# MONITORING THE HEPATITIS C EPIDEMIC IN THE UNITED STATES:

WHAT TOOLS ARE NEEDED TO ACHIEVE ELIMINATION?



#### **ABOUT THIS REPORT**

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This issue brief was developed independently of, but informed by an expert consultation held in Washington, DC in September 2016 of 35 diverse stakeholders, including Hepatitis C medical and non-medical providers, patient advocates, epidemiologists, and federal Hepatitis C policy and program staff.

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#### MONITORING THE HEPATITIS C EPIDEMIC IN THE UNITED STATES: WHAT TOOLS ARE NEEDED TO ACHIEVE ELIMINATION?

Hepatitis C virus (HCV), a chronic viral infection that damages the liver, is a critical public health concern in the United States (US). HCV is the most common cause of viral hepatitis infections in the US, and it can cause severe health complications such as liver cancer or death.¹ Although there is no vaccine to prevent HCV infection, other interventions are very effective in preventing transmission. In addition, recently developed antiviral drugs have been remarkably successful in curing people of this disease. This is leading to a growing consensus in the global health community that HCV can be eliminated as a public health threat worldwide.² The US can lead the way in demonstrating how to eliminate HCV from the population. Questions have arisen, however, over whether the US has the knowledge, resources, and capacity to make this happen. In a recent National Academies of Science, Engineering, and Medicine report,³ the answer is yes.

To eliminate HCV in the US, we must effectively monitor the epidemic and deploy critical public health and health care resources to prevent new infections, screen and diagnose cases, and treat all of those who are infected with the virus.

While expanding access to care and treatment and bolstering the health care workforce are also critically important, these efforts will not be as effective as they could be if we do not have sufficient data to inform our efforts. This brief explores issues related to the HCV cure cascade in the US, with a focus on the current state of HCV data monitoring and surveillance, and identifies new policies and actions to strengthen our capacity to work toward elimination. These recommendations are intended to be practical and achievable.

#### **KEY POINTS**

#### **HCV SURVEILLANCE AND MONITORING**

HCV is the most prevalent cause of viral hepatitis infections in the US and can cause severe health complications such as liver cancer or death. 3.5 million Americans have HCV infection and an estimated 33,900 acute cases (newly-acquired infections within 6 months of a previously negative test) were estimated to have occurred in 2015 alone.

- 1 Chronically infected baby boomers and newly-infected individuals represent two distinct epidemics in the US: Most cases of HCV are in baby boomers, yet most new infections arise among people who inject drugs, which calls for tailored interventions to reach and serve these populations.
- Recently approved direct-acting agents are remarkably successful at curing people with HCV infection: Between 94-99% of persons who successfully complete a course of treatment (typically 8, 12 or 24 weeks of daily drug therapy) maintain HCV viral loads in their bloodstream at "undetectable" levels.
- National monitoring of HCV trends relies on a small number of states and must be strengthened: While 40 states provide acute HCV case report data to the Centers for Disease Control and Prevention (CDC), resource limitations mean that only 14 jurisdictions are currently being funded to provide more detailed surveillance data.
- 4 Eliminating HCV in the US is possible: Strategic investments are needed to realize the potential to treat and cure all people living with HCV. This would yield enormous benefits by producing a healthier population and avoiding preventable health expenditures associated with treatment of liver disease and organ transplantation.

#### **KEY RECOMMENDATIONS**

#### WORKING TO ELIMINATE HCV IN THE US

Even with a constrained federal budget, more resources are needed for HCV surveillance and monitoring and more focused efforts are needed to use data to move us closer to eliminating HCV in the United States.

