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 14-15, 2019
Atlanta, Georgia

Record of the Proceedings

TABLE OF CONTENTS

Page

Minutes of the Meeting 3

Opening Session: May 14, 2019 4

Approval of CHAC Meeting Minutes 6

CDC/NCHHSTP Director's Report 6

HRSA HAB Associate Administrator's Report 11

CHAC Discussion With CDC and HRSA 14

Prevention of Perinatal HIV, Congenital Syphilis, and Perinatal Viral Hepatitis: Updates and Examples from the Field 18

Perinatal HIV Prevention and Congenital Syphilis Programs 19

Activities to Prevent Congenital Syphilis, Perinatal HCV, and Perinatal HIV in Philadelphia 21

Perinatal HIV Prevention: Minnesota's Wrap Around Care Model 25

Perinatal Hepatitis B Virus (HBV) and Congenital Syphilis Prevention in Minnesota 27

Perinatal HBV Prevention 29

Facilitated Discussion 31

Ending the HIV Epidemic: Collaborating Across Boundaries and Responsibilities 35

Overview of Ending the HIV Epidemic 35

Ending the HIV Epidemic: A Plan for America 37

Current Activities of CDC Related to Ending the HIV Epidemic Initiative 39

Ending the Epidemic Planning: Integrating Across Boundaries 41

Achieving Together: A Community Plan to End the HIV Epidemic in Texas 43

Ending the Epidemics: Californians Mobilizing to End HIV, HCV, and STDs 44

Los Angeles County (LAC) HIV/AIDS Strategy for 2020 and Beyond 46

Vote: Reframing the Charge of the CHAC NHAS Workgroup 49

Panel Q&A With Speakers and Discussion 49

Panel Presentation: Ending the HIV Epidemic Centers for AIDS Research (CFAR) as Collaborators with CDC/HRSA 51

Role of the National Institutes of Health CFARs in Ending the HIV Epidemic 51

Ending the Epidemic in the South: The Role of an Institutional CFAR 53

Panel Q&A with Speakers and Discussion 55

HCV Elimination: Institutional Models 57

Veterans Administration's (VA) Experience with HCV Elimination 57

HCV in the Cherokee Nation: Progress After Three Years of Implementing an Elimination Program 58

Brief Presentation on Viral Hepatitis and RWHAP Part B 59
Louisiana HCV Subscription Model and Elimination Program 59
Addressing HCV in Jails and Prisons 60
Question and Answer Period 62
Public Comment Period 63
Preparation for the CHAC Business Session 66
Opening Session: May 15, 2019 66
Recap of Day 1 68
Dating Apps and STD/HIV Risk: Opportunities for Promotion, Prevention, Monitoring, and Evaluation 69
Overview of the American Men's Internet Survey (AMIS) 69
Overview of Building Healthy Online Communities (BHOC) 72
Adolescents and Dating Apps 73
Federal STI Action Plan: CHAC Listening Session 75
CHAC National HIV/AIDS Strategy Workgroup Report 77
CHAC Hepatitis C Workgroup Closeout Report 77
CHAC HIV and Aging Workgroup Report 78
RWHAP Reauthorization Workgroup Report 79
CHAC STD Workgroup Closeout Report 80
CHAC School-Aged LGBTQ Youth Health (SALYH) 81
Workgroup Closeout Report 81
Progress on Updating the HCV Testing Recommendations 82
Update on the Hepatitis C Medicaid Affinity Group 84
CHAC Business Session 86
Business Item 1: New CHAC Ending the Epidemic Workgroup 86
Business Item 2: New CHAC Infectious Diseases (ID) Workgroup 87
Business Item 3: HIV and Aging Resolution 87
Business Item 4: Ryan White HIV/AIDS Program (RWHAP) Reauthorization Workgroup 88
Business Item 5: STD Workgroup Closeout Report 88
Business Item 6: School-Aged LGBTQ Youth Health (SALYH) Workgroup Closeout 88
Business Item 7: Future Agenda Items 88
Closing Session 89
Attachment 1: Participants' Directory 90
Attachment 2: Glossary of Acronyms 92

UNITED STATES 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 14-15, 2019
Atlanta, Georgia

Minutes of the Meeting

The United States (US) 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 14-15, 2019 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 14, 2019

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 (COIs) 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)	No conflicts
Jean Anderson, MD (Johns Hopkins Medical Institutions)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program (RWHAP) and National Institutes of Health (NIH) and stock in Gilead and information technology (IT) companies
Marvin Belzer, MD, FACP, FSAM (University of Southern California, Keck School of Medicine)	Recipient of funding from CDC, HRSA, NIH, and the Substance Abuse and Mental Health Services Administration (SAMHSA)
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Recipient of CDC, HRSA, SAMHSA funding
Paul Gaist, PhD, MPH (Johns Hopkins Bloomberg School of Public Health)	No conflicts
Debra Hauser, MPH (Advocates for Youth)	Recipient of funding from CDC, VIVE, Gilead, and MAC AIDS
Peter Havens, MD, MS (Children's Hospital of Wisconsin)	Recipient of HRSA, NIH, and Gilead funding
Kaye Hayes, MBA (Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Health and Human Services)	No conflicts
Iris Mabry-Hernadez, MD (Agency for Healthcare Research and Quality)	No conflicts
Devin Hursey (U.S. People Living with HIV Caucus)	Recipient of CDC and HRSA funding

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
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
Rosemary Payne (Substance Abuse and Mental Health Services Administration (SAMHSA), HHS)	No conflicts
Susan Philip, MD, MPH (San Francisco Department of Public Health)	Recipient of funding from HRSA/RWHAP, CDC and NIH, Luminostics, Roche Diagnostics and an unpaid public health advisor for GlaxoSmithKline (GSK)
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
Carl Schmid (AIDS Institute, President's Advisory Council on HIV/AIDS)	Recipient of funding HRSA, numerous drug companies, serves on advisory board for numerous drug companies
Linda Scruggs, MHS (Ribbon Consulting Group)	Recipient of funding from HRSA, Gilead, Merck, and SAMHSA
Bradley Stoner, MD, PhD (Washington University School of Medicine)	Recipient of CDC, HRSA, and NIH funding
Lynn Taylor, MD, FAASLD (University of Rhode Island and CODAC Behavioral Health Inc.)	No conflicts
Richard Wild, MD, JD, MBA, FACEP (Centers for Medicare and Medicaid Services)	Wife is an HIV researcher at Emory University

Dr. Mermin confirmed that the 19 voting members and *ex-officio* members in attendance (or their alternates) constituted a quorum for CHAC to conduct its business on May 14, 2019. He called the proceedings to order.

Dr. Mermin made the following announcements regarding CHAC's membership that have occurred since the previous meeting:

- The terms of three CHAC members will expire on May 31, 2019 after service of an additional 180 days: Ms. Dawn Fukuda, Ms. Amy Leonard, and Dr. Jorge Mera. Dr. Mermin expressed CDC's and HRSA's gratitude for their expertise, commitment, and leadership.
- The 2018 CHAC final nomination package has been submitted for the three outgoing members.
- Ms. Rosemary Payne, Senior Nurse Advisor with SAMHSA, replaced Mr. Mitchell Berger, MPH as the *ex-officio* member for SAMHSA. SAMHSA is determining a permanent replacement.

- Mr. Carl Schmid will sit in on behalf of the Presidential Advisory Council on HIV/AIDS (PACHA) and serve as liaison until PACHA determines who they will invite to serve permanently as the liaison representative.

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

Ms. Fukuda welcomed the participants and highlighted the agenda items for the first day of the May 2018 CHAC meeting. CHAC will focus predominantly on congenital syphilis, hepatitis B and C, and hepatitis C elimination and what has been learned from projects in the field and how to apply those lessons to the work being done nationally. She indicated that there would be presentations by Carolyn Wester, MD, MPH in her new role as Director of the Division of Viral Hepatitis (DVH). CHAC also would hear presentations and discussion about the Administration's newly announced initiative, *Ending the HIV Epidemic: A Plan for America,* including what the operationalization of this plan will mean for CHAC. This is an opportunity to make tremendous headway in terms of CHAC's response to HIV and the co-occurring conditions of viral hepatitis and sexually transmitted infections that are connected to HIV and efforts to end the HIV epidemic.

Dr. Laura Cheever thanked everyone for attending and expressed gratitude for the reappointment of Dr. Jean Anderson.

Approval of CHAC Meeting Minutes

A motion was properly placed on the floor by Dr. Peter Havens and seconded by Dr. Jorge Mera to approve the minutes from the November 7-8, 2018 CHAC meeting, with no amendments or further discussion. The minutes were approved unanimously with no abstentions or opposition.

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

Dr. Mermin began with an update on NCHHSTP leadership. Carolyn Wester, MD, MPH has been selected as the DVH Director. Dr. Wester most recently served as Medical Director for HIV, STDs, and Viral Hepatitis at the Tennessee Department of Health (TDH). Michelle Van Handel, MPH was selected as permanent Associate Director for the Center's Program and Performance Improvement Office (PPIO). Ms. Van Handel previously served as Senior Health Scientist in PPIO and worked in the Division of HIV/AIDS Prevention.

In terms of budget updates, the President's Budget proposed for fiscal year (FY) 2020 included an increase of $0.2 billion for NCHHSTP. This included a $53 million increase for infectious diseases and the opioid epidemic program, and $140 million for the first phase of the Ending the

HIV Epidemic (EHE) initiative. The total request regarding the EHE initiative was $291 million, with the majority of the other resources to be allocated to HRSA.

As a reminder, the *HIV Prevention Progress Report, 2019* was presented during the February 2019 CHAC meeting. This monitors the main indicators for the *National HIV/AIDS Strategy for the United States: Updated to 2020*. In terms of the current status, the targets were met for 8 indicators (38%), there was progress on the targets for 9 indicators (43%), and there was no progress or indicators were moving in the wrong direction for 4 targets (19%). Areas of success include increasing viral suppression, decreasing some disparities, increasing pre-exposure prophylaxis (PrEP) prescriptions, and reducing mortality. Areas not moving fast enough include reducing new HIV infections or incidence, increasing linkage to care, and increasing retention in care. Areas not making progress include reducing geographic disparity in HIV diagnosis in the South, reducing non-sterile injections, reducing homelessness, and reducing HIV stigma.

In March 2019, NCHHSTP presented in the CDC *Vital*signs™ report. This once-monthly publication highlights an important public health issue for the nation. This report highlighted the continuum of care in a new way. Instead of starting with the total estimated number of people living with HIV (PLWH) in the country and the proportion along the steps toward viral suppression, this report examined transmission from people at each state of the continuum of care to help better focus where a bigger difference could be made in terms of preventing transmission of new infections.

Overall, 80% of new HIV infections in the US in 2016 were transmitted from nearly 40% of people with HIV who either did not know they had HIV, or who received a diagnosis but were not receiving regular HIV care. About 15% of people in the country who do not know they have HIV are associated with approximately 40% of transmission. Not knowing one's HIV status prevents precautions to prevent transmission. People change behavior when they know they have HIV. For example, accessing antiretroviral therapy (ART) helps dramatically reduce the risk of sexual transmission. The other major area of focus is the 23% who know they have HIV but are not in care, who account for another 40% of transmissions. This highlights the importance of the retention in care and re-engagement for people who have fallen out of care. The 11% of those in regular care but not virally suppressed can be accounted for by a variety of factors (e.g., switching drugs, toxicity, disinterest in ART, not on ART because clinicians are not aware of or have not adopted new guidelines for ART prescriptions). The 51% who are infected with HIV and under care with a viral load suppression are assumed to have 0% risk. The ultimate goal for CDC, HRSA, and CHAC is to increase the proportion with viral load suppression as much as possible.

New information from the Division of Adolescent and School Health (DASH) reports on their approach to school-based primary prevention and some of the health outcomes. CDC-funded school districts observed declines in the percentage of students who initiated sexual activity (from 37.8% in 2015 to 35.4% in 2017), were currently sexually active (26.0% in 2015 to 23.8% in 2017), had four or more sexual partners in their lifetime (from 12.0% in 2015 to 10.0% in 2017), and used a condom last time they had sex (from 56.9% in 2015 to 53.8% in 2017). It was noted that the percentage for "used a condom last time they had sex" may be incorrect. This information will be clarified and reported back to CHAC. Overall, there has been a disproportionate positive benefit in the areas that have been receiving funding from DASH.

A CDC survey of high school students from 10 state and 9 urban school districts found that an average of 1.8% of high school students identify as transgender. These students are more likely than cisgender counterparts to report substance use, suicide risk and attempted suicide, and being victims of sexual and non-sexual violence. These are similar outcomes to work done with other lesbian/gay/bisexual/transgender/questioning (LGBTQ) youth for whom there is a higher risk for poor outcomes among transgender youth. This is an area in which small efforts can make big differences for these students. This has been a major area of interest to members of CHAC. DASH has been able to expand attention to this issue, as well as actions to try to improve the situation for all youth.

Preliminary results from the Division of Tuberculosis Elimination's (DTBE's) *2018 State and City TB Report* show approximately 9000 TB cases, which is a very small reduction from last year. The biggest challenge now is latent tuberculosis infection (LTBI), with 85% of all new TB resulting from reactivation of latent infection. This will challenge all jurisdictions to transfer the focus from treatment of people in TB clinics and programs to begin performing screening for LTBI along with treatment. This is a major change for the program and there is a lot of interest. Some facilities have done this very well. There is a pilot program in Lynn, Massachusetts that has been remarkably successful. However, budget constraints have made this change difficult to achieve as funding has been level for this division.

DTBE also has implemented whole genome sequencing (WGS). Similar to other divisions, including the Division of Tuberculosis Elimination (DHAP), DTBE has receives isolates of TB for many years from local and state health departments. They test the isolates for resistance and provide clinical services, rapidly returning results to providers. As of last year, WGS has been added for all isolates. The plan is to transition completely to WGS if this continues to go well. The outcome of this is the rapid isolation of clusters of TB infection that might otherwise have been mixed up in a community. This can identify TB outbreaks that are transferring from state-to-state. For example, a TB outbreak was identified in Georgia that occurred primarily among homeless individuals and volunteers who spent extensive time in homeless facilities. This outbreak transferred to 10 other states and continued for 3 years before it was brought under control. Ultimately, WGS will help find more genetic indicators of resistance so clinicians can be notified rapidly when isolates are resistant to treatment before more complex culturing has to be done. CDC partnered with Medscape to create an expert video commentary featuring DTBE Director, Dr. Phillip LoBue. This video focuses on educating healthcare professionals on the 2018 updated recommendations on LTBI treatment in terms of the combination of rifapentine and isoniazid (3HP).

STDs continue to increase in the US. There was about a 30% increase between 2013 and 2017 in the absolute number of the three major bacterial STDs of gonorrhea, chlamydia, and syphilis. The major increases are occurring in the rates of primary and secondary syphilis. This is due to a variety of factors, with more discussion and study needed to determine how to reverse this trend. This trend does not just affect adults. There has been a steep increase of about 270% in the number of congenital syphilis (CS) cases since 2012. It is important to note that this is not just a blip, but represents a consistent increase that is tied to increases in primary and secondary syphilis among pregnant women.

An analysis on missed opportunities to prevent CS revealed that about a third of the cases of CS occurred because the mother received late or no prenatal care and was not screened in time, about a third had a positive initial screening test but did not receive appropriate treatment,

and about a third had a negative initial screening but were infected in later pregnancy that was not detected with late second or third trimester screening. At least two thirds of these infections could have been prevented with better, more complete application of the recommended guidelines in the healthcare setting. A third will require helping pregnant women get the prenatal healthcare they need. Reversing the trends in syphilis among women will help reverse the trends in men, which will help prevent pregnant women from getting syphilis in the first place.

In terms of the infectious disease consequences of the opioid crisis, an *MMWR* analysis of drug use among heterosexuals with syphilis showed that from 2013-2017, the primary and secondary syphilis rate increased 73% from 5.5 cases/100,000 to 9.5 cases/100,000. This analysis found that drug use (including methamphetamine, injection drugs, and heroin) more than doubled among heterosexual men and women with syphilis during that period. These data suggest that there is an intersection between the epidemics of heterosexual syphilis transmission and drug use. This varies to some extent geographically, with the West seeming to differ from other parts of the country, but it appears that drug use is a driving factor for at least some of the syphilis outbreaks occurring in the country [Kidd SE, Grey JA, Torrone EA, Weinstock HS. Increased Methamphetamine, Injection Drug, and Heroin Use Among Women and Heterosexual Men with Primary and Secondary Syphilis—United States, 2013–2017. *MMWR* Morb Mortal Wkly Rep 2019;68:144–148; 2].

CDC continues to work with states to control Hepatitis A (HepA) outbreaks. Since 2016, there have been 17,140 cases; 10,088 hospitalizations; and 171 deaths due to the national, multi-state outbreak that the US has been experiencing. HepA primarily affects people who use drugs and people experiencing homelessness, and maps very closely to the opioid crisis. Some states have large increases in overdose deaths as well, but HepA outbreaks have not occurred there yet. This is likely to be due to a mixture of states implementing HepA vaccination appropriately among populations in need, as well as luck. CDC is working diligently to improve vaccination before those populations are affected by an outbreak [CDC National Notifiable Disease Surveillance System (NNDSS)].

It is important to note that HepC virus (HCV) infection varies widely by state. There are limitations to the HepC surveillance system for both acute and chronic disease. Therefore, CDC modeled data in collaboration with Emory University and the University of Albany researchers to estimate HCV prevalence in the US. The estimated HCV prevalence in states ranged from .45% to 2.34%. The highest rates were in the West, Appalachia, and states disproportionately affected by the opioid crisis. This does not match where acute outbreaks of HepC are, given that chronic HepC is affected by the last few decades of risk. Some states had higher rates of injection drug use in the past, unsterile procedures, and nosocomial transmission. Essentially, there is an overlap of past with current risk. There are an estimated 2.4 million people living with HCV in the US and about 40,000 new infections of HCV every year [Rosenberg ES, Rosenthal EM, Hall EW, et al. Prevalence of Hepatitis C Virus Infection in US States and the District of Columbia, 2013 to 2016. JAMA Netw Open. Published online December 21, 20181(8):e186371].

Three new National Action Plans are under revision or development that are being led by the Office of the Assistant Secretary for Health (OASH) in collaboration with many other agencies, especially CDC and HRSA. This includes revisions of the National HIV/AIDS Strategy (NHAS) and *National Viral Hepatitis Action Plan*, as well as development of the first *National STD Action Plan*. The depth and breadth of work that goes into these action plans and the thought process

behind them brings together several government agencies and communities, which helps to determine the most impactful actions that will make a difference for the country.

In terms of the FY2020 President's Budget, CDC's priority activities pertaining to the EHE initiative include the following 5 major pillars:

- Diagnose: Bring HIV testing to everyone who needs it and diagnose infections as early as possible.
- Treat: Promote rapid comprehensive care and start treatment at time of diagnosis.
- Protect: Protect people at risk with proven prevention interventions, including PrEP and Syringe Services Programs (SSPs).
- Respond: Accelerate deployment of effective cluster detection and response systems.
- Workforce: Support on the ground teams to help tailor and ensure effective implementation. This is a recognition that in order to get the job done, both new types of skills and an increase in the number people will be needed in the workforce at all levels.

Mapping was done with 2016-2017 data on the burden of HIV in the US, which shows areas where HIV transmission occurs more frequently. More than 50% of new HIV diagnoses occurred in 48 counties; Washington, DC; and San Juan, Puerto Rico. It is helpful to see that it is not an overwhelming problem, but 7 states have a disproportionate rural HIV epidemic. Part of the phased implementation of the plan is to reduce the infections by 90% in 10 years throughout the nation. It is important to understand how to deal with HIV effectively in more rural and semi-rural areas where resources are often harder to access.

Discussion Points

Dr. Lynn Taylor raised concern that in the analysis of missed opportunities to prevent CS, there needs to be a Step 0 for enhanced preconception care or enhanced prenatal care. It is important to normalize and bring back to center routine treatment, ongoing preconception care, and increasing access to reproductive healthcare. The time to diagnose syphilis is before pregnancy, so there should be campaigns and initiatives to disseminate this information.

In terms of HepA vaccination among vulnerable populations, Dr. Taylor pointed out that the common message from health departments suggests that one HepA vaccination offers up to 95% protection and is sufficient. While administering one vaccination may be sufficient in outbreak situations, she emphasized the importance conveying the message that everyone should be aiming for two vaccines. Dr. Mermin responded that the current recommendation is one vaccine, because this is sufficient for herd immunity in outbreak conditions.

Dr. Belzer expressed concern about the overwhelming STI rates for the past 5 to 10 years. Condom use does not seem to be the prevention answer, particularly for the young adult population. Linking STI testing to HIV testing has been effective in identifying infections earlier and getting people treated. He wondered whether shifting the focus/investment to other strategies like PrEP, post-exposure prophylaxis (PEP), and/or immunizations would be more effective strategies. Dr. Mermin replied that there are areas where existing opportunities can be leveraged much better to reduce STDs, such as making sure that everyone with HIV is screened regularly for STDs. This is a very high-risk population with a high incidence of STDs. Approximately 50% of all cases of syphilis among MSM occur in PLWH. Screening and treating that population will make a major difference in transmission of HIV to others and prevent that

population from getting STDs. Another area would be for STD clinics to become experts in PrEP, because then there would be routine screening for STDs for people at high risk of HIV. People who access and use PrEP are at high risk for STDs, and the guidelines recommend routine screening. Other systematic programmatic expansions could help as well. In addition, there is a need for new technology and new/more effective vaccines. NIH recently announced tens of millions of dollars being focused on new vaccines for STDs, and CDC staff are meeting with NIH to discuss further what is needed.

HRSA HAB Associate Administrator's Report

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

Dr. Cheever covered several topics in the HRSA HAB Associate Administrator's update to CHAC, beginning with a discussion of the FY 2020 President's Budget. The budget request prioritizes reauthorization of the RWHAP to ensure that federal funds are allocated to address the changing landscape of HIV in the US, support data-driven programmatic changes, and simplify and standardize certain requirements and definitions. HRSA also requested a $120 million increase to support the EHE initiative, with $70 million marked for RWHAP and $50 million marked for the HRSA-funded Health Center Program.

In terms of the EHE initiative and the 4 pillars, the health centers have a major role in diagnosing HIV. Over 2 million HIV tests are performed in health centers every year, but this could certainly be increased. Treatment has been the centerpiece of the RWHAP in terms of outlining this initiative. If the RWHAP scales-up to get another 400,000 people in care,that will change the way HIV care is provided in the US. In terms of prevention, HRSA is focused on PrEP within the community health centers. Within the "Respond" pillar, HRSA will be involved as people are either diagnosed with HIV or at high risk for HIV transmission and are referred to HRSA programs.

Ryan White HIV/AIDS Program Services Report (RSR), 2017 was published in December 2018. The RSR is a client-level data reporting requirement that monitors the characteristics of Ryan White HIV/AIDS Program Parts recipients, providers, and clients served. The HRSA RWHAP is a large program with deep impact. The program continues to serve over 500,000 people each year, which is over half the people living with diagnosed HIV in the US. About three quarters of the individuals served are racial minorities and over two-thirds live at or below the Federal Poverty Level (FPL). Approximately 60% of people in the program are over 45 years of age, which is a major success as well as a challenge in terms of meeting the needs of older people with HIV. HRSA data indicated that people in the RWHAP over 60 years of age have a 90% viral suppression rate. Older people are better at staying engaged in care and taking medication. There is much work to do for older people in terms of their unmet needs such as managing numerous co-occurring conditions.

The RWHAP viral suppression rate among patients that had at least one medical visit in 2017 is 86%. That is remarkable considering that about two-thirds are living at or below the FPL with numerous structural barriers to care related to social determinants of health. In terms of the viral suppression rate by state, there were significant increases from 2010 (69.5%) to 2017 (85.9%)

nationally. Disparities continue to be seen in the Southeastern states, where the initiative is focused. While it is known that there are significant barriers in some parts of the country, there are some regional approaches that can be taken to overcome these barriers.

Data on viral suppression comparison between 2010 and 2017 among key populations show significant disparities among several populations, including unstably housed people, youth, transgender clients, and Blacks/African Americans. All disparities have decreased since 2010 due to having focused interventions on these specific populations, both through the NHAS focusing attention on these populations and specifically targeted interventions. The only group where the disparity gap did not diminish is among the unstably housed, although they did see improvements in viral suppression. The key to increasing suppression in this population lies in getting them stably housed. There has been some improvement in terms of a decrease in the proportion of people unstably housed through the RWHAP.

In 2019, some significant changes have been made to the RWHAP RSR reporting instrument for 2020 reporting. Because HRSA has made a commitment to recipients to keep reporting stable and avoid too many changes, this will be the first major change since 2010. The team focused on removing variables that were not producing quality reporting, or were proving difficult to interpret. This resulted in the removal of 14 variables. Some of these variables are very important to collect, such as whether someone has had an HCV testing since diagnosis. In order to continue to address these important variables, HRSA has a chart abstraction contract to collect specific clinical variables from a representative subset of recipients.

Under the current reporting requirements, HRSA RWHAP and recipients do not report in a way that captures the full impact of RWHAP investments at state and local levels. Currently, recipients and subrecipients only report data for service categories that they are directly funding with RWHAP grant dollars. Starting in CY 2020 reporting, recipients and subrecipients will report data for services funded both directly through their grant dollars and through program income and 340B pharmaceutical rebates that were generated as a result of their grant funds. This will more fully demonstrate the services that are provided as a result of the RWHAP investment, and it will allow for HRSA to better report at the national level the impact of the 340B on RWHAP service delivery.

HRSA has been collecting the AIDS Drug Assistance Program (ADAP) data for several years. At this point, the data quality has improved, and the inaugural *Annual ADAP Client-Level Data Report* will be released in FY 2019. The *Annual ADAP Client-Level Data Report* similar to the *RSR Annual Client-Level Data Report,* will include national- and state-level demographic characteristics and service utilization data for ADAP clients. The estimated release is the Fall of 2019. In 2017, 225,970 clients received ADAP services. These services are fairly evenly split between 140,401 clients receiving medication assistance, and 116,596 clients receiving insurance assistance that helps pay premiums and co-pay assistance. The total of these two numbers is more than 225,970 as some clients receive both services simultaneously.

