POSITIVELY AWARE

HIV TREATMENT, PREVENTION AND HEALTH FROM **TPAN**
JULY+AUGUST 2021

WAIT... THERE'S *ANOTHER* HEPATITIS VIRUS?

KNOCKING DOWN MYTHS ABOUT BLOOD DONATION

HOW DO WE ACHIEVE HEPATITIS ELIMINATION?

HEALTH EQUITY, SOCIAL JUSTICE, AND HIV IN THE ERA OF GEORGE FLOYD AND COVID-19

THE 9TH ANNUAL POSITIVELY AWARE

HEPATITIS DRUG GUIDE

Hepatitis C: Stories of stigma and getting cured

EDDIE MENDEZ and **JANICE BROCKMAN**

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TPAN was founded in 1987 in Chicago as Test Positive Aware Network, when 17 individuals living with HIV gathered in a living room to share information and support in response to the HIV/AIDS epidemic. POSITIVELY AWARE is the expression of TPAN's mission to share accurate, reliable, and timely treatment information with anyone affected by HIV.

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BACK ROW, FROM LEFT: THOMAS AMBELANG, SAM FORSYTHE, BERNARD WHITEHEAD, JANICE BROCKMAN. FRONT ROW: EDDIE MENDEZ, ALAA WASFI.

Personal motivation

The experiences that led caregivers and two people living with hepatitis to appear together on the cover

AFTER A PANDEMIC'S ISOLATION, photographing the cover of POSITIVELY AWARE was a chance for the hepatitis linkage-to-care team to connect in person with Janice Brockman and Eddie Mendez, two of the people they helped treat and cure (see "Living with Hepatitis C: Stories of stigma and the search for a cure," on page 16).

"I enjoyed the opportunity," said Thomas Ambelang, HCV linkage-to-care coordinator. "Eddie has always been wonderful to work with, and due to the COVID pandemic, despite working with Janice around treatment for approximately a year, I never had the good fortune to actually meet her. Due to the pandemic, this was the first time in a year where the HCV team had been able to be in the same room at the same time, something we once took for granted."

In part, it was gratitude that prompted Mendez to participate in the photo shoot. "Helping Tom, who has been so gracious, empathetic and informed, motivated me," Mendez, who was treated for HCV in 2019, said, "and if I can help one person, then that's always a good thing."

For Brockman, taking part in the photo shoot was a chance to offer reassurance to people who might be where she's been. She received treatment December 2020 through February of this year. "I wanted to be of help to someone else facing the challenges of having hepatitis C, who might be afraid," she said. "I would highly recommend getting treatment as soon as possible. I felt so much better after being treated. It may sound scary, but the treatment goes by fast and I had no side effects."

As an HCV community engagement specialist at Howard Brown, Sam Forsythe, one of the cover story's co-writers, also wanted to offer reassurance of her own. "I want to show the kind of people we are, hopefully demonstrate our approachability in our photos since care teams and medical settings can often be intimidating or uneasy environments for many people," she said.

"Although they might not think they've had any risks of HCV in their lives, the consequences of an undiagnosed infection are severe enough to warrant a test even if you don't think it could be positive," Forsythe added. "And if it is a positive result, take heart in the fact that those effects happen slowly, and there are ways to get these treatments wherever you are. Some states make it more difficult, but no matter who you are this is treatable, and regardless of what you do, you deserve the treatment."

Taking part in the photo shoot had deeply personal significance for co-writer Alaa Wasfi, RN, BSN. "It wasn't so much as being photographed as much as to take part in something bigger than myself that spreads hope and awareness." she said. "During the pandemic last year, my grandmother in Iraq passed away from hepatitis and cirrhosis complications."

Her experience adds a poignancy to her message for people living with hepatitis C: "Start somewhere. Anywhere. Any small step you take toward your health will accumulate in time, and benefit you eventually. Your hepatitis C and your health conditions do not define who you are. Reach out for help because somewhere out there, there is someone who can extend a hand or perhaps feels the same way as you do. There is no shame, and it's never too late."

—**RICK GUASCO**

Chicago-based photographer **John Gress** photographed the cover, assisted by Brian Guzman.