- **Expand and standardize reporting to the CDC:** Policy makers should phase up active surveillance of HCV in more states and territories, and work with local jurisdictions in identified hot spots. The CDC's Division of Viral Hepatitis (DVH), working with congressional appropriators, should develop a five-year plan for building the capacity to conduct active surveillance in the great majority of US states.
- 2 Utilize electronic medical records to collect data on HCV cases and the cure cascade: State epidemiologists should be funded to establish and utilize an integrated electronic medical records database, which would also provide matching information with cases, such as race, age, gender, and progress of treatment levels.
- **Fund epidemiologic research using clinical data sets:** Clinical care data are a largely untapped resource that relies on data that already exist. In addition to the CDC, agencies across HHS and in other Departments such as Veterans Affairs and Defense should be directed to fund epidemiological research on HCV.
- Integrate improved monitoring of HCV with responses to the opioid epidemic: The Nation is increasingly recognizing the scope of the public health crisis we are facing related to opioid abuse. Preventing and treating HCV must be a signature component of the national response to opioid abuse.
- **Establish and monitor HCV elimination plans across major US health systems:** Strategic plans are needed to eliminate HCV in the United States. One example is the Cherokee HCV elimination project currently being implemented, where the tribe plans to screen 85% of Cherokee Nation health patients between the ages of 20 to 69 by the end of 2018. The Department of Veterans Affairs is also leading the way. Other public programs should be tasked with developing their own elimination plans.

# OVERVIEW OF HCV IN THE UNITED STATES

The Centers for Disease Control and Prevention (CDC) estimate that at least 3.5 million Americans currently have HCV infection.4 and rates of new infections have increased nearly 2.9-fold between 2010 and 2015.5 An estimated 33,900 new infections occurred in 2015 alone.<sup>6</sup> Following its identification as a discrete infection separate from other forms of Hepatitis in 1989,7 treatment for HCV involved the use of toxic, immune boosting drugs that caused seriously debilitating side effects and only succeeded at suppressing the virus about half of the time.8 In the past 3 years, however, new drugs have become available that are believed to effectively cure people of HCV infection. Nearly all people who have successfully completed a course of treatment are able to sustain undetectable levels of the virus in their blood following treatment.9 Thus, these new medications, known as direct-acting antivirals (DAAs), are considered curative therapies for HCV.10 If left untreated, HCV can cause severe scarring of the liver, called cirrhosis, as well as liver cancer, and death.11 Chronic HCV infection is the leading cause of liver transplantation in the US, at an average cost of \$201,110 per transplant.12

Despite the high prevalence of HCV infections in the US and the increasing

number of new cases annually, there is still too little known about the behavior of the disease within different populations, and we do not have enough information to accurately understand the epidemiology of HCV infection across all 50 states or in individual counties and localities. Resource allocation for HCV programming—which includes testing, prevention, and treatment services—is very limited. State and local public health authorities often have extremely constrained fiscal capacity to properly count and track the number of cases of the illness in their jurisdictions. The process of data collection of diagnosed disease cases, called *surveillance*, is an essential tool to understanding how an illness is spreading through a population.

Public health data collection has benefits both in the practical use of information to address prevention and care needs associated with new cases of infection, or *incidence* of the disease in the population, and in providing metrics that help researchers estimate the total number of known and undiagnosed cases of a disease, or the *prevalence* of the disease. Monitoring incidence of new cases and the ability to identify trends associated with the proliferation of an infectious disease are essential to informing public health officers

3.5 million Americans are living with HCV and new infections are rising, with roughly 33,900 new cases of acute infection arising in 2015.

# 52+

AMERICANS OVER AGE 52 (THE "BABY BOOMER" COHORT)

ACCOUNT FOR THE HIGHEST PERCENTAGE OF

CHRONIC (LONG-TERM) CASES OF HCV IN THE US



3 OUT OF 4 AMERICANS LIVING WITH HCV
ARE "BABY BOOMERS"

20-39

YOUNG ADULTS AGED 20-39
ACCOUNT FOR THE HIGHEST RATE OF
NEW (ACUTE) CASES OF HCV.



FROM 2010-2014, NEW CASES OF HCV INCREASED BY 290% on the mechanisms of disease spread within populations, risk factors, and other critical measures. With respect to HCV, these data enable analysts to develop estimates of the true number of undiagnosed infections in the population, and aid in filling the information gap caused by the underdiagnosing of the infection by health care providers, failures in consistent reporting of new cases, and the asymptomatic nature of the infection that rarely prompts the infected to seek medical care. In order for this to occur, there must be an infrastructure that supports identifying new cases and following up with these patients to collect other pertinent information. Comprehensive case surveillance that includes the collection of demographic information, risk behaviors and geographic location are among the most important types of information needed by public health authorities to monitor how this disease is moving though a population, and to develop strategies to get ahead of the epidemic by employing effective prevention interventions.

