurisdictions. The 2016 van Handel study published the CDC analysis and included a map to illustrate the top 220 counties in the United States that are highly vulnerable to new HIV or viral hepatitis infections due to unsafe IDU. The study showed that the infectious disease risks are the same as the factors driving opioid overdoses in these vulnerable counties.

CDC used the 2016 van Handel study as an opportunity to encourage all states to perform local vulnerability assessments with their most complete and up-to-date datasets. For example, Kentucky's presentation of its vulnerability assessment to state and local policymakers played a role in leveraging funding and resources to significantly increase the number of SSPs in the state from 15 in 2016 to 54 in 2018. The 54 SSPs in Kentucky are located in counties that are most vulnerable to rapid HIV outbreaks among PWID.

The 2017 Rickles, *et al.* study reported that Tennessee's vulnerability assessment addressed local needs by including additional variables, such as opioid and heroin overdoses and MME prescribing based on Prescription Drug Monitoring Program data. Both the Kentucky and the Tennessee vulnerability assessments required public health officials to reach out to and build new partnerships with other entities that have an interest in protecting the safety of the populations in their respective states, such as pharmacy boards, public safety, law enforcement, and emergency medical services (EMS). A multidisciplinary, multisectoral partnership will be necessary for states to launch an emergency response to future IDU-related HIV outbreaks.

CDC encouraged states to perform evaluations with novel data sources that were not available in national data sets. The state-level public safety data included drug overdose deaths, particularly from opioids; calls to poison control centers for drug overdoses; administration of Naloxone; arrests for drug possession or sales; and other drug-related crimes. The state-level healthcare system data included treatment for drug overdoses, calls to EMS for drug overdoses, toxicology records from medical examiners, and bacterial infections related to IDU. The statelevel SUD service data included admissions to rehabilitation centers and the administration of MAT (e.g., methadone, buprenorphine, and naltrexone).

The 2018 Lyss abstract was presented at the 2018 CROI and showed that the number of IDUattributed HIV infections decreased from 3,428 in 2010 to 2,249 in 2016. New HIV diagnoses among PWID declined by 34 percent from 2010-2016, but these reductions were not uniform over time and have slowed or stalled. Analyses of these data by demographics show that the focus is placed on Whites (by race), people 13-34 years of age (by age), and outside large central metropolitan areas (by geographic location).

A change in the law in 2016 now permits the use of federal funds to support SSPs, but per federal law, local, county, or state health departments must first consult with CDC to demonstrate a need for SSPs and receive concurrence from CDC that a need exists. Dr. Brooks presented a map to show the jurisdictions where CDC has concurred with local health departments that a need for SSPs exists based on an increased occurrence or risk of viral hepatitis infections or HIV outbreaks reasonably attributable to non-sterile injection of drugs. As

of February 2018, CDC has concurred with 33 states/territories and 7 counties on their determination of need applications.

CDC's commitment to expanding the use of molecular surveillance includes its recent investment in molecular HIV surveillance and cluster/outbreak detection and response. The funding will strengthen state capacity to identify and respond to HIV transmission clusters that serve as a barrier to achieving the national goal of "no new infections." CDC and state/local health departments also will be able to better target resources and prevention activities to stop the further transmission of HIV.

The state recipients will be required to conduct several key activities. First, HIV molecular sequences will be collected and submitted to CDC. Second, analytic tools will be developed for use at national and state levels as well as in the field. Third, data on phylogenetic virus patterns, epidemiology, and recency testing will be linked.

CDC and its partners have developed and disseminated a variety of resources to assist the state recipients over the course of the project period. Planning, detection, and response documents are designed to provide information to a broad range of consumers, communities, and audiences, including surveillance staff and public health professionals. Plans, checklists, planning tools, exercises, and other project materials emphasize the importance of establishing strategic relationships. Extensive TA in cluster detection, prioritization, and response is being offered to health departments. Direct support to the state recipients include the development of rosters with staff responses and TA in the field to Kentucky, Massachusetts, Ohio, Texas, and West Virginia.

Eyasu Teshale, MD

Acting Branch Chief, DVH Epidemiology and Surveillance Branch Centers for Disease Control and Prevention

Dr. Teshale described DVH's response to the opioid crisis in the context of viral hepatitis. CDC received reports of nearly 3,000 acute HCV cases in 2016. Based on these reports, CDC estimated the actual number of acute HCV cases to be nearly 41,200. The number of reported acute HCV cases increased by 3.5-fold from 2010-2016.

By gender, both males and females accounted for the increase in acute HCV cases. By age, people in the 20-29 and 30-39 age groups accounted for the largest increases in the rate of acute HCV from 2010-2016. People in the 20-29 age group had the highest rate of acute HCV in 2016. In addition to an increased incidence of acute HCV in women of reproductive age, the number of infants who were born to women with HCV infections also increased. CDC estimated that 1,700 new HCV infections occurred in newborns in 2015.

By risk factor, 82 percent of people younger than 30 years of age with acute HCV in 2016 reported IDU. By geographic location, states with counties that were most vulnerable to HCV or HIV transmission accounted for the highest incidence of acute HCV. Rural areas of the country still have a disproportionate increase in the incidence of acute HCV, but the urban/rural gap is gradually narrowing.

CDC awarded funds to the University of New Mexico to conduct the "Hepatitis-Treatment and Integrated Prevention Services" (H-TIPS) Study in rural New Mexico over a two-year project

period from 2014-2016. The purpose of H-TIPS was for the recipients to develop and implement an integrated approach for the detection, prevention, care, and treatment of HCV infection among young, non-urban PWID. The key characteristics of 166 adults who participated in the study are summarized as follows. Overall, 58.2 percent were exposed to HCV, of which 68 percent have chronic HCV infection and 32 percent have cleared HCV infection.

The number of reported acute HBV cases declined from 2001-2013, but increased by 20.7 percent from 2014-2015. Moreover, HBV outbreaks due to IDU are continuing to occur. For example, Pasco County, Florida reported 275 acute HBV cases from 2011-2016. CDC currently is providing support to a health department that has identified 23 acute HBV cases among PWID since January 2017.

States voluntarily report their viral hepatis cases to CDC through the National Notifiable Diseases Surveillance System. Due to the recent increase in IDU, however, CDC awarded funds to 14 states in 2017 to strengthen surveillance of viral hepatitis based on the incidence of acute HBV or HCV. CDC also funded seven states to conduct non-traditional surveillance in venues where PWID receive services, such as correctional facilities and linkage to care and treatment centers. The CDC National HIV Behavioral Surveillance System (NHBS) currently collects data on behavioral risk factors for HIV from 22 metropolitan statistical areas (MSAs). CDC recently awarded funding to 10 MSAs to also conduct HCV testing and referral to prevention services, care, and treatment.

CDC, SAMHSA, and the Appalachian Regional Commission co-funded a CoAg, "HIV, HCV, and Related Comorbidities in Rural Communities Affected by Opioid Injection Drug Epidemics in the United States: Building Systems for Prevention, Treatment and Control." The recipients include eight project sites and a next-generation HCV laboratory. The two-stage, multi-method research project aims to achieve two major objectives. First, community responses to the epidemic will be informed through a policy and epidemiology review and mixed-method data collection to fill gaps. Second, community development, testing, and implementation of interventions will be facilitated to prevent and treat the consequences of opioid injection, including overdose, SUD, HIV, HBV, HCV, and other STDs.

CDC investigated HAV outbreaks in multiple states among PWID and homeless people. The consequences of the outbreaks included hospitalization and death. The protracted nature of the outbreaks was due to difficulties in reaching affected communities with prevention services. The CDC Global Hepatitis Outbreak and Surveillance Technology (GHOST) is a cloud-based system that allows users, regardless of their computational expertise, to analyze and visualize transmission clusters in an independent, accurate, and reproducible manner. The CDC Viral Hepatitis Laboratory trained 22 states in the use of GHOST in 2016 and piloted implementation of the system in eight states.

CDC has identified six major areas to target efforts and resources to reach the national 2020 goal of reducing the incidence of acute HCV to 0.25 cases per 100,000 people.

- Support public health surveillance to detect jurisdictions where HCV transmission is occurring
- Apply advanced molecular and computational information technology to strengthen laboratory capacity

- Provide HCV testing, care, and treatment for people with HCV infections
- Support the implementation of comprehensive community-level programs for PWID
- Conduct prevention research to improve the effectiveness of HCV prevention
- Build partnerships to promote prevention strategies in settings that are associated with increased HCV transmission

Panel Presentation: HRSA's Response to the Opioid Crisis

Antigone Dempsey, MEd

Director, HRSA HAB/Division of Policy and Data

Advice Requested from CHAC by HRSA:

- 1. What are CHAC's recommended strategies to engage stakeholders in consortiums that will apply for funding under the Rural Community Opioids Initiative?
- 2. What steps should HRSA programs take to apply best practices in integrating specialized services into primary care settings? Is further research needed in this regard?

Ms. Dempsey moderated a two-part panel presentation for a series of speakers to highlight HRSA's response to the opioid crisis. She introduced the panel of HRSA speakers.

Israil Ali, MPA

Director, Division of National Health Service Corps (NHSC) HRSA Bureau of Health Workforce (BHW)

Natalie Brevard Perry, MN, MPH, FNP-BC

Deputy Regional Administrator HRSA Office of Regional Operations (ORO) Atlanta Regional Office

Aaron Lopata, MD

Chief Medical Officer HRSA Maternal and Child Health Bureau (MCHB)

Kristin Martinsen, MPM

Director, Hospital State Division HRSA Federal Office of Rural Health Policy (FORHP)

CDR Antoine Smith, MPH

Deputy Director, Division of Nursing and Public Health (DNPH) HRSA BHW

Judith Steinberg, MD, MPH

Chief Medical Officer HRSA BPHC

For part 1 of the panel presentation, Ms. Dempsey asked the HRSA presenters to describe opioid-related issues that are affecting their individual programs, key stakeholders, and vulnerable populations. The overviews by the HRSA speakers for part 1 of the panel presentation are outlined below.

HRSA BPHC

Dr. Steinberg reported that the HRSA Health Center Program is on the front line of the epidemic by directly serving populations with high rates of opioid use. HRSA allocates funds to BPHC to support Health Centers in implementing the patient-centered medical home (PCMH) model as the foundation of the delivery of care. The PCMH model is based on the delivery of comprehensive care by a multidisciplinary team that focuses on the entire individual, including their medical, social, and behavioral health needs. The PCMH model particularly emphasizes

the integration of behavioral health, including mental health and SUD services, into primary care.

As of 2016, 70 percent of HRSA Health Centers are recognized as PCMHs by accrediting bodies. BPHC's annual data collection and analysis process has consistently shown that PCMH-recognized Health Centers have better performance in their quality measures than those without this recognition. Health Centers increasingly are including SUD services in the integrated PCMH model and utilizing a multidisciplinary team as an effective approach. However, Health Centers are continuing to address challenges related to recruiting and retaining staff and receiving reimbursement for the services of certain multidisciplinary team members.

In addition to supporting the implementation of the PCMH model, BPHC also is using its HRSA funds to support Health Centers in advancing the provision and integration of SUD services into primary care as well as HIV and HCV treatment and care. BPHC closely collaborates with HAB in this effort because over 50 percent of RWHAP clinics are HRSA Health Centers. The remaining Health Centers that do not receive RWHAP funding also are increasingly including HIV and HCV treatment and care in their services. During the week of May 14, 2018, for example, BPHC will host webinars to provide guidance and present models on the successful integration of HIV and HCV treatment and care in HRSA Health Centers.

In addition to awarding funding to health centers for mental health and SUD service expansion and quality improvement activities BPHC is supporting health centers as they address the opioid epidemic in their communities in the following ways:

- Training and TA are being provided for service expansion and quality improvement activities in Health Centers. Examples are the Opioid Addiction Treatment ECHO and substance abuse warmlines.
- Telehealth is being promoted as a modality to expand access to care in Health Centers. This effort includes additional one funding for telehealth services, technical assistance and training and review of existing policies that serve as barriers to the implementation of telehealth in Health Centers.
- Collaborations are underway with HRSA BHW colleagues to enhance the behavioral health workforce by assisting Health Centers in recruiting and retaining multidisciplinary team members. Most notably, BHW trainees are given opportunities to serve on Health Center multidisciplinary teams during their training.
- HRSA is establishing collaborations with federal partners to ensure that research agendas include studies that are relevant to the provision of primary care-based SUD services and to more fully engage Health Centers in the design and implementation of research.

HRSA FORHP

Ms. Martinsen reported that FORHP does not directly fund clinics, but a wide range of noncategorical grant opportunities are available to states and communities in rural areas of the country. Rural communities can identify their specific needs and apply for funding over a oneor three-year project period. Because non-categorical funding is more flexible than other grant mechanisms, FORHP has funded grant applications submitted by rural communities in the past to address SUD and HIV. FORHP funded a small grant program in 2015 that specifically focused on OUD. The recipients included 10 rural communities that demonstrated their capacity to collaborate with local partners to address OUD, such as law enforcement, healthcare providers, and other stakeholders. FORHP compiled the major findings from this initiative to develop a list of OUD best practices for other rural communities to potentially replicate, adopt, and implement.

FORHP also disseminated the list of OUD best practices to a broader group of rural stakeholders. For example, the administration of Naloxone was a key feature of the grant program. Communities and stakeholders were encouraged to obtain a clear understanding of "Good Samaritan" laws and other policies in their states regarding the use of Naloxone. Project ECHO was promoted as a model for rural communities with limited access to specialists and treatment options. The expansion of prescriptive authorities to allow physician assistants and nurse practitioners to prescribe buprenorphine has been extremely beneficial to rural communities.

FORHP's list of OUD best practices addressed the key advantages and disadvantages of rural communities. On the one hand, many interventions that have been effective in urban/large metropolitan areas cannot be successfully implemented in rural communities due to unique geographic factors, such as smaller populations, a limited number of specialists and providers, and a lack of available resources. On the other hand, the ability to establish new local partnerships is much easier in small rural communities than in large urban communities.

FORHP will release a NOFO by the end of May 2018 to announce the availability of \$100 million in new funding to support rural communities with high rates of OUD. FORHP's funding will target areas of need, including those from CDC's data on the top 220 counties in the United States that are most vulnerable to rapid dissemination of HCV or HIV outbreaks among PWID. FORHP will award up to \$200,000 per year to the recipients to implement OUD prevention, treatment, and recovery interventions in collaboration with at least three partners at the local or regional level.

FORHP's OUD NOFO will be open to all public and non-profit/for-profit private entities in the United States. Non-rural entities are eligible to apply, but all services that are supported by FORHP funding must be targeted to rural communities. FORHP will award the funds to support the first cycle of planning grants (year 1) and the second cycle of planning grants as well as implementation grants (year 2).

HRSA BHW/NHSC

Mr. Ali reported that as a part of HRSA/BHW, NHSC is dedicated to improving the education, training, and service of highly qualified providers. NHSC examines issues that impact the supply, demand, distribution, and preparation of the nation's health workforce to inform program planning and development in policy decision-making. NHSC, HRSA's Title VII programs for the health professional workforce, and HRSA's Title VIII programs for the nursing workforce award funding to increase the number of primary care providers who are committed to serving areas in the nation that have the highest need. At this time, over 10,000 NHSC clinicians serve nearly 11 million people in multiple service delivery areas, including the top 220 counties in the United States that are most vulnerable to rapid dissemination of HCV or HIV outbreaks among PWID.

NHSC was awarded new funding of \$105 million in FY2018 to include and expand access to quality OUD and SUD treatment in rural and underserved areas nationwide. The breakdown of

NHSC's new funding award includes \$30 million to support FORHP's new rural community opioid response and \$75 million to expand the national opioid response in collaboration with partners.

NHSC previously only funded sites that provided comprehensive primary care, but the new funding will allow services to be expanded to include opioid-related care and treatment. At this time, over 33 percent of NHSC providers focus on mental and behavioral health care, but the new funding also will support new substance abuse counselor positions. NHSC will initiate a thorough review of its programs to identify existing evidence-based models and ensure funding awards are well aligned with the sites that have the greatest need.

HRSA BHW/DNPH

CDR Smith reported that within HRSA BHW, DNPH administers Title VII programs for health professions education and Title VIII programs for nursing development. Both programs received increased funding to specifically address the opioid epidemic. DNPH will use this funding to expand and enhance the mental health and substance abuse workforce for multiple disciplines that are under the purview of HRSA's Title VII and Title VIII programs: social workers, counselors, psychiatrists, psychologists, marriage and family therapists, occupational therapists, psychology doctoral interns, behavioral health professionals, and advanced-level nurses (e.g., psychiatric nurse practitioners).

DNPH's allocations of its new opioid-related funding to support Title VII programs and activities for health professions education are highlighted below.

- The Title VII Graduate Psychology Education Program (GPEP) is designed to achieve two major objectives. First, doctoral-level psychologists are prepared to deliver mental health and behavioral health services, including substance abuse prevention and treatment services, in settings that provide integrated primary care and behavioral health services to underserved and/or rural populations. Second, behavioral health and primary care are integrated into clinical practice. The GPEP recipients will use their new opioid-related funding awards from DNPH to develop OUD curricula and provide innovative leadership for all disciplines.
- The Title VII Behavioral Health Workforce Education and Training (BHWET) Program is designed to achieve four major objectives. First, behavioral health internships and field placement programs are expanded. Second, interdisciplinary training is offered to students and interns, faculty, and field supervisors to provide quality behavioral health services to communities in need. Third, efforts are made to increase the number of professionals and para-professionals who are trained to deliver behavioral health and primary care services through integrated professional teams, particularly in HRSAsupported Health Centers. Fourth, the existing behavioral health workforce is expanded to serve people throughout their lifespans in rural and medically underserved areas. The BHWET recipients will use their new opioid-related funding awards from DNPH to target initiatives that focus on MAT and SUD.
- All Title VII programs will expand the OUD workforce by providing support to professionals and para-professionals. This effort will include training to behavioral health students, interns, and post-doctoral residents to deliver integrated and interdisciplinary services in areas with the greatest need and/or demand. DNPH will use its new opioid-related funding for professional trainees to specifically focus on substance use prevention and treatment services, including OUD. Community-based experiential

training on OUD will be enhanced for students who are preparing to become behavioral health para-professionals. DNPH also will use its new opioid-related funding to target OUD experiential training to community-based trainees, including CHWs, counselors, addiction specialists, and other relevant para-professionals.

- Rigorous surveillance and evaluation activities will be conducted in all Title VII programs to achieve the following outcomes:
 - Contribute to and strengthen the existing evidence-based literature on effective OUD prevention strategies, interventions, treatment, research and development of curricula, and training (e.g., train-the-trainer models);
 - o Identify innovative, state-of-the-art technologies to support OUD treatment;
 - Disseminate products, results, and best practices to HRSA's internal and external stakeholders; and
 - Assure accountability and measure the impact of DNPH's opioid-related activities.

DNPH's allocations of its new opioid-related funding to support Title VIII programs and activities for nursing development are highlighted below.

- Innovative academic practice partnerships will be supported to prepare advanced-level primary care nursing students to practice in rural and underserved areas.
- Trainee curricula will be developed and expanded to address key health issues, including the national opioid epidemic.
- The number of advanced-level nurses who are trained to care for opioid-affected populations will be increased.
- Support will be targeted to nursing institutions and organizations that focus on mental health and SUD treatment, proper pain management with appropriate prescribing of opioids, health outcome values, and utilization of telehealth/telemedicine models.
- Support will be targeted to nurse anesthetist trainee programs to ensure alignment with the HHS clinical priority of providing training and education to professionals related to pain management, opioid abuse, and treatment.

HRSA MCHB

Dr. Lopata reported that the mission of MCHB is to improve the overall health, treatment and care, and health outcomes of women, children, and their families. MCHB recipients are funded to develop and implement programs to assist communities in building systems of care, particularly linkage to and retention in care initiatives for pregnant women and children.

MCHB is addressing opioid use in terms of the impact of the epidemic on pregnant women and their newborns. For example, MCHB data showed a nearly five-fold increase in maternal antepartum opioid use from 2000-2009. MCHB data also showed that the rising prevalence in opioid use among pregnant women has led to a sharp increase in neonatal abstinence syndrome (NAS) of nearly 300 percent from 1999-2013. To respond to the national opioid crisis, MCHB is allocating funds to its recipients to support underserved populations and communities that are at higher risk for OUD.

• The MCHB Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program plays a significant role in the community-based system. Most notably, pregnant women are screened for risk factors and comorbidities (e.g., OUD, HIV, and HCV) and are linked to prenatal care. The ability of the MIECHV Program to provide case

management and linkage to critical care services in the homes of pregnant women has been extremely important in improving health outcomes in this population. MCHB funds recipients in all 50 states, 25 tribal entities, and five territories to implement the MIECHV Program. MCHB hopes to collaborate with federal partners to expand the funding and reach of the MIECHV Program in additional communities.

