

Epidemiology of Hepatitis C in Delaware

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Abstract

Infection with hepatitis C virus (HCV) is pervasive throughout the United States of America as we fight the ongoing urban and rural opioid epidemics and rising rates of fatal and non-fatal overdoses. While risk factors for incident HCV abound, our country and the State of Delaware have increasing access to highly effective, short-course, curative HCV treatments. Despite unprecedented medical advances for HCV, as well as expanded HCV screening guidelines calling for universal adult HCV screening and screening during every pregnancy, the epidemiology of HCV at the national and statewide levels continues to be lacking. In attempting to gather, interpret, and present the highest quality available data, we conclude that HCV remains a pressing public and individual health concern for Delawareans, and our nation at large. We urge stakeholders in Delaware to make concerted efforts to fill in the many remaining gaps of HCV epidemiology in order to better inform public health resource allocation, educate the public and healthcare professionals regarding viral hepatitis, and ultimately improve the HCV care continuum, spanning from increasing rates of universal HCV screening and diagnosis to linkage to care to treatment initiation all the way to cure and beyond.

Introduction

Hepatitis C viral infection is increasing in the USA and in Delaware, due in large part to the injection opioid epidemic. HCV is usually asymptomatic in the early stages of disease and, consequently, the majority of individuals infected with HCV are unaware of their status. Although often silent until the development of end stage liver disease, HCV-associated mortality is increasing, especially from liver cancer. Worldwide, liver cancer was the 20th most common cause of death in 2016.¹ In 2040, it is projected to advance to the 13th most common cause of death, which translates to almost a 70% increase in the number of years of life lost worldwide from liver cancer.¹ Viral hepatitis is one of the primary underlying causes of liver cancer.

Prevalence and Incidence in the USA

It is difficult to accurately estimate the prevalence of HCV in the USA. Estimates of chronic HCV vary widely, from 3.5 million Americans² to 2.3 million Americans.³ However, the true prevalence of HCV in the USA remains unknown due to many factors detailed below, and despite blood testing in national sampling studies, the national HCV prevalence is likely to be under-estimated. Many high-risk populations, including homeless, institutionalized, incarcerated and undocumented populations, are **not** accounted for in many prevalence estimates. Therefore, when taking these populations into account, the actual prevalence may be much higher.

More people with opioid use disorder (OUD) are getting infected with HCV, and the recently infected are more likely to infect others in the early stages of their OUD. In March 2020, the US Preventive Services Task Force (USPSTF) changed its recommendation for HCV screening from the 1945-1965 birth cohort to universal screening at least once in their lifetime, aged 18-79 years, and to all pregnant females during each pregnancy (B recommendation).⁴ The committee notes that acute HCV infection has increased approximately 3.8-fold (2010 to 2017) and especially among young adults aged 20 to 39 years who inject drugs. In a commentary on the

new USPSTF recommendations, one expert notes that there are an estimated 44,700 new infections annually, and most of those are likely to be younger individuals associated with injection drug use.⁵

Zibbell and colleagues calculated the annual incidence of reported cases of acute HCV infection using surveillance data from 2004 to 2014. They also reviewed the percentage of admissions to substance use disorder (SUD) treatment facilities. The annual incidence rate of acute HCV infection increased more than twofold (from 0.3 to 0.7 cases/100,000) during that 10-year period. The increase in HCV trended with admissions for injection drug use (IDU) and for people who inject drugs (PWID).⁶

Zibbell and colleagues conclude:

“Substantial increases in the number of persons with opioid use disorders who inject drugs have the potential to thwart the nation’s efforts to control morbidity and mortality associated with HCV infection, consequently undermining the National Academies of Sciences, Engineering, and Medicine’s national strategy for the elimination of hepatitis B and C. It also challenges the Centers for Disease Control and Prevention’s Viral Hepatitis Strategic Plan for 2016 to 2020, which underscores reductions in HCV infections caused by IDU behaviors as a priority area. Integrated health services that include syringe service programs, medication-assisted treatment, and comprehensive HCV testing and linkage to care and treatment of HCV-infected PWID are essential to reduce prevalence and incidence among the population. Increasing access to curative HCV treatment is also a key component of a comprehensive program” (p. 180).⁶