### TWO DISTINCT EPIDEMICS IN THE US

Hepatitis C, like virtually all other infectious diseases, is spread throughout the population. While it exists in all parts of the country and in all population groups, it is not distributed equally. By contrast to some other infectious diseases, HCV cases often fall into one of two distinct cohorts:

BABY BOOMERS (Persons born from 1945-1965)—Generally, these individuals with HCV have been living with the infection for decades, yet are often unaware of it.<sup>13</sup> They may have acquired the infection through blood transfusions or other medical procedures before effective blood screening was implemented or through long ago injection drug use.<sup>14</sup> Baby Boomers are more likely to have health insurance than to be uninsured.<sup>15</sup>

#### NEWLY INFECTED INDIVIDUALS—

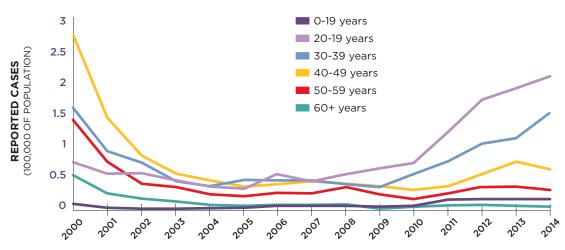
These individuals tend to be younger (aged 18-39), and nearly all cases are acquired through injection drug use.<sup>16</sup> New infections have increased fastest in suburban and rural areas.<sup>17</sup> The newly infected have a higher likelihood of being uninsured than Baby Boomers.<sup>18</sup>

There is a compelling case for focusing efforts on both populations, but they require tailored approaches to be most effective. From a population health perspective, it is imperative to diagnose and treat Baby Boomers to protect their health and to prevent the expenditure of significant health care resources for liver transplants and ongoing medical care associated with advanced disease. Treating newly infected individuals is also important because this cohort represents the source of the largest share of HCV transmissions and to prevent the damage that arises from chronic infection. Thus, to reduce the impact and further spread of the epidemic, it is necessary to treat and monitor this population. Importantly, there are other populations that require tailored responses. People who are incarcerated, veterans, and people living with HIV are all groups at elevated risk for HCV that have unique vulnerabilities to the disease. Tailored responses that focus on these groups also should be part of any strategic national response to the HCV epidemic.

HepVu, launched in April 2017, is the first resource of its kind to provide state-level estimates of past and current HCV infections in the U.S. It was developed by researchers at the Rollins School of Public Health at Emory University, and develops its estimates using existing data and other statistical indicators to create models of disease prevalence in different regions. The most current HepVu estimates of Hepatitis C prevalence in the U.S. appears on the bottom of page 7, at right.

#### INCIDENCE OF ACUTE HEPATITIS C, BY AGE

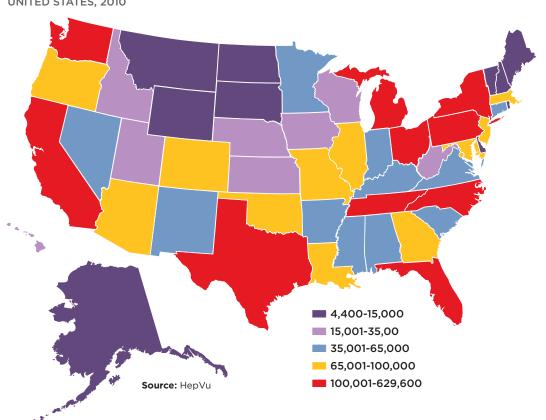
**UNITED STATES, 2000-2014** 



Source: CDC, National Notifiable Surveillance System (NNDSS)

## ESTIMATED NUMBER OF PERSONS LIVING WITH HEPATITIS C

UNITED STATES, 2010



# CURRENT APPROACHES TO MONITORING HCV

The number of cases of a disease is only one piece of the puzzle needed by public health authorities to counter rising incidence of disease. Additional information is needed to better know who is affected, who is most susceptible, the location of the cases, or any other clues that can assist in developing strategies to curb the prevalence. Disease surveillance defines the process of compiling and analyzing these data to develop strategies to prevent and control continued incidence. Timely collection of such information is key to ensuring the quality, veracity, and benefit of these data for the public health authority to effectively address the issue. It is here that the lack of adequate data to monitor such a significant public health problem as HCV becomes apparent. There are two case reporting procedures used in the US for HCV that provide notably different degrees of completeness and accuracy:

