Examining Hepatitis C Treatment
Access: What Nurses Need to Know

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Wednesday, August 12, 2015
1:00 - 2:00 pm EST
Housekeeping

- Participant lines muted during the webinar
- Type questions in the “Question” pane of your Dashboard
- Q & A session at the end of the webinar.
Continuing Nursing Education

Upon full participation in this webinar & completion of an evaluation, participants will be awarded 1.0 contact hours.

The Association of Nurses in AIDS Care (ANAC) is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.
Disclosures

Faculty Conflict of Interest Disclosures

Ryan Clary, Robert Greenwald and Carole Treston have no actual or perceived conflicts of interest related to the content of this webinar.
Learning Objectives

At the conclusion of today’s activity, participants will be able to:

1. Describe the current state of viral hepatitis in the U.S., particularly hepatitis C.
2. Understand the current limitations on patient access to newly approved HCV treatments.
3. Identify advocacy efforts to expand patient access to newly approved HCV treatments.
Agenda

1. Viral hepatitis & role of nurses
   • Carole Treston

2. HCV treatment access
   • Robert Greenwald

3. Advocacy efforts & NVHR
   • Ryan Clary

4. Q & A Discussion
National Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis 2014-2016

1. Educating Providers and Communities to Reduce Health Disparities

2. Improving Testing, Care, and Treatment to Prevent Liver Disease and Cancer
Viral Hepatitis Overview

Hepatitis B  800,000-1.4 mil Americans
Hepatitis C  3.2 mil Americans

- Baby Boomers/ Birth Cohort (1945-65)
- Young IDU
- PLWHA
- Incarcerated persons
- African Americans
- MSM ?
- Medicaid eligible?
Viral Hepatitis Overview

Impact:
12-18,000 Deaths /year (Average 57 yo)
2007: Death rate surpassed HIV
Leading Cause of Liver Cancer & Liver transplants
Impacts QOL, productivity & work absence

Genotypes USA
1 (70%)  2 (16%)  3 (12%)  Others (<2%)
HCV Clinical Advances

Approval of HCV Direct Acting Anti-retrovirals

2013  Sofasbuvir (Sovaldi)

2014  Harvoni

2015  Technivie  Viekira

Daclastivir

Oral regimens 8-12-24 weeks. Cure (SVR) ~ 90%

ASSLD: Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies owing to comorbid conditions. Highest Priority for F3 & F4

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HCV Clinical Advances

Chronic HCV: Non-invasive vs. Liver Biopsy

Fibrotest = Metavir Fibrosis Score

F1 mild fibrosis
F2 moderate fibrosis
F3 advanced fibrosis
F4 cirrhosis

ASSLD: An assessment of the degree of hepatic fibrosis, using noninvasive testing or liver biopsy, is recommended.
Association of Nurses in AIDS Care

Core Ideology: Public policy must be grounded in patient advocacy, human rights, compassion, and social justice. We promote the inclusion of the nursing perspective in promoting the health, welfare, and rights of all individuals affected by HIV and its comorbidities.

Two Fundamental Beliefs:

• Nurses can have an influential and powerful voice as public policy advocates.
• Nurses have expertise related to health care and human rights.
UNDERSTANDING HEPATITIS C VIRUS TREATMENT ACCESS

ROBERT GREENWALD, JD
CLINICAL PROFESSOR OF LAW
DIRECTOR, CENTER FOR HEALTH LAW AND POLICY INNOVATION OF HARVARD LAW SCHOOL

AUGUST 2015
• Examines accessibility of Sovaldi through Medicaid fee-for-service in 10 states
• Also examines Sovaldi access in 5 select states Medicaid managed care plans
• Report and corresponding webinar available at www.chlpi.org

• Evaluates state Medicaid policies for Sovaldi access in 42 states and DC
• Assesses policies in light of treatment guidelines
• Article available online at www.annals.org
LIMITATIONS ON ACCESS TO HCV TREATMENTS

- Limits Based on Stage of Fibrosis
- Restrictions Based on Substance Use
- Prescriber Limitations
- Other restrictions
  - HIV Co-Infection limitations
  - “Once per lifetime” limitations
  - Genotype limitations
  - Previous history of treatment adherence requirements
  - Specialty pharmacy restrictions
  - Exclusivity agreements with insurers

Center for Health Law and Policy Innovation
74% of state Medicaid programs with known criteria (n=42) limit Sovaldi access to people with METAVIR score F3 and higher.

