A Practical Approach to HIV/HCV Co-infection
Focus on Drug-Drug Interactions

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Outline

• Co-infection vs. Mono-infection
• DAA Overview and efficacy in co-infection
• Approaches and tools for identifying and managing drug interactions
• Overview of mechanisms of drug interactions
• Highlights of more common drug interactions
Co-infection Burden and Progression

• 10-15% of HIV patients are co-infected with Hepatitis C (HCV) worldwide¹
  • 25% HIV-infected patients are co-infected with hepatitis C in the US²

• HIV/HCV co-infection more than triples the risk for liver disease, liver failure, and liver-related death.²
  • HCV may also complicate the management of HIV³

• Highly active antiretroviral therapy (ART) slows hepatic disease progression in co-infection⁴

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Antiretroviral Therapy Reduces Hepatic Decompensation

• Estimate the effect of ART on the rate of hepatic decompensation
• Veterans Aging Cohort Study-Virtual Cohort
  • 10,090 HCV/HIV co-infected individuals
• Median follow up: 3.1 years

<table>
<thead>
<tr>
<th>Variable</th>
<th>Person-years</th>
<th>Events</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No ART initiation</td>
<td>10,891</td>
<td>188</td>
<td>reference</td>
</tr>
<tr>
<td>ART initiation</td>
<td>35,553</td>
<td>457</td>
<td>0.72 (0.54-0.94)</td>
</tr>
<tr>
<td>&lt; 2 years since initiation</td>
<td>10,727</td>
<td>154</td>
<td>0.75 (0.56-1.01)</td>
</tr>
<tr>
<td>2-&lt;4 years since initiation</td>
<td>8560</td>
<td>109</td>
<td>0.69 (0.46-1.03)</td>
</tr>
<tr>
<td>≥ 4 years since initiation</td>
<td>16,266</td>
<td>195</td>
<td>0.53 (0.34-0.83)</td>
</tr>
</tbody>
</table>

CI: Confidence Interval

Evolution of Hepatitis C Treatment

- Goal = prevent end-stage liver disease complications
  - Cure defined as sustained virologic response (SVR) 12 weeks after completion of treatment

1991

Interferon (IFN) X 18-24 mon
SVR ~9%*

Ribavirin (RBV) + Peg-interferon (PegIFN) x 48wks
SVR 40-50%*

1998

Boceprevir or Telaprevir + RBV + PEG x 36-48wks
SVR ~70%*

2011

Sofosbuvir/Simeprevir + RBV + PEG x 12-24wks
SVR ~90%*

2013

Interferon-free regimens x 8-12wks
SVR >90%*

2014

*SVR rates reported for genotype (GT) 1

Ghany MG. Hepatology 2011;54(4):1433-44
The Interferon Era

• In the interferon era SVR rates < than those in mono-infected patients

• Additional challenges:
  • Poor tolerability of interferon
  • Limitations in certain populations
    • Depression
  • Added pill burden
  • Drug interactions

• Should HIV-HCV co-infection still be considered a “special population”?3

### Guideline Overview of HIV/HCV Co-infection

<table>
<thead>
<tr>
<th>DHHS HIV Treatment Guidelines</th>
<th>AASLD/IDSA Guidelines</th>
<th>EASL</th>
</tr>
</thead>
</table>
| • ART should be initiated in all HCV/HIV co-infected patients, regardless of CD4 count | • HIV/HCV co-infected persons should be treated/retreated the same as persons without HIV infection | • Indications for HCV treatment are the same as those with HCV mono-infection  
• The same IFN-Free regimens can be used in co-infection as in patients without HIV infection |


