



# EPIDEMIOLOGICAL PROFILE: THE HEPATITIS C EPIDEMIC IN RHODE ISLAND



**RIPHI** RHODE ISLAND  
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## Message from the Director of Health

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This is the first comprehensive epidemiologic report from diverse data sources regarding hepatitis C virus (HCV) for the state of Rhode Island. HCV is the most common blood-borne infection in the United States; an estimated three to five million Americans are chronically infected.<sup>1-2-3</sup> Chronic HCV infection causes hepatic fibrosis, cirrhosis, liver cancer, and liver failure, and is the most common reason for needing a liver transplant. Nationwide, more people die of HCV-related causes than from HIV and 59 other infectious diseases combined.<sup>4</sup> Many individuals with reactive HCV antibody tests never receive follow-up testing to confirm chronic HCV infection. Early diagnosis and treatment can help prevent HCV transmission and reduce HCV-related morbidity and mortality. However, 50% to 75% of chronically-infected individuals are unaware of their infection and will not benefit from these interventions; many are diagnosed when they have advanced liver disease. Advances in HCV treatments can now cure more than 95% of chronically-infected individuals. New treatment regimens present important public health opportunities to reduce HCV-related morbidity and mortality.

Individuals born between 1945 and 1965, known as baby boomers, bear a disproportionate share of the HCV disease burden across the nation. Screening is a critical first step to advance HCV treatment and cure. To identify individuals who are unaware of their infection, the Centers for Disease Control and Prevention (CDC) recommends one-time HCV screening for all individuals born between 1945 and 1965, and ongoing screening for other high-risk populations.

Previous studies estimated that nearly 23,000 individuals in Rhode Island (approximately 2% of Rhode Islanders) are currently chronically infected with HCV.<sup>5</sup> This report characterizes the public health burden of HCV in Rhode Island by using a variety of data sources, including vital statistics, hospitalization and discharge data, and cancer registry data. We also present information from the US Department of Veterans Affairs, Rhode Island Medicaid, the Office of the Health Insurance Commissioner, and the Rhode Island Department of Corrections. We present utilization and HCV trends associated with public health programs such as community-based rapid HCV testing and the ENCORE needle exchange program. We characterize HCV screening in major laboratory and hospital systems, and estimate the number of Rhode Islanders who have been cured of HCV in recent years. We also present important data related to HCV and overdose. Rhode Island is currently experiencing a syndemic of HCV, opioid dependence, and overdose. Rhode Island ranks sixth-highest in the nation for drug overdose death rates and highest in New England. HCV can be an infectious consequence of substance use, particularly when substances are injected; so there is an opportunity to address our HCV and overdose epidemics concurrently.

A comprehensive set of action steps are needed to address the HCV disease burden in Rhode Island. Greater efforts are needed to enhance HCV surveillance, prevention, testing, diagnosis, and treatment. To accomplish this, we will partner with community organizations, medical providers, health systems, and academic institutions throughout Rhode Island. With the information and insights provided in this report, our next step is to continue to work on finalizing a Rhode Island Hepatitis C Strategic Plan that will address four priority areas: expansion of HCV screening, care, treatment, and cure, with a focus on reducing and preventing liver disease and HCV-related morbidity and mortality; strengthening HCV surveillance; education of healthcare providers and communities about HCV screening, care, and cure; and reduction in the transmission of HCV that is a consequence of substance use.

Together with my colleagues at the Rhode Island Department of Health, I wish to thank Dr. Amy Nunn and Dr. Thomas Stopka from the Rhode Island Public Health Institute and Tufts University for their valuable contributions to this report. I also want to acknowledge support from the Association of State and Territorial Health Officials (ASTHO) for providing resources to make this report possible.

Thank you for your interest and support as we build healthier communities in Rhode Island.

Sincerely,



Nicole Alexander-Scott, MD, MPH  
Director, Rhode Island Department of Health

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## Executive Summary

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- There were significant increases in HCV-related deaths in Rhode Island in recent years. In 2014, among Rhode Islanders, there were 102 deaths associated with HCV; this represents a five-fold increase in the last decade. As in other parts of the United States, HCV morbidity and mortality disproportionately impacts white men born between 1945 and 1965.
- There is an overwhelming public health opportunity associated with screening and curing HCV; new medications can cure most individuals living with HCV in eight to 12 weeks and dramatically reduce HCV-related morbidity. HCV screening has increased significantly in Rhode Island in recent years, both in clinical and non-clinical settings. The HCV prevalence rate, based on antibody testing from health systems and laboratories represented in this report ranged from 3.7% to 6%. The percentage of individuals with confirmed chronic HCV who underwent antibody screening is previously unknown; however, based on national estimates, this would likely range from 3.1% to 5.1%. These trends suggest that the HCV disease burden in Rhode Island may be higher than previously estimated.
- RI Medicaid also reported large volumes of HCV screening. Medicaid claims data suggest that approximately 13,000 Medicaid beneficiaries underwent HCV antibody screening in 2014 and in 2015. More than 1,700 HCV genotype test claims were made to Medicaid in 2014-2015, suggesting that there were approximately 1,700 Medicaid beneficiaries with an HCV diagnosis in Rhode Island in 2014 and 2015. It is unknown how many of those individuals sought curative treatment and care services, but RI Medicaid financed HCV treatment for 215 Medicaid beneficiaries in 2015.
- The Rhode Island Department of Corrections (RIDOC) conducts HCV antibody screening for prisoners. The HCV prevalence rates for inmates undergoing antibody screening at the RIDOC is 17%. The RIDOC has increased screening, treatment, and cure efforts in the last year.
- In 2013, the VA adopted CDC guidelines for screening of all baby boomers. As a result, the Providence VA screening rates have increased dramatically in recent years. During the first two quarters of 2016, 70% of all eligible baby boomers at the Providence VA were screened for HCV. The VA also provides medications for treatment for all individuals living with HCV, and more than 100 Providence VA patients were cured of HCV in 2015.
- In addition to large numbers of individuals being screened and treated at the VA, private medical providers across Rhode Island have made tremendous progress in curing Rhode Islanders of HCV. At least 1,100 patients have been cured by private providers in the last two years. Others still await financial approval for curative HCV therapies.
- Treating HCV is cost effective because in the long run, it reduces future HCV-morbidity and saves the lives of people living with HCV. However, expanding access to treatment has up-front costs for individuals, payers, and the broader public health system. While the per-patient costs have declined in the last year as more drugs became commercially available, OHIC estimates that medications for curing HCV contributed to a 0.5% increase in health insurance premiums in Rhode Island in 2015. The high prices of medications have strained state budgets and prompted some health plans to restrict access to drugs for treatment for some patients.
- Lastly, in spite of much greater access and utilization of HCV curative therapies, HCV-related hospitalizations have increased in Rhode Island in recent years.

## **PURPOSE**

Previous studies using mathematical models drawn from national data trends suggested that approximately 12,286 to 16,768 individuals in Rhode Island (1.2%-1.7% of Rhode Islanders) are currently chronically infected with the hepatitis C virus (HCV).<sup>5</sup> Current HCV surveillance infrastructure in Rhode Island is limited. To date, HCV estimates are based on a combination of National Health and Nutritional Examination Survey (NHANES) extrapolation and modeling exercises rather than data collected and reported through an electronic HCV surveillance system. This report is an effort to develop a comprehensive HCV epidemiologic profile for Rhode Island.

## **METHODS**

The team leveraged existing datasets and collected information from new sources, including clinical and community partners, about HCV screening, prevalent infections, incident cases, treatment, and cure. This surveillance report drew on several different public and private data sources as well as in-depth interviews. The Rhode Island Department of Health (RIDOH) has multiple, high-quality data systems in place that has enhanced understanding of the state's HCV epidemic, including vital statistics, cancer registries, and hospitalization data. These systems had not previously been used to improve understanding of local HCV disease burden. The authors proposed leveraging those datasets with existing data sets collected from the publicly-funded needle exchange program and from the community-based agencies that screen for HCV. Third, the authors solicited new information on HCV screening and related outcomes from public and private laboratories, major hospital systems, community health centers, methadone clinics, drug treatment facilities, RI Medicaid, the VA, RIDOH's Center for Vital Records, and the Office of the State Medical Examiners. Fourth, the authors solicited input from the Rhode Island Department of Corrections, which screens and provides curative therapies for many inmates living with HCV. Lastly, the authors drew on secondary data sets related to overdose and syringe access in pharmacies.

All use of counts contained in this report to construct the portions, rates, or other statistics are subject to reliability and privacy verifications specifically under the small new numerator and denominator sections of the state of Rhode Island public health information reporting policy. In addition, most data presented in this report are based on trends in total events rather than individual patients; data could not always be de-duplicated for patients who may have presented multiple times for services. The report nevertheless provides useful information on HCV data and trends for the state of Rhode Island.

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## *Rhode Island Sociodemographic Overview*

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Rhode Island's population is 1,056,298. Rhode Island has the second highest population density in the United States, with 1,033 people per square mile. The state covers an area of 1,045 square miles, of which 40 square miles are coastline. Providence is Rhode Island's capital and its largest city, with a population of 179,207. The population of the state is predominately white (81.4%), but also has a large Latino population (12.4%). African-Americans comprise 5.7% of the population, followed by Asians (2.9%), American Indian/Alaskan Native (0.6%), and Native Hawaiian/Pacific Islander (0.1%). From 2010 to 2014, the median household income was \$56,423, and per capita income was \$33,765. Approximately one in seven Rhode Islanders (14.3%) live in poverty. More than 20% of the population in the state is younger than 18, and more than 68,000 veterans live in Rhode Island. Rhode Island expanded Medicaid in 2013 and now has the second highest rate in the country of individuals with health insurance, following Massachusetts.<sup>6-7-8</sup>



## **HCV in the United States**

HCV is the most common blood-borne infection in the United States. It is estimated that 3.2 million Americans are chronically infected. Chronic HCV infection increases the risk for hepatic fibrosis, cirrhosis, and hepatocellular carcinoma and is the most common reason for needing a liver transplant.<sup>9</sup>

During the past decade, the annual number of deaths attributed to HCV in the United States surpassed the total number of deaths attributed to HIV and 59 other nationally-notifiable infectious diseases combined.<sup>4</sup> The number of deaths associated with HCV in the United States increased from 11,051 in 2003 to 19,368 in 2013. These deaths represented an average annual increase of 865 deaths per year, and an average annual percent increase of 6.2%.<sup>4</sup> Experts believe the increasing HCV-related mortality may be attributed to the fact that many HCV-infected persons are not receiving antiviral therapy and achieving a sustained virologic response, indicative of a cure. The increase in HCV-related deaths highlights the critical need to diagnose and treat patients living with HCV.

The CDC recommends one-time HCV screening for all individuals born between 1945 and 1965, and ongoing screening for other high-risk populations. Screening in clinical settings may not reach individuals at highest risk,<sup>10</sup> and surveillance systems often do not accurately capture acute HCV infection, thereby underestimating true HCV prevalence.<sup>11</sup> Further, based on data estimates from the New York City Department of Health and Mental Hygiene, only half of individuals who test positive for the antibody to HCV (anti-HCV) undergo confirmatory RNA testing.<sup>12</sup> New direct-acting antiviral agents (DAAs) can cure patients with greater than 95% efficacy. However, high prices and high demand for new DAAs has prompted some insurance plans to restrict paying for medications to individuals with advanced liver disease.

## **Current HCV Landscape in Rhode Island**

An estimated 16,603 to 22,660 individuals in Rhode Island (approximately 2% of Rhode Islanders) have been infected with HCV.<sup>5</sup> However, these estimates were based on a combination of extrapolation and statistical modeling approaches rather than data obtained from HCV surveillance systems. In the absence of a robust HCV surveillance system in the state, our knowledge about the local HCV epidemic has been limited. It is estimated that Rhode Island's numbers mirror those of the country, and the number of HCV-related deaths has far surpassed those of HIV infections; however, local trends in HCV-related deaths had not yet been explored.

## **Community Engagement, Advocacy and Other HCV Programs**

### *Rhode Island Hepatitis C Action Coalition (RIHAC)*

The Rhode Island Public Health Institute, in partnership with the Rhode Island Department of Health and the state's leading HCV care providers, joined with key stakeholders to develop the Rhode Island Hepatitis C Action Coalition (RIHAC) in 2014. RIHAC's primary goal is to reduce the HCV disease burden in Rhode Island and to advance HCV screening, confirmatory testing, treatment, and cure. The coalition is comprised of more than 75 stakeholders, including clinicians, advocates, public health officials, community-based agencies, researchers, and public servants. Most of the providers who treat large volumes of HCV patients participate in RIHAC. RIHAC also leads efforts to enhance and scale HCV screening and treatment in the state of Rhode Island through advocacy and education, capacity building, and provider training. RIHAC has helped inform Rhode Island's forthcoming strategic plan for HCV.

### *Rhode Island Defeats Hep C (RID Hep C)*

Supported by an Innovation Fellowship from the Rhode Island Foundation to Lynn E. Taylor, MD, *RI Defeats Hep C* is a comprehensive program to "Seek, Treat, Cure and Eliminate HCV" in the state. *RID Hep C* also aims to reduce illness, suffering, and deaths due to HCV in Rhode Island; save money for the state and Rhode Islanders by enhancing proactive HCV care; and bring resources into the state to help combat the HCV epidemic. *RID Hep C* focuses on the key target populations of baby boomers (anyone born between 1945 and 1965) and people with a history of injection drug use. Recent accomplishments include development of the aforementioned estimates on prevalence of HCV in Rhode Island,<sup>5</sup> and an effort to eliminate HCV at CODAC (RI's only not-for-profit methadone clinic). *RID Hep C* also supports the work of

RIHAC and works with Lifespan, the state's largest healthcare system, to implement routine reflexive HCV RNA diagnostic testing (used to confirm HCV infections detected through initial antibody testing) with all HCV antibody screening for all patients tested for HCV through Lifespan Laboratory Services, which is the largest clinical laboratory in Rhode Island.

*AIDS Care Ocean State (ACOS)*

ACOS is a comprehensive AIDS service organization based in Rhode Island that has been providing HIV healthcare and prevention services to Rhode Island since 1989. ACOS has a long history of accessing and serving the highest-risk clients with culturally and linguistically appropriate HIV/HCV testing and prevention services and was the first community-based organization to provide integrated HIV and viral hepatitis services to Rhode Islanders. ACOS conducts extensive community outreach through fixed and mobile sites and provides services in Providence, Newport, Woonsocket, Pawtucket, Central Falls. ACOS also conducts counseling and testing in bars/clubs, adult venues, and at special events. Along with providing HIV and HCV counseling, testing, and referral services in the field, ACOS also oversees the state's only needle exchange program, ENCORE. ENCORE services, integral to HCV prevention, are integrated with ACOS's other field-based activities and needle-exchange services are provided in the communities listed above. ACOS also has strong partnerships with HIV medical and support services in Rhode Island and has staff with expertise in substance use, homelessness, and poverty issues.

## **Background**

The Rhode Island Department of Health (RIDOH) is the single, centralized health department in the state of Rhode Island and carries out functions of both a local and state health department. RIDOH is home to the Division of Preparedness, Response, Infectious Disease, and Emergency Medical Services (PRIDEMS), which oversees the reporting of nationally- and state-reportable conditions, including acute and chronic HCV infections. PRIDEMS maintains a largely paper-based surveillance system with hard-copy reporting from laboratories and providers. Progress towards developing a comprehensive case-based surveillance system driven by electronic laboratory reporting (ELR) is an important priority for RIDOH.

In Rhode Island, infectious disease surveillance is conducted using the National Electronic Disease Surveillance System (NEDSS) and the NEDSS Base System (NBS). Viral hepatitis surveillance, which includes a focus on hepatitis A, B, and C, is conducted using the NBS but has relied heavily on manual data entry in the past, limited by an absence of dedicated funding and human resources for HCV surveillance. The NBS has the capability of accepting ELR, and connections have been developed with Mayo Laboratories, Laboratory Corporation of America (LabCorps), Imugen (a regional laboratory), and the State Health Laboratory at RIDOH. The movement to ELR is a major success in infectious diseases surveillance. However, these laboratories and health systems only account for a small fraction of all HCV screening that is occurring in Rhode Island.

RIDOH is currently expanding ELR related to HCV surveillance. The Rhode Island Informatics and ELR team is in the process of implementing electronic reporting from the major Rhode Island hospital systems which together account for the vast majority of inpatient services delivered in Rhode Island. Once completed, RIDOH will have near real-time access to HCV antibody and nucleic acid testing (NAT) results, which facilitate confirmation of HCV infections, and a greater opportunity to practice routine surveillance based on laboratory reporting. Rhode Island aims to transform its paper-based surveillance system to an automated ELR in the next one to two years. In the interim, RIDOH will continue to develop these ELR connections in order to accurately estimate the volume of viral hepatitis testing in Rhode Island, including antibody and NAT results. This will inform development of an HCV case reporting system, paving the way for a robust HCV surveillance system.

## **Data Sources used for this report**

Both RIDOH internal and external data sources were compiled and analyzed in the development of this HCV epidemiological profile.

### **RIDOH Internal Data Sources**

- Cancer Registry – RIDOH maintains a registry of all reported cancer diagnoses within the state, including reports of liver cancer and cancer diagnoses among individuals infected with HCV.
- Center for Vital Records – RIDOH collects and maintains a registry of all deaths in Rhode Island, and all deaths among Rhode Island residents. These systems include information on primary and underlying causes of death.
- Hospital Discharge Data – RIDOH collects reports of all hospitalizations from the state's 11 acute-care hospitals. This data include up to 25 diagnostic codes related to the hospitalization of people living with HCV.
- ENCORE Needle Exchange Program – RIDOH supports a needle exchange program that is managed by ACOS. ENCORE collects information on all needle exchange participants, including demographic characteristics, behavioral data, self-reported disease status, and daily needle exchange logs.
- Viral Hepatitis Prevention Program, Community-based HCV screening program – RIDOH contracts with community-based agencies to provide rapid HCV testing to high-risk individuals. Demographic data, behavioral data, and test results are collected and reported to RIDOH.

### **External Data Sources**

- Opioid Overdose Data – RIDOH collaborated with the Rhode Island Governor’s Overdose Prevention and Intervention Task Force to obtain and review data related to opioid overdose trends and injection drug use trends in Rhode Island.
- Health system commercial laboratory HCV testing data – RIDOH collaborated with major health and laboratory systems to analyze data related to HCV screening, confirmatory testing, and genotype testing.
- Methadone Clinics – RIDOH collaborated with the state’s methadone clinics to profile screening practices.
- Rhode Island Department of Corrections (RIDOC) – RIDOH partnered with RIDOC to describe current HCV testing and treatment activities in the correctional system.
- Hepatitis C private providers – RIDOH partnered with major healthcare providers who care for people living with HCV to gain estimates on the numbers of people receiving curative therapies for HCV in Rhode Island.
- Executive Office of Health and Human Services Medicaid Program – RIDOH partnered with the Office of Medicaid to describe screening and treatment claims among Medicaid beneficiaries.
- Providence VA Medical Center – RIDOH collaborated with the local Providence VA Medical Center to describe screening, treatment, and cure trends among the veteran population.

The combination of data from each of these data sources provided a more comprehensive understanding of the HCV epidemic in Rhode Island. This reports aims to highlight the most current data available for HCV.

