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





Virtual Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment February 22, 2018

Table of Contents

Opening of Meeting and Roll Call	3	
HRSA Update	5	
CDC Update	6	
Treatment as Prevention: Messaging Update	7	
2018 National Ryan White Conference on HIV Care and Treatment	8	
CHAC Workgroup Reports and Updates	9	
Other Business	11	
Adjournment	11	
Attachment 1: Participant List	13	
Attachment 2: Public Comment Submitted by the National Coalition of STD Directors	16	
Attachment 3: Core Message Elements about Undetectable Viral Load and HIV		
Transmission	18	





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

CDC/HRSA ADVISORY COMMITTEE ON HIV, VIRAL HEPATITIS, AND STD PREVENTION AND TREATMENT VIRTUAL MEETING February 22, 2018

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 virtual meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHAC). The proceedings were held on February 22, 2018.

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.

The meeting was open to the public (*Attachment 1: Participant List*). Information for the public to attend the CHAC meeting remotely via teleconference was published in the *Federal Register* in accordance with FACA rules and regulations.

Opening of Meeting and Roll Call

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

CHAC Designated Federal Officer (DFO), HRSA

Dr. Cheever called the proceedings to order at 2:14 p.m. ET. Dr. Cheever announced that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record.

Dr. Cheever conducted a roll call to determine the CHAC voting members and ex-officio members (or their alternates) in attendance. 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	Recipient of funding from CDC and HRSA/Ryan	
(Washington State Department of Health)	White HIV/AIDS Program (RWHAP).	
Jean Anderson, MD	Recipient of funding from HRSA/RWHAP and has	
(Johns Hopkins Medical Institutions)	stock in Gilead.	
Marvin Belzer, MD, FACP, FSAM	Recipient of funding from CDC. HRSA/RWHAP,	
(University of Southern California, Keck	Substance Abuse and Mental Health Services	
	Administration (SAMHSA), National Institutes of	
	Health (NIH) and is medical editor for the American Board of Pediatrics.	
Peter Byrd	No conflicts disclosed.	
(Peer Educator and Advocate)		
Dawn Fukuda, ScM	Recipient of funding from CDC and	
(Massachusetts Department of Public	HRSA/RWHAP.	
Health)		
Peter Havens, MD, MS	Recipient of funding from HRSA/RWHAP and	
(Children's Hospital of Wisconsin)	NIH.	
Devin Hursey	Recipient of funding from HRSA/RWHAP.	
(U.S. People Living with HIV Caucus)		
Jennifer Kates, PhD	No conflicts disclosed.	
(Kaiser Family Foundation)	Desiring to finding from ODO and	
Amy Leonard, MPH	Recipient of funding from CDC and HRSA/RWHAP.	
(Legacy Community Health Services) Jorge Mera, MD	HRSA/RWHAP-funded AIDS Education and	
(W.W. Hastings Indian Hospital)	Training Center (AETC) Program and funding	
	from Oklahoma University; advisory board	
	member of Gilead Sciences and AbbVie in 2016.	
Susan Philip, MD, MPH	Recipient of funding from CDC and	
(San Francisco Department of Public Health)	HRSA/RWHAP, research support from Roche	
	Diagnostics, and an unpaid public health advisor	
	for GlaxoSmithKline.	
Michael Saag, MD	Recipient of funding from HRSA/RWHAP and	
(University of Alabama at Birmingham,	CDC and a consultant for BMS, Merck, Gilead,	
School of Medicine, UAB Center for AIDS	and ViiV.	
Research)	Desirient of funding from UDCA (D)A/UAD as d	
Linda Scruggs, MHS (Ribbon Consulting Group)	Recipient of funding from HRSA/RWHAP and pharmaceutical companies	
Bradley Stoner, MD, PhD	Recipient of funding from CDC.	
(Washington University School of Medicine)	Reapient of funding norm ODO.	
Lynn Taylor, MD, FACP	Recipient of funding from HRSA/RWHAP.	
(University of Rhode Island)		
· · · · ·		

CONFLICT OF INTEREST DISCLOSURES

Dr. Cheever confirmed that the 20 voting members and ex-officio members (or their alternates) were in attendance and constituted a quorum for CHAC to conduct its business on February 22, 2018.