**PASSIVE CASE REPORTING** describes the collection of the number of cases of a disease by a health authority through reporting by health care providers, health treatment facilities,

and laboratories. There is no additional follow-up by the public health authority to identify additional cases or ascertain more case-related information.<sup>19</sup> Passive reporting can be likened to drawing a line on a piece of paper for every reported case of an illness to keep a headcount without any other information on the person. Although all states require reporting, it is difficult for them to enforce consistent and complete reporting of all cases and other case-related data needed for effective surveillance.

ACTIVE CASE REPORTING involves proactive efforts by the public health authority to contact providers and laboratories to identify cases and collect other information such as demographics, location, risk factors, or other relevant information that can aid in understanding the proliferation of illness in a community. Active surveillance is more costly and labor-intensive, but can provide a more accurate count of disease cases and improved veracity of the information collected.<sup>20</sup>

Surveillance, the ongoing collection, analysis and interpretation of data on the health status of a community, forms the core of HCV monitoring. Clinical care data and other information help to complete the picture.

### INADEQUATE FOLLOW-UP LEADS TO MISSED OPPORTUNITIES

DESPITE AN ESTIMATED 30,500 CASES DETERMINED IN 2014, ONLY 2,194 ACUTE CASES OF HCV WERE DIRECTLY REPORTED TO THE CDC.

47% (Only 1,030 of those cases) were specifically asked about injection drug use. Of those asked, 68% (702 people) reported injecting drugs within 2 weeks to 6 months of illness onset.

53% (1,164 people) had no responses reported on risk behaviors or exposures.

If the risk profile for these individuals is the same and if all reported HCV cases had been asked about injection drug use, then **792** more people could have been identified who are in need of referral to substance abuse services.

More comprehensive reporting to the CDC of acute HCV infections could identify more opportunities for infection prevention and patient intervention.

Source: CDC Surveillance of Viral Hepatitis (2014), HCV Surveillance, Figure 4.6a.

#### NATIONAL HCV SURVEILLANCE

Every state defines a list of diseases that they mandate by law to be reported by health care providers, including physicians' offices and laboratories, to a designated entity for compilation by the state's public health authority when a case is confirmed. These lists tend to primarily consist of infectious diseases that are easily spread from person-to-person, and that are known to be susceptible to causing outbreaks. The federal government also maintains a list of 61 nationally notifiable diseases, which includes HCV.<sup>22</sup> States are not required to report cases of disease to the federal government, but the CDC-the federal agency tasked with maintaining such health data—urges states and other US jurisdictions to report annual cases of these diseases.<sup>23</sup> The federal government does not have the authority under the Constitution to compel states to share this case information. The CDC and the Council of State and Territorial

Epidemiologists (CSTE), however, work together to develop a consensus on agreed upon case definitions, and recognize their mutual interest that state data be shared with the federal government. Despite this understanding, the consistency and comprehensiveness of state data varies based on a state's capacity to compile this information. While the federal government cannot force states to provide case data, it can condition the receipt of certain federal funding to the reporting of state statistics on those diseases. This strategy, however, is not currently being employed in the context of infectious disease reporting to the CDC. In 2014, 40 states reported to the CDC new acute cases of HCV (passive case reporting) in their jurisdictions.<sup>24</sup> Many states do not report because they do not have staff capacity or resources to investigate the high volume of potential cases they receive.

In 2012, the CDC funded seven jurisdictions—Florida, Massachusetts, New York, Michigan, San Francisco, Philadelphia, and Washington (state)- to conduct enhanced, or active, Hepatitis B and C surveillance for a 4-year period.<sup>25</sup> In these jurisdictions, laboratories were mandated to report positive Hepatitis B and C cases to state or local health departments. The health departments then confirmed the cases and ensured that the reported cases were new infections.<sup>26</sup> From these seven sites, the CDC was able to start to piece together an understanding of the disease burden of HCV in this country. In 2017, the CDC expanded this enhanced surveillance program to fund fourteen states-Florida, Georgia, Indiana, Kentucky, Louisiana, Massachusetts, New Jersey, North Carolina, Ohio, Oklahoma, Tennessee, Utah, Washington, and West Virginia. This supplemental data collection, however, is not without its flaws. Each jurisdiction varies in the extent of investigation it undertakes, with some not even providing basic demographic information such as race/ethnicity or age.27 Thus, even in these jurisdictions, there are missed opportunities to gain a complete picture of ongoing epidemiological trends.