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## Hospitalizations

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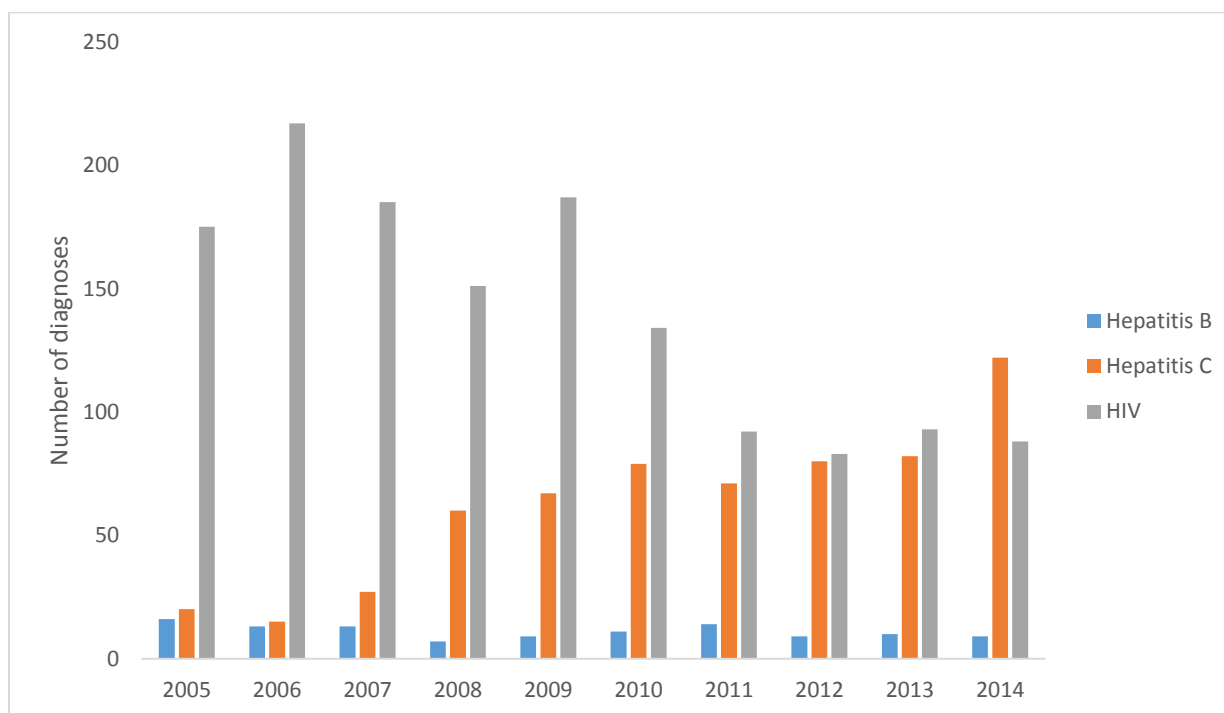
Patients in the United States with chronic HCV are estimated to have a hospitalization rate three times that of people without HCV infection.<sup>13</sup> As the HCV-infected population ages, people living with untreated HCV can develop cirrhosis, liver cancer, and liver failure.

From 2005 to 2014, the number of hospitalizations at Rhode Island acute-care hospitals ranged from 112,715 to 132,455 hospitalizations per year. The hospitalization figures reflect the primary discharge diagnoses of hepatitis B virus (HBV), HCV, or HIV, as well as any additional discharge diagnoses. The authors used International Classification of Diagnosis codes (ICD-9) codes adopted by the Centers for Medicare and Medicaid Services (CMS). These codes provide a standard way to collect, analyze, and interpret healthcare data. Up to 25 diagnostic codes can be reported upon hospital discharge. For comparative purposes, the authors also examined HBV and HIV discharge codes and used the following HCV-related codes: 70.41, 70.44, 70.51, 70.54, 70.70, 70.71; the following HBV codes: 70.2, 70.2, 70.3; and the following HIV codes: 042, V08, 79.53.

There are ICD coding schema for death data and for hospital discharge data (to report medical information). The codes are periodically revised and updated. For all death data, ICD-10 codes replaced ICD-9 codes in 1999. For hospital discharge data, ICD-10-CM replaced ICD-9-CM as of October 1, 2015. Since the hospital discharge data used for this report are prior to October 2015, there are two sets of codes that are utilized given the transition from ICD-9 to ICD-10.

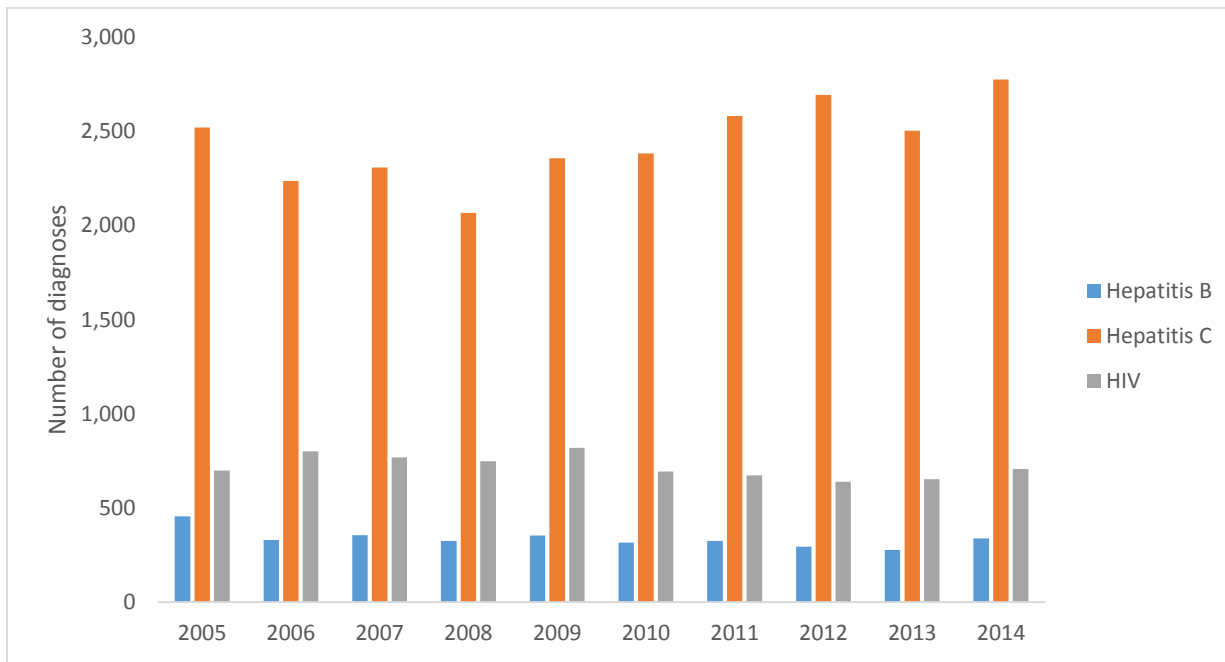
Figure 1 depicts the number of hospitalizations for HBV, HCV, and HIV, based on primary discharge diagnosis from 2005 to 2014. HCV diagnoses increased in the past 10 years from 20 in 2005 to 122 in 2014. During this same time period, HIV diagnoses decreased and HBV diagnoses remained stable.

**Figure 1: Inpatient Hospitalizations with a Primary Discharge Diagnosis of HBV, HCV, or HIV; Rhode Island; 2005-2014**



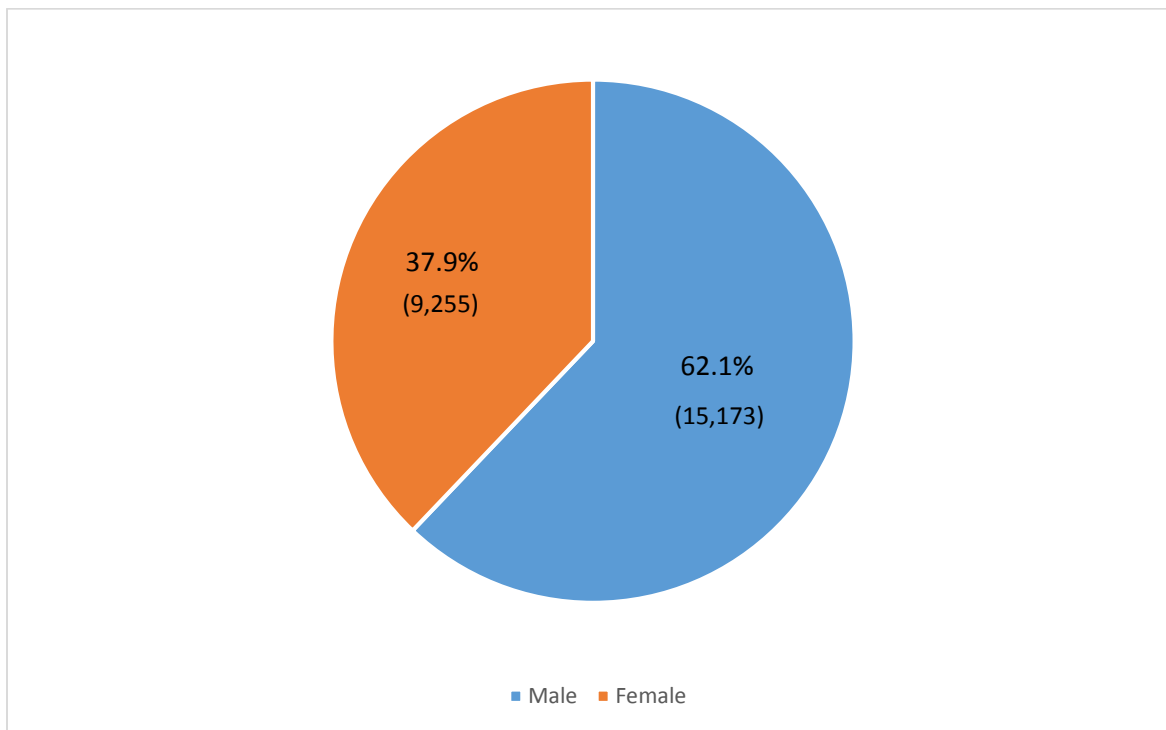
Nationally, deaths attributed to HCV have surpassed the total number of deaths attributed to HIV and 59 other infectious diseases, combined, in recent years.<sup>4</sup> In Figure 2, shows a similar trend in Rhode Island for HCV-related hospitalizations, this data focusing on *any* discharge diagnosis. Discharge diagnosis of HCV remained consistently higher than HIV and HBV hospitalizations combined during the past decade, and increased slightly in recent years.

**Figure 2: Inpatient Hospitalizations with Any Discharge Diagnosis of HBV, HCV, or HIV; Rhode Island; 2005-2014**



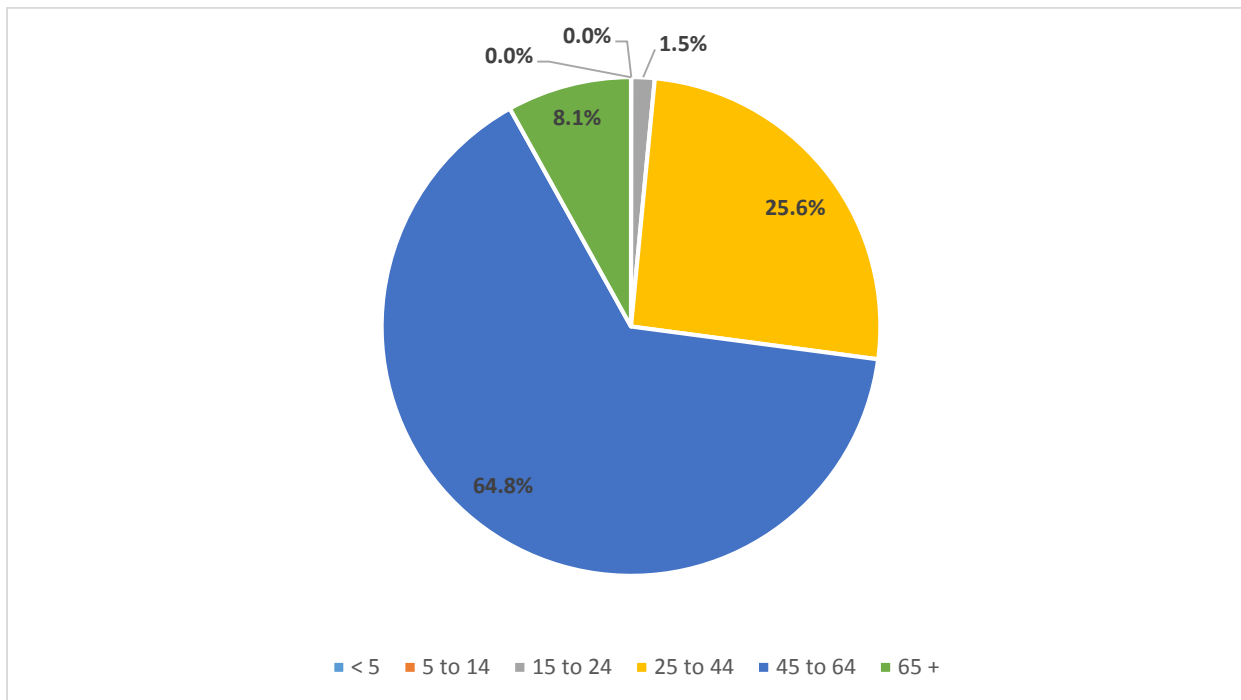
Males in Rhode Island are hospitalized with HCV at a higher rate than females are. More than 60% of hospitalizations in the last 10 years have been among males (Figure 3).

**Figure 3: HCV-Related Hospitalizations by Gender, Rhode Island, 2005-2014**



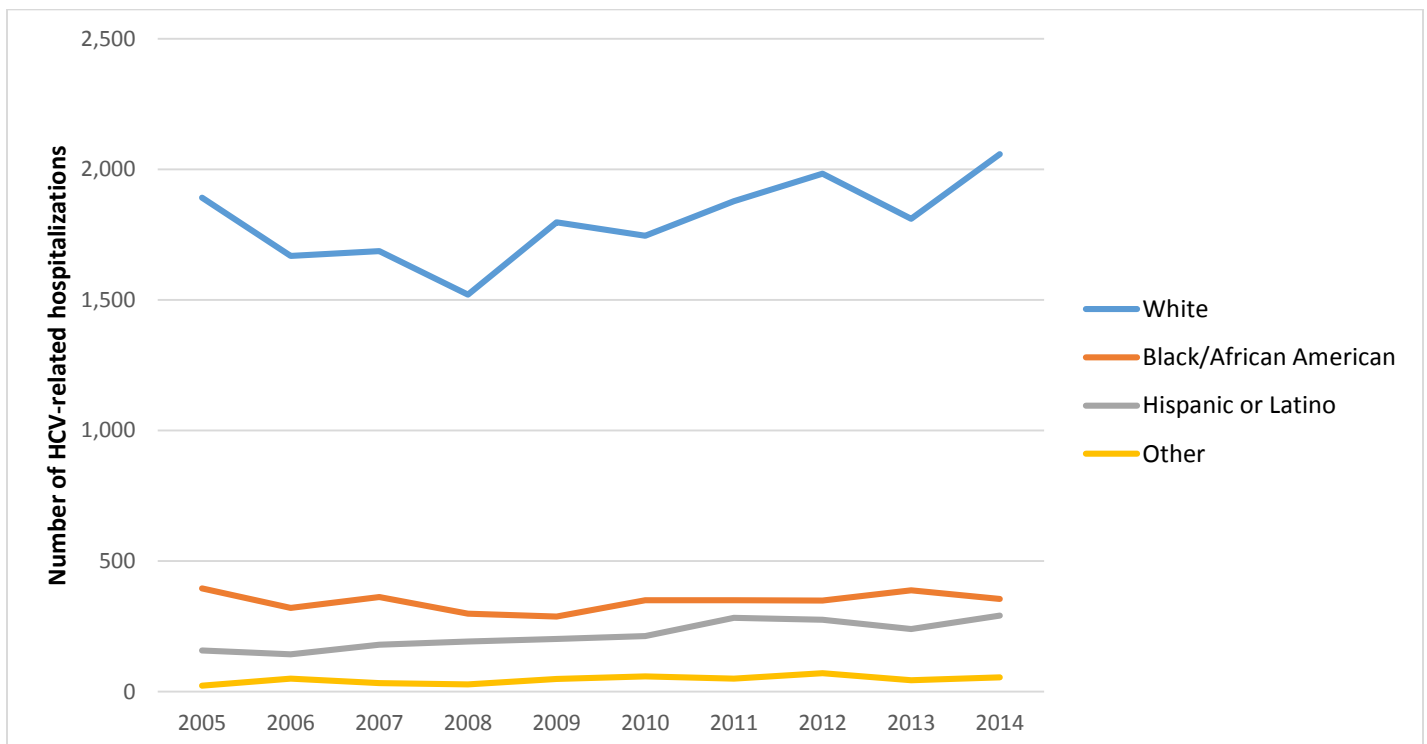
From 2005 to 2014, people ages 45 to 64 accounted for nearly two-thirds (64.8%) of HCV-related hospitalizations in Rhode Island (Figure 4).

**Figure 4: HCV-related Hospitalizations by Age, Rhode Island, 2005-2014<sup>†</sup>**



The total HCV-related hospitalizations remained relatively stable in all racial and ethnic groups in Rhode Island during the past decade, but there was a notable increase among whites, from 1,520 in 2008 to 2,058 in 2014. From 2005 to 2014, the number of HCV-related hospitalizations among whites has remained substantially higher when compared to all other racial and ethnic groups (Figure 5).

**Figure 5: HCV-Related Hospitalizations by Race/Ethnicity, Rhode Island, 2005-2014**



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### *HCV-Related Cancer*

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Liver cancer is a leading cause of cancer deaths in the United States. While there are a number of risk factors for liver cancer, approximately 22% of the cases among individuals age 65 and older are attributed to HCV.<sup>14</sup>

While overall cancer-related deaths are declining nationwide, liver cancer death rates have increased to the highest rate of all cancers.<sup>15</sup> Similarly, liver cancer incidence rates have increased sharply, second only to thyroid cancer.

Trends in Rhode Island suggest that liver cancer incidence rates are increasing in Rhode Island. However, the fraction of liver cancer cases in Rhode Island attributed to hepatitis C in Rhode Island peaked in 2010 and then decreased from 2011 to 2013 (Figures 6 and 7).



