Improving Access & Linkage to Care in Underserved Populations & Baby Boomers

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Clinical Directors Network, Inc. (CDN)
Webcast Series
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Disclosures

- Dr. Miller receives grant funding from Gilead Sciences
Objectives

1. Describe the burden of hepatitis C in the United States and recognize that it is common, deadly and curable

2. Identify barriers to HCV access and linkage to care, focusing on underserved populations and baby boomers

3. Outline solutions to improve access to care, highlighting patient navigation and novel models of care
Polling Question

Who’s participating?

The following best describes my practice/experience:

1. I have very few patients with HCV but want to learn
2. I screen for HCV but am not involved in treatment
3. I have experience treating HCV
4. I am non-clinical but work with clients with HCV infection
Why is hepatitis C important?

1. Hepatitis C is common
2. Hepatitis C is deadly
3. Hepatitis C is curable
HCV Prevalence in the US

Estimated Hepatitis C Antibody Prevalence Rate per 100,000 Persons, 2010

* Data are not shown to protect privacy. See Data Methods. | ** DATA NOT RELEASED TO HEPVU | * DATANOT SHOWN

www.hepvu.org
HCV Disproportionately Affects Subgroups

Patient Characteristics and Prevalence of HCV: NHANES

<table>
<thead>
<tr>
<th>Percent</th>
<th>NHW</th>
<th>NHB</th>
<th>H</th>
<th>HIV pos</th>
<th>HIV neg</th>
<th>Above</th>
<th>Below</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.3</td>
<td>2.2</td>
<td>1</td>
<td>25</td>
<td>1.7</td>
<td>0.9</td>
<td>1.5</td>
</tr>
</tbody>
</table>

NHW: Non-Hispanic White  
NHB: Non-Hispanic Black  
H: Hispanic

Poverty Index Ratio

# Patient Characteristics and Prevalence of HCV: NHANES

<table>
<thead>
<tr>
<th># lifetime sexual partners</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-9</td>
<td>0.7</td>
</tr>
<tr>
<td>10 to 19</td>
<td>2.4</td>
</tr>
<tr>
<td>20-49</td>
<td>4</td>
</tr>
<tr>
<td>50+</td>
<td>6.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lifetime drug use</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>0.9</td>
</tr>
<tr>
<td>Yes</td>
<td>37.5</td>
</tr>
</tbody>
</table>

HCV Disproportionately Affects Subgroups

HCV Disproportionately Affects Baby Boomers

Hepatitis C is Deadly

Time

Normal Liver

Chronic Hepatitis

Cirrhosis

20-25 years

25-30 years

HCC
ESLD
Death

HCV Infection
Of every 100 people infected with Hepatitis C, **75-85 people will develop Chronic Hepatitis C.** If left untreated:

- **60-70 PEOPLE** will develop **CHRONIC LIVER DISEASE**
- **5-20 PEOPLE** will develop **CIRRHOSIS** over a period of 20-30 years
- **1-5 PEOPLE** will die from **CIRRHOSIS** or **LIVER CANCER**

[www.hepvu.org](http://www.hepvu.org)
Hepatitis C kills 20K Americans per year
More than HIV, TB and 58 other infections COMBINED

Annual number of hepatitis C-related deaths vs. other nationally notifiable infectious conditions in the US, 2003-2013

Source: Centers for Disease Control and Prevention
Hepatitis C is Curable!

Cure Rates for Chronic Hepatitis C Therapy

- Standard Interferon 1991: 6%
- Ribavirin 1998: 16%
- Peginterferon 2001: 34%
- PegIFN + RBV: 42%
- PegIFN + RBV + PI: 55%
- 6-12 Months: >70%
- 12 weeks IFN-Free: >90%

Direct Acting Antivirals
- Pro tease inhibitor 2011
- 2nd Gen DAAs 2013

Nelson D. Hepatitis C virus, from discovery to cure. 2016
HCV Screening
Polling Question

What are your HCV screening practices?