## Direct-Acting Antivirals Classes

<table>
<thead>
<tr>
<th>NS3/4A Protease Inhibitors (--previr)</th>
<th>NS5A Inhibitors (--asvir)</th>
<th>NS5B Polymerase Inhibitors (--buvir)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Boceprevir</td>
<td>• Ledipasvir</td>
<td>• Nucleoside analogs</td>
</tr>
<tr>
<td>• Telaprevir</td>
<td>• Ombitasvir</td>
<td>• Sofosbuvir</td>
</tr>
<tr>
<td>• Simeprevir</td>
<td>• Daclatasvir</td>
<td>• MK-3682</td>
</tr>
<tr>
<td>• Paritaprevir</td>
<td>• Elbasvir</td>
<td>• Non-nucleoside analogs</td>
</tr>
<tr>
<td>• Grazoprevir</td>
<td>• Velpatasvir</td>
<td>• Dasabuvir</td>
</tr>
<tr>
<td>• Voxilaprevir</td>
<td>• Pibrentasvir</td>
<td></td>
</tr>
<tr>
<td>• Glecaprevir</td>
<td>• Ruzasvir</td>
<td></td>
</tr>
</tbody>
</table>

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**NS3/4A Protease Inhibitors**
- Boceprevir
- Telaprevir
- Simeprevir
- Paritaprevir
- Grazoprevir
- Voxilaprevir
- Glecaprevir

**NS5A Inhibitors**
- Ledipasvir
- Ombitasvir
- Daclatasvir
- Elbasvir
- Velpatasvir
- Pibrentasvir
- Ruzasvir

**NS5B Polymerase Inhibitors**
- Nucleoside analogs
  - Sofosbuvir
  - MK-3682
- Non-nucleoside analogs
  - Dasabuvir
## Efficacy in Co-Infection

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Approved Genotypes</th>
<th>Pill burden</th>
<th>Efficacy in HIV co-infected</th>
<th>Cost $$$</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELB/GRZ x 12W</td>
<td>1, 4</td>
<td>1/day</td>
<td>87%&lt;sup&gt;3&lt;/sup&gt; 96%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>$$</td>
</tr>
<tr>
<td>ELB/GRZ + RBV x 12W</td>
<td>1, 4</td>
<td>1/day + 6/day</td>
<td>97%&lt;sup&gt;2&lt;/sup&gt;</td>
<td>$$</td>
</tr>
<tr>
<td>LDV/SOF x 12W</td>
<td>1, 4, 5, 6</td>
<td>1 per day</td>
<td>96%&lt;sup&gt;3&lt;/sup&gt;</td>
<td>$$</td>
</tr>
<tr>
<td>OMB/PAR/DAS/r + RBV x 12 – 24W</td>
<td>1a, 1b</td>
<td>4/day + 6/day</td>
<td>94% and 91%, respectively</td>
<td>$$/$$$$$</td>
</tr>
</tbody>
</table>


Efficacy in Co-Infection (2)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Approved Genotypes</th>
<th>Pill burden</th>
<th>Efficacy in HIV co-infected</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOF/SIM ± RBV x 12W</td>
<td>1</td>
<td>2/day + 6/day</td>
<td>93%¹</td>
<td>$$$</td>
</tr>
<tr>
<td>DAC/SOF x 12W</td>
<td>1, 4</td>
<td>1/day + 6/day</td>
<td>94-100%²</td>
<td>$$</td>
</tr>
<tr>
<td>SOF/VEL x 12W</td>
<td>1-6</td>
<td>1/day</td>
<td>92-100%³</td>
<td>$$</td>
</tr>
<tr>
<td>SOF/VEL/VOX x 12W</td>
<td>1-6</td>
<td>1/day</td>
<td>No data</td>
<td>$$$</td>
</tr>
<tr>
<td>GLE/PIB 8 – 12W</td>
<td>1-6</td>
<td>3/day</td>
<td>98 and 99%⁴ respectively</td>
<td>$$</td>
</tr>
</tbody>
</table>


Real World Co-infection Data

- Retrospective, observational of HIV/HCV co-infected Veterans from 126 VA facilities
- SVR12 results available for 90.9% of cohort (905/996)

