Innovative Programs to End the HIV Epidemic: ART Rapid Start

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Southeast AIDS Education & Training Center (SEATEC) Webinar
January 22, 2020
Disclosures

• (CME) Integritas Communications: Funded through Gilead
• (CME) Vindico CME – Funded through ViiV Healthcare
Objectives

1. Describe the Data Pertaining to Rapid ART Start with focus on programs in Southeast
2. Advocate for Rapid Start Approach in Context of Equity
3. Review clinical considerations when initiating rapid ART
4. Identify Potential Hurdles to Implementation
Ending the HIV Epidemic

**GOAL**

- **Diagnose** all people with HIV as early as possible after infection.
- **Treat** the infection RAPIDLY and effectively to achieve sustained viral suppression.
- **Protect** people at risk for HIV using potent and proven prevention interventions, including PrEP, a medication that can prevent HIV infections.
- **Respond** rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.
- **HIV HealthForce** will establish local teams committed to the success of the Initiative in each jurisdiction.

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

Ending the HIV Epidemic: A Plan for America
Regional Breakdown of the 48 Highest Burden Target Counties

WEST
23% OF COUNTIES

MIDWEST
13% OF COUNTIES

NORTHEAST
17% OF COUNTIES

SOUTH
48% OF COUNTIES
5 of 7 of Rural Epidemic States

NUMBER OF PERSONS NEWLY DIAGNOSED WITH HIV, 2016

<table>
<thead>
<tr>
<th>5-5</th>
<th>6-6</th>
<th>7-8</th>
<th>9-10</th>
<th>11-13</th>
<th>14-19</th>
<th>20-29</th>
<th>29-49</th>
<th>50-111</th>
<th>112+</th>
</tr>
</thead>
</table>

AIDSVu.ORG
SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION
Ending the HIV Epidemic: A Plan for America
48 Highest Burden Counties and D.C.

In 67% of the 48 target counties and D.C., the percent of people living in poverty is higher than the national average (14.7%)

In 73% of the 48 target counties and D.C., the percent of people uninsured is higher than the national average (9.4%)

PERCENT OF POPULATION LIVING IN POVERTY, 2015

0 - 12.0  
12.1 - 15.0  
15.1 - 18.0  
18.1+

PERCENT OF POPULATION LACKING HEALTH INSURANCE, 2015

0 - 12.0  
12.1 - 16.0  
16.1 - 20.0  
20.1+
Structural Racism

Slavery Expansion

Failing to Remember

#RobertRayford

Article
October 14, 1988

Documentation of an AIDS Virus Infection in the United States in 1968

Robert F. Garry, PhD; Marlys H. Witte, MD; A. Arthur Gottlieb, MD; et al

Author Affiliations

### Guidelines Endorse

<table>
<thead>
<tr>
<th><strong>DHHS</strong>[^1]</th>
<th><strong>IAS-USA</strong>[^3]</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART to be started immediately or as soon as possible after diagnosis (AII)</td>
<td>Start ART as soon as possible, <strong>including immediately after diagnosis</strong>, if patient is ready</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>WHO</strong>[^2]</th>
<th><strong>NY State DOH</strong>[^4]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended where feasible same day</td>
<td>Offer rapid initiation of antiretroviral therapy (ART)—preferably on the same day (A1) or within 96 hours of diagnosis</td>
</tr>
</tbody>
</table>

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[^4]: Radix A et al. NYSDOH AIDS Institute. 2019
U = U

UNDETECTABLE = UNTRANSMITTABLE

A person living with HIV who has an undetectable viral load does not transmit the virus to their partners.

The International AIDS Society is proud to endorse the U=U consensus statement of the Prevention Access Campaign.
Lifetime Risk of HIV Infection...

