Newly Diagnosed Hepatitis C in the US Commercially Insured Population Before and After the 2012 Implementation of Expanded Screening Guidelines

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BACKGROUND: In the United States in 2014, more than 3 million individuals were estimated to have chronic hepatitis C virus (HCV) infection, including many undiagnosed individuals. In 2012, the Centers for Disease Control and Prevention expanded its HCV testing recommendations to target all adults born between 1945 and 1965, in addition to at-risk individuals, which has led to an increase in newly diagnosed patients. Few studies have explored the medical cost or clinical status of patients who are newly diagnosed with HCV.

OBJECTIVE: To compare the demographics, comorbidities, and medical costs of patients who are newly diagnosed and those who were previously diagnosed with HCV infection.

METHODS: We conducted a retrospective study using 2013 claims data from the Truven Health MarketScan Commercial database to compare patients newly diagnosed with HCV infection in 2013 and patients who were diagnosed before 2013. The patients were divided into 2 cohorts based on the time of diagnosis before and after 2013. All patients were classified by disease stage and by comorbidities, and were required to have continuous health plan enrollment between January 2010 and December 2013. The full-year costs were tabulated for every patient, regardless of the date of diagnosis.

RESULTS: Of the 9193 patients with an HCV diagnosis in 2013 in the database, approximately 26% (N = 2428) were newly diagnosed in 2013, of whom 12% (N = 299) had advanced-stage HCV. The average age of the newly diagnosed patients was 49.5 years versus 54.1 years for previously diagnosed patients. Patients who were previously diagnosed had a higher prevalence of HIV, diabetes, and more severe cancers than patients who were newly diagnosed with HCV. Patients who were newly diagnosed with HCV had a higher prevalence of acute liver failure and drug-induced psychosis. The average annual per-patient per-month (PPPM) medical costs for both groups was approximately $2200 in 2013. The annual medical cost for a patient who was newly diagnosed increased sharply in the year before diagnosis, from approximately $588 PPPM for the 3 years before the diagnosis to approximately $854 PPPM in the year before diagnosis.

CONCLUSIONS: In 2013, the healthcare costs of patients who were newly diagnosed with HCV were similar in their first year of diagnosis to the costs of patients who had been diagnosed previously, although patients who were previously diagnosed had more advanced-stage disease. Patients who were newly diagnosed had 3-fold the healthcare costs in their first year of diagnosis versus the costs in the 3 years before their diagnosis.

KEY WORDS: administrative claims analysis, hepatitis C infection, newly diagnosed hepatitis, screening guidelines, undiagnosed hepatitis

Chronic hepatitis C virus (HCV) infection kills more people than any other infectious disease in the United States, and, as of 2013, mortality associated with this disease has been rising.1 In 2014, the estimated number of persons living with chronic HCV in the United States was 2.7 million, based on data from the 2003-2010 National Health and Nutrition Examination Surveys.2,3 The Centers for Disease Control and Prevention (CDC) and the American Association for the Study of Liver Diseases (AASLD) recommend that everyone born between 1945 and 1965 be tested for HCV,4,5 along with individuals who are at high risk for the virus, such as injection drug users and recipients of blood products in the AIDS epidemic before 1984.

The probability of developing HCV infection is directly related to the length of exposure to the virus.6-9 Among individuals with a single exposure to HCV, the probability of acquiring the disease in the first year is approximately 50%.10-12 After the first year, the probability of acquiring the disease is approximately 10% per year.10-12 However, the probability of acquiring the disease is much greater among individuals with multiple exposures to the virus.10,11,13-20 Among individuals with multiple exposures to HCV, the probability of acquiring the disease within 1 year is approximately 90%, and the probability of acquiring the disease is approximately 90% per year thereafter.10,11,13-20 The probability of acquiring HCV infection is higher among individuals who have been exposed to multiple sources of the virus, such as injection drug users, than among individuals who have been exposed to a single source of the virus, such as blood donors.10-12,13-20 The probability of acquiring HCV infection is much lower among individuals who have been exposed to multiple sources of the virus, such as injection drug users, than among individuals who have been exposed to a single source of the virus, such as blood donors.10-12,13-20
KEY POINTS

➤ Although HCV infection kills more people than any other infectious disease in the United States, many people are unaware of their disease.

