Ongoing Management of the HIV Patient in the Ambulatory Care Setting: Strategies for Achieving Long-term Viral Suppression

Presented as a Midday Symposium and Live Webinar at the 50th ASHP Midyear Clinical Meeting and Exhibition

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Ongoing Management of the HIV Patient in the Ambulatory Care Setting: Strategies for Achieving Long-term Viral Suppression

Agenda

11:30 a.m. – 11:40 a.m.
Welcome and Introductions
Jason J. Schafer, Pharm.D., M.P.H., BCPS, AAHIVP

11:40 a.m. – 11:50 a.m.
HIV Epidemiology and Engagement in Care
Jason J. Schafer, Pharm.D., M.P.H., BCPS, AAHIVP

11:50 a.m. – 12:10 p.m.
Acute HIV Infection
Joseph A. DeSimone, Jr. M.D., FIDSA, AAHIVS

12:10 p.m. – 12:30 p.m.
Switching ART
Joseph A. DeSimone, Jr. M.D., FIDSA, AAHIVS

12:30 p.m. – 12:50 p.m.
Hepatitis C Co-infection
Jason J. Schafer, Pharm.D., M.P.H., BCPS, AAHIVP

12:50 p.m. – 1:00 p.m.
Faculty Discussion and Audience Questions
All Faculty

Faculty

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Associate Professor, Department of Pharmacy Practice
Jefferson College of Pharmacy
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Ongoing Management of the HIV Patient in the Ambulatory Care Setting: Strategies for Achieving Long-term Viral Suppression

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Activity Overview

The epidemic of human immunodeficiency virus (HIV) infection in the United States has changed dramatically in the last 30 years. The widespread use of antiretroviral therapy, in particular, can significantly suppress HIV replication, restore a patient’s immune function, and has resulted in a significant decline in HIV-related morbidity and mortality. As a result, patients on long-term therapy that maintain viral suppression can now manage their infection as a chronic illness and are likely to experience a near-normal life expectancy. Despite the remarkable advances in the management of patients living with HIV infection in the United States, challenges to successful HIV care remain.

This educational activity will apply emerging evidence and current practice guidelines to address contemporary challenges in achieving long-term viral suppression among HIV positive patients commonly encountered in the ambulatory care setting.

Learning Objectives

At the conclusion of this application-based educational activity, participants should be able to

- Outline the diagnosis and management of acute HIV infection.
- Select patients who are appropriate candidates for switching antiretroviral regimens to improve convenience, safety or tolerability.
- Demonstrate the current approach to managing patients with HIV and hepatitis C co-infection.

Additional Educational Opportunities about HIV Coming in 2016

- Web-based activity - Based on today’s live symposium (1.5 hours of CE, please note that individuals who claim CE credit for the live symposium or webinar are ineligible to claim credit for the web-based activity)

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Complete instructions for processing continuing education credit online are listed on the last page.

Webinar Information

Visit www.cemiday.com to find:

- Webinar registration link
- Group viewing information and technical requirements
Ongoing Management of the HIV Patient in the Ambulatory Care Setting: Strategies for Achieving Long-term Viral Suppression

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Clinical Pharmacy Specialist, HIV Ambulatory Care
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Jason J. Schafer, Pharm.D., M.P.H., BCPS, AAHIVP, is Associate Professor of Pharmacy Practice at the Jefferson College of Pharmacy and Clinical Pharmacy Specialist, HIV Ambulatory Care, at Thomas Jefferson University in Philadelphia, Pennsylvania.

Dr. Schafer received his Doctor of Pharmacy degree from Duquesne University and completed a pharmacy practice residency at the Mercy Hospital of Pittsburgh and a second residency specializing in infectious diseases at the Ohio State University Medical Center. He received his Master of Public Health degree from the Jefferson School of Population Health. He is a board-certified pharmacotherapy specialist (BCPS) and is certified by the American Academy of HIV Medicine (AAHIVM) as a practicing HIV Pharmacist (AAHIVP).

Dr. Schafer’s clinical practice site is an HIV specialty ambulatory care clinic in Philadelphia where he provides medication therapy management services. He also provides service to the AAHIVM on its Pharmacist and Credentialing Committees.

Dr. Schafer has published numerous articles on HIV medicine and pharmacotherapy in the medical literature including the ASHP Guidelines on Pharmacist Involvement in HIV Care. He has also been active in ASHP most recently serving as the Infectious Diseases Network Facilitator and as Director at Large for the Section of Clinical Specialists and Scientist’s Executive Committee.
Joseph A. DeSimone, Jr. M.D., FIDSA, AAHIVS
Professor of Medicine
Director, Infectious Diseases Fellowship Program
Sidney Kimmel Medical College
Thomas Jefferson University
Philadelphia, Pennsylvania

Joseph A. DeSimone, Jr., M.D., FACP, FIDSA, is Professor of Medicine and Program Director for the Infectious Diseases Fellowship Program at the Sidney Kimmel Medical College, at Thomas Jefferson University in Philadelphia, Pennsylvania.

Dr. DeSimone graduated from Hahnemann University School of Medicine where he also completed both his Internal Medicine residency and Infectious Diseases fellowship. He is a fellow of the Infectious Diseases Society of America (FIDSA) and a Practicing HIV Specialist (AAHIVS).

He is responsible for teaching infectious diseases and HIV to medical students, internal medicine residents, and infectious diseases fellows at Thomas Jefferson University. Dr. DeSimone has provided clinical care for HIV-infected patients at Thomas Jefferson University for over 15 years and currently cares for over 300 HIV-infected patients in his practice.

He has acted as the principal or co-principal investigator for dozens of clinical trials investigating antiretroviral therapy for persons with HIV infection. Dr. DeSimone has authored numerous publications in peer-reviewed journals and abstract presentations at national meetings. He has received numerous teaching awards while at Thomas Jefferson University including the Dean’s Award for Excellence in Education from the Sidney Kimmel Medical College and Induction into the Gold Humanism Honor Society.
Disclosures

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Learning Objectives

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HIV Epidemiology and Engagement in Care

Jason J. Schafer Pharm.D., M.P.H, BCPS, AAHIVP
Activity Chair
Associate Professor, Department of Pharmacy Practice
Jefferson College of Pharmacy
Philadelphia, Pennsylvania

HIV Infection in the U.S.
AIDS Diagnoses and Deaths in the United States, 1985-2012

Centers for Disease Control and Prevention, HIV/AIDS Surveillance.

