New York State HCV Provider Webinar Series
PCP Treater V. Specialist
Harmit Kalia DO
Objectives

• Define the disease burden of HCV
• Define screening strategies for HCV
• Define the treatment cascade for people with HCV
• How has HCV treatment evolved?
• Who has been treating HCV?
• Role of primary care providers and “specialists”
Global Distribution of Hepatitis C Virus Infection

People Newly Reported with Chronic Hepatitis C in New York City by Zip Code, 2014-2015

146,500 estimated infected with HCV in NYC
Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions

<table>
<thead>
<tr>
<th>Test Outcome</th>
<th>Interpretation</th>
<th>Further Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV antibody nonreactive</td>
<td>No HCV antibody detected</td>
<td>Sample can be reported as nonreactive for HCV antibody. No further action required. If recent exposure in person tested is suspected, test for HCV RNA.*</td>
</tr>
<tr>
<td>HCV antibody reactive</td>
<td>Presumptive HCV infection</td>
<td>A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.</td>
</tr>
<tr>
<td>HCV antibody reactive, HCV RNA detected</td>
<td>Current HCV infection</td>
<td>Provide person tested with appropriate counseling and link person tested to care and treatment.†</td>
</tr>
<tr>
<td>HCV antibody reactive, HCV RNA not detected</td>
<td>No current HCV infection</td>
<td>No further action required in most cases. If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay. In certain situations, ‡follow up with HCV RNA testing and appropriate counseling.</td>
</tr>
</tbody>
</table>

*If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

†It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

‡If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.
Hepatitis C Is Under-Diagnosed in the U.S.

Hepatitis C Is Under-Diagnosed in the U.S.

3.9 million
CDC estimate

Hepatitis C Is Under-Diagnosed in the U.S.

3.9 million CDC estimate

Incarcerated
Homeless
Nursing homes
Hospitalized
Active Military

Hepatitis C Is Under-Diagnosed in the U.S.

3.9 million
CDC estimate

Incarcerated
Homeless
Nursing homes
Hospitalized
Active Military

Hepatitis C Is Under-Diagnosed in the U.S.

5 - 7 million estimated true prevalence

3.9 million CDC estimate

- Incarcerated
- Homeless
- Nursing homes
- Hospitalized
- Active Military

Hepatitis C Is Under-Diagnosed in the U.S.

- Incarcerated
- Homeless
- Nursing homes
- Hospitalized
- Active Military

5 - 7 million estimated true prevalence

3.9 million CDC estimate

25% Diagnosed

Hepatitis C Is Under-Diagnosed in the U.S.

5 - 7 million estimated true prevalence

3.9 million CDC estimate

Large reservoir of infected patients who are undiagnosed

Incarcerated
Homeless
Nursing homes
Hospitalized
Active Military

25% Diagnosed

**Chronic HCV-infected; N=3,500,000.** † Calculated as estimated number chronic HCV-infected (3,500,000) x estimated percentage diagnosed and aware of their infection (49.8%); n=1,743,000.
‡ Calculated as estimated number diagnosed and aware (1,743,000) x estimated percentage diagnosed and aware of their infection (86.9%); n=1,514,667.
§ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage HCV RNA confirmed (62.9%); n=952,726.
II Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage who underwent liver biopsy (38.4%); n=581,632.
¶ Calculated as estimated number with access to outpatient care (1,514,667) x estimated percentage prescribed HCV treatment (36.7%); n=581,883.
**Calculated as estimated number prescribed HCV treatment (555,883) x estimated percentage who achieved SVR (58.8%); n=326,859.
Note: Only non-VA studies are included in the above HCV treatment cascade.
Natural History of HCV Infection

- Exposure (Acute Phase)
  - Resolved: 15% (15)
  - Chronic: 85% (85)
    - Stable: 80% (68)
    - Slowly Progressive: 20% (17)
      - Cirrhosis: 75% (13)
      - HCC Transplant Death: 25% (4)

HCV: Significant Problem

• Requires help from multiple providers to not just diagnose but also treat

• Those who have been treating HCV, will continue to

• Who can be trained to treat?
Evolution of HCV Treatment

New Drugs: Easier and effective Treatment
Over shorter period of time

Goals of Therapy:
Virologic Cure

New York City Department of Health and Mental Hygiene conducted an enhanced surveillance project to better understand the reasons patients are not treated for HCV.

