

JUNE 2019

THE RYAN WHITE HIV/AIDS PROGRAM

**ELIMINATING HEPATITIS C
AMONG PEOPLE LIVING WITH HIV
IN THE UNITED STATES**

**LEVERAGING
THE RYAN WHITE
HIV/AIDS PROGRAM
TO MOVE US
FORWARD**



JUNE 2019

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This issue brief was developed independently of, but informed by an expert consultation held in Washington, DC in April 2018 of approximately 30 diverse stakeholders, including people with HIV and Hepatitis C, HIV and Hepatitis medical and non-medical providers, and federal and state policy and program staff.

The views expressed in this issue brief are those of the authors and not necessarily those of expert consultation participants or external reviewers.

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THE U.S. RESPONSE TO HIV HAS COME A LONG WAY. We have an array of effective and well-tolerated treatments. We know that “U=U” or “undetectable equals untransmittable”, meaning that when people with HIV are durably virally suppressed, they cannot transmit HIV to their sexual partners. We also know that if someone is newly diagnosed with HIV, they can expect to live an essentially normal lifespan. The demands of people and communities affected by HIV, however, were never exclusively about managing the virus. Rather, they were about building the environment where all people with HIV can live long, happy, and healthy lives. These goals require creating social environments that support people with HIV—and it means addressing co-occurring health conditions that can threaten the benefits of effectively treating HIV.

Hepatitis C virus (HCV) has a significant impact on people living with HIV (PLWH), with an estimated one in four people with HIV also having been infected with HCV at some point in their life.¹ HCV is a serious health threat that can cause liver damage, cancer, and even death if left untreated. The virus was not identified until 1989 and a test first became available in 1992.^{2,3} There currently is no vaccine for HCV, and for years the only treatment available involved a nearly year-long course of therapy that came with severe side effects and was only effective at eliminating the virus about half of the time. As a result, HCV was not included in most routine health screenings and universal precautions to prevent

CHARTING THE PATH TO HCV ELIMINATION

THE RYAN WHITE HIV/AIDS PROGRAM IS LIGHTING THE PATH TOWARD HCV ELIMINATION AMONG PEOPLE WITH HIV

The Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) that administers the Ryan White Program have taken several steps to address HCV among people with HIV. This includes creating a HRSA/Medicaid Affinity Group to address coordination across these programs, funding demonstration programs to increase cure rates, and investing in provider education.

To keep moving forward to cure more people with HIV of HCV, four priority actions are needed:

- **Comprehensive efforts to overcome financial, clinical, and other barriers to treatment**
- **Better metrics for tracking progress toward elimination**
- **Increased emphasis on re-screening key populations**
- **Strengthened planning and commitment to HCV elimination in states, communities, and clinics**



ONE IN FOUR PEOPLE WITH HIV IN THE U.S. WILL BECOME INFECTED WITH HCV OVER THEIR LIFETIME

transmission did not exist in health care settings. In the past seven years, however, curative direct-acting antivirals (DAAs) have become available for HCV treatment which are safe, well-tolerated, and are nearly 100% effective.⁴

Treating and curing HCV is critical to the health of people living with HIV for a number of reasons. Health outcomes are worse for people with HIV who have HCV. While 15-25% of people clear an HCV infection without medication, the rate of spontaneous clearing of the virus falls to 5-24% for people with HIV, making it more likely for an acute HCV infection to become persistent in PLWH.^{5,6} HIV/HCV co-infection also accelerates liver disease progression, so it is important to cure HCV to protect the liver from increased damage.⁷ The severe fibrosis caused by undiagnosed or untreated chronic HCV infection can make it difficult for a co-infected person's liver to properly process HIV antiretrovirals, leading to hepatotoxicity and increased risk of death.^{8,9,10}

Additionally, although sexual transmission of HCV is rare, people with HIV are at elevated risk for acquiring HCV by this means. While injection drug use is the greatest risk factor for HCV, sexual transmission of HCV occurs more often in gay and bisexual men living with HIV than gay and bisexual men who are HIV-negative.¹¹

The Ryan White HIV/AIDS Program has a central role to play in eliminating HCV

among people with HIV in the U.S. The Ryan White Program is a federal program that provides a comprehensive system of care for people living with HIV. For uninsured persons with HIV, it can provide a full range of outpatient services to treat HIV and co-occurring conditions. For the nearly 80% of Ryan White clients who have insurance coverage (through Medicaid, Medicare, or private insurance), the program supplements that coverage by paying cost-sharing to make coverage affordable, and helping to fill coverage gaps.¹² The program supports state and local health departments, health centers and HIV medical clinics, and community-based organizations to develop new models of care, enables health departments to monitor and improve patient outcomes, trains the medical and non-medical workforce in advances in clinical care and best practices, and ensures a nationwide system of care is available so that people with HIV can count on high quality care in all parts of the country.

Curing all people with HIV of HCV infection is an achievable goal in the U.S., but it will take determined efforts. This brief will provide an overview of the U.S. HCV epidemic, examine opportunities and barriers to elimination, and explore how the Ryan White HIV/AIDS Program can leverage its leadership role to stimulate a greater focus and faster progress toward eliminating HCV among people living with HIV in the U.S.

ESSENTIAL ROLES OF THE RYAN WHITE HIV/AIDS PROGRAM

- 1) Access to HIV Care:** The Program ensures access to lifesaving HIV care to uninsured and underinsured people living with HIV
- 2) Integrated Care:** The Program provides insurers and providers with models and evidence for how to provide integrated care, bringing together physical and mental health services that support lifelong engagement in HIV care
- 3) Monitoring HIV Outcomes:** The Program supports state and local health departments to innovate in building data and monitoring systems that enable medical and non-medical providers, health plans, health departments and others to work together to improve patient outcomes
- 4) Equipping Workforce to Stay Current:** The Program trains medical and non-medical providers to provide current HIV medical and supportive care to the diverse HIV population
- 5) Nationwide Capacity to Provide High Quality Care:** The Program ensures that capacity to deliver HIV medical care exists in all parts of the U.S.

