

Treating Hepatitis C in a Ryan White Clinic: Breaking down barriers in a changing HCV landscape

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Disclosures

Sarah McBeth has no financial interest to disclose.

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Learning Objectives

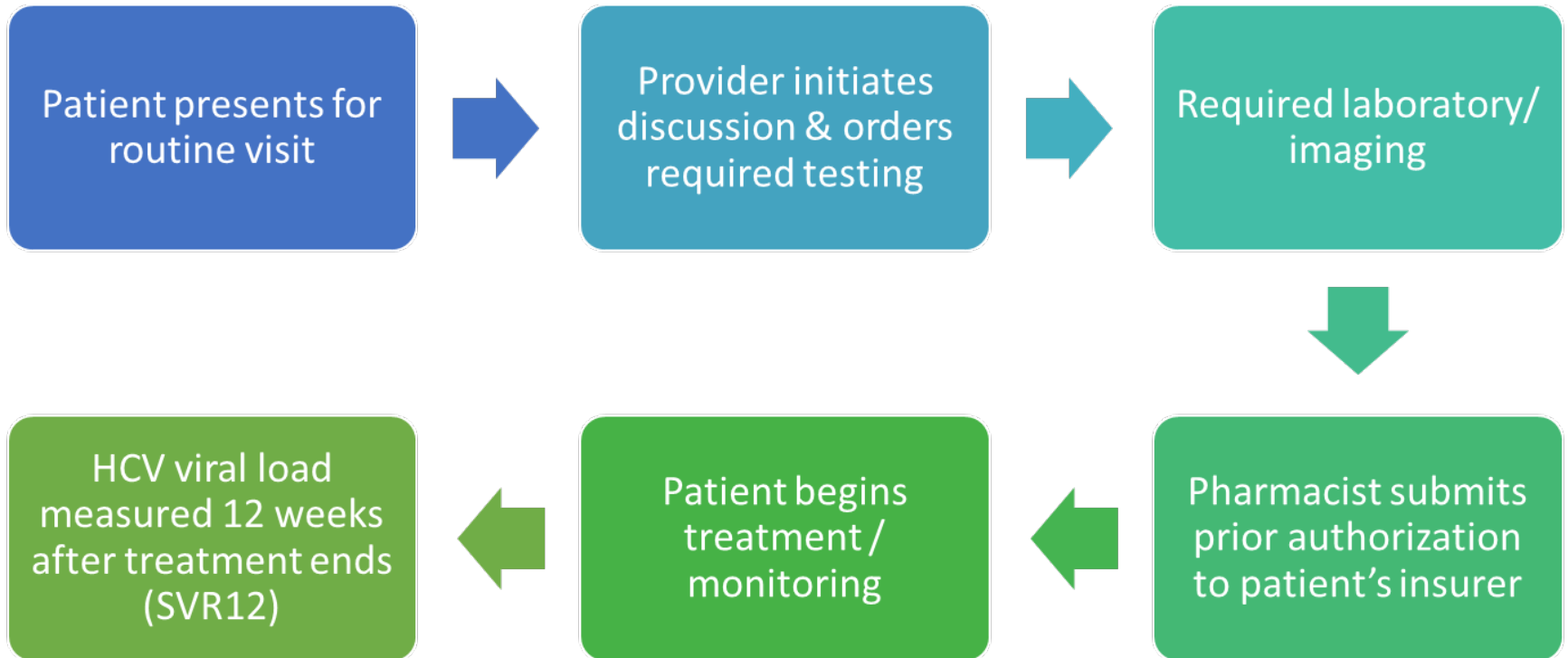
At the conclusion of this activity, the participant will be able to:

1. Identify strategies to reduce barriers to Hepatitis C (HCV) treatment
2. Select appropriate HCV treatment regimens using the HCV Treatment Guidelines

