Challenges in Access to Hepatitis C Care

Jay Kostman, MD
Philadelphia FIGHT Community Health Centers
Objectives

• As a result of participating in this activity, participants will be able to develop programs to increase access to effective HCV therapies

• As a result of participating in this activity, participants will be able to help their patients navigate problems with access to HCV therapies
Outline

• Current Picture of HCV Care cascade
• Barriers to Entry into the Care Cascade
• Difficulties of Obtaining HCV Treatment
• Recommendations for Improving Access to Care Throughout the Cascade
HCV Care Cascade

- Chronic HCV-Infected*: 100%
- Diagnosed and Aware†: 50%
- Access to Outpatient Care‡: 43%
- HCV RNA Confirmed§: 27%
- Underwent Liver Biopsy‖: 17%
- Prescribed HCV Treatment‖: 16%
- Achieved SVR**: 9%

Yehia et al. PLoS ONE 9(7): e101554. doi:10.1371/journal.pone.0101554
Challenges in HCV Prevention and Testing

- Pervasive stigma, as HCV is largely associated with IDU
- Lack of education and awareness, particularly among:
  - Those who are unaware they are infected and were once at risk, largely baby-boomers, many of whom may not be presenting at integrated risk-based HIV/STD testing and referral sites
  - Those currently at risk, including both adults and youth
  - Primary care providers
- Lack of funding for prevention, testing (including rapid testing) and surveillance
Challenges in Linkage to Care and Treatment

- Lack of data on linkage to care: difficulties in tracking individuals from testing sites to care and treatment
- Lack of HCV education among individuals who know their status but do not know next steps to take and/or the importance of harm reduction
- Lack of health insurance to pay for treatment or underinsurance
- Fear of side effects based on past treatment regimens (both among those at risk and those who are aware of their infection)
- Additional barriers can exist for individuals living with past or current substance use disorders and/or mental illness:
  - Provider bias, sobriety periods for initiating treatment, strictly apply standards relative to missed appointments and adherence
Challenges in HCV Care and Treatment Delivery

- Lack of adequate support services for persons with hepatitis C undergoing treatment, including food, housing, and case management

- Not enough treatment providers, and not enough behavioral health providers (particularly for youth)

- Provider Challenges: high level of care coordination required for treatment
  - Providing adherence support
  - Management of anti-viral medications
  - Administrative work/obtaining and renewing prior authorizations
  - Lack of adequate funding for these services and/or case management
Barriers to HCV Treatment in PWID

- **COST**
  - Prohibitive cost of new medicines
  - Antidiversion requirements (viral load tests, empty pill bottles)

- **CRIMINALIZATION**
  - Detention in the name of “rehabilitation”
  - Imprisonment for drug use/possession

- **HEALTH REGULATIONS**
  - Treatment protocols excluding PWID or HIV/HCV coinfection
  - Addition of PWID names to government registries

- **CLINIC**
  - Stigma by health providers

Barriers to Treatment of HCV in People on Opiate Agonist Treatment

Highest prevalence of HCV infection is among persons who use illicit drugs

- Most incident infections are in this population
- Few seropositive IDUs pursue treatment when referred to conventional to conventional evaluation and treatment settings\(^a,b\)

Patient barriers

- Mental health disorders
- Social instability
- Inadequate access to healthcare
- Nonacceptance of treatment

\(^b\) Mehta SH, *J Community Health.* 2008;33:126-133.
Provider and Institutional Barriers to HCV Treatment in IDUs

Lack of training and expertise in the treatment of HCV infection by OTP providers

Providers unwilling to treat HCV infection

Failure to establish and coordinate a multidisciplinary team

Frustration with patients

- Active IDU
- Missed appointments
- Nonadherence to treatment
Real Life HCV Care Cascade--Philadelphia

Viner at al, Hepatology, 2015
A new population of young HCV cases is emerging in Philadelphia.

Number of Individuals

Age

Philadelphia Department of Public Health, personal communication
HCV Medication Cost
Percentage of Medicaid Spending on Prescription Drugs Attributable to Sofosbuvir, 2014

Liao and Fischer, NEJM, 2015
Medicaid reimbursement criteria for sofosbuvir based on the required period of abstinence from drug and alcohol use.