### ALTERNATIVE DATA SOURCES

Even though the majority of states report cases of HCV to the CDC, the passive data reported often lacks much of the specificity and completeness needed for it to be an effective tool in monitoring the ongoing impact of the disease on the population. To try to fill in these gaps, the CDC uses other sources of data:

In 2003, the CDC revised the standard information collected on birth certificates to include an HCV infection that was treated during pregnancy or still present at the time of the birth.<sup>28</sup> **Birth certificate reports** are analyzed that count the number of annual births of babies born to HCV infected women. Basic demographic data, such as race and geographic location, can be gained from this source to identify possible prevalence trends.

The National Health and Nutrition Examination Survey (NHANES), is

an annual survey conducted on a representative sample of 5,000 Americans

JURISDICTIONS

WERE FUNDED BY
THE CDC TO PROVIDE
ACTIVE
SURVEILLANCE DATA.

2014

**35** 

**STATES** 

PROVIDED ONLY PASSIVE HCV DATA TO THE CDC—LIMITED TO THE TOTAL ANNUAL NUMBER OF CASES IDENTIFIED IN THE STATE.

2017

14

**STATES** 

ARE NOW FUNDED BY THE CDC TO REPORT ACTIVE SURVEILLANCE DATA

NONETHELESS, WITH THIS EXPANSION, OUR PICTURE OF THE EPIDEMIC NATIONALLY WILL STILL BE BASED ON FEWER THAN A QUARTER OF THE STATES AND TERRITORIES.

The US simply does not invest sufficient resources to adequately monitor the HCV epidemic. Expanded surveillance and monitoring could spur HCV elimination efforts and improve responses to the opioid epidemic.

from counties across the country. Participants both answer survey questions and undergo medical and laboratory testing to identify illnesses in the population. Data collected from NHANES subjects are used to determine disease prevalence and risk factors in certain US populations.<sup>29</sup>

#### Insurance claims data and laboratory data

are purchased and analyzed by the CDC to capture HCV cases in areas where it receives little to no local data. Laboratory data helps to fill in missing case reports from non-reporting states, and to capture some other metrics such as race, gender and locality. Insurance claims data provides information on how patients are paying for their healthcare (private insurance, Medicaid/Medicare), and what follow-up care they are receiving after diagnosis.

CDC uses the HCV cases identified through these various sources along with surveillance data to analyze the HCV care cascade, and to estimate new HCV diagnoses in young adults, who are a group at high risk of new infections.<sup>30</sup> While these data are a needed contribution, they are still only a fraction of the information needed to most effectively respond to HCV in the United States.

### CLINICAL CARE DATA ARE AN UNTAPPED RESOURCE

Utilization of available forms of clinical data, i.e. data collected through patient care in health care settings, represents a huge opportunity and largely untapped resource for improving the monitoring of HCV. These data are defined as "data collected during the course of ongoing patient care, and are usually obtained at the point of care, such as a medical facility, hospital, clinic or practice."31 Clinical data are comprised of six categories: electronic medical records, administrative data, patient/disease registries, insurance claims data, health surveys and clinical trials data.<sup>32</sup> Clinical data provide medically verified new cases of the disease, and actual head count numbers of incidence of the illness. Most health care providers collect a comprehensive amount of information from patients on their medical history and behavior in addition to basic demographic data. Clinical data can prove to be a treasure-trove of information on disease prevalence for health officials' use after the data have been de-identified to protect patients' identities.

As discussed, providers are required by the states to report cases of certain infectious diseases, including HCV, to state health departments. This is often done on behalf of providers by the laboratories that are conducting testing on blood and biological specimens. The information that is passed on to the states, however, often only contains basic demographic information, and none of the additional information collected by the health care provider is accessible for analysis without the undertaking of additional investigation by the health department. This type of additional investigation and analysis is typically not performed by most states due to the expense involved.