1. I don’t screen for HCV
2. I am aware of the screening guidelines, and screen when I remember
3. I work in a setting with screening prompts, so I screen the majority of patients
3.5 million persons with chronic HCV infection

50% of HCV cases detected

16% treated

7% achieved SVR

3.5 million persons with chronic HCV infection

50% of HCV cases detected

16% treated

7% achieved SVR

HCV Screening: Then and Now

- Pre-2012: CDC recommends risk-based HCV screening
- 2012: CDC adds recommendation for HCV screening for all persons born between 1945-1965
  - 50% of those with hep C unaware of diagnosis
  - 75% hep C patients born 1945-1965
  - Screening + treatment=cost effective

Screening for Hepatitis C Virus Infection in Adults: U.S. Preventive Services Task Force Recommendation Statement

Virginia A. Moyer, MD, MPH, on behalf of the U.S. Preventive Services Task Force*

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Screening for Hepatitis C Virus Infection in Adults
Clinical Summary of U.S. Preventive Services Task Force Recommendation

<table>
<thead>
<tr>
<th>Population</th>
<th>Persons at high risk for infection and adults born between 1945 and 1965</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation</td>
<td>Screen for hepatitis C virus (HCV) infection. Grade: B</td>
</tr>
</tbody>
</table>

Who should be tested?

Persons born between 1945 and 1965

-PLUS-

» Current or past IVDU
» Persons with HIV
» Persons on hemodialysis
» Persons with unexplained high AST/ALT
» Recipients of transfusions/transplants before 1992
» Children born to HCV-infected mothers
» Health care workers after needle stick or mucosal exposure
» Sexual partners of HCV-infected persons

HEPATITIS

DOES NOT DISCRIMINATE.
IT AFFECTS MILLIONS
AND CAUSES LIVER CANCER.

Talk to your doctor about testing.
Early detection can save lives.

www.cdc.gov/hepatitis

BORN FROM
1945 TO
1965?

AMERICANS BORN
DURING THESE YEARS
HAVE THE HIGHEST
RATES OF HEPATITIS C.

Hepatitis C
Can Lead to Liver Cancer.
Most people with Hepatitis C do not feel sick.
Yet liver damage may be silently taking place.
Even if you think you're fine, talk to your doctor about getting tested.

www.cdc.gov/hepatitis

Don't say
“I'm all good”
just because you don't have symptoms.

www.cdc.gov/knowmorehepatitis

KNOW
MORE
HEPATITIS™

Talk to your doctor about getting tested.
Early detection can save lives.
Why Screen at Grady?

Patient Population
- Majority African American
- Under and uninsured
- Baby boomers+ high risk groups
- High prevalence HCV infection
Why Screen at Grady?

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Providers
- Academic internal medicine
- Community-based family practice
- Internal med residents
Why Screen at Grady?

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Providers
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- Internal med residents

The Grady Liver Clinic
- Innovative model for care
- Primary care-based, generalist-run
- Access to care for uninsured
- Screening to cure onsite
Evolution of Routine HCV Screening at Grady

No Program
- Pre-2012
- ? Prevalence

TILT-C
- 2012 – 2015
- 30 months
- 5,282 tested
- 409 HCV Ab+

Grady FOCUS
- 2015 – 2017
- 23 months
- 15,341 tested
- 1,159 HCV Ab+
Creating an Epic Alert Boosted Screening Rates

- This patient has been flagged as needing hepatitis C screening
- An HCV antibody order has been automatically generated
- Please uncheck the box below if patient declines screening

Patient Refused | Clinically not indicated | Already Completed Outside GHS
Patient Path for HCV Testing at Grady

Provider orders HCV Ab test

Patient goes to outpatient lab

HCV Ab -

No further testing

HCV Ab +

HCV Ab low + or indeterminate

Provider orders HCV RNA

Patient returns to lab

HCV RNA +

Patient linked to care

HCV RNA -

No further testing

Patient Navigation
Grady HCV Care Cascade
2012-2017

- 20,596 tested
- 1,569 HCV Ab +
  - 7.6% prevalence
  - 75% tested
  - 66% viremic
  - 77% linked
- 1,171 RNA tested
- 777 HCV RNA +
- 597 linked to care

(Images of Grady and Emory University School of Medicine logos are present.)
# Comparing HCV Screening Outcomes

