
Wednesday, May 4, 2022
America’s Voice for Community Health Care

The National Association of Community Health Centers (NACHC) was founded in 1971 to promote efficient, high quality, comprehensive health care that is accessible, culturally and linguistically competent, community directed, and patient centered for all.
Ensure you’ve connected to audio!

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Follow the unique 3-step process on your screen

**Option 2: “Call Using Computer”**
You must have computer speakers and microphone

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ASKING QUESTIONS VIA CHAT BOX

1. **The chat feature** is available to ask questions or make comments anytime.

2. **Click the chat button** at the bottom of the WebEx window to open the chat box on the bottom righthand side of the window.

3. **Choose “EVERYONE”, as appropriate.**
   - Type your question.
   - Click “Enter” to send your question.
Friendly Reminders

• 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

Amy Killelea, JD
Killelea Consulting
What's New for PrEP?
  - Current PrEP landscape
  - Revised CDC Clinical Guidelines for PrEP
PrEP Access in the U.S.
Financing PrEP
  - USPSTF coverage and cost-sharing requirements
  - Challenges for the uninsured
A National PrEP Program
WHAT’S NEW FOR PREP?
# PREP PRODUCTS ON THE MARKET

<table>
<thead>
<tr>
<th>Product</th>
<th>Administration route</th>
<th>Generic available?</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDF/FTC (brand name Truvada)</td>
<td>Oral, daily pill</td>
<td>Yes</td>
</tr>
<tr>
<td>TAF/FTC (brand name Descovy*)</td>
<td>Oral, daily pill</td>
<td>No</td>
</tr>
<tr>
<td>Long-acting injectable cabotegravir (brand name Apretude)</td>
<td>Injection every two months</td>
<td>No</td>
</tr>
</tbody>
</table>

*Descovy is not currently approved for cisgender women

*All are highly effective and very safe*
<table>
<thead>
<tr>
<th>AVAC</th>
<th>The Years Ahead in Biomedical HIV Prevention Research</th>
<th>Status of select biomedical HIV prevention clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy Trial</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Vaginal Ring</strong></td>
<td>2019</td>
<td>2020</td>
</tr>
<tr>
<td>Dapivirine Ring (Monthly)</td>
<td></td>
<td></td>
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<tr>
<td>F/TAF (Daily pill)</td>
<td>DISCOVER</td>
<td></td>
</tr>
<tr>
<td><strong>Islatravir</strong> (Monthly pill)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IMPower-22</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>IMPower-24</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Long-Acting Injectable</strong></td>
<td>2019</td>
<td>2020</td>
</tr>
<tr>
<td>Cabotegravir (Every two months)</td>
<td>HPTN 083</td>
<td></td>
</tr>
<tr>
<td><strong>HPTN 084</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lenacapivir (Every six months)</td>
<td>PURPOSE 1</td>
<td></td>
</tr>
<tr>
<td><strong>Purpose 2</strong></td>
<td></td>
<td></td>
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</tbody>
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**Additional Information:**
- **Jan 2021**: WHO recommends as an additional prevention choice for women at substantial risk of HIV. Approval under review by a number of regulatory authorities.
- **Oct 2019**: FDA approves F/TAF for adults and adolescents who have no HIV risk from receptive vaginal sex.
- **Randomized controlled trial of monthly islatravir, ongoing in 4,500 women in the US.**
  - On hold, Related islatravir studies showed lower lymphocyte and CD4+ T cell counts in some participants.
- **Randomized controlled trial of monthly islatravir in men and transgender women who have sex with men across the world.**
  - On hold, Related islatravir studies showed lower lymphocyte and CD4+ T cell counts in some participants.
- **Dec 2021**: FDA approves CAB-LA for PrEP in the US. Multiple applications under review with other regulatory bodies.
- **Trial of six-monthly injectable lenacapivir planned in 5,010 AGYW in South Africa and Uganda (alongside daily oral F/TAF).**
- **Trial of six-monthly injectable lenacapivir in 3,000 cisgender MSM, transgender women, transgender men, and gender non-binary individuals.**

**Note:**
- Cabotegravir efficacy update delayed awaiting results of ongoing trials.
<table>
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</thead>
<tbody>
<tr>
<td>• Long-acting, injectable cabotegravir</td>
<td>• HIV RNA test at every interval</td>
<td>• Simple identification of people indicated for PrEP</td>
<td>• 2-1-1 TDF/FTC for MSM (“on demand” or event-driven PrEP)</td>
</tr>
<tr>
<td>• TAF/FTC</td>
<td>• Assess eCrCl every 12 months for persons &lt;50 years of age or with eCrCl ≥90 ml/min at PrEP initiation and every 6 months for all other patients</td>
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PREP ACCESS IN THE U.S.
US IS NOT ON TRACK TO END THE HIV EPIDEMIC

While 25% of people eligible for PREP were prescribed it in 2020, coverage is not equal.