Clinical data also can provide indicators that reveal social conditions that may be affecting disease prevalence and outcomes within certain populations. For example, correlations between rates of HCV and privately insured patients from insurance claims data could elucidate the possible existence of some underlying risk factor within privately insured individuals. Data on race/ethnicity or gender can reveal disparities in incidence or health outcomes that can serve as a call for action. They also permit health departments to focus their efforts and resources on the most critical areas and populations in need of services. Given the limited resources allocated to HCV prevention and treatment, it is essential that health departments, health care insurers, and providers have tools to target resources where they are needed and measure their impact.

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# ELIMINATING HCV WOULD IMPROVE LIVES AND SAVE MONEY



LIVER CANCER RATES WOULD PLUMMET. HCV WAS RESPONSIBLE FOR HALF OF THE NEARLY 23,000 LIVER CANCER DEATHS IN 2012<sup>1</sup>



ALMOST \$300 MILLION A YEAR IN HEALTH CARE COSTS COULD BE SAVED BY AVOIDING THE LIVER TRANSPLANT SURGERIES CAUSED BY HCV.<sup>2,3</sup>



PREVENTION, TREATMENT, AND AWARENESS EFFORTS
WILL SAVE THOUSANDS OF PEOPLE FROM GETTING
INFECTED EVERY YEAR.4

#### Source:

- 1. Centers of Disease Control and Prevention CDC fact sheet—*Viral Hepatitis and Liver Cancer*, accessed March 18, 2017, https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/viral-hep-liver-cancer.pdf
- 2. Health Resources and Services Administration, *HRSA Scientific Registry of Transplant Recipients*, accessed March 10, 2017, https://srtr.transplant.hrsa.gov/annual\_reports/2012/pdf/03\_liver\_13.pdf. The report states that in 2012 (latest data), 1,402 liver transplants were caused by HCV infections.
- 3. Razavi, H., ElKhoury, A. C., Elbasha, E., Estes, C., Pasini, K., Poynard, T. and Kumar, R, *Chronic HCV virus (HCV) disease burden and cost in the United States.* Hepatology, 57: 2164–2170 (2013). The health care cost savings is computed by multiplying the cost of a single liver transplant by the total number of transplant done annually: \$201,110 x 1,402 = \$281.956.220 ≈ \$300 million.
- 4 U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, Surveillance of Viral Hepatitis, 2014 (HCV), accessed March 10, 2017, https://www.cdc.gov/hepatitis/statistics/2014surveillance/commentary. htm#hepatitisC. The report states that approx. 30,500 acute cases of HCV occur annually.

# MOVING TOWARD MORE TAILORED AND EFFECTIVE MONITORING OF HCV TRENDS

The Division of Viral Hepatitis (DVH) within the CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) has primary responsibility for protecting the American people from viral hepatitis. Indeed, the majority of data presented here were published by the DVH. Policy makers should strive to bolster and reinforce current DVH efforts. Maintaining the status quo, however, is inadequate to the task of eliminating HCV in the US. Even within the current fiscally limited climate, there are actions that could have an important impact on giving states, local jurisdictions, and health care providers better tools for tailoring their responses to HCV epidemics they are facing in their jurisdictions.

The overall lack of sufficient data to comprehensively monitor the epidemic in all states, and even more granularly in all counties in the US, is problematic. While researchers estimate that 3.5 million Americans currently have HCV, this number is based on an estimate ranging from 2.5 million to as many as 4.7 million Americans.<sup>33</sup> The extent of this range speaks to the high level of difficulty faced

by researchers in obtaining the necessary data to create more precise estimates. The following five actions should be priorities for improving the monitoring of HCV:

#### 1. EXPAND AND STANDARDIZE REPORTING TO THE CDC

Policy makers should set a goal of phasing up active surveillance of HCV in more states and territories, and as well as working with local jurisdictions in identified hot spots. Whereas DVH is just now expanding the 7 jurisdictions that are funded to conduct active surveillance to 14, DVH, working with congressional appropriators, should develop a fiveyear plan for building the capacity to conduct active surveillance in the great majority of US states. Importantly, this expansion should take place in tandem with other critical DVH activities. We do not recommend redirecting other DVH resources to solely focus on expanding surveillance activities. Developing a standardized reporting rubric that details the specific patient information that must

Even with a constrained federal budget, more resources are needed for HCV surveillance and monitoring—Relatively modest investments, however, can have a big impact.

be provided by clinicians and subsequently passed on to the state could strengthen the utility and comparability of data collected.