➤ This study is based on 2013 claims data and compares the rates of HCV diagnoses before and after the implementation of new screening guidelines.

➤ Among 9193 patients with HCV in 2013, 26% were newly diagnosed and 12% had advanced-stage disease.

➤ Previously diagnosed patients had a higher prevalence of HIV, diabetes, and more severe cancers than newly diagnosed patients.

➤ Newly diagnosed patients had a higher prevalence of acute liver failure and drug-induced psychosis.

➤ The annual medical cost of newly diagnosed patients increased in the year of diagnosis from $7000 to $10,000.

➤ The characteristics of patients with newly diagnosed HCV may shift with recent recommendations for screening all baby boomers.

Survey (NHANES). This prevalence estimate was considered low, because certain high-risk populations (eg, institutionalized, incarcerated, and homeless persons) were excluded from this survey. Researchers estimate that after adjusting for populations excluded from the NHANES, the prevalence of chronic HCV is at least 3.5 million. This number does not include individuals who were infected with HCV and whose disease cleared spontaneously and did not become chronic. Recent studies demonstrated that healthcare costs for HCV-infected individuals are higher than for noninfected individuals, and that those costs increase as the disease progresses.

According to the Centers for Disease Control and Prevention (CDC), the incidence rates for HCV peaked in the 1970s and 1980s. The majority of patients with newly diagnosed HCV today have chronic HCV and are thought to have been infected during the decades of peak HCV incidence rates. Targeted screening is an important strategy to identify asymptomatic patients and to engage them in the healthcare system to improve health outcomes.

In 1998, the CDC issued risk-based screening recommendations targeting individuals who currently or previously used injection drugs, received blood transfusions before July 1992, were receiving chronic hemodialysis, received clotting factors concentrates produced before 1987, were a healthcare or emergency medical services worker with recognized exposure to HCV, or were born to HCV-infected mothers. Risk-based HCV screening was expanded in 1999 to include persons infected with HIV. In 2012 and 2013, the CDC and the US Preventive Services Task Force (USPSTF), respectively, expanded their HCV screening guidelines to include all persons born between 1945 and 1965.

Because HCV infection is often asymptomatic, many individuals are unaware of their status, do not seek care, and can continue to be a source of transmission. It is estimated that as many as half of infected individuals are unaware of their diagnosis. To our knowledge, the financial burden of undiagnosed patients has not yet been explored.

In late 2013, new interferon-free direct-acting antiviral drugs (eg, sofosbuvir) became available. Interferon-free direct-acting antiviral therapy, with its low rate of side effects and high cure rate, took away one obstacle to testing, namely, the adverse effects of earlier HCV therapy. Patients who were newly diagnosed with HCV before receiving interferon-free direct-acting antiviral therapy might have been more likely to have symptoms at the time of diagnosis than newly diagnosed patients in the years immediately after the introduction of interferon-free direct-acting antiviral drugs.

A review of medical costs is useful for comparing patients newly diagnosed and those previously diagnosed with HCV, because treatments for cirrhosis and liver failure have not changed materially since 2013. Given the societal impact of the medical cost of patients with advanced-stage HCV, we expect that insight on newly diagnosed patients and those not yet diagnosed will be of interest to healthcare providers, payers, and policymakers who are interested in what the future demand for HCV oversight and treatment may be.

We compared the previous years’ healthcare costs, demographics, and comorbidities for patients newly diagnosed with HCV in 2013 with those of patients who were previously diagnosed with HCV. Although patients with newly diagnosed HCV are different from undiagnosed patients, examining the experience of newly diagnosed patients before their diagnosis provides an opportunity to explore the undiagnosed population.