THE HCV EPIDEMIC IN THE U.S.: KEY POPULATIONS

HCV is a contagious virus that causes inflammation in the liver and is transmitted through direct blood-to-blood contact. It can remain asymptomatic for many years. Globally, 71 million people have chronic HCV, and 399,000 die annually from HCV-related illnesses, such as cirrhosis or liver cancer.¹³ It is the most common bloodborne infection in the U.S., with approximately 2.4 million Americans living with the disease,¹⁴ leading to over 18,000 deaths in 2016.¹⁵ HCV is not distributed equally across the U.S. population. In fact, there are two distinct cohorts that comprise the majority of cases:

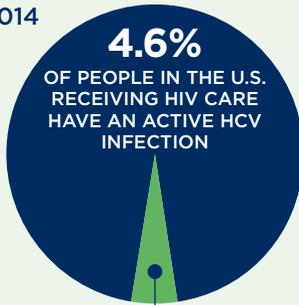
- **Baby Boomers** (Persons born from 1945-1965)—Generally, these individuals with HCV have been living with the virus for decades, yet are often unaware of it.¹⁶ They may have acquired the

infection through blood transfusions or other medical procedures before effective blood screening and universal precautions.¹⁷

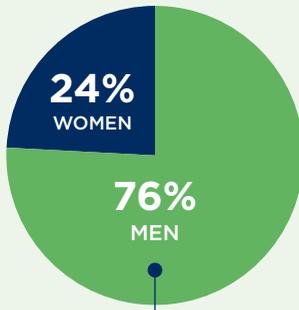
- **New Infections**—These individuals tend to be younger (aged 18-39), and a majority of cases are acquired through injection drug use.¹⁸ These new infections have increased faster in suburban and rural areas, and are on the rise across the country.¹⁹ Because more women of childbearing age are now living with HCV, the U.S. is seeing increased rates of perinatal HCV transmission.²⁰

Among people living with HIV, it can also be useful to think about two distinct groups for which strategies and interventions will require the most emphasis to achieve HCV elimination:

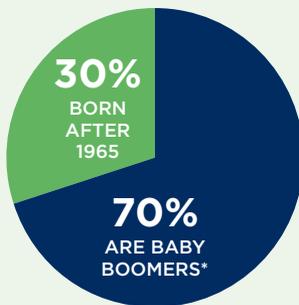
2013-2014



OF THOSE 4.6%...

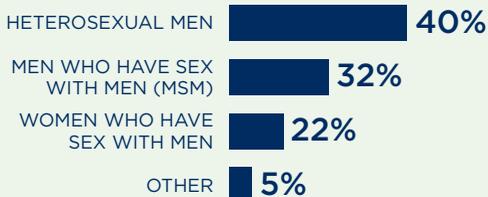


OF THE MEN...



*Born from 1945-1965

PEOPLE IN THE U.S. RECEIVING HIV CARE WHO HAVE ACTIVE HCV INFECTION



NOTES: Velozzi, et al, 2011, J Viral Hepatitis, 18(5):316-324; Weiser J. (2018, June). Disparities in Prevention and Treatment of Hepatitis B and Hepatitis C Among People Receiving HIV Care. National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention Health Equity Speaker Series Atlanta, GA.

- **Gay and Bisexual Men**—These men account for 7 in 10 new HIV diagnoses in the U.S., with 66% arising from sexual risk behavior and 3% arising among gay and bisexual men who also inject drugs.²¹ Gay and bisexual men with HIV have relatively low rates of primary incidence of HCV compared to people who inject drugs, but those who do acquire HCV are at much higher (2-10 times) risk of becoming re-infected.²²

Modeling research indicates that elimination targets could be achieved when all MSM with HIV/HCV co-infection receive HCV treatment within 1 year of diagnosis.²³

- **People who Inject Drugs (PWID)**—Historically, PWID were a larger share of the U.S. HIV epidemic, but due to the increased availability of syringe services programs (SSPs) and other harm reduction efforts, only 6% of new HIV diagnoses in the U.S. in 2017 were attributable to injection drug use.^{24, 25} As the opioid crisis unfolds and we have observed a number of HIV outbreaks tied to injection drug use, it is likely that PWID will increase as a proportion of new HIV diagnoses.

Elimination of HCV in PWID living with HIV is likely only achievable if comprehensive prevention efforts target both HIV-positive and HIV-negative PWID populations.²⁶

Rates of HCV are showing steady increases among gay and bisexual men with HIV, even when injection drug use is not a risk factor. Nonetheless, injection drug use greatly increases the risk of transmission of both viruses, and is the greatest contributor to the increase in new cases of HCV.^{27, 28, 29}

OPPORTUNITIES FOR HCV ELIMINATION

The existence of effective curative treatment has generated excitement over the potential to reduce the burden of

HCV. National and global health policy leaders have begun to chart a path toward eliminating HCV in the U.S. and around the world.^{30, 31} That path in the U.S. likely will happen by eliminating HCV systematically within specific health care settings and will be critical among specific heavily-impacted populations. The U.S. Department of Veterans Affairs (VA) health care program is an integrated health system that is making great strides toward eliminating HCV among its patient population, and is on track to eliminate HCV among its participants by this year.³² The VA serves as an instructive model for implementing an effective elimination strategy. Their approach highlights collaborative efforts throughout the VA Health System to address patients' needs.

Federal and state correctional systems are also critical target settings, with great potential to significantly reduce HCV prevalence and transmission. In the U.S., approximately 1 in 3 persons with HCV spends time in a correctional institution during a one-year period, and 90% of people in corrections return to the community at some point.³³ Prevalence of HCV is disproportionately high among incarcerated persons compared to the general population, and the fact of their confinement can simplify the delivery of care for persons who voluntarily request HCV treatment.³⁴ Nonetheless, financing and delivery of HCV treatment to these populations raises unique challenges.