Dr. Sigounas, the HRSA Administrator, has had a strong interest in making sure that they are better demonstrating the impact of the program in peer-reviewed publications. To this end, a new HRSA HAB eLibrary has been set up. It will be updated quarterly and contain peer-reviewed journal articles demonstrating impact of HRSA RWHAP. Additionally, a series of HRSA HAB-authored and co-authored articles will be published on a rolling basis in PLOS in the coming year.

In terms of policy and program updates, Dr. Susan Robilotto is the new Director of the Division of State HIV/AIDS Programs. She is a physician who has worked in HAB for several years, serving as Chief Medical Officer for the Part A and Part B programs. She worked on program quality and has extensive experience working in prisons on HIV and in a county health department HIV program where she was engaged in a variety of relevant work. Ms. Chrissy Abrahams-Woodland is the new Deputy of the Division of Metropolitan HIV/AIDS Programs. She has worked in HAB for several years in various capacities and is committed to ensuring that HRSA has good community engagement.

There has been an important update to the PCN 13-02 Clarifications on RWHAP client eligibility determinations and re-certifications. This includes clarifications on making rapid eligibility determinations, stipulations that eligibility determinations may be performed simultaneously with testing and treatment, and clarification that recipients and subrecipients assume the risk of recouping HRSA RWHAP funds used for clients ultimately determined to be ineligible. HRSA knows that there are challenges pertaining to the 6-month recertification and has taken a variety of steps to improve this. HRSA is planning to contract an evaluation to collect information on best practices for recertification nationally and examine ways to reduce recipient and client burden around this issue.

In terms of building capacity to end the HIV epidemic, HRSA is working to build collaborative projects across the Part As to facilitate peer-to-peer technical assistance/learning collaborative in this area. HRSA has published a notice of funding opportunity for organizations to request up to $100,000 a year to enhance infrastructure, hiring staff, disseminating and marketing information, conduct community engagement, enhancing core medical and support services, et cetera. The initial plan was to fund 5 HRSA RWHAP Part A recipients for 2 years, but now they are going to try to fund several more. These awards will be made in the Summer of 2019.

HRSA HAB is working with the HRSA Bureau of Primary Care to improve STI screening and treatment among people at risk for HIV. Rutgers University was awarded a grant to work with several different sites in two jurisdictions o determine how to do this at the city and clinic levels. The purpose of initiative this is to increase and improve screening and treatment of STIs among HRSA RWHAP and health center clients. At this point, site visits have been made to all clinical sites to complete needs assessments, and based on these results evidence based and evidence informed interventions will be selected for implementation. Additionally, HRSA HAB is engaged with the Office of the Assist Secretary for Health to develop the first *HHS STD Federal Action Plan*.

To promote community engagement in the HRSA RWHAP program, several activities led by HAB are underway: 1) Building Leaders of Color; 2) Community HIV/AIDS Technical Assistance and Training for Planning (CHATT); 3) Improving Access to Care: Using Community Health Workers to Improve Linkage and Retention in HIV Care; 4) Building Futures for Youth; and 5) Building RWHAP Recipient Capacity to engage PLWH in Health Care Access.

HAB's new efforts at this point are focused on: to improve viral suppression and decrease disparities among patients who are in care, enhance linkage to and engagement in HIV care of the newly diagnosed, and expand re-engagement and retention for those diagnosed but out of HIV care.

CHAC Discussion with CDC and HRSA

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

Ms. Fukuda emphasized the importance of this time to discuss with CDC, HRSA, and other federal agencies opportunities for synergy, integration, and leveraging the infrastructure that has been accomplished by CDC and HRSA. Something that stood out to her about the presentations from Drs. Mermin and Cheever regarded the drive to maximize opportunities to accomplish viral suppression across populations. The opportunity to accomplish integration is an area in which CHAC is particularly critical in terms of the recommendations and questions they pose to CDC and HRSA to respond to HIV, STIs, and TB and making testing available to people who touch the RWHAP. While TB has a separate advisory committee, there are some examples of success in integrating a TB services alongside a RWHAP. Drs. Mermin and Cheever both discussed cluster response and leveraging the RWHAP to receive newly diagnosed people who are identified in clusters. Consideration must be given to the ways in which Field Epidemiologists or Disease Intervention Specialists (DIS) funded by CDC integrate linkage work, which is extremely important. The impact of drug use on infectious disease transmission is critical to consider. While this has been discussed by CHAC primarily in the context of opioids, it is important to consider how stimulants are implicated in some of CHAC's work. Given that there are so many disparities across the country, CHAC must consider how to prioritize the issues of disparity thoughtfully, meaningfully, and compassionately and understand when to let things go.

Discussion Points

Dr. Havens inquired as to whether all of the targeted jurisdictions for the Ending the HIV Epidemic initiative (EHE) mentioned by Dr. Cheever are Part A jurisdictions. Dr. Cheever clarified that of the 50 jurisdictions, 49 are within the existing Part A areas. Cincinnati/Hamilton county is the exception. The approach is to use existing infrastructure versus creating new infrastructures around the initiative.

Dr. Stoner commented that there is opportunity for tremendous synergy between STD and HIV, which have traditionally been siloed. Given that most STD cases are not seen in STD clinics anymore, there has been a hollowing out of the public health infrastructure and the basic core safety net clinics, so STD patients are increasingly presenting to emergency departments (EDs), primary care practitioners (PCPs), or their HIV caregivers. Given this shift, consideration must be given to how to ramp up STD screening. Perhaps a portion of the funding being mobilized for HIV care can be allocated effectively to STD screening in order to achieve synergy, recognizing the pandemic of homelessness, substance abuse, and mental health issues that some patients experience. He pointed out that there is underutilization of PrEP because people feel as though it is not within their area of expertise.

Dr. Cheever indicated that the funding that would be received for the EHE, should Congress appropriate the money to HRSA, initially will focus on out-of-care and newly diagnosed. At the same time, they will continue to ramp up improvement of STI testing and treatment in RWHAP

care. Health centers are looking forward to introducing and expanding PrEP delivery, which offers a natural linkage to STD testing and treatment. Through the pilot she mentioned, they are thinking about how to implement some of the strategies that Seattle has done. One approach is to routinize self-testing such that it does not have to be linked to a clinical visit.

Dr. Anderson inquired as to whether there are any data on unstably housed individuals with lower rates of viral suppression and how that overlaps with mental health issues. Mental health and interpersonal violence are major issues that are not screened for adequately, but have a major impact on HIV and STIs. A common STI seen with HIV is trichomoniasis, which could be considered a marker of risk behavior for HIV acquisition.

Dr. Bolan replied that there certainly is concern about trichomoniasis among women living with HIV. Based on National Health and Nutrition Examination Survey (NHANES) data, trichomoniasis prevalence levels are not very high on a population-level. The primary concern about trichomoniasis and HIV are the potential reproductive health consequences and vaginal discharge, which are clinical issues. Treatment guidelines can highlight the importance of trichomoniasis testing on a regular basis among women living with HIV. She encouraged those who have access to these populations to assess women who have trichomoniasis to determine whether they actually seroconvert with HIV. For example, studies with men who have sex with men (MSM) have shown that primary and secondary syphilis are important risk markers for HIV acquisition.

Dr. Cheever added that most of the data available from the RWHAP does not assess unmet need other than unstable housing. HRSA is aware of the strong linkage and assessed models of providing services to people who are mentally ill, living with HIV, have substance issues, and are homeless. SPNS recipients implemented intensive models that achieved good results, but it is expensive. With the new EHE initiative, recipients may be able to reach into some of those populations. Regarding better addressing interpersonal violence, HRSA is working on a cooperative agreement to rapidly disseminate evidence-informed interventions to several clinics to evaluate how to best integrate IPV screening and community partnerships for RWHAP clients.

Dr. Mermin observed that there seems to be a unique lacuna in the continuum of care related to people falling out of care. There is a documented high rate of suppression among people receiving care, especially in the RWHAP clinics. Yet, there is a mysterious group of people who have been diagnosed, receive some form of care, and then they drop out of care. He wondered whether the data are real and trustworthy, who these mysterious people are, what drives them to fall out of care, and what strategies could be implemented for successful retention.

Dr. Cheever recalled a discussion they had about CDC's out-of-care estimate and whether HRSA's initial estimate for people receiving RWHAP services was correct. HRSA has been able to document that they're client level data estimates are accurate. Throughout the country, several cities have carefully documented who is/is not in care. The out-of-care estimate decreases to about a third when jurisdictions undertake efforts to verify their out of care numbers based on surveillance data. Regardless, the challenges of retention in care are significant. Getting in to be tested is one 7-minute exercise at one point at time; whereas, staying in care is a 50-year process.

Dr. Taylor expressed concern about individuals in a hepatitis outbreak setting who receive only 1 dose of vaccine, but return infected 5 years later. She requested clarification about the messaging in terms of whether they actually are stating that up to 95% of people are protected following 1 dose of vaccine or if they should emphasize to these individuals that at some point, they should receive the second catch-up dose.

Dr. Wester indicated that they absolutely are advocating for the 2-dose series among groups for whom the vaccine is indicated for lifelong protection. The 1-dose is to confer immunity for over 90% for up to 11 years. In outbreak mode with facility-based administration of vaccine versus ascertaining individual risk, the focus is on administering 1 dose and documenting that dose in the immunization registry.

Dr. Taylor stressed that not all states have a vaccine registry, so anything that can be done to promote that would be helpful.

Dr. Saag emphasized how special the RWHAP is. There is an expansion of need and focus to get those who are hard-to-reach to do the STI screening and be involved in PrEP. What they have been doing locally in Alabama is linking community-based service organizations, Federally Qualified Health Centers (FQHCs), and everyone else in the neighborhood to try to determine ways to distribute workloads so that the clinic is not the focal point for everything. In the next 6 months, they will be moving their clinical location to a 50,000 square foot building that will be co-housed with one of the community-based organizations (CBOs) that engages in outreach to LGBTQ youth and will manage STI screening, PrEP, et cetera. Those who test positive will be referred to the clinic. The notion of pooling resources and efforts may be a solution and way forward for many facilities. The EHE funding becomes a driving force in terms of getting people to come together.

Dr. Philip inquired about models of care and navigation, pointing out that to go beyond their walls to engage in outreach will require more funding. However, it is important that outreach comes from clinics rather than someone they do not know.

Dr. Cheever indicated that for the last several years, they have been encouraging their recipients to fund DIS staff as appropriate with RWHAP funds to utilize their skill sets for re-engagement activities. For several years, HRSA has been cataloging interventions that represent best practices for out of care engagement and are working to compile them on the website them in a way that people can easily find them. For the EHE initiative, HRSA has all of the authority with the RWHAP statute to implement treatment activities but will need authority through appropriations to direct funding to the 57 jurisdictions planned for the first 5 years outside of the RWHAP funding. In the President's Budget request, they have asked for broader authority to direct funds. This also would allow for more flexibility beyond the RWHAP, such as engaging other partners to assist in some of the work as Dr. Saag mentioned. HRSA has requested Public Health Emergency (PHE) authority previously successfully utilized to direct ADAP funds to eliminate waitlists and significant cost containment in that program. HRSA also has been working closely with CDC to ensure that activities are seamless even though funding comes through various streams.

Dr. Steinberg indicated that from a health center perspective, the model of care that has been supported in health centers over the last few years is the patient-centered medical home. This naturally involves collaboration and coordination of CBOs. They will continue to support that

type of model. In addition, many health centers are using Community Health Workers (CHWs) and Peer Support Counselors (PSCs) in terms of medication-assisted treatment (MAT). They also will continue to support CHW training and will leverage the current infrastructure to support models that will be effective in terms of HIV prevention and linkage to care.

Regarding an inquiry about STI increases with gonorrhea and syphilis, Dr. Bolan indicated that there are limited data. It is known that the majority of cases are among gay, bisexual, and MSM. Gonorrhea and chlamydia occur predominantly in individuals under 24 years among heterosexual, gay, bisexual, and others. They provide funding to states for surveillance, prevention, and intervention activities. They are now asking states to use a new sampling method to get a representative sample and better demographic information.

Dr. Mermin noted that the disparities are extraordinary. The majority of syphilis cases in the US occur among MSM, but MSM make up a very small proportion of the total population. For example, syphilis is 125 times more common among MSM than in heterosexual men. That disparity is somewhat less for gonorrhea, but an estimated 25% of all new gonorrhea diagnoses occurring among MSM.

Dr. Belzer supports flexibility for those involved in case coordination. For example, California is conducting an experiment to invest major amounts of funding in the coming year in housing. This offers an opportunity to determine whether their RWHAP staff can link with this housing funding and use the synergy to re-engage people and keep people engaged in care.

Dr. Cheever indicated that while the RWHAP is not primarily a housing program, they work very closely with Housing Opportunities for Persons with AIDS (HOPWA). HRSA HAB recipients needs to expand work with SAMHSA state recipients who recently received over $1 billion dollars substance abuse treatment. Very little of this has been accessed by the RWHAP. Consideration must be given to how this can be better leveraged.

In terms of the potential for EHE resources to be made more flexible for HRSA through the EHE mechanism, Ms. Fukuda thought what she heard Dr. Cheever saying was that there may be some flexibility without reauthorization through these specialized funds to conduct some innovative work through HRSA. Perhaps CHAC may wish to make some recommendations with regard to this.

Dr. Havens emphasized that he is a major fan of FQHCs as a way to expand the reach that occurs within the RWHAP population. He praised HRSA for allocating funding and demanding specific products by controlling the data, and requested clarify with regard to whether he understood correctly that they plan to allocate funds to the FQHCs.

Dr. Cheever clarified that in the budget request for the initiative, the FQHC program would have $50 million of the requested funding in the 50 counties and cities in the 7 states.

Dr. Steinberg added that unlike other agencies and the RWHAP, they have $50 million and can move forward for 2020 funding. These funds will be allocated to health centers that are identified in areas that already have the expertise and have dual funding from the FQHC program and the RWHAP. In areas that do not have dually funded centers, they will be looking for health centers that have a relationship with the RWHAP. Those funds will be utilized to increase outreach in communities with regard to HIV, support HIV testing and risk-based

testing, support for those who test positive with treatment on site in a dually funded health center or through linkage to care, and support HIV prevention activities (including PrEP) for those test negative but are at risk for HIV. They recognized the enhanced efficacy of having a PrEP navigator, so care coordination will be provided as well.

Dr. Havens inquired as to whether they could institute the same reporting requirements as the RWHAP, given that this drives care.

Dr. Cheever replied that the FQHC program is ahead in many ways in terms of the way they have been able to take a risk-adjusted look at the quality of each health center. The centers receive special funding for either high quality care or major improvements. As in all large initiatives, there is a need to report on activities and outcomes.

Dr. Steinberg added that they are in the process of developing tri-annual reporting for health centers that are receiving this additional funding, which will include metrics and hiring additional staff.

Dr. Mera works in one of the 7 states with rural burden. A major barrier they have encountered in terms of PrEP is a lack of providers and existing providers being overwhelmed. A perceived barrier among physicians is that they say they can try to detect high-risk individuals, but that they do not have time to deliver the care. One of the solutions they identified based on their HepC program was a collaborative relationship with their pharmacy. Pharmacists are currently treating half of their HepC patients and are rolling out the PrEP program. Their pharmacists can order laboratory tests, and can consult with the PCP if necessary. He recognized that they are a very specific community and that perhaps this could not be rolled out everywhere, and wondered whether any thought had been given to that type of strategy.

Dr. Cheever said that since they first began discussing this internally, she thought that if they were going to make PrEP successful, they should de-medicalize it as much as possible and still safely use it. They are very excited that the Center for AIDS Research (CFAR) will be a part of this, and this is a great question for them to help answer in terms of what models will work well. A potential model is to consider how to better use pharmacists. One issue with regard to using pharmacists is that the laws vary from state-to-state in terms of what pharmacists are permitted to do, which could be very limiting depending upon the state. In addition, telemedicine is being considered as a mechanism to address access to rural patients and stigma.

Prevention of Perinatal HIV, Congenital Syphilis, and Perinatal Viral Hepatitis: Updates and Examples from the Field

Jean Anderson, MD, CHAC Co-chair
Professor, Gynecology & Obstetrics
Johns Hopkins Medical Institutions

Dr. Anderson moderated a panel presentation for a series of speakers to provide updates and examples from the field on the prevention of perinatal HIV, congenital syphilis, and perinatal viral hepatitis. She observed that pregnancy is a major point of contact for the health care system for women, and arguably for their families as well, in terms of opportunities for identification of HIV and other infectious diseases and prevention of prenatal transmission. Now

in the elimination era for HIV perinatal transmission, congenital syphilis was thought to have been eliminated. However, this continues to be an issue. One conundrum regards how to maintain and extend the gains made in terms of HIV and also incorporate and think more holistically in terms of prevention of congenital syphilis and HepB and HepC transmission. She introduced the panel of speakers and opened the floor for their presentations.

Perinatal HIV Prevention and Congenital Syphilis Programs

Margaret Lampe, RN, MPH
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Ms. Lampe reiterated that this is viewed as the elimination era in terms of eliminating perinatal HIV transmission. The goal in the US is a transmission rate of less than 1% and fewer than 1 case of perinatal HIV/100,000 live births. It is believed that this is being achieved, but it is somewhat tricky in terms of the data that are available. The reason the rate is hovering around 1% is that everyone is doing an amazing job in reducing HIV infection in women, so the denominator of women living with HIV getting pregnant is getting smaller every year. While this is an achievement to be proud of, it is important to continue to monitor it as well.

DHAP developed a "Framework to Eliminate Perinatal HIV Transmission in the United States" in 2012. This model illustrates the fluidity, collaborative nature, and way that all of the components need to work together. The central component is comprehensive, real time case finding that was defined in 2012 as a case of HIV infection in a pregnant woman. Surrounding that are reproductive health and family planning and preconception care, which hinges on universal testing in the non-pregnant population as well. Surrounding that are facilitation of clinical and psychosocial HIV services; data and surveillance; ongoing research and long-term monitoring, which is coming to attention more in this era in terms of some signals pertaining to potential teratogenic effects of some of the most effective antiretrovirals that need to be used to end the epidemic; and case review and community action that involves the Fetal Infant Mortality Review (FIMR) methodology, which has been refined to examine local systems issues and how the tools available are working in local communities.

In both the surveillance and prevention components of DHAP's flagship health department Funding Opportunity Announcement (FOA), the 16 jurisdictions are now required to provide perinatal HIV services coordination. This is a major "ask" given all of their competing priorities, but DHAP believes this offers potential opportunities for collaboration with HRSA. The key functions for perinatal services coordination are as follows:

1) Define jurisdictional goals, which includes:
    - Identifying key stakeholders and champions
    - Creating mechanisms for stakeholders to convene and plan
    - Formalizing stakeholder roles and leadership

2) Conduct real-time case finding among:
    - Pregnant women with newly diagnosed HIV infection
    - Women with established HIV infection who become pregnant

3) Integrating perinatal HIV prevention into HIV care, which involves:
    - Promoting preconception care for women and men with HIV
    - Creating novel methods to advance preconception care and care integration
    - Supporting strategies for improving postpartum linkage to care

4) Assuring care coordination to comprehensive medical and psychological care by:
    - Assuring care coordination for treatment and/or prophylactic
    - Prioritizing pregnant women for real-time linkages to care
    - Supporting access to informational resources
    - Creating resources for providers on perinatal HIV prevention

5) Collecting and using surveillance data by:
    - Matching HIV surveillance data to birth registries
    - Collecting data to inform resource planning and utilization
    - Identifying underserved populations

6) Engaging in case review and community action, which includes:
    - Conducting case-reviews (e.g., FIMR-HIV for continuous quality improvement)
    - Prioritizing cases of perinatal transmission
    - Facilitating community action.

DHAP views integration of perinatal HIV prevention into HIV care from a life course perspective in that the same women who get HIV are the same women who get pregnant, who are the same women who have viral rebound after they have their baby, and are either retained or not retained in care postpartum which can be a vulnerable time. DHAP is particularly excited about the EHE opportunities for this life course perspective and not sectioning off prenatal/pregnancy/perinatal as a separate entity.

There is still a long way to go in terms of identifying PLWH and getting them diagnosed. It is important to point out that DHAP published a CDC *Vital*signs™ last December that illustrates that heterosexuals living with HIV go undiagnosed longer than MSM and people who inject drugs (PWID). While the number of heterosexual men is relatively small, they are an important population from a family health perspective in that helping heterosexual men get identified earlier can further reduce incidence in women. In 2015, nearly 40,000 people in the US received an HIV diagnosis. Of those, 1 in 2 had been living with HIV 3 years or more, 1 in 4 had been living with HIV 7 years or more, and 1 in 5 already had the most advanced stage of HIV (AIDS). About 59% of heterosexuals, 42% of PWID, and 29% of gay and bisexual men are at increased risk. Many people at high risk for HIV are not getting tested every year. Median years with HIV at the time of diagnosis in 2015 among males with heterosexual contact is 4.9 years, and with male-to-male contact is 3.0 years.

DHAP has developed a draft updated framework. The areas of emphasis for the Framework 2.0 include an emphasis on providing comprehensive treatment and prevention services for HIV and sexual and reproductive health. This involves earlier diagnosis of HIV in women and men of reproductive potential with partner testing, preconception care and family planning, PrEP, and post-partum retention in HIV care. DHAP would like to pilot test in prenatal clinics, including having men who are undiagnosed learn their status in this setting while their female partner is getting tested. This also would offer an opportunity for disclosure if she is infected and has not

been able to do that. Framework 2.0 also includes a focus on improving surveillance systems, perhaps combining resources among various federal agencies to support understanding of the potential teratogenic effects of some of the important medications needed to end the epidemic. DHAP has noticed through its FIMR-HIV case reviews that mental health and substance abuse are consistent among women who have infants born with HIV. Increasingly, women who are pregnant with HIV are often foreign-born. The women have some special needs, particularly related to breastfeeding. Framework 2.0 has a focus to integrate and improve HIV and mental health/substance abuse prevention and care, and to address foreign-born women.

In contrast to what has been observed in HIV, the number of CS cases have been rising quite dramatically. There were projected to be over 1200 cases in 2018. In terms of stillbirths and neonatal deaths, CS was once thought to have a 40% mortality rate. However, Dr. Bolan's group has determined that this is closer to about 10%. While that is significantly lower, it is still quite a concerning statistic of which to be mindful. Missed opportunities to prevent CS are reflected in the information among mothers of reported congenital syphilis cases (n=918) in the US in 2017. Among these, 309 (34%) received late or no prenatal care and were not screened in time; 61 (71%) received prenatal care, but were not screened in time to be treated adequately for CS; 256 (28%) had a positive initial screening test, but were inadequately treated for CS; 126 (14%) had a negative initial screening test, but later were infected and detected at delivery; and 166 (18%) were missing data.

There are three key prevention opportunities for CS. Upstream prevention strategies include preventing females of reproductive age from getting syphilis, and preventing unintended pregnancies among women with syphilis or at high risk of syphilis. A downstream prevention opportunity is to prevent infected mothers from transmitting syphilis to their fetus/infant during pregnancy. The key functions of congenital syphilis prevention are to: 1) Enhance surveillance and epidemiologic data for public health action to address missed opportunities and root causes by collecting risk factor data for pregnant female syphilis and CS cases, matching pregnant female syphilis cases with vital statistics birth and death records, and performing a Maternal Infant Morbidity review; and 2) Increase identification and prevention of cases by enhancing care coordination and partnerships by prioritizing female syphilis cases for investigation including their sexual partners and pregnancy verification, enhancing case management through linkage to critical programs (MCH, FP, IPV, behavioral health, housing, correctional, et cetera), and increasing syphilis screening in those settings. There are numerous common themes. Putting things together is not always the perfect fit, but there are numerous opportunities to maintain the infrastructure that HIV has created and potentially use that to benefit CS prevention as well.

Activities to Prevent Congenital Syphilis, Perinatal HCV, and Perinatal HIV in Philadelphia

Danica Kuncio, MPH
Viral Hepatitis Program Manager
Philadelphia Department of Public Health

Ms. Kuncio reported on Philadelphia's activities to prevent CS, perinatal HCV, and perinatal HIV. The Commonwealth of Pennsylvania (28 Pa Code 27.89) mandates that pregnant women

in Philadelphia are to be screened for syphilis at the first prenatal encounter, at the third trimester of pregnancy, at delivery, and at delivery of a stillborn child. Philadelphia relies on active case reporting. They have an active DIS/Coordinator who is designated to follow-up with all woman of child-bearing age who are diagnosed with SC. They coordinate between the provider and mother to confirm a woman's pregnancy status and work to facilitate treatment through the provider. If that treatment arm does not work, DIS are also deployed to assist in ensuring that the woman is treated during pregnancy, that additional screening is done before delivery of the infant, and that the infant and mother are treated as necessary. There is a case review of each CS case, which is more informal than a FIMR-HIV review. This more informal CS case review is intended to identify missed opportunities in prenatal care and STD prevention.

Some continued barriers in Philadelphia include lack of or inadequate prenatal care, maternal substance abuse, failure to repeat a serological test for syphilis in the third trimester, treatment failure, and inadequate access to STD clinics and STD outreach activities. Maternal substance use is on the rise and is driving some of these additional risk factors and barriers. The Philadelphia Department of Public Health (PDPH) issued a Health Advisory on October 29, 2018. The trends in Philadelphia are near what is being seen nationally, with a 77% increase between 2015-2017 in the number of cases among women. The majority of those were women of childbearing age. Philadelphia had 6 cases of CS in 2017, with a mean of 4. Though small, this definitely reflected an increase. The majority of women being identified are women who inject drugs, women who have sex with men who inject drugs, or women who exchange sex for money or drugs. This represents a new population that the DIS group is not as familiar with, which has resulted in provision of a lot of training. PDPH has a lot of work to do as the opioid epidemic continues to rise.

Ms. Kuncio provided a quick background to perinatal HCV, which is a newcomer to the conversation. Prenatal HCV is risk-based rather than universal at this time. Women who have a drug use history or have additional risk factors are recommended to be screened. The transmission rate is about 6%, but is over 10% if the mother is co-infected with HIV. There is no proven intervention or PEP that prevents transmission of HCV. Therefore, it is critical to test infants to assess whether transmission has occurred and refer them to care if needed. Direct-acting antivirals (DAAs) can cure HCV. While they are approved for children 12-17 years of age, a lot of success has been demonstrated in ongoing clinical trials to assess the safety/efficacy of DAAs in younger children. The sooner infants are identified as being HCV-positive, the sooner they can be linked to care and treatment, and treatment can be provided when appropriate.

