CDC’s PrEP Clinical Practice Guideline and Strategies for Ending the HIV Epidemic in the U.S.

Thursday, May 19, 2022
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• Today’s Event is being **RECORDED**
• All attendee lines have been **MUTED**
• The **CHATBOX** is open for the duration of this event
• Questions from the **CHAT BOX** will be answered after the presentation is completed.
Today’s Presenter

Dr. Demetre Daskalakis
CDC’s Director of the Division of HIV/AIDS Prevention (DHAP)
CDC’s PrEP Clinical Practice Guideline and Strategies for Ending the HIV Epidemic in the U.S.

Demetre Daskalakis, MD, MPH

Division of HIV Prevention
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
Agenda

- Status of HIV in the United States
- Ending the HIV Epidemic and PrEP
- PrEP Guideline
- Future Opportunities
- Resources
Status of HIV in the United States
National HIV Prevention and Care Efforts Have Reduced HIV Infections From a Peak of 130,000 in the Mid-1980s to Approximately 34,800 in 2019

Estimated Annual HIV Infections in the United States, 2015-2019

- 2015: 37,800
- 2016: 37,900
- 2017: 36,700
- 2018: 36,200
- 2019: 34,800

8% decrease from 2015 to 2019.

1.2 Million People in the United States Have HIV, and Health Disparities Persist

Snapshot of Disparities

Higher HIV Incidence
- Gay and Bisexual Men
- Black/African American Persons
- Hispanic/Latino Persons

Larger Gaps in PrEP Coverage
- Black/African American Persons
- Hispanic/Latino Persons

Lower Rates of Viral Suppression
- American Indian/Alaskan Native Persons
- Black/African American Persons

Higher HIV Prevalence
- Men who have sex with men (MSM)
- Transgender Women

More HIV Outbreaks
- People Who Inject Drugs

Rates of Diagnoses of HIV Infection
Highest in the South
(>50% of all new HIV diagnoses in 2019)

Rates per 100,000 population
- 0.0-5.3
- 5.4-9.0
- 9.1-13.4
- 13.5-42.2
Data classified using quartiles
CDC’s Approach to Ending the HIV Epidemic (EHE) in the United States
Ending the HIV Epidemic in the U.S.

- Diagnose all people with HIV as early as possible
- Treat people with HIV rapidly and effectively to reach sustained viral suppression
- Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs)
- Respond quickly to potential HIV outbreaks to get vital prevention and treatment services to people who need them
PrEP Coverage by Race/Ethnicity 2017-2020

PrEP Coverage

- 2020
  - White: 60.7%
  - Hispanic/Latinx: 14.6%
  - Other Race: 8.7%
  - Black/African American: 8.4%

Prelim. as of Dec 2020
PrEP Coverage by Gender 2017-2020

2020
- Male (sex at birth): 26.0%
- Female (sex at birth): 9.6%
In FY22, CDC plans on significant investments at the federal and jurisdiction level to increase PrEP access, uptake and persistence.

Only 10% of women who could benefit from PrEP were prescribed it in 2020.*

Only 27% of Black/African American, 31% of Hispanic/Latino, and 42% of White gay and bisexual men surveyed by CDC who could have benefited PrEP used it in 2017.**

Among transgender women who were HIV-negative, 92% had heard of PrEP but only 32% had used PrEP in the past 12 months.***
A person with HIV who takes HIV medicine as prescribed and gets and stays virally suppressed or undetectable can stay healthy and has effectively no risk of sexually transmitting HIV to HIV-negative partners.

www.cdc.gov/hiv/risk/art/index.html
PrEP Guideline
What’s Unchanged from the 2017 Guideline

- No changes to:
  - Indications for PrEP use
  - Frequency of follow-up visits for oral PrEP
  - Schedule for HIV and STI testing for oral PrEP
NEW RECOMMENDATION: All sexually active adult and adolescent patients should receive information about PrEP

- Encourage providers to offer PrEP as a core primary care service
  - Reduce missed opportunities for PrEP provision
- Increase knowledge of PrEP among potential users
  - Allow consideration of immediate or future use and PrEP requests
- Increase knowledge of PrEP in the community
  - Those who can recommend to others or support use by family or friends
Daily Oral PrEP Protocol

