US Department of Health and Human Services
Centers for Disease Control and Prevention
Health Resources and Services Administration

Virtual Business Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment April 20-21, 2021

Record of the Proceedings

Contents

Executive Summary

The United States (U.S.) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee (CHAC) on HIV, Hepatitis, and STD Prevention and Treatment. In response to the COVID-19 pandemic, the proceedings were held virtually via Zoom on April 20-21, 2021.

CDC and HRSA provided **agency updates.** Highlights of **CDC's update** include the new syringe services technical package, progress on the Ending the HIV Epidemic (EHE), the launch of a new home HIV self-testing program, addressing HIV criminalization laws, examining how transgender women are disproportionately affected by HIV, a new cooperative agreement to support integrated viral hepatitis programs, improvement in the hepatitis A outbreak, a recent *Morbidity and Mortality Weekly Report* (*MMWR*) addressing how COVID-19 changes in schooling are dramatically impacting child/parent well-being, the considerable increase in sexually transmitted infections (STI) from 2015-2019, the decrease in tuberculosis (TB) incidence that is likely due to reduced transmission/undetected cases during the COVID-19 pandemic, re-competition of Tuberculosis Trials Consortium (TBTC) awards, and the status of responses to CHAC correspondence. Highlights of **HRSA's update** include a summation of 30 years of the Ryan White HIV/AIDS Program (RWHAP) and information about several current efforts, some of HRSA's COVID-19 response efforts, EHE activities, RWHAP EHE recipient accomplishments and activities, Technical Assistance Provider (TAP) analysis of EHE plans, and the Community Engagement Framework and its 5 guiding principles. CHAC members emphasized how impressed they were with the incredible achievements of CDC and HRSA despite the fact that a considerable portion of their workforces have been deployed to assist in the COVID-19 pandemic response.

A presentation was given on a preliminary and high-level **thematic review analysis of jurisdiction EHE plans** that were the result of CDC awarding $12 million from the HHS Minority HIV/AIDS Fund to 32 state and local health departments to develop comprehensive EHE plans that are tailored by and for each community. The thematic review process began in February 2021 and is ongoing. Given that the plans were locally tailored, the thematic review focused on anticipated themes. The presentation highlighted types of community engagement activities, engagement of priority populations, systemic challenges and structural barriers, sample pillar activities (e.g., community engagement, diagnose, treat, prevent, respond), and cross-cutting themes. The analysis found that the plans were affected by the COVID-19 pandemic in terms of the ability of jurisdictions to conduct comprehensive community engagement activities. Nevertheless, many of the plans were creative and innovative. Because the plans were tailored to fit jurisdictional needs, they vary in length, structure, and comprehensiveness. An in-depth examination of these plans will continue and CHAC can expect to hear more details and the newest findings in the future. The plans are intended to be living documents and are, therefore, subject to change. See individual jurisdiction plans at: https://www.cdc.gov/endhiv/action/local-ehe-plans.html.

Presentations were made to update CHAC on **workgroup activities**. The **Perinatal Infectious Disease Workgroup** presented their recommendations to standardize and improve perinatal infection screening and health outcomes; as well as their letter to HHS delineating the background and rationale, priority areas for intervention, and the specific recommendations. Given that it has fulfilled its specified charge, the Perinatal Infectious Disease Workgroup's term will now end. The **Viral Hepatitis Workgroup** reviewed its letter to HHS related to its recommendations focused on the imperative of improving hepatitis C virus (HCV) diagnostics in the US as the key next step in addressing the public health threat of HCV. Given that it has fulfilled its specified charge, the Viral Hepatitis Workgroup's term will now end. The **EHE Community Engagement Workgroup** provided background on EHE community engagement, reviewed the Workgroup's purpose, and summarized the Workgroup's information gathering webinar. Given that its charter will end before the next CHAC meeting, the EHE Community Engagement Workgroup presented recommendations for a vote during this meeting, with the proviso that the related letter will follow for a vote during the next meeting.

Regarding **hepatitis B screening and perinatal hepatitis C testing recommendations**, presentations were made on Food and Drug Administration (FDA) reclassification of HIV and HCV diagnostic tests for which CHAC members were asked to consider the minimum performance standards that should be considered to be maintained to allow for public health benefit of over-the-counter (OTC) HIV self-tests (HIVST); and whether there is a public health benefit for having access to an oral fluid HCV antibody test in the US. A recap was provided of a session from the April 12, 2021 CHAC business meeting that explored the impacts of FDA re-classification of HIV and HCV diagnostics. The presentation on hepatitis C testing recommendations for perinatally exposed infants focused on the increasing prevalence of hepatitis C among reproductive aged individuals, increased identification of pregnant persons infected with HCV, and available curative treatments for children as young as 3 years of age. The next steps are to conduct a systematic review of data to inform testing guidance, perform a cost-effectiveness analysis, and draft guidance for review.

Three panels were assembled to present on several key topic areas. **Panel 1** focused on current and future developments in HIV, HCV, and STD screening and diagnostics. Details were presented on how, building upon the work of others, CDC's Division of HIV/AIDS Prevention (DHAP) researchers have developed macaque models of co-infection with vaginal chlamydia, trichomonas, and syphilis and how these models are being used to evaluate biomedical preventions for HIV and STI. An overview was provided of point-of-care (POC) testing, the state of the science, limitations to testing, and what is currently available for STD screening and diagnostics nationally and internationally. **Panel 2** examined how local health departments and community-based organizations (CBOs) altered and adjusted their services in response to the COVID-19 pandemic. A review was presented of new initiatives embarked upon or refined during the COVID-19 pandemic at the DC Health and Wellness Center and at DC Health. In addition, a presentation was given on how the Southwest Center in Phoenix, Arizona recognized a need that was not being met due to the shelter-in-place order in Arizona for HIV testing and how their HIV/STI testing services have been expanded to meet their clients where they were/are during a pandemic. **Panel 3** provided summary data on adolescent mental health before and during the COVID-19 pandemic, an overview of CDC's framework for school-based mental health programming, and information about what CDC is doing to support student mental health. Examples were presented of empirically informed programming, with a focus on addressing the needs of the most marginalized youth, implementation concerns, and future directions in this area to provide an overview of how schools and communities are addressing youth mental health needs.

CHAC Actions

CHAC members voted unanimously to approve the following recommendations and/or letters to the HHS Secretary:

1. A letter pertaining to CHAC's review and discussion of the available evidence related to potential FDA reclassification of diagnostic tests for HIV infection and HCV infection.
2. The Perinatal Infection Workgroup's recommendations and letter.
3. The Viral Hepatitis Workgroup's letter reflecting recommendations approved during the November 2020 CHAC meeting.
4. The EHE Community Engagement Workgroup's recommendations, with the proviso that a letter will follow for a vote during the next CHAC meeting.
5. A letter from CHAC requesting that CDC's Division of Adolescent and School Health (DASH) convene, support, and consult with a youth advisory council composed of young people from the communities most impacted by health disparities *prior* to finalizing its internal roadmap for reducing adolescent health disparities related to race/ethnicity, sexual orientation, gender identity and geography and at least through the end of its current strategic plan in 2025 to gain valuable insights that help shape the division's research and program strategies.

US 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
April 20-21, 2021

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, Sexually Transmitted Diseases (STDs), and Tuberculosis (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, Hepatitis, and STD Prevention and Treatment (CHAC). In response to the COVID-19 pandemic, the proceedings were held virtually via Zoom on April 21-21, 2021.

The CHAC is a committee chartered under the Federal Advisory Committee Act (FACA) to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on objectives, strategies, policies, and priorities for HIV, viral hepatitis, and STD prevention and treatment efforts for the nation.

Information for the public to attend the CHAC meeting virtually was published in the *Federal Register*, in accordance with FACA rules and regulations. All sessions of the meeting were open to the public. Please see Appendix A for the Participant List.

Day 1: Opening of the Meeting and Roll Call

Sarah Yacoub, MPH
Public Health Analyst
Office of Policy, Planning and Partnerships
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Ms. Yacoub welcomed participants to the CHAC meeting and called the proceedings to order at 1:00 PM Eastern Time (ET). She indicated that members of the public would have an opportunity to provide oral comments at 4:35 PM ET, and that comments would not be accepted during any other point during the meeting.

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 Designated Federal Officer
Centers for Disease Control and Prevention

On behalf of CDC and HRSA, Dr. Mermin welcomed those present and reminded everyone that CHAC meetings are open to the public and that all comments made during the proceedings are a matter of public record. Members should be mindful of potential conflicts of interest (COIs) identified by the Committee Management Office (CMO) and recuse themselves from voting or participating in any discussions for which they could be conflicted. He then conducted a roll call

to determine the CHAC voting members and *ex-officio* members who were in attendance and establish quorum.

Conflict of Interest Disclosures

CHAC Voting Member (Institution/Organization)	Disclosure of Conflict
Wendy Armstrong, MD (Emory University School of Medicine)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program
Jean R. Anderson, MD (The Johns Hopkins Hospital)	Recipient of funding from NIH, HRSA/Ryan White HIV/AIDS Program, and Gilead for a research project; spouse has stock in AbbVie, BMS, and Merck
Jodie Dionne-Odem, MD (University of Alabama, Birmingham)	Recipient of funding from NIH
Travis Gayles, MD, PhD (Montgomery County Department of Health and Human Services)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program and CDC
Debra Hauser, MPH (Advocates for Youth)	Recipient of funding from CDC/DASH, ViiV, and Gilead
Venton Hill-Jones, MSHCAD, PMP (Southern Black Policy and Advocacy Network)	Recipient of funding from Gilead
Devin Hursey (The U.S. People Living with HIV Caucus)	Recipient of funding from Gilead
Shruti Mehta, PhD, MPH (Johns Hopkins Bloomberg School of Public Health)	Recipient of funding from NIH, USAID, Gilead, and Abbott
Gregorio A. Millett, MPH (amfAR, Foundation for AIDS Research)	Recipient of funding from ViiV
Johanne Morne, MSED (AIDS Institute, New York State Department of Health)	Recipient of HRSA/Ryan White HIV/AIDS Program and CDC
Kneeshe Parkinson (Washington University/Project ARK)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program
Robert Riester (Denver Element)	Recipient of funding from CDC and HRSA/Ryan White HIV/AIDS Program, Part A

Leandro Rodriquez, MBA (Latino Commission on AIDS)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program, CDC, SAMHSA
Gloria Searson, MSW Coalition on Positive Health Empowerment	Recipient of funding from Merck, Gilead, ViiV, and AbbVie
Bradley Stoner, MD, PhD (Queen's University)	Recipient of funding from CDC
Lynn Erica Taylor, MD, FAASLD(University of Rhode Island/CODAC Behavioral Healthcare)	Recipient of funding from CDC and NIH

Ex-Officio members in attendance included Dr. Pradip Akolkar of the Food and Drug Administration (FDA); Dr. Paul Gaist of the National Institutes of Health (NIH) Office of AIDS Research; Ms. Kaye Hayes of the HHS Office of HIV/AIDS and Infections Disease Policy (OIDP); Iris Mabry-Hernandez of the Agency for Healthcare Research and Quality (AHRQ); Dr. Douglas Olsen for the Centers for Medicare and Medicaid Services (CMS), Richard Wild (CMS Alternate); and Carl E. Schmid, II of the Presidential Advisory Council on HIV/AIDS (PACHA Liaison Representative) whose organization, HIV + Hepatitis Policy Institute, receives funding from numerous pharmaceutical and diagnostic companies and pharmacies.

Dr. Mermin confirmed that quorum was achieved and that CHAC could move forward with conducting its business on April 20, 2021.

Welcome and Agenda Review

Bradley Stoner, MD, PhD
CHAC Co-Chair, CDC Appointee

Jean Anderson, MD
CHAC Co-Chair, HRSA Appointee

Drs. Stoner and Anderson welcomed everyone to the April 20, 2021 CHAC business meeting. Dr. Stoner thanked the CHAC members, federal officials, CDC and HRSA staff, and the general public in attendance. He welcomed new CHAC members: Dr. Greene, Mr. Riester, and Dr. Rodriquez. He reviewed the agenda for the day and thanked everyone for taking time out of their busy schedules to participate.

DFO Welcoming Remarks & Announcements

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 Designated Federal Officer

Dr. Mermin first thanked the following CHAC members who would be rolling off of the committee from the CDC side, Drs. Brad Stoner and Lynn Taylor, both of whom have been extraordinarily beneficial members of the committee whose input has been greatly appreciated

by members of CHAC and CDC and HRSA. He pointed out that they were scheduled to roll off after the November 2020 CHAC meeting, but kindly agreed to extend their membership 180 days after the expiration of their terms due to awaiting the HHS White House Liaison to select their successors. CHAC typically has 3 members rolling off; however, Dr. Travis Gayles agreed to extend his membership. While it appeared that there would be a short gap in his membership, they are hopeful that the 2 new members replacing Drs. Stoner and Taylor and the extension for Dr. Gayles will be approved within the next few months. Now that Xavier Becerra has been confirmed as the new HHS Secretary, all of the documents awaiting his approval must be modified with his new signature block and returned to HHS. It is expected to be a few more months before the packages are approved and signed and the new members can be invited to the meetings. The CHAC charter was renewed in November 2020, which was sent via email with all of the materials to all of the members.

Dr. Mermin thanked Margie Scott-Cseh for her 18 years of outstanding service to CHAC and for being the "super glue" of the committee. She has undertaken excellent committee management and communications between CHAC members, *ex officios*, and HRSA. She has been a delight to work with at CDC, keeping everything on time and copacetic as they tried to follow all of the regulations and obtain advice. Margie is retiring from CDC later in the month and she and her family will be spending more time together in the next phase of her life. Dr. Mermin said he spoke for everyone in saying how grateful they are for Margie's service to CDC and CHAC and she will be missed. Margie, Staci Morris, and Sarah Yacoub have had the opportunity to overlap. They all did an outstanding job in preparing for this meeting. Dr. Mermin emphasized the importance of committees such as CHAC to have knowledgeable people who are committed and devoted to helping them move forward.

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

Dr. Laura Cheever expressed her gratitude to everyone who took time out to be part of this meeting. She emphasized that the CHAC had provided incredibly good advice and certainly helped to steer a lot of HRSA's work over the last few years. She welcomed new CHAC members from the HRSA side, Dr. Meredith Greene, Dr. Robert Riester, and Mr. Leandro Rodriquez. She also thanked departing members Dr. Marvin Belzer, Dr. Michael Saag, and Dr. Jennifer Kates for the tremendous work they did during their tenure on the CHAC.

CDC Update

RADM 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 Designated Federal Officer

Dr. Mermin reported that one of DHAP's most momentous moments was hiring a new Director, Dr. Demetre Daskalakis, who was in place for a couple of months before he was detailed to the COVID-19 response and is now heading up equity issues for the Vaccine Task Force. Dr. Daskalakis was still able to ensconce himself in the division for those few months and is a very welcomed addition to DHAP and NCHHSTP.

As everyone knows, there has been a major impact of the COVID-19 pandemic on HIV, viral hepatitis, STDs, and TB infections and program responses to those infections. NCHHSTP has deployed well over half of its staff, many with multiple deployments. As of April 2, 2021, there have been 669 employees deployed, with 1125 cumulative deployments accounting for people who have deployed more than once. Currently, 47 employees are deployed and 3 staff will deploy soon. While this is constantly in the background, they have been able to get some work done, including creative science and programmatic and policy activities. Nevertheless, this has been a challenge in the midst of the pandemic as it is for everyone working in public health.

In terms of the infectious disease consequences of drug use, NCHHSTP issued a technical package[1] related to syringe service programs (SSPs) after the last CHAC meeting. Developed in partnership with the National Alliance of State and territorial AIDS Directors (NASTAD), this technical package includes 5 key strategies and approaches for SSPs, including: 1) involving people with lived experience; 2) collecting data at syringe services programs; 3) using a needs-based distribution approach; 4) ensuring program sustainability; and 5) providing and expanding core services such as naloxone, testing for HIV and hepatitis C, linkage to substance use and infectious disease treatment, and other services. While this took a long time to develop, it is anticipated to support activities and standardization as an increasing number of SSPs are expanded throughout the nation. There also is an ongoing technical assistance cooperative agreement related to harm reduction collaborations with NCHHSTP, the National Harm Reduction Technical Assistance (TA) Center, National Harm Reduction Coalition, NASTAD, and the University of Washington.

Regarding HIV, work continues within the Ending the HIV Epidemic (EHE) initiative. In October 2020, CDC hired and sent 7 additional Public Health Field Assignees to EHE jurisdictions across the country to increase the HIV workforce capacity of health departments in these areas. In December 2020, EHE jurisdictions submitted revised jurisdictional plans. In September 2020, CDC awarded $2 million from HHS Minority HIV/AIDS Funds for mass mailing HIV self-tests to transgender women and to racial/ethnic minority communities. This is an extension of a carefully thought-out process for several years in which initial work was done through a randomized controlled trial (RCT) on the efficacy of providing HIV testing through the mail. This was found to work and to be cost-effective, so efforts are underway to determine how to scale it up and still have it focus in a way that would reduce disparities and get people diagnosed and treated. This is tied into a complement of CDC's *Let's Stop HIV Together*™ campaign, which is the *Take Me Home HIV Self-Testing Program* through which 100,000 HIV rapid self-tests are anticipated to be distributed over the next few months. Individuals may request extra tests for their friends to essentially do respondent-driven testing for other people who might be at risk. In that initial trial, that was shown to be highly effective. The *Take Me Home HIV Self-Testing Program* has 2 components, which include: 1) a strategic public health communications campaign; and 2) work with Insignia Federal Group, LLC (IFG) and Building Healthy Online Communities (BHOC) which have developed a web-based ordering portal so that people can assess their risks and order tests online at http://together.takemehome.org.

Efforts to address HIV criminalization laws in the US have moved forward. NCHHSTP began examining these issues more intensely about 8 years ago, first by doing a legal epidemiology evaluation that assessed which states had laws that did not align with current scientific evidence. They worked with the Department of Justice (DOJ) to delineate those laws. DOJ then shared guidance with Attorneys General (AGs) in the nation about reassessing their laws. An ecological assessment was then produced to show whether the laws had any public health effect, which found that there was no noticeable effect on HIV incidence. In January 2021, a

[1] Syringe Services Programs Technical Package (cdc.gov)

commentary was published in *The Lancet*[2] summarizing the existing data about these laws. This commentary notes that 37 US states still have HIV criminalization laws, even though some of the behaviors do not transmit HIV/are highly unlikely to lead to infection; and recommends that states need to align their HIV criminalization laws and application of general statutes with current science. Along with these efforts and efforts by many activists, several states are re-examining their laws and some states actually have changed their laws in the past year.

Data also were produced for the first time from the National HIV Behavioral Surveillance (NHBS) survey[3] that looked at HIV among transgender women. This was a special cycle that included data collection from 7 metropolitan areas. Even though this is referred to as a "national" system, it is actually not the case-based national system. It is focused in large metropolitan areas, which means that it is not always directly representative of rates in the nation as a whole. However, it does offer a sense of what is occurring in these areas. In this cycle, major disparities were observed in HIV prevalence among Black/African American and Hispanic/Latina transgender women. Dramatic differences are seen in prevalence rates, similar to those seen in men who have sex with men (MSM). Among participants testing positive, 62% were Black/African American and 35% were Hispanic/Latina compared to 17% White. Among those who reported having ever received an HIV-positive test result, 63% visited a health care provider (HCP) within 1 month after diagnosis and 90% were currently taking antiretrovirals. This survey also assessed some of the life experiences of transgender women and found that many transgender women experience poverty and homelessness, with 63% living at or below the federal poverty level (FPL), 42% experiencing homelessness in the past 12 months, and 34% receiving money or drugs in exchange for sex because of discrimination and lack of economic opportunities.

Related to viral hepatitis, a new cooperative agreement[4] was issued that supports integrated viral hepatitis programmatic and surveillance activities. Year 1 funding for 2021 is $22,301,157. There are 58 recipients for Component 1 (Surveillance) and 2 (Prevention) and 14 recipients for Component 3 (Special Projects). Inclusion of Component 3 marks the first time in the flagship DVH cooperative agreements that this approach has been taken to innovative projects to move the field of viral hepatitis public health forward. Some exciting projects have been submitted from the health departments. These cooperative agreements support the core viral hepatitis outbreak response, surveillance and prevention activities, and the special projects.

Hepatitis outbreaks have been discussed with CHAC over the past 2.5 years. These outbreaks[5] have been pretty extraordinary, with tens of thousands of people being infected with hepatitis A. Almost half of them were hospitalized and there were hundreds of deaths. It took a lot of effort by multiple health departments to turn the corner on this massive series of outbreaks throughout the country. It has taken a lot of time in the field and at headquarters by DVH and others to be able to stay on top of this. Data from 2011-2017 showed a peak at about 400 cases, a drop that stayed about the same through 2019, and an additional drop with the furtherance of COVID-19. While the hepatitis A epidemic has improved greatly with an 80% reduction in overall cases, it is not resolved. This was a major public health event for the nation. The case-fatality ratios exceed those historically associated with hepatitis A outbreaks. This is thought to be primarily because it was concentrated among people who use drugs (PWUD) and those who were homeless and more likely to become severely ill if infected. The costs were tremendous in terms of personal lives and economically. One analysis looking at related clinical

[2] https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(20)30333-7/fulltex
[3] https://www.cdc.gov/media/releases/2021/p0414-trans-HIV.htm
[4] https://www.cdc.gov/hepatitis/policy/FO-CDC-RFA-PS21-2103.htm
[5] https://aasldpubs.onlinelibrary.wiley.com/doi/10.1002/hep.31645

costs among West Virginia Medicaid beneficiaries from January 2018–July 2019[6] ranged from $1.4 million to $5.6 million for medical care costs alone.

DASH has been heavily involved in the COVID-19 response because so much of the prevention activities, concerns, and testing have revolved around schools. DASH has been overseeing some of the resources to implement programs, assisting with some of the guidance about how to deal with schooling effectively in the time of COVID-19, and highlighting some of the impacts that COVID-19 has had on adolescent and school-aged children beyond just infections to include mental health as well. A recent *MMWR*[7] from DASH showed that some of the efforts to slow SARS-CoV-2 transmission included widespread school closures, shifts to virtual and hybrid educational models, modifications to school-based services such as reducing after school activities, and an overall disruption in the educational experience. There is a fair amount of information from DASH and elsewhere that predicts that the nation will be dealing with the long-term manifestations of COVID-19 among children for a long time. In addition, children and parents have been experiencing additional stress that can increase the risk for some negative health outcomes. It has not been all negative, but there have been some major areas in which some outcomes indicate poor health.

Turning to STD, 2019 surveillance data[8] showed that there were 2.5 million reported cases of chlamydia, gonorrhea, and syphilis. There was about a 30% increase in all cases since 2015, which is the largest increase among congenital syphilis cases with a quadrupling between 2015 and 2019. Some populations continue to be disproportionately affected by STDs, including gay and bisexual men, youth, and racial and ethnic minority groups. An analysis also was done that is easy to state but took an enormous amount of comprehensive work by many people within the division and with external partners[9]. The analysis tried to capture the prevalence and incidence of STIs. Looking at 2018 as an example, the analysis showed that people had nearly 68 million STIs on any given day with nearly $16 billion in direct lifetime medical costs resulting from just the infections acquired in that single year of 2018. The majority of that, $13.7 billion, was for HIV infections associated with or attributed to having an STD. About $755 million was attributed to human papillomavirus (HPV) infections. Over $1 billion was attributed to chlamydia, gonorrhea and syphilis combined. Nearly 75% of the $2.2. billion in non-HIV-related STI medical costs were borne by women because they are disproportionately affected by the medical complications of STIs. This was a large-scale effort to try put the context of STIs and the impact on the wellbeing of the nation into perspective.

New gonorrhea treatment guidance[10] was issued, which recommends monotherapy with 500 mg of ceftriaxone for uncomplicated gonorrhea instead of dual therapy primarily for reasons of antimicrobial stewardship. If chlamydia infection has not been eliminated, the guideline recommends treatment with doxycycline. There are implications for public health practice and monitoring continues for emergence of ceftriaxone resistance, which has not yet been seen, to ensure continued efficacy with the single regimen. If efficacy does not continue over time, the guidance will be reconsidered.

[6] https://www.cdc.gov/mmwr/volumes/70/wr/mm7008a2.htm#suggestedcitation
[7] https://www.cdc.gov/mmwr/volumes/70/wr/mm7011a1.htm
[8] https://www.cdc.gov/media/releases/2021/p0413-stds.html
[9] https://www.cdc.gov/nchhstp/newsroom/2021/2018-STI-incidence-prevalence-estimates-press-release.html
[10] https://www.cdc.gov/mmwr/volumes/69/wr/mm6950a6.htm

Following long-term trends, TB incidence was 20% lower in 2020 than during 2019[11]. That is a much large decrease than would have been expected from following the slower trend over the past decade. The cause of that decrease is still being examined through multiple methods. There are several hypotheses in place, including: 1) physical distancing recommendations might have decreased transmission of TB from active cases; 2) changes in immigration may have changed people coming into the country with TB; and 3) other factors such as missed or late diagnoses could have affected this. All of these factors will be examined, including using whole genome sequencing (WGS) to try to get a better understanding. At least right now, it looks like there was a substantial drop in TB incidence last year. They will have to determine whether that continues in 2021.

Re-competition of the Tuberculosis Trials Consortium (TBTC) was completed for the next 10-year cycle running from 2021-2031. This is the large and very effective research consortium that CDC runs for TB studies with domestic and international collaborations. The 6 new sites for the next cycle include: University of South Carolina; Denver Public Health, Seattle & King County, Cornell University, Case Western Reserve University, and the CAB-V (Canada, Australia, Benin & Vietnam) Network.

In terms of CHAC correspondence, an initial letter was sent from CHAC to Secretary Alex Azar on 7/22/20 on the topic of youth. Drs. Redfield and Engels, CDC Director and HRSA Administrator at the time, sent a letter drafted 9/30/20 to Drs. Jean Anderson and Bradley Stoner. A detailed response was then sent to the Co-Chairs on February 26, 2021.

HRSA Update

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

Dr. Cheever reminded everyone that the HIV/AIDS Bureau's vision is "optimal HIV/AIDS care and treatment for all" and that their mission is to provide leadership and resources to assure access to and retention in high quality, integrated care, and treatment services for vulnerable people with HIV and their families." She emphasized that these have not changed during the pandemic. They are very excited to have been celebrating the 30th anniversary of HRSA's Ryan White HIV/AIDS Program (RWHAP) over the past year.

In terms of organizational announcements, Ms. Yemisi Odusanya has joined the HRSA HAB as a new Senior Advisor on EHE and works directly in the front office with Dr. Cheever and Ms. Hauck. Monique Hitch is the new Deputy of the Division of Metropolitan HIV/AIDS Programs, which is where the Part A and city programs around EHE sit. Ms. Erin Nortrup is the new Deputy of the Division of State HIV/AIDS Programs, which is where the Part B program and the state-level EHE sit. She also expressed gratitude to new members of CHAC and members who are ending their terms. HRSA looks forward to the CHAC's work in the coming years.

Regarding RWHAP updates, HRSA published its 2019 data at the end of 2020[12]. The program served over 568,000 people in 2019, which is over half of all of those with diagnosed HIV. Importantly, almost half (47%) of the RWHAP clients are 50 years of age and older. Three-quarters continue to be racial/ethnic minorities and about 61% live at or below the FPL.

[11] https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7012a1-H.pdf
[12] HRSA. Ryan White HIV/AIDS Program Data Report (RSR) 2019

Therefore, the program continues to be on target with reaching people who are most in need of HIV services. Improvements also continue to be made in health disparities. Viral suppression among key populations served by the RWHAP in 2010 was 69.5% overall nationally. There were significant disparities among African Americans (63.5%), transgender women (61.5%), youth 13-24 years of age (46.5%), and those unstably housed (58.4%). Huge gains were made from 2010 to 2019, when viral suppression among key populations was 88.1% overall nationally. Improvements were made across the board, along with reductions in some of the disparity gaps. There was about an 18.6% improvement in viral suppression from 2010 to 2019 nationally. There were even larger improvements among the groups for whom there were disparities of almost a 22% improvement among African Americans, 22% among transgender women, a remarkable almost 33% among youth 13-24 years of age, and about 19.7% among those unstably housed. Dr. Cheever commended the recipients who have focused through the quality management programs on working specifically among subpopulations known to have disparities to drive those down.

An important part of the work in EHE and in reducing disparities is in compiling practices that are evidence-informed in communities so that others can adopt and implement them. With that in mind, they developed the RWHAB Best Practices Compilation website, which provides streamlined searchable access to proven interventions. The centralized repository is expected to be launched at the end of April 2021, with an online mechanism for people to submit their practices that have worked that will help them display those in a way that is useful for people to take up and use on their own. Also moving forward and scheduled to launch in 2021 is the COMPASS Data Dashboard Project. This is a 5-year project that is going to transform the static data reports into interactive data visualization to help improve data quality and data-driven decision-making at the jurisdiction and individual clinic levels. There will be training for recipients and this will be launched for the general public as well.

