Management of HCV Infection in the Federal Bureau of Prisons

February 7, 2019
Hepatitis C Medicaid Affinity Group

Jeffery D. Allen, M.D., FAAFP
Medical Director
Federal Bureau of Prisons

Objectives

- Describe the demographics of the Federal Bureau of Prisons (BOP)
- Discuss the BOP strategy for management of hepatitis C virus (HCV) infection
- Explain the BOP's transitional care and release planning for HCV

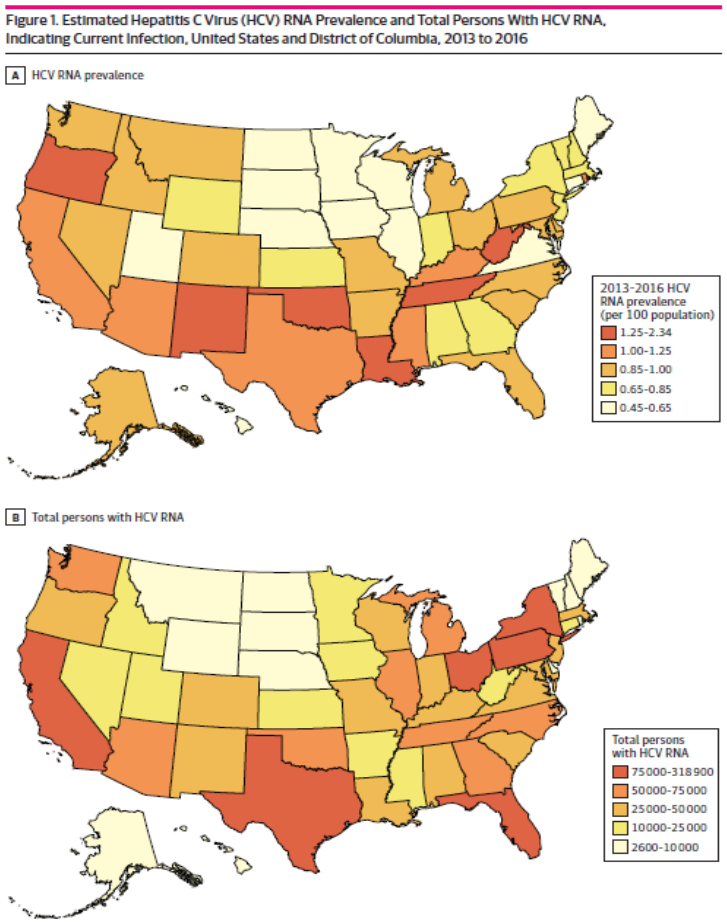
BOP Inmate Demographics

- Total population at BOP facilities - 151,764
- Average age: 41 years
- Gender: 93% male, 7% female
- Race/ethnicity: white- 58%; black- 38%; Hispanic -33% (all races)
- Citizenship: USA-80%; Mexico-13%
- Security levels: high-12%; medium-30%; low-38%; minimum-17%
- Inmates released: 2018- NA; 2017-42,638; 2016-43,864

NA = Not available

Epidemiology of HCV Infection

- Prevalence of chronic HCV in U.S.A.*
  - 2.27 million (0.93% of U.S. population)*
    - 2 million in general population;
    - 9 states have 52% of all HCV cases
  - Approx. 12% to 30% prevalence rates in prison populations
    - 231K incarcerated / institutionalized/homeless
    - Known prevalence in BOP population = 3% to 6%



*https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2719137https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2719137

BOP Strategy for Evaluation & Management of HCV infection

- Current - "Test and Treat"
  - Test all inmates for HCV
    - "Opt-out" approach
    - At intake for newly incarcerated and at various times for inmates not previously tested
  - All sentenced inmates are eligible for treatment
    - Consider pre-trial and pre-sentence inmates with high priority criteria

BOP Strategy for Treatment of HCV infection

- Current
  - All sentenced inmates are eligible for treatment
    - Consider pre-trial and pre-sentence inmates with high priority criteria
  - Prioritize if large numbers of patients to treat
  - All HCV DAAs are non-formulary in the BOP
  - Regional / Central review and approval required

