Monitoring the Hepatitis C Care Cascade Using Administrative Claims Data

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ABSTRACT

OBJECTIVES: With the availability of curative therapies, it is important to ensure that individuals infected with hepatitis C virus (HCV) receive recommended testing, care, and treatment. We sought to evaluate insurance claims data as a source for monitoring progression along the HCV care cascade.

STUDY DESIGN: Longitudinal evaluation of disease progression, from diagnosis to treatment, among commercially insured enrollees with chronic HCV.

METHODS: We validated and used algorithms derived from standardized procedure and diagnosis codes to identify enrollees with chronic HCV in large insurance claims databases to describe the HCV care cascade, including the proportion engaged in HCV-specific care (13 possible definitions), the proportion prescribed HCV treatment, and the proportion who received an HCV RNA test 30 or more days after initiating treatment.

RESULTS: Approximately 90% of individuals with an HCV RNA test procedure code followed by either 3 or more chronic HCV diagnosis codes on different service dates or 2 or more chronic HCV diagnosis codes separated by more than 60 days truly had chronic HCV. Using these algorithms, we identified 5791 HCV cases from January 1, 2013, to June 30, 2014. Among enrollees with HCV, 95% were engaged in HCV care, but only 49% initiated treatment and 43% received a follow-up HCV RNA test 30 or more days after initiating treatment.

CONCLUSIONS: With validated case-finding algorithms, insurance claims data can be used to describe and monitor portions of the HCV care cascade. Although nearly all enrollees with HCV were engaged in HCV care, only half received treatment, indicating that even commercially insured enrollees may find it challenging to access treatment.

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An estimated 3.5 million individuals are currently living with hepatitis C virus (HCV) infection in the United States,[1] more than half of whom are unaware of their status.[2,3] Although 81% of infected individuals were born between 1945 and 1965 (defined as the birth cohort),[4] new HCV infections among younger individuals have increased in recent years.[5] Approximately 75% to 85% of acutely infected individuals develop chronic HCV,[6] which is associated with increased risk of chronic liver disease, hepatocellular carcinoma, and death.[7-9] With the availability of highly effective direct-acting antiviral (DAA) medications, virologic cure can be achieved for more than 90% of treated patients with 8 to 12 weeks of therapy.[10,11] It is critical to monitor how well patients proceed along the HCV care cascade, including appropriate testing, engagement in HCV-specific care (eg, liver disease staging), treatment, and confirmation of virologic cure. Such measures across the cascade could provide important baselines for comparison and highlight factors impacting progression along the cascade, thereby informing targets for improved clinical care and public health intervention.

Although a growing body of research describes the care cascade in a variety of populations and settings across the United States, the data are based on small studies and theoretical models.[12-27] The various methods, settings, and populations under study make it challenging to directly compare findings. Additionally, investigators are limited by the information captured within each data source when determining which steps can be assessed and what metrics are appropriate. Therefore, it is necessary to utilize a variety of data sources to generate an accurate depiction of the HCV care cascade on a national scale to include different types of health insurance coverage (such as commercial, public, and uninsured) and those populations at high risk for HCV infection (such as individuals with a history of injection drug use).

Although not representative of all individuals infected with HCV in the United States, commercial insurance claims databases contain clinical and pharmacy data on millions of individuals. In particular, claims data can be used to monitor national trends

in HCV testing.[28] However, because laboratory test results are not included in claims data, they cannot be used to determine serostatus among those who had an HCV antibody test or identify individuals confirmed to be positive for HCV by HCV RNA detection. Claims data are limited to standard procedure and diagnosis codes for identifying enrollees with a particular disease condition, which may result in misclassification.[29]