<table>
<thead>
<tr>
<th>Setting</th>
<th>Emory/Grady (Atlanta)</th>
<th>UTHSC (San Antonio)</th>
<th>MedStar (DC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>Primary Care Low Income</td>
<td>Inpatient Safety Net</td>
<td>Primary Care</td>
</tr>
<tr>
<td>Population</td>
<td>Baby boomers (93% AA)</td>
<td>Baby boomers (58% Hispanic)</td>
<td>Baby boomers (86% AA)</td>
</tr>
<tr>
<td>Number tested</td>
<td>2,894</td>
<td>4,582</td>
<td>1,123</td>
</tr>
<tr>
<td>HCV Ab+</td>
<td>6.9%</td>
<td>6.9%</td>
<td>8.8%</td>
</tr>
<tr>
<td>HCV RNA+</td>
<td>71%</td>
<td>61%</td>
<td>62%</td>
</tr>
</tbody>
</table>

Barriers to Screening

- Logistical challenges with implementation
- Provider time constraints
- Competing priorities for patients
- Stigma
- Cost of confirmatory testing
- Lack of linkage options
HCV Linkage to Care

- 3.2 million of U.S. population with chronic HCV infection
- 1.6 million (50%) had HCV detected
- 1.0–1.2 million (32–38%) were referred to care
  - 630,000–750,000 (20–23%) had HCV RNA test
  - 380,000–560,000 (12–18%) underwent liver biopsy
  - 220,000–360,000 (7–11%) were treated
  - 170,000–200,000 (5–6%) were successfully treated

“All persons with current active HCV infection should be linked to a practitioner who is prepared to provide comprehensive management”

Usual options:

- Gastroenterology and/or hepatology
- Infectious disease
- Primary care?
Barriers to Specialty Care

• Lack of access to specialists
  • Uninsured population
  • Geographic distance
  • Lack of availability of specialists
• Medical, substance abuse, psychiatric co-morbidities
• Cost of treatment

hcvguidelines.org accessed 12/6/17
Strategies for Access to HCV Care

- Co-localization of services
  - Corrections
  - Substance abuse treatment settings
  - Needle exchanges
- Integrated care
  - Multidisciplinary care coordination
  - Case management and navigation
- Primary care-based treatment
Models for HCV Treatment by PCPs

- Project ECHO (telemedicine)
- HCV specialty clinic run by generalists
  - Grady Liver Clinic
  - Mt. Sinai REACH Program
- Advance practice provider-run free clinic
  - St. Mary’s Health Center
Benefits of HCV care by PCPs

- Pt comfort with provider and site
- Fewer logistical barriers
- Less fragmented care
- Outcomes as good or better than specialty care
Excellent Treatment Outcomes by PCPS

Figure 1. Interim Per Protocol SVR12 by Provider Type. Of 304 patients with available SVR12 results, 93.8% achieved SVR12. There was no significant difference in SVR12 between patients treated by NPs, PCPs, and specialist physicians.
Access to Care: Grady Liver Clinic
Grady Memorial Hospital

- 1,000 bed, urban, safety net hospital
- Largely un-and underinsured, African American population
- Teaching site for Emory and Morehouse SOM
- Home to Primary Care Center (PCC)
  - 60K annual visits
  - Medical Home
  - Resident and faculty providers
Grady Liver Clinic: Goals

• Provide access to comprehensive care for underserved patients with hepatitis C

• Evaluate co-morbidities and assess readiness for hepatitis C treatment

• Initiate and monitor patients on antiviral therapy
Grady Liver Clinic: Model

Structure:
• Primary site at Grady treating hepatitis C
• Three half-day sessions per week
• 80 new referrals per month
• 2,500 patient visits annually
• Start with group education session

Staffing:
• 1-2 attendings per clinic, 6 faculty in pool
• 2 Clinical Pharmacists and 1 Patient Assistance Analyst
• Internal Medicine and Psychiatry residents, GI fellows
• CDC volunteers
• PCC staff (nursing, CA, practice manager)
• Patient Navigator
• Program Coordinator
• Nurse Practitioner
Liver Clinic Sequence