THE 9TH ANNUAL HEPATITIS DRUG GUIDE

JUL+AUG 2021

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COMPILED BY **ANDREW REYNOLDS**

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THE CATEGORY IS...

LONG-TERM REALNESS

What makes a long-term survivor of HIV—what qualities or traits describe them?

That's the question we asked our followers on Facebook, Instagram, and Twitter. They served up some honest feelings and experiences

"One thing I learned a long time ago, is that we didn't have a recipe, and each one of us had found different coping skills to survive and keep surviving. That is Important to remember, that even if we say *survivors*, we are the verb, the action—*surviving*—because the HIV pandemic has not ended."

—JESUS HEBERTO GUILLEN SOLIS

"I have survived almost 24 years. I take my meds, see the doc as scheduled, and try to keep an upbeat outlook on things."

—MAURICE LAMONTAGNE

"Keep serving, no matter what. We always keep serving."

—KENNY MARTINEZ

"Long-term survival means different things to different people, but always should include anyone who has fought and struggled to live and thrive into the future despite the challenging odds and unintended consequences of survival. HIV/AIDS survivors often have experienced many struggles in addition to HIV such as abuse, addiction, stigma, trauma, and many others."

—MATT SHARP

"A long-term survivor is ...someone who is resilient, someone whose answer to problems, troubles is, 'What's next?' in a positive way. Someone who sees value in life and living it (this is much harder than I thought it would be). What makes us ... us? We are, in my experience, an obstinate lot. We're stubborn about life, we have things to do, points to be made, places to go, people to meet, food and drink to celebrate. We celebrate life every day. We're cautiously optimistic and intentionally skeptical."

—HANS-ERICH LK

"When I think of 'long-term' I think of people who were on the front lines when there were no drugs and then somehow survived long enough to take the very first (and very harsh) early treatments which saved their lives but caused serious, long-term problems (neuropathy, kidney disease, lipodystrophy, etc.). However, every day with HIV can feel like an eternity, and someone with only a few years poz may feel 'long-term.' It's all about perspective, right?"

—LILLIAN THIEMANN

"Lonely."

—DOUG MC DONALD

"Strength."

—KENNETH GARATY

"Resilience."

—KIM SAMSON

"Luck."

—GEE POZ

"Wounded, but empowered."

—ROVERS DOG HOUSE OF ART

"It's been 40 years since AIDS first appeared in our lives. I acquired HIV in 1983, making me a long-term survivor. I'm part of a sizeable resilient generation who disprove the meme 'we lost an entire generation to AIDS.' We lost much of a generation, but many of us are still here, surviving against the odds. Today, HIV long-term survivors are 25% of 1.2 million people living with HIV in the US.

"As individuals and communities, we exhibited strengths we didn't know we had. We forged a strong community from the AIDS pandemic. Without access to effective treatments, we were forced to rely on each other and ourselves. With courage and compassion, we survived the darkest days of the plague. Surviving AIDS has given my life meaning and purpose. Now I do what I can to advocate and demand action, not merely to survive but to thrive."

—TEZ ANDERSON

Someone who can process the initial shock, fear, sadness, and perhaps shame—and use the experience to love themselves better and more deeply than before."

—MATTHEW CLORAN

"As a 30-year survivor I would say a sense of spirituality has been important to me. I'd describe myself as ferociously independent; ultimately, I was the only person to get me through these years. Empathy, kindness, willingness to help others, and trust are traits I see in myself."

—EMMA COLE

"If you ask my hubby, he'd tell you, 'he can still be bitchy after 26 years.'"

—YANCEY CHARLES

"Living in the day."

—BARBARA WANGO

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ANDREW REYNOLDS

Dare to dream

Viral hepatitis elimination by 2030

This Hepatitis Drug Guide could be obsolete by 2030. I've often joked that if we do things right, I could be out of work in no time. I would happily welcome that!

In 2016, the World Health Organization made a commitment to eliminate viral hepatitis by 2030. "Elimination" is defined as reducing new infections by 90% and reducing deaths by 65%. It's a daunting but achievable goal. We have the knowledge and the tools: We can cure hepatitis C (HCV). Harm reduction interventions such as syringe service programs and medication-assisted treatment can help prevent new HCV infections. We can vaccinate to prevent hepatitis B (HBV), and treat people who are already infected until a cure is discovered.