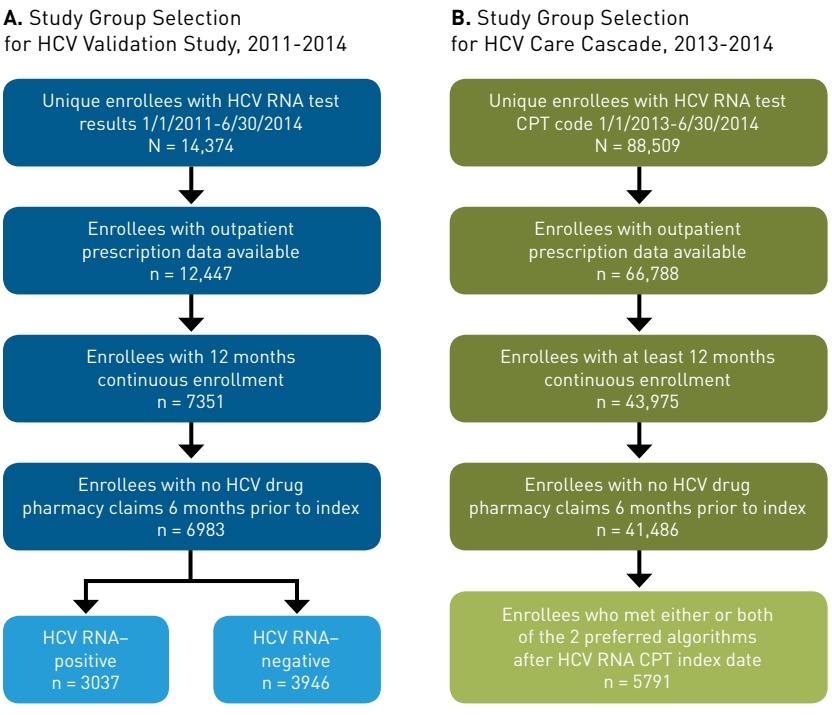
Although algorithms for identifying chronic HCV infection among enrollees with diagnosed liver cirrhosis have been published,[30,31] no algorithm is available to accurately identify enrollees with chronic HCV infection, irrespective of liver disease stage, using standard procedure and diagnosis codes derived from insurance claims data. Using a large commercial insurance claims database, we sought to both validate algorithms to identify enrollees living with chronic HCV and to describe the care cascade among the identified cases.

TAKEAWAY POINTS

Just half of commercially insured enrollees identified by our validated hepatitis C virus (HCV) case-finding algorithms were prescribed HCV treatment, highlighting the need for improved treatment access.

- With the use of validated case-finding algorithms, researchers can describe and monitor the HCV care cascade using administrative healthcare data and identify potential targets for public health intervention.
- This is the first study to describe the cascade among commercially insured enrollees from a large nationally representative claims database.
- Analyses are underway to identify factors impacting progression along the HCV care cascade, from diagnosis to treatment, among infected enrollees in this commercially insured population.

FIGURE 1. Study Group Selection for HCV



CPT indicates Current Procedural Terminology; HCV, hepatitis C virus.

METHODS

Data Source

We obtained enrollment information and insurance claims from Truven Health Analytics MarketScan commercial and Medicare Supplemental Insurance claims databases from 2010 through 2014. These nationally representative data include more than 100 million covered lives, including both commercially insured enrollees younger than 65 years and Medicare-eligible enrollees 65 years or older with employer-sponsored supplemental insurance coverage.[32] Laboratory test results were available in a separate data set for a subset of approximately 3 million enrollees included in the claims database, with linkage using unique identification numbers.

This secondary analysis of deidentified insurance claims data did not require institutional review board approval. All analyses were conducted using SAS software, version 9.3 (SAS; Cary, North Carolina).

Algorithm Validation

Study population. Using Logical Observation Identifiers Names and Codes,[33] we identified all enrollees with at least 1 quantitative or qualitative HCV RNA result in the laboratory test results database from January 1, 2011, to December 31, 2014. Quantitative HCV RNA tests were considered positive if the viral load was 36.2 IU/mL or higher.[34] As some enrollees had several HCV RNA test results available during the study period, the HCV RNA index date was defined by the first positive result among enrollees who were ever positive and the first negative result among enrollees who were always negative. We included enrollees 18 years or older who had prescription drug coverage and no claim for HCV treatment in the 6 months prior to the HCV RNA index date. We also required at least 6 months of continuous enrollment both before and after the HCV RNA index date, limiting the analysis to enrollees with an index date between January 1, 2011, and June 30, 2014 (**Figure 1A**).