1. HCV diagnosis
2. Liver Clinic Education
3. Liver Clinic Visit 1
4. Liver Clinic Visit 2 /Treatment referral

Navigation
## HCV Work-up

<table>
<thead>
<tr>
<th>HCV RNA +</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype Testing</td>
</tr>
<tr>
<td>HAV</td>
</tr>
<tr>
<td>HBV</td>
</tr>
<tr>
<td>HIV testing</td>
</tr>
<tr>
<td>Liver Fibrosis Assessment</td>
</tr>
<tr>
<td>Co-morbidity Assessment (CKD, Meds)</td>
</tr>
</tbody>
</table>

- Medication Choice
FIB-4 Score

Fibrosis-4 (FIB-4) Calculator

The Fibrosis-4 score helps to estimate the amount of scarring in the liver. Enter the required values to calculate the FIB-4 value. It will appear in the oval on the far right (highlighted in yellow).

\[
FIB-4 = \frac{\text{Age (years)} \times \text{AST Level (U/L)} \times \sqrt{\text{Platelet Count (10^9/L)}}}{\text{ALT (U/L)}}
\]

Interpretation:
Using a lower cutoff value of 1.45, a FIB-4 score < 1.45 had a negative predictive value of 90% for advanced fibrosis ( Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 > 3.25 would have a 97% specificity and a positive predictive value of 85% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values < 1.45 or > 3.25. Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

## Recommended HCV Medications

<table>
<thead>
<tr>
<th>Medication</th>
<th>SVR</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ledipasvir/sofosbuvir</td>
<td>&gt;90%</td>
<td>~0 one pill daily</td>
</tr>
<tr>
<td>Elbasvir/grazoprevir</td>
<td>&gt;90%</td>
<td>~8-12 week course</td>
</tr>
<tr>
<td>Velapatasvir/sofosbuvir</td>
<td>&gt;90%</td>
<td>Well-tolerated</td>
</tr>
<tr>
<td>Sofosbuvir/Velpatasvir/Voxilaprevir</td>
<td>&gt;90%</td>
<td></td>
</tr>
<tr>
<td>Glecaprevir/Pibrentasvir</td>
<td>&gt;90%</td>
<td></td>
</tr>
</tbody>
</table>
Grady Liver Clinic
Treatment Timeline

**Treatment Start**
- Lab visit
- Office visit
- Medicine given

**Week 4**
- Lab visit
- Office visit
- Medication given

**Week 8**
- Lab visit
- Office visit
- Medication given

**Week 12**
- Phone visit
- Treatment ends

**12 weeks after treatment**
- Phone reminder
- Lab visit
- Phone call with results
Grady Liver Clinic
HCV Treatment and Cure Rates

- Annual number treated
- Number cured

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-'07</td>
<td>23</td>
<td>21</td>
<td>91</td>
<td>200</td>
<td>516</td>
</tr>
<tr>
<td>2011-'13</td>
<td>4</td>
<td>10</td>
<td>76</td>
<td>178</td>
<td>438</td>
</tr>
<tr>
<td>2014</td>
<td>76</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>178</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>516</td>
</tr>
</tbody>
</table>

*Projected*
## Facilitators of Successful Linkage

- Reflex RNA testing
- Patient navigation
- Fast tracking newly diagnosed
- Group education
- Investing resources into program via 340b
Mt. Sinai REACH Program

- REACH Program (Respectful & Equitable Access to Comprehensive Healthcare) launched in 2002
- New York City, primarily Hispanic and African American, low SES patient population
- Offers community HCV testing, linkage to care and treatment and is staffed by:
  - Medical providers, Nurse
  - Behavioral Health providers
  - Patient navigators
- Patients recruited from primary care sites and community-based outreach and testing program

Parrella et al. APHA Poster, November 2017
REACH Program
Treatment Cascade

- Patients seen: 369
- Patients treated: 155 (42%)
- Eligible for SVR: 86 (55%)
- Achieved SVR12: 86 (100%)

Parrella et al. APHA Poster, November 2017
### Clinic Birth-Cohort (1945-1965) Patients Undergoing HCV Testing

