Overcoming Barriers to HCV Care

STACEY B. TROOSKIN MD PHD
DIRECTOR OF VIRAL HEPATITIS PROGRAMS
PHILADELPHIA FIGHT COMMUNITY HEALTH CENTERS
PHILADELPHIA, PA
Disclosures

Grant Support from Gilead Sciences, FOCUS program
Advisory Board, Gilead Sciences
Epidemiology of HCV in the US

Most common blood-borne infection in the US
- 3.2 million to 5.2 million persons chronically infected
- Birth cohort 1945-1965: 3.27% antibody positive
  - Non-Hispanic blacks: 6.31%
  - Non-Hispanic whites: 2.92%
  - Mexican American/ other: 2.78%

50% to 75% of individuals chronically infected with HCV are unaware of their infection
Treatment cascade for people with chronic HCV infection

- 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%

*3,500,000
Birth Cohort with high rates of HCV


CDC Recommendations for HCV testing

Birth Cohort based screening

- All individuals born between 1945 and 1965 should be tested at least once for HCV
- All individuals outside of this cohort with a HCV risk factor should be screened
- Cost-effective
- 1-time cohort screening would identify about 86% of undiagnosed cases, compared with 21% with risk-based screening

US Preventive Services Task Force: Grade B recommendation
Philadelphia Cascade of Care 2010-2013

- HCV infected (estimate): 30,000
- HCV Ab: 15,000
- HCV RNA: 10,000
- HCV in medical care: 6%
- HCV antiviral treatment: 3%
A new population of young HCV cases is emerging in Philadelphia 2007-2013

Data provided by Dr. Kendra Viner PhD from the Philadelphia Department of Public Health
Heroin Use Has INCREASED Among Most Demographic Groups

<table>
<thead>
<tr>
<th>SEX</th>
<th>2002-2004*</th>
<th>2011-2013*</th>
<th>% CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>2.4</td>
<td>3.6</td>
<td>50%</td>
</tr>
<tr>
<td>Female</td>
<td>0.8</td>
<td>1.6</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AGE YEARS</th>
<th>2002-2004*</th>
<th>2011-2013*</th>
<th>% CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-17</td>
<td>1.8</td>
<td>1.6</td>
<td>--</td>
</tr>
<tr>
<td>18-25</td>
<td>3.5</td>
<td>7.3</td>
<td>109%</td>
</tr>
<tr>
<td>26 or older</td>
<td>1.2</td>
<td>1.9</td>
<td>58%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RACE/ETHNICITY</th>
<th>2002-2004*</th>
<th>2011-2013*</th>
<th>% CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hispanic white</td>
<td>1.4</td>
<td>3</td>
<td>114%</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>1.7</td>
<td>--</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ANNUAL HOUSEHOLD INCOME</th>
<th>2002-2004*</th>
<th>2011-2013*</th>
<th>% CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than $20,000</td>
<td>3.4</td>
<td>5.5</td>
<td>62%</td>
</tr>
<tr>
<td>$20,000-$49,999</td>
<td>1.3</td>
<td>2.3</td>
<td>77%</td>
</tr>
<tr>
<td>$50,000 or more</td>
<td>1</td>
<td>1.6</td>
<td>60%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HEALTH INSURANCE COVERAGE</th>
<th>2002-2004*</th>
<th>2011-2013*</th>
<th>% CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>4.2</td>
<td>6.7</td>
<td>60%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>4.3</td>
<td>4.7</td>
<td>--</td>
</tr>
<tr>
<td>Private or other</td>
<td>0.8</td>
<td>1.3</td>
<td>63%</td>
</tr>
</tbody>
</table>

Heroin Addiction and Overdose Deaths are Climbing

Heroin-Related
Overdose Deaths
(per 100,000 people)

286% increase

Heroin Addiction
(per 1,000 people)

SOURCES: National Survey on Drug Use and Health (NSDUH), 2002-2013.

http://www.cdc.gov/vitalsigns/heroin/
Birth Cohort testing recommendations


- Dashed purple line: 1999–2002


- Dashed purple line: 1999–2002


Oppiod epidemic

CDC. MMWR. August 17, 2012, Vol. 61, No. 4
Percentage of all admissions to substance abuse treatment centers by persons aged 12-29 yrs (N=217,789) by year - Kentucky, Tennessee, Virginia, and West Virginia, 2006-2012
Incidence of acute hepatitis C among persons aged <= 30 years, by urbanicity and year - Kentucky, Tennessee, Virginia and West Virginia 2006-2012

