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MAJOR ARTICLE

The Hepatitis C Care Cascade During the Direct-Acting Antiviral Era in a United States Commercially Insured Population

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Background. Periodic surveillance of the hepatitis C virus (HCV) care cascade is important for tracking progress toward HCV elimination goals, identifying gaps in care, and prioritizing resource allocation. In the pre-direct-acting antiviral (DAA) era, it was estimated that 50% of HCV-infected individuals were diagnosed and that 16% had been prescribed interferon-based therapy. Since then, few studies utilizing nationally representative data from the DAA era have been conducted in the United States.

Methods. We performed a cross-sectional study to describe the HCV care cascade in the United States using the Optum de-identified Clinformatics® Data Mart Database to identify a nationally representative sample of commercially insured beneficiaries between January 1, 2014 and December 31, 2019. We estimated the number of HCV-viremic individuals in Optum based on national HCV prevalence estimates and determined the proportion who had: (1) recorded diagnosis of HCV infection, (2) recorded HCV diagnosis and underwent HCV RNA testing, (3) DAA treatment dispensed, and (4) assessment for cure.

Results. Among 120,311 individuals estimated to have HCV viremia in Optum during the study period, 109,233 (90.8%; 95% CI, 90.6%–91.0%) had a recorded diagnosis of HCV infection, 75,549 (62.8%; 95% CI, 62.5%–63.1%) had a recorded diagnosis of HCV infection and underwent HCV RNA testing, 41,102 (34.2%; 95% CI, 33.9%–34.4%) were dispensed DAA treatment, and 25,760 (21.4%; 95% CI, 21.2%–21.6%) were assessed for cure.

Conclusions. Gaps remain between the delivery of HCV-related care and national treatment goals among commercially insured adults. Efforts are needed to increase HCV treatment among people diagnosed with chronic HCV infection to achieve national elimination goals.

Keywords. hepatitis C elimination; HIV/HCV coinfection; cascade of care; health claims database; hepatitis C monitoring.

Over 2 million people in the United States are chronically infected with hepatitis C virus (HCV) [1, 2]. If left untreated, chronic HCV infection can result in cirrhosis, hepatic decompensation, and hepatocellular carcinoma [3]. The availability of 8- to 12-week, all-oral, direct-acting antiviral (DAA) regimens beginning in 2014 changed the paradigm of HCV treatment. DAAs are well-tolerated and highly curative therapies that can reduce HCV transmission, decrease the risk of HCV-associated morbidity and mortality, and eliminate HCV infection [4, 5]. Recognizing the unique opportunity to cure HCV, the World Health Assembly formulated a global action plan to eliminate HCV as a public health threat by 2030 with the goal of diagnosing 90% of persons with HCV and treating 80% by 2030 [6]. In response to this global initiative, the United States created its own national action plans [7–9] and in January 2021, developed the Viral Hepatitis National Strategic Plan to provide a framework for HCV elimination in the United States by 2030 [10].

The HCV care cascade is a tool used to monitor the delivery of HCV-related care in various settings and is important for monitoring progress toward HCV elimination goals [11, 12]. Existing US national care cascade data are primarily from the pre-DAA era, during which it was estimated that of the 3.5 million people with chronic HCV infection in the United States, 50% were diagnosed and 16% had been prescribed interferon (IFN)-based therapy [11, 12]. Since the introduction of DAA

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therapy, the US Preventive Services Task Force (USPSTF) has updated their guidelines to recommend universal one-time HCV screening [13], access to the US Medicaid program has expanded [14], and availability of HCV treatment has increased nationally [15, 16]. Although HCV care cascades have been reported for various local and state-wide health systems in the United States and HCV-related care metrics have been evaluated using administrative claims databases [15, 17–22], nationally representative data during the DAA era have been limited. Moreover, data describing the HCV care cascade among people with HIV (PWH) in the United States have been limited to single center [23–25] and interval HIV cohort studies [26, 27]. Consequently, there is an immense need to describe the current HCV care cascade in the United States to identify existing gaps in HCV-related care, promote multi-stakeholder involvement and collaboration, and target the allocation of health resources.

In this study, we utilized the Optum de-identified Clinformatics® Data Mart Database to describe the HCV care cascade within a nationally representative sample of commercially insured US adults during the DAA era from 2014 to 2019. We also describe the HCV care cascade among PWH during this period.