HRSA also has specific Technical Expertise Panels to provide more expertise on areas where they feel more progress needs to be made more quickly in terms of programming. In October 2020, they hosted a 3-session virtual Technical Expertise Panel with external experts focused on HIV prevention and treatment among Black cisgender women across the lifespan. This was incredibly moving and powerful in terms of hearing from women with lived experience and experts on what should be considered moving forward. In November, HRSA hosted a 2-session virtual learning Technical Expertise Panels on HIV and Aging. From these, they were able to garner some important information around clinical care issues, health disparities, mental health needs, and the importance of meaningful public engagement. The final Executive Summaries for both panels will appear under “Publications”[13] on HAB’s Fact Sheet webpage.

Work has continued in the last several to reduce burden on recipients. In late 2019, HAB contracted with John Snow to conduct an evaluation of the 6-month recertification and rapid eligibility determination requirements. They learned a lot from that about the culture that has grown up around some of the HAB RWHAP. COVID has helped to message to recipients about what is actually required with regard to eligibility, determination, and recertification and what has been added on over time. The hope is that some of the changes in streamlined processes people have used during the COVID emergency will persist, and they certainly encourage that. Consideration also has been given to simplifying the process for requesting a core medical services waiver. In addition, consideration has been given to leveraging telehealth in terms of identifying strategies and effective practices to support and promote telehealth. While this occurred naturally during the COVID-19 pandemic, there are some great opportunities to leverage telehealth differently to reach people who not been reached. At the same time, it is

[13] https://hab.hrsa.gov/publications/hivaids-bureau-fact-sheets

important to ensure that there is the right balance of telehealth and in-person care and that the digital divide is addressed in a number of ways moving forward with telehealth.

The RWHAP law requires that recipients spend 75% of their services funding on searching for core medical services. There is a waiver process wherein providers have full access to all of those services for all people with HIV in their communities. They can have a public process and request a waiver to be able to spend more funding on some of the other support services that are essential. This was seen during the expansion of the Affordable Care Act (ACA). As more people had insurance and better insurance coverage, more RWHAP dollars could be used to support these services. The process for requesting a waiver was quite extensive in order to ensure that people have full access to RWHAP services before they spent less money on the core services. Over time and with greater expertise among HAB staff and recipient staff, they want to make the process much more streamlined. Public comment is currently being sought on a proposal to simplify core medical services waivers for Parts A-C.

Turning to the COVID-19 response, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) appropriated $90 million in 2020 to help recipients respond to COVID-19 related health service needs for RWHAP clients[14]. Through the end of December 2020, the number of new patients CARES Act-funded RWHAP providers served nearly 18,000 RWHAP-eligible clients with newly identified COVID-19. Each month, tens of thousands of RWHAP-eligible clients and immediate household members received at least one RWHAP core medical or support service using FY 2020 CARES Act funding specifically to focus on needs such as personal protective equipment (PPE), housing, emergency food, and different types of transportation that perhaps were safer than public transport for people with HIV. A considerable amount of work was done by recipients that made a huge difference in the lives of people with HIV.

A program letter was released on January 15, 2021[15] asking recipients to: 1) develop plans for addressing client needs related to health education about and access to COVID-19 vaccines; 2) identify specific COVID-19 vaccine distribution information for their organization and disseminate this information to staff and clients; and 3) communicate with clients about the vaccination status of staff and local availability of the COVID-19 vaccine. The Frequently Asked Questions (FAQs) on COVID-19 vaccine administration fees was updated on March 25, 2021 to explain how HRSA RWHAP recipients can be reimbursed for vaccine administration fees[16]. In the Consolidated Appropriations Act of 2021, language was included to allow HRSA HAB to provide waivers for some of the administrative requirements and penalties in the RWHAP. HRSA HAB released a letter outlining statutory penalties and administrative requirements that will be waived for RWHAP recipients for FY 2020 and FY 2021 RWHAP funding[17]. Specifically, Part A and B recipients with unobligated balances in excess of 5% could have any penalties associated with that waived. Penalties also could be waived for Part B recipients distributing 70% of their funds before September. A process also has been put in place for recipients to ask for waivers around the core medical services requirement in Parts A-C, the 50% EIS requirement for Part C, matching requirements in the Part B ADAP supplemental, maintenance of effort for Parts A-C, and Part F dental programs. HRSA HAB was very glad that Congress gave them the opportunity to provide these flexibilities for recipients. They have heard loud and clear from providers and staff about issues pertaining to provider stress and burnout. HAB has been educating its providers about ways that they can be using the CARES Act funding

[14] Ryan White HIV/AIDS Program COVID-19 Data Report submissions through December 2020 (unpublished)
[15] https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters
[16] https://hab.hrsa.gov/coronavirus/frequently-asked-questions
[17] https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters

specifically to address provider burnout among their staff members, including the use of program income and rebates for that purpose[18].

Turning to EHE activities, Dr. Cheever expressed her excitement about what they have been able to accomplish this year. They had made an assumption that because so many of their staff at the public health department and clinic levels had been deployed so much for COVID-19 instead of focusing on their HIV responsibilities, that progress would not be as great as hoped. Conversely, they found out that their recipients had been able to do a tremendous amount of work in EHE during this first year of funding that began in March 2020. Progress report data[19] from the health centers that received $54 million in FY 2020 Primary Care HIV Prevention (PCHP) funds showed that within 8 months of award 93% had hired new staff (389 FTEs); over 573,000 patients were tested for HIV; 2260 patients were newly diagnosed with HIV and received follow-up within 30 days; and nearly 50,000 patients were prescribed pre-exposure prophylaxis (PrEP). Additionally, between 2014-2019, health centers increased the number of PrEP providers and patients at a higher rate than other care delivery settings in the EHE priority counties[20].

RWHAP EHE-funded providers submitted data to the EHE Triannual Module for the first reporting period of March through August 2020. These data[21] represent clients who received services, of whom nearly 6300 were new to RWHAP and an additional 3600 were re-engaged[22] in RWHAP services. For both new and re-engaged clients, outpatient ambulatory health services was one of the major services provided. For those new to RWHAP, antiretroviral therapy (ART) prescription was the second most common service followed by EHE initiative-specific services. Within EHE, there is the flexibility to have a large variety of types of activities that do not fall categorically into any one RWHAP service to be called EHE services. That was well-used for new patients. For re-engaged cases, medical case management was the second most common service provided. This is thought to be related to some of the underlying factors that led to people being out of care and making sure that these are being addressed as they come back into care. Looking more qualitatively at the evaluation of what RWHAP EHE recipients did[23], many worked on administrative infrastructure and community engagement as their major activities during the initial phase. Over half of recipients formed new partnerships, which had been pushed as a major part of EHE. The TAP, Cicatelli Associates, Inc., was very busy with providing intensive TA and monthly online webinars for the 47 funded EHE jurisdictions, including Rapid ART, partnering with Federally Qualified Health Center (FQHCs), and responding to HIV clusters and outbreaks.

Very important within HAB has been a focus on community engagement. Dr. Cheever shared a graphic created by someone who was listening to the community engagement plenary session at the National Ryan White Conference in August 2020. Within renewed focus on community engagement to meet the goals of EHE, HAB believes that their collective success depends on how well communities are engaged in planning, development, and implementation of HIV care and treatment strategies. HAB identified 5 guiding principles for its community engagement efforts, which are:

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[18] See 45 CFR §§ 75.403 –.405. Based on PCNs 15-03 and 15-04

[19] Internal data, Bureau of Primary Health Care, March-November 2020

[20] Unpublished, preliminary analyses conducted by CDC and HRSA

[21] Unpublished data, HIV/AIDS Bureau, March through August 2020. Clients may have received multiple services and appear in each category of services received

[22] Estimated based on reported numbers of total clients served, new clients, and existing clients

[23] Source: Unpublished data reflecting activities from the first eight months of EHE implementation (March through October 2020), as reported by 47 RWHAP EHE grant recipients in their EHE Year 1 Non-Competing Continuation (NCC) Progress Report; this does not reflect data reported through the EHE Triannual Module

- ❑ Intentional: Plan thoughtfully about how to effectively partner with people with HIV in communities, building on existing strengths within the communities.

- ❑ Committed: Invest in the development of people with HIV and facilitating their access to tools needed to partner and participate effectively. Investments include providing opportunities for training, communication, leadership, development, and hiring people with lived experience.

- ❑ Sustainable: To meet the goals of EHE and ensure that community engagement builds and grows, it is important to establish and maintain sustainable strategies.

- ❑ Flexible and Tailored: Develop innovative strategies for community engagement that is broad and allows for flexibility and acknowledges the required time and process for leadership development. Recipients and sub-recipients are supported to develop creative strategies that are flexible in order to meet people where they are.

- ❑ Transformational: Community engagement is an iterative process that includes ongoing communication and feedback between recipients, sub-recipients, providers, CBOs, and people with HIV. The shared experience centers on the needs of people with HIV and results in the transformative approach needed to support engagement in care and achieve the goals of EHE.

HAB also expects that its recipients work with people with lived experience and communities in ways that support these guiding principles of community engagement.

HRSA was very successful in 2019 in visiting many locations and talking to people with lived experience in health departments. That work, which was done with CDC and HRSA together, helped inform HRSA's approach to developing its programs. HRSA is hosting virtual EHE listening sessions by region in FY 2021. Sessions engage state and local health departments, community health centers, community organizations serving people with HIV, primary care offices, AIDS Education and Training Centers (ATECs), and people with lived experience. HRSA HAB is developing needed tools and providing leadership training to people with HIV. Efforts support ways for people from the community to provide services within their community to engage people into care and treatment. HRSA HAB is supporting organizations to hire people with HIV and is continuing to support community engagement efforts of its national partners and CHAC Workgroup.

EHE Jurisdictional Plans

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Dr. Raizes provided preliminary results of CDC's thematic review of jurisdictional EHE plans. In September 2019, CDC awarded $12 million dollars from the HHS Minority HIV/AIDS Fund (MHAF) to 32 CDC-funded state and local health departments to develop comprehensive EHE plans that are tailored by and for each community. Over the course of 2019-2020, jurisdictions were expected to: 1) engage with existing local prevention and care integrated planning bodies that have experience representing local populations and stakeholders, including HRSA-funded RWHAP Part A and B recipients; 2) engage diverse community perspectives, including new

partners who have not traditionally been at the planning table; 3) prepare a current epidemiologic profile and situational analysis that provides an overview of strengths, challenges, and needs; 4) involve people with HIV and members of local communities disproportionately affected by HIV in the planning process and provide documentation of this; 5) engage with local service providers to deliver prevention, care, and other essential services for people with HIV; and 6) prepare and reach an agreement on a new or updated EHE plan with local planning groups that describes the specific strategies that will be employed locally to achieve EHE objectives.

Draft plans were submitted to CDC by the end of December 2018. HHS, CDC, and HRSA jointly reviewed the draft plans and provided feedback to the jurisdictions in early 2020. It is important to acknowledge that this was an accelerated process. Draft plans were developed in 3 months. Recipients did have an additional 12 months to update those plans, yet progress was interrupted due to COVID-19 despite CDC extending the deadline for jurisdictions to submit their final EHE plans to the end of December 2020. The systematic review process that Dr. Raizes described during this session began in February 2020 and is ongoing. HRSA also is conducting a review of the plans based on their priority areas.

Dr. Raizes pointed out that this presentation had some limitations. First, given CDC guidance for jurisdictions to develop locally tailored plans, this thematic analysis initially used a deductive approach to focus on anticipated themes that would be common across all plans. Consequently, the information in this presentation should not be considered exhaustive. All results are preliminary as the systematic review process is ongoing due to staffing limitations, especially that relate to COVID and the length of some of the plans. Lastly, this presentation does not contain information related to the resources needed to implement plans, administrative collaborations and/or management challenges between state and county health departments, and potential reasons for gaps in the EHE plans. For example, did a jurisdiction not include a priority strategy in their plan because they do not intend to conduct that activity, or is it because they are already conducting that activity using previously allocated funding?

CDC did expect the community engagement process to involve the collaboration of key stakeholders, including the populations most disproportionately affected by the HIV epidemic. Of the jurisdictions, 100% reported engaging local community partners and HIV care and treatment providers. Additionally, 78% of jurisdictions specifically described engaging new or non-traditional partners as advised by CDC's community engagement guidance, which encouraged all jurisdictions to bring new voices to the planning table. CDC advised jurisdictions to implement community engagement strategies that were flexible to ensure that the voices of the community who may not have been members of the existing HIV planning bodies were heard. Consequently, jurisdictions implemented a wide variety of strategies, including conducting focus groups and interviews, using community advisory boards (CABs), and creating steering committees. All jurisdictions reported that COVID-19 impacted their ability to conduct these community engagement activities, although most jurisdictions did report shifting community engagement activities virtually via Zoom and other platforms.

CDC advised jurisdictions to conduct the community engagement process in a holistic manner, and to involve all of the populations disproportionately affected by the HIV epidemic. Persons with HIV, transgender persons, Black/African American MSM, and Black/African American women were the most frequently engaged populations by jurisdiction in the planning process. It is important to note that the number of jurisdictions that engaged each of these populations may be higher as only those jurisdictions that explicitly referenced engaging the population in their plan were tallied for this analysis. Jurisdictions also identified a variety of structural barriers that must be addressed to achieve EHE goals. Systemic racism, economic insecurity and

poverty, education, housing, access to healthcare, and stigma were identified as barriers by at least 75% of the jurisdictions.

In Florida, EHE officials conducted interviews with local leadership, such as the city mayor and county commissioner, to foster EHE champions in each county. In Baltimore, the EHE working groups scored the challenges and needs identified by the community to help prioritize activities and focus their resources. In South Carolina, combating stigma and fear were a significant focus of the planning process. A series of forms gathered a broad perspective on gaps and barriers and reached communities experiencing health disparities that have either not routinely had access to prevention and care programs or who have not felt included.

Over half of jurisdictional plans included creating or expanding self-testing programs, testing in incarceration settings, conducting targeted non-healthcare testing, implementing routine testing in EDs, and integrated STI testing. San Francisco's innovative plan included the creation of a mobile unit and Scouting Team to provide outreach, testing, and referrals within homeless encampments. Their plan also included providing testing for HIV, HCV, and STIs at family events for formerly incarcerated individuals, providing incentives for testing, and funding HIV and HCV screenings at key pharmacies in the jurisdiction.

For the treat pillar, 75% of jurisdictions included rapid linkage to care and their plans, while 63% of the plans included activities to implement or expand telemedicine. Only 9 out of 32 jurisdictional plans explicitly included the integration of STI treatment. Alabama plans to identify people with HIV who are not in care by scaling up their Data to Care (D2C) program and developing a data sharing agreement with the Alabama Medicaid Agency. Alabama's plan also includes activities that will promote long-distance clinical health care through telehealth and will assess the ability to link HIV positive cases to chronic HCV cases. Additionally, Philadelphia's plan includes the creation of low-threshold clinics to access integrated treatment for HIV, STIs, and hepatitis.

For the prevent pillar, 14 out of 32 jurisdictions explicitly included initiating or expanding same day PrEP programs. Additionally, over half of the jurisdictions' plans included Tele-PrEP and over 70% of the plans included PrEP navigation and expanding SSPs as strategies for this pillar. Michigan plans to conduct a robust social marketing campaign with the intent of normalized PrEP use and increase awareness of post-exposure prophylaxis (PEP). Their plan includes partnering with 25- to 35-year-old patients and featuring celebrities and influencers in their advertisements, posting educational information for use on social media, and featuring HIV education on Detroit Public Television (DPTV). Nevada plans to develop materials and PEP and PrEP for survivors of sexual assault and increase access to SSPs through non-traditional methods like mobile outreach, vending machines, and secondary exchange.
Approximately half of all jurisdictions explicitly included conducting enhanced partner services, providing real-time information, developing flexible funding sources, and establishing a dedicated workforce in their plan as per the respond pillar. Arizona plans to humanize their approach to public-facing materials to ensure that misconceptions around cluster detection and molecular data use do not create barriers that prevent people from getting tested. Additionally, Arizona will consider implications surrounding issues of privacy, criminalization, and work with the community to determine how to transparently communicate about clusters while also protecting individual anonymity. Maryland's Prince George's County plans to provide comprehensive training to develop a local Response Team consisting of community outreach workers, DIS staff, and providers. They also plan to ensure that patients are rapidly navigated to care and support services.

Outside of the 4 pillars, jurisdictions identified other priorities including addressing the opioid crisis, HIV criminalization, and the needs of K-12 students in schools. Promisingly, many jurisdictions also recognize the need to address the HIV epidemic from a syndemic and status neutral perspective. Many plans were creative, innovative, and tailored to fit jurisdictional needs. The EHE plans[24] and information on the planning process are posted to 3 websites, including CDC's EHE website, CDC's PS19-1906 website[25], and the NASTAD EHE microsite[26]. Moving forward, CDC will continue an in-depth examination of these plans and report out more detailed and nuanced findings. As a reminder, these plans are living documents and are subject to change.

CHAC Discussion: CDC/HRSA Updates & EHE Jurisdictional Plans

Everyone acknowledged and commended the extraordinary work that CDC and HRSA have been able to accomplish, especially in the midst of the pandemic.

Dr. Taylor observed that the World Health Organization (WHO) has a goal of ensuring 1 brand-new syringe per injection and a targeted 300 per person per year, understanding that this target may be inadequate. With that in mind, she asked whether the CDC SSP Technical Package includes a specific goal for the number of brand-new syringes per person per day.

Dr. Mermin responded that CDC supports needs-based syringe distribution rather than having a preordained limited. Ms. Zeigler added that the SSP Technical Package can be found on this website: https://www.cdc.gov/ssp/

Dr. Morne noted that New York continues to be stunned by the ongoing increase in STIs, particularly given the efforts that have been made around EHE. She wondered whether there is an opportunity to consider a learning collaborative, not necessarily in the usual sense, but to have a space for a dedicated conversation to the response to STIs and better understanding what other jurisdictions are doing. New York has so few physical resources that can be truly dedicated. While New York has declared EHE related to HIV elimination for hepatitis C, they do not have the resources to implement new responses related to STIs. A learning collaborative could be beneficial to many jurisdictions.

Dr. Cheever agreed that more conversation is needed about this. One of the big concerns with the RWHAP is that insufficient self-testing is being done. HRSA is working on this as a priority, but they need to work together with CDC to figure out how to enhance self-testing.

Dr. Mermin added that based on a recent report from the National Academies of Science (NAS) and trying to make recommendations on STIs, CDC has been thinking about this as well and has had consultations. STIs have been going in the wrong direction and consideration must be given to what can be done about it, even with existing resources. Thought also must be given to how to respond as a nation to what is a worsening epidemic of multiple types of infections—even during the time of COVID when social distancing was thought to be physical distancing, which meant distanced.

[24] https://www.cdc.gov/endhiv/action/local-ehe-plans.html
[25] https://www.cdc.gov/hiv/funding/announcements/ps19-1906/ehe-plans.html
[26] https://www.nastad.org/ending-hiv-epidemics

Dr. Stoner said he was very pleased to hear Dr. Cheever talk about the TA work that Cicatelli Associates, Inc. is doing pertaining to the EHE jurisdictional plans. He asked to what extent that is coordinated with the similar program that is underway on the CDC side through the capacity-building assistance programs.

Dr. Cheever indicated that CDC and HRSA are coordinating at the staff level on TA and who is doing what and where to better align that, and they do have monthly calls between the HRSA and CDC staff.

Dr. Raizes added that they are working together to identify an ideal and most efficient way to diagnose the most cases of HIV in the country using all of the technology available. Hopefully, newer technologies will come on board in the near future.

Dr. Parkinson asked how to implement programs across STI prevention when there are youth, HIV and aging, and HIV negative populations. Everybody falls in love and COVID-19 is COVID-19. She wondered how organizations could address that gap of implementation to make sure that they bring the most profound services available to their communities and health departments since “normal” activities are not being done, such as being at the forefront of mobilization of HIV testing. Now that there are COVID-19 drive-up situations where people can be tested, she wondered if any efforts are going into implementation of those same strategies to make sure that people stay safe and practice safer sex.

Dr. Mermin stressed that it is a challenge and that he is not sure about integration so much as thinking specifically about the commonalities for effect, such as making testing easily available and when it can be routine, making it routine. People at risk do not always present to a clinic and where they do go may differ for various people. Where they should be is wherever people go. There also are epidemiological dynamics to consider. Once incidence of infections increases, that means there are more people with prevalent infection who can transmit it. Because it builds in a negative cycle of increasing incidence, it is necessary to concentrate efforts to this scale to reduce it all. The prevention modalities available also have to be considered. It is convenient that there is PrEP for HIV prevention, which empowers people who do not have HIV to protect themselves by a means other than just behavior change and condoms. This is really not available yet for STDs, but people are interested in that question scientifically. Interventions are needed to reduce STIs and they were able to do it in the past. Certainly for syphilis, there was conversation about elimination instead of a quadrupling of congenital syphilis cases. That suggests that it is possible, but also points out how far away they are from that success.

Referring to Dr. Cheever’s point about quality improvement surrounding viral load suppression and people entering care, Dr. Parkinson asked where there are numbers that reflect individuals who are housed and had transportation to meet the deliverable of making their appointments. She also asked whether HRSA would put more dollars into the housing initiative so that people can stay housed and effectively seek the treatment that they ultimately need.

Dr. Cheever said that while they do not have client-level transportation data, they do have client-level housing data. For people who are unstably housed who are truly homeless, very little progress has been made in reducing the disparity gap compared to other types of disparities. Through the RWHAP, more people have been housed. There is a smaller proportion of people who are unhoused now than there were 15 to 20 years ago. HAB continues to work closely with the Housing Opportunities for People with AIDS (HOPWA) program. It was exciting for her to see during COVID that people who have been unhoused for years suddenly could be housed, so they know it can be done. The question regards how to

sustain that over time. In the RWHAP legislation, decisions about where funding goes is made at the local level. She imagines that some of the new EHE funding will be directed to housing. There has been a large increase in HOPWA housing funding recently through the CARES Act. She will look into the transportation question as well and will report back.

Dr. Dionne-Odom emphasized that the data from the pilot projects for home-based testing for both HIV and STI testing is highly compelling. The success rate is greater than most other interventions available. This is a good opportunity to break down the barriers that unfortunately still exist between HIV programs and STI programs. The response must be unified. Every time they talk about reaching people for HIV testing, that should be bundled with STI testing. Patients can do self-testing sampling successfully.

Dr. Mermin added that this also relates to diagnostics and new diagnostics that would be helpful in these efforts. There are not any OTC tests other than HIV, which creates obstacles in terms of getting the job done.

Dr. Anderson asked whether information is being collected on some of the COVID education prevention and vaccine uptake efforts. She is trying to talk to all of the women she sees in her HIV clinic and is finding a surprising degree of vaccine hesitancy. Given the key role that the RWHAP plays in serving individuals with HIV, it seems like an important issue to track and address.

Dr. Cheever indicated that people can report vaccine hesitancy as a topic when they complete the CARES Act information. However, it is not a category that people are tracking on. Certainly, most of that work is probably done within the context of the RWHAP. There is not a reporting item in the RWHAP to do that. It takes about 6 months to a year to get a reporting requirement through the Paperwork Reduction Act (PRA) process. They have not been gathering this information, but she completely agreed with tracking it. She did not think any of her patients have had a vaccine without talking to her first. Whatever the messaging is that is happening more broadly in communities, people want to talk to their doctors before they get the vaccine. She invited CHAC to think about that in terms of potential recommendations going forward.

Dr. Dionne-Odom indicated that they are conducting a vaccine survey with their Multicenter AIDS Cohort Study/Women's Interagency HIV Study (MACS/WIHS) comprised of thousands of people living with HIV. They are seeing the same hesitancy in their clinic that Drs. Anderson and Cheever described.

Mr. Hill-Jones said he appreciated seeing some of the strategies that are working with the jurisdictional plans in some of the states Dr. Raizes mentioned. He is very interested not only as a CHAC member, but also as a person living with HIV to know what will be done to address the cities that are not as successful in terms of implementing a solid plan to get them to 2030.

Dr. Raizes said he understood the frustration, but stressed that this was a review of the plan not a performance review. Performance reviews are part of the funding agreements overtime. Given the timeline of EHE, they are not prepared to share any performance data at this time. There are two processes for these plans. What he described in his presentation was the thematic review of the plans to look for common themes. He did call out jurisdictions for specific innovations that they thought was worthy of sharing with CHAC, but this was more about the thematic trends they are seeing. A second process is underway that does get to the point that Mr. Hill-Jones alluded to, which he would call a "checklist approach" to the requirements. Based on interagency review of the draft plans, recommendations were made in that respect.

Dr. Cheever indicated that they are conducting virtual site visits to jurisdictions, which is the time to have a concrete back-and-forth discussion about any gaps. They also have funded a coordination provider, NASTAD, which is helping with jurisdictions that are having a hard time bringing partners together or bringing enough new partners and providing specific TA around some of those issues.

Dr. Hills-Jones asked whether the site visits involve the community or if it will just be a government-to-government conversation, and what process will be used to engage more stakeholders than just the health departments in order to get a fuller community picture of the EHE needs and the needs for any HRSA work that is attached.

Dr. Cheever indicated some of the site visit work is with the health departments and some of it is with their partners. They have a specific section where people with lived experience in the community are part of the site visits. They have been implementing this in various ways to determine what works best, especially if there are people who wish to remain anonymous on Zoom for instance. At this point, the visits are being done mainly telephonically so that people feel they have some anonymity in that process. In addition to the community call, they have a stakeholder call and health department call as part of the site visits. Part of NASTAD's work as the TA coordinator is about stakeholders, communities, and bringing together partners.

Dr. Mehta asked whether any of the plans specifically talked about how they might leverage COVID-19 efforts, in particular regarding the testing pillar and perhaps integrated testing.

Dr. Raizes reminded everyone that they started with the template of anticipated themes and were not anticipating the impact of COVID at the time they set that up. It is a great question. In CDC's internal reviews, they are already creating a dialogue with the Project Officers at least to be able to give feedback to them on some of those innovations. The telework and telemedicine that he mentioned certainly by inference would suggest a positive adaptation to make part of the general routine. While the jurisdictions were not asked to speak to COVID directly, many chose to do so anyway.

Dr. Rodriquez said it was not surprising to him that homophobia and transphobia came up as systemic structural barriers. However, some interventions that might address that are not included because the overall purpose is to link people to care, link them to PrEP, or get them to use condoms. He asked whether there is any intention for the short- and long-term to develop interventions that will address homophobia and transphobia. For instance, the Act Against AIDS™ campaign included a lot of diversity. When a lot of diversity is shown, it does help. While such campaigns reach the audience, they have to think about how to reach the general public in order to eradicate homophobia and transphobia so that communities feel safe. In the NOFOs that are being published, he is beginning to see language about creating safe spaces. This is great and it was needed for organizations to be involved, be aware, and have the intension to create safe spaces. However, as they are putting together interventions for organizations to follow, they need to talk directly about homophobia and transphobia.

Dr. Cheever noted that HRSA funded a project called ELEVATE (Engage Leadership through Employment, Validation, and Advancing Transformation & Equity), which focuses on providing professional development and training. The training that they have developed through the Building Leaders of Color Project looks at transphobia, stigma, et cetera in terms of how that impacts people. It is more of a TA approach, which she wonders sometimes if that might be the better approach. They recently funded a project through the MHAF, which targets stigma and unconscious bias of providers.

Dr. Raizes noted that Dr. Rodriquez's question pointed to the reason why it is important to both agencies to have the community voice in all of these plans. Even speaking for himself as a clinician, he cannot always find himself acutely aware of all of those considerations. It is important to have the voices of everyone in the community who can keep the planners aware of those types of situations. CDC is committed to the use of data as it pertains to specific populations who are especially under-served by the programs that are available or are most affected by the HIV syndemic. Moving forward, they need to keep thinking about what is correctable among those factors. The fact is, they will not achieve the goals of EHE if they do not pay attention to sub-populations.

Dr. Mermin pointed out that homophobia, transphobia, and racism are problems of the dominant society. They are not the problem of the victims or the people who experience them. To change society, it is necessary to reach out to the groups and the structures that create that environment and that enable it to exist. DASH has been expanding and improving access to Gay-Straight Alliances and other inclusive activities, with very exciting documented positive results. This means that it is possible to change an environment, but schools are more malleable in a way than society at large. They need to think about these issues, and he does not want people to give up because it is hard to change problems. One of the things Dr. Cheever has highlighted for years that he has now incorporated into all of his talks is the changes in viral suppression rates that she has seen in multiple groups over time. That was a concerted effort by HRSA and Ryan White. That was not happenstance. She did not eliminate racism to improve rates disproportionately faster among African Americans than she did on Whites. What she was able to do within the environment of Ryan White was to create an environment that is enabling and supportive of the most vulnerable and focus on improving that outcomes and hopefully others that make people have a healthier life. There is an opportunity to do both at the same time. Part of the EHE is to highlight those opportunities, share them, assess them, determine if they are working, expand them if they are, or do something different if they are not.

