The Burden of Hepatitis C at the Rhode Island Adult Correctional Institutions: A Budget Impact Analysis of Scaling Up Treatment with New and Incoming HCV Therapeutics

John T. Nguyen[†], Josiah Rich[‡*], MD MPH, Brian Montague[‡*], DO MS MPH
Brown University School of Public Health MPH Candidate 2014[†]; Warren Alpert Medical School[‡], The Miriam Hospital*

Background:

- Hepatitis C virus (HCV) infection continues to disproportionately affect incarcerated populations. Upon release, untreated individuals may be at high risk of transmitting the virus to others.
- Sofosbuvir was approved by the FDA in late 2013 and additional all-oral therapies are slated for approval by late 2014 with similar or better safety and efficacy.
- As more effective and less toxic regimens become available, correctional health systems with capped budgets may face difficulty rationalizing treatment deferral on medical grounds and yet clearly do not have the resources to treat all those with active inflammation from hepatitis C.
- The goal of this study is to assess the HCV burden at the Rhode Island Adult Correctional Institutions (ACI) by evaluating clinical characteristics and treatment strategies to inform a budget impact analysis (BIA) of transitioning to the current standard of care as of spring 2014.

Methods:

- Patients with an HCV ICD9 coded diagnosis were first extracted from the ACI electronic medical records. From the remaining population, an additional 10% validation sample was taken to inform overall prevalence estimates (Figure 1).
- A total of 482 records were reviewed for data on HCV positivity, active infection, genotype, staging based on METAVIR scale, prior treatment, and demographics.
- Unit and total drug costs were obtained from the ACI contract pharmacy services and based on current AASLD and IDSA guidelines as of March 2014 (Table 1).
- Aggregate data on clinical characteristics were extrapolated towards the ACI population for estimates of treated patients per treatment strategy (Table 2).
- Total drug costs were evaluated for three treatment strategies: treating all chronic infections, treating any fibrosis, and treating only advanced fibrosis.
- Budget impact was computed as the percentage of pharmacy and overall healthcare expenditures accrued by total drug costs (Table 3).
- Sensitivity analyses informed deviations relative to costs projections of incoming all-oral therapies based on current costs of sofosbuvir combinations (Figure 3).

Figure 1: Data Extraction and Analytic Sample

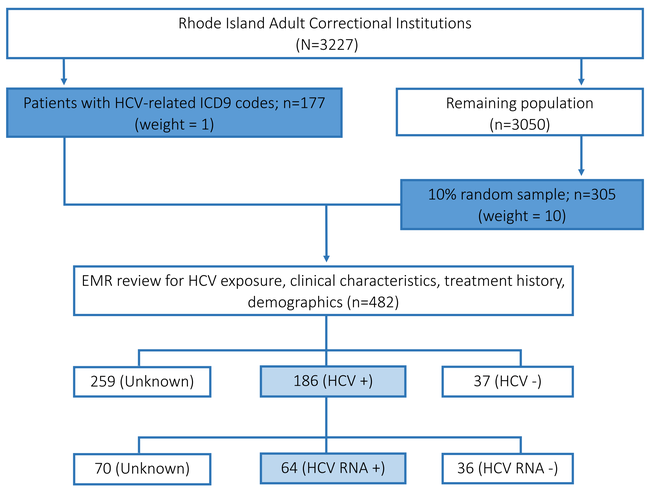


Table 1: Costs and Cure Rates of New Treatment Guidelines by the American Association for the Study of Liver Disease and Infectious Diseases Society of America[7]

	Unit Drug Costs	Correctional Negotiated Cost
sofosbuvir (SOF) - 400 mg	$1,000	$875
pegylated-interferon (PEG) - 180 mcg	$771	
ribavirin (RBV) - 200 mg	$0.30	
	Drug Costs Per Patient Per Treatment Course	Cure Rate
SOF + PEG/RBV (12 weeks) Genotypes 1 and 4	$93,406	90%
SOF + RBV (12 weeks) Genotype 2	$84,101	95%
SOF + RBV (24 weeks) Genotype 3	$168,202	85%

Results

Prevalence Estimation

- There were 176 HCV positives individuals with a coded ICD9 diagnosis. In the 10% validation sample, there were 10 HCV positives, 36 HCV negatives, and 259 individuals with unknown HCV status.
- Known prevalence in the 10% sample group (22%) was applied to the 259 unknowns. After appropriate weighting, HCV prevalence was estimated at 26% or 836 HCV positive individuals at the ACI at any given time.

