HIV Screening, Diagnosis, and Rapid Antiretroviral Therapy Start

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Disclosure Information

- Kento Sonoda, MD, AAHIVS
  - No Disclosures
- Amy J. Kennedy, MD, MS, AAHIVS
  - No Disclosures
- Julie Childers, MD, FASAM
  - No Disclosures
Learning Objectives

1. Apply HIV screening tests into clinical practice
2. Interpret HIV diagnostic test results
3. Identify resources for starting ART immediately after the diagnosis of HIV
Target Audience

- Addiction medicine clinicians in the community setting
- Limited access to HIV specialists
- Introductory level
More than 1.2 M people living with HIV in the U.S.
- 159 K (13%) unaware of HIV infection

New HIV infections (2019): 37 K
- Age group – highest among people aged 25 to 34 (36%)
- PWID: 7% of the new HIV diagnoses

Estimated prevalence of HIV infection among PWID: 1.9%

HIV prevalence by county
New HIV diagnoses by county
New HIV Diagnoses (2019)

- **Black**
  - Population (%): 10
  - HIV Diagnoses (%): 40

- **Hispanic**
  - Population (%): 20
  - HIV Diagnoses (%): 30

- **White**
  - Population (%): 60
  - HIV Diagnoses (%): 50


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Disparities in HIV prevalence

HET: heterosexual
IDU: injection drug user
TM: transgender men
TW: transgender women
Estimated prevalence of HIV infection among PWID: 1.9%
Unprotected sex: more common in PWID

HIV CARE CONTINUUM:
The steps that people with HIV take from diagnosis to achieving and maintaining viral suppression.

- Diagnosed with HIV
- Linked to care
- Received HIV medical care
- Retained in care
- Achieved and maintained viral suppression
HIV Screening (Recommendation)

USPSTF:
- Routine, voluntary HIV screening
- All people aged 15 to 65 years (including all pregnant persons)
- Insufficient evidence to determine optional intervals

CDC:
- Persons at increased risk: at least annually
  - PWID, Persons who exchange sex for money or drugs
  - MSM, heterosexual persons with multiple sexual partners

Consider Repeat HIV Screening

- Anyone who has been sexually active or is sharing needles
- Anyone with sexually transmitted infections
- Anyone with certain medical conditions
  - Pneumococcal pneumonia, tuberculosis
  - Abnormal PAP smear, thrush, recent vaginal candidiasis
  - New onset of psoriasis and seborrheic dermatitis
  - Immune thrombocytopenia, pancytopenia, lymphoma
  - HBcAb+, HCAb+
Rational for HIV Screening

- 75% of pts newly diagnosed w/ AIDS: 4 visits in prior 5 years
  - Time from HIV infection to AIDS: > 5 years

- 60% of pts diagnosed with HIV: no identified risk/encounterDx
  - By risk (MSM, IVDU) only 34% could have been identified

Case 1

A 30-year-old male is here for follow-up. He was evaluated for mild fever, sore throat, myalgia, and fatigue a week ago. HIV 5th generation test: p24 (+) and HIV 1/2 Ab (-).

Which of the following is the most appropriate next step?
1. HIV Viral Load and Treat
2. No further testing
3. T-cell subset testing
4. Western Blot HIV-1 Ab testing
5. POC HIV testing
<table>
<thead>
<tr>
<th>Assay progression</th>
<th>Indirect ELISA (HIV-1,2)</th>
<th>Sandwich ELISA HIV1,2 IgG &amp; IgM</th>
<th>Sandwich ELISA HIV1,2 IgG &amp; IgM + p24 Ag</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 lysate</td>
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<tr>
<td>HIV-2 lysate</td>
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<td>Ab-conjugate</td>
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<td>Patient IgG</td>
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<tr>
<td>Signal</td>
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<td>HIV peptide</td>
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<td>Patient IgM</td>
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<tr>
<td>Ag-conjugate</td>
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<tr>
<td>p24</td>
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<table>
<thead>
<tr>
<th>Year</th>
<th>Generation</th>
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<tbody>
<tr>
<td>1985</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;</td>
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<tr>
<td>1987</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt;</td>
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<tr>
<td>1991</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt;</td>
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<tr>
<td>1997</td>
<td>4&lt;sup&gt;th&lt;/sup&gt;</td>
</tr>
<tr>
<td>2015</td>
<td>5&lt;sup&gt;th&lt;/sup&gt;</td>
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</table>
Markers in Acute HIV Infection