While HCV prevalence may be decreasing as a result of deaths from late complications of HCV (liver failure, liver cancer) as well as the successful cure of some people with direct acting antiviral (DAA) medications, **the rising number of incident HCV cases may outweigh the deaths and cures.** Consequently, the overall national prevalence of HCV may be increasing. For example, in the laboratory-derived Mapping Hep C database⁷ (described more fully below), “the number of RNA-positive HCV patients increased from 200,066 patients in 2013 to 469,550 in 2016” (p. 1087). This rise in reported HCV represents more than a doubling of cases in three years. However, it is unknown whether that represents increased prevalence and incidence versus improved disease detection from more extensive screening, or both.

Deaths from HCV exceed the total number of combined deaths from 60 other infectious diseases, including HIV, pneumonia, and tuberculosis.³ Furthermore, as less than 50% of individuals diagnosed with HCV are linked to care, HCV incidence may be outpacing both cure and death from end-stage disease. Linkage to HCV care may even be in the single digits.⁸ At five federally qualified health clinics (FQHCs) in Philadelphia, although over 90% of infected individuals received test results showing HCV, only 15% of individuals started therapy for HCV.⁹

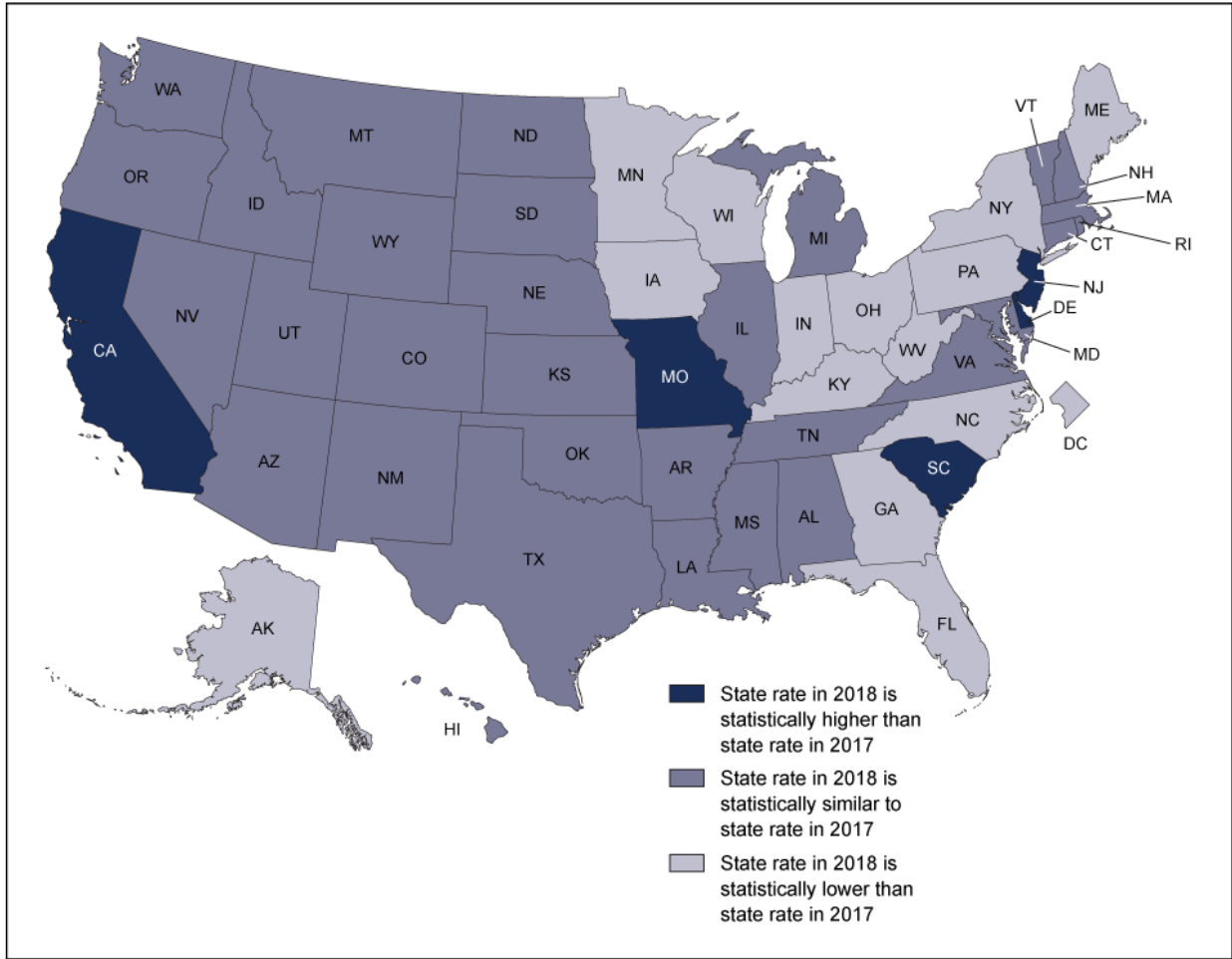
Prevalence in Delaware per National Health and Nutrition Examination Survey (NHANES)