I just don't know when we will get there.

It won't be for lack of trying and the hard work of patients, activists and advocates, medical providers, and the many hard-working public health officials across the public sector. Under President Obama, the Department of Health and Human Services released the first "Viral Hepatitis National Strategic Plan" for the U.S., and we just got a new one earlier this year. For an excellent summary, check out Enid Vázquez's review of it in this issue's "Briefly" section.

We have the tools. We have a plan. And this year, after four years of silence on the issue, President Joe Biden issued a proclamation on National Hepatitis Testing Day (May 19), reasserting the U.S. commitment to viral hepatitis elimination, calling on "all Americans who are at risk for hepatitis to get tested, and for all health care providers to educate their patients about viral hepatitis."

Nice words, but then a couple of weeks later the President's budget flat-funded viral hepatitis at $39.5 million. The CDC estimates that they need $398.6 million to adequately fund the Division of Viral Hepatitis, so this falls very short of what's needed. The U.S. has over 2.4 million people living with HCV and another 860,000 people living with HBV. I'm not very good at math, but I think that's a little over $12 per person with viral hepatitis. That's money that needs to go towards surveillance and data collection, prevention, testing, linkage to care, and so on. Now, states and county health departments also put funding into viral hepatitis, as do private foundations and donors, but without a robust federal response and funding behind the Strategic Plan, we cannot make true progress towards elimination.

But don't just take my word on this—take a look at what my friends and colleagues in the field have to say on pages 44–45. I adore and admire these people so much, and through their leadership and work (and that of many, many others who couldn't be included in these pages), we can get to elimination. They have the ideas and the expertise to make it happen, but we need the funding and political commitment to get there.

I leave you with the words of Dr. Sam So, Lui Hac Minh Professor and Professor of Surgery and Director of the Asian Liver Center at Stanford University:

"Elimination of viral hepatitis in the United States is feasible with a comprehensive prevention and treatment approach and the political commitments at the local, state, and national levels. Put simply, we need primary care providers to screen their adult patients at least once for chronic hepatitis B and C infection, so every adult would know their hepatitis status; and for individuals tested positive, they would be provided with follow-up care according to the national practice guidelines, and they would have access to affordable, unrestricted, curative treatment for hepatitis C, and long-term monitoring and antiviral drug treatment for chronic hepatitis B. Screening and treatment would also need to be coupled with continued efforts to prevent new viral hepatitis infections through hepatitis B and A vaccination and elimination of mother-to-child transmission, needle/syringe exchange, and drug treatment programs."

Listen to Sam. And listen to my friends. And listen to people living with or at risk for viral hepatitis about their needs. If we adequately fund viral hepatitis and trust the viral hepatitis community to do the work, I will be out of work...and maybe, just maybe, it will be before 2030.

Andrew

The President's budget flat-funded viral hepatitis at $39.5 million. The CDC estimates that they need $398.6 million to adequately fund the Division of Viral Hepatitis, so this falls very short of what's needed.

ENID VÁZQUEZ @ENIDVAZQUEZPA

Briefly

Preventing HIV with just six shots a year

A long-acting medication now being used once a month for HIV may soon be used every other month for HIV prevention.

ViiV Healthcare announced that it has submitted a rolling new drug application (NDA) to the U.S. Food and Drug Administration (FDA) in May for cabotegravir as pre-exposure prophylaxis, or PrEP.

In two clinical trials, HPTN 083 and HPTN 084, one injection of long-acting cabotegravir showed superiority over daily use of Truvada, a PrEP medication already on the market. "HPTN" stands for HIV Prevention Trials Network.

Although tolerable and more than 95% effective in preventing HIV when used as prescribed, taking a daily pill of Truvada for PrEP can be burdensome for some people. New options are highly desirable—different strokes for different folks.

ViiV Healthcare reported that it plans to submit parts of its regulatory requirements as they are ready, starting in December. Hence a "rolling" application instead of submitting its evidence for a new drug approval all at once, as is usually done.

The FDA approved the NDA. Approval of the new PrEP medication could come as early as the first half of next year.

