

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



**Meeting of the
CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis and STD Prevention and Treatment
October 25-26, 2017
Rockville, Maryland**

Record of the Proceedings

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Minutes of the Meeting

The U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, 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, Viral Hepatitis and STD Prevention and Treatment (CHAC). The proceedings were held on October 25-26, 2017, at 5600 Fishers Lane, Pavilion, Rockville, Maryland.

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

Information for the public to attend the CHAC meeting in person or participate remotely via teleconference was published in the *Federal Register* in accordance with FACA rules and regulations. All sessions of the meeting were open to the public (*Attachment 2: Participant Directory*).

Opening Session: October 25, 2017

Laura Cheever, MD, ScM
Associate Administrator, HRSA, HAB
CHAC Designated Federal Officer (DFO), HRSA

Dr. Cheever conducted a roll call to determine the CHAC voting members, ex-officio members (or their alternates), and liaison representative in attendance. She announced that CHAC meetings

are open to the public and all comments made during the proceedings are a matter of public record. She reminded the CHAC voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and to recuse themselves from voting or participating in these matters.

CONFLICT OF INTEREST DISCLOSURES

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Richard Aleshire, MSW, ACSW (Washington State Department of Health)	Recipient of funding from CDC and HRSA/Ryan White HIV/AIDS Program (RWHAP).
Jean Anderson, MD (Johns Hopkins Medical Institutions)	Recipient of funding from HRSA/RWHAP and National Institutes of Health (NIH) and has stock in Gilead.
Marvin Belzer, MD, FACP, FSAM (University of Southern California, Keck School of Medicine)	Recipient of funding from CDC, HRSA/RWHAP and NIH.
Peter Byrd (Peer Educator and Advocate)	No conflicts disclosed.
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Recipient of funding from CDC and HRSA/RWHAP.
Debra Hauser, MPH (Advocates for Youth)	Recipient of funding from CDC.
Peter Havens, MD, MS (Children's Hospital of Wisconsin)	Recipient of funding from HRSA/RWHAP and the National Institute of Child Health and Human Development.
Devin Hursey (U.S. People Living with HIV Caucus)	Recipient of from HRSA/RWHAP.
Amy Leonard, MPH (Legacy Community Health Services)	Recipient of funding from CDC and HRSA/RWHAP.
Jorge Mera, MD (W.W. Hastings Indian Hospital)	HRSA/RWHAP-funded AIDS Education and Training Center (AETC) Program and funding from Oklahoma University; advisory board member of Gilead Sciences and AbbVie in 2016.
Greg Millett, MPH (amfAR)	Advisory board member of VIVE Initiative
Susan Philip, MD, MPH (San Francisco Department of Public Health)	Recipient of funding from CDC and HRSA/RWHAP and an unpaid public health advisor for GlaxoSmithKline.
Michael Saag, MD (University of Alabama at Birmingham, School of Medicine, UAB Center for AIDS Research)	Recipient of funding from HRSA/RWHAP and NIH and a consultant for BMS, Merck, Gilead, and ViiV.
Linda Scruggs, MHS (Ribbon Consulting Group)	Recipient of funding from HRSA/RWHAP.
Bradley Stoner, MD, PhD (Washington University School of Medicine)	Recipient of funding from CDC.
Lynn Taylor, MD, FACP (The Warren Alpert Medical School of Brown University)	Recipient of funding from HRSA/RWHAP.

Dr. Cheever confirmed that the 15 voting members and ex-officio members in attendance (or their alternates) constituted a quorum for CHAC to conduct its business on October 25, 2017. She called the proceedings to order at 9:01 a.m. and welcomed the participants to the CHAC meeting.

Dr. Cheever welcomed four new members to the CHAC. The new members are:

- Marvin Belzer, MD, FACP, FSAM, University of Southern California, Keck School of Medicine;
- Devin Hursey, U.S. People Living with HIV Caucus;
- Jennifer Kates, PhD, Vice President and Director Global Health and HIV Policy, Kaiser Family Foundation; and
- Michael Saag, MD, University of Alabama at Birmingham (UAB), School of Medicine, UAB Center for AIDS Research.

Approval of the May 2017 Draft CHAC Meeting Minutes

CHAC Action

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

CHAC approved the draft May 10-11, 2017, meeting minutes with no changes or further discussion. There was one abstention.

HRSA Administrator Introductory Remarks and HRSA Update

Laura Cheever, MD, ScM

Associate Administrator, HRSA, HAB
CHAC DFO, HRSA

Dr. Cheever introduced the new HRSA Administrator, George Sigounas, MS, PhD. Dr. Sigounas became HRSA Administrator on May 1, 2017.

George Sigounas, MS, PhD

Administrator, HRSA

Dr. Sigounas welcomed CHAC members. He commented that since coming to HRSA in May he has learned that the programs are very well run at both headquarters and the regional offices. He hopes to bring new energy and ideas to HRSA while maintaining the focus on direct care and serving HRSA's targeted populations. He hopes to promote innovation and collaboration within HRSA and to optimize the use of resources so that even more people can be provided services. Mental health and substance use disorder services are emerging priorities.

Jim Macrae, MPP, MA

Associate Administrator, HRSA, Bureau of Primary Health Care (BPHC)

Mr. Macrae provided an update on HRSA's Health Center Program, which serves 26 million people – 1 in 12 people across the United States. Health centers provide a significant amount of HIV-related services. In 2016, nearly 1,400 HRSA-funded health centers provided HIV-related services. This included HIV testing for 1.42 million patients, linking 83.2 percent of people living with HIV (PLWH) to care, and providing care to 158,323 PLWH (over 634,906 visits).

The Partnership for Care (P4C) Demonstration Project is designed to build sustainable partnerships among CDC-funded state health departments and HRSA-funded health centers to support expanded HIV service delivery in communities highly affected by HIV, especially among racial/ethnic minorities. State health departments and health centers will work together to increase the identification of undiagnosed HIV infection, establish new access points for HIV care and treatment, and improve HIV outcomes along the continuum of care for PLWH. In 2016, 22 P4C health centers tested 41,962 patients for HIV for the first time in their lives, with 90.8 percent of PLWH linked to care within 90 days of their HIV diagnosis. Lessons learned from P4C include the importance of leadership and staff buy-in, use of multidisciplinary care teams, enhancement of electronic health records (EHRs), and building strategic state and local partnerships.

Addressing hepatitis C virus (HCV) has been a challenge for health centers. Health centers engage in prevention, screening, diagnosis, and treatment activities and need guidance in how to conduct these activities.

Priorities for the Health Center Program include expanding the use of telehealth, especially in rural areas and for the treatment of mental health and substance use disorders. Addressing substance use continues to be a challenge for primary health care providers, including health centers. To help health centers address substance use disorders, BPHC released a funding announcement and received more than 1,200 applications. Other priorities for the Health Center Program include oral health, case management, patient education, and care team development.

Discussion

Dr. Anderson asked whether HRSA is addressing the intersection between substance use, mental health, and violence, especially intimate partner violence (IPV). Mr. Macrae stated that BPHC has initiated workgroups focused on helping the Bureau become a more trauma-informed organization. BPHC is currently conducting a pilot study in ten health centers focused on IPV. Health centers need to integrate IPV screenings and build partnerships with organizations in their community that focus on this issue.

Ms. Fukuda asked whether there are patient navigators to help patients with HCV. Given the complexity of treatment, this service is critical, but stated that often, patient navigation services are not reimbursed. Mr. Macrae stated that there are discretionary funds in health center grants and that enabling services are those most often funded by health centers, followed by oral care. BPHC is exploring ways to encourage more enabling services.

Dr. Mermin asked if there are ways to facilitate screening for STDs. For example, if blood is drawn for another screening, could STD screening also be conducted? Mr. Macrae stated that some health centers are conducting “opt out” routine STD screening and many care teams have

instituted standing orders related to STD screening. Care teams allow for more engagement with patients. Other members of the care team, besides the physician, can engage patients around STDs. BPHC is exploring ways to reward health centers for providing whole patient care and not just compensation by visit. The Bureau is also looking for ways to factor in the social determinants of health.

Laura Cheever, MD, ScM

Associate Administrator, HRSA, HAB
CHAC DFO, HRSA

Dr. Cheever provided the HAB update. Ryan White HIV/AIDS Program (RWHAP) funding for FY 2017 is over \$2.3 billion. The AIDS Drug Assistance Program (ADAP) and RWHAP Part A make up the majority of the funding. In 2016, RWHAP served 551,567 clients. Of these, 97 percent were PLWH. Nearly three-quarters of clients are people of color and approximately two-thirds of clients are living at or below the Federal Poverty Guidelines (FPG). Men make up 71.4 percent of clients, women are 27.3 percent, and transgender individuals are 1.3 percent.

RWHAP clients have achieved a viral suppression rate of 84.9 percent among those who had at least one medical care visit and viral load measurement, significantly better than the rate for PLWH who are not served by the program. Of particular note, populations that have had lower rates of viral suppression – transgender individuals, the unstably housed, and youth – all have viral suppression rates above 70 percent and have had significant improvements since 2010.

HAB has initiated some activities to address challenges facing the program. HAB has launched a program to support the design, implementation, and evaluation of innovative interventions that coordinate HIV care and treatment and housing and employment services to improve HIV health outcomes for RWHAP clients.

HCV and HIV coinfection is also a challenge. An estimated 20-25 percent of RWHAP clients are coinfecting with HCV. HRSA HAB is committed to eliminating HCV coinfection in the RWHAP. HRSA HAB has two initiatives supported by the Secretary's Minority AIDS Initiative to increase the capacity for HCV treatment. To support this, HRSA HAB's National HIV Curriculum has a module on HCV/HIV coinfection.

The involvement of PLWH has always been a hallmark of the RWHAP. Recent initiatives include supporting increased engagement of youth and transgender women of color living with HIV in leadership opportunities. Another initiative focuses on increasing the use of community health workers to strengthen the health care workforce and improve access to healthcare and health outcomes for racial/ethnic minority PLWH. Other HAB initiatives include addressing the HIV care continuum in southern metropolitan areas and providing technical assistance to RWHAP Parts A and B jurisdictions to support integrated HIV planning implementation.

In addition, HAB has been working to disseminate findings and increase implementation of best practices from the models of care studies it supports. These evidence-based interventions focus on transgender women, Black men who have sex with men (MSM), integration of behavioral health into primary care, and responding to trauma. In addition to these activities, HAB is developing four evidence-informed care and treatment interventions related to linkage and retention and Special Projects of National Significance (SPNS) projects that focus on incarceration, buprenorphine, outreach, and re-engagement and retention.

CDC/NCHHSTP Director's Report

RADM Jonathan Mermin, MD, MPH

Director, CDC, NCHHSTP
CHAC DFO, CDC

Dr. Mermin announced that Brenda Fitzgerald, MD is the new Director of CDC. She is committed to evidence-based work and strongly supports state and local health departments. CDC has released an *Updated HIV/AIDS Prevention Strategic Plan, 2017-2020*. It reflects advances in prevention science, including pre-exposure prophylaxis (PrEP).

Another focus is HCV; cases have tripled since 2010. CDC has partnered with the National Institute on Drug Abuse to help communities develop comprehensive approaches to prevention and treat consequences of opioid use. It is a five-year project. He noted that there are states that have laws in place that impact access to HCV services, such as mandatory sobriety.

Dr. Mermin stated that STDs are at record highs, especially syphilis in MSM and women, congenital syphilis and gonorrhea in MSM. Drug-resistant gonorrhea remains a concern and 2016 data show that azithromycin-resistant gonorrhea strains are on the rise in the United States. CDC has developed an infographic about rising STD rates that can be customized by states. CDC has also awarded funds to nine state/city health departments to enhance the response to congenital syphilis.

For school-based health policies and practices, national surveys indicated improvement in policies and practices to prevent violence, bullying, and suicide. Improvements are still needed in student health education, substance use prevention, and HIV and STD services. CDC developed new communications products related to the Youth Risk Behavior Surveillance System (YRBSS). This includes a new infographic and palm cards for professionals.

Dr. Mermin announced a call for papers for the *Journal of Public Health* focused on disparities in the prevention and treatment of HIV, viral hepatitis, STDs, and TB in the United States. The deadline is January 31, 2018.

Discussion

Dr. Saag asked how PLWH not served by the RWHAP are factored into estimates of the number of PLWH not in care. Dr. Mermin stated that there are 1.1 million PLWH and 15 percent of these are not diagnosed. Approximately 200,000 receive care outside of the RWHAP. They are monitored through the National HIV Surveillance System (NHSS).

Dr. Saag asked about the possibility of the U.S. government purchasing HCV treatment, similar to what is done by the Australian government. In Australia, the government purchases a large number of doses at a discount. The drugs must be used within a certain period. Dr. Mermin said that Australia negotiated a price for the drugs. Some states are looking into a similar agreement. The U.S. Department of Veterans Affairs (VA) has been very successful with HCV treatment, as has the HHS/Indian Health Service.

Dr. Taylor stated that in her practice she encounters people who have not disclosed their HIV status to their sex partners. This becomes a serious issue when patients see their providers less frequently as they achieve viral suppression – there are fewer opportunities to raise this issue with patients. In addition, providers do not have time to follow up on partner notification. She asked what the role of RWHAP providers is in reaching out to partners and stated that there needs to be a systematic approach. Dr. Cheever stated that the RWHAP does not generally directly fund partner notification, but, instead, partners with health departments that fund this activity and have the personnel and expertise.

Dr. Taylor asked if the use of PrEP could lead to increases in STDs, but she indicated that STD rates were increasing prior to PrEP. In addition, PrEP guidelines call for screening and treatment of STDs every three to six months. Following the guidelines could lead to a decrease in STD rates.

Dr. Stoner asked how HAB is working to ensure stable housing for RWHAP clients, given the relationship between stable housing and better health outcomes (e.g., viral suppression). Dr. Cheever stated that the RWHAP is well positioned to address the social determinants of health and that, by statute, RWHAP-supported support services must be linked to health outcomes. The RWHAP funds temporary housing and works with U.S. Department of Housing and Urban Development (HUD) to link clients to stable housing.

Mr. Hursey asked about services for people who experience IPV, adding that people experiencing IPV may not feel safe disclosing it and, therefore, may not access necessary services related to IPV. Dr. Cheever stated that HRSA recently completed an organization-wide strategy to address IPV, including activities funded through the RWHAP Part D and an evidence-based interventions expansion program that was recently funded.

Strategies to Link and Engage PLWH Who Are Out Of Care

CAPT Tracy Matthews, MHA, RN

Deputy Director, HRSA, HAB, Division of Policy and Data

CAPT Matthews introduced the panel discussion designed to provide data on PLWH who are not in care; information on systematic strengths, challenges, and gaps; and to describe the use of data to inform strategies on how HRSA and CDC can reach and engage PLWH who are not in care.

Joseph “Buzz” Prejean, PhD

Branch Chief, CDC NCHHSTP, Division of HIV/AIDS Prevention, Behavioral and Clinical Surveillance Branch

The following are three CDC systems that provided data on PLWH who are out of care:

- National HIV Behavioral Surveillance (NHBS);
- National HIV Surveillance System (NHSS); and
- Medical Monitoring Project (MMP).

With these data systems, there are multiple ways to define “in care” and within the systems, one can define “medical care visit” differently. For example, NHSS only collects data on reported CD4 and viral load tests, whereas MMP also collects data on provider visits whether a CD4 or viral load test was conducted or not. The NHSS reports on data from 37 states and the District of Columbia, which have complete laboratory reporting. In those areas there were 653,962 PLWH, of which 27.5 percent were reported as out of care (defined as having no CD4 or viral load test reported in 2014, the latest year for which data were available). The MMP collects data on a sample of persons reported to NHSS in participating jurisdictions. Of these, 13.3 percent were determined to be out of care (defined as having fewer than two care visits in the 12 months preceding their interview, or having two care visits NOT separated by 90 days).