- The MCHB Healthy Tomorrows Partnership for Children's Program (HTPCP) supports innovative community-based projects to improve access to care, particularly in vulnerable and underserved populations. Of all 40 HTPCP recipients, six currently are conducting developmental screening and assessments of substance abuse-exposed children with or without a history of NAS. At the community level, an HTPCP recipient in Tennessee partnered with a local substance abuse treatment center to pilot support groups for mothers and infants with NAS and/or drug exposure. The collaboration in Tennessee resulted in the partners initiating treatment for mothers and providing critical support while their infants were in newborn intensive care units.
- The MCHB Alliance for Innovation on Maternal Health (AIM) was launched in 2014 as a four-year CoAg with a diverse group of partners, including federal and state public health agencies, consumer groups, and other stakeholders. AIM established these relationships to assist state-based teams in implementing evidence-based maternal safety bundles, including a patient safety bundle for the obstetric care of women with OUD. The patient safety bundles have been found to be extremely effective in improving the safety and health outcomes of pregnant women with OUD.

HRSA ORO

Ms. Brevard Perry reported that ORO represents HRSA in all 10 HHS regions of the country. The primary role of ORO is to provide regional leadership, contribute expertise, and serve as a resource for building external cross-sector partnerships, including CDC and CHAC. ORO also serves as an internal liaison to all HRSA bureaus and offices. HRSA Regional Offices are available to assist federal, state, and local partners in developing strategies to address the opioid crisis and/or creating plans to respond to an outbreak.

Examples of activities that are underway in the HRSA Regional Offices to respond to the opioid crisis are highlighted below.

- At the federal level, all 10 HRSA Regional Offices serve on a Federal Opioid Task Force or Council that is led by the HRSA Regional Director or Regional Health Administrator.
- At the regional level, the HRSA Regional Office in Philadelphia (Region III) established the Mid-Atlantic Training Collaboration with 55 training sites to refocus and align their existing curricula, decrease duplication, and maximize their region-wide approach to the opioid crisis. Region III will be a recipient of an HHS Honor Award in May 2018 to recognize its success in convening the 55 training sites.
- The HRSA Regional Office in New York City (Region II) formed the Interagency Federal Partners Council that has been replicated in other regions throughout the country. Region II also established a Health Collaborative with 20 CBOs to assist communities in developing opioid-related preparedness plans.

For part 2 of the panel presentation, Ms. Dempsey asked the HRSA speakers to describe effective interventions that their programs are implementing at this time to respond to the opioid crisis. The overviews by the HRSA speakers for part 2 of the panel presentation are outlined below.

HRSA BPHC

Dr. Steinberg reported that HRSA has awarded funds over the past two years to expand mental health and SUD services, including medication assisted treatment, in HRSA Health Centers. The funding greatly enhanced the capacity of Health Centers to provide integrated mental health and SUD services.

The Health Centers used their service expansion funds in FY2016 and FY2017 to launch innovative programs, interventions, and other activities to respond to the opioid crisis. Several examples of these initiatives are highlighted below.

- Health Centers throughout the country are implementing various models of care in their communities to respond to the opioid crisis. A special edition of the HRSA Health Center Program's weekly newsletter, <u>Primary Health Care Digest</u>, featured 10 of these promising practices. The newsletter was released on April 11, 2018 to specifically focus on the opioid epidemic.
- The Massachusetts Nurse Care Manager Model is based on a multidisciplinary team approach that includes a nurse care manager who helps coordinate the complex care needs of patients who receive medication assisted treatment. Providers who have the DATA 2000 waiver to prescribe buprenorphine are more apt to prescribe when they are supported by a multidisciplinary team.
- The PCC Community Wellness Center in Illinois has fully integrated a team approach that includes a behavioral health clinician, primary care physicians, and a psychiatric nurse practitioner who is either onsite or available via telemedicine. This Health Center also implemented a chemical dependency clinic that serves as a hub for the assessment of patients for SUD services and the provision of intensive behavioral health services. The clinic initiates MAT for patients, stabilizes patients, and maintains patients on MAT.
- Community Care of West Virginia launched a centralized, onsite pain management clinic due to prescriptions of high-dose opioids to treat chronic pain in the community. The multidisciplinary clinic includes behavioral health services.
- The Opioid Addiction Treatment ECHO was established to transfer knowledge from specialists to primary care physicians to provide patients with expanded access to expert treatment and care. The OAT ECHO includes virtual didactic training and provider to provider case consultations. At this time, 150 Health Centers are participating in the ECHO Project.
- "Substance abuse warm lines" are now available for providers to contact an expert at nearly the point of care to obtain guidance on dosing, management of drug withdrawal, and other issues related to opioid treatment and care.

Dr. Steinberg confirmed that HRSA will continue to support the Health Centers in their efforts to further expand the integration of mental health and substance abuse services. Most notably, the enactment of the Bipartisan Budget Act of 2018 will allow HRSA to allocate ongoing and one-time funding to the Health Centers for the implementation of evidence-based quality improvement models and service expansion.

Dr. Steinberg concluded her remarks by announcing the rollout of <u>HRSA's new opioid webpage</u>. The webpage includes detailed information on opioid-related TA and resources that are available to recipients.

HRSA ORO

Ms. Brevard Perry reported that the clinical field strength of the HRSA Regional Offices can be leveraged to increase awareness of the national opioid crisis among providers and the general public. Regional offices also facilitate cross-sector collaboration to develop region-specific strategies to address the crisis. Most notably, nearly 40 percent of ORO staff in the 10 HHS regions are clinical providers. Professions include physicians, nurses, psychologists, licensed clinical social workers, marriage/family counselors, a pharmacist and a physical therapist.

Ms. Brevard Perry conveyed that the National Viral Hepatitis Action Plan identified low awareness of viral hepatitis among providers and the general public as a major barrier to reversing the trend of increased cases. The significant role of the HRSA Regional Offices in increasing national awareness of viral hepatitis can now be applied to address the national opioid crisis.

Ms. Brevard Perry encouraged the federal, state, and local partners to visit the <u>ORO website</u> as the first step in establishing a strong relationship with the HRSA Regional Offices.

SAMHSA's Role in the HIV Continuum of Care

Gerlinda Somerville, MPH

Health Systems Branch Chief, Center for Substance Abuse Treatment Substance Abuse and Mental Health Services Administration

Advice Requested from CHAC by HHS/SAMHSA:

- 1. What actions should be taken to enhance bi-directional collaboration among the recipients of different HHS agencies, e.g.:
 - Improve client recruitment and retention?
 - Provide access to HIV and hepatitis primary care and behavioral health services?
 - > Establish partnerships to support the co-location and integration of services?
- 2. What collaborative efforts should be launched in the training units of HHS agencies to strengthen bi-directional learning between recipients and project officers, e.g.:
 - Enhance knowledge of HIV, viral hepatitis, SUD, OUD, co-occurring disorders, and mental health?
 - Convene joint recipient meetings across agencies?
- 3. What steps should be taken to increase data sharing among the HHS agencies?

Ms. Somerville presented an overview of SAMHSA's role in the HIV care continuum. SAMHSA is one of 11 of HHS's operating divisions. The mission of SAMHSA is "to reduce the impact of substance abuse and mental illness on America's communities." The enactment of the 21st Century Cures Act in December 2016 elevated SAMHSA's leadership to the level of the HHS Assistant Secretary.

SAMHSA's organizational structure is highlighted as follows. The National Mental Health and Substance Use Policy Laboratory plays a key role in reshaping SAMHSA's efforts to incorporate more science into evidence-based practices through the use of prevention, treatment, and support services that are offered by behavioral health practitioners and clinicians. The laboratory includes a new model that provides funding to recipients to secure TA from external sources. Funding also is being allocated to the SAMHSA centers at this time to establish their individual Addiction Technology Transfer Centers (ATTCs). A SAMHSA Regional Administrator

is housed in each of the 10 HHS regions to collaborate with federal, state, and local partners in the field.

SAMHSA's impact on the HIV care continuum is described as follows. All SAMHSA recipients who are SUD treatment providers are required to perform HIV testing and rigorous case management, including linkage to care services. Clients who are engaged in SUD care are more likely to be on ART. SAMHSA's HIV activities are aligned with the goals of the National HIV/AIDS Strategy (NHAS).

- For NHAS Goal 1, "reduce new HIV infections," SAMHSA is focusing on reducing HIV risk behaviors among young gay and bisexual males.
- For NHAS Goal 2, "improve health outcomes for PLWH," SAMHSA is focusing on reducing homelessness.
- For NHAS Goal 3, "reduce HIV-related disparities," SAMHSA is focusing on gay/bisexual men, young Black gay/bisexual men, transgender individuals, women, and people living in the South.

SAMHSA conducts and/or co-funds several external HIV initiatives in close collaboration with its HHS partners, including OHAIDP, HRSA, CDC, and NIH. SAMHSA's internal HIV initiatives are conducted by multiple centers across the agency. For example, CSAT administers the Substance Abuse Block Grant that includes an HIV set-aside for states and jurisdictions with a rate of 10 or more HIV cases per 100,000 people. These "designated" states are required to obligate and spend 2 to 5 percent of their block grant funds on early HIV intervention services.

CSAT administers three "Targeted Capacity Expansion: Substance Use Disorder Treatment for Racial/Ethnic Minority Populations at High-Risk for HIV/AIDS" (TCE-HIV) programs. Ms. Somerville presented a map to illustrate the overlap between the TCE-HIV recipients and the HIV burden in FY2018. SAMHSA hopes that the TCE-HIV programs can serve as linkage to care sites for RWHAP clients who need SUD treatment.

CSAT launched the TCE-HIV program for high-risk populations in FY2015. The 24 recipients were awarded \$500,000 on average. CSAT launched the TCE-HIV program for racial/ethnic minority women in FY2016. The 26 recipients were awarded \$500,000 on average. CSAT launched the TCE-HIV program for young BMSM and other high-risk populations in FY2016, but this program also addressed hepatitis infection. The 59 recipients were awarded \$500,000 on average. The NOFO language for all three TCE-HIV programs allows the recipients to use up to 5 percent of their annual funding awards to pay for FDA-approved medications for the treatment of SUD and make referrals to MAT providers.

CSAT established internal collaborations with other SAMHSA centers and formed an external partnership with CDC to implement the TCE-HIV programs. The Minority AIDS Initiative (MAI) Continuum of Care pilot was launched to integrate HIV prevention and medical care into mental health and substance abuse treatment programs for TCE-HIV racial/ethnic minority populations. The Secretary's Minority AIDS Initiative Fund (SMAIF) is being used to achieve specific project outcomes, such as establishing new or enhancing existing linkages to SSPs; introducing testing and referral to treatment for viral hepatitis into CSAT's opioid treatment programs; and using peer navigators to provide opioid prevention education.

The "Targeted Expansion: MAT-Prescription Drug and Opioid Addiction" project is being implemented to expand and enhance access to MAT services for people with OUD. The funding was awarded to states with the highest rates per capita of primary treatment admissions for heroin and opioid misuse. Priority was given to states with the most dramatic increases in heroin and opioid misuse based on data reported to the SAMHSA Treatment Episode Data Set (TEDS). The funding was awarded over three fiscal years: \$1 million to each of the 11 states in the FY2015 cohort; \$1 million to each of the 11 states in the FY2016 cohort; and \$2 million to each of the six states in the FY2017 cohort. The FY2018 NOFO for this project is currently undergoing the SAMHSA clearance process.

"State Targeted Response (STR) to the Opioid Crisis" grants were awarded to address the opioid crisis by increasing access to treatment, reducing unmet treatment needs, and decreasing opioid overdose-related deaths. A funding formula was used to award the STR grants to 59 states and territories based on their unmet needs for OUD treatment and drug poisoning deaths. However, the funding formula did not fully respond to the opioid crisis in three states. As a result, these states were awarded one-year supplemental funding of \$333,333. The recipients are using their STR grants to conduct prevention, treatment, and recovery activities for OUD. A total of \$1 billion was awarded to the recipients in FY2017 and FY2018.

SAMHSA collected data by gender, race, age, and ethnicity to determine the demographics of 16,524 clients who were enrolled in TCE-HIV programs from FY2013-FY2017. The largest proportions of clients who received TCE-HIV program services over this time period were males (57 percent), African Americans (51.5 percent), people in the 25-34 age group (31.7 percent), and non-Hispanics (70.3 percent). At intake, the coverage rates of TCE-HIV programs in FY2013 and FY2017 were the same at approximately 94 percent. However, declines at intake were observed in FY2014-FY2016. At the six-month follow-up, the coverage rates of TCE-HIV programs slightly declined from 66.5 percent in FY2013 to 63.6 percent in FY2017. However, increases were observed in FY2015-FY2016.

Ms. Somerville presented a series of tables to illustrate the monthly consolidated evaluation reports that SAMHSA produces on the TCE-HIV programs. These reports reflect data that SAMHSA collects from all of the TCE-HIV program recipients on HIV positivity, linkages to HIV medical care, viral hepatitis testing, the status of viral hepatitis cases and the provision of services, and viral hepatitis vaccination.

SAMHSA's HIV/SUD programs are designed to expand SUD treatment, behavioral health services, and viral hepatitis services for high-risk populations in U.S. counties with the highest HIV prevalence rates. SAMHSA has identified four key outcomes for its HIV/SUD programs: (1) reduce the risk of HIV; (2) reduce new HIV and viral hepatitis infections by increasing HIV and viral hepatitis testing and diagnosis; (3) increase the provision of linkage to HIV care, including ART; and (4) provide information on PrEP and postexposure prophylaxis (PEP) through HIV.gov resources, webinars, and peer-to-peer interactions.

SAMHSA targets its HIV/SUD programs to African American, Latino, and other racial/ethnic minority men and women to ensure their access to and receipt of appropriate behavioral health services. SAMHSA recipients conduct the following activities to comply with the HIV/SUD program requirements.

- For "HIV testing and case management," SAMHSA recipients perform preliminary HIV rapid antibody testing at the client's enrollment, including rapid fourth-generation HIV diagnostic testing. Linkages are made to confirmatory HIV testing and follow-up is performed on the client's HIV status. A case management plan is developed that includes a comprehensive assessment of the client's needs. An individualized service plan also is created within 30 days for clients who have positive preliminary and confirmatory HIV test results. The service plan includes referrals, linkages to follow-up care and treatment, and the identification of stable housing.
- For "behavioral health outcomes and treatment/recovery services for SUD and cooccurring disorders," SAMHSA recipients reduce the negative impact of behavioral health problems. Access to and retention in treatment for behavioral health conditions are increased. HIV test kits and counseling sessions that are purchased with SAMHSA funds, data on rapid HIV and confirmatory test results, and risk behaviors are reported to the Rapid Testing Data Collection System. National outcome measures are reported, including employment/education, stability in housing, involvement with the criminal justice system, social connectedness, and abstinence from drugs/alcohol at the sixmonth follow-up. HIV core indicators, such as HIV/hepatitis positivity and housing, also are reported.
- For "viral hepatitis testing and referral to treatment," SAMHSA recipients perform HBV and HCV testing for all clients at risk. The recipients also use 5 percent of their funding awards for HBV/HCV antibody and confirmatory testing, HAV/HBV vaccination, testing kits and supplies, and staff training on viral hepatitis testing.

Ms. Somerville presented a series of maps with data from the National Survey of Substance Abuse Treatment Services to illustrate the number of facilities that screen for TB, STDs, HCV, and HIV. She also highlighted the success stories of two SAMHSA recipients.

- "Village Virgin Islands Partners in Recovery: Susanna's Place" uses its TCE-HIV funding to provide a safe and secure refuge for women in the U.S. Virgin Islands. For example, this organization completely changed the life and future of a woman with an HIV/SUD comorbidity who previously was homeless, victimized, and traumatized. A care navigator played a pivotal role in guiding the client to HIV/SUD care and treatment services, counseling, public housing, employment training, and other important wraparound services.
- "Volunteers of America of Los Angeles" uses its MAI funding to integrate HIV prevention, substance use, and mental disorder services into permanent health care. These activities are particularly targeted to PLWH who are at high risk of behavioral disorders. The target populations include racial/ethnic minorities, ex-offenders, homeless people, and people who are lesbian, gay, bisexual, transgender, or questioning (LGBTQ). For example, this organization obtained a Section 8 voucher to provide permanent housing to a senior who is living with HIV, had been homeless for the past 12 years, and is in recovery for alcohol and behavioral disorders.

SAMHSA is continuing to address several major challenges in its HIV care continuum programs. Most notably, recruitment and retention efforts are lacking for both SAMHSA recipients and program clients. For example, workforce development activities need improvement to specifically leverage expertise in behavioral health and SUD/co-occurring disorders. SAMHSA intends to partner with HRSA to specifically address this issue. A large proportion of clients who are enrolled in SUD treatment services are not retained at the six-month follow-up. Moreover, cultural competency has not been fully integrated into services for racial/ethnic minority populations and the LGBTQ community. Several SAMHSA recipients are not achieving two critical performance measures: (1) the integration of primary care and behavioral health services and (2) the collection and analysis of data to assess the effectiveness of their programs.

Ms. Somerville concluded her presentation by presenting a list of resources for SAMHSA's TCE-HIV programs that will be helpful to diverse audiences, including clinicians, the general public, and families of people living with OUD.

- Grant announcements and awards
- <u>Recovery-oriented care and recovery support systems for people with mental disorders</u> <u>and/or SUD</u>
- <u>Rapid Testing Data Collection System</u>
- <u>SAMHSA's TIP 63: Medications for Opioid Use Disorder</u>
- Surgeon General's Report on Alcohol, Drugs, and Health
- Opioid-related training materials from SAMHSA ATTCs
- "Reduce Your Risk: Substance Use/Abuse from HIV.gov"
- "Taking Care of Yourself: Mental Health from HIV.gov"

CHAC DISCUSSION: FEDERAL RESPONSE TO THE OPIOID CRISIS

The CDC, HRSA, and SAMHSA speakers provided additional details on the following topics in response to specific questions by the CHAC members.

- Efforts by CDC/DUIP to collect data to identify a correlation between the ability of jurisdictions to reduce prescription opioid rates and successfully decrease the number of opioid overdoses.
- Efforts by SAMHSA to collect data on the proportion of clients who are being screened for HIV and viral hepatitis and linked to care among all clients who are enrolled in SAMHSA-funded programs.
- Efforts by CDC to collect robust surveillance data to document the linkage between opioid use and other STDs, particularly syphilis and gonorrhea.
- The proportion of HRSA-funded Health Centers that are providing SUD and mental health services in primary care settings in the top 220 counties with the greatest vulnerability to HIV or HCV outbreaks among PWID.

CHAC GUIDANCE

CHAC applauded CDC, HRSA, and SAMHSA for launching a vigorous federal response to the national opioid crisis. Several CHAC members noted that the federal agencies are investing a significant level of funding and other resources; providing outstanding support to their recipients to implement innovative and integrated projects nationwide; and leverage the expertise and capacity of key partners. The CHAC members provided extensive input on the federal response to the opioid crisis.

• Dr. Taylor provided feedback in response to the two questions posed by CDC/DUIP.

- Question 1: How can individuals who have experienced an opioid overdose be connected with HIV and viral hepatitis programs in addition to substance use treatment? The federal agencies should offer incentives to HIV and viral hepatitis providers who prescribe buprenorphine in communities. An "RWHAPlike" metric should be developed to quantify and validate the care that HIV and viral hepatitis clinicians provide to patients who are on MAT.
- Question 2: What are some HIV/viral hepatitis linkage to care models that would also be effective in the SUD space? Most jurisdictions in the country have no funding to apply existing linkage to care models to OUD/SUD treatment settings. Most notably, RWHAP provides linkages to care for HIV, but pharmaceutical funding is the only mechanism to support linkages to care for viral hepatitis. The recipients of the federal agencies are implementing innovative models to deliver co-located, integrated care at a physical location or through virtual telehealth technology. The federal agencies should scale-up and allocate funding to support the implementation of the most successful telehealth models. The broad dissemination and funding of telehealth best practices will be particularly helpful to jurisdictions that have no access to Project ECHO.
- Dr. Saag and other CHAC members provided their perspectives on the role of the federal agencies in the opioid crisis.
 - Methadone treatment historically has been restricted to certain clinical sites and medical licenses. For example, opioid prescribers can only write methadone prescriptions for pain. The federal agencies should reexamine these restrictions to remove as many barriers as possible to the expansion of addiction treatment services in the ongoing opioid crisis.
 - Federal agency recipients, CBOs, and other groups have demonstrated tremendous compassion, dedication, and commitment to address the opioid crisis in communities across the country. However, the significant level of federal investments will not be sufficient to combat the opioid crisis. Most notably, a trained and experienced workforce is not available in Federally Qualified Health Centers (FQHCs) or in other settings to launch an adequate response to this daunting national crisis.
 - The existing primary care model will not be effective in implementing an integrated system of care for patients with complex co-morbidities, including SUD/OUD, trauma, mental health problems, infectious diseases, and homelessness. To date, federal funding for contingency management has been limited to research projects and a small number of grant opportunities. However, contingency management is the most widely used approach in SUD treatment and is often included in clinical behavior analysis. The federal agencies should explore strategies and leverage funding to increase the integration of contingency management into MAT services.
- Dr. Mera raised the possibility of training MAT providers at SAMHSA-funded sites to deliver HCV treatment to patients who also require opioid substitution therapy (OST) and/ or psychiatric care. This integrated approach will close gaps in the HCV cascade from diagnosis to cure and also will decrease the number of patients who are lost to care. He urged SAMHSA to launch a pilot project to determine the feasibility and effectiveness of this model.

