

Barriers to HCV Treatment in a Women's Facility

Brian McPhee, MS1

Megan Mahoney, MD

Lori Kohler, MD

Correctional Medicine Consultation Network

University of California, San Francisco

Objectives

- Background
- Methods
- Results
- Discussion
- Recommendations

Background

- HCV prevalence high in prisons- 15%-40%¹
- Intravenous drug use leading risk factor
- Women incarcerated for IDU-related criminal offenses²

¹Boutwell, Allen, Rich. Opportunities to Address the Hep C Epidemic in the Correctional Setting. *Clinical Infectious Diseases*. 2005;40:S367-72.

²Harrison PM, Karberg JC. Prison and jail inmates at midyear 2002. National Criminal Justice document 198877. Washington, DC: Bureau of Justice Statistics, 2003.

Historical Barriers to Treatment

- 1) Duration of Stay
- 2) Access to Subspecialty Care
- 3) Lack of Funding
- 4) Psychiatric Illness
- 5) ALT Level
- 6) HIV Co-infection

Recent Evidence

- 1) Psychiatric Illness and Substance Use: Not a barrier if remote or adequately treated¹
- 2) ALT Level: Pts w/normal ALT may deteriorate histologically and respond to tx²
- 3) HIV: Coinfection common. Pts respond to treatment³

¹ Paris JE. Potential legal pitfalls of HCV management in corrections and how to avoid them. *Infectious Diseases in Corrections Report*. September 2007. Spotlight Article.

² Pearlman B, Paris JE. Hot Topics in Hepatitis C. HEPP Report on Infectious Diseases in Corrections. 2004;7(6):1-4.

³Cengiz C, Park JS, Sarah N et al. HIV and Liver diseases: Recent clinical advances. *Clinics in Liver Disease*. 2005;9:647-66.

HEPATITIS C CLINICAL MANAGEMENT

Who?
 Anyone who wants it
 h/o IVDU
 Risk factors
 Clinical findings of HCV

SCREENING & INITIAL DIAGNOSIS

- Antibody
- Hepatitis Panel
- LFT's

HCV antibody (+)

CHECK FOR VIRAL PRESENCE

Qualitative PCR
 Reflex Quantitative PCR

< 45 years old

✓ ALT q month x 3
 if ALT > 2x normal

(+)
 Vaccinate
 Hepatitis
 A/B

> 45 years old

If ALT < 2x normal
 ↓
 not eligible for treatment
 ↓
 Enroll CCP
 ↓
 Repeat ALT q year

Evaluate for possible treatment

Exclusion Criteria	<ul style="list-style-type: none"> • Parole date • Poorly controlled cardiopulmonary, cerebrovascular or thyroid disease, blood dyscrasias, seizures, cancer, diabetes mellitus (hemoglobin A_{1c} >8.5%), or renal insufficiency (creatinine >2 mg/dL) • Decompensated cirrhosis – e.g. albumin <3, jaundice, ascites, varicoes, coagulopathy 	<ul style="list-style-type: none"> • Autoimmune disease • WBC <1,500/mm³, platelets <75,000/mm³ • Hemolytic anemias, or hemoglobin <11gm/dL or hematocrit <33% • Solid organ transplant • HIV infection w/CD4 count <300 • Poorly controlled psychiatric/psychological condition • Serious suicidal behavior in the past 12 months 	<ul style="list-style-type: none"> • History of illicit drug/alcohol use within past 6-12months • Inability to cooperate with treatment • Inability to give informed consent • Age >60 years • Pregnancy – a pregnancy test is required prior to initiating therapy
	↓		

GENOTYPE

1, 4, 6

2, 3

Parole date ≥ 16 months

Parole date ≥ 10 months

ONCE ELIGIBLE FOR TREATMENT

LIVER BIOPSY (MAR)

Refer to CCP f/u q 6-12 mo consider repeat liver biopsy q 4 years

Stage 2-3 fibrosis
 ≥ Stage 2 fibrosis (HIV)

TREATMENT

1, 4, 6

2, 3

✓ viral load @ 3 mo

Non-Responders

Responders

< 2 log ↓

> 2 log ↓

9 more months treatment (12 months total)