TABLE 1. Results of Algorithm Validation for Identifying Enrollees Living With Chronic HCV in MarketScan Commercial and Medicare Supplemental Insurance Claims, 2011-2014

		Met Algorithm	HCV Positive	PPV	NPV	Sensitivity	Specificity
Algorithm	Code Combinations	n	n	%	%	%	%
1	HCV RNA test followed by ≥1 HCV code[a]	5934	2175	37	18	72	5
2	HCV RNA test followed by ≥2 HCV codes on different service dates[a]	2308	1896	82	76	62	90
3	HCV RNA test followed by ≥3 HCV codes on different service dates[a]	1755	1517	86	71	50	94
4	HCV RNA test followed by ≥1 chronic HCV code[b]	2528	1961	78	76	65	86
5	HCV RNA test followed by ≥2 chronic HCV codes on different service dates[b]	1616	1389	86	69	46	94
6	HCV RNA test followed by ≥2 chronic HCV codes in >30 days[b]	1322	1162	88	67	38	96
7	HCV RNA test followed by ≥2 chronic HCV codes in >60 days[b]	1131	1001	89	65	33	97
8	HCV RNA test followed by ≥2 chronic HCV codes in >90 days[b]	926	822	89	63	27	97
9	HCV RNA test followed by ≥3 chronic HCV codes on different service dates[b]	1177	1056	90	66	35	97

HCV indicates hepatitis C virus; *ICD-9-CM*, *International Classification of Diseases, Ninth Revision, Clinical Modification*; NPV, negative predictive value; PPV, positive predictive value.
[a] *ICD-9-CM* codes: 070.41, 070.44, 070.51, 070.54, 070.70, 070.71, V02.62.
[b] *ICD-9-CM* codes: 070.44, 070.54.

Developing and testing algorithms. Using Current Procedural Terminology (CPT) codes for an HCV RNA test (87520, 87521, or 87522) and various combinations of *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) codes for HCV infection (070.41, 070.44, 070.51, 070.54, 070.70, 070.71, and V02.62), we developed and tested the accuracy of 9 algorithms to identify chronic HCV cases using inpatient and outpatient claims data (Table 1). Using the HCV RNA index test results as the gold standard, we calculated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value for each algorithm. Our goal was to describe the HCV care cascade among enrollees with chronic HCV; thus, we selected algorithms with the highest PPV for most accurate case identification.

HCV Care Cascade

Study population. To target the era of DAA treatment regimens, we identified claims for RNA testing from inpatient and outpatient files from January 1, 2013, to June 30, 2014. Claims were deduplicated by service date to identify each enrollee's first test during the study period, defined as the RNA CPT index date. Enrollees 18 years or older with at least 6 months of continuous enrollment both before and after the RNA CPT index date, prescription drug coverage, and no treatment for HCV during the 6-month look-back period were included in the analysis (Figure 1B). We then applied the 2 algorithms with the highest PPV from the validation study and described enrollees living with chronic HCV by age group, birth cohort, sex, US Census division, and insurance plan type.

Defining and describing the cascade. To describe the care cascade, we examined inpatient, outpatient, and pharmacy claims between the RNA CPT index date and December 31, 2014, for each enrollee. Enrollees had between 6 and 24 months of claims data available for review, depending on when their RNA CPT index date and dates of continuous enrollment occurred.