Medicaid reimbursement criteria for sofosbuvir based on documented liver fibrosis stage required for reimbursement
Current Challenges in HCV Care

- Approximately 8 hrs of staff time per patient
- 1 to 4 months to go through the process
Incidence and Determinants of Denial of DAA Therapy by Type of Insurance During the First 6 Months of the Modern HCV Treatment Era

Aims and Hypotheses:

**Aim 1**: Determine incidence of absolute denial of DAA prescription in US chronic HCV patients, by type of insurance

- **Hypothesis**: Denial more common for Medicaid than Medicare, commercial insurance

**Aim 2**: Identify determinants of absolute denial

- **Hypothesis**: US Medicaid, no cirrhosis

Lo Re et al, Clin Gastro Hepatol, 2016
Selection of Patients Prescribed DAAs in 4 States

Lo Re et al, Clin Gastro Hepatol, 2016
Incidence of DAA Denial by Insurance Status

Lo Re et al, Clin Gastro Hepatol, 2016
# Time to DAA Fill

<table>
<thead>
<tr>
<th>Days to DAA Fill</th>
<th>Medicaid (n=270)</th>
<th>Medicare (n=755)</th>
<th>Commercial (n=919)</th>
<th>P-Values Medicaid vs. Medicare</th>
<th>P-Values Medicaid vs. Comm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>24 (13 – 49)</td>
<td>14 (10 – 21)</td>
<td>14 (9 – 22)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>With Denial, But Filled</td>
<td>46 (32 – 68)</td>
<td>35 (21 – 51)</td>
<td>32 (25 – 59)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Without Denial</td>
<td>14 (8 – 21)</td>
<td>13 (9 – 17)</td>
<td>13 (9 – 19)</td>
<td>0.3</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Lo Re et al, Clin Gastro Hepatol, 2016
Conclusions

• Absolute denial of DAA therapy:
  – 16% of patients prescribed DAAs
  – 46% with Medicaid, longer time to fill

• Factors associated with denial of DAA:
  – Medicaid, lack of cirrhosis
  – Earlier time period

• Denial of DAA therapy → adverse outcomes
Real World Access from the TRIO Network

19% of Cirrhotic (F4) Patients were Non-Starts/Pending

- F0-2: 19% Non-Starts, 4% Pending (n=231/1,004)
- F3: 16% Non-Starts, 3% Pending (n=41/266)
- F4: 15% Non-Starts, 4% Pending (n=112/593)

Dieterich et al, HepDart, 2015
Relationship Between Fibrosis Stage and Non-Starts of DAA Therapy

Dieterich et al, HepDART, 2015
What can we do to move individuals living with HCV through the Care Continuum?

Viner et al., Hepatology, 2015
Creating hepatitis materials for health centers and community based organizations

There are two phases of a hepatitis C infection:

**ACUTE**
- June 6
- Hepatitis C infections are called “acute” during the first six months after you have been infected.
- It is possible for your body to fight off an acute infection without the help of doctors or medicine.
- Most acute infections cannot be fought off, so see a doctor to get tested if you think you have hepatitis C.

**CHRONIC**
- Forever
- Acute infections your body cannot fight off are called “chronic” and can remain in your body for a lifetime.
- Without medical help, a chronic infection can cause serious health issues such as liver cancer or death.
- There are new medications that can CURE your infection with very minimal side effects.

Get tested. Know the difference.

It takes two tests to see if you have hepatitis C.

**ANTIBODY**
- An Antibody test detects if you have been exposed to hepatitis C.
- A positive result only means that you have been exposed to hepatitis C.
- If your Antibody test is positive, you need to take an RNA test to know if you are currently infected with hepatitis C.

**RNA**
- An RNA test can tell if you are currently infected with Hepatitis C.
- If you test positive, there are new medications that can CURE your hepatitis C infection with very minimal side effects!
- A negative test result means that your body fought off the infection without medical help.

Get tested. Know the difference.
Strengthening relationships with community partners

- **Prevention Point Philadelphia (PPP)** a multi-service public health organization serving injection drug users (IDU) and other vulnerable populations.
  - Syringe exchange, free HIV testing and HCV screening, support groups, linkage to care, food, clothing and referrals.