METHODS

Study Design and Data Source

We conducted a cross-sectional study using healthcare claims of adult beneficiaries in the Optum de-identified Clinformatics® Data Mart Database (OptumInsight, Eden Prairie, MN, USA) between January 1, 2014 and May 31, 2020. Optum is a national administrative healthcare database that contains claims data for commercially insured beneficiaries from a large US insurer that enrolls >15 million individuals annually. Optum contains claims data for individuals with both medical and prescription coverage and is ideal for evaluating the HCV care cascade because it: (1) serves as a comprehensive source of healthcare information for a large group of commercially insured individuals in the United States, (2) includes a population that is geographically diverse, and (3) includes claims for medical diagnoses (recorded using International Classification of Diseases, Ninth or Tenth Revision [ICD-9/-10] codes), procedures (recorded using Current Procedural Terminology [CPT] and Healthcare Common Procedure Coding System [HCPCS] codes), and dispensed drugs (identified by National Drug Codes [NDC]). This study was approved by the University of Pennsylvania institutional review board.

Study Patients

Optum health plan members were eligible for study inclusion if they were at least 18 years of age and had at least 12 months of continuous enrollment between January 1, 2014 and December 31, 2019. Individuals with multiple periods of continuous enrollment were included after meeting the qualifying continuous 12-month minimum.

Main Study Outcomes

The primary outcomes were the proportion of individuals estimated to have HCV viremia in Optum who had: (1) recorded diagnosis of HCV infection (defined as the presence of ≥1 hospital or ≥2 outpatient ICD-9/-10 diagnoses of acute, chronic, or unspecified HCV [Supplementary Table 1] during the study period, which has been shown to have a >88% positive predictive value [PPV] for identifying HCV infection [28, 29]); (2) recorded diagnosis of HCV infection and underwent HCV RNA testing (to identify patients potentially linked into HCV care) based on at least one HCV RNA CPT or HCPCS code (which has been shown to have PPVs ranging between 82–86% for confirmed chronic HCV infection in claims data [30]); (3) at least one dispensing for DAA treatment (determined by NDC codes); and (4) assessment for cure of HCV infection based on HCV RNA CPT or HCPCS codes recorded ≥12 weeks after the end of the DAA regimen's days' supply.

Study Data

We collected the following information for the analyses: date of birth, diagnoses of HCV infection and HIV infection (defined by ≥1 hospital or ≥2 outpatient ICD-9/-10 diagnoses of HIV [Supplementary Table 1] [31]), HCV RNA CPT and HCPCS codes (Supplementary Table 2), and pharmacy claims for DAA treatments determined via NDC codes (Supplementary Table 3), including dates dispensed and days supplied. NDC codes were identified using Lexicon Plus (Cerner Corporation, Kansas City, KS, USA).

Statistical Analysis

Primary Analysis: Overall HCV Care Cascade

We estimated the proportion and 95% CI (Wald interval) for each step of the HCV care cascade within Optum as follows:

Step 1: Since birth year is a major determinant of HCV prevalence, to estimate the number of individuals with HCV viremia between January 1, 2014 and December 31, 2019, we first stratified eligible individuals into the following three birth cohorts: (1) born before 1945, (2) born between 1945 and 1969, and (3) born after 1969 [32]. We then estimated the number with HCV viremia within each birth cohort by multiplying the number of eligible Optum beneficiaries in that birth cohort by the previously published HCV prevalence estimate: 0.0021 (0.21%) for those born before 1945, 0.0163 (1.63%) for those born between 1945 and 1969, and 0.0051 (0.51%) for those born after 1969 [32]. These prevalence estimates were generated using statistical modeling and multiple data sources, including the National Health

and Nutrition Examination Survey (NHANES), National Vital Statistics System data, and external literature to capture high-risk populations (ie, individuals who inject drugs, are homeless, or are incarcerated) [32]. To accurately estimate the prevalence of HCV viremia in a commercially insured sample, we then additionally adjusted each birth cohort estimate of HCV viremia by a weight that represented the reported prevalence of HCV viremia among persons with private insurance in NHANES 2015–2018 (prevalence = 0.59) divided by the prevalence of HCV viremia in the total population in NHANES 2015–2018 (prevalence = 0.96) for a weight of 0.61 [33]. The sum of the estimates of prevalence of HCV viremia in these birth cohorts served as the denominator for calculating the proportions in Steps 2–5.