HIV Infection in the US
Patient engagement in the continuum of HIV Care

- Of the 1.2 million people living with HIV in the U.S. in 2011, an estimated 86% were diagnosed.
- 14% (or 1 in 7 people living with HIV) were unaware of their infection
- Patient engagement decreases at each stage in the continuum

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HIV Infection in the US
Patient engagement and Transmission of HIV

92% of new HIV infections are attributable to people with HIV who are not in medical care, including those who are not diagnosed.


HIV Infection in the US
Patient engagement in the continuum of HIV Care

Of the 70% of people living with HIV who are not virally suppressed:
A. 66% are diagnosed, but not engaged in regular HIV care
B. 20% do not know they are infected
C. 10% are prescribed ART, but have not yet achieved viral suppression
D. 4% are in HIV care, but are not prescribed ART


HIV Infection in the US
Patient engagement in the continuum of HIV Care

• Closing the gaps
  – Improvements in HIV testing and diagnosis
  – Emerging strategies for linking and retaining patients in care
  – Evolving recommendations for when to initiate antiretroviral therapy
  – Achieving and maintaining viral suppression


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Patient Case-August 2015

- PT is a 37 YO AA female; ER 8/17/15.
- 5 days abdominal pain, dysuria, foul-smelling urine, vomiting.
- Observed overnight, dx pyelonephritis, sent home with oral cephalosporin.
- While in observation unit, offered HIV screening per ED protocol.
- HIV Antigen(Ag)/Antibody (Ab) 4th-generation enzyme immunoassay (EIA) reactive.
- Reports prior negative HIV testing.
- New monogamous male sexual partner 6 months ago after 7 years of abstinence. Partner serostatus unknown.

In patients with a reactive 4th-generation HIV Ag/Ab result, what test should be performed next?

a. HIV-1 Western blot
b. HIV-2 Western blot
c. HIV viral RNA quantitative assay (viral load)
d. HIV-1/HIV-2 discriminatory immunoassay
e. CD4 cell count
If reactive HIV-1/2 Antigen/Antibody Combination Immunoassay...

Perform HIV-1/2 Antibody Differentiation Immunoassay

- HIV-1 (+) HIV-2 (-)  
- HIV-1 (-) HIV-2 (+)  
- HIV-1 Antibodies Detected  
- HIV-2 Antibodies Detected  
- HIV-1 Infection  
- HIV-2 Infection  
- Dual HIV-1 and HIV-2 Infection

HIV-1/HIV-2 differentiation assay (Multispot)

http://www.fda.gov/downloads/BiologicsBiologicalDrugs/ApprovedProducts/ProductApprovalAnnouncements/ucm091384.pdf [accessed 2015 Oct]
The HIV-1/HIV-2 differentiation assay (Multispot) results are both non-reactive. What should be done next for PT?

a. HIV-1 Western blot
b. CD4 cell count
c. HIV viral RNA quantitative assay (viral load)
d. Inform the patient that she is definitely infected with HIV
e. Inform the patient she is definitely not infected with HIV

See page 35 for enlarged view
Acute (Primary, Early) HIV Infection

- Systemic:
  - fever
  - weight loss

- Pharyngitis
- Mouth:
  - sores
  - ulcer

- Esophagus:
  - sores

- Muscles:
  - anorexia

- Liver and spleen:
  - enlargement
  - vomiting

- Central:
  - malaise
  - headache
  - neuropathy

- Lymph nodes:
  - lymphadenopathy

- Skin:
  - rash

- Gastric:
  - nausea


Unexpected Clinical Manifestations of Primary HIV-1 Infection


See page 36 for enlarged view
Awareness of Serostatus Among People with HIV, and Estimates of Transmission

- ~20% Unaware of Infection
- ~49% of New Infections
- ~80% Aware of Infection
- ~51% of New Infections

People Living with HIV/AIDS: 1,200,000

New Sexual Infections Each Year: 50,000

Hall HI et al. AIDS. 2012; 26:893-6.

PT comes to office 5 days later to learn of confirmed diagnosis. HIV viral load is >10 million copies; CD4 count is 600 cells/mm³. Should this patient be treated with ART and when?

a. Yes, immediately (today)
b. Yes, in 4 weeks (after genotype available)
c. No, since CD4 count is >500 cells/mm³.
d. Not yet, since she needs time to process her new diagnosis.
e. Not sure

<table>
<thead>
<tr>
<th>Table 1</th>
<th>THEORETICAL RATIONALE FOR AND POTENTIAL DISADVANTAGES OF INITIATING ART DURING ACUTE INFECTION</th>
</tr>
</thead>
</table>
| Reasons for ART in acute HIV infection | Reduction in the risk of viral transmission  
Preservation of HIV-specific immune function, including the generation of the survival of CD4 cells that are involved in the initial response to HIV infection  
Suppression of the initial burst of viral replication with a decrease in the magnitude of viral dissemination, which reduces reservoir size and may preserve gut-associated lymphoid tissue  
Potential reduction in the emergence of viral variants associated with the suppression of viral replication  
Potential to reduce the severity and duration of illness during asymptomatic acute HIV infection  
Potential to reduce the risk of HIV superinfection (i.e., infection with a second strain of HIV) |
| Reasons for not initiating ART during acute HIV infection | Development of drug resistance if therapy fails due to subtherapeutic or insufficient suppression of viral replication  
Adverse effects on quality of life as a result of drug toxicities  
Failure to commence to lifelong ART |

Providing same day, observed ART to newly diagnosed HIV+ outpatients is associated with improved virologic suppression

Christopher D. Pilcher, Hiroyu H. Hatano, Aditi Dasgupta, Diane Jones, Sandra Torres, Fabiola Calderon, Erin Domicco, Wendy Hartogensis, Clarissa Ojina-Norvell, Elhin Gerig, Monica Gandhi, Diane Havlir

University of California, San Francisco
San Francisco General Hospital

Milestones of care:
SFGH, 2006-2013

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RAPID Demonstration Project
July 2013-December 2014