Cabotegravir for HIV therapy is used once monthly with another long-acting injectable, rilpivirine. The combination of the two gluteal (butt) shots are provided under the brand name Cabenuva.

Trogarzo: Update on infants

Based on animal data, the FDA updated the drug label for Trogarzo (ibalizumab-uiyk) in April to include the potential for immunosuppression in infants exposed to the medication inside the womb. The FDA said that while the 20 monkey moms given Trogarzo in a study received a higher level than is used in people, the potential for immunosuppression in human infants "is possible." In the infant monkeys exposed to Trogarzo in utero, there was observed a reversible effect on the immune system—a lower level of B cells and CD4 T cells within four weeks of birth. Most of the immunosuppression observed disappeared one to three months after birth, as the drug left the body and concentrations were almost undetectable in the baby monkeys.

One of the exposed infants died 24 days after birth, however, from a systemic viral infection. The FDA reported it's possible that the death was due to the drug exposure.

Trogarzo is a long-acting HIV medication important for its use in people who are highly treatment-experienced for whom many of the other medications won't work.

The FDA also reported no "malformations or premature births" and stated that, "In addition, no maternal toxicities, including no changes in maternal lymphocyte subsets or effects on embryo-fetal survival, were observed."

See Section 8.1 (Pregnancy) in the prescribing information at trogarzo.com.

Hep C meds for children

Two important medications for hepatitis C virus (HCV) can now be taken by even younger children than before. In June, the FDA approved new pellet formulations of Epclusa and Mavyret, allowing the age for treatment to drop. Epclusa can now be taken by children age 3 and older (as opposed to age 6 and older previously). Mavyret can now be taken by children age 3 and older (as opposed to age 12 and older previously).

"In the United States, as of 2018 there were approximately 35,300 to 60,500 children living with HCV and incidence has been on the rise," reported Gilead Sciences, the maker of Epclusa. "Mother-to-child transmission, the most common cause of HCV infection in children, increased 161% from 2009 to 2017, with intravenous drug use representing the primary driver of HCV infection among women of childbearing age."

See the Epclusa and Mavyret drug pages in this issue.

Treatment activists release diversity report on clinical trials

The AIDS Treatment Activists Coalition (ATAC) produced an extensive report analyzing data on diversity in HIV clinical trials conducted by pharmaceutical companies.

Led by Liz Barr, PhD, MS, the study reviewed participant demographics in HIV studies conducted 2010–2020 by four companies active in HIV research and development—Gilead, Janssen, Merck, and ViiV. ATAC gathered publicly available information from clinicaltrials.gov for HIV drug studies completed by the four companies, and analyzed study information to characterize trends in participant diversity.

Among HIV trial participants, the report found that male participants were over-recruited by 34%; race-specific data went unreported in 65% of studies, and, when reported, was incomplete. Geographic diversity was also lacking; a majority of study sites were in the U.S., although 75% of people living with HIV are in Africa and Southeast Asia. *Missing Data, Missing Diversity: Participant*

Demographics in Industry Studies 2010-20 can be read at AIDStreatmentactivists.org/diversity-report.

A five-minute video presentation of the report is at croiwebcasts.org/console/player/47450?mediaType=slideVideo, as part of a "Science Spotlight" for the Virtual Conference on Retroviruses and Opportunistic Infections (vCROI 2021).

La Bodega launches podcast

In last year's hepatitis drug guide, writer Michelle Simek told the story of a special hepatitis C clinic in Buffalo, New York and its founding doctor, Anthony "Tony" Martinez, AAHIVS ("Not your basic bodega," July+August 2020). This year, just in time for this hepatitis drug guide, Dr. Martinez has launched a podcast telling one patient's story of substance use, hepatitis C diagnosis and treatment, and now leading the life she longed for. Dr. Martinez announced that the four-part series is a dream years in the making. He hopes it inspires others, including providers, with its story of triumph. The podcast is produced in collaboration with Practice Point CME. Available through Apple Podcasts, Google Podcasts, iHeartRadio, and Spotify; the podcast can be found at bit.ly/patient-perspectives-on-hcv-podcast.