- **African American MSM**: 1 in 2
- **Hispanic MSM**: 1 in 4
- **White MSM**: 1 in 11

- **African American Men**: 1 in 20
- **African American Women**: 1 in 48
- **Hispanic Men**: 1 in 48
- **Hispanic Women**: 1 in 227
- **White Men**: 1 in 132
- **White Women**: 1 in 880

CDC. February 2016
Interpret Outcomes in Context of Setting

**Global Progress**
53% of All PWH Are Virally Suppressed

- **Diagnosed**: 90%
- **On Treatment**: 90%
- **Virally Suppressed**: 90%
- **86%**

**US Progress**
57% of All PLWH Are Virally Suppressed

- **Diagnosed**: 90%
- **Retained**: 90%
- **Virally Suppressed**: 90%
- **85%**

79%
78%

- **90%**
- **85%**
- **57%**
- **80%**


Adapted from Carlos del Rio
RCTs: Global Setting

Ford N et al. *AIDS* 2018
SFGH RAPID Model

HIV+ Diagnosis
- Disclosure
- Referral
- Scheduling

1st Clinic Visit
- Registered
- Insured
- Housing/SU/MH
- Counseling
- Labs

1st PCP Visit
- Medical evaluation
- ART criteria met

ART Start
- Pills taken

Viral Load Suppressed
- VL monitoring
- Adherence
- Retention

RAPID Visit and ART Start
- Disclosure, counseling, registration
- Insurance
- Housing/SU/MH
- Labs
- Counseling
- Medical eval

PCP visits
- VL monitoring
- ART management
- Adherence
- Retention

MH, mental health; PCP, primary care provider; SU, substance use.
SFGH: RAPID – Uptake of Same day ART

Key Sociodemographics

<table>
<thead>
<tr>
<th></th>
<th>RAPID</th>
<th>Universal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homelessness</td>
<td>11 (28%)</td>
<td>13 (25%)</td>
</tr>
<tr>
<td>Uninsured</td>
<td>39 (100%)</td>
<td>47 (100%)</td>
</tr>
<tr>
<td>Illicit Substance Use</td>
<td>18 (46%)</td>
<td>18 (38%)</td>
</tr>
</tbody>
</table>

RAPID: Quick and Durable Viral Suppression
2013 – 2017 SF DPH

Patients With VL <200 Copies/mL at Last VL Recorded
91.2%

Patients Ever Achieving VL <200 Copies/mL 1 Year After ART Start
95.8%

Patients With VL <200 Copies/mL at Last VL Recorded
91.2%

Years Since ART Start
N = 255

Grady Infectious Disease Program: The Ponce de Leon Center

Who do we serve?

- 71% Male, 28% Female, <1% Transgender
- 84% Black/African American, 9% White, 5% Latino
- 14% <= 24, 35% 25-44, 51% >=45 years of age
- 32% < FPL, 60% < 2X FPL
- 42% uninsured, 26% Medicaid, 21% Medicare
- 64% Stage 3 (AIDS)

Medicaid NONEXPANSION State
# REACH: Rapid Entry and ART in Clinic for HIV

## Goals
1. Clinician visit and ART access within 72 hours of clinic presentation
2. Decrease time to viral suppression

## Health System Changes to Facilitate Program Implementation

<table>
<thead>
<tr>
<th>ACTION</th>
<th>LEVEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove eligibility restrictions for clinic enrollment</td>
<td>EMA Ryan White office</td>
</tr>
<tr>
<td>Loosen administrative requirements for clinic enrollment</td>
<td>EMA Ryan White office; hospital system</td>
</tr>
<tr>
<td>Remove TB skin test as requirement for clinic enrollment</td>
<td>Clinic administration</td>
</tr>
<tr>
<td>Enhance access to <em>New Patient</em> provider visits</td>
<td>Hospital system; clinic administration</td>
</tr>
<tr>
<td>Enhance provider education on <em>Rapid Starts</em></td>
<td>Clinician</td>
</tr>
<tr>
<td>Enhance support for accessing ART, regardless of payer</td>
<td>Pharmacy administration</td>
</tr>
<tr>
<td>Continue access to ongoing ART-adherence education</td>
<td>Nursing</td>
</tr>
</tbody>
</table>