<table>
<thead>
<tr>
<th>All patients: 12 weeks or less</th>
<th>GT1 N= 905</th>
<th>LDV/SOF N=685</th>
<th>LDV/SOF +RBV N=131</th>
<th>OMB/PRV/ DAS/r N=27</th>
<th>OMB/PRV/ DAS/r + RBV N=62</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall SVR</td>
<td>90.9 (823/905)</td>
<td>92.1 (631/685)</td>
<td>86.3 (113/131)</td>
<td>88.9 (24/27)</td>
<td>88.7 (55/62)</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>85.9 (176/205)</td>
<td>87.6 (113/129)</td>
<td>83.9 (52/62)</td>
<td>100 (3/3)</td>
<td>100 (26/26)</td>
</tr>
<tr>
<td>No cirrhosis</td>
<td>92.4 (647/700)</td>
<td>93.2 (518/556)</td>
<td>88.4 (61/69)</td>
<td>87.5 (21/24)</td>
<td>80.6 (29/36)</td>
</tr>
</tbody>
</table>

### Real World Co-infection Data (2)

<table>
<thead>
<tr>
<th>Patients who completed 12 weeks</th>
<th>GT1 N=766</th>
<th>LDV/SOF N=569</th>
<th>LDV/SOF +RBV N=119</th>
<th>OMB/PRV/ DAS/r N=23</th>
<th>OMB/PRV/ DAS/r + RBV N=55</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall SVR</td>
<td>94.3 (722/766)</td>
<td>95.3 (542/569)</td>
<td>90.8 (108/119)</td>
<td>95.7 (22/23)</td>
<td>90.9 (50/55)</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>91.9 (159/173)</td>
<td>94.4 (102/108)</td>
<td>90.6 (48/53)</td>
<td>100 (2/2)</td>
<td>70 (7/10)</td>
</tr>
<tr>
<td>No cirrhosis</td>
<td>94.9 (563/593)</td>
<td>95.4 (440/461)</td>
<td>90.9 (60/66)</td>
<td>95.2 (20/21)</td>
<td>95.6 (46/45)</td>
</tr>
</tbody>
</table>

Real World Co-infection Data (3)

• IDSA/AASLD recommends against 8 weeks LDV/SOF for co-infection

• Overall SVR in those who received 8 weeks vs. 12 wks
  • LDV/SOF x 8 weeks: 94.6% (70/74)
  • LDV/SOF x 12 weeks: 95.3% (542/569)

• Those meeting 8 week criteria and received:
  • LDV/SOF x 8: 98.1% (51/52)
  • LDV/SOF x 12: 95.7% (310/324)

• Overuse of 12 week LDV/SOF regimens has been demonstrated in clinical trials of mono-infected patients
  1
  • Excess costs

Managing drug-drug interactions in HIV-HCV
Drug Interaction Resources

• Prescribing information
• University of Liverpool sites
  • http://www.hiv-druginteractions.org/
  • http://hep-druginteractions.org/checker
  • Mobile apps available from Google Play and the App Store

• Guidelines
  • IDSA/AALSD
  • DHHS HIV Guidelines

• Review articles by field experts
  • Jennifer Kiser, University of Colorado Denver

• Meeting abstracts
  • The Liver Meeting (AASLD)
  • CROI
Detailed D-D Information

• Drug interaction resources often lack specific information
  • Mechanisms
  • Actionable recommendations
  • References
Chicken or the Egg?

• Adjust ART to suit HCV regimen
  • Insurance preferences
  • Renal function
  • Treatment history
  • Liver function

• Adjust HCV regimen to suit ART regimen
  • Patient with HIV resistance and limited options
An Approach to Interactions

• Step 1: Verify is drug interaction is limited to particular HCV regimen vs all/most regimens
  • e.g. PPI with ledipasvir/sofosbuvir vs. phenytoin with all
• Step 2: Clarify indication for interacting medication
  • Is primidone for seizures or tremors?
• Step 3: Determine if interacting medication can be changed
• Step 4: Assess need for taper/washout period
• Step 5: Stop interacting medication, start substitute
• Step 6: Monitor patient closely
Mechanisms of Interactions

• pH dependent interactions

• Cytochrome P450 interactions

• Membrane transporters
  • P-Gp
  • BCRP
  • OATP1B1/3
pH Dependent Interactions