While the Ryan White Program is far less centralized than the VA Health System and has less direct control over the delivery of care than correctional institutions, the program provides a similar opportunity to leverage its existing system of care and relationships with patients, providers, and the community to increase HCV screening among its clients and provide HCV treatment for those with co-infection. Most of the people served by the Ryan

White Program maintain longstanding relationships with providers funded by the program and thus remain connected to the program's system of care over a period of many years. This may provide an additional incentive for the clinics and health systems where Ryan White clients receive care and services to take a long-term view by integrating routine periodic HCV screening and providing treatment to cure HCV infection. Even though the majority of Ryan White clients have insurance coverage that should cover the cost of treatment, the program can pay for medication and treatment costs for those clients without another source of coverage or with inadequate coverage.³⁵

BARRIERS TO HCV ELIMINATION

Before people can be treated for HCV, they must be screened to determine if they have the virus. Screening of those at greatest risk of acquiring HCV must increase as the crucial first step to identify new cases, reduce further transmission, and get people treated. Once a confirmatory test is done, the U.S. HCV treatment guidelines from the American Association for the Study of Liver Disease (AASLD) call for providing treatment to all persons with a confirmed diagnosis of HCV and who do not have an end-stage life threatening illness or a contraindication for treatment.³⁶ Despite these clinical guidelines, access restrictions imposed by insurers and health care programs, the cost of the medications (which make it virtually impossible for most people to finance without external assistance), inadequate provider capacity to treat HCV and prescribe therapy, and other barriers have limited access to HCV treatment. Of the 469,550 HCV diagnoses made in 2016, only 66,033 (14%) were cured.³⁷

Many insurers have established clinical staging criteria that are in direct conflict with the aforementioned AASLD clinical

PROGRESS TOWARD ELIMINATING HCV IN THE U.S. IS CONTINGENT ON BETTER MEETING THE HEALTH CARE AND HARM REDUCTION NEEDS OF PEOPLE WHO INJECT DRUGS

practice guidelines. For example, many insurers require patients to have moderate to severe liver scarring, as defined by an F2 or higher fibrosis score, before authorizing treatment. Others require that a patient with a history of substance abuse have a documented period of sobriety prior to authorizing treatment, often for 6 months to a year. In some cases, prescriber restrictions limit which providers can write prescriptions for DAAs to only certain specialists, making it more difficult for a greater number of doctors to treat people with HCV and severely encumbering access to treatment for many in need.³⁸

Intravenous drug use is currently the leading cause of new HCV infections in the U.S.³⁹ A significant factor causing rising rates of HCV is a nationwide increase in the number of persons who inject drugs (PWID) as part of a burgeoning epidemic of opioid misuse, as well as increased injection of methamphetamine and other substances.^{40, 41, 42} In 2016, over 68% of the new cases of HCV in the U.S. reported to the Centers for Disease Control and Prevention (CDC) for which risk behavior information was available indicated past or current use of injection drugs.⁴³ Many of the same behaviors that put people at risk for contracting HCV (such as sharing needles and other injection equipment that contains blood) also increase the risk of contracting HIV, although HCV transmission is much more likely to occur from the use of non-sterile syringes or works (equipment used to prepare and inject drugs) than HIV transmission due to HCV viral load in blood being 10 times higher than the concentration of HIV in infected blood.⁴⁴

The exploding rate of opioid misuse has become a political and public health priority in the U.S. In October 2018, the President signed the SUPPORT for Patients and Communities Act, a comprehensive, bipartisan law aimed at providing states and community-based organizations the resources needed to improve prevention, treatment, and recovery initiatives.⁴⁵ The law seeks to address the many social and health challenges associated with the opioid epidemic, and authorizes programs and resources to support housing, family services, and health care. Part of this comprehensive strategy includes a \$40 million per year allocation over a 5-year period to the CDC to assist state and local governments to enhance their surveillance capacity of opioid-use related infectious diseases and increase testing and linkage to care for HIV, HCV, and other infectious diseases as part of substance use treatment.⁴⁶ Of the 42 states that reported new cases of acute HCV to the CDC in 2016, 22 saw an increase in cases from the previous year.⁴⁷ Current funding levels only provide for 14 states to conduct enhanced surveillance for HCV,⁴⁸ which does not allow for an accurate and comprehensive understanding of the scope of the nation's HCV epidemic and the proliferation of the illness in particular communities.

Even as policy makers recognize the need to respond to the health care crises that stem from injection drug use, stigma and discrimination experienced by PWID continue to impede effective policy responses. Many in the general public malign people with HCV because they associate the disease with unfavorable behaviors and think of it as a disease solely

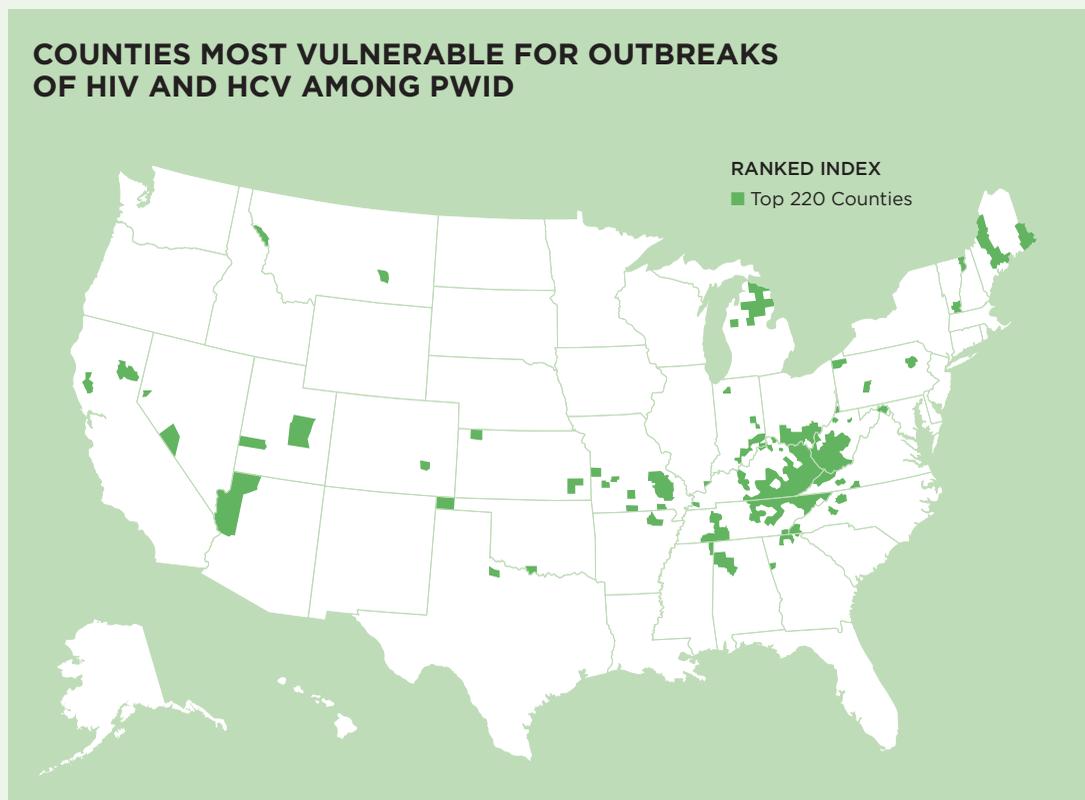
SCOTT COUNTY, INDIANA: A FLASHING RED LIGHT THAT HIV AND HCV OUTBREAKS ARE HAPPENING AND MORE MUST BE DONE TO PREVENT THEM

