Delivering PrEP: 
A Strategy for Ending the HIV Epidemic in America

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15 October 2020
ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA

GOAL:

75% reduction in new HIV infections in 5 years
and at least 90% reduction in 10 years.

PHASE 1: Focused effort to reduce new infections by 75% in 5 years

PHASE 2: Widely disseminated effort to reduce new infections by 90% in the following 5 years

PHASE 3: Intense case management to maintain the number of new infections at < 3,000 per year
Key actions to help end the HIV epidemic

HIV tests determine the next prevention step, PrEP or HIV treatment.

**TEST FOR HIV**

- 86% of people with HIV know they have it.
  - **TARGET:** 95%

**PREVENT**

- People without HIV, but at risk for it, can take PrEP as prescribed to prevent getting HIV.
  - **HAVE PREP PRESCRIPTION**
    - 18%
    - **TARGET:** 50%

**TREAT**

- People who know they have HIV should take medicine daily to control the virus.
  - **HAVE HIV UNDER CONTROL**
    - 63%
    - **TARGET:** 95%
The Current State: Limited PrEP Provision
Estimated HIV Incidence among Persons Aged ≥13 Years
2010–2018—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Bars indicate the range of the lower and upper bounds of the 95% confidence intervals for the point estimate.

* Difference from the 2010 estimate was deemed statistically significant (P < .05).
Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2018—United States and 6 Dependent Areas

N = 37,741

Note. Data for the year 2018 are considered preliminary and based on 6 months reporting delay. Data have been statistically adjusted to account for missing transmission category. "Other" transmission category not displayed as it comprises less than 1% of cases.

- Male-to-male sexual contact: 66%
- Heterosexual contact—Female: 16%
- Heterosexual contact—Male: 7%
- Injection drug use (IDU)—Female: 3%
- Injection drug use—Male: 4%
- Male-to-male sexual contact and IDU: 3%

1.5% Transgender Female (n=554)
<1% Transgender male (n=47)

*Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.
Rates of Diagnoses of HIV Infection among Adults and Adolescents by Sex and Race/Ethnicity, 2018—United States

Note. Data for the year 2018 are considered preliminary and based on 6 months reporting delay.

*Hispanics/Latinos can be of any race.
Number of New HIV Diagnoses in Delaware, 2008-

- 75% male
- 25% female
- 65% Black
- 13% Hispanic
- 20% White
Number of PrEP Users in Delaware, 2012-2018

- 93% male
- 7% female
- 4600 with indications
- 8.7% coverage
Rates of HIV Diagnoses in the US, 2018

<table>
<thead>
<tr>
<th>State</th>
<th>Rate per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>13.3</td>
</tr>
<tr>
<td>NV</td>
<td>20.0</td>
</tr>
<tr>
<td>AZ</td>
<td>13.4</td>
</tr>
<tr>
<td>NM</td>
<td>6.9</td>
</tr>
<tr>
<td>OK</td>
<td>7.2</td>
</tr>
<tr>
<td>AR</td>
<td>11.2</td>
</tr>
<tr>
<td>MS</td>
<td>19.3</td>
</tr>
<tr>
<td>LA</td>
<td>25.5</td>
</tr>
<tr>
<td>TX</td>
<td>19.2</td>
</tr>
<tr>
<td>FL</td>
<td>25.6</td>
</tr>
<tr>
<td>AK</td>
<td>3.3</td>
</tr>
<tr>
<td>HI</td>
<td>5.3</td>
</tr>
</tbody>
</table>

Source: Harris et al, MMWR, 2019

PrEP Coverage, US States, 2018

Source: Harris et al, MMWR, 2019
PrEP Coverage by Race Ethnicity and Sex, 2018

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>% Coverage (Coverage)</th>
<th>% Coverage (Indications)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>42.1</td>
<td>28.9</td>
</tr>
<tr>
<td>Black</td>
<td>39.6</td>
<td>10.9</td>
</tr>
<tr>
<td>Hispanic</td>
<td>25.4</td>
<td>25.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>% Coverage (Coverage)</th>
<th>% Coverage (Indications)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>20.8</td>
<td>81.4</td>
</tr>
<tr>
<td>Women</td>
<td>6.6</td>
<td>18.6</td>
</tr>
</tbody>
</table>
Models of PrEP coverage impact on HIV incidence
Key factors in effective PrEP use

- Higher uptake among those at substantial risk ("coverage")
- High medication adherence
- Persistent use of PrEP throughout periods of risk of HIV exposure