Multiple factors come into play in determining out of care rates. For example, opinions differ on what is considered adequate care. Within the MMP, most participants believed they were receiving adequate care, even those who were classified as out of care. Many participants who were considered out of care had achieved viral suppression while many participants who were considered to be in care had not achieved viral suppression. These findings indicate that participants who may not be receiving the standard of care were virally suppressed and/or still thought they were receiving quality care. In addition, participants had many reasons for being out of care. The most common reason reported was that there were obstacles in their lives that made it difficult to get care. Other common reasons reported by participants included problems with finances or insurance, not feeling sick, transportation challenges, and the health care provider not scheduling a follow up appointment within the time specified by guidelines. For PLWH who have achieved viral suppression, their physician may schedule appointments every 12 months or longer.

Dr. Prejean referred to the recently published funding opportunity, *Integrated HIV Surveillance and Prevention Programs for Health Departments*, CDC’s flagship health department funding opportunity. This initiative is designed to increase the percentage of people who know their status, and link people to biomedical and behavioral interventions as appropriate and help them stay there, with the ultimate goal of improving viral suppression among all people living with HIV, and decreasing HIV transmission. It supports services to increase PrEP and post-exposure prophylaxis (PEP) uptake, and behavioral interventions designed to support adherence to treatment. In addition, CDC’s Prevention Research Synthesis Project publishes the *Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention* with chapters on risk reduction interventions, medication adherence interventions, and interventions to support linkage, retention, and re-engagement in HIV care. The *Compendium* includes five evidence-based interventions and nine evidence-informed interventions. Capacity-building assistance is available to health departments and community-based organizations in these areas.

Julie Dombrowski, MD, MPH

Associate Professor of Medicine, University of Washington, and Deputy Director, Public Health, Seattle and King County HIV/STD Program

The Seattle and King County HIV/STD Program has engaged in a significant data-to-care effort to re-engage PLWH lost to care. As the program engaged in this process, the most significant finding is that most PLWH who appear to be out of care are not actually out of care. When they analyzed their data, they found that the vast majority of PLWH had moved, died, or transferred care. Additionally, in most cases, data-to-care efforts did not lead to successful re-engagement in HIV care. For example, with the Madison Clinic data-to-care activities, only 20 PLWH (out of 157

eligible cases) were re-linked to care. Furthermore, many PLWH who achieve successful outcomes (e.g., re-linkage, viral suppression) do so without intervention. They concluded that the data-to-care approach requires significant effort to identify a very small number of PLWH who were actually out of care.

Given the small number of PLWH who are actually lost to care, the Seattle and King County HIV/STD Program has sought to improve retention/re-engagement interventions and offer out-of-care PLWH something different than the same system that failed to engage them in the first place. The MAX Clinic (MAXimum Assistance) is designed to remove access barriers and offers walk-in access to medical care, direct phone access to case managers, text message communication, and a focus on harm reduction. In addition, various incentives are used to encourage PLWH to remain engaged in treatment. These include snacks and meal vouchers, cell phones, bus passes, \$25 payment for medical visits and blood draws, and \$50 payment for achieving viral suppression. Medical case managers help with both outreach and navigation. Other support includes a day program with adherence support, housing case managers, jail release planners, and an office-based opioid treatment team. Of the clients served by the MAX Clinic, 80 percent have achieved viral suppression, with 54 percent achieving continuous viral suppression.

Antoine D. Brantley, MPH

Data Analyst, Louisiana Office of Public Health, STD/HIV Program

The Louisiana Links Program is a data-to-care strategy that was implemented on a statewide basis beginning in October 2013. It utilizes surveillance data to identify PLWH who are newly diagnosed and not linked to care; previously diagnosed, but in need of re-engagement; and in care, but not achieving viral suppression. It is an electronic referral system that provides weekly, automated updates. The weekly updates are an important aspect of the program's success.

The outreach and navigation process includes attempts to locate RWHAP clients until all methods are exhausted. Linkage coordinators are health department staff who have access to the data on a regular basis. Once contact with the client is established, staff attend the first few clinic and supportive service appointments with the client. Providers are selected based on clients' needs. "Red carpet" treatment is provided and reminders are sent. Follow up with the client continues for the first three months. The program uses an approach described as "radically affirming and holistic," which seeks to understand the barriers and opportunities related to mental health, substance use, language, poverty, immigration status, domestic violence, community violence, and family dynamics. Frontline staff receive training on how to address the challenges faced by PLWH.

As with the Seattle program, analysis of the data resulted in a very high number of cases that were ineligible for follow up. Of PLWH identified, October 2013-June 2017, 8 percent of those lost to care were re-engaged. For clients that are re-engaged, there are very good results. Baseline viral suppression rates were at 25 percent. This has increased to as high as 71 percent and is currently at 64 percent. Clients report being linked to more appropriate care providers, an increase care and treatment literacy, better service navigation, and improved connections to family and sexual partners. Programs that facilitate transition from incarceration for PLWH also exist.

Challenges experienced by Louisiana Links include quality of surveillance data, revising enrollment expectations, and designing services for clients who are not well served by existing services.

Erika Samoff, PhD

HIV/STD/Hepatitis Surveillance Manager, North Carolina Department of Health and Human Services, Division of Public Health, Communicable Disease Branch,

North Carolina conducts the data-to-care approach on a statewide basis. Surveillance, care, drug dispensing, and insurance data are used to generate an out-of-care list, which is updated monthly. The definition of out-of-care is no evidence of a medical visit in 12 months. The PLWH on the list tend to be older and have been diagnosed with HIV for many years. To prioritize their efforts, the health department focuses on those who have been out of care for less than three years. It also focuses on certain demographic groups, such as MSM of color and women.

Bridge counselors conduct the investigation. As with the other programs, very few of the PLWH on the list are actually lost to care. For example, 53 percent of PLWH on the list are actually in care (i.e., patient churn).

As with the other programs, PLWH perceptions and challenges play a major role in accessing care due to a number of issues, such as lack of transportation, language barriers, and cultural issues. Specifically, PLWH in rural areas experience significant challenges in accessing care due to a lack transportation and few providers. Other challenges include concerns about cost of care, judgment on the part of providers, drug use, homelessness, and family concerns. In addition, Latinos in North Carolina, given their relatively recent residency in the state, are a population that is hard to reach. To address these challenges, the health department is providing cultural competency training to help with re-engagement. In addition, HIV health equity clinics focus on providing PLWH access to care that is culturally competent.

Discussion

Dr. Mermin asked if any of the data-to-care efforts are using pharmacy data to track those on ART, and to glean whether they are filling their prescriptions. Doing so would provide insight into those who are actually maintaining their treatment regimen. Dr. Dombrowski noted that these data would be very beneficial and that they have been in contact with commercial pharmacies. The challenge is the sharing of data. Dr. Cheever added that collecting pharmacy data is difficult given that there are many local pharmacies and mail order pharmacies. Many programs use missed medical visits and/or gaps in laboratory data to track PLWH who have fallen out of care. Ideally, using pharmacy data would allow more real-time identification of potential gaps in care and is worth pursuing further.

Dr. Havens stated that RWHAP Part D recipients have case managers that work with pharmacies and that also conduct home visits for medication management. Mail order delivery of medications continues to be a problem in terms of monitoring whether patients fill prescriptions and are taking their medications. He added that navigators are a key piece in re-engagement. The navigators should not be based at a specific provider, thus, allowing navigators to focus on linking PLWH to the best provider for their needs.

Dr. Taylor asked how data-to-care interventions can be expanded to all RWHAP recipients, given limited resources, which are forcing many clinics to become less welcoming/accommodating to the hard-to-reach clients in terms of limiting walk-ins, etc. Dr. Dombrowski noted that clinics need to focus on patient-centered care.

Dr. Saag stated that there are some African countries that have achieved the 90-90-90 goals established by the Joint United Nations Programme on HIV/AIDS (UNAIDS)/World Health Organization (WHO). He asked how the U.S. could achieve this success. Dr. Mermin stated that countries use different methodologies to measure their success.

Mr. Aleshire noted that King County has achieved the UNAIDS/WHO goals. He also reported that patients are monitored through ADAP and case managers are notified if medications are not picked up.

Dr. Williamson noted the importance of client relationships within a clinic. With small clinics, it is easier to notice when patients drop out of care as their absence is noted by others. This can serve as a very strong motivation to stay in care.

Public Comment

Jules Levin

National AIDS Treatment Advocacy Program

Mr. Levin stated that more research is necessary on effective linkage to care and PrEP, especially in relation to transmission of HIV. He emphasized that PLWH do not want to transmit the virus. He stated that he is looking forward to the discussion related to aging and HIV as this is a very important issue.

Rebekah Horowitz

National Coalition of STD Directors

The increasing STD rates in the United States require a national response. Congenital syphilis must be addressed. Ms. Horowitz asked how the RWHAP, BPHC, and CDC will address STDs. She noted that recent funding for congenital syphilis is one time only. Long-term funding is required to address congenital syphilis and a public health emergency should be declared.

Jeff Klausner, MD, MPH

David Geffen School of Medicine, University of California, Los Angeles

Kimberly Miller

Senior Policy Officer, HIV Medicine Association (HIVMA)

Dr. Klausner and Ms. Miller thanked the CHAC for the opportunity to provide public comments on behalf of the Infectious Disease Society of America (IDSA), HIVMA, and the Pediatric Infectious Diseases Society (PIDS). They reported that IDSA represents more than 11,000 physicians, scientists, and other health care professionals who specialize in infectious diseases. HIVMA is a professional society nested within IDSA representing more than 5,000 HIV clinicians and researchers working on the front lines of the HIV, HCV, and other STD epidemics. The 1,100 PIDS members are the core professionals advocating for the improved health of children with infectious diseases both nationally and around the world, participating in critical public health and medical professional advisory committees that determine the treatment and prevention of infectious diseases, immunization practices in children, and the education of pediatricians.

Their comments focused on the unprecedented rise in STD cases across the country, as described by the CDC in the September 2016 Sexually Transmitted Disease Surveillance Report. The CDC reported that the majority of these new diagnoses (1.6 million) were cases of Chlamydia, but there were also 470,000 new gonorrhea cases and almost 28,000 cases of primary and secondary syphilis. If left undiagnosed and untreated, all three of these preventable diseases can have serious health consequences, including infertility, life-threatening ectopic pregnancy, stillbirth in infants, multisystem organ disease due to syphilis including ocular disease and neurosyphilis, and increased risk for HIV transmission.

These findings should serve as a wake-up call that business as usual will no longer suffice with regard to addressing the STD crisis and concerted timely action from the federal government is of the essence, including declaration of a national public health emergency on this issue. They urged HRSA and CDC to take the lead in articulating a national STD control strategy to mount a comprehensive accelerated response that would include the following components.

Support an FY 2019 budget request for a \$40 million increase in STD funding to provide a much needed jump-start for state and local health departments and clinics to fight the rise in STDs. Federal funding for state and local public health infrastructure and personnel is insufficient to allow for the necessary follow-up and partner services for the more than two million new STD cases, including HIV, that are reported annually. We will not be able to curtail these epidemics without a significant boost in the resources to stop the spread of STDs and enhance preparedness for emerging threats such as drug-resistant gonorrhea.

Commit to ending congenital syphilis, the significant increase in which may be linked to opioid use. The CDC has indicated its intention to strengthen the congenital syphilis response with focused efforts to improve diagnosis and treatment of pregnant women and ensure prompt treatment of newborns in the ten states hardest hit by congenital syphilis. This should include activities consistent with WHO recommendations to achieve the goal of eliminating mother-to-child transmission of syphilis or congenital syphilis, with benchmarks and an estimation of resources required to achieve this endpoint. Every case of congenital syphilis should be considered a sentinel public health event, including investigation of missed opportunities for diagnosis and treatment by health care providers. We have tools to eliminate congenital syphilis and must invest the resources necessary to do so.

Support expanded provider education on STD screening recommendations and clinical presentation of STDs. We must accelerate efforts to educate clinicians about the importance of STD screening, including extra-genital screening, periodic screening for those who are HIV-infected, and screening every three months for those on PrEP. Ways to reach clinicians could include partnerships with medical provider and public health organizations, clinical medical education, and training opportunities, flyers or posters for clinics, podcasts, smart phone apps, social media outreach, and other resources.

Support measures to address price and supply issues for penicillin. We urge CDC and HRSA to undertake measures to ensure timely availability of appropriate medications for treating STDs. Since May 2016, the Food and Drug Administration (FDA) has sounded the alarm about a dangerous shortage of Bicillin L-A (Penicillin G benzathine or BPG). This shortage seriously hampers efforts to treat syphilis. Currently there is only one supplier of BPG in the U.S. Public and transparent engagement with that supplier is urgently needed among federal and local officials, advocates, and professional organizations. We urge a federal review of this shortage to

assess its causes and develop solutions to address immediate issues and help ensure a reliable supply of this important medicine.

Even when BPG is available, its cost can be a barrier to access that we urge you to address. One way to do this would be by declaring the STD epidemic a public health emergency, which might allow additional flexibility regarding the use of 340B medications. The 340B program offers discounted prices for outpatient prescriptions for certain safety-net providers. This would be extremely helpful to improve treatment access in areas where price and supply are barriers. Penicillin is an old and inexpensive drug that costs only pennies per dose to manufacture and yet the price of BPG has skyrocketed. As an example, at an Atlanta-based clinic without access to 340B pricing, the price is \$318 per dose. Because of BPG's high price, insurers are not fully covering provider costs or are not covering BPG at all. We offer two specific examples but there are likely many more, the Aetna Medicare 2017 Comprehensive Formulary considers BPG a non-preferred (Tier 4) drug and Anthem's national formulary does not include BPG on its formulary. Due to price and coverage restrictions, any physicians, including obstetricians and gynecologists are referring their patients to local health departments for treatment, causing treatment delays and even loss to follow-up for treatment. These high prices and the insurance industry's response to them are unacceptable, in general, but unconscionable in the context of a public health crisis. One way to immediately address this would be to allow health departments to use their 340B procurement authority to buy BPG at the significantly lower 340B price and then distribute the medication to local public health designated providers and sites that diagnose and treat syphilis. We also urge HHS to work with private insurers to consider additional opportunities to expand access to BPG.

Increase efforts to educate providers on partner notification and treatment services and encourage the use of expedited partner therapy (EPT). Most states require treating providers to make a good faith effort to notify partners of patients with STDs including syphilis. Given the limited or absence of local public health resources to conduct partner notification activities, enhancing provider awareness of their responsibility could help facilitate timely and effective partner notification and treatment. In August 2006, CDC recommended the practice of EPT for certain populations and specific conditions, and CDC continues to recommend it in Sexually Transmitted Diseases Treatment Guidelines, 2015. According to CDC analysis, EPT is currently permissible in 41 states, potentially allowable in seven states, and prohibited in two states (Kentucky and South Carolina). However, more clinician training is needed to engage them in partner notification services and encourage the use of EPT where appropriate. Continuing to address reimbursement issues for EPT in the private sector also will be crucial to implementation.

Advocate for re-establishment of clinical quality measures for STD screening. When the National Quality Forum (NQF) last undertook review of the infectious diseases measures set (clinical quality measures that are used in the various federal quality improvement and value-based incentive programs), many measures were retired or dropped, including the measure for STD screening. We recommend that CDC and HRSA work with the NQF to develop and submit for NQF endorsement updated STD screening measures in order to promote clinician adherence to treatment guidelines with regard to STD screening.

Thank you for your consideration of our views, and please call on us as a resource as the Committee considers ways to better address the STD epidemics. We can be reached through Colin McGoodwin of IDSA cmcgoodwin@idsociety.org, Kimberly Miller of HIVMA at kmiller@hivma.org, or Christy Phillips of PIDS at cphillips@idsociety.org.