**Figure 6: Frequency of Newly-Diagnosed Liver Cancer Cases and Percentage of Cases with Hepatitis C at Diagnosis, Rhode Island, 2005 - 2013**

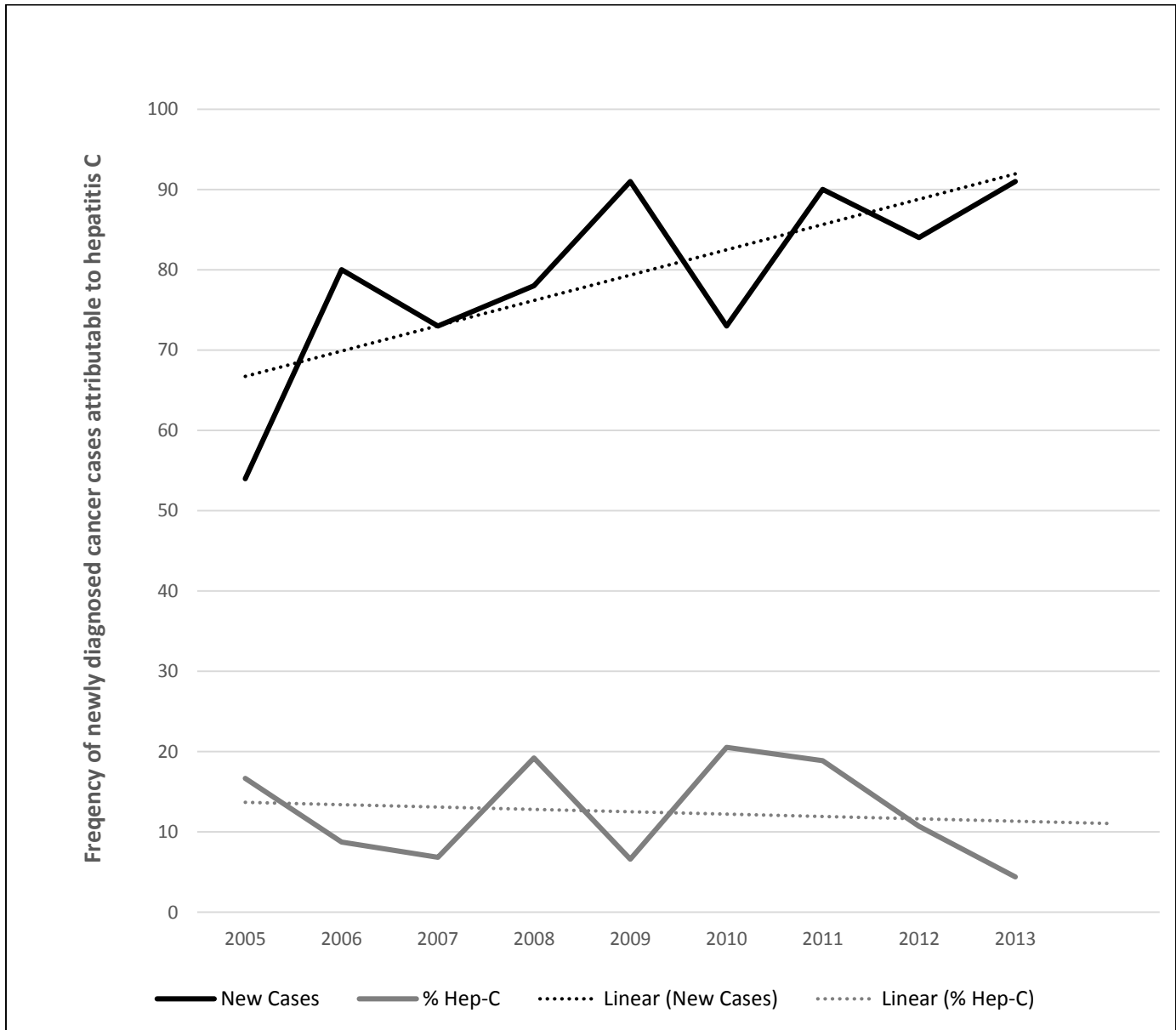
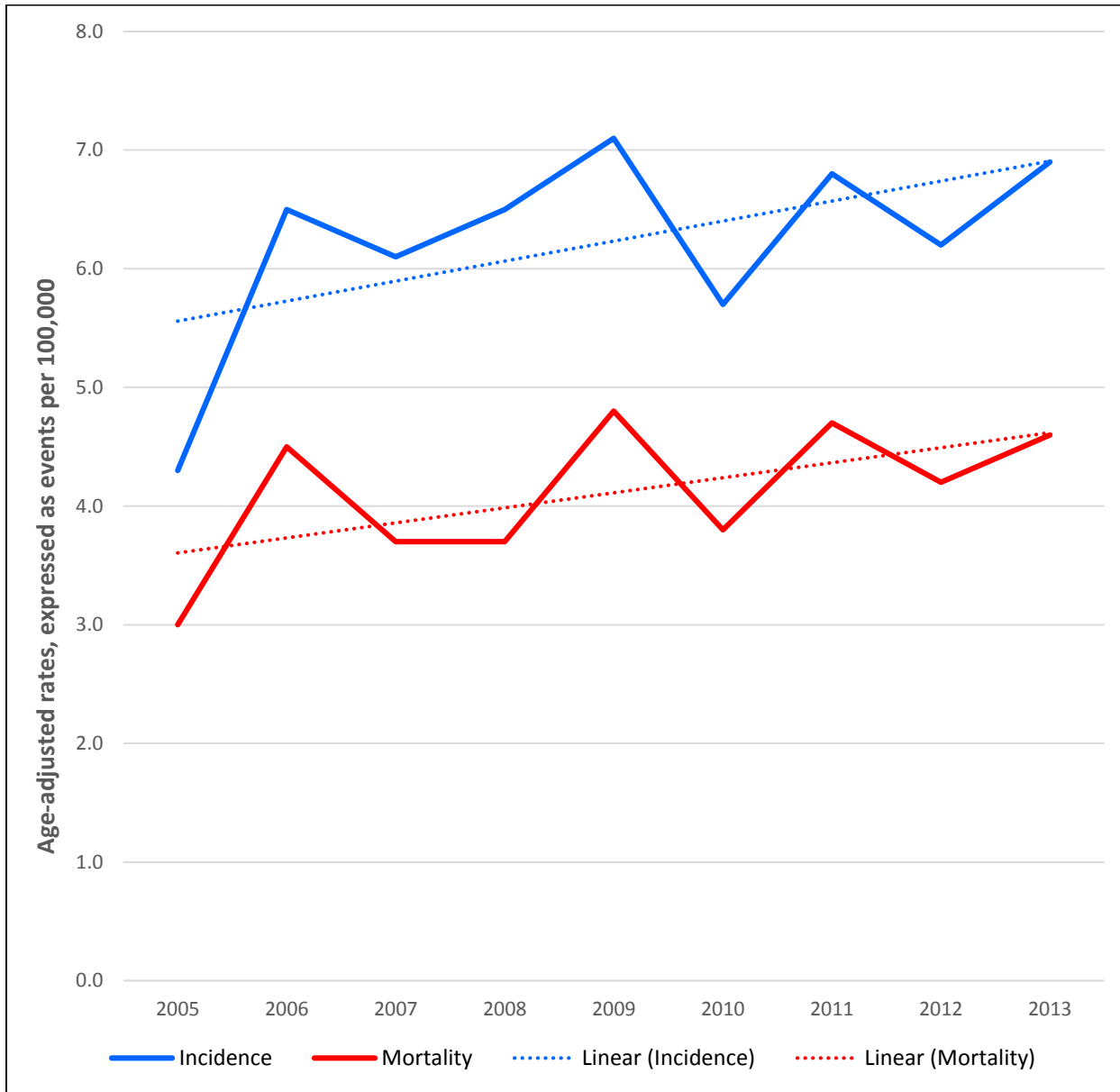


Figure 7: Age-Adjusted Liver Cancer Rates, Rhode Island, 2005-2013



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## HCV-Related Mortality

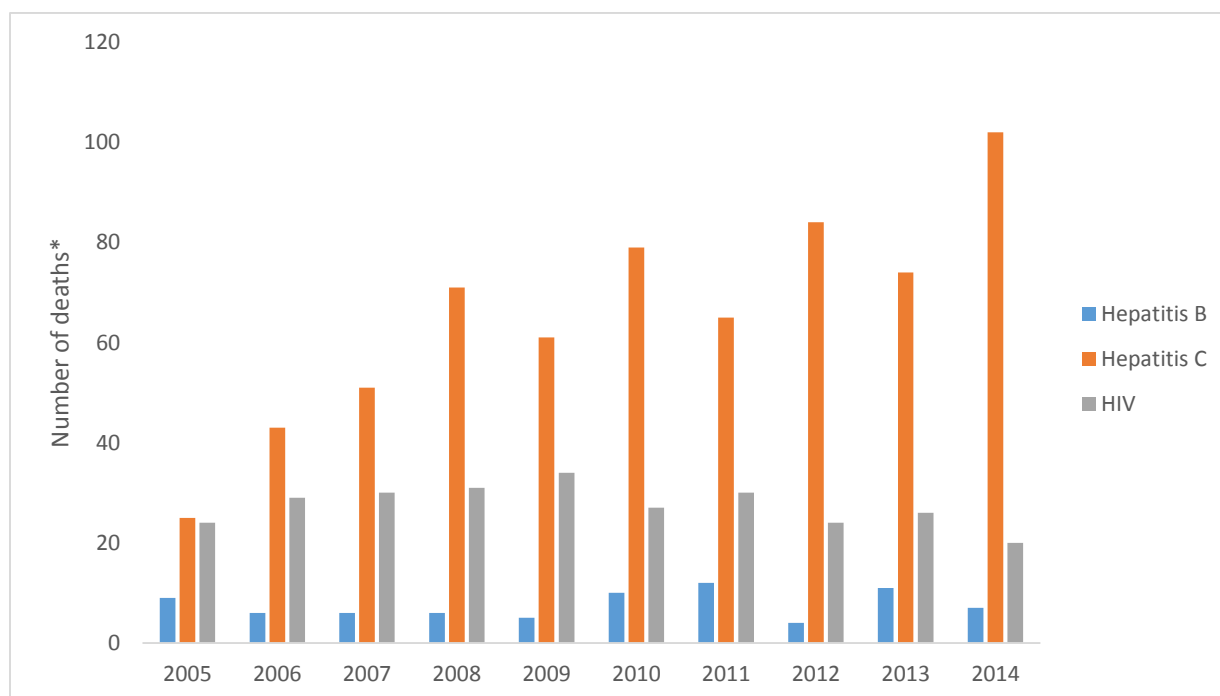
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Chronic HCV infection increases the risk for hepatic fibrosis, cirrhosis, liver failure, and hepatocellular carcinoma, and is the most common reason for needing a liver transplant.<sup>9</sup> Nationwide, the annual number of deaths attributed to HCV surpassed the mortality total of HIV and 59 other nationally notifiable infectious diseases, combined, in recent years.<sup>4</sup>

The RIDOH Center for Vital Records collects data on death occurrences in Rhode Island and deaths among Rhode Island residents outside of Rhode Island through routine sharing of data with local and national partners. The Center's database was reviewed to determine the number of deaths attributable to HCV from 2005 to 2014. Vital statistics data were also reviewed to determine the number of deaths attributable to hepatitis A virus (HAV), HBV, and HIV. HAV-associated deaths include reported death certificates with ICD-10 codes of B15.0, B15.9, HBV-associated deaths included reported death certificates with ICD-10 codes of B16.0, B16.1, B16.2, B16.9, B17.0, B18.0, B18.1. HCV-associated deaths included reported death certificates with ICD-10 codes of B17.1, B17.11, B18.2, B19.2, B19.21 and HIV-associated deaths included reported death certificates with ICD-10 codes of [B20.0-B24, R75].

There was a relatively steady increase in HCV mortality from 2005 to 2014 (Figure 8). During this timeframe, there were a total of 655 reported deaths in Rhode Island that had HCV listed as a primary or underlying cause of death, compared to 275 deaths associated with HIV, and 76 deaths associated with hepatitis B (Figure 8). The number of deaths related to HCV has increased four-fold in the last 10 years. These trends are similar to national trends. Because HCV is a frequently under-reported cause of death nationwide, these estimates likely underestimate the true HCV mortality burden in Rhode Island.<sup>4</sup>

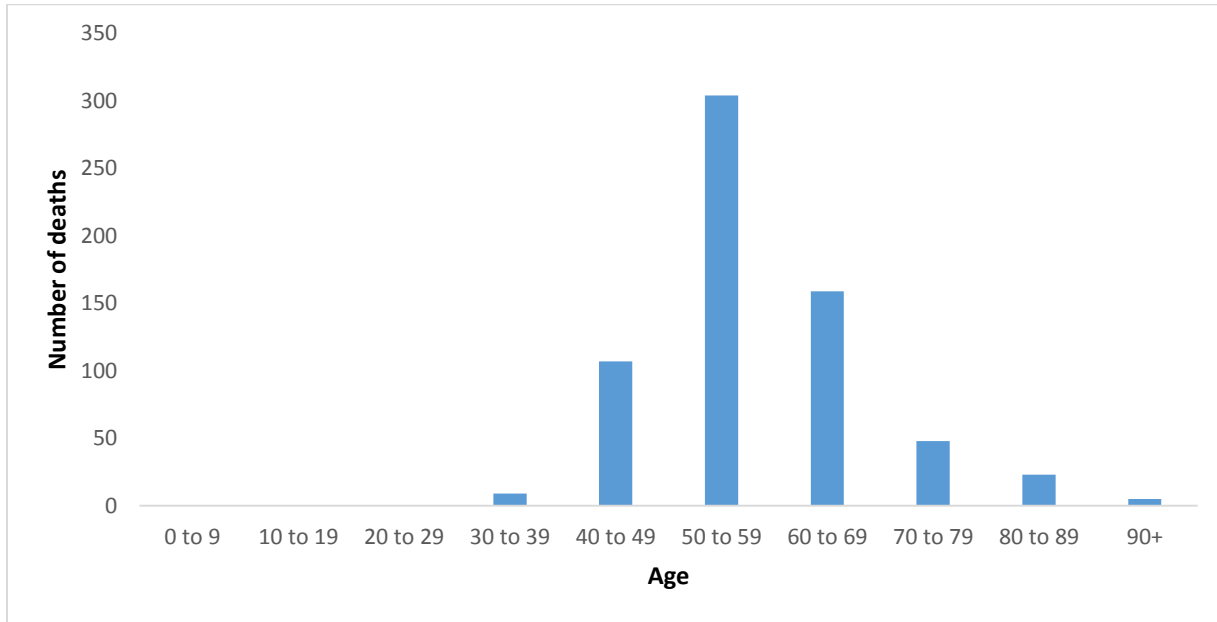
**Figure 8: Deaths Associated With Viral Hepatitis and HIV, Rhode Island, 2005-2014**



*\*Data in Figure 8 include all deaths in Rhode Island, regardless of state of residence.*

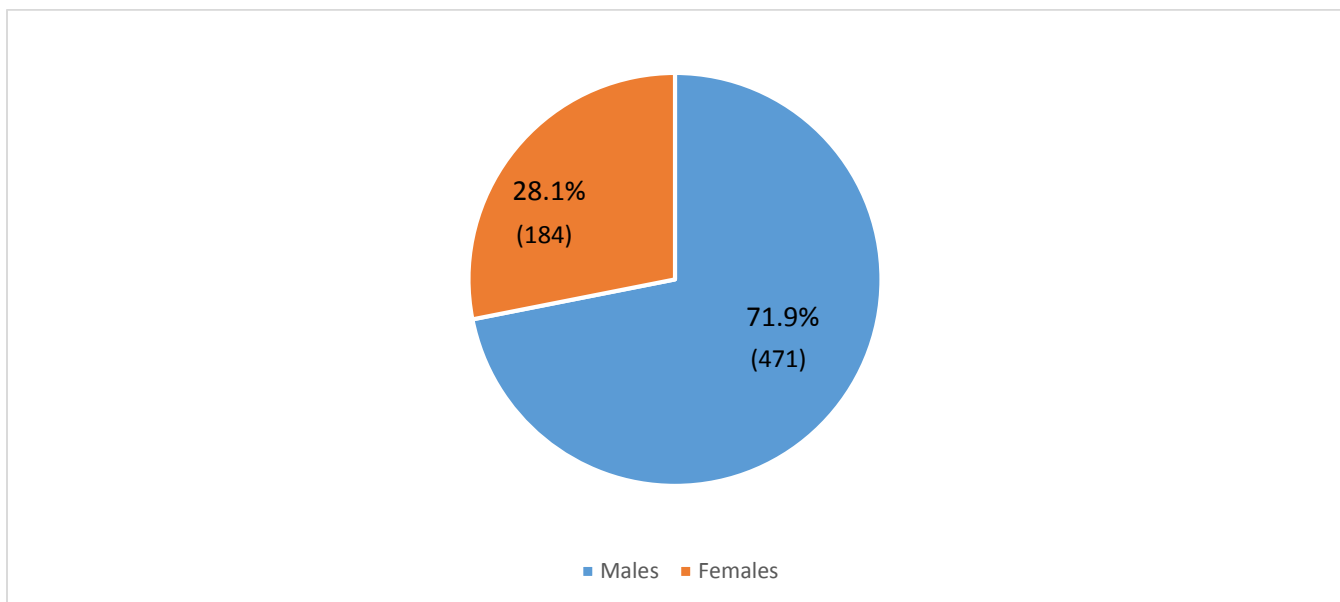
Most deaths associated with HCV were among males and nearly 50% of all deaths were age 50 to 59 at the time of death (Figure 9). More than 75% of HCV decedents were age 45 to 64 at the time of death, and the mean age was 58. This Rhode Island mortality trend is similar to nationwide trends.

**Figure 9: Deaths Associated with HCV Infection by Age, Rhode Island, 2005-2014**



Nearly three-quarters (71.9%) of HCV-related deaths in Rhode Island were among men during the past decade (Figure 10), while 28.1% were among women.

**Figure 10: Deaths Associated with HCV infection by gender, Rhode Island, 2005-2014**



**Background and nomenclature related to HCV screening**

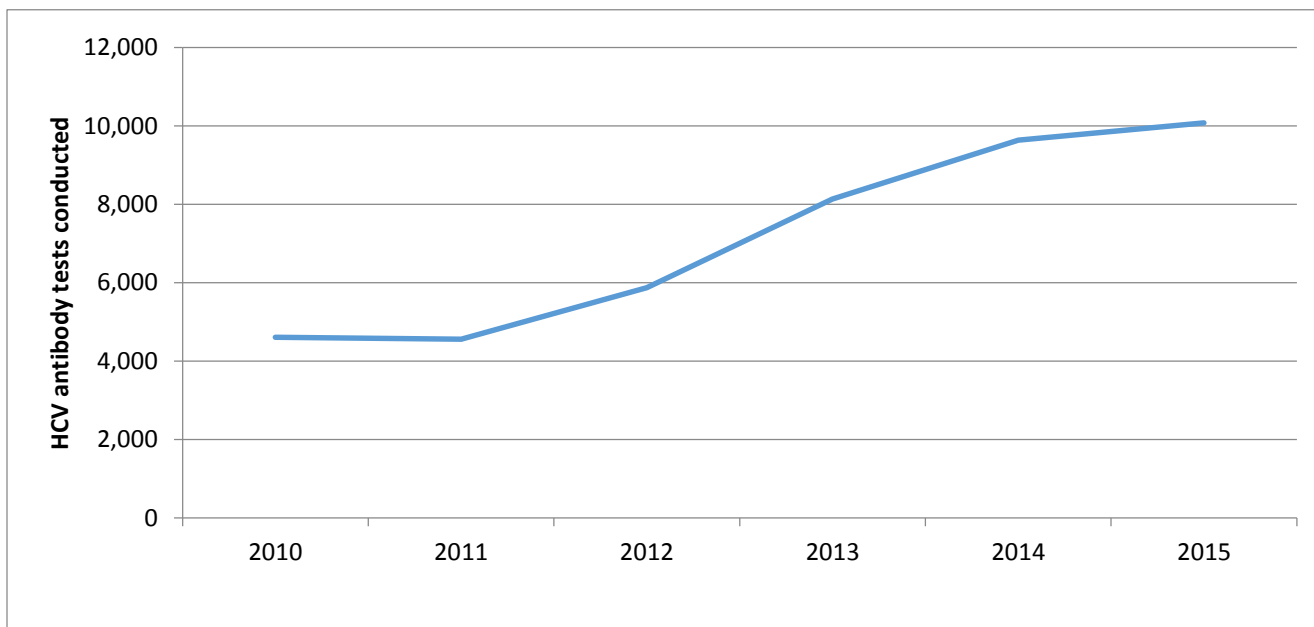
HCV antibody tests are the most commonly used HCV screening tests. The test detects HCV antibodies, which indicate a previous exposure to HCV. However, approximately 15% of all individuals exposed to HCV clear the virus and never develop chronic HCV. The “anti-HCV prevalence rate” refers to the percentage of individuals with reactive (but not necessarily confirmed) HCV test results. HCV RNA quantitative and qualitative testing can be used to confirm chronic HCV infection; HCV quantitative testing measures HCV viral RNA. Genotype data are collected to identify specific HCV types and strains, which is often used to help guide appropriate treatment options.

HCV data from several health systems and laboratories was collected for the years 2005 to 2015. HCV antibody screening and HCV confirmatory screening have increased dramatically in Rhode Island in the last decade. The anti-HCV prevalence rate for health systems and laboratories reporting screening data ranged from 3.7% to 7%. The percentage of individuals with confirmed chronic HCV is unknown; however, based on national estimates that 85% of individuals with reactive HCV tests have confirmed chronic HCV, this would likely range from 3.1% to 6.0%.