- Ms. Fukuda asked CDC and HRSA to require their recipients to establish new partnerships with SAMHSA recipients and use different approaches to improve the engagement of and outreach to PWID. Recipients of CDC-funded HIV, viral hepatitis, and STD prevention programs and HRSA-funded RWHAP sites should be included in this effort. For example, a recipient with a dual funding award could be required to target a percentage of its CDC prevention grant to PWID and allocate a percentage of its STR grant to conduct screening and collect SUD data from SAMHSA-funded sites. Most notably, Massachusetts used its STR grant from SAMHSA to support overdose education and Naloxone distribution.
- Dr. Taylor expressed her full support of Ms. Fukuda's comments. She was in favor of integrating HIV care into methadone clinics and substance abuse treatment centers. She conveyed that Rhode Island implemented an integrated model by allocating a small portion of its RWHAP funding to a methadone clinic.
- Dr. Havens emphasized the need for CHAC to formally recommend an expansion of the current CDC/HRSA partnership to include other HHS agencies to address the opioid crisis. SAMHSA-funded substance abuse/mental health programs will be a critical partner, but the Indian Health Service (IHS) and HRSA-funded FQHCs also will play an important role in addressing the opioid crisis in primary care settings in rural areas.
- Dr. Stoner provided several remarks in follow-up to the comments by Dr. Havens. He
 pointed out that CDC, HRSA, and SAMHSA already have established an interagency
 partnership in terms of training. Most notably, the three federal agencies convened joint
 conferences for recipients of the CDC-funded National Network of STD/HIV Prevention
 Training Centers, HRSA-funded AETCs, and SAMHSA-funded ATTCs to network and
 share training materials. He raised the possibility of the three federal partners replicating
 the integrated training model for integrated service delivery.

CDC, HRSA, and SAMHSA thanked the CHAC members for their thoughtful comments and insightful guidance on potential strategies to address the opioid crisis at the federal level. The federal agencies made several remarks in follow-up to CHAC's rich discussion.

- SAMHSA and HRSA responded to the comments by the CHAC members regarding integrated care and treatment models.
 - Dr. Daviss explained that Dr. Mera's proposed approach likely will be more successful if primary care providers at SAMHSA-funded sites rather than MAT providers are trained to deliver HCV treatment to OUD patients.
 - Dr. Steinberg conveyed that another potential model to consider is the integration of primary care into behavioral health clinics, including access to HIV and HCV treatment.
 - Dr. Cheever also saw the benefits of patients receiving integrated care and treatment services at one site, but she emphasized the need to address complex system-level issues. Most notably, efforts have been made in the past to integrate primary care into methadone programs. However, people who violated the program rules and regulations were not allowed to remain in the program. In these cases, the integrated program resulted in a dual disruption of the client's primary care and MAT services.

- Dr. Mermin described a potential option that might be simpler to implement than a fully integrated care and treatment program. SAMHSA should systematically collect individual-level data from its recipients and share these datasets with its federal partners to ensure the delivery of prevention, care, and treatment services. For example, blood and urine samples that are routinely collected by providers at SAMHSA-funded sites can be easily tested for HIV, HCV, and STDs. Moreover, the following data element from SAMHSA would be extremely helpful to CDC: Of "[number]" people who received SUD treatment in the past year, "[number]" were screened and "[number]" were positive for HIV, HCV, or STDs. Dr. Mermin confirmed that CDC welcomes the opportunity to closely collaborate with SAMHSA to develop and implement a new interagency datasharing agreement.
- Dr. Daviss responded to Dr. Mermin's specific comments and highlighted SAMHSA's overall efforts to improve its opioid-related data collection activities.
 - SAMHSA collects individual-level data on multiple variables through TEDS, but the data elements that Dr. Mermin proposed are not included in the system at this time. However, Dr. Daviss made a commitment to serve as a strong champion at SAMHSA to expand TEDS to include new screening data elements for HIV, HCV, and STDs. He also planned to contact Dr. Mermin after the meeting to initiate discussions on establishing a new CDC/SAMHSA interagency data-sharing agreement.
 - SAMHSA currently is revising the language in its NOFOs to provide recipients with clearer, more explicit guidance on "required" versus "optional" data elements to collect from their programs.
 - Dr. Elinore McCance-Katz, the SAMHSA Assistant Secretary, has expressed a strong interest in collecting patient-generated data directly from patients. To support this effort, SAMHSA is exploring the development of a new Smartphone application for patients to easily submit medical information, such as their HIV viral load levels.
- HRSA, CDC, and SAMHSA provided clarifying remarks in response to Ms. Fukuda's comments regarding integrated funding to address the opioid crisis.
 - Dr. Cheever explained that a federal agency (e.g., HRSA) has no authority or control over the allocation of funding awarded to its recipients from another federal agency (e.g., SAMHSA). However, the federal agencies can serve as a high-level external convener to strengthen collaborations and establish strategic partnerships between their recipients and federal partners.
 - Dr. Mermin agreed that opportunities are available for recipients with funding awards from multiple federal agencies to address a variety of opioid-related issues. For example, CDC and HRSA jointly awarded funding to their recipients to develop and implement "Jurisdictional HIV Prevention Plans," but SAMHSA is not involved in this initiative at this time. However, CDC and HRSA can encourage their joint recipients to devote a portion of their funding awards to address substance abuse and mental health issues in their jurisdictional HIV prevention plans.
 - Dr. Daviss clarified that STR grants are one-time funding awards to states rather than multi-year CoAgs. As a result, states are not likely to use their STR grants to build programs that must be supported by their individual resources in the future. CHAC's recommendations on different approaches for recipients to use

their federal funding awards to address the opioid crisis should focus on ongoing "RWHAP-like" funding rather than one-time STR grants.

- Dr. Cheever returned to the comments by Dr. Havens regarding CHAC's formal support of an expansion of the current CDC/HRSA partnership to address the opioid crisis. She pointed out that prior to the opioid crisis, CDC and HRSA agreed to leverage every possible opportunity to integrate their prevention, care, and treatment programs. To improve the federal response to the ongoing opioid crisis, she conveyed that CHAC can submit a formal recommendation to CDC and HRSA to include SAMHSA in their integrated programs during the development of new NOFOs.
- Ms. Dempsey informed CHAC that HHS and HRSA have formed opioid workgroups at the department and agency levels, respectively. She encouraged CHAC to consider these groups while drafting its formal recommendations to the federal agencies. Ms. Kaye Hayes is the CHAC *ex-officio* member for HHS/OHAIDP. She added that ADM Brett Giroir, the Assistant Secretary for Health, leads the HHS opioid response and is the appropriate point of contact for the HHS opioid workgroup.
- Dr. Daviss announced that HHS is developing new opioid metrics for the individual agencies to monitor positive changes and identify areas for improvement. Several metrics address HCV, but none mention linkage to care.

Panel Presentation: Syringe Services Programs Perspectives and Experiences

Alice Asher, PhD, RN

Division of Viral Hepatitis Centers for Disease Control and Prevention

Advice Requested from CHAC by CDC/DVH:

- 1. Does CHAC require additional information on the effectiveness of SSPs? What should be the next area of focus for the science?
- 2. What steps can be taken to advance the dialogue on the science supporting the value of SSPs that was developed in the 1990s?
- 3. What actions should the North Carolina Harm Reduction Coalition (NCHRC) take to share its experiences with other states in changing North Carolina legislation to support SSPs?
- 4. What actions can NCHRC take to improve its service delivery, particularly screening and referral to care in rural areas?
- 5. What actions can the Atlanta Harm Reduction Coalition (AHRC) take to deliver much needed services in its environment?
- 6. What support can the federal government provide to AHRC?
- 7. What steps can be taken to share the San Francisco Street Medicine Program (SFSMP) model with other organizations?

Dr. Asher moderated a panel presentation for a series of guest speakers to describe their perspectives on and experiences with SSPs in the field. Before introducing the panel, however, she presented an overview of SSPs.

Overview of Syringe Services Programs Science and Practice

Dr. Asher defined "SSPs" as community-based programs that provide a key pathway to multiple services:

- Drug use, viral hepatis, and HIV prevention
- Sterile needles and ancillary injecting equipment
- Safe disposal methods of injecting equipment
- Referrals to mental health services and SUD treatment
- HIV and viral hepatitis testing and linkage to care
- Other services to prevent HIV and viral hepatitis (e.g., counseling, condoms, and PrEP)
- HAV and HBV vaccination
- Overdose prevention education and Naloxone distribution

The 2017 Canary study presented unpublished data on PWID and SSPs. In the United States, 6.6 million people reported ever injecting a drug in their lifetime. Of 775,000 people who reported injecting a drug in the past year, 334,000 (or 43 percent) were living with HCV infection. As of early 2017, 270 SSPs were operating in the United States. Of people 15-29 years of age with HCV, only 20 percent were found to live within 10 miles of an SSP.

The Canary study estimated that approximately 2,200 additional programs are needed to provide proximal access to syringe services. As of April 2018, CDC has given approval for 39 states and counties to redirect a portion of their federal funding awards to support SSPs based on local data that demonstrated a risk for or an ongoing outbreak of HIV and/or viral hepatitis.

CDC collected NHBS data to address the myths and misconceptions of SSPs that have persisted over time. CDC designed the NHBS to monitor HIV infection, risk behaviors, HIV testing, and the use of prevention services in three key populations: MSM, PWID, and heterosexuals at high risk for HIV infection. CDC surveys each NHBS population every three years on an annual rotating cycle.

The 2015 NHBS survey assessed the coverage of SSPs in 20 geographically diverse cities in the United States and examined the HIV risks and protective behaviors among PWID. "SSP coverage" was determined by the number of syringes for each person who injected drugs in one year. The "number of syringes" was estimated based on the distribution of syringes by all operational SSPs in each of the 20 cities and the sizes of PWID populations in each city.

CDC used NHBS data to develop models to address three myths that are associated with SSPs. The models were controlled for age, gender, race/ethnicity, homelessness, and peer network size. Moreover, the outcomes of the participants in the models were based on every two-fold increase in SSP coverage.

• To address the first myth, "the ability of SSPs to increase high-risk practices," the outcome variables in the model showed that SSP participants had a low likelihood of receptively sharing syringes; receptively sharing syringes with two or more people; or sharing other injection equipment (e.g., cookers, filters, and water).

- To address the second myth, "the ability of SSPs to promote syringe use in communities," the outcome variable in the model showed that program participants had a high likelihood of disposing of used syringes.
- To address the third myth, "the ability of SSPs to increase risky behaviors," the outcome variable in the model showed that program participants had a low likelihood of having sex with a casual partner without a condom.

The fourth myth, "the ability of SSPs to increase crime," is well documented in the literature based on published studies from 2000-2017. The studies found no evidence of an association between SSPs and increased illegal drug use or crime. The studies noted that as many as 1 in every 3 law enforcement officers might be stuck by a used needle over the course of their careers. Needlestick injuries were found to be one of the most concerning and stressful events experienced by law enforcement officers and have been ranked as equivalent to a knife or gunshot wound. The studies found that SSPs help to protect the public and first responders by providing safe syringe disposal methods and reducing the presence of syringes in communities.

In addition to research that has addressed the four myths associated with SSPs, other studies have demonstrated the essential role of SSPs. For example, the 2014 Aspinall, *et al.* study reported that SSPs reduced the risk of HIV infection by 56 percent. The 2017 Platt, *et al.* study reported that the combined use of OST and needle syringe programs is associated with a 74 percent reduction in the risk of HCV acquisition.

SAMHSA data from 2014-2016 clearly documented the unmet need for opioid treatment services. In 2014, opioid injections accounted for 360,707 admissions for drug treatment (or 22.3 percent of all admissions). In 2015, however, SAMHSA reported OUD in nearly 2.4 million Americans. Of the entire population with reported OUD in 2015, nearly 80 percent did not receive treatment.

The 2000 Hagan, *et al.* study and the 2006 Latkin, *et al.* study found that SSPs facilitated entry into substance use treatment. The studies reported that PWID who were SSP participants were 2.8 times more likely to reduce the amount of drugs injected compared to non-SSP participants. Moreover, new SSP participants were 5 times more likely to enter drug treatment than non-SSP participants. PWID who were SSP participants also were 3.5 times more likely to stop injecting compared to non-SSP participants.

The 2010 and 2012 Islam, *et al.* studies and the 2015 Des Jarlais, *et al.* study described the key role of SSPs in three major areas:

- Access to sterile injecting equipment and disposal
- Risk reduction education
- Opportunities to engage in care
 - Access to primary care (e.g., a higher likelihood of connecting with primary care when meeting a healthcare provider on the street)
 - Testing and screening services
 - Patient navigation and case management
 - Naloxone distribution
 - HAV and HBV vaccination
 - Access to mental health and social services
 - Access to reproductive health services

To estimate the global demand of PWID, data were collected from 12 countries that have populations of at least 10 million residents and available information on the number of their operational SSPs. Of the 12 countries, Spain was estimated to have the lowest rate of 6 PWID per SSP, while the United States was estimated to have the highest rate of 3,279 PWID per SSP. Overall, the number of SSPs in the United States has significantly increased over time due to two major events: (1) the HIV/AIDS epidemic in the 1990s and (2) the HIV outbreak in Scott County, Indiana in 2015 that was related to IDU.

Dr. Asher concluded her overview by informing the participants that federally funded recipients have incorporated innovations over time to deliver SSP services, such as pharmacy sales, mobile units, vending machines, web-based orders of supplies, and peer-to-peer service delivery. She formally introduced the guest speakers and opened the floor for the presentations of their creative SSP activities in the field.

SSP Perspectives and Experiences: Atlanta, Georgia

Mona Bennett

Founder, Atlanta Harm Reduction Coalition

Ms. Bennett described AHRC's perspectives on and experiences with providing linkage to care and harm reduction services in a limited legal environment. AHRC was established in 1994 as an SSP with public health students from the Rollins School of Public Health at Emory University who all served as volunteers. AHRC slowly shifted from all volunteers to paid staff positions over time as grant proposals began to be awarded and other funding streams were identified. The new resources also allowed AHRC to add new harm reduction programs and services to meet the needs of the community.

AHRC's services to its clients are highlighted as follows. Syringes and other safe supplies (e.g., cookers, cotton pellets, straws, pipe covers, alcohol pads, clean water, and nutritious food) are collected, safely disposed of, and distributed. A mobile health unit offers HIV and HCV testing and provides linkages to care. AHRC hopes HRSA will expand the 340B Drug Program for hospitals to receive reimbursement for its clients who are referred for HCV treatment.

AHRC has a history of addressing the legal uncertainties regarding syringe exchange in the state of Georgia. Most notably, the current paraphernalia law in Georgia "prohibits an individual or a corporation to sell, lend, rent, lease, give, exchange, or otherwise distribute a hypodermic syringe or needle unless the drug-related object will be used for a legitimate medical purpose."

AHRC has made efforts in four separate legislative sessions to increase the flexibility of Georgia's paraphernalia law and allow SSPs to legally operate in the state. The current law has served as a major barrier to AHRC's ability to leverage funds, build or sustain partnerships, and expand its services. For example, the Georgia Department of Public Health is not eligible to submit a determination of need application to CDC to redirect a portion of its federal funds to support SSPs in the state.

Despite the limitations of the current legal environment in Georgia, AHRC remains committed to saving lives by stopping the spread of bloodborne diseases, particularly HIV, HBV, and HCV. Moreover, CDC recently awarded funding to AHRC. AHRC will continue to attempt to expand Georgia's paraphernalia law in the next legislative session. Most notably, clients who are in

possession of syringes obtained from AHRC are in violation of the law and are subject to arrest. AHRC will continue its advocacy efforts to make harm reduction a statewide policy in Georgia because the benefits of this public health strategy are well demonstrated. Harm reduction also treats people with dignity and respect.

AHRC's next steps will be to continue to leverage existing and upcoming opportunities to expand the current limited legal environment in Georgia. For example, new legislation to legitimize SSPs throughout the state is close to being passed. State policymakers are continuing to be educated on the public health consequences of restricting harm reduction services in Georgia. In November 2016, Fulton County formally approved the delivery of harm reduction services within its geographic borders with no legal consequences.

SSP Perspectives and Experiences: North Carolina

Robert Childs, MPH

Executive Director, North Carolina Harm Reduction Coalition

Mr. Childs described NCHRC's perspectives on and experiences with serving as a model to create a favorable policy environment and effectively deliver harm reduction services to rural areas in North Carolina. NCHRC is the largest comprehensive harm reduction provider in the state of North Carolina. NCHRC's key activities include grassroots advocacy; resource development; coalition building and organizing; and the provision of direct services to people who are made vulnerable by drug use, sex work, overdose, immigration status, gender, HIV, viral hepatitis, and STDs.

NCHRC members previously operated as an illegal SSP to provide PWID with syringes, Naloxone, and other supplies. However, NCHRC currently operates as a legal SSP and closely collaborates with several groups in the state that traditionally have opposed harm reduction services, such as legislators, law enforcement, and faith leaders. NCHRC fully engaged these groups by crafting specific messaging to decrease the emphasis on public health and place a stronger focus on the law enforcement and occupational safety benefits of harm reduction services.

State data were collected to determine the number of medication or drug overdose deaths among North Carolina residents from 1999-2016 by category of intent: unintentional, self-inflicted, undetermined, or assault. The 1,965 deaths from all categories of intent that were reported in 2016 reflected a 440 percent increase since 1999 (or more than 1,000 deaths per year). Unintentional overdoses from fentanyl and heroin are driving this massive increase. Most notably, heroin, fentanyl, and fentanyl analogues accounted for 78.1 percent of opioid overdose deaths that were reported in the second quarter of 2017.

In addition to mortality data, morbidity data also were collected on IDU in the state of North Carolina. The data showed that acute HCV cases reported in North Carolina increased by more than 500 percent from 2009-2016. However, NCHRC estimates the actual burden to be four to five times higher because HCV testing by SSPs that specifically targets PWID in North Carolina is minimal. State data on likely PWID from 2010-2015 showed that heart valve infections associated with IDU increased 13.5 times and sepsis increased 4 times.

NCHRC launched a tremendous response to the opioid crisis in the state of North Carolina with virtually no federal or state funding. NCHRC successfully passed nine legislative provisions and introduced new legislation that currently is pending. NCHRC provided assistance to Georgia, Indiana, South Carolina, Tennessee, and other states in the development of their harm reduction legislation. The harm reduction legislation in North Carolina is highlighted below.

2013

- Decriminalization of syringes and sharps instruments that are declared to law enforcement prior to a search
- 911 Good Samaritan Law and community Naloxone access

2015

- Community biohazard collection and decriminalization of residue in syringes that is declared to law enforcement
- Pharmacy standing orders and Good Samaritan protections for people who are on parole, probation, and pretrial release
- Naloxone funding

2016

- Operation of legal syringe exchange programs (SEPs) at diverse sites
- Funding for Law Enforcement-Assisted Diversion (LEAD) programs to decrease the number of low-level drug offenders who are arrested and increase the number of these individuals who are referred to mental health or harm reduction services
- Standing orders for Naloxone that are issued by the state medical director at all North Carolina pharmacies

2017

- Strengthen Opioid Misuse Prevention (STOP) Act of 2017: Expanded Naloxone access and expanded syringe exchange funding
- Naloxone funding
- "Fair Chance" hiring policies (pending)

NCHRC focused on two major areas to ensure the success of its efforts to change harm reduction legislation in the state of North Carolina. First, strong advocacy and outreach were conducted to engage a diverse group of stakeholders, including people who use or have used drugs and their loved ones; harm reduction leaders; law enforcement to discuss the public safety aspects of SEPs; faith leaders to discuss the morals of SEPs; and state legislators.

Second, several key strategies were implemented: relationship and coalition building; media coverage; dissemination of universal, non-partisan political messages; distribution of fact sheets to replace myths with accurate information; good will by all entities to enact harm reduction legislation in a "stepping stone" approach; and ongoing communications to reach agreement on common issues or concerns.

NCHRC is pleased that its efforts to change harm reduction legislation in North Carolina have resulted in a number of positive outcomes. As of March 31, 2018, 27 active SEPs were operating in 32 counties in North Carolina with no federal or state funding. However, other SEPs that have not submitted paperwork to the North Carolina Division of Public Health to be formally recognized as "active" might be operating in the state as well. NCHRC operates the

only active first responder SEPs in the country that allow fire departments and/or EMS to provide Naloxone, recovery resources, syringes, and sterile injection supplies to people in the community who need these services.