Angelique Griffin

Gilead Science FOCUS Initiative

Gilead launched the FOCUS program in 2010 to develop replicable model programs that embody best practices in HIV screening and linkage to care. The program now has 96 partner organizations in 17 cities across the United States that are heavily impacted by HIV. The program is focused on expanding HIV and HCV screening, especially screening in emergency departments (EDs) and using the EHR to identify patients who have previously been in care.

Undetectable Viral Load and HIV Transmission Messaging Update**Nathan Fecik, MPH**

Public Health Advisor, HHS, Office of the Assistant Secretary of Health, Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)

Reduced viral load is associated with reduced transmission of HIV. Treatment as prevention (TasP) and the achievement of viral suppression is considered the single most important strategy for ending new HIV infections. However, it is important to acknowledge limitations. Studies have shown that while high numbers of participants achieve viral suppression, often over 80 percent, fewer people maintain viral suppression. In two studies, one-third of participants did not maintain viral suppression for one to two years.

In order to ensure optimal response to TasP, it is essential to have consistent messaging. Federal agencies have used different terminology, such as “zero risk,” “zero or almost zero risk,” and “negligible risk.” Such differences can result in confusion. In response, an HHS working group is focused on developing consistent messages about the effectiveness of HIV testing and viral suppression to prevent sexual transmission of HIV. The working group has identified core message elements. An example of an effective, consistent message is, “People living with HIV who take HIV medications daily as prescribed and achieve and then maintain an undetectable viral load for at least six months have effectively no risk of sexually transmitting the virus to an HIV-negative partners.”

The working group also identified secondary messaging topics related to using TasP as a risk reduction strategy. These include key benefits of HIV treatment, research found no linked transmissions, time to suppression, adherence, frequency and stability of viral load monitoring, viral blips, STDs and pregnancy, and talking to partners about TasP.

CDC has already added TasP-related messaging to its landing page and incorporated language in National Gay Men’s HIV/AIDS Awareness Day promotions. The website, HIV.gov, has incorporated the language in blog posts. Next steps related to the messaging include federal agencies updating their materials, CDC conducting message testing, finalization of messages, and integration of messages across websites, social media, and communications campaigns.

CHAC Treatment as Prevention Workgroup Report

Amy Leonard, MPH

Vice President of Public Health Services, Legacy Community Health Services
CHAC Member and Workgroup Chair

Ms. Leonard opened the discussion by asking CHAC members' response to the HHS working group's messaging around TasP. Several members expressed that TasP can be very liberating for PLWH – if they achieve viral suppression, they will not transmit the virus. The desire not to transmit HIV can also reinforce adherence. However, members raised multiple issues and concerns, including, but not limited to, the following:

- Messaging related to TasP is divisive and does not take into consideration the experiences of all PLWH. For example, some PLWH cannot achieve viral suppression because they are infected with a strain of HIV that is not responsive to ART.
- The six-month timeframe may be confusing to the target audience. Why six months? What happens after six months?
- Members were concerned about how to craft messages in the context of sexual health. What will the messaging be around STDs? PLWH who are virally suppressed are still at risk of other STDs and active STDs could result in HIV transmission.
- While messaging must be comprehensive and address concerns of stakeholders, it must also remain simple to ensure uptake by both frontline staff and PLWH. Messages should also be tailored to the sexual partners of PLWH and address PrEP, STDs, and condoms.
- Drug users, especially people using methamphetamine, have issues related to viral suppression and viral blips. These populations may need tailored messaging.

Dr. Mermin stated that extensive message testing will take place and there will be different messages tailored to different audiences (e.g., providers, PLWH). Testing will also explore how to address difficult issues such as the six-month period and what to tell people about varying rates of viral suppression over time.

Ms. Leonard asked members to consider possible recommendations for CDC and HRSA. For example, should CDC and HRSA require their recipients to integrate TasP-related objectives and messaging?

School-Aged LGBTQ Youth Health Workgroup Report

Debra Hauser, MPH

President, Advocates for Youth
CHAC Member and Workgroup Chair

The workgroup is currently focusing on exploring the evidence related to interventions designed to support lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth in schools. The workgroup invited a speaker on this topic.

What School Strategies, Interventions, Program, Environments Make a Positive Difference in the Lives of LGBTQ Youth

Joseph G. Kosciw, PhD

Chief Research and Strategy Officer, Gay, Lesbian & Straight Education Network (GLSEN)

GLSEN is a national education organization focused on ensuring safe schools for all students – one where every child learns to respect and accept all people, regardless of sexual orientation or gender identity/expression. GLSEN conducts research on these issues and assists chapter and student leaders and other safe school advocates in conducting local research and evaluation to document, promote, and improve local efforts.

U.S. schools are hostile environments for a large number of LGBTQ youth, as the research demonstrates.

- Feelings of safety – 57.6 percent of LGBTQ students felt unsafe at school because of sexual orientation, 43.3 percent because of gender expression.
- Anti-LGBTQ language – 98.1 percent students heard “gay” used in a negative way at school; 67.4 percent heard these remarks frequently or often.
- Experiencing victimization – 70.8 percent of LGBTQ students were verbally harassed because of sexual orientation, 54.5 percent because of gender expression.
- Experiencing discrimination – 81.6 percent of LGBTQ students reported that their school engaged in LGBT-related discriminatory policies/practices; 66.2 percent reported to have personally experienced anti-LGBT discrimination.

LGBTQ students face a more hostile school climate than their non-LGBTQ peers. They are more likely to be bullied/harassed, to have experienced sexual harassment and/or cyberbullying, and to have missed school in the past month because they felt unsafe/uncomfortable. In addition, they are more likely to report that they do not plan to complete high school. This hostile school climate has been shown to impact LGBTQ students’ academic success. It also impacts mental health, with high rates of depression and low self-esteem.

There has been improvement. The incidence of homophobic remarks have declined (remarks about gender expression have not). School climate for LGBTQ has improved over time, yet remains hostile for many.

LGBTQ students with greater access to school resources report better school experiences. These resources include student clubs (i.e., gay/straight alliances), inclusive curricular resources, supportive educators, and comprehensive policies. While many schools do not offer these important resources, the numbers have been growing. Even one supportive educator in a school can make a difference.

While there has been improvement, the impact varies. Many trainings are not specific to LGBTQ youth; they focus on broader topics, such as bullying. These do not seem to have an impact on the environment for LGBTQ students. Trainings should focus on building skills. School staff receive information, but they do not know how to put what they have learned into practice. Likewise, generic policies are not effective. Policies need to be specific to LGBTQ youth – they must be inclusive and comprehensive.

School-based health education often does not meet the needs of LGBTQ youth, thus the youth seek information elsewhere. Only 5.7 percent of LGBTQ students report being taught LGBTQ-specific, relevant, and positive information in health education at school. LGBTQ students are much more likely than their non-LGBTQ peers to seek health information online.

In response to these needs, GLSEN calls for more research on best practices for educator interventions to support LGBTQ youth and development of comprehensive sexual education for LGBTQ youth.

Recap Day One/Review Day Two

Dawn Fukuda, ScM, CHAC Co-Chair

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

Ms. Fukuda presented the following summary of the day's proceedings:

- Update from HRSA on the role of health centers in the delivery of HIV and HCV care.
- Update from CDC including information on the updated HIV/AIDS prevention strategic plan and responses to increasing HCV transmission, increasing STD transmission, and the opioid crisis.
- Update on RWHAP, including 2016 RWHAP Services Report (RSR) data.
- Data-to-care strategies.
- Effective services for the subset of PLWH who are extremely difficult to retain in care, such as an acuity-based system for those facing significant challenges in their lives.
- Evolving STD epidemic and the possible need to declare a public health emergency.
- HHS messaging related to TasP.
- Improving the school environment for LGBTQ youth.

Discussion

Members discussed the day's presentations and possible actions and recommendations.

TasP

- The data are sufficient to support the TasP messaging. Patients are looking to federal agencies for a statement.
- Federal agencies need to provide leadership. Timing is critical. There is already information about TasP available, such as "U=U." There also needs to be an effort to reach skeptics with the evidence, including skeptical scientists and policymakers. Currently there are laws related to HIV transmission that are based on inaccurate science. These can be very stigmatizing for PLWH.
- Providers need guidance from federal agencies so they can begin developing their own messaging related to TasP.
- Accompany TasP messaging with messages about PrEP and condoms.
- Develop messages that are inclusive (e.g., messages for people who cannot achieve viral suppression).

Addressing the STD Epidemic

- Members expressed concerns about the implications of declaring a public health emergency. Would it make a difference in addressing the epidemic? Are there specific actions that would result with the declaration?
- A public health emergency could allow for the re-allocation of resources and the development of performance measures related to STDs. AETCs could be mobilized.
- Some members felt that declaring a public health emergency would be counter-productive. It would raise expectations, but would be unlikely to result in additional resources. Others thought the additional visibility could be important.
- The CHAC could adopt some of the recommendations in the IDSA/HIVMA/PIDS public comment.
- The CHAC needs more information on what CDC and HRSA are doing to improve STD screening.
- The STD epidemic should be addressed in the context of holistic sexual health.

Re-engagement in Care

- The CHAC should consider recommendations to HRSA about identifying and disseminating best practices related to re-engagement, such as open appointments, longer appointments, intensive case management, etc.

LGBTQ Youth

- The workgroup has developed recommendations for CHAC consideration.
- There was not enough time at the meeting for a thorough discussion of this issue.

HIV and Aging

- Mr. Byrd stated that HIV and aging is a huge issue and the CHAC needs more time to address it. Members should consider how to frame the issue for future discussions.

Dissemination of Best Practices

- RWHAP national conferences provide a venue for HAB to disseminate information on best practices related to TasP, STDs, and re-engagement.

Dr. Cheever recessed the meeting at 5:00 p.m. on October 25, 2017.

Opening Session: October 26, 2017

Laura Cheever, MD, ScM

Associate Administrator, HRSA, HAB
CHAC DFO, HRSA

Dr. Cheever conducted a roll call to determine the CHAC voting members, *ex-officio* members (or their alternates), and liaison representatives in attendance. She announced that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record. She reminded the CHAC voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and to recuse themselves from voting or participating in these matters.

CONFLICT OF INTEREST DISCLOSURES

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Richard Aleshire, MSW, ACSW (Washington State Department of Health)	Recipient of funding from CDC and HRSA/Ryan White HIV/AIDS Program (RWHAP).
Jean Anderson, MD (Johns Hopkins Medical Institutions)	Recipient of funding from HRSA/RWHAP and National Institutes of Health (NIH) and has stock in Gilead.
Peter Byrd (Peer Educator and Advocate)	No conflicts disclosed.
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Recipient of funding from CDC and HRSA/RWHAP.
Debra Hauser, MPH (Advocates for Youth)	Recipient of funding from CDC.
Peter Havens, MD, MS (Children's Hospital of Wisconsin)	Recipient of funding from HRSA/RWHAP and the National Institute of Child Health and Human Development.
Devin Hursey (U.S. People Living with HIV Caucus)	Recipient of from HRSA/RWHAP
Amy Leonard, MPH (Legacy Community Health Services)	Recipient of funding from CDC and HRSA/RWHAP.
Jorge Mera, MD (W.W. Hastings Indian Hospital)	HRSA/RWHAP-funded AIDS Education and Training Center (AETC) Program and funding from Oklahoma University; advisory board member of Gilead Sciences and AbbVie in 2016.
Greg Millett, MPH (amfAR)	Advisory board member of VIVE Initiative.
Susan Philip, MD, MPH (San Francisco Department of Public Health)	Recipient of funding from CDC and HRSA/RWHAP and an unpaid public health advisor for GlaxoSmithKline.
Michael Saag, MD (University of Alabama at Birmingham, School of Medicine, UAB Center for AIDS Research)	Recipient of funding from HRSA/RWHAP and NIH and a consultant for BMS, Merck, Gilead, and ViiV.
Linda Scruggs, MHS (Ribbon Consulting Group)	Recipient of funding from HRSA/RWHAP.
Bradley Stoner, MD, PhD (Washington University School of Medicine)	Recipient of funding from CDC.
Lynn Taylor, MD, FACP (The Warren Alpert Medical School of Brown University)	Recipient of funding from HRSA/RWHAP.

Dr. Cheever confirmed that the 19 voting members and ex-officio members in attendance (or their alternates) constituted a quorum for CHAC to conduct its business on October 26, 2017. She reconvened the meeting at 9:01 a.m. and welcomed the participants to the CHAC meeting.

HIV/AIDS Bureau Data Dashboards, Benchmarking, and Case Mix Adjustment Initiatives

Laura Cheever, MD, ScM

Associate Administrator, HRSA, HAB
CHAC DFO, HRSA

Dr. Cheever introduced the session. She stated that it is a priority for HAB to use RWHAP data to demonstrate the effectiveness of the program and identify areas for improvement. Data dashboards (both internal and external) will allow users, including project officers, recipients, clients, and stakeholders, to more easily access, use, and measure RWHAP client, service, and outcomes data. Benchmarking allows for the comparison of client outcome data. HAB anticipates using benchmarking for quality improvement.

Stacy Cohen

Branch Chief, HRSA, HIV/AIDS Bureau, Division of Policy and Data, Evaluation, Analysis, and Dissemination Branch

Miranda Fanning

Branch Chief, HRSA, HIV/AIDS Bureau, Division of Policy and Data, Data Management and Analysis Branch

This project will allow RWHAP recipients, HAB leadership and project officers, clients, and other stakeholders to:

- Monitor service utilization and health outcomes of RWHAP clients;
- Access and compare recipient-level data to state and national performance measures and benchmarks;
- Identify disparities in care outcomes to focus efforts or improvement; and
- Track progress toward achieving national goals toward ending the epidemic.

Data dashboards are interactive online portals that allow users to track key data. Dashboards use data visualizations to simplify complex datasets and provide users with customizable, “at a glance,” awareness of program performance. The proposed dashboards will allow users to more easily access, understand, monitor, and compare RWHAP service utilization and HIV-related health outcomes data. The long-term goal is to make service site-level outcomes data available to the public. A user friendly, interactive visualization interface allows users to generate tailored reports and monitor progress toward RWHAP and national goals.

Benchmarking is a methodology that allows for the comparison of performance to an external standard or a similar entity’s performance. It can be used to facilitate or motivate quality improvement activities. It can also help clinical service sites compare client outcomes data to other service sites. To implement benchmarking, HAB proposes to develop a risk adjustment model that adjusts for factors that are outside of the control of the service site and have been shown in literature to be associated with clinical outcomes. The risk-adjustment model incorporates client-level characteristics (case-mix) that are associated with differences in client outcomes that are not affected by a RWHAP site’s services. For example, youth ages 13-24 have been shown to have lower viral suppression rates than other age groups. A clinic with many clients in this age group could have lower viral suppression rates.

HAB held a technical expert panel (TEP) in September 2017 that brought together experts to provide individual input to HAB on this topic. TEP participants made many suggestions, including:

- Work closely with stakeholders throughout development and deployment;
- Provide context to visualized data and obtain input on what information should be displayed;
- Display ribbon or badge on dashboard for service sites showing high performance; and
- Share data in a way that service sites can compare client outcomes data to other sites with similar characteristics.

In FY 2018, HAB anticipates initial development and pilot testing of the internal dashboards and finalization of the benchmarking methodology. External dashboards are anticipated in FY 2019 with the release of the public-facing site in FY 2020. Technical assistance will be provided to project officers and recipients during the roll out.

Discussion

Ms. Fukuda asked if HAB could link to other data sets, such as surveillance data, to include PLWH who are out of care and provide a broader picture of health outcomes. Ms. Cohen stated that HAB is exploring this, but there are many issues related to linking to other data sets. Under consideration are ADAP data and census data. Neither CDC nor HAB use personal identifiers in their data sets.

Dr. Saag asked if there would be any consequences for RWHAP recipients related to performance. Data can be manipulated to misrepresent performance. Dr. Cheever stated that the focus is on quality improvement. Eventually, pay-for-performance may be considered, but that will not occur in the near future.