Methods

This retrospective study includes data from the Truven Health MarketScan Commercial database, a medical database that includes annual private-sector health data from approximately 100 US payers. The database contains more than 35 million commercially insured lives, which is approximately 1 of every 6 employees and dependents in the United States, and is geographically

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Table 1 Newly Diagnosed and Previously Diagnosed HCV Populations, by Age-Group

<table>
<thead>
<tr>
<th>Age-group</th>
<th>Newly diagnosed patients, N (%)</th>
<th>Previously diagnosed patients, N (%)</th>
<th>Total patients, N</th>
<th>Total female patients, N</th>
<th>Newly diagnosed female patients, %a</th>
<th>Previously diagnosed female patients, %b</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18 yrs</td>
<td>30 (65.2)</td>
<td>16 (34.8)</td>
<td>46</td>
<td>23</td>
<td>56.7</td>
<td>37.5</td>
</tr>
<tr>
<td>18-25 yrs</td>
<td>200 (60.0)</td>
<td>132 (39.8)</td>
<td>332</td>
<td>164</td>
<td>48.5</td>
<td>50.0</td>
</tr>
<tr>
<td>26-35 yrs</td>
<td>136 (46.1)</td>
<td>159 (53.9)</td>
<td>295</td>
<td>155</td>
<td>52.9</td>
<td>52.2</td>
</tr>
<tr>
<td>36-45 yrs</td>
<td>237 (36.2)</td>
<td>417 (63.8)</td>
<td>654</td>
<td>286</td>
<td>46.0</td>
<td>42.4</td>
</tr>
<tr>
<td>46-55 yrs</td>
<td>841 (26.0)</td>
<td>2388 (74.0)</td>
<td>3229</td>
<td>1241</td>
<td>40.9</td>
<td>37.6</td>
</tr>
<tr>
<td>56-64 yrs</td>
<td>984 (21.4)</td>
<td>3653 (78.6)</td>
<td>4637</td>
<td>1544</td>
<td>36.3</td>
<td>32.8</td>
</tr>
<tr>
<td>Total</td>
<td>2428 (26.4)</td>
<td>6765 (73.6)</td>
<td>9193</td>
<td>3413</td>
<td>41.0c</td>
<td>40.0d</td>
</tr>
</tbody>
</table>

*aThe 2 female percentages for each row are independent of each other and would not sum to 100% except by chance. P values were calculated using Welch’s t-test. 
*bSignificant relative to previously diagnosed female patients (P <.01). 
*cSignificantly different from previously diagnosed patients (P <.01). 
*dSignificantly different from previously diagnosed patients (<.01). 

HCV indicates hepatitis C virus.

identified as newly diagnosed with HCV with a 36-month look-back period had been diagnosed at some earlier time.

Disease Stage and Comorbidities

We used the 2014 Centers for Medicare & Medicaid Services US Department of Health and Human Services (HHS)-Hierarchical Condition Categories (HCC) risk-adjuster model to assign patients to their HCV disease stages. HHS-HCC is a concurrent model designed for the commercially insured population to predict a patient’s cost in the same year as the input data. The model has separate sets of factors for each of the different metallic levels for health insurance specified by the Affordable Care Act. The HHS-HCC classification includes 4 hierarchical stages of liver disease based on ICD-9 diagnosis codes, including chronic HCV (HCC037), cirrhosis of the liver (HCC036), end-stage liver disease (ESLD; HCC035), and liver transplant (HCC034).

Comorbidities, such as diabetes, were also identified by applying HHS-HCC criteria. We labeled HCV-infected status other than chronic HCV (HCC037) as “advanced HCV disease stages.” The risk scores for individuals were calculated using the HHS-HCC 2014 gold risk coefficients, which were chosen because the Market-Scan Commercial database cost-sharing is, in aggregate, approximately gold level.

Costs

The all-cause medical and pharmacy costs were summarized for this analysis. The amounts reported represent the negotiated terms between the insurers and the healthcare providers, and include insurance payments and patients’ out-of-pocket costs. The medical costs included inpatient admissions, outpatient and ambulatory surgical center facility bills, professional charges, services incurred by independent laboratory facilities, transportation, and other miscellaneous costs such as eye care, hearing aids, acupuncture, and dental services when covered under the medical benefits. The pharmacy costs were segmented into the 2 categories of antiviral drugs (including HCV treatments) and all other drugs. The costs were calculated for each calendar year separately for patients newly diagnosed with HCV and for previously diagnosed patients, regardless of the date of diagnosis, and were reported as per patient per month.

Statistical Analysis

To determine statistical significance when comparing newly diagnosed patients with HCV with previously diagnosed patients, we calculated P values using a t-test for 2 independent sample comparison of means tests with adjustments for unequal variance. Patients with newly diverse. It represents the medical experience of insured subscribers and their dependents for active employees, early retirees, COBRA continuation beneficiaries, and Medicare-eligible retirees with employer-provided supplemental plans. We restricted our analysis to members whose employee status was indicated as active or unknown, plus their dependents, and we excluded those enrolled in capitated health plans.