EMA, eligible metropolitan area; TB, tuberculosis.
Figure 1

TOTAL New Enrollees:
Jan 1 – July 31, 2016
299

PRE-REACH:
Jan 1 – May 15
159

Excluded: 42
Virally suppressed (<200): 31
On ART from inpatient: 4
Admit from Enroll: 2
Pregnant: 2
Research: 1
Moved: 1
Transferred: 1

POST-REACH:
May 16 – July 31
140

POST-REACH Analyzed
90

Excluded: 50
Virally suppressed (<200): 30
On ART from inpatient: 10
Admit from Enroll: 6
Research: 2
Moved: 1
Died: 1

PRE-REACH Analyzed
117
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Median or n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Young Black Men</strong></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>35 (25-45)</td>
</tr>
<tr>
<td>African American</td>
<td>188 (91%)</td>
</tr>
<tr>
<td>Male</td>
<td>165 (80%)</td>
</tr>
<tr>
<td><strong>Socioeconomic Challenges</strong></td>
<td></td>
</tr>
<tr>
<td>Uninsured (Ryan White only)</td>
<td>118 (57%)</td>
</tr>
<tr>
<td>Unstable housing</td>
<td>126 (61%)</td>
</tr>
<tr>
<td>Income</td>
<td>$8,796</td>
</tr>
<tr>
<td><strong>Psychosocial Challenges</strong></td>
<td></td>
</tr>
<tr>
<td>Active substance use</td>
<td>91 (44%)</td>
</tr>
<tr>
<td>Mental health disorders</td>
<td>54 (26%)</td>
</tr>
<tr>
<td><strong>Biomedical Complexity</strong></td>
<td></td>
</tr>
<tr>
<td>CD4 count</td>
<td>146 cells/µL</td>
</tr>
<tr>
<td>ART experienced</td>
<td>83 (40%)</td>
</tr>
</tbody>
</table>

All patients newly enrolled in the clinic from January 1–July 31, 2016: N=299
Patients in 6 week REACH pilot: N=90

## ARVs During Rapid Entry

<table>
<thead>
<tr>
<th></th>
<th>Pre-REACH N (%)</th>
<th>Post-REACH N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initiated ART</strong></td>
<td>111 (95)</td>
<td>85 (94)</td>
</tr>
<tr>
<td><strong>Anchor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDF</td>
<td>67 (60)</td>
<td>36 (47)</td>
</tr>
<tr>
<td>TAF</td>
<td>16 (14)</td>
<td>22 (24)</td>
</tr>
<tr>
<td>ABC</td>
<td>27 (24)</td>
<td>26 (29)</td>
</tr>
<tr>
<td>AZT</td>
<td>1 (1)</td>
<td>--</td>
</tr>
<tr>
<td><strong>NRTI sparing</strong></td>
<td></td>
<td>1 (1)</td>
</tr>
<tr>
<td><strong>Backbone</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTG</td>
<td>55 (49)</td>
<td>49 (59)</td>
</tr>
<tr>
<td>EVG</td>
<td>27 (24)</td>
<td>22 (26)</td>
</tr>
<tr>
<td>DRV</td>
<td>27 (24)</td>
<td>12 (14)</td>
</tr>
<tr>
<td>EFV</td>
<td>1 (0.8)</td>
<td>1 (1.2)</td>
</tr>
<tr>
<td>Lop/r</td>
<td>1 (0.8)</td>
<td>--</td>
</tr>
<tr>
<td>RPV</td>
<td>--</td>
<td>1 (1.2)</td>
</tr>
</tbody>
</table>
### Results: Process Improvement ↓ Time to VS

#### Days to Clinical Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Pre-REACH N=117</th>
<th>Post-REACH N=90</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days to 1st scheduled provider visit</td>
<td>14.0 (11.9, 16.2)</td>
<td>3.7 (1.1, 6.2)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Days to 1st attended provider visit</td>
<td>12.1 (6.4, 22.8)</td>
<td>2.1 (0.9, 4.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Days to ART start</td>
<td>22.0 (12.7, 38.1)</td>
<td>4.4 (2.3, 8.4)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Attended 1st scheduled visit</td>
<td>85 (73)</td>
<td>73 (81)</td>
<td>NS</td>
</tr>
<tr>
<td>Viral suppression</td>
<td>87 (74)</td>
<td>61 (68)</td>
<td>NS</td>
</tr>
</tbody>
</table>