HRSA and CDC staff participating in the meeting were introduced. CHAC co-chairs, Dawn Fukuda and Peter Byrd, also welcomed participants.

HRSA Update

Laura Cheever, MD, ScM

Associate Administrator, HRSA, HAB CHAC DFO, HRSA

HRSA Priorities

Dr. Cheever presented the priorities of HRSA Administrator, Dr. George Sigounas.

- Increase awareness of HRSA activities, in particular, promoting awareness to increase access to services.
- Improve collaboration across HRSA Bureaus and Offices to better leverage resources and improve effectiveness. Dr. Sigounas asked HAB to work more closely with the Bureau of Primary Health Care. The two Bureaus have recently released a joint Notice of Funding Opportunity (NOFO).
- Optimize Regional Offices, especially as HRSA's "eyes and ears" on the ground.
- Prioritize publication in peer-reviewed literature and promote HRSA's publications.

2018 National Ryan White Conference on HIV Care and Treatment (NRWC)

Dr. Cheever announced the 2018 NRWC. More information on the conference was provided later in the meeting.

New Resources from the RWHAP

Dr. Cheever announced that HAB released three important resources that are available on the HAB website:

- Annual Client-Level Data Report, 2016;
- Revised and updated State Profiles; and
- Program-specific fact sheets.

CHAC Transitions

Dr. Cheever acknowledged two CHAC ex-officio members who have left their respective Agencies and are no longer members of the CHAC: Melinda Campopiano, SAMHSA, and Andrey Ostrovsky of the Centers for Medicare and Medicaid Services (CMS). Lisa Kaplowitz, who has been serving as Dr. Campopiano's alternate, has also left SAMHSA and will no longer be serving on the CHAC. SAMHSA will be identifying a permanent replacement. Richard Wild, who has been serving as alternate ex-officio for CMS, will continue in that position until a permanent replacement from CMS is identified. In addition, Dr. Cheever acknowledged Dr. Mildred Williamson for her service as the Presidential Advisory Council on HIV/AIDS (PACHA) liaison representative to the CHAC. Once new PACHA members are named, a new liaison will be identified. Dr. Cheever announced that the CHAC is recruiting new members and there will be an announcement about the application process in the Federal Register. More information is available from CDR Holly Berilla.

Public Comment

Given that it was a short business meeting as follow up to the October 2017 full CHAC meeting, there was no public comment period during the meeting. The National Coalition of State STD Directors submitted written comments on December 18, 2017 (Attachment 2).

Future CHAC Meetings, 2018

The next in-person CHAC meeting will be held in Atlanta, May 9-10, 2018. HRSA will sponsor the fall 2018 in-person meeting in Rockville, November 7-8, 2018.

CDC Update

RADM Jonathan Mermin, MD, MPH

Director, CDC, NCHHSTP CHAC DFO, CDC

CDC Transitions

Dr. Mermin announced that Anne Schuchat, MD (RADM, USPHS) is Acting Director of CDC, replacing Brenda Fitzgerald, MD. Dr. John Ward, former Director of the Division of Viral Hepatitis at NCHHSTP, CDC, will be seconded to the Taskforce for Global Health. Mr. Jeffrey Efird will serve as Acting Director of the Division of Viral Hepatitis until a permanent replacement is identified. CDC will be advertising this position and Dr. Mermin asked CHAC members to encourage qualified individuals to apply. Ms. Rachel Powell is serving as Acting Associate Director for Communications Science, Health Communication Science Office. A permanent Director should be identified in the next two months.

Awarded Integrated Funding Announcements for HIV, January 2018

These five-year cooperative agreement awards to state health departments integrate HIV surveillance and prevention funding. A total of \$400 million per year will be awarded. In addition, the awards integrate several programmatic activities. These include:

- Identification of and rapid response to clusters and outbreaks;
- Expanding data to care (i.e., ensuring people living with HIV [PLWH] are linked and retained care) using surveillance and program information; and
- Supporting states for high-impact HIV prevention.

Funding Announcement for School-Based HIV Prevention

Activities include surveillance (Youth Risk Behavior Surveillance System [YRBSS]), school-based HIV/STD prevention, and Technical Assistance (TA) and capacity building for education departments.

