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Quality of Hepatitis C care at an urban tertiary care medical center

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Abstract

Background—More effective treatment for Hepatitis C Virus (HCV) creates an opportunity to improve health outcomes.

Objective—To use Centers for Medicare and Medicaid Services (CMS)-defined HCV quality indicators (QI) as a framework to assess the quality of care at an urban safety net hospital.

Design—Retrospective cohort.

Participants—Patients engaged in care (at least 2 outpatient visits, and minimum 6-month follow-up time) between 2005 and 2011.

Outcomes measures—1) HCV ribonucleic acid (RNA); 2) genotyping; 3) treatment; and 4) Hepatitis A and B vaccination. Study time was divided into three periods: 1) 2005-2006; 2) 2007-2008; 3) 2009-2011.

Key results—3,018 met inclusion criteria; 13% were human immunodeficiency virus co-infected. Only 1% completed CMS QI evaluated. Later time periods were independently associated with greater rates (aHR for HCV testing, 1.15; 95% CI, 1.04-1.28).

Conclusions—Quality of care is improving, but it remains suboptimal. Initiatives are needed to increase QI completion.

Keywords

Hepatitis C; HIV/AIDS; treatment; quality of care

Introduction

Hepatitis C virus (HCV) infection affects 3.8 million people in the United States (US) and it is responsible for approximately 12,000 liver disease-related deaths annually.^{1,2} Given recent improvement in treatment effectiveness and the anticipated burden of end-stage liver disease with untreated HCV, the Centers for Disease Control and Prevention (CDC) in 2012 expanded guidelines to include one-time screening for HCV among all individuals born between 1945 and 1965.³ Such recommendations will likely increase the number of individuals identified with HCV infection. Screening is only the first step, however, in a long cascade of HCV care leading ultimately to HCV therapy and potentially cure. Previous reports demonstrate that few patients with known HCV infection are treated for HCV.⁴ While new, highly effective therapies will likely increase enthusiasm for treatment among both patients and providers, significant scale-up of HCV therapy requires that those identified with HCV infection link to high-quality medical care that includes both routine assessment of HCV infection status, degree of fibrosis progression, and secondary prevention of additional hepatic insults. Despite the clear need to develop and expand the capacity to treat HCV infection, little is known about the quality of care that patients receive after linkage to- and engagement in care at urban safety net hospitals.

HCV quality indicators are included in the list of Centers for Medicare and Medicaid Services (CMS) measures.⁵ CMS-defined HCV quality indicators (QI) include confirmation of HCV infection with ribonucleic acid (RNA) testing, Hepatitis A (HAV) and B (HBV) vaccination, alcohol counseling, antiviral treatment, HCV genotype testing prior to treatment, HCV RNA testing prior to treatment and at 12 weeks, and birth control use during treatment. A study using a large U.S. health insurance company research database showed that only 18.5% of patients in their network received all recommended CMS HCV QI measures evaluated.⁶ Many HCV-infected patients, however, receive care at urban centers and do not have private insurance. Little is known about completion of CMS HCV QI at an urban medical center located in an underserved community with a high proportion of injection drug users.

Our goal was to determine the quality of care of HCV-infected patients at an urban safety net hospital. We used completion of CMS-defined HCV QI as a framework to define quality of care. Further, we evaluated measures beyond those defined by CMS, such as referral to a gastroenterologist (GI) or infectious disease (ID) specialist, and screening for hepatocellular carcinoma among patients with advanced liver fibrosis. Such data are foundational to efforts to improve the HCV care delivery system, and could inform future interventions to increase the quality of HCV care.

Methods

Setting

Boston Medical Center (BMC) is the largest safety net hospital in New England and its mission is to provide excellent and accessible care to all in need. Approximately 73% of BMC patients are from an underserved population and two-thirds are racial or ethnic minorities.

Study Design

We used the electronic medical record to construct a retrospective cohort of patients seen at BMC between 2005 and 2011 with documented HCV infection by either serology or diagnostic codes. Data elements included demographics, laboratory values, diagnostic imaging, prescriptions, and dates and locations of all clinical visits. We used the database to investigate patterns of HCV care among the cohort.

Study Population

Inclusion criteria included: (1) Current or past HCV infection, defined as either a documented reactive HCV antibody, or clinical diagnosis of HCV based on International Statistical Classification of Diseases and Related Health Problems, 9th edition (ICD-9) codes; (2) engagement in care, defined as having at least 2 outpatient visits at BMC and at least 6-months of follow-up time between January 1st, 2005, and October 31st, 2011. The aim of the analysis was to assess the quality of care for patients actively engaged with medical providers. Subjects therefore began contributing observation time at their first outpatient visit following initial documentation of HCV infection (either by HCV antibody serology or diagnostic codes) and were censored at the date of the last visit in the database.