Before 2016, PDPH did some work matching its registry and birth records. This identified that greater than 1% of births in Philadelphia are to HepC-positive women. The opioid epidemic is driving this overlap. Most concerning for PDPH was that gaps in the testing were occurring. They identified that only 15% of infants were appropriately screened for HepC when born to HepC-positive women. This prompted some follow-up work that identified that the primary barrier was communication issues in that pediatricians never knew about the mothers' HepC status. An additional issue is that infants were often lost to the care of their primary pediatrician by their second birthday and testing never took place.

Seeing these issues, the PDPH established a Perinatal Hepatitis C Program (PHCP), which was modeled significantly after the Perinatal Hepatitis B Program (PHBP). The PHCP has one fulltime employee and a lot of in-kind support to try to address perinatal HepC with limited resources. The goals of the PHCP are to: 1) identify HCV-positive pregnant women; 2) work

with the mother and pediatrician to ensure the child is tested and linked to care if necessary, 3) work with mother and provider to ensure that the mother is linked to care for her own infection, 4) provide support and resources to prenatal and pediatric providers, and 5) understand the population of HCV-positive women, their clinical experiences, and risks associated with transmission.

In terms of identification, PDPH has continued its registry match with its birth certificates. Mother-infant pair identification methods have included: Birth Certificate - HCV Registry match, Birth Certificate indication of HCV (Ceased using; sensitivity: 51%), Electronic Reporting of Pregnancy status, Biweekly reporting from birthing facilities, and Provider Reporting. In addition, they want to identify women during pregnancy to be aware of their status, build a relationship with them, and link them to care as soon as possible. They have been using laboratory reporting of pregnancy status. Certain reference laboratories embed International Classification of Diseases (ICD)-10 codes into the Health Level 7 (HL7) messaging of laboratories that come to the health department.

To enhance provider reporting, the health regulation changed in July 2017 to require reporting of pregnancy in an HCV-positive woman. Once they have this information, they work with the pregnant woman to provide education about the risk of perinatal transmission and to request her consent and for her collaboration to work with the pediatrician to get the child tested. The pediatrician is informed of the exposure by letter and telephone contact. Once consent is received, PDPH works with the pediatrician to communicate the exposure that has or will take place and provide them guidance for appropriately testing infants for HepC. They follow up with the provider and mother as needed until the infant is screened, lost-to-follow-up, or becomes 27 months of age.

There are multiple national testing recommendations for HepC in children, which causes a lot of provider confusion. They have tried to bridge that, but have decided to emphasize testing in the first year of life. The vulnerable populations covered in the program are often transient, lost-to-follow-up, or do not have guardianship. Thus, the earlier the testing can take place, the more reliable it is. The baseline was 15% before 2016, but has recently increased to over 50% once someone interacts with the program. While not perfect, this definitely represents progress.

In regard to maternal Hepatitis C care**,** DAAs are not indicated for use in pregnant women. However, cases have been presented during national meetings that indicated perhaps this will be possible in the future. Postpartum treatment is critical regardless. Linking the mother to care is important for reducing household and perinatal transmission. Taking advantage of this opportunity to work with a woman who is engaged in medical care who generally may not be is imperative. They work to link women as soon as possible to HepC care regardless of when treatment can be initiated, just to develop that relationship as soon as possible. Due to limited resources and time, this is an area in which PDPH has not been able to give its all, so they would like to enhance their efforts here. There are opportunities for conversations regarding contraception and family planning as well. PDPH collects extensive data through chart abstractions and provider and patient interviews about birth outcomes, maternal factors, and other HCV testing information.

Provider education is critical. In addition to the one-on-one guidance, PDPH offers in-service presentations and guidance materials to emphasize that there is a risk of HCV in pregnant women in Philadelphia; that communication must be built between prenatal providers,

obstetricians, pediatricians, and the mother; and that screening is critical in these populations. In terms of challenges and considerations, pediatricians often do not know about a child's HCV exposure. Foster/adoptive parents or guardians may not know the child's or mother's HCV status. Universal HCV screening of pregnant women is occurring in some locations in Philadelphia. Following in-service education, some providers opted in once they realized that their patient populations were vulnerable and they were probably missing cases. Confidentiality of the mother's HCV status, especially when she is no longer the guardian, is something PDPH has tried to be very sensitive about. They have had some pushback from providers regarding pediatric testing approaches and in-house policies. Despite these challenges, a lot of progress has been made. PDPH is seeing over 3% of births in Philadelphia are to HCV-positive women now, so their workload is increasing. However, they are optimistic that they are on the right track and are making some progress.

The work in perinatal HIV prevention and surveillance has been extensive in Philadelphia for a while. Surveillance has been conducted since 1999 and includes PHER/Pediatric HIV case surveillance, eHARS match to vital statistics birth records, data to care activities, and FIMR-HIV. Prevention includes extensive perinatal HIV prevention coordination by an Advanced Care Nurse who does outreach to prenatal providers regarding HIV testing and treatment, perinatal case management, partner services, and FIMR-HIV.

In particular with the FIMR-HIV, the Case Review team comprised of participants who are stakeholders in the community and the prevention world meet 10 times a year to review 2 to 3 cases each time. That information is reviewed by the Community Action Team, which meets 2 times a year, to identify missed opportunities in systems in Philadelphia that could improve outcomes for perinatal HIV. The reasons for the success of this program is because of its collaborative nature. This program brings all parts of the perinatal prevention system together along with community stakeholders, identifies missed opportunities for prevention of perinatal HIV transmission and near-misses, sets and addresses the priorities for perinatal HIV prevention, and has been highly successful in implementing action steps identified to close gaps in prevention of perinatal HIV transmission.

An example of success of the FIMR-HIV program is the implementation of Perinatal HIV Prevention Coordination work in Philadelphia. In 2012, funding was received to support an Advanced Practice Nurse to address a gap that was found through the FIMR-HIV, which was that HIV testing was not occurring in every prenatal care setting. This individual follows a Pharmaceutical Liaison Model to promote HIV testing in prenatal care settings, conduct peer-to-peer trainings and disseminate prevention educational materials, organize grand rounds on prevention of perinatal HIV transmission, and collect as much data as possible to create a feedback loop to inform the feedback FIMR-HIV process.

Another need that was identified was inconsistent implementation of Prenatal Case Management (PCM) across agencies. An RFP was published for PCM and Implementation of PCM standards. The activities were to provide intensive perinatal case management to HIV-infected pregnant and postpartum (up to 1 year) women to promote viral suppression and to prevent perinatal HIV transmission, coordinate the medical team during pregnancy, and provide antiretroviral therapy (ART) medication adherence support.

The Contraception Committee, which is part of the Fetal Infant Mortality Rate Community Action Team (FIMR CAT), have identified a lot of issues regarding contraception access for women.

For example, a lot of pregnancies were not planned, contraception was not being provided for women identified as HIV-positive and pregnant. The Contraception Committee has developed a resource guide to ensure access to long-acting reversible contraceptives (LARCs), advocated for/achieved reimbursement for postpartum LARC placement, implemented a Ryan White (RW) performance measure on preconception counseling utilizing the "One Key Question," and advocating/implementing the continuity of contraception use among women entering the Philadelphia County Jail System.

Some additional FIMR-HIV-informed projects have included the following:

- Development and implementation of ongoing HIV prevention training to child welfare staff, including information on infant exposure, mother-to-child transmission, and timeliness of treatment.
- Ongoing education to the Department of Behavioral Health and Intellectual disability Services (DBHIDS) MH and SA case managers and providers working with MH/SA populations about HIV testing and treatment.
- Development of FAQs for PrEP for women beyond pregnancy care.

Based on data from 2015-2017, the trends for perinatal HIV exposure and transmission have decreased. The PDPH has received HRSA funding for elevation among HepC among people who are HIV-positive. The collaboration between the HIV and HepC group has been exceptional, and HepC has been incorporated into the FIMR-HIV process in Philadelphia.

Perinatal HIV Prevention: Minnesota's Wrap Around Care Model

Cheri Booth, RN, MSN, MPH, PHN
Children's Hospitals and Clinics of Minnesota

Ms. Booth noted that Minnesota is a lower incidence state, with only 286 cases of perinatal HIV reported in 2018. Of the 65,000 births annually, only about 50 to 70 (0.001%) that they know of are to HIV-positive women. The state surveillance system combines the birth and HIV registries to look for cases. Minnesota has a higher population of people who are foreign born, with 59% of program patients being foreign born and 50% of those being from African countries. The state accepts a great deal of refugees and has one of the highest concentrations of Somalian refugees. Minnesota's perinatal transmission rate is less than 2%.

Minnesota's Wrap Around Care Model is hopefully a model for what other programs can do. They have a state mandate that requires reporting of HIV+ screening in a pregnant woman to the state department of health. There is a standing Commissioner's Order with the Minnesota Department of Health (MDH) that if a woman is out of care at 20 weeks pregnant, the Commissioner can utilize the MDH as a resource to reach out to these women. There are two dedicated RN perinatal HIV Care Coordinators with ability to travel. They can meet clients at home, clinics, treatment facilities, et cetera. One is located at the county hospital and deals only with cases who are inside of that hospital facility, which is about 10 to 15 cases per year. Ms. Booth is responsible for the rest of the state. While she is housed in Children's Hospitals and Clinics of Minnesota, her work is not primarily with children patients. While a number of babies

present there for screening and she sees and follows up with them in the clinic with their provider, the vast majority of her patients are from completely different health institutions.

There are a number of challenges, one of which is non-centralized care obstetrics and HIV care. There are hundreds of care sites across many systems, but there is no unified medical records system. Given that Minnesota has a lower incidence and a fewer number of births, it also means that their out-of-state providers and even some of the Twin City providers are not used to HIV perinatal care. They are not as familiar with the testing, language, and reporting. This makes her job more complex. Part of her job is to be the nurse and engaging in activities such as assessments, follow-ups, and care. The other part of her job is as an educator who is working with providers. They have a grant for capacity-building and identifying healthcare systems that are not doing the greatest job about reporting the pregnancies of positive women, and are not doing as good a job as they should be at making sure those test results are being reported. So, part of her job is to educate providers.

Ms. Booth's job is in part to develop relationships with all of the labor and delivery hospitals. Minnesota has experienced some maternity deserts that are occurring across the country, with hospitals closing their maternity delivery centers and concentrating them in areas with higher populations. Sometimes, that makes her job easier. However, this is very challenging for patients who have to drive one to two hours. Sometimes they do not make it and end up in EDs and deliver where hospitals do not provide this service on a routine basis, may not have someone on staff, and may not be prepared to handle the mother's care or the pediatric follow-up and prescribing of the appropriate medications and testing. She also coordinates with local pharmacies around the hospitals, especially if the hospital does not have a discharge pharmacy, to ensure that the medications for moms and infants are provided. This can be very challenging. Even in her own institution where they see babies, if they find an infant who happens to need all 3 medications, they may not be able to get them in an oral solution when needed. Part of it is working ahead of time to ensure that medications are available, which they try to do in the month before a woman is due.

Minnesota has a 20-Week Rule and much of what they do depends upon this. When a mother is reported to MDH, they call to make sure she is in case. A lot of times these mothers are finding out for the first time that they are HIV-positive. They try to get them educated and connected to care, but this does not always work as planned. The Commissioner's Order under this rule allows MDH to share information with Children's so that they may contact patients directly to offer coordinated care services and imminent delivery planning. It also allows for Children's to provide care planning and consultation for labor and delivery centers and pediatricians who care for HIV+ pregnant women and their babies. More often than not, mothers will accept these services when they realize that there is dedicated support available to them. This is a safety net for them. They would rather find out from patients directly who are referred to them from various programs, but if they do not, at least they know there is a safety net. They also have what they are calling "Imminent Delivery Planning," which they are in the process of finalizing. They had their first case recently in which they ran through the drill of thinking they needed to use it. They were able to get everything in order before the Commissioner's Order needed to be fulfilled. The plan essentially allows them to assist an out-of-care pregnant women and hopefully narrow down which hospital. The delivery plan includes information about viral load, instructions for the mother based on viral load, instructions for the baby, et cetera. This will help to inform people in pharmacy, pediatrics, labor and delivery, postpartum, et cetera in advance so that they will be prepared. There is a 24-hour Physician Access Line for provider consultation and a referral

network for birth support doulas, Adult Rehabilitative Mental Health Services (ARMHS), Healthy Beginnings, county public health, parenting programs, et cetera.

They also have a FIMR-Fetal and Infant Mortality Review that assesses, reviews, and works to improve process and service systems. They had one transmission in 2017, which was part of their review. Sadly, they could not find a lot different that could have been done with that case because the mother was virally suppressed and everything went the way that it was supposed to go. Yet, it still happened. It was a hard and emotional reminder for those doing this work that transmission of HIV can occur in the best of scenarios. One of the nice things that has come out of this is a mechanism by which to ensure that azidothymidine (AZT) is accessible. That same process has been implemented to ensure that infant medications will be available as well. Because Children's Hospitals and Clinics of Minnesota takes care of HIV perinatal and pediatric cases, they need to do more. They identified and trained some Champions and created a connection between the hospital providers and Champions. They now have identified and trained obstetric, pediatric, and adult HIV providers who have become a secondary network for HIV perinatal and pediatric care provision.

Children's Hospitals and Clinics of Minnesota is comprised of two facilities, both of which are in the Twin Cities about 14 miles apart in St. Paul and Minneapolis. They recently added a gender health clinic and a PrEP clinic for adolescents. They have Case Managers and Peer Navigators. Medical family case management is offered to all HIV+ pregnant women, HIV+ children, and adolescents. Pregnant women can remain in case management for up to 3 years after delivery. As part of nursing services, women also receive biopsychosocial assessment and assessment for intimate partner violence (IPV). There is a major focus on trauma-informed care because some refugees were coming from areas where unthinkable things were occurring, and their care needs to be addressed adequately and appropriately. Ms. Booth is currently assessing how many weeks gestation women are at the time they are referred to her and at the time they are diagnosed to determine whether it is possible to move the clock back on that to get them diagnosed prior to pregnancy. They are engaged in efforts with their adult providers to get partners tested, and are also working heavily on safer discloser. While a lot of these efforts are in process, she feels like they are on the right track to making a major impact even with a small program.

Perinatal Hepatitis B Virus (HBV) and Congenital Syphilis Prevention in Minnesota

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Dr. Mody indicated that the Hepatitis B Perinatal Program has been operating for about 30 years. During this timeframe, the coordination of this program has varied between nurses and epidemiologists. At is inception, it was led by nurses. In more recent years, the program has been led by epidemiologists. This has been helpful because they have been able to take a close look at the data to make some program improvements. Minnesota has between 400-450 babies born each year to HepB virus surface antigen (HBsAg), which is the fourth highest in the nation

behind California, Texas, and New York. Minnesota is a centralized state in terms of reporting and surveillance, but HepB case management is all done by local public health departments. Local public health departments are responsible for making sure that vaccination series for infants are completed, completing the post-vaccination serologic testing, and patient education. Both Minnesota Department of Health (MDH) and local public health are involved in provider education.

MDH relies a lot on local public health. To make this more doable and successful, MDH reimburses local public health for case management. The two largest counties in the metropolitan area, Ramsey and Hennipen, are paid annually with lump sum contracts. In about 2013, performance benchmarks were tied into these contracts to ensure that they are vaccinating and completing post-vaccine serologic testing done on time. As a result of these benchmarks, there have been dramatic improvements in performance. All other counties reimbursed on a case-by-case basis at the time of completion at $500 per case and $250 if a second course of vaccination is needed. Approximately 80% of all cases occur in the 7-county metropolitan area, while the remainder of Minnesota does not see many cases. Despite not having to respond as frequently, there are still high levels of engagement from local public health. This is accomplished in part through quarterly calls with all local public health departments throughout the state, as well as an in-person meeting once every two years.

In terms of case management, health providers are supposed to report all pregnant women with laboratory tests positive for HBV to MDH. However, they have to reach out extensively to providers to ascertain whether women of childbearing age (14-46 years of age) may be pregnant. MDH sends resources to providers for each infant and sends letters to each family during pregnancy and following birth. Reminders are sent before the third vaccine is due and before the post-vaccine serologic timepoint. MDH and local public health make phone calls to providers and families as needed. They send reports of upcoming deliveries sent to delivery hospitals each month so that they can be prepared for the delivery and the immune globulin (IG) PEP. Calls also are made to educate providers for every missed pregnancy and baby.

A major success is utilization of the Minnesota Electronic Disease Surveillance System (MEDSS). All case management is done in MEDSS, with local public health having the ability to enter data directly into the system. This has improved workflows, reports, and tasks and simplified tracking of cases. Almost all of the counties are using this and there has been noticeable improvement in terms of timeliness of data reporting. Approximately 98% of cases are followed by local public health in MEDSS. Real-time data are shared by MDH and local public health. There have been notable improvements in outcomes since moving into MEDSS in 2013. As noted, performance benchmarks are in place for two of the largest counties. There have been huge improvements in the timeliness of data entry and program outcomes. There have been major improvements in making sure all infants are receiving their second and third vaccines on time. The program at MDH has been such a major success, CDC has implemented some of these benchmarks in the upcoming 5-year grant cycle. No infants have been identified as being infected with HepB since 2016.

In terms of challenges, pro-active reporting of pregnancies is nearly non-existent. There have been increases in vaccine hesitancy and out-of-hospital births, which has raised some new challenges for Minnesota. There are limited educational materials in some areas, including postnatal care for infected women and materials translated into a variety of languages. They are working on translation now.

A major spike in early syphilis cases among women in Minnesota in approximately 2013. The 2018 data now in and finalized and the number of these cases has increased to 94. It is not surprising that with this large spike in syphilis cases among women, there has been a resurgence in CS in Minnesota. In 2015, CS showed up again for the first time after several years of having no cases. In 2016, the state worked with a variety of clinical partners throughout the state to develop some guidance. Minnesota is one of six states that has no state laws or regulations requiring syphilis screening during pregnancy. The new guidance as of January 2016 is to screen all women twice during pregnancy, at the first prenatal visit, early in third trimester, and at delivery regardless of any known risk factors. Roughly two years later, they assessed the first two years of data and considered whether all women need to be screened three times or if this could be scaled back somewhat. The decision was made to scale back and the revised guidance as of February 2019 is to screen all women twice during pregnancy, at the first prenatal visit, early in the third trimester, and then many women should also be screened at delivery based on a variety of risk factors. Additional guidance is disseminated through professional societies, talks, and online.

In terms of next steps for combatting CS in Minnesota, they are in the early stages of developing a FIMR process for CS with a clinical advisory group. They also are participating in a national Congenital Syphilis Special Interest Group (SIG). They have been selected to participate in a time-limited Evaluation and Program Improvement Capacity Program for which MDH has chosen to focus on developing and evaluating a larger CS response plan.

Perinatal HBV Prevention

Noele Nelson, MD, PhD, MPH
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Dr. Nelson gave an overview of perinatal HepB and prevention strategies at the national level, the US Perinatal Hepatitis B Prevention Program (PHBPP), and HepB vaccination in terms of national coverage.

HBV transmission occurs through percutaneous or mucosal exposure to infectious blood or body fluids. About 80% to 90% of infants who are infected with HBV become chronically infected. About 25% of individuals chronically infected will develop cirrhosis or liver cancer and die prematurely. HBV-infected infants are usually asymptomatic, so infection undetected in infancy might not be diagnosed until disease has progressed.

The key steps to preventing perinatal transmission of HBV include maternal screening, infant vaccination and post vaccination serologic testing (PVST). All women should be tested for hepatitis B surface antigen (HBsAg) with each pregnancy. This provides an opportunity to link the mother to care, for maternal treatment, and for prevention of mother-to-child transmission. The American Association for the Study of Liver Diseases (AASLD) suggests antiviral therapy to reduce perinatal HBV transmission when the maternal HBV deoxyribonucleic (DNA) level is greater than 200,000 IU/mL. CDC's Advisory Committee on Immunization Practices (ACIP) has adopted this language in the updated vaccination recommendations. Infant vaccination for infants born to HBsAg-positive women is critical within 12 hours of birth. This includes HepB

vaccine and hepatitis B immune globulin (HBIG), as well as completion of the HepB vaccine series according to schedule. PVST includes tests for both HBsAg and antibody to HBsAg (anti-HBs). This should be done at 9-12 months of age if the series is completed on schedule or 1-2 months after the final dose in the series if series completion is delayed. PVST should never occur before 9 months of age, because earlier testing may detect anti-HBs from HBIG administered at birth and not from vaccination. Testing at 9 months also maximizes the likelihood of detecting late HBV infection.

In 1990, CDC funded the PHBPP. This program is housed in the National Center for Immunization and Respiratory Diseases (NCIRD). It is funded through CDC Immunization Cooperative Agreements Section 317 funding. The program is in 64 jurisdictions (50 states, 6 cities, 5 territories, 3 Freely Associated Island Nations). PHBPP's aims are identification of all HBV-infected pregnant women, timely receipt of infant PEP, infant post-vaccination serologic testing after completion of the HepB vaccine series, and revaccination of infants who do not respond to the initial HepB vaccine series.

In 2016, only 32 cases of perinatal HepB were reported to CDC from 13 states. Since 2012, the number of cases reported has been under 50. However, a 2009 modeling study estimated that 952 chronic hepatitis B cases occur each year among persons infected with HBV at birth, for a baseline annual rate of 3.84% among infants born to HBsAg-positive women. This model employed estimates of the annual number of births to HBsAg-positive pregnant women from data from the PHBPP, national immunization surveys, and published literature. The reported cases to the PHBPP are likely lower than the modelled numbers for a number of reasons, including infants reported to the program who did not receive post-vaccination serologic testing so they were not identified, or infants who were case-managed outside of the PHBPP.

A key component of perinatal prevention is identifying births to HBV-infected women. In terms of identified births to HBsAg-positive women compared to total expected births to HBsAg-positive women from 2008-2014, the total expected births to HBsAg-positive women were about 25,000 per year during this time period. However, approximately 50% of the total annual births to HBsAg-positive women in the US were case-managed by the PHBPP. Thus, there is a major gap in what is estimated and the actual identified births.

Until 2014, estimates were generated using a model based on natality data from the National Center for Health Statistics (NCHS) and HBsAg-positive seroprevalence by race and ethnicity. These prevalence estimates were primarily estimated from National Health and Nutrition Examination Survey (NHANES). The methodology for determining births to HBsAg-positive mothers changed in 2015 to include maternal childbirth from all US states and DC in an attempt to address the evolving HBsAg prevalence worldwide. The greatest number of births to HBsAg-positive mothers still come from women born outside the US. This model estimated that 5666 fewer births to HBsAg-positive women than did the previous model. In 2015, an estimated 20,628 infants were born to HBsAg-positive women in the United States. This helps to close the gap slightly, but there remains a large gap between women who are identified and the expected births to HBsAg-positive women.

In terms of national trends in PHBPP indicators from 2008-2016, the percentage of infants in the program who received both hepatitis B vaccine and HBIG within 1 calendar day of birth has been ≥95% since 2008. However, the percent of infants receiving HBIG and the HepB vaccine series by 12 months of age was less than 82% in 2016. This reflects great room for

improvement in that time period. The percent of infants who received post-vaccination serologic testing was 65% in 2016. This is an increase from 56% in 2008, but there is still a long way to go. This is particularly concerning because these infants who were infected but did not respond to vaccine will be missed if testing is not performed, not done correctly, or not documented. In addition, if HBsAg is not done, it will not be known whether babies are infected until disease may already have progressed.

In 2016, a total of 3218 cases of acute HBV infection were reported to CDC. There was a major decline in the number of acute cases reported as vaccine recommendations were implemented starting in 1982. Vaccination of infants from HBsAg-positive women was recommended in 1984, in all US infants in 1991, and birth dose in 2005. After adjusting for under-ascertainment and under-reporting, an estimated 20,900 acute HBV cases occurred in 2016. To reiterate the recommendations, all infants born to HBsAg-positive women should receive HepB vaccine and HBIG within 12 hours of birth, administered at different injection sites. Only single-antigen HepB vaccine should be used for the birth dose. It is recommended that the HepB vaccine birth dose be given within 24 hours of birth for medically stable infants weighing ≥2,000 grams and born to HBsAg-negative mothers. This aligns with the World Health Organization (WHO) recommendations. The recommendations vary slightly depending upon birthweight and maternal status.

Regarding efficacy, it is known that HBIG provides a short-term increase in anti-HBs for about 3 to 4 months. This might improve protection until the infant responds to vaccine. For prevention of mother-to-child transmission of HBV, HBIG alone is about 71% effective and HepB vaccine alone is about 75% effective. The efficacy of HBIG and hepatitis B vaccine combined is approximately 94%. This is based on infants born to HBsAg-positive and HBeAg-positive mothers. About 90% of infants born to HBsAg-+/HBeAg-+ women will become infected without PEP; no vaccine or HBIG. The infection rate is much less if the mother is HBeAg-negative (and has a low viral load); as low as 30% without PEP.

Birth dose coverage was about 73.6% in 2017. This coverage has increased substantially since the birth dose recommendation in 2005, and has been stable at about 70% since 2012. This is well below the Healthy People 2020 target of 85%. In children 19-35 months of age, the coverage reached 90% in 2000 and has been steady since, near or above the HP2020 target of 90%; coverage was 91.4% in 2017.

In conclusion, to decrease perinatal HepB infections the following are needed: 1) increased identification of HBsAg-positive pregnant women with maternal management and maternal third trimester antivirals, if indicated; 2) timely infant post-exposure prophylaxis and infant management; 3) increased HepB birth dose coverage overall; and 4) increased post-vaccination serologic testing of infants born to HBsAg-positive mothers.

Facilitated Discussion

Dr. Taylor said that she has been told that vaccinating the women is outside of the purview of perinatal epidemiology programs, even though by definition pregnancy is a marker for heterosexual sexual intercourse. The women are now at risk postpartum of acquiring incident HepB before the next pregnancy. CHAC has discussed many times that pregnancy is often an

opportunity to engage women in healthcare, but they will keep missing this opportunity to vaccinate susceptible women if vaccinating them is outside of the purview of perinatal programs. She asked CHAC and CDC to clarify over time whether CDC can revisit the adult HBV vaccination recommendations with the ACIP Workgroup given rising rates of HBV due to the opioid crisis and room to improve upon risk-based vaccination. She could imagine a campaign "Two for the Price of One" showing the mother and infant together getting vaccinated to make sure women do not leave the hospital without being vaccinated, and then the woman will not show up during the next pregnancy with HepB. They also need to talk about women who are HBsAg-positive with chronic infection and offer antiviral therapy if their HepB viral load is >200,000 IU/mL. If part of the program is allowed to include referring women to care, then they need access to care to ensure that their HepB DNA level is less than >200,000 IU/mL at the next visit. A question about the HepB perinatal programs regards whether they are able or need to further consider horizontal transmission. There are other barriers to care, including fear of deportation. Many women from hyperendemic regions of the world who are in this country may be fearful of accessing care. If a woman is identified as HBsAg-positive and the infant receives HBIG and vaccine, there is still a potential for horizontal transmission because HepB is so much more infectious than the other perinatally transmitted infections.