Treatment as Prevention Messaging Update

Richard Wolitski, PhD

Director, HHS, Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)

Dr. Wolitski discussed the activities of the HHS ad hoc working group focused on updating messages on the impact of viral suppression on HIV transmission. The group comprises representatives from CDC, HRSA, SAMHSA, and NIH.

Dr. Wolitski thanked the CHAC for the letter calling for consistent and accurate messages throughout HHS that was sent to Acting HHS Secretary Eric Hargan. The letter called on HHS to promptly provide recommendations and guidance to clinicians in the field about integrating prevention messages into services. At this point in time, HHS does not have a comprehensive plan for integrating consistent messages. Instead, HHS will engage with its Agencies to determine the most appropriate approaches for updating and integrating these messages into the large number of existing guidance and resources.

Dr. Wolitski presented a handout (Attachment 3) that describes the core message element related to undetectable viral load and HIV transmission that were agreed to by the Agencies participating in the working group. The working group found the process of translating research findings into real world practices very challenging. For example, in clinical trials subjects are tested monthly, outreach protocols are in place in the event a subject misses a test, and there are protocols in place should a subject fail to achieve or maintain viral suppression. This standard of care is not available in the real world. The working group sought to develop recommendations that represent a conservative approach that could achieve similar results in the real world.

An issue of concern raised by the CHAC was the messaging related to maintaining viral suppression for six months. The working group's recommendation for messaging is that antiretroviral treatment (ART) is known to work when:

- It is taken daily as prescribed; and
- An undetectable viral load is achieved and then maintained for at least six months.

The six-month timeframe is in response to the data on the variability of viral load and the importance of establishing a viral load over time in order for the results to be consistent over time. The concern was that if no timeframe is provided, a person could start using treatment as prevention (TasP) as their primary risk-reduction strategy after one undetectable viral load result. The six-month timeframe provides some confidence that, if the message is implemented as delivered, the person can expect comparable results. Data also indicates that most people who begin ART achieve viral suppression within six months, so the message aligns with these data.

The working group is currently waiting for the results of CDC message testing that is being conducted in Atlanta, Jackson, Los Angeles, and Detroit. The testing focuses on subjects' understanding of the messages. The working group will review and incorporate CDC's results and then work with Agencies to revise and update materials. In addition, the working group will be working with Agencies to address inconsistencies in messaging and to integrate messages into both prevention and care programs.

The working group is also considering secondary messages that will be necessary to address questions from both clinicians and patients. These questions include:

- What does it mean that the research found no linked transmission?
- What does suppression mean?
- What does adherence mean?
- How frequently should viral load be measured?

Other issues that need to be addressed include viral blips, STDs, pregnancy, and how to talk to partners about transmission.

Dr. Wolitski stated that HHS leadership is supportive of and committed to this process.

2018 National Ryan White Conference on HIV Care and Treatment

CDR Cathleen Davies, Tamika Martin, and Melinda Tinsley

HRSA/HAB 2018 NRWC Executive Co-Chairs

The 2018 National Ryan White Conference on HIV Care and Treatment (NRWC) will take place December 11-14 at the Gaylord National Harbor Hotel and Convention Center in Oxon Hill, Maryland. The Clinical Conference will take place December 9-11, allowing participants to attend both events. The theme for the conference is *Catalyzing Success: Advancing Innovation*. *Leveraging Data. Ending the HIV Epidemic*.

There are six conference tracks:

- Increasing Access, Engagement, and Retention in HIV Care and Treatment Focuses on best practices and models for access to, engagement, retention, and re-engagement in HIV care and treatment that result in improved health outcomes for PLWH.
- **Data Utilization** Examines data integration, data analysis, and data utilization with a focus on how these activities improve engagement/re-engagement, service delivery, and public health approaches to ending the HIV epidemic and curing hepatitis C virus in the RWHAP.
- Leveraging Innovative Practices to Improve Outcomes and Address Emerging Priorities Highlights new and innovative models for PLWH engagement, HIV workforce development and deployment, service integration, and service delivery that lead to improvements in health outcomes along the HIV care continuum, as well as addressing emerging priorities such as curing hepatitis C virus in the RWHAP, behavioral health integration, and the opioid epidemic.
- Clinical Quality Management and Clinical Improvement Examines the fundamentals and best practices for clinical quality management programs to measure and improve HIV service delivery and health outcomes with the ultimate goal of reducing health disparities.
- RWHAP Planning and Resource Allocation: Collaborative Partnerships and Community Engagement Focuses on requirements and best practices for integrated planning, program implementation, workforce development, and resource allocation and utilization, including examples of collaborative partnerships and community engagement initiatives that result in a quality, comprehensive system of HIV prevention, care, and treatment that is responsive to the evolving HIV epidemic.