Step 2: We calculated the proportion of patients with HCV viremia who had a recorded diagnosis of HCV infection between January 1, 2014 and December 31, 2019.

Step 3: We calculated the proportion of patients with HCV viremia who had both a recorded diagnosis of HCV infection and underwent confirmatory HCV RNA testing between January 1, 2014 and December 31, 2019.

Step 4: We calculated the proportion of patients with HCV viremia who were dispensed at least one fill for a DAA between January 1, 2014 and May 31, 2020. We evaluated for DAA fills through May 31, 2020 to minimize the likelihood of missing dispensed DAA treatments among individuals who may have been diagnosed with HCV toward the end of our study period. If individuals were dispensed more than one treatment course, only the first course was analyzed.

Step 5: We calculated the proportion of patients with HCV viremia who were assessed for sustained virologic response ≥12 weeks after completing DAA therapy (SVR12) between January 1, 2014 and May 31, 2020. We also determined the proportion of individuals who were tested for cure ≥4 weeks after the end of the last DAA prescription's days' supply to minimize the likelihood of missing individuals tested for cure within 12 weeks of completing DAA therapy.

Secondary Analysis: HCV Care Cascade Among PWH

We described the HCV treatment cascade among PWH. We estimated the number of PWH who had HCV coinfection by multiplying the number of persons diagnosed with HIV by 0.15 (15%), which represented the approximate prevalence of HCV infection among PWH during the study period [34, 35]. To accurately estimate the prevalence of HCV viremia in a sample of commercially insured PWH, we additionally adjusted the estimate of HCV viremia among PWH by a weight that represented the prevalence of HCV among persons with private insurance in NHANES 2015–2018 (prevalence = 0.59) divided by the prevalence of HCV viremia in the total population in NHANES 2015–2018 (prevalence = 0.96) for a weight of 0.61 [33]. This estimate of the number of PWH who had HCV coinfection served as the denominator for calculating the proportions in steps 2 through 5 above.

RESULTS

Study Population

Between January 1, 2014 and December 31, 2019, there were 41,764,118 individuals with any healthcare coverage during the study period, of whom 21,838,227 met inclusion criteria (Figure 1). The study population had a median length of continuous enrollment of 2.7 (interquartile range [IQR]: 1.7–4.2) years. The median age of the sample was 48 (IQR: 32–65) years; 51.5% were female, and 15% percent were born before 1945, 38.5% were born between 1945–1969, and 46.5% were born after 1969. Of the 21,838,227 beneficiaries who met inclusion criteria, 120,311 (0.55%) were estimated to have HCV viremia based on national HCV prevalence estimates by birth cohort and insurance status. The adult beneficiaries excluded for having <1 year of continuous coverage had a median length of continuous enrollment of 190 (IQR: 91–305) days; median age of 40 (IQR: 26–55) years; 50.0% were female; and 5.8% were born before 1945, 32.3% were born between 1945–1969, and 46.5% were born after 1969.

Overall HCV Care Cascade

Among the 120,311 adult beneficiaries estimated to have HCV viremia, 109,233 (90.8%; 95% CI, 90.6%–91.0%) had a recorded diagnosis of HCV infection, 75,549 (62.8%; 95% CI, 62.5%–63.1%) had both a recorded diagnosis of HCV infection and underwent HCV RNA testing, 41,102 (34.2%; 95% CI, 33.9%–34.4%) had DAA treatment dispensed, and 25,760

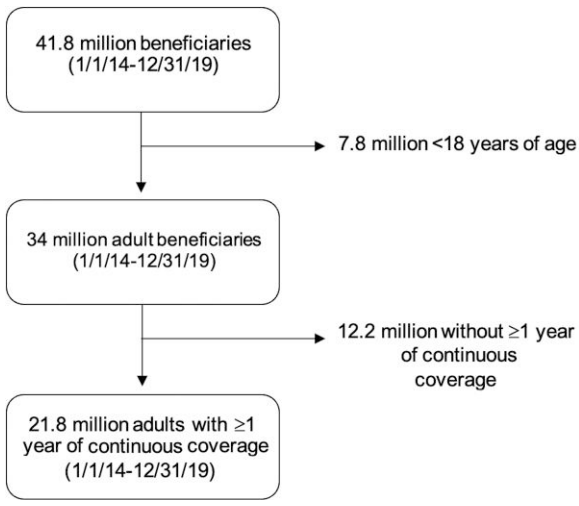

Figure 1. Selection of eligible health plan members within the Optum de-identified Clinformatics® Data Mart Database between January 1, 2014 and December 31, 2019.