COURTESY TONY MARTINEZ

DR. PODCASTER: MARTINEZ

CDC issues new HIV numbers

Three new HIV surveillance reports were released May 27 by the U.S. Centers for Disease Control and Prevention (CDC). The cover letter tying in the statistics is a work of art. It's from Demetre Daskalakis, MD, MPH, the CDC's recently appointed Director of the Division of HIV/AIDS Prevention, for the agency's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

The good news? "Data suggest the progress seen in recent years is likely linked to increased uptake of key prevention and treatment strategies in recent years, such as pre-exposure prophylaxis (PrEP) and ongoing treatment and care, which are necessary to maintain viral suppression. These trends are encouraging although substantial gaps remain."

Some key points made:

- "From 2015 to 2019, the number of HIV infections among MSM [men who have sex with men] decreased 9% overall and infections among young MSM aged 13-24 years declined 33% overall, with declines in young MSM of all races, although young Black/African American and Hispanic/Latino MSM continue to be severely and disproportionately affected.
- "In terms of overall race/ethnicity, while HIV infections were somewhat lower in 2019 among African American, Hispanic/Latino, and White persons than in 2015, none of these declines were statistically significant—but, together, they contributed to an overall national-level decline.
- "The South also continues to be disproportionately affected, accounting for more than half of new HIV infections in 2019.
- "The number of HIV infections in 2019, compared with 2015, remained stable among persons who inject drugs (PWID), due likely in part to the ongoing opioid crisis.
- "Finally, the estimated percentage of diagnosed infections among persons living with HIV at year-end 2019, compared with 2015, increased 2%. At year-end 2019, an estimated 1.2 million persons aged 13 years and older were living with HIV infection, including about 13% of persons whose infection had not been diagnosed."

"Overall, these reports suggest improvements in linkage to care, viral suppression, and increased PrEP use are likely contributing to recent progress," Dr. D's letter continues. "However, the reports also signal an urgent need to expand and improve HIV prevention, care, and treatment for groups who could most benefit."

See Dr. Daskalakis's full letter, with links to the three reports (including PrEP use), at bit.ly/CDC-new-report-2021-05-27.

Happy anniversary, U=U

It was five years ago, in July 2016, when the U = U campaign kicked off and changed the world, letting everyone know that HIV cannot be transmitted by people with undetectable viral load who are on antiviral therapy. Undetectable equals Untransmittable ("U = U" for short) is the creation of the Prevention Access Campaign (preventionaccess.org), founded by Bruce Richman after he learned the astounding news that he could not pass on his HIV.

It was in 2006 when the Swiss Statement declared that people living with HIV who have undetectable viral load on antiviral therapy and no other STIs cannot transmit the virus through sexual contact. In the years before and since then, many struggles were made over the protective effect of HIV treatment for uninfected partners. But the knowledge today is solid. U.S. HIV treatment guidelines discuss Treatment as Prevention (TasP); GO TO hivinfo.nih.gov.

Correction

In "The Forgotten Generation" (May+June 2021), Emily Carson's correct age is 31, not 36. POSITIVELY AWARE apologizes for the error.

Briefly

New AIDS czar named

The Biden administration's new AIDS czar is an out gay Black man who's been living with HIV since 2005. Harold Phillips has been named director of the White House Office of National AIDS Policy (ONAP).

Phillips has more than 20 years' experience in the field. He most recently served as senior HIV advisor and chief operating officer of the Ending the HIV Epidemic (EHE) initiative in the Office of Infectious Disease and HIV/AIDS Policy (OIDP) at the U.S. Department of Health and Human Services. Before that, he was director of the Office of HIV/AIDS Training and Capacity Development at the Health Resources and Service Administration's HIV/AIDS Bureau, where he was deputy director of the Ryan White HIV/AIDS Program Part B and AIDS Drug Assistance Programs. He has also previously worked at NMAC (formerly the National Minority AIDS Council).

In an open letter to Phillips, NMAC CEO Paul Kawata said, "With your new appointment, community needs you to fight. While we are very happy that you got this job, it only works if you fight for us. As a member of the White House's Domestic Policy Council, we need you to bring the fight to end HIV to them. Too many people think the epidemic is over. Your voice represents more than you, it is the voice of the multitude of communities fighting HIV."