Data collection

We extracted from the electronic medical record information on age, gender, race, laboratory values, immunization status and HCV treatment initiation.

Outcomes

Primary outcomes included CMS-defined HCV QI including: 1) HCV RNA testing for patients with reactive HCV antibody; 2) HCV genotype testing for patients with positive HCV RNA; 3) HCV treatment for patients with HCV viremia; and 4) HAV and HBV vaccination or documentation of immunity for all HCV-infected patients. We investigated these outcomes throughout the entire study period and we also determined the proportion of patients who completed all five quality measures evaluated. We defined HCV antiviral treatment initiation as the presence of a prescription for pegylated-interferon alfa and ribavirin on the medication list. We defined HAV and HBV vaccination as receiving at least one dose of HAV or HBV vaccine. We considered patients to be immune to HAV if reactive HAV antibody was documented in the record. Likewise, we considered patients immune to HBV if reactive HBV surface antibody was documented. We did not include two other CMS QI (birth control during treatment and alcohol use counseling), as we could not obtain these data with our data extraction method.

Secondary outcomes included quality metrics based on the American Association for the Study of Liver Diseases (AASLD) HCV care guidelines: 1) evaluation by either a gastroenterologist (GI) or infectious diseases (ID) specialist; 2) hepatic fibrosis staging for patients with known chronic HCV infection; and 3) screening for hepatocellular carcinoma (HCC) in patients with cirrhosis.⁷

Hepatic fibrosis staging—We determined the number and percentage of patients with HCV viremia who underwent either liver biopsy, liver ultrasound, or commercially available serum testing to stage liver fibrosis (FIBROSpect II®, Prometheus Laboratories, San Diego, California) or FibroSURE™ (Laboratory Corporation of America, Raritan, NJ, United States).

Screening for hepatocellular carcinoma (HCC)—As HCC screening is recommended only for those with cirrhosis⁷, we first identified patients with advanced liver disease, and then determined the rate of HCC screening among them. As few patients in the cohort ever underwent liver biopsy, we performed sensitivity analyses where we identified those with advanced fibrosis using four alternative methods including: 1) FIB-4 index; 2) aspartate aminotransferase (AST)-to-platelet ratio (APRI) index; 3) age ≥ 50 (as injection drug users infected in their 20s would likely have significant fibrosis by age 50); and 4) cirrhosis identified on the problem list. FIB-4 and APRI are non-invasive tests assessing hepatic fibrosis by combining commonly available biochemical parameters.^{8,9} FIB-4 is calculated using the following formula: $\text{age (years)} \times \text{AST level [U/L]} / (\text{platelets [10}^9\text{/L]} \times (\text{ALT [U/L]})^{1/2})$. FIB-4 index greater than 3.25 is an indication of significant fibrosis.⁸ APRI is determined using the following formula: $(\text{AST [U/L]} / \text{platelets [10}^9\text{/L]}) \times 100$. APRI index greater than 1.50 corresponds to significant fibrosis.⁹ We defined screening for HCC as having at least 1 liver ultrasound, magnetic resonance imaging (MRI), or alpha fetoprotein (AFP) performed after HCV diagnosis.

Subspecialist evaluation—We also compared completion of QI between patients who were seen by a subspecialist with those without subspecialist evaluation. Subspecialist evaluation was determined by reviewing outpatient clinic registration data for visits with gastroenterologists or infectious disease specialists after HCV diagnosis. Exposure variables included in the analyses were age at baseline, gender, race, insurance type (private vs. public), HIV infection diagnosed either by reactive serology testing or noted on the problem list, birthplace (U.S. vs. foreign born), and history of substance abuse or psychiatric illness identified on the problem list, time period (Time Period 1=2005-2006, Time Period 2=2007-2008, and Time Period 3= 2009- 2011).

Statistical analyses

We used descriptive statistics to determine the proportion of patients with each outcome (eg., vaccination or confirmation of HCV RNA testing). Variables significant in univariate analysis and potential confounders were subsequently included in Cox proportional hazards modeling. We divided the study time into 3 periods: 1) 2005-2006; 2) 2007-2008 and 3) 2009-2011 for the analysis. Given that we had seven years of observation, the study time was divided into two periods of two years and one of three years. We used hazard ratios

with 95% confidence intervals and all p-value significance levels were two-sided. Statistical analyses were performed with STATA 12 (STATA, College Station, TX).