6 mo treatment

Exclusion Criteria – CDCR

- Parole date
- Autoimmune disease
- History of illicit drug/alcohol use in past 6-12 mos
- Poorly controlled cardiopulmonary, cerebrovascular or thyroid disease, diabetes mellitus (hemoglobin A_{1C} >8.5%), or renal insufficiency (creatinine >2 mg/dL)
- WBC <1,500/mm³, platelets <75,000/mm³
- Undergoing treatment for opportunistic infxn
- Hemolytic anemias, or hemoglobin <11gm/dL blood dyscrasias, seizures, cancer, or hematocrit <33%
- Poorly controlled psychiatric/psychological condition prior to initiating therapy
- Inability to cooperate with treatment
- Inability to give informed consent
- Allergy to ribivirin or interferon
- HIV infection w/CD4 count <300
- Age >60 years old
- Solid organ transplant
- Nonresponse to previous treatment
- Pregnancy
- Decompensated cirrhosis – e.g. albumin <3, jaundice, ascites, varices, coagulopathy
- Serious suicidal behavior in the past 12 months

Study Design

- Question: What are the principal barriers to HCV treatment in prison in general and CDCR specifically?
- Descriptive Quantitative Retrospective Analysis
- Cohort: Unique pts seen in HIV clinic Aug 1-06 through July 31-07

Data Collection

- HCVAb, Quantitative Viral Load
- Viral Genotype, LFTs
- Psych Hx, Parole Date, Comorbidities
- HCV Tx Hx
- Pts reassessed at each visit

Analysis

- Retrospectively analyzed HIV/HCV pts for barriers
- Each pt assigned unique barrier according to algorithm:
 - ▶ Adequate Length of Stay?
 - ▶ If Yes: Poorly Controlled Psych Illness?
 - ▶ If No Psych: Normal ALT level, Poorly Controlled Comorbidity (HIV, HTN), Non-response to Previous Treatment?