• Overall feasibility of a health systems intervention for same-day outpatient ART for newly diagnosed HIV infection
• Deployed in context of extensive existing services for navigation, linkage and retention
• Initially targeted to new patients with acute HIV infection (HIV Ab – within 6 months)
• Extended in 2014 to include active opportunistic infection (OI), CD4<200 cells/mm³

RAPID Intervention Components

• Facilitation of same day appointments
• Flexible scheduling for providers (on-call back-up)
• ART regimens pre-approved for use prior to genotyping or lab testing
• Available as 5-day starter packs
• Accelerated process for health insurance initiation
• Recommendation for 1st dose to be taken observed in the clinic

New SFGH patients, RAPID era: 2013-4

<table>
<thead>
<tr>
<th>Indicator</th>
<th>RAPID Cohort (n=39)</th>
<th>Universal ART (n=47)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sociodemographics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age: mean(range)</td>
<td>32 (21-47)</td>
<td>35 (19-68)</td>
<td>NS</td>
</tr>
<tr>
<td>Male: n (%)</td>
<td>39 100%</td>
<td>43 92%</td>
<td>NS</td>
</tr>
<tr>
<td>Non-white ethnicity</td>
<td>23 59%</td>
<td>34 72%</td>
<td>NS</td>
</tr>
<tr>
<td>Homeless</td>
<td>11 28%</td>
<td>13 25%</td>
<td>NS</td>
</tr>
<tr>
<td>Uninsured</td>
<td>39 100%</td>
<td>47 100%</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Staging</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute (Ab&lt;6m)</td>
<td>21/30 70%</td>
<td>8/31 26%</td>
<td>0.001</td>
</tr>
<tr>
<td>Log₁₀VL</td>
<td>4.9 (2.8-6.6)</td>
<td>4.5 (1.6-6.1)</td>
<td>NS</td>
</tr>
<tr>
<td>CD4 mean (range)</td>
<td>474 (3-1391)</td>
<td>417 (11-1194)</td>
<td>NS</td>
</tr>
</tbody>
</table>

VL=viral load
**Uptake of same-day ART**

% on ART

Days after ART offer/clinician visit

**RAPID program era 2013-4: acceptability and safety**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>RAPID (n=39)</th>
<th>Universal (n=47)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acceptability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall ART uptake</td>
<td>39 (100%)</td>
<td>40 (85%)</td>
<td>NS</td>
</tr>
<tr>
<td>Engaged in care (appt &lt;6 mos)</td>
<td>35 (90%)</td>
<td>40 (85%)</td>
<td>NS</td>
</tr>
<tr>
<td>Transferred care</td>
<td>8 (21%)</td>
<td>11 (23%)</td>
<td>NS</td>
</tr>
<tr>
<td>Provider switched</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ART simplification</td>
<td>10 (26%)</td>
<td>0 (0%)</td>
<td>0.001</td>
</tr>
<tr>
<td>ART Toxicity</td>
<td>2 (5%)</td>
<td>0 (0%)</td>
<td>NS</td>
</tr>
<tr>
<td>Genotype-driven modification</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>NS</td>
</tr>
</tbody>
</table>

*all outcomes determined as of last followup (up to 18 months post referral)*

**Engagement Timeline, SFGH**

CD4-guided (2006-9)

Universal (2010-3)

RAPID

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Conclusions

- It was feasible to implement same-day ART initiation for outpatients with newly diagnosed HIV in a well resourced, public health clinic setting.
- Same day ART was highly acceptable to both patients and providers.
- Same day ART was associated with improved rates of virologic suppression.
- No excess toxicity or other adverse effects of starting ART immediately at the first visit were seen.
- Expansion of the RAPID model citywide in 2015.


Patient Case

- PT defers treatment at time of diagnosis.
- Returns to office one year later.
- Asymptomatic.
- Viral load 200,000 copies/mL; CD4 600 cells/mm³.
- Estimated GFR 110 mL/min/1.73m².
- Takes no other meds.

Is treatment with ART recommended for PT?

a. Yes
b. No
c. Not sure.
START Study:
Initiation of ART in Early Asymptomatic HIV Infection

Multicontinental Study (n=4685)
HIV-positive adults
Treatment-naive
CD4 >500 cells/mm³

Randomization 1:1
Immediate ART (n=2326)
Deferred ART (n=2359)

5/2015: DSMB recommends stopping trial
Deferred arm offered ART

Primary outcome a composite outcome of 2 major components:
• Any serious AIDS-related event
  • Death from AIDS or any AIDS-defining event, HIV-related lymphoma
• Any serious non-AIDS-related event
  • CVD (myocardial infarction, stroke, or coronary revascularization) or death from CVD, end-stage renal disease (initiation of dialysis or renal transplantation) or death from renal disease, non-AIDS-defining cancer (except for basal-cell or squamous-cell skin cancer) or death from cancer, and any death not attributable to AIDS

When to Start Therapy:
Balance Now Favors Early ART

- Drug toxicity
- Preservation of limited Rx options
- Risk of resistance (and transmission of resistant virus)

- ↑ potency, durability, simplicity, safety of current regimens
- ↓ emergence of resistance
- ↓ toxicity with earlier therapy
- ↑ subsequent treatment options
- Risk of uncontrolled viremia at all CD4 levels
- ↓ transmission
Recommendations for Initiating ART: Considerations

- “Patients starting ART should be willing and able to commit to treatment and should understand the benefits and risks of therapy and the importance of adherence.”
- Patients may choose to postpone ART
- Providers may elect to defer ART, based on an individual patient’s clinical or psychosocial factors, but ART should be started as soon as it is feasible to do so

Per the DHHS 2015 guidelines, which of the following is currently recommended as a first-line regimen for this patient?

a. Efavirenz/tenofovir disoproxil/emtricitabine (EFV/TDF/FTC)
b. Rilpivirine/tenofovir disoproxil/emtricitabine (RPV/TDF/FTC)
c. Atazanavir/ritonavir (ATV/r) plus TDF/FTC
d. Elvitegravir/cobicistat/TDF/FTC (EVG/cobi/TDF/FTC)
e. Darunavir/ritonavir (DRV/r) plus abacavir/lamivudine (ABC/3TC)