Randomly selected 300 adults with chronic HCV

Information collected on demographics, treatment, and barriers to treatment from these 300 patients and their providers by telephone, fax, mail, and medical record review.
179 Providers: Barriers to treatment

- 41% - co-occurring conditions.
- 28% - patients not keeping follow-up or referral appointments with specialists as common barriers to treatment.
- 22% - they do not prescribe HCV medications and instead refer patients to specialists for treatment.
89 patients citing barriers to treatment:

- 34% - co-occurring conditions
- 29% - concerns about side effects
- 24% - not feeling sick
- 17% - waiting for a better treatment regimen
- 13% - medication costs or insurance issues.

11 providers and 10 patients denied any barriers to treatment.

Conclusion: Increase provider capacity, change provider behavior and improve patient awareness of new medications.
Perceived Barriers to HCV Treatment

Government Related
- Government restricts treatment
- Insufficient funds allocated to HCV
- Lack of promotion for HCV treatment

Patient Related
- Fear of side effects
- Medication expense
- Laboratory expense
- Low success rate of treatment
- Fear of stigma related to HCV
- Preference for alternative therapy
- Desire to wait for newer therapies
- Difficulty with administration
- Treatment duration
- Patient declines liver biopsy
- Inaccessibility of experienced providers

Provider Related
- Treatment limited to government-mandated centers
- Lack of office infrastructure to treat patients
- Insufficient reimbursement for physicians
- Unable to obtain necessary labs for treatment
- Limited access to medications or labs
- Insufficient training for HCV management
- Lack of referral to HCV providers by other physicians
- Lack of proper storage for medications

Payer Related
- Insurance plan does not cover treatment
- High out-of-pocket expense for patients
- Restricted insurance coverage for patients with HCV
- Insurance plans will not cover RNA/genotyping
- Excessive paperwork requirements
- Insurance plans limit which physicians treat HCV
- Insurer does not cover serum markers of fibrosis
- Insurance plans do not cover medications for side effects
- Liver biopsy required for treatment

HCV Burden on Primary Care Clinicians

• Formidable task for Primary care clinicians:
  – Increasing number of patients diagnosed
  – Subsequently link to care
  – Already mandated to screen individuals born between 1945 and 1965 (the Baby Boomer Generation).
Disparities in Absolute Denial of Modern Hepatitis C Therapy by Type of Insurance

- Prospective cohort study
- 2321 patients
- DAA prescriptions submitted to specialty pharmacy
- There are significant disparities in access to DAA-based treatments

Medicaid, Private Insurers Begin To Lift Curbs On Pricey Hepatitis C Drugs

2016: States including Florida, New York, Delaware and Washington — as well as some private insurers — have recently lifted restrictions on expensive hepatitis C medications

Surveyed 452 physicians (Program Directors)

Response rate 61%-

- The majority of PDs (78%) believed that chronic HCV represented a significant problem for primary care
- 61.9% believed their program should take steps to build capacity in HCV treatment.
- Opportunity to train family physicians and position them on the frontline as HCV treatment
High Efficacy of HCV Treatment by Primary Care Providers: The ASCEND Study

• Multi-center, open label, phase IV clinical trial of 600 patients
• HCV+ patients of three community health centers in Washington DC were identified and distributed in a non-randomized manner to receive treatment from either
  – Nurse practitioner (NP)
  – Primary care physician (PCP)
  – Specialist (BC/BE Infectious Disease or Hepatology)
• Providers underwent uniform 3-hour training on IDSA-AASLD therapeutic guidelines
• Patients were treated with ledipasvir and sofosbuvir (LDV/SOF) as per FDA label
• The primary outcome: SVR12
• Adherence to visits at 4, 8, and 12 weeks (all -7 to +14 days), were categorized by a composite score of attendance
High Efficacy of HCV Treatment by Primary Care Providers: The ASCEND Study