Mr. Aleshire commented that in Washington all RWHAP funds are used for ADAP. Other services are paid for with 340B rebate funds. Services supported with 340B funds are not reported in the RSR. He strongly encouraged HAB to have recipients report these data to HAB. Dr. Cheever said that HAB is looking at ways to capture these data. Mr. Aleshire added that the ADAP Data Report (ADR) captures insurance status at time of enrollment. Many clients are subsequently enrolled in insurance, so this is actually under reported in the ADR. HAB should look at collecting data for some indicators, such as insurance status, on a regular basis, not just once.

Dr. Havens stated that HAB should focus on the denominator in determining the benchmarking formula and on including the clients for which providers are accountable. This would ensure that RWHAP recipients are held accountable for the patients under their care.

HIV and Aging Workgroup Update

Peter Byrd, CHAC Co-chair Workgroup Co-Chair

Mr. Byrd proposed a framework for considering HIV and aging. He proposed exploring the following aspects of HIV and aging:

- Neurological;
- Psychosocial; and
- Behavioral.

Specific issues that should be considered include:

- Nursing home models for PLWH;
- Cardiovascular disease;
- Renal issues;
- Depression, mental health, and trauma-related issues;
- Elder abuse;
- Access to geriatric subspecialty care and other necessary specialties;
- Increasing cultural competence related to aging; and
- Workforce issues.

Dr. Saag suggested that the issue could be framed by looking at unique aspects of aging for PLWH, such as earlier onset of cardiovascular disease, frailty, etc.

Ms. Fukuda suggested that HAB explore RSR data to determine services utilization needs of older PLWH.

CAPT Ilze Ruditis of HHS/Substance Abuse and Mental Health Services Administration (SAMHSA) stated that resources on HIV and aging are available from the SAMHSA-HRSA Center for Integrated Health Solutions.

Input Requested by CHAC from Members

Mr. Byrd asked CHAC members to provide input on the following key questions regarding HIV and aging:

1. What challenges are related to care delivery?
2. What challenges are related to service providers?
3. What partnerships are necessary?
4. What pilot programs are necessary?
5. Where is more research necessary?

Congenital Syphilis Panel

Letha Healey, MD

Medical Officer, HRSA, HAB

Dr. Healey introduced the panel on congenital syphilis.

Gail Bolan, MD

Director, CDC, Division of STD Prevention (DSTDP)

Congenital syphilis rates have increased significantly since a low in 2011. There was an 88 percent increase in cases from 2012 to 2016. Rates of primary and secondary syphilis in women also increased 111 percent during this time. Cases are concentrated in specific states – California, Texas, Florida, Louisiana, Georgia, Maryland, Arizona, Illinois, and Ohio accounted for 73 percent of cases in 2016. In some areas, the increase seems to be tied to poverty and substance use disorders, with both methamphetamine and opioids. In 2016, there were 628 reported cases of congenital syphilis. For the mothers of these cases, many did not receive adequate screening and treatment during their pregnancy. Over 25 percent of mothers of these cases in 2016 did not receive any prenatal care.

Dr. Bolan noted that there is a need to improve both early screening and timely treatment. In addition, biomedical advances are critically needed to improve diagnostic tests to detect active infection, expand effective antimicrobial options, and support vaccine research.

In response, CDC convened a Syphilis Summit in January 2016 with national experts and issued a Syphilis Call to Action in April 2017. While other actions are outlined for gay, bisexual and other men who have sex with men, specific congenital syphilis actions identified include the following:

- Enhancing maternal and congenital syphilis surveillance to capture maternal syphilis, fetal syphilis, stillbirths, infant morbidity, and congenital syphilis cases averted;
- Congenital syphilis case reviews using the infant morbidity review board model in selected states/counties to identify missed opportunities that could inform public health prevention interventions;
- Developing a congenital syphilis prevention cascade to monitor the progress in addressing the congenital syphilis epidemic;
- Developing tools and best practices that can be used to assess local context of congenital syphilis cases and to implement high impact interventions;
- Working with other CDC Centers (e.g., Division of Reproductive Health - Pregnancy Risk Assessment Monitoring System, Birth Defects Division-Zika surveillance registries); other federal agencies (HRSA/Maternal and Child Health Bureau, HRSA/Bureau of Primary Care, HHS/Office of Women's Health, SAMHSA), and partner organizations (American College of Obstetricians and Gynecologists, American Academy of Pediatrics, Association of Maternal and Child Health Programs, March of Dimes) to sound the alarm; and
- Updating the *1988 Guidelines for the Prevention and Control of Congenital Syphilis*.

CDC has provided funding to nine state or local STD prevention programs to strengthen their response to congenital syphilis.

Judith Steinberg, MD, MPH

Chief Medical Officer, HRSA, BPHC

Health centers are an important source of care for women of childbearing age (ages 15-44). Over 6.7 million women of childbearing age received care from health centers in 2016. Of these, 599,848 were prenatal patients (295,913 delivering) – 74 percent of these women had their first prenatal visit in the first trimester and 8 percent gave birth to low birth weight babies. Two of the 16 Uniform Data Set (UDS) Clinical Quality Measures relate to prenatal care – early entry into prenatal care and low birth weight.

Health centers do not collect data on congenital syphilis. In 2016, health centers treated 214,478 patients with syphilis or other STDs.

Aaron M. Lopata, MD, MPP

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

The mission of the MCHB is to improve the health of America's mothers, children, and families. MCHB has an FY 2017 budget of \$1.24 billion, with \$551 million going to the Title V Maternal and Child Health (MCH) Block Grant Program (for states) and \$377 million for the Maternal, Infant, and Early Childhood Home Visiting Program.

The State Block Grant program has played an important role in the increase in the percentage of infants born to mothers who receive early prenatal care in the U.S. Rates improved from 71 percent in 2007 to 77 percent in 2015. The State Block Grant program has played a lead role in the 18 percent decline in infant mortality in the U.S. from 7.2 infant deaths per 1,000 live births in 1997 to 5.9 infant deaths per 1,000 in 2015.

State MCH programs play a role in ensuring that OB/GYN and pediatric providers are current on CDC guidelines, including guidelines related to STDs and HIV. State MCH programs work with providers to ensure that all pregnant women who test positive for syphilis are treated without delay. However, nearly 30 percent of congenital cases in 2014 were among pregnant women who tested positive, but received no treatment. Another 21 percent received inadequate treatment.

California is an example of how a state MCH program worked to address this challenge. In response to rising congenital syphilis rates, the MCH program: worked with local health departments to identify causes; reached out to infected pregnant women to ensure that they and their partners received treatment; intensified follow-up on contacts of syphilis cases, particularly women of childbearing age; and promoted linkages to prenatal care and prenatal screening, including third trimester and delivery screening.

The Maternal, Infant, and Early Childhood Home Visiting Program supports visits to women during the first trimester. It presents a unique opportunity to identify women at risk for syphilis and can play a role in early prenatal care syphilis screening and follow up, including timely treatment.

Lisa Masinter, MD, MPH, MS

Medical Director, Chicago Department of Public Health, Bureau of Maternal, Infant, Child and Adolescent Health

The Chicago Department of Public Health's (CDPH's) Maternal, Infant, Child, and Adolescent Health program has three main areas of programming – maternal and women's health, nutrition/ Women, Infants, and Children (WIC), and child and adolescent health. The program works to address congenital syphilis through various activities. These include the Adverse Birth Outcome Reporting System, home visit coordination, Maternal Mortality Review Committee, and the Perinatal Advisory Committee. It also collaborates with every birthing hospital to address postpartum needs. The HealthyChicagobabies.org website has information on congenital syphilis. There also has been a prenatal care media campaign. The program is also working to increase awareness about HIV and other STDs through the Chicago Wears Condoms campaign and the Chicago Healthy Adolescents and Teens website. However, more coordination and collaboration between public health and prenatal providers is needed. The program has been successful in reaching out to prenatal providers on Zika. This could be a model for coordination on congenital syphilis.

Irina Tabidze, MD, MPH

STI Epidemiologist, Chicago Department of Public Health, HIV/STI Bureau

Cook County, Chicago, had 1,018 cases of primary and secondary syphilis in 2016. Rates have risen dramatically for men and remained fairly level for women. Most cases of congenital syphilis are among African Americans and concentrated in the south and west side of Chicago.

Of cases of congenital syphilis, 39 percent of women did not receive prenatal care. Of those who did receive prenatal care, 60 percent did not receive adequate treatment. The provision of adequate treatment has been impacted by the shortage of penicillin G benzathine (Bicillin L-A).

In response to the increase in congenital syphilis cases, CDPH has engaged in the following activities:

- Enhanced congenital syphilis surveillance activities and data collection through a web-based surveillance and case management system and by using Adverse Pregnancy Outcome Reporting System (APORS) data to identify cases.
- In collaboration with the state of Illinois, developed the Congenital Syphilis Morbidity and Mortality Case Review Board with over 30 members to identify gaps to inform public health action.
- Conducted exploratory interview of females diagnosed with syphilis. They found that most women have a history of STDs, but had little information about syphilis. The women report having positive experiences with disease intervention specialists (DIS) and indicated that they learned more about STDs from DIS than from their physician.

In March 2016, CDPH launched a congenital syphilis media campaign with posters, bus ads, and provider materials. The campaign was a very cost-effective way to raise awareness. For example, the bus ads cost only \$5,000.

Discussion

Dr. Stoner asked if health centers collect data on STDs. Dr. Steinberg stated that the UDS is being modernized and BPHC is reviewing the data set.

Dr. Anderson asked if cases of congenital syphilis are under-reported, especially in terms of stillbirths. Dr. Bolan stated that collection of stillbirth data is a challenge and improvement is needed in completing reporting forms. If syphilis is reported in pregnant women, DIS can follow-up with the mother to ensure adequate treatment and facilitate evaluation of other children in the household. DIS could also follow-up with mothers of stillbirths and test for syphilis if not done at the time of delivery to prevent possible future cases of congenital syphilis. Dr. Tabidze added that Chicago has worked on this issue using Adverse Pregnancy Outcomes Reporting System data, which led to the identification of additional cases.

Dr. Anderson asked why women do not receive prenatal care. Dr. Bolan stated it is complex, such as drug testing laws of pregnant women in some areas and women fear losing their child. Dr. Tabidze added that women prefer to go to an STD clinic than a private provider – STD clinics are confidential and free. Providing prenatal care in STD clinics better meets the needs of these women. Dr. Bolan added that in some areas STD clinics are not the provider of choice for women, so it depends on the area.

Dr. Anderson stated that screening for syphilis in the third trimester should be routine. She also stated that CDC should address the shortage of penicillin G benzathine (Bicillin L-A).

Dr. Saag asked why women do not complete treatment. Dr. Tabidze stated that sometimes treatment is provided too late to treat the fetus. In other cases, the course of treatment is not completed or the woman is referred to a clinic that stocks benzathine penicillin and is lost to follow-up and not treated. In some cases, the baby is premature and delivered before treatment can take place. Dr. Bolan added that the correct treatment is provided in most cases.

Dr. Williamson asked whether there is a requirement with Title V that requires collaboration with local health departments and other stakeholders on STDs. Dr. Lopata stated that MCHB does not place requirements on block grants. States do have to provide details on their plan and MCHB encourages collaboration. In addition, MCHB recognizes that there needs to be improved coordination between the home visit program, which started in 2010, and Title V. Dr. Williamson stated that federal agencies need to have better coordination and demand that states carry out specific activities. With reducing perinatal transmission of HIV, intensive case management played a major role. It is also important to address IPV, sexual assault, and survival of childhood abuse.

Dr. Mermin asked if HRSA could recommend that all pregnant women receiving home visits be screened for syphilis and HCV, given that there is already guidance related to such screenings for pregnant women. Dr. Lopata stated that states must use evidence-based models and that a specific process must be followed to add new requirements. Dr. Mermin added that both mothers and children could be screened for perinatally transmitted infections by the home visit program and provided treatment if necessary.

Dr. Havens stated that the pediatric demonstration projects, launched by MCHB, became RWHAP Part D and had a significant impact on perinatal transmission of HIV and the treatment of pediatric

HIV. He suggested that MCHB might launch a similar initiative with HCV and congenital syphilis in the hardest hit jurisdictions. Dr. Lopata said that MCHB is supportive of demonstration projects.

STD Workgroup Update

Susan Philip, MD, MPH

Deputy Health Officer, San Francisco Department of Health, Disease Prevention and Control,
Population Health Division
CHAC Member and Workgroup Co-Chair

Bradley Stoner, MD, PhD

Associate Professor of Medicine, Washington University School of Medicine
CHAC Member and Workgroup Co-Chair

The CHAC STD workgroup is made up of 17 members, all experts in the field of STDs and HIV both from the public and private sectors. The workgroup has reviewed the CDC's draft recommendations for providing quality clinical STD services. The recommendations focus on levels of STD care and outline the minimum services that should be available at each level. The two levels of care are basic STD care and specialized STD care. Basic service provision sites included HIV care, primary care, family planning, federally qualified community health centers, adolescent health, school-based health clinics, and others.

The workgroup's draft recommendations for CHAC consideration address seven categories:

- Sexual history and physical examination;
- Prevention;
- Screening;
- Partner services;
- Evaluation of STD-related conditions;
- Laboratory tests and treatment; and
- Treatment.

In its review, the workgroup made general comments related to recommendations and identified areas for clarification.

Discussion

Mr. Byrd stated that there is a shortage of dermatologists available to remove venereal warts. Dr. Stoner stated that STD clinics provide treatment for warts and this shortage might be specific to a geographic area.

Dr. Cheever asked what evidence the workgroup is using to identify the appropriate level of care services. Dr. Stoner stated that the workgroup relies on a Delphi model with expert review.

Dr. Bolan stated that the guidelines outline services that should be available in the various settings and that providers would then use the CDC STD treatment guidelines to determine if the service is recommended for their patient.

Mr. Hursey asked why there are no guidelines for anal Pap smears for MSM. Dr. Bolan stated that there is insufficient evidence to support this recommendation. CDC continues to monitor the evidence and makes changes accordingly.

Dr. Saag asked that for recommendations that include the word “should” would there be punitive actions if providers did not carry out the task. Dr. Bolan stated that this is guidance for providers. They are tools, not rules.

Perinatal Viral Hepatitis Workgroup Update

Peter Havens, MD, MS

Pediatric Infectious Disease Specialist, Children’s Hospital of Wisconsin
CHAC Member and Workgroup Co-Chair

The number of reproductive-aged women with acute and past/present HCV infection was over 31,000 in 2014, double the number of cases in 2006. In more than 90 percent of people infected, HCV can be cured with direct acting antiviral agents (DAAs) administered daily for eight to 12 weeks. Safety and efficacy during pregnancy has not yet been established. Treatment before pregnancy is optimal to prevent infant infection and maternal disease progression. Current HCV testing recommendations are risk based. There is no specific recommendation to test all pregnant women. Universal one-time screening has been shown to be cost effective. Screening for HCV during pregnancy could help to identify infected individuals and linked them to care.

The workgroup has several recommendations for the CHAC to consider:

- Current recommendations related to identifying, linking to care, and treating women of childbearing potential and pregnant women with HCV and infants exposed to HCV are not effective and need to be revised.
- Universal HCV screening of all pregnant women is strongly recommended.
- Artificial barriers to treatment (e.g., waiting for liver damage, cessation of drug use) should be removed.
- Define best testing for infants. Currently available data suggest RNA at one to two months of age could be appropriate since waiting until 18 months leaves too many infants untested.
- CHAC should recommend that CDC publish guidance on these issues.

The CHAC may want to engage in further discussion on these issues, including the following:

- Screen using HCV ab with reflex RNA.
- Universal testing of pregnant women when operationally easiest.
- Universal testing of pregnant women in areas of high prevalence.