U.S. DHHS Guidelines, April 2015: What to Start

Recommended Regimens

- Integrase strand transfer inhibitor (INSTI)-based
  - Dolutegravir/abacavir/lamivudine (DTG/ABC/3TC)*
  - Elvitegravir/cobicistat/TDF/FTC (EVG/cobi/TDF/FTC)
- Raltegravir (RAL) plus TDF/FTC
- Ritonavir-boosted protease inhibitor (PI/r)-based
  - Darunavir/ritonavir (DRV/r)/plus TDF/FTC

*Only for pts who are HLA-B*5701 negative. Only for pts with pre-ART CD4 < 70 mil/mm3. Non-nucleoside reverse transcriptase inhibitors (NNRTIs) and Atazanavir/ritonavir (ATV/r), previously classified as “recommended,” are now “alternative regimens”

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U.S. DHHS Guidelines, April 2015: What to Start

**Alternative Regimens**

- NNRTI based: EFV/TDF/FTC
- R/F/TVF/FTC

- PI based:
  - ATV/COBI + TDF/FTC
  - ATV + TDF/FTC
  - DRV/COBI + ABC/3TC
  - DRV/COBI + TDF/FTC

*Only for pts with pre-ART HIV-1 RNA < 100,000 copies/mL and CD4+ > 200 cells/mm3.
†Only for pts with pre-ART CrCl ≥ 70 mL/min.
‡Only for pts who are HLA-B*5701 negative.

- An alternative regimen may be the preferred regimen for some patients.

**ACTG 5257: Cumulative Incidence of Virologic or Tolerability Failure**

- **Difference in 56-wk cumulative incidence**
  - ATV vs RAL 15% (10% to 20%)
  - DRV vs RAL 7.5% (2.2% to 12%)
  - ATV/r vs DRV/r 7.5% (2.2% to 12%)


**SINGLE: DTG + ABC/3TC Superior to EFV/TDF/FTC in ART-Naive Pts to Wk 144**

- Open-label extension, excluding pts with hepatitis B virus (HBV)
- Emergent resistance in those with VFI: 0/39 (DTG) vs 7/33 (EFV)

- 95% CI for Difference
  - ATV/COBI vs EFV/TDF/FTC: 7.4% (2.7% to 12.3%)
  - ATV/r vs EFV/TDF/FTC: 7.4% (2.7% to 12.3%)

Comparing the Integrase Inhibitors

<table>
<thead>
<tr>
<th>Agent</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
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</table>
| Raltegravir (RAL) | • Longest experience  
|            | • Fewer drug interactions than EVG, DTG | • Twice daily dosing (for now)  
|            | • Once-daily dosing             | • No coformulation                                                           |
| Etritgravir (ETG) | • Single-tablet regimen (STR)  
|            | • Once-daily dosing             | • Requires Cobicistat  
|            |                               | • Cobicistat drug interactions similar to RTV                                |
| Daltegravir (DTG) | • The only non-TOF–containing STR  
|            | • Once-daily dosing             | • Cumulated with Cobicistat only                                             |
|            | • Higher barrier to resistance  
|            | • Few drug interactions         |                                                                               |
|            | • Active against some RAL– and EVG-resistant virus                         |                                                                               |

Together, the results of STARTMRK, GS 102 and 103, SINGLE, FLAMINGO, and ACTG 5257 suggest that integrase inhibitor–based regimens are the preferred starting regimens in the majority of patients.

FLAMINGO: DTG Superior to DRV/r in ART-Naive Pts to Wk 96

Molina et al. HIV Drug Therapy Glasgow 2014; Glasgow, UK. Slides O153.
PT starts EVG/c/TDF/FTC. One year later:
Viral load undetectable; CD4 count
900 cells/mm³; GFR now 70 mL/min/1.73 m²;
HLA B-5701 is positive.
Next step?
  a. Observe on EVG/c/TDF/FTC until GFR drops below
     30 mL/min/1.73 m²
  b. Switch EVG/c/TDF/FTC to Raltegravir (RAL) plus
     TDF/FTC
  c. Switch EVG/c/TDF/FTC to DTG/ABC/3TC
  d. Switch EVG/c/TDF/FTC to EVG/c/TAF/FTC

TAF (tenofovir alafenamide)

- Tenofovir disoproxil (TDF) associated with severe renal adverse events in 1-2%
- Conflicting data on reversibility of renal impairment after discontinuation of TDF
- TAF is tenofovir (TFV) prodrug with 91% less circulating plasma tenofovir exposure and increased intracellular concentration

Tenofovir Alafenamide (TAF): Novel Prodrug of Tenofovir

- 91% lower plasma TFV levels minimize renal and bone effects while maintaining high potency for suppressing HIV

See page 37 for enlarged view
Study 109: Switch to Tenofovir Alafenamide-Containing Single-Tablet Regimen

Switch to E/C/F/TAF (n=959)
Continue Tenofovir DF-Based Regimen (n=477)

Primary Endpoint
Week 48
HIV RNA <50 Copies/mL

Week 48
HIV RNA <50 Copies/mL

E/C/F/TAF: elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide.
TAF 10mg.
Tenofovir DF-based regimens:
• Elvitegravir/COBI/FTC/TDF (n=459).
• Efavirenz/FTC/TDF (n=376).
• Boosted atazanavir + FTC/TDF (n=601).

Median CD4: 662–675 cells/mm3.
Median eGFR: 106–108 mL/min.

Study 109: Virologic Outcomes at Week 48 Following Switch to Tenofovir Alafenamide-Containing Single-Tablet Regimen

Remaining HIV RNA <50 copies/mL

E/C/F/TAF
TDF-based regimens

Prior ART Regimen

0% 20% 40% 60% 80% 100%

All Patients (n=1436/1436)
EFV/FTC/TDF (n=451/229)
P<0.001

P<0.001

P<0.001

P<0.001

P<0.001

*Not met noninferiority criteria (treatment difference: 4.1 [1.6 – 6.7]).