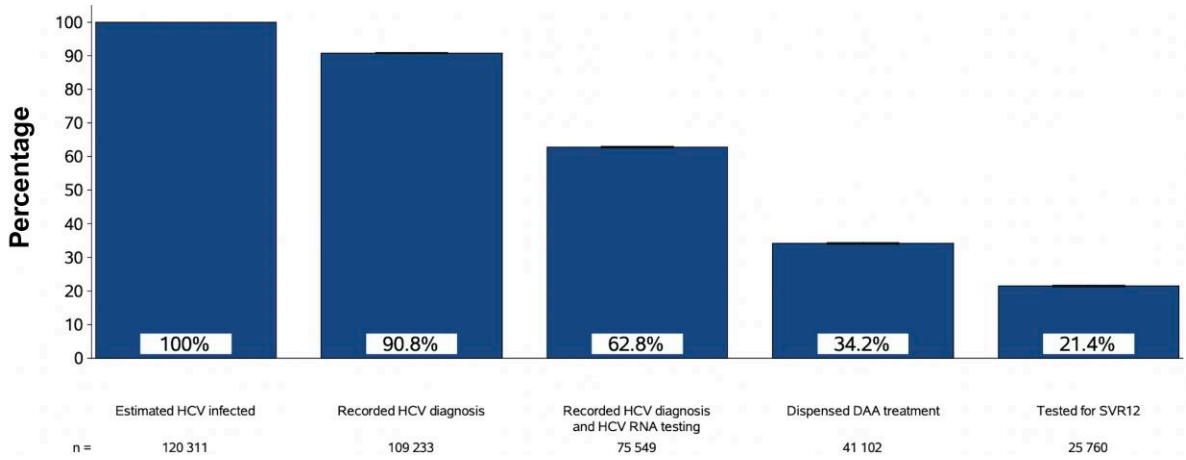

Figure 2. Hepatitis C care cascade within the Optum de-identified Clinformatics® Data Mart Database between January 1, 2014 and December 31, 2019. The proportion dispensed direct-acting antiviral therapy and assessed for sustained virologic response was determined through May 31, 2020. Bars indicate 95% CI. Abbreviations: DAA, direct-acting antiviral; HCV, hepatitis C virus; SVR12, sustained virologic response ≥12 weeks after completing therapy.

(21.4%; 95% CI, 21.2%–21.6%) were tested for SVR ≥12 weeks after completion of their DAA treatment regimen (Figure 2).

Of the 41,102 individuals dispensed DAA therapy, 62.7% (25,760) were tested for SVR ≥12 weeks after completion of their HCV treatment regimen, and an additional 2,747 individuals had HCV RNA testing 4–12 weeks after the end of therapy. Among the 41,102 individuals dispensed DAA therapy between January 1, 2014 and May 31, 2020, 54.8% were dispensed sofosbuvir/ledipasvir, 15.6% were dispensed sofosbuvir/velpatasvir, 12.2% were dispensed glecaprevir/pibrentasvir, 9.1% were dispensed sofosbuvir, and 8.3% were dispensed other DAAs; 94.6% were dispensed at least 8 weeks of DAA therapy.

HCV Care Cascade Among PWH

Between January 1, 2014 and December 31, 2019, there were 53,946 PWH identified in Optum, of whom 4,973 (9.2%) were estimated to have HCV coinfection. Among these persons, 3,915 (78.7%; 95% CI, 77.6%–79.9%) had a recorded diagnosis of HCV infection, 2,798 (56.3%; 95% CI, 54.9%–57.6%) had both a recorded diagnosis of HCV infection and underwent HCV RNA testing, 1,357 (27.3%; 95% CI, 26.0%–28.5%) were dispensed DAA therapy, and 1,001 (20.1%; 95% CI, 19.0%–21.2%) were tested for SVR12 (Figure 3).

DISCUSSION

In this study, we identified gaps between the current delivery of HCV-related care and national treatment goals among a commercially insured US population, with the largest drop-off observed in the treatment of HCV-infected individuals. We also identified similar gaps in the current delivery of HCV-related care among PWH and found that the proportions diagnosed and dispensed DAA treatment are suboptimal for achieving HCV elimination goals among HIV/HCV-coinfected individuals. Our study highlights multiple opportunities for improving HCV-related care, particularly with regards to treatment of HCV, which is critical for HCV elimination.