CDC Algorithm (4th Generation)

HIV-1/2 Antigen/Antibody Immunoassay

(+)

(-)
Negative for HIV-1 and HIV-2 antibodies and p24 Ag

HIV-1/HIV-2 Antibody Differentiation Immunoassay

HIV-1 (+) HIV-2 (-)
HIV-1 antibodies detected

HIV-1 (-) HIV-2 (+)
HIV-2 antibodies detected

HIV-1 (+) HIV-2 (+)
HIV antibodies detected

HIV-1 (-) or Indeterminate
And
HIV-2 (-) or Indeterminate

HIV-1 NAT

HIV-1 NAT (+)
Acute HIV-1 infection

HIV-1 NAT (-)
Negative for HIV-1


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# Interpretation and Plan (5th Generation)

- Acute infection (window 2 weeks) and chronic infection

<table>
<thead>
<tr>
<th>Result</th>
<th>Interpretation</th>
<th>Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>p24(-) HIV1/2 Ab(-)</td>
<td>HIV(-)</td>
<td>No further testing</td>
</tr>
<tr>
<td>p24(+) HIV1/2 Ab(-)</td>
<td>Acute infection</td>
<td>Viral load, Tx</td>
</tr>
<tr>
<td>p24(-) HIV1 Ab(+)</td>
<td>Chronic infection</td>
<td>Viral load, CD4, Tx</td>
</tr>
<tr>
<td>p24(-) HIV2 Ab(+)</td>
<td>Chronic infection</td>
<td>Refer to ID</td>
</tr>
</tbody>
</table>
You saw a 28-year-old male through telemedicine 2 days ago. You ordered HIV 5th generation screening test, which showed HIV-1 infection.

How do you deliver the news of HIV diagnosis?
Delivering Test Results

- In a private area & In a direct, neutral tone

- If negative, provide HIV prevention counseling (ie PrEP)

- If positive,
  - Patient education
  - Linkage to Care HIV (scheduling a follow-up appointment)
  - Partner notification requirement: depends on states (sexual partner, needle sharing partner)

Telling others. CDC. State HIV Laws. The Center for HIV Law and Policy.
Case 2

❖ Jared is a 28 yo man with hx of opioid and methamphetamine use disorders. He uses via both injection and smoke/oral routes. He presents to clinic today to get started on buprenorphine-naloxone for his OUD.

❖ As part of your routine initial exam you order a CMP, HIV, HCV, and STI testing.

❖ 24 hours later you review his results and his HIV test is positive (5th generation test, p24 negative, HIV 1 antibody positive)
What is your next step?

A) Repeat HIV screening test
B) Check HIV viral load
C) Refer to an HIV/infectious disease specialist
D) Start patient on antiretroviral medication (ART) now
Case 2

- There are no infectious disease specialists in your area.

- You call Jared and ask him to come in to discuss lab results. You call the lab and add on a HIV viral load and CD4 count.

- Viral load comes back with 10,000 copies/ml
- CD4 comes back at 550 cells/dl
When do we start ART?