Ethics Statement

The Boston University Medical Center Institutional Review Board approved this study.

Results

5,495 patients with either reactive HCV serology or ICD-9 for HCV were identified. Of those, 264 patients were never seen again at BMC and 2,213 did not meet the follow-up time or age required for inclusion (Figure 1). 3,018 subjects met inclusion criteria and contributed a median of 31 months of follow-up time (interquartile range 18 to 51 months) (Table 1). The cohort was composed predominantly of males (62%); 48% were White, 29% Black, 17% Latino, 3% Asian and 3% other/unknown. 406 (13%) were HIV co-infected. 618 (20%) were foreign born, while 53% had a history of substance abuse and 28% had psychiatric history.

Primary Outcomes

2,065 (68%) underwent HCV RNA testing between 2005 and 2011 (Table 2). Of the 1,659 patients with detectable viremia, 620 (37%) had genotype performed and 285 (17%) initiated treatment for HCV infection. 461 (15%) and 852 (28%) were vaccinated or had documented immunity to HAV and HBV, respectively. Only 20 (1%) completed all five QI evaluated (Table 2).

Factors associated with completion of HCV QI—We separately evaluated factors associated with the completion of five CMS-defined QI: 1) HCV RNA testing; 2) HCV genotype testing for patients with HCV viremia; 3) HCV treatment for patients with HCV viremia; 4) HAV and 5) HBV vaccination or documented immunity. Age, Black race/ethnicity, private insurance and diagnosis during time period 2 (2007-2008) and time period 3 (2009-2011) were independently associated with completion of HCV RNA PCR testing in multivariable analyses controlling for age, gender, race, insurance type, substance use, psychiatric history, HIV status, birthplace and time period (Table 3 and Supplementary Tables 1-4).

Secondary Outcomes

Of the 2,065 patients who underwent HCV RNA testing, 1,659 (80%) had detectable viremia, and 56% of those with detectable viremia were seen by a subspecialist (GI or ID). Those seen by a subspecialist were more likely to have HAV vaccination, HBV vaccination, and HCV genotyping performed (Table 4). Among those seen by subspecialists, HAV vaccination, HBV vaccination and HCV genotyping were completed prior to subspecialist evaluation in 18%, 28% and 6%, respectively. We also determined that by the last subspecialist visit available, rates of completion for HAV vaccination, HBV vaccination and genotyping increased to 99%, 99% and 96%, respectively.

1,131 patients (55%) had disease staging with either MRI, ultrasound or commercially available serum testing for liver fibrosis. 369 patients had laboratory assessment allowing FIB-4 calculation and 552 had adequate data to calculate APRI. Of those, 199 patients had a FIB-4 index or APRI compatible with cirrhosis. Of those with cirrhosis based on FIB-4, 152 (76%) had HCC screening performed while 78 (46%) with cirrhosis based on APRI had evaluation for possible HCC. Of the 144 patients who had cirrhosis on their problem list, 92% had HCC screening performed. We identified 1,093 patients who were 50 years old or greater. Of those, 631 (58%) had HCC screening.

Discussion

Advances in HCV therapy have created increased enthusiasm for screening. The CDC has revised HCV screening guidelines to include one-time screening of those born between 1945 and 1965. For enhanced screening efforts to be clinically beneficial, however, patients identified need access to standard of care practice. This analysis demonstrates that at a large, urban, safety net hospital and academic medical center, completion of CMS-defined quality measures has been improving over time; however, only 1% received high-quality care as defined by the CMS metrics evaluated. In multivariable modeling, age, Black race/ethnicity, private insurance and time periods between 2007-2008 and 2009-2011 were independently associated with higher quality. Exploration of additional quality metrics based on American Association for the Study of Liver Diseases (AASLD) recommendations revealed that when providers were aware that a patient was cirrhotic, as evidenced by the inclusion of “cirrhosis” on the problem list, nearly all patients received at least one screening for HCC, however a substantial proportion of patients with laboratory evidence of advanced liver disease (24-54%) never received HCC screening.