RESTRICTIONS BASED ON SUBSTANCE ABUSE

- 88% of state Medicaid programs have substance use criteria
- 50% require periods of abstention (range = 1 - 12 months)

Twenty-nine states (69%) have restrictions based on prescriber type

- In 14 states (33%), the prescriber has to be a specialist (Gastroenterology, Hepatology, Infectious Diseases or Liver Transplant)

- In 15 states (36%), treatment decisions may be made by a non-specialist if there is consultation with a specialist

Such policies are in direct contrast to the broader prescribing policies associated with historic HCV treatment with pegylated interferon and ribavirin

ILLINOIS SOVALDI PRIOR AUTHORIZATION CRITERIA: MORE RESTRICTIVE THAN MOST STATES

Coverage
+ Non-preferred drug

Fibrosis
+ Metavir score of $\geq$F4

Substance Use
+ No evidence of substance abuse in past 12 months

Prescriber Limitations
+ If prescriber is not a specialist, required one-time written consultation within past 3 months
Coverage
+ Preferred drug

Fibrosis
+ No restrictions (form inquires)

Substance Use
+ No restrictions (form inquires about current use)

Prescriber Limitations
+ No restrictions

Additional Restrictions
+ No additional restrictions based on HIV Co-infection or previous adherence
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<tr>
<td><strong>Fibrosis</strong></td>
<td>F3-4</td>
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<tr>
<td><strong>Requirements Related to Substance Use</strong></td>
<td>Not abused substances for 6 months</td>
<td>Abstain from use for 6 months and participation in supportive care</td>
<td>No substance abuse within past 6 months OR receiving counseling services</td>
<td>Must be referred to specialist; abstinence for 6 months; ongoing participation in treatment; psychosocial supports</td>
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<tr>
<td><strong>Prescriber Limitations</strong></td>
<td>Prescribed by or in consultation with specialist</td>
<td>Prescribed by or in consultation with specialist</td>
<td>Prescribed by specialist</td>
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<td><strong>HIV Co-Infection</strong></td>
<td>Yes, with non-suppressable viral load or elevated MELD scores</td>
<td>Not without meeting additional requirements above</td>
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<td>Yes, if compliant with antiretroviral therapy as indicated by undetectable viral load</td>
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<td><strong>Additional Adherence Requirements</strong></td>
<td>No history of nonadherence; enrollment in monitoring program</td>
<td>Must demonstrate understanding of proposed treatment and display ability to adhere</td>
<td>Must be assessed for potential non-adherence</td>
<td>No record of non-adherence and willing to commit to monitoring</td>
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<td>Fallon Health</td>
<td>Tufts</td>
<td>Harvard Pilgrim</td>
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<td><strong>Requirements Related to Substance Use</strong></td>
<td>Not engaged in any habits that would negate the efficacy of the medications</td>
<td>No illicit abuse within past 6 months OR receiving counselling services/seeing addiction specialist</td>
<td>None</td>
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<td><strong>Prescriber Limitations</strong></td>
<td>Prescribed by specialist</td>
<td>Prescribed by specialist</td>
<td>Prescribed or supervised by specialist</td>
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<tr>
<td><strong>HIV Co-Infection</strong></td>
<td>Must meet other criteria</td>
<td>Must meet other criteria</td>
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<td><strong>Additional Adherence Requirements</strong></td>
<td>Must have history of adherence and a psychological and behavioral habits assessment to determine if therapy is appropriate</td>
<td>Must be assessed for potential non-adherence</td>
<td>None</td>
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Shift the focus from cost to cure

+ Recognize payor concerns, but accurately assess the value of cure
+ With supplemental rebates the cure is now ~$40,000 - 50,000
+ Comparative effectiveness matters
  + We paid over ~$250,000 per HCV cure in interferon age
  + In HIV, no cure and we pay ~$10,000 per year for life for HAART
+ Pharmacy budgets may increase but others will decrease
+ U.S. government sets pharma laws with varying perspectives if effective – if not, change laws, rather than deny access to HCV cure
+ Medicaid is an entitlement program in part to grow to meet the demands created by innovation
Hepatitis must be addressed as a serious public health issue

+ Screening and treatment have significant individual and public health benefits

+ Baby boomer generation is not the end of the epidemic, with increasing evidence of growing incidence in young people

+ Other serious diseases are not similarly treated (i.e., requiring disease progression or sobriety) and this undermines the public health response

+ Insurers should adopt, not ignore, lessons learned from HIV treatment guidelines, where early and unrestricted access is the rule
Both public and private health insurance laws preclude restrictive, unfair and discriminatory HCV treatment access practices

- Under the Medicaid Act all prescription drugs of a manufacturer who enters into rebate agreements must be covered, with only exceptions allowed for safety and clinical effectiveness.
  
