HEPATITIS C: COMMUNITY AND PUBLIC HEALTH PERSPECTIVE

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HCV GUIDELINES IN CORRECTIONS
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RELEVANT DISCLOSURES

- Chad Zawitz: speaker, consultant Gilead Sciences; speaker AbbVie
OBJECTIVES

- Hepatitis C is a major public health concern both inside and outside of correctional settings. We will explore the current national HCV treatment guidelines in the context of correctional settings. We will also discuss primary care management of Hepatitis C including general guidance on when a referral to a specialist should be considered. Finally, from a community-based perspective we’ll look at the public health impact of improving HCV management in correctional settings.

Learning objectives:

1) Review current Hepatitis C treatment guidelines
2) Discuss management options for correctional primary care providers
3) Consider the public health impact of improving HCV management in correctional settings
AASLD/IDSA HCV Guidelines

- HCV management is rapidly evolving
- Published guidelines change frequently
- FBOP typically adapts guidelines
Anticipate additional changes with recent and pending approval of new HCV antivirals and new clinical data
AASLD/IDSA HCV Guidelines

- These guidelines include many aspects of HCV management including:
  - Testing
  - Linkage to Care
  - Treatment Considerations
  - Special Populations
  - Counseling and Harm Reduction
AASLD/IDSA HCV Guidelines

- **Staging HCV:**
  - Biopsy (no longer gold-standard)
  - Non-invasive: Fibroscan, Fibrosure/Fibrotest, APRI and others
  - Referral to specialist if Metavir F3 or higher
  - Specialist will also consider if additional referral to transplant service is necessary
AASLD/IDSA HCV Guidelines

- Treatment is recommended for ALL chronic HCV patients except those with short life expectancy (<12 months)
- Immediate treatment is “highest priority” for F3 and higher, compensated cirrhosis, transplant recipients, and those with severe extrahepatic manifestations
AASLD/IDSA HCV Guidelines

“High Priority” patients include: F2, HIV-coinfection, HBV coinfection, other coexistent liver disease, debilitating fatigue, DM, porphyria
AASLD/IDSA HCV Guidelines

- Persons at elevated risk of transmission may yield transmission reduction benefits:
  - MSM, IVDU, Incarcerated, Hemodialysis, HCV Females of Child-bearing Potential, Healthcare Workers Performing Exposure-prone Procedures
AASLD/IDSA HCV Guidelines

- Cost Considerations are addressed in these guidelines.
- For Corrections, “State prisons and jails are usually excluded from Medicaid-related rebates and often do not have the negotiating leverage of larger organizations and may end up paying higher prices than most other organizations.”
Affordability:

An intervention that is cost-effective is not necessarily affordable. Affordability refers to whether a payer has sufficient resources in its annual budget to pay for a new therapy for all who might need or want it within that year.
DAA options and duration of treatment are dependent on HCV genotype, HCV viral load, stage of disease, formulary concerns, co-morbidities, potential drug interactions, other factors

Please refer to [www.hcvguidelines.org](http://www.hcvguidelines.org) for listing of currently recommended specific agents (changes rapidly)
AASLD/IDSA HCV Guidelines

- Guidelines also address what is **NOT RECOMMENDED**
- This includes PEG/RIBA with or without any other DAA for genotype 1, any monotherapy with any agent
- No PEG/RIBA, any monotherapy, or telaprevir/boceprevir/ledipasvir based regimens for genotype 2 and 3, and PEG/RIBA with or without SIM, or any monotherapy for genotype 4
Monitoring of patients prior to and on therapy:
- CBC, Hepatic function panel, calculated GFR, HCV genotype, quantitative viral load before treatment
- Clinic visits or phone contact as clinically indicated while on rx to monitor for adherence, adverse events, and potential drug interactions (www.hep-druginteractions.org)
AASLD/IDSA HCV Guidelines

- After 4 weeks on rx (and as clinically indicated):
  - CBC, creatinine/GFR, hepatic function panel
  - Any 10-fold increase in ALT at 4 weeks should prompt discontinuation of therapy
  - HCV viral load testing at 4 weeks during rx and 12 weeks after EOT
  - Treatment should NOT be discontinued if viral load testing is not done/available at these intervals (no response-guided therapy)
  - Consider HCV RNA testing at 24 weeks after EOT
AASLD/IDSA HCV Guidelines

- SVR 12 can be considered a cure
- Pre-treatment F3 or higher should have ongoing surveillance for HCC every 6 months
- Any rx failure should continue to have routine surveillance for HCC and signs/sx of cirrhosis
- For pre-treatment F2 or lower, if SVR, post-rx follow up is the same as for those never infected with HCV
- Ongoing surveillance for reinfection in those with ongoing HCV risk factors
AASLD/IDSA HCV Guidelines

- Primary Care Providers should always implement harm reduction counseling and management measures in every HCV patient, and those at-risk
AASLD/IDSA HCV Guidelines

- Abstinence from ETOH and referral to ETOH treatment
- Evaluation for co-morbid conditions that may accelerate HCV progression: HIV, HBV
- Vaccinations for HAV/HBV
- Education on avoidance of transmission to others (e.g. no blood or organ donation, no sharing needles, personal effects, etc)
- Consider minimizing exposure to acetaminophen (educate on products containing it)
AASLD/IDSA HCV Guidelines