BOP Priority Criteria

- BOP priority criteria for treatment
  - Priority Level 1: High Priority
  - Priority Level 2: Intermediate Priority
  - Priority Level 3: Low Priority
- Current role of priority criteria
  - Used to prioritize for treatment not to determine eligibility

Priority Level 1: High Priority

- Advanced hepatic fibrosis or cirrhosis
  - APRI ≥ 2, clinical cirrhosis, or liver biopsy stage 3-4 / 4
- Liver transplant recipients
- Hepatocellular carcinoma
- Comorbid conditions associated with HCV
  - Cryoglobulinemia with renal disease or vasculitis
  - Certain lymphomas / hematologic malignancies
  - Porphyria cutanea tarda
- Immunosuppressant Medications
  - Chemotherapy, TNF inhibitors, other immunomodulators
- Continuity of care
  - New BOP intakes arriving on HCV medication

Priority Level 2: Intermediate Priority

- Progressive fibrosis
  - APRI score ≥ 0.7
  - Metavir fibrosis stage ≥ 2 on liver biopsy (if done)
- Medical conditions assoc. with more rapid progression of fibrosis
  - Coinfection with HBV or HIV
  - Comorbid liver disease (autoimmune hepatitis, hemochromatosis, fatty infiltration or steatohepatitis)
  - Diabetes mellitus, & other conditions with insulin resistance
- Chronic kidney disease with GFR < 60
- Birth Cohort 1945-1965

Priority Level 3: Low Priority

- APRI < 0.7
- Stage 0 to 1 on liver biopsy

Selecting An Appropriate DAA Regimen

- **Factors that affect regimen selection**
  - Genotype
  - HCV treatment history & resistance associated substitutions
  - Presence of cirrhosis, compensated or decompensated
  - Potential drug-drug interactions
  - Cost and ease of administration
- **Special considerations required for**
  - Decompensated cirrhosis
  - Liver transplant recipients
  - Chronic kidney disease with GFR < 30

Additional Factors for Consideration of Treatment

- Positive factors
  - Life expectancy > 18 months
  - Sufficient time to complete tx prior to release
  - Willingness and ability to adhere to tx regimen.
- Negative factors
  - Pregnant
  - Ongoing prohibited substance use / high risk behavior
  - Reinfection after HCV treatment while incarcerated

BOP Strategy for Selecting a DAA Regimen

- Step 1:
  - Identify AASLD recommended regimens based on genotype, fibrosis stage, and prior treatment experience
- Step 2:
  - Assess for drug interactions
- Step 3:
  - Use the most cost effective medication from steps 1 and 2

HCV Medication Costs

- AASLD: "In general, when given a choice between recommended HCV DAA regimens, the less costly regimen is preferred as a more efficient use of resources (even if it requires multiple tablet dosing)."*
- Cost of DAA medications may vary based on individual contracts

** https://www.hcvguidelines.org/*

HCV Treatment Options in 2019

- 3 *Classes of HCV DAA Medications*
  - NS3/4A Protease Inhibitors (-previr)
  - NS5A Inhibitors (-asvir)
  - NS5B (Polymerase) Inhibitors (-buvir)
- DAA combination therapy options
  - Elbasvir/grazoprevir (Zepatier®)
  - Glecaprevir/pibrentasvir (Mavyret®)
  - Ledipasvir/sofosbuvir (Harvoni®)
  - Paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira XR™)
  - Sofosbuvir/velpatasvir (Epclusa®)
  - Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)