 RWHAP Fiscal and Grant Management Boot Camp - TA track focusing on training RWHAP recipients and subrecipients on fiscal and grant management requirements and best practices.

Participation has been expanded for this year's conference; capacity is 4,500 participants. At previous conferences, participation was limited. This year, more subrecipients and consumers actively engaged with the RWHAP in their community will be able to attend.

There will be four plenary sessions. Sessions will focus on one of the tracks. There will also be a plenary session featuring federal partners. CHAC members are encouraged to suggest plenary speakers.

There will be workshops (30- and 90-minute) and poster sessions. The request for abstracts will be released soon. Internal and external reviewers will be necessary. CHAC members are encouraged to volunteer or suggest reviewers.

Save-the-date cards have already been distributed. The conference website will be live in the coming weeks.

CHAC Workgroup Reports and Updates

STD Workgroup

Susan Philip, MD, MPH and Bradley Stoner, MD, PhD

The letter on increasing STD rates was sent to DHHS. A response has not been received. Following the October meeting, the letter went through various revisions and CDC review.

Treatment as Prevention Workgroup

Amy Leonard, MPH

The letter on TasP was sent to the Director of CDC and Administrator of HRSA in November. One of the recommendations in the letter focused on providing guidance to providers about TasP.

Dr. Wolitski replied that there is agreement that providing this guidance is important. The question is how to do it, either within existing structures or by creating a new, stand-alone strike force. As the HHS working group moves forward, it will be seeking feedback from the participating Agencies on how this should be done. Dr. Wolitski asked for feedback from Dr. Cheever and Dr. Mermin.

Dr. Cheever stated that HAB is promoting TasP through RWHAP TA activities and resources, including the NRWC and through the AETCs. Dr. Mermin stated that CDC is incorporating TasP messages into existing materials for clinicians, PLWH and their partners, and other at-risk groups. CDC is working with the HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV Panel to incorporate TasP. The panel has formal procedures for evaluating data and coming to consensus – essentially a system for grading the evidence. CDC is also working to identify areas where more nuanced messages may be necessary (e.g., viral blips). This can also serve to identify areas where more research is necessary. Dr. Wolitski added that it is necessary to determine the appropriate body to provide more guidance. Does the DHHS Antiretroviral Panel, which focuses on care and treatment, have the necessary expertise? Should

additional experts be added to this body? Since TasP relates to prevention, would Public Health Service guidelines be more appropriate?

Ms. Leonard asked if there could be an awareness campaign, such as *Greater than AIDS*. Dr. Wolitski stated that funding of such a campaign could be done through the Secretary's Minority AIDS Initiative and that DHHS is considering prioritizing this in the next round of funding.

Ms. Leonard suggested that TasP messaging be incorporated into CDC Capacity Building Assistance (CBA) and evidence-based interventions materials, similar as was done with information of pre-exposure prophylaxis (PrEP). Dr. Mermin stated that CDC is focusing on the HIV continuum of care and prevention with positives. Integrating this information into the CBA materials is a great opportunity. CDC has heard that some clinicians are quite negative about TasP or interpret the data negatively. There is a role for both CDC and HRSA in ensuring that this information is disseminated in a way that it is interpreted effectively.

Dr. Saag stated that there are varying comfort levels on the part of clinicians when it comes to telling patients that they will not transmit HIV if they achieve viral suppression. Support and guidance from DHHS will be helpful.

Dr. Belzer asked if there has been any analysis done based on the actual antiretroviral treatments being used. There are different drugs being prescribed and not all are as effective in achieving viral suppression. Dr. Mermin stated that the best marker is undetectable viral load. However, clinicians should be asking how to best get a patient to viral suppression. In addition, patients have many questions about viral suppression and may want to use additional forms of protection with their partners, such as condoms or PrEP.