Among enrollees with chronic HCV, we calculated the proportions who were engaged in HCV-specific care, were actually treated for HCV, and received an HCV RNA test 30 or more days after initiating treatment. Enrollees were considered to be engaged in HCV-specific care if they met at least 1 of 13 definitions of engagement (Table 2) or if they were prescribed HCV treatment but did not meet any of our 13 definitions of engagement. These definitions included different diagnostic tests or procedures used to stage or monitor the progression of liver disease. Enrollees were identified as having initiated treatment if at least 1 outpatient pharmacy claim included a National Drug Code for an FDA-approved drug to treat HCV.[35] We also calculated the proportion of those treated who ever received a DAA as part of their treatment regimen and described the DAA types dispensed. Finally, we calculated the proportion of enrollees who received a follow-up HCV RNA test by CPT code 30 or more days after initiating HCV treatment, because an RNA test is currently recommended for monitoring individuals during antiviral therapy[36] and serves as an indicator for continued engagement in care.

TABLE 2. Definitions,[a] Coding Methods, and Results for Engagement in HCV-Specific Care Among Enrollees With Chronic HCV in MarketScan Commercial and Medicare Supplemental Insurance Claims Data, 2013-2014 (n = 5360/5791)

Definition	Coding Method	Met Definition[b]	
		n	%
Visit with a specialty provider[c]	≥1 claim with gastrointestinal or infectious disease specialist provider type	4117	77
Abdominal ultrasound[c]	≥1 claim with CPT code 76700 or 76705	2354	44
Hepatic function panel[c]	≥1 claim with CPT code 80076	1947	36
Genotype after HCV RNA test	≥1 claim with CPT code 87902	1607	30
Liver biopsy[c]	≥1 claim with CPT code 47000, 47001, or 47100	1049	20
Alanine aminotransferase[c]	≥1 claim with CPT code 84460	659	12
Abdominal computed tomography[c]	≥1 claim with CPT code 71450, 71460, 71470, 71476, 71477, or 71478	548	10
Abdominal magnetic resonance imaging[c]	≥1 claim with CPT code 74181 or 74183	433	8
AST[c]	≥1 claim with CPT code 84450	347	6
HCV FibroSURE	CPT codes 82172, 82247, 82977, 83010, 83883, and 84460 on the same service date	230	4
AST to platelet ratio index[c]	CPT codes 84450 with 85025 or 85049 on the same service date	217	4
Hepascore	CPT codes 82247, 82977, 83520, and 83883 on the same service date	92	2
Fibroscan	≥1 claim with CPT code 91200	0	0

AST indicates aspartate aminotransferase; CPT, Current Procedural Terminology; HCV, hepatitis C virus; *ICD-9-CM*, *International Classification of Diseases, Ninth Revision, Clinical Modification*.
[a]List of definitions generated by a panel of 7 health scientists, including 3 physicians.
[b]There were 145 enrollees who did not meet 1 of these definitions but initiated HCV treatment and were subsequently counted among those engaged in HCV-specific care.
[c]On the same claim as at least 1 HCV *ICD-9-CM* diagnosis code: 070.41, 070.44, 070.51, 070.54, 070.70, 070.71, or V02.62.

RESULTS

Algorithm Validation

We identified 6983 eligible enrollees in the laboratory test results dataset with at least 1 HCV RNA test result between January 1, 2011, and June 30, 2014; 3037 (43%) were HCV RNA–positive. Algorithm 9, an HCV RNA test followed by 3 or more chronic HCV *ICD-9-CM* diagnosis codes on different service dates, yielded a PPV of 90%. Algorithms 7 and 8, an HCV RNA CPT code followed by 2 or more chronic HCV *ICD-9-CM* codes separated by more than 60 days, and an HCV RNA CPT code followed by 2 or more chronic HCV *ICD-9-CM* codes separated by more than 90 days, respectively, each yielded a PPV of 89% (Table 1). We elected to apply algorithms 7 and 9 to the full claims database to maximize the number of cases identified.

HCV Care Cascade

From January 1, 2013, through June 30, 2014, we identified 88,509 unique enrollees with an HCV RNA test who met our study criteria. Of these, 5791 enrollees with chronic HCV were identified by 1 or both of the algorithms (**Table 3**). Half (51%; n = 2981) of this population was aged 50 to 59 years, with 4816 (83%) included in the birth cohort and 55% enrolled in preferred provider organization plans. Males made up 64% of the population, which was also geographically diverse.

