Treatment rates and prevalence of high priority comorbidities for treatment initiation in people with hepatitis C

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Background

Approval of novel antivirals with fewer adverse events and higher viral clearance rates, in conjunction with updated recommendations by the Centers for Disease Control and Prevention that all adults born between 1945 and 1965 be tested for Hepatitis C Virus (HCV)[1], has precipitated a dramatic shift in the management of HCV in the United States. In addition, clinical guidelines specify high priority comorbidities indicating the need to initiate HCV treatment.[2] These factors, combined with an aging population, warrant better understanding of HCV treatment use in clinical practice.

Objective

To report HCV treatment rates in a large population of people diagnosed with HCV, as well as the prevalence of high priority comorbidities for treatment initiation and total health care costs for both treated and untreated groups.

Methods

Study Design: Retrospective, descriptive analysis

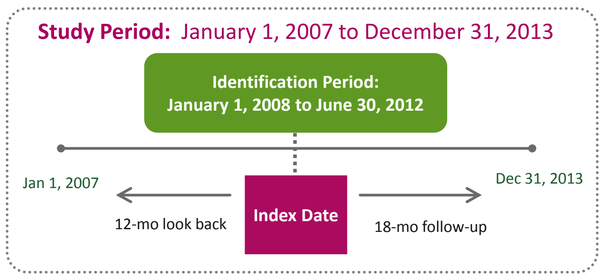
Data Source: Pharmacy and medical claims, and enrollment data, from the Humana Research Database, which includes data from approximately 17.1 million members nationwide across commercial, Medicare Advantage and prescription drug plans from 2007 to present.

Inclusion and Exclusion Criteria:

- Individuals aged 19-89 years, with commercial or Medicare Advantage insurance and an initial diagnosis of HCV (ICD-9/CPT codes: V0262, 07041, 07044, 07051, 07054, 07070, 07071, G8461, G8463, 4150F, 4153F) between 1/1/2008 and 6/30/2012 were eligible for inclusion.
- Continuous enrollment with the health plan was required for ≥12 months before and ≥18 months after the first diagnosis of HCV to ensure complete follow-up.
- Patients diagnosed with hepatitis B virus (ICD-9/CPT codes: 070.20-070.23, 070.30-070.33, V02.61) or evidence of HCV treatment on or before the first HCV diagnosis date (index date) were excluded.

Outcomes and Statistical Analyses:

- HCV treatment was defined as any prescription claim for one or more of the following, alone or in combination: pegylated interferon, ribavirin, boceprevir, telaprevir, interferon alfa-2b, interferon alfacon-1.
- Priority conditions were defined as type 2 diabetes mellitus, renal failure, proteinuria, nephrotic syndrome, membranoproliferative glomerulonephritis, liver failure, HIV-co-infection, porphyria cutanea tarda, type 2 or 3 essential mixed cryoglobulinemia with end organ damage.
- Mean total costs (plan- and patient-paid) were assessed over the observation period using generalized linear models with log link and gamma distribution, controlling for age, gender, geographic location, Deyo-Charlson Comorbidity Index, RxRisk-V Score, and pre-index medical and pharmacy costs.



Results

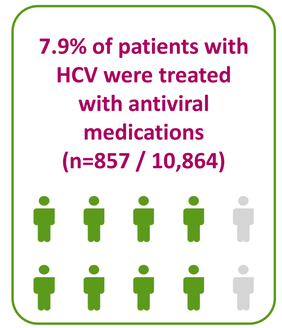
Table 1. Baseline Demographics

The study population (N=10,864) was predominately white (70.6%) and male (55.5%) with a mean age of 60.3 years

Measure	All HCV Patients n=10,864	Treated HCV Patients n=857	P value
Age, years, Mean (SD)	60.3 (12.1)	54.9 (10.2)	<0.0001
Gender, No. (%)			<0.001
Female	4832 (44.5%)	325 (37.9%)	---
Male	6030 (55.5%)	532 (62.1%)	---
*Race/Ethnicity, No. (%)			0.21
Caucasian	5654 (70.6%)	347 (72.6%)	---
African American	1450 (18.1%)	73 (15.3%)	---
Hispanic	233 (2.9%)	15 (3.1%)	---
Other/Unknown	669 (6.2%)	43 (5.0%)	---
Plan Type, No. (%)			<0.0001
Commercial	2858 (26.3%)	379 (44.2%)	
MAPD	8006 (73.7%)	478 (55.8%)	
Rx Risk-V Comorbidity Score, Mean (SD)	5.4 (3.1)	5.0 (3.0)	0.005
Deyo-Charlson Comorbidity Index, Mean (SD)	1.4 (2.1)	1.1 (2.0)	<0.0001
Pre-Index All-Cause Healthcare Costs, Mean (SD)	$1,106 ($2,930)	$1,378 ($5,482)	0.02