Selecting a DAA Regimen* Genotype 1, 4, 5, or 6

Condition	Treatment Options by HCV Genotype[D]			
	Genotypes 1a and 1b[E,F,G]		Genotype 4	
	No Cirrhosis	Compensated Cirrhosis	No Cirrhosis	Compensated Cirrhosis
Treatment-Naïve	▸ EBR/GZR: 12 wks ▸ GLE/PIB: 8 wks ▸ LDV/SOF: 12 wks ▸ SOF/VEL: 12 wks	▸ EBR/GZR: 12 wks ▸ GLE/PIB: 12 wks ▸ LDV/SOF: 12 wks ▸ SOF/VEL: 12 wks	▸ EBR/GZR: 12 wks ▸ GLE/PIB: 8 wks ▸ LDV/SOF: 12 wks ▸ SOF/VEL: 12 wks	▸ EBR/GZR: 12 wks ▸ GLE/PIB: 12 wks ▸ LDV/SOF: 12 wks ▸ SOF/VEL: 12 wks
Treatment-Experienced w/ PEG-IFN + RBV	▸ EBR/GZR: 12 wks ▸ GLE/PIB: 8 wks ▸ LDV/SOF: 12 wks ▸ SOF/VEL: 12 wks	▸ EBR/GZR: 12 wks ▸ GLE/PIB: 12 wks ▸ SOF/VEL: 12 wks	▸ EBR/GZR: 12 wks ▸ GLE/PIB: 8 wks ▸ LDV/SOF: 12 wks ▸ SOF/VEL: 12 wks	▸ EBR/GZR: 12 wks ▸ GLE/PIB: 12 wks ▸ SOF/VEL: 12 wks
Treatment-Experienced w/ PI + PEG-IFN + RBV	▸ GLE/PIB: 12 wks ▸ LDV/SOF: 12 wks ▸ SOF/VEL: 12 wks	▸ GLE/PIB: 12 wks ▸ SOF/VEL: 12 wks	NA	NA
Treatment-Experienced w/ SOF + RBV + PEG-IFN *OR* SOF + PI +/-RBV	▸ GLE/PIB: 12 wks (1a or 1b) ▸ SOF/VEL/VOX: 12 wks (1a) ▸ SOF/VEL: 12 wks (1b)	▸ GLE/PIB: 12 wks (1a or 1b) ▸ SOF/VEL/VOX: 12 wks (1a) ▸ SOF/VEL: 12 wks (1b)	▸ SOF/VEL/VOX: 12 wks	▸ SOF/VEL/VOX: 12 wks
Treatment-Experienced w/ NS5A inhibitor	▸ SOF/VEL/VOX: 12 wks	▸ SOF/VEL/VOX: 12 wks	▸ SOF/VEL/VOX: 12 wks	▸ SOF/VEL/VOX: 12 wks

- *Table excerpted from BOP Clinical Guidance, available at https://www.bop.gov/resources/health_care_mngmt.jsp.*
- *Refer to the AASLD/IDSA website for most current recommendations, www.hcvguidelines.org*

+ *An 8 week course of LDV/SOF may be considered for TN who are non-black race, not HIV infected, and have an HCV RNA < 6 million IU/ml.*

HCV Statistics: Expenditures

FY	Approvals	Treated	Expenditure	Medications
2010	363	N/A	$1,950,026	Peg/RBV
2011	494	277	$1,931,064	Late 2011 added BOC, TVR
2012	371	348	$4,378,238	
2013	387	366	$4,168,807	
2014	180	138	$5,917,436	Added SOF, SOF/SMV, Harvoni
2015	222	227	$13,646,354	Added DCV, Technivie, Viekira XR
2016	311	342	$14,033,347	Added Zepatier, Epclusa
2017	904	765	$27,581,085	Added Mavyret
2018	1683	NA	$24,982,235	Added Vosevi

HCV Statistics: Outcomes

- Population of inmates available for 12 week post-treatment viral load (Genotypes 1, 2, and 3)

Outcome	Total
SVR	88%
D/C	1%
Failure	8%
Refused on treatment	1%
Other	2%

- SVR < 90% likely due to high numbers with cirrhosis prioritized for treatment
- D/C: ADR/labs, noncompliance, other reasons

HCV Statistics: BOP Liver-Related Mortality

Liver-related deaths	2014	2015	2016	2017
Total numbers	42	52	22	15
Percentage of all deaths	8.6%	11%	5.6%	3.9%
Rank order	4th	3rd	4th	7th