The National Health and Nutrition Examination Survey (NHANES) utilized a statistical model to calculate HCV prevalence as well as to assess HCV mortality and narcotic overdose mortality from the National Vital Statistics System death records from 1999 to 2016.¹⁰ The study authors determined the prevalence estimates of current HCV RNA at the state level. The NHANES sampling frame includes only non-institutionalized populations, thereby underestimating the prevalence. Findings include a tripling of HCV incidence in recent years due primarily to illicit drug injection and needle sharing during this opioid crisis. They also calculated that subpopulations that are unrepresented in the NHANES-based estimates (incarceration, unsheltered homelessness) account for about 11% of HCV positive RNA prevalence. This assumption of an 11% positive RNA prevalence for chronic HCV was based on literature review of studies in these homeless and incarcerated populations.¹¹ Rosenberg and coauthors¹⁰ initially used each state's prevalence of positive RNA, but then they combined it with cause-specific death rates from HCV infection as well as narcotic overdose to try to ascertain a true prevalence. They also used the American Community Survey from 2012 to 2016 to estimate population denominators for the non-institutionalized population statewide. State-specific HCV mortality on death certificates was reviewed and added to the database, as well as narcotic overdose mortality, the latter of which is an outcome known to correlate with HCV infection.

The rate of narcotic overdose mortality in Delaware is increasing. Data from the CDC show that the overdose death rate in Delaware was higher in 2018 than in 2017.¹² While there were 14 states where the death rate from overdoses was lower in 2018 than in 2017, Delaware was one of 5 states trending in the opposite direction: more deaths.¹² Figure 1 visually represents the problem.

Figure 1. Change in age-adjusted drug overdose death rates, by state: United States, 2017 and 2018¹³

Figure 2. Change in age-adjusted drug overdose death rates, by state: United States, 2017 and 2018



NOTES: Deaths are classified using the *International Classification of Diseases, 10th Revision*. Drug-poisoning (overdose) deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Access data table for Figure 2 at: https://www.cdc.gov/nchs/data/databriefs/db356_tables-508.pdf#2. SOURCE: NCHS, National Vital Statistics System, Mortality.

In Delaware, using a denominator of 719,400 for the 2016 adult population, the sampling frame from NHANES alone estimated that there are 5600 individuals with positive HCV RNA, (95% confidence intervals 4800-6500). With additional populations not included in the NHANES sampling frame, the number of infected individuals in Delaware increased to 6300 individuals, for a prevalence of 0.86%.¹⁰ Bradley et al. also analyzed NHANES laboratory data and found that persons born between 1945 to 1965 had the highest prevalence of HCV infection, but that new infections are increasing among the young due to intravenous drug use.¹³ The prevalence (per 100) and prevalence ratios (PRs in reference to > 1969 cohort) in Delaware per Bradley’s calculations can be viewed in Table 1.

Table 1. Prevalence (per 100) of HCV in Delaware per Bradley’s Calculations

	< 1945 cohort	1945-1969 cohort	>1969 cohort
Prevalence	0.14	1.40	0.55
PRs	0.25	2.54	1.08

The authors conclude that new HCV infections have increased especially among young people who inject drugs and that treating HCV can prevent new transmissions.