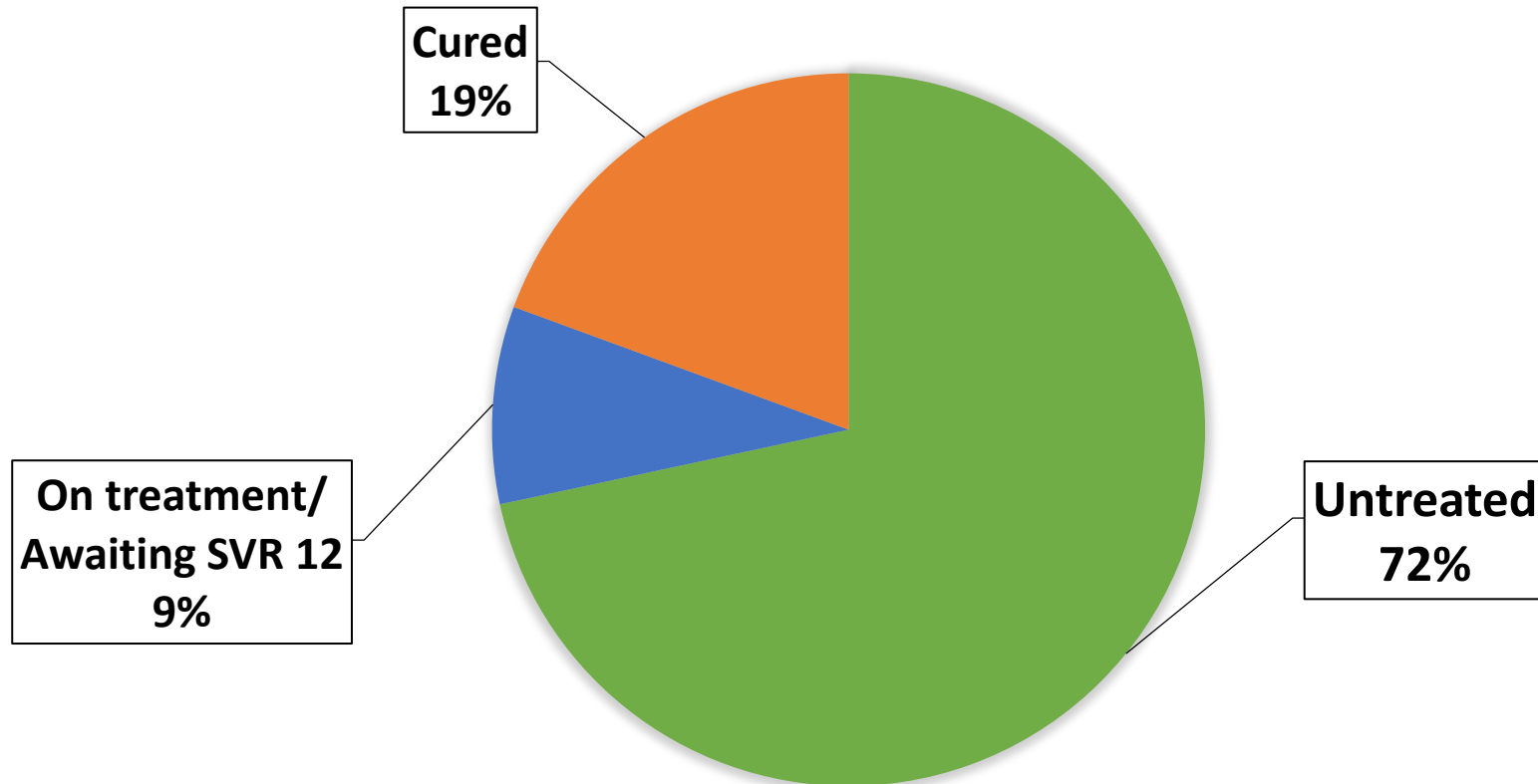
Pittsburgh AIDS Center for Treatment (PACT)

- Large, urban, university-based clinic
- Serves 1633 HIV-infected adults
- 134 patients with HCV co-infection
- Began treating HCV among HIV/HCV co-infected patients in February 2014

