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

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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.
- 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).

Results

Prevalence Estimation
- There were 176 HCV positive 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.

Methods

Table 1: Costs and Care Rates of New Treatment Guidelines by the American Association for the Study of Liver Disease and Infectious Diseases Society of America†

<table>
<thead>
<tr>
<th>Treatment Strategy</th>
<th>Unit Drug Costs</th>
<th>Corrected Correlated Costed Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir (GFL) 400 mg peginterferon alpha-2b 180 mcg RBV 200 mg</td>
<td>$1,000</td>
<td>$875</td>
</tr>
<tr>
<td>Peginterferon alfa-2b 180 mcg RBV 200 mg</td>
<td>$775</td>
<td>$73</td>
</tr>
<tr>
<td>Peginterferon alfa-2b 180 mcg RBV 200 mg</td>
<td>$30</td>
<td>$0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Percentage</th>
<th>Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>69%</td>
<td>38%</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>8%</td>
<td>18%</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>6%</td>
<td>15%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Treatment Strategy</th>
<th>Treating All (n=359)</th>
<th>Treating Any Fibrosis (n=508)</th>
<th>Treating Advanced Fibrosis (n=204)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated Costs</td>
<td>$640</td>
<td>$651</td>
<td>$170</td>
</tr>
<tr>
<td>Total Drug Costs</td>
<td>$20,116,293</td>
<td>$15,779,070</td>
<td>$2,152,891</td>
</tr>
</tbody>
</table>

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.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 new 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 go beyond merely a “sticker shock” phenomenon and needs to be seriously reevaluated as HCV transitions into a more curable disease.
- As all-or-none 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.

Acknowledgements

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References
- 2. Allen SA, Sp
- 4. Allen SA, Sp
- 5. Lawitz E, A Budget Impact Analysis of Scaling Up Treatment with New and Incoming HCV Therapeutics.
- 10. Lawitz E, A Budget Impact Analysis of Scaling Up Treatment with New and Incoming HCV Therapeutics.

Figure 1: Data Extraction and Analytic Sample

Figure 2: Treatment Decision rules and Strategies

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

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