NCHRC distributed 74,723 Naloxone kits from August 2013-March 2018 to urban and rural areas in North Carolina, other states, and law enforcement agencies. Naloxone is a non-addictive prescription medication that is associated with up to a 50 percent decrease in deaths by reversing opiate overdoses. The medication can be administered via a nasal spray or an intramuscular injection and cannot be abused or cause an overdose.

Naloxone can restore breathing and consciousness in one to three minutes for a total duration of 30-90 minutes. As of February 28, 2018, urban and rural communities in North Carolina reported 10,405 opioid overdose reversals with Naloxone. As of March 31, 2018, 224 law enforcement agencies across 87 counties in North Carolina carried Naloxone and reported a total of 1,199 opioid overdose reversals.

NCHRC recently changed some of its internal programs and tailored multiple interventions to more effectively respond to the increase in fentanyl overdose deaths in North Carolina. The unprecedented availability of inexpensive heroin and fentanyl has led to more deaths. NCHRC received new funding to launch a fentanyl test strip program to examine cookers and determine the level of this drug in the local supply in various environments in North Carolina.

NCHRC collected preliminary data from six test sites in North Carolina from September 1, 2017 to March 31, 2018. The data collected to date showed that positive fentanyl test strips were lowest in Greenville (12 percent); slightly above mid-range in Fayetteville and Durham (56-67 percent); and highest in Greensboro, Wilmington, and Raleigh (90-100 percent).

NCHRC is continuing to target its harm reduction services to rural areas in North Carolina. NCHRC's activities in this regard include training rural law enforcement personnel; forming new rural SEPs; building and sustaining rural harm reduction organizations; distributing Naloxone in rural areas; and collaborating with health departments and opioid treatment programs/providers (OTPs) in rural communities.

NCHRC established key partnerships to deliver harm reduction interventions and facilitate syringe exchange in non-traditional gathering locations of rural communities, such as pawn shops, laundry mats, gas stations, supermarket parking lots, and the private homes of families and friends. NCHRC is maintaining its focus on harm reduction services in rural areas of North Carolina due to several challenges: housing issues; stigma; isolation; and the lack of rural SEPs, evidence-based treatment, transportation, upward mobility, mental health services, and trauma services.

NCHRC and other SSPs/SEPs across the country are examining hundreds of legal "safe injection spaces" in Canada and Europe to potentially replicate the success of this intervention in the United States. SSPs/SEPs are engaged in this national effort due to four major factors.

- PWID in the United States can safely use injection drugs only in medical care settings at this time.
- "Underground" safe injection spaces have been established in jurisdictions throughout the United States to address the needs of local communities.

- Several published studies have described the benefits of safe injection spaces as an effective, evidence-based intervention to address the opioid crisis by reducing mortality.
- To date, none of the safe injection spaces in Canada and Europe have reported an IDUrelated death due to overdose.

The ongoing analysis by NCHRC and other SSPs/SEPs found that decriminalizing the personal possession of drugs in Portugal and other countries has led to significant decreases in overdoses, HIV, and HCV among PWID as well as increases in stable housing and other successful long-term outcomes in this population. Moreover, the successful outcomes of the international experiences demonstrate the massive failure of the U.S. approach to criminalize people who use drugs. NCHRC recognizes the need to implement effective decriminalization models to launch a meaningful response to the opioid crisis at federal, state, and local levels.

Overall, NCHRC has learned that the following components are essential to effectively link SSP/ SEP clients to OTP, HIV, and/or HCV services in both urban and rural areas: trust, availability of services and staff, transportation, child care, stable housing, stigma reduction, affordable costs, solid relationships, and "on-demand" services at partner facilities.

SSP Perspectives and Experiences: San Francisco, California

Jamie Carter, MD, MPH

Primary Care Addiction Medicine Fellow San Francisco Department of Public Health (SFDPH)

Dr. Carter described the SFSMP Team's perspectives on and experiences with delivering street medicine to clients in San Francisco. The Street Medicine and Shelter Health Program was established as a division of SFDPH to serve as a transitional primary care model with the following components: accessible, acceptable, and effective care; a comprehensive approach to health care that considers SDOH; collaborations with other organizations; and a strategy to transition stabilized clients to traditional primary care.

The Street Medicine and Shelter Health Program serves the highest risk and most vulnerable homeless populations, including people who are chronically homeless and are not able to successfully access other care that is available in San Francisco. The SFSMP Low Barrier Buprenorphine Program (LBBP) was established based on political interest in 2016 to decrease public drug injection in San Francisco. City officials received multiple complaints of the dramatic rise in syringes and human waste on the street. As a result, SFDPH and the SFSMP Team designed the program to specifically address PWID on the street.

The LBBP is targeted to PWID on the street who have severe OUD due to their injection of heroin and methamphetamines. OUD is a chronic medical condition that is characterized by a loss of control and compulsive use of opioids despite the harm of these drugs. OUD treatment includes a first-line medication of methadone or buprenorphine and is effective in retaining patients in care, decreasing mortality, reducing opioid use, decreasing infectious disease transmission, and improving other health and social outcomes. Methadone is a highly regulated medication that is dispensed daily through an OTP or a methadone clinic. Buprenorphine is prescribed in an office-based setting by a waivered provider.

The LBBP is needed because data show that only 20 percent of people with OUD receive any treatment. Of all people who receive treatment, only 37 percent are provided with evidence-based medication. The SFSMP Team identified barriers at multiple levels to providing OUD treatment with buprenorphine to PWID on the street.

Patient-Related Barriers

- No insurance, identification, or phone
- Difficulty making appointments
- Reluctance or unwillingness to leave a partner, pets, or property on the street
- Lack of trust of physicians
- Outstanding warrants or other criminal justice complications
- Chaotic drug use
- Acute medical issues
- Frequently lost or stolen medication

Prescriber-Related Barriers

- Judgment and stigma
- Unwillingness to provide same-day prescriptions
- Discharge of patients who have ongoing drug use, are not abstinent, or miss appointments
- Concerns for diversion of medication
- Perceptions of patients as "difficult," "time-consuming," or "manipulative"

System-Related Barriers

- Insufficient number of providers/prescribers
- Lack of same-day access to care
- No support to help patients navigate the fragmented system of care

The SFSMP Team designed the LBBP to specifically address these barriers. The key program components include engagement by peer outreach workers on the street; availability of drop-in appointments at a small open-access medical clinic or a harm reduction syringe access program; same-day comprehensive assessment and education by a clinician; same-day prescriptions for buprenorphine; and collaboration with a pharmacy that has a harm reduction philosophy and will dispense buprenorphine to patients with no identification or insurance.

The LBBP takes a harm reduction approach to providing buprenorphine treatment to PWID on the street. A flexible care plan is specifically designed for patients based on their individual barriers or needs. Support and treatment are provided to patients who have goals other than abstinence, continue to use drugs, and have difficulty with regular, consistent follow-up. The primary goal of the LBBP is retention in care, while its secondary goals are improved health, reduction in opioid use, and abstinence.

The results of the one-year pilot of the LBBP are highlighted as follows. The 95 patients in the pilot were medically and psychiatrically complex, including 58 percent with a chronic medical condition, 66 percent with a psychiatric condition, and high rates of other substance use (e.g., 61 percent with methamphetamine use). After the initial visit, 70 percent of patients returned to the site of care. Interruptions in treatment were common with 42 percent of patients experiencing an interruption in their treatment of 1 month or greater before returning to care.

Retention in care decreased from 62 percent in month 1 to 22 percent in month 12. Retention on buprenorphine decreased from 37 percent in month 1 to 22 percent in month 12. The relatively stable rate of retention on buprenorphine over the one-year pilot was extremely promising because PWID on the street are one of the most marginalized patient populations. The urine toxicology tests showed that 36 percent of patients were negative for opioids.

Of patients who returned after the initial visit, 34 percent had at least one opioid-negative test result and 14 percent had abstinence from opioids on all tests. In addition to collecting LBBP data, the SFSMP Team's interviews with patients also showed a decrease in opioid use and improved health. Dr. Carter presented quotes from some of the LBBP patients.

The SFSMP Team is continuing to address major challenges in implementing the LBBP. Most notably, the demand for the program outweighs the capacity of the team. Barriers to transitioning patients to formal SUD treatment programs have not been resolved. The other challenges include diversion issues, the need for methamphetamine use disorder treatment, and the inability to meet the basic needs of patients.

The results of the pilot showed that the LBBP successfully engaged and retained a subset of highly vulnerable patients in care. Continuous treatment with buprenorphine over the one-year pilot was observed in approximately 25 percent of patients, but intermittent use of buprenorphine was found to be more common. Although several patients continued to use heroin and methamphetamines, the evidence showed decreased opioid use and abstinence in some patients.

Continuous treatment with buprenorphine and opioid abstinence are goals of the LBBP, but intermittent treatment with buprenorphine and decreased opioid use also should be viewed as valid outcomes due to the significant reduction in opioid and injection-related harms. Patients overwhelmingly reported decreased use of heroin and other substances, stronger capacity to engage in medical care, and improved health.

The SFSMP Team maintains a strong partnership with the 6th Street Harm Reduction Center (HRC) in San Francisco to provide patients with HIV and HCV screening, linkages to care, and treatment. Screening of HIV and HCV is available Monday through Friday for two hours per day. Linkage, Integration, Navigation, and Comprehensive Services (LINCS) navigators ensure linkages to HIV care in a primary care-based setting or through the SFSMP Team. HCV navigators ensure linkages to HCV treatment through the SFSMP Team, in a primary care-based setting, or at the 6th Street HRC.

An HCV navigator at the 6th Street HRC leads weekly meetings of an HCV group that is open to patients who are recently diagnosed, undergoing treatment, or have an interest in treatment. The other incentives include a breakfast club and onsite lockers for patients to store their medication. The traditional practice required patients to be engaged in primary care and "ready" for HCV treatment. However, the philosophy of the 6th Street HRC is to first treat patients in a familiar setting and then provide linkages to primary care to address other goals of the patient during and after treatment. This philosophy minimizes the fatigue of patients after treatment, empowers patients to achieve other health goals, and reaches patients at highest risk who previously were unable to engage in primary care.

During the weekly meetings of the HCV group at the 6th Street HRC, a nurse practitioner evaluates the patients, performs laboratory tests, conducts follow-up, prescribes HCV treatment, and coordinates with a community pharmacy to obtain assistance on the prior authorization process. The 6th Street HRC has evaluated 22 patients for HCV since August 2017. Based on the preliminary results, 13 patients started and completed HCV treatment with no interruptions. Of the 13 patients, six were cured based on a sustained virologic response (SVR) for 12 weeks and seven are awaiting their SVR results.

Overall, the treatment outcomes achieved by the SFSMP Team and the 6th Street HRC showed that the highest risk and most vulnerable patients can be reached by providing medical care in harm reduction settings, such as SSPs. Patients who access harm reduction services also are interested in medical care and addiction treatment, but the demand for these services outweighs the capacity in San Francisco. The LBBP engages patients in care, decreases opioid use and injection-related harms, and improves the health and well-being of patients. SSPs can serve as a home for successful HCV treatment of PWID.

CHAC DISCUSSION: SSP PERSPECTIVES AND EXPERIENCES

CHAC applauded the leadership of the SSPs in Atlanta, North Carolina, and San Francisco for their ongoing commitment, dedication, and determination to saving the lives of people in their states and localities who are vulnerable and marginalized. The CHAC members were impressed by the diverse approaches and innovative models of the SSPs to deliver services in community-based settings that are both responsive to and respectful of their patient populations.

Ms. Bennett, Mr. Childs, and Dr. Carter provided additional details on the following topics in response to specific questions by the CHAC members.

- NCHRC's interest in expanding its harm reduction services in North Carolina to include increased linkages to buprenorphine and methadone treatment, additional legal services to further decriminalize drug use in the state, and wider availability of child care services.
- Potential strategies to "normalize" and integrate SSPs into mental health care, family practice, primary health care, and drug treatment centers.
- Effective approaches to link PWID who have no prior connection to the healthcare system to ongoing SUD/OUD treatment and care services.
- The interest of the SFSMP Team in engaging "addiction-specific" navigators to guide and support patients who are on buprenorphine.
- The feasibility of replicating successful international models in the United States that have resulted in tremendous declines in overdose deaths, particularly the safe injection spaces for PWID in Canada, Portugal, and Norway.
- Opportunities for individual states to treat SUD/OUD as a medical or health issue rather than criminalize the use of illicit drugs (e.g., legal exemptions for states to establish safe injection spaces; the discretion of state law enforcement agencies to change their practices., and the authority of states to amend their existing laws).

Panel Presentation: HIV Transmission Risk in the Context of Antiretroviral Use and Viral Suppression

A panel of federal agency representatives presented updates to guide CHAC's continued discussion on HIV transmission risk in the context of ART use and viral suppression.

CDC Message Testing for High-Impact Prevention: Viral Suppression and TasP

Jo Stryker, PhD

Chief, Prevention Communication Branch, DHAP Centers for Disease Control and Prevention

Dr. Stryker summarized the key results of CDC's message testing for high-impact prevention that focused on viral suppression and TasP. The purpose of CDC's message testing was three-fold: (1) determine the participants' awareness and comprehension of various terminology; (2) explore the experiences of PLWH with their HIV health care and providers; and (3) assess the novelty, clarity, comprehension, motivational appeal, and suggested improvements on viral suppression and TasP messages.

To achieve these goals, CDC conducted one-hour in-depth interviews with a total of 88 individuals who were recruited from four cities: 24 participants from Atlanta, Georgia; 24 participants from Jackson, Mississippi; 19 participants from Los Angeles, California; and 21 participants from Detroit, Michigan. The eligibility criteria included participants who were sexually active, 18-64 years of age, and currently or recently in a serodiscordant relationship or had more than one sex partner in the past year. The recruitment targets included at least 50 percent MSM, at least 33 percent PLWH, and at least 25 percent in a serodiscordant relationship. The demographics of the participants are highlighted below.

- By age, 54 participants (61 percent) were 35-64 years of age.
- By gender, 72 participants (82 percent) were male.
- By race, 42 participants (48 percent) were African American; 36 (41 percent) were White; and 10 (11 percent) were Latino.
- By sexual identity, 61 participants (72 percent) were gay, bisexual, or other MSM.
- By HIV status, 40 participants (46 percent) were PLWH.
- By educational status, 21 participants (26 percent) had a high school education or less.

The interviews first focused on the participants' awareness and comprehension of various terminology. For "viral load," 80 percent of participants were aware of the expression and 53 percent provided the correct definition. For "UVL," 82 percent of participants were aware of the expression and 49 percent provided the correct definition. PLWH accounted for 62 percent of participants who correctly defined UVL.

For "viral suppression" or "suppressed viral load" (SVL), 42 percent of participants were aware of the expressions and 15 percent provided the correct definition. PLWH accounted for 59 percent of participants who were aware of viral suppression and SVL. People with an HIV-

negative or unknown status accounted for 62 percent of participants who correctly defined these terms. For "U=U," 20 percent of participants were aware of the expression. MSM accounted for 71 percent of participants who were aware of U=U. In a subgroup of 31 participants, 48 percent defined U=U as "you cannot transmit HIV to a partner if you are undetectable" and 35 percent did not believe the expression.

The following series of messages on risk estimate was tested with 86 participants.

- "People who are living with HIV should take medicine to treat HIV as soon as possible after diagnosis. If people living with HIV take HIV medicine daily as prescribed, they can get an undetectable viral load."
- "Getting and keeping an undetectable viral load is the best thing people living with HIV can do to stay healthy."
- "If people living with HIV take HIV medicine as prescribed, their viral load can become undetectable. If it stays undetectable, they have effectively no risk of transmitting HIV to an HIV-negative partner through sex. This is one of the best ways to prevent transmitting HIV."

The term "effectively no" risk was the interim term selected by HHS to quantify the magnitude of risk pending the results of this message testing of various alternatives. The alternatives included "almost no," "insignificant," "negligible," or "extremely low to no" risk. The version of the risk quantifier was randomly rotated for the participants to observe the series of messages above with different versions of the risk quantifier.

The positive and negative feedback that the participants provided on the risk estimate messages is set forth in the tables below.

Participants' Responses	Number of Participants	
Positive initial reaction to the messages	28	
Disliked nothing	15	
Agreed with the messages	13	
Informative, clearly written, and helpful at clarifying confusion	20	
Sounds hopeful and shows that life is not over for PLWH	7	
Motivational	4	
Important	13	
Emphasis on taking medication and starting early	5	
Felt better about their HIV status, sounded positive, and could help to reduce stigma	8	

POSITIVE FEEDBACK

Participants' Responses	Number of Participants	
Negative initial reaction	21	
Disagreed/messages are "untrue"	14	
Gives false sense of security and permission to participate in risky behaviors	8	
Confusing, unclear, and not very informative	6	
Confusing, unclear, and not very informative: Risk statement	5	
Confusing, unclear, and not very informative: Meaning of "undetectable"	3	
Oversimplifies adherence	6	
Omitted information about cost	1	
Omitted information on the difficulty of adherence	1	
Disagreed that having a UVL is the best method to prevent transmitting HIV	3	

The participants were shown all versions of the risk quantifier and asked a series of questions to assess the version that was most appealing; most and least easily understood; easiest and hardest to understand; represented the smallest and largest risk; and would most encourage PLWH to take their HIV medications as prescribed to achieve and maintain a UVL (motivational). The majority of participants found "extremely low to no risk" to be the most appealing, easiest to understand, and motivational risk statement. Most participants also found this terminology to convey the smallest risk. As presented in the table on the following page, no differences were observed in these results based on HIV status.

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	Effectively	Almost			Extremely Low
	No	No	Insignificant	Negligible	to No
Appeal (n=83)	19%	25%	4%	2%	67%
Easiest to Understand (n=44)	5%	20%	5%	2%	45%
Hardest to Understand (n=44)	5%	2%	11%	36%	0%
Largest Risk (n=65)	8%	28%	31%	14%	11%
Smallest Risk (n=64)	25%	14%	14%	6%	48%

**This question, "Select the top two message that would encourage you to take HIV medicines as prescribed to get and stay undetectable," was only asked of participants with HIV.

CDC formulated several recommendations based on the results of testing its HIV risk estimate messages for high-impact prevention. In terms of viral suppression, unfamiliar or confusing terminology should not be introduced to reduce the potential for consumer audiences to reject the messages. "UVL" should be exclusively used whenever possible in messages that are targeted to consumer audiences. However, the inclusion of a footnote in the messages should be considered to provide a definition of viral suppression and note if the descriptions apply to both UVL and SVL.

With respect to the term used to quantify the sexual transmission risk when individuals with HIV achieve and maintain viral suppression, results suggested that messages for consumer audiences should use the terminology of "extremely low to no risk." The message testing results indicated that this terminology will most effectively support two collective public health objectives: (1) increase comprehension of the powerful prevention benefit of achieving and maintaining viral suppression and (2) motivate PLWH to take the necessary steps to help reach this goal. However, CDC acknowledges that these results might not apply to other audiences.

CDC's message testing with healthcare providers included interviews with 13 key opinion leaders from the "Prevention IS Care[™]" Campaign for HIV care providers. The preferences of the providers were mixed on using the terminology of "effectively 100 percent reduction" or "effectively no risk." Some providers believed that the absence of a number made the terminology less absolute and found the use of a number to be helpful. The use of the five risk statements in messages for both providers and/or patients led to equivocal results. Most notably, none of the providers recommended the use of "insignificant risk" and only one provider recommended the use of "negligible risk."

Update by the HHS Viral Suppression Messaging Workgroup

Richard Wolitski, PhD

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

Advice Requested from CHAC by HHS/OHAIDP:

- 1. Are the workgroup's recommendations appropriate? Should variability in the messages be encouraged when CDC and HRSA target similar audiences?
- 2. What opportunities are available to integrate updated TasP messages in existing programs and services?
- 3. Should the federal agencies continue to collaborate to harmonize the provision of their messages on HIV prevention, care, and treatment? What other topics or issues might have inconsistent messaging between the federal agencies or within different programs or materials of the same agency?

Dr. Wolitski provided an update on the HHS cross-agency workgroup discussions that have been occurring related to accurate and concise communications on viral suppression and TasP. He reviewed the workgroup's consideration of information from CDC's message testing and its discussions with community advocates. He highlighted several challenges that arose from this process, including different understanding of the meaning of words. He described the reaction of community advocates to the wording, "extremely low to no risk," that had the best evaluation in the message testing.

Dr. Wolitski discussed the need to account for both message testing results and perspectives from other stakeholders. However, he expressed a commitment by the workgroup to developing and implementing TasP messages that are accepted and understood by a diverse and wide range of audiences.

Because of the diversity of opinions on this issue, the workgroup proposed a recommendation to give the agencies the option to choose from three different phrases to communicate the impact of having an UVL. The two preferred phrases are "effectively no risk" and "negligible risk." "Extremely low to no risk" might be used if message testing with a target audience shows this phrase to be superior to the other two terms.