Dr. Nelson responded that in terms of vaccination during pregnancy, pregnant women are currently recommended to receive HepB vaccine if they have another existing risk factor for HepB infection. For women of childbearing age, CDC will be revisiting the adult recommendations with the ACIP Workgroup in the coming months to years.

Dr. Rody indicated that the state is not making any recommendations other than what CDC/ACIP recommend. Postpartum linkage to care for the mother is one of the challenges. Their program has seen multiple women return with several births and they do not remember being followed during their previous pregnancies for chronic HepB infection. There is still a lot of work that needs to be done in terms of education. Part of that would involve linkage to care. Regarding susceptibility status of household members, they generated pocket cards for obstetric and pediatric clinicians. The card discusses making sure other household members are immunized as soon as a woman is identified as being positive.

Dr. Taylor pointed out that the recommendation about women who are susceptible to HepB only being vaccinated if they have another risk has been open to interpretation, and the default may be not to vaccinate these adult women. Since there often are multiple sets of recommendations, she contacted the lead author of the AASLD article. The author responded that it is true that in their hepatology journal and the AASLD guidelines, they do not recommend vaccinating all susceptible women who could become pregnant or are pregnant because they are following the CDC/ACIP recommendation and are not clear about whether this means all women or just women at risk. They also do not know what they meant by "at risk." Clarification of some of these issues would be helpful.

Dr. Havens pointed out that they just heard presentations from people who are apologizing for one or zero cases of perinatally-acquired HIV. If this is not a success story of the collaboration between CDC and HRSA, then they are losing contact with reality. CDC has been laboring tirelessly for many years to achieve this, and it is amazing. He recognized that while CS has increased, HIV has decreased amazingly. He recalled that Ms. Kuncio said that there is a requirement in Philadelphia for reporting HepC-positive women and that Dr. Mody said that

there is a reporting requirement for HepB-positive women in Minnesota. This is difficult to do and he wondered how they made this work.

Ms. Kuncio indicated that Philadelphia has a reporting requirement for HepC, HepB, and HIV. It is very difficult. They made the regulation change in 2017 and heard nothing. This identified some issues with their communication with providers. They were relying heavily on the Health Alert Network (HAN) and identified that putting out proclamations was not necessarily getting the information to the people who need it. Having direct conversations and in-services with providers has helped a lot. They build relationships through their perinatal HepB, HepC, and HIV programs, which has helped as well. Some recent work by a newly formed Neonatal Abstinence Syndrome (NAS) Program with which their Perinatal HepC Program overlaps a lot has worked to model off of some Zika prevention work requiring that providers in labor and delivery units report every two weeks on any births to HepB- or HepC-positive women, children born with NAS, et cetera. They have seen a huge uptick with this influx of supportive services. It is difficult to ask providers to report something else, so they are trying to make it as easy as possible for them and build streamlined conversations for that.

Ms. Booth added that this works in the sense that they receive a fairly decent amount of reports. The issue they are having is the “hot potato” problem. They have their adult ID providers on whom they rely heavily to be the primary reporter if one of their patients is pregnant. They rely on their OB providers to report positive women, but they think ID will take care of it and ID thinks that OB will take care of it. Some place in between is a mother who does not get connected. Part of the capacity-building upon which they are embarking is to address this OB gap in reporting. Ideally, reporting would come from an OB reporter.

Seizing an opportunity that the Zika response provided, Dr. Lampe indicated that they worked with the Office of the National Coordinator (ONC) for Health IT. It did not have an impact on Zika, but the idea was to leverage that opportunity to have an impact for all of the things they were discussing during this session. They are working on HL7 messaging and making pregnancy status reportable along with other notifiable conditions through the electronic medical record (EMR) in such a way that it is not burdening the HCPs themselves. This is being spearheaded by their colleagues in CDC’s Center for Surveillance, Epidemiology, and Laboratory Services (CSELS). They are trying to keep the Subject Matter Experts within DHAP abreast of that so that as things are coming along, Council of State and Territorial Epidemiologists (CSTE) and others are made aware. This is not occurring 100% yet, but this is some of the work of keeping systems going.

Dr. Bolan added that there is a lot recognized through the Zika surveillance, given that the National Center on Birth Defects and Developmental Disabilities (NCBDDD) did not have experience with communicable diseases and did not realize that information had to go from the county health department, to the state health department, to CDC. Dr. Peggy Honein has been forward-thinking and reached out to the Division of Sexually Transmitted Disease Prevention (DSTDP) in terms of CS and HIV. They now have a workgroup that is focused on building a holistic, unified maternal infant surveillance system or registry. DSTDP harmonized their data with the Zika data and they have a 90% match in terms of variables. The only part that varied was the diagnostic test used or the clinical symptoms to be collected. They are hopeful that there can be one system instead of everyone building separate silos for all of the emerging maternal issues.

Ms. Fukuda emphasized the importance of thinking about the opportunities from a mom-centered perspective and her health and health promotion. She was reminded of the late 1980s with the idea of the mom as the vector of disease and that being her primary relevance. She cautioned them in thinking about HIV-positive women who intend to have babies. Many of them do now, which is a wonderful place to be. Framing this as a health promotion intervention for mothers and parents. In the context of the Undetectable Equals Untransmittable (U=U) movement and all of the treatment and prevention lessons being learned, she wondered if that was being factored into the messaging in the work that is being done with the women and families they are reaching.

Ms. Kuncio replied that in their enhanced surveillance efforts in general in Philadelphia, they have those conversations with women to convey the importance of thinking about perinatal transmission and if they are planning to have children and to promote the woman's health as well. They try to avoid conversations that are blame-oriented, because these women are living their lives and the pregnancy may be intentional or not, but it can be an opportunity for conversation.

Ms. Booth added that this is an opportunity for trauma-informed care. People experience trauma in very different ways. For many people, the diagnosis itself is a trauma. Personally, when she is doing intake with a client and meeting her for the first time, she focuses on doing the work that she does so that the mom can normalize her birth. If Ms. Booth is there and other people are supporting the mom to ensure that the delivery plan is at the hospital waiting for her and the Labor and Delivery Coordinator is aware of the plan, the mother does not have to worry about whether the medications are there, disclosure has been discussed, who is going to take care of her baby, et cetera. By doing good footwork, they are creating a much more normalized process. Ms. Booth frames it as them being in care and taking their medication is a gift they are giving themselves and their infant, and that their job in this process is to grow a human and experience that birth in the way that they have visualized it for themselves and not to be thinking about HIV.

Regarding an inquiry posed about the reference to an HIV transmission that occurred in Minnesota in a woman who was virally suppressed and how confident they were that this individual was virally suppressed throughout the pregnancy, Ms. Booth indicated that CDC was involved in this afterwards and it was thoroughly investigated. She was doing care coordination with the mother, who attended all of her appointments and taking her medication, and they had the records of the mother's viral suppression throughout the pregnancy and it still happened. They conducted some testing to make sure there was not a different source, and the baby did match the mother's HIV. The response was simply that this still happens.

Dr. Lampe added that they know that U does not = U in the context of perinatal transmission, especially in breastfeeding. The messaging around U=U is complicated in this domain. Something that made a major impression on her 20 years ago was a mother who said they told her if she did everything right, she would have an uninfected baby, but her baby was infected. Her care going forward was disrupted because she distrusted the system. However, the numbers of mothers who have infected babies now are small. U=U is very exciting and important. Steering away from the perinatal transmission piece momentarily, MSM who are living with HIV want to become parents now as well. Some thought must be given to messaging about how to help them safely become parents and not infect their egg or the woman with whom

they create a baby. In terms of breastfeeding perinatal transmission, it is pretty clear that U does not necessarily = U.

Dr. Mermin stressed the importance of case examples because these helps to talk about different risk factors and to present information. He encouraged everyone to collect as much information as possible about cases that have resulted in perinatal or breastfeeding transmission, especially when associated with known and documented viral suppression in the mother. This would tell a more faceted story than is now being assumed, and perhaps could avoid the situation of distrust.

Dr. Mody indicated that the plan for the one case in Minnesota are to write it up, which is in the works.

Dr. Anderson emphasized that particularly with foreign-born women, they are seeing a return to earlier days in terms of disclosure issues and with the desire to breastfeed. Some women may be breastfeeding surreptitiously. They learned in their setting, from labor and delivery nursing staff, that there were women who expressly desired to breastfeed were treated somewhat punitively with threats of Child Protective Services (CPS) referrals. They must examine this type of issue, because it is a recipe for disaster.

Ending the HIV Epidemic: Collaborating Across Boundaries and Responsibilities

John Brooks, MD
HIV Epidemiology Research Team Lead, DHAP
Centers for Disease Control and Prevention

Dr. Brooks moderated a panel presentation for a series of speakers to describe ongoing activities to end the HIV epidemic by collaborating across boundaries and responsibilities. He introduced the panel of speakers and opened the floor for their presentations.

Overview of Ending the HIV Epidemic

Eugene McCray, MD
Director, Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Dr. McCray emphasized that as everyone knows, HIV has cost America too much for too long. Over 700,000 Americans have lost their lives to HIV since 1981. Without intervention, another 400,000 Americans will get HIV over the next 10 years. The federal government has spent approximately $28 billion in research, prevention, care, and treatment annually. The US has access to the most powerful HIV prevention and treatment tools in history and knows what works. Now the time has come to ensure that those tools reach the people who could benefit most from these advances.

In the 1980s, the peak incidence was near 130,000 annually. From 1985-2012, interventions had driven infections down to <50,000 annually. From 2013-present, HIV infections stabilized after a period of decline. While there has been significant progress since the 1980s, declines in new HIV diagnoses have stalled since 2013. Currently, there are still about 40,000 new diagnoses per year.

HIV disproportionally affects some populations. Data continue to show that gay and bisexual men, especially African American and Latino gay and bisexual men; transgender individuals; women of color; and people living in the South have a high burden of HIV infection. Data also show a troubling trend of increased diagnoses in smaller populations such as American Indians/Alaska Natives (AI/AN) for whom diagnoses increased 34% from 2012-2016.

A critical point has been reached in which the tools are available to get to zero new HIV infections, as well as the data to understand where intervention is needed. If communities are given access to all of these resources, including the money and data they need, the HIV epidemic in the US can be ended. With an estimated lifetime healthcare cost of approximately $500,000 per person infected, achieving the program goals will reduce healthcare expenditures by over $100 billion over the next decade.

The EHE initiative is meant to be a whole-of-society approach. No one is expected to do this alone. This will be a joint collaboration between affected communities, PLWH, federal partners, state and local health departments, academia, private sectors, and others. The goal is highly ambitious, which is to achieve a 75% reduction in new HIV infections in 5 years and at least 90% in 10 years. To achieve this goal, it is imperative to rapidly diagnose new HIV infections; ensure that people with HIV get effective medical treatment; protect people from being infected by ensuring access to comprehensive prevention, treatment, PrEP, SSPs, et cetera; and quickly respond to and stop new outbreaks. CDC will work with jurisdictions to ensure that they have the personnel they need to achieve these goals.

It is known that more than 50% of new HIV diagnoses occurred in only 48 counties; Washington, DC; and 1 municipality in San Juan, Puerto Rico. In addition, 7 states have a substantial rural burden with over 75 cases and 10% or more of their diagnoses in rural areas. It is known where most of the diagnoses are concentrated. By targeting resources to these locations, CDC believes they will reach more minority populations at risk for HIV. The data on burden of HIV shows the areas where HIV transmissions are occurring. However, looking at the jurisdictions that are targeted for the EHE initiative shows that it will be possible to reach more minority populations at risk for HIV. Nationally, the Hispanic/Latino population represents 24% of HIV diagnoses, but they account for 31% of the HIV diagnoses in the target counties. Black/African Americans represent 44% of diagnoses in the nation and in identified counties, but they account for 56% of diagnoses in rural states. Targeting these areas also will target disparities in the hardest hit areas.

Ending HIV in America will require an infusion of resources to employ strategic practices in the right places and targeted to the right people. All of HHS is committed to ending the HIV epidemic in America. The President's 2020 Budget Request proposes the following funding allocations and activities for each agency:

<u>CDC: $140 Million</u>

- Test and diagnose new cases

- Rapidly link newly infected individuals to treatment
- Connect at-risk individuals to PrEP
- Expand HIV surveillance
- Directly support states and localities in the fight against HIV

HRSA: $120 Million
- Increase direct health care and support services, further increasing suppression among patients in the target areas
- Expanded PrEP services, outreach, and care coordination in community health centers

Indian Health Services (IHS): $25 Million
- Screen for HIV and prevent and treat HepC

NIH-CFARs: $6 Million
- Refine implementation strategies to assure effectiveness of prevention and treatment interventions

OASH: Maintain Current Funding
- Project coordination, communication, management, and accountability
- Leadership of the Minority AIDS Initiative

SAMHSA: Maintain Current Funding
- Minority AIDS Program

The federal initiative also will leverage state and local planning efforts to end HIV. Building on current planning efforts will help jumpstart the initiative in places already thinking about ending the HIV epidemic in their community. Many locations already have developed plans or are in the process of creating those plans. While each of these plans have different goals, targets, and focus areas, CDC believes this can leverage enthusiasm in the work that already is being done.

In closing, there is an unprecedented opportunity to end the HIV epidemic in the US. It is possible to bend the curve and the time is now to do it.

Ending the HIV Epidemic: A Plan for America

Laura Cheever, MD, ScM
Associate Administrator HIV/AIDS Bureau
Health Resources and Services Administration
CHAC DFO

Dr. Cheever reminded everyone that as mentioned earlier, for EHE, HRSA's proposed President's Budget requests $70 million for the RWHAP and $50 million for HRSA-funded Health Center Program in FY 2020.

In terms of Pillar One (Diagnose) the Community Health Centers are a key entry point for people with HIV who are undiagnosed. They care for patients who are living at or below 200% of the FPL. Many of the medically underserved in this country go to Community Health Centers,

which conduct nearly 2 million HIV tests annually. These centers have the capacity to expand outreach within their communities and increase routine and risk-based HIV testing.

Regarding Pillar Two (HIV Care and Treatment), people with HIV who take medication daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to their HIV negative partner. In addition to the individual benefit of individuals with HIV on treatment e living long and healthy lives, maintaining an undetectable viral loads helps to end the epidemic for the country. Given the funding and the flexibility to direct the funds to the identified jurisdictions, HRSA will focus on providing care to those not yet virally suppressed. This includes those who are in care for whom there are still gaps, those diagnosed and out of care, and the newly diagnosed. To do this, HRSA will increase capacity by funding RWHAP Parts A and B in the identified jurisdictions; and encourage initiation of rapid HIV treatment to achieve viral suppression and stop transmission; and provide technical assistance to the identified jurisdictions. As discussed earlier, among the 50 cities and counties HRSA is targeting, 49 exist within 39 existing Part A jurisdictions. The one exception is Hamilton County, which is Cincinnati. The plan is to fund Part B in the 7 targeted states as well as Ohio for Cincinnati and the 39 Part A jurisdictions where the focus counties reside.

With regard to Pillar Three (Prevent) the health centers will be using the $50 million specifically for PrEP services implementation. The plan is initially to focus in year one on providing funding to co-funded RWHAP and Community Health Center-funded recipients and sites. The reason to start there is because there is significant cultural humility around LGBTQ communities and PrEP champions in many of these sites. The plan is to rapidly take the successes and expand to more Community Health Centers in future years, including those that are not co-funded by the RWHAP.

To expand care and treatment to 400,000 people in the US, the models of care will have to be expanded. Community Health Centers will be an important part of that effort. There are some examples of tremendous success already, so it is clear that this can be done.

It is quite clear that Community Health Centers have support services to work outside of their walls, but it will take a tremendous amount of work to have people at high risk for HIV infection to recognize it and seek PrEP services. Many people, especially young people, do not adequately assess their own risk. To that end, HRSA will be working closely with CDC to help them work at the community level on messages around PrEP, risk, and how to better identify risk to help promote that care and treatment in Community Health Centers for PrEP. The RWHAP is going to support workforce capacity around PrEP through the AIDS Education and Training Center (AETC) Program, which by statute is the only RWHAP part that can work on HIV prevention .

In terms of Pillar Four (Respond), it will be important for the RWHAPs to work very closely with health departments so that patients with HIV in clusters are referred to the RWHAP for treatment services or patients identified as high-risk are referred into Community Health Centers for PrEP and other prevention services. HRSA will be working with that specifically to ensure that those linkages are in place. As mentioned earlier, to meet the challenges ahead, it is imperative to improve viral suppression and decrease disparities among patients who are in care, enhance linkage to and engagement in HIV care of the newly diagnosed, and expand re-engagement and retention for those diagnosed but out of HIV care.

Regarding next steps, HRSA is coordinating very closely among the federal agencies and will continue to do that. CDC is receiving funding from the Minority AIDS Initiative at the Secretary level to allocate planning grants. HRSA will work closely with CDC on this. Jurisdictions are encouraged to build upon existing plans. HRSA's HAB plans to release several Notice of Funding Opportunities (NOFOs), including one for the RWHAPs Parts A and B, one for TA and coordination, and one for workforce capacity development, including for PrEP through the ATECs. HRSA believes that community engagement is very important and has a strong history of community engagement in the RWHAP, but needs to do much more of this to ensure that they truly are working with people across their lifespans and with people who have not been well-represented previously.

Current Activities of CDC Related to Ending the HIV Epidemic Initiative

John Brooks, MD
HIV Epidemiology Research Team Lead, DHAP
Centers for Disease Control and Prevention

If funded, Dr. Brooks indicated that CDC's intends to address issues in all four of the pillars, as well as the workforce issue. In terms of the Diagnose Pillar, the one thing that is most important to CDC at least in the focused jurisdictions, is fulfilling its role in getting every person eligible and for whom appropriate testing is recommended to be tested at least once in their lifetime; and to ensure that those who merit repeat testing due to increased risk are tested annually or more often. CDC looks forward to leveraging some innovative new ideas about how to perform point of care testing and laboratory-based testing. One thing they would like to see advanced is automated HIV testing for anyone who passes through a healthcare center. It is known that many people undiagnosed with HIV have had a clinical encounter in the preceding year, but were not offered HIV testing even though they may have been an appropriate candidate for it.

With regard to the Treat Pillar, treatment will be handled predominantly by HRSA, but the combined role of CDC and HRSA is to get people virally suppressed. CDC will be helping by ensuring that as people are diagnosed, they are linked to effective antiretroviral therapy as soon as possible, and that persons who are identified as being out-of-care are brought back into care and helped to stay in care and remain adherent to the care they are receiving. CDC will be doing some internal work going through the agency's national surveillance system to try to eliminate a lot of duplicate reporting. That is a major problem currently with quickly identifying persons with HIV who may be out of care. Cleaning up the system will help CDC get information about what is occurring to decision-makers more quickly.

Regarding the Protect Pillar, CDC will be promoting all of the regular prevention intervention that the agency already promotes, but will place a particular emphasis on PrEP and syringe service programs as under-utilized interventions that are very effective. Florida and Georgia passed state laws in 2019 that permits syringe service programs. These are two states where there is a high burden of disease, so they look forward to that resource being made available to PWID.

In terms of the Respond Pillar, CDC looks forward to accelerating the deployment of cluster detection and response systems. While this activity is somewhat controversial, the public health benefit outweighs the risk, which CDC is working hard to mitigate. This activity is something that

has been occurring more centrally at CDC, but they look forward to moving it out more proximal to health departments so that they can begin to do this themselves. This effort has done a great job of identifying clusters and focusing where public health resources are directed to prevent new infections.

Regarding the workforce, CDC has some activities in the Public Health Associate Program (PHAP) and also will be providing funds through the agency's NOFOs to the sites to ensure that they have the support they need on the ground to move the initiative forward. One of the most frequent complaints they hear from sites is that they would like to do everything that is recommended, but they do not have the people to do it.

One of the efforts CDC has been engaged in more recently is introducing the EHE Initiative to the public and the agency's many partners. CDC and other collaborating HHS agencies' leadership have been making visits throughout the country. CDC has visited Baltimore and Detroit. The idea is to present to the public a unified face—that this is not an activity that is just CDC, or just HRSA, or just NIH. Instead, this is an HHS activity. To that end, the HHS agencies are working very closely together. They also have been delivering a lot of presentations and engaging in meetings with stakeholders, such as: PACHA, National HIV Prevention Conference (NHPC), Act Now: End AIDS Coalition, HIV Medical Association (HIVMA), National Alliance of State and Territorial AIDS Directors (NASTAD), Association of State and Territorial Health Officials (ATSHO), and American Conference for the Treatment of HIV (ACTHIV).

The first of CDC's NOFOs for the EHE Initiative is for the local community EHE planning. CDC is preparing a NOFO to provide resources that will support the drafting of local community EHE plans by Phase 1 Jurisdictions. This will be funded with FY19 Minority AIDS Initiative Funds. The NOFO will be managed by CDC on behalf of HRSA and CDC, given that these plans will have to integrate all of the activities being done by both agencies. The goal is to build on existing HIV planning activities and EHE plans, with a focus on community engagement in the planning and execution of plans. The anticipated NOFO publication date is Summer 2019, with an award date expected in late September 2019.

The main EHE NOFO award is contingent upon Congressional FY20 appropriation. For this, CDC is drafting a 5-year EHE NOFO. The anticipated NOFO publication is in the Summer/Fall 2019, with a plan to align the timing with the HRSA NOFO so that people can be considering both at once. The proposed award date is January 2020, which is subject to the availability of funding. Announcement of this NOFO will occur before the award for the local community EHE plans NOFO to inform the content of those plans. CDC hosted three 2-hour calls with stakeholders for input regarding this NOFO (e.g., HIV community, public health, clinical care).

Additional activities include working with the PHAP and its graduates to staff field workforce and assisting CFAR leadership develop an implementation research agenda. This year, CDC will be able to take advantage of at least 6 graduates of the program and embed them in health departments in the target jurisdictions. Over 30 responses were received to the notice about this opportunity within 2 days. They also are assisting the CFAR leadership to develop an implementation research agenda. One of the stated goals of CFAR is to ensure that they also engage in implementation research relevant to the EHE. CFARs often have clinical experts and recognized leaders in HIV that the community knows and respects.

Ending the Epidemic Planning: Integrating Across Boundaries

Marlene McNeese
Assistant Director, Disease Prevention and Control Division
Houston Health Department

Ms. McNeese briefly described Houston Health Department's (HHD's) process and experience for implementation of its EHE plan, as well as partnerships that they created in their plans with respect to monitoring and evaluation. She emphasized the complexity of the way in which HIV, STD, and housing funds related to HIV are administered in the City of Houston-Harris County. Part of the challenge includes all of the federal sources of funds and where they land locally in an administrative agency. Part A is managed locally by HHD's county public health colleagues, while Part B is managed by their colleagues at the state. Prevention of HIV/STD rests with Ms. McNeese at the city HHD. HHD is the only directly funded jurisdiction for HIV that is not directly funded for STD. Housing is managed through their housing colleagues.

Though Ms. McNeese said she did not know whether it was in spite of or due to that complexity, HHD has a very long-standing history and relationship of partnering and collaborating particularly around planning activities, as well as implementation of HIV care and prevention activities with their RWHAP and Community Planning Group (CPG) colleagues and other planning groups in Texas. They have long since had joint planning products, epidemiologic profiles, and needs assessments. They have had good cross-pollination over the years during which they have had members serve in membership and leadership roles in both planning bodies. Some of their federal major projects and responses, they have had implementation groups that were formed collectively.

Development of HHD's EHE began in November 2015. Legacy Community Health Services, one of their large FQHC systems, received a Southern REACH grant from AIDS United and the Ford Foundation to develop a plan to end the epidemic in the City of Houston. Some may argue that this is not ideally the way they would want to start the EHE planning, but that is the way it occurred for them. They were required to use an intersectional and social/racial justice approach as a part of that grant, which made a difference in the way they implemented their strategies and planned what they would do.

Given the political climate at the time, the Texas Department of State Health Services (DSHS) was not ready to move forward with a statewide plan, but fully supported and was involved in the Houston plan development. HHD started a lot of community stakeholder engagement meetings, much like most areas of the country have done in the development and implementation of their plans. HHD drafted and launched their plan in 2016 on World AIDS Day. Part of the challenge of that timeline included the fact that they had just completed their CDC/HRSA required integrated plan, and part of the angst and confusion that was created at the time pertained to how the new EHE plan would align with the existing integrated plan. There also was the challenge with community members who served in the integrated planning process in terms of whether they even had the energy or bandwidth to move right into a new development for EHE.

One of the wisest things they did was review the existing EHE plans for New York State, San Francisco, DC, and others. They also looked for and received TA from Housing Works, Harvard Law School Center for Health Law & Policy Innovation, and others who already had helped those jurisdictions in creating their plans. They created a crosswalk between existing integrated plan goals and outcomes that HHD as a community continued to see as a priority and goal versus what was missing. The HHD plan was divided into 5 sections that provide recommendations pertaining to the following topics: 1) Prevention (5 recommendations); 2) Access to Care (7 recommendations); 3) Social Determinants of Health (4 recommendations); 4) Criminal Justice (5 recommendations); and 5) Policy and Research (12 recommendations).

Ms. McNeese noted that surprisingly enough, sections 3, 4, and 5 were not addressed in their integrated plans. She thought that some of the reasons that occurred is because they have public health professionals and community advocates who have been engaged in integrated planning for a long time, who centered their thoughts on what strategies and activities they could support using those funds versus an aspirational look toward ending the epidemic. This resulted in these three sub-priorities rising to the top. It is clear that more needs to be done within those three areas, particularly being in the South and the State of Texas.

The HHD framework is simple and mirrors what a lot of other agencies or areas are doing with respect to the 90-90-90 Goals. Their diversity of stakeholders included PLWH in affected communities that fall outside of the traditional community advocates with whom they work in terms of HIV planning. They assessed alternative models of community partnerships that were underway in their area, such as My Brother's Keeper (MBK) Houston. MBK Houston was a partnership in which there was a large, widescale structural intervention around young men and boys of color in Houston-Harris County that included representations from the school systems, criminal justice agencies, county sheriff's department, medical societies, et cetera—well outside the traditional breadth of what they have done in public health.