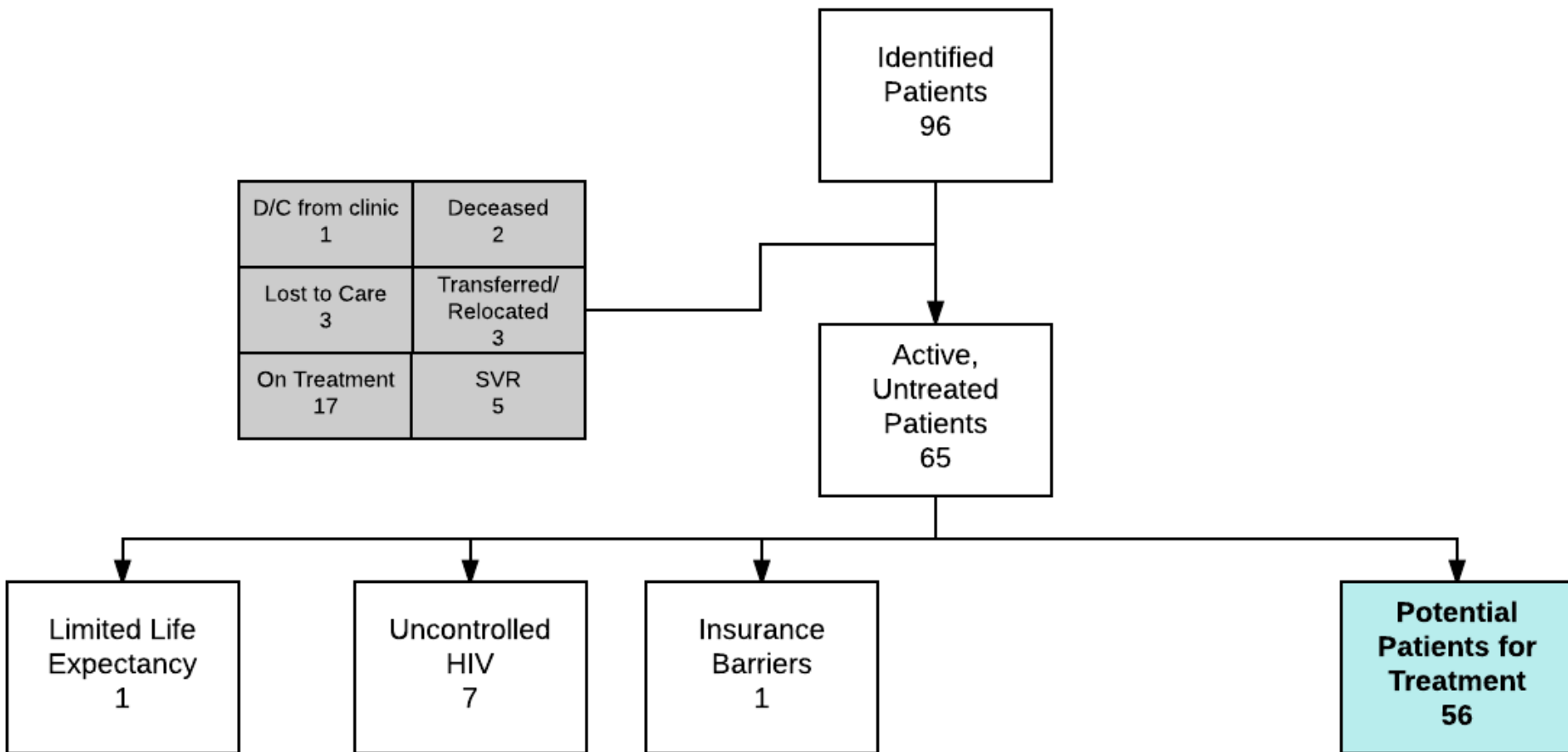
PACT HCV Treatment Protocol