Policymakers also have need to have true incidence estimates. Learning from how HIV incidence is estimated, DVH needs new resources to strengthen screening and diagnosis, as well as new funds for modeling studies, surveys to measure prevalence, and to develop algorithms that help the CDC to estimate HCV incidence. Further, expanded monitoring of access to treatment also is needed to achieve HCV elimination.

# 2. UTILIZE ELECTRONIC MEDICAL RECORDS TO COLLECT DATA ON HCV CASES AND THE CURE CASCADE

The widespread use of electronic medical records in health care holds the potential for collecting a range of information on HCV incidence and to analyze the followup care accessed by patients following diagnosis. What is lacking is a system to centralize and analyze these data. A principle recommendation made by the National Academies of Sciences in the Phase Two Report on the nation's Hepatitis Elimination Strategy noted that better utilization of electronic medical records information could improve the consistency, quality and accuracy of case reports made by states by lessening the burden on providers and laboratories to report new cases to state health authorities that is required under the current scheme.34 The current requirement for providers and labs to file reports strains their already limited time and personnel resources, and often leads to incomplete reporting.35 This information instead could be pulled together by state epidemiologists from an integrated electronic medical records

database, which would also provide matching metrics with cases, such as race, age, gender, and progress of treatment. Some pilot initiatives have been developed by the Massachusetts Technology Collaborative that extract, compile, and analyze public health data from electronic medical records.<sup>36</sup>

# 3. FUND EPIDEMIOLOGIC RESEARCH USING CLINICAL DATA SETS

As discussed, clinical care data are a largely untapped resource that relies on data that already exist. Therefore, greater efforts are needed to fund analyses of such data. In addition to the CDC, agencies across HHS, including the Centers for Medicare and Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Institutes of Health (NIH), the Health Resources and Services Administration (HRSA), the Agency for Health Care Research and Quality (AHRQ), the Office of Minority Health (OMH), the Indian Health Service (IHS) and other agencies should be directed to fund epidemiological research on HCV. Indeed, the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) within the Office of the Assistant Secretary for Health, working with the office of the Assistant Secretary for Planning and Evaluation (ASPE) could be tasked with convening an interagency process to identify high priority research questions and coordinate research across agencies. Consideration also should be given to working with agencies outside of HHS such as the Departments of Veterans Affairs and Defense. In addition to funding analyses on the major health care programs, i.e. Medicaid and Medicare, studies should be funded in available pharmacy and other data sets that cross payers.

# 4. INTEGRATE IMPROVED MONITORING OF HCV WITH RESPONSES TO THE OPIOID EPIDEMIC

The Nation is increasingly recognizing the breadth of the public health crisis we are facing related to the opioid abuse. Indeed, drug overdose deaths have been rising dramatically. By 2009, more Americans died each year from drug overdoses than from automobile accidents.<sup>37</sup> The majority of these deaths are attributable to opioid abuse.<sup>38</sup> Encouragingly, many stakeholders are beginning to respond and the Administration has pledged new resources to respond to this crisis.

There was a recent HIV outbreak in Scott County, Indiana that generated significant national attention that was linked to injection of Oxymorphone. A community that had historically recorded about five HIV infections per year experienced 181 diagnoses in one twelve month period.<sup>39</sup> While the HIV diagnoses garnered attention, 92% of the diagnosed HIV cases were co-infected with HCV, and many more people had HCV, but not HIV.40 Moreover, CDC modeling of acute HCV cases suggests that 220 US counties are at imminent risk of HIV outbreaks. A key input to this model was rates of acute HCV infection.<sup>41</sup> Therefore, as critical as it is to build the capacity and to fund substance abuse prevention and treatment, preventing and treating HCV also must be elevated as a signature component of the national response to opioid abuse.

