Hepatitis C virus (HCV) treatment outcomes in the primary care setting

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BACKGROUND

Since 2010, the New York State Department of Health (NYSDOH) has provided funding to 13 primary care sites to integrate hepatitis C virus (HCV) care and treatment. Primary care settings include: community health centers, hospital based clinics and drug treatment programs. Eight (8) of the funded programs provide services to HCV monoinfected persons, while the remaining five (5) provide services to HIV/HCV coinfected persons. Funded programs provide comprehensive primary care and HCV care and treatment utilizing a multidisciplinary team approach. All programs offer wrap-around services, such as care coordination, peer and supportive services, etc. At each of these programs, it is the primary care provider managing and treating HCV. Each program maintains a linkage agreement with an HCV specialist who provides ongoing consultation when needed.

OBJECTIVE

The purpose of this study was to determine HCV treatment outcomes for patients being treated by a primary care provider (PCP) in a primary care setting throughout NYS. (Figure 1)

METHODS

The 13 HCV Care and Treatment Programs submitted data to the NYSDOH on a randomly selected sample of patients enrolled in their programs from October 2012 through September 2013, to measure eight performance indicators (PI) and determine sustained virologic response (SVR) rates. Sample sizes were determined accounting for an unequal proportion of treated and untreated patients. Patients treated were deemed medically eligible for HCV treatment and were treated during the review period. Data were collected in SurveyMonkey® and analyzed using IBM SPSS Statistics version 22.0.

RESULTS

During the review period, a total of 611 patient records were reviewed for PI and SVR. Table 1 represents data collected on the total sample (N=611). Table 2 represents data collected on a subset of patients who were treated for HCV during the review period (N=315).

For all patients, HCV monoinfected programs performed better when compared to the HIV/HCV coinfected programs on the following indicators: treatment adherence, alcohol counseling and mental health assessment. (Table 1) For treated patients, HIV/HCV coinfected programs performed be better on the PI "RNA testing before treatment" and HCV monoinfected providers performed better on the PI "treatment adherence addressed". (Table 2)

Table 1: HCV Performance Indicators – All Patients (N=611)

	% Co-infected[1] (n=289)	% Mono-infected[1] (n=322)	% Total[1] (N=611)
Treatment adherence addressed	68.8%	85.4%	77.5%
HAV vaccine	89.9%	88.8%	89.3%
HBV vaccine	87.4%	89.4%	88.3%
Alcohol counseling	79.9%	95.6%	88.2%
Mental health assessment	81.1%	94.4%	88.1%

[1] Percentages are based on the number of individuals that answered each question and not the overall "n". Missing data was excluded from the denominator.

Table 2: HCV Performance Indicators – Treated Patients (N=315)

	% Co-infected[1] (n=139)	% Mono-infected[1] (n=176)	% Total[1] (N=315)
RNA testing before treatment	98.6%	86.9%	92.0%
RNA testing after treatment	81.7%	85.6%	84.1%
SVR reached	76.3%	76.8%	76.6%
Treatment adherence addressed	88.4%	98.9%	94.3%

[1] Percentages are based on the number of individuals that answered each question and not the overall "n". Missing data was excluded from the denominator.

Table 3: Sustained Virologic Response Rates[1]