Kawata added that among the communities needing to be addressed are long-term survivors and people aging with HIV. "While PLWH are living longer, they also face multiple challenges from aging and HIV," Kawata said. "The Biden-Harris administration needs to create and implement a comprehensive 'standard of HIV care' for this growing community."

As ONAP director, Phillips said he plans to incorporate the Biden-Harris administration's priorities into the current strategy, and include additional input from other federal agencies to help address social determinants of health and improve health equity.

READ the announcement of Phillips' appointment here: bit.ly/new-White-House-AIDS-czar-appointed. **—RICK GUASCO**

HIV treatment guidelines updated

Several updates were made June 3 to the U.S. HIV treatment guidelines from the Department of Health and Human Resources (DHHS). The guidelines are regularly updated by a panel of experts.

- "The Panel now recommends that a dolutegravir (DTG) [Tivicay, found in Dovato, Juluca, and Triumeq]-based regimen can be prescribed for most people with HIV who are of childbearing potential.
- "Raltegravir [Isentress]-based regimens as initial antiretroviral therapy (ART) have been moved from the category of 'Recommended Initial Regimens for Most People with HIV' to 'Recommended Initial Regimen in Certain Clinical Situations.'
- "For patients with virologic failure, the Panel's recommendation of 'A new regimen should include at least two, and preferably three, fully active agents' has been changed to 'A new regimen can include two fully active drugs if at least one with a high resistance barrier is included (e.g., DTG or boosted darunavir [Prezista; Prezcobix]).'
- "[The section on 'Poor CD4 Recovery and Persistent Inflammation'] has been revised to include updates on studies describing mechanisms for declining CD4 counts despite suppressive ART [undetectable viral load] and a review of the status of experimental interventional strategies to reduce persistent inflammation. It also includes an explanation for why monitoring levels of inflammation is not currently recommended in clinical practice.
- "[The section on 'Adolescents and Young Adults with HIV'] has been revised extensively to include current epidemiologic data on HIV in adolescents and young adults (AYA) in the United States, unique challenges faced by this population compared to their adult counterparts, [and] the importance of assisting AYA in navigating optimal transition from pediatric to adult clinical care setting.
- "[The section on 'Women with HIV'] has been updated to include a review of the literature on weight gain in women after initiation or switch of ART. Updated data describing the prevalence of neural tube defects in infants born to women who were receiving either DTG or efavirenz [Sustiva, found in Atripla] during conception have been added. Information regarding hormonal therapy and antiretroviral (ARV) drug interactions has been updated. A new subsection offering considerations regarding menopause in women with HIV and its potential impact on ART is included.
- "A subsection has been added to [the section on 'Substance Use Disorder and HIV'] discussing factors to consider when contemplating the use of long-acting injectable CAB plus RPV [Cabenuva] in people with substance use disorder and HIV."

Other updates include tuberculosis (TB) treatment, cost considerations for HIV therapy, and drug interactions (including information about Cabenuva and Rukobia). See "What's New in the Guidelines?" at clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines. **GO TO** hivinfo.nih.gov.

PHILLLIPS: KALAMAZOO COLLEGE

U.S. plan to end viral hepatitis

Yes, the U.S. has a plan. In fact, this year saw the fourth version of it in a decade.

"Viral hepatitis is a serious, preventable public health threat that puts people who are infected at increased risk for liver disease, cancer, and death," says the *Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021–2025)*, or "Hepatitis Plan" for short.

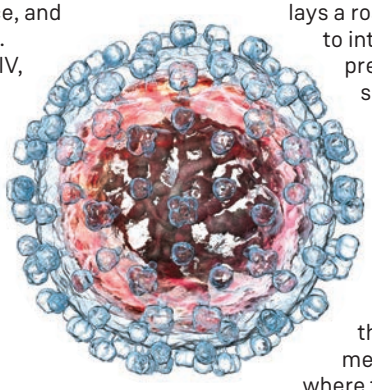
While previous versions looked at all hepatitis viruses (A–E), the latest focuses on A, B, and C. And as the document points out, A and B can be prevented by vaccines, and C can be cured 95% of the time in eight to 12 weeks with a tolerable course of treatment.