<table>
<thead>
<tr>
<th></th>
<th>Baseline 2014</th>
<th>2015 Program Implementation</th>
<th>2016 Jan-July</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Age-Cohort Patients (1945-1965) seen in calendar year</td>
<td>380</td>
<td>577</td>
<td>431</td>
</tr>
<tr>
<td>Number and % of Age-Cohort Patients with one-time Age-Cohort Testing</td>
<td>5.0% (19)</td>
<td>67.8% (391)</td>
<td>70.7% (305)</td>
</tr>
<tr>
<td>HVC+ (RNA detected following CDC testing algorithm)</td>
<td>4</td>
<td>19</td>
<td>23</td>
</tr>
</tbody>
</table>

As of 2016, the clinic increased age-cohort one-time HCV testing 65.7% from 2014 baseline.
EMR Alerts

There are no overdue alerts today for this patient.

- [G] Colonoscopy > 50  08/19/2016
- [G] Hepatitis C Virus Screening  08/19/2016
- [G] FIT > 50  08/19/2016
- [G] PSA > 40  08/19/2016
- [Rx] NSAIDS (CMP WITH RENAL FUNCTION TEST)  08/19/2016

There are no overdue alerts today for this patient.
### HCV Management Form

#### Patient Demographics

<table>
<thead>
<tr>
<th>Medical Record</th>
<th>DOB</th>
<th>Last Name</th>
<th>First Name</th>
<th>Gender</th>
<th>Race/ethnicity</th>
<th>Other</th>
<th>Post Medical History</th>
<th>Medications</th>
</tr>
</thead>
</table>

#### Social History

- **Drug Use (current):**
- **Surgical History:**
- **Family History:**
- **Allergies:**
- **History of Viral Infections:**

#### Secondary Prevention Education & Interventions

- **Tuberculosis Immune:**
- **HIV/AIDS:**
- **Current Naloxone:**
- **Other奋:****

#### Pre-Treatment Evaluations

- **History of Prior Treatment:**
- **History of Prior Medication:**

#### Laboratory Evaluation

- **APRI Score:**
- **ALF Score:**
- **CTP Score:**

#### Treatment Monitoring

- **Treatment Start Date:**
- **Projected End Date:**
- **12 weeks:**
- **24 weeks:**

#### Treatment Recommendations

- **Medication 1:**
- **Medication 2:**
- **Medication 3:**

---

*Developed by: St. Joseph/Candler Health System, St. Mary's Health Center, Emory University School of Medicine*
Systemic Barriers to Access to HCV Treatment

- High cost & uninsured patient population
  - Patient Assistance programs
  - Co-pay assistance
  - Dedicated staff for prior authorization & patient assistance program applications
- Medication restrictions based on:
  - Fibrosis stage
  - Substance use
  - Provider type
New York

State of Medicaid Access Report

LIVER DAMAGE RESTRICTIONS

Fee-For-Service (FFS) does not have liver damage requirements. Six Managed Care Organizations (MCOs), Excellus Health Plan, HealthNow New York, New York State Catholic Health Plan, United Healthcare, WellCare and YourCare Health Plan, follow FFS liver damage criteria. Two MCOs, Healthfirst PPO and MetroPlus Health Plan, specifically reference the American Association for the Study of Liver Disease/Infectious Disease Society of America (AASLD/IDSA) guidelines in their prior authorization (PA) criteria but don’t specify liver damage requirements. Seven MCOs, Affinity Health Plan, Capital District Physicians Health Plan, Health Insurance Plan of Greater New York, HealthPlus LLC, Independent Health Association, MVP Health Plan, and Molina Healthcare, have limited coverage information publicly available and their liver damage requirements are unclear. One MCO, New York-Presbyterian Community Health Plan, does not provide any coverage information publicly.

Sobriety Restrictions

Prescriber Restrictions

Recommendations

READ FULL STATE REPORT

https://stateofhepc.org/report/#findstate
From: The Changing Burden of Hepatitis C Virus Infection in the United States: Model-Based Predictions

Summary

- Hepatitis C is common, deadly and curable
- All baby boomers need one time screening for HCV and those with chronic infection should be referred to care
- Barriers to specialty care are common for underserved populations
- Novel models of care, including treatment by PCPs, address these barriers
- We can achieve HCV elimination with a combination of screening, linkage to care, and treatment
Thank you!

Questions?