Other than in the beginning with the Southern REACH grant, monitoring and evaluation was an unfunded activity, meaning that they did not have dedicated staff embedded to do this work with respect to the organizing and collaboration and hammering out what the benchmarks would be for measuring whether they were successful. To date, the DSHS now supports at least one and there is discussion about how that can be expanded to city and county health departments as well. Staffing this is a challenge. Some of the new charges to helping them in the epidemic requires an increase in the public health workforce that does not currently existing, particularly in the areas of epidemiology, surveillance, and navigation support in and around the medical work.

Ms. McNeese emphasized that transparency is critical. They have been very open in terms of discussing what works and what does not work with regard to implementation, and in revisiting the plans to determine what adjustments need to be made moving forward. HHD felt that EHE required a complete change in the entire health care delivery system. They sit in a state with the highest rate of uninsured persons and they are a non-Medicaid expansion state. Simple access to healthcare is the number one issue and potential driver of their epidemic. They needed to think beyond just strategy implementation that is traditional to the work to consider how to change the medical systems, a lot of which may need responses from policy changes. It is imperative in the planning to consider time for addressing racial and social injustices, particularly in the South. It is not a matter of simply expanding how often HIV testing is offered. Some of the systems people have to access need an overall and change as well.

Achieving Together: A Community Plan to End the HIV Epidemic in Texas

Shelley Lucas, MPH
Manager, HIV/STD Prevention and Care Branch
Texas Department of State Health Services

Texas is very proud to be the first Southern state to launch a statewide EHE plan. Houston developed its city plan, The Roadmap to END HIV, in 2016, setting the stage for a statewide plan to come later. The development of the Texas plan is somewhat different from most states as the plan is not branded through the State health department. The Texas plan is a community plan that was developed by and for the community. This is potentially a key strategy for other Southern states. Many states have not attempted to develop a plan yet, possibly due to the political issues and conservatism that Southern states face. However, Ms. Lucas is hopeful that with the President's Initiative, that will change. In Texas, it is indeed changing the conversation. Their Executive Commissioner, Dr. Phillips, was able to endorse the President's Initiative.

The vision for Texas, which was adapted from the National HIV/AIDS Strategy, is to become a state where HIV is rare and every person will have access to high quality prevention, care, and treatment regardless of their age, race, ethnicity, gender identity, sexual orientation, or socio-economic circumstances. To support that vision, *Achieving Together: A Community Plan to End the HIV Epidemic in Texas*, was launched in November 2018. The plan took almost a year to develop and it represents over 1000 hours of work and contributions from over 100 community leaders. The community partners like to call it more than a plan - they call it a movement. They certainly took that approach in developing the plan. They used very descriptive, strong language because they wanted it to be aspirational plan. They want to change the way that HIV services are rendered in Texas. They want to change the way that people living with HIV are seen and treated. The intent is to create systems that provide connection and support, and create stigma-free environments where people can access care to not only survive but to thrive.

To that end, they began by creating an overarching set of guiding principles that would drive conversations on how to develop the plan. The principles were focused on social justice, equity, advocacy, community, integration, and empowerment, with the intent to create a framework for what the community wanted to achieve through the plan. There are seven different jurisdictions that operate in Texas, and the plan had to be actionable and adaptable enough for everyone to see their community and their work within the framework.

The plan is based on four goals that build upon the foundation of HIV prevention, care, and treatment that has been built over the last three decades. The four goals are to: 1) reduce HIV transmission and acquisition; 2) increase viral suppression; 3) eliminate health disparities; and 4) cultivate a stigma-free climate. The partners then identified six focus areas in order to achieve the goals of the plan, which are to:

- Cultivate an environment that is stigma-free and inclusive
- Address issues of mental health, substance abuse, housing, and criminal justice
- Collaborate, cooperate, and coordinate across systems
- Connect clients, providers, and communities
- Promote the continuum of HIV prevention, care, and treatment

- Provide culturally appropriate prevention, care, and treatment

They believe that with focused attention and dedicated work, the goals can be achieved. They also recognize that there is no hierarchy amongst the focus areas. They all have to work together in collaboration and coordination.

In terms of measures, they wanted to align with other efforts underway in the state. There are two Fast-Track Cities in Texas and an additional one just came on board, so they adopted the Fast-Track Cities measures and then included an additional measure to decrease the number of individuals who acquire HIV.

Achieving Together will continue to be community-driven in that a core group are creating materials for people to utilize in their communities with messaging around the plan, which will support community champions in addressing this at the local level.

Ending the Epidemics: Californians Mobilizing to End HIV, HCV, and STDs

Phil Curtis
Director of Government Affairs
APLA Health

Mr. Phil Curtis noted that APLA Health was formerly the AIDS Project Los Angeles, but is now a community health center operating three FQHCs in Los Angeles County. He presented on their community-driven EHE Coalition in California. The EHE Coalition was initiated by the community and university partners in the California HIV/AIDS Research Program, which is funded by the University of California. The community partners include APLA Health, Project Inform, and the Los Angeles LGBT Center. The University of California San Francisco (UCSF) and the University of California Los Angeles (UCLA) are the university partners. A portion of that grant that is dedicated to policy research funds a broad range of efforts to bring evidence-based research to bear on emerging HIV/AIDS policies and programs across the state, and has supported most of the convening of the EHE Coalition has conducted over the past year.

Before describing the EHE Coalition's efforts and progress, Mr. Curtis outlined some top-line California epidemiological data. These data played a significant role in the EHE Coalition's decision to advance an effort to address three different epidemics of HIV, HCV, and STD. California reported some 5000 new HIV infections in 2016, the largest number in the country. Additionally, California reports too few people virally suppressed through treatment, and low PrEP uptake. The state estimates that about 220,000 people are good candidates for PrEP. The best estimate at this point is that some 40,000 individuals are on PrEP, and they know that PrEP uptake is very low among the most impacted populations, including African American and Latino gay men. The state also estimates that about 400,000 Californians are infected with HCV, most of whom do not know it. California's STD rates have been escalating and breaking state records for years.

In 2016, the California State Office of AIDS issued a document titled *Laying the Foundation for Getting to Zero*. This document is a roadmap for reducing HIV in California and also was the states required integrated HIV surveillance, prevention, and care plan. The partners in the policy

research grants decided at the time that the best use of resources going forward would be to augment and advance the state's efforts toward getting to zero. They knew from the start that there were things that the community could do that a state agency could not. To begin with, they knew that advocacy would be required to increase collaboration among the state agencies service people living with and at risk of HIV, HCV, and STDs. Those agencies include the California Department of Public Health (CDPH), which oversees HIV, STDs, and Hepatitis; Corrections; Education; and Covered California, which is the state healthcare exchange; and most important, the California Department of Health Care Services (DHCS), which operates the state's MediCal program. MediCal was greatly expanded under the Affordable Care Act (ACA) and now provides care, treatment, and services to more than a third of PLWH in California. MediCal also provides PrEP and PEP to low-income individuals at risk of HIV.

They thought that as community partners with a long history of advocacy they were in a better position than the state to engage highly impacted communities, and advocate for the political will and additional resources that would be necessary to drive the EHE effort. As the EHE Coalition began to form, it was clear that there was a lot of energy behind addressing HIV, HCV, and STDs for a number of reasons. There is a significant population overlap between HCV and HIV, especially among the drug user population. The STD epidemic in California is clearly driven by the populations most at risk for HIV, including MSM, women of color, and transgender individuals. A major factor in their decision was that the state bureaucracy itself is in the process of integrating its HIV, HCV, and STD divisions. The Community Coalition also had it sights set on the 2018 election. They knew that they were going to have a new administration in Sacramento, and they asked all of the campaigns during the election to support their EHE effort. They saw the new administration as a new opportunity. While California had aggressively expanded healthcare coverage during Governor Jerry Brown's administration and had reduced the uninsured levels by record numbers down to 7% of the population, health advocates in general felt that public health efforts had been neglected and they thought that the new administration might agree.

The EHE Coalition convened its first community meeting in April 2018, bringing together public health advocates, administrators, providers, communities from across the state, and every level of government. Then Lieutenant Governor Gavin Newsom supported the plan during his campaign, and he was elected Governor in 2018. Not long after his inauguration in March 2019, the EHE Coalition released its *Community Consensus Statement* calling on the Governor and the Legislature to stand up a high-level state task force to develop and implement a California plan to end the epidemic. Currently, over 150 organizations throughout California have signed on to the Coalition's *Consensus Statement*, and they continue to circulate the document, The *Consensus Statement* emphasizes the need for a department-level task force with the political gravitas to pull together the various state divisions that can address these syndemics. It also emphasizes the tools available to end the epidemics (e.g., screening, testing, linkage to and retention in care, PEP, PrEP). It also addresses SDOH and health disparities in California. The goals that were laid out in the *Community Consensus Statement* are consistent with the National HIV Strategy and many other state and local plans that have been developed across the country. The Coalition Workgroups will continue to meet. At this point, they have a list of nearly 100 "game changers" or interventions that participants in the workgroups believe could have significant impact on these syndemics.

The California Alliance of HIV Advocates working alongside the Community Coalition has submitted three General Funds budget requests this year that include $20 million each for HIV

prevention; HCV prevention, testing, linkage to care; and STD prevention and treatment. These are requests to reinvest in state-funded HIV prevention programs, which were entirely cut from General Funds in 2009, and to help build HCV infrastructure and address STDs. Governor Newsome recently mentioned the EHE Coalition in his May revised budget and called for a $40 million investment in new funding in infectious diseases, but he has yet to publicly endorse the Cross-Departmental Task Force or to allocate funding explicitly for HIV, HCV, and STDs. Nevertheless, they are on his administration's list of priorities. For the moment, they will focus their advocacy on the Legislature, which proposes its own budget before conferencing with the Governor. The Coalition also conducted an "End the Epidemics Day of Action" in Sacramento on April 30th. They brought together about 70 consumer and community participants to meet with Legislative offices and the Governor's healthcare staff. The Coalition's statewide working groups, which now include over 100 participants, will continue to meet. The policy research grant will support 8 to 10 town hall meetings on ending the epidemics across the state over the next two years, including in the 8 highly impact counties in California that are included in the President's Plan to End AIDS.

Los Angeles County (LAC) HIV/AIDS Strategy for 2020 and Beyond

Mario J. Pérez, MPH
Director, Division of HIV and STD Programs
Los Angeles County Department of Public Health

Mr. Pérez indicated that in September 2016, California Office of AIDS launched a plan titled, *Laying a Foundation for Getting to Zero*. Separately, a number of jurisdictions throughout California developed and launched their own plans. The third prong to this effort was some of the advocacy occurring statewide, some of which Mr. Curtis described, ensure that their statewide partners are fully enlisted in this process. Mr. Pérez described the LAC experience.

The LAC work began a few years ago in response to a community appetite for having a strategy. They spent much of 2016 thinking about their efforts and reviewed 33 plans from across the country in much the same way Houston did, which helped to inform their approach. On World AIDS Day in 2017, they launched the LA County HIV/AIDS 5-year strategy to begin in 2018 with benchmarks they wanted to meet by 2022. The document describes the goals and approach, considers issues such as poverty and stigma, mentions the role of STDs in the HIV epidemic and LAC's HIV control efforts, and discusses issues pertaining to substance use. LAC has 1850 new HIV infections annually. The strategy goals straightforward and are to: 1) reduce annual HIV infections to 500 by 2022; 2) increase the proportion of PWHL who are diagnosed to at least 90% by 2022; and 3) increase the proportion of diagnosed PLWH who are virally suppressed to 90% by 2022. They have been sharing publicly that the third goal is probably going to be the hardest to achieve.

One of the reasons that California did not do a county/city dyad presentation is because LAC has 10.2 million residents, is comprised of 4085 square miles, and has 88 incorporated cities. They have the second largest epidemic in the country after New York City with 60,946 estimated PLWH at the end of 2016. The number of new diagnoses were approximately 48,974 at the end of 2016. Until the number of new diagnoses significantly exceeds the new infections, the undiagnosed number will persist. The number of deaths in 2016 was over 500, with a little

over 200 attributed specifically to HIV disease. Viral suppression was about 60% county-wide. For people in this LAC system who have at least one contact with the healthcare system, viral suppression is about 88%. The current best estimate is that there are approximately 18,000 HIV-negative persons in LAC on PrEP.

One key element of the LAC strategy is that as they were planning for healthcare delivery across 4000 square miles, it was important to have smaller planning districts. Historically, they have adopted an 8-Service Planning Areas (SPA) in their exercises. This has become too large for people to grasp, so they adopted a 26 Health Districts approach. Health Districts are embedded in SPAs. Most SPAs have 4 Health Districts, but some have 1, 3, or 5. Within SPA 4, there are 3 highly impacted areas. The Hollywood-Wilshire Health District is part of SPA 4 and shoulders about a quarter of the entire HIV epidemic. It was important for LAC to set very discrete targets based on much smaller geographic boundaries. For each Health District, they have estimates on the number of undiagnosed, number of HIV tests needed in the next 5 years, number of persons enrolled in PrEP by 2022, maximum number of new infections in 2022, HIV diagnosis target by 2022, and the viral suppression target by 2022. They think this allows partners in much smaller areas to assume more responsibility for those goals. They also want a viral suppression goal. In this instance, they remind people of the specific Health District's achievement in 2015, what the 2022 goal is, and they break out the viral suppression rate by racial/ethnic group, age, and gender. Based on a specific Health District's area of success or progress or areas of shortcomings or deficiencies, they also articulate the 4 or 5 things they want that Health District to focus on rather than the whole body of work tied to the strategy. They also have maps of each SPA that includes major streets as an element of the planning so that people understand what neighborhoods they are talking about. For each Health District, they also provide a sense of the size geographically, the total population in the Health District, the number of PLWH, and where it ranks in terms of HIV rate across the 26 Health Districts. They also superimpose all of the community and healthcare delivery assets in that area, not all of which are active contributors to the goals, which offers the opportunity to get them involved.

They have 7 distinct groups, so in the spirit of making sure people understand their responsibilities, they have outlined extensively what they want each group to do. The roles for each group follow:

<u>Public and Private Sector Providers</u>

- Help normalize and expand HIV testing
  - Implement mandatory routine opt-out HIV testing in key public and private hospitals and health clinics operating in California for a time-limited basis
- Understand the multiple social and environmental factors that influence HIV-related health inequities
- Improve cultural humility
- Develop innovative strategies that promote HIV-related equity
- Support seamless testing, disclosure, and linkage to care efforts
- Support the delivery of Medical Care Coordination that promotes a holistic service delivery approach to mitigate the effects of homelessness, poor mental health, and substance abuse
- Address HIV-specific workforce-related issues including volume of clinical specialists and mental health practitioners, along with staff retention and burnout issues

Health Plans

- Offer incentives for providers that achieve viral suppression among sub-populations with the lowest rates of suppression
- Mandate that all health plans share aggregate, protected public health information (PHI) data on viral load and retention rates, as well as PrEP enrollment measurement metrics with California Office of AIDS and local health departments
- Improve STD screening and treatment rates

Elected and Non-Elected Policy Makers

- Promote and enact Los Angeles County HIV/AIDS Strategy policy recommendations
- Fully fund the California PrEP Assistance Program to meet the biomedical needs of all residents at highest risk for HIV infection
- Support statewide treatment as prevention (U=U) and biomedical HIV prevention media campaigns
- Fully fund STD prevention and treatment services
- Ongoing service as ambassadors and champions

LAC Partners

- Advocate for policies that increase data sharing and eliminate barriers preventing robust information exchange
- Enhance collaboration with county housing services to prioritize people living with HIV into housing
- Recognize and address the importance of cultural humility among service providers and advocates for all County services/programs
- Leverage every available resource for STD prevention and treatment services

Consumers

- Serve as ambassadors of the Los Angeles County HIV AIDS Strategy (LACHAS) and actively promote the goals and spirit of the Strategy
- Participate in Commission on HIV Public Policy Committee's LACHAS Workgroup
- Engage and educate health care and public health stakeholders at the Health District level

Commission on HIV

- Monitor and advise the Board of Supervisors on the implementation of the LACHAS
- Engage in frequent and intentional communication and collaboration with DHSP and other partners
- Convene planners and stakeholders to identify a process for engaging stakeholders at the Health District level
    - Convene LACHAS-specific community forums throughout Los Angeles County

DHSP

- Convene an Interagency Working Group comprised of representatives of multiple government stakeholders at the state, county and city levels
- Develop new relationships and partnerships and strengthen long-standing partnerships with health plans, health systems, academia, private corporations, philanthropic organizations, elected and non-elected officials, and other government institutions

They have been clear from the beginning that there are a number of things that can derail their progress, such as changes to the healthcare landscape locally and nationally, fluctuations in federal funding, lack of support for re-alignment of funds, limited capacity, inequities in healthcare utilization due to SDOH, and limited political will.

In 2019, DHSP will continue and expand strategy outreach and awareness efforts to non-traditional health care partners and systems, local and state elected officials, and CBO/provider leadership. They will convene and Interagency Working Group comprised of government stakeholders at the state, city, and county levels, refine data and metrics used to measure progress, advance modeling efforts with UCLA Center for HIV Identification, Prevention and Treatment Services (CHIPTS), and develop a medium to long-term PrEP financing strategy. In Fall 2019, they will provide a data and metrics update. Strategy progress reports will be published in December 2019, 2020, 2021. In December 2022, they will review strategy successes and challenges.

Vote: Reframing the Charge of the CHAC NHAS Workgroup

Ms. Fukuda recapped that they heard from CDC and HRSA about their plans and intentions in terms of responding to the opportunities associated with the EHE plan. They also heard some excellent examples from their colleagues in Texas, California, and LAC which illustrate how some concrete planning work already has occurred. Planning has involved policy, program, and community collaboration and how that can stimulate some recommendations that CHAC may make. She reminded everyone that CHAC has the NHAS Workgroup. The Co-Chairs were going to try to call in, because the EHE plan creates an opportunity for CHAC to revisit that workgroup. However, they were both attending a meeting in Geneva and were unable to call in.

A motion was properly placed on the floor by Dr. Saag and seconded by Ms. Hauser to approve the reframing of the charge of the NHAS Workgroup to become the EHE Workgroup of CHAC. The motion was approved unanimously with no further discussion, abstentions, or opposition.

Panel Q&A with Speakers and Discussion

Dr. Brooks noted what a rich experience it had been. At the federal level, they have been approaching this with one perspective for some time. To hear how the states and local jurisdictions are addressing this was instructive. He asked the presenters to discuss ways in which the two different health departments synergized and what the barriers people might need to consider in a similar situation.

Ms. McNeese from Houston said the first thing that came to mind was how much involvement was required by each entity in the development and creation of the plan. They often had representation from the state in their workgroups, which sometimes were convened weekly or monthly. This direct involvement in the discussions and development and creation of the plan laid the groundwork for some of their thinking about how they would proceed in framework development and guidance for the state and vice versa. Houston participated intensely with the development the Texas plan. There has been some discussion about movement toward one

comprehensive plan for Texas, which would reduce community and partner confusion. One barrier for them initially centered on the timeline. They were at different stages in terms of planning, which became a major hurdle for them since they had just completed one plan already.

Building on what Ms. McNeese said, Ms. Lucas added that a great opportunity for synergy and the way they were able to harness so many voices was by using the statewide planning body. The Texas HIV Syndicate was the basis of the group that developed *Achieving Together*. On their syndicate area all of the various planners who are in the Part A jurisdictions, so they had every Part A planner at the table. She agreed that it is a dream to get to one plan. The Part A jurisdictions use a lot of the rich data for grant purposes and applications, so there is still a need for all of that. One of the greatest barriers regards how to meet all of the needs without continuously writing numerous plans.

Dr. Mermin asked whether any of them had any epidemiological results or other data related to their outcomes that show that this has worked.

Ms. McNeese replied that they saw a slight decline in new diagnoses; however, she was not sure that they were comfortable enough yet to attribute that to the success of the implementation of this plan. They also have been rapidly engaged in routine HIV screening efforts throughout the state and within the city for a number of years, and they think that finally is yielding some of these outcomes.

From the LAC perspective, Mr. Pérez reported that they continue to see an increase in PrEP enrollments, although they have some skepticism about the accuracy of that estimate. They just launched a new HIV testing RFP county-wide for the next 5 years that changes how they will approach HIV case finding that aligns with their strategy, and they will place much more emphasis on social sexual network testing and using some of those new tools. It is too early for them to gauge the impact of the strategy on the work. The strategy does call for support for about 1.9 million HIV tests over a 5-year span at a cost of about $69 million. They have a fraction of those funds, but not the full amount. Meeting some of these goals will require additional resources and capacity.

Devin Hursey expressed gratitude to Ms. McNeese for including the social justice component. He said he was personally insulted when Dr. Brooks said that the benefits of cluster data far outweigh the risks. As a Black/Latino man from the State of Missouri living with HIV, HIV criminalization is a serious issue. The law in the State of Missouri does not consider condom use or intent. It all depends on disclosure. He thinks that cluster data is a disaster and the HIV community is calling for a moratorium on the use of cluster data. On top of that, he has a stack of articles in which those data were misused. They need to have a serious conversation about the harm that is caused by molecular surveillance data. That is a social justice issue. The criminal justice system impacts Black people in a very particular way. This country is very hostile to people who are undocumented in this country, which came up several times during this meeting. He found an article that stated specifically which street in Seattle these women were living on, which said that they were homeless and used drugs. His understanding of Seattle is that they ship people out of the city when they are homeless. Misuse of those data is very irresponsible.

Dr. Brooks suggested that it may be reasonable for the CHAC to consider including something like this in the agenda for an upcoming meeting.

Ms. Fukuda pointed out that molecular surveillance is new and coming from a state that was seriously impacted by outbreaks, it was incredibly useful in Massachusetts. However, they also learned the ways in which Mr. Hursey's cautions were very important.

Mr. Hursey added that the law in the State of Missouri requires that the health department assist the prosecution in bringing a case against somebody. A subpoena is not needed for that.

Panel Presentation: Ending the HIV Epidemic Centers for AIDS Research (CFAR) as Collaborators with CDC/HRSA

John Brooks, MD
HIV Epidemiology Research Team Lead, DHAP
Centers for Disease Control and Prevention

Dr. Brooks moderated a panel presentation for two speakers to describe the role of CFAR in ending the epidemic. He introduced the two speakers and opened the floor for their presentations.

Role of the National Institutes of Health CFARs in Ending the HIV Epidemic

Michael Saag, MD, CHAC Member
Director, UAB Center for AIDS Research
University of Alabama at Birmingham School of Medicine

Dr. Saag pointed out that they had seen examples of how leadership in individual communities have had great success. In other areas, leadership has not really coalesced. In some of those places the leadership role has been assumed by local or regional CFAR sites.

CFARs were created in 1988 by NIH in response to the AIDS epidemic. What a CFAR should do, if it is working well, is add value to what is already occurring in a local institution and community. For example, if an investigator has an R01, they are already going to get that work done. Taking credit for what already would have happened does not count. What counts is how the added value helps new grants get funded and how investigators at the CFAR site can work together. This synergy contributes to the overall mission.

The goals of the CFAR program are to foster high quality, multidisciplinary HIV research; promote local control by allowing scientific and fiscal flexibility; add value to the HIV/AIDS research agenda; provide economies of scale; create synergy and collaboration; and support early career investigators through pilot studies and mentoring. Some CFARs were defunded last year and others were added, but within the current CFAR network, there is pretty good geographical distribution and it looks very much like the map of the key areas that are being targeted in the Ending the HIV Epidemic. In areas where there is need, there is a lot of opportunities for CFARs to engage.

Structurally, CFAR has 5 required cores: Administrative Core, Basic Science Core, Clinical Core, Developmental Core, and Scientific Working Group(s). A Scientific Working Group is a coalition of like-minded people working on a common scientific theme. The UAB site has had a Strategic Working Group for Ending the HIV Epidemic that has been in place for about 7 years. While this coalesced for UAB and several other CFARs, that is not necessarily true for every CFAR.

There are many ways that CFARs work together as a network. Inter-CFAR working groups include:

- Implementation Science Working Group
- CFAR Social and Behavioral Sciences Research Network
- Antiretrovirals for Prevention Working Group
- Faith Initiative Working Group
- Collaboration on HIV Research in Women
- CFAR Collaboration on HIV in Corrections
- CFAR Network of Integrated Clinical Systems (CNICS)
- CFAR Biostatistics Network
- HIV and Aging Working Group
- National CFAR CAB Coalition
- CFAR HIV/TB Co-Infection Consortium
- HIV/AIDS Related Malignancy Working Group
- CFAR Sub-Saharan Africa Working Group
- Cytometry Interest Group

Regional CFAR-CFAR partnerships include Mid Atlantic CFAR Consortium, HIV in the Southeast Coalition, and California Health Disparities Initiative.

Alabama has a specific CFAR Initiative entitled “The Alabama Quality Management Group (AQMG)”, which is comprised of all seven HIV Ryan White clinics in the state. The seven clinics submit de-identified individual-level data via the CDC/ADPH-funded Data for Care (D4C) project and then meet at the UAB CFAR every quarter for a face-to-face meeting to discuss the data. This allows for an innovative statewide cohort of approximately 7000 PLWH that leverages AQMG Continuous Quality Improvement (CQI) data for outcome tracking. The reporting infrastructure includes quality indicators that help the identification of people who are infected but do not know it. The infrastructure can also be used to track PrEP outcomes. The biggest challenge, however, are the finding people who have been diagnosed and fall out of care and remain in the community. The AQMG are focused like a laser beam on this population through these clinics.

Using the CFAR as a structure, the Alabama Scientific Working Group is able to draw in collaborations with the state health department and community organizations. While using the CFARs to help coordinate the effort to End the HIV Epidemic, it is not a one-size-fits-all. The take home point is that all epidemics are local and all solutions are local. Rather than a top-down approach, it is important to start from the bottom-up. UAB has a lot of investigators who have worked in Sub-Saharan Africa through PEPFAR. They are taking lessons learned about community engagement there and bringing it into rural Alabama, which is very exciting. For example, through an R01 grant received by Dr. AadiaRana, they are able to cover a 3-state area (Alabama, Mississippi, and Louisiana) to find local solutions to local areas using practices

that have worked in other locations around the world. The relationships that are established are very nimble and are modified to fit any area.