In this sample of commercially insured individuals, we found that the largest gap in HCV-related care was in the initiation of HCV treatment. Despite the availability of highly efficacious and safe DAA regimens, only 34% of adult beneficiaries estimated to have HCV viremia were dispensed DAA therapy. This estimate is similar to the 35% prevalence of DAA treatment initiation recently reported in a separate sample of recipients of private insurance in HealthVerity, a nationwide administrative claims database [36]. Our estimates are also similar to several other studies that utilized administrative claims to describe HCV care delivery during the DAA era, with any differences likely due to differences in study design [15, 21, 30]. While our findings reflect an improvement in HCV treatment since the pre-DAA era, they also highlight the critical need to expand treatment access among HCV-infected individuals to meet national HCV elimination goals. Treatment expansion will require eliminating insurer-related barriers to DAA therapy, integrating HCV treatment into primary care settings, and continuing to identify HCV-infected individuals and linking them into care. Lastly, a key target for HCV elimination in the United States will be expansion of DAA access and treatment of high-risk populations, such as persons who inject drugs, are incarcerated, or are homeless.

We also found that a proportion of health plan members with HCV remained undiagnosed from 2014 to 2019. In our study, 91% of individuals estimated to have HCV viremia had a recorded diagnosis of HCV infection and 63% had both a recorded HCV diagnosis and confirmatory HCV RNA testing. This is an improvement from the pre-DAA era, when

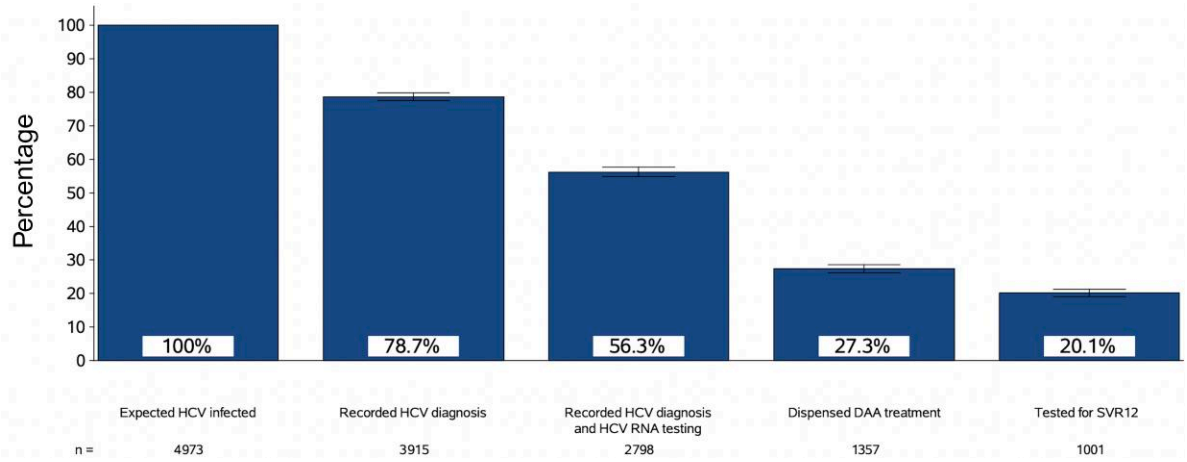

Figure 3. Hepatitis C care cascade for people with HIV coinfection within the Optum de-identified Clinformatics® Data Mart Database between January 1, 2014 and December 31, 2019. The proportion dispensed direct-acting antiviral therapy and assessed for sustained virologic response was determined through May 31, 2020. Bars indicate 95% CI. Abbreviations: DAA, direct-acting antiviral; HCV, hepatitis C virus; SVR12, sustained virologic response ≥12 weeks after completing therapy.

50% of persons with HCV infection were diagnosed and only 27% completed confirmatory HCV RNA testing [11]. Our findings are consistent with reported increases in HCV diagnosis seen in previous studies [15, 37, 38].