Discussion

Dr. Anderson stated that the American Congress of OB/Gyn and the NIH/National Institute of Child Health and Human Development were involved in the discussions and expressed concerns about the recommendations. Specifically, they were concerned about the increased burden on obstetricians to counsel women, especially where treatment during pregnancy is not

recommended and it might lead to an increase in operative delivery, even though this is not recommended.

Dr. Taylor stated that the workgroup's recommendations do not address women of childbearing age who inject drugs and are on contraception. Everyone should be screened. Dr. Anderson noted that risk-based screening is not effective with pregnant women. Women do not disclose their risk behaviors. Universal screening is an opportunity to identify these women and link them to care. The women encounter the health care system due to pregnancy.

Ms. Fukuda stated that due to the opioid crisis, everyone should be screened.

CHAC Business Session

Dawn Fukuda, ScM, CHAC Co-Chair

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

The CHAC considered resolutions and recommendations on several issues addressed during the meeting.

Expanded Guidelines for HCV Screening of Women of Childbearing Potential and in Pregnancy

Proposed Resolution

Background and Rationale: The epidemic of HCV is a profound healthcare and public health challenge. There are estimated to be 3.5 million persons living with HCV in the United States (range 2.5 - 4.7 million). New HCV infections in the U.S. have nearly tripled since 2010 and CDC estimates that approximately 34,000 persons are newly infected with HCV in this period. The National Notifiable Diseases Surveillance System (NNDSS) (Ly et al 2017) estimates that the number of reproductive-aged women with acute and evidence of past or present HCV-infection doubled from 15,500 in 2006 to 31,039 in 2014. It is also estimated that up to 29,000 HCV-infected women gave birth each year from 2011-2014, with an estimated 1,700 infants perinatally infected with HCV. Cost-effective analysis suggests that HCV screening (using HCV antibody+/HCV-RNA+ as definition of infection) is cost effective at the prevalence threshold of 0.1 percent. Preliminary data from multicenter observational cohort of HCV in pregnant women found a prevalence of 1.7/1000. HCV can be cured in >90 percent of persons with DAAs, although safety of HCV treatment during pregnancy has not yet been established.

Recommendations:

- 1.) CHAC recommends that CDC issue guidance to encourage universal HCV screening of pregnant women in the U.S.** Women of childbearing potential are at risk for HCV and pregnancy, at a time when women are most likely to engage with the health care system, this provides a unique opportunity to identify HCV infection for linkage to treatment after pregnancy and prevention of transmission in subsequent pregnancies. Also, related to universal screening:

- a. Risk-based screening should not be recommended because of the link with illicit drug use; fear of stigma and concern about involvement with child protective authorities often results in denial of risk and may result in refusal of testing in those with risk factors.
 - b. Prevalence-based screening may be considered, but requires more surveillance data than is currently available and is more operationally challenging.
- 2.) **CHAC recommends that CDC issue guidance to support HCV RNA testing of exposed infants at 1-2 months of age.**
- 3.) **CHAC acknowledges that current epidemiologic and cost-effectiveness data also supports universal one-time HCV screening for all U.S. individuals over 18 years of age, including women of childbearing potential and urges CDC to strongly consider this strategy.** Identification and treatment of HCV-infected individuals will save lives and reduce further transmission.
- 4.) **CHAC recommends that CDC issue guidance to support HCV antibody testing with reflex HCV RNA testing to identify individuals in need of treatment.**
 - a. **Those individuals who are HCV ab+/HCV RNA may not represent clearance of past infection requiring counseling regarding risk or re-infection.**
- 5.) **CHAC recommends CDC gather further surveillance data on HCV infection to inform operational activities around HCV prevention and treatment.**
- 6.) **CHAC recommends that CDC devote resources to exploring effective linkage to care strategies for HCV-infected mothers and exposed infants.**
- 7.) **CHAC recommends that CDC advocate for removal of artificial barriers to treatment (e.g. liver fibrosis scores, drug abstinence, requirements for specialist providers).**

CHAC Action

The CHAC discussed passage of this recommendation, with two minor changes to recommendations numbers 3 and 4, to emphasize the importance of linking to opioid treatment.

Ms. Fukuda called for an action on the resolution. Dr. Lynn Taylor properly placed a motion on the floor for the CHAC to approve the resolution. Dr. Bradley Stoner seconded the motion. The motion was passed unanimously by the CHAC.

The recommendations will be submitted to the Director, CDC.

STD Workgroup Document on Draft CDC Recommendations for Basic and Specialized Settings

Proposed Resolution

Background and Rationale: The CDC, NCHHSTP, DSTDP has developed a draft document on *Recommendations for Providing Quality STD Clinical Services*. These recommendations focus on clinical operations and will serve as a complement to the CDC *Sexually Transmitted Diseases Treatment Guidelines*. The main objectives of the document are to define levels of STD care and outline minimum services to be available by each level. The CHAC STD workgroup was charged with reviewing the draft document of the *Recommendations for Providing Quality STD Clinical Services* and providing their findings.

The key questions used in reviewing the document included the following:

- General overall comments.
- Is there content that should be included that is currently not in the document?
- Does any of the information/recommendations need further clarification?
- Are there concerns about any of the recommendations?

The recommendations in the document address seven main categories:

- 1) Sexual History and Physical Examination;
- 2) Prevention;
- 3) Screening;
- 4) Partner Services;
- 5) Evaluation of STD-related Conditions;
- 6) Laboratory Tests;
 - At the time of the patient visit;
 - Clinical laboratory;
- 7) Treatments;
 - On site; and
 - Prescription.

The STD workgroup's recommendations are presented in Attachment 1.

CHAC Action

Ms. Fukuda called for an action on the resolution. Dr. Peter Havens properly placed a motion on the floor for the CHAC to approve the resolution. Dr. Jean Anderson seconded the motion. The motion was passed unanimously by the CHAC.

The recommendations will be submitted to the Director, CDC.

Response to STD Epidemic

Proposed Resolution

Rates of reported STDs continue to rise in the U.S., causing great concern for the health and well-being of the nation. Chlamydia, gonorrhea, and syphilis cause untold suffering and can lead to devastating long-term consequences if not treated promptly and properly, as well as ongoing sexual and perinatal transmission. As such, the CHAC strongly urges CDC and HRSA leadership to consider the following actions with regard to the current STD crisis:

- 1.) Rising rates of STDs must be recognized as an urgent public health threat in order to focus greater public attention and mobilize the resources necessary for effective prevention and control. Federal agencies must advocate for increased FY 2019 funding to support expanded screening, testing, treatment, partner services, and provider education activities across the nation.
- 2.) Greater professional engagement must occur across HIV and STD prevention platforms to amplify critical resource impact and to address the co-transmission of HIV and other STDs. HIV prevention messages must emphasize the critical need for STD screening among populations at risk, and STD prevention messages must include HIV screening and prevention (e.g., PrEP) as part and parcel. Toward this end, the CHAC requests:
 - a. Formal presentations at the May 2018 CHAC meeting from HRSA/HAB and CDC/DHAP/DSTDP and CDC/ Division of Adolescent and School Health (DASH) to discuss:
 - Outcomes of current prevention activities implemented in 2017;
 - Future strategic planning to ramp up STD prevention; and
 - CHAC advice and suggestions for improving this work.
 - b. Consideration to hold an urgent technical consultation in early 2018, which would pull together experts from a variety of disciplines, to discuss novel ways to support STD prevention efforts across NCHHSTP divisions.
- 3.) The emphasis on congenital syphilis elimination in the U.S. must be continued and expanded, with a focus on enhanced screening and treatment of pregnant women, and enhanced training of health professionals who provide prenatal and perinatal care.
- 4.) Cost and supply barriers to essential STD medications must be quickly addressed through creative, meaningful engagement with agencies and organizations responsible for medication availability and access. Supply limitations, stock-outs, and cost run-ups of such essential medications as benzathine penicillin G, doxycycline, and gemifloxacin are unacceptable and will only serve to perpetuate the current crisis.
- 5.) Provide visible and forceful leadership to the nation's health care workforce with regard to best practices in STD clinical care. This includes the development and dissemination of expanded guidelines for quality care, greater use of expedited partner therapy (EPT)

where appropriate, and seamless integration of STD screening and treatment in HIV clinical care and prevention.

- 6.) Work toward the development of metrics that could be incorporated as quality measures in different health systems, to monitor the extent to which providers adhere to best practices in STD clinical care and prevention. These may be tied to reimbursement or clinical scorecards, with the goal of increasing adherence across a variety of clinical venues.

CHAC Action

Ms. Fukuda called for an action on the resolution. Dr. Michael Saag properly placed a motion on the floor for the CHAC to approve the resolution. Ms. Amy Leonard seconded the motion. The motion was passed unanimously by the CHAC.

The recommendations will be submitted to the Director, CDC.

Additional Discussion

Ms. Hauser asked that CDC address the issue of whether long-acting reversible contraception could be contributing to increases in STDs. CDC's Division of Reproduction Health should be included in these discussions.

High-Impact Investment through Schools to Improve LGBTQ Health and Well-being

Debra Hauser, MPH

President, Advocates for Youth
CHAC Member and Workgroup Chair

The workgroup has used data from the YRBSS, which reports on six types of health-risk behaviors that contribute to the leading causes of death and disability among youth and adults. These data have provided insights on violence, bullying, drug use, depression, and suicide. In response, the workgroup has worked to call attention to these data. In the proposed resolution, the workgroup calls for CDC to prioritize interventions that have been shown to improve LGBTQ health and well-being.

Discussion

Dr. Anderson asked whether there are best practices for gay student organizations, especially around being more inclusive of people of color. Ms. Hauser stated that these organizations vary widely, but they have been shown to change the environment within a school. She encouraged CHAC members and others who are aware of strategies to promote racial inclusiveness in these organizations to provide this information.

Dr. Havens asked whether HRSA addresses teacher education. Dr. Cheever stated that she is not aware of HRSA programs focusing on teachers. MCHB has done some work around bullying. CDC's DASH does conduct teacher training and funds education agencies to carry out this work. Ms. Hauser added that DASH receives \$32 million in funding, which is not enough funding to carry out the work necessary. In addition, many school districts lack the political will to carry out this work.

Dr. Williamson stated that gay straight alliances (GSAs) tend to be in more affluent schools and schools are often very segregated. It is necessary to foster GSAs in all schools and they need to be more inclusive of people of color. Community-based organizations can play a role in this. They can work directly with schools. The U.S. Department of Education funds some of these organizations. Ms. Hauser stated that there are effective community-based organizations, but that they need funding.

Mr. Hursey asked if the workgroup's recommendations address intersectionality (i.e., reflect different identities such as gay, person of color, living with HIV, etc.). Ms. Hauser said that the document is based on all the evidence that the workgroup could identify. Teachers should be trained to work with the populations they serve and intersectionality must be addressed at the school district level.

Proposed Resolution

Research indicates sexual minority young people (LGBTQ young people) are at higher risk for stigma and discrimination than their heterosexual counterparts.¹ Victimization by peers is one of the strongest predictors of school disengagement, and research indicates LGBTQ students experience high levels of victimization in schools.² Analysis from the 2015 National YRBSS – the first to include questions on sexual orientation and same sex sexual behavior at the high school level – indicates lesbian, gay, bisexual and questioning (LGBQ) young people are, in fact, more likely to develop risky health behaviors than their heterosexual peers. In the 2015 National YRBSS, LGB students reported a significantly higher prevalence of being bullied at school (34.2 percent vs. 18.8 percent), being forced to have sexual intercourse (17.8 percent vs. 5.4 percent), experiencing physical dating violence (17.5 percent vs. 8.3 percent), and experiencing sexual dating violence (22.7 percent vs. 9.1 percent). They also were significantly more likely to report having ever used drugs, including hallucinogens (LGB, 11.5 percent; questioning, 15.7 percent; straight, 5.5 percent), heroin (LGB, 6.0 percent; questioning, 9.3 percent; straight, 1.3 percent), methamphetamines (LGB, 8.2 percent; questioning, 10.8 percent; straight, 2.1 percent), and prescription drugs not prescribed by a physician (LGB, 27.5 percent; questioning 24.3 percent; straight, 15.5 percent).³ While there is limited data about the experiences of LGBTQ middle school youth, research indicates that harassment and bullying is most prevalent at the middle school level and often targets young people perceived to be LGBTQ by their peers.⁴

In addition, and perhaps as a result, LGBQ students reported being significantly more likely to have felt sad or hopeless than their heterosexual peers (LGB, 60.4 percent; questioning, 46.5 percent; straight, 26.4 percent) and reported a higher prevalence of suicide-related behaviors over the past year than their heterosexual counterparts, including seriously considering suicide (LGB, 42.8 percent; questioning, 31.9 percent; straight, 14.8 percent), making a suicide plan (LGB, 38.2 percent; questioning, 27.9 percent; straight, 11.9 percent), attempting suicide (LGB, 29.4 percent; questioning, 13.7 percent; straight, 6.4 percent), and having a suicide attempt that resulted in an injury, poisoning, or overdose that required medical treatment (LGB, 9.4 percent; questioning, 4.7 percent; straight, 2.0 percent).³

To date, the YRBSS has not successfully included a question that accurately assesses gender identity, although a question was piloted in 15 locales in the 2017 YRBSS and results are pending. Nevertheless, research shows gender expansive and transgender young people experience high levels of discrimination and harassment – often at even greater rates than their LGB peers do.

For instance, in GLSEN's 2015 National School Climate Survey, a large majority of LGBTQ students (85.7 percent) reported hearing negative remarks specifically about trans people, including phrases like "tranny" or "he-she," and 40.5 percent of these students reported hearing these remarks "frequently" or "often." Moreover, school policies often target LGBTQ and especially transgender students as the 2015 Survey found that over half of transgender students (50.9 percent) were prevented from using their preferred name or pronoun (compared to 19.9 percent of LGBTQ students overall) and over half of transgender students (60 percent) were forced to use a bathroom or locker room that corresponded with their legal sex regardless of their gender identity or gender expression.⁴

Finally, lesbian and bisexual high school females experience nearly twice the rate of unintended pregnancy than do their heterosexual peers.⁵ African-American/Black and Latino/Hispanic YMSM, and transgender women, including transgender women of color, continue to acquire HIV at disproportionate rates.⁷

School-based Interventions

Research indicates there are strategies, tactics, and interventions schools can undertake to improve the health and well-being of LGBTQ young people.