Starting in late 2014, Scott County, a rural county in southern Indiana, experienced an HIV outbreak tied to injection of the opioid oxymorphone. Whereas the county had experienced about 5 HIV diagnoses per year prior to this outbreak, 181 cases were diagnosed from November 2014 through November 2015. Of 159 cases on which phylogenetic testing was performed, all but two were linked to one person with HIV who was introduced into a network of people who inject drugs (PWID).¹

A startling facet of this outbreak that received very little public attention is that more than 92% of those with HIV had a HCV co-infection, indicating that this might be a larger public health problem than previously thought.

Other states such as Massachusetts and West Virginia also have seen increases in HCV rates.² These states are ranked 1 and 2 respectively for highest rate of new cases of HCV in 2016. Massachusetts' HCV incidence rate is 6 times the national average.²

This map shows counties potentially vulnerable for outbreaks of HIV and HCV among PWID.³



1. Peters et. al.(2016), HIV Infection Linked to Injection Drug Use of Oxymorphone in Indiana, 2014-2015, *New England Journal of Medicine*, 375(3), 229-239.
2. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Surveillance for Viral Hepatitis*, United States, 2016.. <https://www.cdc.gov/hepatitis/statistics/2016surveillance/index.htm>
3. Van Handel, M. M., Rose, C. E., Hallisey, E. J., Kolling, J. L., Zibbell, J. E., Lewis, B., Bohm, M. K., Jones, C. M., Flanagan, B. E., Siddiqi, A. E., Iqbal, K., Dent, A. L., Mermin, J. H., McCray, E., Ward, J. W., ... Brooks, J. T. (2016). County-Level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections Among Persons Who Inject Drugs, United States. *Journal of acquired immune deficiency syndromes* (1999), 73(3), 323-331.

caused by moral failings.^{49, 50} This thinking also has had an impact on resource allocation decisions, with federal funding for preventing and treating HCV well below any objective assessment of need and well below comparable investments in preventing and treating HIV, other sexually transmitted infections (STIs), and other infectious diseases. Without adequate funding, it is impossible for the nation's health authorities to accurately collect data on new cases of the disease, monitor trends in screening, prevalence, and treatment within sub-populations, and develop a reliable understanding of the impact the illness has on the public health.

While policy makers have responded to the opioid crisis, addressing the impact of infectious disease has received little attention and funding relative to other priorities, such as overdose prevention. For example, the total federal investment in the CDC's Division of Viral Hepatitis is only \$39 million dollars per year,⁵¹ which includes all funds provided to state and local health departments to fund surveillance of all types of hepatitis, educate health care providers and the public, and promote and implement screening programs.

The increase in public interest and recognition of PWID as people dealing with the serious chronic health condition of addiction is an opportunity to include controlling infectious disease among PWID as an integral part of a comprehensive strategy to address the opioid crisis. We can begin to demand elected officials and the health care industry significantly increase resources and prioritize efforts for timely HCV treatment and other serious conditions associated with injection drug use.

POLICY RECOMMENDATIONS FOR THE RYAN WHITE PROGRAM TO ELIMINATE HCV AMONG PEOPLE WITH HIV

The Ryan White HIV/AIDS Program is the anchor of the HIV response in the U.S.. It is not only a major payer for health care services for people living with HIV, it is also the leader of efforts to innovate and continuously respond to new information, new trends, and new issues. As such, it is only natural that we turn to the program to lead the way toward eliminating HCV. The leadership of HRSA's HIV/AIDS Bureau is actively working with its grantees to sharpen their focus on treating HCV among people with HIV. This does not mean that they alone are responsible for HCV elimination among people living with HIV, but their leadership is necessary to guide the health system's response. With all stakeholders working together, the following four steps would move us closer toward elimination of HCV among people living with HIV:

Comprehensive efforts to overcome financial, clinical, and other barriers to treatment

Some obstacles to eliminating HCV among people living with HIV defy simple solutions. In the case of people living with HIV receiving services through the Ryan White HIV/AIDS Program, financing the medication costs, which is often the biggest barrier to HCV treatment, may be less of a barrier in this program. Nonetheless, any barrier, large or small, can impede our ability to achieve elimination. A strength of the Ryan White Program is its flexibility and adaptability that enable it to respond to multi-faceted problems that may express themselves in different ways in different clinics or parts of the country. Some providers report that their experience with insurance approvals for HCV treatment, for example, leads them to believe that only one course of treatment

HHS AND HRSA ARE RESPONDING TO HCV AMONG PEOPLE WITH HIV

National Viral Hepatitis Action Plan¹: The HHS Office of Infectious Disease Policy (OIDP) publishes and is responsible for implementing the National Viral Hepatitis Action Plan. The current iteration of the plan establishes national priority strategies for the 2017-2020 period. People living with HIV, men who have sex with men (MSM) (who account for 70% of new HIV infections), and people who inject drugs are all priority populations for the plan.

Hepatitis C Medicaid Affinity Group²: OIDP, in collaboration with the Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), and the Substance Abuse and Mental Health Services Administration (SAMHSA), established a quality improvement state-based learning project, with a goal of improving HCV outcomes among Medicaid enrollees with hepatitis C. The Affinity Group has provided technical assistance to more than nine states on improving HCV testing and treatment, including data sharing and analyses, provider capacity building, and expanding treatment for people who inject drugs.