Dr. Hauser implored CDC, as a public health agency, to try to squash the anti-trans bills that are sweeping the states. These are bad for everyone, but they are very bad for young people.

Dr. Armstrong noted that she did not hear anything with regard to the plans about workforce issues. By diagnosing and linking patients to care, they are going to struggle critically with workforce. Perhaps that needs to be tackled more centrally than jurisdictionally.

Dr. Raizes indicated that the plans are more about what to do, but perhaps lack information about how to do it or overcome challenges. It is important to have ongoing conversations and a performance component to assess shortcomings.

Dr. Cheever added that HRSA has facilitated getting the ATECs on board about focusing on expanding the workforce. The National HIV Curriculum has been integrated into residency and other types of programs of people who are still in training. Leveraging that kind of work will get them a lot further faster. HRSA needs to push that out on their end nationally.

CHAC Workgroup Reports, Member Discussion, & Additional Business

Perinatal Infectious Disease Workgroup

Jean Anderson, MD
Workgroup Chair
Professor, Gynecology & Obstetrics
Johns Hopkins Medical Institutions

Dr. Anderson reminded everyone that they gave a presentation during the last meeting, but did not get to vote on the recommendations. A summary was provided during that meeting of some of the facts, an update was given on the quadrupling of congenital syphilis cases since 2015, and the argument for addressing some of the issues related to perinatal infections was demonstrated. As a reminder, the Perinatal Infectious Disease Workgroup's charge was to advise CDC and HRSA regarding prevention, screening, and diagnosis of prenatal infections, focusing on syphilis, HCV, HBV, and HIV in pregnancy and in women of reproductive potential. The workgroup decided to focus on 4 areas, which were discussed at length previously. For the purpose of this session, Dr. Anderson reviewed the 4 areas and specific recommendations within each for CHAC to consider as follows:

Focus Area #1: Aligning Perinatal ID Screening Recommendations

- It is recommended that CDC/HRSA consider convening a meeting with representatives of relevant professional societies to discuss the rationale and importance of:
  → Universal screening for HIV, hepatitis B, hepatitis C and syphilis in pregnancy; and
  → Standardization of testing recommendations across societies.

- A goal of the meeting would be to achieve consensus and encourage advocacy regarding the need for better alignment of laws and regulations around screening for infections in pregnancy.

Focus Area #2: Standardized Laboratory Pregnancy Panels

- It is recommended that CDC/HRSA work with relevant professional societies, the Council of State and Territorial Epidemiologists (CSTE) and laboratory representatives to support development of standard pregnancy panels and timing of perinatal infection testing to support coordination of standard pregnancy panels through commercial labs.
- Panels may serve as a prompt to remind providers of screening recommendations and remove the risk of ordering the wrong test. Providers could opt-out of individual tests, if indicated, and could order diagnostic testing at any time.
- It is recommended that CDC/HRSA work in support of a requirement for laboratory reporting of pregnancy status when reporting results of HIV, HBV, HCV and syphilis.

Focus Area # 3: Linkage Between Obstetrical and Pediatric Records

- It is recommended that CDC/HRSA support the conclusions and recommendations of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) (https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendations) for implementation to improve medical record linkage between maternal and infant records.
- Potential concerns with 21st Century Cures Act-fathers will have legal access to relevant information in infant/children's medical records, including information about maternal health if present.

Focus Area #4: Reducing Silos Between Perinatal Infections

- Case review boards may be a viable model to help reduce silos between perinatal infections. It is recommended that CDC/HRSA authorize pilot projects to explore integration of existing case review boards across relevant perinatal infections to allow more coordination and efficient use of resources.
- It is recommended that CDC/HRSA encourage collaborations and partnerships at the state level between public health departments, community organizations and health care providers to identify pregnant women with infections (e.g., HIV, syphilis, HBV, HCV), particularly those not engaged in care, in order to blend resources and enhance workforce capacity to address complex patient needs.

COVID-19 Considerations

- With the advent of the COVID-19 pandemic, the workgroup realized that there has been a reduction in STI testing due to diversion and shortage of human and material resources, reduced access to services, and in some cases avoidance of care because of fear of exposure. The workgroup felt that it was appropriate to recommend that CDC/HRSA explore opportunities to expand home-based and self-testing for STIs for pregnant individuals.

Focus Area #3 already has been addressed by an NIH Task Force on research specific to pregnant and lactating women. Workgroup members, some of whom served on this NIH Task Force, thought it would be very helpful for CDC and HRSA to support the conclusions and recommendations related to this Task Force regarding implementation to improve medical record linkage between maternal and infant records. She thought it was worth noting that now that the 21st Century Cures Act has taken effect and is a federal law, her own institution is talking about how to address this. The fact is that although they will have to request it, fathers will have access to relevant information in the infant and children's medical record. That will include information about maternal health status if that is present, including mothers who have HIV or test positive for one of the other perinatal infections.

Dr. Anderson pointed out that the second recommendation in Focus Area #4 is a new recommendation that was added since the presentation given during the last meeting. It came from a conference call she had with CDC colleagues in the Perinatal HIV Prevention Activities group and also relates to a prior presentation to CHAC a couple of years ago.

In the interest of time and in order to try to expedite this process, the working group developed a letter in advance that was included in the members' packets. Dr. Anderson explained that the letter included a background and rationale, some of the facts that have been discussed, priority areas for intervention, and the specific recommendations she just reviewed.

Hepatitis Workgroup

Lynn Taylor, MD, FACP, FAASLD
Workgroup Chair
Research Professor, University of Rhode Island
Director, HIV and Viral Hepatitis Services CODAC Behavioral Health
Director, RI Defeats Hep C University of Rhode Island

Dr. Taylor reminded everyone that during the November 2020 CHAC meeting, the CHAC passed a resolution and was presenting the recommendations described below for CHAC's consideration. These recommendations focus on the imperative of improving HCV diagnostics in the US as the key next step in addressing the public health threat of HCV. As such, the

CHAC strongly urges CDC and HRSA leadership to consider the below actions with regard to the nation's HCV epidemic. Intentionally putting the recommendations at the beginning of the letter is prudent, given that Secretary Becerra is a busy person and should see these first. The recommendations are as follows:

It is recommended that CDC/HRSA:

1. Adopt a national HCV testing strategy based on single-step ribonucleic acid (RNA)-based testing, as the pillar of the US HCV elimination effort. Development, validation, and regulatory approval of point-of-care (POC) molecular (HCV RNA) fingerstick and dried blood spot (DBS) diagnostic testing should be prioritized & accelerated to rapidly scale up diagnosis and facilitate access, while antibody screening should be phased out.

2. Implement a national, coordinated, efficient approach to development of optimal HCV diagnostics.

3. Make progress regarding these recommendations despite the COVID-19 pandemic. Lessons learned from SARS-CoV-2 testing may inform next steps regarding 1-step HCV molecular diagnostics and large-scale rollout. HCV self-testing outside clinical settings is particularly advantageous in situations with restricted movement, as seen under COVID-19, where access to health care services and diagnostic testing are more limited.

The letter then goes through the background and rationale. The CHAC members reviewed and agreed upon this and there is only one difference, which is an added reference. Here are the key points in the letter:

- Diagnosing our HCV-undiagnosed populations as quickly as possible is the next key step necessary to avert liver-related morbidity/mortality and stem rising incidence for the second biggest infectious disease killer in the US.

- The development of all-oral, well-tolerated, short-duration, pan-genotypic direct-acting antivirals (DAAs) with high cure rates paved the way to cure those with HCV. In 2019, American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) endorsed universal treatment, followed by the recommendations for universal screenings by CDC and the United States Preventive Services Task Force (USPSTF).

- Yet, the impact of DAAs in decreasing HCV burden at the population level is contingent on the level of diagnostic testing.

The workgroup explained in the letter that the 2-step diagnostic process is the key bottleneck in the HCV cascade to cure. There is a big drop-off between antibody, which denotes exposure to the infection, and Hep C RNA, which identifies infection. Phlebotomy is required for HCV antibody diagnosis, which is a tremendous barrier for people. The most affected group is comprised mostly of people who inject drugs (PWID).

They talked about the ideal simplified HCV care delivery test-to-treat. The way to get to this is to eliminate the 2-step diagnostic process by providing rapid POC finger-prick RNA testing. The POC tests are not available, but there are tests available that allow diagnosis at the site of patient care using fingerstick capillary whole blood. This enables test and treat and self-testing. The next step is to make HCV RNA POC diagnostic testing available for wide-scale treatment. The testing should be rapid, simple, cost-effective, with high sensitivity and specificity, and

minimally invasive. An example is provided of the first POC HCV RNA test, Xpert® HCV Viral Load Fingerstick by Cepheid in Sunnyvale, California and then explain that the alternate pathway is DBS testing. The only thing new here is a reference for an article in the *Journal of Infectious Diseases* (*JID*) published a few weeks ago giving an example of Hologic's Aptima® HCV viral load assay as being effective in DBS.

The letter concludes by saying that scientific advances and lessons learned from molecular diagnostic testing for SARS-CoV-2 should be harnessed for large-scale HCV diagnostic testing in the US. Many of the laboratory platforms may be used for both viruses. Experience with SARS-CoV-2 highlights the need for a common framework to ensure that HCV diagnostics are accurate and reliable. It will be more effective to develop, validate, authorize, and produce a small number of well-designed tests manufactured in large quantities than to simultaneously develop and authorize scores of products. Breakthrough diagnostics must be priced so that they can meet public health need, with transparent collaborations to create mechanisms for price control.

In closing, Dr. Taylor said it was her understanding that this might bring them to the end of the Hepatitis Workgroup. They certainly have contributed to and think and reached goals in terms of recommendations for universal HCV screening rather than just testing of pregnant women. They have recommendations and a letter ready to go, which hopefully would be approved. She mentioned that HCV is very different. Every other infection discussed and focused on by the CHAC are classic STIs. HCV is not. It is primarily a marker for injection drug use. The workgroup includes people with experience in patient care, medical care of people who use drugs, people who inject drugs, people living with HCV. A different paradigm is needed for HCV than the approaches taken for the other infections dealt with on the CHAC. Dr. Taylor expressed her hope that if the workgroup is ending, others can be brought to the CHAC who have that experience, training, and expertise but do not have the COI. What happens very commonly in the space of HCV is that people who have the clinical experience and know a lot about HCV have a conflict of interest with Gilead and AbbVie—those who make the medications. The CHAC must pay attention to COI to ensure that the really important work of the CHAC is not marred by a COI.

EHE Community Engagement Workgroup

Vinton Hill-Jones, MSHCAD, PMP
Workgroup Chair
Chief Executive Officer
Southern Black Policy and Advocacy Network, Inc.

Mr. Hill-Jones emphasized the importance of community engagement and planning in the fight against HIV. The HIV epidemic impacts different communities differently; therefore, it was recognized that the EHE jurisdiction plans must be tailored for each of the jurisdictions and their areas. It is important to focus not only on the key EHE pillars, but also on some other important issues such as stigma, discrimination, and systems under which local health departments must operate to get the work done. That can be a support or a hindrance to effective community engagement in the EHE activities. There are two key populations of interest in the conversation about community engagement. One is people living with HIV and the other is everyone outside of the health department as a part of the HIV community that is working in concert with local and state health department to do this work. Community engagement remains a key component and was a requirement to develop and refine the EHE plans including focus groups, community advisory boards, town hall meetings, ad hoc committees, and HIV planning bodies

and the use of social media, webinars and conference calls are all tools to facilitate community engagement.

The EHE Community Engagement Workgroup was established to address 4 key areas, which are to: 1) review and consider the effectiveness of community engagement in the development of the EHE jurisdictional plans; 2) identify and highlight innovative strategies that EHE jurisdictions have employed to successfully engage stakeholders during COVID-19; 3) identify effective innovations that can be replicated in other jurisdictions; and 4) meet with key stakeholders to inform recommendations. The workgroup had an information gathering webinar in which they discussed EHE in a couple of different domains, starting with planning and design. Some of the key feedback that was given at the end of last year follows:

Planning and Design

- There must be conversations with regard to transparency to ensure that communities outside of the health departments are aware of future planning deadlines. Future deadlines should include a clear expectation of when communities should be involved in planning. It is important to ensure moving forward that they do not let go of the actual plans themselves. They must honor that these plans are living and breathing plans that should be updated regularly.
- Clarity must be provided on engagement and the roles of rural jurisdictions. A number of health departments are in need of understanding community engagement not only from the sense of reporting, but also in terms of the intentional involvement of community in every part of the process.
- In the design for the next round, it is important to be specific about the documentation on how the various entities are working within the community and engaging those not previously engaged.
- Information to consider featuring on the AHEAD dashboard:
    - → Note the timeline of where we are within the EHE process, broken down by federal agency
    - → Feature data broken down by demographics
    - → Include jurisdictional budget and expenditures
    - → Utilize the dashboard to share all available information
- Visibility is important and the success of community engagement can depend on how early in the planning process that input from the community is received (i.e., planning of activities vs. providing a report of planned activities).
- EHE should be a vision for the entire HIV workforce. While community members should be as excited as colleagues from CDC and HRSA on the progress of the EHE initiative, many are not happy with the progress of EHE work and that has to be revisited. They must figure out how to align and create a shared vision that everyone can be happy about and all log the work that each of the 48 jurisdiction and 7 states are engaged in with EHE work.
- EHE jurisdictions should be encouraged to engage networks of PLWH, not just as consumers and clients but as thought leaders. They must continue to center the voices of PLWH and center the need for building the technical capacity for PLWH to be able to maneuver in health departments and CBOs so that they can be allowed to make a long-term and supportive impact because they are resourced in a way that mirrors the resources of this initiative.
- EHE resources must be allocated to community partners. This is a big issue across the country. Many community organizations have not received a dime of the funds that have been allocated to health departments through grants or other opportunities to be able to do this work.

Implementation

- Create guidance to ensure EHE community resources are going toward organizations that have the leadership and expertise to implement the work.
- PLWH coalitions should be funded. Houston and other communities have had success with the model of using a community-owned coalition that acts as a representation for community work moving forward. This type of funding should be built in and funded directly to communities.
- There should be flexibility and understanding of changing landscapes to needs.
- A way CDC and HRSA could be proactive and respond to problems identified is by creating a federal point of contact for community members to engage if a person is not getting information from their local jurisdiction.

Evaluation

- CDC should develop a better understanding of the strategies for increasing PrEP access for key populations (Black communities, cis and transgender women, etc.).
- There should be transparency about workforce and organizations who receive funds to determine if it matches with the communities that need the services. Determine if this matches with current evaluation techniques.
- We should embrace participatory data collection and give communities authority over processes.
- Data should be segregated culturally and have all information specific and broken down by groups.

Technical Assistance

- EHE Technical Assistance partners must meet with each jurisdiction to develop community specific engagement work plans.

Mr. Hill-Jones concluded with some considerations for CHAC to discuss. First, more guidance is needed from CDC and HRSA regarding EHE 2-year guidance and the instructions around the implementation and to revisit planning. As a result of COVID, there is a flawed plan in process that took place in 2020 and that must be revisited and must be a part of future guidance. Second, a lot of health departments are at a standstill on the CDC/HRSA integrated plan because they do not know what the integrated process is going to reveal as far as what planning process needs to take place. Third, CHAC was asked to review a community engagement letter from CHAC to CDC/HRSA specifically regarding how to improve community engagement practice, activities, and guidance over the next 6 months. The next 6 months will be critical as they are now in Year 2 and are moving into a situation in which Year 2 has already started for HRSA and CDC will begin Year 2 in the fall, so there is a need to check in with this 6-month process to provide some key recommendations.

Establishment of a DASH Youth Advisory Council

Debra Hauser, MPH
CHAC Member
President, Advocates for Youth

Ms. Hauser indicated that she primarily deals with DASH at CDC. She reviewed DASH's strategic plan, which is good. In terms of the notion of community engagement, there is an objective within that strategic plan indicated that they should identify a mechanism to hear from young people, their families, and their communities by 2025. However, the objective to create the roadmap for the work is by 2021. She requested that CHAC entertain the possibility of

sending a letter to DASH asking them to move up that timeline to create a Youth Advisory Council that specifically addresses all of the issues discussed with regard to community engagement so that young people would be involved who represent the communities that are disproportionately impacted by health-related issues that typically include communities that are targeted for oppression that leads to disparities. She expressed her willingness to write the letter for CHAC's review and discussion.

Business Session and Member Discussion on Workgroup Reports

Perinatal Infectious Disease Workgroup

- HCV is not a heterosexually transmitted STI, but it is lumped together with other infections. It should be distinct in the letter. Women, by definition, who are pregnant and have penile-vaginal intercourse are at risk for HIV, HepB, and the others. HCV is a biological marker for injection drug use and has to be treated as such. To reduce adverse reproductive health outcomes for persons who are pregnant and infected with HCV, the priority interventions are evaluation and treatment of substance use disorder (SUD) and overdose prevention. The way it is written in the letter will lead incorrectly to pharmaceutical treatment of HCV in pregnancy. Separate HCV out in the "Background and Rationale" and make clear that HCV is driven by the opioid crisis. Under "Priority Areas for Intervention," add #5 to identify unmet SUD treatment among reproductive age women.
- It was suggested that perhaps a combined letter would be better than two, although separate workgroups developed these recommendations. While there is some interrelationship, there was concern that a single letter might dilute the message and the workgroup output. While the issues are overlapping to be sure, each workgroup intensively focused on these issues and had separate agendas to a certain extent. In addition, important time could be lost.
- **Point of Order:** The Perinatal Infectious Disease Workgroup's recommendations were presented during the previous CHAC meeting but were not voted on due to lack of time. They were presented for approval during this meeting, along with the letter. The decision was made to put forth the recommendation for approval so that edits based on CHAC feedback could be incorporated into the letter for further discussion and a vote.

Hepatitis C Workgroup

- The biggest barrier to having a significant testing and diagnostic campaign in the US is the lack of funding. CDC receives only $39.5 million for hepatitis for the whole country for A, B, and C. Perhaps that could be added to the letter.
- New testing technologies are needed and that is a barrier. However, antibody testing should not be disregarded. Having the exiting tests are critical to identifying people with HCV, such as in SSPs and other areas out in the field. Perhaps the letter could recognize that there are existing technologies and that what the letter is recommending would be part of it and not the only thing for the future. It will take many years to develop the needed technology.
- This letter may not be the avenue to address funding. The financial resources issue has been raised for several years and they have been told that it is not going to be that easy for CHAC to recommend in a letter to HHS to fix that problem. The workgroup has tried to focus on what CHAC can do, which is how this evolved to focus on the diagnostics.
- While the need to have HepC diagnostics get out to people is appreciated, the existing antibody tests that can be used to reach people wherever they are do not provide HepC diagnosis. They denote exposure to HepC. Other nations are moving to single-step. Other technologies are available and need to be submitted to FDA to downgrade some of the classifications. COVID-19 has proven that this can be done rapidly.

- This echoes the discussion from the previous week on HepC diagnostics. The letter is more of an aspirational goal. CHAC has done this before and perhaps has an aspirational role.
- **Point of Order:** The Hepatitis C Workgroup's recommendations were approved during the last CHAC meeting. The goal for this meeting was to approve the letter based on the recommendations. Funding issues were not a part of the recommendations, but it was noted that CHAC is free to incorporate whatever advice it deems necessary and prudent into its communications.

EHE Community Engagement Workgroup

- The federal POC is specifically for the grantee, not necessarily the community. While it was suggested that perhaps the Project Officer could fill the gap between the grantee and the community, it was noted that Project Officers do not have a direct relationship with sub-recipients. When there are issues between a grantee and sub-recipient, the Project Officer is trained to maintain a bright line and not enter into it because they do not have any authority in that area.
- A letter and/or recommendation from CHAC would be beneficial in terms of helping jurisdictions have the talking capacity to help them continue to build awareness, achieve meaningful buy-in, and blend all perspectives.
- Community members, PLWH, should be involved in all policy, programmatic, and funding decisions. It would be beneficial to list those things out for accountability.
- Oftentimes, community members are presented with decisions that are highly technical and use language that is difficult to understand. They must be provided with the necessary education to navigate this. HRSA continues to do a great job hiring a lot of women, especially Black women. It would be valuable to pay attention to the workforce and ensure that community members who know the community, organizations, partners, et cetera are considered for those positions. It is important to align a person with lived experience with professional training, experience, and appropriate compensation to reach into the communities.
- In terms of communications, it is important to ensure that community members are informed and that the processes are transparent.
- **Point of Order:** This workgroup still has work to do and will develop recommendations and a letter for presentation, discussion, and a vote.

DASH Establishment of a Youth Advisory Council

- **Point of Order:** Ms. Hauser will draft a letter to DASH, to be presented to CHAC for review and consideration, requesting that DASH move up the timeline to create a Youth Advisory Council that specifically addresses all of the issues discussed by CHAC with regard to community engagement as a mechanism to hear from young people, their families, and their communities.

Potential FDA Reclassification of Diagnostic Tests for HIV and HCV Infection

- CHAC's discussion during its business meeting on April 12, 2021 regarding the FDA's potential reclassification of diagnostic tests for HIV and HCV infection could serve as the requisite public comment.
- The draft letter was circulated to CHAC members. It includes a summary of the CHAC deliberations and statements people made that were taken from the transcripts, with names attached. Named responses can be maintained if no one objects or statements can read, "A CHAC member stated . . ." If names are used, there is a typographical error in Dr. Taylor's name in the Lynne needs to be changed to Lynn.

- A statement is made in the first iteration of the letter that the "committee agreed that OTC tests for HIV could be an important additional tool." It has since been pointed out to CHAC that there are existing OTC tests so the wording may need to be edited to state, "New OTC tests could be important additional tools."
- Dr. Anderson read the two summary statements in the letter:
  - → *The committee agreed that OTC tests for HIV could be an important additional tool for accomplishing Ending the HIV Epidemic goals. Slightly lower test sensitivity and specificity as compared to clinical settings might be acceptable, at least initially, if followed by test refinement and improvement in subsequent iterations.*
  - → *Rather than pursue oral HCV antibody testing, the committee strongly recommended that the HCV diagnostics field move toward single-step diagnosis of current infection (both in point of care settings and otherwise), which would most certainly include the availability of HCV core antigen and/or RNA rapid diagnostic tests.*
- Thinking about highly medicalized settings, perhaps "and otherwise" needs to be removed from the second summary statement.
- One of the requests that the world asks of public health is to be practical. The use of testing technologies differs depending upon where one is. Depending on the technology, it can be more effective in hospitals to run an antibody test first and then a PCR test. Then the PCR test would be done on only a small proportion of the overall screened samples. A relatively accurate test is better than no test at all. Even an antibody test can have its uses. Because there is a linkage to care challenge, it would be beneficial for the field of diagnostic technology to advance further down the pathway as described by the letter. It would be very beneficial to have POC and OTC tests that are detecting virus itself. There was support for incorporating these thoughts.
- **Point of Order:** The letter will be revised and brought back to CHAC for review, consideration, and a vote.

CHAC Actions

1. Dr. Anderson made a motion that the recommendations presented during this meeting as the output of the Perinatal Infections Workgroup be approved by CHAC for specific recommendations to CDC and HRSA. Dr. Taylor seconded the motion. CHAC unanimously approved the Perinatal Infection Workgroup's recommendations.
2. Ms. Hauser made a motion that CHAC entertain a possible letter to DASH advising them to create a Youth Advisory Council by the end of 2021. Mr. Hursey seconded the motion. CHAC unanimously approved the motion to consider the letter.

Update from the Presidential Advisory Council on HIV/AIDS

Liaison Carl Schmid, MBA
Executive Director
HIV + Hepatitis Policy Institute

Mr. Schmid noted that it was really good to listen to CHAC's deliberations, especially hearing the updates and the positive results from the EHE initiative. It is something that PACHA has been impressed with as well. They also have been focusing on the community plans and are finally seeing those. He was disappointed that there were so many holes, so he went to the website. While not all of the jurisdictions have plans, it was great to see the report and the common threads between the jurisdictions. He also enjoyed hearing Mr. Hill-Jones' report ,

Benton's report about community engagement. PACHA has been focused on that as well and will be interested in CHAC's further deliberations on that matter.

He reported that PACHA last met on March 8-9, 2021. They were glad to welcome Dr. Wendy Armstrong as the new CHAC liaison to PACHA. During that meeting, PACHA focused on how the various domestic HIV programs can better fulfill, the President's Executive Order issued on January 20, 2021 on his first day in office that was titled, "Advancing Racial Equity in Support for Underserved Communities Through the Federal Government." Federal HIV programs focus on those communities already, but always could do a better job. They heard from federal officials, a panel representing women and HIV, and various national community leaders from the HIV community, including CHAC member Greg Millett. Based on the comments, including public comments, PACHA passed a resolution titled, "Resolution on Ensuring Equity and Justice in Ending the HIV Epidemic." A copy of the resolution was included in CHAC members' packets. Mr. Schmid highlighted the following recommendations from that resolution that:

- The White House Office of National AIDS Policy (ONAP) be reestablished and staffed with a diverse group of people, including those living with HIV, and BIPOC, women, LGBTQ+, and persons with a history of drug use;
- Additional PACHA members be appointed who fully represent the communities most impacted by HIV, including people living with HIV who are also transgender, BIPOC, seniors, youth, persons using injection drugs, and women;
- In accordance with the Presidential Executive order on Advancing Racial equity that HIV data be collected at a more granular level so that data can be disaggregated by ethnicity within races, by inclusive gender identities, by disability type, by primary language spoken, and other demographics to better understand disparities, address racial misclassification, focus resources and interventions, and understand service reach and health outcomes;
- Performance and outcome measures be monitored at the granular levels noted above, and assess whether or not the epidemic is being ended in an equitable manner for all, and if it is not, adjust resources and approaches to end the injustice of the disparities;
- Federal funding and technical assistance for EHE should be increased, including the Minority AIDS Initiative, and prioritized for community-based organizations and the IHS system that are led by and staffed by members of the communities most impacted by HIV and have demonstrated trustworthiness and a proven track record of successful service delivery within these communities, and hold states accountable for distributing federal resources in this manner;
- The HIV National Strategic Plan be fully funded and implemented, with focused attention and resources devoted to the components of the plan that address the social determinants of health, syndemics (e.g. STIs, hepatitis, substance use, mental health), and stigma, while leveraging and coordinating with the resources and programs of other parts of the federal government;
- Review and modify algorithms for PrEP eligibility and treatment services that factor in social determinants of health to increase access to prevention and treatment services for BIPOC persons, persons living with disabilities, transgender persons, and others at increased risk for HIV;

PACHA is looking forward to continuing EHE under the Biden Administration and are pleased with many of the actions that already have been taken to increase healthcare, address racial and LGBT equality, and focus on the social determinants of health (SDOH). They also have been pleased with the rollback of some of the harmful regulations put in place by the last administration. Finally, they are pleased that the Biden Administration has proposed an increase for the EHE of $267 million.

The next PACHA meeting is planned for July or August 2021. In the interim, they will continue to focus on sharing results from the funding that is being dedicated to EHE, holding federal agencies and grantees accountable, assessing how to better achieve results, and determining what policy changes are needed or have been made to achieve the results. They also are looking forward to working with the new Assistant Secretary of Health (ASH), Dr. Rachel Levine, and discussing with her the next steps for PACHA, including adding additional members. A couple of people's terms have expired, and they will be rolling off. There are several vacancies as well.

Discussion Points

Dr. Riester requested additional information about the membership process for PACHA. Mr. Schmid indicated that this was not yet known, but that they will be discussing this with Dr. Lavine. This is up to the administration. In the past, there have been *Federal Register Notices* (*FRNs*), announcements, et cetera.

Dr. Stoner asked whether a change has been observed in the sense of the mood of the PACHA members since January 20, 2021. Not to politicize it, but PACHA was under a lot of turmoil in its previous iteration. Mr. Schmid emphasized that they are pleased with the items he mentioned in his report. PACHA was very critical of some of the actions of the previous administration, but was also very positive about the focus on HIV and the additional dollars. Under the new administration, additional progress can be obtained.

Public Comment

Ronald P. Hattis, MD, MPH
Secretary, Beyond AIDS Foundation

I am Ronald Hattis, Secretary and Past President of the Beyond AIDS Foundation. This is a brief synopsis of our written testimony, which I hope committee members will read for the rationale and details of our recommendations. For over 3 decades, we have promoted improved strategies for HIV prevention and control. Among our leaders are former major metropolitan STD and HIV directors, health officers, EIS officers, PACHA members, and HIV and other ID specialists. We hope to renew our ongoing dialogue with both agencies and hope for inclusion in future CDC consultations. Our recommendations are based in part on findings of our survey of state and territorial HIV/AIDS directors published in 2019 and AIDS Education and Prevention, which has been provided to the committee. This revealed marked inconsistencies of policy and practices among jurisdictions.