**East Side Clinical Laboratory**

East Side Clinical Laboratory (ESCL) has more than 50 locations in southeastern Massachusetts and Rhode Island. ESCL accounts for approximately 67% of outpatient laboratory work for the state of Rhode Island. ESCL provides laboratory services to federally-qualified health centers (FQHCs) in Rhode Island, including the Providence Community Health Centers, which serve more than 50,000 patients. From January 2010 to December 2015, ESCL reported conducting 47,367 HCV antibody tests. Among all individuals screened during this period, 4.40% were HCV antibody positive. ESCL also conducted 6,679 HCV viral load tests and 1,294 HCV genotype tests. HCV screening conducted by ESCL has increased over time (Figure 11).

**Figure 11: HCV Antibody Screening Conducted by East Side Clinical Laboratory, 2010-2015**



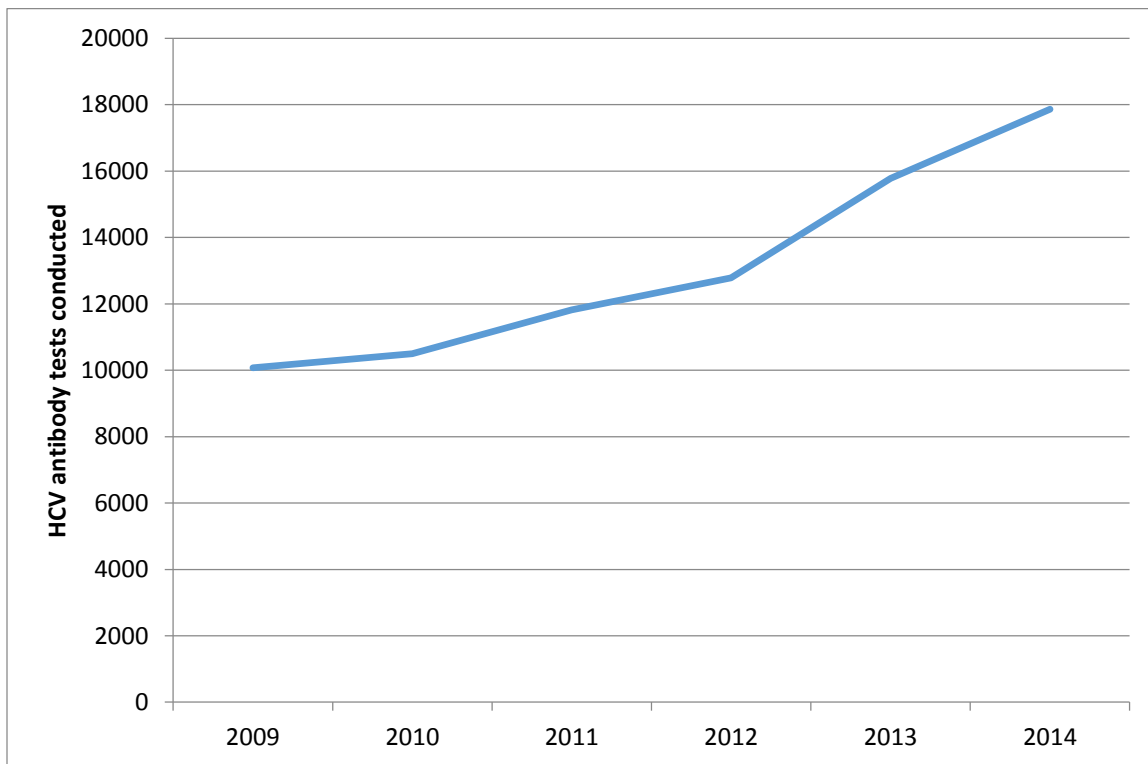
## Lifespan

Lifespan is a statewide health system that serves 25,000 to 30,000 patients annually. Lifespan includes Rhode Island Hospital, The Miriam Hospital, Bradley Hospital, Newport Hospital, and Hasbro Children’s Hospital (the pediatric division of Rhode Island Hospital). Lifespan also partners with the Warren Alpert Medical School of Brown University. Lifespan provides laboratory services to several federally-qualified health centers, including Thundermist Health Center and Blackstone Valley Community Health Care, which, respectively, serve 42,000 and 13,000 patients annually.

In March 2016, Lifespan started using reflexive RNA testing, in accordance with CDC HCV screening guidelines. This means that whenever a patient has a preliminary positive HCV antibody test, the patient’s blood will automatically be tested using an HCV RNA test. This policy was adopted to ensure that individuals with preliminary positive HCV tests receive HCV confirmatory testing. When Lifespan implemented the Epic electronic medical reporting system, it incorporated an electronic prompt to remind providers to offer HCV screening to all baby boomers. Data are not yet available to assess the impact of this policy on HCV diagnosis, but this policy is considered a best practice.

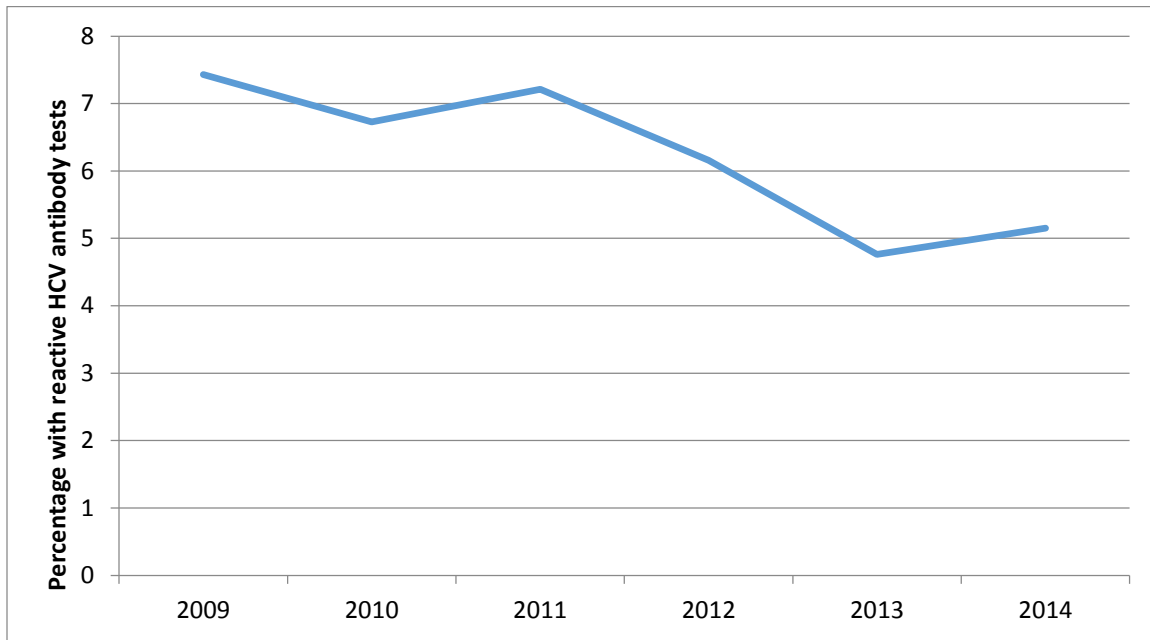
HCV antibody screening at Lifespan increased steadily from approximately 10,000 tests in 2009 to almost 18,000 tests in 2014 (Figure 12).

**Figure 12: HCV Antibody Screening Conducted By Lifespan, 2009-2014**



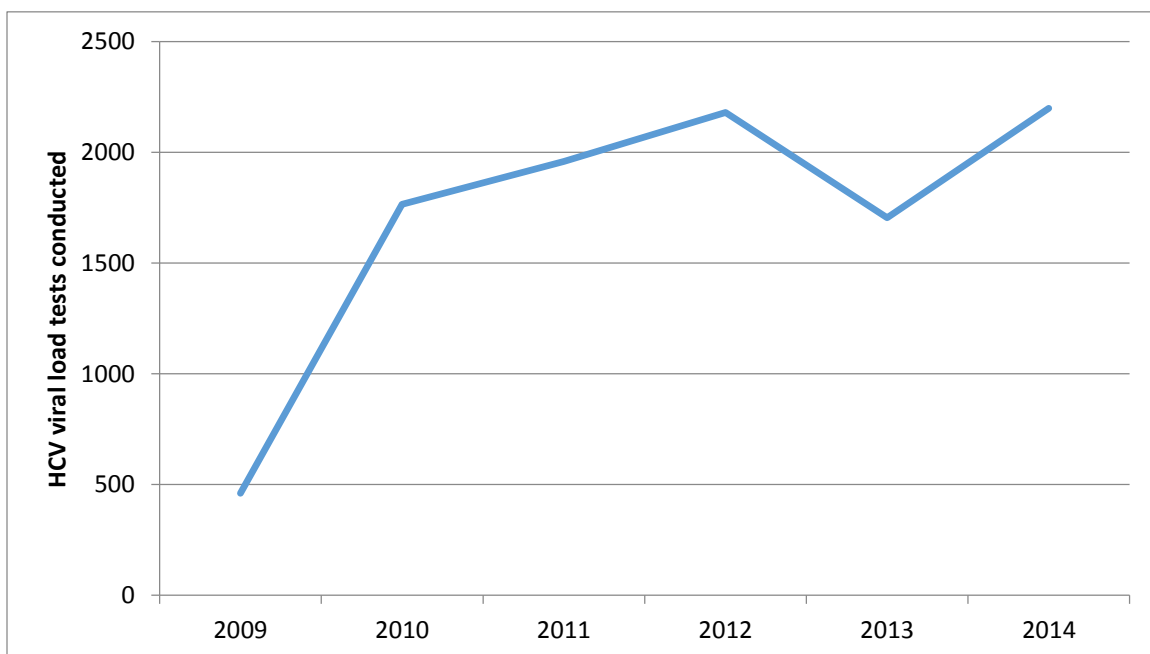
Anti-HCV prevalence rates in the Lifespan declined from 7.43% in 2009 to 5.15% in 2014. This may be attributable to larger numbers of individuals undergoing screening after new direct acting agents (DAAs) came to market (Figure 13).

**Figure 13: Anti-HCV Prevalence Rates at Lifespan, 2009-2014**



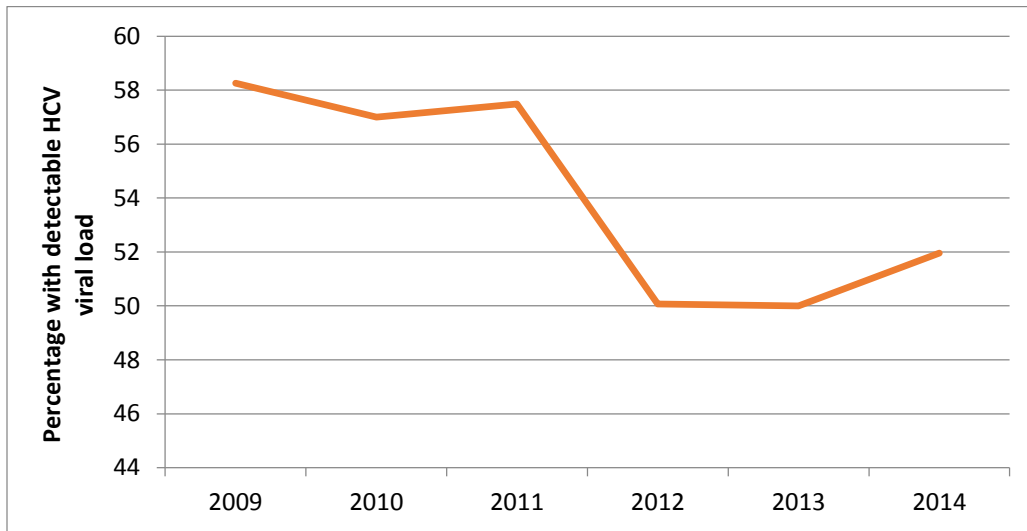
The number of HCV viral load tests, the test conducted on people living with HCV to determine whether they have chronic HCV infection, dramatically increased from 2009 to 2012 at Lifespan. Despite a slight decrease during 2013, HCV quantitative viral load tests reached an all-time high in 2014, when 2,198 tests were conducted (Figure 14).

**Figure 14: HCV Viral Load Tests Conducted at Lifespan, 2009-2014**



The fraction of individuals with detectable HCV viral RNA decreased slightly during the five-year span, from 58.8% in 2009 to 51.96% in 2014 (Figure 15).

**Figure 15: Percentage of Patients with Detectable HCV Viral Load Tests, Lifespan, 2009-2014**



Taken together, data from figures 14 and 15 suggest that Lifespan diagnosed approximately 1,200 individuals with chronic HCV in 2014.

#### **Quest and The Laboratory Corporation of America**

Quest Diagnostics and The Laboratory Corporation of America (LabCorps) both process a high volume of HCV-related laboratory tests annually. Quarterly laboratory testing reports are disseminated to jurisdictions across the United States through data sharing with the CDC. These reports help describe testing trends from these large commercial laboratories. One limitation of these data is that they only represent providers and practices who use Quest and LabCorps as reference laboratories; in addition, the population of providers and practices utilizing Quest and LabCorps may change over time, influencing testing volumes.

Quest Diagnostics reported conducting 14,065 HCV antibody tests from 2011-2015. Among those screened, 3.7% were HCV antibody-positive. Anti-HCV prevalence rates differed by gender and age cohort. Men had an anti-HCV prevalence of 5.2%, whereas women had anti-HCV prevalence of 2.5%. Among both men and women, individuals age 45 to 64 were disproportionately impacted (Figures 16, 17).

LabCorps reported HCV antibody screening rates from 2012-2015. LabCorps provides HCV screening rates per 10,000 patients screened and reported a three-fold increase in reactive HCV antibody testing from 2012 to 2015; 41 individuals underwent HCV RNA screening.



Figure 16: Males with Reactive HCV Antibody Tests by Age; Quest Laboratories, 2011-2015; LabCorp, 2012-2015<sup>†</sup>

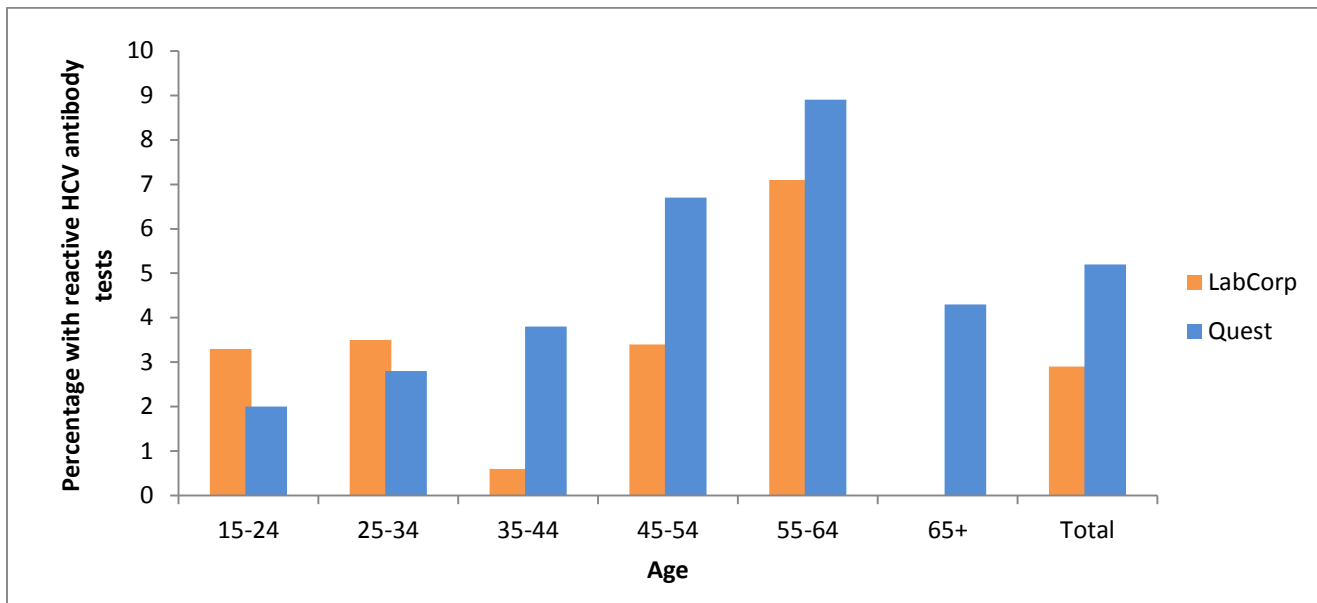
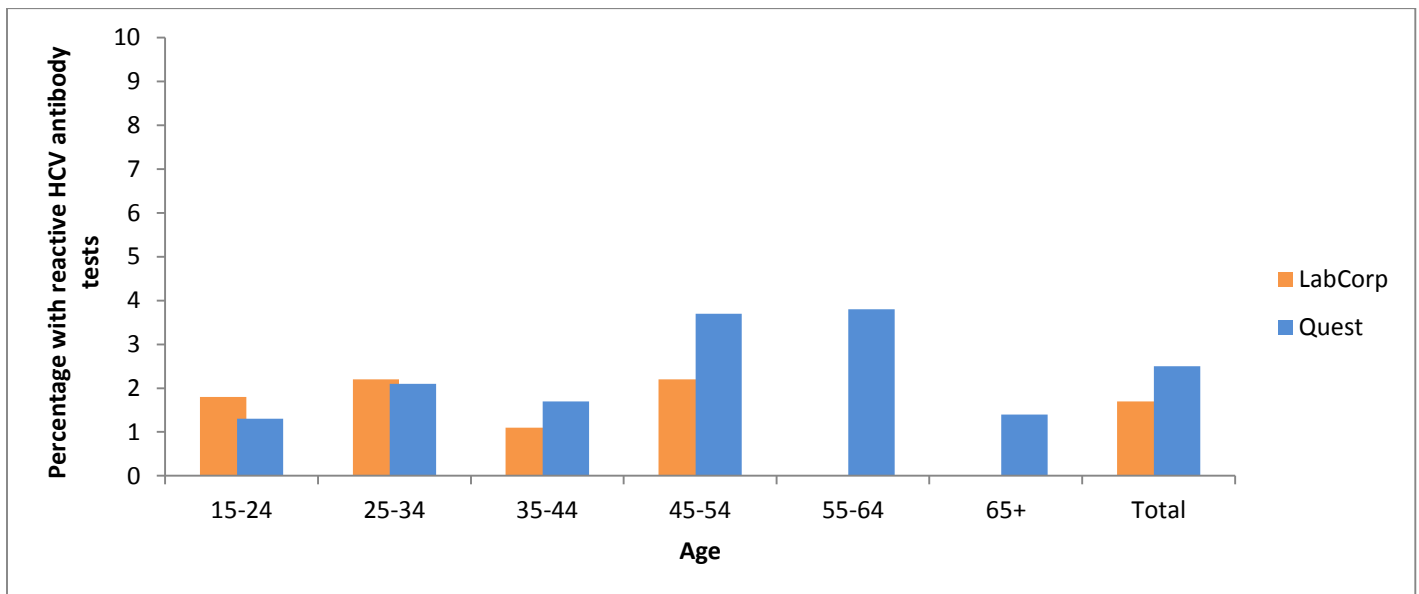


Figure 17: Females with Reactive HCV Antibody Tests by Age; Quest Laboratories, 2011-2015; LabCorp, 2012-2015<sup>†</sup>

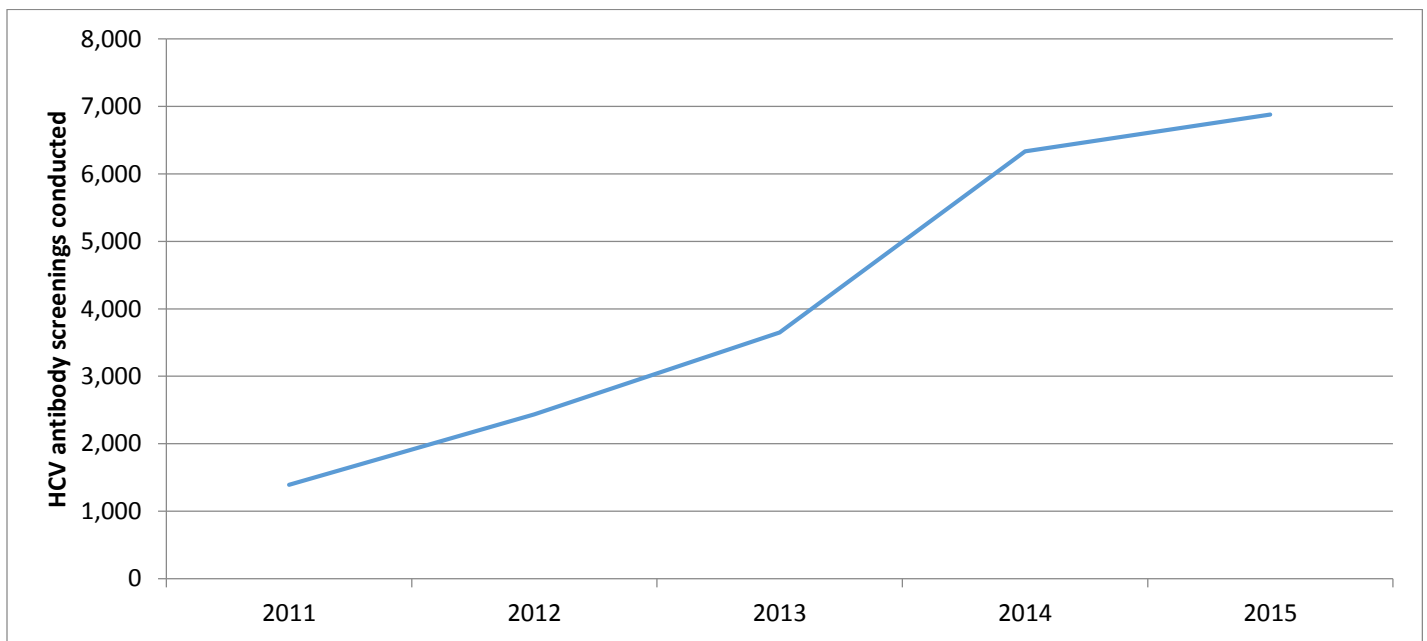


## CharterCARE

CharterCARE is a regional care network that includes two acute-care hospitals (Our Lady of Fatima Hospital and Roger Williams Medical Center). CharterCARE also has a regional care center, a rehabilitation center, a home health services company, and a long-term care facility. CharterCARE reported providing HCV screening to more than 29,000 individuals from 2005 to 2015. More than 18,000 of these tests were conducted by Our Lady of Fatima Hospital, and more than 11,000 were conducted at Roger Williams Medical Center.