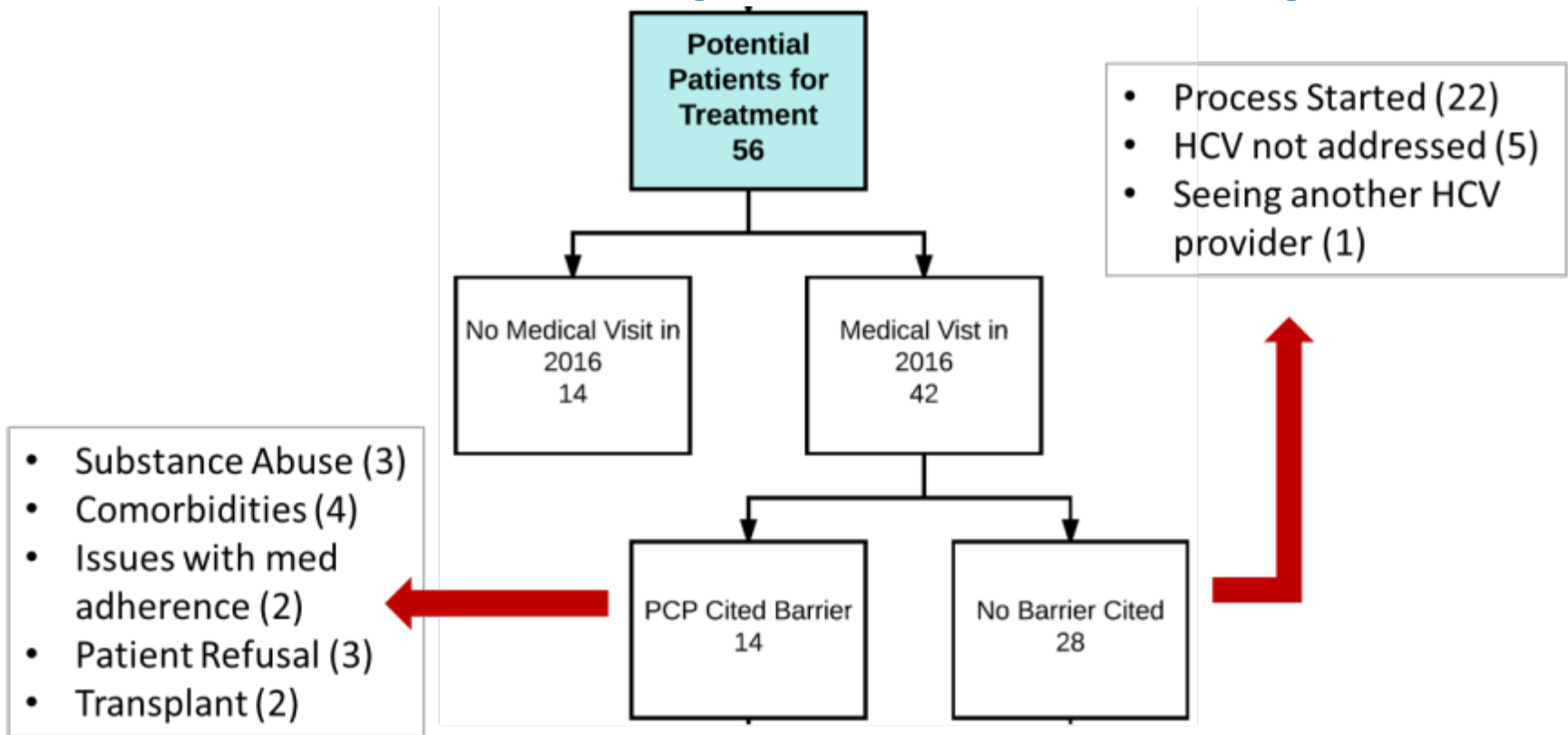
HIV/HCV Co-infected Patients at PACT (End of 2015)