Barriers and Best Practices

- Administrative hurdles
  - Check lists and order sets
  - Team medicine
- Cost
  - Non-formulary requests
  - Pharmaceutical contracts
  - Budget project codes / set-asides
- Knowledge deficits / lack of experience
  - Clinical Guidance & education
  - Co-management
  - HCV pharmacist consultants

Data Mining and Analytics

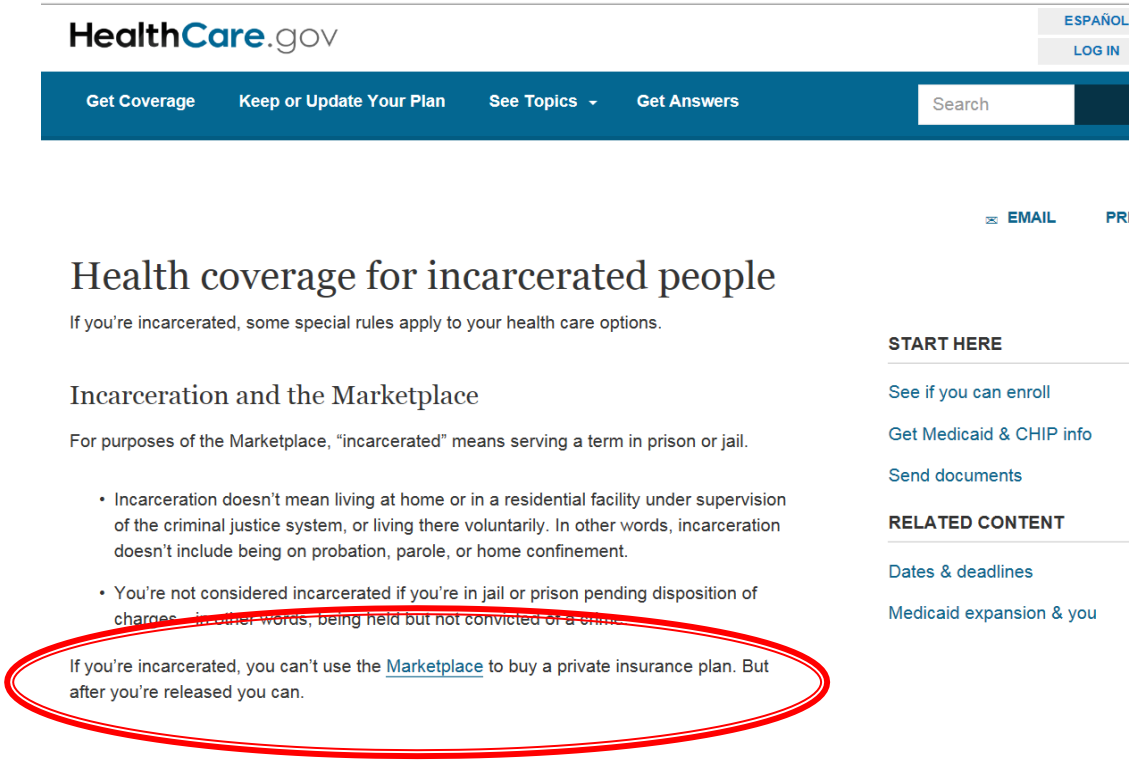
- Data drives decision-making
  - Intake screening for HCV / prevalence rates
  - Prevalence rates of each genotype
  - Treatment outcomes
  - Clinical care utilization evaluation
  - Mortality reviews

Transitional Care / Release Planning (1 of 3)