Teacher Training as the Highest-impact Priority

Research indicates that availability of supportive school staff is key in helping LGBTQ young people feel safer in their schools. LGBTQ students who reported having supportive school staff experienced less victimization, reported greater psychological well-being, and had better academic outcomes. The presence of supportive educators also mitigated the effects of victimization on students' mental health, and emotional and academic support from educators had positive effects on students' academic and psychological well-being.⁸ Supportive school staff had stronger positive effects on the school environment and student well-being than other LGBTQ-related school supports, including supportive student clubs; positive representations of LGBTQ people, history, and events in the curriculum; and comprehensive anti-bullying/harassment policies.⁸

Gay Straight Alliances

Research indicates the mere presence of a GSA in a school helps to improve the health and well-being of LGBTQ students in that school. A meta-analysis, of 15 primary studies, including 62,923 participants, suggests GSAs are correlated with lower levels of victimization of LGBTQ young people in schools.⁹

Students who had a GSA in their school were less likely to hear "gay" used in a negative way often or frequently (59.3 percent compared to 77.1 percent of students who did not have a GSA in their school); were less likely to hear homophobic remarks such as "fag" or "dyke" often or frequently (51.0 percent vs. 68.0 percent); were less likely to hear negative remarks about gender expression and transgender people often or frequently (gender expression: 59.6 percent vs. 66.8 percent; transgender people: 35.9 percent vs. 46.0 percent); were more likely to report that school personnel intervened when hearing homophobic remarks (20.6 percent vs. 12.0 percent said that staff intervene most of the time or always); were less likely to feel unsafe because of their sexual orientation than those without a GSA; experienced lower levels of victimization related to their sexual orientation and gender expression; reported a greater number of supportive school staff and more accepting peers; and felt more connected to their school community than students without a GSA.⁹

Enumerated Anti-Discrimination and Anti-Bullying Policies

Anti-discrimination and anti-bullying policies are essential but are only effective in improving LGBTQ students' health and well-being when they are enumerated. Almost all principals (96 percent) reported having anti-bullying policies; however, less than half had policies that specifically addressed bullying on the basis of sexual orientation (46 percent) and on the basis of gender identity (39 percent).¹⁰ Research has demonstrated a distinct difference between general anti-bullying policies and those that enumerate bullying based on sexual orientation, gender identity, and gender expression (SOGIE). LGBTQ students report similar levels of harassment in schools that have general, non-inclusive policies, as those with no anti-bullying policies. LGBTQ students in schools with SOGIE-inclusive policies, on the other hand, report a more positive climate.¹¹ In a 2016 study, which was the first to measure the relationship between schools' anti-bullying policies and LGBTQ students' feelings of safety and victimization, the "findings showed that LGBTQ students in districts with SOGIE-inclusive [sexual orientation and gender identity/expression] anti-bullying policies reported significantly greater feelings of safety, less victimization experiences (e.g., harassment and assault based upon sexual orientation and gender expression), and less social aggression than those students in districts with generic policies or no/unidentified policy. In fact, the researchers found LGBT students with a generic anti-bullying policy or no/unidentified policy did not differ from one another on most measures of safety and victimization used in the study."¹²

Inclusive Curricula

According to GLSEN's 2015 National School Climate Survey, less than a quarter of LGBTQ students (22.4 percent) received classroom lessons with positive representations of LGBTQ people, history, or events. However, the 2015 Climate Survey found that for those students who received LGBTQ-inclusive classroom lessons, the LGBTQ-inclusive curriculum was strongly correlated with more positive school climates. More specifically, LGBTQ students in schools with LGBTQ-inclusive curriculum were less likely to hear "gay" used in a negative way often or frequently (49.7 percent of students with inclusive curriculum vs. 72.6 percent of students without inclusive curriculum), were less likely to hear homophobic remarks such as "fag" or "dyke" often or frequently (40.6 percent vs. 64.1 percent), were less likely to hear negative remarks about gender expression and trans people often or frequently (gender expression: 50.7 percent vs. 66.6 percent about gender expression and 26.8 percent vs. 44.5 percent about transgender people), were less likely to feel unsafe because of their sexual orientation (40.4 percent vs. 62.6 percent), were less likely to miss school in the past month (18.6 percent of students with an inclusive curriculum missed school in past month because they felt unsafe or uncomfortable compared to 35.6 percent of other students), were less likely say they might not graduate high school (1.4 percent vs. 4.1 percent) and less likely to not plan on pursuing post-secondary education (5.1 percent vs. 7.0 percent), and were more likely to report that their classmates were somewhat or very accepting of LGBTQ people than other students (75.8 percent vs. 41.6 percent).⁴

In addition, LGBTQ-inclusive sex education is essential for assisting LGBTQ young people to gain the knowledge and skills necessary to protect themselves from unintended pregnancies, HIV and other STDs, and dating violence. Recent technological advances, including PrEP and PEP as well as new ARTs, show great promise for ending the HIV epidemic. Data indicate, however, that African-American and Latino young MSM remain at disproportionate risk for contracting HIV and few have knowledge about or access to these new technologies.¹³ In fact, as of October 2017, the packaged prescription drug for PrEP, Truvada, has not been approved for HIV prevention among adolescents.¹⁴

Linkages to Services

LGBTQ young people experience bullying, depression, violence, and drug use at disproportionate rates than their heterosexual peers.¹¹ As such, it is essential that they be able to access confidential, LGBTQ and youth-friendly health care services in the community. Support from school personnel, including linkages to and referrals from trusted school staff to community-based health care services, can assist LGBTQ youth to access and remain in care.^{2, 4, 11}

Suicide Prevention Training

Although suicide is the third leading cause of death among youth ages 10-19 in the U.S., many school districts do not have comprehensive policies and procedures in place relating to youth suicide and its prevention. Although research has been limited, it has shown that training high school personnel as gatekeepers is an important strategy. Study findings reinforce the importance of training individuals in frequent contact with adolescents to recognize when a young person is in distress, assess suicide risk, and refer the young person to support resources. Such trainings increase knowledge, confidence, and feelings of competence.¹⁵

With respect to school-based strategies that are targeted at students themselves, the Yellow Ribbon gatekeeper approach is the primary program that has been evaluated. A recent evaluation suggests that implementation of a Yellow Ribbon school-based suicide prevention program in mid-west schools led to significant improvements in suicide-related knowledge, comfort level, and behavioral intent for help-seeking in case of suicidal thoughts among adolescents. In fact, more than 77 percent of respondents reported feeling comfortable seeking help for suicidal thoughts after Yellow Ribbon training compared to 57 percent prior to training.¹⁶

Primary Recommendations:

- The CHAC strongly urges CDC/DASH to prioritize, invest in, and advocate for the following high-impact, evidence-based interventions.
- Professional development for middle and high school teachers regarding LGBTQ students, their health, rights, and needs to increase their support for LGBTQ students in their school buildings.
- To assist schools in training their staff, CDC should:
 - Fund efforts to identify the core content and skills necessary to build educators' support for LGBTQ young people, and
 - Help develop cost-effective, high-impact mechanisms to provide professional development for school-based middle and high school educators regarding LGBTQ students' health and well-being.

In addition, CHAC recommends that CDC continue to prioritize, invest in, and advocate for the following:

- The creation of GSAs in middle and high school.
- LGBTQ enumerated anti-discrimination and anti-bullying policies and programs in middle and high school.
- LGBTQ-inclusive curricula that provide students with positive images of LGBTQ people, history, and events in middle school and high school.

- Health education, and in particular sex education, that is LGBT-inclusive and offers demonstrations regarding proper condom use and up-to-date information about technological advances in HIV prevention and care.
- Linkages between schools and community-based, LGBTQ-reflective and youth-friendly health care services that include HIV and STD prevention and care, mental health counseling, suicide prevention and crisis intervention, and drug and alcohol treatment.
- Comprehensive and LGBTQ-inclusive suicide prevention policies and programs, including teacher training.
- The development of and inclusion in the state, local and national YRBSS of a question that effectively assesses gender identity.

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CHAC Action

Ms. Fukuda called for an action on the resolution. Dr. Peter Havens properly placed a motion on the floor for the CHAC to approve the resolution. Dr. Lynn Taylor seconded the motion. The motion was passed unanimously by the CHAC.

The recommendations will be submitted to the Director, CDC.

Identification and Dissemination of Best Practices in HIV Care Settings

Proposed Resolution

The CHAC considered the following actions:

- 1.) **HRSA should continue to solicit successful intervention from recipients and publish resources of best practices across HIV service programs.**
- 2.) **HRSA should present best practices form states/cities/programs at one or more national conferences (e.g., the RWHAP National Conference), sessions at other national meetings, as well as in published guidance or practice manuals.**
- 3.) **HRSA should continue to prioritize, invest in, and advocate for low-threshold, accessible models of care to re-engage PLWH who are out of care.**
- 4.) **HRSA should offer capacity building and technical assistance services to HIV programs to improve engagement and retention in care services.** HRSA should identify/develop/promote the core content necessary to provide professional development regarding cultural sensitivity training to clinicians and staff interacting with PLWH to encompass ethnic/racial/cultural/ linguistic minorities and differences; sexual and gender minorities and differences; low literacy/educational/economic disadvantages; drug-involved populations; people contending with correctional systems; persons with unstable housing; disability; and geriatric/aging populations.

Discussion

Dr. Havens asked how HAB could work to ensure that recipients incorporate best practices. Dr. Cheever stated that with the RWHAP, decisions related to services and activities are made at the local level. Recipients have reported that they do not have funding to expand activities. It is challenging to simply maintain existing services.

Dr. Havens stated that the data-to-care presentations demonstrate the challenge of reaching the small number of PLWH who are difficult to retain in care. It is necessary to explore how the system must be changed to address the needs of this small population of PLWH. It needs to be viewed as a positive change – making the system better. Many view the process of re-engagement negatively.

Mr. Millett stated that the programs presented during the panel were carried out with supplemental funding and asked what RWHAP recipients could do if they do not have supplemental funding for

these activities. Dr. Cheever stated that in the past HAB has made information technology (IT) funds available, but RWHAP recipients have not accessed them. Some states are using 340B rebate funds and others use discretionary funds. Jurisdictions have been working incrementally to carry out these activities.

Mr. Aleshire stated that RWHAP recipient site visits provide an opportunity to share best practices.

CHAC Action

Ms. Fukuda called for an action on the resolution. Mr. Richard Aleshire properly placed a motion on the floor for the CHAC to approve the resolution. Mr. Greg Millett seconded the motion. The motion was passed unanimously by the CHAC.

The recommendations will be submitted to the Administrator, HRSA.

Consistent Messaging Across Federal Programs for Treatment as Prevention (TasP)

Proposed Resolution

Members of the CHAC met on October 25-26, 2017, and discussed the proposed language from the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) regarding the effectiveness of TasP, and the potential for TasP to reduce new HIV infections in the United States. CHAC members would like to express our strong support for the proposed message from OHAIDP, and the clear articulation that when HIV-positive individuals accomplish durable viral suppression that there is effectively no risk of transmission to sexual partners. CHAC members are also appreciative of the consultative process to develop his messaging, including participation from providers, advocates, and people living with HIV. We support the ongoing efforts by OHAIDP to test different TasP messages within the community and to determine the best ways to communicate the effectiveness of TasP to different audiences (people living with HIV, people who are HIV negative, medical providers, and others).

CHAC members strongly recommend that CDC and HRSA, along with other HHS federal agencies, promptly provide guidance to the field (inclusive of providers, advocates, frontline staff, and others) about how to integrate TasP messaging into HIV prevention and care services. There is tremendous enthusiasm to meaningfully integrate TasP into our prevention efforts, and we rely on the federal agencies to provide clear, consistent, and unified direction about how to describe the relative effectiveness of viral suppression to prevent sexual transmission of HIV. CHAC members also recommend a comprehensive TasP message that continues to emphasize the importance of complementary and highly-effective HIV prevention, including condoms and pre-exposure prophylaxis (PrEP). In addition, we appreciate the recognition that there is a need for sensitivity in using different messaging for individualized situations, such as the cases where some HIV-infected individuals may not be able to accomplish viral suppression due to medication tolerance or drug resistance challenges.

Discussion

Ms. Leonard stated that sexual health and family planning should be added to the section about a comprehensive message related to TasP.

Dr. Stoner asked if the CHAC had come to any conclusion about the statement related to maintaining viral suppression for six months. Ms. Fukuda stated that recommendations need to be evidence-based. Dr. Mermin stated that there is an element of risk related to almost all prevention strategies, including condoms and PrEP; however, these are still recommended.

Mr. Hursey stated that more discussions with PLWH advocates are necessary. Ms. Fukuda asked Mr. Hursey to provide the names of organizations that the CHAC should consult. Mr. Millett added that OHAIDP has been consulting with some advocacy organizations. Ms. Leonard stated that it might not be possible to get a consensus from the PLWH community.

Ms. Leonard stated that CHAC should continue to have discussions related to TasP.

CHAC Action

Ms. Fukuda called for an action on the resolution with the suggested revisions related to the inclusion of sexual health and family planning. Ms. Linda Scruggs properly placed a motion on the floor for the CHAC to approve the resolution. Ms. Debra Hauser seconded the motion. The motion was passed unanimously by the CHAC.

The recommendations will be submitted to the Acting Secretary, HHS.

Response to Declaration of the Opioid Crisis as a Public Health Emergency

Mr. Millett stated that the President has declared the opioid crisis a public health emergency. An estimated \$78 billion is necessary to address the opioid crisis in the United States. The President's plan does not call for any new funding. It will allow states to shift federal funds dedicated for HIV to address the opioid crisis. Given the significant gains that have been made in addressing HIV, the CHAC needs to emphasize the importance of maintaining current funding and efforts.

Mr. Millett added that in the early years of the HIV epidemic there was inadequate funding. More than 30 years later, HIV remains a challenge. A similar mistake should not be made in addressing the opioid crisis. Adequate funding would allow communities to address the crisis and prevent future suffering by those impacted by the opioid epidemic.

Discussion

Dr. Saag stated that the CHAC's statement should emphasize the harm that would result from shifting funds away from HIV. In addition, HIV-related funds are insufficient to address the opioid crisis, given the \$78 billion estimated cost. Mr. Millett added that funding to HRSA and CDC for HIV has been relatively level.

Dr. Taylor stated that "crisis" and "epidemic" have different definitions – epidemics related specifically to infectious diseases. This is an opportunity to educate.

Mr. Millett added that Congress has allocated \$2 billion to address the opioid crisis. Even with the HIV-related funding, this would be insufficient. Dr. Kaplowitz added that the funding from Congress is only for two years. States are just now initiating activities, which will require years to implement. Long-term funding is necessary.

CHAC Action

Ms. Fukuda called for a resolution for CHAC to draft a statement that will be circulated to CHAC members for comment and revision. Dr. Lynn Taylor properly placed a motion on the floor for the CHAC to approve the resolution. Ms. Linda Scruggs seconded the motion. The motion was passed unanimously by the CHAC.

The resolution will be submitted to the Acting Secretary, HHS.

Closing Session

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

The next CHAC meeting will be held in Atlanta, Georgia, from May 9-10, 2018. The meeting will be open to members of the public via webinar and teleconference.

Suggested Presentations

CHAC members suggested presentations for the May 2018 meeting:

- Presentation on the connection between the opioid crisis and infectious disease; and
- Presentation by Elinore McCance-Katz, MD, PhD, Assistant Secretary for Mental Health and Substance Use, HHS.

The CHAC meeting was adjourned at 2:49 p.m. 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.

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

H. Dawn Fukuda, ScM, Co-Chair (Date)
CDC/HRSA Advisory Committee on HIV,
Viral Hepatitis and STD Prevention and
Treatment



Attachment 1: STD Workgroup Review of Draft Document- Recommendations for Providing Quality STD Clinical Services

STD Workgroup: Review of Draft Document-Recommendations for Providing Quality STD Clinical Services

Summary Report, October 2017

This document summarizes the main findings from the draft document, Recommendations for Providing Quality STD Clinical Services review for feedback to the Centers for Disease Control and Prevention, Division of STD Prevention. Findings are based on individual comments by STD workgroup members.

Prepared by Susan Philip, Bradley Stoner, STD Workgroup Co-chairs with Roxanne Barrow and Letha Healey, Federal Liaisons

Background

The Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC, has developed a draft document on *Recommendations for Providing Quality STD Clinical Services*. These recommendations focus on clinical operations and will serve as a complement to the CDC *Sexually Transmitted Diseases Treatment Guidelines*. The main objectives of the document are to define levels of STD care and outline minimum services available to clients seen at each level, if recommended in the CDC *Sexually Transmitted Diseases Treatment Guidelines*.

Methods

The CHAC STD Workgroup was charged with reviewing the draft document of the *Recommendations for Providing Quality STD Clinical Services* and providing their findings.

Dr. Susan Philip, Deputy Health Officer, San Francisco Department of Health and Dr. Bradley Stoner, Associate Professor of Medicine, Washington University School of Medicine in St. Louis, served as the CHAC STD Workgroup Co-chairs. Dr. Roxanne Barrow, Medical Officer, CDC, DSTDP and Dr. Letha Healey, Division of Domestic HIV Programs, Office of HIV/AIDS Training & Capacity Development & Office of Program Support HIV/AIDS Bureau, HRSA, served as the Federal Liaisons. The workgroup consisted of seventeen (17) subject matter experts from the field of STDs and HIV in both the public and private sector.