* 95% confidence interval.
New cases of HCV and deaths from old infections are both on the rise

<table>
<thead>
<tr>
<th>Estimated Actual New Cases of HCV (range)</th>
<th>2011 (estimated)*</th>
<th>2012 (estimated)*</th>
<th>2013 (estimated)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16,500 (7,200-43,400)</td>
<td>24,700 (19,600-84,400)</td>
<td>29,700 (23,500-101,400)</td>
</tr>
</tbody>
</table>

* Actual acute cases estimated to be 13.9 times the number of reported cases in any year

<table>
<thead>
<tr>
<th>Est. No. of Chronic Cases In the United States</th>
<th>No. of Death Certificates listing HCV as a Cause of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7-3.9 million</td>
<td>2010</td>
</tr>
<tr>
<td></td>
<td>16,627†</td>
</tr>
</tbody>
</table>

* Underlying or contributing cause of death in most recent year available (2013)
†Current information indicates these represent a fraction of deaths attributable in whole or in part to chronic hepatitis C

http://www.cdc.gov/hepatitis/hcv/statisticshcv.htm
The Chronic Hepatitis Cohort Study (CHeCS)
Doubling of mortality rate, 2007-2013
Evolution of HCV Treatment

- **1986**
  - IFN 6 m

- **1998**
  - IFN 12 m
  - IFN/RBV 6 m

- **2001**
  - IFN/RBV 12 m
  - PEG 12 m

- **2002**
  - PEG/RBV 12 m

- **2011**
  - BOC/TVR

- **2013-present**
  - New DAAs

SVR RATE (%)

Adapted from Strader DB. Clin Liver Disease 2012, 1:1; 6-11.
SVR (Cure) Associated with Decreased All-Cause Mortality

Van der Meer et al. JAMA 2012; 308:2584

530 patients with advanced fibrosis, treated with interferon-based therapy, and followed for 8.4 (IQR 6.4-1.4) years
Philadelphia Cascade of Care 2010-2013

Number of Individuals

<table>
<thead>
<tr>
<th>Status</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV infected (estimate)</td>
<td>30,000</td>
</tr>
<tr>
<td>HCV Ab</td>
<td>14,500</td>
</tr>
<tr>
<td>HCV RNA</td>
<td>6,600</td>
</tr>
<tr>
<td>HCV in medical care</td>
<td>400</td>
</tr>
<tr>
<td>HCV antiviral treatment</td>
<td>90</td>
</tr>
</tbody>
</table>

Philadelphia Cascade of Care 2010-2013
Community based testing

A testing and linkage to care campaign that stimulates demand for and provides HIV and HCV testing across an entire zip code.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>49.1</td>
</tr>
<tr>
<td>African American</td>
<td>91.0</td>
</tr>
<tr>
<td>Single</td>
<td>81.1</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>&lt;47</td>
<td>71.0</td>
</tr>
<tr>
<td>47-67</td>
<td>29.0</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>17.6</td>
</tr>
<tr>
<td>High school degree/GED</td>
<td>50.9</td>
</tr>
<tr>
<td>At least some college</td>
<td>31.5</td>
</tr>
<tr>
<td>Income</td>
<td></td>
</tr>
<tr>
<td>Less than $10,000</td>
<td>46.4</td>
</tr>
<tr>
<td>$10,000 - $14,999</td>
<td>18.7</td>
</tr>
<tr>
<td>$15,000 - $29,999</td>
<td>17.8</td>
</tr>
<tr>
<td>&gt; $30,000</td>
<td>17.1</td>
</tr>
<tr>
<td>Self-identified sexual orientation</td>
<td></td>
</tr>
<tr>
<td>Heterosexual</td>
<td>89.0</td>
</tr>
<tr>
<td>Gay/Lesbian</td>
<td>4.9</td>
</tr>
<tr>
<td>Bisexual</td>
<td>6.1</td>
</tr>
<tr>
<td>Ever incarcerated</td>
<td>36.3</td>
</tr>
</tbody>
</table>