Study 109: Other Outcomes and Summary

• Discontinuations due to adverse events
  – E/C/F/TAF: 0.9%
    • Renal events (n=2), other events (n=7)
  – TDF-based regimen: 2.5%
    • Renal events (n=7), other events (n=3)

• Patients who switched to E/C/F/TAF versus TDF-based regimen were
  – Significantly more likely to maintain virologic suppression (P<0.001)
  – Significant improvements in spine and hip BMD (P<0.001)
  – Significant improvements in proteinuria and other markers of renal function (P<0.001)
Study 112: Switch to E/C/F/TAF in Patients With Renal Impairment

Phase 3 study (96 weeks)
Treatment-experienced
Open-label
HIV RNA <50 copies/mL
eGFR 30-69 mL/min

Switch to E/C/F/TAF
(n=242)

Primary Endpoint
Week 24
Change From Baseline in eGFR

Mean Change in eGFR at Week 48
(Cockcroft-Gault)

-0.6 -0.4 0 0.2 1.8

All Patients
Yes
No

Actual GFR at Week 24
(Iohexol Clearance)

50 50 55 49
TDF in Previous Regimen

58 63 53 52
No

Baseline
Week 24

Change in eGFR (mL/min)

-0.6 0.2

All Patients
Yes
No

Actual GFR (mL/min)

58 63 63
TDF in Previous Regimen

50 49 50
No

Baseline
Week 24

Significant improvements after E/C/F/TAF switch (P<0.05)
- Spine and hip bone mineral density
- Urinary tubular proteins and fractional excretion of uric acid
- Albuminuria and proteinuria
- Cholesterol fractions in patients not on a TDF-based regimen at time of switch

These 48-week data support the renal and bone safety of E/C/F/TAF in HIV patients with renal impairment (eGFR 30-69 mL/min)

Permission from Practice Point Communications.

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Recent Switch Studies: Suppressed

<table>
<thead>
<tr>
<th>Trial</th>
<th>From</th>
<th>To</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>GS-123&lt;sup&gt;1&lt;/sup&gt;</td>
<td>RAL + TDF/FTC</td>
<td>EVG/TDF/FTC/COBI</td>
<td>✔</td>
</tr>
<tr>
<td>GS-264&lt;sup&gt;4&lt;/sup&gt;</td>
<td>EFV/TDF/FTC</td>
<td>TDF/FTC/RTV</td>
<td>✔</td>
</tr>
<tr>
<td>Strategy-NRTI&lt;sup&gt;5&lt;/sup&gt;</td>
<td>NNRTI + TDF/FTC</td>
<td>EVG/TDF/FTC/COBI</td>
<td>✔</td>
</tr>
<tr>
<td>Strategy-PI&lt;sup&gt;6&lt;/sup&gt;</td>
<td>PIs + TDF/FTC</td>
<td>EVG/TDF/FTC/COBI</td>
<td>✔</td>
</tr>
<tr>
<td>SPIRIT&lt;sup&gt;7&lt;/sup&gt;</td>
<td>PIs + 2 NRTIs</td>
<td>RPV/TDF/FTC</td>
<td>✔</td>
</tr>
<tr>
<td>SPIRAL&lt;sup&gt;8&lt;/sup&gt;</td>
<td>PIs + 2 NRTIs</td>
<td>RAL + 2 NRTIs</td>
<td>✔</td>
</tr>
<tr>
<td>SALT&lt;sup&gt;9&lt;/sup&gt;</td>
<td>ATV/r + 2 NRTIs</td>
<td>ATV/r + 3TC</td>
<td>✔</td>
</tr>
<tr>
<td>OLEP&lt;sup&gt;10&lt;/sup&gt;</td>
<td>LPV/r + 2 NRTIs</td>
<td>LPV/r + 3TC</td>
<td>✔</td>
</tr>
<tr>
<td>SWITCHMARK&lt;sup&gt;11&lt;/sup&gt;</td>
<td>LPV/r + 2 NRTIs</td>
<td>RAL + 2 NRTIs</td>
<td>✔</td>
</tr>
<tr>
<td>HARNESS&lt;sup&gt;12&lt;/sup&gt;</td>
<td>3rd agent + 2 NRTIs</td>
<td>RAL + ATV/r</td>
<td>✔</td>
</tr>
</tbody>
</table>

Patient Case

- MA is a 34 year old woman with HIV/HCV infections diagnosed in 2005
- Never treated for HCV because she refuses to take interferon (IFN)
- She is aware of the new HCV medications and asks if she can be treated

- ART History:
  - Raltegravir/emtricitabine/tenofovir (2009 – 2013; reports missing PM doses)
  - Elvitegravir/cobicistat/emtricitabine/tenofovir (2013 – present)

- HIV Labs
  - HSV viral load < 20 copies/mL (x 2 years), CD4 cell count: 550-650 cells/mm^3

- HCV Labs
  - Genotype 1a, HCV viral load = 3,400,000 copies/mL, Metavir score = 2

- Other Labs
  - AST = 45 IU/L, ALT = 75 IU/L, SCR = 1.3 mg/dL

How would you approach treating this patient’s HCV infection?

a. Start HCV treatment now
b. Delay HCV treatment until liver disease is more advanced
c. D/C ART, treat HCV, then restart ART

Hepatitis C Infection

Treatment is NOT what it used to be...

SVR Rates for Approved Therapies in HIV-1/HCV Patients
Treating Co-infection is NOT what it used to be...

SVR (%) according to genotype for HIV/HCV co-infected patients receiving Peg-interferon plus ribavirin for 48 weeks

**SVR**

<table>
<thead>
<tr>
<th>HCV genotype</th>
<th>APRICOIT* (n=289)</th>
<th>Ribavic* (n=205)</th>
<th>ACTG 5071* (n=66)</th>
<th>Ribavis* (n=205)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>42%</td>
<td>82%</td>
<td>29%</td>
<td>62%</td>
</tr>
<tr>
<td>Genotype 2/3</td>
<td>73%</td>
<td>73%</td>
<td>54%</td>
<td>44%</td>
</tr>
</tbody>
</table>

*80-85% receiving ART
*60-65% with undetectable HIV RNA


HIV/HCV Co-infection

Similar response rates in HIV/HCV co-infected patients compared to HCV mono-infected patients

<table>
<thead>
<tr>
<th>SVR-12 (%)</th>
<th>HIV/HCV Co-infection</th>
<th>HCV Mono-infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>82-84%</td>
<td>95-96%</td>
<td>95-97%</td>
</tr>
<tr>
<td>132/156</td>
<td>132/156</td>
<td>132/152</td>
</tr>
</tbody>
</table>