1) Acute HIV
2) CD4 < 200 cells/dl
3) CD4 < 500 cells/dl
4) CD4 > 500 cells/dl
5) All of the Above
ART “Rapid Start”

Day 1

New HIV Diagnosis

Days 1-7

Follow RIA protocol
Obtain Baseline Bloodwork
Focused Medical/Psychological Evaluation
Prescribe ART
First HIV Primary Care Visit

Rapid Initiation of ART (RIA) Frequently Asked Questions (ny.gov)
Current Recommendations for Same-Day ART Initiation

- Rapid start or initiating ART on same day as HIV is diagnosed is an emerging strategy to reduce loss to follow-up and decrease time to viral suppression.

- Evidence base limited but growing, and outcomes favorable thus far

<table>
<thead>
<tr>
<th>DHHS(^1)</th>
<th>WHO(^2)</th>
<th>IAS-USA(^3)</th>
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</table>
| **Recommended** at time of diagnosis (when possible) or soon afterward  
  - Resource intensive  
  - US experience from observational trials | **Recommended** for all PWH, including same day, if patient is ready* | **Start ART as soon as possible, including immediately after diagnosis, if patient is ready** |

*Rapid initiation defined as within 7 days of diagnosis. Priority should be given to patients with advanced disease.*
1. ART substantially reduces HIV transmission (by >95%)

2. Survival benefit with initiation of ART, even at CD4 count >500

Why do we start ART early?

3. ART regimens are effective, safe, convenient (1 pill/day), and well tolerated

4. People with HIV have higher levels of inflammation and endothelial dysfunction which improves with ART
Initial Lab Work-Up

HIV Tests
- Repeat HIV screen (if first screen done outside system)
- HIV Viral Load
- CD4 Count
- HIV Genotype (integrase only if concern for resistance*)

Basic Labs
- CBC, CMP, UA
- A1c, Lipids

Co-occurring infections
- STI testing – gonorrhea, chlamydia, syphilis, trichomonas (in women)
- Hepatitis serologies (A, B, C)
- Toxoplasmosis IgG
- TB (ppd or IGRA)
- Cryptococcus antigen

DHHS ART Guidelines, 2019
DHHS Opportunistic Infections Guidelines, 2019
# Follow-Up or ART Modification

<table>
<thead>
<tr>
<th></th>
<th>2-8 Weeks After ART Initiation or Modification</th>
<th>Q 4 to 8 Weeks Until VL &lt; 200</th>
<th>Q 3 to 4 months (First 2 years)</th>
<th>Q 6 months</th>
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</thead>
<tbody>
<tr>
<td>Viral Load</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>CD 4 count</td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td>BMP</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>LFTs</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Nucleoside Reverse Transcriptase Inhibitors</td>
<td>Integrase Inhibitors</td>
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<td>-------------------------------------------</td>
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<tr>
<td>Emtricitabine FTC</td>
<td>Dolutegravir DTG</td>
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<tr>
<td>Lamivudine 3TC</td>
<td>Bictegravir BTG</td>
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<tr>
<td>Abacavir ABC</td>
<td>Elvitegravir EVG.cbc</td>
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<tr>
<td>TenofovirAF TAF</td>
<td>Raltegravir RAL</td>
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<td>TenofovirDF TDF</td>
<td>Cabotegravir CAB</td>
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<tr>
<td>Zidovudine ZDV/AZT</td>
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<tr>
<th>Protease Inhibitors</th>
<th>Non-nucleoside Reverse Transcriptase Inhibitors</th>
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<tbody>
<tr>
<td>Darunavir DRV.cbc</td>
<td>Efavirenz EFV</td>
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<tr>
<td></td>
<td>Rilpivirine Ril</td>
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<tr>
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<td>Doravirine Dor</td>
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Most common antiretroviral medications 2022

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### Recommended Regimens for Rapid ART