Our most important recommendations for CDC and HRSA include:

- That certain changes be made in CDC and HRSA grant eligibility and accountability, and that more oversight be provided, and accountability required by both agencies regarding adherence to grant conditions. We recommend enhanced routine site visits for evaluation, education, and guidance.
- That CDC recommendations and grant requirements specify more standardized public health outreach to newly diagnosed patients and their providers, particularly for rapid linkage to care and partner services. Twenty percent of jurisdictions did not routinely contact all diagnosed patients. Forty percent did not try to contact their own providers.
- That CDC recommend and include as a grant requirement that monitoring of missed viral loads men received in the past year for diagnosed patients suggests no active treatment.

- That monitoring of genotype results become a CDC recommendation, with results forwarded to CDC for analysis. Only 30% of jurisdictions even received such results.
- That all jurisdictions be encouraged to supplement grants with their own money for HIV prevention. Twenty-eight percent of jurisdictions had no prevention funds other than their CDC grants.
- That there would be more joint screening efforts for HIV, STIs, and viral hepatitis and more joint health education about their shared prevention measures, and that PrEP providers urge condom use to prevent other STIs.
- That HRSA grant recipients be expected to attempt to contact patients to remind them of upcoming appointments, to follow-up on missed appointments, and when possible, to schedule HIV care on the same half-day as primary and specialty care. Providers otherwise funded should be encouraged to act similarly.
- That PrEP costs be covered for uninsured patients, especially seronegative partners of Ryan White patients. HRSA efforts in this direction have been appreciated.
- That training be made available nationwide to primary care providers on starting immediate HIV treatment. Presentations that I have used to provide such training are linked from our written testimony.

I am honored to have had this opportunity to provide input today. I welcome any questions now or after this meeting at ronhattis@AOL.com or beyondaids.org. Thank you.

Debra Fraser-Howze, MPA
Retired Senior Vice President and Current Consultant
Government and External Affairs, OraSure Technologies, Inc.,
Founder, National Black Leadership Convention on AIDS
Author, Minority HIV/AIDS Initiative
Founder, Choose Healthy Life

I asked Giffin to allow me to speak today. Giffin is also on the phone. I am the Retired Senior Vice President of Government and External Affairs at OraSure Technologies, Inc. I still consult with them. I am the Founder of the National Black Leadership Commission on AIDS, Inc. (NBLCA), Author of the Minority HIV/AIDS Initiative, and a Founder of Choose Healthy Life, which has to do with Black clergy.

I could speak today because of something that I read in regard to the committee's recommendation in the area of phasing out antibody testing. I asked that because when I read it, and in working with OraSure and almost 40 years of advocating for testing for HIV, Ebola, and COVID, I've not seen a committee like this, a government-sponsored committee, sort of recommend the elimination of phasing out of any testing modality that is actually working for some in the community, with over 3,300,000 bringing hundreds of thousands into care. Understanding that it is not perfect, but the issue of not letting perfect be the enemy of the good, the issue of sending a letter to HHS asking for the elimination of something was a concern. We're fully agreed that it is fully acceptable for CDC and FDA to put many resources, focus their resources, on rapid molecular testing. We agree that that's the way to go. We're trying to go that way ourselves. It's not an issue of whether or not that would be the better situation. Of course it would. But right now, we don't have that and to recommend the phasing out, I'm concerned that at some point, there will be a movement of somebody will say, "Well, you know, your own committee said to phase out antibody testing." Because the way it was written, it looked like all antibody testing and they would just move forward in that vein.

So, I spoke to a number of people in the community and not all the community is aware that the recommendation is being made to eliminate or phase out. As I said, let me answer this again, I am the retired Senior Vice President of Government and External Affairs at OraSure and I still consult with OraSure. So, I want to be very, very clear on that. But, I wear a number of different hats in this conversation and one of them is the hat that I wear for the community. And the concern that I have that, you know, I've seen this test work. I've seen this test bring people into care that wouldn't be in care otherwise. The notion that we would recommend to a government body to phase it out or eliminate it is troubling, particularly for those people on the ground that have not yet had a voice in this. And I ask two things and I'll end there. One is, is there going to be an avenue to allow the community to have some discussion around this? And that you know, based on, you know, some of the things that even Dr. Mermin just said, and is there a possibility to amend the letter that's going to HHS so it doesn't say "phase out" or eliminate. Let it be a letter that recommends molecular testing and moving it forward as rapidly as possible. We're all in favor of that, but to eliminate a testing modality was of concern and we'd like to make that recommendation that the letter is not a strong black and white phase it out. Again, I want to say that I still consult with OraSure, I am retired Senior Vice President of Government and External Affairs at OraSure, and with all my other hats, NBLCA, everything. But, my focus right now is community.

Dr. Mermin expressed appreciation to Ms. Fraser-Howze for speaking with CHAC. He explained that as part of the procedure, CHAC does not respond to public comment. However, CHAC does listen to public comment and will take her oral and written comments into account as they progress in producing any documents.

Recap of Day 1

Jean Anderson, MD
CHAC Co-Chair, HRSA Appointee

Bradley Stoner, MD, PhD
CHAC Co-Chair, CDC Appointee

Dr. Anderson recapped that it had been a fascinating and reproductive day. They heard from CDC and HRSA, who share the impressive work they have done—especially during the pandemic. Dr. Mermin noted that over half of the staff of the center have been deployed to the COVID response. Some of the things they have accomplished include development and completion of an SSP Technical Package. There has been a lot of work on EHE from both CDC and HRSA, the attempt at a commentary in *The Lancet HIV* addressing HIV criminalization laws, the transgender survey, and the work surrounding COVID in schools and the dramatic effect on child and parent wellbeing. In terms of STDs, they continue to hear about increases during COVID and also over time with a 4-fold increase in congenital syphilis in a 4-year period and the pretty dramatic statistic that 1 in 5 individuals in the US had an STI in 2018. In terms of HRSA, great congratulations on the 30th anniversary of Ryan White, which continues to be a landmark program serving over 50% of individuals with HIV in the US. There have been dramatic improvements in viral load suppression of an approximately 19% increase in viral load suppression over the last 10 years, with significant improvement in very important and often hard to reach sub-populations. Soon to come out are the best practices compilation and data dashboard. They heard from and will bring to closure 2 workgroups on hepatitis infections as well as perinatal infections. Recommendations were made, approved, and during the second day of the meeting they will have final letters to vote on. Meanwhile, the EHE Community Engagement Workgroup, which has done incredible work, will continue and work toward formal

recommendations and a letter. There also will be a letter to DASH to vote on concerning the development of a Youth Advisory Council.

Dr. Stoner added that he was very impressed about how much work was actually done during COVID in these areas. It would have been very easy to say that because everybody is deployed elsewhere that they were just holding things together. Some of the things he heard and was impressed with were the SSP Technical Package, the analysis of the extent to which transgender persons are disproportionately affected by HIV, the hepatitis outbreak that is ongoing and how CDC is addressing that, a new gonorrhea treatment guideline, and the STI prevalence data. He personally would like to see a little bit more integration between EHE, the jurisdictional plans, and STI treatment. He was disheartened that in the jurisdictional plans, only 28% explicitly included STI treatment as part of their approach. That does not mean that they are not going to, but it was not listed in Dr. Raizes presentation. At the same time, HRSA has 50,000 new patients on PrEP which is incredible. Reducing the disparities in viral load suppression over the last 10 years is a remarkable achievement. There are positives, but there is still work to be done. Vaccine hesitancy is a really important issue around COVID. HRSA and CDC both will be addressing this. The workgroups represent incredible efforts performed by CHAC members. Dr. Stoner said his hat was off to everybody on this committee for the volunteer time that the members take to give their expertise to the government around perinatal testing, hepatitis, and the ongoing effort around the jurisdictional plans. He is proud to have been part of the group. While his term is coming to an end, he said he knew it would be in good hands with his wonderful colleagues.

Adjournment

Dr. Mermin thanked everyone for a wonderful first day and the great turnout, which made the discussions quite robust. He adjourned the meeting at 5:00 PM ET and CHAC stood in recess until 1:00 PM ET the next day.

Day 2: DFO Opening of Meeting and Roll Call

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 Designated Federal Officer
Centers for Disease Control and Prevention

Dr. Mermin called the proceedings to order at 1:00 PM ET and welcomed participants to the second day of the CHAC meeting. He conducted roll call and asked members to disclose any COIs. COIs did not differ from the previous day and are reflected in the table on pages 8 and 9 of this document. He confirmed that 14 voting members were in attendance, which established quorum for the CHAC to conduct its business on April 21, 2021.

Recap of Day 1 & Outline of Objectives/Process for Day 2

Bradley Stoner, MD, PhD
CHAC Co-Chair, CDC Appointee

Jean Anderson, MD
CHAC Co-Chair, HRSA Appointee

Dr. Stoner welcomed everyone to the second day of the April 2021 CHAC meeting. He thanked all of the CHAC members for the hard work they did the previous evening to organize, edit, and modify letters and recommendations. This resulted in an exciting group of work products to share, discuss, and vote on later in the day. He remined everyone that they heard some excellent updates from CDC and HRSA the previous day about their work in this space. Despite the continuation of the COVID pandemic, progress is being made on a number of fronts in HIV and STI prevention and viral hepatitis. They heard about progress on the EHE jurisdictional plans. Updates from the 3 working groups conveyed some very interested findings and recommendations leading ultimately to letters being written or in the process of being written. He reviewed the agenda for the second day and thanked everyone for taking time out of their schedule to attend and serve on this committee.

Dr. Anderson extended her congratulations on the hard work done the previous day, emphasizing that they had gotten a lot done. She took this opportunity to thank Dr. Stoner, who will be rotating off of the CHAC after this meeting. She thanked him for being a superb Co-Chair and for his thoughtful leadership.

Hepatitis B Screening & Perinatal Hepatitis C Testing Recommendations

Session Introduction

Carolyn Wester, MD, MPH
Director, Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Wester expressed gratitude for the opportunity to provide CHAC with 2 brief updates from CDC's Division of Viral Hepatitis (DVH) regarding current efforts to establish and update national viral hepatitis testing recommendations. For brief context, the number of acute HepC cases has continued to increase dramatically over the past decade, particularly among reproductive age adults and associated with injection drug use. Over half of the acute cases progress to chronic infection. HepC chronic infections are now heavily impacting multiple generations. This shifting epidemiology, coupled with about 40% of people living with chronic HepC being unaware of their infection, helped to inform the development of CDC's recently updated national HepC testing recommendations, which now include universal one-time testing of all adults in the US and pregnant persons during every pregnancy. By expanding the screening to include pregnant persons during every pregnancy, increased identification is anticipated of infants who were perinatally exposed to HepC. In anticipation, CDC has initiated the process to develop national perinatal HepC testing recommendations.

With the introduction of routine childhood HepB vaccination beginning in 1991, phenomenal progress has been made in preventing new cases of HepB among children and adolescents in the US over the past 4 decades. However, progress in reducing the overall rates of acute HepC infections in the US has stalled with the highest rates seen in adults in their 30s, 40s, and 50s.

Furthermore, over two-thirds of people living with chronic HepB are estimated to be unaware of their infection, resulting in missed opportunities to access care and treatment for themselves and to prevent inadvertent transmission. In the context of these data, CDC has current efforts underway to update national HepB testing recommendations.

Hepatitis C Testing Recommendations for Perinatally Exposed Infants

Monique Foster, MD, MPH
Medical Officer, Epidemiology and Surveillance Branch
Division of Viral Hepatitis
Centers for Disease Control and Prevention

Dr. Foster briefly described CDC's plan to develop HCV testing recommendations for infants and children. Identifying infants and children who have been exposed and possibly infected with HCV is crucial, as an increasing prevalence of HepC has been seen among persons of reproductive age. There are now recommendations that pregnant persons be tested during pregnancy, which hopefully will lead to increased identification of infections during each pregnancy. Lastly, there is curative treatment available for children as young as 3 years of age.

CSTE released the case definition for perinatal hepatitis C in 2018, so infections can be captured for surveillance purposes. The laboratory criteria for diagnosis requires HCV RNA positive test results for infants between 2 to 36 months of age, OR HCV genotype test results for infants between 2 to 36 months of age or greater; OR HCV antigen test results for infants between 2 to 36 months of age or greater. A confirmed case would meet laboratory criteria and have no known exposure to HCV other than perinatal exposure. In terms of the current testing recommendations that exist among the relevant professional associations, there are no current recommendations in regard to infant testing directly from the USPSTF or CDC. Of the recommendations that do exist, the most consistent is to test exposed infants with an HCV antibody test at or after 18 months of age. There is no clear guidance regarding HCV RNA testing at 2 months of age, despite this testing possibly decreasing the number of untested infants who would have to wait until 18 months to be diagnosed. Of course, increased cost of RNA testing would need to be considered. The current recommendations from the various organizations are not currently being practiced. Multiple studies using different data sources[27] have shown that only 16% to 30% of HCV-exposed infants underwent any testing for infection. "Adequately" is defined in the Kuncio study as an HCV antibody test performed after 18 months of age or an RNA test performed after 12 months of age.

To inform CDC's planned recommendations, two PICO questions were defined examining population, intervention, comparison, and outcomes. The first PICO question is, "Among infants perinatally exposed to HCV, does an HCV RNA test performed at 2 to 12 months of age compared to an HCV antibody test at or after 18 months of age increase identification of HCV infections, increase linkage to care and treatment, and decrease cirrhosis and death attributable to HCV?" The population there is perinatally exposed infants, the intervention being the RNA testing during the first 2 to 12 months of life, and the comparison being the antibody testing at or after 18 months of life. Outcomes were included that have benefits and harms. The second PICO question is, "Among all infants, does HCV RNA during the 2 to 12 months of life compared to antibody testing at or after 18 months increase identification of infections, and linkage to care and decrease cirrhosis and deaths attributable to HCV?" The population for this question is all infants with the same intervention and comparison. There are slightly different benefits and harms.

[27] Lopata et al. Pediatrics 2020; Kuncio et al. Clin Infect Dis. 2016; Chappell et al. Pediatrics. 2018

In terms of next steps, the plan is to conduct a systematic review of the current data and literature along with modeling to determine the number of potentially infected infants who would be identified depending on which test is used and the timing of those tests. The hope is to conduct modeling for cost-effectiveness of the two populations perinatally exposed in all infants. After a review of the literature and data, the plan is to begin drafting the guidance and then open it up to peer review and public comment.

Proposed Guidelines: Universal Hepatitis B Screening for Adults

Erin Conners, PhD, MPH
Epidemiologist, Prevention Branch
Division of Viral Hepatitis CDC
Centers for Disease Control and Prevention

Dr. Conners shared the progress on the proposed guidelines for universal HepB screening for adults. Based on 2011 to 2016 data from the National Health and Nutrition Examination Survey (NHANES), there are 863,000 people living with HepB infection in the US. There is a newer estimate from a meta-analysis by Wong et al[28] that found that the prevalence may actually be as high as 2.4 million. However, CDC is in the process of verifying chronic HepB estimates. Based on these NHANES data, of those people living with chronic HepC, only about a third[29] are aware of their infection.

The last official CDC guidelines for HepB testing were published in 2008[30] and they follow a risk-based strategy for screening. In 2017 CDC, collaborated with the American College of Physicians (ACP) to publish a best practices guide[31] which added the advice to screen at-risk adults using three screening tests, as well as expanded the risk groups that were in the 2008 guidelines. This best practices guide was not an official CDC recommendation. To date, the steps taken to update the HepB screening recommendations have included assessing the need for an update using a guideline development decision tool, convening an internal CDC working group, developing research questions and initiating the systematic reviews, and collaborating with partners to complete an economic analysis of universal screening. The changes being considered for the updated guidelines include adding a one-time universal screening of all adults; continuing routine screening of at-risk, susceptible persons or unvaccinated adults and expanding the current risk group; and recommending the use of 3 serological tests (HbsAg, anti-Bs, anti-HBc) for screening. In terms of the timeline for the planned activities, systematic reviews will be completed in May and recommendations will be drafted and submitted into CDC clearance by the summer. This will be followed by an opportunity for external peer review and a FRN to facilitate public comment and engagement. The plan is to present an update to the CHAC in November 2021.

In terms of the methods and results to date, the research question for a universal screening systematic review is, “Does universal screening for HBV in unvaccinated adults, compared with risk-based screening, reduce morbidity, mortality, and disease transmission?” Similar research questions are being used for the systematic reviews for the additional risk groups, which include adults who are currently or formerly incarcerated, adults with HCV, and adults with another STI. While they are gathering the evidence, they are evaluating whether to recommend

[28] Wong RJ, et al. Hepatology. 2021
[29] Kim, et al. J Viral Hepal. 2019
[30] Weinbaum, *MMWR*
[31] Abara, *Ann. Intern. Med.*

an age cutoff, use a birth cohort, or establish a prevalence threshold below which screening would not be recommended.

To share some of the results from the completed cost-effectiveness analysis, a 2021 Prevention Policy Modeling Lab cost-effectiveness analysis[32] found that universal screening of persons aged 18 to 69 is cost-savings and reduces morbidity and mortality. Assumptions of the model included using this 2011-2016 NHANES prevalence estimates multiplied by the percentage of people unaware of their infection to arrive at an undiagnosed prevalence of 0.24%. They also assumed that testing occurred is part of routine healthcare visits, and that patients eligible for treatment were prescribed generic drugs. The authors found a cost-effectiveness threshold of $50,000 per quality adjusted life year (QALY), universal screening remains cost-effective if the prevalence of HCV in a population is above 0.03%, the annual cost of treatment is less than about $10,000, and screening costs remain below $81. For reference, the cost of all screening tests is about $28—significantly cheaper than the threshold. Separately, the ACIP Hepatitis C Vaccines Workgroup is considering the evidence on universal HepB vaccination in adults. ACIP and DVH are coordinating the publication of both the screening and vaccination guidelines.

CHAC Discussion

Regarding the 3 screening tests recommended, Dr. Anderson asked whether there have been discussions with some of the national laboratories about bundling these tests.

Dr. Conners said that the have tried previously to work with laboratories for perinatal screening to bundle tests into a panel. While she was not sure if similar conversations had occurred for the screening recommendations, but she agreed that it would help facilitate provider screening with the 3 tests.

Dr. Wester said that other than what Dr. Conners already described within the context of existing prenatal recommendations, those conversations have not yet occurred because they are waiting for the recommendations to be finalized. Once they go through clearance, peer review and public comments have been received, and are moving closer to the finish line, they absolutely will engage in those conversations.

Dr. Riester asked whether they have actual exposure rates for the perinatal rate.

Dr. Foster indicated that they do not have exposure rates yet because where data are available, the testing is not very consistent. They do know that for infants who are exposed to mothers who are infected with HCV, the transmission rate is approximately 5% to 6%. Co-infection with HIV is higher.

Dr. Wester added that they only know the pregnant persons who have been tested and identified. Birth certificate data are a couple of years old already. For 2015-2016, the estimate was about 0.4% of all live births were exposed perinatally to HCV. However, that is in the absence of routine testing recommendations. Once the antenatal testing recommendations are put into place, there will be a much better idea. Even with what they believe is an under-estimate of the actual scenario, 0.4% of the 4 million births that occur every year would still mean about 16,000 or so perinatally exposed infants every year.

[32] Unpublished, CDC, 2021 but recently accepted for publication with CID; Patel et al. CID. 2019

Dr. Mermin noted that in the description for the screening methodology, only routine screening was recommended for people who are unvaccinated for HBV. That may be difficult information to know if they incorporate it into electronic health records (EHRs) because someone could have been vaccinated in another healthcare system decades ago. He knows that the cost-effective analyses are robust to changing that because the prevalence would go down if vaccinated people who were included in screening were included. In addition, there are recent estimates in which HBV prevalence is considerably higher than previous NHANES data indicated. He asked whether vaccinated people were incorporated in the methodology for the cost-effectiveness.

Dr. Conners said she believed it was incorporated into the methodology for the cost-effectiveness analysis. Because the recommendation is under development, they still have to look at key pieces of information. In addition to the one-time universal screen of all adults, there is a population of people who are continually at-risk of potentially acquiring HBV as a new infection. This may be a smaller group as vaccination rates are increased, but that piece of the recommendation still needs to be ironed out in the language. There is the broader recommendation 1 time and then routine screening for those who are at-risk.

Dr. Wester noted that one of the bullets on Dr. Conners' slide was about considering birth cohorts in the algorithm. As mentioned in the introductory remarks, a routine universal pediatric vaccination has been recommended since 1991 and then subsequent catch-up. Yet, adults are 18 years of age and older and that cohort is currently 30 years of age. Though not 100%, there is very good coverage in that birth cohort. Questions come into play regarding whether it is only for people born before 1991 and up to 69 years of age. They are trying to tease all of this out.

Dr. Mermin pointed out that because quite a high proportion of people with undiagnosed chronic HBV in the country moved here from places where HBV vaccination of infants was not universal when they were born, he would love to incorporate into the modeling exactly what Dr. Wester highlighted.

Dr. Dionne-Odom emphasized two very compelling facts that Dr. Conners shared, which were that two-thirds of people with HBV in the US are not aware of the infection and the cost-effectiveness analysis shows cost-savings for universal screening, which is not easy to get for infectious diseases in the US. To her, those two items are strong and compelling evidence to support a universal screening recommendation. She asked whether those data were used to tweak the initial questions and if they still plan to go through the path of which risk groups and how they should be defined to compare to universal screening. Perhaps that time, energy, and the team's expertise could be better used elsewhere if there already is a compelling story for universal screening. Breaking down into risk groups results in losing people. When there is already a compelling story to test everyone, asking providers to figure out who is at-risk is problematic.

Dr. Conners indicated that within their research question, what they are specifically teasing out from the systemic review is the prevalence among the different aged populations in order to fine-tune which cohort they may recommend testing for. They are strongly considering universal screening, but the implementation of it and who it applies to are the pieces they will get from the systematic review.

Dr. Taylor expressed her gratitude and emphasized that many people are looking forward to HBV universal screening and universal vaccination coming down the pike. In terms of the perinatal HCV issue as they think about the infants born with HCV, she hopes that any recommendations that come out are in the context of understanding that this is about a failure of preventing and treating HCV in women of childbearing potential. This is the same population in which overdose rates are rising. Hopefully, this comes out in the context of providing better care for people who inject and use drugs and expanding access to treatment. At the federal level, there continue to be issues with state restrictions and the Drug Enforcement Administration (DEA). She hopes that recommendations will be framed in the context of better upstream care and preventive efforts.

Panel 1: Current and Future Developments in HIV, HCV, and STD Screening and Diagnostics

Session Introduction

S. Michele Owen, PhD Associate
Director, Laboratory Science
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Dr. Owen introduced Dr. Janet McNicholl from CDC, who presented on a Macaque model for evaluating biomedical preventions for HIV and STIs. She was followed by Dr. Charlotte Gaydos from Johns Hopkins University, who provided an overview on the science of POC testing.

Macaque Models of STI to Evaluate Biomedical Preventions for HIV and STI

Janet McNicholl, MD
Preclinical Team Lead, Laboratory Branch
Medical Officer, Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Dr. McNicholl thanked CHAC for the opportunity to speak about work that has been taking place in the Laboratory Branch in the DHAP at CDC for about 10 years. She explained how they use Macaque models of sexually transmitted infections to evaluate the impact of STI prevention for HIV using antiretroviral (ARV)-based PrEP on the ability of antibody-based prevention for HIV to work, and multi-purpose preventions for HIV and STI.

The first model that they developed was a macaque model of non-ulcerative STI using pigtail macaques, which they choose to work with because they have a reproductive cycle with regular menstrual cycling like women. They were using *chlamydia trachomatis* (CT) and *trichomonas vaginalis* (TV). The model recapitulates human disease and it built on work that had been originally performed by Dorothy Patton at the University of Washington who developed the chlamydia model[33]. CDC's work was the first to combine chlamydia with another STI. They also have developed a rectal CT/LGV model that Dr. McNicholl did not discuss during this presentation.

One question when they developed this model regarded whether these two STIs increased the risk of simian HIV infection in the macaque model. Animals were infected with CT and TV and then challenged in a repeat low-dose fashion with the simian HIV deficiency virus called

[33] Patton 1997, 2006; Henning 2011, Vishwanathan 2017

$SHIV_{SF162P3.}$ The relative risk of SHIV infection was increased in this model compared to in the absence of STI[34]. This was determined by looking at the number of menstrual cycles that it took to become infected. Fewer menstrual cycles were observed in the STI-infected animals compared to the controls.

To better represent the epidemic of STI in young women, they also thought about developing a *treponema pallidum* (TP) model and wondered about adding depot medroxyprogesterone acetate (DMPA). Someone from their team has for the first time established a vaginal syphilis model. Looking at the vaginal vault of pigtail macaques who had been exposed to TP approximately 2 or 3 three weeks prior to the narrow band imaging (NBI). NBI allows them to see redness and ulcerations. Some animals were infected with TP, chlamydia, and trichomonas to combine ulcerative and non-ulcerative STIs. Lesions appear at about 10 days and persist for months. Seroconversion is seen at about 3 weeks[35].

These two models have been used to evaluate HIV PrEP. Prior published work from their work showed that in a macaque model they could use a combination of emtricitabine and tenofovir disoproxil, they could see 100% protection from repeat low-dose challenge with SHIV. However, when animals were infected with chlamydia and trichomonas there were breakthrough infections. This was not powered for statistical significance, but it is the first time they have seen that PrEP in their animal models is negatively impacted by STI.

They recently established a macaque model using cabotegravir long-acting (CAB-LA), which recently has been shown to be very effective at HIV prevention in men and women. They have tested to see whether the double STI or the triple STI negatively impact the protection that is seen in macaques. The animals were challenged with a repeat low dose of SHIV and they were first tested in the double STI model, and then the animals were rolled over into the triple STI model. This very powerful HIV PrEP modality completely withstood the STI, so there was no impact of either ulcerative or non-ulcerative STI using CAB-LA as PrEP.

Most recently, they have evaluated broadly neutralizing antibodies (bNAbs) to determine whether the STI model negatively impacts PrEP. The one that they used is called 10-1074. This is a second generation bNAb from the VRC01 that recently went through a Phase III clinical trial. This is much more potent, has greater breadth, and is currently in Phase I/II clinical trials. and has greater brat and is incurred clinical trials in Phase I and Phase II. The question regarded whether the bNAb efficacy was impacted. In fact, the bNAb did durably protect against multiple challenges in the triple STI model. However, the STI animals required almost 10 times as much neutralizing antibody to prevent infection, which raises questions about the clinical impact of STI on bNAbs being used as preventions.

Their new directions are moving into thinking more about multi-purpose prevention for HIV and STI and how they can use the macaques models of double or triple STI to evaluate oral doxycycline, which is being explored as STI PEP currently in Phase III trials in the US for MSM. There are little data on the correlative protection for MSM and there are no data efficacy for women, they are using their STI model and linked human studies to evaluate oral doxycycline and inform dosing modalities (e.g., mucosal distribution, efficacy, windows of protection). This may lead into a whole new area of topical multi-purpose prevention. Their branch does not do STI vaccine work, but when they presented their work at various venues, they have had a lot of interest from colleagues who are interested in vaccines for chlamydia and syphilis and they are collaborating with Dr. McNicholl and colleagues to better understand their current models.

[34] Henning 201

[35] Tansey, 2018

A Step Forward for STD Point-of-Care (POC) Technologies

Charlotte A. Gaydos, MS, MPH, DrPH, FIDSA
Professor, Division of Infectious Disease
Johns Hopkins University

Dr. Gaydos presented a landscape overview of some POC tests that Johns Hopkins has for STDs or STIs. She reviewed the performance characteristics of some of the currently and newly available STD POC diagnostic tests, discussed some of the ones that are in clinical trials and promising ones in development, and mentioned what happened to some STI testing during COVID.

The reason for wanting to use POC for STIs[36] is that infected patients can be treated immediately and appropriate therapy can be expedited according to the correct diagnosis. This reduces empirical treatment and is good antibiotic stewardship. It improves compliance and minimizes loss to follow-up. It decreases the risk for forward transmission while a patient waits a few days to 2 weeks to get the results of their tests. As a result, sequelae risks are lowered and the patient experience can be improved by having an opportunity for counseling. However, wait time is very important for how long patients will stay in a clinic. For this presentation, Dr. Gaydos concentrated on chlamydia, gonorrhea, trichomonas, and syphilis.
The following 6 tests are FDA-cleared:

1. Gene Xpert, (CT, NG, TV, HPV)
2. Binxio (formerly Atlas) (CT NG)
3. OSOM Rapid TV Antigen Test (females)
4. Solana POC Trichomonas Assay (females)
5. POC Syphilis Health Check
6. DPP HIV/Syphilis

Dr. Gaydos firmly believes that POC tests for STIs go hand-in-hand with self-collection, and cited a nice review article by Ogale et al regarding self-collected samples[37].