*ALI-1 was conducted in patients with advanced cirrhosis and post-transplant patients
**ALI-4 was conducted for genotype 3 patients with and without cirrhosis

Kwe P et al. EASL 2015, Abstract S270; Del Bello DP et al. AASLD 2014, Abstract S90A

HIV/HCV Co-infection

Delaying HCV Treatment Leads to Liver Disease Progression

- HIV co-infection accelerates fibrosis progression among HCV-infected persons
- Controlling HIV may mitigate progression to some extent, but ART is not a substitute for HCV treatment
- Co-infected patients have more liver-related and overall mortality than HCV-monoinfected patients
- Achieving SVR reduces the incidence of liver related death and improves survival in co-infected patients

Delaying HCV Treatment Leads to Liver Disease Progression

CD4+ guided ART interruption was associated with significantly greater risk of disease progression and death compared to continuous ART
- RR 2.5 (95% CI: 1.8-3.6; p<.001)

Includes increased CVD, liver, and renal-related deaths:

<table>
<thead>
<tr>
<th>Complications</th>
<th>No. of Events</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe complications</td>
<td>114</td>
<td>2.5</td>
</tr>
<tr>
<td>CVD, liver, renal deaths</td>
<td>31</td>
<td>1.4</td>
</tr>
<tr>
<td>Nonfatal CVD events</td>
<td>63</td>
<td>1.1</td>
</tr>
<tr>
<td>Nonfatal hepatic events</td>
<td>14</td>
<td>1.2</td>
</tr>
<tr>
<td>Nonfatal renal events</td>
<td>7</td>
<td>2.5</td>
</tr>
</tbody>
</table>

All co-infected patients are candidates for HCV therapy

HIV disease must be stable before initiating HCV treatment

Interrupting HIV treatment to manage HCV infection is not recommended

Recommended ART regimens for co-infected patients are the same as those recommended for patients without HCV

Co-infected persons should be treated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications

HIV/HCV Co-infection

Which HCV treatment strategy do you recommend?

a. Keep ART and start sofosbuvir/ledipasvir
b. Change ART and start sofosbuvir/ledipasvir
c. Keep ART and start daclatasvir + sofosbuvir
d. Change ART and start simeprevir + sofosbuvir
e. Keep ART and start paritaprevir/ritonavir/ombitasvir plus dasabuvir (PrOD)

HIV/HCV Co-infection

Recommended HCV Treatment Regimens in Patients
with or without HIV Co-infection

<table>
<thead>
<tr>
<th>Population</th>
<th>SMV + SOF</th>
<th>LDV/SOF</th>
<th>OMV/PTV/RTV + DDV</th>
<th>DCV + SOF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1a, no cirrhosis</td>
<td>12 wks ± RBV</td>
<td>12 wks</td>
<td>24 wks + RBV*</td>
<td>12 wks</td>
</tr>
<tr>
<td>Genotype 1a, cirrhosis</td>
<td>24 wks ± RBV**</td>
<td>12 wks</td>
<td>24 wks + RBV</td>
<td>24 wks ± RBV</td>
</tr>
<tr>
<td>Genotype 1b, no cirrhosis</td>
<td>12 wks</td>
<td>12 wks</td>
<td>12 wks</td>
<td>12 wks</td>
</tr>
<tr>
<td>Genotype 1b, cirrhosis</td>
<td>24 wks ± RBV</td>
<td>12 wks</td>
<td>24 wks ± RBV</td>
<td>24 wks ± RBV</td>
</tr>
</tbody>
</table>

**Confirmed absence of Q80K polymorphism

DCV=daclatasvir

**HIV/HCV Co-infection**

**AASLD/IDSA Guidance. It’s all about the interactions!**

<table>
<thead>
<tr>
<th>Regimen</th>
<th>SOF/SMV</th>
<th>SOF/LDV</th>
<th>SOF/DCV</th>
<th>OMV/PTV/RTV + DSV</th>
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</thead>
<tbody>
<tr>
<td>EVG/COB/TAF/TC</td>
<td>SOF↑</td>
<td>LDV↑</td>
<td>DSV↑</td>
<td>No data</td>
</tr>
<tr>
<td>RAL/TDF/TC</td>
<td>SOF↑</td>
<td>LDV↑</td>
<td>No data</td>
<td></td>
</tr>
<tr>
<td>EVG/COB/TDF/TC</td>
<td>No data</td>
<td>SOF↑</td>
<td>DSV↑</td>
<td>No data</td>
</tr>
<tr>
<td>EVG/TCV</td>
<td>SOF↑</td>
<td>No data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ETV/ABV/TDF</td>
<td>No data</td>
<td>SOF↑</td>
<td>No data</td>
<td></td>
</tr>
</tbody>
</table>

- TAF is a p-glycoprotein substrate (like TDF)
- TAF bioavailability increases with cobicistat which increases TFV plasma levels
  - The TAF dose is adjusted down to 10mg in EVG/COB/TAF/TC to compensate
- LDV and TAF co-administration also leads to mild increases in TFV exposure through p-glycoprotein inhibition.
- Despite increases in TFV with LDV, TPF plasma levels remain much lower with TAF versus TDF and within the range that has not lead to adverse renal effects or bone loss
- ETV/ABV/TDF may be co-administered with LDV/SOF without dose modification

**References:**

HIV/HCV Co-infection
AASLD/IDSA Guidance: it’s all about the interactions!