The workgroup met on four separate occasions via teleconference from August 4, 2017 through September 29, 2017:

- 1) Orientation and overview of *Recommendations for Providing Quality STD Clinical* document (*one hour*) – Friday, August 4, 2017 (9:30 am PT/11:30 am CT/12:30 pm ET)
- 2) Review part 1 Basic STD Care Recommendations (*90 minutes*) – Friday August 18, 2017 (9:30 am PT/11:30 am CT/12:30 pm ET)
- 3) Review part 2 Specialized STD Care Recommendations (*90 minutes*) –Friday, September 15, 2017 (9:30 am PT/11:30 am CT/12:30 pm ET)
- 4) Review of comments/findings to be presented to the CHAC during the October meeting (*30-45 minutes*) – Friday, September 29, 2017 (9:30 am PT/11:30 am CT/12:30 pm ET)

Each workgroup member had an opportunity to review the full document and provide their individual feedback based on the key questions.

Key Questions

The key questions used in reviewing the document included the following:

- 1) General overall comments
- 2) Is there content that should be included that is currently not in the document?
- 3) Does any of the information/recommendations need further clarification?
- 4) Are there concerns about any of the recommendations?

Recommendation Categories

The recommendations in the document address seven main categories:

- 1) Sexual History and Physical Examination
- 2) Prevention
- 3) Screening
- 4) Partner Services
- 5) Evaluation of STD-related Conditions
- 6) Laboratory Tests
 - a) At the time of the patient visit
 - b) Clinical laboratory
- 7) Treatments
 - a) Onsite
 - b) Prescription

Findings

The collective feedback from the individual workgroup members are summarized by recommendation category. The outline of the recommendations are displayed in section A and the workgroup input is listed in section B.

I. SEXUAL HISTORY AND PHYSICAL EXAMINATION

A. Sexual History and Physical Examination – Guideline Recommendation

BASIC AND SPECIALIZED STD CARE	
<ul style="list-style-type: none"> ❖ A physical examination including external genital examination for patients with STD-related symptoms or concerns <u>should</u> be available as a basic and specialized STD care service ❖ A pelvic examination <u>should</u> be available as a basic and specialized STD care service 	
BASIC STD CARE	SPECIALIZED STD CARE
<ul style="list-style-type: none"> ❖ A sexual history and risk assessment <u>should</u> be available as a basic STD care service at the following patient visits: <ul style="list-style-type: none"> • Initial comprehensive visit • Each reproductive, genital or urologic visit • Annual visit ❖ A sexual history and risk assessment at each visit unrelated to reproductive, genital, or urologic concerns <u>would not</u> be expected as a basic STD care service ❖ Anoscopy <u>would not</u> be expected as a basic STD care service for patients with rectal signs or symptoms ❖ Colposcopy <u>would not</u> be expected as a basic STD care service for female patients with abnormal PAP smears 	<ul style="list-style-type: none"> ❖ A sexual history and risk assessment <u>should</u> be available as a specialized STD care service at every visit for patients with STD-related symptoms or concerns including behavioral and pregnancy intention ❖ Anoscopy <u>should</u> be available as a specialized STD care service for patients with rectal signs or symptoms ❖ Colposcopy <u>should</u> be available as a specialized STD care service for female patients with abnormal PAP smears

B. Sexual History and Physical Examination – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE
<ul style="list-style-type: none"> • Add last menstrual cycle in history as a reminder for contraception but also for screening and treatment considerations for pregnant women • Describe physical exam for males in more detail in text and table • Change “external” to “anogenital” examination • Thermometer <ul style="list-style-type: none"> ▪ Move from laboratory onsite ▪ Add language that thermometer is for vital signs • Anoscopy <ul style="list-style-type: none"> ○ Clarify type of anoscopy as “routine/general/standard” or “high resolution” ○ List “routine/general/standard” anoscopy as “should” be available

- List “high resolution” as “**could**” be available as clinically appropriate in patients with abnormal anal pap smears
- Add “digital rectal exam” before anoscopy
- Include language regarding examination and anoscopy in text and footnote

BASIC STD CARE

- Clarify pelvic exam including a speculum exam under basic services. If it means Pap smear, it should be stated.
- Change “**annual visit**” to “**at least annually, if not otherwise done**” for the recommendation, “*A sexual history and risk assessment **should** be available as a basic STD care service at the following patient visits: 1) initial comprehensive visits, 2) each reproductive, genital or urologic visit, and 3) annual visit.*”
- Change from “**would not**” to “**could**”-“A sexual history and risk assessment at each visit unrelated to reproductive, genital, or urologic concerns **would not** be expected as a basic STD care service.”

SPECIALIZED STD CARE

- Consider including language for substance abuse disorders in history taking section

KEY DISCUSSION POINTS

- The physical exam should be more descriptive for males
- The genital exam description should be broadened to include the anogenital exam
- The type of anoscopy should be described as “routine/general/standard” anoscopy and “**should**” be available in both the basic and specialized section
- Ensure language for sexual history at the basic level captures patients at high risk who may have disconnected care

II. PREVENTION

A. Prevention – Guideline Recommendation

BASIC AND SPECIALIZED STD CARE

- ❖ **The following prevention services should be available as a basic and specialized STD service:**
 - Onsite hepatitis B vaccination
 - Onsite HPV vaccination
 - Brief single STD/HIV prevention counseling (up to 30 minutes)
 - Pre-exposure prophylaxis for HIV (PrEP) and Nonoccupational postexposure prophylaxis for HIV (nPEP) risk assessment, education and referral/linkage

BASIC STD CARE	SPECIALIZED STD CARE
<ul style="list-style-type: none"> ❖ The following prevention services <u>could</u> be available as a basic STD service: <ul style="list-style-type: none"> • Onsite condom provision • Onsite hepatitis A vaccination • Onsite emergency contraceptive pills or by prescription • Brief contraceptive counseling or referral • Pre-exposure prophylaxis for HIV (PrEP) and Nonoccupational postexposure prophylaxis for HIV (nPEP) provision • Linkage to HIV care, contraceptive counseling, family planning services, and behavioral health services, if indicated • Moderate intensity STD behavioral counseling (≥30 minutes) ❖ The following prevention service <u>would not</u> be expected to be available as a basic STD service: <ul style="list-style-type: none"> • High intensity STD behavioral counseling (≥2 hours) 	<ul style="list-style-type: none"> ❖ The following prevention services <u>should</u> be available as a specialized STD service: <ul style="list-style-type: none"> • Onsite condom provision • Onsite hepatitis A vaccination • Onsite emergency contraceptive pills • Brief contraceptive counseling or referral • Pre-exposure prophylaxis for HIV (PrEP) and Nonoccupational postexposure prophylaxis for HIV (nPEP) provision • Linkage to HIV care, contraceptive counseling, family planning services, and behavioral health services, if indicated ❖ The following prevention services <u>could</u> be available as a specialized STD service: <ul style="list-style-type: none"> • Moderate intensity STD behavioral counseling (≥30 minutes) • High intensity STD behavioral counseling (≥2 hours)

B. Prevention – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE
BASIC STD CARE
<ul style="list-style-type: none"> • Change onsite condom provision from “could” to “should” • Change onsite hepatitis A vaccination from “could” to “should” for providers that care for MSM • Change onsite emergency contraceptive pills or by prescription from “could” to should” • Change brief contraceptive counseling or referral from “could” to should” • Change linkage of HIV care from “could” to “should” or “should be available or referral to a place of availability especially HIV linkage to care.” Inconsistent to have PrEP and nPEP risk assessment education and referral/linkage as a “should” but linkage to HIV care a “could”.
SPECIALIZED STD CARE
<ul style="list-style-type: none"> • Keep onsite hepatitis A and hepatitis B vaccination as “should” be available • Change language “PrEP for HIV...” and “nPEP for HIV...” to “HIV PrEP” and “HIV nPEP” • nPEP <ul style="list-style-type: none"> ○ List starter pack as “should” with speedy linkage. ○ List 28-day supply as “could” with linkage to pharmacy/primary care in a tiered approach. ○ The nPEP regimen “should” be available to patient within an expeditious timeframe of presenting to the clinical setting. This can include the combination of starter pack with linkage for remaining 28-day supply or the linkage for the complete 28-day supply.

KEY DISCUSSION POINTS

- nPEP and PrEP should be separate services
- If HIV screening/testing is available and HIV care is not available, “linkage to care” should be required in both specialized and basic STD care
- Add language to the text to clearly define what is meant by “linkage to care”
 - Contact with a linkage to care specialist
 - Not a passive referral but actively working with local public health resource to ensure active handoff linkage to care for full navigation of services
- Guidance on nPEP provision should ensure prompt provision of regimen. Consideration should be given to language regarding the process to allow for policy and procedure flexibility in various health care systems

III. SCREENING

A. Screening – Guideline Recommendation

BASIC AND SPECIALIZED STD CARE

- ❖ **Screening and assessment for the following should be available as a basic and specialized STD care service:**
- Gonorrhea
 - Chlamydia
 - Syphilis
 - Hepatitis B
 - Hepatitis C
 - HIV
 - Cervical cancer

BASIC STD CARE

- ❖ **Above recommendations**

SPECIALIZED STD CARE

- ❖ **Screening and assessment for the following could be available as a specialized STD care service:**
- Trichomoniasis

B. Screening – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE

- Clarify anatomical sites for gonorrhea/chlamydia screening to include extra-genital sites
 - Need more specific language for gonorrhea to include extra-genital in “should”.
 - Consider including language to indicate what would be needed for extra-genital screening.
- Consider adding footnote that clinical settings may have challenges using self-collected specimens if they have not been validated by their laboratory

BASIC STD CARE

- Add trichomoniasis as “**could**”
 - Clinical settings may consider having trichomonas screening available
 - Include language from 2015 STD Treatment Guidelines regarding trichomonas screening in HIV-positive women

SPECIALIZED STD CARE

- Change trichomoniasis screening from “**could**” to “**should**”
 - Trichomonas screening in HIV-positive women is a recommendation in the 2015 STD Treatment Guidelines
- Add anal cancer as a “**could**”
 - Anal pap is not a CDC recommendation although the guidelines acknowledge that it is the standard of care in many settings.
 - Can perform anal cancer screening using digital rectal exam and anoscopy.

KEY DISCUSSION POINTS

- Although the trichomoniasis screening guidelines have a limited scope, trichomoniasis screening should be added to basic as a “**could**” and changed to a “**should**” in specialized. In addition, it would be consistent with the recommendations for laboratory tests at the time of the patient visit
- Although anal pap is not a CDC recommendation, it is a standard of care in many settings. Therefore, anal cancer screening “**could**” be done in specialized settings
- Outline in the text the steps that may be involved providing extragenital testing
 - There is no FDA cleared extragenital tests and laboratories have to do their own validation to report results for clinical use
 - Clinical settings may have issues accessing laboratories that do extragenital testing
 - If a laboratory does not have capacity, the clinical settings may need to reach out to develop new relationships with laboratories that do have the capacity.
 - Some laboratories may have difficulty in doing the validations because there are no current standards

IV. PARTNER SERVICES

A. Partner Services – Guideline Recommendation

BASIC AND SPECIALIZED STD CARE

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

BASIC STD CARE	SPECIALIZED STD CARE
<ul style="list-style-type: none"> ❖ The following partner services could be available as a basic STD service: <ul style="list-style-type: none"> • Interactive counseling for partner notification by the patient 	<ul style="list-style-type: none"> ❖ The following partner services should be available as a specialized STD service: <ul style="list-style-type: none"> • Interactive counseling for partner notification by the patient ❖ The following partner services could be available as a specialized STD service: <ul style="list-style-type: none"> • Health Department Disease Intervention Specialist partner elicitation and follow-up

B. Partner Services – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE
<ul style="list-style-type: none"> • Include DIS services in both basic and specialized care • Need footnote for EPT to include the range the legal challenges (e.g., federal tort claim act for FQHC)
BASIC STD CARE
<ul style="list-style-type: none"> • Add DIS <ul style="list-style-type: none"> ○ Primary providers should be encouraged to be more aware of DIS. ○ DIS are not just doing partner services. DIS are often involved with counseling newly diagnosed syphilis and HIV cases and linking them to services. ○ Providers should inform patients that DIS will be involved which can help facilitate positive interactions with DIS. ○ It is important to prepare patient and improve the patient’s understanding of the purpose of the interaction.
SPECIALIZED STD CARE
<ul style="list-style-type: none"> • Clarify location of DIS services as onsite or linkage <ul style="list-style-type: none"> ○ Onsite-list as “could” ○ Linkage-list as “should” • Be explicit which illness and populations should receive DIS services <ul style="list-style-type: none"> ○ Include language that settings are encouraged to develop relationships with their local HD so that they can involve DIS in the cases they routinely investigate based on resources available in the jurisdiction.
PARTNER SERVICES – KEY DISCUSSION POINTS
<ul style="list-style-type: none"> • Direct provision or prescription where it is legal it should be widely available • Parameters for EPT should go beyond the maps. Include language that highlights limitations-<i>EPT where legal and not otherwise prohibited.</i> • DIS services should be added in basic settings and expanded in specialized settings to better describe type of services provide and location

V. EVALUATION OF STD-RELATED CONDITIONS

A. Evaluation of STD-Related Conditions – Guideline Recommendation

BASIC AND SPECIALIZED STD CARE	
<ul style="list-style-type: none"> ❖ Evaluation (history and examination) for the following STD-related conditions <u>should</u> be available as a basic and specialized STD service: <ul style="list-style-type: none"> • Genital ulcer disease • Male urethritis syndrome • Vaginal discharge syndrome • Pelvic inflammatory disease • Genital warts • Ectoparasitic infections 	
BASIC STD CARE	SPECIALIZED STD CARE
<ul style="list-style-type: none"> ❖ Evaluation (history and examination) for the following STD-related conditions <u>could</u> be available as a basic STD service: <ul style="list-style-type: none"> • Proctitis 	<ul style="list-style-type: none"> ❖ Evaluation (history and examination) for the following STD-related conditions <u>should</u> be available as a specialized STD service: <ul style="list-style-type: none"> • Proctitis

B. Evaluation of STD-related Conditions – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE
<ul style="list-style-type: none"> • Add language on pharyngitis and epididymitis • Separate anoscopy. <ul style="list-style-type: none"> ○ List anoscopy as “should” for specialized and “could” for basic • Consider defining symptoms that constitute these conditions for clarification. For example, male urethritis and vaginal discharge syndrome. Consider adding in footnotes. • Add other systemic conditions <ul style="list-style-type: none"> ○ Generalized dermatological evaluation conditions/Systemic or dermatologic conditions compatible with or suggestive of an STD cause ○ Include as a line in the table as systemic/dermatologic and explain in text what would be needed to assess • Include neurologic evaluation (otic, ocular)

BASIC STD CARE

- Inconsistencies
 - Review text on proctitis (line 455-456). It contradicts table. The text states, “Primary health care providers and STD specialists need to evaluate patients.” However, the table says for basic services “could” evaluate proctitis.
 - Recommendation that vaginal discharge “should” be evaluated but not having trichomonas testing as “should” is discordant.
 - Consider using “anogenital” to include perirectal. It would avoid the disconnect between 459 A and B (slide) because they are both in “should”.
 - If pelvic exam is listed as “should” then it makes sense that anal exam is a “**should**” for everyone. Primary providers can do rectal exams. They routinely do them for occult stool.
 - Change proctitis from “**could**” to “**should**”
 - Pelvic exam is a “should” and includes a speculum exam. However, for men, proctitis includes an anorectal visual expectation as “could”.