The first of the tests cleared is the Gene Xpert. This has been around for a number of years. It is very simple to perform. Everything happens in the cartridge once the cartridge is inserted into the platform. It is FDA cleared for chlamydia and gonorrhea as a single test and also for trichomonas, urine from men and women, cervical swabs, vaginal swabs, and self-collected vaginal swabs. It is not yet Clinical Laboratory Improvement Amendments (CLIA)-waived. One of the newer tests is the Binxio, which used to be called Atlas Genetics. It has very high sensitivity for chlamydia with both vaginal swabs and male urine, as well as good sensitivity for gonorrhea. Specificity is great for all of the test. It is FDA-cleared and was CLIA-waived just last week. This is the first CLIA-waived amplified test to appear on the market.

The OSOM Rapid TV Antigen Test. It is based on the membrane protein used in mouse antibodies. It is FDA-cleared and CLIA-waived. It has been around since 2005 and has really good sensitivity and specificity for a lateral flow test. The recently-cleared Solana POC Trichomonas Assay is an amplified test unlike the OSOM test whether it was compared to a nucleic acid amplification test (NAAT) as the reference or wet prep and culture, which is what

[36] Gaydos. Rapid CT/NG DX: improve clinical management: clinical trial. Ann Emerg Med 74:36-44, 2019; Ronn. Potential for POCT reduce chlamydia: mathematical modeling. CID 2020, 70:1816–1823
[37] Ogale Y, et al. Review self collected samples BMJ Glob Health 2019;4:e001349.

the FDA cleared. Sensitivity and specificity were very good in the study. It is moderately complex, meaning that it has to be performed in a laboratory. It is FDA-cleared, but because it has to be performed in a laboratory, it is not CLIA-waived.

For syphilis, there is the POC Syphilis Health Check test that is FDA-cleared and CLIA-waived. It is a rapid immunochromatographic test for which the results are ready in 10 minutes. It has two steps, is easy to perform, and agrees very well with other treponemal tests. It can be done on serum, plasma, whole blood, or finger-stick blood. The colored bands have to be read by the individual as to whether there is a positive line and whether there is a control line. Recently FDA-cleared is the DPP test, which is a combination test for HIV and syphilis. It takes about 15 minutes. It is FDA-cleared but not yet CLIA-waived. One of the big advantages of this test is that it comes with a reader that snaps over the top of the control and the lines for syphilis and HIV and these are shown in the box and the reader, so it takes the subjectivity out of reading a line on a strip. In terms of the sensitivities, specificities, and positive and negative percent agreement that were submitted to the FDA for the clearance. It has great sensitivity and specificity for HIV and for the positive percent agreement and negative percent agreement for *T. pallidum*. Positive tests for either one of these organisms has to be followed-up by a second test for HIV to confirm this. If the *T. pallidum* test is positive, it would have to be followed-up by a rapid plasma reagin (RPR) test to stage the degree of syphilis.

Dr. Gaydos also described a couple of tests that are either in clinical trials or under development and are coming along in the pipeline. The first one is the Visby (formerly Click). This tests for CT, NG, and TV in 20 minutes. This potentially is one of the tests because it requires no platform. Everything happens inside of the cartridge that could be sold someday OTC. The results of the FDA trial were published in *The Lancet* recently[38]. This test has good sensitivity and specificity. This trial was run in about 1800 women, so this test is only for women for vaginal swabs.

There is a new test under development by the engineers at Johns Hopkins. This is a mobile NAAT (MobiNAAT) for gonorrhea that gives results in 15 minutes. The test cartridge is tiny and everything takes place in the little cartridge once it is put in the small platform. You can see is very small. Next slide will show that. Not only does it test for gonorrhea, but it has the capacity in 15 minutes to see whether or not gonorrhea is sensitive or resistant to ciprofloxacin. An advantage is that if the wild type is present, meaning ciprofloxacin is susceptible, the patient could know in 15 minutes and let the clinic know that they have gonorrhea and then ciprofloxacin could be used.

There are barriers to implementing POC tests. As much as it would be nice for them to be used, there is money involved for instruments and consumables. The site would have to obtain a CLIA license if the tests were CLIA-waved. Tests have to be validated, training manuals have to be developed, the proficiency of the operators must be tested, there could be problems getting the results into the EMR, and there is the workflow disruption and space considerations in a clinic that will be using, as well as billing and reimbursement information[39]. Some studies that Johns Hopkins has done show that it is important to go to value propositions before POC tests are implemented and consider the stakeholders who are involved in all aspects of using a POC test.

[38] Morris SR, et al. A Cross Sectional Study of Performance of a single use rapid point-of-care PCR device for the detection of Neisseria gonorrhoeae, Chlamydia trachomatis and Trichomonas vaginalis. Lancet ID. DOI: https://doi.org/10.1016/S1473-3099(2020)30734-9

[39] Korte B, Rompalo A, Manabe YC, Gaydos CA. Overcoming Challenges with the Adoption of Pointof-Care Testing: From Technology Push and Clinical Needs to Value Propositions. Point of Care, 19:77-83, 2020

In conclusion, POC have great potential and maybe someday will be available OTC. However, there are barriers to successful implementation that need to be overcome which can be costly, time-consuming, and require learning new skill sets. Better POC tests are coming, so the future is promising.

In terms of what happened to STI testing during COVID nationwide and the Iwantthekit (IWTK) public health program in Baltimore that is effective in Maryland. The IWTK program has been in place since 2004 and has screened over 10,000 people with these tests. In December 2019, the IWTK was shut down quickly and they moved to stay-at home orders when the Baltimore City Health Departments were closed. IWTK was reopened in April 2020. They went from about 134 orders per month before COVID hit to about 450 per month afterward because the STD clinic in Baltimore told people who were interested in getting a test that they should go to IWTK for their testing. They started offering home HIV testing kits with EHE funding in January 2020. Once the Baltimore City Health Department closed, the requests for these kits went up drastically. They sent out over 1400 kits thus far. Once COVID hit, the positivity rates and tests per month increased because each patient could order a vaginal swab, penile swab, throat swab, or rectal swab.

CHAC Discussion

Dr. Mermin asked Dr. McNicholl whether the breakthrough infections in PrEP seen in the pigtail macaques that have not been seen in humans due to STIs and an order of magnitude difference in susceptibility to infection in bNAb studies. He wondered whether it could be that the pigtail macaques are different in some fundamental way in terms of the effects of STIs, though other studies seem to correlate. For Dr. Gaydos, he asked what the characteristics would be if she could have 2 new tests developed.

Dr. McNicholl said that while mice and monkeys are not humans, both the pigtail and rhesus macaque models that have been used over the decades have been very predictive of the level of a drug that is needed to prevent HIV infection in humans. The levels of drugs that protect in animal models have been supportive and translated in the clinical trials of TRUVADA® and recent cabotegravir trials. However, their STI model is probably more aggressive than the STI burden that a woman would have. The doses of chlamydia and trichomonas that are being used in the studies are probably well in excess of what a woman would have. It is possible that they are “pushing the envelope” in terms of the impact of STI on TRUVADA®. They are very encouraged by the cabotegravir data, particularly that DMPA had no impact. One limitation of the clinical trials of TRUVADA® or any biomedical prevention in terms of determining the effect on an STI is that people are screened before they enter the trials and are brought back frequently for STI treatment and testing. If there was an impact in a Phase III clinical trial, it would not represent what would be in Phase IV as preventions are rolled out. The public health message from the TRUVADA® work might be that it is important to emphasize that the trial subjects return for frequent testing and treatment.

Dr. Gaydos said tests for chlamydia, gonorrhea, and trichomonas are close to where they need to be. They stand up well to cost-effectiveness studies and modeling studies showing that they can have an effect on the epidemic. Her wish for perfect tests would be a new POC test that could diagnose active syphilis and at the very least, a dual platform test for simultaneous diagnosis of treponemal and RPR.

Dr. Anderson expressed her excitement about Dr. McNicholl's work, particularly regarding the possibilities of multi-purpose protective technologies. One of the complicating factors in female physiology is the dramatic variation in hormonal levels throughout the menstrual cycle and pregnancy. It is known that pregnant women appear to be more vulnerable to HIV when controlling for sexual behavior. DMPA was mentioned and there are other aspects as well that may be a critical feature of protection in women. One of the barriers that has arisen during the time of COVID is that laboratories often will not accept self-collected specimens. She asked whether Dr. Gaydos had any thoughts about whether there are ways CHAC could assist with this in terms of recommendations.

Dr. McNicholl said that hormonal contraceptives, the menstrual cycle, pregnancy, and menopause all affect the vaginal physical structure. Animal models cannot recapitulate every situation. An interesting observation they have made is that in the presence of DMPA, they are finding it very difficult to infect the animals with trichomonas. That may be an effect of DMPA thinning so that the epithelial layers are gone. In terms of multi-purpose prevention technologies, their focus always has been to try to model the most at-risk women from a public health perspective. Going forward, the priority probably would be using DMPA and 2 or 3 STIs. They certainly could go back to assess STI risk and the impact of doxycycline on animals that were either in follicular phase or luteal phase with and without DMPA. The top priority is always whatever is the most representative model of the epidemic at the time. That is probably where they will start with their multipurpose prevention technologies (MPTs) work.

Dr. Gaydos confirmed that there is a major problem with laboratories being able to accept home collection of samples for STIs, because no commercial company has ever sought FDA approval to collect samples at home and mail them to a laboratory for testing. The solution for this is for each laboratory to do a validation assay of home collected samples, but these are difficult to do. A recommendation from CHAC could be to ask what the diagnostic companies could do to perform these studies or work with the FDA to show that home collection of samples for STIs can work, is private and convenient, and is good public health. In view of all of the home collection that has been done for COVID testing, her wish is for approval of home collection for STIs. This is particularly appealing to young adolescents where most of these infections are known to occur, because they can request home collection without their parents knowing they are sexually active.

Dr. Dionne-Odom asked whether Dr. McNicholl thought one explanation could be tissue level and whether she measured the levels in the macaques.

Dr. McNicholl indicated that they have looked at the levels and believe that the reasons for the breakthroughs may be a class-specific effect in the sense that inhibitors require the MPTs to work. With local inflammation, competing MPTs make it harder for the inhibitors to work. Another thought is that an environment was created in their work where HIV gets in easier and penetrates deeper.

Dr. Mehta thought the IWTK data Dr. Gaydos showed beautifully illustrated the impact of home-based testing in the context of the pandemic. Part of the appeal of home-based testing is the ability to reach groups who are not otherwise reached. She asked whether there were any demographic differences or other differences in the groups they reached as they saw the curve increase in terms of how this might apply in the future with regard to disparities and who might be reached.

Dr. Gaydos indicated that they are looking at the demographics. They noticed a higher return rate in men who requested rectal kits and they noticed a higher prevalence of rectal gonorrhea. There are many outcomes that have the potential to change the way testing is done. They offer this as part of a research program for one of their PrEP programs in which people are requested to come in for HIV and STI testing 4 times a year. People can conveniently do this at home as part of their screening tests. She thinks changes will occur because of the ability for people to do this without having to go to a clinic, both for PrEP and for those who just want an STI screen. It will be interesting to see whether this shifts back post-pandemic to everyone going to a clinic or if they will end up with a hybrid model in which people do both.

Dr. Armstrong asked whether there are plans to validate the POC testing for non-urine non-cervical samples. For clinics, this would be incredibly valuable for rectal and pharyngeal samples in particular.

Dr. Gaydos indicated that there are plans to do so, but self-collection has not yet been validated by any of the companies for rectal or throat samples. People do prefer to collect their own rectal and throat samples, particularly the rectal samples. She thinks validation will be done for in-clinic and POC tests.

Panel 2: Local Adaptations by Health Departments and CBOs in Response to COVID-19

Panel Introduction

Laura H. Bachmann, MD, MPH
Chief Medical Officer, Division of STD Prevention
Centers for Disease Control and Prevention

Dr. Bachmann introduced the session presenters, who described how their facilities adjusted their services to pivot in response to the COVID-19 pandemic.

COVID-19 and Innovations for Sexual Health Services in DC

Adam Visconti, MD, MPH
Chief Medical Officer, HIV/AIDS, Hepatitis, STD, and TB Administration
District of Columbia Department of Health

Dr. Visconti indicated that DC Health approaches STI services in a multifaceted way. While they provide HIV and STI testing services in-house, they also provide test provision and capacity assistance to partners and school/young adult services in schools and CBOs. They understand that testing is just one part, so they also are involved in education and outreach through sex-positive social marketing and provider education, outreach, and results communication. They also acknowledge the importance of field investigation in terms of DIS and Data to Care. As an addition to all of those services, they have the privilege to be able to conduct some direct service provision. This is provided at the DC Health and Wellness Center (DCHWC), for which Dr. Visconti serves as the Medical Director.

The DC Health and Wellness Center is the district's only government-funded sexual health and TB clinic. They provide STI diagnosis and treatment; TB screening, diagnosis, and management of all active TB cases; Rapid ART; vaccinations; and contraception. They also provide a lot of ancillary supportive services as well, including mental health counseling and insurance navigation. One of the unique parts about this clinic is that not only are they very confidential, but also they provide very limited billing. The services are provided at low or no

cost to anyone who lives, works, or plays within the district. This is included with medical evaluation, counseling and any medications provided on-site. The clinic also serves as a referral and consultation center for local area providers.

When COVID-19 occurred in the district, stay-at-home orders were implemented in late March 2020. This happened at a concerning point in DC, because there was a marked increase in January and February in gonorrhea, chlamydia, and syphilis rates compared to 2019. Once stay-at-home orders were implemented, there was a natural decrease in the number of positive cases that were reported to their surveillance. DC Health implemented telework. DCHWC served as the official site for the COVID medical isolation and quarantine. For about two months, they were providing medical evaluation only for COVID cases within DC. But they realized that their services had to change, so they had to limit walk-in services and space clients appropriately physically and temporally. They developed and implemented rigorous health and safety protocols, but understood that it was extremely important to provide continuity of services for clients and the community because sexual health is truly essential.

They thought about two ways of accelerating some previous ideas that they had conceived before COVID, but COVID offered a ripe opportunity to do that. These fall generally within two lanes. One was basically to expand the clinic-based approach through Express Clinic, telemedicine, and Rapid ART. The other was to expand some more remote options, which was through launching GetCheckedDC.org that offered walk-in and mail-out STI and HIV testing services.

Express Clinic started in May 2020. This was limited to about 2 days per week and the goal was to provide providerless testing. The implementation process of this was fairly rapid. They mapped clinical flow, developed standard operating procedures (SOPs), offered some standing orders, and trained allied health staff. In terms of the process, the patient calls in advance for an appointment, there is self-collection of specimens by the patients after completing a check-list of their desired screenings and confirming the exclusion criteria that they did not need to see a provider at that visit, and Rapid HIV testing with phlebotomy is provided. They got these visits down to about 17 to 18 minutes, which is where they currently stand. Express Clinic is staffed mostly by their allied health support staff (e.g., registration staff, medical assistants, a phlebotomist, and one physician for laboratory review and communicating results). Based on data from May 2020 after the implementation took presence comparing Express Connect to their regular mostly symptomatic walk-in STI clinic, there were fairly similar rates of chlamydia tests, lower rates of urogenital gonorrhea tests, similar rates of chlamydia rectal tests, lower rates of gonorrhea rectal tests, and lower rates overall. There were 3 individuals newly diagnosed through Express Clinic, who were triaged to a provider and started on Rapid ART at that same visit.

The telemedicine services option was expanded in May 2020. Previously, this was provided mostly in terms of TB patients. A synchronous virtual encounter platform was implemented that was on the EMR. The use of the CDC and NYC Health Syndromic Management Protocols was extremely helpful in terms of prioritizing in-person versus telemedicine appointments. Staff were trained on that and this was staffed by 1 physician and 2 physician assistants who worked 2 days per week, with additional consultations as needed. While they tried to push telemedicine services, they also maintained in-clinic, albeit for more symptomatic patients. After a pretty aggressive promotion, they averaged 50 to 70 visits within the clinic. There was not always a full panel for the providers who were being assigned. Often, patients were offered the choice of whether they could see a provider in-clinic or do a telemedicine appointment. Patients often opted to see a provider in-clinic, so that is what they have done. In the last couple months, they

have tried to expand this in terms of TelePrEP to offer completely remote PrEP services. There has been pretty sufficient interest with that as well.

Rapid ERT started in January 2019 with a goal to facilitate engagement in high quality, culturally competent HIV care, expedite time to viral suppression, and reduce community transmission. The process is basically that anyone who comes into the clinic, either diagnosed in-clinic or referred by a community provider) is provided with an appointment as soon as possible—often within 24 hours. DCHWC uses integrase inhibitor (II)-based one-pill regimen provided in-hand and then they work closely with DCHWC's mental health support and insurance navigators. There is a lot of quality control (QC) and quality assurance (QA) involved with the RAPID ART cohorts. This started with just a couple of providers, but most of the providers at the clinic have been trained to do Rapid ART over 2019 and 2020. Pre- and post-COVID, a big change they saw was that more people had pre-existing diagnoses occurring. Often these are people who are virally suppressed, have experienced insurance changes, and have other things happening due to COVID as well. DCHWC has maintained very high viral suppression rates.

The GetCheckedDC.org web platform, one of the more remote testing opportunities, was launched for home HIV testing in June 2020 and home or walk-in STI testing in September 2020. The aim was to allow patients to basically access HIV and STI testing at their own convenience. The home/STI testing was done through a remote laboratory and home HIV testing was done through an OraSure® kit that was mailed out to people who requested it. The walk-in STI/HIV testing was done through a partnership with a large national laboratory company. This was developed through a similar landing page and this backed into a REDCap® survey. The patient basically selects whether they want home testing or if they want to have walk-in testing. If they request home testing, that information is entered through the remote laboratory and then a package is sent to the patient. They were actually packing the home HIV testing themselves. For walk-in STI testing, DCHWC would place the order. The patient would go to the national laboratory company, and then DCHWC would inform the patients of the results. This was done mostly through support staff through disease investigators, with some clinical support from clinicians for order placement and results communication.

Overall during this period, for mail HIV testing over 1200 tests were distributed This resulted in one confirmed positive result and one false positive result. From mail out testing, they had about 1000 a year genital and pharyngeal tests and about 400 rectal tests. In terms of the overall demographics, roughly a majority of people had employer-sponsored health insurance. It was a generally older age group. The median age was about 33 years old and a variety in terms of sexual partners. This was targeted well, with about half of the requests coming came from zip codes within DC and about three-quarters from the top 10 zip codes. This also was used appropriately. About 10% of people have never tested and about a third of people had not done testing within the last 3 months. Often, there were two groups. People either really liked it because of convenience or because of secondary COVID-19.

In terms of walk-in testing at the LabCorp center, there was a lower percentage of testing. Some chlamydia was diagnosed and there were 2 new HIV diagnoses. Both individuals were started on Rapid ART in 2 days and both were virally suppressed at 60 days. No new HBV, HCV, or syphilis infections were identified. DCHWC's treatment completion rate was 100%. In an overall comparison between the standard clinic, Express Clinic, and walk-in clinic Express Clinic had a higher test positivity percentage. In terms of overall patient visits, by December they were able to match the volume that they we were able to do pre-COVID. Overall in 2020, there were 6601 encounters for 3196 patients.

Overall, expansion of services during COVID is definitely possible with a government-run clinic. This was really necessary for DCHWC to be able to adhere to its associated COVID-associated health and safety protocols. They feel like these are essential services, especially during the pandemic when the options for testing were very limited. They believe that providerless options explain access, but generally from the positivity rate they found that they were likely reaching lower populations with lower risk due to the lower positivity percentage from what we saw from tests. This also was backed up by DCHWC's existing clinic and they provided very good, comprehensive, free services. This can be a draw despite the risk of having to come into the clinic and the inconvenience. Rapid ART also was critical and provided a necessary bridge service for patients, especially for people who are experiencing insurance changes and things that were happening during COVID.

Expanding HIV/STI Testing During a Pandemic

Emily Halling
Government Grants and Contract Manager
Southwest Center

Ms. Halling noted that while she is the Government Grants and Contracts Manager, during the 2020 pandemic she was part of the testing team. The Southwest Center started as Body Positive in 1990. In non-COVID years, they serve about 30,000 individuals, perform about 9,000 HIV tests, and conduct approximately 15,000, STI tests. Some of their funding sources include Title X; 340B; Ryan White Parts A, B, and C; CDC; and the Arizona Department of Health Services (ADHS). They have a medical clinic that offers ART, primary care, family planning, HIV medical care, HIV and STI testing and treatment, PrEP, PEP, behavioral health, medical case management, nutrition for people who are positive, presence of navigation, behavioral interventions, and outreach.

Arizona's stay-at-home order started March 31, 2020 at 5 pm. At that point, they had already halted in-person HIV testing in the HIV and STI testing clinic and started implementing TeleVisits for all services. The medical clinic was still taking patients in-person as a last resort and on a case-by-case basis. If anybody needed labs, they would have them come in. Otherwise, visits were done virtually. They started thinking about how to serve clients since they were still in need. People were still engaging in sexual acts. Just because there is a pandemic, that sex does not stop. The first step was to think about how to connect with clients, what their clients need, and what they could do immediately to assist clients. They began by starting the E Sexual Health clinic through GoToMeeting, which had an open room Monday through Friday 8 am to 6 pm. American Sign Language (ASL) and Spanish were available. The purpose was to answer sexual health questions about where to receive testing, what to do for ART, et cetera. They created a resource guide to ensure that they were giving accurate information. They staggered the schedule for staffing and locked the chat once someone entered the room to ensure that nobody would come in. They did not ask people to identify themselves and just navigated a lot of questions.

HIV TeleTesting began in June 2020. They had started using the Healthvana patient portal at the end of 2019, which is where they collect patient information, demographics, and e-sign consents. Clients can see their information, consents, and test results. They utilized GoToMeeting and the OraQuick® HIV test. Clients were given a link to Healthvana to complete their e-paperwork and it was easy for them to e-sign and use the patient portal. Each tester created a recurring GoToMeeting room that was given to the clients after they scheduled their appointment. The process was that the client would contact the Testing Department by phone or through a specific email that was created just for people looking for testing services. They

would confirm that the client had access to GoToMeeting. If a client did not have a phone with a camera, they could still talk them through how to administer the test. If a client needed ASL or spoke Spanish, they would be assigned to the proper tester. After the client filled out all of the e-paperwork through Healthvana, the appointment was made.

For the testing session, once the client entered the virtual room, the tester confirmed the client's identity and locked the GoToMeeting session. The tester would walk the client through how to administer the test. The client and tester would discuss risks, questions, et cetera while awaiting the results. The tester would help the client interpret the HIV test and at that point, depending on the results, the tester would make appropriate referrals. For those who tested positive, they would try to get the Early Intervention Specialist and PrEP Navigator into that meeting if the client agreed to that so they could meet virtually face-to-face. After using this process for a couple of months, the decision was made to open drive-through HIV testing in August 2020. The Healthvana Patient Portal was used for the drive-through testing as well. This was the first time that testers were meeting with clients face-to-face, so they were in full personal protective equipment (PPE). There will be a really cute picture of testers later on. A parking garage was utilized to minimize how hot it was, but it was still very warm. The drive-through testing center was run on Tuesdays and Thursdays.

The next step was HIV and STI TeleTesting that began in October 2020. This was the same processes that had been used for HIV. They did not have rapid STI testing. They used oral, rectal, and urine collection for chlamydia and gonorrhea. At the beginning of 2021, they acquired funding from ADHS to continue doing TeleVisits for STI services. Clinic-based testing began in October 2020 for HIV and STI testing. Because it was in clinic, they were able to offer the syphilis blood draw. They started with one tester and would stagger schedules, but moved to two testers in November 2020. Now all 5 testers are in the clinic. At the beginning, they had full PPE. The appointments were an hour long to allow time for questions, potential positives, cleaning the testing rooms, and paperwork.

In terms of outcomes for June-December 2020, they did 514 total HIV tests (78 TeleTests, 211 drive-through, and 225 in-clinic). They had 9 newly diagnosed positives (2 TeleTests, 3 drive-through, and 4 in-clinic). There were 467 STI tests total (16 TeleTests, 451 in-clinic tests) that identified 38 total STI positives (0 TeleTests, 23 in-clinic chlamydia/gonorrhea, 15 syphilis). For January-March 2021, because the clinic has remained open and more people are becoming vaccinated, they have had an influx of in-clinic tests. They still have drive-through testing for HIV as well. During this timeframe, they had a total of 8 newly diagnosed HIV positives compared to the 9 at the end of 2020. They have done 622 total HIV tests and 1412 STI tests (6 TeleTests and 1406 in-clinic). Among the STI tests, 144 total were positive.

CHAC Discussion

Dr. Stoner asked whether the DC Express Clinic would continue and if the Southwest Center had any plans for drive-through STI testing. He could imagine a scenario in which people could pick up a kit, drive home to collect the samples, and then take the samples back. He also asked whether either group ran into reimbursement issues.

Ms. Halling said that they have done drive-through STI testing. When they go to bars to do outreach, they also take kits that people can take home with them. They also are partnering with sober living facilities to deliver kits. People can still pick up STI testing through the drive-through as well. In terms of reimbursement issues, the Southwest Center has a separate HIV testing clinic that has separate funding. They already do this through grant awards and testers

were already being paid to do this, so they started the alternate testing methods rather than sitting around the clinic where no one was presenting.

Dr. Visconti indicated that the positive reception they got from their clients probably means that the Express Clinic will continue. These visits were previously taking about 30 to 40 minutes, which was expedited in the Express Clinic. They are in the process of expanded the Express Clinic to be able to offer same-day results. Regarding reimbursement issues, for the Express Clinic and mail-in clinic, they did not try to get reimbursed. The labs that were done at Express Clinic were submitted through the normal lab mechanisms to try to obtain reimbursement. They experienced no difference in the percentage of labs that were accepted or denied through that mechanism. They are debating whether to do this more in the future to increase their financial solvency.

In terms of the need for additional staff and logistical support, Dr. Anderson asked what advice they would give to programs that may not have access to a lot of additional support and what they would prioritize. Related to TeleTesting, she asked about how they addressed potential risk for interpersonal violence to the individuals, particularly those who tested positive.

Dr. Visconti said that they were operating with less staff than they normally have. A lot of their staff were detailed to COVID, but it balanced out in terms of the workflow because there was less clinic volume than usual. Support staff spent a lot of time on registration and lab entries. Phone calls stayed about the same. For them, it was really about getting buy-in from the support staff from the beginning. When they were designing this, they held weekly meetings in which they reviewed and mapped clinic flow. The staff really took ownership. Being able to leverage staff and get them interested in doing this can be done with an existing workforce. They have a unique model of some additional ancillary support staff who were able to help as well. Overall, it was about repurposing existing staff. Everyone pitched in and did an amazing job.

Ms. Halling indicated that those involved in the TeleTesting sessions already were testers and they wanted more appointments to be set. There were less people calling the front desk and no one was coming to the clinic to get tested for a while, so there was less paperwork. Having Healthvana was very helpful as well. In terms of interpersonal violence, people who did not feel safe at home could go to mobile testing sites where they did feel safe and could test themselves there. The staff did warm handoffs and would have people present to the clinic if they felt like the person was not safe in their environment. They had trained staff who could provide the proper resources a client needed. It was a group effort.

Dr. Stoner asked what the “low-hanging fruit” was in terms of what would be the easiest thing to get done, and whether they experienced any Health Insurance Portability and Accountability Act (HIPAA) issues with results notification, etc.

Ms. Halling said she thought the drive-through site was the easiest. They already buy tests for their outreach services, so they had those tests. Another clinic across the hall from them was doing COVID testing Monday, Wednesday, and Friday so they already had set aside parking spaces. Southwest Center used the spaces on Tuesdays and Thursdays when the other group was not testing. That was an easy transition. They already had been doing virtual sessions since 2019 and had been very busy already, so it was easy to transition to drive-through clinics. The testers loved how busy the drive-through got and it is still pretty busy, which is fascinating and great. The did not experience any HIPAA issues because they used the Healthvana Patient Portal that is password-protected. They used to have to call people with results, which was more of an issue than Healthvana.