Patients aged ≤64 years as of the end of 2013 were identified as diagnosed with HCV if they had at least 1 acute inpatient, observation, emergency department, or nonlaboratory/nonradiology physician claim with an HCV International Classification of Diseases, Ninth Edition (ICD-9) diagnosis code in any position incurred in 2013 (see Appendix Table 1 at www.AHDBonline.com). We included all patients diagnosed with HCV who were continuously enrolled from January 2010 through December 2013.

In 2013, we identified 9193 commercially insured patients with an HCV diagnosis and continuous enrollment from 2010 through 2013 (see Appendix Table 2 at www.AHDBonline.com). Among this population, 2428 (26%) patients met our criteria of being newly diagnosed with HCV, because they had no HCV-related diagnoses in the previous 36 months (2010-2012 claims). Of the approximately 2428 newly diagnosed patients, 12% (N = 299) had advanced-stage HCV. As expected, decreasing the look-back period increased the count of patients whose first diagnosis appeared in 2013. Specifically, 24-month and 12-month look-back periods yielded 31% and 41% of patients, respectively, as being newly diagnosed with HCV. It is possible that some patients...
diagnosed disease and those previously diagnosed with HCV were compared without adjustment for demographic or other variables, with the goal of developing descriptive statistics.

**Results**

The average age of patients newly diagnosed with HCV was 49.5 years compared with 54.1 years for previously diagnosed patients. The cumulative percentage of patients aged ≤30 years was 11.5% for newly diagnosed patients compared with 2.9% reported by previously diagnosed patients. There was a higher proportion of females than males aged ≤30 years among the newly diagnosed patients. The age and sex distribution for both cohorts is provided in Table 1. Because the prevalence of HCV is heavily skewed toward older-aged patients, older newly diagnosed patients are more likely to emerge from patients who have been infected with HCV for many years, whereas younger patients are more likely to be newly infected.

The distribution of HCV disease stage in 2013 for newly and previously diagnosed patients is provided in Table 2. Patients with newly diagnosed HCV had a lower prevalence (12.3%) of advanced disease stage (cirrhosis, ESLD, and liver transplant) compared with 21.9% for previously diagnosed patients. Of patients with newly diagnosed disease, 4.6% had ESLD in 2013 compared with 7.7% of previously diagnosed patients.

**Comorbidities**

Certain clinical conditions are known to frequently occur in people with HCV. Table 3 provides the details of 15 of the most common HCV-related comorbidities in the study population, including relative ratios and P values. The number of these comorbidities was similar in both cohorts. Drug-induced psychosis was 8.1% in newly diagnosed patients versus 4.7% for previously diagnosed patients (P ≤.01). In addition, newly diagnosed patients had a 2.5% prevalence of acute liver failure versus 1.3% for previously diagnosed patients (P ≤.01). Conversely, newly diagnosed patients had a significantly lower prevalence (P ≤.01) for HIV (HCC001), diabetes (HCC019, HCC020, HCC21), and severe cancers (HCC009) than previously diagnosed patients. The prevalence of the 10 additional comorbidities examined was not statistically different between the 2 cohorts.

The average HHS-HCC risk score, which is based on age, sex, and diagnosis codes, was higher in the previously diagnosed patients (7.80) than in newly diagnosed patients (6.92; P ≤.01). The lower risk scores among newly diagnosed patients are consistent with the lower average age, which is an important component of the risk adjuster. The lower average age is also correlated with a significantly lower prevalence (P ≤.01) for HIV (HCC001), diabetes (HCC019, HCC020, HCC21), and severe cancers (HCC009) than previously diagnosed patients. The prevalence of the 10 additional comorbidities examined was not statistically different between the 2 cohorts.

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with a lower number of diagnoses, which is the other component of the risk-adjustment model.

Costs

In 2013, the average allowed monthly medical cost per member for patients newly diagnosed with HCV was $1817, which is more than 5 times higher than the average cost of $330 PPPM across all commercially insured members in the MarketScan database. The average annual PPPM medical costs for both groups was approximately $2200 in 2013. This number reflects the full calendar year of costs for both groups. The newly diagnosed patients were diagnosed, on average, by midyear; an analysis of monthly costs may show additional relationships.