CFAR funding has been received from NIH, primarily through NIAID. A supplement to End the HIV Epidemic was received on May 8th and another is anticipated at the end of the month. The goal is to align with HHS partners to genuinely collaborate rather than duplicate.

Ending the Epidemic in the South: The Role of an Institutional CFAR

Wendy Armstrong, MD
Medical Director, Ponce de Leon Center at Grady Health System
Emory University School of Medicine

Dr. Armstrong pointed out that this presentation was meant to describe one example of what works. Four of the counties targeted by the EHE Initiative include Dekalb, Fulton, Cobb, and Gwinnett. There is a widespread epidemic in the state that is marked by widespread health disparities, with minorities fairing more poorly. Any of their interventions must consider that background and be local. Thinking about the goals of the initiative and where CFAR fits in, there are many unanswered questions that require good implementation science to gather evidence to define the pathway. As the Director of a large RWHAP clinic, she would love to have all of the money so that she could just expand capacity. However, she needs to know what works. Implementation science is critical in terms of identifying how to spend the money they are going to get and what will work in Atlanta. The EHE acknowledges that the US is a country of microepidemics that require local and adaptive solutions.

Most of the studies Dr. Armstrong shared are funded by smaller CFAR local grants, microgrants of a few thousand dollars, or CFAR supplements. The Emory CFAR not only encompasses the university and all of the graduate schools therein, but also has a special and critical relationship with Morehouse School of Medicine. It also includes all of the care sites affiliated in Atlanta (Emory University Hospital, Emory University Hospital Midtown, Grady Health System, and the Atlanta VA Medical Center). These care sites serve about 12,000 patients within the Georgia epidemic. The Emory CFAR is responsible for 20 counties, all of the veterans in the state, and all those less than 24 years of age who do not have other insurance or means to go elsewhere. This is a nice collaboration between a university and a huge clinical catchment area.

Thinking through the pillars again, Dr. Armstrong showed examples of how the CFAR work locally informs the pillars. In terms of protect and how they successfully roll out PrEP, they already know from work by one of their CFAR investigators that in terms of the PrEP to need ratio, the number of PrEP users over the number of HIV diagnoses, a low number is bad. This defines their area in the South. Most PrEP users right now are white and there is very little PrEP use among persons of color and women.

Based on a study of young Black MSM (YBMSM) in the South, who a CFAR supplement allowed them to offer PrEP and make access easy and drug available to 200 men. Among those 200 men, 16 seroconverted and 15 of those 16 were not biomedical failures. They were individuals who were either at low PrEP adherence, discontinued PrEP, contemplated PrEP and were interested in it but never started it, or refused PrEP all together. Though they all had

access, there were still a lot of PrEP failures. They know that 63% of patients discontinued PrEP, with the first discontinuation at an average of 200 some days. There were as many as 5 on and off starts for many of these patients. While access is important, this informs them about what they do locally and how they are going to roll out PrEP. They need to identify different solutions. CFAR helps them think about the right messaging, how to improve self-perception of risk and acceptability, what the right communication style is in this community (social networks, social media, mobile apps), and non-traditional settings (pharmacies, bath houses, mobile vans, and PrEP@Home.

In terms of treatment, they know that retention of care is the biggest gap in the care continuum, that there are almost no proven interventions, and the SDH are extremely important. At any moment in a one-year snapshot in time, they can say that 84% are virally suppressed. But looking at people longitudinally, only 43% are virally suppressed for 36 months who enter care at Time 0. The question regards how to address that locally with the Atlanta population.

Other studies used Health Information Exchanges (HIEs), so there is a ping to a physician when someone who has been out-of-care by state public records enters an ED for example and have been out-of-care for more than a year. In terms of behavioral economics, consideration should be given to setting financial incentives to let patients pick their own outcomes such as rewards for viral suppression or showing up at clinic visits and whether that changes outcomes. It did in Atlanta.

Though not a CFAR study, one study examined how to address retention. This study looked at high intensity retention teams for very vulnerable patients with substance use issues who were hospitalized and had uncontrolled HIV. While the high intensity retention teams only showed a small increase at the 6-month mark, the endpoint of the intervention, in viral suppression there was a 96% study retention. That is a very important result. Even if they cannot get people to take daily pills, this is a model for how to retain people in the community as soon as long-acting drugs are available in their clinic so that they can do directly observed therapy.

Some works in progress including the following:

- Bringing the clinic to the community: A mobile multidisciplinary HIV treatment model to reengage out-of-care patients
- Project ENRICH: Examining retention in care and health literacy
- Rapid entry to care and its effect on long-term retention in the South
- Effects of physical therapy on opiate use and viral suppression.

Another benefit for the Emory CFAR has been in the Respond Pillar. This is not about clusters, but it is imperative to have good data. Local data are needed to understand whether interventions are working and how to be flexible within that. The Emory CFAR has helped enormously in the development of a database for the Grady patients with about 6200 active patients and 13,000 overall. They will be adding their other hospitals sites that have a database for a total of about 17,000 patients. Like PEPFAR, that lets them be accountable for what they are doing and know if they need to be flexible and nimble in how they respond.

Under the Diagnose Pillar, they have distributed 818 home-based HIV/STI testing kits across 10 projects. They have a variety of venue-based testing initiatives (EDs, neighborhood health clinics, Latino events, health fairs), and couples testing for injection drug users.

In terms of the Workforce Pillar, one of the goals of CFAR is to train, mentor, and support the next generation of HIV/AIDS researchers and leaders. This program has been very successful across the country. In addition, one of the other efforts locally is capacity-building for Historically Black Colleges and Universities (HBCU) in collaboration with Morehouse University. This is another area in which capacity needs to be increased.

The Emory CFAR has had a role on the Fulton County Task Force on HIV/AIDS. This was not a CFAR-driven only initiative, but there has been CFAR investigator leadership through the whole lifetime of that. They had a county initiative because that is where the political will was at the time. The goal is to use this as a jurisdictional strategy to start looking at their four counties in the EHE Initiative, as well as intentionally use this as a blueprint for this state.

In summary, CFARs, particularly those in targeted counties or states, have a critical role to play. For the EHE initiative, a shift to implementation science and understanding local barriers to progress in reducing new infections is critical. Interdisciplinary approaches, championed by CFAR, is particularly important in the South where SDH have a significant effect. Infrastructure for timely access to local data is a benefit that CFAR can provide, and they also can support for jurisdictional plans to EHE.

Panel Q&A with Speakers and Discussion

Dr. Brooks reminded everyone that the CFARs are funded through NIAID. There is a parallel group, AIDS Resource Centers (ARCs) that are funded through the National Institute of Mental Health (NIMH) that work in very much the same way as the CFARs.

Dr. Gaist expressed gratitude for mention of the ARCs through NIMH as well as the CFAR Social and Behavioral Sciences Research Network, which is longstanding. There also is an Implementation Science Working Group through this effort. Those may also need to be focused on for some additional attention and resources as well in order to do what they do so well in this particular effort for the initiative.

Dr. Bolan said that as someone who worked both in an academic institution and health department for many years, she thought a lot people have never heard of CFARs. She was curious in this new effort of trying to do more and having everybody at the table what kind of strategies they are considering so that it is not the scientists swooping in and telling programs what to do, but that it is a two-way street. In a lot of programs, the best model is embedding academics a couple of days a week to work in the health departments to understand the context of program implementation.

Dr. Saag replied that the relationships they now have with the local health departments in some of the major areas are very important and they had not had them before to be very honest. They did this with HepC and following that model, which got them going into HIV. It does not hurt that the current State Health Officer was a former fellow at UAB. It is all about relationships, trust, sharing responsibility, not duplicating efforts, and especially not coming in from the top-down. They are focused on a grassroots up approach.

Dr. Armstrong said she thought Birmingham was a very good example of how things did not go well, but now are going much better. It is all of the attributes of the people at the tables. A lot of times it is really important for the academic community to recognize the importance of public-academic partnerships and also encouraging fellows to take leadership positions in public health departments. The biomedical needs now, especially in STD, HIV, and hepatitis are critical. The number of programs that actually have a lot of clinicians playing important leadership roles needs some attention.

Dr. Saag modified what he earlier. All epidemics for local, all solutions are local, and all politics are local.

Dr. Armstrong agreed. The Emory CFAR has both models in Atlanta where one of the health department has a really good academic in the health department and a great collaboration. They are trying to build that with other health departments in the affected counties where that model has not traditionally existed and is critical.

Dr. Brooks asked what kind of barriers there are when trying to work as a CFAR with the public health department. People are probably wondering why this is not happening more. It should because it seems so easy. However, he was imagining that it is not as easy people might think.

Dr. Saag pointed out that it depends totally on the people at the end of the day. It is the people at the CFAR and/or academic institution and their approach/attitude that has to be checked and opened up. When that is done successfully, it opens up all kinds of doors. It is like anything else in life. It is about what can be done together. It is not about credit. It is about what talent each person/group brings to the table and how this becomes truly synergistic. When it is presented that way, and the funding is shared, and the trust is there, it can be magical. In fact, to do this EHE, it has to be magical. There is no time for nonsense. Fortunately, in a number of locations this has worked extremely well. It is working well at Emory and Birmingham. Tennessee is starting to work. They are all in this together and that is what is nice about it. There has been a need for a long time to coalesce around a mission and a purpose. While they do not have the funding of the Space Program as somebody said earlier, they certainly have the mission of not just landing a person on the moon but ending the HIV epidemic.

Dr. Armstrong agreed completely. There are a couple of important barriers, one of which is money. Many health departments are stretched so thin that there is barely enough money to cover STDs, HIV, and all of the other missions. In fact, the ability to gather data and analyze that quickly is limited by a how many people they have it that they can deploy to do that job versus keeping fingers and dikes. She also agreed that people are important, but it also about making sure that academics do not impose themselves in a way that is inappropriate and that there is a good two-way street of listening.

Dr. Saag added that he was not sure about Houston, but LA, San Francisco, and New York are pretty well-funded from their state. The health departments in the South, especially Alabama and Georgia, are not very well-funded. When they we met with Scott Harris the first time to talk about this, he said, “Guys, I think it's great you're doing on this. I'm right now knee-deep in trying to get sanitation straight so that we don't have polluted waters.” They are still working literally at Ground Zero on a lot of simple public health issues. In terms of working together and providing mutual funding, CDC could help a lot in directing funding for these efforts.

Ms. Fukuda said that one of the things NIH must have done is when they gave money to CFARs, they told them that applicants would have to demonstrate collaboration with state and local health departments. They had a number of CFARs come to them. It was great because they got to give them some intelligence about how it fit into the planning work. It was very collaborative and very exciting.

Dr. Brooks said the other challenge he heard from the health department side was that it is not just resources, but they are so overburdened with all the other work they are doing it is difficult to partner.

HCV Elimination: Institutional Models

Carolyn Wester, MD, MPH
Director, Division of Viral Hepatitis
Centers for Disease Control and Prevention

Advice Requested from CHAC by the HCV Elimination Panel:

- What characteristics from these models should be / can be replicated in other settings to improve testing and linkage to care and treatment?
- How federal coverage and/or the advantages in pricing be extended to state and local correctional facilities for medications of public health significance?
- What can be done to include hepatitis C screening and engagement in care as quality metrics for health systems?
- How can the time to procure DAA's be reduced to access these medications on site facilitating test and treat models?
- How to expand opt-out HCV screening statewide and generate buy-in, especially within hospital systems?

Dr. Wester moderated a panel presentation for a series of speakers to describe HCV elimination institutional models that have been implemented in diverse prevention and care settings. She introduced the panel of speakers and opened the floor for their presentations.

Veterans Administration's (VA) Experience with HCV Elimination

Maggie Chartier, PsyD, MPH
Deputy Director, HIV, Hepatitis, and Related Conditions Programs
Office of Specialty Care Services
Veterans Health Administration (VHA)

Dr. Chartier gave an overview of HCV treatment in the Veterans Health Administration, which is the largest integrated health care system in the US. It provides care at 1,250 health care facilities, including 172 VA Medical Centers and 1,069 outpatient sites of care of varying complexity (VHA outpatient clinics) and serves over 9 million Veterans enrolled in the VA health care program.

VA is the single largest provider of HCV care in the US. In October 2014 over 168,000 Veterans in VA care had been diagnosed with chronic HCV and had not been treated. VA has treated more patients for HCV than any large health care system in the US. Every Veteran in VA care diagnosed with HCV is followed in VA's National Hepatitis C Clinical Case Register

Over 118,000 Veterans have been treated with oral HCV antivirals since they became available in January 2014 with an estimated 25,941 HCV patients in VA care remaining to be treated. Among veterans with SVR testing data available, overall SVR (cure) rate for the Nation with the oral HCV regimens is 96.9 percent. Among all veterans started on DAA treatment the SVR rate is 87.4 percent (intent to treat). An estimated 10,000 to 15,000 Veterans in VA care with HCV awaiting treatment are not currently willing or able to initiate or complete HCV treatment.

A greater proportion of Veterans in care with HCV remaining to be treated are difficult to engage in care.

Patient determinants around treatment include that: they are uninterested; they decline treatment; they cannot be reached by phone or mail; they are unable to adhere to therapy, medical appointments or treatment. Psychosocial determinants that affect infection or treatment include homelessness, substance or alcohol abuse, and mental health. Unstable/uncontrolled medical comorbidities such as non-curative hepatocellular cancer also affect treatment.

HIV, Hepatitis, and Related Conditions Programs sponsor quality improvement initiatives to address gaps in care and anticipate system-wide needs. In 2014, in response to availability and efficacy of new DAAs, HHRC launched the Hepatitis C Innovation (HIT) National Collaborative with teams in each Veterans Integrated Service Network (VISN). In 2018, due to success in HCV treatment, teams have expanded to focus on cirrhosis care and management.

Hepatic Innovation Teams (HIT) are multidisciplinary, network-level teams led by a HIT Coordinator that work locally to contribute to national goals, participate in national calls and working groups, and have monthly virtual meetings and annual face-to-face meetings.

The Collaborative Leadership Team is engaged in program management and facilitation, including setting national goals. It coaches the HITs to improve processes and to advocate for patients and on behalf of the HITS, while also building community amongst the HIT members and VISN Hepatitis Innovation Teams (HITS). Finally, the Collaborative Leadership Team identifies low performers and pairing them with strong practices.

Over a four-year period, four national meetings were held to infuse lean practices for quality improvement and problem solving.

HCV in the Cherokee Nation: Progress After Three Years of Implementing an Elimination Program

Jorge Mera, MD, FACP, CHAC Member
Director, Infectious Diseases
Cherokee Nation

Dr. Mera gave an overview of Cherokee Nation ealth Services (CNHS). The CNHS is a sovereign nation within a nation. It is the second largest Indian Nation with approximately 350,000 citizens. It is the largest tribal health system in the USA, and provides medical services to 130,000 AI/AN, of whom 90 percent access the health system, and 60 percent access primary care. There is one central hospital, 8 outlying clinics, 1 million visits per year—and a unified electronic health record.

The CNHS HCV Elimination is focused on a population of AI/NA who accessed the CNHS, screening 85 percent of those who accessed it, and documenting the encounter with any department, whether HCV screening and or evaluation was offered at that department or not. Eighty-five percent of those who had a detectable HCV RNA found by a provider trained in HCV management and who initiated treatment are to have documented cure.

Several holes remain in the process. For example, ideally, screening would be included as a quality measure. Ideally, people would be tested and treated at an onsite point of care. Ideally, NSP programs would be legal and available and there would be no barriers to MAT. In terms of outcome measures, mortality and incidence data would be easier to obtain. In the meantime, the team is working to share its experiences with IHS and with its neighbors, including the OSDH HCV elimination program and to redefine its goals. All these elements—and more—would move the program forward in its efforts to achieve HCV elimination.

Brief Presentation on Viral Hepatitis and RWHAP Part B

Laura Cheever, MD, ScM
Associate Administrator, HRSA HAB
CHAC DFO, HRSA

Dr. Cheever gave an update on the RWHAP program and noted that several recipients had presented or would present information from their programs.

Louisiana HCV Subscription Model and Elimination Program

Emilia Myers, MPH
Viral Hepatitis Coordinator, Office of Public Health
STD/HIV/Hepatitis Program
Louisiana Department of Health

In Louisiana, 40,263 persons reported with an HCV diagnosis from 2007 to 2017. Louisiana has high rates of liver and bile duct cancers driven by both HBV and HCV. It has the 5th highest rate (10.1 per 100,000 population) of liver and bile duct cancers and ranks 3rd for rate (8.4 per 100,000 population) of death from liver and bile duct cancers. It's estimated 112,424 Louisianans[3] are at very high risk for acquiring HCV through injection drug use. This causes a costly per-patient treatment price that severely limits access.

In 2016, we received a letter of complaint that we were only treating a small portion of those who were eligible for treatment and that there were significant gaps in care. We recognized that

we had reached a perfect storm for opportunity and collaboration to end the HCV crisis in our state. We needed to join forces between the DOH, the Office of the Secretary, the Department of Corrections, the Infectious Disease and Epidemiology Program, the STD/HIV/Hepatitis Program, the Office of Behavioral Health Program, the Bureau of Community Preparedness, the Louisiana Hepatitis C Coalition, Medicaid, and the Community.

From 2016 through 2019, we have worked with partners to receive funding in a variety of ways, from Big Pharma and philanthropy, using several models. The modified subscription model involves an agreement with Gilead's Asegua Therapeutics to use the authorized generic of Epclusa for individuals enrolled in Medicaid or in the correctional system. The plan is to launch in July 2019. This gives unrestricted access to the drug for 5 years. Payment will be equal to or less than what the State is currently spending. This is a Win-Win-Win: Manufacturers get predictable revenue, likely gain in market share, good news. The state gets predictable expenditures, dramatic increase in access to treatment, enables campaign to eliminate HCV. Louisianans get increased SVR, reduced morbidity, reduced mortality.

Our Hepatitis C Elimination Model will achieve several goals, beyond establishing the subscription model. It will also expand provider capacity to treat Hepatitis C, educate public on availability of cure and mobilize priority populations for screenings; strengthen HCV surveillance to link persons previously diagnosed to treatment, expand HCV screening and expedited linkage to care, implement harm reduction and complementary treatment strategies and extend elimination efforts to all populations within the state.

The project involves any number of public health experts and workers, and a number of basic costs: Community Health Worker/ Peer Supporters, Linkage to Cure Specialists, Syringe Service Program Navigators, Public Health Detailer, Provider Network Director, Hepatitis C Specialist Consultant, Epidemiologist/ IT, Corrections Clinical Director, Laboratory costs, Hepatitis A and B vaccination, Hepatitis C information and equipment.

Addressing HCV in Jails and Prisons

Lara Strick, MD, MSc
Clinical Associate Professor, University of Washington
Statewide Infectious Disease Consultant, Washington State Department of Corrections

The correctional population plays a significant role in the HCV epidemic given the high prevalence of HCV in correctional facilities. The impact on the national epidemic depends on whether you look at who is incarcerated on a given day or the number of people who pass through a correctional facility over a given year. Based on more recent data, close to half the people living with HCV may be incarcerated over a year's time.

Estimating the prevalence of HCV in corrections is difficult because people in prisons and jails and are not included in community surveys (e.g., NHANES). In addition, most correctional facilities don't have an electronic medical record, are able to dedicate little to no funding to data collection and analysis, and there is no standard way to report HCV prevalence. For Washington State, for example, a mid-size prison system, the average daily prison census is about 16,500 people who are housed in 12 facilities. That population includes the resident

population—but statistics may just include the intake population, or also include people who are on work release, or those who are on parole or probation. In our system, a recent study with Boston University, published in the American Journal of Prevention Medicine, examined the HCV prevalence of our intake population over a 5-year period. Of the 83 percent of people who were HCV Ab tested (n=24,600), 20 percent were found to be positive. Forty-nine percent of these were HCV RNA tested at 6 months to confirm chronic infection (n=2,400), and of these, 72 percent (n=1,700) were confirmed positive. The Liver Fibrosis Stage was also reported. Depending on how you look at this data, the prevalence of people living with chronic HCV infection could be reported anywhere from 4 to 20 percent.

A data collection strategy was established in Washington State through their contract with the lab vendor, who has an electronic database of test results. The contract ensures that all lab results are sent back to the state in usable data files. Using this data, the state was able to create a repository of information about all inmates, and to sort that data for the entire prison population to determine who had ever been tested or treated for HCV as well as determine their APRI score (an estimation of liver fibrosis).

The State of Washington uses a modified project ECHO for HCV Review and a nurse and a practitioner participate at each facility. The program to treat the prison population has become more streamlined as the primary providers become increasingly knowledgeable about HCV via ECHO by allowing the on-site physician to approve simpler, straightforward cases. As medication costs decrease, the process for medication distribution has allowed patients to keep their HCV medications in their cells.

But the bottom line is that correctional facilities ARE different. They are NOT healthcare facilities. They may be a pivotal player in public health, but they are not really health care facilities and tend to limit treatment to what they feel is medically necessary care. *Estelle vs. Gamble* guaranteed access to care and established what constitutes violation of 8th amendment, including that deliberate indifference to a serious illness can constitute cruel & unusual punishment. However, correctional facilities have fixed financial budgets, they are politically driven, funds are earmarked for particular programs and leaders must balance costs for all care (e.g. diabetes, heart disease, opiate use disorder, mental health and substance use—often leaving the latter two for cuts when funds are limited). Currently courts are dictating care for hepatitis C, but sometimes this is at the expense of some of these other important medical services.

The reality is that correctional systems must partner with public health since such a large burden of the HCV epidemic is in correctional facilities. In terms of the cost of medications, there are several strategies to get better pricing. Washington uses a “Netflix”-like model, similar to Louisiana, others use the 340b model. Regardless, the cost of Hepatitis C treatment remains expensive and often not affordable. From a clinical standpoint, correctional facilities need to prioritize the treatment of patients who are sicker first. From a public health standpoint, it may be the younger people who are the higher risk for transmission and a priority. The funding silos need to meet somewhere in the middle.

We also need to find ways to transition people on HCV treatment and be sure that whether people are in the community on treatment or in prison and on treatment, that as they transition between settings, they remain on treatment without gaps. Perhaps there are ways to change Medicaid policy to enable seamless treatment during these transitions by acting a bridge.

There has been concern about people in corrections becoming re-infected upon release which has been used as an excuse not to offer treatment to certain patients. We have implemented a harm reduction program, that includes discussing safe injecting, tattooing and sex, but these topics are often not addressed in other correctional communities. In addition, we are exploring the idea of using Disease Intervention Specialists and Partner Services similar to the HIV response to reach out to and treat entire social networks of patients releasing from prison to reduce their risk of reinfection.

Question and Answer Period

A question and answer period were opened for the floor. CHAC questioners did not identify themselves.

Several questions had to do with the logistics of the programs at the VA, and whether it was difficult to get medications to the patients, particularly when patients were homeless. In one case, the grant prohibited purchase of medications, so usual channels were used to purchase medications (i.e., private insurance, Medicare, Medicaid, and so on). For several patients, not having medication meant losing patients. Not having medication on the shelf was a problem for some patients who could not return for treatment. It could take one or two weeks to two to three months to get approval for medication depending on the insurer.

In terms of access to medication, the VA tries to simplify access, either through mail order medications, courtesy supplies at any VA in the country because all VAs have records of treatments.

Extensive comments by some CHAC members were difficult to hear due to quality of equipment and recording. Speakers did not identify themselves.

In the VA one-third of providers are pharmacists. Opiate substitution and MAT are an issue. The cap on MAT panels is a problem for providers, especially in areas where there are so few providers. Clinical pharmacists are well-suited to expand PrEP and go beyond Hep C.

In terms of the VA, our PBM office has excellent tactics for negotiating drug prices because we have such a large population. There is power in numbers, as the Louisiana presentation demonstrated.

The Washington State presenter noted the challenges of suboxone prescribing. The office is now beginning to provide inductions of suboxone or vivitrol for people who are being released and who have opioid use disorder. We are finding challenges because of the number of jails in the state, each of which has a different policy. Many jails are going with Vivitrol only, rather than going for Suboxone as well.

Lab-triggered screening—occurs when the phlebotomist would automatically add a screening for all patients between the ages of 18 and 62. We offered informed consent but there was controversy over whether this was a true opt-out, so the program was dropped.

Public Comment Period

Dear Committee Members:

The American Nurses Association (ANA) is pleased to submit public comments to the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment in advance of your May 14-15 meeting. We appreciate the inclusion of an agenda item on collaboration across responsibilities. Registered Nurses (RNs) have historically been on the front lines of care for persons living with HIV/AIDS (PLWHA)[1] and continue to play a crucial role in both care and prevention. RNs serve in multiple direct care, care coordination, and administrative leadership roles, across the full spectrum of health care settings. ANA urges the Committee to recommend steps for the lead agencies to expand and support engagement of nurses and nursing communities as collaborative partners in federal initiatives to end HIV.

ANA is the premier organization representing the interests of the nation's 4.0 million RNs, through its state and constituent member associations, organizational affiliates, and individual members. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. ANA members also include the four advanced practice registered nurse roles (APRNs): Nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs) and certified registered nurse anesthetists (CRNAs).[2] ANA is dedicated to partnering with health care consumers to improve practices, policies, delivery models, outcomes, and access across the health care continuum.

The Administration has announced a goal of reducing new HIV infections by 75 percent in the next five years and by 90 percent in the next 10 years. To achieve this ambitious agenda, the Secretary of the Department of Health and Human Services (HHS) has recognized the need to target resources to a select group of "hotspot" areas where HIV is most rapidly spreading. Secretary Alex Azar called for creation of local HealthForces to expand prevention and treatment in these areas.[3]

RNs and APRNs are well positioned to lead and participate in the collaborative teamwork needed for this undertaking. As discussed more below, RNs and APRNs are indispensable to HIV care and prevention efforts. Key collaborative roles for RNs and APRNs in local Health Forces include: 1) Coordinating care for PLWHA to ensure their best treatment outcomes and

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[1] Austin, Diana. The Unbroken Chain: Three Decades of HIV/AIDS Nursing. Science of Caring, University of California San Francisco. November 2014.

[2] The Consensus Model for APRN Regulation defines four APRN roles: Certified nurse practitioner, clinical nurse specialist, certified nurse-midwife and certified registered nurse anesthetist. In addition to defining the four roles, the Consensus Model describes the APRN regulatory model, identifies the titles to be used, defines specialty, describes the emergence of new roles and population foci, and presents strategies for implementation. Web: APRN Consensus Model.