We chose to identify health plan members with a recorded HCV diagnosis based on ICD-9/10 diagnosis codes given the possibility that HCV-infected individuals may have completed HCV RNA testing out-of-network or before our study period. To classify HCV diagnosis, we used a previously validated algorithm that has been shown to have >80% PPV for a confirmed HCV diagnosis [28, 30, 39]. We also identified those with a recorded HCV diagnosis who underwent confirmatory HCV RNA testing to serve as a proxy for linkage to care. While we were unable to determine the proportion who were truly viremic given the absence of available laboratory data, we suspect that a high proportion are viremic in the presence of at least 2 outpatient HCV diagnosis codes. Our findings are likely reflective of improved HCV screening initiatives, including birth cohort HCV screening recommendations and use of electronic medical record alerts for HCV testing. However, continued attention to HCV diagnosis and linkage into care will be necessary to achieve HCV elimination. To this end, in 2020, the USPSTF and US Centers for Disease Control and Prevention recommended one-time HCV screening in all adults [13], but other initiatives such as state-mandated screening and opt-out screening in acute care settings could further improve HCV diagnosis nationally [40, 41].

Because HIV/HCV coinfection represents a high-risk subgroup, we conducted a separate analysis to evaluate the HCV care cascade among PWH in Optum. Despite the increased risk of liver complications among persons with HIV [42], we found that HIV/HCV-coinfected individuals had lower proportions of HCV diagnosis, HCV RNA testing, and HCV treatment than those without HIV. Notably, only 27% of beneficiaries with HIV and HCV coinfection were dispensed DAA treatment through May 2020. It is challenging to make direct comparisons with other studies, as prior analyses were limited to single center [23–25] and interval cohort studies [26, 27]. Possible explanations for the low prevalence of HCV treatment initiation might include lower engagement in medical care among PWH, variable access to subspecialty care, and concern for DAA–antiretroviral drug interactions. However, it is possible that we might have inaccurately estimated the prevalence of HCV coinfection, as its prevalence in commercially insured PWH is unknown; however, we did adjust our estimates for the prevalence of HCV viremia among persons with private insurance [33]. Furthermore, we might have incompletely captured HCV treatment if DAAs were obtained outside of their commercial health plan, such as through AIDS Drug Assistance Programs. Our findings underscore the need for further analyses to evaluate the HCV care cascade among PWH, including accurately determining the prevalence of HIV/HCV coinfection nationally and by insurance type.

Our study has several potential limitations. First, we may have inaccurately estimated the prevalence of HCV infection in our sample. We utilized national birth cohort HCV prevalence estimates to estimate the prevalence of HCV infection by birth cohort [32]. Moreover, as high-risk populations with HCV viremia may not be well represented in our commercially insured sample, we additionally adjusted the birth cohort estimates of HCV viremia by a weight accounting for the reported prevalence of HCV viremia among persons with private insurance during the DAA era (NHANES 2015–2018) [33]. However, if beneficiaries changed insurers or had dual coverage with Medicare, their HCV-related care might not have been captured in Optum.

Second, the use of claims may have resulted in misclassification of HCV or HIV infection. Additionally, the lack of sufficient laboratory testing to confirm HCV viremia among those tested may have resulted in misclassification bias. While historically around 70% of HCV-seropositive individuals are viremic, we suspect that individuals who have at least 2 outpatient HCV diagnosis codes have a higher likelihood of being viremic.

Third, the low prevalence of HIV infection in our study population makes the HCV care cascade more reliant on knowing the true prevalence of HCV coinfection among PWH. Additional studies are needed to describe the HCV care cascade among PWH in various settings.

Fourth, our results are not generalizable to other populations heavily affected by HCV infection, such as individuals who inject drugs, are incarcerated, are homeless, or are enrolled in state Medicaid programs. To the extent that other large systems such as correctional systems or state Medicaid programs are able to create similar care continua, a more complete picture of HCV treatment in the United States could be derived.

Finally, we did not evaluate changes in the care cascade over time given that our study period was 6 years in duration; however, this period represented the initial 6 years of the DAA era.

In conclusion, our findings identified persistent gaps between the current delivery of HCV-related care and national treatment goals. Our study suggests that ongoing efforts are needed to improve HCV-related care and achieve HCV elimination in the United States. Periodic evaluation of the HCV care cascade is critical to monitoring national progress toward HCV elimination. Future studies should evaluate the delivery of HCV-related care among patients with Medicaid and within other high-risk populations, as well as monitor the delivery of HCV-related care over time.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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Patient consent. This study did not include factors necessitating patient consent.

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