Table 4 Medical PPPM Costs of Patients with Newly Diagnosed HCV in Years Leading Up to Diagnosis

<table>
<thead>
<tr>
<th>Stage at diagnosis in 2013</th>
<th>Newly diagnosed patients, N</th>
<th>3 years before newly diagnosed, PPPM costs $ (95% CI)</th>
<th>2 years before newly diagnosed, PPPM costs $ (95% CI)</th>
<th>1 year before newly diagnosed, PPPM costs $ (95% CI)</th>
<th>Year of diagnosis, PPPM costs $ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noncirrhotic</td>
<td>2129</td>
<td>563 (420-705)</td>
<td>617 (469-764)</td>
<td>810 (664-958)</td>
<td>1591 (1376-1805)</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>167</td>
<td>631 (356-906)</td>
<td>665 (392-938)</td>
<td>679 (434-925)</td>
<td>2765 (1650-3880)</td>
</tr>
<tr>
<td>End-stage liver disease</td>
<td>112</td>
<td>785 (167-1402)</td>
<td>815 (268-961)</td>
<td>904 (586-1221)</td>
<td>2594 (254-4284)</td>
</tr>
<tr>
<td>Liver transplant, including posttransplant status</td>
<td>20</td>
<td>1784 (0-3856)</td>
<td>1378 (0-2797)</td>
<td>6707 (0-14,530)</td>
<td>2073-15,723</td>
</tr>
<tr>
<td>Total</td>
<td>2428</td>
<td>588 (458-718)</td>
<td>626 (494-750)</td>
<td>854 (709-999)</td>
<td>1817 (1602-2032)</td>
</tr>
</tbody>
</table>

*Medical costs, excluding prescription drug costs.

bNewly diagnosed patients only.

CI indicates confidence interval; PPPM, per-patient per-month.

Discussion

Despite a lower average age, 12.3% of newly diagnosed patients had advanced-stage HCV, which suggests that many patients’ disease is not identified early. Still, this portion is lower than the 21.9% of patients previously diagnosed with HCV who have advanced-stage disease.

Comorbidities are a marker of the course of HCV, as well as of mortality outcomes. Patients previously diagnosed with HCV had a higher prevalence of HIV, diabetes.

The pharmacy PPPM costs in 2013 were significantly higher in previously diagnosed patients than in newly diagnosed patients for HCV antiviral prescriptions ($206 vs $131, respectively; P < .01) and for all other prescriptions ($310 vs $263; P = .04). Of note, the HCV antiviral PPPM costs in this study do not reflect the impact of interferon-free direct-acting antiviral drugs, which were launched after November 2013 and created a surge in prescription drug costs for patients with HCV. A comparison of the average medical and pharmacy PPPM costs in 2013 for newly diagnosed and previously diagnosed patients is shown in Table 5.

Table 5 Cost Comparison Between Newly Diagnosed and Previously Diagnosed Patient Populations

<table>
<thead>
<tr>
<th>Diagnosis status</th>
<th>Patients, N</th>
<th>Members’ months of medical coverage, N</th>
<th>Members’ months of prescription coverage, N</th>
<th>2013 medical cost PPPM</th>
<th>2013 prescription cost PPPM (excluding antiviral drugs)</th>
<th>2013 antiviral drugs cost PPPM</th>
<th>2013 total cost PPPM</th>
<th>2013 risk score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly diagnosed</td>
<td>2428</td>
<td>29,136</td>
<td>18,524</td>
<td>$1817 (95% CI, $1602-$2032)</td>
<td>$263 (95% CI, $237-$289)</td>
<td>$131 (95% CI, $97-$166)</td>
<td>$2211 (95% CI, $1992-$2433)</td>
<td>6.920</td>
</tr>
<tr>
<td>Previously diagnosed</td>
<td>6785</td>
<td>81,180</td>
<td>50,452</td>
<td>$1679 (95% CI, $1545-$1808)</td>
<td>$310 (95% CI, $290-$330)</td>
<td>$206 (95% CI, $182-$230)</td>
<td>$2192 (95% CI, $2058-$2326)</td>
<td>7.802</td>
</tr>
<tr>
<td>Total</td>
<td>9193</td>
<td>110,316</td>
<td>68,976</td>
<td>$1713 (95% CI, $1601-$1824)</td>
<td>$298 (95% CI, $282-$314)</td>
<td>$186 (95% CI, $166-$206)</td>
<td>$2196 (95% CI, $2052-$2311)</td>
<td>7.569</td>
</tr>
</tbody>
</table>