#### Days to Viral Suppression

- Pre-REACH: 57 days to VS (IQR 41, 70)
- Post-REACH: 77 days to VS (IQR 62, 96)

ICI, confidence interval; QR, interquartile range.
Late Presenters Need More

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Early ≤ 90 days after diagnosis</th>
<th>Late &gt; 90 days after diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-REACH n = 47</td>
<td>Post-REACH n = 29</td>
</tr>
<tr>
<td>Days to 1&lt;sup&gt;st&lt;/sup&gt; scheduled provider visit</td>
<td>12 (4, 19)</td>
<td>4 (2, 7)</td>
</tr>
<tr>
<td>Days to 1&lt;sup&gt;st&lt;/sup&gt; attended provider visit</td>
<td>14 (6, 20)</td>
<td>5 (2, 7)</td>
</tr>
<tr>
<td>Attended 1&lt;sup&gt;st&lt;/sup&gt; scheduled visit</td>
<td>37 (79)</td>
<td>26 (90)</td>
</tr>
<tr>
<td>Days to ART initiation</td>
<td>17 (11, 27)</td>
<td>5 (3, 10)</td>
</tr>
<tr>
<td>Viral Suppression</td>
<td>41 (87)</td>
<td>24 (83)</td>
</tr>
</tbody>
</table>

86% 64%
Late Presenters Need More

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Early ≤ 90 days after diagnosis</th>
<th></th>
<th>Late &gt; 90 days after diagnosis</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-REACH n = 47</td>
<td>Post-REACH n = 29</td>
<td>P value</td>
<td>Pre-REACH n = 70</td>
</tr>
<tr>
<td>Days to 1st scheduled provider visit</td>
<td>12 (4, 19)</td>
<td>4 (2, 7)</td>
<td>&lt;.0001</td>
<td>17 (9, 21)</td>
</tr>
<tr>
<td>Days to 1st attended provider visit</td>
<td>14 (6, 20)</td>
<td>5 (2, 7)</td>
<td>0.0003</td>
<td>20 (10, 29)</td>
</tr>
<tr>
<td>Attended 1st scheduled visit</td>
<td>37 (79)</td>
<td>26 (90)</td>
<td>0.3480</td>
<td>48 (69)</td>
</tr>
<tr>
<td>Days to ART initiation</td>
<td>17 (11, 27)</td>
<td>5 (3, 10)</td>
<td>0.0002</td>
<td>24 (13, 41)</td>
</tr>
<tr>
<td>Viral Suppression</td>
<td>41 (87)</td>
<td>24 (83)</td>
<td>0.7392</td>
<td>46 (66)</td>
</tr>
</tbody>
</table>

86% 64%
More needed...Especially Re-entry

Cox proportional hazard model: Time to VS

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted Hazard Ratio</th>
<th>95% Confidence Interval</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-REACH</td>
<td>1.825</td>
<td>1.276</td>
<td>2.609</td>
</tr>
<tr>
<td>ART Naïve</td>
<td>1.733</td>
<td>1.192</td>
<td>2.518</td>
</tr>
<tr>
<td>INSTI use</td>
<td>1.477</td>
<td>0.925</td>
<td>2.358</td>
</tr>
<tr>
<td>Baseline VL</td>
<td>0.842</td>
<td>0.711</td>
<td>0.997</td>
</tr>
</tbody>
</table>

Adjusted Logistic Regression: Achieving VS

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted Odds Ratio</th>
<th>95% Confidence Interval</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-REACH</td>
<td>0.821</td>
<td>0.418</td>
<td>1.611</td>
</tr>
<tr>
<td>ART Naïve</td>
<td>2.231</td>
<td>1.131</td>
<td>4.400</td>
</tr>
<tr>
<td>INSTI use</td>
<td>2.606</td>
<td>1.204</td>
<td>5.641</td>
</tr>
<tr>
<td>Baseline VL</td>
<td>1.243</td>
<td>0.871</td>
<td>1.773</td>
</tr>
<tr>
<td>Black/African American</td>
<td>0.484</td>
<td>0.127</td>
<td>1.852</td>
</tr>
</tbody>
</table>