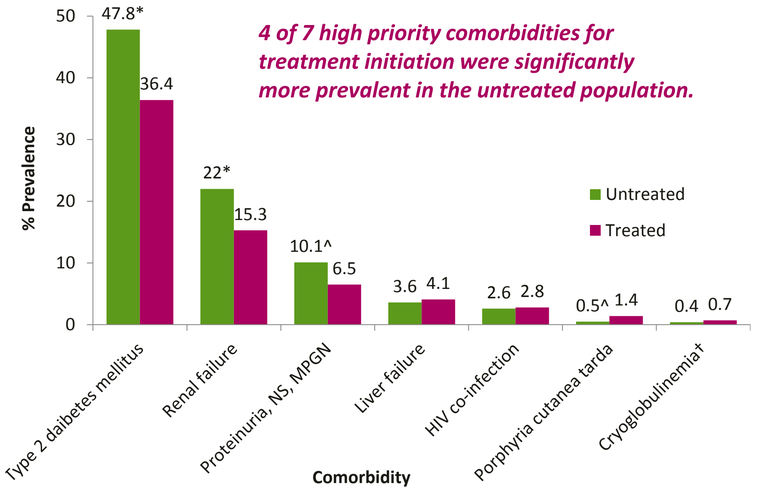
**Medicare only;* SD=standard deviation; MAPD=Medicare Advantage Prescription Drug

Figure 1. Prevalence of Treatment



Treated patients were younger, had lower comorbidity scores and pre-index health care costs

Figure 2. Prevalence of Priority Comorbidities for HCV Treatment Initiation



4 of 7 high priority comorbidities for treatment initiation were significantly more prevalent in the untreated population.

**P*<0.0001 vs. treated; ^*P*<0.001 vs. treated; NS=nephrotic syndrome; MPGN=membranoproliferative glomerulonephritis
†Type 2 or 3 essential mixed cryoglobulinemia with end organ manifestations

Table 2. Cost Differences Between Treated and Untreated Patients over 18 Months of Follow Up

In the HCV treated population, total mean healthcare costs were significantly higher and HCV treatments accounted for $28,024 per treated patient.

	Untreated n=10,007	Treated n=857	P value
	Mean	Mean	Unadjusted
Total Healthcare Costs	$61,774	$90,687	<0.001
Medical	$50,228	$46,449	0.50
Inpatient	$26,136	$19,631	0.51
Outpatient	$18,777	$23,462	<0.001
Emergency Room	$2,451	$2,102	<0.01
Pharmacy	$11,546	$44,238	<0.001
Index (1st) HCV Product	-	$24,529	-
Non-index (2nd) HCV Product	-	$3,495	-
Non-index, Non-HCV Product	$11,546	$16,214	<0.001

Implications for Policy and Practice

- Despite available treatment options, the vast majority of patients diagnosed with HCV were untreated.
- The prevalence of high priority comorbidities for treatment initiation was higher for multiple conditions in untreated group, suggesting that clinical guideline recommendations for whom to initiate HCV therapy are not being fully applied in practice.
- The high cost of HCV treatments underscores the need to initiate therapy in the right patients at the right time.

Limitations

- Patient factors such as genotype, sustained virologic response, disease severity, reasons for treatment discontinuation and other factors that could influence treatment decisions could not be obtained or controlled for.
- Limitations common with claims analyses (missing values, inability to capture all relevant confounders, etc.) pertain to this study.
- The study time period excluded newer direct acting antivirals and all oral regimens approved since June 2013. Future research should assess how newer HCV therapies can be used appropriately in highest priority populations.

References

1. Smith BD, Morgan RL, Beckett GA, et al; CDC. Recommendations for the identification of chronic hepatitis C virus infection among persons born during 1945-1965. *MMWR*. 2012;61:1-32.
2. American Association for the study of liver diseases/Infectious Disease Society of America/International Antiviral Society-USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Updated September 25, 2014. Accessed May 14, 2015.

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