*The HCV antiviral PPPM costs do not reflect the impact of innovative curative treatments widely adopted in 2014.

bSignificantly different from previously diagnosed patients (P < .05). (Note: P > .01). P value was calculated using a 2 independent sample comparison of means test with unequal variance t-test.

Cl indicates confidence interval; HCV, hepatitis C virus; PPPM, per-patient per-month.
tes, and severe cancers. Acute liver failure and drug-induced psychosis were more prevalent in newly diagnosed than in previously diagnosed patients, suggesting that newly diagnosed patients could have been identified through the implementation of risk-based screening guidelines or through symptomatic screening. For the 10 additional HCV comorbidities examined, no significant differences in prevalence were observed between the 2 cohorts based on the t-test results. These results suggest that a broad range of extrahepatic complications can arise by the time of diagnosis and can persist thereafter.

The medical costs of newly diagnosed HCV in the years leading up to diagnosis were lower than in the year of diagnosis ($588 PPPM 3 years before diagnosis vs $1817 PPPM in the year of diagnosis). The PPPM costs of patients with newly diagnosed HCV were higher in the years before diagnosis for those who were diagnosed at later stages of the disease than in those diagnosed with early-stage HCV, but the costs were still lower than those in the year of diagnosis.

In the year of diagnosis, the cost of patients newly diagnosed with HCV was not significantly different from previously diagnosed patients ($1817 PPPM vs $1675 PPPM, respectively). However, the risk score of newly diagnosed patients was significantly lower (6.92) than that of previously diagnosed HCV (7.80). This observation (using concurrent risk scoring) is consistent with patients previously diagnosed with HCV being older and having more advanced disease states, as well as having a higher prevalence of certain comorbidities (eg, HIV, diabetes, and cancer).

The age and sex differences may partially account for the various prevalence rates for HIV, diabetes, and cancer. It is also possible that patients diagnosed with HIV, diabetes, or cancer are more likely to be screened for HCV and are thus diagnosed at an earlier date than they otherwise would have been.

**Limitations**

This study has several limitations. The data come from a large commercially insured population, which implies the socioeconomic status represents a population with employer-sponsored insurance. Other populations with different characteristics or access to care could exhibit different outcomes.

In addition, the commercial population described in this study had continuous insurance coverage; therefore, its utilization, coverage, and access-to-care characteristics may differ from patients who are not continuously enrolled in a health plan. Consequently, the results of this study may not apply to other patient populations.

Furthermore, using 3 years of look-back to identify patients with newly diagnosed HCV could mean that some patients identified as being newly diagnosed might have been diagnosed earlier but were not actively treated during the look-back period.

Finally, curative treatment for HCV before the introduction of interferon-free direct-acting antiviral drugs in 2013 was not common at the time of this study, and we did not attempt to distinguish patients who received curative treatment. Therefore, the costs analyzed in this study do not reflect the recent surge in the use of all-oral interferon-free direct-acting antiviral drugs.

**Conclusion**

This study described the commercially insured US population who were newly diagnosed with HCV in 2013 and compared them with patients previously diagnosed with HCV, specifically examining demographics, comorbidities, and healthcare costs. The characteristics of patients newly diagnosed with HCV reflect the impacts from the expanded CDC/USPSTF screening guidelines (promulgated in 2012 and 2013), which include the 1945 to 1965 birth cohort screening in addition to the previous existing non–age-specific risk-based screening recommendations. In their year of diagnosis, newly diagnosed patients in 2013 had a medical costs burden similar to previously diagnosed patients.

To our knowledge, there is limited evidence on the economic burden of undiagnosed HCV. This analysis identifies and examines patients with newly diagnosed HCV to provide a window into the undiagnosed populations and to provide information on the characteristics of patients newly diagnosed with HCV.