Prevalence and Associated Mortality in USA and Delaware per Delaware Department of Health Reports and Centers for Disease Control Data

Although HCV is a reportable infectious disease, it is most certainly underreported due to a variety of factors. The CDC estimates that there are approximately 14 times more acute HCV infections than are reported,¹⁴ and some suggest that figure may be an underestimate.¹³

State-level data of new cases of confirmed chronic HCV are not available for DE on the CDC website. However, there were 50 cases where HCV was listed as the underlying cause of death on death certificates in DE in 2017.¹³ Thus, a crude estimate of the overall death rate for HCV as the underlying cause of death in DE is 5.3 per 100,000.¹⁵ In 2015, 1200 cases of HCV were reported to the DE Dept. of Health (DOH). In 2016, there were 2592 cases of HCV reported.¹⁶

Presuming that the cases for 2016 were **new** cases not previously reported, the calculated incidence rate is 272 cases per 100,000 individuals (0.027%) in DE.¹⁶ The numbers of cases in Delaware cannot be compared to national data due to administrative differences in reporting, as the Delaware registry combines both incident and prevalent cases of HCV. Furthermore, the challenge of incomplete data ascertainment persists.

According to the Center for Community Research report on HCV Epidemiological Profile prepared by the University of Delaware for the Division of Public Health in December, 2017, there is a bimodal distribution of new HCV cases reported in 2016.¹⁶ The highest number of cases was in those over 51 years of age (932 cases), followed by those 20-29 years of age (675 cases) and then those 30-39 years of age (600 cases).¹⁶ More than half (52%) of the reported HCV cases in 2016 involve individuals living in New Castle County. However, the incidence rate is higher in Sussex (315.1 per 100,000) and Kent Counties (315.7 per 100,000). The age cohort with the highest rate of HCV is among those 20-29 years of age (527.5 per 100,000), although about 1/3 of the individuals reported to the DOH are over 51 years of age.¹⁶

Prevalence and Associated Mortality in Delaware per HepVu Map

The HepVu website,³ sponsored by Emory University, combines data from several surveillance studies and presents state-specific data in a clickable map to view HCV prevalence and mortality statistics with further stratification by age, race, sex, and several other demographic factors. This website also visually collates the relationship between HCV and the opioid epidemic. Between 2013 and 2016 in Delaware, there were an estimated 860 of every 100,000 people living with HCV (0.86%) with 6300 unique individuals estimated to be living with HCV.¹⁷ During this time, narcotic overdose mortality was 25.78 for every 100,000 people (0.026%). In 2017 in Delaware, there were a total of 49 reported HCV-related deaths, or approximately 5 per 100,000 people (0.005%). At this time, the statewide opioid prescription rate was 68.3 per 100 people.¹⁷

Prevalence and Associated Mortality in USA and Delaware per Mapping Hep C Database

A commercial web-based site, sponsored by Abbvie Pharmaceuticals, combines two large commercial laboratory datasets of HCV antibody and RNA testing and other laboratory characteristics from 2013-2017. The site lists results by state.¹⁸ For Delaware, in 2017 there were:

- 36,939 individuals screened with HCV Antibody (Ab) test with 2,916 positive test results.
- Extrapolated data estimate that in Delaware there may be as many as 11,490 individuals with a positive HCV Antibody test as of 2017. However, the Antibody test proves exposure only, not active infection.

The same map shows a total of 1,913 individuals with detectable HCV RNA, with an extrapolated estimate of 6,732 RNA positive individuals (actively infected) in Delaware.

Upon closer review of the Mapping Hep C database, amongst the individuals with detectable HCV RNA, the vast majority (79.4%) were infected with genotype 1 followed by genotype 2 (10.3%), 3 (9.5%), 4 (0.6%) then 5 and 6 combined (0.2%).