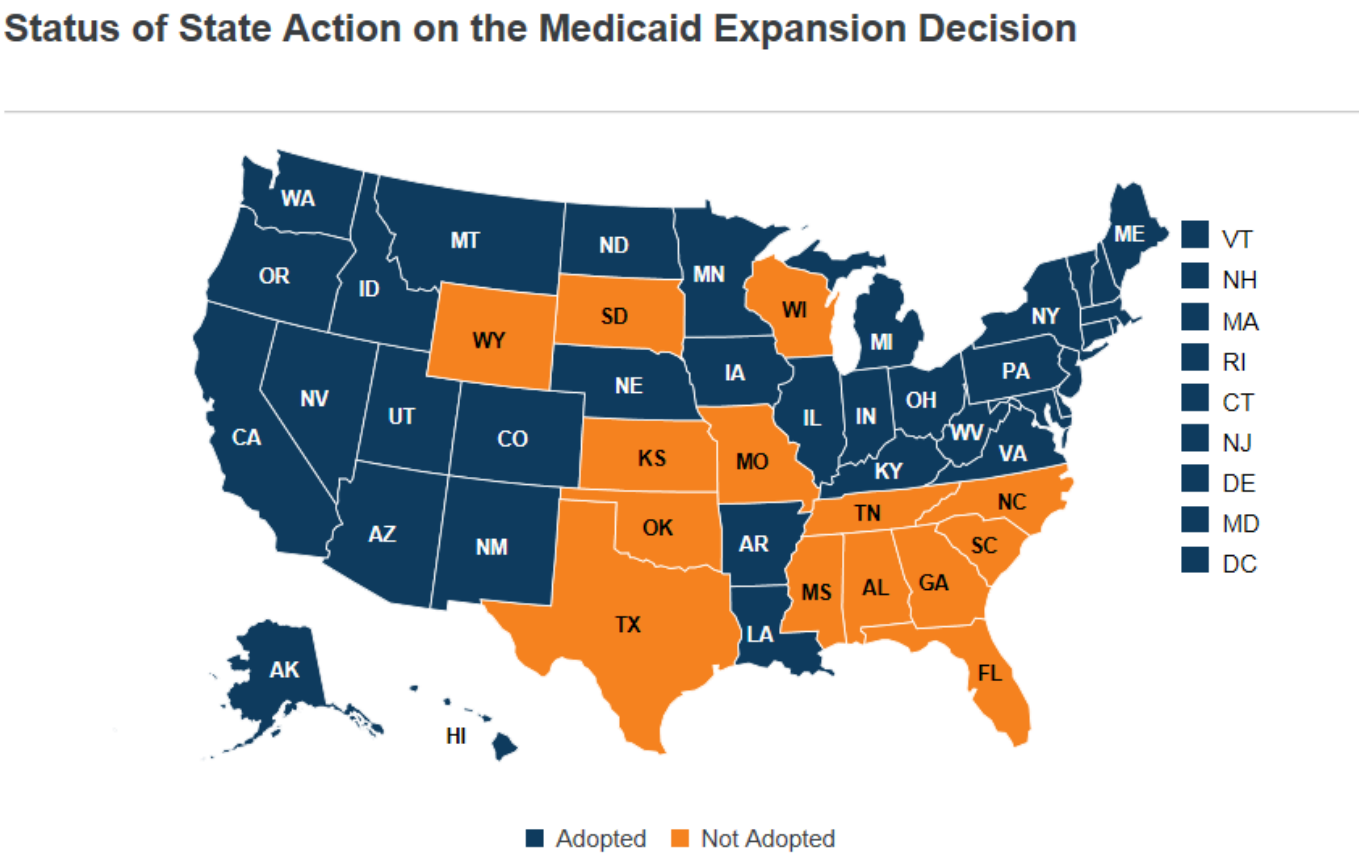
- HCV treatment ordinarily not started if insufficient time to complete before release.
  - If started, will usually send enough medication with patient to finish treatment after release
- Social worker involved in release planning for ill / medically disabled inmates (Care 3 or 4)
  - Facilitates application for health care coverage, medical appointments, placement, etc.
  - Not specific for follow up of HCV

Transitional Care / Release Planning (2 of 3)

- Numerous challenges facing inmates releasing from prison



Transitional Care / Release Planning (3 of 3)



Summary
BOP HCV Management

- Opt-out HCV screening for all BOP inmates
- All sentenced BOP inmates eligible for treatment consideration
- Review of all HCV treatment requests
- DAA regimen selection based follows AASLD guidelines.

Management of HCV Infection in the Federal Bureau of Prisons

- Discussion
  - Comments *or*
  - Questions