Early detection and linkage to care for asymptomatic patients with chronic HCV are critical to improving HCV-associated morbidity and mortality, as recognized by the updated CDC recommendations for screening. Although this study demonstrates that the medical cost burden of HCV among newly diagnosed patients is comparable to that of previously diagnosed patients, the burden in the years before diagnosis is considerably lower. These findings can be used to inform further research into the characteristics of patients with newly diagnosed HCV. ■

**Acknowledgments**

The authors wish to thank Andrew Bochner and Motoharu Dei for their review of the data analytics and statistical process.

**Source of Funding**

Financial support for this study was provided by AbbVie.

**Author Disclosure Statement**

Mr Pyenson, Ms Dieguez, and Ms Ferro received re-
search support from AbbVie, and are consultants to numerous organizations in healthcare through Milliman; Ms. Mavinkurve reported no conflicts of interest; Dr. Sanchez Gonzalez is an employee of and has stock options in AbbVie.

References

STAKEHOLDER PERSPECTIVE

Importance of Health Outcomes Research for the Treatment of Hepatitis C Infection

By Jack E. Fincham, PhD, RPh
Professor, Department of Pharmaceutical and Administrative Sciences, Presbyterian College School of Pharmacy, Clinton, SC

PATIENTS: The prevalence of chronic hepatitis C virus (HCV) infection in the United States is estimated to be between 2.7 million and 3.9 million. The World Health Organization estimates that 71 million people globally have chronic HCV, and 399,000 people are dying from the disease annually. The transmission of HCV infection often occurs through the sharing of injection equipment during drug use, the reuse of medical equipment or inadequate sterilization, or the transfusion of unscreened blood and blood products.

The impact of anti-HCV treatment or the lack of treatment for patients needing care will have tremendous epidemiologic, economic, and quality-of-life outcomes for public and private health insurance programs. Untreated HCV infection can lead to liver cirrhosis, end-stage liver disease, liver cancer, liver failure, the need for a liver transplantation, and death. In addition, HCV infections have extra hepatic immunologic effects on conditions such as cryoglobulinemia vasculitis and lymphomas. The Global Burden of Disease Liver Cancer Collaboration estimated that between 1990 and 2015, the incidence of liver cancer increased by 75%. In 2015, 854,000 incident cases of liver cancer and 810,000 liver cancer–related deaths were reported globally, which contributed to more than 20 million disability-adjusted life-years.

New and effective medications providing a cure for hepatitis C have become available. In the future, patients with HCV will have opportunities to access breakthrough therapies, and US estimates place the sales of hepatitis antivirals to approach $45 billion to $55 billion
in 2020. The spending on medications to treat viral hepatitis was estimated to be $15.7 billion in 2016. Despite the availability of new effective treatments, Aitken and Kleinrock found that in the United States, “Fewer new patients received treatment for hepatitis C in 2016 than in the prior year...[and] between 2.4 to 4.4 million infected patients remain.” They conclude that the widely discussed price of new therapies might have influenced patients to avoid seeking care, despite the cure rates for new therapies.

PATIENTS/PAYERS: The cost of anti-HCV medications must not be the only data to consider regarding treatment options. In US Medicaid programs, patients’ access to new HCV treatments has been limited because of cost factors alone. Focused health outcome studies must be prominently used when considering treatment options that may at first appear too costly.

Economic outcomes will always be important, but clinical and quality-of-life considerations must be equally as important. In the United States, public third-party payers, such as Medicaid and Medicare, need to consider cost-effectiveness and cost-utility analyses in addition to the evaluation of the cost of medications alone.

Cost-effectiveness studies have shown positive benefits for HCV screening nationally and internationally, as well as for new treatment options. In a US study of targeted, routine risk-based rapid testing versus a one-time hepatitis C screening strategy, the latter option was shown to be more cost-effective. Globally, in South Korea, one-time screening and treatment for HCV has proved to be more cost-effective than screening for HCV and delaying treatment.

The results of health outcome studies of the cost-effectiveness, health benefits, and financial costs of HCV treatment have shown that new treatments for HCV are cost-effective per person, but increased demand for the drugs may limit treatment options through government third-party payers.

New anti-HCV medications are more cost-effective than the previously available therapy options. The results of studies such as those in the article by Pyenson and colleagues are very encouraging, and have shown that the expenses for HCV therapy are outweighed by the benefit to patients, families, payment programs, and society at large.