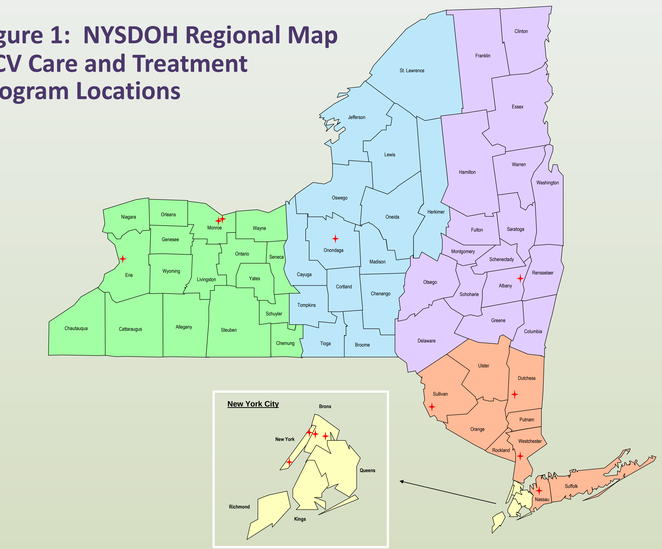
	# Treated (N=315)	% Treated	# Reached SVR (N=187)	% Reached SVR	# Reached SVR within Strata of Category[2] (N=183)	% Reached SVR within Strata of Category[2]
Gender	(n=315)		(n=187)		(n=183)	
Male	221	70.2%	126	67.4%	123	55.7%
Female	92	29.2%	59	31.6%	58	63.0%
Transgender	2	0.6%	2	1.1%	2	100.0%
Genotype	(n=311)		(n=185)		(n=181)	
Genotype 1	253	81.4%	147	79.5%	143	56.5%
Genotype 2	27	8.7%	21	11.4%	21	77.8%
Genotype 3	24	7.7%	14	7.6%	14	58.3%
Genotype 4	6	1.9%	2	1.1%	2	33.3%
Genotype 5	0	0.0%	0	0.0%	0	0.0%
Genotype 6	1	0.3%	1	0.5%	1	100.0%
Race/Ethnicity	(n=280)		(n=161)		(n=158)	
White, non-Hispanic	79	28.2%	57	35.4%	57	72.2%
Black, non-Hispanic	93	33.2%	41	25.5%	38	40.9%
Hispanic	99	35.4%	55	34.2%	55	55.6%
Other	9	3.2%	8	5.0%	8	88.9%
Fibrosis	(n=310)		(n=185)		(n=181)	
No scarring	73	23.6%	48	26.0%	47	64.4%
Minimal scarring	31	10.0%	17	9.2%	17	54.8%
Scarring	33	10.7%	22	11.9%	21	63.6%
Bridging fibrosis	35	11.3%	20	10.8%	20	57.1%
Cirrhosis	48	15.5%	20	16.8%	20	41.7%
Other	28	9.0%	16	8.9%	16	57.1%
Unknown	47	15.2%	31	16.8%	29	61.7%
Not indicated	11	3.6%	9	4.9%	9	81.8%
Patient refused biopsy	4	1.3%	2	1.1%	2	50.0%
Treatment Type	(n=313)		(n=187)		(n=183)	
Peg/Rbv/DAA	219	70.0%	131	70.0%	129	70.5%
Peg/Rbv	94	30.0%	56	30.0%	54	57.4%

[1] Restricted to chart review of "treated" patients only.
[2] Percent restricted to those who had an RNA test following treatment completion (for example, % of males who had an RNA test post treatment who reached SVR = 55.7%).

RESULTS

For the patients treated for HCV (N=315), the overall SVR rate was 76.6%, 76.8% among HCV monoinfected and 76.3% among HIV/HCV coinfected patients. Those most likely to reach an SVR were male (67.4%); Genotype 1 (79.5%); with minimal or no fibrosis (35.2%). There were no differences noted by race/ethnicity. The majority were being treated with a Direct Acting Anti-viral, i.e., Telaprevir or Boceprevir containing regimen (70 %). (Table 3)

Figure 1: NYSDOH Regional Map HCV Care and Treatment Program Locations



CONCLUSION

Highly effective HCV treatments allow more people living with HCV to be cured. However, limited capacity within specialty clinics is a barrier to accessing the treatments. The newer treatments are less complex and have fewer side effects, enabling PCPs with the knowledge and skills to successfully treat HCV in primary care settings. These results demonstrate that PCPs are able to effectively care for and treat persons infected with HCV, thus increasing access to HCV treatment beyond specialty clinics.

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