Ongoing Rapid Entry at IDP

IDP Rapid Entry Draft Programmatic data

Non Rapid N=418
Rapid Entry (72h) N=496
CrescentCare Start Initiative
December 2016

• FQHC (started as ASO) w/ robust support services available
• Medicaid EXPANSION

CrescentCare Start Initiative (CCSI):
Patients newly diagnosed with HIV are seen by a provider within 72 hours (optimally same-day) and provided 30 days of ART.

Early Intervention Services (EIS):
Same protocol but patients contacted our clinic over 72 hours since diagnosis.
Range: 4 days – 25 years

Adapted from: J. Halperin
Procedures/Evaluation

Medical Provider Visit:
- HIV Lifecycle, importance of adherence, U=U discussed
- Comorbidities assessed
- Physical Examination
- TAF/FTC/DTG recommended by medical leadership (30 day-supply)
- Provider option to not rx, alter medications if suspected resistance
- First Dose DOT

Post-Provider Visit:
- Enroll in insurance programs
- Intake Labs obtained
- Social Work services for those with urgent needs

• Inclusion:
  • Enrolled 12/2016 – 2/2018
  • 6 month lab f/u at crescent care

• CCSI 126
  • 4 lost to f/u

• EIS 69
  • 1 died after hospital D/C
  • 1 declined ART on day #1

Adapted from: J. Halperin
## CrescentCare START: Baseline

<table>
<thead>
<tr>
<th></th>
<th>CCSI (n=126)</th>
<th>EIS (n = 69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median</td>
<td>29</td>
<td>29</td>
</tr>
<tr>
<td>Female</td>
<td>27 (21.4)</td>
<td>10 (14.5)</td>
</tr>
<tr>
<td>African American</td>
<td>81 (64.3)</td>
<td>48 (69.9)</td>
</tr>
<tr>
<td>Latinx</td>
<td>15 (11.9)</td>
<td>7 (10.1)</td>
</tr>
<tr>
<td>MSM</td>
<td>73 (57.9)</td>
<td>42 (60.9)</td>
</tr>
<tr>
<td>STI at entry</td>
<td>48 (38.1)</td>
<td>32 (46.4)</td>
</tr>
<tr>
<td>&lt;100% FPL</td>
<td>49 (39)</td>
<td>25 (36)</td>
</tr>
<tr>
<td>Uninsured</td>
<td>65 (52)</td>
<td>38 (56)</td>
</tr>
<tr>
<td>Mental health Dx</td>
<td>25 (20)</td>
<td>23 (33)</td>
</tr>
<tr>
<td>Baseline CD4</td>
<td>444 (265, 640)</td>
<td>271 (124, 459)</td>
</tr>
</tbody>
</table>

*P < 0.05*
CD4 Count, Viral Suppression, Transmitted Resistance

CCSI
- All but two patients received TAF/FTC + DTG
- 118/126 genotypes were performed and reviewed.
- 22/118 (19%) with transmitted resistance
- 18 with NNRTI resistance
- 3/22 with M184V/I with two previously on PrEP
- 4/22 with multiple PI mutations including L90M
- All patients with transmitted resistance achieved viral suppression.
- No ART changes due to renal/hepatic toxicity

EIS
- All but three patients received TAF/FTC + DTG
- 63/69 genotypes were performed
- 6/63 (9.5%) with transmitted resistance.
- 5 with NNRTI mutations
- 2/6 with M184V/I no previous PrEP exposure
- All patients with transmitted resistance achieved viral suppression
- No ART changes due to renal/hepatic toxicity
CCSI Continuum of Care

Halperin J et al. OFID. 2019
Barriers to Implementation

• **Structural/systemic**
  1. HIV testing/diagnosis occurs off-site; ie, referral to clinic
  2. Complex eligibility criteria - eg, CD4 count, income, residence
  3. Access to medications without payer source
  4. Scheduling and provider availability