For 1,749 individuals in Delaware who also had laboratory fibrosis (F) scores available, the distribution (in percentage) is as follows: F0-F1 (51.6%), F2 (21.3%), F3 (9.8%), and F4 (17.3%). This distribution, which is skewed towards the lower end of fibrosis, is important. Per current guidelines, the vast majority can be treated without associated imaging or procedures before initiating drug therapy or after drug therapy for later surveillance.¹⁹

- In 2017 there were 428 individuals who were treated (actual data), regardless of the type of therapy. However, there were 47 less individuals treated in 2017 compared to 2016, representing a decrease of 9.9%.¹⁸
- Using modeling from the Mapping Hep C site, the year of achieving all World Health Organization (WHO) targets of incidence, diagnosis, and treatment in Delaware would not be until 2038.

In Delaware, according to the modeling by Abbvie, 733 infected individuals need to be treated annually to achieve WHO treatment target date of 2030.¹⁸

This database has several limitations. Firstly, the database consists solely of patients who have given informed consent (for data sharing). It is not known whether those individuals who have heightened privacy regulations by virtue of Code of Federal Regulation (CFR) 38 or 42 status (Veterans Affairs and alcohol and drug treatment programs, respectively) or incarcerated individuals are included in these data sets. Assuming that these classes of individuals are not included in the above data, the extrapolated estimate of 6,732 infected individuals in Delaware in 2017 may still be a conservative number, considering the higher prevalence of HCV among these unique subpopulations. Moreover, the database only includes datasets derived from two regional, large laboratories, further leading to a likely under-representation of the true HCV prevalence in Delaware secondary to incomplete data ascertainment.

Perinatal Transmission of HCV

The number of infected individuals may be increasing with both horizontal as well as vertical transmission as more women with OUD are having children born with HCV infection. Between 2009 to 2014, maternal HCV infections nearly doubled among reporting states in the United States.²⁰ In Delaware, the rate of HCV among neonates per 1,000 live births in 2014 was 2.6 – 5.0.²⁰ Overall trends for the US show that the HCV infection rate increased in neonates at delivery from 0.8 per 1,000 live births in 2000 to 4.1 in 2015, but among women with OUD, there were increases from 87.4 to 216.9 among 1,000 live births.²¹ That represents a 148% increase of HCV infection among women with OUD. Yet, these figures may underestimate the

prevalence of OUD and HCV infection due to lack of screening and stigma, among other factors.

According to the University of Delaware Hepatitis C Epidemiologic Profile report (Table 39; p. 34), among those 0-9 years of age, the medical claims for Medicaid recipients with HCV diagnoses rose from 20 in 2009 to 51 in 2015; which is about a 2.5 times increase in Medicaid claims in 6 years in the youngest cohort in Delaware.¹⁶

Morbidity and Mortality from HCV and Its Consequences

As stated in the introduction, HCV-associated mortality, especially from liver cancer, is increasing. Rosenberg et al. note that about half of those with chronic HCV develop progressive liver disease, which may include cirrhosis and liver cancer.¹⁰ According to the Delaware Cancer Registry, which was started in 1996, liver cancer (hepatocellular cancer) nearly doubled from 2006 to 2015 with 46 cases in 2006 and 74 cases in 2015.¹⁶ Thus, these data support the increasing prevalence of manifestations of end stage HCV and the advancing stages of disease without treatment.

Other Demographic Factors and Linkage to HCV Care

What are some of the other demographic characteristics of individuals with HCV in Delaware that may impact access to HCV care and treatment? According to the University of Delaware Hepatitis C Epidemiologic Profile report,¹⁶ “patients with HCV are disproportionately likely to be uninsured or Medicaid eligible” (p. 6). Moreover, HCV prevalence is inversely related to income. A report examining the burden of HCV in commercial and managed Medicaid populations (not necessarily in Delaware) found that the overall prevalence rate of HCV is 7.5 times higher in the Medicaid population compared to a commercially insured population.²² If we can assume that those with Medicaid are 7.5 times higher to have HCV than the commercially insured population,²² then the HCV-infected population in Delaware definitely lacks linkage to care and treatment.