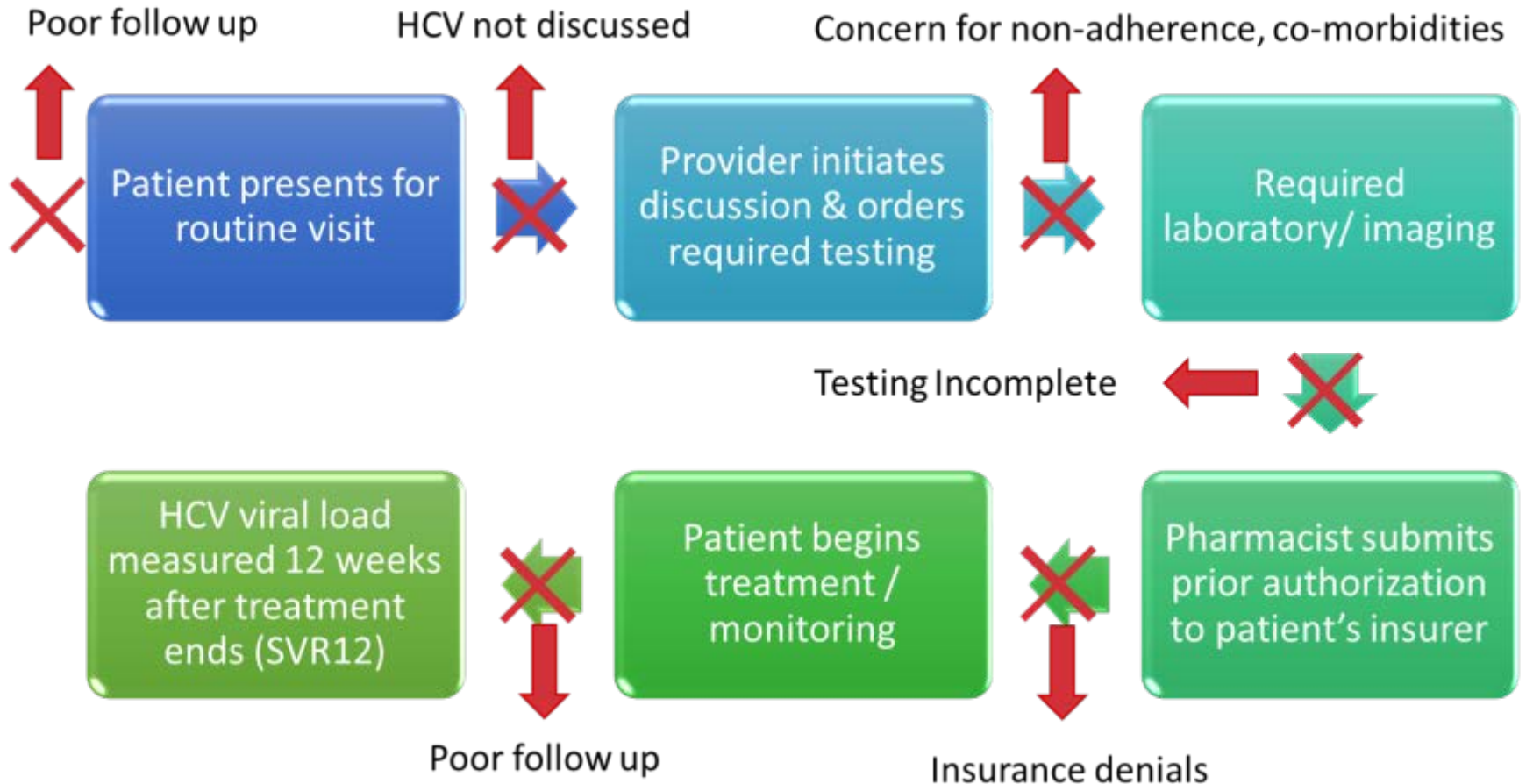
Untreated HCV Co-infected Patients (End of 2015)



Untreated HCV Co-infected Patients (End of 2015)



Barriers Can Occur at Every Step



hcvguidelines.org

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AMERICAN ASSOCIATION FOR
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**HCV Guidance:
Recommendations for
Testing, Managing, and
Treating Hepatitis C**

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Patient MG

47 year old male with a history of :

- HIV, on DRV/r + ABC + 3TC, CD4 479 and viral load undetectable
- HCV, genotype 4, failed two IFN-based regimens in the past
- End stage renal disease, on hemodialysis
- Hypertension
- Polysubstance abuse (2-3 drinks daily, MJ, cocaine)
- Chronic pancreatitis
- GI bleeding

Meds

Abacavir, Calcium acetate, Carvediolol, Citalopram, Darunavir, Lamivudine, Pantoprazole, Pravastatin, Ritonavir, Valsartan

Can MG be treated for HCV?

- 1) No. He is on hemodialysis so cannot take any DAA regimens.
- 2) No. Medication interactions will prevent the use of any DAA regimen.
- 3) No. He is actively drinking alcohol and using cocaine.
- 4) Yes!