<table>
<thead>
<tr>
<th></th>
<th>PrEP Initiation Visit</th>
<th>Follow-up visits (q 3 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV Status</strong></td>
<td>• HIV Ag/Ab test (lab preferred)</td>
<td>• HIV-1 qualitative RNA + Ag/Ab</td>
</tr>
<tr>
<td><strong>Renal status</strong></td>
<td>• eCrCL</td>
<td>• Assess q 6 months if baseline</td>
</tr>
<tr>
<td></td>
<td>&gt;60 ml/min (F/TDF or F/TAF)</td>
<td>Age ≥50 years or eCrCl &lt;90 ml/min</td>
</tr>
<tr>
<td></td>
<td>&gt;30 ml/min (F/TAF)</td>
<td>Otherwise assess Q 12 months</td>
</tr>
<tr>
<td><strong>STI infection status</strong></td>
<td>• Syphilis serology for all</td>
<td>• Repeat STI screen for MSM/TGW q 3 months</td>
</tr>
<tr>
<td></td>
<td>• GC and CT NAAT at sites of exposure for MSM and TGW</td>
<td>• Repeat STI screen for heterosexually active men and women q 6 months</td>
</tr>
<tr>
<td></td>
<td>• GC for women</td>
<td>• CT screen for heterosexually active men and women q 12 months</td>
</tr>
<tr>
<td><strong>Lipid screen</strong></td>
<td>• Only for persons prescribed F/TAF</td>
<td>• Repeat q 12 months for persons prescribed F/TAF</td>
</tr>
<tr>
<td><strong>Screen for active HBV</strong></td>
<td>Hepatitis B serology</td>
<td>If not done at initiation visit</td>
</tr>
<tr>
<td><strong>Prescription</strong></td>
<td>90 day supply</td>
<td>90 day refill if HIV test is negative</td>
</tr>
</tbody>
</table>
Prescribing 2-1-1 Event-Driven PrEP

- Only for adult MSM/TGW who:
  - request non-daily dosing
  - have sex infrequently (e.g., less often than once a week) and
  - can anticipate sex (or delay sex) to permit the doses at least 2 hours prior to sex

- Prescribe F/TDF with 30-day supply before next HIV test

- Anticipate and advise how to safely switch between daily and 2-1-1-dosing
# Cabotegravir Injection PrEP Protocol

<table>
<thead>
<tr>
<th>HIV Status</th>
<th>PrEP Initiation Visit</th>
<th>Follow-up visits (q 2 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 qualitative (or quant) RNA + Ag/Ab</td>
<td>• HIV-1 qualitative (or quant) RNA + Ag/Ab</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STI infection status</th>
<th>PrEP Initiation Visit</th>
<th>Follow-up visits (q 2 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis serology for all</td>
<td>• Syphilis serology for all</td>
<td>• Repeat STI screen for MSM/TGW q 4 months</td>
</tr>
<tr>
<td>GC and CT NAAT at sites of exposure for MSM and TGW</td>
<td>• GC and CT NAAT at sites of exposure for MSM and TGW</td>
<td>• Repeat STI screen for heterosexually active men and women q 6 months</td>
</tr>
<tr>
<td>GC for women</td>
<td>• GC for women</td>
<td>• CT screen for heterosexually active men and women q 12 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescription</th>
<th>PrEP Initiation Visit</th>
<th>Follow-up visits (q 2 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide cabotegravir injection at initiation visit and again 1 month later</td>
<td>Provide cabotegravir injection q 2 months if HIV test is negative</td>
<td></td>
</tr>
</tbody>
</table>
Future Opportunities
Increasing PrEP Providers

- Now is the time to incorporate PrEP deeper into primary care
  - The U.S. Preventive Services Task Force (USPSTF) assigns a grade A recommendation for primary care preventive care
  - CMS FAQ supports that both the medications and the clinical services that support PrEP should be covered by insurers without out-of-pocket cost to the patient
  - PrEP is a highly effective primary care intervention, but we need more providers to educate their patients about PrEP and prescribe it
Increasing Number of PrEP Prescribers in U.S.

In 2019:

- There were 66,000 PrEP prescribers
  - Compared to 9,600 in 2014
  - 68% were physicians
  - 30% were NPs or PAs

- 4% of all active providers had prescribed PrEP
  - 13% of family practitioners
  - 34% of ID physicians

- 50% of PrEP patients prescribed by 3% of PrEP providers

Future Opportunities for PrEP

- PrEP delivery methods and venues
- Evaluating PrEP choices
  - Researching the power of choice
- USPSTF grade review underway
  - Supporting USPSTF review of newer PrEP choices
Resources
The CDC HIV Campaign: Let’s Stop HIV Together

Content Areas:

- Stigma/Patient Centered Care
- Testing
- Prevention
- Treatment and Care

Consumers

Clinicians
Resources for Clinicians

- **PrEPline 855-448-7737 (855-HIV-PrEP) Toll-free**
  - Clinical care questions
  - Access to advanced diagnostics for
    - Ambiguous test results
    - Person who acquire HIV while prescribed PrEP

- **NASTAD**
  - Billing and coding guide

- **HIV Nexus**
  - [https://www.cdc.gov/hiv/clinicians/index.html](https://www.cdc.gov/hiv/clinicians/index.html)
HIV Nexus: A Clinical Resource