This analysis adds to a limited body of evidence suggesting that HCV-infected patients receive less than optimal HCV care. Prior studies have focused on patients with private insurance⁶ or among patients followed in the Veteran Affairs (VA) system.^{10,11} Many HCV-infected individuals, however, do not have private health insurance and rely on safety net hospitals like BMC for care. Our study describes a large, diverse urban population with over 3,000 HCV-infected patients who are engaged in care, and likely better reflects the experience of patients at large, urban hospitals. We found that only 1% of HCV-infected individuals received HCV QI evaluated compared with 18% in the previous study conducted among patients with private insurance.⁶ Of note, the previous study used a more stringent definition of “quality care,” including the criteria used in this analysis, plus receipt of antiviral therapy and testing for HCV RNA after 12 weeks of therapy. We elected not to include HCV treatment in this analysis because HCV treatment was marginally effective throughout the study period. As a result, many patients who received excellent quality care may have chosen to defer therapy until such a time that more easily tolerated regimens were available. Despite the more difficult to attain definition of “quality” in the previous study, however, patients in that private insurance network were nearly 20 times more likely to receive high quality care than those patients in this study.

Our data revealed higher completion of QI in later years. This observation might be related to the dissemination of new findings on more effective therapies and the increasing evidence

of the burden of HCV disease. It is likely that findings became more widespread during later time periods.

Nevertheless, improving adherence to certain quality indicators such as treatment initiation will require additional patient education to overcome the negative reputation of interferon-based treatment. Interferon-free treatment with recently published findings suggesting a more favorable side-effect profile might increase the rate of treatment acceptance and thus adherence to this quality indicator.¹²

Although two-thirds of the hospital population are racial/ethnic minorities, the largest racial/ethnic group was white patients who accounted for 48% of the cohort. This discrepancy might be related to the racial make-up of the HCV-infected population in the state. Information from the State Department of Public Health reports that the HCV-infected population in the state is predominantly white.¹³ It is also possible that white patients were more likely to be engaged in care and therefore were more likely to be included in the cohort.

After multivariable adjustment, we also found that patients who had been seen by a subspecialist were more likely to have QI completed (Table 4). In addition, we also found that rates of QI completion increased after subspecialist evaluation. Generalists might be less likely to adhere to QI measures because they must simultaneously address multiple comorbidities, making it difficult to prioritize HCV. Recognizing that there is currently limited capacity in the U.S. to provide HCV therapy, some have called for the development of models to treat HCV in primary care.¹⁴⁻¹⁶ Our results, however, raise a cautionary note that subspecialist attention is associated with higher quality HCV care. Developing multidisciplinary approaches that include subspecialists is, therefore, important to expanding HCV care capacity in the U.S. Indeed, previous work such as the Extension for Community Healthcare Outcomes (ECHO) project demonstrates that such collaborative approaches are successful.^{15,16}

It is also notable that in our study private insurance was associated with completion of HCV RNA testing, HAV vaccination and treatment initiation. This was surprising in a health care system where providers are not reimbursed based on insurance type. This might be explained by unmeasured confounding that we were not able to control for in our analysis. For example, those with private insurance might have been more likely to be employed and live in a social environment more conducive to retention in care. In addition, patients with public insurance might have social stressors affecting their engagement in care. For instance, this group might have childcare or transportation issues that might limit their ability to present for follow-up visits.¹⁷ We also found an association between Black race/ethnicity and increased RNA PCR testing. Improved outcomes seen among Black patients might be related to the social services programs available at the hospital. There is an extensive program including medical case managers, patient navigators and social workers who reach out to groups traditionally known to be at high-risk.¹⁸

There are limitations to our study. First, the data were collected at a single site and might not be generalizable to other health care settings. Nevertheless, it is notable that our hospital is

similar to other large urban tertiary care centers with similar underserved patient populations. Secondly, our findings depend on accurate physician documentation and we could not account for testing performed at other facilities that might not have been well-documented in the medical record. Thirdly, we were also not able to capture the impact of factors such as patient treatment refusal that might have influenced our findings. We were not able to assess the refusal rate given our method of data abstraction and it is possible that patients with private insurance might be more likely to be engaged and follow through with care. Lastly, as our data abstraction method did not involve an extensive review of physician notes, we could not report on CMS-defined quality measures such as alcohol counseling.

This analysis demonstrates that while the quality of HCV care has improved over time, it remains suboptimal at an urban safety net hospital. As highly effective HCV therapies become available, interventions are needed to increase the proportion of patients who receive HCV disease staging, appropriate vaccinations, and surveillance for HCC, such that they are prepared to initiate HCV treatment. As completion of quality measures was greater for patients seen by a subspecialist, a multidisciplinary approach involving primary care physicians and subspecialists might improve outcomes. Future studies are needed to identify potential intervention strategies, and to address barriers to improving the quality of HCV care.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Study Flow diagram
HCV: Hepatitis C Virus