[3] Azar, Alex. Ending the HIV Epidemic: A Plan for America. Department of Health and Human Services blog, February 5, 2019.

prevent transmission; and 2) Providing access to prevention and related services, including direct care by NPs and other APRNs.

1. Coordinating Care for PLWHA

   The NHAS recognizes that care coordination and linkages across settings are key aspects of effectively treating PLWHA and reducing risks of risk of transmission. RNs play a key role in care coordination and should be considered key collaboration partners in the Administration's efforts to reduce HIV infection by ensuring viral suppression in PLWHA.

   Patient-centered care coordination is a core professional standard and competency for all RN practice. Based on a partnership guided by the health care consumer's and family's needs and preferences, the RN is integral to patient care quality, satisfaction, and the effective and efficient use of health care resources. RNs are qualified and educated for the role of care coordination, especially with high risk and underserved populations[4] for including those with a need for multiple providers to treat complex chronic conditions – notably HIV/AIDS and the comorbidities associated with it.

   RNs who have care coordination responsibilities for PLWHA have the training and ability to support individuals to remain in care, adhere to their medications, and ultimately maintain viral suppression. They also coordinate or partner with other providers who treat HIV-related and non-HIV-related conditions and connect patients to community supports needed to remain in care[5]. Initiatives to address HIV should incorporate strong roles and resources for nurses to participate at all levels.

   ANA urges the Committee to recommend that HRSA identify ways to support and incentivize roles for RNs in federally-funded HIV care. For instance, ANA believes there is a significant opportunity to work with the Centers for Medicare and Medicaid Services (CMS) to develop a Medicaid payment model that allows for the direct payment of RN care coordination activities for PLWHA and for those at high risk of HIV/AIDS infection. ANA recommends that CDC consider ways to expand resources for RN leadership roles in local health departments engaged in new HIV initiatives.

2. Access to Prevention and Preventive Care

   Expanding access to preventive services, including post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP), is a top priority in the NHAS. ANA believes that RNs and APRNs, especially NPs, are indispensable to equipping a local HealthForce to implement this priority.

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[4] American Nurses Association (ANA). ANA Official Position Statement: Care Coordination and Registered Nurses' Essential Role. June 2012.

[5] ANA. The Value of Nursing Care Coordination. June 2012. Web: The Value of Nursing Care Coordination: A White Paper of the American Nurses Association

Federal HIV initiatives present a unique opportunity to integrate APRNs as full partners. As the Administration has recognized, APRNs such as NPs "can safely and effectively provide some of the same healthcare services as physicians, in addition to providing complementary services."[6] In many states, NPs are engaged in primary care practice and are in a position, at a minimum, to facilitate access to PEP and PrEP. While state licensing requirements vary widely, NPs in 22 states and the District of Columbia[7] can prescribe without physician oversight. In the federal Veterans Affairs medical system, NPs are also able to prescribe, by virtue of full practice authority granted in 2017.

Further, NPs are more likely than physicians to practice in rural and underserved areas. Indeed, expanded practice for NPs and other APRNs is often cited as a solution to shortages of primary care physicians.[8] While the Administration has recommended state reforms to expand APRN scope of practice, we believe more can and should be done at the federal level to drive this agenda. Targeting resources in identified HIV hotspots, as the Administration proposes, presents a unique opportunity to leverage APRN capacity and promote expanded practice scopes.

Similarly, RNs and NPs in community-based primary care roles are well positioned to support patients in adhering to their PEP and PrEP regimens. NPs and RNs regularly counsel patients on medication use and the health benefits of adherence. In addition, RNs in outpatient settings play an important role connecting patients to other health care providers and community resources addressing social determinants. This is an especially valuable role in HIV care and prevention. Many people at high risk for HIV also have other health care conditions and may also confront unstable and unjust housing and food insecurity. These factors can present significant challenges to medication adherence and to remaining in care. To meet these challenges effectively, it is imperative that RNs and APRNs be included fully in programs expanding access to PEP and PrEP..

ANA urges the Committee to explore opportunities to support the fullest and best use of RNs and APRNs in CDC and HRSA initiatives specifically to expand access to PEP and PrEP. At a minimum, funding opportunities should strongly encourage participation of non-physician practitioners, such as RNs and APRNs, practicing to the full extent of their license and qualifications. More specifically, HRSA could partner with CMS to pilot an innovative payment and delivery model for APRNs to provide, and be reimbursed for, direct HIV prevention services.

We look forward to opportunities to engage with the Administration on strategies to end HIV, and to improve outcomes for PLWHA and people at high risk for HIV/AIDS. We thank the

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[6] HHS, Department of Labor, and Department of the Treasury. Reforming America's Healthcare System Through Choice and Competition, 2019

[7] California Health Care Foundation, California's Nurse Practitioners: How Scope of Practice Laws Impact Care, September 2018.

[8] See HHS, Department of Labor, and Department of the Treasury. 2019.

Committee for considering our recommendations and engaging with CDC and HRSA to advance these recommendations.

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 5:20 p.m. on May 14, 2019.

Opening Session: May 15, 2019

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

Dr. Cheever conducted a roll call to determine of CHAC voting members and *ex-officio* members, determining that a quorum was present. She announced that CHAC meetings are open to the public and that all comments made during the proceedings are a matter of public record. She 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.

CONFLICT OF INTEREST DISCLOSURES

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest (funding recipient or consulting services)
Richard Aleshire, MSW, ACSW (Washington State Department of Health)	No conflicts
Jean Anderson, MD (Johns Hopkins Medical Institutions)	Recipient of funding from HRSA/RWHAP and NIH and stock in Gilead and IT companies
Marvin Belzer, MD, FACP, FSAM (University of Southern California, Keck School of Medicine)	Receipt of funding from CDC, HRSA, NIH, and SAMHSA
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Receipt of funding from CDC, HRSA, NIH, and SAMHSA
Paul Gaist, PhD, MPH (Johns Hopkins Bloomberg School of Public Health)	No conflicts
Debra Hauser, MPH (Advocates for Youth)	Recipient of funding from CDC, VIVE, Gilead, and MAC AIDS
Peter Havens, MD, MS (Children's Hospital of Wisconsin)	Recipient of HRSA, NIH, and Gilead funding
Kaye Hayes, MBA (Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Health and Human Services)	No conflicts
Iris Mabry-Hernadez, MD (Agency for Healthcare Research and Quality)	No conflicts
Devin Hursey (U.S. People Living with HIV Caucus)	Works for a RWHAP-funded clinic
Jorge Mera, MD (W.W. Hastings Indian Hospital)	Recipient of CDC and HRSA funding; recipient of an HCV elimination grant from the Gilead Foundation; recipient of speaker fees from Gilead Sciences
Rosemary Payne (Substance Abuse and Mental Health Services Administration (SAMHSA), HHS)	No conflicts
Susan Philip, MD, MPH (San Francisco Department of Public Health)	Recipient of funding from HRSA/RWHAP, CDC and NIH, Luminostics, Roche Diagnostics, and unpaid public health advisor for GSK
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
Linda Scruggs, MHS (Ribbon Consulting Group)	Recipient of funding from HRSA, Gilead, Merck, and SAMHSA
Bradley Stoner, MD, PhD (Washington University School of Medicine)	Recipient of CDC, HRSA, and NIH funding

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest (funding recipient or consulting services)
Lynn Taylor, MD, FAASLD (University of Rhode Island and CODAC Behavioral Health Inc.)	No conflicts
Richard Wild, MD, JD, MBA, FACEP (Centers for Medicare and Medicaid Services)	No conflicts

Recap of Day 1

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

Ms. Fukuda welcomed 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 thanked everyone for a fantastic and busy meeting the previous day, and requested that everyone be thinking about particular topics they would like to see on the agenda for the November 2019 meeting.

Recapping the presentations and discussion from the first day, she reminded everyone that they heard presentations related infectious disease in the perinatal context. Dr. Havens identified some perinatal panels and associated Current Procedural Terminology (CPT) codes that can be used to order infectious disease testing. One of the concerns the group raised regarded whether there are opportunities for different kinds of coordination across infectious disease screening in the context of pregnancy or pre-pregnancy for women of childbearing potential.

There were a number of presentations related to new EHE Initiative. They were reminded that while funding has been recommended, it has not yet been appropriated. However, it seems like a great time to start planning and thinking about coordination across the federal agencies. There was discussion about the importance of viral suppression, as well as the workforce. They heard some examples from Texas and LAC about their planning that could serve as models or highlight ways to do some of this work heading into the EHE Initiative. They also heard about the CFARs connected to the EHE Initiative. They spent a fair amount of on the topic of HepC elimination and heard about models in the VA, the Cherokee Nation, and in the corrections setting.

A number of recommendations were made by members, and they were reminded that there was a letter generated to HHS Secretary Azar in February 2019 that captured a number of the recommendations that arose again related to the potential for a Medicaid bridge for people who are incarcerated, thinking about laboratory panels that could be routinized, and other approaches in corrections. They wanted to ask CHAC staff if they could get an update on what occurred after that February letter was received and if there will be any response to the recommendations included in that letter.

Conversation also arose about uses of molecular surveillance, as well as the ethical constructs that are used to think about data-to-care interventions more broadly. This prompted some of the members to suggest that perhaps the next meeting should include presentations on molecular surveillance, as well as exploration of the kinds of ethical questions they need to be asking as they head into another phase of EHE so that they can think about protecting the populations they are supposed to serve.

Dating Apps and STD/HIV Risk: Opportunities for Promotion, Prevention, Monitoring, and Evaluation

Rachel Kachur, MPH
Health Communications Specialist,
Division of STD Prevention
Centers for Disease Control and Prevention

Ms. Kachur moderated a panel presentation for a series of speakers to describe available opportunities to use dating apps for the promotion, prevention, monitoring, and evaluation of STD/ HIV risk. The session also provided an overview of current efforts to use dating app technology and to partner with its owners for prevention activities. She highlighted what is currently known about dating app use among key populations, gaps in knowledge and research, and efforts to form partnerships with business owners.

Data about online dating and hook-up sites in general are very limited, so they are just now beginning to understand these behaviors. While there are still a lot of gaps, what is known is that between 15% and 24% percent of US adults have ever used online dating sites or mobile dating apps. About 6% percent report having used those dating apps in the past 30 days. Among MSM, 54% have reported having had sex with a man that they first met online in the past 12 months. Most of the HIV and STD studies available on dating apps focus on MSN.

There are differences between what are called “dating apps” what “hook-ups.” Tinder or Bumble were originally designed to connect people for long-term relationships, while hook-up apps were primarily designed for anonymous hooking up and were mainly used by MSM. Over time, the behavioral distinctions between these two apps have blurred such that users of all types report using the apps for casual dating, hookup sex, or long-term relationships. Sometimes the difference between the apps are the level and type of information that has is exchanged within the profiles. Both types of apps can be very specific. There are dating apps for farmers, bears (a terms used to describe a larger, harrier men), et cetera. Ms. Kachur indicated that for this session, “dating apps” meant all types of dating apps.

Overview of the American Men’s Internet Survey (AMIS)

Travis Sanchez, DVM, MPH
Associate Professor, Department of Epidemiology
Rollins School of Public Health, Emory University

Dr. Sanchez presented data from Emory University's annual online survey, AMIS. They have data from 2013 through 2018. He presented data through the 2017 cycle. AMIS is conducted every year online with MSM. Its main purpose is to assess trends in HIV-related risk behaviors, use of testing services, and access to prevention services. The eligibility for AMIS is be least 15 years of age, a US resident, identify as a cis-male, and ever having had sex with another male. Recruitment is done through advertisements across multiple websites and mobile apps. Previous participants are also allowed to take subsequent year survey, so participants are re-invited. They do not incentivize the survey. The AMIS survey is taken freely by participants. The core survey includes demographics, sexual and substance use behaviors, HIV/STI testing and diagnosis, HIV prevention use, mental health, and stigma/discrimination. The survey takes about 20 minutes.

In terms of the overall sample size, they have conducted 60,000 surveys over that entire 6-year period. There are at least several hundred surveys and every US state, with some states having several thousand surveys during that period of time. The most recent year was just completed in December 2018. Even for single years, there are several hundred surveys in each state. Overall, the AMIS sample approximates the US Census population, though it is important to note that the US Census population is not necessarily the population at most risk of HIV infections. While AMIS has good representation of non-white persons, it tends to under-represent Black/African American and Hispanic/Latino persons relative to risk for HIV infection. They also skew slightly younger, with a higher proportion of 15 to 24-year olds. They have good representation from the different Census regions. A substantial proportion of the population is from rural areas. About 10% or so of the participants self-identify as living with HIV infection.

Regarding behavioral data from AMIS, for PLWH or not, there was an increase in condom less anal intercourse in the past 6 years. Trends in substance use were broken down into two categories, marijuana use and other types of drugs uses. During the analysis timeframe, there were significant increases in drug usage for all groups except for other drug usage among HIV positive individuals. Regarding STI testing and diagnosis data, significant increases have occurred over time in testing and diagnoses, with PLWH infection having a much higher rates of testing.

The story is a little bit different in terms of HIV testing. Overall, the trend in HIV testing during this past 6 years has been increasing. When these testing data are broken down by age, there is a significant decrease in HIV testing in the past 12 months among the youngest age group 15 to 24 years of age. All of the other groups have a significant trend going up, except maybe for a downturn in 2018. Another year's worth of data will be needed to determine whether that trend is decreasing for the other age groups as well. But for the 15 to 24-year-old, is definitely decreasing. They also have looked at whether this decrease in this last year data is due to year-to-year trends and recruitment sources, but that is not the case. Even when they controlled for that, they still saw decreased.

Regarding the dating app, it is important to remember that they recruit from all types of different online resources, including dating apps. What they have noticed over the past 5 years is that the way people met their most recent sex partner has substantially changed. In 2013, the vast majority of participants met their most recent partner in In Real Life (IRL). A smaller proportion had met their most recent sex partner some other way. As IRL is decreasing, the app partner was decreasing. Dating apps became more common for meeting sex partners, and is now the most common. In the 2018, this was still going up.

In terms of the types of sites people are using, overwhelmingly Grindr is the most common place people met their sex partners in every state and every population. Broken down by demographic characteristics, there is no difference in people meeting their partner through dating apps by whether they lived in a major urban area or not. There does not appear to be a large difference in in this by race or ethnicity. There may be a slightly higher proportion among those who are Hispanic and those who are other multiple races. There is a difference in age groups. Participants 18 to 39 years of age have a big jump and are increasing steadily in the portion who are meeting their partners through dating apps. There is a lag in the 40 plus year olds.

Looking at three risk indicators (condom less anal intercourse, discordant condom less intercourse, and drug usage), those who met their sex partners through the apps had significantly higher prevalence of all of those risk behaviors compared to those who met in real-life. It is also important to note that those who are meeting their sex partners on the apps had a significantly higher number of partners.

The story is not all negative. They also see higher rates of HIV testing and STI testing in the population that met their most recent sex partner on apps compared with in real-life. Another shift is that they are looking at whether people are using features in the dating apps that are allowing them to negotiate safer sex or understand their partner's HIV status. There is a profile option in Grindr about people talking about their HIV status and the types of prevention that they wanted to engage in, so the survey asked a question about whether they had used any of those features to decide whether or not to have sex with partner. About 73% of the AMIS participants reported using any of those features. A larger proportion reported using just the HIV status than the preferred sexual health strategy through the app, but it seems like about the same proportion having some conversations with their partner. There did not appear to be any substantial demographic group differences in whether people used these features.

To summarize the data, there are increasing trends in risk behaviors and STI testing and diagnosis. Recent HIV testing is increasing for most MSM, but is decreasing among MSM 15 to 24 years of age. There are increasing trends in meeting partners on dating apps for all groups, except teen MSM. Dating apps are now the most common way MSM meet sex partners, except teen and 40+ MSM. Compared to meeting partner IRL, those who met partner on dating apps are more likely to be engaging in risk behaviors, but also more likely to have had recent HIV and STI testing. Nearly 3/4 of MSM are using dating apps for HIV prevention-related information about their possible partners. Many also used this information to identify the HIV status and prevention preferences of their most recent sex partner. However, the majority of people are still doing this by talking to their partner rather than relying solely on the apps.

In terms of how CDC can help, support is needed to expand online and app-based behavioral epidemiology and intervention research; to develop better approaches to reach young MSM for testing, such as mailed testing; and for support of online ordering of home testing through dating apps.

Overview of Building Healthy Online Communities (BHOC)

Dan Wohlfeiler, MPH
Jen Hecht, MPH
Co-Founders, Building Healthy Online Communities (BHOC)

The BHOC goals are to build self-sustaining features into dating apps that promote health and informed choices; reduce stigma; coordinate and improve advertising and messaging, and coordinate interactions between public health and sites and apps. Our public health partners include CDC, the National Alliance of State and Territorial AIDS Directors, the National Coalition of STD Directors, YTH, AIDS United, San Francisco AIDS Foundation, University of Washington, Johns Hopkins University, Yale, and Emory University. Among our website and app partners are Adam4Adam, Daddyhunt, Dudesnude, BarebackRT.com, Gay.com, Grindr, Hornet, POZ personals, GROWLr, and Scruff, which reach a broad cross-section of men.

Since 2009 we have consistently sought stakeholder input and feedback to prioritize interventions. The first survey asked 18 website owners/managers: "How likely would you be to implement each idea?" It asked 82 HIV/STD directors which ideas they thought would be most likely to reduce HIV and/or STD transmission. Finally, it asked 3,050 MSM website users which interventions they would you be most likely to use. Since then, BHOC has continued to gather input from our public health partners and app users through online surveys and meetings.

Based on survey results, BHOC has prioritized the following activities: making personal app profile options more explicit (including HIV status, condom use, having an undetectable viral load, taking PrEP); providing automatic HIV/STD testing reminders at users' choice of interval; offering comprehensive sexual health information on the Building Healthy Partners Online website; coordinating advertising design and placement; promoting best practices relating to how to work with the apps; offering an anonymous online partner notification site (Tell Your Partner) and DIS training; and launching an anti-stigma campaign, NiceAF. Users support these sexual health strategies. App owners have incorporated many structural features and have shared resources through links and ads. Since it launched in November 2016, 15.5 million unique viewers have visited Grindr's Sexual Health Resource Center, for which BHOC provides content and guidance.

CDC can help by providing more guidance on advertising, including recommending and/or mandating that creative for advertising produced with public dollars should be in the public domain and recommending which media metrics grantees should report on. It can offer guidelines for when and how to promote outbreak alerts that take into account severity of diseases, rates and numbers of infections, and guidance on outreach efforts. The CDC can help fill in data gaps on which syphilis cases report meeting partners on which apps, and supporting an online home testing distribution network, convert GetTested into a one-stop-shop sexual health portal, and support modeling efforts to establish the minimum percentage profile options need to be accurately and completely filled out in order to have a population-level impact on reducing new STD and HIV infections.

Adolescents and Dating Apps

Laura Widman, PhD
Assistant Professor, Department of Psychology
North Carolina State University

What do dating apps mean for adolescents? Adolescents are a different population—they may be similar to adults, but they are really different. Most of us remember how awkward that time was in our own lives—and it is important to recognize that adolescents are not mini-adults. We really need to keep a developmental lens as we consider their experiences.

Adolescence is a period of rapid physical and emotional development. It is an important time for brain development. Incredible developments of the limbic system occur, but the prefrontal cortex has not developed—so there is no real decision-making braking system. We see the initiation of dating and sexual relationships.

We see the beginning of sexual relationships—but also risk-taking. It is a very vulnerable time when we talk about STDs. While 57 percent of teens had sexual intercourse by 12th grade, 46 percent did not use a condom at last intercourse. Youth make up 25 percent of sexually experienced population but acquire 50 percent of STDs.

Adolescents have unprecedented access to technology. In 2018, almost 45 percent of teens are online "almost constantly," compared to just one-quarter in 2015. Nearly all U.S. teens have access to a smart phone. The most popular platforms for adolescents are YouTube (85 percent), Instagram (72 percent), Snapchat (68 percent), Facebook (51 percent) and Twitter (32 percent).

Are adolescents using apps to meet relationship or sexual partners? Is app use associated with sexual risk or protective behavior for adolescents? We don't see a common dating app, but data suggest some of them are. But we do not have clear answers. There are limited empirical data, no clear definition of what we mean by "dating apps" for adolescents and some unique challenges for research with youth using dating apps.

We do know that adolescents are meeting partners online. A 2015 Pew survey of 13 to 17-year olds showed that 35% of U.S. adolescents had had a romantic relationship. Of these, nearly one-quarter had met that person online.

These data are from 2015, so likely an underestimate. There's no data on sexual activity with online activity with these partners, and no data on gender or minority youth.

Several apps and websites have been developed that are geared toward youth, such as myLOL, Crushzone, Skout, and TeenDatingSite. These sites say you "must be" 13 to 19 or 21 to join, but there's almost no empirical work on these sites. There are ethical challenges about research on these sites, limited monitoring of how old people really are.

What's more common is how teens use social media to meet partners. Adolescents use sites for adults. Youth use social media to meet partners for example, 14 to -17-year-old young MSM

are using Grindr to meet partners, nearly half of those had some type of sexual encounter. Teens who used the app were more likely to have condom less sex, but also were more likely to have gotten HIV tested. Unique risks for navigating site with older men.

It's important to caution against pathologizing, especially for youth. It might help with normal developmental tasks, such as intimacy, identity formation, and to satisfy sexual curiosity. It can be a source of connection for sexual/gender minority use.

More research is needed to answer questions such as:

- How many youths are meeting partners online?
- Do the venues promote risk taking, or are youth who seek partners online already prone to risk behavior?
  - Among college students using Tinder, likelihood of unprotected sex no different if participants met partner through app or in-person.[9]
- Can we use these venues for early sexual health promotion?

It's time to increase access to sexual health information online. Digital technology can promote adolescent health: 84 percent of 13–18-year olds use the internet for health information. It's a natural way that we can connect with them. We can use the internet to promote testing and primary prevention programs. There are a number of these programs that take out the awkward health ed teacher—who is still needed and valuable—but materials that are needed and valuable.

Dr. Widman and colleagues published a 2018 meta-analysis of the effect of technology-based interventions to reduce STIs and unintended pregnancy among youth; the analysis included 16 randomized-controlled trials involving 11,525 subjects ages 13 to 24. The evidence found that compared to controls, tech-based programs improved condom use, delayed intercourse, increased sexual health knowledge, and led to safer sex norms.

During the discussion one member pointed out the segregation, transphobia, racism, and vulnerability of the worlds created on these apps. This CHAC member urged researchers to bear these points in mind.

BOHC panelist agreed that there are many problems in the world of apps but felt that the apps and public are aligned in belief that both want users to have a positive, safe experience. It is true that demographics are different on different apps, but many people are on different apps, although the largest number are on Grindr. Grindr has changed its gender options, which has changed who accesses which apps.

BOHC is working with Yale researchers who found information about online stigma and mental health and sexual health and ways to establish more polite interactions. There are concerns about the transactional sex piece (e.g., sex work).

[9] Green et al 2018

There are no numbers to date between testing and diagnosis in terms of app users. There is an association but no causal relationship. There seemed to be significant interest in this question but hard to hear speakers. This led to questions of liability for infection—if someone met someone via an app and became infected, would the app owner be liable. Legal precedent seemed to indicate that the site would not.

People go on the apps looking for relationships and partners—and for sex, and vice versa. The speaker recommended an article from *The Atlantic Magazine* called *The Sex Recession*.

Several CHAC members posed questions about data on significance of adolescent cellphone use and implications for real-life relationships and intimacy. These questions led to concerns about online bullying. The panelist noted that there are many nuances to questions of adolescent technology use.

At this point the speakers became very difficult to hear and the questions became very lengthy.

Federal STI Action Plan: CHAC Listening Session

Carol Jimenez, JD
Deputy Director for Strategic Initiatives
Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)
U.S. Department of Health and Human Services

The Office of the Assistant Secretary for Health (OASH) is transforming the current "sick care system" into a "health promoting system" with a three-pronged approach, which aims at:

- Health for all: Assure that everyone has a fair and realistic opportunity to optimize their health
- Health by all: Distribute and democratize health care knowledge, capabilities, and delivery
- Health **in** all: Prioritize health considerations in all sectors and policy areas

The Office of HIV/AIDS and Infections Disease Policy (OHAIDP) advises the Secretary, OASH, and other senior HHS officials, and coordinates the work of HHS on health policy and program issues related to the diseases stated in its name and with a focus on blood and tissue safety and availability in the United States. It plays a coordinating roll within HHS and across the United States in developing roadmaps. These have included the 2015 National HIV Strategy, and the more recent National HIV/AIDS Strategy Updated to 2020, and the National Viral Hepatitis Action Plan. It was in the process of developing a first-ever National STI Action Plan for which a web page has been released and public comment is waited. Virtual listening systems are underway with large participation. One had more than 600 listening sites.

Ms. Jiminez reviewed key statistics about the rise of STIs in the United States, and then gave an overview of the STI Federal Action Plan, which is a five-year action plan to develop actionable strategies to address the four STIs with the highest rates and effect on the health of the nation. She noted the representatives from throughout HHS, including Housing and Urban Development (HUD), Department of Education (ED), VHA, Department of Justice (DOJ), and Department of Defense (DOD) on the steering committee created the robust partnership behind

the plan. In addition, several listening sessions have been completed. For one, more than 600 sites participated. A notice was published in the Federal register, soliciting comments, which were due by June 3. Ms. Jiminez stressed the importance of public comments in formulating the plan, which is to be released in 2020.

Comment cards were distributed to the members of CHAC, it easier and although members were not required to complete these, Ms. Jiminez noted that using them ease the task of OHAIDP staff charged with reviewing, analyzing, and responding to comments, especially if they want to reach out to commenters for clarification or additional information. Topics of special interest to the Federal agency were published in the Federal Register, but recognizing that CHAC represent experts, were also open to hearing other ideas and responses.

The questions of most concern to OHAIDP included:

- How should the federal government address rising rates of STIs?
- What strategies can federal agencies implement to improve the efficiency, effectiveness, coordination, accountability, and impact of our national response to increasing rates of STIs for all priority populations?
- What are the barriers to people getting the quality STI health services they deserve?
    - What strategies can federal agencies implement to overcome these barriers?
- How can federal agencies influence, design and implement STI-related policies, services and programs in innovative and culturally responsive ways for priority populations?
- How can the federal government help to reduce STI-associated stigma and discrimination?