• Absorption of medications can be pH dependent
  • Ledipasvir and velpatasvir

• Data regarding SVR rates conflicting with PPIs
  • No difference in SVR rates with daily PPI/appropriately managed $^{1,2}$
  • PPI use factor that predicted non-SVR$^3$

• Management strategies vary based on acid reducer and HCV regimen
  • Ledipasvir and velpatasvir recommendations differ with regard to PPIs
    • Please refer to package labeling

pH Dependent Interactions: Management

• Example management strategies (ledipasvir):
  • PPIs: D/C if possible; max dose PPI omeprazole 20 mg QD; must be taken at the same time on an empty stomach
  • H2 antagonists: Do not exceed famotidine 40 mg BID
  • Antacids (including calcium carbonate): Space antacids by 4 hours

• Providing written instructions to patients:
  • Please reduce omeprazole to 20 mg daily (one capsule). Omeprazole must be taken at the exact same time as ledipasvir/sofosbuvir TOGETHER ON AN EMPTY STOMACH.
  • Please reduce calcium carbonate/vitamin D tablet to once daily and take this in the evening at least 4 hours before or after ledipasvir/sofosbuvir.
  • Take Maalox at nighttime to avoid the drug interaction
Cytochrome P450 (3A4)

- CYP450 isoenzyme system: Responsible for breakdown of many medications
  - Substrate: What is acted on by inducers/inhibitors
  - Inducer: Reduces concentrations of substrates
  - Inhibitor: Increases concentrations of substrates

- Common CYP450 interactions:
  - Statins and protease inhibitors
  - Rifampin and many antiretrovirals
Drug Transporters

• Transporter proteins in the liver, kidney, or intestines
• Move medications from one compartment to the next through efflux or uptake
• P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), organic anion transporting polypeptide (OATP)
• Inhibition or induction of these transporter can lead to increased or decreased medication concentrations in the blood
### DAA Enzymatic and Drug Transporter Interactions

<table>
<thead>
<tr>
<th>Substrate</th>
<th>Inhibition</th>
<th>Induction</th>
<th>Transporter Inhibition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simeprevir</td>
<td>3A4, P-gp</td>
<td>1A2</td>
<td>P-gp</td>
</tr>
<tr>
<td>Paritaprevir</td>
<td>3A4, P-gp</td>
<td>2C8, UGT1A1</td>
<td>P-gp, OATP1B1, BCRP</td>
</tr>
<tr>
<td>Grazoprevir</td>
<td>3A4, OATP1B1, P-gp</td>
<td>3A4</td>
<td>BCRP</td>
</tr>
<tr>
<td>Ledipasvir</td>
<td>P-gp</td>
<td></td>
<td>P-gp, BCRP, OAT1B1/3</td>
</tr>
<tr>
<td>Ombitasvir</td>
<td>3A4, P-gp</td>
<td>2C8, UGT1A1</td>
<td></td>
</tr>
<tr>
<td>Daclatasvir</td>
<td>3A4, P-gp</td>
<td></td>
<td>P-gp, OAT1B1/3, BCRP</td>
</tr>
<tr>
<td>Elbasvir</td>
<td>3A4, P-gp</td>
<td>3A4 (weak)</td>
<td>P-gp, BCRP</td>
</tr>
<tr>
<td>Velpatasvir</td>
<td>3A4, 2C8, 2B6, P-gp</td>
<td></td>
<td>P-gp, BCRP, OAT1B1/3</td>
</tr>
<tr>
<td>Sofosbuvir</td>
<td>P-gp, BCRP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dasabuvir</td>
<td>3A4, 2C8, 2D6, P-gp</td>
<td>UGT1A1</td>
<td>BCRP, OCT1</td>
</tr>
<tr>
<td>Ribavirin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Key Abbreviations:**
- OATP: Organic anion-transporting polypeptide
- UGT1A1: UDP-glucuronosyltransferase 1A1
- P-gp: P-glycoprotein
- BCRP: breast cancer resistance protein

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## Common Antiretroviral Enzymatic and Drug Transporter Interactions