#### DHHS\[^1\]

<table>
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<tbody>
<tr>
<td>★ BIC/FTC/TAF</td>
</tr>
<tr>
<td>DTG + (TAF or TDF) + (3TC or FTC)</td>
</tr>
<tr>
<td>(DRV/RTV or DRV/COBI) + (TAF or TDF) + (3TC or FTC)</td>
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<table>
<thead>
<tr>
<th>Regimens Not Recommended</th>
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<tbody>
<tr>
<td>NNRTI-based regimens or DTG/3TC</td>
</tr>
<tr>
<td>due higher rate of transmitted NNRTI and NTRI drug resistance</td>
</tr>
<tr>
<td>Regimens requiring ABC until HLA-B*5701 test results received</td>
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#### IAS-USA\[^2\]

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<td>★ BIC/FTC/TAF</td>
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<td>DRV/RTV + (FTC or 3TC)/(TAF or TDF)</td>
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<tr>
<th>Regimens Not Recommended</th>
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<tbody>
<tr>
<td>NNRTI-based regimens due to concerns over transmitted drug resistance (K103N)</td>
</tr>
<tr>
<td>Regimens requiring ABC until HLA-B*5701 test results received</td>
</tr>
</tbody>
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Halperin J and Rockstroh 2019, DHHS Guidelines 2019, Saag 2018
Why integrase inhibitors?

High barrier to resistance
Well-tolerated, minimal side effects
Minimal drug-drug reactions
Where to go for help

- UCSF – national clinician conference center
  - National Clinician Consultation Center (ucsf.edu)
- AETC – AIDS Education and Training Center
- DHHS – Department of Health and Human Services
- CDC – Center for Disease Control
5-minute updates in HIV treatment/HIV Prevention
Primary Prophylaxis Guidelines

Prophylaxis against disseminated mycobacterium avium complex (MAC)

- **No longer recommended** for adults/adolescents who immediately initiate ART (AII)
- Only recommended in patients with HIV not on ART/viremic with CD4 <50

Two RCT, placebo-controlled trials + observational data demonstrates people with HIV on ART have minimal risk of developing MAC

Daley, IDSA, 2020
High Yield: Clinical Decision Points

- **CD4 <200** Begin PJP prophylaxis -> (Bactrim DS QD or MWF)
- Risk for Candida (no prophylaxis)
- **CD4 <100** Toxoplasmosis prophylaxis (if IgG+) -> (Bactrim DS QD)
- **CD4 <50** Risk for MAC (no prophylaxis)
- Risk for CMV retinitis (no prophylaxis)

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ART/PrEP updates

ART

- Long-acting injectable ART
  Cabotegravir/rilpivirine (integrase/NNRTI)

PrEP

- TDF/FTC (Truvada) once daily
- NEW: TAF/FTC (Descovy) once daily
  Not for women at risk through sex
- NEW: Long-acting injectable cabotegravir (integrase inhibitor)
Sexually Transmitted Infection Updates

- Uncomplicated gonococcal infection: ceftriaxone 500mg IM x1 (increased from 250mg)

- Chlamydia infection: doxycycline 100mg BID x 7 days (prior 1gm azithromycin x 1)

- Hepatitis C: Screening now include all adults 18-79 years of age

MMWR, Dec 2020, USPFTF, March 2020
Final Takeaways

- Test everyone for HIV (opt-out)
  - Repeat HIV screening annually and consider PrEP for anyone at high risk

- All HIV+ patients should receive ART
  - Decreased transmission, increased survival with rapid start
  - First line Rapid Start ART: Integrase inhibitor or Darunavir/c with TAF/FTC
Any Questions?
Acknowledgement

- Peter Veldkamp, MD, MSc
  Professor of Medicine, Division of Infectious Diseases,
  University of Pittsburgh School of Medicine
Resources (Website)

1. National HIV Curriculum. Created by University of Washington. [https://www.hiv.uw.edu](https://www.hiv.uw.edu)
   - Submit your care online
   - Call for a Phone Consultation

References


2. AIDSVu [https://map.aidsvu.org/map](https://map.aidsvu.org/map)


11. CDC. 2018 Quick reference guide: recommended laboratory HIV testing algorithm for serum or plasma specimens.
References


## References