Additionally, OIDP administers the Secretary's Minority AIDS Initiative Fund (SMAIF). SMAIF is currently supporting two HCV demonstration project initiatives that are being led by the HRSA HIV/AIDS Bureau to administer with Ryan White Program recipients:

• **Jurisdictional Approach to Curing Hepatitis C among People of Color Living with HIV:** Starting in 2016, SMAIF funded 5 jurisdictions (Part A jurisdictions are New York City, Philadelphia, PA, and Hartford, CT and Part B jurisdictions are Louisiana and North Carolina) to increase their capacity to provide screening, care, and treatment for HIV/HCV co-infected persons.

• **Curing Hepatitis C among People of Color Living with HIV:** Starting in 2017, SMAIF funding is supporting two research institutions (University of Texas at San Antonio and Yale University) to increase the capacity of Ryan White Program clinics to prevent, provide care, and treat HCV. The initiative is also coordinating with SAMHSA substance use disorder (SUD) treatment providers to deliver behavioral health and SUD treatment support.

The HRSA HIV/AIDS Bureau is committed to curing all Ryan White clients with HIV/HCV co-infection of HCV³ and also is engaged in the following activities to enhance expanding provider capacity to HCV cure HCV among people with HIV:

• **HRSA/Medicaid Affinity Group:** HRSA and the Centers for Medicare and Medicaid Services (CMS) established an affinity group to collaborate on issues of common interest, with improving HCV outcomes being one priority topic. The Affinity Group has provided technical assistance to more than nine states on improving HCV testing and treatment.

• **AETC:** The Ryan White Program's AIDS Education and Training Center (AETC) National Coordinating Resources Center developed a free online training curriculum on HIV/HCV co-infection for health care providers.

1. <https://www.hhs.gov/hepatitis/action-plan/national-viral-hepatitis-action-plan-overview/index.html>
2. <https://www.hhs.gov/hepatitis/action-plan/federal-response/hepatitis-c-medicare-affinity-group/index.html>
3. <https://www.hhs.gov/hepatitis/blog/2017/12/01/progress-curing-hcv-among-people-living-with-hiv-in-the-us.html>

will be approved. Thus, notwithstanding clinical guidelines about what is most effective for individual patients, they will delay recommending treatment until they believe the person is maintaining their recovery from substance use. This may call for greater educational efforts about current treatment guidelines. Other obstacles (such as low prioritization of HCV screening or treatment, limited client awareness of the importance of treating HCV, concern over side-effects, etc.) likely can be overcome through standardized practice guidelines promulgated by HRSA that address both clinical recommendations and allowable expenses and other issues that come up within the Ryan White Program. The Ryan White Program, through both focused efforts by HRSA and its health department recipients, can not only improve HCV outcomes within its program, but it also can educate and influence insurers and providers on the current standard of care and approaches to working collaboratively to move toward elimination.

Better metrics for tracking progress toward elimination

It is recognized that underinvestment in HCV prevention at the CDC is problematic and has consequences, among which include a limited capacity to conduct surveillance of the disease and estimate incidence and prevalence necessary for a strong public health response that is able to direct resources to the communities with the greatest needs.⁵² A related challenge in the context of clinical care is whether there are adequate metrics being used to identify success or failure in screening and treating HCV. This challenge applies to health systems in general, but also applies to the Ryan White Program.

The metrics currently in use within the Ryan White Program are inadequate and do not support HCV elimination. There are several metrics that HRSA monitors

regarding screening, and the Ryan White Program does a reasonably good job of screening the majority of its clients for HCV infection at least one time when they initially enroll. New metrics, however, are needed. It is important to acknowledge that providers already are overwhelmed with the number of metrics on which they are being required to report. While incredibly difficult to let go of any reporting requirements, HRSA should consider some options for reducing recipient reporting burden. These options could include, as one component, the elimination of a certain percentage of clinical indicators (for example, CD4 monitoring that may be less relevant than in the past) in order to facilitate the addition of a small number of tailored new metrics related to HCV re-screening and treatment.

For a successful elimination plan, the priority must be to collect the key metrics needed to monitor progress toward elimination, such as risk behaviors for HCV infection, rates of HCV screenings, the regularity of these screenings (especially among those at greatest risk of infection), screening results (both negative and RNA confirmatory positive results), treatment starts, clinical staging at treatment start, and treatment success rates (referral to care, treatment initiation, treatment completion, 12-week sustained virological response). A helpful rubric would be to align these screening metrics with the AASLD screening recommendations to promote compliance with the guidelines, which call for all persons to receive a one-time screening for HCV, and annual screening for PWID and for men living with HIV who have condomless sex with men.⁵³ HRSA may consider holding consultations with health department recipients and clinical providers and consumers both to solicit feedback on existing indicators that have become less clinically relevant and prioritize new indicators, specifically with the charge to stakeholders being to be parsimonious and the net result is better HCV monitoring with less overall provider burden.

Increased emphasis on re-screening key populations

The existing Ryan White Program metrics for HCV screening demonstrate that the program and its grantees use the screening indicators to ensure relatively high one-time screening for HCV among people with HIV. A weakness comes in with respect to re-screening. The AASLD recommends at least annual HCV testing for persons with ongoing risk factors, such as injection drug use or for people with HIV who engage in condomless sex with men. Periodic testing is recommended for those with other ongoing risk factors for HCV exposure.⁵⁴ At present, Ryan White grantees do not report on re-screening rates, and it is uncertain that, notwithstanding the AASLD guidelines, Ryan White Program clients are being re-screened as indicated. The Ryan White Program is well positioned to routinely screen clients at high risk for HCV infection and reinfection. Modeling analysis predicts that early diagnosis and retreatment of infections in combination with harm reduction can reduce HCV incidence by 90%.⁵⁵

Strengthened planning and commitment to HCV elimination in states, communities, and clinics

Notably, HRSA leadership and others have stated that paying the medication cost is not the primary barrier to higher cure rates. Some Ryan White recipients (i.e. grantees) face other limitations that may impede their HCV elimination efforts, including resource and staffing shortages due to an overwhelming need to address not only HIV infection, but also co-occurring substance use disorders, mental health challenges, inadequate infrastructure to deliver timely high quality care, and other problems. Other programs and clinics, however, have implemented highly effective programmatic strategies to reduce HCV prevalence in their communities that are both sustainable and well-integrated into their practice model.