Results

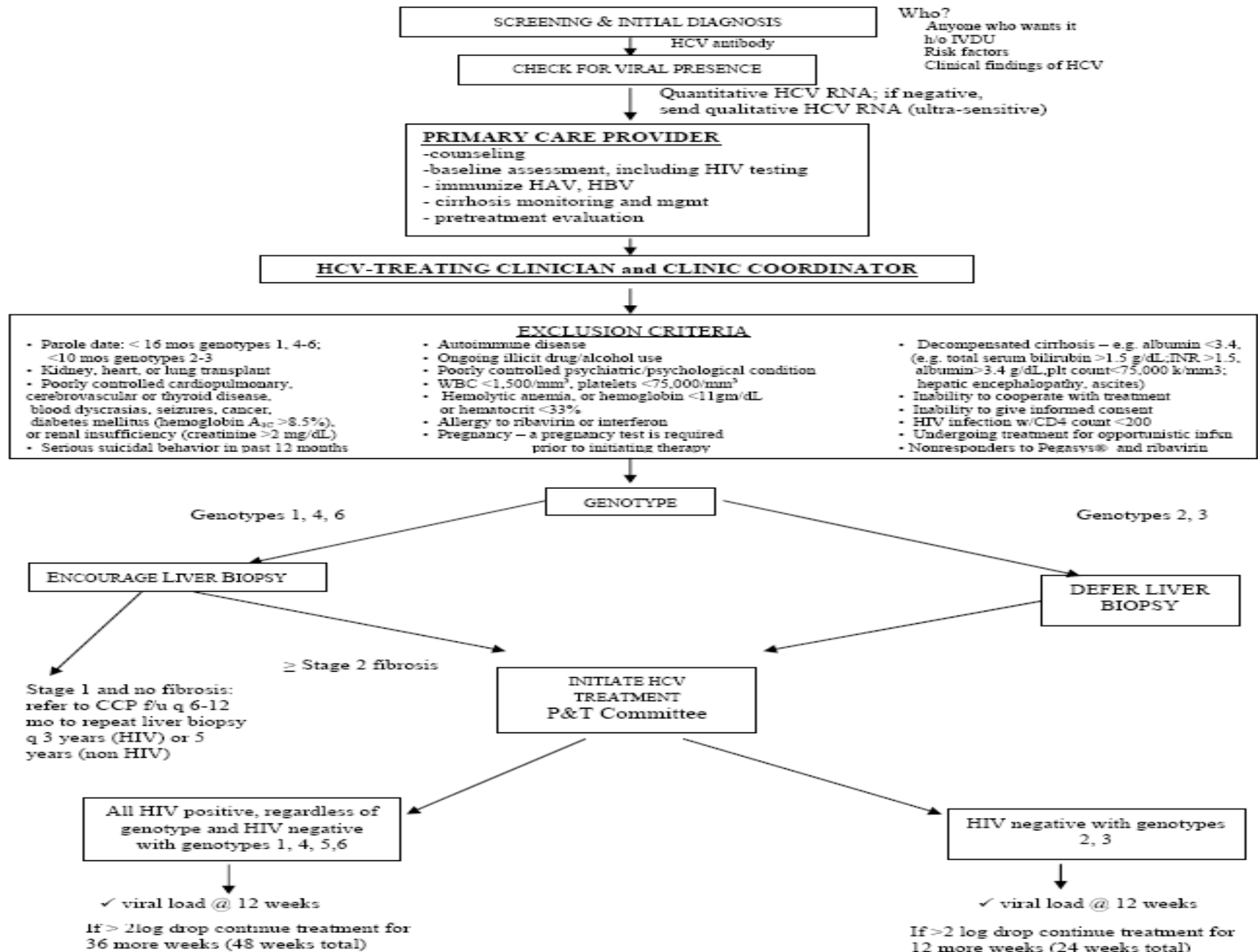
Participants n = 210

HCV Ab +	77 (36.7%)
HCV RNA +	63 (81.8%)
Eligible for Tx	8 (12.7%)
Current Tx	2 (25%)
Awaiting Liver Biopsy	1 (12.5%)
Declined Tx	1 (12.5%)
Undecided	4 (50%)
Ineligible for Tx	55 (87.3%)
Length of Stay	42 (76.3%)
Poorly Controlled Psych Illness	6 (10.9%)
Poorly Controlled HIV	4 (7.3%)
Normal ALT Levels/Age <45	1 (1.8%)
Poorly Controlled HTN	1 (1.8%)
Nonresponse to Prev Tx	1 (1.8%)

Discussion

- Similar barriers seen nationwide
- California Department of Corrections and Rehabilitation revising guidelines based on evidence
- Restrictions due to Hx of Substance Use, Normal ALT, and Age reexamined
- Limited to HIV/HCV women in CA facility
- May be applicable to other prison systems

ALGORITHM FOR HEPATITIS C TREATMENT



Exclusion criteria- recommended revisions

- Parole date
- Autoimmune disease
- Ongoing illicit drug/alcohol use
- Poorly controlled cardiopulmonary, cerebrovascular or thyroid disease, diabetes mellitus (hemoglobin A_{1C} >8.5%), or renal insufficiency (creatinine >2 mg/dL)
- WBC <1,500/mm³, platelets <75,000/mm³
- Undergoing treatment for opportunistic infxn
- Hemolytic anemias, or hemoglobin <11gm/dL blood dyscrasias, seizures, cancer, or hematocrit <33%
- Poorly controlled psychiatric/psychological condition prior to initiating therapy
- Inability to cooperate with treatment
- Inability to give informed consent
- Allergy to ribivirin or interferon
- HIV infection w/CD4 count <200
- Nonresponders to Pegasys® and ribavirin
- Solid organ transplant
- Pregnancy
- Decompensated cirrhosis – e.g. albumin <3, jaundice, ascites, varices, coagulopathy
- Serious suicidal behavior in the past 12 months

Other recommended revisions

- No age or ALT criteria
- Liver biopsy bypassed for geno 2 and 3
- Use of growth factors encouraged
- Team model of care proposed

Acknowledgments

- Correctional Medicine Consultation Network
- California Department of Corrections and Rehabilitation
- California Prison Health Care Receivership
- Patients!!