• Drug interaction resources
  – AASLD/IDSA/IAS–USA hepatitis C guidelines
  – U.S. DHHS Adult and Adolescent HIV guidelines
  – www.hiv-druginteraction.org
  – www.hep-druginteractions.org

Key Takeaways

• Early HIV diagnosis, initiation of ART and engagement in care are essential to achieving long-term viral suppression.
• Switching ART in response to adverse events can be performed successfully but must be done carefully to maintain viral suppression.
• Successful treatment of both HIV and HCV in co-infected patients requires the management of significant drug interactions.
**CDC and APHL: Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens**

**Perform HIV-1/2 Antigen/Antibody Combination Immunoassay**

- Reactive: HIV-1 (+) or Indeterminate
- Nonreactive: HIV-1 (-) or Indeterminate

**Perform HIV-1/2 Antibody Differentiation Immunoassay**

- HIV-1 (+) or Indeterminate
- HIV-1 (-)
- HIV-2 (-)
- HIV-1 (+)
- HIV-2 (+)
- HIV-1 Antigens Detected
- HIV-2 Antigens Detected

**HIV Infection**

- Acute HIV-1
- Reactive for HIV-1
- Negative for HIV-1 and HIV-2 Antigens and p24Ag

**HIV-2 Infection**

- Reactive for HIV-2
- HIV-1 (-) or Indeterminate

**Dual HIV-1 and HIV-2 Infection**

- Reactive
- Nonreactive
- Negative for HIV-1 Infection

Note: new algorithm may not be uniformly adopted in all settings. If a rapid 3rd generation test is used with a positive test result, confirmation is needed with a more specific test (eg, Western Blot).


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ACTG 5257: Cumulative Incidence of Virologic or Tolerability Failure

Difference in 96-wk cumulative incidence
(97.5% CI)

- ATV/r*
- RAL*
- DRV/r*

Favors RAL
ATV/r vs RAL 15% (10% to 20%)

Favors RAL
DRV/r vs RAL 7.5% (3.2% to 12%)

Favors DRV/r
ATV/r vs DRV/r 7.5% (2.3% to 13%)

*Plus TDF/FTC.


SINGLE: DTG + ABC/3TC Superior to EFV/TDF/FTC in ART-Naive Pts to Wk 144

- Open-label extension, excluding pts with hepatitis B virus (HBV)
- Emergent resistance in those with VF: 0/39 (DTG) vs 7/33 (EFV)

*HIV-1 RNA < 50 copies/mL as defined by FDA Snapshot algorithm.
^10% noninferiority margin.


Tenofovir Alafenamide (TAF): Novel Prodrug of Tenofovir

- 91% lower plasma TFV levels minimize renal and bone effects while maintaining high potency for suppressing HIV

TAF 25 mg

Courtesy of Gilead Sciences
HIV/HCV Co-infection
AASLD/IDSA Guidance... It's all about the interactions!

Tenofovir DF

Enterocytes

P-gp

Ledipasvir
Ritonavir
Cobicistat

Gut Lumen

Tenovir Absorption

Blood Stream

Tenofovir Absorption

BCRP: Breast Cancer Resistance Protein

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Self-assessment Questions

The polling questions included in this presentation are listed below as a learner assessment tool. You may wish to note the correct answers and rationale as you follow along with the speaker.

Patient Case #1

- PT is a 37 YO AA female; ER 8/17/15.
- 5 days abdominal pain, dysuria, foul-smelling urine, vomiting.
- Observed overnight, dx pyelonephritis, sent home with oral cephalosporin.
- While in observation unit, offered HIV screening per ED protocol.
- HIV Antigen(Ag)/Antibody (Ab) 4th-generation enzyme immunoassay (EIA) reactive.
- Reports prior negative HIV testing.
- New monogamous male sexual partner 6 months ago after 7 years of abstinence. Partner serostatus unknown.

1. In patients with a reactive 4th-generation HIV Ag/Ab result, what test should be performed next?
   a. HIV-1 Western blot.
   b. HIV-2 Western blot.
   c. HIV viral RNA quantitative assay (viral load).
   d. HIV-1/HIV-2 discriminatory immunoassay.
   e. CD4 cell count.

2. The HIV-1/HIV-2 differentiation assay (Multispot) results are both non-reactive. What should be done next for PT?
   a. HIV-1 Western blot.
   b. CD4 cell count.
   c. HIV viral RNA quantitative assay (viral load).
   d. Inform the patient that she is definitely infected with HIV.
   e. Inform the patient she is definitely not infected with HIV.
3. PT comes to office 5 days later to learn of confirmed diagnosis. HIV viral load is >10 million copies; CD4 count is 600 cells/mm$^3$. Should this patient be treated with ART and when?
   a. Yes, immediately (today).
   b. Yes, in 4 weeks (after genotype available).
   c. No, since CD4 count is >500 cells/mm$^3$.
   d. Not yet, since she needs time to process her new diagnosis.
   e. Not sure.

**Patient Case Continued**
- PT defers treatment at time of diagnosis.
- Returns to office one year later.
- Asymptomatic.
- Viral load 200,000 copies/mL; CD4 600 cells/mm$^3$.
- Estimated GFR 110 mL/min/1.73m$^2$.
- Takes no other meds.

4. Is treatment with ART recommended for PT?
   a. Yes.
   b. No.
   c. Not sure.

5. Per the DHHS 2015 guidelines, which of the following is currently recommended as a first-line regimen for this patient?
   a. Efavirenz/tenofovir disoproxil/emtricitabine (EFV/TDF/FTC).
   b. Rilpivirine/tenofovir disoproxil/emtricitabine (RPV/TDF/FTC).
   c. Atazanavir/ritonavir (ATV/r) plus TDF/FTC.
   e. Darunavir/ritonavir (DRV/r) plus abacavir/lamivudine (ABC/3TC).
6. PT starts EVG/c/TDF/FTC. One year later: Viral load undetectable; CD4 count 900 cells/mm$^3$; GFR now 70 mL/min/1.73 m$^2$; HLA B-5701 is positive. What is the next step?
   a. Observe on EVG/c/TDF/FTC until GFR drops below 30 mL/min/1.73 m$^2$.
   b. Switch EVG/c/TDF/FTC to Raltegravir (RAL) plus TDF/FTC.
   c. Switch EVG/c/TDF/FTC to DTG/ABC/3TC.
   d. Switch EVG/c/TDF/FTC to EVG/c/TAF/FTC.