As with many aspects of HIV care, great things are happening in specific clinics and communities to cure more people with HIV of HCV. One of the biggest challenges is to consistently elevate such success in states and local communities, at planning councils, and among advocates for people with HIV. Information on best practices should be compiled and disseminated throughout the Ryan White Program to assist those entities struggling with barriers such as low rates of HCV screening or patient engagement to learn from the success of others. This would set the course for the development of a consistent standard of practice for HCV elimination throughout the Ryan White network. To achieve this requires doing several things, including requiring states and local jurisdictions to develop HCV elimination plans. It also means having planning councils and other community stakeholders advocate for funding for targeted efforts to expand HCV treatment access.

As discussed in the text box on page 9, HRSA HAB has focused on developing jurisdictional models of care so that when states and local communities decide to take deliberate steps to cure more people with HIV of HCV, there are models to do so.

CONCLUSION

The Ryan White HIV/AIDS Program has given truth to the phrase, living with HIV. It embodies how the U.S. has collectively come together to create a nationwide response to HIV, and as treatment discoveries and new and better models of care have given people with HIV more tools and more pathways to lead long and healthy lives, it remains the system of care that enables our mix of public and private insurance programs to effectively meet the needs of people with HIV.

Undiagnosed and untreated HCV infection can have a devastating effect on the health and quality of life of people living with HIV, and could undermine the benefits of achieving and maintaining HIV viral suppression. As we continue to look to the Ryan White HIV/AIDS Program to provide leadership in focusing efforts and responding to critical clinical and access to care challenges, we are also counting on its leadership to move us closer to eliminating HCV among all people living with HIV in the United States.

ENDNOTES

- 1 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Coinfection with HIV and Viral Hepatitis*, Retrieved from <https://www.cdc.gov/hepatitis/hiv-hepatitis-coinfection.htm>
- 2 *Id.*
- 3 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. (2013). *Hepatitis C: Information on Testing & Diagnosis* [Fact sheet]. Retrieved from <https://www.cdc.gov/hepatitis/hcv/pdfs/hepctestng-diagnosis.pdf>
- 4 Fung, J (2015). Era of direct-acting antivirals in chronic hepatitis C: Who will benefit? *World Journal of Hepatology*, 7(24), 2543-2550.
- 5 van de Laar, T.J.W., Matthews, G.G., Prins, M., & Danta, M (2010). Acute hepatitis C in HIV-infected men who have sex with men: an emerging sexually transmitted infection. *AIDS*, 24, 1799-1812. doi: 10.1097/QAD.0b013e32833c11a5
- 6 Hagan, H., Jordan, A.A., Neurer, J., & Cleland, C.M., (2015), Incidence of sexually transmitted hepatitis C virus infection in HIV-positive men who have sex with men. *AIDS*, 25, 2335-2345.
- 7 HepMag, (n.d.). *How Does HIV Affect Hepatitis C?*, Retrieved from <https://www.hepmag.com/basics/hepatitis-c-basics/hiv-affect-hcv>
- 8 Chen, T., Ding, E.L., Seage, G.R., & Kim, A.Y., (2009). Meta-Analysis: Increased Mortality Associated with Hepatitis C in HIV-Infected Persons Is Unrelated to HIV Disease Progression, *Clinical Infectious Diseases*, 49(10), 1605-1615, <https://doi.org/10.1086/644771>
- 9 van de Laar, et. al., *supra*, at note 5.
- 10 Sulkowski M.S., Thomas D.L., Chaisson R.E., & Moore RD. (2000). Hepatotoxicity Associated With Antiretroviral Therapy in Adults Infected With Human Immunodeficiency Virus and the Role of Hepatitis C or B Virus Infection. *JAMA*, 283(1), 74-80. doi:10.1001/jama.283.1.74
- 11 Hagan et. al, *supra* at note 6.
- 12 U.S. Department of Health and Human Services, Health Resources and Services Administration. (2018). *Ryan White HIV/AIDS Program Annual Client-Level Data Report 2017*. Retrieved from <https://hab.hrsa.gov/sites/default/files/hab/data/datareports/RWHAP-annual-client-level-data-report-2017.pdf>
- 13 World Health Organization (WHO). (18 July 2018). *Hepatitis C*. Retrieved from <http://www.who.int/en/news-room/fact-sheets/detail/hepatitis-c>
- 14 Hoffmeister, M.G., Rosenthal, E.M., Barker, L.K., Rosenberg, E.S., Barranco, M.A., Hall, E.W., Edlin, B.R., Mermin, J., Ward, J.W., & Ryerson, A.B. (2019), Estimating Prevalence of Hepatitis C in the United States, *Hepatology*, 69(3), 1020-1031
- 15 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), *Surveillance of Viral Hepatitis—United States, 2016, Table 4.5—Number and rate of hepatitis C—related deaths, by demographic characteristic and year—United States, 2012-2016*, [Table]. Retrieved from <https://www.cdc.gov/hepatitis/statistics/2016surveillance/index.htm#tabs-3-5>
- 16 US Department of Health and Human Services - Centers for Disease Control and Prevention. (2016). *HCV: Why People Born from 1945-1965 Should Get Tested* [Factsheet]. Retrieved from <https://www.cdc.gov/know-morehepatitis/media/pdfs/factsheet-boomers.pdf>
- 17 *Id.*
- 18 Suryaprasad, A et., al., Emerging Epidemic of HCV Virus Among Nonurban Persons Who Inject Drugs in the United States, 2006-2012. (2014). *Clinical Infectious Disease*, 59(10), 1411-1419.
- 19 *Id.*
- 20 U.S. Department of Health and Human Services - Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR). (2016). *Increased Hepatitis C Virus (HCV) Detection in Women of Child-bearing Age and Potential Risk for Vertical Transmission—United States and Kentucky, 2011-2014*. Retrieved from <https://www.cdc.gov/mmwr/volumes/65/wr/mm6528a2.htm>
- 21 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. (November 2018). *HIV Surveillance Report, Volume 29: Diagnoses of HIV Infection in the United States and Dependent Areas, 2017*, Retrieved from <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf>