The workgroup included the statement that PLWH should "achieve and maintain an undetectable viral load for at least six months" as the minimum threshold for using TasP as a strategy. The workgroup made this recommendation to minimize the number of PLWH whose viral loads vary between viral load monitoring tests. However, the workgroup recognized that the science on the six-month duration for TasP is not as strong as the supporting evidence for other TasP components. As a result, the workgroup has agreed to leave the six-month component out of the core messaging. The statement can be included as a secondary message as appropriate.

The workgroup's ongoing discussions of this complex issue led to the following decision. HHS is no longer recommending that PLWH achieve and maintain a UVL for at least six months as the minimum threshold for using TasP as a strategy. However, the HHS agencies can continue

to communicate this as a secondary message. HHS will continue to monitor the research and adjust the messaging as needed ag a future date.

The informal group has completed its core charge and is no longer meeting on a regular basis. However, the workgroup will convene ad hoc meetings as needed and/or collaborate with other HHS groups to address broader national issues. For example, the workgroup's future activities might focus on (1) routinely evaluating the effectiveness of TasP messages by the HHS agencies as new data are collected and public knowledge of TasP increases over time; (2) exploring strategies to increase the uptake of PrEP nationally; and (3) reviewing the HIV-related content across HHS agency websites to ensure the delivery of consistent messages. To provide guidance to clinicians on the use of TasP, the HHS Panel on ART Guidelines for Adults and Adolescents has agreed to review the evidence as part of their ongoing discussions.

CHAC DISCUSSION: TASP MESSAGING

CHAC commended Drs. Stryker and Wolitski for their leadership at CDC and HHS/OHAIDP, respectively, in thoughtfully addressing the key concerns and issues raised by the CHAC membership and community stakeholders throughout the country. CHAC also applauded CDC for gathering a tremendous amount of qualitative data from its one-hour interviews with 88 participants. CHAC acknowledged the importance of the efforts at the federal level to support TasP messaging with rigorous data.

The CHAC members made several comments and suggestions for the federal agencies to consider in their ongoing TasP messaging activities.

- Ms. Leonard proposed several next steps for the federal agencies to consider to improve TasP messaging.
 - The HHS Workgroup's decision to allow the federal agencies to use "extremely low to no risk" in their TasP messages is questionable. This terminology might be confusing to CBOs in the field because the language indicates that the risk of transmitting HIV is still possible. Because CBOs rely on the federal agencies to provide firm guidance on the development and dissemination of public health messages, these organizations should be given clear advice on selecting the most appropriate risk statement for their TasP messages. Moreover, guidance from the federal agencies on TasP messaging should be incorporated into the NOFOs for recipients that receive HIV prevention, care, and treatment funding from CDC and HRSA.
 - The majority of participants (61 percent) in CDC's TasP message testing study were 35-64 years of age. The federal agencies should include more young people under 30 years of age in their future research on TasP messaging.
 - The HHS Workgroup's future plans to evaluate the effectiveness of TasP messaging also should focus on the impact of these messages on treatment adherence, access to medications, and stigma reduction.
- Mr. Hursey expressed strong opposition to "extremely low to no risk" as a TasP message. Although this terminology was the most appealing to participants in CDC's TasP message testing study, the language might not have been well understood. Most notably, 26 percent of the participants had a high school education or less. For example, the "extremely low risk" part of the message might be ignored, while the "no risk" part of the message might lead PLWH to engage in different sexual practices. The

misinterpretation of the message could lead to adverse outcomes for PLWH, particularly those who reside in states or jurisdictions that criminalize HIV non-disclosure. Moreover, messaging related to the inability of PLWH with a UVL to transmit HIV does not effectively address stigma. This terminology appears to indicate that stigmatizing PLWH with a detectable viral load is acceptable. The messaging should be designed to be inclusive and reduce stigma of PLWH with both detectable and undetectable viral loads.

- Dr. Taylor made a suggestion in follow-up to Mr. Hursey's comments. The TasP messages convey that PLWH with a UVL have "effectively no risk," "extremely low to no risk," or a "negligible risk" of transmitting HIV. She agreed that these messages will not reduce stigma if PLWH are still legally required to disclose their HIV status. She advised the federal agencies to evaluate the impact of TasP messaging on disclosure of HIV status.
- Dr. Stoner emphasized the need for the federal agencies to integrate STD testing messaging into U=U messaging. Although PLWH with a UVL are unable to transmit HIV, this same population is at risk for acquiring and transmitting syphilis, gonorrhea, and chlamydia.
- Dr. Belzer recognized that the federal agencies will develop and disseminate different TasP messages to consumer and provider audiences. However, he also noted the importance of tailoring the language based on the specific purpose of the messages, such as decreasing HIV transmission, reducing stigma, engaging and retaining PLWH in care, or improving overall quality of life.

The federal agencies made several remarks in response to CHAC's comments and suggestions.

- CDC and HRSA informed CHAC of the actions that will be taken to address Ms. Leonard's suggestions.
 - Dr. Eugene McCray, Director of DHAP, conveyed that DHAP will reach out to colleagues at the NIH National Institute of Mental Health to explore opportunities to collaborate on new research to determine the impact of TasP messages on treatment adherence, access to medications, and stigma reduction. Moreover, clear guidance on TasP messages will be distributed to recipients who receive HIV prevention funding from CDC, particularly Capacity Building Assistance providers that directly collaborate with CBOs.
 - Dr. Cheever confirmed that the RWHAP providers who receive HIV care and treatment funding from HRSA will be educated about the TasP messaging guidelines issued by the HHS. In preparation for the release of these guidelines, HAB will include a session for the RWHAP providers to discuss this topic during the NRWC in December 2018.
 - Dr. Stryker announced that CDC released a new NOFO, "Capacity Building Assistance for High-Impact HIV Prevention," to accelerate the dissemination of viral suppression messaging to both consumer and provider audiences. The DHAP Capacity Building Branch is extensively involved in developing training materials, establishing continuing medical education programs, and updating existing provider toolkits.

• Drs. Mermin and McCray responded to the comments by Mr. Hursey and Dr. Taylor. Due to the complex issues associated with viral suppression, CDC will ensure that its TasP messaging is supported by strong science and the delivery of accurate, understandable information to the public. Regardless of whether their viral loads are detectable or undetectable, for example, CDC still encourages all PLWH to disclose their HIV status to sexual partners. Similar to U=U Campaign messaging. However, CDC is aware of concerns regarding increased stigma or legal implications related to the disclosure or non-disclosure of HIV status. CDC also is interested in informing the public of the small body of evidence that shows an interruption in ART use will cause the viral loads of PLWH to return to baseline levels within 14 days on average.

CDC's Coordinated Response to Hepatitis A Outbreaks

LCDR Monique Foster, MD, MPH

Medical Epidemiologist, Division of Viral Hepatitis Centers for Disease Control and Prevention

Advice Requested from CHAC by CDC/DVH:

- 1. What different actions should CDC take to respond to and ultimately end HAV among users of illicit substances?
- 2. What are the best steps to engage federal and non-federal stakeholders in conducting resource-intensive HAV vaccination and outreach efforts in communities?
- 3. What critical components of the public health infrastructure are needed to target and provide HAV vaccination to at-risk populations?
- 4. What are CHAC's recommendations to CDC to provide guidance on improving outreach, particularly to populations at risk for HAV infection, IDUs, and homeless individuals?

Dr. Foster presented an overview of CDC's coordinated response to HAV outbreaks. In the prevaccine era, cyclical increases of HAV occurred every 10-15 years and more than 21,000 HAV cases were reported annually. Based on current data, however, the United States is now characterized as an extremely low endemic HAV country.

The 2007 Craig, *et al.* study showed a dramatic decline in the number of HAV cases identified in the United States from 1994-2017. Widespread implementation of the universal childhood vaccination recommendation was a direct contributor to this public health success. However, CDC's surveillance and unpublished data on the number of reported HAV cases associated with outbreaks in the United States from 2007-2017 all showed striking increases since 2015.

Several studies were published in 2015-2016 to document the factors that have caused the shift in HAV epidemiology. Past outbreaks were associated with asymptomatic children. A large population of adults are not immune to HAV. Older individuals are more likely to experience severe disease and adverse outcomes. The uptake of HAV vaccination is low among at-risk adults.

CDC has contributed its expertise, staff, and TA to respond to multiple HAV outbreaks. Since July 1, 2016, over 2,800 HAV cases associated with outbreaks have been reported and the CDC Viral Hepatitis Laboratory has sequenced over 1,600 specimens. These outbreaks included foodborne transmission of HAV from frozen scallops from Hawaii and frozen

strawberries from multiple states. The person-to-person outbreaks included transmission of HAV from homeless individuals, IDUs/non-IDUs, and MSM.

The body of evidence is extremely small on HAV immunity among homeless populations in the United States. The 2009 Hennessey, *et al.* study reported that that older age, the duration of homelessness, and IDU might indicate HAV immunity.

The HAV outbreak in California included 704 cases, primarily among homeless individuals, that have been reported as of May 7, 2018. The response included the deployment of CDC's Epidemic Intelligence Officers and staff from the U.S. Department of Housing and Urban Development in May 2017. The federal partners implemented an incident command structure (ICS) to effectively coordinate teams in the field, mobilize interagency funding streams, and address public health emergencies that were declared in the state of California as well as in San Diego and Los Angeles Counties.

The mass HAV vaccination activities included "foot teams," social service providers, and medical providers who targeted their efforts to homeless individuals and people in jails and detention centers. Handwashing stations were installed and additional public toilets were made available at homeless encampments in San Diego.

The 1997 Villano, *et al.* study reported a high incidence of HAV infections among substance users. The study noted direct person-to-person transmission related to crowding and poor hygiene as a key factor in the high prevalence of HAV in this population. However, the evidence is mixed on whether IDU substantially contributes to the risk of acquiring HAV.

The HAV outbreak in Michigan included 815 cases, primarily among substance users, that have been reported as of May 7, 2018. The response included the deployment of a CDC field team in October 2017 and the implementation of an ICS. Michigan successfully leveraged \$7.2 million from state legislators to support its HAV outbreak response. CDC established collaborations with state and local partners in Michigan to target HAV vaccination efforts and outreach to MSM, people in drug treatment centers, and people in county jails.

The 1996 McMahon, *et al.* study and the 1998 Craig, *et al.* study reported that vaccination is the cornerstone of controlling community outbreaks of HAV. The studies noted that PEP alone might not effectively control outbreaks. The studies also found that targeted vaccination to groups at the highest risk for HAV is the best strategy to control the spread of disease. However, primary prevention with adequate vaccination of at-risk groups is the preferable approach.

Several states have reported local transmission of HAV clusters among IDUs and non-IDUs, including Arkansas, Indiana, Kentucky, Missouri, Ohio, and Utah. CDC's responses to the HAV outbreaks demonstrated the challenges in conducting general outreach to substance users due to the limited ability of these populations to access medical care or their mistrust of government officials because of mental illness or fear of arrest. Efforts to engage substance users in care also are difficult due to their prioritization of other issues, such as addiction treatment, housing instability, or other health problems. CDC has provided health departments with clear guidance to overcome these barriers.

• Partner with behavior specialists and disease intervention specialists

- Promote participatory planning of HAV vaccination and outreach efforts to generate the community's endorsement of these events
- Maintain a consistent presence in the community
- Launch adequate education and advertising campaigns

In addition to disseminating recommendations, CDC also has conducted and/or funded research to expand viral hepatitis vaccination of substance users in diverse settings. The 2014 Perlman, *et al.* study described the benefits of targeting substance abuse treatment centers to provide vaccination to substance users. Based on the outcomes of previous viral hepatitis outbreaks, these settings play a critical role in engaging individuals in prevention and healthcare services. Most notably, the provision of vaccination and prevention efforts as early as possible in an individual's drug use history is particularly important in viral hepatitis. Moreover, onsite vaccination in substance abuse treatment centers significantly increases the initiation and completion of the entire vaccine series.

The 2014 Perlman, *et al.* study described the benefits of targeting jails to provide vaccination to substance users. The study reported that 60-80 percent of incarcerated individuals self-report current or previous illicit drug use. As a result, jails provide an opportunity to vaccinate a large number of people who typically are difficult to reach. Jails also serve as a solid setting to track vaccinations and address other medical problems related to illicit drug use.

Several studies that were published from 1993-2009 described the benefits of targeting EDs to provide vaccination to substance users due to their long history of and expertise in providing care to hard-to-reach populations. EDs also provide opportunities to rapidly respond to public health threats and serve as effective venues to successfully conduct vaccination campaigns. However, key personnel and strong champions should be identified early to ensure the success of ED-based vaccination efforts.

The 2006 Weeks, *et al.* study described the benefits of using peer mentors to provide vaccination to substance users. Peer mentors typically are recognized as leaders and play an important role in helping substance users to overcome their mistrust of government officials and providing health departments with contact information of other people in their networks who use illicit substances. Moreover, peer mentors with experience in outreach efforts are more confident in communicating with substance users, conveying key educational messages, and promoting vaccination.

Overall, CDCs responses to the HAV outbreaks showed that many adults have no immunity to the disease because a universal adult vaccination recommendation has not been developed and implemented, particularly for at-risk populations. Increases in mortality and morbidity, such as disease complications and hospitalizations, were expected from the HAV outbreaks. Several states reported increases in HAV outbreaks over the past two years. HAV vaccination of and outreach to at-risk populations are extremely resource-intensive, but vaccination remains the cornerstone of outbreak control in communities.

CHAC DISCUSSION: CDC'S HAV OUTBREAK RESPONSE

Dr. Foster provided additional details on the following topics in response to specific questions by the CHAC members.

- CDC's current guidance for health departments, substance abuse treatment facilities, and jails to use TWINRIX (i.e., HAV inactivated/HBV recombinant vaccine) to provide viral hepatitis vaccination to substance users.
- CDC's outstanding efforts in addressing SDOH issues in its response to the HAV outbreak in California (e.g., the installation of handwashing stations, clean water facilities, and public toilets in homeless encampments in San Diego).
- CDC's collaborations with local partners to successfully integrate HAV vaccination into the existing SSP network in Louisville, Kentucky and replicate this model in other states and localities.

Ms. Fukuda noted that time constraints did not permit CHAC to provide advice in direct response to the questions posed by Dr. Foster and several other presenters over the course of the meeting on day 1. Because the vast majority of the presenters' questions focused on the opioid crisis, she confirmed that the members would discuss and determine CHAC's next steps and/or formal actions on this issue during the Business Session on the following day.

Public Comment Period

George Fistonich

Senior Advocacy and Policy Manager HIV Medical Association (HIVMA)

Mr. Fistonich read a letter into the public record for CHAC's consideration. The letter was signed on May 7, 2018 by Dr. Melanie Thompson (HIVMA Chair); Dr. Paul Auwaerter (President of the Infectious Diseases Society of America); and Dr. Paul Spearman (President of the Pediatric Infectious Diseases Society). The letter is reproduced below in its entirety with no changes to the content.

"Dear CHAC Members:

On behalf of the HIV Medicine Association (HIVMA), Infectious Diseases Society of America (IDSA), and Pediatric Infectious Diseases Society (PIDS), we thank you for the opportunity to provide public comments and to express the urgency of addressing the infectious consequences of the national opioid epidemic. IDSA represents nearly 12,000 physicians, scientists and other healthcare professionals who specialize in infectious diseases (ID), HIVMA represents more than 6,000 clinicians and researchers working on the front lines of the HIV, viral hepatitis and other STD epidemics, and PIDS represents 1100 professionals dedicated to the treatment, control and eradication of infectious diseases affecting children.

Many of our members grew alarmed recently by the rising rates of infections they have seen in their clinics and hospitals as a consequence of opioid use. IDSA and HIVMA formed a joint working group to address the opioid epidemic and its associated infections, including HIV and viral hepatitis. ID and HIV providers also are seeing more cases of injection-related bacterial infections, such as infective endocarditis and skin and soft tissue infections. Together, the public health, economic, and human costs of these infections are taking a substantial toll on our institutions, patients, their families, and communities.

Our organizations recently released both a fact sheet explaining these complications and a comprehensive set of policy recommendations including screening for HIV and viral hepatitis, surveillance for infective endocarditis, and access to coordinated ID, substance use and mental health treatment to prevent relapse and new infections. While the national attention on preventing overdose deaths and treating addiction is crucial to reversing the course of this public health crisis, our response must be comprehensive and must also address the infectious diseases associated with opioid use and other substance use disorders.

We highlight below key high-impact recommendations identified by IDSA, HIVMA, and PIDS:

Expand access to syringe services programs, safe injection or consumption sites, and other evidence-based prevention strategies:

Syringe services programs are highly effective for preventing transmission of HIV, hepatitis B (HBV), hepatitis C (HCV) and other infections through injection drug use. We strongly support CDC efforts to expand access to syringe access programs. CDC should also continue educating on the effectiveness and public health benefits of syringe access programs and providing technical assistance and financial support. With recent outbreaks of HIV linked to injection drug use in Kentucky, Ohio and Massachusetts, it is imperative that we expand access to this low cost, highly effective intervention. IDSA and HIVMA also 2 support safe consumption sites as venues to provide supervised and hygienic access to sterile equipment for individuals who inject drugs that also provide access to overdose management and prevention, screening for infectious diseases, health education, and linkage to opioid addiction treatment and other medical care. This public health crisis demands innovative and comprehensive responses that employ all available tools to reduce harms and connect individuals with substance use disorder to effective healthcare and treatment.

Take steps to evaluate the magnitude of the impact of infective endocarditis and other infections that are complications of injection drug use. Generate national and regional data to help inform the development of prevention and treatment programs:

The rates of infective endocarditis are increasing dramatically among people who inject drugs, but no public health system is in place to monitor this condition. National data to evaluate the scope of the problem is urgently needed to help affected communities identify outbreaks earlier. This is critical because HIV and HCV are often asymptomatic for years, but infective endocarditis will cause hospital admission in a matter of days or weeks due to the severity of symptoms. Our members report increasing morbidity and mortality rates due to infective endocarditis among young adults who inject drugs. The associated healthcare expenditures are significant, with costs reaching \$5 million annually for opioid use disorder patients being reported by one hospital. We urge CDC to continue evaluating appropriate methods for monitoring and analyzing trends in infective endocarditis and other bacterial infections. Such data will help identify outbreaks early and inform more effective prevention and treatment interventions. IDSA and HIVMA support legislation currently considered in Congress that would authorize \$40 million in new funding for CDC to increase capacity for conducting surveillance on HIV,

viral hepatitis and infective endocarditis as well as to expand clinician training, including for ID and HIV providers.

Ensure an adequate and qualified healthcare workforce by expanding access to loan forgiveness programs to healthcare providers caring for individuals with substance use disorder and related infectious diseases. Leverage telehealth to improve access to expert HIV and ID care and substance use treatment. Work with the Substance Abuse and Mental Health Services Administration to provide HIV and ID providers with the training and supports necessary to provide medication-assisted treatment (MAT) to patients with HIV and other infectious diseases who also have substance use disorders:

The pressing need for a sufficient ID and HIV workforce continues to grow in response to emerging infections and ongoing public health epidemics including the opioid crisis. Yet, fewer physicians are entering fields of ID and HIV medicine largely due to significant medical school debt. The average medical school debt rests at \$200,000. This burden places tremendous pressure on young physicians to pursue more lucrative careers in medicine. Alarmingly, there has been a 20 percent decline in individuals pursuing ID fellowship training over the past five years, and the CDC predicts a serious shortfall in HIV providers by 2019.

To build the necessary workforce capacity for the opioid epidemic, we support bills being considered in Congress that would expand loan forgiveness for healthcare providers including infectious disease and HIV clinicians who care for individuals with substance use disorder. We also continue to recommend the designation of Ryan White-funded clinics as approved sites for the National Health Service Corps program to incentivize physicians-in-training to consider working at Ryan White clinics, all of which serve vulnerable and underserved populations.

Telehealth programs such as Project ECHO have also demonstrated effectiveness at increasing provider knowledge and improving patient outcomes. We urge HRSA to increase support for these programs and work with the Centers for Medicare and Medicaid Services to ensure adequate reimbursement for the range of services and associated consultation and preparation that can be provided by telehealth.

ID and HIV providers stand squarely at the intersection of infectious diseases and the opioid epidemic. They are a critical and logical resource to build capacity and increase access to MAT. Limited physician education and stigma are barriers to prescribing medical treatment for addictive diseases. Limited reimbursement for treatment and essential supportive services, such as care management, is a major obstacle to expanding MAT. We urge HRSA to provide greater access to training in addiction medicine and other supportive resources, including guidance to support the integration of MAT into ID/HIV clinical practices through the AIDS Education and Training Centers and other programs. We also urge exploration of mechanisms to provide adequate reimbursement for provision of services necessary to treat addictive diseases.