- In January 2014, PDPH launched a program offering free confirmatory HCV RNA testing to PPP clients.
  - 3 PDPH investigators received phlebotomy training
  - 1x/week, investigators draw blood from any PPP clients testing positive for HCV antibody
Recommendations to Increase HCV, Outreach, Prevention and Testing Programs

• Expand outreach, testing and surveillance, including rapid testing with reflexive confirmatory testing
  o Increase peer-based strategies for educating IDUs
  o Outreach should also occur through non-medical community groups, such as Faith-Based organizations

• Increase youth education, including increased engagement/collaborative efforts

• Target baby-boomer screening in primary care settings through use of electronic health records and prompts

• Increase behavioral health program collaboration with HCV prevention and testing initiatives
Recommendations to Increase Linkage to Care and Treatment

- Increase access to insurance and cost-sharing subsidies
  - Medicaid expansion, coverage of testing, and treatment needs of individuals living with or at risk for HCV, including drug formularies
- Increase provider knowledge of HCV
- Increase availability of peer support for individuals living with HCV to provide culturally appropriate outreach and education
- Integrate behavioral health and HCV treatment programs
- Create statewide and/or local HCV strategic plans, and include the creation of viral hepatitis consumer advisory boards
Real World Care Cascade from a Community Based Program With Navigation

Trooskin et al, JGIM, 2015
Recommendations to Improve HCV Care and Treatment Delivery

• New medications have provided treatment options with far fewer side effects and more successful outcomes

• Create supportive services programs for low-income individuals living with HCV

• Explore new and existing opportunities for providing coordinated, integrated HCV care through national and state payment and care delivery reform
  o Tele-health models such as ECHO
  o Increase reimbursement for care coordination/case management/peer support services, including development of third-party reimbursement for tele-health initiatives
  o Patient-centered medical homes, Medicaid Health Homes
HCV care in future

Primary Care Providers

• Test HCV
• Manage easy-to-treat population by themselves
• Co-manage more complex patients with experts

Specialists

• Treat complex patients
• Determine an indication, initiate treatment, and refer back to PCP (a shared-care model)
• Surveillance and management of cirrhotic patients
Key Challenges with Integration in Primary Care

- HCV expertise
  - E.g. Project ECHO model of care delivery
- Potential costs/burden to health center
  - HCV medications
    - Coverage restrictions
    - Prior authorizations
    - Patient assistance programs
  - Lab tests, imaging, biopsies
    - Uninsured
    - Imaging/biopsies may not be needed
  - Medical visits
    - On average, about 3 visits during 12 week treatment
Key Challenges with Integration in Primary Care

- Liver fibrosis assessment
  - Interventional radiology
  - Non-invasive alternatives
    - serum markers, transient elastography

- Medication-related issues
  - Adherence
  - Drug-drug interactions
  - Side effects

- Ongoing alcohol and drug use

- Cirrhosis
  - Hepatocellular carcinoma screening
  - Referral to GI/transplant team
HCV Treatment Opportunities

- Specialty Clinic
- Primary Care
- Hospital
- Methadone Clinic
- Inpatient Rehab
- Jail
- Prison
- Homeless Shelter
- TB Clinic
- SNF
- Street medicine
- Needle Exchange
- Outpatient rehab

Courtesy, Mission Neighborhood Health Center, SF
Conceptual Model: The Medical Home for Drug Users

- Trauma Informed Care
- Wound care
- Medication Assisted Treatment
- Case Management
- Behavioral Health
- Addiction Counseling and Linkage
- Primary Care
- Hepatitis and HIV Treatment

Harm Reduction

Courtesy, Mission Neighborhood Health Center, SF
Window of Opportunity for HCV Treatment

Treatment is most likely to be successful when these criteria are met

- Adherence to treatment
- Housing
- Nutritional supplementation
- Access to health services
- Absence of excessive drug use
- Access to mental health services
- Teachable moments via videoconferencing
  - HCV-infected inmates
  - Inmates’ peers
  - Staff
Can HCV Become a Rare Disease?

Van Nuys et al, Health Affairs, 2015
“The availability of simple, safe and curative regimens creates opportunities for improving the health of the millions of patients living with HCV infection. At a population level, the effect of HCV medications will be determined by affordability and equitable access to HCV testing, care, and treatment. Only through these improvements can our focus be directed to what matters most: reducing the morbidity and mortality associated with HCV infection, stopping HCV transmission, and ultimately eliminating HCV as a public health threat in the US and worldwide.”

Ward and Mermin, NEJM, 2015
ACTHIV 2016: A State-of-the-Science Conference for Frontline Health Professionals