- 22 Martin, N.K., Boerekamps, A., Hill, A.M., & Rijnders, B.J.A. (2018) Is hepatitis C virus elimination possible among people living with HIV and what will it take to achieve it?, *Journal of the International AIDS Society*, 21(2), 51-59.
- 23 *Id.*
- 24 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. (November 2018). *HIV Surveillance Report, Volume 29: Diagnoses of HIV Infection in the United States and Dependent Areas, 2017*, Retrieved from <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf>. In 2017, gay and bisexual men who also inject drugs accounted for 3% of all HIV diagnoses, bringing the total percentage of HIV cases in 2017 where injection drug use was a risk behavior to 9%. See U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *HIV in the United States and Dependent Areas*, <https://www.cdc.gov/hiv/statistics/overview/atagance.html>
- 25 Des Jarlais, D.C., Kerr, T., Carrieri, P., Feelemyer, J., & Arasteh, K. (2016). HIV infection among persons who inject drugs: ending old epidemics and addressing new outbreaks. *AIDS*, 30(6), 815-825.
- 26 Martin, *supra*, at note 22
- 27 van de Laar, *supra*, at note 5.
- 28 Samandari, T., Tedaldi, E., Armon, C., Hart, R., Chmiel, J.S., Brooks, J.T., Buchacz, K., & The HIV Outpatient Study Investigators (2017). Incidence of Hepatitis C Virus Infection in the Human Immunodeficiency Virus Outpatient Study Cohort, 2000-2013, *Open Forum Infectious Diseases*, 4(2), <https://doi.org/10.1093/ofid/ofx076>
- 29 Myers, T., Allman, D., Xu, K., Remis, R.S., Aguinaldo, J., Burchell, A., Calzavara, L., & Swantee, C., (2009). The prevalence and correlates of hepatitis C virus (HCV) infection and HCV-HIV co-infection in a community sample of gay and bisexual men. *International Journal of Infectious Diseases*, 13(6), 730-739. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/19186090>
- 30 National Academies of Sciences, Engineering, and Medicine. (April 11, 2016). *Eliminating the public health problem of hepatitis B and C in the United States: Phase one report*. Washington, DC: The National Academies Press. Retrieved from <http://nationalacademies.org/hmd/Reports/2016/Eliminating-the-Public-Health-Problem-of-Hepatitis-B-and-C-in-the-US.aspx>
- 31 National Academies of Science, Engineering, and Medicine. (March 28, 2017). *A national strategy for the elimination of hepatitis B and C: Phase two report*. Washington, DC: The National Academies Press, Retrieved from <http://nationalacademies.org/hmd/reports/2017/national-strategy-for-the-elimination-of-hepatitis-b-and-c.aspx>
- 32 United States Department of Veterans Affairs, Office of Public and Intergovernmental Affairs, *VA on path to cure 100,000 Veterans of hepatitis C*. (March 18, 2019). [News release]. Retrieved from <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5219>
- 33 HepCorrections (2019). Introduction. Citing to Varan et. al: Hepatitis C seroprevalence among prison inmates since 2001: still high but declining. (2014). *Public Health Reports*, 129, 187-195. Retrieved from <http://www.hepcorrections.org/intro>
- 34 Spaulding, A.C., Kim, A.Y., Harzke, A.J., Sullivan, J.C., Linas, B.P., Brewer, A., Dickert, J., McGovern, B.H., Strick, L.B., Trestman, R., & Ferguson, W.J. (2013). Impact of New Therapeutics for Hepatitis C Virus Infection in Incarcerated Populations. (2013). *Topics in Antiviral Medicine*, 21(1), 27-35. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3875217/pdf/tam-21-27.pdf>
- 35 U.S. Department of Health and Human Services, Health Resources & Services Administration.(n.d.). *HRSA Ryan White Global HIV/AIDS Programs, Part B: Grants to States and Territories*. Retrieved from <https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/part-b-grants-states-territories>
- 36 American Association for the Study of Liver Disease (AASLD) - Infectious Diseases Society of America (IDSA). (May 24, 2018). *HCV Guidance: Recommendations for testing, managing, and treating hepatitis C*. Retrieved from <http://www.hcvguidelines.org/full-report/hcv-testing-and-linkage-care>

- 37 Chirikov, V.V., Marx, S.E., Manthena, S.R., Strezewski, J.P., Saab, S. (2018). Development of a Comprehensive Dataset of Hepatitis C Patients and Examination of Disease Epidemiology in the United States, 2013-2016. *Advances in Therapy*, 35(7), 1087-1102. <https://doi.org/10.1007/s12325-018-0721-1>
- 38 National Viral Hepatitis Roundtable & Harvard Law School - Center for Health Law and Policy Innovation. (2017). *Hepatitis C: State of Medicaid Access*. Retrieved from <https://stateofhepc.org/>
- 39 Zibbell, J.E., Asher, A.K., Patel, R.C., Kupronis, B., Iqbal, K., Ward, J.W., & Holtzman, D. (2018). Increases in Acute Hepatitis C Virus Infection to a Growing Opioid Epidemic and Associated Injection Drug Use, United States, 2004 to 2014. *American Journal of Public Health*, 108, 175-181. <https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2017.304132>
- 40 Al-Tayyib, A., Koester, S., Langegger, S., & Raville, L. (2017). Heroin and Methamphetamine Injection: An Emerging Drug Use Pattern. *Substance use & misuse*, 52(8), 1051-1058.
- 41 Glick, S.N., Burt, R., Kummer, K., Tinsley, J., Banta-Green, C., Golden, M.R. (2018). Increasing methamphetamine injection among non-MSM who inject drugs in King County, Washington. *Drug and Alcohol Dependence*, 182, 86-92. <https://doi.org/10.1016/j.drugalcdep.2017.10.011>
- 42 US Department of Justice, Drug Enforcement Agency. (October 2018). *2018 National Drug Threat Assessment*. Retrieved from <https://www.dea.gov/sites/default/files/2018-11/DIR-032-18%202018%20NDTA%20%5Bfinal%5D%20low%20resolution11-20.pdf>
- 43 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), *Surveillance of Viral Hepatitis—United States, 2016*. [Commentary]. Retrieved from <https://www.cdc.gov/hepatitis/statistics/2016surveillance/commentary.htm>
- 44 Thomas, D.L., Leoutsakas, D., Zabransky, T., & Kumar, M.S. (2011). Hepatitis C in HIV-infected individuals: cure and control, right now. *Journal of the International AIDS Society*, 14, 22. <https://doi.org/10.1186/1758-2652-14-22>
- 45 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act), Pub. L. No. 115-271 (2018). Retrieved from <https://www.congress.gov/bill/115th-congress/house-bill/6>
- 46 *Id.* at §7141.
- 47 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC). *Surveillance of Viral Hepatitis—United States, 2016, Table 4.1—Reported cases of acute hepatitis C, nationally and by state and jurisdiction—United States, 2012-2016*. [Table]. Retrieved from <https://www.cdc.gov/hepatitis/statistics/2016surveillance/index.htm#tabs-3-1>
- 48 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Informational Brief on CDC Hepatitis Funded Program: Strengthening Surveillance*. Retrieved from <https://www.cdc.gov/hepatitis/policy/InfoBrief-StrengtheningSurveillance.htm>
- 49 Northup, J.M. (2017). A dirty little secret: stigma, shame and hepatitis C in the health setting. *Medical Humanities*, 43, 218-224. <http://dx.doi.org/10.1136/medhum-2016-011099>
- 50 Hepmag. (n.d.). *Stigma and Hepatitis C*. Retrieved from <https://www.hepmag.com/basics/hepatitis-c-basics/stigma>
- 51 U.S. Department of Health and Human Services, *Centers for Disease Control and Prevention, Centers for Disease Control and Prevention FY 2019 Operating Plan*, [PDF file]. Retrieved from <https://www.cdc.gov/budget/documents/fy2019/fy-2019-cdc-operating-plan.pdf>
- 52 O’Neill Institute for National and Global Health Law – Hepatitis Policy Project. (2017). *Monitoring The Hepatitis C Epidemic in the United States: What Tools are Needed to Achieve Elimination?* Washington, DC: Canzater, S., & Crowley, J.S. Available online at http://oneill.law.georgetown.edu/media/HEPC_Brief_1_PF.pdf
- 53 American Association for the Study of Liver Disease (AASLD) - Infectious Diseases Society of America (IDSA). *HCV Guidance: Recommendations for testing, managing, and treating hepatitis C: HCV Testing and Linkage to Care*. Retrieved from <https://www.hcvguidelines.org/evaluate/testing-and-linkage>
- 54 *Id.*
- 55 Martin, *supra*, at note 22.