Leverage the HRSA Ryan White HIV/AIDS Program and its successful model for treating HIV and serious co-occurring conditions to ensure that people with HIV are effectively treated for substance use disorders and to build capacity to serve

individuals with substance use disorders not yet infected with HIV who need treatment for viral hepatitis and other infectious diseases:

Since 1990, Ryan White-funded clinics have created and sustained the public health infrastructure necessary to provide the kind of comprehensive care required to successfully treat a complex chronic infection like HIV, while managing serious coexisting conditions in a patient population challenged by low income, unstable housing, lack of access to transportation, and high rates of substance use and mental health disorders. Over the last six years, viral suppression rates for Ryan White patients increased from 70% to 85% despite level funding, demonstrating the program's effectiveness. Ensuring access to substance use and mental health treatment for the large percentage of patients in need is one of the biggest challenges faced by Ryan White-funded sites. This existing national infrastructure with multi-disciplinary care supported by the Ryan White Program should be leveraged by prioritizing the clinics for non-Ryan White funding to expand capacity for substance use treatment, case management and care coordination for individuals not yet infected with HIV but who need treatment for viral hepatitis and other infectious diseases.

Thank you for your consideration of our views. Please call on us as a resource as the Committee considers how to enhance the federal response to the infectious diseases consequences of the opioid crisis. We can be reached through HIVMA senior policy manager George Fistonich at <u>gfistonich@hivma.org</u>, IDSA program officer for public health policy Colin McGoodwin at <u>cmcgoodwin@idsociety.org</u>, and PIDS executive director Christy Phillips at <u>cphillips@idsociety.org</u>."

Bruce Richman, JD, EdM

Founder and Executive Director Prevention Access Campaign (PAC)

Mr. Richman returned to CHAC's earlier discussion on the role of HIV disclosure in TasP messaging. PAC emphasizes the moral imperative for all PLWH to disclose their HIV status to ensure that their sexual partners are not harmed. PLWH with a UVL are encouraged to educate their sexual partners on their inability to transmit HIV, but PAC consistently reiterates the need to consider the interpersonal and legal consequences related to HIV disclosure.

Mr. Richman questioned whether CDC's recipients and sub-recipients will be required to use or have the option of using "effectively no risk," "extremely low to no risk," or a "negligible risk" in their TasP communication and training materials that are supported by CDC prevention funds. He also requested clarification on the ability of the TasP messages to address stigma and criminalization issues because all three risk statements convey that PLWH still have a low risk of transmitting HIV.

Dr. Mermin made several comments in response to Mr. Richman's questions. First, CDC's dissemination of TasP messages will be accompanied by clear guidance to its recipients and sub-recipients. Second, the participants in CDC's message testing study overwhelmingly preferred "extremely low to no risk," but some CHAC members and external stakeholders did not support this terminology.

Dr. Mermin acknowledged that the actual wording of the TasP messages might need to be slightly revised for specific audiences prior to national implementation, but the solid data collected by CDC to support these messages are consistent and have not changed. Moreover, CDC hopes that the HHS Panel on ART Guidelines for Adults and Adolescents will develop and release standardized clinical practice recommendations on the use of TasP messages. Most notably, the availability of department-wide guidelines will assist the HHS agencies in rapidly and easily resolving confusing or inconsistent TasP terminology.

Dr. Brooks added that at the non-federal level, a critical component of the U=U Campaign is to restore dignity and self-determination to PLWH. At the federal level, the HHS agencies will make every effort to clearly communicate the risk statements in the TasP messages. For example, CDC will use its rigorous message testing data to convey that no HIV transmissions were observed in the TasP study populations.

CHAC Treatment as Prevention Workgroup Report

Amy Leonard, MPH

Senior Director of Public Health Services Legacy Community Health Services CHAC Member & Workgroup Chair

Ms. Leonard reported that the TasP Workgroup drafted a letter in November 2017 for the CHAC Co-chairs to finalize, sign, and submit to Mr. Eric Hargan, the Acting HHS Secretary. The letter included the following language: "The CHAC members strongly recommend that CDC and HRSA, along with other HHS federal agencies, promptly provide guidance to the field (inclusive of providers, advocates, frontline staff, and others) about integrating TasP messaging into HIV prevention and care services."

Ms. Leonard pointed out that the CDC and HHS/OHAIDP updates on TasP presented by Drs. Stryker and Wolitski, respectively, during the current meeting satisfied CHAC's recommendation to the Acting HHS Secretary. As a result, the TasP Workgroup has fulfilled its charge and is dissolved at this time.

Ms. Fukuda asked the participants to join her in applauding Ms. Leonard for her leadership of the TasP Workgroup over the past year. The workgroup members also were commended for their important contributions to this effort.

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 agenda items on the first day of the CHAC meeting, including the overviews, updates, panel presentations, and key outcomes from CHAC's discussions. She noted two topics that might warrant CHAC's formal action during the Business Session on the following day.

- CHAC expressed strong support to form a new workgroup that would be charged with proposing language on RWHAP reauthorization to submit to HRSA/HAB for consideration.
- CHAC will consider the multiple presentations that were made by the federal agencies and SSPs in the field on their ongoing efforts to respond to the national opioid crises. CHAC will revisit its discussion on the opioid crisis during the Business Session to determine whether to take a vote and submit a formal recommendation to the HHS Secretary or establish a new workgroup to address this issue in more detail.

Ms. Fukuda pointed out that in addition to these two topics, the CHAC members also are free to place formal motions on the floor for other issues during the Business Session and call for CHAC's vote.

With no further discussion or business brought before CHAC, Ms. Fukuda recessed the meeting at 5:10 p.m. on May 9, 2018.

Opening Session: May 10, 2018

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 and *ex-officio* members 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 17 voting members and *ex-officio* members in attendance (or their alternates) constituted a quorum for CHAC to conduct its business on May 10, 2018. He reconvened the proceedings at 8:49 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. She highlighted the key outcomes from the overviews, updates, panel presentations, and CHAC's discussions on the first day of the meeting. She noted that the updates on the second day of the meeting would include the CHAC workgroup reports and a panel presentation by DASH and its recipients on adolescent and school health activities in the field. In addition to proposing future agenda items, she emphasized that a significant portion of the Business Session likely would focus on determining CHAC's formal role in the national opioid crisis.

CHAC School-Aged LGBTQ Youth Health (SALYH) Workgroup Report

Amy Leonard, MPH

Senior Director of Public Health Services Legacy Community Health Services CHAC Member & Workgroup Co-chair

Ms. Leonard reported that the SALYH Workgroup will continue to regularly convene meetings to review new data from several sources, including the Gay, Lesbian & Straight Education Network (GLSEN) and the Youth Risk Behavior Surveillance System (YRBS). The workgroup will use the findings from its data review to draft recommendations on LGBTQ youth health for CHAC's consideration and formal approval during the November 2018 meeting.

Ms. Leonard was pleased that Dr. Belzer and Mr. Hursey announced their interest in joining the SALYH Workgroup as new members. The CHAC Committee Management Specialists, CDR Holly Berilla at HRSA and Ms. Margie Scott-Cseh at CDC, will ensure that the two new members are added to the workgroup's upcoming meeting schedule and are provided with materials from the workgroup's previous meetings.

Ms. Fukuda announced that Dr. Mermin distributed a letter with CDC's detailed responses to CHAC's recommendations to improve the health and well-being of young people who are LGBTQ. The letter was dated May 8, 2018 and was distributed to the CHAC members for review.

CHAC Hepatitis C Workgroup Report

Peter Havens, MD, MS Pediatric Infectious Disease Specialist Children's Hospital of Wisconsin CHAC Member & Workgroup Co-chair

Advice Requested from CHAC by the HCV Workgroup:

1. What is the best approach for CHAC to provide support to CDC to advance the implementation of the workgroup's HCV recommendations?

Dr. Havens reported that after CHAC's formal approval of the recommendations by the HCV Workgroup during the October 2017 meeting, CHAC submitted a letter to CDC leadership on December 4, 2017. CDC confirmed its receipt of CHAC's letter on December 21, 2017. CHAC's seven HCV recommendations to CDC are highlighted below.

- CDC should issue guidance to encourage universal HCV screening of pregnant women in the United States.
- CDC should issue guidance to support HCV RNA testing of exposed infants at 1-2 months of age. Similar guidelines exist for infants who are perinatally exposed to HIV.
- CDC should issue guidance to support HCV antibody testing with reflex HCV RNA testing to identify individuals in need of treatment (e.g., <u>Recommended Testing</u> <u>Sequence for Identifying Current HCV Infection</u>).

- CDC should gather further surveillance data on HCV infection, including expanded data on women of childbearing potential and infants.
- CDC should use surveillance and other data to inform operational activities around HCV prevention and treatment.
- CDC should devote resources to exploring effective linkage to care strategies for HCVinfected mothers and exposed infants, including substance use disorder treatment services.
- CDC should advocate for the removal of artificial barriers to treatment (e.g., liver fibrosis scores, drug abstinence, or requirements for specialist providers).

In its response, CDC asked Dr. Mermin to review CHAC's letter and HCV recommendations, discuss the letter with his HRSA counterpart, and provide a response. Dr. Mermin's detailed responses to CHAC's seven HCV recommendations were included in a letter dated May 8, 2018. The letter was distributed to the members for review. CDC announced its plans to prioritize the development and release of new guidelines for universal HCV testing during pregnancy and expanded HCV recommendations for the general adult population.

Sarah Schillie, MD, MPH, MBA

Medical Epidemiologist, Division of Viral Hepatitis Centers for Disease Control and Prevention

Dr. Schillie described CDC's next steps and timelines to prioritize the development and release of its new HCV recommendations. DVH will hire a new staff member to perform the systematic literature review as part of CDC's standard guideline development process (30-40 days). The new DVH staff member will complete the systematic literature review (approximately three months). The findings will be used to draft an *MMWR* article with the HCV guidelines (two months). The document will go through CDC clearance. After the CDC clearance process is completed, the HCV guidelines will be submitted to the *MMWR* for publication as official CDC recommendations.

CHAC STD Workgroup Report

Bradley Stoner, MD, PhD Associate Professor of Medicine

Washington University School of Medicine CHAC Member & Workgroup Co-chair

Advice Requested from CHAC by the STD Workgroup: 1. What additional STD-related tasks should the workgroup consider for the future?

Dr. Stoner reported that the STD Workgroup includes 17 subject-matter experts from public and private sectors who were convened to review and provide input on CDC's draft *Recommendations for Providing Quality STD Clinical Services*. The workgroup began fulfilling its charge by holding a series of teleconferences from August-September 2017 to conduct an indepth analysis of the guidelines. The workgroup presented a report of its findings to CHAC during the October 2017 meeting. CHAC formally approved the workgroup's report. The workgroup looks forward to CDC's update on its next steps to finalize and publish the STD Clinical Services Guidelines.

The STD Workgroup sent a letter on the STD epidemic to the CDC Director and the HRSA Administrator, but the agencies have not yet sent a response to CHAC. The letter emphasized the need for STDs to be recognized as an urgent public health threat.

The STD Workgroup completed its charge and has not convened any teleconferences over the past few months. However, the workgroup is interested in retaining its membership and shifting its focus to congenital syphilis. Most notably, the workgroup is proposing a new charge to assist CDC in its efforts to promote congenital syphilis screening and prevention, particularly in the context of serologic testing during pregnancy.

The STD Workgroup is aware of concerns that have been raised regarding the typical practice of bundling third-trimester HIV testing and rapid plasma reagin (RPR) for syphilis. The workgroup's position is that RPR testing should be performed at 28 weeks rather than 32 weeks of pregnancy to identify the acquisition of syphilis much earlier. In its new charge, the workgroup proposes to review the literature to determine the extent of the problem and draft recommendations for CHAC's consideration and formal approval. The workgroup also welcomes the opportunity to continue to provide guidance to CDC on its portfolio of STD prevention activities.

Gail Bolan, MD

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

Dr. Bolan was pleased to report that DSTDP has thoroughly reviewed and compiled the findings of the STD Workgroup. She confirmed that the comments and suggestions by the workgroup greatly enhanced and improved CDC's draft *Recommendations for Providing Quality STD Clinical Services*. She thanked all of the workgroup members for their outstanding efforts in this regard.

Dr. Bolan announced that she expects to receive the final draft of the STD Clinical Services Guidelines by the end of May 2018 and initiate the CDC clearance process. However, the guidelines likely will not be published in the *MMWR* until early 2019 because DSTDP recognizes the need to obtain wider input from multiple audiences. For example, DSTDP recently presented the draft guidelines at the NCHHSTP "Primary Care and Public Health: Partners in Prevention" meeting that was convened on May 7-8, 2018. DSTDP received feedback from several national primary care organizations that were in attendance, but none of the leaders of these groups had knowledge of the existence of the guidelines. As a result, DSTDP will host a webinar to obtain broad input on the guidelines from the general public.

Dr. Bolan fully supported the STD Workgroup's proposal to maintain its membership and undertake a new charge to assist CDC in addressing congenital syphilis. She identified two major areas in which DSTDP would welcome the workgroup's assistance and expertise. First, the *Sexually Transmitted Diseases Treatment Guidelines* need to be updated due to its role as one of CDC's flagship documents. However, the lengthy document includes multiple chapters and requires subject-matter expertise from various disciplines to update. To reduce the burden of this effort, DSTDP will take a "living document" approach by only updating the sections of the guidelines that require revisions.

Second, a key recommendation in the CDC Syphilis Action Plan was for DSTDP to update the *Congenital Syphilis Prevention and Control Guidelines* with more recent data. The document has not been revised since 1988.

CHAC HIV and Aging Workgroup Report

Richard Aleshire, MSW

HIV Client Services Program Manager Washington State Health Department CHAC Member & Workgroup Co-chair

Michael Saag, MD

Professor, UAB Center for AIDS Research University of Alabama at Birmingham School of Medicine CHAC Member & Workgroup Co-chair

Advice Requested from CHAC by the HIV and Aging Workgroup:

- 1. What is CHAC's feedback on the workgroup's proposed clinical assessments for aging HIV patients?
- 2. What is CHAC's feedback on the process and goals of these clinical assessments?

Mr. Aleshire and Dr. Saag reported that the HIV and Aging Workgroup engaged in extensive discussions to streamline and clarify its charge. The workgroup did not reach full consensus on its current charge because several members were in favor of extending their efforts beyond the scope of CHAC's charter by addressing broader, unique age-related issues as part of a research agenda.

The workgroup generally agreed to address two key issues in its charge: (1) determine the need for clinical assessments of aging HIV patients and (2) translate the clinical assessments into recommendations for HRSA/HAB to consider implementing in RWHAP clinics. However, the workgroup acknowledges the need to further refine its charge. Most notably, the workgroup benefitted from Mr. Aleshire's firsthand experience and perspectives as a PLWH for 30 years. For example, aging PLWH typically are uncertain whether their current health status is related to the normal aging process versus HIV, such as the long-term effects of taking HIV medications.

Dr. Saag presented the HIV and Aging Workgroup's preliminary draft recommendations on clinical tests that RWHAP clinics can perform for aging HIV patients. A clinical needs assessment for aging HIV patients can be readily performed in RWHAP clinics with the same approach that is used in geriatric clinics or centers. However, a decision is needed on the age at which a clinical needs assessment should be performed on aging HIV patients.

General cognitive assessments include basic questions to determine the patient's thinking capacity; brief neurocognition testing; and referral for formal, more in-depth neurocognition testing if the results are positive. Frailty and mobility assessments include an evaluation of the patient's falling episodes, sit/stand capacity, walking speed, and balance.

RWHAP clinics currently are implementing cardiovascular risk reduction interventions for their HIV patients at all ages. A general assessment includes diet, weight, exercise, family history, and smoking status; cessation programs for smokers; blood pressure control; statin use to lower

cholesterol; and aspirin use to reduce the risk of heart attack and stroke. However, the use of Abacavir in HIV patients is controversial.

RWHAP clinics currently are performing cancer screening of their HIV patients. Depending on the patient's gender and age, the cancer screening tests include breast screening, including transgender individuals; Pap smears where indicated; colonoscopies; prostate-specific antigen tests to detect prostate cancer; skin examinations to detect melanoma; and periodic urinalyses to detect hematuria (i.e., blood in the urine). Routine use of computed tomography scans of the chest to detect early lung cancer lesions in long-term smokers has been a longstanding debate in the general medical literature.

STD screening includes an assessment of sexually active people. Routine STD screening for aging HIV patients should be the same as for the general HIV population. A nutrition assessment includes a dietary assessment and weight reduction programs. This assessment should be performed for aging HIV patients, particularly since obesity rates continue into late adulthood. A sleep assessment includes an evaluation of the duration and quality of sleeping, regular snoring, and the presence or absence of sleep apnea. Sleep studies show that sleep apnea becomes a more common condition as people age.

RWHAP clinics currently address polypharmacy (i.e., the use of four or more medications) and drug-drug interactions that can impact the quality of life. Polypharmacy is more common in people over 65 years of age than in any other age group. This assessment focuses on the adverse effects or complications of medications; dosing or overdosing of medications; the long-term effects of HIV medications; and opioid use and reduction.

A mental health assessment addresses the patient's feelings of an accelerated aging process, depression, demoralization, isolation, and loneliness. A substance use/alcohol use assessment includes referrals to treatment or interventions if problems are identified. An assessment of daily living activities is unique to older patients. This assessment includes the patient's budget management or fiscal competence; ability to readily access and use the bathroom; bladder and bowel continence; ability to prepare and eat meals; and ability to walk.

A home safety assessment includes a home visit, when indicated, and occupational therapy. A domestic/interpersonal violence assessment (e.g., elder abuse) addresses the legal reporting requirements that are mandated by individual states. A caretaker assessment focuses on the individual caretaker, the frequency of their home visits, the availability of support systems, and the potential for "caretaker burnout."

Based on CHAC's guidance, the HIV and Aging Workgroup will draft a resolution on "feasible" clinical assessments of aging HIV patients that HRSA/HAB should consider implementing in RWHAP clinics. The workgroup will present the draft resolution during the November 2018 meeting for CHAC's review, discussion, and formal vote.

CHAC DISCUSSION: HIV AND AGING WORKGROUP REPORT

The CHAC members provided input in response to the workgroup's request for feedback on its next steps.

• Dr. Taylor advised the workgroup to address an additional issue in its ongoing efforts to refine its charge. The workgroup should evaluate the advantages and disadvantages of

providing treatment and care to aging PLWH by provider type. For example, RWHAP clinic providers have the highest level of expertise in HIV treatment and care, but the RWHAP budget is not maintaining pace with its client population because PLWH who remain in care are living longer. Primary care physicians prioritize the treatment and care of chronic illnesses and basic medical conditions in their brief patient visits and typically do not address HIV or other infectious diseases. Geriatricians specialize in providing treatment and care for age-related conditions, but these providers have no training, skills, or experience in HIV.

 Dr. Mera encouraged the workgroup to develop practical recommendations on the use of available screening tools to detect defined conditions in PLWH at specific ages and time points in their lifespans, such as cognitive dysfunction or motor dysfunction.

The federal agencies provided several comments in response to the HIV and Aging Workgroup report and CHAC's discussion.

- Dr. Cheever provided feedback on two key issues. First, she thanked the workgroup for revising its charge to be clearer, much more focused, and better aligned with CHAC's charter to advise HRSA on treatment and care issues of PLWH. Second, she expressed her support of Dr. Taylor's suggestion for the workgroup to conduct an evaluation on the provision of treatment and care to aging PLWH by provider type. Based on her personal medical experience, for example, geriatricians generally are not primary care physicians in many healthcare markets and typically conduct a one-time assessment to determine the frailty or other health issues of elderly patients. She also agreed that efforts are needed to build a strong HIV knowledge base in the geriatrician community.
- Dr. McCray was in favor of Dr. Mera's proposal to use available screening tools over the lifespans of PLWH. For example, clinical data have demonstrated that PLWH should be screened at younger ages than people with an HIV-negative status to prevent certain conditions. Most notably, the inability to routinely screen young PLWH for glucose intolerance can lead to the development of severe onset of adult diabetes as these people age.
- Ms. Dempsey provided guidance to the workgroup in three major areas.
 - The workgroup was established in direct response to recommendations by a panel that was convened during the November 2016 CHAC meeting. The panelists included PLWH who were 50 years of age and older or long-term survivors of HIV. The panelists emphasized the importance of giving equal attention to the health care, mental health, and support needs of the aging PLWH population. The workgroup is commended for its efforts in including a mental health assessment of aging PLWH in its preliminary draft recommendations. Ms. Dempsey noted that Ms. Carolyn Massey, Executive Director of Older Women Embracing Life, Inc., served on the panel and was a 23-year survivor of HIV at the time of the November 2016 CHAC meeting. She regrettably announced that Ms. Massey recently passed away, but HIV was not her cause of death.
 - The workgroup should recommend the development and dissemination of tools, TA materials, and other resources to assist RWHAP clinic providers in becoming more familiar with and addressing the unique health issues of aging HIV patients.