HIV and Aging Work Group

Peter Byrd and Richard Aleshire, MSW, ACSW

Mr. Byrd reported that the work group is using both data and experiential information to frame the issue. The work group has been struggling to narrow the focus since HIV and Aging is such a broad topic. The group is also working to expand the work group and identify future speakers. The work group will be distributing a questionnaire to CHAC members for their input.

Mr. Byrd stated that work group members believe that it is necessary to have a clinician serve as co-chair of the work group, given that the recommendations will probably focus on treatment and services.

Dr. Saag volunteered to serve as a co-chair. Mr. Aleshire will remain on the work group as co-chair, and Mr. Byrd agreed to remain on as consultant and member.

Dr. Saag suggested narrowing the focus of the work group to the unique aspects of aging with HIV, and identify things that clinicians should be doing with this patient population (e.g., screening, interventions, etc.) and that can make a difference in quality of life.

School-aged LGBTQ Youth Health Work Group

Amy Leonard, MPH

The work group is meeting the week of February 26 and is working on a letter with recommendations.

Perinatal Viral Hepatitis Work Group

Peter Havens, MD, MS

The letter that was finalized at the October meeting was sent to CDC. CDC reported that it is hiring staff to conduct a literature review to rank the quality of the evidence that can be used to develop recommendations. CDC also provided a Morbidity and Mortality Weekly Report on testing issues during pregnancy.

Dr. Taylor asked if information could be added to the letter. Some clinicians are carrying out elective cesarean sections in women infected with hepatitis C virus. There are no data indicating that this is effective in preventing transmission. Can information be added that hepatitis C virus is not an indication for an elective cesarean section? Dr. Havens stated that the letter is final. This would be addressed in guidelines if there is sufficient data to support a recommendation.

Other Business

Congenital Syphilis

Peter Havens, MD, MS

Dr. Havens stated that the written public comment from the National Coalition of State STD Directors on congenital syphilis raised important issues in terms of using existing infrastructure to address congenital syphilis. CDC and HRSA have been very effective in addressing perinatal transmission of HIV. Dr. Havens asked if this capacity can be leveraged to address congenital syphilis and perinatal hepatitis C virus. Dr. Cheever stated that HAB is working to increase focus on STDs and has recently released a NOFO on improving STD screening and treatment. HAB will be working with the HRSA Bureau of Primary Health Care and CDC on this issue, particular STD screening and treatment in the context of primary care. Dr. Bolan added that Division of STD Prevention has followed up with Division of HIV/AIDS Prevention and the HRSA Maternal and Child Health Bureau to ensure that STD screening and treatment is addressed. She suggested this as a topic at a future CHAC meeting.

Dr. Havens added that the RWHAP Part D Program grew out of the Title V Maternal and Child Health Services Block Grant Program. Dr. Bolan stated that addressing this issue has been challenging due to the restrictions imposed by the continuing resolution.

Adjournment

Ms. Fukuda thanked the CHAC members for their continued participation. She also thanked the CDC and HRSA leadership and staff for their support of the CHAC.

Items requiring follow up from this meeting include:

- Address leadership, administration, and focus areas for HIV and Aging work group;
- Suggest speakers for HRSA NRWC;
- Ongoing work on TasP messaging in terms of updating resources and disseminating messages to key audiences; and
- Ongoing work on the perinatal hepatitis C virus transmission guidelines process.

Dr. Cheever adjourned the meeting at 3:30 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 CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (Date)

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

Attachment 1: Participant List

CHAC Members Present

Mr. Peter Byrd, Co-Chair Ms. Dawn Fukuda, Co-Chair Mr. Richard Aleshire Dr. Jean Anderson Dr. Marvin Belzer Dr. Peter Havens Mr. Devin Hursey Dr. Jennifer Kates Ms. Amy Leonard Dr. Jorge Mera Dr. Susan Philip Dr. Michael Saag Ms. Linda Scruggs Dr. Bradley Stoner Dr. Lynn Taylor

CHAC Members Absent

Ms. Debra Hauser Mr. Greg Millett

CHAC Ex-Officio Members Present

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

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

Mr. Richard Haverkate Indian Health Service

Ms. Kaye Hayes Office of HIV/AIDS and Infection Disease Policy, U.S. Department of Health and Human Services