• **Provider/staff beliefs**
  1. “That’s how we’ve always done it.”
  2. Preparatory lab results must be known; ie, serum creatinine, hepatitis B and C serology, genotype
  3. Latent TB infection screening must be performed first

• **Patients’ attitudes and beliefs**

• **Patients’ psychosocial comorbidities**
  1. Unstable housing
  2. Food insecurity
  3. Mental illness
  4. Substance use
Pre-Rapid Entry Implementation

- Step in enrollment process when patient could be turned away and not given PCP appt until step completed
Post Implementation Patient Enrollment

1. Patient arrives
2. Patient has required documents? Yes/No
   - Yes: Waiting area
   - No: Assigned peer navigator to assist with documentation, but still continues along enrollment process
3. Chest x-ray & attending review
   - Positive: TB symptom screen
   - Negative: Waiting area
4. Nurse assessment
   - Waiting area
5. Financial counselor assesses payor source and required RW documents
   - Patient receives PGP appointment
6. Health educator visit
   - Waiting area
SF DOH: Community-wide coordination

Rapid ART Delivery

Testing Sites
- Magnet
- City Clinic
- Other Testing Sites (GLIDE, API Wellness, AHP)

Rapid ART Hubs
- Kaiser
- SFGH
- Private
- Other Insurance Mandated Clinics

ROVING LINCS COORDINATOR
Stationed @ Magnet/SFAF Serving Multiple Test Sites

LINCS – linkage, integration, navigation, comprehensive services

Slide: adapted from Buchbinder S. Getting to Zero: https://www.sfdph.org/dph/files/sfchip/GettingToZero-HIV.pdf
How to get Antiretrovirals

• No payer source and no documentation to enroll in Ryan White (RW)
  – Manual patient assistance program
    • Can be time intensive, but not impossible
  – Starter packs: need to find funding source for this
    • Expedited insurance applications (eg, San Francisco)

• Enrolled in RW, but awaiting AIDS Drug Assistance Program (ADAP) application completion
  – Stop-gap medications
  – Co-pay cards

• Medicaid expansion (eg, Louisiana)
  – “…a gift from the heavens.” –Halperin
# Clinical Guidance – what to start

<table>
<thead>
<tr>
<th>DHHS[1]</th>
</tr>
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<tbody>
<tr>
<td>• Avoid NNRTI-based regimens</td>
</tr>
<tr>
<td>• Recommended regimens&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>BIC/FTC/TAF</td>
</tr>
<tr>
<td>DTG + tenofovir&lt;sup&gt;c&lt;/sup&gt;/FTC</td>
</tr>
<tr>
<td>DRV/r or DRV/c&lt;sup&gt;b&lt;/sup&gt; + tenofovir&lt;sup&gt;c&lt;/sup&gt;/FTC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IAS-USA&lt;sup&gt;[3]&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Recommend unboosted INSTI regimens (other than DTG/ABC/3TC) as initial therapy</td>
</tr>
<tr>
<td>BIC/FTC/TAF or DTG + FTC/TAF</td>
</tr>
</tbody>
</table>

---

Key Facilitators of RAPID Intervention

- Same-day appointments
- Flexible provider scheduling (on call backup)
- ART-regimen preapproval prior to genotyping or lab testing
- Availability of ART starter packs
- Patient navigator
- Accelerated process for health insurance initiation
- Observation of first ART dose in clinic (recommended)
- Guarantee sustained access to ART
Some fearful of rapid entry – it’s all about context

Too fast to stay on track? Shorter time to first anti-retroviral regimen is not associated with better retention in care in the French Dat’AIDS cohort