Engagement in HCV-specific care. Among the 5791 enrollees with HCV, 5360 met at least 1 definition of engagement in HCV-specific care (**Figure 2**). We also included 145 enrollees who were prescribed HCV treatment but did not meet any of our 13 definitions of engagement as engaged in HCV-specific care. These individuals were likely to have been evaluated prior to receiving HCV treatment, but their evaluation events were not captured in these claims data. Therefore, 5505 enrollees within our cohort of chronic HCV cases (95%) were engaged in HCV-specific care following HCV RNA testing. The most common definitions for engagement in care were through the identification of a gastrointestinal or infectious disease specialist provider type (77%), abdominal ultrasound (44%), hepatic function panel (36%), and genotyping (30%) (Table 2).

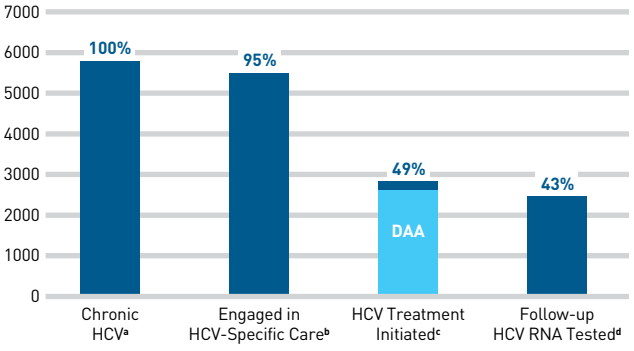
Initiation of HCV treatment and follow-up RNA testing. Of those enrollees identified as having chronic HCV, 2843 (49%) had a claim for HCV treatment, with 2633 of those patients (93%) receiving a DAA medication as part of their treatment regimen. Among those prescribed DAAs, 75% received sofosbuvir, 10% received sofosbuvir and ledipasvir, 11% received telaprevir, 4% received boceprevir, and 1 enrollee received ombitasvir, paritaprevir, and ritonavir (data not shown). Among those who initiated HCV treatment, 2475 (87%) had at least 1 follow-up HCV RNA test 30 or more days after their first HCV treatment claim. Among those prescribed DAAs, 1489 (57%) had at least 1 HCV RNA test 20 or more weeks after initiating treatment (data not shown).

TABLE 3. Characteristics of the Chronic HCV Care Cascade Study Group[a] (N = 5791)

Characteristics	n	%
Age group, years		
18-29	270	4.66
30-39	219	3.78
40-49	670	11.57
50-59	2981	51.48
60-69	1570	27.11
≥70	81	1.40
Birth year group		
1945-1965	4816	83.16
Other birth years	975	16.84
Sex		
Male	3708	64.03
Female	2083	35.97
Census division[b]		
New England	250	4.32
Middle Atlantic	866	14.95
East North Central	664	11.47
West North Central	178	3.07
South Atlantic	1211	20.91
East South Central	344	5.94
West South Central	678	11.71
Mountain	346	5.97
Pacific	1067	18.43
Other/missing	187	3.23
Insurance plan type		
Managed care[c]	1160	20.03
Point-of-service[d]	495	8.55
High-deductible[e]	588	10.15
Preferred provider organization	3187	55.03
Comprehensive	265	4.58
Missing	96	1.66

HCV indicates hepatitis C virus.
[a]Enrollees who met validated HCV case-finding algorithms: an HCV RNA procedure code followed by either 2 chronic HCV diagnosis codes in more than 60 days or 3 chronic HCV diagnosis codes on different service dates.
[b]New England: CT, MA, ME, NH, RI, VT; Middle Atlantic: NJ, NY, PA; East North Central: IL, IN, MI, OH, WI; West North Central: IA, KS, MN, MO, ND, NE, SD; South Atlantic: DC, DE, FL, GA, MD, NC, SC, VA, WV; East South Central: AL, KY, MS, TN; West South Central: AR, LA, OK, TX; Mountain: AZ, CO, ID, NM, MT, NV, UT, WY; Pacific: AK, CA, HI, OR, WA; Other/missing: Puerto Rico, unknown state of residence.
[c]Exclusive provider organization and health maintenance organization plans.
[d]Capitated and noncapitated point-of-service plans.
[e]Consumer-driven and high-deductible health plans.