Chronic HCV can effectively be treated by PCP
- F1-F3 Fibrosis
- Child’s A cirrhosis
- Naïve
- Experienced (?IFN)

Treating Provider Characteristic Total Cohort (n=800) NP (n=150) PCP (n=156) Specialist (n=294)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total Cohort (n=800)</th>
<th>NP (n=150)</th>
<th>PCP (n=156)</th>
<th>Specialist (n=294)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>58.7</td>
<td>58.2</td>
<td>59</td>
<td>58.7</td>
</tr>
<tr>
<td>Male (%)</td>
<td>416 (63.9)</td>
<td>109 (72.7)</td>
<td>114 (73.1)</td>
<td>193 (65.7)</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black*</td>
<td>578 (96.3)</td>
<td>140 (93.3)</td>
<td>156 (100)</td>
<td>282 (95.9)</td>
</tr>
<tr>
<td>White</td>
<td>20 (3.3)</td>
<td>9 (6.0)</td>
<td>0</td>
<td>11 (3.7)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (0.3)</td>
<td>1 (0.2)</td>
<td>0</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Infection Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV</td>
<td>458 (76.3)</td>
<td>127 (84.7)</td>
<td>109 (69.9)</td>
<td>222 (75.5)</td>
</tr>
<tr>
<td>HIV/HCV*</td>
<td>142 (23.7)</td>
<td>23 (15.3)</td>
<td>47 (30.1)</td>
<td>72 (24.5)</td>
</tr>
<tr>
<td>Genotype</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td>431 (76.3)</td>
<td>104 (69.3)</td>
<td>113 (72.4)</td>
<td>214 (72.8)</td>
</tr>
<tr>
<td>1b</td>
<td>169 (28.2)</td>
<td>46 (30.7)</td>
<td>43 (27.7)</td>
<td>80 (27.2)</td>
</tr>
<tr>
<td>Fibrosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>80 (13.3)</td>
<td>22 (14.7)</td>
<td>20 (12.8)</td>
<td>38 (12.9)</td>
</tr>
<tr>
<td>1</td>
<td>90 (15)</td>
<td>23 (15.3)</td>
<td>29 (18.6)</td>
<td>39 (12.9)</td>
</tr>
<tr>
<td>2</td>
<td>212 (35.3)</td>
<td>54 (36.0)</td>
<td>50 (32.1)</td>
<td>108 (36.7)</td>
</tr>
<tr>
<td>3</td>
<td>97 (16.2)</td>
<td>22 (14.7)</td>
<td>29 (18.6)</td>
<td>46 (15.7)</td>
</tr>
<tr>
<td>4</td>
<td>121 (20.2)</td>
<td>29 (19.3)</td>
<td>28 (18.0)</td>
<td>64 (21.8)</td>
</tr>
<tr>
<td>Previous Treatment (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experienced</td>
<td>106 (17.7)</td>
<td>29 (19.3)</td>
<td>27 (17.3)</td>
<td>50 (17.0)</td>
</tr>
<tr>
<td>Naive</td>
<td>494 (82.3)</td>
<td>121 (82.7)</td>
<td>129 (80.7)</td>
<td>244 (82.9)</td>
</tr>
</tbody>
</table>

Interim per Protocol SVR12 by Provider Type (n=304)

Visit Adherence by Provider Type (n=409)

Kattakuzhy S. EASL. Poster LBP524 April 2016.
Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers

- Echo program - developed to improve access to complex medical problems
- Video conferencing technology used to train primary providers remotely
- Effective way to treat HCV in underserved communities.
High Efficacy of Non-Specialist Lead HCV Treatment with DAAs - Methods

Two Urban Health Systems

16 Providers

5 NP
5 PCP
6 Specialist (ID/Hepatology)

Uniform 3-hour Training

600 Patients

LDV/SOF 8-24 Weeks

SVR12
Adherence

Kattakuzhy S, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. LBP524.
Interim per Protocol SVR 12 by Provider Type (n=382)