<table>
<thead>
<tr>
<th>CD4 cell count at HIV diagnosis/µL</th>
<th>&lt;300</th>
<th>300–350</th>
<th>350–500</th>
<th>&gt;500</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at diagnosis (Years, median, IQR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N = 1594</td>
<td>41 (33–51)</td>
<td>37 (29–47)</td>
<td>34 (27–44)</td>
<td>34 (27–43)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>End of study (%)</th>
<th>In care</th>
<th>Changed place of care</th>
<th>Lost to follow-up</th>
<th>Dead</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 1589</td>
<td>75.2</td>
<td>7.7</td>
<td>11.8</td>
<td>5.3</td>
</tr>
<tr>
<td>N = 1593</td>
<td>76.4</td>
<td>9.2</td>
<td>12.6</td>
<td>1.8</td>
</tr>
<tr>
<td>N = 1588</td>
<td>75.5</td>
<td>10.7</td>
<td>12.9</td>
<td>0.9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sex and way of acquisition (%)</th>
<th>MSM*</th>
<th>MSW*</th>
<th>Women</th>
<th>Trans gender M→W</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 1575</td>
<td>15.8</td>
<td>37.7</td>
<td>29.6</td>
<td>19.5</td>
</tr>
<tr>
<td>N = 1613</td>
<td>23.8</td>
<td>25.6</td>
<td>26.4</td>
<td>29.3</td>
</tr>
<tr>
<td>N = 1572</td>
<td>29.1</td>
<td>20.1</td>
<td>22.4</td>
<td>31.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ART 3rd drug (%)</th>
<th>bPF</th>
<th>NNRTI*</th>
<th>INSTI*</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 1573</td>
<td>69.7</td>
<td>8.5</td>
<td>13.7</td>
<td></td>
</tr>
<tr>
<td>N = 1611</td>
<td>58.0</td>
<td>22.0</td>
<td>14.5</td>
<td></td>
</tr>
<tr>
<td>N = 1570</td>
<td>51.2</td>
<td>25.7</td>
<td>17.2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time from first visit to ART (days, median, IQR)</th>
<th>From diagnosis to first visit</th>
<th>From diagnosis to ART</th>
<th>From diagnosis to undetectable VL</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 1574</td>
<td>9 (3–19)</td>
<td>12 (6–22)</td>
<td>13 (6–27)</td>
</tr>
<tr>
<td>N = 1575</td>
<td>14 (7–27)</td>
<td>21 (7–56)</td>
<td>42 (14–144)</td>
</tr>
<tr>
<td>N = 1572</td>
<td>228 (150–300)</td>
<td>212 (132–336)</td>
<td>239 (140–419)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time from first medical visit to first ART (days)</th>
<th>&lt; 9</th>
<th>9–27</th>
<th>28–90</th>
<th>&gt; 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 1881</td>
<td>79.9</td>
<td>84.5</td>
<td>85.9</td>
<td>85.2</td>
</tr>
<tr>
<td>N = 1784</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alive and in care at month 12 after ART prescription (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time from diagnosis to undetectable VL (days; median, IQR)</th>
<th>194 (108–351)</th>
<th>210 (130–361)</th>
<th>232 (152–357)</th>
<th>527 (311–924)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of first ART (months; median, IQR)</td>
<td>14 (5–32)</td>
<td>17 (7–35)</td>
<td>21.5 (7–39)</td>
<td>22 (7–42)</td>
</tr>
<tr>
<td>End of study situation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dead (%)</td>
<td>2.2</td>
<td>3.1</td>
<td>1.9</td>
<td>0.9</td>
</tr>
<tr>
<td>LTFU (%)</td>
<td>14.3</td>
<td>12.4</td>
<td>13.4</td>
<td>12.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VL &lt; 50 copies/mL after 6 months of ART (%)</th>
<th>72.1</th>
<th>69.8</th>
<th>78.9</th>
<th>79.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>VL &lt; 50 copies/mL after 12 months of ART (%)</td>
<td>78.0</td>
<td>81.5</td>
<td>84.1</td>
<td>81.4</td>
</tr>
<tr>
<td>VL &lt; 50 copies/mL after 18 months of ART (%)</td>
<td>83.7</td>
<td>85.5</td>
<td>86.9</td>
<td>87.9</td>
</tr>
</tbody>
</table>

Published: September 6, 2019 • https://doi.org/10.1371/journal.pone.0222067
HPTN 071: PopART -= Universal Test and Treat