**MSM**

<table>
<thead>
<tr>
<th>Adherence by Drug Concentration</th>
<th>HIV Incidence per 100 PY</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 pills/week</td>
<td>4.7</td>
</tr>
<tr>
<td>&lt;2 pills/week</td>
<td>2.3</td>
</tr>
<tr>
<td>2-3 pills/week</td>
<td>0.6</td>
</tr>
<tr>
<td>≥4 pills/week</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**Annual number of US persons prescribed Truvada for PrEP**

- 2012: 0
- 2013: 5000
- 2014: 10000
- 2015: 15000
- 2017: 20000
- 2017: 25000
- 2018: 30000
**Rapid PrEP Scale-up = Measurable Impact**

**IAS 2018 Abstract 1037**

- Sexual health clinic serving MSM
- From 2011-2016
  - HIV incidence dropped 56%
  - PrEP use increased “exponentially” from 3 to 729
  - % with VL suppression increased slightly from 92-95%

<table>
<thead>
<tr>
<th>Year</th>
<th>HIV diagnoses (N=703)</th>
<th>New HIV infections per 100 persons tested</th>
<th>Annual Percent change in HIV rates</th>
<th>PrEP Consults (N=1318)</th>
<th>% of HIV patients with undetectable viral load</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>126</td>
<td>2.31</td>
<td></td>
<td>3</td>
<td>92</td>
</tr>
<tr>
<td>2012</td>
<td>120</td>
<td>2.02</td>
<td>-12.6</td>
<td>5</td>
<td>91</td>
</tr>
<tr>
<td>2013</td>
<td>145</td>
<td>2.45</td>
<td>21.2</td>
<td>27</td>
<td>93</td>
</tr>
<tr>
<td>2014</td>
<td>118</td>
<td>1.85</td>
<td>-24.3</td>
<td>94</td>
<td>94</td>
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<tr>
<td>2015</td>
<td>112</td>
<td>1.60</td>
<td>-13.5</td>
<td>460</td>
<td>94</td>
</tr>
<tr>
<td>2016</td>
<td>82</td>
<td>1.03</td>
<td>-36.0</td>
<td>729</td>
<td>95</td>
</tr>
</tbody>
</table>
Effect of Rapid Scale-up of PrEP among MSM, Australia

Figure 2: Number of recent HIV infections in New South Wales
Figure shows data for the 12 months before commencement of recruitment to EPIC-NSW (n=149, “before”) and the 12 months after the 3700th EPIC-NSW participant was recruited (n=102, “after”) by age, country or region of birth, and area of residence. NSW = New South Wales.

Source: Grulich et al, Lancet HIV, 2018
More PrEP = Fewer HIV Infections

EAPC in HIV Diagnoses of Persons Age ≥13 in US States Grouped Into PrEP Use Quintiles
USA 2012–2016

EAPC – estimated annual percent change in HIV diagnoses

Sullivan PS et al. IAS 2018
Indications for PrEP Education and Provision
Informing Patients about PrEP

- PrEP should be as well known as other preventive health care
- Not all patients will need or use PrEP but all should be aware of it
  - Can inform family and friends who may benefit from it
  - Normalizes PrEP use and reduces stigmatizing assumptions
  - Motivates acknowledging behaviors or requesting PrEP

- Inform
  - All sexually active adults and adolescents
  - All HIV-positive patients
  - Pre-sexual adolescents when discussing onset of sexual activity
  - Persons with recent substance use problems, including injection drug use
Identifying Sexual Indications

1. Sex with men, women, or both?
   - Yes
     - HIV+ partner?
       - Yes
         - Unknown or detectable viral load?
           - Yes
             - Prescribe PrEP
           - No
             - Always used condoms?
               - Yes
                 - Prescribe PrEP
               - No
                 - Had bacterial STI in past 6 months?
                   - Yes
                     - MSM: GC, chlamydia, or syphilis
                       - No
                         - MSW and WSM: GC or syphilis
                           - Yes
                             - Prescribe PrEP
                           - No
                             - No
2. No
   - 1 or more sex partners of unknown HIV status?
     - Yes
       - Always used condoms?
         - Yes
           - Prescribe PrEP
         - No
           - Had bacterial STI in past 6 months?
             - Yes
               - MSM: GC, chlamydia, or syphilis
                 - No
                   - MSW and WSM: GC or syphilis
                     - Yes
                       - Prescribe PrEP
                     - No
                       - No
Identifying Injection Indications