Dr. Visconti said that the Express Clinic was the "lowest hanging fruit." It required the least amount of additional systems that had to be in place. They used their existing laboratory contract and existing clinical staffing. They worked with some existing templates and it was easy enough to develop their own. The Express Clinic got off the ground the quickest and has sustained the highest amount of interest. This reaches the existing clientele who already know about the clinic and with whom they already have a rapport. Because trust has already been built, the clients are more willing to "go with the flow." The other components required more effort. They did not experience any HIPAA issues either as they had a lot less phone calls and a lot more emails. The emails are provided by the patient. They used their existing EMR portal that already was compliant. Though not a substantial portion of their efforts, telemedicine was somewhat more concerning. Sometimes people would take the call and be in the midst of doing the visit when they would say they would need to go to another room. This was concerning because they do not know who is on the other side of the smartphone or what the situation is.

Dr. Riester asked whether either group took advantage of the situation to distribute safer sex kits.

Ms. Halling indicated that they already have Nice Packages, which is their condom distribution program. They would include a Nice Package and informational materials with the test kits, including a flyer to order more condoms. They had a very large increase of online condom orders from the Nice Package program.

Dr. Visconti said that they had good synergy because the people who were packing the mailout HIV kits were the people who also package their mailout condom kits. This was a great marketing opportunity to provide a lot of additional information, and it also expanded to different populations who might not have been aware of all of the services they provide. People were very appreciative of receiving swag, condoms, and information with their test kits.

Panel 3: The Path to Resilience: The Intersection between the COVID-19 Pandemic, Adolescent Mental Health, & Schools' Role in Supporting Student Mental Health & Promoting Health Equity

Panel Introduction

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

Dr. Ethier explained that this panel would highlight summary data on adolescent mental health and what CDC is doing to support mental health; highlight examples of empirically informed programming, with a focus on addressing the needs of the most marginalized youth; and summarize how schools and communities are addressing youth mental health needs. The vision that guides DASH is one where youth have the knowledge, skills, and resources that they need not only during their adolescence, but also to help them move into a healthy adulthood. Adolescence is a key time for most health issues, including mental health. Behaviors, and experiences start to solidify, setting up the trajectory for the later years. It is also the last time that most adolescents are together in one place with the opportunity for wide scale intervention in schools before youth set off into the next phase of their development.

It has been recognized for a number of years that for many adolescents, key indicators of mental health have been moving in the wrong direction—even prior to the COVID-19 pandemic. The data Dr. Ethier highlighted were collected through the Youth Risk Behavior Survey (YRBS), which is a nationally representative survey administered in high school classrooms every two years. Data collected between 2009 and 2019 serve as a valuable pre-COVID snapshot of adolescent mental health. Overall, indicators of adolescent mental health had already been moving in the wrong direction. The proportion of youth who experienced persistent feelings of sadness or hopelessness, defined in the survey as feeling so sad or hopeless for at least two weeks in the past year that students were unable to continue their usual activities, had increased significantly between 2009 and 2019. This is an indicator of depressive symptoms. In 2019, over a third of students indicated that they had experienced these feelings over the last year. Increases also were seen in suicidal thoughts, making a suicidal plan, and attempted suicide. Although no group was doing particularly well in this area, female students experienced depressive symptoms at almost double the proportion compared to their male counterparts. Almost 70% of students who identified as sexual minority youth indicated that they had persistent feeling of sadness or hopelessness in the past year. Sexual minority youth included students who identified as lesbian, gay, or bisexual; who said they were not sure of their sexual identity; or who had any same-sex partners. Data on suicidal thoughts and behavior look very similar.

The pandemic hit in March 2020, bringing with it family, school, and community disruption. From the existing literature on trauma and studies published to date on the mental health impacts of the pandemic, COVID-19 and the disruption the pandemic has caused in the lives of adolescents is expected to exacerbate all of the issues highlighted from the 2009-2019 data. The severity of that impact will likely differ by individual context, including age, prior history of trauma, prior state of mental health, social and emotional supports, and experience with school closures. It is also known that the COVID-19 pandemic has more severely impacted communities of color. Although it is not yet possible to say all of the ways in which this will affect mental health, it will be extremely important to consider the impact of inequity when addressing adolescent mental health, especially in supporting students of color.

Although there is not yet a robust literature on the impact of COVID-19, there is still research that demonstrates the strain that the pandemic is having on the mental health of youth and families. For example, a recent study found strong associations between feelings of loneliness and depression and mental health problems up to 9 years after social isolation, predicting that similar effects will be seen following the social isolation necessitated by the COVID-19 pandemic. One of the few longitudinal studies on adolescent mental health during the COVID-19 pandemic found increases among Australian youth in depressive symptoms and anxiety, and significant decreases in life satisfaction over the course of the pandemic. An *MMWR* published in November 2020, found that the proportion of children's mental health-related emergency visits increased beginning in April 2020 soon after schools closed and remained elevated through October 2020. DASH recently published an *MMWR* examining the relationship between virtual versus in person learning modes and indicators of family stress, including parents' and children's mental health. This report found that parents of children receiving any virtual instruction were more likely to report that their children's mental or emotional health had worsened. They also were more likely to report their own emotional distress, concerns about job stability, and childcare challenges. Importantly, virtual instruction was far more commonly reported by Black and Hispanic parents than White parents.

These findings are particularly important to highlight for this discussion because they demonstrate that the mental health and well-being of children and adolescents has been specifically impacted by school closures. Mental health is suffering because youth are not in school. Because it is known that schools play a critical role in the health of adolescents, and knew this prior to COVID-19, this has only been reinforced by the mental health impacts that are seen in adolescents who have been out of school. The good news is that this means schools also provide a great opportunity to mitigate those impacts, support adolescence, and promote their health and well-being. In terms of how schools can support students, from DASH's work on school-based HIV and STD prevention, it is known that schools in addition to academic learning have the ability to do three things really well to support students if they have the resources to do them. The first is to provide quality health education that is medically accurate, developmentally appropriate, culturally relevant and inclusive, and provide the knowledge and skills as the basis for health decisions and experiences. Second, schools can be a gateway for connections to needed youth-friendly, inclusive health services in school and in communities, including mental and behavioral health services. Third, schools provide daily environmental supports for students that can support them and make them feel safe, affirmed, and connected.

Connectedness is the sense of being cared for, supported, and belonging. It is what some might call a high leverage solution, because just focusing on increasing connectedness between youth and their schools or youth and their families can improve outcomes such as the risk of being a victim or a perpetrator of violence, having multiple sexual partners or an STD, misusing prescription drugs or using illicit drugs, and/or experiencing emotional distress during adolescence and well into adulthood. DASH's work to improve the safety and supportiveness of school environments is particularly designed to improve school connectedness. It is known that the activities that school districts are asked to implement improve indicators of mental and emotional health. For instance, DASH has looked at the impact of lesbian, gay, bisexual, and transgender (LGBTQ)-supportive policies and practices that include having Gay-Straight Alliances (GSAs) or gender and sexuality alliances, identifying safe spaces for LGBTQ youth in schools, and providing professional development for educators. GSAs impact youth in schools and not just youth who identify as lesbian, gay, or bisexual, but also students who identify as heterosexual.

Among students who identify as lesbian, gay, or bisexual, simply having a GSA in a school reduces the likelihood that students will say that they were absent from school due to safety concerns, that they were threatened or endangered with a weapon at school, and that they were injured in a suicide attempt. More broadly among the students who identify as heterosexual, having a GSA in a school not only reduces the likelihood of the risks just mentioned, but in addition reduces the likelihood of physical dating violence, seriously considering suicide, making a suicide plan, and attempting suicide. It is known that others of these individual LGBTQ-supportive policies and practices also individually impact or similarly impact these outcomes, as well as the total sum of LGBTQ policies and practices impacting health and well-being among students.

There are a number of strategies to employ across health education, health services, and safe and supportive environments as shown in this table:

Health Education	Health Services	Safe and Supportive Environments
• Implement curricula designed to promote mental and emotional health (including mental health literacy)	• Expand the school- and community-based mental health workforce • Increase partnerships between school and community partners to expand access to mental health services • Provide mental health support for staff	• Implement policies and practices that support social and emotional learning • Implement school-based service-learning and mentoring programs • Establish or enhance student-led inclusive clubs • Support staff mental health
Engage families and communities Train staff		

This list is not exhaustive and it is important to recognize that there is still more to understand to ensure equity in schools. It is known that these strategies will not be truly effective unless students of color are supported in the ways that serve them best. The COVID-19 pandemic has shown the world what was already known. Schools play a crucial role in the health of students. However, there is much more work to do to address inequities, serve students equitably, and improve adolescent mental health.

Schools' Role in Supporting Student Mental Health and Promoting Health Equity

Prerna Arora, PhD
Assistant Professor of Psychology and Education
Teachers College Columbia University

Dr. Arora discussed comprehensive school mental health systems. The systems provide a full array of supports and services that promote positive school climate, social emotional learning (SEL), and mental health and well-being while also reducing the prevalence and severity of mental illness. Further, these systems are built on a strong foundation of district and school professionals, including administrators and educators, as well as specialized instructional support personnel that include individuals such as school psychologists, school social workers, and school nurses—all in strategic partnership with students, families, and community health and mental health partners. These systems also assess and address the social and environmental factors that impact mental health, including public policies and social norms that shape mental health outcomes. Effective comprehensive school mental health systems contribute to improved student and school outcomes, including greater academic success, reduced exclusionary disciplinary practices, improved school climate and safety, and enhanced student social, emotional, and behavioral function.

There are many core factors of comprehensive school mental health systems. These include educators and student instructional support personnel, collaboration and teaming, multi-tiered systems and supports, evidence-informed services and supports, cultural responsiveness and equity, and data-driven decision-making. Dr. Arora discussed multi-tiered systems and supports cultural responsiveness and equity as critical components of comprehensive school mental health system. A full array of tiered evidence-based processes, policies, and practices called Multi-Tiered Systems of Support (MTSS) promotes mental health and reduces the prevalence and severity of mental illness among students in schools. Based on a public health framework, prevention is an underlying principle across all three tiers. Tier 1 focuses on promoting mental health and preventing occurrences of problems, Tier 2 focuses on preventing risk factors or early-onset problems from progressing, and Tier 3 focuses on individually intervening to address more serious concerns that impact student's daily function. This MTSS approach

ensures that all students may access the service array, including students in both general and special education, and that all students will have exposure to universal mental health supports.

Mental health promotion services and supports in Tier 1 are mental health-related activities, including promotion of positive school social, emotional, and behavioral skills and well-being which are designed to meet the needs of all students regardless of whether they are at-risk for mental health problems. These include efforts to promote positive school climate and staff well-being. These are often activities that are implemented at a school-wide or grade-wide level. Tier 2 includes early intervention services and supports. These are to address mental health concerns that are provided for students who have already been identified through various avenues such as needs assessment, screening, referral, or other school teaming processes. These are students who are experiencing mild distress, functional impairment, or being at-risk for a given concern or problem. When problems are identified early and supports are put into place, positive youth development is promoted and problems can be eliminated or reduced.

Examples of these types of programs include small group interventions for students identified with similar needs, such as chronically absent students. These are also brief individualized interventions, such as motivational interviewing (MI) or problem solving-based interventions, mentoring programs, or low-intensity classroom-based support such as daily report cards. Tier 3 includes treatment services and supports to address mental health concerns that are provided to students who are already experiencing significant distress or functional impairment. These are examples of more traditional forms of mental health interventions, such as individual group or family-based services for students who have identified or diagnosed social, emotional, and behavioral needs. It is important to note that these needed supports and services are fluid. Students need different levels of support at different times throughout their development. They may go back and forth through tiers and also, these tiers are layered. Students who receive higher levels of support continue to benefit from universal mental health promotion supports throughout that.

In terms of cultural responsiveness and health equity in the context of school mental health, Dr. Arora brought attention to a quote from the World Health Organization (WHO), ". . . A person's mental health and many common mental disorders are shaped by various social, economic, and physical environments operating at different stages of life. Risk factors for many common mental health disorders are heavily associated with social inequalities, whereby the greater the inequality the higher the inequality in risk . . ." With this in mind, all aspects of a comprehensive school mental health system are critical to consider and be responsive to the specific cultural views, beliefs, and behaviors of families and communities and to ensure access to mental health supports and services in a manner that is equitable and reduces disparities across all students. Stigma, cultural adaptations of evidence-based interventions, reducing health disparities and disproportionality, meaningful family partnership representing all families, and cultural competence should all be considered in various aspects of comprehensive school mental health services and supports.

Regarding recommendations of how this is done, to create a positive learning environment for students of all cultural backgrounds, several additional approaches have been used to improve mental health services in schools. First, it must be recognized that mental health is not solely a condition internal to a student, but is more likely a product of one's environment and ways of thinking. For example, students who are not socially excluded would be less likely to have depression. Therefore, environmental factors that are contributing to positive or negative mental health should first be sought out. It is also important to recognize that what it means to be "mentally healthy" depends on definitions that vary from place to place. Likewise, definitions of mental illness or attempts to describe variations from the norm are generally culture-specific.

Giving these variations, mental health might need to be defined with regard to a community's norms. To ensure that definitions of mental health and illness are just, any assessment of individual or collective mental health should take an ecosocial approach or one that "opens the question of whether our current social arrangements are the only possible or desirable orders of social coexistence."

A vital aspect of all levels of the system is that services be culturally responsive. Cultural background, language, ethnicity, and religion are important parts of students' lives. They shape the beliefs and influence their behaviors. Therefore, both curriculum and services should be responsive to students' cultural backgrounds, their level of acculturation, and their cultural values. If the student is concerned that receiving mental health services would negatively affect the cohesiveness of their family because of family members' perceptions of mental health, educators and mental health professionals could consider visiting the family to gain an understanding of the family's values and create connections between school, work, and family practices. Providing culturally responsive mental health supports also require service providers to realize their own biases and stereotypes and seek to understand others' histories and understandings of the issues they want to talk about. A culturally responsive school mental health provider, such as a school psychologist or school counselor, should undergo continuous professional learning to increase their ability to provide high-quality services to the members of the school population through prevention, screening, assessment, and intervention. Teachers should also seek to increase their multicultural awareness and recognize their biases and historical institutional oppression. Recommendations from the Equity in Mental Health Framework include a focus on the mental health and well-being of all students, guidance to various student subgroups, diverse and culturally competent faculty and staff, national and international equity issues/events, accessible and safe communication and an effective response system, culturally and linguistically appropriate services and supports, and disaggregated key data points.

To summarize, when these comprehensive school mental health systems are put into place, research suggests that students experience improvements in social awareness, decision-making capacity and relationship skills, better academic outcomes, fewer special education referrals and decreased need for restrictive placements, fewer disciplinary practices, and increased student engagement and feelings of connectedness with their school. Dr. Arora included some examples of the personal work she has done and in which she is currently engaged and some recently funded projects that look at ensuring cultural responsiveness in various Tier 1 and Tier 2 practices, as well as examples from others of critical work in these areas.

Adolescent Mental Health: Schools' Role in Supporting Student Mental Health and Promoting Health Equity

Kevin Gogin, MFT
Director of Safety and Wellness
School Health Programs, Student, Family, and Community Support Department
San Francisco Unified School District

Mr. Gogin indicated that San Francisco Unified School District (SFUSD) has about 55,000 students in transitional kindergarten through 12th grade. The Student and Family Service Division is aligned with the district's mission to provide each and every student with the quality instruction and equitable support required to thrive in the 21st Century. This large division includes social workers, nurses, community health outreach workers, after school supports, school counselors, attendance, attendance liaisons, and a number of other programs.

For a snapshot of SFUSD's 2019 middle school YRBS data, there was not a statistical change. However, there was a concerning change in the percentage of middle school students who ever seriously thought about killing themselves and those who have made a plan. Similarly for their YRBS high school data, there has been an increase in those students who have considered attempting suicide and those who have felt sad or hopeless. These are pre-COVID and school closure data, which they are especially concerned about given these data. Looking closer at feeling sad or hopeless for high school students, LGB students are at disproportionate risk for harm. They are also very concerned about their Philipinx and Hispanic Latinx students.

Their priority during this time of distance learning was that the district implemented a Family Wellness Check. Every family in the district received a call from an adult at school, with the option for follow-up. Basic needs were assessed in terms of housing, food, technology access, books, mental health supports, and hygiene. Health and wellness activities were promoted for students and staff that included a focus on SEL and concrete needs such as meal drop off, technology support, and hygiene kits. The hygiene kits they created were made available at community hubs throughout the city where students could access them as needed since school-based health and wellness centers were closed during these times. They also organized School site Coordinated Care Teams to: 1) identify students who were previously receiving supports and interventions and link them to supports virtually; 2) connect new student referrals to services; and 3) conduct follow-up Family Wellness Checks.

Staff assigned to Pre-K through 8th grade included a School Social Worker (SSW), School District Nurse (SDN), and AmeriCorps members. Staff assigned to the high school Wellness Program included Wellness Coordinators (WC) who are credentialed SSW, SDN, Community Health Outreach Workers (CHOW), and a Mental Health Therapist through a CBO with which the SFUSD partners. Additional centrally deployed services included Mental Health Interns and Foster Youth Services Interns. They have about 70 interns who are placed in schools throughout the district. Access to student support services includes outreach and education to families and our school staff, outreach and education to students, virtual wellness drop-in for students, and explicit referrals from teachers, families, and students.

An ongoing challenge they have found in distance learning is in-depth, ongoing mental health supports have changed. Students do not have the ability to have private, confidential, 50-minute sessions the way they might have had before for regular check-ins and ongoing assessing of students. They also have engaged with families more this past year than ever before for those students who are registered as receiving services under minor consent. The SSWs, SDNs, and School Staff meet via video conferencing on a regular basis with students and families as a way to assess needs and to provide interventions and tailor those as best they can, given the distance learning experience.

Individual student support services currently up and running in SFUSD middle and high schools include virtual drop-in support, counseling, nursing services, and case management as needed. Group/Student Spaces include affinity groups (LGBTQ+, Young women and men, BSU, Latinx and more), Healing Circles, group mentoring, and youth leadership opportunities. Outreach and education include Zoom classroom presentations led by Youth Outreach Workers and wellness and community providers, and virtual school-wide events as another way to build relationships and attachment to schools.

CHAC Discussion

Dr. Stoner asked Dr. Arora what type of assessments are done to identify the students in Tier 2 and Tier 3 for early intervention.

Dr. Arora indicated that they use a variety of ways. In an ideal system they are having whole school screening with global mental health measures, some that are publicly available and some that are not depending on what the school chooses. They have quick screeners that every child completes periodically once a semester, at the start of the year, or after particular crises. Based on that, students are followed up who indicate a higher level of need and are engaged in a more detailed assessment. That could be an assessment including input from the teachers and parents, for example. Some of that is definitely more relevant for younger children and less so for adolescents, so screening is developmentally appropriate as well. When they receive referrals from teachers and parents, they use specific measures to address the particular concerns. Behavioral problems are often thought of as the most obvious, so many people want to restrict their assessments to oppositional types of behaviors and behavior problems. However, it is also known that those behaviors sometimes underlie other mental health issues like trauma or depression. Because of that, they try to think of more broadband assessments that assess the whole school. She shared the following links:

- https://measuringsel.casel.org/wp-ontent/uploads/2018/11/Framework_EquitySummary-.pdf
- http://www.schoolmentalhealth.org/Resources/Mental-Health-Screening/
- https://www.nasponline.org/about-school-psychology/media-room/press-releases/nasp-guidance-for-ensuring-student-well-being-in-the-context-of-the-chauvin-trial

Ms. Hauser said she has been reading lately about SEL and the idea that it inculcates young people or is driven by the values of the majority community and whitewashes some of the cultural behaviors of other young people. This is something they are grappling with in sex education and she wondered whether Dr. Arora had any thoughts or an opinion on this.

Dr. Arora indicated that a lot of work is being done in an area called Transformative SEL, which is aimed at educational equity. This is a form of SEL intended to promote equity and excellence among all children and focuses on issues of race and ethnicity as a first step to addressing the broader range of inequalities. Jagers et al[40] describe practices to promote Transformative SEL. They list things such as classroom community building as being critical, which includes conducting morning meetings, setting individual and classroom goals and expectations, and engaging in collaborative problem solving. SEL addresses some of that already, but Transformative SEL takes into account adding the promotion of ethnic-racial identity development in the context of SEL. This includes recognizing and assessing the impact of one's beliefs and biases, understanding one's strengths, and grounding and affirming one's cultural heritage(s). Jagers also talks about cultural integration. This includes connecting student's cultural assets to academic concepts and skills, such as designing history lessons that resonate with students' backgrounds; encouraging student reflection on their own lives and society; and supporting student cultural competence by facilitating learning about their own and other cultures. The way they do this is by adding additional competencies to the traditional SEL model and different activities to do that. This is what she was getting at before about thinking more broadly about what it means to be in good mental health. Developing those in collaboration with the community itself (e.g., family advocates, youth advocates, community

[40] Robert J. Jagers, Deborah Rivas-Drake & Brittney Williams (2019) Transformative Social and Emotional Learning (SEL): Toward SEL in Service of Educational Equity and Excellence, Educational Psychologist, 54:3, 162-184, DOI: 10.1080/00461520.2019.1623032

members) and thinking about what the community also prioritizes would be a critical aspect of integrating that with SEL across the school.

Ms. Hauser pointed out that many of the strategies used at the middle and high levels in terms of school connectedness are pulled from SEL approaches. When they orient those around reducing stigma and providing safe spaces for LGBTQ youth, they are finding that this changes the school environment in a way that impacts all youth. They are now doing some work to try to understand what changes. Anytime there is a focus on reducing stigma, improving consent, reducing harassment, educating the adults in an environment on how to be culturally appropriate for one group, there is an opportunity to do that across the board for all youth. Most SEL programs are focused on the K-6 area. Those are the roots of how these issues need to be addressed. They must be done, to Dr. Arora's point, in culturally rich ways so that all of the cultural and social needs of children are being addressed. Moving into the middle school and high school years, it is important to understand how development changes and therefore how the practices have to be changed.

Mr. Gogin added that what it means on the ground is that they are unpacking previously approved curricula that address social emotional interventions or lessons. To that effect, they are also doing very concrete training about what it means to be trauma-informed and with a racial equity lens for students. Part of the role of the Care Team is to determine when student names come up why they are being referred for additional assistance and if they need to work with a particular teacher around general classroom management and building a sense of connection within that classroom. As they know, black and brown children are sent from classrooms at a greater rate than white students.

Dr. Anderson asked when a mental health problem is identified how often that identification comes from the family and if not, how interaction is done with a family when something is identified that needs to be addressed.

Mr. Gogin responded that since they have been in distance learning, more family referrals have come via phone from families to the SFUSD. When they had the luxury of being in a brick and mortar building with their students, many of the students had the ability and the agency could walk in and request assistance themselves. Many of their students from 7th grade and above are seeking services under confidential minor consent. They always try to include families as they are able, but that varies given the nature of the referral or the student need. They work with the student on that, but they do try to work with families in many ways. They are finding now that young people are absorbing the challenges in a different way since they have been at home. Unemployment, food insecurity, and housing insecurity are the realities of youth in San Francisco. Being trapped at home with the adults all day has made it more real for young people. They also have worked with their city partners and the Department of Public Health to get wraparound services for students and families to provide additional resources to help with all the other parenting challenges that they are finding as well as being teachers, parents, and providers.

Dr. Riester noted that some young adult teachers were probably adolescents during certain events such as 911, the Columbine shooting, et cetera. Recent events of the summer, at the Capitol, and across the country are sometimes difficult for the teachers themselves to explain to young people. He thinks they need to keep in mind those younger teachers and wondered whether there is anything in place that deals with younger teachers in any of these programs.

Mr. Gogin responded that given the violence against black and brown citizens in this country, they have been poised and have completed a number of trainings around how to address that in classroom settings. They also created curricula to address this so that teachers have a tool. They worked with their SSW so that they can provide Healing Circles for students who want a space to talk about it with their peers. The challenge this year has been that they have been doing this remotely. As students begin returning to schools, they are assuming that these very real instances that are affecting the lives of children, young teachers, and older teachers that this work will continue in person moving forward.

Dr. Ethier indicated that DASH has been fortunate enough to receive some 21st Century Cures Act dollars that they have been able to layer into all of their 1807 grantees to address some of these issues. They have had a number of listening sessions with their grantees about staff mental health, focused on educators and schools staff broadly. It has been a tough year. There are districts in some areas of the country where teachers and school staff have been back in person since early Fall 2020, but a number of districts continue to be fully virtual and others are in between. She does not think any model is more or less protective in terms of mental health for teachers and school staff. There is a lot that goes along with each of those. What should be put in place for educators and school staff is probably less known that what should be done for students, but their districts are putting a number of strategies in place to support their educators and school staff. She can provide more specifics about that moving forward.

Dr. Arora added that national agencies such as the National Association of School Psychologists (NASP) are putting out a lot of resources for educators on how to support their students, as well as guidance on supporting the providers themselves during such events and the potential impact on mental health.

Dr. Stoner emphasized what a fantastic panel this had been, with excellent presentations on really important topics.

Business Session: CHAC Votes on 5 Letters

Bradley Stoner, MD, PhD
CHAC Co-Chair, CDC Appointee

Jean Anderson, MD
CHAC Co-Chair, HRSA Appointee

Dr. Stoner reminded everyone that one of the tasks CHAC is asked to do is to provide advice, which must be voted upon by CHAC members. CHAC often generates letters and votes on recommendations. This is an opportunity for CHAC to make its voice heard by CDC and HRSA regarding CHAC's recommendations. CHAC was asked to consider and vote upon 4 letters and 1 set of recommendations from a working group. While during the meeting this was divided among two sessions, all letters and recommendations are combined here for continuity.

Letter 1: Pertaining to CHAC's Review/Discussion of the Available Evidence Related to Potential FDA Reclassification of Diagnostic Tests for HIV and HCV Infections

This letter was a result of the CHAC Business Meeting on April 12, 2021. This initially was presented to CHAC members as a summary of those deliberations. Feedback was received on the letter with regard to HIV and HCV testing classification. The language was modified to make it more scientifically accurate and to reflect the sentiment of what occurred in the meeting. The revised version was distributed to CHAC members earlier in the day. This letter

provides CHAC advice to the FDA. While CHAC members did not come to agreement, the letter reflects a broad view about how CHAC members feel about these issues. Some CHAC members' names were mentioned in the document. The sense was that FDA sees value in this, but names can be stricken for those who prefer not to be identified.

CHAC Discussion

- Dr. Dionne-Odom asked whether there should be some discussion based on the public comment session from the previous day during which an individual felt strongly about CHAC not recommending stopping tests.
- Dr. Taylor said that while she appreciated and always welcomed public comments, the individual who spoke about revising CHAC's letter to remove the statement about stopping testing works for OraSure who makes the test. The concern was about not supporting the new oral antibody. The antibody testing for HCV was developed in 1989 and HCV RNA testing was developed in 1991. There have been 20 years to succeed with this process of antibody RNA, which has not occurred. The epidemic has only mushroomed. This has been hashed out over several years and while the thought is appreciated, the specific concerns of two people were addressed by removing language about phasing out the antibody testing in the Viral Hepatitis Workgroup letter. That does not mean they think they should go against all of the evidence that shows antibody testing that is widely available in the community, POC finger-prick, would be enhanced in any way by adding an oral antibody test.
- Dr. Stoner emphasized that the letter is simply a reflection of the deliberations CHAC had during a previous meeting. It does not represent the consensus view of CHAC. It is simply a summary of the discussions. In that sense, it is not controversial. People have strong feelings about this.
- Dr. Wester asked whether the members believe that a single viral detection test will be sufficient to start antiviral treatment.
- Dr. Taylor responded that there is evidence from Australia on test-to-treat and there are ongoing studies in the US. Clinically, she does it. She has been working on HCV since the 1990s and does test-to-treat as soon as she gets an RNA. That does not mean that is the way it has to be rolled out in every setting. Different tools are needed for different settings. The goal is for someone to be able to walk up to a table in the field, get a fingerstick, and receive a pill if positive for virus.
- Dr. Stoner pointed out that on the HIV side, it is seeing the cascade and worrying about the drop-off from testing from antibody, but it is not a diagnostic test. This letter simply says that CHAC would like the field to move toward direct single-step testing. It does not say to get rid of antibody. It simply says that oral antibody may not be the way to go.

CHAC Action

Dr. Anderson made a motion to approve the letter regarding potential FDA reclassification of diagnostic tests for HIV and HCV infections. Dr. Taylor seconded the motion. The vote carried unanimously to adopt the letter and summary of CHAC's deliberations and move it forward.

Letter 2: Perinatal Infection Workgroup's Letter Reflecting Recommendations Approved on April 20, 2021

Dr. Stoner reminded everyone that the Perinatal Infection Workgroup's recommendations were approved the previous day. The idea was that they would then review the letter today after it went through a round of editing throughout the night. Dr. Anderson walked the group through the edits. The primary difference was that, as Dr. Taylor pointed out the previous day, HCV is different from the other perinatal infections in that it is a marker for injection drug use rather than STIs. She left track changes on in the edited letter to highlight a sentence reflecting this in the "Background and Rationale" section, the addition of language about HBV birth dose vaccination in the "Facts" section to make that a priority, the addition of bullet #5 under "Priority Areas" pertaining to reducing the unmet SUD treatment need among reproductive age women; and the addition of bullet #7 under "Recommendations" regarding identification and treatment of SUD. They wanted to make sure that they were giving it appropriate weight, because it is going off in a little different direction to bring in identification and treatment SUD.