CHAC members and the public were invited to respond. One member encouraged the Federal government to make a bold statement about recognizing that although each person must take individual control, we recognize that the safety net has been hollowed out, that STIs are asymptomatic, and that we must provide a much broader community-based response. We need a robust response in Federal outreach and screening, beyond individual response. We must deal with stigma, and how society deals with STI. Education and condom promotion are essential, but so is community-based response.

CHAC member suggested that to increase awareness of STI requires a blitzkrieg of information. Increasing awareness must come with increasing access to treatment. If the private sector cannot provide adequate treatment, the government must aggressively manufacture and provide treatment. If this can be done for defense, i.e., take over manufacture of certain products, it can be done for medicine.

Karen from National Coalition of STD Directors responded by reading comments from her membership, which focused on broad goals and subsets of goals within these. Among broader goals suggested were to improve STI surveillance, expand STI screening, improve STI treatment, engage all disciplines of medicine and nursing, expand clinical and basic research. Within these broad goals were several subsets, such as the following:

- Improve surveillance so that data sharing occurs within and among systems
- Improve efforts to identify hotspots
- Engage new options for testing since stigma prevents people from seeing a provider—such as home testing and telemedicine
- Increase options for school-based testing
- Improve and increase clinician training to enable them to gather sexual health history to understand STI risk and exposure
- Include USDA to include WIC, SNAP-Ed and others
- Include public and private insurance
- Work to develop vaccinations against STI
- Work with NIH and pharma to develop new diagnostic and treatment modalities
- Engage and encourage the voices of people living with STI to be included in campaigns

A CHAC member, commented on the concern about how to engage young people in responding to a National Action Plan, as it is not generally something they generally think about.

CHAC National HIV/AIDS Strategy Workgroup Report

Gregorio Millett, MPH
Vice President and Director of Public Policy
amfAR
CHAC Member & Workgroup Co-chair

Mr. Millett provided updates on the workgroup's progress.
Co-chairs: Jennifer Kates and Gregorio Millett
Members: Debra Hauser, Devin Hursey, Susan Philip, Michael Saag, Lynn Taylor
Next steps: The newly established EHE Workgroup will use its first meeting to officially reframe its charge and shift its focus to identifying opportunities within HHS's new EHE initiative.

CHAC Hepatitis C Workgroup Closeout Report

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

Dr. Havens stated that the workgroup charge was to identify current gaps in knowledge of HCV prevalence among pregnant women and perinatal transmission of the virus, and to recommend to CDC and HRSA possible approaches to care of persons with HCV infection in the context of this knowledge.

Issues regarding perinatal HCV:
The workgroup reviewed literature, had fact-finding meetings, and prepared a report of the findings to the full CHAC. After a CHAC vote on the findings, CHAC prepared a resolution which CHAC sent as a letter to the CDC director dated December 4, 2017. The CDC director

responded December 21, 2017. CDC continues working on the issues raised by the CHAC workgroup as outlined in a letter to CHAC from Dr. Mermin dated May 8, 2018.

Unified response to the Opioid Epidemic:
The workgroup reviewed literature, had fact-finding meetings, and prepared a report of the findings to the full CHAC. After a CHAC vote on the findings, CHAC prepared a resolution which CHAC sent as a letter to the Secretary on February 12, 2019. As of April 30, 2019, there has been no response from the Secretary.

Proposed option: The CHAC Co-chair confirmed that the Perinatal Subgroup of the HCV Workgroup has fulfilled its charge and recommended closing the subgroup.

Proposed option: The HCV Workgroup was scheduled to present its closeout report to CHAC. However, based on the importance of viral hepatitis (in general) and HCV (in particular) to multiple populations, the CHAC Co-chair proposed retaining the workgroup with an expanded charge. Several issues were suggested for inclusion in the workgroup's broader charge: perinatal HCV, HCV in women of reproductive age, hepatitis B virus (HBV) vaccination, HCV diagnostic tools, and ethical considerations. An additional suggestion was to use the workgroup to assist CDC in developing a fact sheet for practitioners to better understand the biologics and scientific differences between perinatal HIV, congenital syphilis, and perinatal viral hepatitis.

Proposed option: Reframe the charge and rebrand the existing HCV Workgroup as the Viral Hepatitis Workgroup and form a Perinatal Health/HIV, Viral Hepatitis, and Syphilis in Women of Reproductive Age Subgroup. Proposed option: Establish a new Perinatal Infections Workgroup.

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:
- Review and Approval of the Draft Resolution?

Mr. Aleshire and Dr. Saag presented the following resolution, which passed unanimously.

> Whereas, HIV is an infectious disease that originally was untreatable and led to death in hundreds of thousand US citizens and persons around the world; and
> Whereas, over the last 2 decades highly effective antiretroviral therapy was developed that enables those infected with HIV to live near-normal lifespans; and
> Whereas, as a result of the widespread use of antiretroviral therapy HIV-infected individuals are growing older leading to a dramatic increase in the median age of persons

attending clinics around the US, such that most patients in care are now over the age of 50; and

Whereas, older individuals with HIV (> 50 years) encounter multiple comorbid conditions, often 5 to 10 years sooner than their age-matched non-HIV-infected contemporaries; and
Whereas, provision of care to older HIV-infected persons present unique challenges that are greater than those of aging individuals who are not HIV-positive, including management of cardiovascular, cancer, liver disease, renal dysfunction, diabetes and other comorbid conditions along with high rates of osteoporosis, sexually transmitted infections, frailty, cognitive impairment, malnutrition, sleep disorders, poly-pharmacy, mental health disorders, substance and alcohol use disorders, domestic partner violence, and isolation/ loneliness; and
Whereas, while clinicians providing care to older HIV-infected patients ideally should screen for all the above disorders, multiple barriers exist that interfere with the implementation of routine screening and treatment of such disorders; and
Whereas, HRSA and CDC can work with clinics and providers to create, develop and implement standards of care for older HIV-infected individuals in order to improve activities of daily living, overall functionality, and long-term outcomes for those aging with HIV;
Therefore, be it resolved that CHAC recommends that HRSA and CDC develop, in conjunction with provider and patient representatives, specific standard assessments and interventions to improve health outcomes for older individuals living with HIV, that are in addition to those for people who are not HIV-positive;
Be it further resolved that, once developed, HRSA and CDC work with providers with guidance regarding best practices to implement and sustain the assessments and interventions over time;

Be it further resolved, that HRSA and CDC will provide appropriate training and resources to assure full implementation of the Care of the Older HIV Patient (COHP) plan through HRSA and CDC sponsored clinical sites;
Be it further resolved that HRSA and CDC will hold clinics and providers accountable for implementation of the COHP program and outcomes of the COHP initiative will be made publicly available.

RWHAP Reauthorization Workgroup Report

Antigone Dempsey, Med
Director, Division of Policy and Data
HRSA HAB

A proposal was made to table the activities of the workgroup because reauthorization of RWHAP is not being considered at this time. None of the CHAC members objected to tabling the workgroup.

CHAC STD Workgroup Closeout Report

Susan Philip, MD, MPH
Deputy Health Officer and Director, Disease Prevention and Control
San Francisco Department of Public Health
CHAC Member & Workgroup Co-chair

Bradley Stoner, MD, PhD
Washington University School of Medicine
CHAC Member & Workgroup Co-chair

Advice Requested from CHAC by the STD Workgroup:

- Acknowledgement of Workgroup activity completion?
- Future recommendations?

Composition

- CHAC STD Workgroup Co-chairs: Dr. Susan Philip and Dr. Bradley Stoner
- Workgroup members: Seventeen (17) subject matter experts from public and private sector
- CDC and HRSA liaisons: Dr. Roxanne Barrow and Dr. Letha Healey

Purpose/Goals

- To review CDC draft document - *Recommendations for Providing Quality STD Clinical Services*
- To present summary findings and recommendations to CHAC.
- Review process
  - Four teleconferences in Aug./Sept. 2017
  - Workgroup comments collated and organized by CDC/HRSA staff
- Findings
  - Summary findings presented at Oct. 2017 CHAC meeting
  - Follow-up letter to DHHS Secretary
- Other activities
  - Additional recommendations for STD prevention
- Next Steps
  - Finalization and publication of Clinical Services document
  - STD Workgroup close-out

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

Debra Hauser, MPH
President, Advocates for Youth
CHAC Member & Workgroup Co-chair

Our Charge:

- Share findings on LGBTQ youth risk behaviors and protective factors
- Identify promising practices, gaps, and research opportunities likely to have the biggest impact on the health and safety of LGBTQ youth in schools, out of school settings, and healthcare.
- Create a blueprint of programmatic interventions, communications strategies, and policies to help guide CDC and HRSA decision-making.

Members of the Workgroup

- CHAC Members/Staff
  Deb Hauser, Advocates for Youth
  Amy Leonard, Legacy Health
  Peter Byrd, Peer Educator
  Jennifer Kates, Kaiser Family Foundation
  Sara Zeigler, CDC/NCHHSTP
  Sharon Wong, CDC/NCHHSTP
  Margie Scott Cseh, CDC
  Holly Berilla, HRSA
  Shelley Gordon, HRSA
- Other Members
  Joanne Keatley, Center of Excellence on Transgender Health
  Ellen Kahn, HRC
  Katie Adamson, YMCA of the USA
  Aite Aigbe, HRSA/MCHB
  Renatta Boyd, HRSA/HIV/AIDS Bureau
  Eliza Boyd, GLSEN
  Kathleen Ethier, CDC/DASH
  Laura Kissock, Fenway Health
  Steve Mendlesohn/Amit Paley, Trevor Project
  Justin Rush, True Colors.

Activities

- Widely distributed information regarding LGBQ youth risk behaviors and protective factors as identified on the 2015, 2017 YRBSS

Post card for distribution
Conference presentations
Articles in newsletters

- Co-convened meeting of researchers and experts on LGBTQ youth risk and protective factors to identify evidence-based programs and strategies as well as gaps in the research base related to improving LGBTQ youth health and wellbeing.

- Sponsored speakers from various Organizations to present their research regarding LGBTQ youth health and well-being at the working group meetings and at CHAC.

Outcomes

Summarized findings in a letter to CHAC, requesting CDC prioritize funding for:

1) The programs and strategies that work to improve LGBTQ+ youth health and wellbeing through schools:

   - Professional Development for Educators

   - Student-led Clubs, such as GSAs

   - LGBTQ-Inclusive Sex Education, History, Science, etc.

   - Health Services Provision or Linkage to Schools
     - mental health
     - sexual health
     - drug and alcohol intervention/treatment
     - suicide intervention

   - Safe and Supportive School Environments

2) Continued research to fill gaps in knowledge.

Progress on Updating the HCV Testing Recommendations

Blythe Ryerson, PhD, MPH
Associate Director of Science, DVH
Centers for Disease Control and Prevention

CHAC recommended CDC issue guidance to encourage universal HCV screening of pregnant women in the US (12/4/2017). CDC determined review of pregnancy-specific recommendations would be conducted in parallel with an update to the all-adult recommendation. A 'evidence-to-recommendations' framework was developed. A systematic review of literature was conducted.

- Formulated draft recommendation statement
  - Peer and public review
  - Publication and dissemination.

- Evaluation

Guidelines Development Process

- Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology used to inform the guideline development process:
  - Is the problem a public health priority?
  - How substantial are the desirable anticipated effects?
  - How substantial are the undesirable anticipated effects?
  - Do the desirable effects outweigh the undesirable effects?
  - Does the target population feel that the desirable effects are large relative to the undesirable effects?
  - Is there important uncertainty about or variability in how much people value the main outcome?
  - Is the option acceptable to stakeholders?
  - Is the option a reasonable and efficient allocation of resources?

- Because of paucity of direct evidence informing screening strategy, chain of indirect evidence was also considered:
  - HCV prevalence in the general U.S. population and subpopulations
  - Harms of screening
  - Linkage to care.

Questions:

Is the problem a public health priority?
How Substantial are the desirable anticipated effects?
How Substantial are the undesirable anticipated effects?
Do the desirable effects outweigh the undesirable effects?
Does the target population feel that the desirable effects are large relative to the undesirable effects?
Is there important uncertainty about or variability in how much people value the main outcomes?
Is the option a reasonable and efficient allocation of resources?

Although the overall certainty of the direct evidence for critical outcomes is low, hepatitis C is a public health priority. Prevalence is high for a curable disease. Incidence is increasing. Desirable anticipated effects high relative to undesirable effects. Identification and treatment of HCV infections is likely valued and acceptable to stakeholders. Universal testing will be cost effective and likely feasible to implement at a prevalence above 0.1%

Draft Recommendation Language

- At least once in a lifetime hepatitis C screening for all adults aged 18 years and older, except in settings where the prevalence of HCV infection is less than 0.1%, and

- Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of hepatitis C infection is less than 0.1%.

Regardless of age or setting prevalence, all persons with risk factors should be tested for hepatitis C once, with periodic testing while risk factors persist.

- "Setting" left intentionally broad; could include state elimination program, state or local public health department or program , hospital system, individual provider, correctional institution, syringe service program.

- Onus is on system/provider to screen until they can demonstrate an HCV RNA prevalence below the 0.1% threshold

Next steps include:

- June 30, 2019 – MMWR submitted to CDC clearance

- August 31, 2019 (tentative) – Peer and public comment period begins
  - Expert peer review (six independent reviewers)
  - Webinar series with targeted stakeholders and partners [← All CHAC members will receive invitation; opportunity to comment.]
  - Federal Register Notice for public

- November 30, 2019 (tentative) – CDC (public) response to peer review and public comments

- December 2019 (tentative) – Revised MMWR submitted to CDC clearance

- January 31, 2019 (tentative) – Submission to MMWR for publication

Update on the Hepatitis C Medicaid Affinity Group

Carol Jimenez, JD
Deputy Director for Strategic Initiatives, OHAIDP
U.S. Department of Health and Human Services

Hepatitis C Medicaid Affinity Group

Approximately 2.5 million people in the United States are living with HCV infection.
A disproportionate number of these individuals receive public insurance including Medicaid or are in correctional settings.
One recent analysis estimated that in one year HCV infection led to:

- More than 2.3 million outpatient medical visits.
- More than 73,000 emergency room visits; and
- A cost of more than $15 billion for inpatient visits for one year.

Despite simplified treatments for HCV that lead to improved health outcomes, many Medicaid programs have implemented restrictions that reduce access.
High/fluctuating drug cost, growing competition, litigation, and advocacy are rapidly changing HCV treatment policies in many states and health systems.

Purpose of the Group

Foster state collaboration and the sharing of promising practices.
Support states in developing and implementing innovative HCV-related policies and programs
Increase the number and percentage of Medicaid beneficiaries diagnosed and successfully treated for HCV

Federal Partners

Centers for Disease Control and Prevention (CDC)
Centers for Medicare and Medicaid Services (CMS)
Health Resources and Services Administration (HRSA)
– HIV/AIDS Bureau (HAB)
– Bureau of Primary Health Care (BPHC)
Office of Minority Health (OMH)
Substance Abuse and Mental Health Services Administration (SAMHSA)

Expert Consultants include: VA, IHS, DOJ (Bureau of Prisons) and academia.

All states were invited to join. Notice of the Hepatitis C Medicaid Affinity Group was disseminated broadly and to Medicaid and public health viral hepatitis contacts. Participants joined on a volunteer basis. Expression of Interest Forms were brief and required signatures of leadership from the state Medicaid program and Health Department.

In year one, several states focused on special populations including people who inject drugs and women of childbearing age. In year two, the suggested focus is on corrections.

Components of the Expression of Interest Form

Provide information on:

HCV prevalence and treatment rates among the Medicaid population
Barriers to treatment and cure
State activities and proposed strategies to address barriers
Names and contact information of workgroup participants

State activities include State-driven action plan development, monthly calls with presentations based on participant interests, state updates on activities, challenges, etc., input from federal partners, two 1.5-day meetings in Washington, D.C., technical assistance, e.g., support from federal partners and special topic calls for specific tracks, including corrections, and reporting: progress on Action Plans and HCV-related outcomes measures.

Several states focused on special populations:
People who inject drugs (year one and two)
Women of childbearing age (year one and two)
Corrections (year two)

Year 1 Affinity Group Activities

Development and implementation of self-identified action plans
Calculating the HCV care cascade, leveraging work conducted by the HIV Affinity Group.
Enhancing provider knowledge of HCV testing and treatment
Assessing and revising prior authorization processes for HCV medication
Improving treatment for people who inject drugs
Get information and resources from this group at the Hepatitis C Medicaid Affinity Group website.

Action Plan completion: 8 of the 9 states.
Progress on Action Plan:

- 3 states made significant progress on their Action Plans;
- 4 states made good progress on their Action Plans.

Monthly webinars were attended by an average of 32 state participants and 14 federal partners on each call.
Webinar attendance:

- 8 states attended all monthly webinars; across all monthly webinars, 93% of participants rated sessions as a 4 or 5 on a scale of 1-5 for being clear, comprehensive and helpful.

Final evaluation results indicated that an overwhelming majority of participants were very satisfied with the group and would continue the work into the future.

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: New CHAC Ending the Epidemic Workgroup

CHAC unanimously approved reframing the charge and rebranding the existing "National HIV/AIDS Strategy" Workgroup as the "Ending the HIV Epidemic" (EHE) Workgroup.

Co-chairs: Jennifer Kates and Gregorio Millett

Members: Debra Hauser, Devin Hursey, Susan Philip, Michael Saag, Lynn Taylor

Next steps: The newly established EHE Workgroup will use its first meeting to officially reframe its charge and shift its focus to identifying opportunities within HHS's new EHE initiative.

Business Item 2: New CHAC Infectious Diseases (ID) Workgroup

The CHAC Co-chair confirmed that the Perinatal Subgroup of the HCV Workgroup has fulfilled its charge and recommended closing the subgroup. The HCV Workgroup was scheduled to present its closeout report to CHAC. However, based on the importance of viral hepatitis (in general) and HCV (in particular) to multiple populations, the CHAC Co-chair proposed retaining the workgroup with an expanded charge. Several issues were suggested for inclusion in the workgroup's broader charge: perinatal HCV, HCV in women of reproductive age, hepatitis B virus (HBV) vaccination, HCV diagnostic tools, and ethical considerations. Also discussed curing HCV before pregnancy and treating co-existing substance use disorder with opioid agonist therapy and harm reduction pre-conception given that HCV is a biologic marker for injection drug use in the U.S. currently. This can also decrease risk of reinfection in the women and more importantly, decrease their risk of overdose.

An additional suggestion was to use the workgroup to assist CDC in developing a fact sheet for practitioners to better understand the biologics and scientific differences between perinatal HIV, congenital syphilis, and perinatal viral hepatitis.

The proposed option: Reframe the charge and rebrand the existing HCV Workgroup as the Viral Hepatitis Workgroup and form a Perinatal Health/HIV, Viral Hepatitis, and Syphilis in Women of Reproductive Age Subgroup.

The option was proposed to establish a new Perinatal Infections Workgroup. CHAC unanimously approved establishing a new workgroup that will focus on infectious diseases (syphilis, HCV, HBV, and HIV) in the context of perinatal transmission, pregnant women, and women of reproductive age.

Co-Chairs: Jean Anderson and Peter Havens

Members: CHAC members with an interest in joining the new workgroup will contact Dr. Anderson (janders@jhmi.edu) and Dr. Havens (PHavens@mew.edu).

Preliminary charge: The workgroup will (1) develop perinatal recommendations regarding infectious diseases (syphilis, HCV, HBV, and HIV); (2) provide guidance for practitioners to identify these infections in their patients; and (3) help practitioners to interpret infectious disease data.

Business Item 3: HIV and Aging Resolution

CHAC unanimously approved the HIV and Aging Resolution with no changes.

Business Item 4: Ryan White HIV/AIDS Program (RWHAP) Reauthorization Workgroup

A proposal was made to table the activities of the workgroup because reauthorization of RWHAP is not being considered at this time. None of the CHAC members objected to tabling the workgroup.

Business Item 5: STD Workgroup Closeout Report

The workgroup presented the closeout report for its existing charge. However, the workgroup will be retained with a new charge, particularly providing advice and recommendations on the Federal STI Action Plan.

Business Item 6: School-Aged LGBTQ Youth Health (SALYH) Workgroup Closeout

The workgroup presented its closeout report. Debra Hauser will serve on the new EHE Workgroup and will present the SALYH findings to the membership.

Business Item 7: Future Agenda Items

The CHAC Co-chair reviewed the topics that the members proposed to be placed on future meeting agendas.

Presenter	Agenda Item
CHAC DFOs	Follow-up on the response to CHAC's February 2019 letter to the HHS Secretary regarding the potential for a Medicaid bridge for people who are incarcerated.
To Be Determined	Overview of ethical issues and potential questions that should be considered in implementing molecular surveillance. • This presentation should include examples and lessons learned from states that have utilized molecular surveillance data.
U.S. Food and Drug Administration	Overview of HCV diagnostic tools.
Dr. Kathleen Ethier	Update on SALYH research and the potential of developing a broad SALYH prevention strategy, including targeted interventions.

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 13-14, 2019, 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.

_____

Jean R. Anderson, MD, 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

Dr. Jean Anderson, Co-chair
Ms. Dawn Fukuda, Co-chair
Mr. Richard Aleshire
Dr. Marvin Belzer
Ms. Debra Hauser
Dr. Peter Havens
Mr. Devin Hursey
Dr. Jorge Mera
Mr. Gregorio Millett
Dr. Susan Philip
Dr. Michael Saag
Ms. Linda Scruggs
Dr. Bradley Stoner
Dr. Lynn Taylor

CHAC Members Absent

Dr. Jennifer Kates
Ms. Amy Leonard

CHAC *Ex-Officio* Members Present

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

Ms. Rosemary Payne
Substance Abuse and Mental Health Services Administration

Dr. Richard Wild
Centers for Medicare & Medicaid Services

CHAC *Ex-Officio* Members Absent

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

CHAC Liaison Representative Member Present

Mr. Carl Schmid
Presidential Advisory Council on HIV/AIDS

CHAC Designated Federal Officers

Dr. Laura Cheever
HRSA HAB Associate Administrator

Dr. Jonathan Mermin
CDC/NCHHSTP Director

Federal Agency Attendees

Dr. Sevgi Aral (CDC)
Dr. Laura Bachmann (CDC)
Dr. Lisa Barrios (CDC)
Dr. Andres Berruti (CDC)
Dr. Gail Bolan (CDC)
Dr. John Brooks (CDC)
Dr. Kate Buchacz (CDC)
Cecily Campbell, Esq. (CDC)
Ms. Janet Cleveland (CDC)
Ms. Casey Copen
Dr. Hazel Dean (CDC)
Ms. Antigone Dempsey (HRSA)
Dr. Kathleen Ethier (CDC)
Mr. Steve Evener (CDC)
Ms. Erica Figueroa (CDC)
Ms. Lauren Fitzharris
Mr. Paul Fulton (CDC)
Mr. Thomas Gift (CDC)
Dr. Sean Griffing (CDC)
Ms. Heather Hauck (HRSA)

Dr. Letha Healey (HRSA)
Dr. Laura Haderxhanaj (CDC)
Ms. Carol Jimenez (OHAIDP/HHS)
Dr. Saugat Karki (CDC)
Ms. Theresa Jumento (HRSA)
Ms. Rachel Kachur (CDC)
Dr. Yury Khudyakov (CDC)
Ms. Margaret Lampe (CDC)
Ms. Caitlin Leach (CDC)
Ms. Brandy Maddox (CDC)
CAPT Tracy Matthews (HRSA)
Dr. Eugene McCray (CDC)
Mr. Ninad Mishra (CDC)
Ms. Staci Morris (CDC)
Dr. Noele Nelson (CDC)
Ms. Rebecca Payne (CDC)
Dr. William Pearson (CDC)
Ms. Karina Rapposelli (CDC)
Dr. Raul Romaguera (CDC)
CDR Melanie Ross (CDC)
Dr. Blythe Ryerson (CDC)
Ms. Latasha Sanders (CDC)
Ms. Margie Scott-Cseh (CDC)
Dr. Judith Steinberg (HRSA)
Dr. Paul Weidle (CDC)
Dr. Carolyn Wester (CDC)
Ms. Rachel Wingard (CDC)
Ms. Sara Zeigler (CDC)

Guest Presenters/ Members of the Public

Dr. Wendy Armstrong
Emory University School of Medicine

Ms. Cheri Booth
Children's Hospitals and Clinics of Minnesota

Dr. Maggie Chartier
Veterans Health Administration

Ms. Taryn Couture
National Coalition of STD Directors

Mr. Phil Curtis
APLA Health

Ms. Danica Kuncio
Philadelphia Department of Public Health

Shelley Lucas
Texas Department of State Health Services

Ms. Emilia Myers
Louisiana Department of Health

Ms. Marlene McNeese
Houston Health Department

Dr. Rajal Mody
Minnesota Department of Health

Mr. Mario J. Perez
Los Angeles County Department of Public Health

Ms. Juli Powers
JSI

Mr. Ace Robinson

International Association of Providers of AIDS Care

Dr. Travis Sanchez
Rollins School of Public Health, Emory University

Dr. Anne Spaulding
Emory University

Dr. Lara Strick
Washington State Department of Corrections

Ms. Cathalene Teahan
Georgia AIDS Coalition

Dr. Laura Widman
|North Carolina State University

Mr. Dan Wohlfeiler and Ms. Jen Hecht
Co-Founders, Building Healthy Online Communications

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
EHR	Electronic Health Record

Acronym	Definition
EHE	Ending the HIV Epidemic
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

Acronym	Definition
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 Treatment Programs/Providers
OUD	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
PLWH	Person/People Living with HIV
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
RPR	Rapid Plasma Reagin
RWHAP	Ryan White HIV/AIDS Program
SALYH	School-Aged LGBTQ Youth Health
SAMHSA	Substance Abuse and Mental Health Services Administration
SDOH	Social Determinants of Health
SDUSD	San Diego Unified School District
SEAs	State Education Agencies
SEPs	Syringe Exchange Programs
SFDPH	San Francisco Department of Public Health
SFSMP	San Francisco Street Medicine Program
SGM	Sexual and Gender Minority
SMAIF	Secretary's Minority AIDS Initiative Fund
SSEs	Safe and Supportive Environments
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
TA	Technical Assistance
TasP	Treatment as Prevention
TB	Tuberculosis
TCE-HIV	Targeted Capacity Expansion: Substance Use Disorder Treatment for Racial/Ethnic Minority Populations at High-Risk for HIV/AIDS
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