SPECIALIZED STD CARE

KEY DISCUSSION POINTS

- A general systemic condition should be included to ensure neurologic and dermatological presentations of conditions such as syphilis are emphasized
- Add language on pharyngitis and epididymitis

VI. LABORATORY-AT THE TIME OF THE PATIENT VISIT

A. Laboratory at the Time of the Patient Visit Guideline Recommendation

BASIC AND SPECIALIZED STD CARE

At the time of the patient visit

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

BASIC STD CARE	SPECIALIZED STD CARE
<p>At the time of the patient visit</p> <ul style="list-style-type: none"> ❖ The following tests <u>could</u> be available onsite as a basic STD service with results available during the patient visit: <ul style="list-style-type: none"> • Test for trichomoniasis • Test for bacterial vaginosis • Test for vulvovaginal candidiasis • Urinalysis with microscopy • Rapid point of care test for HIV ❖ The following tests <u>would not</u> be expected during the patient visit as a basic STD service: <ul style="list-style-type: none"> • Gram, methylene blue or gentian violet stain for urethritis • Stat qualitative non-treponemal serologic test for syphilis • Dark field microscopy for syphilis 	<p>At the time of the patient visit</p> <ul style="list-style-type: none"> ❖ The following tests <u>should</u> be available as a specialized STD service with results available during the patient visit: <ul style="list-style-type: none"> • Gram, methylene blue or gentian violet stain for urethritis • Stat qualitative non-treponemal serologic test for syphilis • Test for trichomoniasis • Test for bacterial vaginosis • Test for vulvovaginal candidiasis • Urinalysis with microscopy • Rapid point of care test for HIV ❖ The following tests <u>could</u> be available onsite as a specialized STD service with results available during the patient visit: <ul style="list-style-type: none"> • Dark field microscopy for syphilis

B. Laboratory at the Time of the Patent Visit – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE
<ul style="list-style-type: none"> • Clarify STAT qualitative non-treponemal test (RPR/VDRL) compared to rapid point of care treponemal tests
BASIC STD CARE
<ul style="list-style-type: none"> • Change tests for trichomoniasis, bacterial vaginosis, vulvovaginal candidiasis, and rapid point of care test for HIV from “could” to “should”. • Phlebotomy is listed as a “should”. <ul style="list-style-type: none"> ○ Although syphilis testing is important, if the goal is to expand the basic STD services, having phlebotomy as a “should” may be restrictive for some settings to move into basic. There should be a balance between barriers and raising expectations. ○ Could use clarifying language in parentheses - “onsite or by referral”. • Urine dipstick <ul style="list-style-type: none"> ○ Some settings are not allowed to do urine dipstick and have to send urinalysis. Others can perform urine dipstick but must complete on-line training. • Extra-genital testing <ul style="list-style-type: none"> ○ Extra-genital and self-collected testing requires laboratory validation. Some settings may not have access. Need footnote to describe what is required to perform these tests. • Clarify purpose of finger stick <ul style="list-style-type: none"> ○ Rapid HIV and/or syphilis rapid test ○ Would an oral HIV be sufficient as a “should” • Rapid point of care for HIV

- Pro: Changing “**could**” to “**should**” is an endorsement that is valuable. This will be useful in low incidence populations. If a laboratory has fourth generation, that is sufficient. Many facilities may have difficulty in maintaining rapid test.
- Con: Primary care settings should do HIV testing. However, it is unreasonable to have rapid on-site HIV testing as a “should” which requires training staff and administering the test appropriately. If rapid testing is not available, it is ok. Leave as “could”.

SPECIALIZED STD CARE

- Add pregnancy test as “**should**”
- Move thermometer to physical exam section and add language that thermometer is for vital signs.
- Add rapid point of care hepatitis C testing as “**could**”

KEY DISCUSSION POINTS

- Rapid point of care for HIV
 - Pros and cons for changing to “should” at the basic level centered on capability, training, and resources vs. emphasizing value of test.
 - Observational-come up to certain level of care, then “**could**”
 - Aspirational- be aspiring for ideal, then “**should**”
 - If the goal is for patient to get an HIV test and receive the results quickly, the point of care test is not exclusive of providing this
 - Where possible it “**should**” be available whenever possible
 - Incidence low-“**could**” vs high-“**should**”

VII. LABORATORY-CLINICAL LABORATORY

A. Laboratory-Clinical Laboratory – Guideline Recommendation

BASIC AND SPECIALIZED STD CARE

Clinical Laboratory

- ❖ The following tests should be available through a clinical laboratory as a basic and specialized STD service:
 - Urogenital NAAT for gonorrhea and chlamydia
 - Extragenital (pharynx, rectum) NAAT for gonorrhea and chlamydia
 - Quantitative non-treponemal serologic test for syphilis
 - Treponemal serologic test for syphilis
 - HSV viral culture or PCR
 - HSV type specific serology
 - HIV test using a strategy to detect acute infection
 - HIV viral load
 - Oncogenic HPV NAATs with Pap smear

BASIC STD CARE	SPECIALIZED STD CARE
<p>Clinical Laboratory</p> <p>❖ The following tests could be available through a clinical laboratory as a basic STD service:</p> <ul style="list-style-type: none"> • Gram stain or methylene blue or gentian violet stain for urethritis • Gonorrhea culture • Gonorrhea antimicrobial susceptibility testing • NAAT for trichomonas • Pregnancy test 	<p>Clinical Laboratory</p> <p>❖ The following tests should be available through a clinical laboratory as a specialized STD service:</p> <ul style="list-style-type: none"> • Gonorrhea culture • Gonorrhea antimicrobial susceptibility testing • NAAT for trichomonas • Pregnancy test

B. Laboratory-Clinical Laboratory – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE
<ul style="list-style-type: none"> • Clarify pelvic exam including a speculum exam under basic services. If it means Pap smear, it should be stated. • Clarify HIV testing using strategy to detect acute infection. <ul style="list-style-type: none"> ○ If statement means antigen antibody testing, it should be stated specifically ○ Add clarifying language can be included in the text to indicate what it means to assess acute illness and offer options-“ 4th generation antigen antibody or 3rd generation antigen antibody plus RNA as appropriate” • Add footnote to include option for referral for acute infection testing if not available through clinic. Clinic setting should have knowledge of where the testing can be done. • If nPEP and PrEP services are available, baseline guideline testing “should” be available
BASIC STD CARE
<ul style="list-style-type: none"> • Change pregnancy testing from “could” to “should” • Change trichomoniasis testing from “could” to “should”
SPECIALIZED STD CARE
<ul style="list-style-type: none"> • Change pregnancy test from “could” to “should” and “should” in onsite • Expected that oncogenic HPV NAATs with Pap smear would be a “could” instead of “should” in STD clinic setting. • Reconsider anti-microbial susceptibility testing for gonorrhea as “should” <ul style="list-style-type: none"> ○ Assess reasonable access and feasibility of anti-microbial susceptibility testing for gonorrhea • Tests should be available for hepatitis A/B/C
KEY DISCUSSION POINTS
<ul style="list-style-type: none"> • If nPEP and PrEP services are available, baseline guideline testing “should” be available for basic and specialized • Assess reasonable access and feasibility of anti-microbial susceptibility testing for gonorrhea in specialized settings

VIII. TREATMENTS-ON-SITE

A. Treatment-on-Site – Guideline Recommendation

BASIC AND SPECIALIZED STD CARE
<p>Onsite</p> <p>❖ Treatments for the following STDs <u>should</u> be available onsite as a basic and specialized STD service:</p> <ul style="list-style-type: none"> • Chlamydia (including EPT) • Cervicitis • Nongonococcal Urethritis • Proctitis

BASIC STD CARE	SPECIALIZED STD CARE
<p>Onsite</p> <p>❖ Treatments for the following STDs <u>could</u> be available onsite as a basic STD service:</p> <ul style="list-style-type: none"> • Gonorrhea (including alternative treatments for EPT and use in the setting of allergies) • PID • Syphilis • Provider-applied regimens for genital warts • Emergency Contraception • Pre-exposure prophylaxis for HIV (PrEP) and Nonoccupational postexposure prophylaxis for HIV (nPEP) <p>❖ Treatments for the following STDs <u>would not</u> be expected onsite as a basic STD service:</p> <ul style="list-style-type: none"> • Persistent and recurrent cervicitis and nongonococcal urethritis 	<p>Onsite</p> <p>❖ Treatments for the following STDs <u>should</u> be available onsite as a specialized STD service:</p> <ul style="list-style-type: none"> • Gonorrhea (including alternative treatments for EPT and use in the setting of allergies) • PID • Syphilis • Trichomoniasis • Bacterial Vaginosis • Provider-applied regimens for genital warts • Emergency Contraception • Pre-exposure prophylaxis for HIV (PrEP) and Nonoccupational postexposure prophylaxis for HIV (nPEP) <p>❖ Treatments for the following STDs <u>could</u> be available onsite as a specialized STD service:</p> <ul style="list-style-type: none"> • Persistent and recurrent nongonococcal urethritis/cervicitis

B. Treatment-on-Site – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE

- Define “onsite”- provide full course of appropriate medication before patient leaves the clinic

BASIC STD CARE

- Proctitis
 - For consistency: proctitis diagnosis is listed as a “could”. The workgroup suggestion is to change proctitis diagnosis to “should”. With the treatment for proctitis as a “should”, the document will be consistent. Proctitis examination/diagnosis and treatment will be a “should”.
- EPT
 - Need footnote for EPT to include some of the legal challenges (e.g., federal tort claim act for FQHC)
 - Need clarification that EPT is recommended for heterosexual contacts rather than MSM. Consider including footnote that EPT is not currently recommended for gonorrhea in MSM.
 - Not clear this is feasible as a “should”-what would be the funding stream. Not sure how many of these facilities could provide EPT onsite other than prescription mediated.
 - Language is included for gonorrhea as alternative treatment but no language for EPT for chlamydia. Language should be included for EPT for chlamydia.
- Change PID from “**could**” to “**should**” since all components of gonorrhea/chlamydia treatment is in “should”. PID is under “should” in diagnosis section.
- HIV testing
 - HIV care is not expected but HIV linkage to care is expected.
 - Concerns that linkage suggests a comprehensive linkage system that requires dedicated staff onsite.
 - Could use “Referral to care” language.
 - Linkage to care must be more comprehensive than just making an appointment.
 - In some settings, the State takes on the role of linkage to care. Primary care providers should be aware of how to access linkage services and refer patients into care.
 - Consider language stronger than referral but not an impediment to meet linkage goals. “Establishing a patient into care and optimally providing linkage to care services” and/or include footnote that describes possibilities for resources for linkage to care.

SPECIALIZED STD CARE

- Herpes
 - Distinguish between acute and episodic herpes
 - Add primary herpes as “**should**”
- Move BV to prescription and/or change to “**could**” as onsite
- Add epididymitis to the list
- Add acute/newly diagnosis HIV care as “**could**”
 - Include language that initiating care requires linkage to longitudinal care and should be done with appropriate testing
 - Ensure language is clear that the intent of “**could**” is that treatment is available and is dispensed following an appropriate protocol
- Keep nPEP “**should**”
- Change PrEP to “**could**”
- Clarify language on nPEP and PrEP in text whether it refers to starter pack or 28 day regimen
- Add evaluation of abnormal Pap as “**could**”

KEY DISCUSSION POINTS

- Emphasis should be made on ensuring HIV linkage if HIV testing done at basic setting and treatment for acute HIV as a “**could**” in the specialized setting
- Add sentence describing what “linkage to care” consists of and how providers can contact local/state health departments for a list of linkage to care providers that may serve their region
- Distinguish type of herpes for onsite treatment in specialized
- Alternate therapy for gonorrhea “**should**” be available in specialized

IX. TREATMENTS-PRESCRIPTION

A. Treatment-Prescription – Guideline Recommendation

BASIC AND SPECIALIZED STD CARE

Prescription

- ❖ All recommended STD treatments **should** be available by prescription as a basic and specialized STD service:
 - Herpes
 - Vulvovaginal candidiasis
 - Urinary Tract Infection (UTI)
 - Patient-applied regimens for genital warts

BASIC STD CARE

Prescription

- ❖ All recommended STD treatments **should** be available by prescription as a basic STD service.
 - Gonorrhea (including alternative treatments for EPT and use in the setting of allergies)
 - Chlamydia (including EPT)
 - Trichomoniasis
 - Bacterial Vaginosis
 - Emergency contraception
 - Pre-exposure prophylaxis for HIV (PrEP) and Nonoccupational postexposure prophylaxis for HIV (nPEP)

SPECIALIZED STD CARE

Prescription

- ❖ Above recommendations

B. Treatment-Prescription – STD Workgroup Feedback

BASIC AND SPECIALIZED STD CARE
BASIC STD CARE
<ul style="list-style-type: none">• Change EPT from “should” to “could” for basic onsite EPT<ul style="list-style-type: none">○ Unrealistic expectation for EPT onsite without funding.○ EPT realistic by prescription except for FQHC○ Primary care providers will be confused.
SPECIALIZED STD CARE
<ul style="list-style-type: none">• Add acute/newly diagnosis HIV care as “could”<ul style="list-style-type: none">○ Include language that initiating care requires linkage to longitudinal care and should be done with appropriate testing○ Need clarification on what “could” means○ Ensure language is clear that the intent of “could” is that treatment is available and is dispensed following an appropriate protocol• Add PrEP as “should”• Add Herpes-recurrent/suppressive therapy as “should”• Add BV as “should”• Add ectoparasitic infections (pubic lice and scabies)• UTI<ul style="list-style-type: none">○ Add urine culture to diagnostic test list as “could”○ Adding prostatitis might be beyond the scope of most Specialized STD Clinics
KEY DISCUSSION POINTS
<ul style="list-style-type: none">• Specialized settings should have treatments for high morbidity and infections conditions• Move BV to onsite to prescription as a “should”

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Attachment 2: Participant Directory

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Dr. Marvin Belzer
Ms. Debra Hauser
Dr. Peter Havens
Mr. Devin Hursey
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U.S. Food and Drug Administration

Dr. Paul Gaist
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Mr. Richard Haverkate
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Attachment 3: Glossary of Acronyms

ADAP	AIDS Drug Assistance Program
ADR	ADAP Data Report
AETC	AIDS Education and Training Center
APORS	Adverse Pregnancy Outcome Reporting System
ART	Antiretroviral Therapy
BPG	Penicillin G Benzathine
BPHC	Bureau of Primary Health Care
CDC	Centers for Disease Control and Prevention
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
DAAs	Direct Acting Antiviral Agents
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DIS	Disease Intervention Specialist
DSTD	Division of STD Prevention
ED	Emergency Department
EHRs	Electronic Health Records
EPT	Expedited Partner Therapy
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FY	Fiscal Year
GSA	Gay Straight Alliance
HAB	HIV/AIDS Bureau
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HIVMA	HIV Medicine Association
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
HUD	Housing and Urban Development
IDSA	Infectious Disease Society of America
IHS	Indian Health Service
IPV	Intimate Partner Violence
LGBTQ	Lesbian, Gay, Bisexual, Transgender, and Questioning
MCH	Maternal and Child Health
MCHB	Maternal and Child Health Bureau
MMP	Medical Monitoring Project
MSM	Men Who Have Sex with Men

NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention
NHBS	National HIV Behavioral Surveillance
NHSS	National HIV Surveillance System
NIH	National Institutes of Health
NNDSS	National Notifiable Diseases Surveillance System
NQF	National Quality Forum
OB/GYN	Obstetrics/Gynecology
OHAIDP	Office of HIV/AIDS and Infectious Disease Policy
PEP	Post-exposure Prophylaxis
PIDS	Pediatric infectious Diseases Society
PLWH	People Living with HIV
PrEP	Pre-exposure Prophylaxis
P4C	Partnership for Care Demonstration Project
RSR	RWHAP Services Report
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services
SOGIE	Sexual Orientation, Gender Identity, and Gender Expression
SPNS	Special Projects of National Significance
STDs	Sexually Transmitted Diseases
TasP	Treatment as Prevention
TB	Tuberculosis
TEP	Technical Expert Panel
UDS	Uniform Data Set
UNAIDS	Joint United Nations Programme on HIV/AIDS
VA	U.S. Department of Veterans Affairs
WHO	World Health Organization
WIC	Women, Infants, and Children Food and Nutrition Service
YRBSS	Youth Risk Behavior Surveillance System