CharterCARE provided laboratory data on HCV antibody screening conducted from 2011-2015 (Figure 18) and anti-HCV positivity from 2014-2016. CharterCARE reported 6.26% anti-HCV prevalence for 2005-2015. CharterCARE also reported conducting almost 8,000 HCV viral load tests from 2005-2015; 910 individuals also underwent genotype testing during this same time period. Anti-HCV positivity was 7% in 2014, 6% in 2015, and was 4.9% during the first six months of 2016.

**Figure 18: HCV Antibody Screenings Conducted By CharterCARE, 2011-2015**



These analyses are subject to several limitations. They do not represent all of the health systems in Rhode Island, but likely account for approximately 70% of all outpatient laboratory services and 50% of inpatient health system services. In addition, data from these distinct health systems and laboratories were provided in different formats. Health systems and laboratories provided data for the time frames they had available, which differed by institution. Some systems were able to disaggregate trends by race, gender, and age, while others were not. Some systems provided HCV antibody screening data, while others provided HCV screening, with viral load, RNA quantification, and genotype data. The authors could not link antibody screening data to confirmatory screening at the patient level, and did not have information on the number of individuals cured of HCV who completed confirmatory screening. Moreover, HCV antibody screening, viral load testing, RNA quantification, and genotype testing may not occur in the same years.

In health systems data, de-duplication of client entries can be complex. Some systems may contain duplicate entries for clients who had multiple clinical visits through the years, which may elevate overall screening numbers; however, this is likely a relatively small fraction of the overall population. Lastly, there may also be some overlap with reported laboratory data and data from large health systems, but there is likely little overlap between laboratory and health system data presented here.

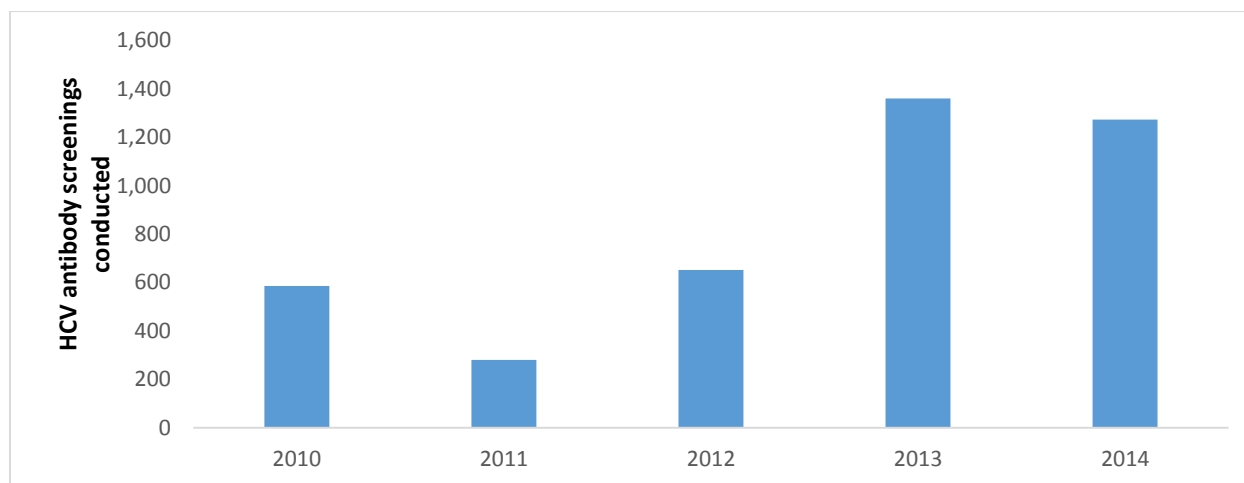
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*Overview of Community-Based HCV Screening Programs*

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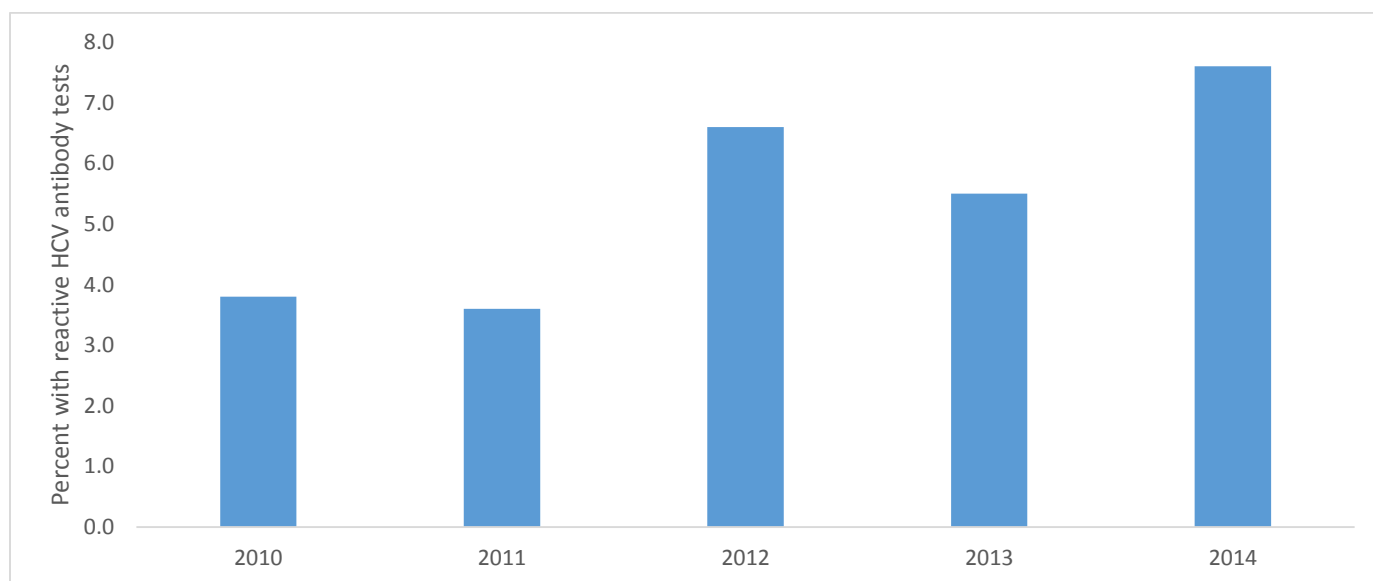
The RIDOH Integrated HIV/Viral Hepatitis Counseling, Testing, and Referral System (CTR) has funded up to seven agencies to provide non-clinical, community-based HCV screening. The seven funded community-based agencies included AIDS Care Ocean State (ACOS), AIDS Project Rhode Island (APRI), MAP Behavioral Health Services, Amos House/Project Renew, Project Weber, and Sojourner House. Community-based HCV screening in state-funded agencies in Rhode Island have increased more than two-fold between 2010 and 2014 (Figure 19).

**Figure 19: HCV Screening in Community-Based Settings, Rhode Island, 2010-2014**



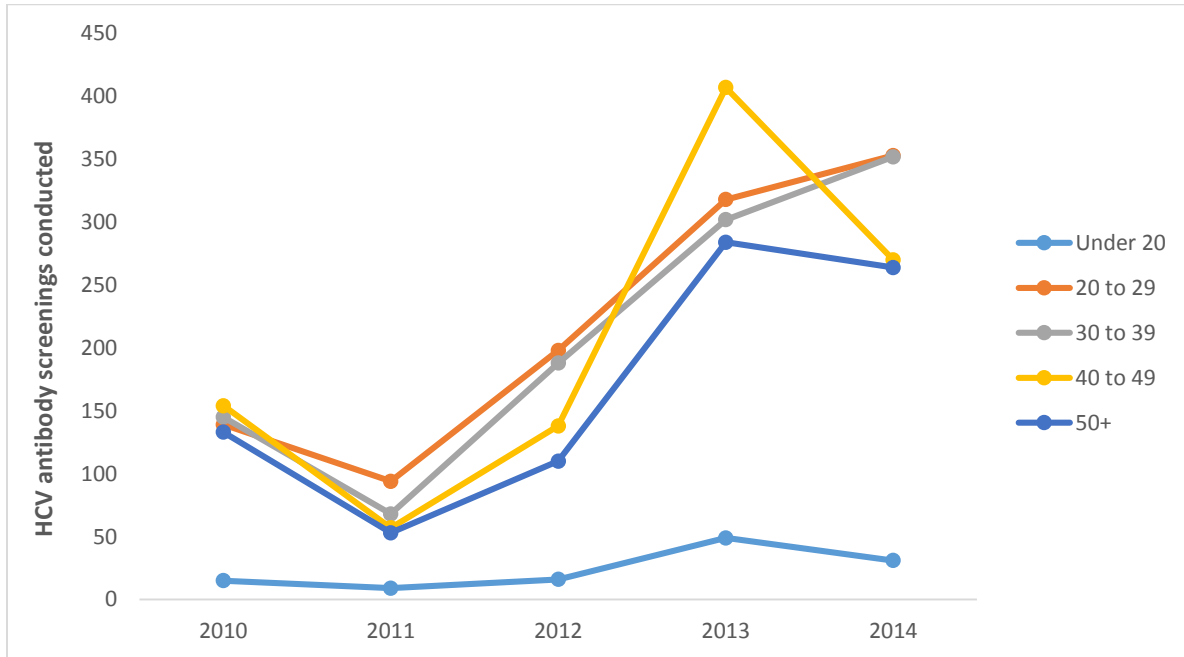
Anti-HCV prevalence in community-based testing programs increased from 2011 to 2014 and reached 7.6% in 2014. (Figure 20).

**Figure 20: Individuals with Reactive HCV Tests in Community-Based Settings, Rhode Island, 2010-2014<sup>†</sup>**



Antibody screening tests conducted in community-based settings more than doubled from 2010 to 2014. Community-based HCV screening has increased in all age groups from 2011 to 2014 in Rhode Island, but screenings for Rhode Islanders ages 20 to 29 outpaced screening in other age groups, followed by Rhode Islanders ages 30 to 39.

**Figure 21: HCV Screening in Community-Based Settings by Age, Rhode Island, 2010-2014**

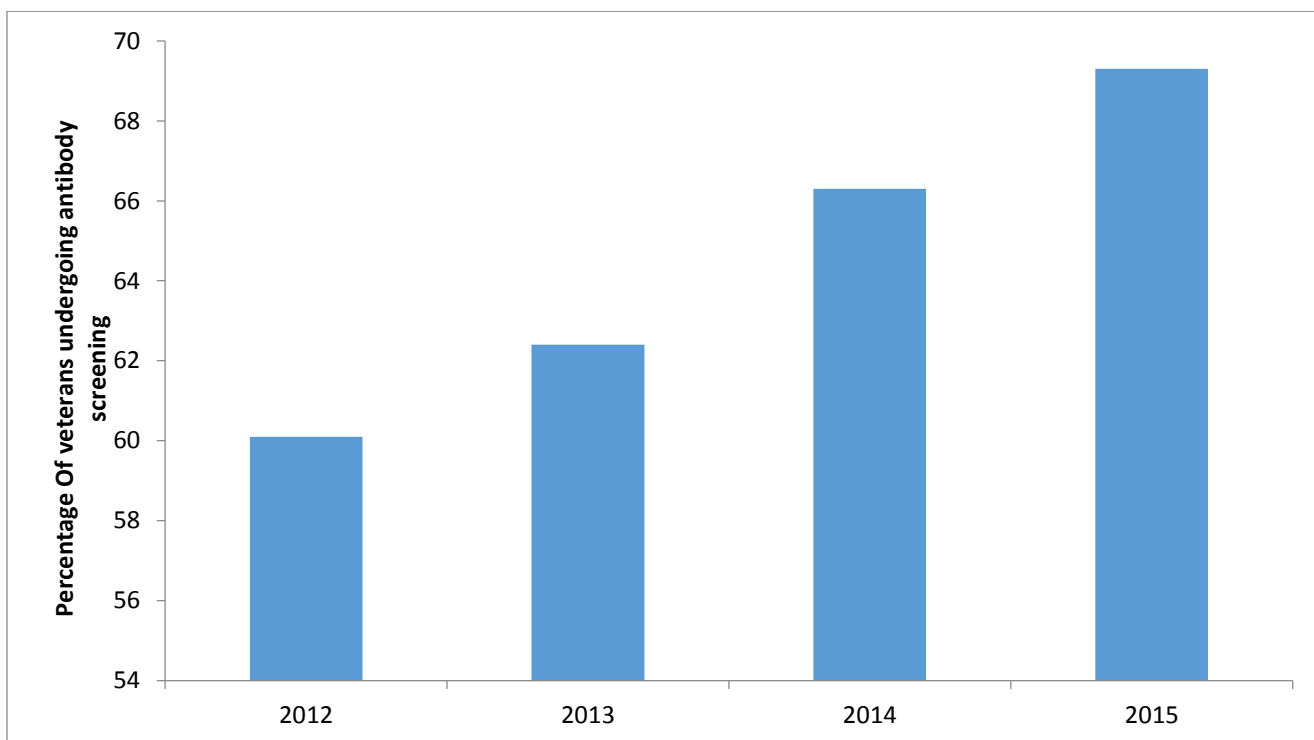


More than one-third of people who inject drugs who were screened were HCV-antibody positive (35.1%), while non-PWID related anti-HCV positivity rates were 1.1%.

The US Department of Veterans Affairs (VA) is the single largest HCV provider in the United States. In 2013, the Veteran's Health Administration (VHA) Directive assigned the VHA National Viral Hepatitis Program the responsibility of providing primary guidance on VHA policy and the authority to oversee the processes to improve the quality of prevention, diagnosis, and care of viral hepatitis across the system. Under this directive, the VA aims to identify veterans living with viral hepatitis and provide them with high-quality care and treatment.<sup>16</sup>

The Providence VA Medical Center provides care to veterans from Rhode Island and eastern Massachusetts. The Providence VA Medical Center reported significant increases in HCV screenings from 2012 to 2015 (Figure 22). By 2015, nearly 70% of patients in the baby boomer cohort underwent HCV antibody screening. The VA reported curing 102 people of HCV, and only 7% of individuals who were provided curative therapies experienced treatment failures due to adverse events or poor adherence.

**Figure 22: Percentage of Veterans in the Baby Boomer Age Cohort Undergoing Antibody Screening at the Providence VA Medical Center, 2012-2015**



RI Medicaid claims data was assessed for HCV screening and diagnosis patterns in the state for 2014 and 2015. More than 30,000 HCV-related observations were included in Medicaid data during this timeframe (Appendix A). The RI Medicaid data include duplicated clients, and it is estimated that approximately 15,000 unique clients living with HCV are represented. More than half (53%) of the HCV-related claims were associated with clients ages 25 to 54.

The authors assessed HCV-related claims for HCV screening procedures in three ways:

1. All HCV procedures in aggregate;
2. First HCV procedure captured in Medicaid claims; and
3. Last HCV procedure captured in Medicaid claims.

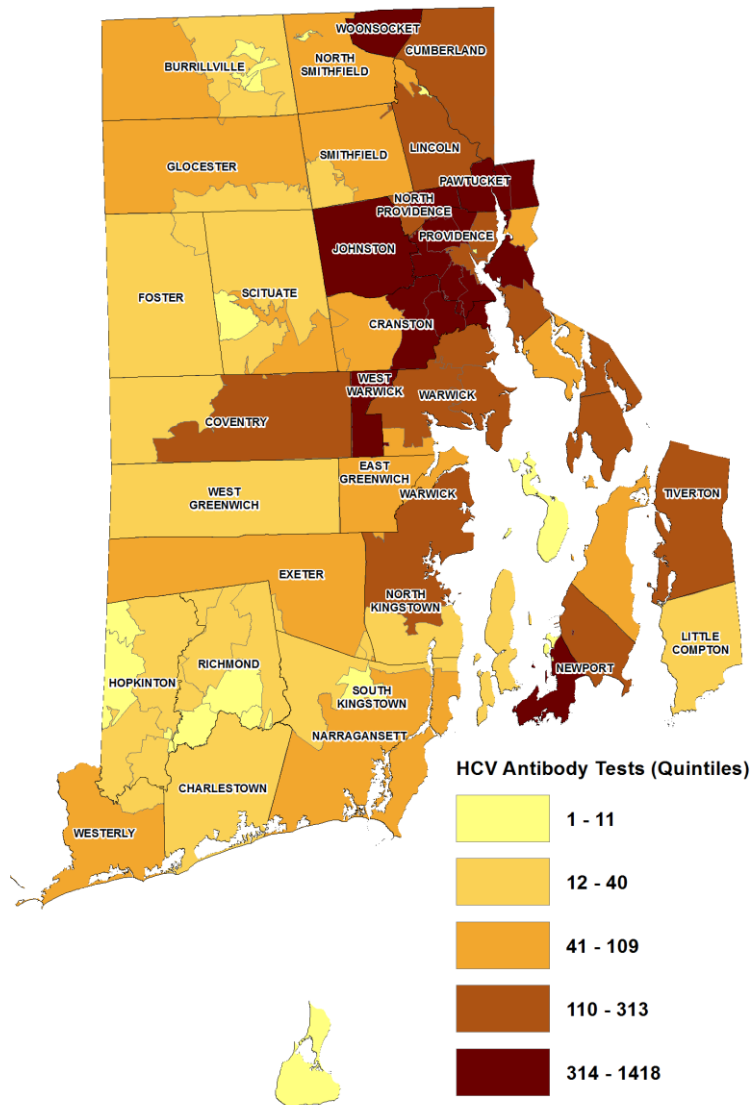
As with any claims data, these claims data may not fully represent clinical outcome data, but are the best proxy indicators currently available.