What are some considerations for treating MG's HCV?

- On hemodialysis
 - Is there a renally dosed regimen?
- Past hepatitis C treatment
 - Will this affect DAA choice or length of treatment?
- Drug interactions
 - Will his ART regimen need to be changed?
- Polysubstance abuse
 - Will he be compliant with a course of DAA?

⊕ Retreatment of Persons in Whom Prior Therapy Has Failed

⊕ Monitoring Patients Who Are Starting Hepatitis C Treatment, Are on Treatment, or Have Completed Therapy

⊕ Unique Patient Populations: Patients with HIV/HCV Coinfection

⊕ Unique Patient Populations: Patients with Decompensated Cirrhosis

⊕ Unique Patient Populations: Patients Who Develop Recurrent HCV Infection Post-Liver Transplantation

⊕ Unique Patient Populations: Patients with Renal Impairment

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Patient MG: Hemodialysis

Recommended Regimens for Patients with Severe Renal Impairment, Including Severe Renal Impairment (Creatinine Clearance [CrCl] <30 mL/min) or End-Stage Renal Disease (ESRD)

Recommended regimens are listed in groups by level of evidence, then alphabetically.

- **For patients with genotype 1a, or 1b, or 4 infection and CrCl below 30 mL/min, for whom treatment has been elected before kidney transplantation, daily fixed-dose combination of elbasvir (50 mg)/grazoprevir (100mg) for 12 weeks is a Recommended regimen.**

What are some considerations for treating MG's HCV?

- Past hepatitis C treatment
 - Will this affect DAA choice, length of treatment?

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Genotype 4 PEG-IFN/Ribavirin Treatment-Experienced Patients Without Cirrhosis - Recommended

Recommended regimens are listed in groups by level of evidence, then alphabetically.

- **Daily fixed-dose combination of paritaprevir (150 mg)/ritonavir (100 mg)/ombitasvir (25 mg) (PrO) and weight-based ribavirin for 12 weeks is a Recommended regimen for patients with HCV genotype 4 infection, who do not have cirrhosis, in whom prior treatment with PEG-IFN/ribavirin has failed.**

Rating: Class I, Level A

- **Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg) for 12 weeks is a Recommended regimen for patients with HCV genotype 4 infection who do not have cirrhosis, in whom prior treatment with PEG-IFN/ribavirin has failed.**

Rating: Class I, Level A

- **Daily fixed-dose combination of elbasvir (50 mg)/grazoprevir (100 mg) for 12 weeks is a Recommended regimen for patients who have HCV genotype 4 infection, who do not have cirrhosis, who experienced virologic relapse after prior PEG-IFN/ribavirin therapy. Genotype 4 patients with prior on-treatment virologic failure (failure to suppress or breakthrough) while on PEG-IFN/ribavirin should be treated with 16 weeks and have weight-based ribavirin added to the treatment regimen.**

Rating: Class IIa, Level B

- **Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) for 12 weeks is a Recommended regimen for patients with HCV genotype 4 infection, who do not have cirrhosis, in whom prior treatment with PEG-IFN/ribavirin treatment has failed.**

Rating: Class IIa, Level B

What are some considerations for treating MG's HCV?

- Drug interactions
 - Will his ART regimen need to be changed?

- ⊕ Retreatment of Persons in Whom Prior Therapy Has Failed
- ⊕ Monitoring Patients Who Are Starting Hepatitis C Treatment, Are on Treatment, or Have Completed Therapy
- ⊕ Unique Patient Populations: Patients with HIV/HCV Coinfection
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- ⊕ Unique Patient Populations: Patients Who Develop Recurrent HCV Infection Post-Liver Transplantation
- ⊕ Unique Patient Populations: Patients with Renal Impairment

Patient MG: Drug Interactions

- **Elbasvir/grazoprevir should NOT be used with cobicistat, efavirenz, etravirine, nevirapine, or any HIV protease inhibitor.**







Rating: Class III, Level B



- MG is currently on darunavir, a protease inhibitor
 - To treat his HCV, he will require ART switch

hep-druginteractions.org

Having trouble viewing the interactions? [Click here for the Interaction Checker Lite.](#)