FIGURE 2. Care Cascade Among Enrollees Living With HCV in MarketScan Commercial and Medicare Supplemental Insurance Claims Data, 2013-2014



CPT indicates Current Procedural Terminology; DAA, direct-acting antiviral; HCV, hepatitis C virus; *ICD-9-CM*, *International Classification of Diseases, Ninth Revision, Clinical Modification*.
[a]Enrollees identified with chronic HCV infection by validated algorithms applied to insurance claims data: HCV RNA CPT code followed by 2 or more chronic HCV *ICD-9-CM* diagnosis codes separated by more than 60 days (algorithm 7), or HCV RNA CPT code followed by 3 or more chronic HCV *ICD-9-CM* codes on different service dates (algorithm 9).
[b]Enrollees meeting at least 1 of 13 different definitions of engagement in care (Table 2).
[c]Enrollees who filled prescriptions for HCV treatment. DAA indicates enrollees who were ever prescribed DAA drugs as part of their HCV treatment regimen. Those not prescribed DAAs were treated only with interferon-based regimens.
[d]Enrollees with HCV RNA CPT code 30 or more days after initiating HCV treatment.

DISCUSSION

This is the first study to validate algorithms for identifying individuals living with HCV that utilized a large insurance claims database and HCV RNA laboratory test results linked to claims. Two of the 9 algorithms we tested had high PPVs, 90% and 89%, respectively, for detecting cases of HCV. The ability to correctly identify individuals with current HCV infection in administrative data is an important first step toward understanding the quality of clinical management and treatment and supporting strategic changes for quality improvement. Among those identified by the algorithms, we found that 95% of enrollees with chronic HCV were engaged in HCV-specific care and 49% initiated HCV treatment. Although the relatively high proportion engaged in HCV-specific care is encouraging, our findings highlight that even individuals with commercial insurance coverage may find it challenging to access HCV treatment.[37-39] Increased access can be demonstrated over time through monitoring the cascade at a national level using large administrative databases, including Medicare and Medicaid.

Algorithm Validation

Administrative healthcare data have been used to develop algorithms for identifying persons diagnosed with HCV among patients with cirrhosis.[30,31] Kramer et al and Niu et al found that identifying 1 to 3 HCV *ICD-9-CM* codes of any type resulted in PPVs as high as 93% and 97%, respectively, among HCV-infected enrollees with cirrhosis compared with electronic health record data. We did not limit our analysis to enrollees diagnosed with cirrhosis, and we observed

an improvement in PPV when we tested algorithms including only codes for chronic HCV (070.44 or 070.54). Although the sole use of these 2 codes resulted in reduced sensitivity, our aim was to identify the algorithms with the highest PPVs so that we could increase the probability of identifying true cases for describing the chronic HCV care cascade.

HCV Care Cascade

Engagement in HCV-specific care. Insurance claims data provide an opportunity to identify several laboratory tests, diagnostic procedures, or specialty provider visits that can be used to demonstrate that enrollees are engaged in HCV-specific care. We elected to use 13 definitions in an attempt to identify as many engaged enrollees as possible. Other investigators have defined engagement in different ways, such as referral for HCV care,[18,20,22] 1 or more visits with a healthcare provider or specialist,[12,13,16,21,23-25,27] and a certain number of HCV tests within a specified time period.[23,26] Although 95% of enrollees with chronic HCV were engaged in HCV-specific care in our study, the observed or estimated proportion of engaged study participants varies widely among other published cascades, from as low as 6% up to 89%,[21,23] demonstrating potential effects of variation in study setting, population, and methodology on observed estimations of engagement. In addition, we found that 77% of enrollees with chronic HCV were engaged in HCV-specific care through a visit with either a gastrointestinal or infectious disease specialist. Among previously published cascades, the highest reported proportion of enrollees positive for HCV attending a specialty visit for HCV care was 52%.[15] The relatively higher proportion we observed may reflect better access to, and retention in, care among a commercially insured population.

