Socio-Demographic and Clinical Correlates of Treated versus Untreated Members with Hepatitis C in a State Medicaid Program

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Background

- Chronic Hepatitis C (CHC) is a blood-borne, viral infection that affects an estimated 2.7 million persons in the United States.
- The high medication acquisition costs of new direct-acting antiviral (DAA) treatment regimens places a significant burden on the payer system, and provokes further analysis of the treatment populations.
- Drug-drug interactions among medications for the treatment of CHC and the medications commonly used in other comorbidities may decrease the efficacy of CHC treatment or contraindicate concomitant use during CHC treatment.

Objectives/Specific Aims

Identify socio-demographic and clinical characteristics of Oklahoma Medicaid members associated with the receipt of HCV treatment.

Methods

- A cross-sectional study design was used.
- Study participants were Oklahoma Medicaid enrollees (≥18 years) diagnosed with HCV.
- Pharmacy and medical claims from January 1, 2014 through March 31, 2015 were analyzed.
- Descriptive statistics were used to summarize the distribution of demographics, comorbidities, and clinical profile by those receiving treatment versus those untreated.
- Multivariable logistic regression was used to examine the association between the receipt of HCV treatment and socio-demographic and clinical characteristics (including the use of cytochrome P450 (CYP450) inducer/inhibitor use) among Oklahoma Medicaid members while controlling for potential confounding factors.

Results

Table 1a. Descriptive summary of HCV patient socio-demographic and clinical characteristics by treatment status (N=5,024)

	Treated (N=270)	Untreated (N=4,754)
Demographics		
[1]Age in years: Median (IQR) **	53 (15)	48 (20%)
[2]Gender: n (%) **		
Male	131 (49%)	1,948 (41%)
Female	139 (51%)	2,806 (59%)
[3]Race/Ethnicity: n (%)		
White	219 (81%)	3,755 (79%)
Black	18 (7%)	380 (8%)
Others	29 (11%)	552 (12%)
Missing	4 (1%)	67 (1%)
Treatment Details		
Treatment Initiation: n (%)		
Treatment before July 1, 2014	165 (61%)	-
Treatment after July 1, 2014	105 (39%)	-
Length of Treatment: n (%)		
Unknown (Rx before July 1, 2014)	165 (61%)	-
8 Weeks	15 (6%)	-
12 Weeks	65 (24%)	-
16 Weeks	1 (<1%)	-
24 Weeks	24 (9%)	-
Regimen: n (%)		
ledipasvir/sofosbuvir	61 (23%)	-
simeprevir	1 (<1%)	-
sofosbuvir + simeprevir	22 (8%)	-
sofosbuvir	184 (68%)	-
ombitasvir/paritaprevir/ ritonavir + dasabuvir	2 (<1%)	-

1Wilcoxon Independent sample test , 2Chisquare test of independence, 3Fisher exact test
p<0.01**, p<0.05*

Results

Table 1b. Descriptive summary of HCV patient socio-demographic and clinical characteristics by treatment status (N=5,024), Continued

	Treated (N=270)	Untreated (N=4,754)
Previous or Current Use of Cytochrome P450 Enzyme Medications		
[1]CYP450 Inducers present: n (%)	10 (4%)	301 (6%)
[1]CYP450 Inhibitors present: n(%)**	161 (59%)	2,359 (49%)
[3]CYP450 Categories: n (%) **		
0 (No CYP450 Drug)	80 (30%)	1,960 (41%)
1 (Inducer Only)	5 (2%)	92 (2%)
2 (Inhibitor Only)	114 (42%)	1,622 (34%)
3 (Substrate Only)	23 (9%)	307 (7%)
4 (Inducer and Inhibitor)	3 (1%)	114 (2%)
5 (Inducer and Substrate)	1 (<1%)	36 (<1%)
6 (Inhibitor and Substrate)	43 (16%)	564 (12%)
7 (All 3 Present)	1 (<1%)	59 (<1%)
Patient Clinical Profile		
[3]Genotype: n (%) **		
Unknown (Rx before July 1, 2014)	165 (61%)	4751 (99)
1, 1a, 1b	6(2%),53(20%),16(6%)	0(0%), 0(0%), 0(0%)
2, 2a, 2b	7(3%), 1(<1%), 11(4%)	1(<1%),0(0%),0(0%)
3, 3a	7 (3%), 4 (2%)	1 (<1%), 1 (<1%)
Other Health Conditions		
[2]Overall CCI: Median (IQR)**	3 (4%)	2 (3%)
HIV: n (%)[3]		
No	266 (99%)	4,633 (98%)
Yes	4 (1%)	121 (2%)
[1]Liver Disease Present: n (%) **		
No	13 (5%)	1,837 (39%)
Yes	183 (68%)	2,373 (50%)
Sequelae of Chronic Disease	74 (27%)	544 (11%)
[1]Cancer (non-tumorous): n (%)		
No	248 (92%)	4,366 (92%)
Yes	22 (8%)	388 (8%)
[1]Diabetes: n (%)		
No	251 (93%)	4,437 (93%)
Yes	19 (7%)	317 (7%)
[1]Congestive Heart Failure: n (%)		
No	240 (89%)	4,202 (88%)
Yes	30 (11%)	552 (12%)
[3]Fibrosis Score: n (%) **		
Unknown (Rx before July 1, 2014)	165 (61%)	-
1	3 (1%)	-
2	26 (10%)	-
3	20 (7%)	-
4	54 (20%)	-
Transplant	2 (1%)	-
[1]Type of HCV Diagnosis**		
HCV diagnosis specified	259 (96%)	3197 (67%)
HCV diagnosis unspecified	11 (4%)	1557 (33%)