HEP Drugs	Co-medications	Drug Interactions
<input type="text" value="Search HEP drugs..."/>	<input type="text" value="Search co-medications..."/>	Switch to table view
<input checked="" type="radio"/> A-Z <input type="radio"/> Class <input type="radio"/> Trade	<input checked="" type="radio"/> A-Z <input type="radio"/> Class	Reset Checker
<input checked="" type="checkbox"/> Elbasvir/Grazoprevir 	<input checked="" type="checkbox"/> Pantoprazole 	No Interaction Expected
<input type="checkbox"/> Adefovir 	<input type="checkbox"/> Abacavir 	Elbasvir/Grazoprevir
<input type="checkbox"/> Boceprevir 	<input type="checkbox"/> Acamprosate 	Pantoprazole

Patient MG

Elbasvir/grazoprevir can be used in patients on hemodialysis

It can also be used in patients with genotype 4 who failed IFN in the past

Requires 16 weeks and addition of ribavirin in some cases

Elbasvir/grazoprevir interacts with his current ART regimen

Planning switch to an integrase inhibitor-based regimen


- Need to establish fibrosis stage
- MG is pursuing a work-up for kidney transplant
- He recently began attending Alcoholic Anonymous and Narcotics Anonymous

Patient RC

- RC is a 53 year old with HIV, HCV, depression, tobacco abuse, past opiate abuse
- HIV well-controlled on DTG/ABC/3TC, CD4 622, viral load undetectable
- Acquired HIV and HCV through IVDU in the 1990's, no prior treatment
- Quit IVDU four years ago, maintained on buprenorphine/naloxone
- HCV genotype 1a, HCV viral load: 1.4 million
- Fibrosis score (from Fibroscan): F3, normal ultrasound

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Treatment Options for GT1a

Genotype 1a Treatment-Naïve Patients Without Cirrhosis - Recommended

Recommended regimens are listed in groups by level of evidence, then alphabetically.

- **Daily fixed-dose combination of elbasvir (50 mg)/grazoprevir (100 mg) for 12 weeks is a Recommended regimen for treatment-naïve patients with HCV genotype 1a infection who do not have cirrhosis and in whom no baseline NS5A RAVs¹ for elbasvir are detected.**
Rating: Class I, Level A
- **Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) for 12 weeks is a**

- **Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) for 12 weeks is a Recommended regimen for treatment-naïve patients with HCV genotype 1a infection who do not have cirrhosis.**

Rating: Class I, Level A


- **Daily simeprevir (150 mg) plus sofosbuvir (400 mg) for 12 weeks is a Recommended regimen for treatment-naïve patients with HCV genotype 1a infection who do not have cirrhosis.**
Rating: Class I, Level A
- **Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg) for 12 weeks is a Recommended regimen for treatment-naïve patients with HCV genotype 1a infection who do not have cirrhosis.**
Rating: Class I, Level A
- **Daily daclatasvir (60 mg*) plus sofosbuvir (400 mg) for 12 weeks is a Recommended regimen for treatment-naïve patients with HCV genotype 1a infection who do not have cirrhosis.**
Rating: Class I, Level B

Patient RC

Prior authorization for Ledipasivir/sofosbuvir submitted to commercial insurer



Denied due to lack of documentation of GFR>30. Creatinine & GFR submitted w/ reapplication.



Denied. "This regimen is not appropriate for use since documentation shows presence of HIV co-infection."

What would you do next?

- 1) Appeal
- 2) Use ADAP to get ledipasvir/sofosbuvir drug coverage
- 3) NS5a resistance testing, followed by application for elbasvir/grazoprevir
- 4) Apply for paritaprevir/ritonavir/ombitasvir/dasabuvir
- 5) Give up



Patient RC

An appeal was denied.



NS5A resistance testing was performed and revealed no predicted drug resistance.



Prior authorization for elbasvir/grazoprevir was submitted and was **approved!**

Summary

- A variety of barriers can prevent HIV/HCV co-infected patients from getting HCV treatment
- HCV guidelines are accessible and easy to use
- Provider persistence and an expanding armamentarium of DAA medications will allow more people to be treated for HCV

Contact Information

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