Approximately 15,000 HCV screening claims were noted in aggregate, while approximately 13,000 HCV claims were captured when looking solely at first or last procedure alone during 2014 and 2015. These findings suggest that 13,000 Medicaid beneficiaries underwent HCV antibody screening in 2014 and 2015.

More than 6,000 HCV viral load test claims were submitted, with approximately 2,000 viral load tests noted when considering first or last assessment alone. More than 1,700 HCV genotype test claims were submitted to Medicaid in 2014-2015, suggesting that a minimum of approximately 1,700 Medicaid beneficiaries were diagnosed with HCV in Rhode Island from 2014-2015.

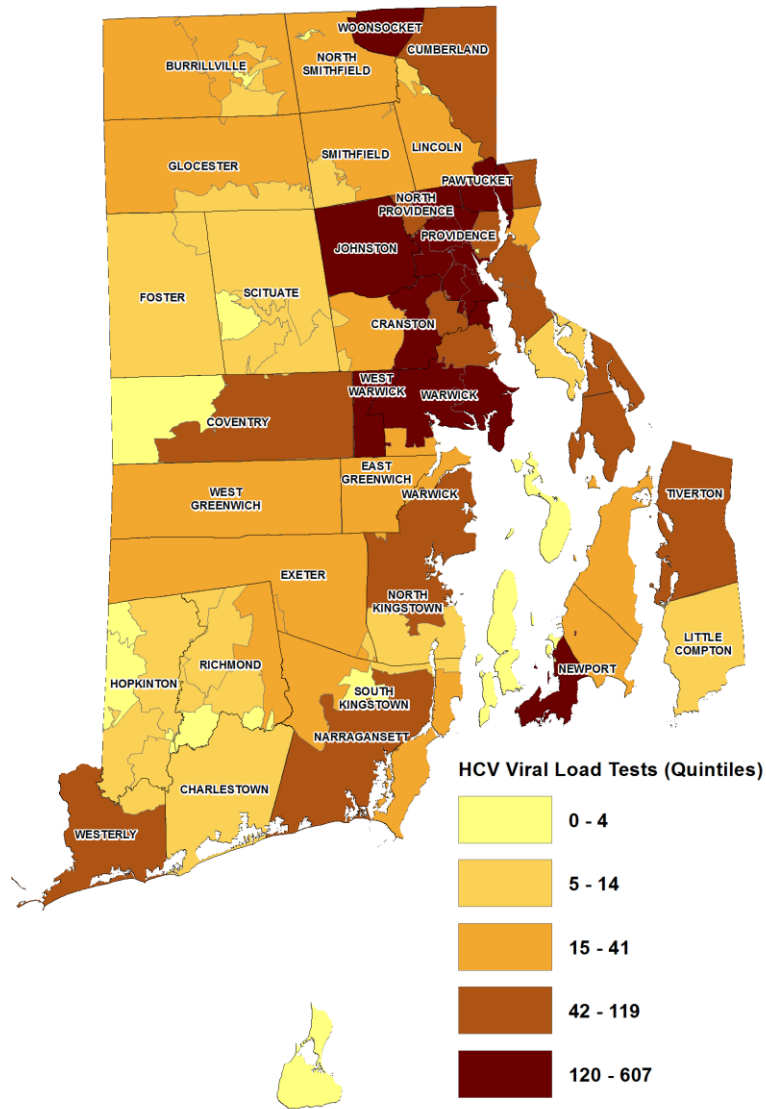
The geographic distribution of HCV screening, viral load, and genotype tests (Figures 23, 24, and 25) show that the largest number of HCV screening claims are for clients who live in Providence, Woonsocket, Pawtucket, Cranston, Johnston, West Warwick, and Newport. For more detail on HCV services captured in Medicaid data, see Appendix A.

**Figure 23: RI Medicaid Claims for HCV Antibody Tests by ZIP Code, Rhode Island, 2014-2015**



The antibody test data are categorized by quintiles. In developing quintile categories, all of the HCV test counts were ordered from lowest to highest at the ZIP code level and were divided into five equal categories, with equal numbers of ZIP codes in each quintile. The lowest quintile represents ZIP codes that fall within the first to 20<sup>th</sup> percentile of test counts, and the highest quintile represents ZIP codes that fall within the 80<sup>th</sup> to 100<sup>th</sup> percentile.

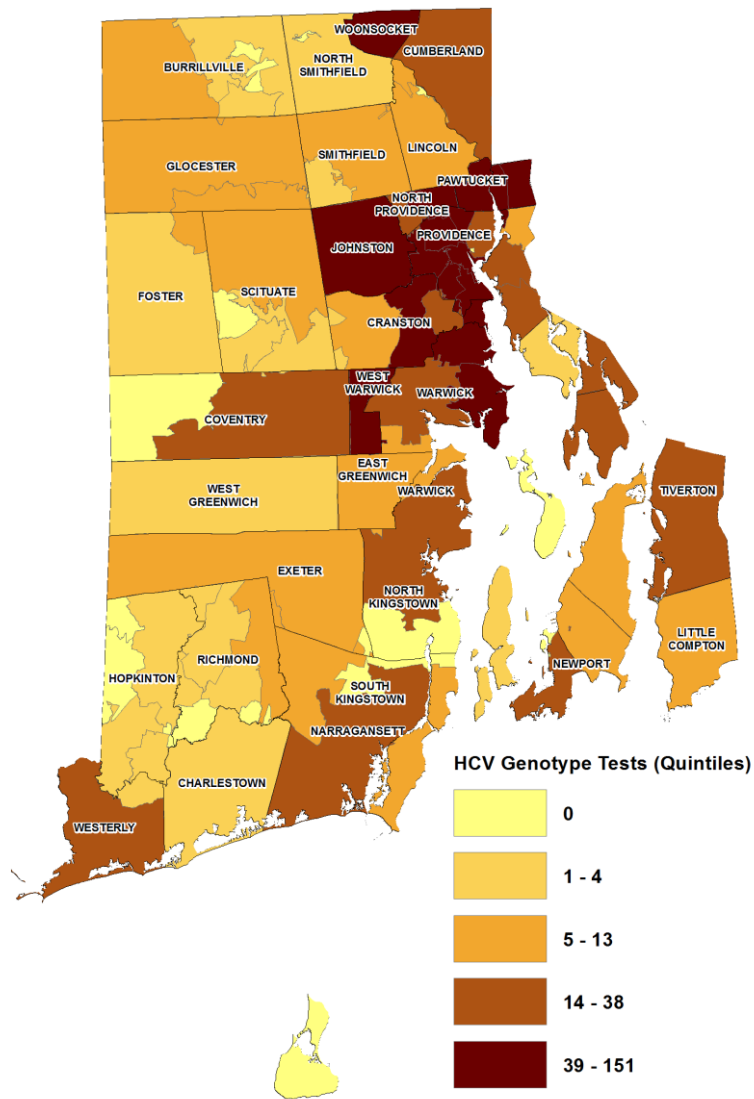
**Figure 24: RI Medicaid Claims for HCV Viral Load Tests by ZIP Code, Rhode Island, 2014-2015**



The viral load test data are categorized by quintiles. In developing quintile categories, all of the HCV viral load counts were ordered from lowest to highest at the ZIP code level and were divided into five equal categories, with equal numbers of ZIP codes in each quintile. The lowest quintile represents ZIP codes that fall within the first to 20<sup>th</sup> percentile of test counts, and the highest quintile represents ZIP codes that fall within the 80<sup>th</sup> to 100<sup>th</sup> percentile.



**Figure 25: RI Medicaid Claims for HCV Genotype Tests by ZIP Code, Rhode Island, 2014-2015**

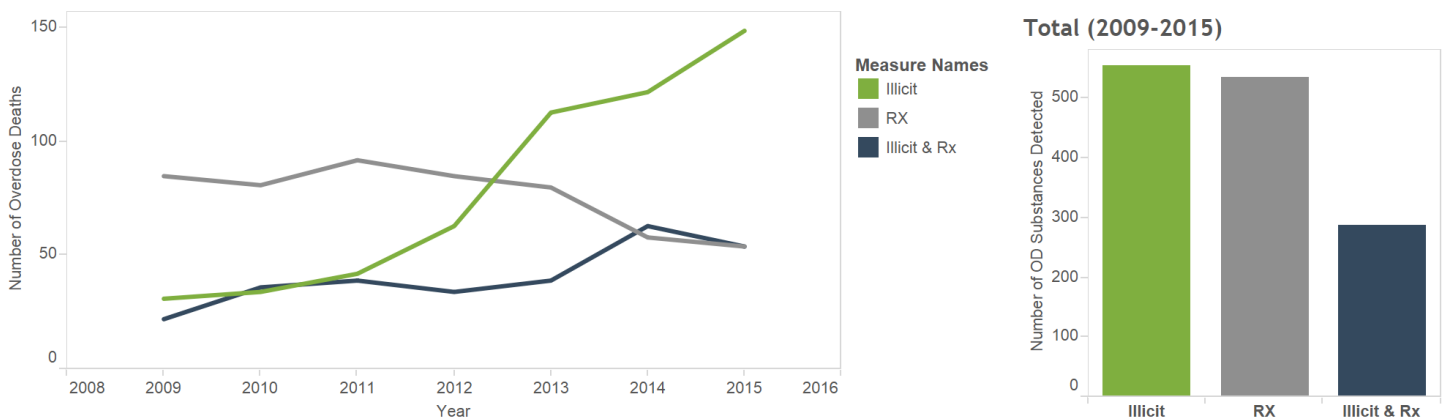


The genotype test data are categorized by quintiles. In developing quintile categories, all of the genotype test counts were ordered from lowest to highest at the ZIP code level and were divided into five equal categories, with equal numbers of ZIP codes in each quintile. The lowest quintile represents ZIP codes that fall within the first to 20<sup>th</sup> percentile of test counts, and the highest quintile represents ZIP codes that fall within the 80<sup>th</sup> to 100<sup>th</sup> percentile.

## Opioid Overdose in Rhode Island

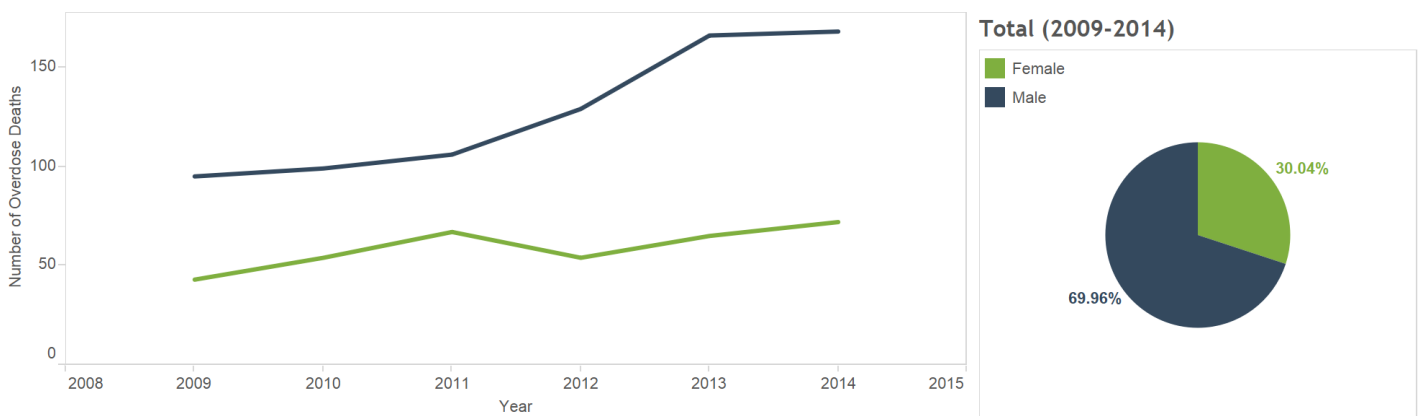
Rhode Island is currently experiencing a syndemic of HCV, opioid dependence, and overdose.<sup>17</sup> Rhode Island ranks sixth highest in the nation for drug overdose death rates and highest in New England. There were 241 confirmed unintentional overdose deaths in Rhode Island in 2014, as compared to 138 in 2009 (19.4 per 100,000 people).<sup>18-19</sup> The number of fatal overdoses increased to 257 in 2015. Among those who died from an overdose, approximately 40% had evidence of recent injectable drug use (Figure 26). HCV is a common infectious consequence of injectable drug use. Many individuals experiencing overdose may also be living with HCV, so addressing these two crises in tandem presents a public health opportunity.

**Figure 26: Overdose Deaths by Drug Type, Rhode Island, 2009-2015**



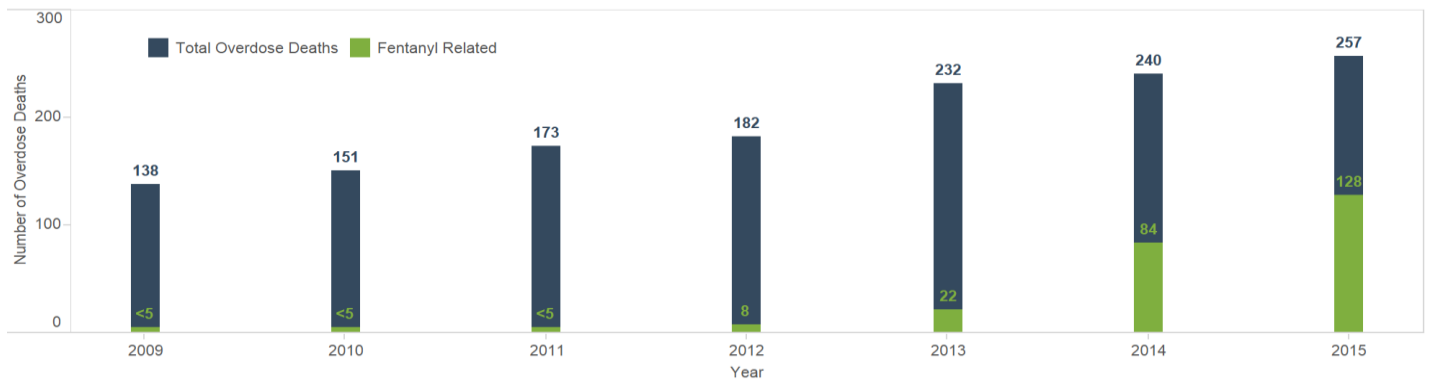
Approximately 30% of all fatal overdose cases in 2015 were among women, and 70% of deaths were among men (Figure 27). The median age of decedents was 41. There are at least five times as many non-fatal as fatal overdoses in Rhode Island. Preliminary data from 2016 overdose registries suggest that these trends continue; 28 individuals fatally overdosed during the first two months of 2016.

**Figure 27: Overdose Deaths by Gender, Rhode Island, 2009-2014**



In the past six years, there have been significant changes in the types of substances causing fatal overdoses in Rhode Island. In 2012, overdose deaths involving illicit drugs surpassed deaths involving prescription drugs. In the past year, illicit drugs contributed to 150 overdose deaths in Rhode Island. There has also been an increase in fentanyl-related overdose deaths. Fentanyl is a prescription opioid that is used frequently as an anesthetic and pain reliever during and following clinical procedures. Much of the heroin in Rhode Island is now cut or mixed with fentanyl and used illicitly to increase heroin's potency. Fentanyl is approximately 40 times more potent than heroin so even a small dose could lead to overdose. Approximately 50% of fatal overdoses in Rhode Island were fentanyl-related in 2015, a dramatic increase from 35% in 2014 (Figure 28).

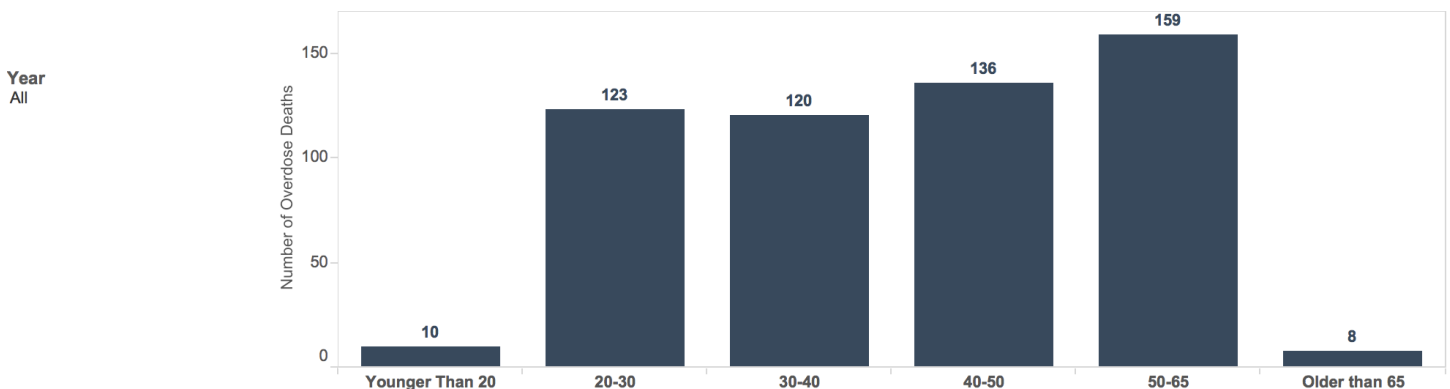
**Figure 28: Overdose Deaths Associated with Fentanyl, Rhode Island, 2009-2015\***



\*Counts less than 5 were suppressed to prevent potential identification and breaches of confidentiality

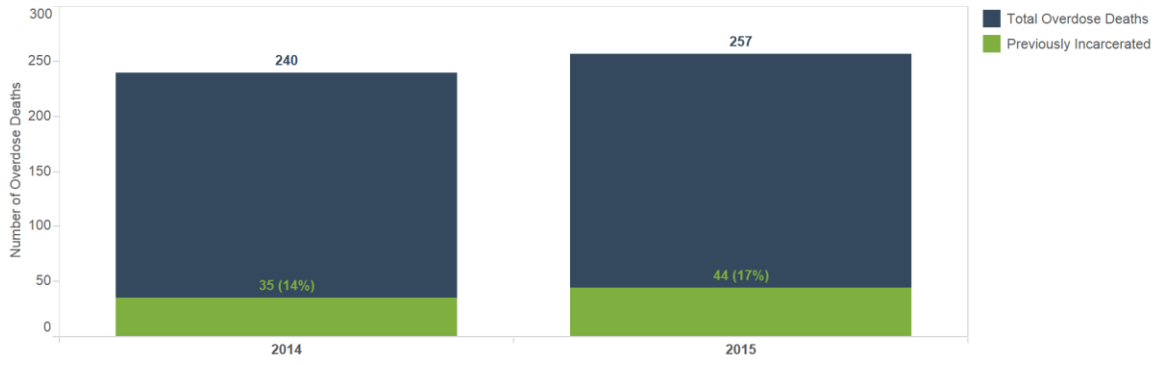
New HCV cases are likely increasing as a result of, or in tandem with, illicit opioid use. Given that neighboring states are reporting concurrent increases in prescription opioid use, heroin use, opioid overdose, and HCV infections, similar trends are anticipated in Rhode Island. For example, estimated HCV cases among Massachusetts residents age 15 to 29 increased by 137% from 2002-2013.<sup>21-22-23</sup> The median age for overdose deaths in Rhode Island was 41 in 2015, indicating that individuals experiencing overdose in Rhode Island may be older than those in Massachusetts, where overdose disproportionately affects individuals age 15 to 30.