- Overall: 25%
- Black/African American: 9%
- Hispanic/Latino: 16%
- White: 66%

For more information, visit cdc.gov/nchhstp/newsroom
DISPARITIES IN PREP ARE INCREASING

Figure 27. PrEP Coverage among Persons Aged ≥16 Years during 2019, by Selected Characteristics—United States

CDC, Monitoring Selected National HIV Prevention and Care Objectives By Using HIV Surveillance Data United States and 6 Dependent Areas, 2019: National Profile
GEOGRAPHY PLAYS OUTSIZED ROLE IN PREP ACCESS

Figure 26. PrEP Coverage among Persons Aged ≥16 years, by Area of Residence, 2019—United States

CDC, Monitoring Selected National HIV Prevention and Care Objectives By Using HIV Surveillance Data United States and 6 Dependent Areas, 2019: National Profile
INSURANCE STATUS ASSOCIATED WITH HIV DIAGNOSIS RATES

RATES OF HIV DIAGNOSIS

WITHOUT HEALTH INSURANCE (%)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>&lt; 4</th>
<th>4.00 - 7.99</th>
<th>8.00 - 13.99</th>
<th>≥ 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-24 years</td>
<td>13.7</td>
<td>22.8</td>
<td>35.1</td>
<td>56.8</td>
</tr>
<tr>
<td>25-34 years</td>
<td>18.7</td>
<td>27.2</td>
<td>39.5</td>
<td>64.7</td>
</tr>
<tr>
<td>35-44 years</td>
<td>10.7</td>
<td>19.9</td>
<td>35.8</td>
<td></td>
</tr>
<tr>
<td>45-54 years</td>
<td>7.2</td>
<td>13.8</td>
<td>24.0</td>
<td></td>
</tr>
<tr>
<td>≥55 years</td>
<td>2.7</td>
<td>3.6</td>
<td>6.4</td>
<td>9.8</td>
</tr>
</tbody>
</table>

ABSOLUTE DISPARITIES

(PREVENTABLE CASES)

PER 100,000 POPULATION

If those in the lowest insurance coverage tracts lived in the highest insurance coverage tracts, then ____ cases would have been prevented.

- 18-24 years: 43 cases prevented
- 25-34 years: 46 cases prevented
- 35-44 years: 25 cases prevented
- 45-54 years: 17 cases prevented
- ≥55 years: 7 cases prevented

FINANCING PREP
## A FRAGMENTED SYSTEM

<table>
<thead>
<tr>
<th></th>
<th>Medication</th>
<th>Labs</th>
<th>Clinic visits</th>
<th>Outreach, adherence counseling, linkage</th>
</tr>
</thead>
</table>
| **Insured**| USPSTF Grade A means no cost sharing for PrEP medications*, labs, and clinic visits for most private insurance plans and all Medicaid expansion programs (Medicare and traditional Medicaid left out)  
*Plans may charge cost sharing for Descovy and Apretude | 340B program income may support labs | 340B program income may support clinic visits                     |                                         |
| **Uninsured** | Ready Set PrEP                  | 340B program income may support labs | 340B program income may support clinic visits                     | 340B program income may support these services |
|            | Manufacturer assistance programs | Some state PrEP drug assistance programs cover labs | Some state PrEP drug assistance programs cover clinic visits | Some state PrEP drug assistance programs may support these services |
|            | 340B                            | CDC HIV prevention funds may cover lab services | CDC HIV prevention funds may cover personnel services related to provision of PrEP medication as long as support services are also provided | CDC HIV prevention funds may support these services |
“It’s kind of expensive for a disease I don’t have.”

“I stopped using [PrEP] because it became too much of a hassle to keep verifying my information every month. That I didn’t have a job, that I didn’t have income. And it started making me feel bad.”

“I go to an LGBT health clinic for my PrEP because primary care doctors really don’t know anything about PrEP.”
WHAT DOES PRICE HAVE TO DO WITH IT?