CHAC Discussion

- Dr. Dionne-Odom indicated that her concern is that the workgroup focuses on testing. There is a lot that could be said about the management and treatment of all of these infections in pregnancy. However, they did not go into treatment in the letter in order to keep the focus on testing. Obviously, substance use related to HCV is a very important topic that probably warrants its own letter. To her, item #7 seemed out of scope with the rest of the document. She liked it in the background and discussion about priority areas. In terms of specific recommendations, she tended to think that focus is more likely to be accomplished than putting too much into something as important as this is.
- Dr. Taylor expressed concern that in reviewing the literature, state policies related to substance use in pregnancy are becoming more punitive in the US. If should be made very clear that this is a medical condition. If no context is given to reflect that testing women in pregnancy and identifying HVC in women who are pregnant, who might currently be using substances or have in the past used substances, this could put them in jeopardy more than help them.
- Dr. Stoner asked whether the working group has considered this as part of its discussion and if not, perhaps it should be removed. He reminded everyone that these letters are part of the work products of the CHAC workgroups.
- Dr. Anderson replied that the workgroup did not go into this. She was trying to include a recommendation to match the focus area. She thought the issue was appropriate to bring up in the letter, but if they remove it as a recommendation they might need to remove it as a focal area.
- Dr. Dionne-Odom said that to her, a priority area for intervention is future focus—other things that need to be done. She was comfortable leaving it as a priority area and removing the recommendation.
- Dr. Taylor noted that this would be her last meeting. She said she would be comfortable with the suggested changes to the letter as long the CHAC continues to consider how to protect women from potential incarceration due to punitive laws. Because it is a biologic marker for substance use, they do not want women identified as having HCV to be incarcerated and/or have their children taken away rather than receiving medical care and support. She understood and supported the approach to keep SUD in as a priority, but to remove the recommendation.

CHAC Action
Dr. Taylor made a motion to approve the Perinatal Workgroup's letter to the HHS Secretary. Dr. Dionne-Odom seconded the motion with an amendment to keep the language regarding SUD as a priority area, but to strike the SUD recommendation. The vote carried unanimously to adopt the letter and move it forward.

Letter 3: Viral Hepatitis Workgroup's Letter Reflecting Recommendations Approved during the November 2020 CHAC Meeting

Dr. Taylor reminded everyone that the recommendations were already agreed upon by CHAC in November 2020. Three small changes were made in the letter based on input received. In the first recommendation, the word "adopt" was changed to "promote and prioritize." A second change to the first recommendation was the removal of the wording "while antibody screening should be phased out." The first recommendation now reads, "It is recommended that CDC/HRSA promote and prioritize a national HCV testing strategy based on systematic single-step RNA-based testing, as the pillar of the US HCV elimination effort. Development, validation, and regulatory approval of point-of-care (POC) molecular (HCV ribonucleic acid (RNA)) fingerstick and dried blood spot (DBS) diagnostic testing should be prioritized and accelerated to rapidly scale up diagnosis and facilitate access."

The third change was to the second paragraph on the second page of the letter beginning with "The US relies on a two-step diagnostic paradigm . . ." To be very clear about the limitations of the antibody to the RNA process, specific additional wording was added, "Outside of highly medicalized environments -- such as the hospital setting, where phlebotomy is available and antibody reflexed to RNA more feasible (although automatic reflexive RNA is still not universally performed in U.S. laboratories) -- many are lost to care between antibody and RNA testing. The drop-off between antibody screening and diagnostic testing represents the biggest loss in the cascade to cure. It prolongs identification of persons with HCV, lengthens viremic time for transmission and development of liver damage, and leaves people not knowing whether they are infected." Another request was received to incorporate HCV antigen testing. While many would support the CDC and HRSA pursuing that, that is not what the workgroup focused or what was voted on in November 2020. In terms of the process, they do not have the ability now to incorporate antigen testing.

CHAC Discussion
- As an individual, Dr. Taylor said she would support incorporating HCV antigen testing as an additional tool as long as they do not end up with a 2-step process.
- Dr. Wester asked whether CHAC wanted to substitute HCV "viral testing" rather than "RNA testing." Core antigen testing may be an option in the future.
- Dr. Taylor clarified that the workgroup focused and voted on the optimal diagnostic testing. They understand that there is interest in pursuing core antigen testing and she personally supports that, as a point of order, the recommendation was agreed to and voted upon by the CHAC in November 2020 and could not be added to the letter at this point.

CHAC Action
Ms. Hauser made a motion to approve the Viral Hepatitis Workgroup's Letter to the HHS Secretary. Ms. Searson seconded the motion. The vote carried unanimously to adopt the letter and move it forward.

Letter 4: A letter from CHAC requesting that CDC's Division of Adolescent and School Health (DASH) Convene, Support, and Consult with a Youth Advisory Council

Ms. Hauser reminded everyone that DASH has a great strategic plan, but there is an issue with that plan in that it states that DASH wants to hear from and be informed by young people, parents, and communities by 2025. Yet, the internal roadmap to how they are going to address health disparities caused by race and other inequities is to be done by 2021. The letter, which CHAC agreed to consider for review and a vote the previous day, requests that DASH convene, support, and consult with a Youth Advisory Council composed of young people from the communities most impacted by health disparities prior to finalizing its internal roadmap for reducing adolescent health disparities related to race/ethnicity, sexual orientation, gender identity, and geography and at least through the end of its current strategic plan in 2025 to gain valuable insights that help shape the division's research and program strategies. The letter then includes some best practices regarding how to go about convening and supporting a Youth Advisory Council. Though she initially suggested that the Youth Advisory Council meet quarterly, a former CHAC member suggested that it would be better for them to meet monthly to build rapport and for young people to be comfortable.

CHAC Discussion
- Dr. Stoner pointed out that while it is important to establish the Youth Advisory Council, the deadline to do so by December 2021 seems ambitious.
- Dr. Armstrong asked how far along DASH is in completing the strategic plan.
- Ms. Hauser indicated that the strategic plan goes from 2020 to 2025, so they are about hallway through it.
- Mr. Rodriquez said he could not escape the fact that they heard earlier that LGBTQ youth are more vulnerable to suicide, mental health, and navigating trauma. He was glad to see this project presented, but because of his story, he could not help but think about places like Puerto Rico (PR) and the US Virgin Islands (USVI) where homophobia and transphobia are varied. As inclusive as the letter is, it states that this Youth Advisory Council will focus on the South of the US. He wondered if there would be space to make an effort to outreach to folks in PR and the USVI. Particularly for PR, there might need to be some adjustments. For example, there may be youth who want to be represented who might not feel comfortable speaking English. Spanish, not English, is the first language in Puerto Rico so translation might be needed in order to provide an equitable place for them to be represented. While he understood the needs in the South, he wondered whether there would be an option to expand the Youth Advisory Council to include folks from the territories.
- Ms. Hauser thought it could be expanded to include youth from the territories. In the letter, she was trying to reflect that the communities from which these young people should be drawn is really where the health disparities are. She thought it was very fair to add the territories. The South and rural communities were included because they are known to have health disparities, but it feels appropriate to include PR and USVI due to their health disparities. She will add this to the letter.

CHAC Action
Dr. Riester made a motion to approve the letter to DASH regarding the identification of a Youth Advisory Council, with the addition of engaging youth from PR and the USVI. Dr. Morne seconded the motion. The vote carried unanimously to adopt the letter and move it forward.

Letter 5: The EHE Community Engagement Workgroup's Recommendations

Dr. Anderson reminded everyone that Dr. Hill-Jones provided an excellent presentation the previous day of the work of the EHE Community Engagement Workgroup. After the last meeting, they noticed that the term of reference for this workgroup would end before the next CHAC meeting. Given the importance of this issue, they wanted to bring back the recommendations for CHAC to discuss and vote on, with the letter to be forthcoming that reflects these recommendations. There is precedent for that within CHAC. Dr. Hill-Jones pointed out that the recommendations are pretty self-explanatory and break the conversation of EHE community engagement into four key areas: Planning & Design, Implementation, Evaluation, and Technical Assistance. He briefly reviewed the recommendations, which he had described in detail during the workgroup presentations the previous day. While the CHAC would vote on the recommendations during this session, it was with the proviso that a letter would follow to be considered and voted upon in a future CHAC meeting.

Discussion Points
- Dr. Taylor agreed that PLWH who volunteer should be funded. Perhaps the recommendations should be more specific. For example, often community members volunteer for many years and all they get is a bus ticket, gift card, and lunch. Many people are living in poverty, so this is not sufficient.
- Dr. Hill-Jones agreed and said he thought this was the essence of dividing up this conversation of community engagement. There are times when there is a report back that warrants a gift card or meal. But when community members are tapped into for their knowledge and expertise, that should be compensated like any other consult who is leveraged to work on their behalf.
- Mr. Hursey pointed out that this was written to say that networks of PLWH are really developing the HIV workforce.
- Ms. Parkinson added that PLWH have developed the spaces, implemented the spaces, diffused the spaces, and live in the community and do not like the bought in place mentality. Give us what we come for, give us what we asked, and allow us to make change to the landscape of this journey.
- Dr. Hill-Jones clarified that this is a recommendation that they are putting forth, but they need to have a systems conversation about what the recommendation of implementation activities look like to support this happening. They cannot control people's funding mechanisms, but the suggestion of language around how to compensate HIV coalitions that may not be planning councils because of the legality around members of planning councils being supported in a funded sense by jobs, internships, or honoraria is important. There needs to be another conversation that task forces and other bodies that represent PLWH have the ability to use that body to bring in and support the workforce and the workforce processes that need to be created. A perfect example is that if those things had been in place, it could have helped offset the support that many health departments needed as their staff were being re-allocated to the COVID response. They saw many times in 2020 even though they had a vibrant HIV workforce advocate community in place, because all of the power was centered in the health departments, EHE processes came to a standstill as

health departments had to deal with their staffs being pulled into the COVID response. That is just one example of how the process can stop if the entire HIV community is not wrapped up around and meaningfully involved in all parts of the process to keep this plan moving.

- Ms. Parkinson emphasized that with the EHE community plan, they cannot forget about women and PLWH over 50 years of age and making sure they are implemented in the processes, because once they age up, they have to make sure there is a movement for them as well.

CHAC Action

Dr. Riester made a motion to approve the EHE Workgroup Recommendations. Mr. Hursey seconded the motion. The vote carried unanimously to adopt the recommendations and move them forward.

Dr. Anderson noted that this meeting drew to a close the Viral Hepatis and Perinatal Infections Workgroups. The EHE Community Engagement Workgroup is ongoing until September 2021, but has completed its terms of reference as well. CHAC will be awaiting a letter from that group as a final product.

Next Meeting / Proposed Agenda Items

The next CHAC meeting will be November 3-4, 2021. The following future agenda item was proposed:

- Additional attention should be paid to placing perinatal HCV in the context of access to evaluation, care, and treatment for a group of women who might be highly stigmatized and who, without access to care, could be funneled into the criminal justice system rather than the medical model. Consideration is not being given to the evidence and what constitutes good medical care for these women. It would be helpful to hear from an Obstetrician/ Gynecologist who is certified in addiction medicine. Two suggested experts are: 1) Dr. Rachel Epstein at Boston Medical Center; and 2) Dr. Mishka Terplan at Virginia Commonwealth University who also serves as the Addiction Medicine Consultant for the Virginia Department of Medicaid Service and is a consultant for the National Center on Substance Abuse and Child Welfare.

Adjournment & Certification

Dr. Mermin reiterated his appreciation for such a great CHAC meeting even though they were meeting virtually. There were great recommendations, outstanding discussions, and presentation of information that was very useful and will allow HRSA and CDC to incorporate it into their work.

Dr. Cheever applauded the incredible amount of work that was done and wrapped up during this CHAC meeting. They have been working on a number of efforts for quite a while now. To see it all bear fruit was very exciting. She thanked Drs. Stoner and Anderson for “wrestling the bear to the ground” to get through a variety of letters. She invited those with ideas for the next agenda to submit them to the POCs for the agencies. With no further business, she officially adjourned the meeting at 5:00 PM ET.

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

Bradley Stoner, MD, PhD, Co-Chair — Date
CDC/HRSA Advisory Committee on HIV,
Viral Hepatitis, and STD Prevention and Treatment

Attachment A: Participant List

CHAC Members Present

Dr. Jean Anderson (Chair)
Dr. Bradley Stoner (Chair)
Dr. Wendy Armstrong
Dr. Jodie Dionne-Odem
Dr. Travis Andre Gayles
Ms. Debra Hauser
Mr. Venton Hill-Jones
Mr. Devin Hursey
Dr. Shruti Mehta
Mr. Greg Millett
Dr. Johanne Morne
Ms. Kneeshe Parkinson
Mr. Robert Riester
Mr. Leandro Rodriquez
Ms. Gloria Searson
Dr. Lynn Erica Taylor

CHAC Members Absent

Dr. Meredith Greene

CHAC *Ex-Officio* Members Present

Dr. Pradip N. Akolkar
US Food and Drug Administration

Dr. Paul Gaist
National Institutes of Health

Ms. Kaye Hayes
U.S. Department of Health and Human Services

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

Dr. Douglas Olsen
Centers for Medicare and Medicaid Services

Dr. Richard Wild (Alternate)
Centers for Medicare and Medicaid Services

CHAC *Ex-Officio* Members Absent

Dr. Neerja Gandotra
Substance Abuse and Mental Health Services Administration

Mr. Richard Haverkate
Indian Health Service

CHAC Liaison Representatives Present

Carl E. Schmid, II
HIV + Hepatitis Policy Institute

CHAC Designated Federal Officers

Dr. Laura Cheever
Health Resources & Services Administration
HIV/AIDS Bureau Associate Administrator

Dr. Jonathan Mermin
Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention Director

Presenters

Prerna Arora, PhD
Assistant Professor of Psychology and Education
Teachers College Columbia University

Laura H. Bachmann, MD, MPH
Chief Medical Officer, Division of STD Prevention
Centers for Disease Control and Prevention

Erin Conners, PhD, MPH
Epidemiologist, Prevention Branch
Division of Viral Hepatitis CDC
Centers for Disease Control and Prevention

Kathleen Ethier, PhD
Director, Division of Adolescent and School Health CDC
Centers for Disease Control and Prevention

Presenters (continued)

Monique Foster, MD, MPH
Medical Officer, Epidemiology and Surveillance Branch
Division of Viral Hepatitis
Centers for Disease Control and Prevention

Kevin Gogin, MFT
Director of Safety and Wellness
School Health Programs, Student, Family, and Community Support Department
San Francisco Unified School District

Charlotte A. Gaydos, MS, MPH, DrPH
Professor, Division of Infectious Disease
Johns Hopkins University

Emily Halling
Government Grants and Contract Manager
Southwest Center

Janet McNicholl, MD
Preclinical Team Lead, Laboratory Branch
Medical Officer, Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Michele Owen, MD
Associate Director, Laboratory Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Elliott Raizes, MD
Acting Senior Medical Advisor
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

Carl Schmid, MBA
Executive Director
HIV + Hepatitis Policy Institute

Adam Visconti, MD, MPH
Chief Medical Officer, HIV/AIDS, Hepatitis, STD, and TB Administration
District of Columbia Department of Health

Carolyn Wester, MD, MPH
Director, Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Attachment B: List of Acronyms

AASLD	American Association for the Study of Liver Diseases
ACA	Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ADHS	Arizona Department of Health Services
AG	Attorney General
AHEAD	America's HIV Epidemic Analysis Dashboard
AHRQ	Agency for Healthcare Research and Quality
ARV	Antiretroviral
ART	Antiretroviral Therapy
ASH	Assistant Secretary of Health
ASL	American Sign Language
ATECs	AIDS Education and Training Centers
BHOC	Building Healthy Online Communities
BIPOC	Black, Latinx, American Indian/Alaska Native, Asian American and Pacific Islander, and Other Communities of Color
bNAbs	Broadly Neutralizing Antibodies
CAB-LA	Cabotegravir Long-Acting
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
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
CHOW	Community Health Outreach Worker
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
CMO	Committee Management Office
COI	Conflicts of Interest
CSTE	Council of State and Territorial Epidemiologists
CT	*Chlamydia Trachomatis*
DAAs	Direct-Acting Antivirals
DASH	Division of Adolescent and School Health
DBS	Dried Blood Spot
DCHWC	District of Columbia Health and Wellness Center
DEA	Drug Enforcement Administration
DFO	Designated Federal Officer
DHAP	Division of HIV/AIDS Prevention
DMPA	Depot Medroxyprogesterone Acetate
DOJ	Department of Justice
DPTV	Detroit Public Television
DVH	Division of Viral Hepatitis
EHE	Ending the HIV Epidemic

ELEVATE	Engage Leadership through Employment, Validation, and Advancing Transformation & Equity
EIS	Epidemic Intelligence Service
EMR	Electronic Medical Record
FACA	Federal Advisory Committee Act
FAQs	Frequently Asked Questions
FDA	Food and Drug Administration
FPL	Federal Poverty Level
FQHC	Federally Qualified Health Center
FRN	Federal Register Notice
FTE	Full Time Equivalent
GSAs	Gay-Straight Alliances
HAB	HIV/AIDS Bureau
HCP	Health Care Provider
HCV	Hepatitis C Virus
HHS	(United States Department of) Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Tests
HOPWA	Housing Opportunities for People with AIDS
HPV	Human Papillomavirus
HRSA	Health Resources and Services Administration
IDSA	Infectious Disease Society of America
IFG	Insignia Federal Group, LLC
IWTK	Iwantthekit
JID	*Journal of Infectious Diseases*
LGBTQ	Lesbian, Gay, Bisexual, and Transgender
MobiNAAT	Mobile Nucleic Acid Amplification Test
MACS/WIHS	Multicenter AIDS Cohort Study/Women's Interagency HIV Study
MHAF	Minority HIV/AIDS Fund
MI	Motivational Interviewing
MMWR	*Morbidity and Mortality Weekly Report*
MPTs	Multipurpose Prevention Technologies
NHANES	National Health and Nutrition Examination Survey
MSM	Men Who Have Sex With Men
MTSS	Multi-Tiered Systems of Support
NBI	Narrow Band Imaging
NASTAD	National Alliance of State and Territorial AIDS Directors
NAT	Nucleic-Acid
NAAT	Nucleic Acid Amplification Test
NBLCA	National Black Leadership Commission on AIDS, Inc.
NCC	Non-Competing Continuation
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NHBS	National HIV Behavioral Surveillance

NIH	National Institutes of Health
ONAP	Office of National AIDS Policy
PACHA	Presidential Advisory Council on HIV/AIDS
PCHP	Primary Care HIV Prevention
PEP	Post-Exposure Prophylaxis
PPE	Personal Protective Equipment
OIDP	HHS Office of HIV/AIDS and Infections Disease Policy
OTC	Over-The-Counter
PACHA	Presidential Advisory Council on HIV/AIDS
POC	Point-of-Care
PPE	Personal Protective Equipment
PrEP	Pre-Exposure Prophylaxis
PRGLAC	Pregnant Women and Lactating Women
PWID	People Who Inject Drugs
QALY	Quality Adjusted Life Year
RAPID	Rapid ART Program for Individuals with an HIV Diagnosis
RCT	Randomized Controlled Trial
RNA	Ribonucleic Acid
RPR	Rapid Plasma Reagin
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SDN	School District Nurse
SDOH	Social Determinants of Health
SEL	Social Emotional Learning
SFUSD	San Francisco Unified School District
SSP	Syringe Services Program
SSW	School Social Worker
STD	Sexually Transmitted Disease
TAP	Technical Assistance Provider
TB	Tuberculosis
TBTC	Tuberculosis Trials Consortium
TV	*Trichomonas Vaginalis*
US	United States
USPSTF	United States Preventive Services Task Force
WC	Wellness Coordinators
WHO	World Health Organization
YRBS	Youth Risk Behavior Survey

Attachment C: CHAC Letters

CDC/HRSA ADVISORY COMMITTEE

on HIV, Viral Hepatitis and STD Prevention and Treatment

April 21, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

The Centers for Disease Control and Prevention/Health Resources and Services Administration (CDC/HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) met via Zoom on April 12, 2021. During this meeting, CHAC reviewed and discussed the available evidence related to potential FDA reclassification of diagnostic tests for human immunodeficiency virus (HIV) infection and hepatitis C virus (HCV) infection.

CHAC members considered evidence presented by CDC scientists about the potential benefits of reclassifying HIV and HCV tests, including:

- new reclassifications could streamline FDA's regulatory review, resulting in timelier patient access to accurate and reliable diagnostics.
- a streamlined and less costly process could attract new manufacturers to this market and could facilitate development of a point-of-care HCV RNA tests and HIV self-tests.
- new tests could receive a Class II designation if they have predicate devices for comparison.
- a Subject Matter Expert (SME) review to consider the public and individual health benefit of an oral fluid HCV diagnostic and the performance metrics for both an oral HCV diagnostic and over-the-counter (OTC) HIV tests could assist the Food and Drug Administration (FDA) in their review of new proposed devices.

Inasmuch as FDA has requested SME feedback on these issues to assist in their review of future oral and OTC diagnostic tests, we hereby submit the summary of CHAC deliberations around these issues for FDA consideration. Thank you for your attention to these important issues affecting the health and wellness of the nation.

The Advisory Committee advises the Secretary, the CDC Director and the HRSA Administrator of the U.S. Department of Health and Human Services on activities related to prevention and control of HIV/AIDS, viral hepatitis and other STDs, the support of health care services to people living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS, viral hepatitis and other STDs.

Summary of CHAC Deliberations
HIV and HCV FDA Classification

HIV

1. What are the minimum performance standards that we should consider as important to maintain for public health benefit of over-the-counter (OTC) HIV self-tests?
    a. Would it be acceptable to have different performance characteristics for self-tests compared to tests performed by trained individuals in clinical or outreach settings?

Summary statement: *The committee agreed that additional OTC tests for HIV could be an important tool for supporting HIV testing, prevention, and treatment goals. Slightly lower test sensitivity and specificity as compared to clinical settings might be acceptable (similar to the current FDA-approved OTC test), if followed by test refinement and improvement in subsequent iterations.*

From Dr. Bradley Stoner: We will need a lot of tools to get to Ending the HIV Epidemic goals; a short-term fall-off in sensitivity/specificity for newly available OTC HIV tests would be acceptable to help move toward this goal, as long as there is eventual improvement in sensitivity/specificity. It is disheartening to see more tests available in other countries than in US.

From Dr. Shruti Mehta: We need tools like self-testing, even if we have to accept a short-term fall-off in sensitivity/specificity. This is an important tool for HIV.

From Robert Riester: Despite having personal experience with self-fingerstick testing for T2 diabetes, he found that performing a dried blood spot (DBS) test for hemoglobin A1c (analogous to DBS testing for HIV) was not a simple process, and would therefore recommend supervised testing, if possible. The lancet was unfamiliar, it was a struggle to fill 5 sample holes with blood, and instructions were unclear whether holes had to be filled completely. Results were available about 2 weeks after mailing in. Even with these challenges, he would be willing to do a similar DBS test again for convenience.

From Dr. Jean Anderson: The discussion was favorable regarding need for additional HIV point-of-care tests and slightly lower sensitivity and specificity as compared to clinical setting would be acceptable.

HCV

2. Is there a public health benefit for having access to an oral fluid HCV antibody test in the U.S.?
    a. If yes, and if the oral fluid HCV antibody test was less sensitive than the fingerstick HCV antibody test, how much sensitivity loss could be tolerated before the test would no longer be useful?

Summary statement: *Rather than pursue oral HCV antibody testing, the committee strongly recommended that the HCV diagnostics field move toward single-step diagnosis of current infection (in point-of-care settings and potentially in other settings), which would include the availability of HCV viral testing with core antigen and/or RNA rapid diagnostic tests.*

From Dr. Lynn E. Taylor: In contrast to HIV, antibody tests are not diagnostic for HCV. It is a disservice to patients to provide an unclear test result without definitive diagnosis of current viremia. Rather, what is needed is a point-of-care test for HCV RNA. There is no evidence from a review of the literature presented in the slides that an oral HCV antibody test will bring us closer to HCV elimination, arguing instead for developing point-of-care HCV viral testing in place of point-of-care antibody testing; evaluating another anti-HCV test is a poor use of time and effort.

From Ms. Gloria Searson: Agree that an oral anti-HCV test lacks public health benefit; reluctant to put more resources toward testing that does not provide a benefit toward getting infected persons into treatment and cure. Clinicians lack staff to do the extra work for the step between antibody test and getting person diagnosed and linked to care.

From Dr. Shruti Mehta: What we need is single test for HCV diagnosis. When providing care for persons who inject drugs (PWID), even a one-day or one-week delay to complete testing may lead to loss to follow-up of half or more.

From Dr. Bradley Stoner: We're all aware of the drop-off in HCV cascade of care without a one-step diagnostic, and the need for single-step diagnostic test.

From Dr. Jean Anderson: There is a fair degree of agreement that an oral anti-HCV test would not advance public health goals; the need is for point-of-care diagnosis of current infection.

Thank you for your efforts on behalf of the populations served by our committee, and of our committee members.

Respectfully,

Jean R. Anderson, MD
CHAC co-chair

Bradley Stoner, MD, PhD
CHAC co-chair

cc:
Dr. Laura Cheever, Associate Administrator, HRSA
Dr. Jonathan Mermin, Director NCHHSTP, CDC
CHAC Members

CDC/HRSA ADVISORY COMMITTEE

on HIV, Viral Hepatitis and STD Prevention and Treatment

April 21, 2021

Xavier Becerra J.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

The Centers for Disease Control and Prevention/Health Resources and Services Administration (CDC/HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) met virtually on November 5 and 6, 2020. During this meeting, the CHAC passed a resolution and is sending recommendations, described below, for your consideration. These recommendations focus on addressing the imperative of improving hepatitis C virus (HCV) diagnostics in the U.S. as the key next step in HCV elimination. As such, the CHAC strongly urges CDC and HRSA leadership to consider the below actions with regard to our nation's HCV epidemic.

Recommendations:

1. It is recommended that CDC/HRSA promote and prioritize a national HCV testing strategy based on systematic single-step RNA-based testing, as the pillar of the U.S. HCV elimination effort.

   Development, validation, and regulatory approval of point-of-care (POC) molecular (HCV ribonucleic acid (RNA)) fingerstick and dried blood spot (DBS) diagnostic testing should be prioritized and accelerated to rapidly scale up diagnosis and facilitate access.

2. It is recommended that CDC/HRSA implement a national, coordinated, efficient approach to development of optimal HCV diagnostics.

3. It is recommended that CDC/HRSA makes progress regarding these recommendations despite the ongoing COVID-19 pandemic.

   In fact, lessons learned from the COVID-19 pandemic may inform next steps regarding one-step HCV molecular diagnostics and large-scale rollout.

Background and Rationale

The Viral Hepatitis Workgroup is charged to assist in the development of feasible guidance related to enhanced HCV diagnostics. Diagnosing our HCV-undiagnosed populations in the U.S. as quickly as possible is the next key step necessary to avert liver-related morbidity and mortality and stem rising HCV incidence. HCV is the second biggest infectious disease killer in the U.S. behind SARS-CoV-2. HCV incidence in the U.S. tripled from 2009 to 2018, due to the opioid crisis. The development of all-oral, well-tolerated, short-duration, pan-genotypic direct-acting antivirals (DAAs) with high cure rates (>95%) paved the way to cure those with HCV. Benefits of cure include reduced transmission, decreased liver-related morbidity and mortality as well as all-cause mortality, diminished need for liver transplantation and improved quality of life.

By 2019, universal treatment was recommended by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, followed by the 2020 recommendations for universal screening by the CDC and U.S. Preventive Services Task Force. However, the impact of DAAs in decreasing the HCV burden at the population level is contingent on the level of testing and diagnosis.

The U.S. relies on a two-step diagnostic paradigm of HCV antibody to evaluate for previous exposure, followed by HCV RNA testing (via real-time polymerase chain reaction (PCR) or transcription-mediated amplification (TMA)) performed in a centralized lab on serum or plasma from venous puncture, to diagnose active infection. This creates a bottleneck in the HCV cascade to cure and impedes the test-to-treat optimal standard of care. Phlebotomy presents a barrier for people who inject drugs, people without ready access to healthcare, and under COVID-19 circumstances. The two-step process requires multiple healthcare visits. Outside of highly medicalized environments -- such as the hospital setting, where phlebotomy is available and antibody reflexed to RNA more feasible (although automatic reflexive RNA is still not universally performed in U.S. laboratories) -- many are lost to care between antibody and RNA testing. The drop-off between antibody screening and diagnostic testing represents the biggest loss in the cascade to cure. It prolongs identification of persons with HCV, lengthens viremic time for transmission and development of liver damage, and leaves people not knowing whether they are infected.