Testing and Linkage to Care Protocol

OraQuick® rapid HCV antibody test reactive

Blood draw for confirmatory HCV PCR

HCV RNA Detected

Patient Navigator notifies patient and provides counseling + insurance assessment

Patient Navigator notifies patient and provides counseling

HCV RNA Not Detected

Uninsured

Patient Navigator facilitates appointment with clinical social worker

Insured with no known primary care provider

Patient Navigator facilitates PCP acquisition

Insured with a primary care provider

PCP Visit

Obtain Referral to subspecialist
HCV Patients

1,301 participants were tested for HCV
  ◦ 3.9% anti-HCV seroprevalence
  ◦ 2.8% chronically infected

8% of anti-HCV positive participants were already engaged in HCV care

Of those chronically infected individuals:
  ◦ 58% aware of infection but not engaged in care
  ◦ 36% uninsured
  ◦ 58% had an Audit-C score commensurate with alcohol use disorder
  ◦ 80% participants had serious co-morbidities such as mental illness and addiction
Do One Thing Campaign HCV Testing and Linkage to Care Cascade n=1,301

Lessons Learned from *Do One Thing*

The HCV care continuum is complex

Multiple barriers exist
- Referrals
- Obtaining medication for patients/ payer restrictions

Patient navigation is key when patients are tested via outreach

Outreach testing and community engagement is a way to re-engage individuals living with HCV not currently in care

Immediate blood draw for PCR confirmatory testing is necessary
- Local hospital labs can partner to process and test specimens on nights and weekends

These informed our design of C A Difference
Clinical Testing

Community Testing

Patient Navigation

Subspecialty Care for HCV
Integrated Community Based HCV Testing: Lessons Learned

Integrating HCV testing into existing HIV and STI testing programs has advantages
- Sustainability from diversified funding sources
- Reaches individuals at greatest risk
- 1183 tested, anti-HCV seroprevalence 11.5%

Education is required for staff
- Testers should be trained phlebotomists

Communication is key when community testers do not also act as the patient navigator

Maintaining a low patient navigator to patient ratio is critical
Clinical Testing

Community Testing

Patient Navigation

Subspecialty care for HCV
Patient needs HCV Confirmatory testing

To Be Done: hcvconfirmatory

HCV RT-PCR, Quant (Non-Graph)
Impact of HCV Testing Prompts on Type of HCV Screening Test Ordered

[Graph showing percentage of tests ordered from January 2014 to December 2014, with two lines representing preferred tests and other tests, indicating a decrease in preferred tests and an increase in other tests after July 2014.]
Impact of EMR prompts on Percentage of Eligible Baby Boomers Tested for HCV

*EMR prompts added July 2014
Integrating HCV Testing into primary care: Lessons Learned

The prevalence of HCV is high in urban primary care practices

- 6029 patients tested, anti-hcv seroprevalence 8.23%

PCPs are busy! Testing has to be easy and meaningful

- Eliminate outdated or less useful tests from testing menus

Educate the providers and their staff & provide feedback

Get to know your IT staff

- Learn what your EMR can and cannot do
- The more that testing can be automated, the better
- QC must be a part of the process

The role of the navigator often differs in a clinical testing model
Next steps

The Jonathan Lax Treatment Center
The Youth Health Empowerment Project
The John Bell Health Center

COMMUNITY BASED TESTING
Syringe Exchange Program
Drug Treatment Programs
Homeless shelters
Opioid substitution programs
Senior Centers
Philadelphia Cascade of Care 2010-2013

Number of Individuals

- HCV infected (estimate): 30,000
- HCV Ab: 15,000 (47%)
- HCV RNA: 6,000 (22%)
- HCV in medical care: 3,000 (6%)
- HCV antiviral treatment: 900 (3%)

Philadelphia Cascade of Care 2010-2013

AASLD/IDSA: Who should be treated?

Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.