So, what's the problem?

There's still a need for more people to get tested and treated. Among other things, the ongoing opioid epidemic has led to an increased rate of hepatitis C virus (HCV) infections among young adults. And it's known that as with HIV treatment, hepatitis therapy has the added benefit of preventing transmission to sex partners.

But people often don't go in for testing or treatment due to stigma, discrimination, payor resistance, and other problems.

Shades of HIV, the Hepatitis Plan points to a syndemic behind the problem of viral hepatitis. According to the document, "A syndemic occurs when health-related problems—such as viral hepatitis, HIV, STIs, substance use disorder (SUD), and social determinants of health—cluster by person, place, or time."



HEPATITIS C VIRUS

ISTOCK

"Communities disproportionately impacted by viral hepatitis often grapple with a range of challenges across the social determinants of health. The interplay of factors such as poverty, inadequate housing and transportation, food insecurity, medical mistrust, access to care, access to mental health care, language and cultural barriers, education, stigma, and discrimination must be addressed to reduce health disparities," according to the report. "People with viral hepatitis face stigma and discrimination because of a number of factors (for example, SUD, risk behaviors, sexual orientation, gender identity, race and ethnicity, co-infection with HIV) in addition to the stigma associated with viral hepatitis. Intersectional stigma may impact prevention and care-seeking behavior."

Which is why, the document notes, that, "An integrated approach to hepatitis and related public health challenges will reduce fragmented care and ultimately reduce viral hepatitis infection rates. This Plan lays a roadmap to integrate prevention, screening, and linkage to care for all components of the syndemic, so that we can meet people where they are with no wrong point of entry to health care and related systems. This approach is especially important for people in at-risk settings and circumstances, such as people experiencing homelessness, people with an SUD, and people in correctional systems, for whom system-wide solutions pose additional and unique challenges."

For gay and bisexual men, for example, 10% of new hepatitis A and 20% of new hepatitis B infections are in this group, despite the availability of vaccination. Moreover, "Gay, bisexual, and other men who have sex with men, in particular those with HIV, also have a higher chance of getting hepatitis C." Risk factors include condomless receptive anal sex, exposure to blood during sexual activities (again, without taking precautions), the presence of another STI, and sometimes recreational drug use.

POSITIVELY AWARE Hepatitis Editor Andrew Reynolds points out that the plan "has been around since the Obama years. And there's no funding given to put the plan into action."

Despite the advocacy concerns, the comprehensive plan has seen some positive results.

For the 2020 goals, for example, the plan is "on track" for reductions in deaths related to hepatitis C both among African Americans specifically as well as in the general population. "Trending in the right direction" is the provision of hepatitis B vaccination for newborns (pregnant women with hepatitis B risks should be vaccinated). But other goals to be achieved by last year, such as reducing new hepatitis C infections among people aged 20 to 39, are "not on track." (Statistics take a while to be collected and analyzed, which is why results for 2020 are not yet in.)

"Treatment for SUD and harm reduction approaches, such as SSPs [syringe services programs], have been shown to prevent an estimated 75% of hepatitis C infections, but these interventions must be maintained over time," the plan notes.

There are five overarching goals:

1. Prevent new viral hepatitis infections
2. Improve viral hepatitis-related health outcomes of people with viral hepatitis
3. Reduce viral hepatitis-related disparities and health inequities
4. Improve viral hepatitis surveillance and data usage
5. Achieve integrated, coordinated efforts that address the viral hepatitis epidemics among all partners and stakeholders [referring to, for example, health departments and people with viral hepatitis]

With a blueprint out there for all to see—providers and advocates alike—the Hepatitis Plan may be on track to see its vision statement fulfilled:

"The United States will be a place where new viral hepatitis infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination. This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance."