NADAC* Pricing Trends (Per Tablet)

Data from National Average Drug Acquisition Cost (data.medicaid.org); chart courtesy of Tim Horn at NASTAD
TDF/FTC VS. TAF/FTC PRESCRIBING

Results

- Total
- F/TDF
- F/TAF

Approval for HIV treatment
Approval for PrEP

Persons prescribed PEP (N)

Year and quarter


Slide from Dr Karen Hoover's presentation to CROI 2021.
WE AREN’T ENGAGING NONTRADITIONAL PREP PROVIDERS

- Domestic violence clinic
- Local health department
- Clinical PrEP Providers
- Mobile HIV unit
- Syringe services program
340B CHALLENGES

• Generic competition threatens 340B revenue
• Gilead ended its reimbursement practices for its Advancing Access Program for uninsured patients where 340B entities where reimbursed at usual and customary price instead of acquisition cost
• Manufacturers are continuing to challenge the program, including use of multiple contract pharmacies
A NATIONAL PREP PROGRAM
To meet this ambitious target and ultimately end the HIV/AIDS epidemic in the United States, the Budget includes $850 million across HHS to aggressively reduce new HIV cases by increasing access to HIV prevention and care programs and ensuring equitable access to support services. This includes increasing access to pre-exposure prophylaxis (also known as PrEP) among Medicaid beneficiaries, which is expected to improve health and lower Medicaid costs for HIV treatment. The Budget also proposes a new mandatory program to guarantee PrEP at no cost for all uninsured and underinsured individuals, provide essential wrap-around services through States and localities, and establish a network of community providers to reach underserved areas and populations.

9.8B for National PrEP Program over 10 years,
A national PrEP financing and delivery program for the uninsured, under-insured and Medicaid beneficiaries must be:

- Accessible
- Simple
- Affordable
- Sustainable
- Equitable
- Adaptable
# CORE ELEMENTS OF A NATIONAL PREP PROGRAM

<table>
<thead>
<tr>
<th>Part A</th>
<th>A national bulk purchase of PrEP medications with availability through a large pharmacy network for people who are uninsured or covered by Medicaid. Access at the pharmacy should be seamless for the consumer.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part B</td>
<td>Options for clinical settings to (1) provide on-site dispensing and (2) offer laboratory services for those without coverage. These opportunities can allow clinics to provide PrEP more frequently and effectively.</td>
</tr>
<tr>
<td>Part C</td>
<td>A national network of nontraditional community sites to offer PrEP, supported by telehealth. This network can reach people who do not regularly access clinical health services.</td>
</tr>
</tbody>
</table>
PART A: FAIR PUBLIC HEALTH PRICES FOR MEDICATIONS

- Streamlined federal negotiation for the price of PrEP medications for National PrEP Program
  - Generic TDF/FTC
  - Other PrEP formulations should be part of federal bulk purchase and made available based on clinical evidence
- Distribution through contracts with pharmacy network and to clinical providers who are able to dispense PrEP onsite
PART B: OPTIONS FOR THE CLINICAL SYSTEM TO PROVIDE ON-SITE DISPENSING AND LAB SERVICES FOR THOSE WITHOUT COVERAGE

- Clinicians should be able to order PrEP medications from a distributor to support same-day starts.
- Clinicians should be able to access laboratory services for patients who do not now have a source of payment.
PART C: A BROAD NETWORK OF NONTRADITIONAL COMMUNITY SITES FOR PREP ACCESS SUPPORTED BY TELEHEALTH

- Broaden PrEP provider network, building off of CDC HIV prevention grantees, and including outreach programs, mobile prevention units, domestic violence shelters, drug treatment centers, and others.

- These programs should receive additional federal grant support to (1) educate and train their staff on PrEP and (2) establish a mechanism to connect clients with telehealth providers for PrEP access. States should develop this network to assure it is responsive to the needs of diverse communities at risk for HIV.

- The federal program would also engage a limited number of telehealth providers for PrEP in each state. Each community partner should be linked to a telehealth provider.
WHAT ELSE IS NEEDED?

- PrEP access requires an array of outreach, counseling, education, and linkage services, and clinical visit costs.
- Capacity building assistance is also critical to ensure a broad network of PrEP providers are prepared to engage in dramatic scale up of the intervention.
- Continue to invest in community health centers to expand PrEP access.
- Increase CDC HIV prevention funding for PrEP provider network.
- A national PrEP program could also serve as a model for more efficient use of other medical products essential to public health (e.g., naloxone).
WHAT COULD WE DO WITH $1B PER YEAR?

National PrEP Program

- Prescription drugs
- Lab services
- Clinical services
- Non-clinical support & navigation services
- Demand creation and education activities
RESOURCES

• National PrEP program proposal from Johns Hopkins University faculty and colleagues:

• Amy Killelea (amyk@killeleacounseling.com)
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Twitter.com/NACHC
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Linkedin.com/company/nachc
YouTube.com/user/nachcmedia
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#ThankYouCHCs

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