Patient Case #2
- MA is a 34 year old woman with HIV/HCV infections diagnosed in 2005
- Never treated for HCV because she refuses to take interferon (IFN)
- She is aware of the new HCV medications and asks if she can be treated
- ART History:
  - Raltegravir/emtricitabine/tenofovir (2009–2013; reports missing PM doses)
  - Elvitegravir/cobicistat/emtricitabine/tenofovir (2013–present)
- HIV Labs
  - HIV viral load < 20 copies/mL (x 2 years), CD4 cell count: 550-650 cells/mm$^3$
- HCV Labs
  - Genotype 1a, HCV viral load = 3,400,000 copies/mL, Metavir score = 2
- Other Labs
  - AST = 45 IU/L, ALT = 75 IU/L, SCr = 1.3 mg/dL

7. How would you approach treating this patient’s HCV infection?
   a. Start HCV treatment now.
   b. Delay HCV treatment until liver disease is more advanced.
   c. D/C ART, treat HCV, then restart ART.
8. Which HCV treatment strategy do you recommend?
   a. Keep ART and start sofosbuvir/ledipasvir.
   b. Change ART and start sofosbuvir/ledipasvir.
   c. Keep ART and start daclatasvir + sofosbuvir.
   d. Change ART and start simeprevir + sofosbuvir.
   e. Keep ART and start paritaprevir/ritonavir/ombitasvir plus dasabuvir (PrOD).
# Abbreviations

## HIV Drug Classes

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>CCR5</td>
<td>C-C chemokine receptor 5</td>
</tr>
<tr>
<td>INSTI</td>
<td>integrase strand transfer inhibitor</td>
</tr>
<tr>
<td>NNRTI</td>
<td>nonnucleoside reverse transcriptase inhibitor</td>
</tr>
<tr>
<td>NRTI</td>
<td>nucleoside (or nucleotide) reverse transcriptase inhibitor</td>
</tr>
<tr>
<td>PI</td>
<td>protease inhibitor</td>
</tr>
<tr>
<td>PI/r</td>
<td>ritonavir-boosted protease inhibitor</td>
</tr>
</tbody>
</table>

## HIV Drugs

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>3TC</td>
<td>lamivudine</td>
</tr>
<tr>
<td>ABC</td>
<td>abacavir</td>
</tr>
<tr>
<td>ATV</td>
<td>atazanavir</td>
</tr>
<tr>
<td>ATV/r</td>
<td>atazanavir/ritonavir</td>
</tr>
<tr>
<td>COBI</td>
<td>cobicistat</td>
</tr>
<tr>
<td>DRV</td>
<td>darunavir</td>
</tr>
<tr>
<td>DRV/r</td>
<td>darunavir/ritonavir</td>
</tr>
<tr>
<td>DTG</td>
<td>dolutegravir</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>efavirenz</td>
</tr>
<tr>
<td>EVG</td>
<td>elvitegravir</td>
</tr>
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<td>FTC</td>
<td>emtricitabine</td>
</tr>
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<td>LPV</td>
<td>lopinavir</td>
</tr>
<tr>
<td>LPV/r</td>
<td>lopinavir/ritonavir</td>
</tr>
<tr>
<td>MVC</td>
<td>maraviroc</td>
</tr>
<tr>
<td>RAL</td>
<td>raltegravir</td>
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### Ongoing Management of the HIV Patient in the Ambulatory Care Setting:
#### Strategies for Achieving Long-term Viral Suppression

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>RPV</td>
<td>rilpivirine</td>
</tr>
<tr>
<td>RTV</td>
<td>ritonavir</td>
</tr>
<tr>
<td>TAF</td>
<td>tenofovir alafenamide</td>
</tr>
<tr>
<td>TDF</td>
<td>tenofovir disoproxil</td>
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</table>

#### Hepatitis C Virus Drugs

<table>
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<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOC</td>
<td>boceprevir</td>
</tr>
<tr>
<td>DAA</td>
<td>direct-acting antiviral</td>
</tr>
<tr>
<td>DCV</td>
<td>daclatasvir</td>
</tr>
<tr>
<td>DSV</td>
<td>dasabuvir</td>
</tr>
<tr>
<td>IFN</td>
<td>interferon</td>
</tr>
<tr>
<td>LDV</td>
<td>ledipasvir</td>
</tr>
<tr>
<td>OMV</td>
<td>ombitasvir</td>
</tr>
<tr>
<td>PegIFN</td>
<td>peginterferon</td>
</tr>
<tr>
<td>PrOD</td>
<td>paritaprevir/ritonavir/ombitasvir plus dasabuvir</td>
</tr>
<tr>
<td>PTV</td>
<td>paritaprevir</td>
</tr>
<tr>
<td>RBV</td>
<td>ribavirin</td>
</tr>
<tr>
<td>SMV</td>
<td>simeprevir</td>
</tr>
<tr>
<td>SOF</td>
<td>sofosbuvir</td>
</tr>
<tr>
<td>TVR</td>
<td>telaprevir</td>
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#### Miscellaneous

<table>
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<tr>
<td>Ab</td>
<td>antibody</td>
</tr>
<tr>
<td>Ag</td>
<td>antigen</td>
</tr>
<tr>
<td>EIA</td>
<td>enzyme immunoassay</td>
</tr>
<tr>
<td>GT</td>
<td>genotype</td>
</tr>
<tr>
<td>HBV</td>
<td>hepatitis B virus</td>
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</tbody>
</table>
**Ongoing Management of the HIV Patient in the Ambulatory Care Setting: Strategies for Achieving Long-term Viral Suppression**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Term Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV</td>
<td>hepatitis C virus</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>NAAT</td>
<td>nucleic-acid amplification testing</td>
</tr>
<tr>
<td>SVR</td>
<td>sustained virologic response</td>
</tr>
<tr>
<td>VF</td>
<td>virologic failure</td>
</tr>
<tr>
<td>VL</td>
<td>viral load</td>
</tr>
</tbody>
</table>
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3. Enter the attendance code announced during the session and click submit.
4. Click Claim for any session.
5. Complete the evaluation.
6. Once all requirements are complete (indicated with a green check mark), click Claim Credit.
7. Review the information for the credit you are claiming. If all information is correct, check the box at the bottom and click Claim. You will see a message if there are any problems claiming your credit.

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2. Enter the enrollment code announced during the webinar in the Enrollment Code box and click Redeem. The title of this activity will appear in a pop-up box on your screen. Click on Go or the activity title.
3. Complete all required elements. Go to step six above.

<table>
<thead>
<tr>
<th>Activity Date:</th>
<th>Code:</th>
<th>CE Hours:</th>
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<tbody>
<tr>
<td>Monday, December 7, 2015</td>
<td>_ _ _ _ _</td>
<td>1.5</td>
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</table>

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