HCV genotype testing is recommended for all individuals chronically infected with HCV to guide providers in selecting the most appropriate treatment regimen.[40] We found that just 30% of enrollees with HCV received a genotype test after their HCV RNA CPT index date. However, we used this metric to define engagement in care after diagnosis of HCV infection, and genotype tests are often done on the same date as the HCV RNA test; therefore, 30% is a minimum estimate of the true proportion that were ever genotype-tested. That proportion has been reported to be as low as 6.1% and as high as 75.4% in previously published cascades.[14,16]

Initiation of HCV treatment and follow-up RNA testing. Just less than half of the enrollees in the cascade study group initiated HCV treatment by the end of the study period. As we only required a minimum of 6 months of continuous enrollment following the HCV RNA CPT index date, we may not have captured all treatment events for enrollees in this population who had less observation time. However, our minimum estimate is higher than values reported in other published cascades, which range from 3% to 46%.[12,13,15,16,18-27] This may reflect the advantage of studying a commercially insured population in care in the era of DAA treatment regimens.

Our finding that 75% of those who initiated HCV treatment were prescribed sofosbuvir is not unexpected considering the timing of our study period and the FDA approval of sofosbuvir in December 2013. Additionally, although we do not have laboratory results to determine who among our care cascade study group ultimately achieved virologic cure, we did determine that 87% of treated enrollees continued to be engaged in care through follow-up RNA testing 30 or more days after initiating treatment.

Limitations

Our study is subject to certain limitations. First, these analyses were conducted among a subset of commercially insured enrollees and are not generalizable to all HCV-infected individuals in the United States. Second, it is possible that enrollees included in the validation study were misclassified by HCV RNA test result if enrollees we classified as always negative had a positive test result prior to January 1, 2011. Third, because we selected algorithms based on PPV to maximize accuracy, our algorithms may not be suitable for other evaluations, such as estimating HCV prevalence.

Finally, we were not able to describe the care cascade for HCV-infected enrollees in MarketScan who were not identified by the algorithms. However, among 1098 enrollees testing positive for HCV RNA identified in the MarketScan laboratory test results subset, during the same time period, we found that 79% were engaged in HCV-specific care and just 30% initiated treatment (data not shown). It is not surprising that fewer enrollees in the RNA-positive subset were engaged and subsequently treated, as our algorithms selected individuals based on chronic HCV diagnosis codes documented at healthcare encounters; individuals not having chronic HCV-related encounters will not be selected. It is possible that we have selected enrollees who were already exhibiting signs of advanced liver disease and prioritized for treatment. Additional analyses are under way to further examine the differences between the cascades developed using the validated algorithms and the subset of enrollees with laboratory test results.

CONCLUSIONS

We have successfully validated 2 algorithms to identify cases of chronic HCV in claims data and described the HCV care cascade among those identified by the algorithms. In addition to utilizing these algorithms to identify cases of HCV in other sources of claims data, analyses are under way to identify predictors of progression along the cascade. Although 95% of enrollees chronically infected with HCV were engaged in HCV care and 49% initiated HCV treatment, our findings indicate that commercially insured enrollees in care may still find it challenging to access HCV treatment. Additionally, a previous analysis of trends in HCV antibody testing among MarketScan enrollees demonstrated that just 3% of individuals born from 1945 to 1965 and 2% of persons born in other years received

an antibody test in 2014,[28] highlighting a clear need for improved uptake of national testing recommendations.[6] It will be important to continue to monitor the HCV care cascade over time to ensure that all individuals living with HCV receive recommended care and treatment. ■

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