3 arm cluster-randomised trial with 21 communities

- Arm A:
  - Full PopART intervention
  - Immediate ART irrespective of CD4 count

- Arm B:
  - PopART intervention except
  - ART initiation according to current national guidelines

- Arm C:
  - Standard of care at current service provision levels
  - ART initiation according to current national guidelines

7 communities per arm (N=21)

- 12 in Zambia
- 9 in S. Africa

~2,000 random sample from each community:

Population Cohort
N ~ 42,000

Primary outcome: HIV incidence at 36 months

PopART intervention package
- Annual rounds of Home Based Voluntary HIV Testing by Community HIV-care Providers (CHiPs)
- Health promotion, Active Referral and/or Retention in Care support by CHIPs for the following:
  - Voluntary Medical Male Circumcision (VMMC) for HIV negative men
  - Prevention of Mother to Child Transmission (PMCT) for HIV positive women
  - HIV treatment and care for all HIV positive individuals
  - Promotion of sexual health and TB services
  - Condom provision
- ART irrespective of CD4-count or immune-status provided at the local health centre in Arm A

Time from diagnosis to ART: 10 mo → 6 mo (7 communities)

Hayes r et al NEJM 2019; Seeley J et al. AIDS Behav 2019
HPTN 071: PopART = Universal Test and Treat

3 arm cluster-randomised trial with 21 communities

- Arm A: Full PopART intervention including immediate ART irrespective of CD4 count
- Arm B: PopART intervention except ART initiation according to current national guidelines
- Arm C: Standard of care at current service provision levels including ART initiation according to current national guidelines

7 communities per arm (N=21)

- ~2,000 random sample from each community: Population Cohort N ~ 42,000

Primary outcome: HIV incidence at 36 months

PopART intervention package:
- Annual rounds of Home Based Voluntary HIV Testing by Community Health Workers
- Health promotion, Active Referral and/or Retention in Care support
  - Voluntary Medical Male Circumcision (VMMC) for HIV prevention
  - Prevention of Mother to Child Transmission (PMTCT) for newborns
  - HIV treatment and care for all HIV positive individuals
  - Promotion of sexual health and TB services
  - Condom provision
- ART irrespective of CD4-count or immune-status provided at the time of diagnosis

Time from diagnosis to ART: 10 mo → 6 mo (7 communities)

Hayes r et al NEJM 2019; Seeley J et al. AIDS Behav 2019

• Group c
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- Hayes R et al NEJM 2019; Seeley J et al. AIDS Behav 2019
Rapid Start Supports Equity

• AA men are more likely to have delays in ART initiation even after seeing a prescribing provider.

• No better demonstration of commitment to a community than same-day immediate access to a provider.

• Dazon from Sister Love: “See my brothers and sisters as your own. If you do then, of course, you will see patients same-day, start same-day and love same-day.”
Rapid Entry is Part of a Package

HIV Care Continuum

- Patient navigators
- Clinic-based buprenorphine
- Clinic-based surveillance
- Rapid-entry ART initiation
- PrEP
- ARTAS
- Enhanced personal contacts
- EMR alerts (virology fast track)
- Innovative retention-in-care strategies

CDC LRC Compendium
Immediate ART Initiation: Guide for Clinicians

February 14, 2019

Susa Coffey, MD, AETC National Coordinating Resource Center, UCSF Center for HIV Information
Oliver Bacon, MD, MPH

https://aidsetc.org/blog/immediate-art
Domestic Rapid Start Consortium

- Boston
- New York
- Philadelphia
- Atlanta
- Miami
- New Orleans
- Baton Rouge
- Orlando
- San Antonio
- Austin
- Houston
- Alexandria
- Birmingham
- Washington D.C.
- San Francisco
- Phoenix
- Tucson
- Albuquerque
- Los Angeles
- Chicago

Best Practices

Logistical Hurdles

Research

The Third \( U = \text{UNIVERSAL} \)

Contact: Jeremiah Rastegar
jrastegar@uabmc.edu
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• Thanes Vanig