1. **Ever Injected Drugs?**
   - Yes
     - **Injected past 6 months?**
       - Yes
         - **Shared injection equipment?**
           - Yes
             - Prescribe PrEP
           - No
             - **Injection partner(s) with HIV?**
               - Yes
                 - Prescribe PrEP
               - No
                 - No
     - No

   - No
Standard PrEP Provision
Prescribing PrEP

At substantial risk

- Schedule follow-up visit within 3 months

Prescribe PrEP

- Support medication adherence
  - Counsel about dosing and side effect management

No (acute) HIV infection

- Provide/refer for risk reduction services, e.g., MAT

Normal renal function? (eCrCl)

- If HIV infection confirmed: begin treatment
  - test for resistance

when indicated:
  - assess hepatitis B status
  - assess pregnancy status
  - STI testing

Clinical Considerations:
  - Co-morbidities
  - Medications
FDA-approved daily oral PrEP medications

- **Approved for adults and adolescents (weighing at least 35kg)**
  - F/TDF (Truvada, generic)
    - Emtricitabine+tenofovir disoproxil fumarate
    - Estimated creatinine clearance ≥60 ml/min
    - Effectiveness studied in all transmission risk groups and both sexes
  - F/TAF (Descovy)
    - Emtracitabine + tenofovir alafenamide
    - Estimated creatinine clearance ≥30 ml/min
    - Effectiveness only studied in MSM and TGW
    - Not approved for persons exposed to HIV through receptive vaginal sex
F/TDF or F/TAF?
Helping Patients Afford PrEP Medication

- Health plan marketplace PrEP coverage calculator (NASTAD)
- Gilead medication assistance and co-pay plan
  - Uninsured or insurance declines to cover PrEP
  - Household income <500% of federal poverty level
  - US residence
- HHS “Ready Set PrEP” program
  - Uninsured or insurance declines to cover PrEP
  - US residence
- Generic F/TDF soon available
- USPSTF A grade – no out of pocket cost for most insured (2021)
Practice Variations in PrEP Provision
Adaptations to PrEP Care in the COVID Era

- **Telemedicine visits for initiation and follow-up visits**
  - Voice calls
  - Web/smartphone video visits
  - Web portal results

- **Laboratory testing**
  - HIV self-test (with phone image documentation)
  - Mailed kits for STD and creatinine self specimen collection (Molecular Testing Labs)
  - Lab-only visits

- **Medication**
  - Prescribe a 90-day supply to reduce pharmacy visits
Rapid Start PrEP

Same Day PrEP Prescription

PrEP Evaluation Visit
- Rapid Test HIV-
- PrEP education
- Draw lab specimens
- Benefits Navigation
- Prescribe PrEP
- Schedule follow-up

Get prescription filled

Lab results return
Notify patient to discontinue PrEP if labs indicate

Same Day PrEP Start

PrEP Evaluation Visit
- Rapid Test HIV-
- PrEP education
- Draw lab specimens
- Benefits Navigation
- Prescribe PrEP
- Provide 30-day supply
- Schedule follow-up

Lab results return
Notify patient to discontinue PrEP if labs indicate

1-7 days

0-few days

PrEP Follow-up Visit
- Labs
- Adherence support
- Refill prescription
- Schedule follow-up
Stopping and Re-starting PrEP

- High rates of HIV acquisition before starting and after stopping daily PrEP

- Safely starting and stopping daily PrEP use
  - Best option for those with long breaks between sexual exposure (e.g., > a week)
  - Need HIV test before restarting
A Less-preferred Adaptation

- **Event-driven PrEP ("2-1-1")**
  - Not FDA-approved or CDC-recommended
  - Difficult dosing schedule, easy to miss critical doses
  - Provides less coverage of sexual exposures than daily PrEP
  - Unclear how often HIV tests are needed for safety
  - Only studied for MSM (risk of inadvertent disclosure)
  - Only studied for F/TDF
PrEP medications approaching FDA review

- **Cabotegravir**
  - Noninferiority RCT in MSM and TGW stopped early for efficacy
    - Injection weeks 5 and 9 then every 2 months vs daily oral F/TDF
    - 66% reduction in risk of HIV infection among those given CAB compared to F/TDF
  - Superiority RCT in cisgender women ongoing
    - Next scheduled DSMB review in November

- **Dapivirine vaginal ring**
  - 2 RCTs in southern Africa showed partial efficacy
    - 27-33% reduction in HIV acquisition;
    - Recent approval by European Medicines Agency
    - Planned submission for FDA review in mid-late 2021
Resources
PrEP Resources for Clinicians and Patients