<table>
<thead>
<tr>
<th>Provider Type</th>
<th>Percentage with SVR12</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>95.2% (98/103)</td>
</tr>
<tr>
<td>PCP</td>
<td>97.3% (72/74)</td>
</tr>
<tr>
<td>Specialist</td>
<td>92.7% (190/205)</td>
</tr>
<tr>
<td>Total</td>
<td>94.2% (360/382)</td>
</tr>
</tbody>
</table>

Kattakuzhy S, et al. 51st EASL; Barcelona, Spain; April 13-17, 2016. Abst. LBP524.
HCV: “Difficult-to-Treat” Group

- HIV/HCV Co-infection (?)
- Decompensated Cirrhosis
- Liver Transplant Recipients
- Renal Failure / Kidney Transplant recipients
- Non Responders / DAA Failures
- PWID

Patients that were difficult to treat in the interferon era can now be safely treated with DAA; but may require special expertise, monitoring or skill to treat

HIV/HCV Co-Infection: Considerations

- High prevalence of HCV co-infection
- Rapid progression of HCV-related liver disease
- Poor response to interferon-alfa based treatment regimens
- Drug interactions ARVs and DAAs
- Estimated 4-5 million co-infected patients worldwide
- Prevalence 10-15%, up to 50% in HIV patients who inject or have injected in the past
- Increased sexual transmission in MSM (increase possibility of reinfection)
**HIV/HCV Co-Infection**

- **Successful HCV treatment** must be combined with:
  - Strategies to reduce the risk of re-infection following SVR
  - **Education on risk**
  - Access to programs to promote needle-exchange
  - Opioid substitution therapy
  - Healthy sexual behavior and the use of protective barrier methods.

Resource to Check for Drug Interactions

HEP Drug Interaction Checker
Access our comprehensive, user-friendly, free drug interaction charts. Providing clinically useful, reliable, up-to-date, evidence-based information

Start Now

<table>
<thead>
<tr>
<th>Drug</th>
<th>Do Not Coadminister</th>
<th>Potential Interaction</th>
<th>No Interaction Expected</th>
<th>No Clear Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antacids</td>
<td>🌟</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>🌟</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cannabis</td>
<td>🌟</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>🌟</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clindamycin</td>
<td>🌟</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dabigatran</td>
<td>🌟</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

www.hep-druginteractions.org
HIV/HCV Co-Infection

• Antiretroviral drug switches, when needed, should be done in collaboration with the HIV practitioner.

HCV Guidance:
Recommendations for Testing, Managing, and Treating Hepatitis C

http://www.hcvguidelines.org/
Decompensated Cirrhosis: Child’s B/C

- Liver dysfunction with reduced elimination of drug may cause toxicity and further decompensation (Simeprevir, Sofosbuvir)
- Reduced exposure/efficacy due to hypoalbuminemia but free drug concentration does not change (no dose adjustment requirement)
- Protease Inhibitors are not used
- Overall SVR rates are lower with advanced cirrhosis compared to those with less fibrosis or portal hypertension
- Consideration for Liver transplantation and timing of HCV treatment
- MELD Purgatory
HCV After Liver Transplantation

- Increased risk for developing ESLD, 25% in 5 years
- Major consideration is DAA interaction with either tacrolimus or cyclosporine
- Simeprevir and daclatasvir only slightly increase cyclosporine or tacrolimus exposure
- Sofosbuvir does not have any clinically significant DD interactions with tacrolimus/cyclosporine
- 3D regimen can be used as long as drug monitoring of calcineurin inhibitors is performed (risk of calcineurin toxicity)

Challenging comorbidity HCV and CKD are associated with higher mortality rates

- Certain DAA treatment regimens achieve high SVR rates in patients with decompensated cirrhosis or severe renal impairment but not both

- Elbasvir/grazoprevir and ombitasvir/paritaprevir/ritonavir/dasabuvir have favorable pharmacokinetic profiles for patients with severe renal impairment, but only available for GT 1 and 4

- Contraindicated in decompensated cirrhosis.