  - While states have more discretion under prior authorization, even here courts have supported challenges when access is severely curtailed or final authority to provide drugs does not rest with the prescribing health care providers.
  
  - Under Massachusetts law, as well as in other states, state medical necessity laws require even fewer restrictions on access to effective, life-saving medications.
  
  - Under the ACA differential treatment of HCV rises to the level of a discriminatory insurance practice.
**Next Steps: Advocate for Broader Access for Many People Living with Hepatitis by Securing Adequate Coverage**

**Federal**

- Urge Congressional support of increased funding for hepatitis research, prevention, screening and vaccination, linkage to care, and surveillance.
- Urge Congressional support for viral hepatitis testing law that will expand education and testing for Hepatitis B and C.
- Urge CMS Administrator to advise State Medicaid Programs regarding the appropriate coverage of prescription drugs for patients with hepatitis C.

**State**

- Advocate for Medicaid expansion.
- Advocate before the pharmacy and therapeutics committee in your state as the members (providers, clinicians, and others) decide which drugs are included on formularies and what prior authorization criteria are attached to each drug.
- Monitor state Medicaid fee-for-service and managed care organizations and advocate for strong and consistent coverage criteria.
Ensuring Hepatitis C Treatment Access For All

Ryan Clary
Executive Director
August 12, 2015
NVHR’s Mission and Vision

The National Viral Hepatitis Roundtable is a broad coalition working to fight, and ultimately end, the hepatitis B and hepatitis C epidemics. We seek an aggressive response from policymakers, public health officials, medical and health care providers, the media, and the general public through our advocacy, education, and technical assistance.

NVHR believes an end to the hepatitis B and C epidemics is within our reach and can be achieved through addressing stigma and health disparities, removing barriers to prevention, care and treatment, and ensuring respect and compassion for all affected communities.
2014: Missed Opportunities

• Arrival of HCV cure should have been met with action, planning & leadership
  – New, effective treatments with high cure rates/low side-effects
  – Second chance for many who didn’t succeed with earlier treatment
  – Opportunity for those “warehoused”
  – Elimination of poor treatment outcomes for African Americans
  – Treatment as prevention – minimize new infections among people who inject drugs
  – Encourage people to get tested/linked to cure
  – Major public health victory: eliminate hepatitis C in the United States
2014: Challenges

• Massive PR campaign by payors
• Media obsession with $1,000/pill
• Misinformation/misunderstanding
• Stigma
• Lack of respect for science and expertise
• Little attention to the voice and needs of people with hepatitis C
• Resistance to expanding hepatitis C testing because of access problems
2015: New Opportunities, Continued Challenges

- Competition has led to price reductions
- Exclusivity deals: expanded access vs. patient choice
- Significant victories in some state Medicaid
- Little/no movement in other Medicaid
- Growing advocacy movement
- Research/data bolsters our argument
- Media continues to be focused primarily on cost
The Advocacy Campaign

• Reframing the message
• Small, dedicated coalition focused on ensuring the cure is available to everyone with hepatitis C
• December 2014 meeting with key HHS officials
• Advocacy with Centers for Medicare & Medicaid Services/guidance to states
• Policy research/analysis: Harvard Law School/CHLPI
• Assisting state level advocates
• Media advocacy/bring the voice of people with hepatitis C
How You Can Help

- HCV Treatment Access listserv (rclary@nvhr.org)
- Letter to editor
- Collect/send access stories (rclary@nvhr.org)
- Connect with state level advocates (rclary@nvhr.org)
- Social media: #ideserveahepccure
Thank You

Ryan Clary
Executive Director
National Viral Hepatitis Roundtable
rclary@nvhr.org
www.nvhr.org
Q & A Discussion

Additional questions?
Email Erin at erin@anacnet.org
Resources

National Viral Hepatitis Roundtable  www.nvhr.org

The Center for Health Law and Policy Innovation  www.chlpi.org

Restrictions for Medicaid Reimbursement of Sofosbuvir


National Viral Hepatitis Action Plan  www.hhs.gov/ash/initiatives/hepatitis
Continuing Nursing Education

To be awarded contact hours for this webinar, complete the evaluation found at www.nursesinaidscare.org/CNEHCV

Additional questions? Email Erin at erin@anacnet.org

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