**Figure 29: Overdose Deaths by Age, Rhode Island, 2014-2015**



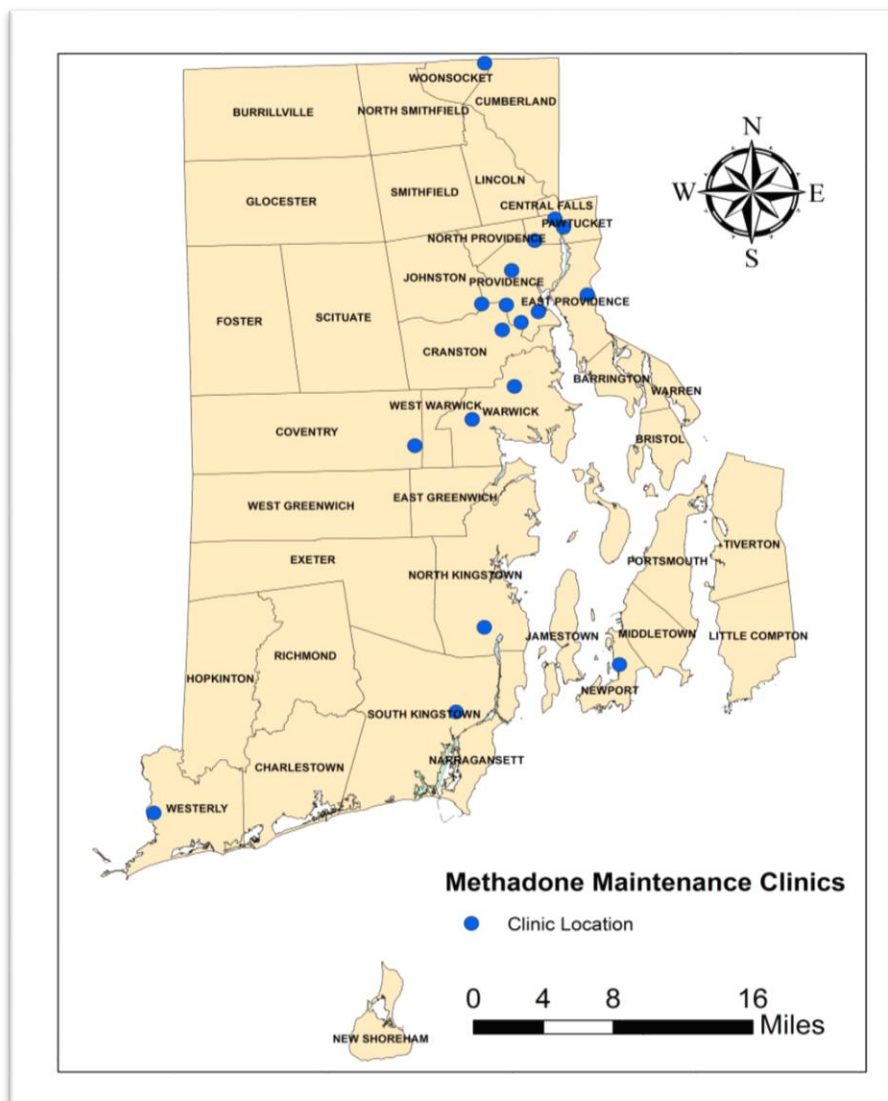


**Figure 31: Proportion of Overdose Decedents Released from the RIDOC within One Year Of Death, 2014-2015**



Rhode Island has 18 methadone clinics serving opioid and injection drug users throughout the state (Figure 32). These include the Addiction Recovery Institute (two clinics); Center for Treatment and Recovery (two clinics); Discovery House (two clinics); CODAC (five clinics); the Journey to Hope, Health and Healing (three clinics); Judy’s House, SSTAR of Rhode Island, Kent Hospital Mothers on Methadone Program, and the Providence VA Medical Center methadone clinic. Most Rhode Island methadone clinics do not routinely screen patients for HCV or treat patients living with HCV. However, CODAC routinely screens and rescreens all patients for HCV and performs confirmatory diagnostic viral load testing. CODAC estimates that it screened approximately 900 patients in 2015. CODAC also offers HCV prevention, care, and treatment services to its clients on site. Data about seropositivity rates and the number of HCV-positive patients receiving confirmatory RNA testing and curative therapy at CODAC are not yet fully available, but preliminary data suggest HCV cure rates among CODAC patients are higher than 95%. Given the disproportionate burden of HCV infection among people who inject drugs (PWID) and individuals with a history of substance use, expanding HCV screening and linkage to care among methadone clinic patients presents a public health opportunity.

Figure 32: Methadone Maintenance Clinic Locations, Rhode Island, 2016



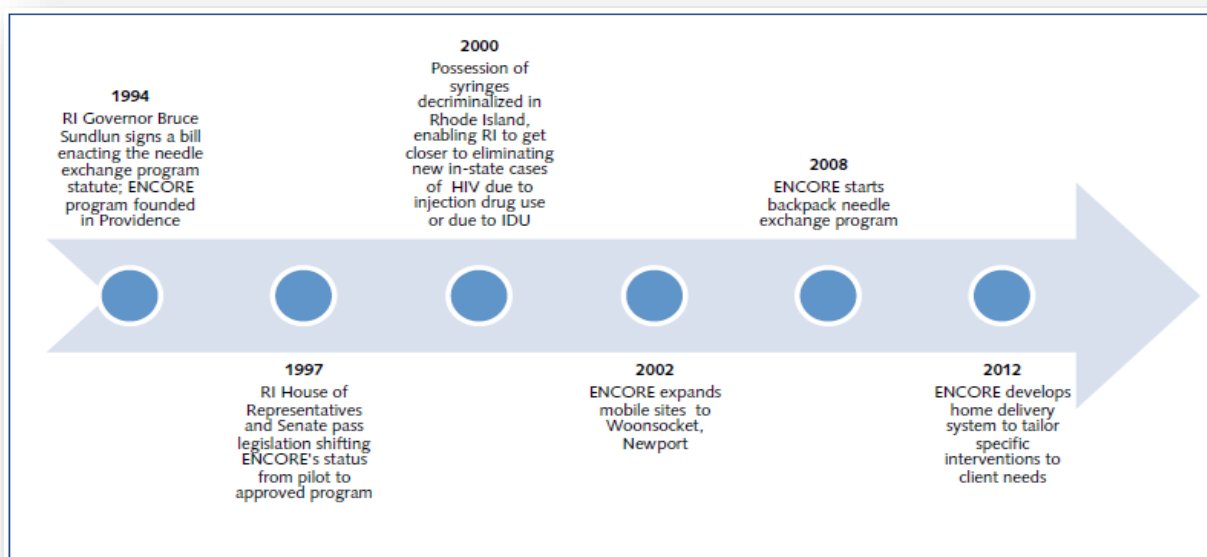
Needle exchange programs (NEPs) are a core component of harm reduction programs for PWID.<sup>26</sup> Through the provision of sterile needles, NEPs help to reduce injection-mediated risks that are correlated to HIV and HCV transmission. NEPs also provide essential wrap-around health services and disease screening opportunities, including HCV screening, to PWID who are often disconnected from mainstream healthcare systems.

### THE ENCORE PROGRAM

AIDS Care Ocean State (ACOS) runs the state-funded NEP called ENCORE. The ENCORE program has existed in Rhode Island since 1994, and as of the writing of this report, operates three fixed sites and a mobile/street-based exchange unit, where a van and a team of outreach workers go out into the community to actively seek out PWID in five cities: Providence, Woonsocket, Newport, Pawtucket and Central Falls.

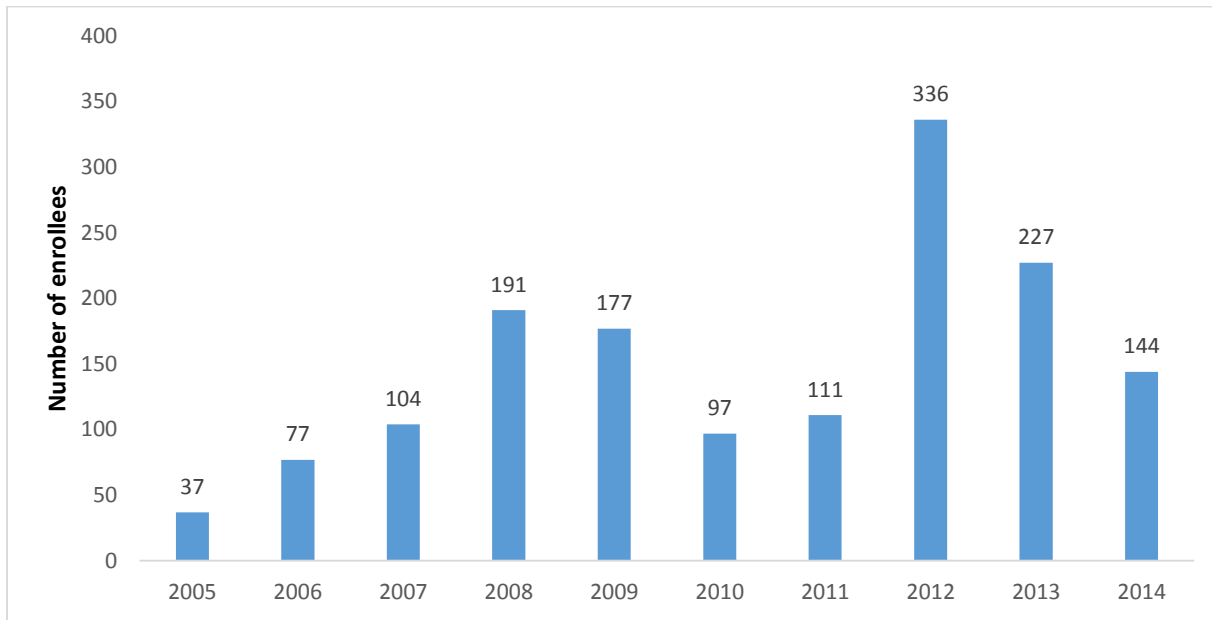
The acronym ENCORE stands for Education (on blood-borne pathogen prevention); Needle exchange (to reduce risk of transmitting blood-borne pathogens), Counseling (on reducing risks and following through on medical care and treatment options), Outreach (into the community to help identify clients for the program) and Referrals (to healthcare and social service agencies and drug treatment). In 2005, ENCORE became Rhode Island's first free testing site that tested for HCV antibodies. A more detailed timeline of significant achievements in ENCORE's history is detailed in Figure 33.

Figure 33: ENCORE Needle Exchange Program Significant Achievements, 1994-2012



The ENCORE Program collects data on its clients through an enrollment interview completed on the first visit to ENCORE. From 1994 to 2011, the ENCORE program averaged about 150 new enrollees every year. From 2012 to 2014, the average was much higher due to high enrollment numbers in 2012 and 2013. Preliminary data from 2015 suggests that enrollment increased once again, higher than pre-2012 averages.

**Figure 34: New Enrollees to the ENCORE Needle Exchange Program, 2005-2014**



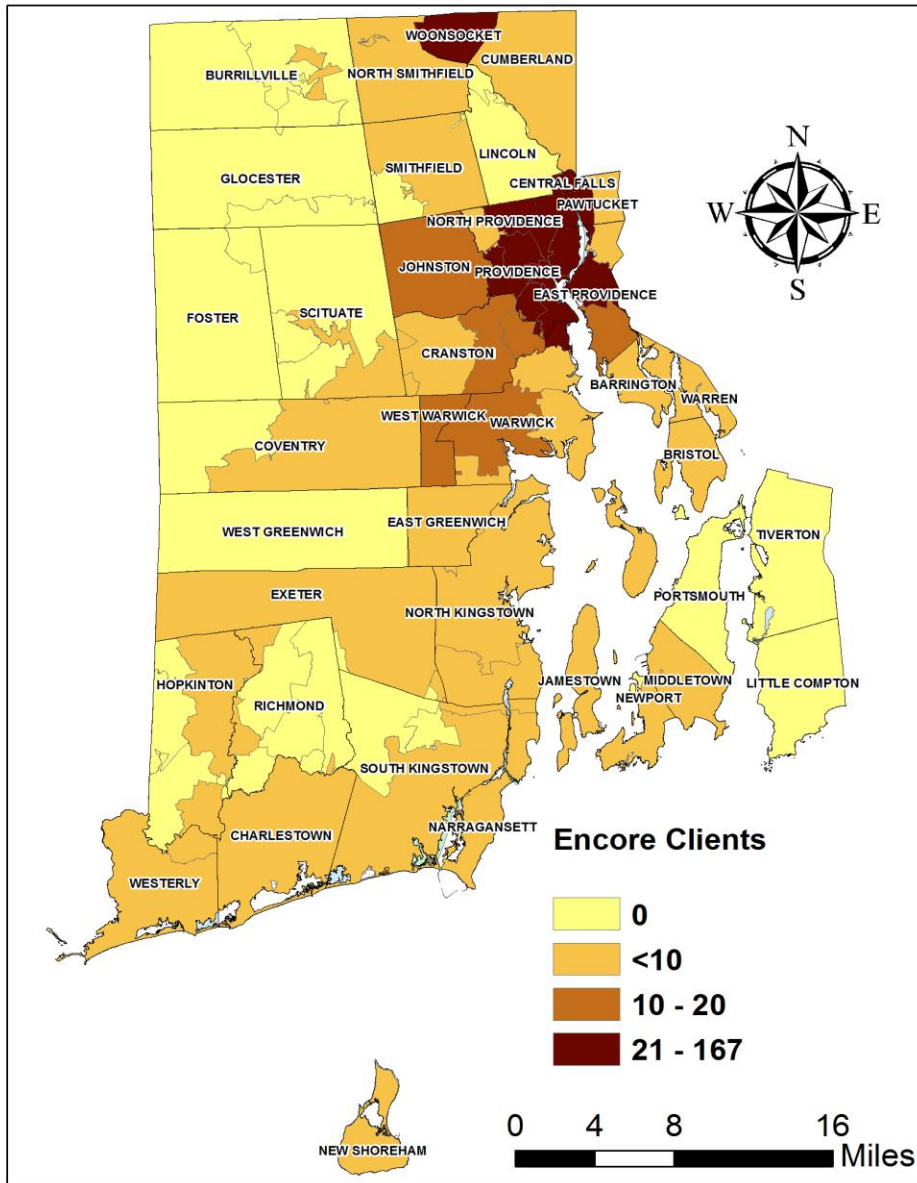
*Note: In 2012, a new client coding system was implemented and the number of enrollees included both new and existing clients.*

From 2012 to 2014, 43% of ENCORE clients reported a history of chronic HCV infection. By way of comparison, 10% of clients in the same time period reported that they were HIV-positive. Among clients from 1994 to 2011, low levels of blood-borne virus testing were reported, with only 26% having received an HCV test in the past year, and 30% having received an HIV test in the past year.

The majority of clients enrolled in ENCORE reside in Providence County (88.8%) and about two-thirds of all clients reside in the City of Providence. Other ENCORE clients reside in Woonsocket, Pawtucket, Central Falls, and Warwick, cities where large numbers of people living with HCV also reside. Thus, ENCORE services appear to be targeting key locations where HCV screening, prevention, and linkage to care is most needed. Figure 35 portrays the geographic distribution of clients enrolled to the ENCORE Program between 2012 and 2014.



Figure 35: Number of Encore Needle Exchange Program Enrollees by ZIP Code, 2012-2014



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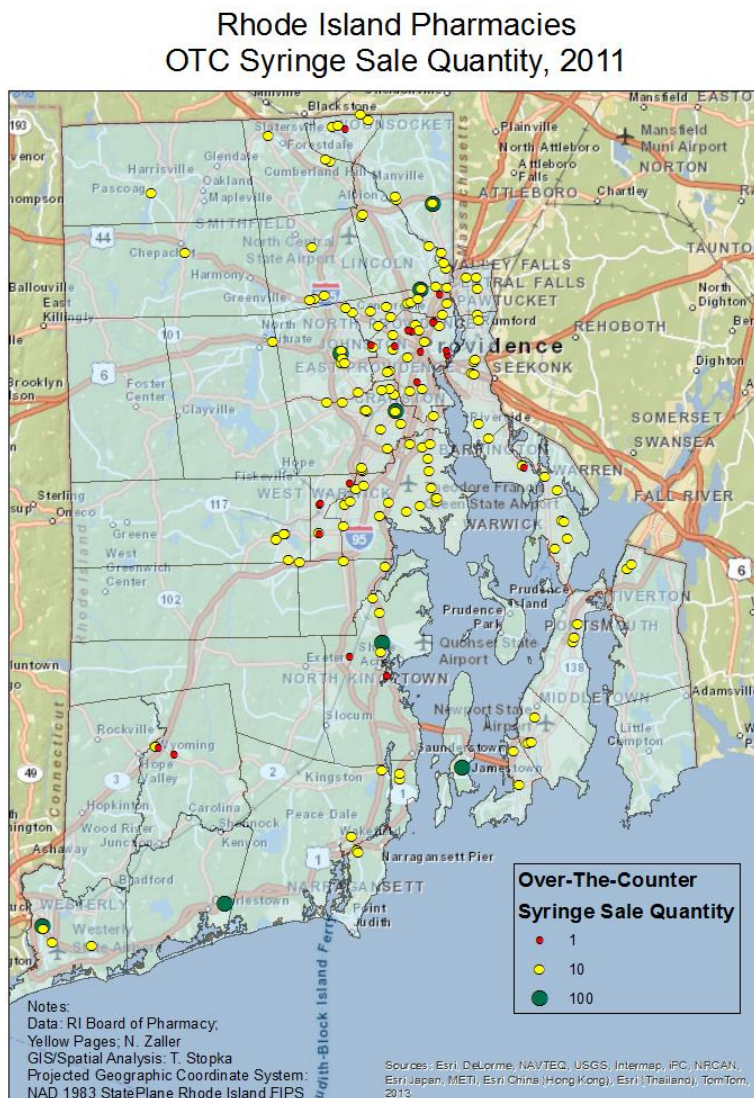
## Pharmacies

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### Pharmacy Access to Syringes

Pharmacies have the potential to play an important role in HCV screening, prevention, and linkage to care. Over-the-counter (OTC) sterile syringe sales help to reduce risks for blood-borne disease transmission among PWID. Rhode Island permits OTC sales of syringes without a prescription. This law has helped reduce the infectious consequences of substance use, including HIV and HCV. Figure 36 depicts the quantity of syringes sold by pharmacies across Rhode Island. Overall, access to OTC syringes in Rhode Island pharmacies appears strong in key towns and cities where elevated numbers and rates of HCV have been reported (Providence, Woonsocket, Pawtucket, Central Falls, and Warwick). In the more rural areas of the state, access to OTC syringe sales is limited, which may have detrimental effects on HCV transmission risks among PWID who live further away from larger cities and towns. Most pharmacies report selling 10-packs of syringes, which cost between \$2 and \$4, and some pharmacies sell single syringes, which cost more per unit but can sell for \$1 or less per syringe.

**Figure 36: Over-the-Counter Syringe Sales in Pharmacies, Rhode Island, 2011**



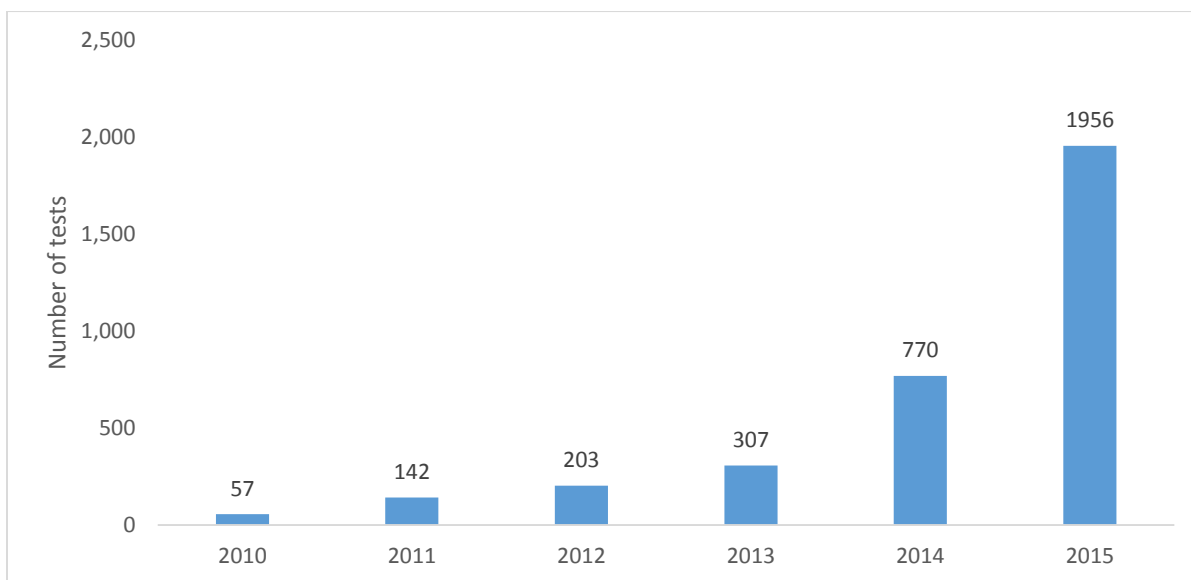
### Background

All adults under correctional supervision in Rhode Island fall within the Rhode Island Department of Correction's (RIDOC) jurisdiction. According to RIDOC, there are approximately 3,200 adults residing within the RIDOC and approximately 14,000 individuals cycle through, annually.