- The NIH Women's Interagency HIV Study is including balance, mental acuity, and other types of tests for older women living with HIV. The workgroup should review the data from this study to inform its next steps.
- Dr. Paul Gaist is the CHAC *ex-officio* member for NIH. He advised the workgroup to also recommend a psychosocial assessment to determine the life experiences and ongoing stressors of aging HIV patients. Providers can use the results of a psychosocial assessment to develop an effective care regimen for aging HIV patients and recommend social supports or other resources to address their needs. Moreover, the workgroup should review published studies in the literature that have documented an increase in sexual activity and HIV risk with older age. Overall, providers should be educated on older age as an important transition in the lifespan regardless of whether the person is living with or without HIV.

Ms. Fukuda concluded the discussion by advising the HIV and Aging Workgroup to thoughtfully consider the comments and suggestions by the CHAC members and the federal agencies. During the November 2018 CHAC meeting, the workgroup should be in a position to present revised clinical assessments of the aging PLWH population or a clear plan of its next steps. She thanked the workgroup members for their outstanding efforts to date in addressing this complex issue and their ongoing commitment to improving the treatment and care of the aging PLWH population.

Panel Presentation: Sexual and Gender Minority (SGM) Youth Health

Kathleen Ethier, PhD

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

Advice Requested from CHAC by CDC/DASH:

1. What steps can DASH take to better describe strategies for Safe and Supportive Environments (SSEs) and strengthen its messaging on the implications of these activities on youth health outcomes?

Dr. Ethier reported that the panel presentation would cover two major areas. First, CHAC submitted a letter to CDC on January 10, 2018 with its SALYH recommendations to improve the health and well-being of LGBTQ youth. DASH would highlight its ongoing activities and future efforts to respond to these recommendations. Second, school districts in the field would provide their perspectives on the progress and challenges in implementing school-based policies and practices to address SGM youth health.

For the first part of the panel presentation, Dr. Ethier presented DASH's responses to the six SALYH recommendations that CHAC submitted to CDC on LGBTQ youth.

CHAC Recommendation 1: Prioritize, invest in, and advocate for professional development of middle and high school teachers regarding LGBTQ students, their health, student rights, and needs

DASH released NOFO 1308, "Promoting Adolescent Health Through School-Based HIV/STD Prevention and School-Based Surveillance," as a five-year CoAg that will end on July 31, 2018. State/local education agencies (SEAs/LEAs) and non-governmental organizations (NGOs) were

funded to provide educator professional development to ensure high quality HIV and STD prevention to all youth, including SGM youth.

The American Psychological Association used a portion of its funding award for SEAs/LEAs to attend the Respect Workshop. The workshop aimed to improve the knowledge, attitudes, and skills of school staff to make schools safe and supportive for LGBTQ students. The workshop also provided the participants with information on direct services that can be delivered and promoted the implementation of school-based policies and practices that address school climates, school connectedness, peer and family support, access to community resources, and inclusive sex education.

DASH recently released NOFO 1807, "Promoting Adolescent Health Through School-Based HIV Prevention," as a five-year CoAg that will begin on August 1, 2018. The new CoAg will build the capacity of SEAs/LEAs to provide professional development that will ensure health education instruction meets the needs of all youth, including LGBTQ youth.

CHAC Recommendation 2: Create Gay-Straight Alliances (GSAs) in middle and high schools

DASH data show that its funded SEAs/LEAs have made a great deal of progress in this area under NOFO 1308. Selected school districts that recommend or require schools to have a GSA increased from 58.3 percent in the fall of 2014 to 85 percent in the fall of 2017. Selected schools that have a GSA increased from 47.6 percent in the fall of 2014 to 73.7 percent in the fall of 2017. SEAs/LEAs will use their new funding awards under NOFO 1807 to continue to support GSAs in middle and high schools.

CHAC Recommendation 3: Develop LGBTQ-enumerated

anti-discrimination and anti-bullying policies and programs

DASH reviewed its information and other materials that are provided to school districts and the general public. Based on this review, DASH revised infobriefs that are posted on the CDC.gov website to include the most up-to-date research summaries on bullying. Moreover, several scientific papers with YRBS data on state policies and practices currently are undergoing the CDC clearance process. DASH will continue to make every effort to ensure that its recommendations to school districts on supporting students, including LGBTQ students, are based on the most recent data.

CHAC Recommendation 4: Create LGBTQ-inclusive curricula,

including sexual health curricula

DASH data show that its funded SEAs/LEAs have made tremendous progress in adopting and implementing quality sexual health curricula. From the fall of 2014 to the fall of 2017, selected school districts within funded SEAs that have adopted sexual health curricula increased from an average of 44.4 to 89.4 percent in middle schools and from an average of 46.2 to 88.3 percent in high schools. Over this same time period, schools within funded LEAs that have implemented sexual health curricula increased from 61 to 81 percent in middle schools and from 83 to 91 percent in high schools.

DASH is uncertain of the extent to which its funded SEAs/LEAs have adopted and implemented sexual health curricula that are inclusive of LGBTQ students. Most notably, the adoption of curricula is at the discretion of LEAs at the local level. Moreover, DASH uses the Health Education Curriculum Analysis Tool (HECAT) to provide guidance, direction, and assistance to

SEAs/LEAs in conducting a clear, complete, and consistent analysis of quality health education curricula. However, LGBTQ inclusiveness is not a part of the HECAT process at this time. DASH will apply the lessons learned and experiences of the current SEAs/LEAs under NOFO 1308 to enable the new SEAs/LEAs under NOFO 1807 to make improvements in this area.

CHAC Recommendation 5: Provide linkages between school and community-based LGBTQ-reflective and youth-friendly health care services

DASH data show that its funded SEAs have made outstanding progress in this area. From the fall of 2014 to the fall of 2017, selected districts that provide linkages substantially increased. Among 18 funded SEAs, the development of referral guides increased from a median of 72 to 93 percent and the development of written procedures for referrals to offsite youth-friendly health providers increased from a median of 28 to 48 percent. However, DASH acknowledges the need to conduct a rigorous evaluation of the community-based referral sites, in general, and the extent to which these sites are LGBTQ-friendly, in particular.

CHAC Recommendation 6: Offer comprehensive and LGBTQ-inclusive suicide prevention policies and programs

DASH does not have a line-item in the CDC budget to support suicide prevention activities. However, DASH recognizes the importance of addressing suicide prevention and acknowledges the critical role of schools in responding to and preventing youth suicide. Compared to heterosexual youth, LGB youth are three times more likely to contemplate suicide and five times more likely to have attempted suicide.

The CDC Division of Violence Prevention developed and released *Preventing Suicide: A Technical Package of Policy, Programs and Practices*, but this publication is not targeted to schools and youth. As a result, efforts are underway to adapt the suicide technical guidance document to specifically address adolescent and school health issues. DASH will continue to collaborate with and obtain advice from the CHAC SALYH Workgroup on strengthening its focus on suicide prevention for LGBTQ youth.

In addition to responding to CHAC's six SALYH recommendations to CDC, DASH also has been conducting other adolescent and school health activities in three major areas. First, an *MMWR* article with the tremendous 2017 YRBS dataset will be released to the public on June 14, 2018. Due to the extremely large size of the 2017 YRBS report, DASH also will issue a smaller, more focused companion document to specifically target four risk areas for youth: high-risk substance use, sexual behavior, violence victimization, and mental health/suicide. Moreover, the summary of SGM youth data in the YRBS report will highlight ongoing disparities in this population and emphasize the need for increased assistance to and support of this subset of youth in schools.

Second, DASH is partnering with the Human Rights Campaign due to its collection of a much more focused national dataset on LGBTQ youth. Third, DASH will continue to collaborate with GLSEN due to the upcoming release of its new School Climate Survey in the fall of 2018. DASH, the Human Rights Campaign, and GLSEN will conduct joint presentations of their three complementary datasets.

Dr. Ethier concluded her portion of the panel presentation by thanking CHAC for providing CDC with thoughtful and helpful guidance. She confirmed that DASH and its recipients will continue to apply CHAC's recommendations in the new five-year CoAg to further improve the health and

well-being of LGBTQ youth. She introduced the panel of guest speakers and opened the floor for their overviews.

Rachel Miller, MEd

San Diego Unified School District (SDUSD)

Ms. Miller presented a slide with several images to illustrate the programs and community partnerships that SDUSD has built over the past five years of the CoAg. SDUSD used its 1308 funding award from CDC/DASH to create SSEs for LGBTQ students. Some of these programs are highlighted as follows. Although some GSA Clubs were established in schools prior to 2013, the number of these clubs in schools has greatly increased since that time. GSAs were in approximately 50 percent of high schools and no middle schools in 2013, but are now in all SDUSD high schools and middle schools (or nearly 60 schools).

Research has shown that GSA Clubs serve as SSEs to all students who are victims of bullying and harassment, including LGBTQ students. Other studies have shown that LGBTQ students who do and do not join GSA Clubs feel safer on campus. Efforts are underway in SDUSD to increase the activity and visibility of GSA Clubs. Most notably, SDUSD elementary schools have expressed an interest in adapting the GSA Club model and implementing a diversity club or a support club on their campuses.

LGBTQ students have higher rates of victimization, bullying, harassment, and suicide, but are extremely reluctant to report these incidents directly to school staff. These data led SDUSD to create a district-wide online bullying reporting form for students, parents, or community members to anonymously report incidents as a victim or a witness. In addition to LGBTQ status, the form also includes options to report victimization, bullying, or harassment incidents based on race/ ethnicity, religion, body appearance, and other factors.

The bullying reporting form initially was piloted in one school and evaluated, but is now posted on all 226 SDUSD school websites as well as the district website. The completed reports are electronically transmitted to the school principal and two district offices to ensure that each incident is investigated and resolved. Moreover, the form has empowered students to report other incidents that occur beyond school property, such as sexual harassment and child abuse.

SDUSD implemented an LGBTQ-affirming sex education curriculum in middle/high schools in accordance with a California law that requires positive affirmation of different sexual orientations and gender identities as well as the exploration of gender roles and expectations. The SDUSD Board affirmed the adoption of the sex education curriculum in July 2017. The curriculum has been extremely well received by SDUSD teachers and students.

SDUSD is a participant of the "National OUT for Safe Schools" Campaign for school staff throughout the district, including custodial and transportation staff, to voluntarily wear a badge to show support for LGBTQ and all other students who need SSEs.



Students have reported feeling safer and more supported due to school staff wearing the badges on their campuses. However, SDUSD did not issue a press release or launch marketing efforts to widely publicize the National OUT for Safe Schools Campaign due to opposition from a vocal subgroup of the San Diego community. As a result, SDUSD launched a train-the-trainer program for school leaders to train and retrain their staff on general LGBTQ cultural competency. These initial trainings are now being supplemented by in-depth training from SDUSD's LGBTQIA+ Education and Advocacy staff.

Georgi Roberts, MLS

Brooke Sharples, MEd

Fort Worth Independent School District (FWISD)

Ms. Roberts reported that FWISD is a large urban school district in Fort Worth, Texas with a population of 86,000 students. Rigorous data were used to educate FWISD school principals and other leadership on disparities in extensive bullying, HIV, STDs, and teen pregnancy among LGBTQ students. The data showed that these factors impact academic achievement. After a thorough review of these data, FWISD leadership approved the rollout of supportive programs, curricula, and other resources for LGBTQ students.

FWISD used its 1308 funding award from CDC/DASH to collaborate with an NGO to train nurses, counselors, social workers, and teachers on addressing the specific needs and concerns of LGBTQ students. School staff has shown a great deal of support for the curricula and policies for LGBTQ students, but a small subgroup of the Fort Worth community has voiced strong opposition.

Ms. Sharples presented a slide with several images to illustrate FWISD's ongoing efforts to promote SSEs for LGBTQ students. Image 1 was a photograph of the "FWISD Ally" lanyard that represents the presence of trusted adults for all students, particularly those who are LGBTQ. The trusted adults provide support to students and make referrals to a nurse, social worker, or counselor if needed. The number of lanyards that are being worn in FWISD schools is rapidly increasing because the trusted adults repeatedly give their lanyards to interested students and obtain replacements. The students are asked to inform their peers of the availability of FWISD allies.

Images 2 and 3 included (1) a photograph of Ms. Roberts and Ms. Sharples during the Human Rights Campaign's fifth annual "Time to Thrive" Conference in February 2018 and (2) a quote and a photograph of an FWISD health teacher/coach during the Stonewall National Education Project Symposium in April 2018. The FWISD Ally lanyard was worn by staff at both of these national events to initiate dialogue on this important initiative.

Image 4 was a photograph of a handwritten poster to illustrate the components of a "safe school." The poster reflects the thoughts and perspectives of high school students who

participated in this exercise. FWISD also conducts the "safe school" activity with student teachers and student support services staff.

CHAC DISCUSSION: LGBTQ YOUTH

CHAC thanked DASH for providing detailed and thoughtful responses to its six SALYH recommendations that were submitted to CDC for consideration and action. Several members made additional suggestions for DASH to consider to improve these activities.

- Ms. Leonard confirmed that the CHAC SALYH Workgroup looks forward to continuing to collaborate with CDC, its recipients, and external partners in DASH's new five-year CoAg. She particularly thanked Drs. Mermin and Ethier for providing outstanding leadership at the federal level to support LGBTQ projects, curricula, and other resources at the state and local school district levels.
- Dr. Belzer urged DASH to address the socioeconomic disparities and cultural attitudes that serve as barriers to establishing GSAs in schools. For example, GSAs are much more likely to be formed in schools with predominantly White student populations than in schools with large African American or Latino student populations. Moreover, schools with large racial/ethnic minority student populations typically focus their efforts on concerns that are more of a priority than LGBTQ issues, such as high STD, teen birth, and poverty rates and low-income levels. He advised DASH to compile and provide the new recipients under NOFO 1807 with lessons learned and best practices to ensure that GSAs are widely established and maintained in all schools.
- Mr. Hursey reiterated that he looks forward to serving on the CHAC SALYH Workgroup as a new member. He noted two areas in which the workgroup should provide advice and guidance to DASH under the new five-year CoAg: (1) research on sexual violence among disempowered youth, particularly LGBTQ youth who are homeless or living with disabilities and (2) racial/ethnic disparities within SGM youth.
- Mr. Haverkate proposed several suggestions to refine DASH's adolescent and school health activities for all youth, including LGBTQ youth, based on his role as the *ex-officio* member for IHS.
 - DASH should conduct, collect data on, and widely disseminate the results of resiliency training for victims or potential victims of bullying.
 - DASH should review and utilize the findings of the 2015 U.S. Transgender Survey (USTS) as a key resource in its ongoing LGBTQ youth activities. The USTS is conducted by the National Center for Transgender Equality and is the largest survey of transgender people in the United States. Most notably, the 28,000 respondents to the 2015 USTS represented all 50 states, the District of Columbia, and U.S. territories. The USTS also serves as the best sample of American Indian/ Alaska Native (AI/AN) transgender people. IHS routinely uses USTS data to justify the rationale for outreach and other efforts to improve the health and well-being of LGBTQ youth in Indian Country.
 - DASH should expand the rich YRBS dataset to strengthen its focus on racial/ethnic minorities within SGM youth, but AI/AN youth also should be included in this effort.
 - SDUSD and FWISD both used a portion of their 1308 funding awards to implement programs for school staff to wear badges/lanyards to demonstrate

support for LGBTQ students. However, both school districts reported that small subgroups of the San Diego and Fort Worth communities, respectively, voiced opposition to providing resources for LGBTQ students. As a result, DASH should distribute clear guidance and effective strategies to prevent victimization, bullying, or harassment of teachers and other school staff that wear the badges/lanyards. DASH also should conduct an evaluation to obtain honest and critical feedback on whether educators are wearing badges/lanyards based on their actual support of LGBTQ students or "political/school-based pressure."

 DASH should place more emphasis on widely publishing the outcomes of LGBTQ initiatives that are conducted by its recipients. Most notably, HRSAfunded FQHCs, IHS-funded clinics, and hospitals typically have limited knowledge of and experience in addressing the sexual orientation or gender identity needs of youth. Moreover, clear linkages have been established to connect DASH-funded school districts to local sources of care for youth, but no relationships have been developed to translate these efforts from schools to healthcare centers.

Ms. Malaika Washington is a Lead Health Education Specialist at CDC/NCHHSTP. She was pleased to announce that other LEAs have used their 1308 funding awards from CDC/DASH to expand their badge/lanyard programs beyond teachers. For example, school resource officers, school-based health clinic staff, and police officers in New York City and the District of Columbia are wearing badges and lanyards to further support their ongoing interactions with LGBTQ youth.

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 facilitated a review of the business items that warrant CHAC's formal action at this time, follow-up discussion, or requests for future agenda items.

Business Item 1: Approval of the Draft CHAC Meeting Minutes

Ms. Fukuda entertained a motion for CHAC to approve two sets of minutes for the in-person meeting in October 2017 and the virtual meeting in February 2018. A motion was properly placed on the floor by Dr. Peter Havens and seconded by Dr. Bradley Stoner for CHAC to approve both sets of meeting minutes.

CHAC unanimously approved the Draft October 25-26, 2017, and the Draft February 22, 2018, Meeting Minutes with no changes or further discussion.

Business Item 2: New CHAC RWHAP Reauthorization Workgroup

Ms. Fukuda returned to CHAC's previous suggestion to establish a new RWHAP Reauthorization Workgroup and entertained a formal motion this regard.

Action	Description
Co-Chair's call	Mr. Richard Aleshire properly placed a motion on the floor for CHAC to establish a new RWHAP Reauthorization Workgroup that will be charged with proposing recommendations for submission to and consideration by the HHS Secretary and HRSA/HAB. Dr. Michael Saag seconded the motion.
Outcome of the vote	The motion was unanimously passed by 12 CHAC voting members.
Next steps	 CDR Holly Berilla and Ms. Margie Scott-Cseh will circulate an email to identify the CHAC members who will chair and serve on the new RWHAP Reauthorization Workgroup as members. Efforts will be made to engage Dr. Jennifer Kates and other CHAC members with policy expertise.

Business Item 3: New Resolution by the HCV Workgroup

Dr. Havens called for CHAC's formal support and endorsement for the HCV Workgroup to draft a new resolution regarding the integration of viral hepatitis services to close the gap between HCV antibody testing, diagnosis of the disease, and treatment. He proposed several topics that potentially will be covered in the workgroup's draft resolution.

- Integrated HCV testing, diagnosis, and treatment services should be targeted to jails and prisons. New approaches are needed to address the unwillingness or reluctance of correctional systems to use funds from their limited budgets to treat incarcerated people who are living with HCV.
 - The Federal Bureau of Prisons (BOP) should diagnose and treat HCV and provide HAV and HBV vaccination to its incarcerated populations.
 - CMS should issue a new policy that will allow people with short-term incarceration in local jails and state prisons to maintain their Medicaid benefits.
 - Representatives from the CMS HCV Medicaid Affinity Group should be invited to a future CHAC meeting to present its emerging recommendations, including Medicaid coverage of or restrictions for incarcerated populations.
- HRSA should establish a system in all FQHCs to diagnose and treat people living with HCV. HRSA should replicate the system based on the Cherokee Nation's HCV model program that includes key staff positions to address all stages in the HCV cascade: nurses, patient navigators, case managers, and CHWs. HRSA should promulgate HCV quality measures that would be directly linked to the funding awards of FQHCs.
- HRSA should routinely review the availability and delivery of HCV care in all FQHCs, particularly in rural areas. The performance of FQHCs should be measured based on

their efforts to advance toward the ultimate goal of implementing universal HCV screening.

Dr. Havens acknowledged that the BOP and CMS recommendations must be addressed to the HHS Secretary because CHAC is not chartered to directly advise these two federal agencies. He also noted that based on CHAC's formal approval of the draft resolution, the HCV Workgroup might be rebranded as the "Viral Hepatitis" Workgroup to account for its expanded focus on HAV and HBV.

Action	Description
Co-Chair's call	Ms. Dawn Fukuda properly placed a motion on the floor for CHAC to support and endorse the HCV Workgroup's proposal to draft a new resolution on the integration of viral hepatitis testing, diagnosis, and treatment services. Dr. Jorge Mera seconded the motion.
Outcome of the vote	The motion was unanimously passed by 12 CHAC voting members.
Next steps	 The HCV Workgroup will circulate the draft resolution to the CHAC membership via email for review and input. If FACA rules do not permit Federal Advisory Committees to vote electronically, the HCV Workgroup will call for CHAC's formal vote on the draft resolution during the November 2018 meeting.

Business Item 4: Presidential Advisory Council on HIV/AIDS (PACHA)

Ms. Hayes reported that in addition to serving as the CHAC *ex-officio* member for HHS/OHAIDP, she also is the Executive Director of PACHA. PACHA is not operating as a Federal Advisory Committee at this time, but a number of excellent applications were submitted in response to a call for new members that was issued in December 2017. Efforts are underway at the White House Office of Public Liaison to review and officially approve the new member applications and reseat PACHA in the near future. Moreover, high-level HHS officials and HIV partners in the field have voiced strong support to reestablish PACHA.