- Cessation of all illicit drug use, counsel to enter drug-rx programming
- Recommend at least annual testing for those without HCV who remain at-risk
- Persons co-infected with HIV should use barrier precautions; others should be counseled of low but potential risk of sexual transmission
FINAL POINTS IN CORRECTIONS

- Many HCV patients are scared
- Reassurance and education go a long way
- In most patients, HCV progression is slow and not everyone will develop cirrhosis or cancer
- *Always* attempt to continue therapy in patients who enter corrections *without interruption*
- Remind patients that treatment may be *deferred* but is not denied
**Final Points in Corrections**

- Linkage to community care is essential/crucial
- Interruption in therapy has unknown associated risks including resistance, rx failure, and some states will not cover more than 1 lifetime treatment
- Duration of incarceration plays a major role in determining if rx can be appropriately initiated (jails vs prisons)
THANK YOU

- Questions will be addressed after Rich Feffer’s lecture
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**Disclosure**

- I do not have any relevant financial relationships with any commercial interests.
Scale of the HCV Epidemic

- CDC estimates 3.2 million* living with HCV - Most common blood borne infection in US
- CDC says ~24,000 new infections annually (give a range of 19,600 – 84,400)
- Approaching $9 billion in HC costs and rising¹,²
- Severe liver complications expected to peak over the next decade

Pricier treatment overtakes $1,000-per-pill hepatitis C drug

Some fear breakthrough drugs like a new $1,350 hepatitis C pill could drive up U.S. health care costs.

New drugs offer hope, barriers for hepatitis C patients

Treating 5 percent of hepatitis C patients with new drugs would reduce cost and infections, study shows

The health care system would save more lives and money if patients were treated with the latest drugs earlier, researchers at USC and other institutions find

large undiagnosed population - price of medication - provider education - insurance companies as gatekeepers

Most challenges to curing hepatitis C aren't medical
WHAT’S BEING DONE?

HCV Treatment Timeline


Sustained Virologic Response (%)

- IFN 6m: 6%
- IFN 12m: 16%
- IFN + RBV 6m: 34%
- IFN + RBV 12m: 42%
- PEG 12m: 39%
- PEG + RBV 12m: 55%
- PEG + RBV + PI 6-12m: 70%
- PEG + RBV + Sofosbuvir 3m: 90%
- Multiple DAAs: 95%
WHAT’S BEING DONE?

- 3.2 million infected
- 50% (1.6 million) detected
- 31%-38% (1.0-1.2 million) referred to care
- 7%-11% (220K-360K) treated
- 5%-6% (170K-200K) successfully treated
WHAT’S BEING DONE?

- Baby boomer cohort and other risk-based testing efforts
- Medicaid and insurance companies prioritizing treatment, current treatment limitations include:
  - Limits on access based on degree of fibrosis
  - Restrictions based on substance use
  - Prescriber limitations (access to specialist)
  - Additional prior authorization criteria (ie once-in-a-lifetime rule, history of Tx adherence)
  - Insurer based restrictions (ie exclusivity agreements)
- Treatment is cost-effective and cost per cure is lower than previous therapies
- Drug discounts happening*
The Unfortunate Reality

The cure is here – safer, more tolerable, shorter duration, more effective

More incarcerated people interested in hepatitis C treatment

Prisons forced to prioritize due to lack of resources and capacity

Most people with hepatitis C in prison won’t get treated while incarcerated
While they can’t do it alone, prisons and jails are key

- ~17.4% of US prisoners have HCV (likely 10-20%)
- 30% of people with HCV spend at least one night in prison or jail each year
- Screening and treatment have been shown to be both feasible and cost-effective in corrections
- We know that risk behaviors persist in prisons and jails despite zero-tolerance policies and that disease transmission occurs

Incarceration is a moment of opportunity
- Medical interventions
- Educational and prevention interventions
- Linkage to community-based resources
WHY THE PUBLIC SHOULD CARE

- Taxpayer money now, or later?
- Screening for and treating HCV in corrections has been shown to be feasible and cost-saving to society at large
- Direct impact on community health: 95% of correctional inmates will be released
- “HCV is a communicable disease – treatment is prevention – ensuring we cure (the most at risk) populations means that we can dramatically decrease new infections” (NVHR)
- Our society protects incarcerated people from deliberate indifference to a serious medical need and prisoners have a constitutional right to health care
- A variety of intervention opportunities exist in correctional settings
HCV AND INCARCERATION: OPPORTUNITY MENU

- Treat and cure
- Regular testing and confirmatory testing
- Patient counseling and education
- Prevention and accurate routes of transmission in prison and community - harm reduction strategies
- HAV/HBV Vaccination
- Staging, monitoring
- Prepare for future treatment as much as possible
- Evaluate insurance and patient assistance options
- Referrals to local community resources
WHAT YOU CAN DO

- Educate yourself and your patients
- Learn and apply HCV treatment guidelines when possible
- Talk to your administrators, legislators, and decision-makers
- Make hepatitis C care a priority in your institution
- Keep the public health benefit in mind
- Understand that treatment is only one of many helpful interventions for hepatitis C
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