<table>
<thead>
<tr>
<th>Substrate</th>
<th>Substrate</th>
<th>Inhibition</th>
<th>Induction</th>
<th>Transporter Inhibition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efavirenz</td>
<td>3A4, 2B6</td>
<td>2C8, 2C9</td>
<td>3A4, 2B6, 2C19</td>
<td></td>
</tr>
<tr>
<td>Etravirine</td>
<td>3A4, 2C9, 2C19</td>
<td>2C9, 2C19</td>
<td>3A4</td>
<td></td>
</tr>
<tr>
<td>Rilpivirine</td>
<td>3A4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atazanavir</td>
<td>3A4</td>
<td>3A4, 2C8, 2C9</td>
<td></td>
<td>BRCP</td>
</tr>
<tr>
<td>Darunavir</td>
<td>3A4, P-gp</td>
<td>3A4, 2D6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ritonavir</td>
<td>3A4, 1A2, 2B6, 2D6, P-gp</td>
<td>2C8, 3A4, 2C9, 2E1</td>
<td>1A2, 2B6, 2C9, 2C19</td>
<td>P-gp, BRCP</td>
</tr>
<tr>
<td>Cobicistat</td>
<td>3A4</td>
<td>3A4, 2D6</td>
<td></td>
<td>BCRP, OATP1B1, OATP1B3</td>
</tr>
<tr>
<td>Raltegravir</td>
<td>UGT1A1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elvitegravir</td>
<td>3A4, UGT1A1/3</td>
<td></td>
<td>2C9</td>
<td></td>
</tr>
<tr>
<td>Dolutegravir</td>
<td>3A4, P-gp, UGT1A1/3/9</td>
<td></td>
<td></td>
<td>OCT2</td>
</tr>
</tbody>
</table>

OATP: Organic anion-transporting polypeptide  
UGT1A1: UDP-glucuronosyltransferase 1A1  
P-gp: P-glycoprotein  
BCRP: breast cancer resistance protein  
Tenofovir and DAA Interactions

- Ledipasvir and velpatasvir increase tenofovir concentrations
- Summary of tenofovir recommendations based on creatinine clearance and concurrent ART agents

<table>
<thead>
<tr>
<th>Creatinine Clearance and Concurrent ART</th>
<th>Velpatasvir/sofosbuvir</th>
<th>Ledipasvir/sofosbuvir</th>
</tr>
</thead>
<tbody>
<tr>
<td>CrCl ≥ 60 mL/min</td>
<td>Monitor for TDF side effects</td>
<td>Monitor for TDF side effects</td>
</tr>
<tr>
<td>CrCl &lt; 60 mL/min</td>
<td>Avoid TDF use</td>
<td>Avoid TDF use</td>
</tr>
<tr>
<td>CrCl ≥ 60 mL/min + ritonavir or cobicistat</td>
<td>Monitor for TDF side effects</td>
<td>Avoid TDF use</td>
</tr>
<tr>
<td>CrCl &lt; 60 mL/min + ritonavir or cobicistat</td>
<td>Avoid TDF use</td>
<td>Avoid TDF use</td>
</tr>
</tbody>
</table>

- Tenofovir alafenamide (TAF) can be considered as an alternative to tenofovir disoproxil fumerate (TDF)
- No changes in renal function noted with TDF use in real world data²

Ribavirin and NRTI Interactions

• *In vitro*, ribavirin reduces phosphorylation of zidovudine, stavudine, lamivudine
  • In vivo analysis does not show an impact on NRTI concentrations
• Concerns for exacerbations of anemia with co-administration of zidovudine and ribavirin
  • Consider discontinuation of zidovudine
• Hepatic decompensation risk with zidovudine and interferon-alfa +/- ribavirin
Frequency of Antiretroviral and DAA Interactions