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

Dr. Richard Wild Center for Medicare and Medicaid Services

CHAC Liaison Representative

Liaison from Presidential Advisory Council on HIV/AIDS to be named

CHAC Designated Federal Officers

Dr. Laura Cheever HRSA/HAB Associate Administrator

Dr. Jonathan Mermin CDC/NCHHSTP Director

Federal Agency Attendees

Ms. Christina Barney **CDR Holly Berilla** Dr. Gail Bolan Ms. Cecily Campbell Mr. Gary Cook Ms. Antigone Dempsey Ms. Laura Eastman Ms. Miranda Fanning Ms. Tanya Geiger Ms. Anne Hanessian Mr. John Hannav Ms. Heather Hauck Dr. Letha Healey Ms. Connie Jorstad Ms. Theresa Jumento Ms. Gladys Lewellen Mr. Garet Lum **CAPT Tracy Matthews** Dr. Eugene McCray Mr. John Milberg Mr. Robert Mills Mr. John Moore Mr. Harold Phillips Mr. Raul Romaguera Ms. Melanie Ross Ms. Margie Scott-Cseh Ms. Kim Shields Ms. Natalie Solomon Ms. Rene Sterling Ms. April Stubbs-Smith Ms. Abigail Viall Ms. Michelle Vanhandle Mr. Steven Young

Guest Presenters

CDR Cathleen Davies HRSA/HAB

Tamika Martin HRSA/HAB Melinda Tinsley HRSA/HAB

Dr. Richard Wolitski Director, HHS/OHAIDP

Attachment 2: Public Comment Submitted by the National Coalition of STD Directors

NCSD would like to thank CHAC for the opportunity to provide comment on the discussion of congenital syphilis that took place at the October meeting since the public comment occurred before this session took place.

More than two million cases of chlamydia, gonorrhea, and syphilis were reported in the United States in 2016. On September 26, the Centers for Disease Control and Prevention (CDC) issued its 2016 STD surveillance report showing that STDs at the highest rates ever in the United States, with staggering health consequences for millions of Americans. The report also underscores that existing disparities are deepening. We are at unprecedented highs for STD rates. The CDC's Division of STD Prevention has laid out a call to action to address syphilis rates, but they cannot combat STD rates on their own. There is enough of a problem here that we must all own this and change how we are addressing STD prevention and control. STDs can no longer be someone else's priority, they must be the priority of us all.

After a steady decline from 2008-2012, data shows a sharp increase in congenital syphilis rates. There was an 88% increase in congenital syphilis from 2012 to 2016. In 2016, the number of congenital syphilis cases was the highest that it has been since 1998—with 628 reported cases of congenital syphilis, including 41 syphilitic stillbirths, and the national rate was 15.7 cases per 100,000 live births. In the panel on congenital syphilis, Dr. Gail Bolan highlighted that there are successes of adverted cases with as many as 75% of congenital syphilis cases adverted but that there are states with rates as low as 50% of cases adverted and 26% of mothers had no prenatal care. The CDC has provided additional funding for congenital syphilis with a new grant opportunity for those jurisdictions with the highest rates, but this funding is one-time only and, therefore, cannot be a complete response to the extremely high rates of congenital syphilis currently facing the United States.

In her presentation, Dr. Judy Steinberg from the Bureau of Primary Care stated that the BPC does not collect data on congenital syphilis. The Bureau serves approximately 26 million people (or 1/12 of the people across the United States); this information collection could be key to knowing more about adverted cases of congenital syphilis as well as having a truer picture of the congenital syphilis cases. The PHB does require the reporting of two Quality Insurance measures dealing with prenatal care already, as well as one dealing with STDs. Dr. Aaron Lopata of the Maternal and Child Health Bureau at HRSA stated that Title V has a critical role in ensuring that all pregnant women are screened for syphilis at their first prenatal visit and those who are "high-risk" are additionally screened in the third trimester. Nearly 30% of congenital syphilis cases were those that had no treatment and 21% had inadequate treatment.

With the information from the presentations at the meeting in mind, we ask the following questions and request that CHAC ask the respective Bureaus for answers:

- How is the Bureau of Primary Care able to participate in efforts to tackle these congenital syphilis rates?
 - At a minimum, how can it be incentivized for health centers to collect data on congenital syphilis? How can the Title V block grant be used to motivate syphilis testing and treatment to prevent cases of congenital syphilis?