Rating: Class I, Level A
Current Challenges in HCV Care: Wholesale Acquisition Costs

- LED/ SOF x 8 weeks $63,000
- LED/ SOF x 12 weeks $94,500
- VEL/ SOF x 12 weeks $74,760
- ELB/ GRA x 12 weeks $54,600
- PrOD x 12 weeks $83,319
- SIM/SOF x 12 weeks $150,360
- DAC/ SOF x 12 weeks $148,000

- WAC does not include negotiated discounts and rebates

Arlene Price, Janssen (Personal Communication)
http://www.hepatitis.uw.edu/patient-treatment/drugs/simeprevir-drug
www.fairpricingcoalition.org
Current Challenges in HCV Care

Restrictive criteria for drug approval for many payers

- Sobriety requirement
- Prescriber requirement
- Disease severity requirement
- HIV may not be a mitigating factor

Arduous prior authorization process for providers

Canary LA et al., Ann Intern Med. 2015;163(3):226-228
Current Challenges in HCV Care

Approximately 8 hrs of staff time per patient
1 to 4 months to go through the process
When insurance will not cover drugs what are the options?

Wait for new drugs to be approved
  ◦ No guarantee that those will be covered/ patient will qualify

Wait until patient qualifies
  ◦ Sobriety
  ◦ Worsening fibrosis

Take legal action

Apply to patient assistance programs to obtain free drug
  ◦ There is only one company that does this currently
  ◦ Financial information to qualify
  ◦ Proof that patient does not qualify for insurance
  ◦ Challenging to navigate
Incidence of Absolute Denial of DAA Therapy, By Insurance

Figure Legend
- Absolute denial of DAA prescription
- Denial of DAA prescription preceding fill

N=2321
Nov 2014 through April 2015

<table>
<thead>
<tr>
<th>Category</th>
<th>Absolute Denial</th>
<th>Denial Preceding Fill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>29.7%</td>
<td>16.2%</td>
</tr>
<tr>
<td>US Medicaid</td>
<td>70.8%</td>
<td>46.3%</td>
</tr>
<tr>
<td>US Medicare</td>
<td>18.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Commercial</td>
<td>18.7%</td>
<td>10.2%</td>
</tr>
</tbody>
</table>
Advocacy in Philadelphia

Philadelphia-area collective dedicated to improving the continuum of hepatitis C prevention, care, and support services in Philadelphia

www.hepcap.org
HepCAP

Bimonthly public meetings
- Scientific updates
- Local Epidemiology
- Access to care: challenges and best practices
- Advocacy

Primary Care Provider Education

Coalition and Relationship building
- May 1 2015 State Wide HCV Summit
- State Medicaid, P&T
## Changes to State Medicaid Rx Restrictions

<table>
<thead>
<tr>
<th>2014</th>
<th>2015/2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>F3/F4</td>
<td>F2 for HCV Mono infected patients</td>
</tr>
<tr>
<td>No exception for HIV patients</td>
<td>F0 for HIV/HCV Coinfection or anyone with extrahepatic manifestation</td>
</tr>
<tr>
<td>No drugs or alcohol for 6 months</td>
<td>No sobriety requirement</td>
</tr>
<tr>
<td>Specialist Physician</td>
<td>Experienced provider</td>
</tr>
</tbody>
</table>
All Pennsylvanians deserve access.
You can help improve the cascade!

Locally:

Come to the next HepCAP meeting
   ◦ Wednesday December 7th 2016 @ 5:30pm, Department of Public Health 500 S Broad Street

Nationally:

www.NVHR.org
Welcome to the NVHR Hepatitis C Resources Page

NVHR’s program aims to increase the number of people born 1945-1965 (baby boomers) and other communities at risk tested for hepatitis C. This page has information for providers, patients, and organizations and highlights the work of our community partners.

PROGRAM QUICKLINKS
- Hepatitis C Baby Boomer Homepage
- Implementing Electronic Medical Record Prompts
- AllScripts EMR
- Epic EMR Prompts
- Provider Training
- Research Articles and Presentations
- Patient Resources
- NVHR Fact Sheets
- Testing Day Events and
Thank you!

Do One Thing Team
◦ Amy Nunn ScD, Brown University

C a Difference Team
◦ Lora Magaldi, MA C a Difference Project Coordinator
◦ Carla Coleman, MBA Linkage Coordinator
◦ Ta-Wanda Preston, Outreach specialist
◦ Students, volunteers, patients

Alex Shirreffs MPH, Government Co-Chair of HepCAP
◦ HepCAP members

NVHR
◦ Ryan Clary
◦ Tina Broder
◦ Emily Stets

Gilead FOCUS and Prevent Cancer Foundation