#### 5. ESTABLISH AND MONITOR HCV ELIMINATION PLANS ACROSS MAJOR US HEALTH SYSTEMS

Major public health successes generally do not just happen. Rather, our biggest successes often arise through concerted efforts. In the context of HIV, several states and local jurisdictions are making progress at driving down HIV diagnoses through the development and implementation of plans to end HIV. Similar strategic plans are needed to eliminate HCV in the United States. One example of this is the Cherokee HCV elimination project currently being implemented.<sup>42</sup> The tribe plans to screen 85% of Cherokee Nation health patients between the ages of 20 to 69 by the end of 2018. The Cherokee Nation screened 23,000 patients in the program's first year, and 400 new patients tested positive, and nearly 300 are either being treated or have been cured of HCV.43

The Department of Veterans Affairs recognized the high rate of HCV among veterans and is leading the way toward eliminating HCV in the Veterans Health Programs.<sup>44</sup> Other health care programs and systems should be tasked with developing their own elimination plans. This includes the Ryan White HIV/AIDS Program, given the significant overlap between the HIV and HCV epidemics.

Importantly, the various correctional systems in the US are a critical environment for preventing and treating HCV. Federal policy makers should be tasked with developing an elimination plan for the Bureau of Prisons, as well as devising strategies for inducing and supporting state and local efforts to monitor and work toward HCV elimination within each state's correctional system.

#### CONCLUSION

HCV is a serious public health threat. Recent treatment advances and increased attention on the opioid epidemic create new opportunities for progress and demand new efforts to appropriately allocate prevention and treatment resources where they are most urgently needed.

Unlike some pressing problems where the scope of need is so large it can be immobilizing, modest new investments can have a significant impact. Boosting the capacity to monitor the HCV epidemic can move the Nation toward eliminating HCV as a public health threat in the United States.

#### **ENDNOTES**

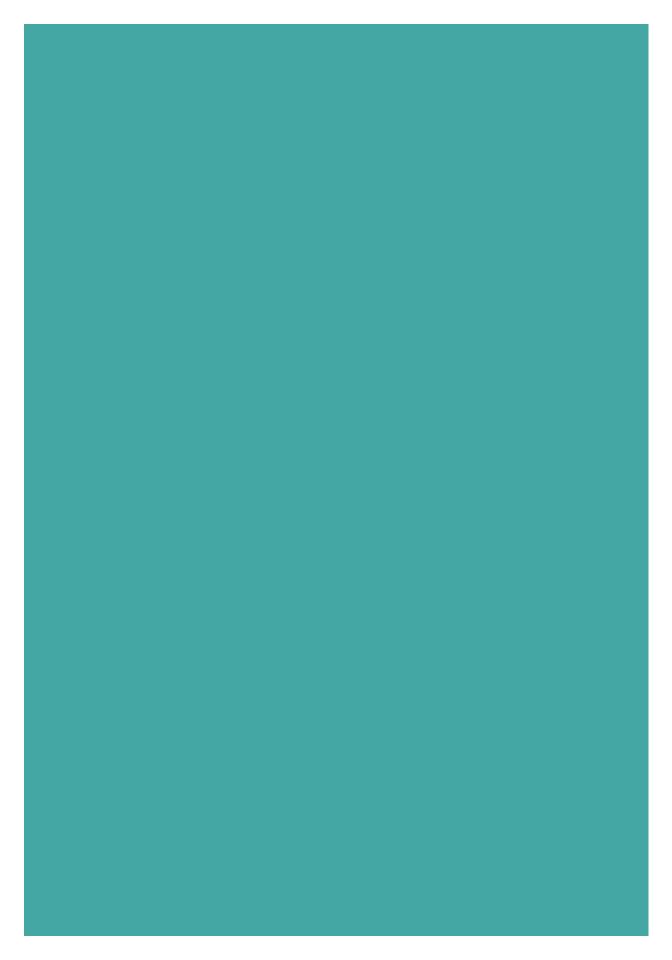
- 1 U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC), Factsheet, - What is Viral Hepatitis? - Accessed March 25, 2017, https://www.cdc.gov/hepatitis/abc/
- 2 The World Health Organization has sponsored several meetings and summits with health leaders from across the world to spur a collective effort to address global viral hepatitis elimination. A report on the first of such summits is available at this link: http://www.who.int/mediacentre/news/releases/2015/eliminate-viral-hepatitis/en/
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