Title: Use of HCV+ donors does not affect HCV clearance with directly acting antiviral therapy but shortens the wait time to kidney transplantation

- 43 renal transplant recipients with 4 different DAA regimens
- 100% achieved a sustained viral response by 12 weeks after therapy
- DAA regimens were well tolerated
- Recipients of HCV+ organs experienced significantly shorter wait-times to transplantation, 485 days (IQR 228-783) versus 969 days (IQR 452-2008) p=0.02.
DAA Failures

- DAA failures occurs in roughly 10% of chronic hepatitis C patients treated outside clinical trials.
- Most cases are relapses instead of viral breakthroughs on therapy.
- Occur more frequently in treatment-experienced patients, those with advanced cirrhosis and HCV genotypes 3 or 1a.
- DAA failure is rare in non-cirrhotics patients (seen only when therapy is given for < 12 wks).
- Virologic breakthrough during DAA therapy = poor drug adherence.
- DAA failure is frequently associated with emergence of RAVs.
- HCV drug resistance testing will help choosing the most convenient salvage DAA regimen as re-treatment of prior DAA failures.

Predictors of DAA Treatment Failure

Baseline
- Advanced cirrhosis
- Genotype 3
- RAVs
- Prior interferon failure
- Elevated serum HCV-RNA
- IFNL4 unfavorable

On-treatment
- Drug adherence
- Side effects
- Drug interactions

RAVs: Resistance-associated variants; IFNL4: interferon lambda 4.
Considerations for HCV Retreatment in DAA Failures

- **Virologic challenges**
  - Presence of RAVs (prior DAA failure)
  - Exclude HCV genotype shift (misinterpretation)
  - Exclude HCV reinfection (risk behaviors)

- **Strategic management**
  - Adding ribavirin
  - Extent the length of therapy

- **Maximize drug benefit**
  - Avoid drug interactions (comorbidities)
  - Prevent and manage side effects
  - Ensure drug adherence
RAV’s: Replacement by Wild Type After Stopping Therapy

Sofosbuvir: High Barrier to Resistance

Retreatment Options for DAA Failures

Prior DAA Failure

- PegIFN + RBV
- O Sofosbuvir
- Sofosbuvir

NS3 Protease Inhibitors
- Telaprevir
- Boceprevir
- Simeprevir

NS5A Inhibitors
- Ledipasivir
- Daclatasvir

NS3 Protease Inhibitors plus NS5A Inhibitors
- Paritaprevir + Ombitasvir
- Grazoprevir + Elbasvir

Retreatment Options

- Sofosbuvir
- Ledipasivir
- Daclatasvir
- Simeprevir

- NS3 Protease Inhibitors
- NS5A Inhibitors

RAV Testing

HCV in People Who Inject Drugs: PWID

- Main risk group for transmission
- HCV prevalence range <20%->80%, ~ 50%
- Younger patients with less advanced liver disease and therefore strategies which target more severe liver disease may have little to no impact on the epidemic
- Provider concerns surrounding potential poor treatment outcomes among PWID persist
- Established programs are built on existing infrastructure for drug user: addiction clinics, community health centers and prisons
- HCV treatment needs to be combined with prevention strategies to reduce reinfection, and ensure stable reductions in transmission occur
- Opiate substitution therapy and needle and syringe programs are effective at reducing an individuals’ risk of HCV acquisition
- Combination HCV treatment and harm reduction strategies: reduce HCV incidence, and prevent reinfection post treatment.
Successful Treatment of Chronic Hepatitis C with Triple Therapy in an Opioid Agonist Treatment Program

On-treatment characteristics of 50 HCV-infected patients treated on-site with triple therapy at opiate agonist treatment program.

- **Active drug use during treatment**
  - Used during treatment: 22 (45)
  - No use during treatment: 27 (55)

- **Model of care**
  - Group treatment: 38 (76)
  - Individual treatment: 12 (24)

- **Directly observed treatment**
  - Pegylated interferon only: 44 (88)
  - Pegylated interferon + oral meds: 6 (12)

- **DAA adherence**
  - $90.1 \pm 0.15$
  - <90%: 13 (29)
  - ≥90%: 32 (71)

- **Ribavirin adherence**
  - $91.8 \pm 0.15$
  - <90%: 10 (21)
  - ≥90%: 37 (79)