- How can the Title V block grant be used to motivate syphilis testing and treatment to prevent cases of congenital syphilis?
 - Is there the possibility of a congenital syphilis demonstration project that could be funded through the Maternal and Child Health Bureau like there was to address perinatal HIV in the 1980s?
- How could Part D of the Ryan White CARE Act serve as a model of prevention and treatment for congenital syphilis? The Ryan White HIV/AIDS Program Part D has an existing focus on women who are pregnant or may become pregnant and HIV prevention and, since this is likely women who are also at risk for congenital syphilis, could HRSA look into a demonstration project to reduce congenital syphilis rates as part of Part D?

It is time to change how we address STDs. We all, across federal, state, and local government, and the private sector, need to change or things are never going to improve; this is a public health emergency that impacts everyone and should be an all-hands-on-deck situation with everyone focusing on how we can address STDs in the United States immediately. This session at the CHAC demonstrates that there is concern across federal, state, and local government to address these sky-rocketing rates of congenital syphilis, but also that there is a lot of coordination across these different areas that must occur.

Attachment 3: Core Message Elements about Undetectable Viral Load and HIV Transmission (v 1.0)

<u>Core Message Elements</u> - It is recommended that all communications seek to convey these key concepts. Some types of communications that are very brief would not be able to get across all of these points. For example, a banner would not need to have all of this info, but ideally the communication would be able to link to a more complete set of information.

The wording here is the wording that is based on the discussions and review of the available evidence within the HHS ad hoc working group.

The intervention is:

- Taking HIV medications (preferred term); or
- Taking medications to treat HIV (acceptable term); or
- Taking antiretroviral therapy (ART) (acceptable term).

It is used by:

- People living with HIV (preferred term)
 - Persons living with HIV, women or men living with HIV, or subsets of the population such as PWID living with HIV, etc. are all acceptable.

To prevent:

- Sexual transmission of HIV to partners who are HIV-negative (preferred term)
 - Variations that convey this same information are acceptable;
 - Variations should convey that the data are limited to sexual transmission from someone who has the virus to someone who does not;
 - Terms like "infected," "carrier," and "victim" should not be used in communications about this issue; and
 - Studies include heterosexual and homosexual couples. Messages are the same for both heterosexual and same-sex sexual behaviors.

Known to work when:

• Taken daily as prescribed (preferred term)

AND

- An undetectable viral load is achieved and then maintained for at least six months (preferred term)
 - Minor variations on these that retain all of the key concepts are acceptable (e.g., "taken every day as prescribed").
 - Both information about medication adherence AND keeping viral load suppressed should be communicated in all messages).
 - Achieved = a single viral load test that is undetectable.

• Maintained + all viral load test results are undetectable for at least six months after the first undetectable viral load test results was achieved.

Magnitude of effect:

- "Effectively no risk"
- Consensus was not reached on the best term in the federal workgroup, however, everyone indicated that "effectively no risk" was an acceptable term.
- Feedback from health care provider and health department webinar supported this choice.
- Discussions and email from Bruce Richman indicated the support of PAC and its partners for this term.
- Will test "effectively no risk" along with other terms such as:
 - Almost no risk;
 - Effectively no risk;
 - Extremely low to no risk;
 - o Insignificant risk; and
 - Negligible.

Examples of Top Line Messages that Include These Elements:

People living with HIV who take HIV medications daily as prescribed and achieve and then maintain an undetectable viral load for at least six months have effectively no risk of sexually transmitting the virus to an HIV-negative partner.

OR (to illustrate how messages will incorporate other elements).

Scientific advances in HIV care and treatment are game changers that can get us to the vision of a future in which new HIV infections are rare. There is effectively no risk of sexual I transmission of HIV when people living with HIV are taking HIV medications as prescribed and have achieved and maintained an undetectable viral load for at least six months.

Additional Key Messaging Issues:

- Key Benefits of HIV Treatment
- Research Found No Linked Transmission
- Time to Suppression
- Adherence
- Frequency of Viral Load Monitoring
- Stability of Viral Load Monitoring
- Viral Blips
- STIs
- Pregnancy
- Talking to Your Partner about Treatment as Prevention

Ongoing/Future Activities:

Review of CDC message testing results.

• Identification of an advisory body to review available data and develop recommendations related to additional key issues where appropriate.