Few HCV-infected Delawareans have received HCV treatment due to a myriad of contributing factors, one of which may be insurance as mentioned above. Additionally, low levels of HCV treatment in Delaware may be, in part, due to administrative restrictions, as the state did not expand DAA treatment access through the complete elimination of fibrosis restrictions until January 2018.²³ Additional historical restrictions including but not limited to the provision that only sub-specialists such as hepatologists or infectious diseases specialists could prescribe DAA therapy and the requirement for patients to provide a recent and/or negative urine drug screen were further barriers in the prescribing and approval of HCV treatment. Limited data on Delaware Medicaid clients receiving HCV prescriptions between 2012-2015 (p. 35; Table 41) demonstrate that prior to 2015 most infected individuals were treated with ribavirin and interferon, whereas the DAAs started to be more widely prescribed in 2015.¹⁶

From 2012 to 2015 there were a total of 485 prescriptions for HCV treatment in Delaware (Table 2).¹⁶ In 2015, DAAs were first used, probably leading to the increase in therapy that year. There was no searchable information in DE available after 2015 for Medicaid data, however.

Table 2. Prescriptions for HCV Treatment in Delaware

Year	Number with Prescriptions
2012	171

2013	100
2014	69
2015	145

Stigma is one of the main causes that HCV-infected individuals do not seek care and why linkage to care is so abysmal.²⁴ The experts on the National Academy of Sciences panel conclude:

“Stigma remains difficult to overcome and was raised by [OUD] programs as a perennial problem, as was the potential for additional stigma among people who use drugs and have also been diagnosed with an infectious disease... Stigma ... may keep someone from seeking care“ (p. S-10).²⁴

In addition, other factors contribute to a failure of treatment of these infected individuals. Talal et al. note that not only stigma but also the “chaotic lifestyles” that persons with SUD lead may preclude treatment of HCV in a traditional setting.²⁵ They also note that 68-80% of HCV infections in developed countries happen in those with SUD.²⁵ The logical conclusion is to treat these infected individuals where they are located: bring the “medical home” of HCV treatment to them: specifically, in medication assisted treatment (MAT) programs.

The participants of the above-referenced National Academy of Sciences monograph²⁴ further conclude:

“...there is a great deal to be accomplished at the intersection of opioid use disorder and infectious diseases at many points in the health care system, as well as across society more broadly. It is essential to dismantle the barriers impeding prevention and treatment. Patients, families, and society writ large cannot afford delay, and it is the committee’s hope that the strategies outlined here may alleviate the burden of these dual epidemics” (p. S-15).²⁴

Conclusion

There have been many different databases and methodologies for estimating the prevalence of HCV in the USA and Delaware. Regarding Delaware, the major databases and methodologies include: NHANES, HepVu, Mapping Hep C, and reported cases to DE DOH. NHANES and HepVu estimate 6300 HCV cases from 2013 to 2016. Mapping Hep C estimates over 6700 cases in 2017, but there were 2592 HCV cases reported to DE DOH in 2016 alone. HCV estimates range from 6300 to over 6700 individuals with all estimates suffering from incomplete data ascertainment leading to the under-reporting of statewide HCV incidence and prevalence. Using the calculations of the Mapping Hep C database, 733 infected individuals in Delaware need to be treated annually to achieve the WHO treatment target date of 2030 for HCV elimination. Yet, not enough Delawareans are receiving treatment. Moreover, even with recent guideline updates to support universal adult HCV screening there is inadequate screening and diagnosis of HCV cases and an HCV care continuum in dire need of improvement.

Nevertheless, screening, diagnosis and linkage to care, administrative requirements for prior authorization, stigma, the “chaotic lifestyle” of the HCV-infected individual, and other non-quantifiable factors all lead to under-treatment of HCV in the Delaware population. Since HCV is co-epidemic with the opioid epidemic, it makes sense to treat both OUD and HCV

simultaneously at the same site: either at the opioid treatment program (with methadone, buprenorphine/naloxone, or long-acting naltrexone) or in primary care clinic (with buprenorphine/naloxone, or long-acting naltrexone). The provision of HCV care at the client's pre-existing medical home aids in diminishing stigma and potential barriers to HCV care. Clearly, there is an urgent need to co-locate OUD treatment programs and infectious diseases treatment, especially HCV treatment. Treat both. And treat them now.

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