Ms. Fukuda proposed a motion for CHAC to send a letter to the HHS Secretary, with a copy to the HHS Assistant Secretary for Health, to reinforce its strong support of PACHA. CHAC will raise the following points in its letter.

- CHAC's affirmative statement on the importance of PACHA will be highlighted.
- The urgent need for the Administration to rapidly reseat the PACHA membership will be emphasized.
- The value of PACHA's contributions to high-level government officials, CHAC, and key stakeholders will be described.

Action	Description
Co-Chair's call	Ms. Dawn Fukuda properly placed a motion for CHAC to formalize and reinforce its support of PACHA in a letter to the HHS Secretary. Dr. Peter Havens seconded the motion.
Outcome of the vote	The motion was unanimously passed by 12 CHAC voting members.
Next steps	 Ms. Fukuda will consult with Ms. Hayes to obtain language on the diversity of the PACHA membership. CHAC's letter will emphasize the importance of representation by a broad range of constituencies during the call for PACHA nominations. Ms. Fukuda will draft and distribute the letter to the CHAC membership for review and comments. After the approval/clearance process is completed, the draft letter will be revised (if needed), finalized, placed on CHAC letterhead, signed by the CHAC Co-chairs, and submitted to the HHS Secretary.

Business Item 5: CHAC's Role in the Opioid Crisis

Ms. Fukuda asked the CHAC members to provide their insights and perspectives on establishing a new "Opioid Response Workgroup." The members extensively discussed a preliminary charge for the new workgroup and proposed potential topics for the workgroup to address.

- The workgroup's charge will be to conduct research, synthesize the available evidence, and recommend best practices to CDC and HRSA to address the opioid crisis in the context of HIV, viral hepatitis, and STDs.
- The workgroup's draft recommendations will focus on improving the existing CDC/HRSA/ SAMHSA interagency partnership; fully engaging other parts of HRSA outside of HAB (e.g., FORHP and the BPHC Health Center Program); and addressing the infectious disease consequences of the opioid crisis.
- Ms. Fukuda and Dr. Mera volunteered to serve on the new workgroup. If the workgroup continues to operate after their terms expire on November 30, 2018, however, they will be able to serve as external ad hoc members only. Other CHAC members also emphasized the need for IHS representation on the new workgroup.

Dr. Mermin noted that CHAC's preliminary charge for the new "Opioid Response Workgroup" is extremely broad and the proposed topics are vague. If a formal vote is taken to approve the establishment of the workgroup, he advised CHAC to specify a concrete charge, identify a limited number of high-priority focus areas, and clearly delineate key goals for CDC and HRSA to achieve. Based on Dr. Mermin's advice, the CHAC members proposed two priority areas for the new workgroup to address: (1) opioid overdoses and (2) the massive number of people who are diagnosed with HCV, but are not accessing treatment.

CHAC took no formal action on establishing a new "Opioid Response Workgroup" due to the inability of the members to clearly articulate and define a charge.

CHAC's further consideration and discussion of Dr. Mermin's guidance resulted in the members proposing a clearer charge and a more focused direction for the new opioid workgroup.

- The workgroup's charge will be to propose recommendations to CDC and HRSA on improving policies, infrastructures, environments, and support to establish and maintain comprehensive drug user health programs in states, including SSPs.
- The workgroup's recommendations will focus on TA, data collection, and other specific resources for CDC and HRSA to offer to states that do not currently support or have no interest in establishing SSPs.

CHAC agreed by general consensus to take the following actions.

- Mr. Peter Byrd, Dr. Jorge Mera, and Dr. Lynn Taylor will serve on the new workgroup as members.
- The new workgroup will appoint a chair; identify an appropriate name to reflect its focus on "drug user health policies and support;" and recommend best practices for this specific component of the opioid crisis.
- The new workgroup will consider Dr. Taylor's suggestions as a starting point in advising HRSA on the collection and dissemination of best practices for the care of drug-involved populations in RWHAP clinics as well as the delineation of best practices for creating a low-threshold environment. Most notably, "opioid-related best practices" in RWHAP clinics should include buprenorphine integration, onsite access to syringe services, flexible hours, same-day appointments, and wide availability of Naloxone.

Business Item 6: HCV Laboratory Research and Testing

Dr. Taylor reported that she recently reviewed the CHAC charter. Based on the language in the "Description of Duties" section, CHAC is authorized to advise the HHS agencies on viral hepatitis laboratory research. As a result, she called for CHAC's approval of a formal recommendation or the establishment of a new workgroup on HCV laboratory research, particularly to promote one-step HCV viral load diagnostic testing in the United States.

Dr. Havens fully supported Dr. Taylor's suggestion. He noted that HIV laboratory testing is not well understood. In a previous study, for example, NIH researchers did not understand that an HCV antibody-positive/HIV viral load-negative test result is equivalent to no infection in pregnant women and no mother-to-child transmission.

Dr. Mermin proposed an option to address the comments by Drs. Taylor and Havens. Instead of CHAC submitting a formal recommendation or establishing a new workgroup, a panel presentation on HCV laboratory research and testing will be convened during the November 2018 meeting.

Business Item 7: Future Agenda Items

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

Presenter	Agenda Item
To Be Determined	 Panel Presentation: Impact of the opioid crisis in rural communities in the context of HIV, viral hepatitis, and STDs. Potential topics to include: Investments by CDC and HRSA to address the three infectious diseases in rural areas and key outcomes of any assessments that have been conducted with these resources. Recent data on the epidemiology of the three infectious diseases in rural areas, including geographic mapping data as well as data on the alignment between funding for the three infectious diseases and the opioid crisis in rural areas. Existing care delivery systems to serve rural populations. Efforts by HRSA-funded FQHCs and SAMHSA-funded sites to address underserved populations in rural areas, particularly those in the top 220 most vulnerable counties in the country. Existing data-sharing agreements between CDC, HRSA, or SAMHSA and rural-based agencies (e.g., IHS and tribal clinics) and plans by the federal agencies to periodically publish the findings from these interagency datasets. After the panel presentation, CHAC will determine whether to draft a recommendation and call for a formal vote on the opioid crisis in rural communities in the context of HIV, viral hepatitis, and STDs. In the decision-making process, CHAC will consider the new NOFO that HRSA/FORHP will release in May 2018 to announce the availability of \$100 million in new funding to support rural communities with high rates of OUD.
CHAC Membership	 Follow-up Discussion: CHAC's role in launching a strong response to the opioid crisis in the context of HIV, viral hepatitis, and STDs CHAC's discussion will include an extensive review of existing model programs that potentially can be replicated: RWHAP, Cherokee Nation, U.S. Department of Veteran Affairs, and the CMS HIV Health Improvement Affinity Group and HCV Medicaid Affinity Group. These programs have a strong infrastructure, dedicated funding, and a demonstrated track record in screening, delivery of HIV or HCV treatment, and evaluation. After the follow-up discussion, CHAC will determine whether the new opioid workgroup should address this issue in its limited scope of "drug user health policies and support" or if separate, formal action is needed.
To Be Determined	 Panel Presentation: HCV Laboratory Research and Testing Overview by FDA on HCV diagnostics, including lower costs and the easier regulatory approval process. Overview by the CDC Viral Hepatitis Laboratory on the pipeline of future HCV diagnostics. Overview by a commercial company that has implemented HCV reflex testing. Overview of the positive impact of implementing the joint CDC/Association of Public Health Laboratories recommendations on HCV laboratory diagnostics.

Presenter	Agenda Item
Dr. Kathleen Ethier	 Panel Presentation: Ongoing activities by DASH and its recipients to address SGM youth health Update by a panel of DASH recipients on the lessons learned and experiences of their "badge/lanyard" initiatives as well as key outcomes from evaluations and analyses of data from these efforts. After the panel presentation, CHAC will determine whether these interventions have been effective, led to positive changes, and can be recommended to HRSA to promote in Health Centers as best practices. CHAC will identify its next steps and decide whether formal action is needed.
CHAC Workgroup Co-chairs	 The SALYH Workgroup will present draft recommendations on CDC's LGBTQ youth health activities based on its review of new data from GLSEN, YRBS, and other sources. The HCV Workgroup will call for CHAC's formal vote on its draft resolution on the integration of viral hepatitis services to close the gap between HCV antibody testing, diagnosis of the disease, and treatment. The STD Workgroup will report its initial progress on its new charge of assisting CDC/DSTDP in updating the Sexually Transmitted Diseases Treatment Guidelines and/or the Congenital Syphilis Prevention and Control Guidelines with more recent data. The HIV and Aging Workgroup will present its revised clinical assessments for the aging PLWH population or outline a clear plan of its next steps.

Closing Session

CHAC applauded the federal agencies and their recipients for their excellent and informative presentations over the course of the meeting. The members particularly thanked Drs. Mermin and Cheever for their ongoing leadership, support, and roles as strong champions of important community-based issues at CDC and HRSA, respectively.

Drs. Mermin and Cheever thanked the CHAC members for continuing to provide sound advice to CDC and HRSA to improve the national impact of their HIV, viral hepatitis, and STD prevention and treatment activities.

The next CHAC meeting will be hosted by HRSA on November 7-8, 2018, in Rockville, Maryland. The meeting will be open to members of the public via webinar and teleconference.

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 Dr. Marvin Belzer Dr. Peter Havens Mr. Devin Hursey Ms. Amy Leonard Dr. Jorge Mera Dr. Michael Saag Dr. Bradley Stoner Dr. Lynn Taylor

CHAC Members Absent

Ms. Debra Hauser Dr. Jennifer Kates Mr. Gregorio Millett Dr. Susan Philip Ms. Linda Scruggs

CHAC Ex-Officio Members Present

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

Dr. Steven Daviss Substance Abuse and Mental Health Services 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. Iris Mabry-Hernandez Agency for Healthcare Research and Quality

Dr. Richard Wild Centers for Medicare & Medicaid Services

CHAC Designated Federal Officers

Dr. Laura Cheever HRSA HAB Associate Administrator

Dr. Jonathan Mermin CDC/NCHHSTP Director

Federal Agency Attendees

Mr. Israil Ali (HRSA) Dr. Alice Asher (CDC) Ms. Carmen Ashley (CDC) Dr. Laura Bachmann (CDC) Dr. Grant Baldwin (CDC) Dr. Lisa Barrios (CDC) Mr. Greg Bautista (CDC) CDR Holly Berilla (HRSA) Dr. Gail Bolan (CDC) Dr. John Brooks (CDC) Dr. Laura Bull (CDC) Cecily Campbell, Esq. (CDC) Dr. Hazel Dean (CDC) Dr. Shanna Dell (CDC) Ms. Antigone Dempsey (HRSA) Dr. Brian Edlin (CDC) Dr. Kathleen Ethier (CDC) Dr. Monique Foster (CDC)

Dr. Jennifer Fuld (CDC) Ms. Anne Hanessian (HRSA) Ms. Heather Hauck (HRSA) Dr. Letha Healey (HRSA) Ms. Theresa Jumento (HRSA) Mr. Michael Lionbarger (CDC) Dr. Aaron Lopata (HRSA) Dr. Cynthia Lyles (CDC) Ms. Kristin Martinsen (HRSA) CAPT Tracy Matthews (HRSA) Dr. Eugene McCray (CDC) Mr. John Milberg (HRSA) Ms. Rebecca Payne (CDC) Ms. Natalie Brevard Perry (HRSA) Dr. Catherine Rasberry (CDC) Dr. Hilary Reno (CDC) Dr. Raul Romaguera (CDC) CDR Melanie Ross (CDC) Dr. Blythe Ryerson (CDC) Dr. Sarah Schillie (CDC) Ms. Margie Scott-Cseh (CDC) CDR Antoine Smith (HRSA) Ms. Gerlinda Somerville (SAMHSA) Dr. Judith Steinberg (HRSA) Dr. Riley Steiner (CDC) Dr. Jo Stryker (CDC) Dr. Eyasu Teshale (CDC) Ms. Malaika Washington (CDC) Dr. Paul Weidle (CDC) Ms. Amber Wilson (NIH) Dr. Richard Wolitski (HHS/OHAIDP) Ms. Sara Zeigler (CDC)

Guest Presenters/ Members of the Public

Ms. Mona Bennett Atlanta Harm Reduction Coalition

Dr. Jamie Carter San Francisco Department of Public Health

Mr. Robert Childs North Carolina Ham Reduction Coalition

Mr. George Fistonich HIV Medical Association

Mr. Frank Hood The AIDS Institute

Ms. Alyssa Kitlas National Alliance of State and Territorial AIDS Directors

Ms. Rachel Miller San Diego Unified School District

Bruce Richman, Esq. Prevention Access Campaign

Ms. Georgi Roberts Fort Worth Independent School District

Mr. Carl Schmid The AIDS Institute

Ms. Brooke Sharples Fort Worth Independent School District





Attachment 2: Glossary of Acronyms

Acronym	Definition
ADAP	AIDS Drug Assistance Program
AETCs	AIDS Education and Training Centers
AHRC	Atlanta Harm Reduction Coalition
AI/AN	American Indian/Alaska Native
AIM	Alliance for Innovation on Maternal Health
ART	Antiretroviral Therapy
ATTCs	Addiction Technology Transfer Centers
BHW	Bureau of Health Workforce
BHWET	Behavioral Health Workforce Education and Training
BMSM	Black Men Who Have Sex With Men
BOP	Federal Bureau of Prisons
BPHC	Bureau of Primary Health Care
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHCs	Community Health Centers
CHWs	Community Health Workers
CMS	Centers for Medicare & Medicaid Services
CoAg	Cooperative Agreement
CROI	Conference on Retroviruses and Opportunistic Infections
CSAT	Center for Substance Abuse Treatment
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DHAP	Division of HIV/AIDS Prevention
DNPH	Division of Nursing and Public Health
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
DUIP	Division of Unintentional Injury Prevention
DVH	Division of Viral Hepatitis
ECHO	Extension for Community Healthcare Outcomes
EDs	Emergency Departments

Acronym	Definition
EHR	Electronic Health Record
EMS	Emergency Medical Services
FACA	Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
FORHP	Federal Office of Rural Health Policy
FPL	Federal Poverty Level
FQHCs	Federally Qualified Health Centers
FWISD	Fort Worth Independent School District
FY	Fiscal Year
GHOST	Global Hepatitis Outbreak and Surveillance Technology
GLSEN	Gay, Lesbian & Straight Education Network
GPEP	Graduate Psychology Education Program
GSAs	Gay-Straight Alliances
HAB	HIV/AIDS Bureau
HAV	Hepatitis A Virus
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HECAT	Health Education Curriculum Analysis Tool
HHS	U.S. Department of Health and Human Services
HIVMA	HIV Medical Association
HRC	Harm Reduction Center
HRSA	Health Resources and Services Administration
H-TIPS	Hepatitis-Treatment and Integrated Prevention Services
HTPCP	Healthy Tomorrows in Partnership for Children's Program
ICS	Incident Command Structure
ID	Infectious Diseases
IDSA	Infectious Diseases Society of America
IDU; IDUs	Injection Drug Use; Injection Drug Users
IHS	Indian Health Service
LBBP	Low Barrier Buprenorphine Program
LEAD	Law Enforcement-Assisted Diversion
LEAs	Local Education Agencies
LGBTQ	Lesbian/Gay/Bisexual/Transgender/Questioning
LINCS	Linkage, Integration, Navigation, and Comprehensive Services
LTBI	Latent Tuberculosis Infection
MAI	Minority AIDS Initiative
MAT	Medication-Assisted Treatment
MCHB	Maternal and Child Health Bureau
MIECHV	Maternal, Infant, and Early Childhood Home Visiting
MME	Morphine Milligram Equivalents

MMWR Morbidity and Mortality Weekly Report MSAs Metropolitan Statistical Areas MSM Men Who Have Sex With Men NAS Neonatal Abstinence Syndrome NCHHSTP National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention NCHRC North Carolina Harm Reduction Coalition NGOs Non-Governmental Organizations NHAS National HIV/AIDS Strategy NHBS National HIV Behavioral Surveillance System NHSC National Health Service Corps NIH National Institutes of Health NOFO Notice of Funding Opportunity NRWC National Ryan White Conference OHAIDP Office of HIV/AIDS and Infectious Disease Policy ORO Office of Regional Operations OST Opioid Substitution Therapy OTPs Opioid Use Disorder PAC Prevention Access Campaign PACHA Presidential Advisory Council on HIV/AIDS PCMH Patient-Centered Medical Home PEP Postexposure Prophylaxis PIDS Pediatric Infectious Diseases Society PL	Acronym	Definition
MSMMen Who Have Sex With MenNASNeonatal Abstinence SyndromeNCHHSTPNational Center for HIV/AIDS, Viral Hepatitis, STD and TB PreventionNCHRCNorth Carolina Harm Reduction CoalitionNGOsNon-Governmental OrganizationsNHASNational HIV/AIDS StrategyNHBSNational HIV/Behavioral Surveillance SystemNHSCNational Health Service CorpsNIHNational Institutes of HealthNOFONotice of Funding OpportunityNRWCNational Ryan White ConferenceOHAIDPOffice of Regional OperationsOSTOpioid Substitution TherapyOTPsOpioid Substitution TherapyOUDOpioid Use DisorderPACPrevention Access CampaignPACHAPresidential Advisory Council on HIV/AIDSPCMHPatient-Centered Medical HomePEPPostexposure ProphylaxisPIDSPediatric Infectious Diseases SocietyPLWHPerson/People Living with HIV	MMWR	Morbidity and Mortality Weekly Report
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NHASNational HIV/AIDS StrategyNHBSNational HIV Behavioral Surveillance SystemNHSCNational Health Service CorpsNIHNational Institutes of HealthNOFONotice of Funding OpportunityNRWCNational Ryan White ConferenceOHAIDPOffice of HIV/AIDS and Infectious Disease PolicyOROOffice of Regional OperationsOSTOpioid Substitution TherapyOTPsOpioid Treatment Programs/ProvidersOUDOpioid Use DisorderPACPrevention Access CampaignPACHAPresidential Advisory Council on HIV/AIDSPCMHPatient-Centered Medical HomePEPPostexposure ProphylaxisPIDSPediatric Infectious Diseases SocietyPLWHPerson/People Living with HIV	NCHRC	North Carolina Harm Reduction Coalition
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PCMHPatient-Centered Medical HomePEPPostexposure ProphylaxisPIDSPediatric Infectious Diseases SocietyPLWHPerson/People Living with HIV	PAC	Prevention Access Campaign
PEPPostexposure ProphylaxisPIDSPediatric Infectious Diseases SocietyPLWHPerson/People Living with HIV	PACHA	Presidential Advisory Council on HIV/AIDS
PIDS Pediatric Infectious Diseases Society PLWH Person/People Living with HIV	PCMH	Patient-Centered Medical Home
PLWH Person/People Living with HIV	PEP	Postexposure Prophylaxis
	PIDS	Pediatric Infectious Diseases Society
DrED Dre Evreevre Drenhydevie	PLWH	Person/People Living with HIV
Pre-Exposure Prophylaxis	PrEP	Pre-Exposure Prophylaxis
PWID People Who Inject Drugs	PWID	People Who Inject Drugs
RPR Rapid Plasma Reagin	RPR	Rapid Plasma Reagin
RWHAP Ryan White HIV/AIDS Program	RWHAP	Ryan White HIV/AIDS Program
SALYH School-Aged LGBTQ Youth Health	SALYH	School-Aged LGBTQ Youth Health
SAMHSA Substance Abuse and Mental Health Services Administration	SAMHSA	Substance Abuse and Mental Health Services Administration
SDOH Social Determinants of Health	SDOH	Social Determinants of Health
SDUSD San Diego Unified School District	SDUSD	San Diego Unified School District
SEAs State Education Agencies	SEAs	State Education Agencies
SEPs Syringe Exchange Programs	SEPs	Syringe Exchange Programs
SFDPH San Francisco Department of Public Health	SFDPH	San Francisco Department of Public Health
SFSMP San Francisco Street Medicine Program	SFSMP	San Francisco Street Medicine Program
SGM Sexual and Gender Minority	SGM	Sexual and Gender Minority
SMAIF Secretary's Minority AIDS Initiative Fund	SMAIF	Secretary's Minority AIDS Initiative Fund
SSEs Safe and Supportive Environments	SSEs	Safe and Supportive Environments
SSPs Syringe Services Programs	SSPs	Syringe Services Programs

Acronym	Definition
STD	Sexually Transmitted Disease
STOP	Strengthen Opioid Misuse Prevention Act of 2017
STR	State Targeted Response
SUD	Substance Use Disorder
SVL	Suppressed Viral Load
SVR	Sustained Virologic Response
ТА	Technical Assistance
TasP	Treatment as Prevention
ТВ	Tuberculosis
TCE-HIV	Targeted Capacity Expansion: Substance Use Disorder Treatment for
TEDS	Treatment Episode Data Set
U=U	"Undetectable Equals Untransmittable"
USTS	U.S. Transgender Survey
UVL	Undetectable Viral Load
YRBS	Youth Risk Behavior Surveillance System