Table 2: Extrapolating Distributions of Clinical Data for Estimate of Budget Impact

	Percentage	Estimate
ACI Population	100%	3227
HCV Ab (+)	26%	836
HCV RNA (+)	67%	559
Estimated Distribution of Genotype Among HCV RNA (+)		
Genotype 1	69%	385
Genotype 2	8%	42
Genotype 3	18%	98
Genotype 4	6%	35
Estimated Distribution of Staging Among HCV RNA (+)		
Stage 0	9%	51
Stage 1-2	55%	305
Stage 3-4	36%	204

Estimate of HCV positive cohort based on prevalence estimate (26%) applied to cross-sectional census of ACI population as of February 2014. Percentages may not sum to 100% due to rounding. Known genotype distribution of HCV positive population was applied to estimated number of chronic infections. Known staging distribution of HCV population was applied to estimated genotype frequencies.

Figure 2: Treatment Decision rules and Strategies

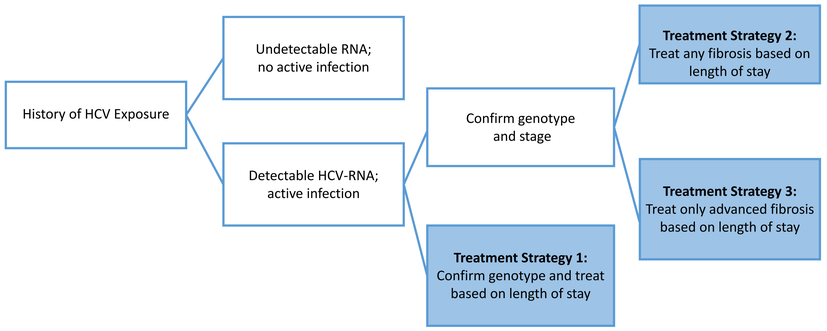
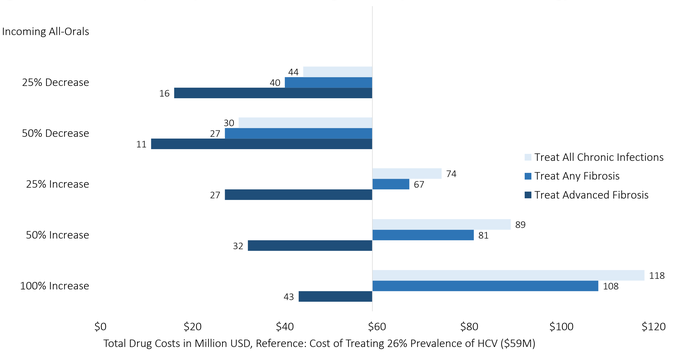


Table 3: Estimated Pharmacy and Overall Budget Impact of New HCV Treatment Guidelines by Treatment Scenarios

	Treat All (n = 559)	Treat Any Fibrosis (n = 508)	Treat Advanced Fibrosis (n = 204)
Estimated Cures	500	455	170
Total Drug Costs	$59,156,293	$53,773,070	$21,532,891
Budget Impact			
ACI 2014 Pharmacy Budget[8]: $2,723,669			
Proportion of pharmacy expenditures	2172%	1974%	791%
ACI 2014 Healthcare Services Budget[8]: $19,889,269			
Proportion of overall healthcare expenditures	297%	270%	108%
Cost Per Patient Cured: $118,210			

Figure 3: Sensitivity Analyses of Total Drug Costs by Treatment Strategy



Discussion

- Study limitations include missing data and small sample size (15% of total population) which would affect prevalence estimates and data extrapolation of clinical characteristics for cost modeling. However, the 26% prevalence estimate was consistent with other Rhode Island studies in this population and the distribution of fibrosis staging is similar to a large cohort study on the natural history and prevalence of fibrosis in HCV patients[2, 4, 9, 11].
- Cost projections simplify the treatment decision process that would normally involve other factors such as length of stay, early treatment success, contraindications, and treatment complications.
- This BIA corroborates the immense burden incurred upon correctional health. Even in a liberal 50% reduction in total drug costs for incoming all-orals based on the current cost of sofosbuvir combinations, it would still cost nearly $30 million to treat everyone in corrections while the cost for treating advanced fibrotic patients would cost around $11 million, all in a matter of three to six months.
- Corrections will essentially be forced to consider other cost-savings options unless these “miracle drugs” are dramatically more cost-accessible to both individuals and healthcare systems.

Conclusions

- From a public health perspective, all institutions share the burden of HCV, regardless of their actual constituencies. Finding other means of financially supporting HCV treatment in corrections is critical if correctional institutions are to uphold their legal mandate to provide the community standard of care.
- Rising HCV treatment costs goes beyond merely a “sticker shock” phenomenon and needs to be seriously reevaluated as HCV transitions into a more curable disease.
- As all-oral regimens are approved by late 2014, treatment strategies that are both cost-effective and public health conscious will be needed. For the HCV epidemic to have any hope of eradication, treatment must be accessible and equitable, especially for more vulnerable populations.

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