### Hepatitis C Virus Testing Trends at RIDOC

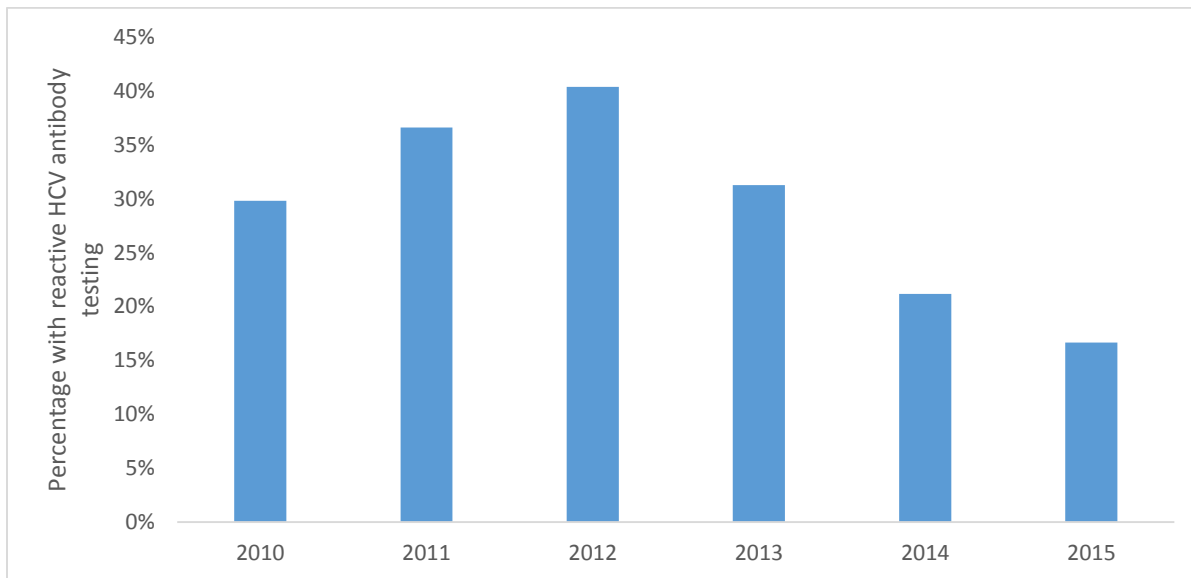
Since 2010, the number of HCV antibody tests conducted has increased dramatically from 57 in 2010 to 1,956 in 2015 (Figure 37). The RIDOH State Health Laboratory (SHL) conducts viral hepatitis antibody testing for RIDOC. Additional confirmatory testing is conducted by commercial laboratories.

**Figure 37: HCV Antibody Tests at RIDOC, 2010-2015**



Anti-HCV prevalence rates at RIDOC have varied through the years. This is likely attributed to an effort to move away from risk-based screening toward routine screening. In 2015, the most recent year for which data were available, 17% of inmates who underwent HCV antibody screening had preliminary positive tests (Figure 38). However, these may not capture the overall anti-HCV prevalence because there is not yet a universal HCV screening policy at the RIDOC.

**Figure 38. Anti-HCV Prevalence of HCV Tests at the RIDOC, 2010-2015<sup>†</sup>**



In May 2016, there were 84 adults with confirmed, chronic HCV residing within the RIDOC, of whom 83 are male. More than 50% of individuals with a known detectable viral load were born between 1960 and 1979 and the majority of individuals were non-Hispanic whites.

The RIDOC reported that 16 individuals have been treated with interferon-free regimens, of whom 10 individuals were successfully cured of HCV. One individual failed treatment and the others were awaiting final confirmation to determine if treatment was successful. An additional three individuals were still undergoing treatment. Nearly 65% of individuals treated were born between 1960 and 1969.

#### **Department of Corrections Health Fair and Hepatitis C Screening Program**

HCV testing at the Department of Corrections is conducted on a voluntary basis for inmates upon sentencing. HCV antibody testing is offered to all minimum security inmates, including at a health fair where HCV antibody testing was offered to all inmates. Two hundred and six inmates were tested at a health fair in the spring of 2016.

As of April 2016, 70% (244 out of 350) of inmates at minimum security were tested for HCV, and of these, 13% had a preliminary positive antibody test. Individuals subsequently underwent HCV confirmatory screening. Among individuals with a preliminary positive antibody test, 75% had a detectable HCV viral RNA. Among those in this sample with confirmed chronic HCV, 25% identified as African American/Black, 25% as Hispanic/Latino, and 50% as Caucasian/White. Thirty-eight percent were age 50 to 59, 34% were age 40 to 49, 22% were age 30 to 39, and 6% were age 20 to 29. Within this sample, two were recently cured of HCV with interferon-free treatment regimens.

#### **Overview of Rhode Island Department of Corrections: Research Studies**

Recent research studies in Rhode Island focused on HCV rapid testing within populations in various stages of interaction with correctional programs. Beckwith *et al.* found that rapid testing of inmates within Rhode Island corrections facilities was feasible, facilitating detection of a fair number of HCV positive inmates, especially among white and former injection drug using inmates, and providing HCV health education opportunities. Beckwith found, however, that HCV linkage to care was limited upon release from corrections facilities, calling for interventions to link and cure individuals upon release from the RIDOC.<sup>29</sup>

Zaller and colleagues tested a rapid HCV screening program among Rhode Island individuals who were on probation and parole, as this population often does not access healthcare services. One hundred and thirty probationers and parolees accepted the rapid HCV test, and 12 individuals tested preliminary positive. Zaller found, however, that only four of

these individuals presented to a community-based clinic for confirmatory HCV testing,<sup>30</sup> highlighting a need for HCV services in and upon release from the RIDOC.

It should be noted that these studies were conducted prior to the advent of direct-acting and highly efficacious HCV medications. With the current availability of such medications, treatment of people within the corrections population in Rhode Island presents a unique opportunity to clear the HCV virus within the walls of Rhode Island prisons, which will translate into reduced risk for HCV transmission in local communities into which probationers are ultimately released.

Taken together, these data suggest that inmates in Rhode Island have high rates of HCV. The RIDOC is expanding efforts to screen and treat inmates living with HCV. There is also a public health opportunity to improve linkage to HCV care for inmates upon release.

### **HCV screening and treatment**

The CDC recommends one-time screening for HCV for all individuals born between 1945 and 1965 and ongoing screening for other high-risk populations. Screening in clinical settings may not reach individuals at highest risk,<sup>10</sup> and surveillance systems often do not accurately capture acute HCV infection, thereby underestimating true HCV prevalence.<sup>11</sup> Furthermore, only half of individuals who test positive for anti-HCV undergo confirmatory RNA testing.<sup>12</sup> Until recently, most HCV treatments required injectable medications that can cause unpleasant side effects such as depression, fatigue, insomnia, and lowering of blood counts. There are currently no liver transplant centers in Rhode Island. Patients in need of a liver transplant are referred out of state, usually to one of several centers in Massachusetts.

In recent years, there has been significant progress in the discovery and FDA approval of new and highly-effective HCV treatments. These medications, called directly acting antiviral agents (DAAs), are oral, well-tolerated, safe, highly effective, and maintain high (95%) sustained virologic response (SVR) rates with eight to 24 weeks of therapy.<sup>31</sup> Recent advances in HCV treatment to cure present an important public health opportunity to reduce HCV-related morbidity, mortality, and transmission. For the first time, there is hope that HCV can be eliminated.<sup>12-26</sup>

Many public and private insurers also require prior authorization for payment, as prices for DAAs range from approximately \$17,000 per patient, per year to \$80,000 per patient, per year. Because of the high costs and overwhelming number of Americans living with HCV, some insurance companies immediately added the new medications to formularies in 2014, and others waited up to a year to add DAAs to their approved formularies. Some payers have restricted drugs for treatment to individuals with advanced fibrosis. Fibrosis scores are a commonly used metric to evaluate liver damage, and are rated on a scale of stage 0 to stage 4. A normal liver is between stage 0 and 1. Light fibrosis is found at stage 2, while stage 3 denotes severe fibrosis. Cirrhosis is equivalent to stage 4, where scar tissue exists throughout the liver.

Disagreements about drug pricing and payments have delayed access to DAAs for many patients in the United States. Discussions about the appropriate pricing structures for these medications have been contentious and have culminated in lawsuits in several states. In 2015 and 2016, many health payers nationwide, including Medicaid programs across the nation and in New England, have lifted restrictions on fibrosis scores for treatment.

To better understand the HCV treatment landscape in Rhode Island, infectious disease and hepatologists providers who treat a large share of HCV patients in Rhode Island were surveyed. This was not an exhaustive or comprehensive list, but it is estimated that these clinicians provide care to 75% or more of HCV patients in Rhode Island who are in care for HCV and receiving treatment. Providers also indicated that they had “harbored” many patients living with HCV until 2014, reserving treatment for patients until new DAA medications were released and approved by the FDA. Even after the FDA approved medications, providers reported that they were initially unable to treat many people living with HCV because of payer restrictions on expensive medications.

Physicians also reported large volumes of time-intensive, prior-authorization paperwork associated with accessing appropriate all-oral medications for their patients. However, all noted that access to medications has improved over time, and most agreed that most private payers in Rhode Island do now pay for preferred DAAs, irrespective of liver staging. However, providers also noted that some Medicaid patients have been unable to access DAAs because Rhode Island Medicaid (RI Medicaid) only approves DAAs for treatment of individuals with stage 3 or stage 4 fibrosis scores.

Cumulatively, providers surveyed reported curing approximately 1,200 individuals and reported only eight patients failing treatment, usually because they experienced side effects. Medicaid reported paying for treatment for 215 individuals in 2015. Providers surveyed for this analysis estimated that 350 Medicaid patients await treatment because they have fibrosis scores of stage 1 or stage 2. While these results may not capture the comprehensive picture of all

patients who have been cured of HCV or those who await curative therapies, they provide important preliminary data about trends in HCV treatment and cure.

**Health Insurance Premiums: Office of the Health Insurance Commissioner**

The Office of the Health Insurance Commissioner (OHIC) estimates that increased utilization of drugs for HCV treatment contributed to rising costs of insurance premiums in the state of Rhode Island. In 2014 and 2015, the average cost of HCV DAAs reported by insurance plans was \$30,000 per month, or an average of \$90,000 per cure. Plans reported covering nearly all of the DAAs available in the marketplace but require prior authorization from providers, and cost sharing with patients varies by insurance plan. Most insurance companies limit prescribing authority to gastroenterologists, infectious disease physicians, HIV specialty providers, or hepatologists.

Preliminary data from 2016 suggests that DAA costs per patient declined significantly, but the number of individuals being treated has risen significantly.

OHIC estimates that healthcare premiums will increase by approximately 0.5% due to increases in utilization of medications associated with treating and curing HCV.

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## *Conclusion*

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This is the first attempt to comprehensively evaluate HCV data for public health action in the state of Rhode Island. Morbidity and mortality related to HCV is increasing, as evident by the increases in hospitalizations and deaths associated with HCV. Liver cancer rates are also increasing, though the link to HCV infection is less clear. At the same time, trends indicate that screening and confirmatory testing of HCV infection are also on the increase, though progress still needs to be made. And finally, with the advent of improved treatment regimens, additional focus needs to be placed on understanding who is infected, the availability of treatment options, and the success with curing HCV infection. These and other lessons learned from this process will help guide future public health initiatives and health system policy, as well as provide a basis for future grant funding for continued efforts to eliminate HCV in Rhode Island.



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## *Acronyms and Abbreviations*

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AIDS: Acquired Immune Deficiency Syndrome  
ACOS: AIDS Care Ocean State  
APRI: AIDS Project Rhode Island  
ASTHO: Association of State and Territorial Health Officials  
BRFFS: Behavioral Risk Factor Surveillance System  
CDC: Centers for Disease Control and Prevention  
CODAC: Cranston Outpatient Drug Free Treatment Center  
CTR: Counseling, Testing, and Referral System  
DAA: Direct-Acting Antivirals  
DPH: Department of Public Health  
ELR: Electronic Laboratory Recording  
EMR: Electronic Medical Records  
eHARS: Enhanced HIV/AIDS Reporting System  
ENCORE: Education, Needle Exchange, Counseling, Outreach, and Referral  
FDA: United States Food and Drug Administration  
HAV: Hepatitis A Virus  
HBV: Hepatitis B Virus  
HCC: Hepatocellular Carcinoma  
HCV: Hepatitis C Virus  
HCV Antibody: HCV Antibody Testing  
HCV RNA: HCV RNA Testing  
HIV: Human Immunodeficiency Virus  
IDU: Injection Drug User  
NAT: Nucleic Acid Testing  
NBS: National Base System  
NEDSS: National Electronic Disease and Surveillance System  
NHANES: National Health and Nutritional Examination Survey  
PRIDEMS: Division of Preparedness, Response, Infectious Disease, and Emergency Medical Services  
PWID: People Who Inject Drugs  
RID Hep C: Rhode Island Defeats Hepatitis C  
RIDOC: Rhode Island Department of Corrections  
RIDOH: Rhode Island Department of Health  
SAMSHA: Substance Abuse and Mental Health Services Administration  
SSTAR of RI: Stanley Street Treatment and Resources of Rhode Island  
SVR: Sustained Virologic Response  
TEDS: Treatment Episode Data Set  
UNOS: United Network for Organ Sharing  
WEDSS: Wisconsin Electronic Disease Surveillance System  
MDPH: Massachusetts Department of Public Health  
VA: Department of Veteran Affairs  
VHA: Veterans Health Administration

**Please note the following footnote where it appears in the report:**

**†These percents should be interpreted with caution due to questionable statistical reliability.**

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Appendix A: Medicaid Claims Data for HCV Services in Rhode Island, 2014 - 2015<sup>†</sup>

	Total		Male		Female		Youth (15-29)		Baby Boomer <sup>a</sup>	
	#	%	#	%	#	%	#	%	#	%
<b>Medicaid Observations</b>	49,441	100.00	18,867	38.16	30,574	61.84	12,539	25.36	18,225	36.86
<b>HCV Observations</b>	30,070	60.82	12,646	67.03	17,424	56.99	6,670	53.19	12,275	67.35
<b>HCV Clients</b>	17,151	34.69	5,884	31.19	11,267	36.85	5,227	41.69	5,187	28.46
<b>RI HCV Clients</b>	17,035	34.46	5,853	31.02	11,182	36.57	5,203	41.49	5,156	28.29
<b>Age</b>										
<15	308	1.81	132	2.26	176	1.57				
15-24	2,728	16.01	449	7.67	2,279	20.38				
25-34	4,462	26.19	968	16.54	3,494	31.25				
35-44	2,976	17.47	1,077	18.40	1,899	16.98				
45-54	3,270	19.20	1,571	26.84	1,699	15.19				
55-64	2,791	16.38	1,420	24.26	1,371	12.26				
65-74	419	2.46	203	3.47	216	1.93				
75-84	64	0.38	25	0.43	39	0.35				
85+	17	0.10	8	0.14	9	0.08				
<b>Race</b>										
American Indian <sup>b</sup>	72	0.73	28	38.89	44	61.11	22	30.56	15	20.83
Asian Pacific Islander	220	2.24	78	35.45	142	64.55	54	24.55	75	34.09
Black	1,483	15.12	553	37.29	930	62.71	443	29.87	519	35.00
Spanish surname	1,055	10.76	371	35.17	684	64.83	196	18.58	458	43.41
White	6,976	71.14	2,682	38.45	4,294	61.55	1,726	24.74	2,576	36.93
<b>HCV Diagnoses</b>										
Carrier <sup>c</sup>	528	29.56	326	61.74	202	38.26	37	7.01	283	53.60
Unspecified <sup>d</sup>	113	6.33	60	53.10	53	46.90	5	4.42	72	63.72
Acute <sup>e</sup>	-	-	-	-	-	-	-	-	-	-
Chronic <sup>f</sup>	1,145	64.11	673	58.78	472	41.22	52	4.54	729	63.67
<b>Total Current Procedures</b>										
Acute Hepatitis Panel <sup>g</sup>	-	-	-	-	-	-	-	-	-	-
Antibody <sup>h</sup>	15,680	66.18	4,467	28.49	11,213	71.51	5,729	36.54	3,670	23.41
Viral Load <sup>i</sup>	6,223	26.27	3,465	55.68	2,758	44.32	460	7.39	3,630	58.33
Genotype <sup>j</sup>	1,789	7.55	1,021	57.07	768	42.93	148	8.27	923	51.59

<b>First Client HCV Procedure</b>	16,234									
Antibody	13,554	83.49	3,845	28.37	9,709	71.63	5,008	36.95	3,194	70.39
Viral Load	2,369	14.59	1,317	55.59	1,052	44.41	196	8.27	1,307	73.06
Genotype	311	1.92	164	52.73	147	47.27	27	8.68	146	71.05
<b>Last Client HCV Procedure</b>	15,539									
Antibody	13,090	84.24	3,617	62.62	9,473	37.38	4,913	6.05	2,986	70.39
Viral Load	1,920	12.36	1,035	67.24	885	32.76	176	3.88	1,014	73.06
Genotype	529	3.40	312	63.12	217	36.88	37	5.87	248	71.05

Note: A “-” represents censored cells due to small numbers.

Note: HCV classifications determined by HCV related Diagnostic and CPT codes.

Note: RI classification based on State listed in last observation for client.

Note: Age, race, HCV diagnoses, total current procedures, first and last client HCV procedure percents are based on row totals.

Note: Age, race, and HCV diagnoses (diagnostic code) based on last entry for client.

Note: Total current procedures are based on all HCV related CPT codes. They are a summation of all entries, not unduplicated.

<sup>a</sup>Baby Boomer is someone born between 1945 and 1965. This variable was calculated based on age and year of test.

<sup>b</sup>Due to small sample size, American Indian data have a relative standard error of 23%.

<sup>c</sup>Carrier HCV diagnosis based on diagnostic codes V0262 and Z2252.

<sup>d</sup>Unspecified HCV diagnosis based on diagnostic codes 07041, 07051, 07070, 07071, B1920, B1921.

<sup>e</sup>Acute HCV diagnosis based on diagnostic codes B1710 and B1711. Data are suppressed due to relative standard error >30%.

<sup>f</sup>Chronic HCV diagnosis based on diagnostic codes 07044, 07054, and B182.

<sup>g</sup>Acute hepatitis panel tests based on CPT code 80074. No acute hepatitis tests recorded during a client's first or last visits. Data are suppressed due to relative standard error >30%.

<sup>h</sup>Antibody tests based on CPT code 86803 and 86804.

<sup>i</sup>Viral load tests based on CPT code 87521 and 87522.

<sup>j</sup>Genotype tests based on CPT code 87902.

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