- HIV/HCV coinfected patients  (n=249) enrolled July 2014 to Dec 2015
- ART regimens consisted of:
  - NRTI (96%): TDF 65%, FTC 63%, ABC 27%, 3TC 30%
  - NNRTI (37%): efavirenz 15%, rilpivirine 11%, nevirapine 6%, etravirine 4%
  - PI (29%): atazanavir 12%, darunavir 12%, lopinavir 6%
  - INSTI (48%): dolutegravir 22%, raltegravir 20%, elvitegravir/cobicistat 6%
- Sofosbuvir/ledipasvir and sofosbuvir/daclatasvir had least potential for interactions with ART

Percent of Current Antiretroviral Regimens Suitable for Coadministration with DAAs for Genotype 1 and 4 HCV Treatment

- SOF/LDV: 100%
- OMB/PRV/DAS/r: 64%
- GZR/EBR: 49%
- SOF + SIM: 49%
- SOF + DCV: 100%
- SOF/VEL: 73%

N=128

ART for Co-infected, HIV Treatment Naïve

• Consider selecting ART in anticipation of HCV treatment
• If all recommended treatment naïve antiretroviral regimens are options, consider one with less potential interactions with DAAs
  • Examples: dolutegravir based or raltegravir based (recommended regimens), rilpivirine based (alternative regimen)
  • Ritonavir, cobicistat, or TDF regimens tend to have more interactions
ART for Co-Infected, HIV Treatment Experienced

• ART with higher potential for interactions with DAAs
  • Ritonavir or cobicistat-boosted protease inhibitors
    • Can increase DAA concentrations
  • Efavirenz and etravirine
    • CYP enzyme inducers can decrease DAA concentrations

• If a switch in ART is needed in a virologically suppressed patient
  • Review past regimens and resistance testing
  • Within class switches should maintain virologic control if no viral resistance
  • Close viral load monitoring within the first three months after switch
  • Goal: maintain HIV viral suppression

Primary Care: Common DAA Drug Interactions

• Check your drug-drug interaction resource
• Important to consider the entire medication list, including over the counter medications and herbal supplements
• Clarify indication and dosing for concurrent medication
  • Example: cardiovascular risk category for statin therapy or confirming anticonvulsants for epilepsy
• Determine if alternatives to concurrent medication exist
• Consult with prescribing physician and/or pharmacist
DAA and Cardiovascular Medication Interactions

- Amiodarone: contraindicated with all current DAA regimens
  - Serious symptomatic bradycardia
  - Consultation with cardiology is advised

- Anti-hypertensives:
  - Amlodipine, diltiazem, verapamil: caution with CYP 3A4 inhibitors

- Statins are P-gp and BCRP substrates
  - Pravastatin has the least potential for interactions
  - Patients with high cardiovascular risk: consider switching to high dose pravastatin for duration of DAA treatment
  - Patients with low cardiovascular risk: consider holding statin
  - Consider consultation with cardiologist
DAAs and Mental Health and Neurology Medication Interactions

• Anti-convulsants:
  • Carbamazepine, oxcarbazepine, phenytoin, phenobarbital, primidone
  • P-gp and CYP enzyme inducers
  • Lead to decreased DAA concentrations
  • Consult with neurology regarding alternatives such as levetiracetam

• Antidepressants:
  • For many DAA regimens, no adjustments are needed
  • DAA CYP enzyme inhibitors – watch for increased antidepressant concentrations and side effects
DAAs and Miscellaneous Agent Interactions

- Alpha-blockers
  - Caution with CYP inhibitors, monitor blood pressure

- Contraceptive agents
  - Ethinylestradiol containing product + OMB/PAR/DAS/r can lead to hepatoxicity and increased liver function tests
  - Progestin containing products are recommended during treatment
  - Can restart ethinylestradiol products 2 weeks after completing therapy
Takeaway Points

• Hepatitis C treatment has similar efficacy in co-infected patients compared to mono-infected patients

• HIV-HCV co-infection--- Still a special population?
  • Drug-drug interactions
  • Important to utilize your resources to identify and manage drug-drug interaction
  • Faster progression
  • Short course therapies?

• What to do for special subpopulations
  • Co-infected patients with DAA treatment experience
  • Patients with drug interactions and renal failure
A Practical Approach to HIV/HCV Co-infection

Focus on Drug-Drug Interactions

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