THE RYAN WHITE POLICY PROJECT

SEEKS TO GENERATE AND EVALUATE IDEAS for adapting the Ryan White HIV/AIDS Program to be maximally effective in a changing health system.

OTHER RESOURCES FROM THE RYAN WHITE POLICY PROJECT

In 2015, the Ryan White Policy Project released three policy briefs related to policy questions tied to strengthening the Program as the health system changes. These can be found at bit.ly/HIVpolicyproject.



2019

QUICK TAKE: THE RYAN WHITE HIV/AIDS PROGRAM

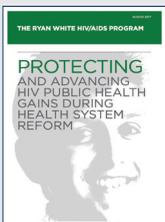
This Quick Take document discusses how the Ryan White HIV/AIDS Program is leading the way in getting people with HIV virally suppressed by ensuring stable access to HIV primary care and medication along with critical support services. The documents describes the parts of the Ryan White Program and the importance of the program for meeting the health care needs of people with HIV and addressing new challenges.



2018

BIG IDEAS: LEVERAGING THE RYAN WHITE PROGRAM TO MAKE RAPID START OF HIV THERAPY STANDARD PRACTICE

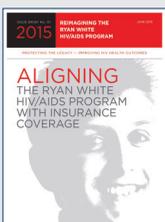
This report examines the role of the Ryan White Program in making rapid start of ART a reality. Starting people with HIV on antiretroviral therapy (ART) on the same day that they are diagnosed has been shown to decrease the time to viral suppression and may also improve retention in care, yet there are numerous financial and other barriers to adoption of rapid start across the health system.



2017

THE RYAN WHITE HIV/AIDS PROGRAM: PROTECTING AND ADVANCING HIV PUBLIC HEALTH GAINS DURING HEALTH SYSTEM REFORM

This issue brief examines the changing role of the Ryan White program and how it supports Medicaid, Medicare, and private insurance to prevent HIV transmission and reduce health care spending.



EARLIER YEARS

ALIGNING THE RYAN WHITE HIV/AIDS PROGRAM WITH INSURANCE COVERAGE

REFINING RYAN WHITE HIV/AIDS PROGRAM ADMINISTRATIVE ACTIVITIES TO INCREASE POPULATION-LEVEL IMPACT

BOLSTERING THE HIV CLINICAL AND NON-CLINICAL WORKFORCE

the 1990s, the number of people in the UK who are employed in the public sector has increased from 10.5 million to 13.5 million. The public sector has become a major employer in the UK, and this has implications for the way in which the public sector is managed and the way in which it is funded.

The public sector is a complex and diverse organisation, and it is difficult to define it precisely. However, it is generally understood to include the following:

- The central government, including the Treasury and the Home Office.
- The local authorities, including the police and the fire service.
- The health service, including the National Health Service (NHS).
- The education system, including the schools and the universities.
- The social services, including the housing and the social care.

The public sector is a major employer in the UK, and it has a significant impact on the economy. It is a major source of tax revenue, and it provides a wide range of services to the public. The public sector is also a major employer of people with disabilities, and it has a significant role to play in the social and economic development of the UK.

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RYAN WHITE WAS AN INDIANA TEENAGER WITH HEMOPHILIA



who was diagnosed with HIV in 1984. He was an object of fear and he faced extreme discrimination when he attempted to attend school in the early years of the HIV epidemic. He was one of the first people that the Nation came to know as living with HIV and he was a prominent champion for an inclusive response toward all persons living with the virus. Ryan died of AIDS in 1990 before he was able to complete high school. His mother, Jeanne White Ginder continues to advocate for HIV/AIDS issues and educate the public about the impact of this disease.

Later in 1990 when the Congress enacted the first comprehensive national response to HIV, pulling together a few smaller and more targeted initiatives, they named the law the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The Program has had bipartisan support and has been reauthorized in 1996, 2000, 2006, and 2009. Today, the Program works with cities, states, and local community-based organizations to provide services to more than a half a million people living with HIV.

The passion, perseverance, and dedication to providing a caring response to all people in the United States living with HIV as embodied by the Ryan White HIV/AIDS Program is a lasting legacy of Ryan White and the many other people living with HIV and their friends, families, and care providers over the course of the epidemic. The Program has become an indispensable linchpin in the Nation's response to the HIV epidemic in the United States.