• PrEP Clinical Practice Guideline and Provider’s Supplement
• CDC HIV NEXUS
  https://www.cdc.gov/hiv/clinicians/index.html
• Gilead Medication Assistance Plan
  https://www.gileadadvancingaccess.com/
• HHS Ready, Set, PrEP Program
  https://www.getyourprep.com/
• NASTAD PrEP Health Plan Calculator
  https://nastad.checkbookhealth.org/prepcost/2020/
PrEP Care Guidance during COVID-19

• Dear Colleague Letters
  ✓ HIV DCL
  ✓ PrEP DCL
  ✓ STD DCL
EHE is More than PrEP Delivery

- **EHE Framework includes 4 pillars**
  - Diagnose
  - Treat
  - Prevent
    - Including increased availability and use of comprehensive Syringe Services Programs (SSPs)
  - Respond

- **EHE activities include expanding the EHE workforce in jurisdictions**

- **EHE is collaboration with multiple federal agencies**
  - CDC, HRSA BPHC, HRSA HAB, IHS, SAMHSA, NIH

- **Monitoring progress toward goals critical to reduce HIV incidence**
HIV tests determine the next prevention step, PrEP or HIV treatment.

86% of people with HIV know they have it.
TARGET: 95%

PREVENT
People without HIV, but at risk for it, can take PrEP as prescribed to prevent getting HIV.

HAVE PREP PRESCRIPTION 18%
TARGET 50%

TREAT
People who know they have HIV should take medicine daily to control the virus.

HAVE HIV UNDER CONTROL 63%
TARGET 95%
HIV Testing and Diagnosis

- Increase
  - Routine HIV screening in clinical settings
  - HIV testing in non-clinical settings
  - Access to HIV self-testing (“home testing”)
  - Frequency of HIV testing among persons at high risk of acquiring HIV
  - Early detection of HIV
HIV tests determine the next prevention step, PrEP or HIV treatment.

86% of people with HIV know they have it.
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People without HIV, but at risk for it, can take PrEP as prescribed to prevent getting HIV.

HAVE PREP PRESCRIPTION 18%
TARGET 50%

TREAT
People who know they have HIV should take medicine daily to control the virus.

HAVE HIV UNDER CONTROL 63%
TARGET 95%
HIV Treatment and Viral Suppression

- **Increase**
  - Immediate linkage to HIV care at first positive HIV test
  - Rapid initiation of antiretroviral treatment after diagnosis
  - Use of interventions to support medication adherence
  - Rapid re-engagement of persons who drop-out of care
  - Durable viral suppression ("U=U")
HIV-negative Partners Who Could Benefit from PrEP

Transmissions
- 38 Undiagnosed HIV+
- 43 Diagnosed but not in care
- 20 In care but not virally suppressed

Persons
- 15 Undiagnosed HIV+
- 23 Diagnosed but not in care
- 11 In care but not virally suppressed
- 51 HIV-negative Partners

Respond

- Develop partnerships, processes, data systems, and policies to facilitate robust, real-time cluster detection and response
- Investigate and intervene in networks with active transmission
- Identify and address gaps in programs and services revealed by cluster detection and response
Monitoring Progress

- **AHEAD: America’s HIV Epidemic Analysis Dashboard**
  - [https://ahead.hiv.gov/](https://ahead.hiv.gov/)

- **Leading indicators**
  - Diagnoses
  - Viral Suppression
  - Linkage to HIV medical care
  - PrEP coverage

- **Intermediate goal**
  - Knowledge of HIV status

- **Overarching goal**
  - HIV incidence
Diagnoses refer to the number of people diagnosed with HIV infection in a given year, regardless of when infection occurred.

Knowledge of Status

Knowledge of status is the estimated percentage of people with HIV who have received an HIV diagnosis.

Linkage to HIV Medical Care

Linkage to HIV medical care is the percentage of people diagnosed with HIV in a given year who have received medical care for their HIV infection within one month of diagnosis.

Viral Suppression

Viral suppression is the percentage of people living with diagnosed HIV infection who have an amount of HIV that is less than 200 copies per milliliter of blood, in a given year.

PrEP Coverage

PrEP coverage is the estimated percentage of individuals prescribed PrEP among those who need it.

Incidence

Incidence is the estimated number of new HIV infections in a given year.
The United States will become a place where new HIV infections are rare…

National HIV/AIDS Strategy