Other countries eliminate this barrier by providing rapid, POC, finger-prick RNA testing. Molecular (HCV RNA) POC tests now available allow diagnosis at the site of patient care using fingerstick capillary whole blood. Single-step diagnosis enables a test-to-treat model of care and facilitates self-testing in which a person collects her/his/their own specimen, and interprets the result. HCV self-testing outside clinical settings is particularly advantageous in situations with restricted movement, as seen under COVID-19, where access to health care services and diagnostic testing are more limited.

The next essential step is to make HCV RNA POC diagnostic testing available in the U.S. to facilitate wide-scale treatment. The ideal diagnostic testing should be rapid (i.e., results in 1 hour or less), simple (requiring minimal equipment and training), cost-effective, sensitive, specific,

painless and minimally invasive (utilizing sample types such as capillary whole blood). For example, a promising rapid POC finger-prick RNA test, Cepheid's Xpert® (Sunnyvale, California) HCV Viral Load Fingerstick, detects and quantifies HCV RNA from 100µL with comparable performance to other available HCV RNA assays.

An alternative option is DBS testing, which is easy and inexpensive to collect, but does not yield immediate results. DBS samples are stable once dried and readily transported and stored, thus providing a convenient and affordable sampling solution in resource-limited settings. DBS samples can be used for testing for other viruses including human immunodeficiency virus and hepatitis B virus. For example, Hologic's (Marlborough, Massachusetts) Aptima® HCV viral load assay detects active infection from DBS samples with comparable performance to other available HCV RNA assays and is clinically comparable to results obtained from plasma.

Scientific advances and lessons learned from molecular diagnostic testing for SARS-CoV-2 should be harnessed for large-scale HCV diagnostic testing across the U.S. Many of the laboratory testing platforms may be used for both viruses. We need common approaches to validating test design and performance, regardless of whether there is an emergency. Experience to date with SARS-CoV-2 highlights the need for a common framework to ensure that all clinical tests are accurate and reliable.

When a public health threat such as the HCV epidemic warrants large-scale testing, it is more effective to authorize a small number of well-designed and validated tests manufactured in large quantities, than to simultaneously develop and authorize scores of diagnostics. A small number of test designs could be developed or identified by the U.S. government alone or in collaboration with the testing community, then manufactured by the CDC, preset contract manufacturers, commercial manufacturers or laboratories, which would speed up development, validation, authorization, production, launch and testing. As inaccurate results pose a high risk to public safety, it is imperative that diagnostic assays are rigorously assessed during review. There should be quality assurance programs and processes for oversight of POC testing at the federal level to ensure high performance.

"Breakthrough HCV diagnostics should not be priced so that they cannot meet public health need. Some things are simply too important to public health to leave their distribution to the private interests vying against each other in the U.S. healthcare system. Transparent collaborations are required to understand relationships and costs/mark-ups associated with diagnostic companies, distributors, service providers and government, and to help develop mechanisms to control end-prices and volume pricing."

Thank you for your leadership and your continued commitment to ensure that HCV elimination efforts are directed by the most current science and in advancing shared efforts to accomplish national goals.

Thank you for your efforts on behalf of the populations served by our committee, and of our committee members.

Respectfully,

Jean R. Anderson, MD
CHAC co-chair

Bradley Stoner, MD, PhD
CHAC co-chair

cc:
Dr. Laura Cheever, Associate Administrator, HRSA
Dr. Jonathan Mermin, Director NCHHSTP, CDC
CHAC Members

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CDC/HRSA ADVISORY COMMITTEE

on HIV, Viral Hepatitis and STD Prevention and Treatment

April 21, 2021

Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
MS H21-10
Atlanta, GA 30333

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane, Rm 14-71
Rockville, MD 20857

Dear Dr. Walensky and Mr. Engels:

The Centers for Disease Control and Prevention/Health Resources and Services Administration (CDC/HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) met on April 20-21, 2021. During this meeting, the CHAC considered deliberations and recommendations from the Perinatal Infections Working Group, constituted by CHAC and including CHAC members and additional subject matter experts (SME); these recommendations were approved by the entire CHAC and are sent for your consideration.

Background and Rationale

Sexually transmitted infections (STIs) that occur during pregnancy, including HIV, syphilis and hepatitis B virus infection, carry significant risk to pregnant individuals and their infants. STIs can result in adverse pregnancy outcomes, such as pregnancy loss and stillbirth, preterm birth and congenital infection in the newborn. In the era of the COVID-19 pandemic, numbers of reported cases of gonorrhea, chlamydia and syphilis have taken an abrupt downturn; this is thought to be due not to a decline in STI cases, but rather to reductions in testing related to multiple factors. It is likely that this applies to pregnant individuals as well as those in the general population and may further exacerbate disparities in national STI rates according to age, race, and access to health care. Screening for treatable and curable infections in pregnancy improves outcomes. Hepatitis C (HCV) virus infection, rather than a classic STI, is a blood borne pathogen and a marker for

maternal injection drug use. With numbers of HCV infections rising among individuals of childbearing age and in pregnancy, the number infants born with HCV infection is also increasing.

Facts about perinatal HIV/HBV/syphilis and HCV transmission in the United States:

- Elimination of perinatally-acquired HIV is possible. While an estimated 5000 individuals living with HIV give birth annually, HIV diagnoses declined 54% among children 2014-2018 and in 2018 only 65 cases of perinatal transmission were reported[1].
- Missed opportunities in preventing perinatal HIV transmission today often relate to lack of testing in pregnancy altogether or failure to re-test in late pregnancy after primary infection has occurred.
- Although an estimated 95% of pregnant individuals receive prenatal hepatitis B surface antigen (HBsAg) testing, fewer than half of the expected births to HBsAg-positive persons are identified and only 76.3% of all infants receive the HBV birth dose vaccination[2], resulting in missed opportunities to prevent HBV infection in infants.
- From 2014-2018, the rate of syphilis cases in reproductive-age women (15-44 years) increased by 165%.[3] Between 2015 and 2019, the rate of congenital syphilis cases increased by approximately four-fold.[4]
- Current trends in the epidemiology of HCV show an increasing proportion of cases among reproductive-age women. HCV infection rates in pregnancy nearly doubled between 2009-2014 and there are an increasing number of children with perinatally acquired HCV driven by the U.S. opioid crisis.[5]
- A CDC literature review and cost-effectiveness analysis suggests that universal screening for HCV in pregnancy will reduce HCV-attributable mortality by 16% among individuals tested and linked to curative treatment after pregnancy. Universal screening can also increase the proportion of infants born to persons with hepatitis C, who are identified as HCV-exposed, from 44% to 92%.[6]
- Based on this analysis and on the recognition that risk-based screening is inadequate to identify all persons with HCV infection, CDC issued new guidelines in 2020 recommending universal HCV screening in pregnancy.[6]

Priority areas for intervention: We have identified five areas in need of intervention to improve prevention, screening, and diagnosis of HIV, viral hepatitis and STIs in pregnancy:

1. **Lack of alignment of perinatal infection screening recommendations**: There is variation across jurisdictions and professional societies with regards to laws/regulations and recommendations about screening for relevant perinatal infections during pregnancy. Some of this variation includes the timing of prenatal screening and whether screening is

risk-based or universal. This has created a barrier to appropriate screening and contributes to confusion regarding the standard of care.

2. **Need for standardized laboratory pregnancy panels**: There are no standardized laboratory panels for testing in pregnancy across electronic patient medical record systems and reporting of pregnancy status is inconsistent. This gap, coupled with the variation in regulations and recommendations noted above, can result in missed screening and prevention opportunities during pregnancy. In the current system, providers can order the wrong type of test or at the wrong time.
3. **Linkage between maternal and pediatric records**: It is well-recognized that there is a need to share prenatal care records in order to ensure appropriate follow-up and management of the baby. Due to the "disconnect" between maternal and infant medical records, in many cases clinicians caring for newborns cannot see the results of testing for infection during pregnancy. Linkage of these records would likely improve testing rates among infants who were exposed to infection in-utero or at delivery.
4. **Reducing silos between different perinatal infections**: The current vertical approach to different perinatal infections involves duplication of effort and ineffective use of funds.
5. **Reducing the unmet substance use disorder treatment need among reproductive age women**: To reduce adverse maternal or infant outcomes in pregnant individuals with HCV, the priority interventions are evaluation and treatment of substance use disorder and overdose prevention. Although beyond the scope of the charge to this Working Group, future efforts should include promotion and prioritization of identification and treatment of substance use disorder in pregnant individuals.

Specific Recommendations: The following represent consensus recommendations from CHAC

1. It is recommended that CDC/HRSA consider convening a meeting with representatives of relevant professional societies to discuss the rationale and importance of:
    a. universal screening for HIV, hepatitis B, hepatitis C and syphilis in pregnancy; and
    b. standardization of testing recommendations across societies.

One goal of the meeting would be to achieve consensus and encourage advocacy regarding the need for better alignment of laws and regulations around screening for infections in pregnancy.

1. It is recommended that CDC/HRSA work with relevant professional societies, the Council of State and Territorial Epidemiologists (CSTE) and laboratory representatives to support development of standard pregnancy panels and timing of perinatal infection testing to support coordination of standard pregnancy panels through commercial labs.

Panels may serve as a prompt to remind providers of screening recommendations and remove the risk of ordering the wrong test. Providers could opt-out of individual tests, if indicated, and could order diagnostic testing at any time.

2. It is recommended that CDC/HRSA work in support of a requirement for laboratory reporting of pregnancy status when reporting results of HIV, HBV, HCV and syphilis.
3. It is recommended that CDC/HRSA support the conclusions and recommendations of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) (https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendations) for implementation to improve medical record linkage between maternal and infant records.
4. Case review boards may be a viable model to help reduce silos between perinatal infections. It is recommended that CDC/HRSA authorize pilot projects to explore integration of existing case review boards across relevant perinatal infections to allow more coordination and efficient use of resources.
5. It is recommended that CDC/HRSA encourage collaborations/partnerships at the state level between public health departments, community organizations and health care providers to identify pregnant individuals with infections (e.g., HIV, syphilis, HBV, HCV), particularly those not engaged in care, in order to blend resources and enhance workforce capacity to address complex patient needs.
6. With the advent of the COVID-19 pandemic there has been a reduction in STI testing due to diversion and shortage of human and material resources, reduced access to many services and/or avoidance of care because of fear of exposure. It is recommended that CDC/HRSA explore opportunities to expand home-based/self-testing for STIs for pregnant individuals.

Thank you for your efforts on behalf of the populations served by our committee, and of our committee members.

Respectfully,

Jean R. Anderson, MD
CHAC co-chair

Bradley Stoner, MD, PhD
CHAC co-chair

cc:
Dr. Laura Cheever, Associate Administrator, HRSA
Dr. Jonathan Mermin, Director NCHHSTP, CDC
CHAC Members

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CDC/HRSA ADVISORY COMMITTEE

on HIV, Viral Hepatitis and STD Prevention and Treatment

April 21, 2021

Xavier Becerra J.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

The Centers for Disease Control and Prevention/Health Resources and Services

Administration (CDC/HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) met on April 21, 2021. During this meeting, the CHAC passed a resolution and is sending the recommendations, described below, for your consideration.

Background

In 1997, the Centers for Disease Control and Prevention defined community engagement as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people".

Community engagement strategies involve those most impacted by health disparities in authentic partnerships with public health professionals to jointly assess the causes, document the impacts, and identify potential solutions to ameliorate these disparities and promote the health and wellbeing of the affected community. To be effective, community members must be meaningfully engaged and recognized as experts in their own lives with insight into the issues, barriers, and opportunities that impact the health and wellbeing of their community.

Youth engagement is a community engagement strategy in which adult-professionals partner with young people most impacted by an issue in order to jointly identify strategies to redress the root causes, symptoms, and consequences of that issue. For youth engagement to be effective, the contributions of both the adult-professionals and the young people must be recognized and valued. Authentic youth engagement can assist public health professionals to better understand the circumstances, supports, opportunities, and barriers that impact young people's health and well-being and lead to the design and implementation of more effective interventions.

The Advisory Committee advises the Secretary, the CDC Director and the HRSA Administrator of the U.S. Department of Health and Human Services on activities related to prevention and control of HIV/AIDS, viral hepatitis and other STDs, the support of health care services to people living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS, viral hepatitis and other STDs.

The Division of Adolescent and School Health's (DASH's) Strategic Plan, 2020 – 2025 recognizes the importance of community engagement and includes an objective under *Strategic Imperative A:* to establish by 2025, "a mechanism to hear from youth, parents and families to inform DASH's strategies." The strategic plan also includes under *Strategic Imperative B* the objective to develop by 2021, "an internal DASH roadmap for reducing adolescent health disparities related to race/ethnicity, sexual orientation, gender identity and geography."

Recommendations

CHAC calls on the Secretary to prioritize the engagement of young people most impacted by health disparities in HHS efforts to ameliorate these disparities. Specifically, CHAC requests that CDC/DASH convenes, supports, and consults with a youth advisory council composed of youth people from communities most impacted by health disparities ***prior*** to finalizing its internal roadmap for reducing adolescent health disparities related to race/ethnicity, sexual orientation, gender identity and geography. Further, CHAC recommends that DASH continues to support, sustain, and regularly consult with this youth advisory council, at least through the end of its current strategic plan in 2025, to gain valuable insights that help shape the division's research and program strategies.

To that end, CHAC recommends the following:

- By December 2021, CDC/DASH should recruit and begin supporting a youth advisory council composed of at least 15 young people, ages 16 to 24, from communities most affected by health disparities related to race/ethnicity, sexual orientation, gender identity and geography in order to influence DASH's internal roadmap and strategies for reducing adolescent health disparities.

- CDC/DASH should recruit young people most impacted by health disparities, including, but not limited to: young women of color; gay youth, particularly gay youth of color; transgender young people, particularly transgender youth of color; gender expansive youth; Native American and Pacific Islander youth; youth from rural communities; and young people from the South of the United States.

- CDC/DASH should develop mechanisms to support this youth advisory council by providing youth members an orientation to the work of the council and to DASH, a dedicated staff person with an affinity for young people, stipends for members' participation, and opportunities to network with each other and DASH staff.

- CDC/DASH should provide DASH staff with youth-adult partnership training prior to engaging with the youth advisory council.

- CDC/DASH should convene the youth advisory group at least quarterly and empower these young people to share their experiences, including the challenges they face, as well

as the opportunities and systems that helped them build their resilience and acquire health behaviors.

- CDC/DASH should on a regular basis present its roadmap, program plans, and evaluation strategies for reducing adolescent health disparities related to race/ethnicity, sexual orientation, gender identity and geography to the youth advisory council for its feedback.

Thank you for your leadership and your commitment to ensuring prevention efforts are directed by the most current science in partnership with community engagement, and in advancing shared efforts to accomplish national goals.

Respectfully,

Jean R. Anderson, MD
CHAC co-chair

Bradley Stoner, MD, PhD
CHAC co-chair

cc:
Dr. Laura Cheever, Associate Administrator, HRSA
Dr. Jonathan Mermin, Director NCHHSTP, CDC
CHAC Members

Attachment D: Public Comment Letters

BEYOND AIDS

Reversing the HIV Epidemic Through Sound Public Health Policy

April 5, 2021

TO: CO-CHAIRS OF CHAC, AND TO DRS. MERMIN AND CHEEVER
(c/o MARGIE SCOTT CSEH)

On behalf of the Beyond AIDS Foundation, I am hereby providing our written testimony, including current recommendations to both HRSA and CDC, **for the April 20, 2021 CHAC meeting. To supplement and personalize this written testimony, I am requesting an opportunity to make a brief virtual presentation during public comment at this meeting.** This testimony and request are in follow-up to my email correspondence with Ms. Margie Scott-Cseh of December 31, 2020 and February 2, 2021. **Our Foundation hopes that this will be a beginning of ongoing direct dialog among our Foundation leaders and appropriate leaders in each of the two agencies**, including Drs. Mermin, Daskalakis, Cheever, and appropriate designees. We would also like to be included in CDC consultations.

By way of introduction, the Beyond AIDS Foundation has been instrumental in influencing improved public health prevention policies for HIV/AIDS for over 22 years (one early example was the achievement of nationwide HIV reporting by name). Our leadership includes HIV specialists and public health academicians. Some of us have served as metropolitan HIV/AIDS and STD directors, health officers, PACHA members, EIS officers, Ryan White providers, and/or in other key roles,

We believe that our current recommendations can assist in implementation of the NHAS HIV/AIDS Strategy and the End the Epidemic Initiative. They have implications for future grants from both agencies, and for accountability regarding fulfillment of grant conditions. Although we mostly deal with HIV, we are also urging an increase in combined screening and health education for HIV, STDs, and viral hepatitis, in keeping with the mission of CHAC. We think that many if not most of our proposals can probably be implemented without significantly increased federal funding, by redirecting some funds. However, as mentioned below, we also urge more efforts to raise state, local, and private sector prevention funding to supplement federal resources.

We also submitted proposals along the same lines as these recommendations for consideration in the update of the National HIV/AIDS Strategy. **We would appreciate an opportunity to discuss activities for implementation** of that strategy at the CDC and HRSA levels, particularly the portions on prevention and on a more coordinated response in dealing with HIV/AIDS. **Any assistance that CHAC can provide to promote this dialog would be appreciated.**

Our first five recommendations below are based on the findings of our **survey of state and territorial HIV/AIDS Directors, published in 2019 in AIDS Education and Prevention (full text provided to the committee), including its conclusions/recommendations.** Our survey revealed **deficiencies and rather marked inconsistencies of policy and practices** among jurisdictions.

Western Regional Office: 1275 W. Park Ave,. # 7718 ▲ Redlands, CA 92375 ▲ www.beyondaids.org ▲
info@beyondaids.org

Our most important recommendations relevant to HRSA and CDC include:

- That certain changes be made in CDC and HRSA grant eligibility and accountability, and that more oversight be provided and accountability required by both agencies regarding adherence to grant conditions. The Ending the Epidemic Initiative could provide an impetus for such changes. For example, basic CDC prevention and surveillance grants tend to be distributed to states and large metropolitan areas and to be regularly renewed based in large part on demographic criteria. Special additional grants tend to go appropriately to areas with more diagnoses, but it would be optimal to also reward any areas that achieve decreasing rates and earlier detection of diagnoses due to increasing effective prevention. Currently, applications to both agencies must be competently prepared, but we believe **there should be more checking as to whether the funded services are competently and effectively fulfilled.** CDC and HRSA, in their RFPs, should call for applications to identify specific weaknesses and deficiencies of their individual HIV/AIDS programs, and to include commitments to correcting these, in each funded jurisdiction or agency. Conditions for funding should include that current recommendations, and new policy directions related to the NHAS and Ending the Epidemic from CDC and HRSA will be implemented by the respective jurisdictions. The grant recipients should have an opportunity to negotiate with CDC regarding these goals, and then should be accountable for doing their best to achieve them. Any goals that are not reached during a funding period should be emphasized even more specifically and strongly in the next renewal grants. **CDC should consider expanding its site visits to include all prevention and surveillance grant recipients**. Although carrying the potential of withholding of some funds for non-compliance, the approach should be non-punitive and focused on education and guidance. The investment should be worthwhile, helping to assure more uniform adherence to CDC recommendations nationwide, adequate staffing and follow-through for grant-funded activities, and CDC should end up getting more of its grant money's worth.

- That CDC increasingly stress **expansions in the concept of surveillance, to include public health monitoring of patients' entry into and progression along the HIV Care Continuum.** Specifically, there is a need for CDC recommendations, and grant requirements, for **more standardized outreach to newly diagnosed patients and their providers** (if any). Minimum purposes should be to help assure the most rapid possible linkage to and initiation of care, partner services, and referrals for other services as indicated. This need not require absolute uniformity, as we found eight jurisdictions that reported admirable patient outreach "extras" such as screening for substance abuse and mental illness, answering patient questions on disease course or managing acute HIV, referrals to ADAP, social services, and/or assistance in obtaining health insurance. It should remain possible for jurisdictions to continue to fund these out of CDC grants. We are more concerned about the 36% of states and territories that did not routinely attempt to contact either all reported patients or all providers when those existed. Sometimes, in some locations, the main purpose in contacting providers or patients was to gather data to complete reporting forms, rather than to assist in overall public health goals such as facilitating progression along the HIV Care Continuum.

- That CDC recommend additional new directions for HIV surveillance (e.g., expansion of "data to care") by public health departments to monitor and facilitate patient progression at critical points further along the HIV Care Continuum, especially **retention in care.** RFPs can indicate

that part of the grant money is to be spent on these activities. As a specific example, 42% of states and territories were already **tracking MISSED viral load** results (as well as persistently high results) in diagnosed and reported patients, and contacting at least providers when no viral load result had been received in the past year, despite this not yet being a CDC recommendation. **We recommend that this become a CDC recommendation and a grant requirement.** Previously diagnosed patients for whom viral load results have not been received for a year should have outreach to determine whether they never entered or have dropped out of care (in which case renewed linkage efforts should be implemented), have moved to other jurisdictions (in which case those jurisdictions should be informed), or whether some laboratories are not complying with reporting requirements (in which case jurisdictions should intensify work with those labs). HRSA should meanwhile continue to strongly emphasize the need for monitoring of viral load (as well as CD4 counts) in care funded by Ryan White.

- That **monitoring of genotype results become a CDC recommendation** for which federal money can be used. Results should be **forwarded to CDC** for analysis and detection of emerging viral resistance throughout the country to current medications. Currently, this type of surveillance depends on supplemental grants, and is therefore somewhat sporadic, with geographic and population gaps. In our survey, only 38% of public health departments received these results. Progress in this direction should include encouraging states that are not yet receiving genotype results to work to assure **that genotypes be considered as HIV results and thus reportable by laboratories to public health, or that specific regulations require their reportability.** The less-commonly-performed phenotypes could be added to this program. HRSA's Ryan White program guidelines should meanwhile emphasize the appropriate indications for baseline and repeat genotype testing. Currently, there is not uniformity in which classes of drugs are included in genotypes. Both agencies could use their influence to help standardize them, specifically encouraging the inclusion of integrase strand transfer inhibitors.

- That all jurisdictions be encouraged to **supplement CDC grants with some of their own money for HIV prevention**. Incentives could be provided by offering supplements to the grants as matching funds. Currently, New York state requires all counties to raise HIV prevention funds and adds a hefty state contribution, but in our survey, 28% of states and territories had no funds to spend other than their CDC grants. The COVID-19 pandemic and the accompanying recession may have reduced or diverted staff and funding from HIV to make the situation worse. This makes funding solicitation from the private sector, as we found had been achieved in several jurisdictions, worth considering.

- That the NHAS, as well as the viral hepatitis strategy and the new STD strategy, include activities to better coordinate prevention efforts for HIV with other diseases included in CHAC's mission, specifically other STDs and viral hepatitis. This could begin with **more joint screening efforts, and more joint health education about safer sex and avoidance of needle sharing.** As we promote PrEP, we should place more emphasis on **urging condom use with PrEP,** not only to further enhance HIV protection but alto to prevent a whole range of other sexually-transmitted infections that are prone to increase when condoms are discontinued.

- That HRSA grant recipients, including clinics receiving Ryan White funds, be expected to attempt to contact patients to **remind them of upcoming appointments, and to follow up on**

missed appointments, so as to increase retention in care as part of the HIV/AIDS Care Continuum. When possible, **HIV care appointments should be scheduled in close proximity on the same half day as primary and other specialty care.** Recently enhanced emphasis on case management in the Ryan White program, described briefly by Dr. Cheever at the March PACHA meeting, could provide an increased opportunity help assure these services and to elicit and help resolve barriers to care, such as lack of transportation, child or elder care responsibilities, and work obligations without sick leave allowances. Both agencies should also utilize their educational capabilities and leadership influence to encourage providers funded through the private sector to similarly contact patients for reminders, to follow up if appointments are missed, and when possible to coordinate multiple appointments so as to minimize the need for separate travel.

- That ways be determined to **cover PrEP for uninsured patients**. The recent USPSTF recommendation for PrEP should increase insurance coverage, but for those without any, it will not help. It is my understanding that Ryan White funds are currently restricted by law for care of HIV-positive persons. Should a change in the statute by recommended, or can a special category of grants be established by either HRSA or CDC? This is a topic on which we corresponded with Dr. Stoner in 2019. Dr. Cheever's presentation at PACHA in March indicated that HRSA is making progress on funding PrEP for seronegative partners of patients.

- That training be made available nationwide to **primary care providers (PCPs) on the baseline lab tests and HHS-recommended starting medications** for treatment-naive patients. PCPs have the capability to initiate treatment immediately, without a wait for an infectious disease or HIV specialist referral. If drugs with negligible viral resistance are utilized, treatment does not need to be delayed until lab results come back. Referrals or consultations with specialists can occur later as needed. I have personally provided such training to resident physicians at Loma Linda University, in as little as a 1-hour session. Both short and longer slide presentations that I have used for such training are posted on our Foundation's Web site, at **http://www.beyondaids.org/resources.html**.

There is considerable overlap these days between the prevention mission of CDC and the originally treatment-oriented mission of HRSA including the Ryan White program, in part because of the effectiveness of treatment as prevention. This makes coordination between the two agencies increasingly important. CHAC can fill a critical role in facilitating this, as well as helping to coordinate our public health strategies for HIV, STDs, and viral hepatitis. Therefore, **I am honored to have had this opportunity to provide input to this important committee.**

Sincerely,

Ronald Hattis, MD, MPH

Ronald P. Hattis, MD, MPH
Secretary, Beyond AIDS Foundation
Mobile: 909-838-4157

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OraSure Technologies, Inc.

April 19, 2021

Re: OraSure Technologies remains a partner in eradicating HCV

Dear Members of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment,

OraSure Technologies has stood as a long-time partner in addressing HIV and HCV both domestically and internationally. As the first company to bring several game-changing, rapid diagnostic tools to market, we believe firmly in developing innovative solutions and services that are backed by science and empower individuals to take action related to their health. Our priority will always be ensuring that user-friendly tests are available for all individuals, particularly communities historically marginalized from healthcare systems.

We have a once-in-a-generation opportunity. Today, **direct-acting antivirals make curing HCV possible; however, without expanded access to testing, individuals will remain unaware of their status**. In the US, HCV disproportionately impacts individuals under 30, American Indian/ Alaskan Native populations and persons who inject drugs.[1] Social and structural influencers of health deeply impact health outcomes in the U.S. and have exacerbated HCV-related healthcare related disparities.

As a leader in the field of diagnostics, we agree with the members of CHACHSPT that a point of care molecular confirmatory test for HCV would be a dramatic step forward in the fight to eradicate HCV in the United States. As such, we are working to bring these types of tests to market and would support both regulatory science engagement as well as efforts from the community and government agencies in making this possible. There is no panacea for HCV testing, and **it will take a toolkit of tests that can work together to identify and link patients to care**. While molecular HCV testing holds great promise, the leading molecular HCV test internationally has a longer turnaround time, is more expensive, and requires a desktop platform that is not conducive to high volume testing or outreach settings like correctional facilities and syringe exchange programs. Additionally, a point of care molecular HCV test will likely not be brought to market in the U.S. for years given the studies for regulatory approval and current economics involved with such a test. In the meantime, the HCV burden continues to grow in this country, and **we need to act now to optimize the current HCV toolkit while the work is done to ultimately bring a point of care confirmatory ultimately to market.**

[1] CDC, 2018 Viral Hepatitis Surveillance Report

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Given the growing HCV epidemic across the US and an on-going public health crisis, action is needed today to ensure that individuals can get tested, learn their HCV status, and link to curative treatment. **An HCV oral fluid rapid test would be an important addition to the HCV diagnostics toolkit to eliminate HCV in the US**. Based on feedback from our clinical and advocacy partners, we see four key value points for an oral fluid test:

1. **Patients prefer oral fluid** testing to fingerstick testing. There is extensive published data showing this for both Hepatitis C and HIV.
2. An **oral fluid rapid test requires less steps to conduct making it more user friendly**, which is critical especially for outreach settings where the HCV burden is highest like correctional facilities and syringe exchange programs.
3. The **sensitivity of an oral fluid rapid test for viremic patients is nearly the same as the current fingerstick test**.
4. An **oral fluid rapid test lays the groundwork to ultimately have an HCV self-test** available to patients and health departments thereby replicating the public health success of the HIV self-testing programs and further empowering individuals to take charge of their health.

As the U.S. undertakes the important work of the Ending the HIV Epidemic Initiative and National Viral Hepatitis Roadmap to Elimination, OraSure stands ready as a committed partner to public health departments, healthcare providers, and community-based organizations.

Sincerely,

Giffin Daughtridge, MD MPA
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