1Chisquare test of independence, 2Wilcoxon Independent sample test, 3Fisher exact test
p<0.01**, p<0.05*

Table 2. Logistic regression results of the association between HCV treatment and patient characteristics summarized as adjusted Odds Ratios (AOR)

Characteristic	AOR (95% CI)
Race category	
White	Reference
Black	0.71 (0.43, 1.18)
Other	1.05 (0.69, 1.58)
Unknown	1.55 (0.54, 4.43)
CYP450 Substrate	
No	Reference
Yes	1.29 (0.95, 1.74)
CYP450 Inducer	
No	Reference
Yes	0.63 (0.33, 1.21)

Table 3. Logistic regression results of the association between HCV treatment and patient characteristics stratified by Gender summarized as adjusted Odds Ratio (AOR with 95%CIs)

	Male AOR (95%CI)	Female AOR (95%CI)
Characteristic		
Age (in years)	1.04 (1.02, 1.06)	1.01 (0.99, 1.03)
CCI* for specified HCV	0.87 (0.79, 0.95)	0.94 (0.86, 1.03)
CCI* for unspecified HCV	0.38 (0.21, 0.67)	0.41 (0.23, 0.73)

*Charlson Comorbidity Index

Results

Figure 1. Probability of Receiving HCV Treatment by Patient Age and Gender

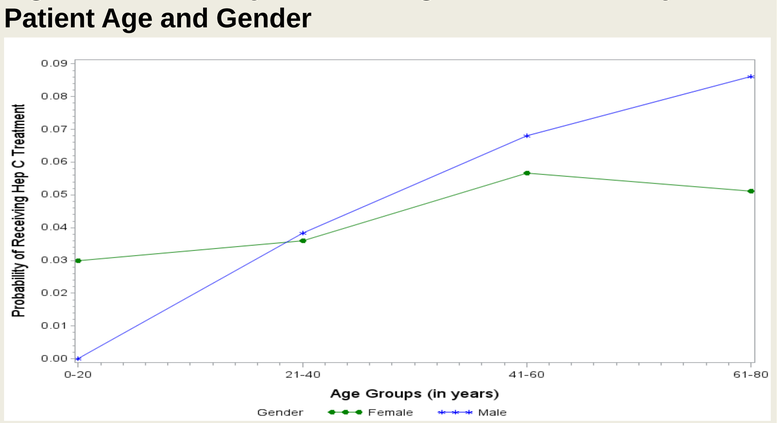

Table 4. Logistic regression results of the association between HCV treatment and liver disease status stratified by use of Inhibitors summarized as adjusted Odds Ratio with (95%CIs)

	Inhibitors Prescribed AOR (95%CI)	No Inhibitors Prescribed
Liver Disease Status		
No	Reference	Reference
Liver Disease Present	10.27 (3.55, 29.76)	16.89 (5.22, 54.63)
Sequelae of Chronic Disease	37.19 (11.31, 122.31)	27.18 (7.20, 102.65)

Conclusions

- This study of adult Medicaid members with HCV indicated that an increased odds of receiving HCV treatment was associated with advanced sequelae of liver disease and among males, specifically as a function of increasing yearly age and fewer comorbid conditions.
- HCV treatment was also associated with the concurrent use of P450 inhibitors in those with sequelae of chronic liver disease manifestations.
- While continued work is warranted concerning the reasons for and implications of these treatment patterns, results suggest different clinical management practices may be present.

Limitations

- Due to limited sample size, analyses based upon specific CYP450 substrates or inducers could not be conducted.
- As administrative claims data are predominantly used for billing purposes, these data may have coding errors and omissions.
- In addition to the lack of detailed clinical information, other unmeasured confounders may also exist.

References

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Disclosure Statement

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