- Serves as a one-stop hub for resources designed to support clinicians
- Contains latest research and information on HIV prevention, screening, and treatment
- Provides access to free continuing medical education programs
- Highlights CDC guidelines and recommendations
- Includes patient education materials

www.cdc.gov/HIVNexus
Helping Patients Pay for PrEP Care

- Commercially insured patients have no out-of-pocket cost for medication, clinical care, and lab tests
  - USPSTF Grade A recommendation
  - CMS/Dept of Labor no-cost coverage rule

- Uninsured persons
  - Healthcare.gov
    - Get 2022 health coverage. Health Insurance Marketplace® | HealthCare.gov
  - Free medication
    - Ready, Set, PrEP (hiv.gov)
    - Gilead Medical Assistance Program (oral PrEP)
    - ViiV Medical Assistance Program (cabotegravir injections)
Health Department Resource to Pay for PrEP Care

- PrEP ancillary support services now allowable use of CDC HIV funds
  - Up to 15% of health department HIV prevention award PS18-1802
  - Lab costs, navigation, mobile units, etc.
  - Does not cover purchase of PrEP medications
CDC Priorities
Priorities for 2022

- Prioritizing Health Equity
- Expanding Self-Testing Efforts
- Strengthening Syndemic Collaborations

Result: Status Neutral Approach
What is the Status Neutral Approach?
Status Neutral HIV Prevention and Care

People whose HIV tests are negative are offered powerful prevention tools like PrEP, condoms, harm reduction (e.g. SSPs), and supportive services to stay HIV negative.

Prevention Pathway
- Prevents getting HIV
- High Impact HIV Prevention
- HIV and STD Testing

Culturally Inclusive and Responsive Quality Care

Treatment Pathway
- Prevents transmitting HIV
- HIV Primary Care
- Effective Treatment

Newly Diagnosed with HIV

Follow CDC guidelines to test people for HIV. Regardless of HIV status, quality care is the foundation of HIV prevention and effective treatment. Both pathways provide people with the tools they need to stay healthy and stop HIV.

People whose HIV tests are positive enter primary care and are offered effective treatment and supportive services to achieve and maintain viral suppression.
How CDC is Advancing Status Neutral Care

- Encouraging integrated service delivery
- Conducting implementation science
- Building partnerships
Advancing Status Neutral Care

- **PS22-2209: Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic**
  - This NOFO will fund organizations to work in TG clinics and partner with TG CBOs to develop community-to-clinic models for integrated status-neutral HIV prevention and care services, gender-affirming services, and primary health care.

- **PrEP Program and Ancillary Support Services Guidance for Health Department**
  - This guidance allows flexibility to utilize CDC’s flagship health department funding for program recipients to pay for CDC-recommended clinical care costs related to PrEP as payor of last resort.
Prioritizing Health Equity
National Center for HIV, Viral Hepatitis, STD, and TB Prevention’s (NCHHSTP) Equity Initiative

A transformational long-term strategy to help us achieve equity within our workplace and eliminate health disparities by addressing racism and other systems of oppression.

The Equity Initiative builds on decades of successful work—by NCHHSTP staff, our partners, and advocates—giving us a strong foundation of proven strategies and bold ideas to advance equity and reduce health disparities.
The DHP Change Team will focus on three areas:
A. Workplace Culture
B. Workplace Policies and Procedures
C. Research, Policy, Programs and Partnerships
Expanding HIV Self-Testing
CDC Self-Testing Efforts

CDC was awarded approx. $2.0M in FY20 Minority HIV/AIDS Funding (MAF) for HIV self-testing projects.

100,000 HIV self-test kits were distributed online at no cost: https://together.takemehome.org/
Strengthening Syndemic Collaborations
What is a Syndemic

A syndemic is a set of linked health problems that interact with each other in an environment of social injustice and results in an increase in the amount or severity of disease in a population.
CDC HIV Prevention funding, guidelines, and technical assistance support syndemic approaches where diseases interact or connect.

**Setting**
- Syringe Services Programs
- STI Clinics
- Community-Based Organizations
- Health Departments
- Community Health Centers

**Services**
Testing, Prevention, and Linkage to treatment for STIs, VH, and HIV

**Flexible Funding**
- Core HIV infrastructure
- Support for SDOH activities
- Supporting linkage to other needed services (housing, transportation, substance use disorder treatment, etc.)
CDC’s Syndemic Approach

PEOPLE, PLACE, POLICY AND SCIENCE MATTER
Key actions to Address Syndemics

- Put people first
- Focus on equity
- Put your money where your epidemic is
- Leverage policy as a public health tool
- Prioritize Innovation
Today, we have an unprecedented opportunity to end America’s HIV epidemic.
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Linkedin.com/company/nachc
YouTube.com/user/nachcmedia
Bi-monthly themed e-newsletter dedicated to providing resources to community health center care teams
Using Data to Improve Care
Learning Collaborative

SESSION 4  5/20/2022  12 p.m. ET

Quality Improvement for Immunizations

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THANK YOU TO ALL COMMUNITY HEALTH CENTERS

#ThankYouCHCs

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