---

**Telaprevir (n=42) or boceprevir (n=8) in combination with pegylated interferon and ribavirin**

- **DAA Patients**: 50
- **ERVR**: 30
- **ETR**: 35
- **SVR24**: 31

---

*Missing data.*
On-treatment characteristics of 50 HCV-infected patients treated on-site with triple therapy at opiate agonist treatment program.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%) or Mean (± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active drug use during treatment*</td>
<td></td>
</tr>
<tr>
<td>Used during treatment</td>
<td>22 (45)</td>
</tr>
<tr>
<td>No use during treatment</td>
<td>27 (55)</td>
</tr>
<tr>
<td>Model of care</td>
<td></td>
</tr>
<tr>
<td>Group treatment</td>
<td>38 (76)</td>
</tr>
<tr>
<td>Individual treatment</td>
<td>12 (24)</td>
</tr>
</tbody>
</table>

DAA adherence:
- 90.1 ± 0.15
  - <90%: 13 (29)
  - ≥90%: 32 (71)

Ribavirin adherence:
- 91.8 ± 0.15
  - <90%: 10 (21)
  - ≥90%: 37 (79)

Telaprevir (n=42) or boceprevir (n=8) in combination with pegylated interferon and ribavirin

Opioid agonist treatment programs represent an opportunity to safely and effectively treat HCV.

Elbasvir-Grazoprevir to Treat Hepatitis C Virus Infection in Persons Receiving Opioid Agonist Therapy

- Randomized, placebo-controlled, double-blinded, multi-center trial
- 301 treatment-naive patients with chronic HCV genotype 1, 4, or 6 infection who were at least 80% adherent to visits for opioid agonist therapy
- Immediate-treatment group (ITG) received elbasvir–grazoprevir for 12 weeks; the deferred-treatment group (DTG) received placebo for 12 weeks, no treatment for 4 weeks, then open-label elbasvir–grazoprevir for 12 weeks.

- SVR12 was 91.5% in the ITG and 89.5% in the active phase of the DTG.
- Urine Drug Screen results were positive in 62% of patients in the ITG and 53% in the DTG and remained relatively stable throughout treatment; did not affect adherence or efficacy
- 6 had reinfection

Elbasvir-Grazoprevir to Treat Hepatitis C Virus Infection in Persons Receiving Opioid Agonist Therapy

- Randomized, placebo-controlled, double-blinded, multi-center trial
- 301 treatment-naive patients with chronic HCV genotype 1, 4, or 6 infection who were at least 80% adherent to visits for opioid agonist therapy
- Immediate-treatment group (ITG) received elbasvir–grazoprevir for 12 weeks; the deferred-treatment group (DTG) received placebo for 12 weeks, no treatment for 4 weeks, then open-label elbasvir–grazoprevir for 12 weeks.
- SVR12 was 91.5% in the ITG and 89.5% in the active phase of the DTG.
- Urine Drug Screen results were positive in 62% of patients in the ITG and 53% in the DTG and remained relatively stable throughout treatment; did not affect adherence or efficacy.
- 6 had reinfection

HCV treatment is effective and well tolerated in PWID who are receiving Opioid Agonist Therapy.

HCV in People Who Inject Drugs: PWID

- PWID should be counselled on the importance of adherence in attaining an SVR
- A history or recent IDU are not associated with reduced SVR and decisions to treat should be made on a case-by-case basis
- PWID with ongoing social issues, history of psychiatric disease and those with more frequent drug use during therapy are at risk of lower adherence and SVR and need to be monitored closely during therapy
- HCV treatment for PWID should be considered on an individualized basis and delivered within a multidisciplinary team setting
- Access to harm reduction programs, social work and social support services should be a component of HCV clinical management
- Universal access to therapy is required

Summary

• Chronic HCV is an under diagnosed disease
• Efforts should continued to be made to screen and link affected patients to care
• Treatment of HCV is short course, less toxic and highly efficacious
• Efforts are ongoing to increase HCV providers
• Some PCP are treating HCV with DAA and this is encouraging
• Complex, difficult to treat patient populations should be treated by a specialist