Table 1

Baseline characteristics

Characteristics	(N=3,018) N (%)
Age at HCV diagnosis	
Mean (SD)	45 (12)
Median	46
Range	(18-89)
Male	1,879 (62)
Race/Ethnicity	
White	1,447 (48)
Black	863 (29)
Latino	526 (17)
Asian	106 (3)
Other/Unknown	76 (3)
Insurance	
Public	1,986 (66)
Private	825 (27)
Other/Unknown	207 (7)
History of substance abuse	1,597 (53)
History of psychiatric illness	836 (28)
History of HIV infection	406 (13)
Birth place	
US	2,395 (79)
Non US	618 (20)
Unknown	5 (1)
No. visits after diagnosis	
Mean	17
Median	10
Range	(2-240)
Follow-up time, months	
Mean	35
Median	31
IQR	(18-51)

HCV: Hepatitis C; HIV: Human Immunodeficiency Virus; SD: standard deviation; US: United States; IQR: interquartile range.

Table 2

Completion of Centers for Medicare and Medicaid Services Hepatitis C quality indicators

Quality Indicators	Total N (%)
General Care	(N=3,018)
Confirmation using RNA PCR	2,065 (68)
Hepatitis A vaccination or immunity	461 (15)
Hepatitis B vaccination or immunity	1,092 (36)
Hepatitis A and Hepatitis B vaccination or immunity	324 (11)
Treatment-related care	(N=1,659) [†]
Treatment if viremia present	286 (17)
Genotype testing if viremia present	620 (37)
	(N=286) [‡]
Genotype testing if treated	88 (31)
Number of quality indicators	(N=3,018)
Any one	2,334 (77)
Any two	1,420 (47)
Any three	636 (21)
Any four	213 (7)
Any five	21 (1)

HCV: Hepatitis C

RNA PCR: ribonucleic acid polymerase chain reaction

[†]Total Number of patients with viremia[‡]Total number of patients treated

Table 3

Factors associated with Hepatitis C RNA PCR testing

Predictors	Univariate Hazard Ratio (95% CI)	Univariate p-value	Adjusted Hazard Ratio (95% CI)	Adjusted p-value
Age	0.99 (0.98-1.0)	.04	0.99 (0.98-1.00)	.005
Gender (Male vs. Female)	1.10 (0.94-1.29)	.25	1.06 (0.97-1.16)	.20
Race				
White	Reference	--	--	--
Asian	1.20 (0.78-1.84)	.41	1.12 (0.86-1.47)	.40
Black	1.26 (1.05-1.52)	.01	1.23 (1.11-1.38)	<.001
Latino	1.39 (1.11-1.73)	.004	1.09 (0.93-1.29)	.26
Other	0.68 (0.42-1.08)	.10	0.89 (0.65-1.23)	.48
Substance use	1.27 (1.09-1.48)	.003	1.08 (0.98-1.20)	.11
Psychiatric history	1.08 (0.91-1.28)	.38	0.94 (0.85-1.05)	.29
HIV	1.02 (0.81-1.27)	.89	0.99 (0.87-1.12)	.84
Birthplace				
US	Reference	--	--	--
Non-US	1.16 (0.95-1.40)	.14	1.05 (0.91-1.24)	.48
Unknown	1.90 (0.21-17.05)	.57	1.90 (0.71- 5.08)	.45
Insurance				
Public	Reference	--	--	--
Private	1.21 (1.01-1.44)	.04	1.15 (1.04-1.27)	.01
Other/Unknown	0.95 (0.7-1.28)	.72	1.08 (0.90-1.30)	.39
Period				
2005-2006	Reference	--	--	--
2007-2008	0.86 (0.71-1.04)	.12	1.15 (1.04-1.28)	.01
2009-2011	0.55 (0.45-0.66)	<.001	1.31 (1.16-1.47)	<.001

HIV: human immunodeficiency virus; RNA PCR: ribonucleic acid polymerase chain reaction; US: United States.

Table 4

Completion of Hepatitis C quality indicators among patients seen by subspecialist vs. those without subspecialist evaluation.

Quality Measure	Univariate Odds Ratio (95% CI)	Univariate p-value	Adjusted Odds Ratio [†] (95% CI)	Adjusted p-value
Hepatitis A vaccination or immune in patients with viremia	3.40 (2.75-4.21)	<.001	3.05 (2.29-4.06)	<.001
Hepatitis B vaccination or immune in patients with viremia	1.61 (1.28-2.03)	<.001	2.16 (1.58-2.97)	<.001
Genotype testing in patients with viremia	3.21 (2.68- 3.85)	<.001	2.22 (1.76-2.80)	<.001

[†] Controlling for age, gender, race, HIV status, substance use, psychiatric history and birthplace. HCV treatment was not included given collinearity between subspecialist evaluation and treatment.