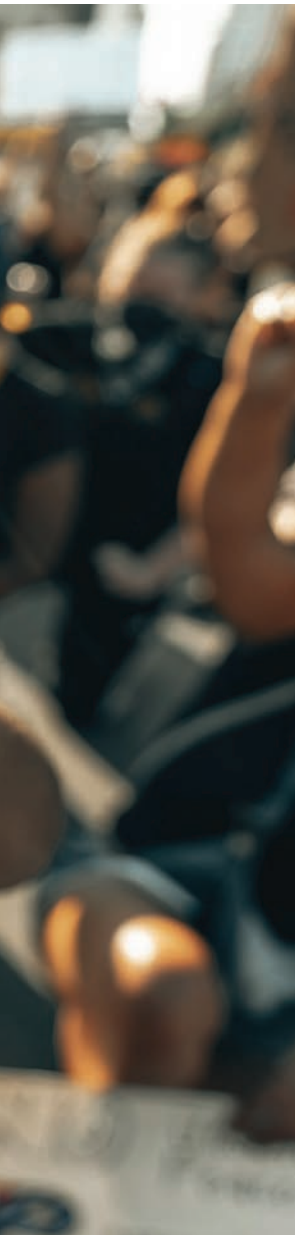
GO TO bit.ly/hhs-hepatitis-strategic-plan.

There is also an Opioid Plan, bit.ly/hhs-opioid-plan.

Health equity, social justice, and HIV in the era of George Floyd and COVID-19

BY **MICHAEL BRODER**

Health disparities in HIV based on race and ethnicity have been with us since the start of the epidemic. Community-based advocacy to address such disparities is equally long-lived. The year 2020, however, brought these inequities to levels of public prominence never seen before. The two epochal events that brought about this shift were the COVID-19 epidemic that began with the 2020 New Year, and the murder of George Floyd, a Black man, at the hands of white police officer Derek Chauvin in Minneapolis on May 25. Here, we look at how disparities based on race and ethnicity have shaped the HIV epidemic for 40 years, as well as how the understanding of these disparities, and the societal response to them, has changed in the era of George Floyd and COVID-19.



CLAY BANKS-UNSPLASH

The concept of syndemics in HIV and COVID-19

Like the HIV epidemic, the COVID-19 pandemic emerged against a backdrop of disparities in healthcare access, health outcomes, and social determinants of health. In the past two decades, the concept of syndemics has been used to explain health disparities in HIV, and the same concept has quickly emerged as a useful lens of analysis for COVID-19. The term "syndemic" was coined in the mid-1990s by Merrill Singer, a medical anthropologist at the Hispanic Health Council in Hartford, Connecticut. It refers to a complex of two or more medical conditions or social determinants of health that overlap and interact in a synergistic manner, each fueling the other in a vicious cycle of cause and effect. In a seminal 1996 article, Singer conceptualized the close interconnections among violence, substance use, and HIV. Rather than separate conditions, Singer conceived of substance abuse, violence, and HIV as a closely interrelated complex of health and social crises that take an ongoing and significant toll on the lives and well-being of affected communities. Singer coined the acronym SAVA (substance abuse, violence, and AIDS) to underscore the connections among these public health crises. The violence referred to in the concept of the SAVA syndemic takes many forms, including gang violence, violence in jails and prisons, intimate partner violence, child abuse, and violence against sex workers, among others.

Social determinants of health

Writing about COVID-19–related health disparities, Clare Bambra and colleagues in the United Kingdom note that non-white racial and ethnic groups, people living in poverty and related forms of socioeconomic deprivation, and people in marginalized groups such as the homeless or unstably housed, incarcerated people, and street-based sex workers generally have a greater number of coexisting non-communicable diseases (NCDs). Moreover, non-infectious health conditions among these groups are often more severe and occur at a younger age. This includes higher rates of almost all of the known underlying clinical risk factors that increase the risk of severe illness and death from COVID-19. These conditions include hypertension, diabetes, asthma, chronic obstructive pulmonary disease (COPD), heart and cardiovascular disease, liver disease, renal (kidney) disease, cancer, obesity, and smoking. These inequalities in chronic conditions, Bambra and colleagues point out, arise as a result of inequalities in exposure to social determinants of health such as working conditions, unemployment, access to essential goods and services, housing, and access to healthcare.

Overlapping disparities in HIV and COVID-19

In October 2020, the O'Neill Institute for National and Global Health Law at Georgetown University published a report on the overlapping health disparities associated with HIV and COVID-19. The limited data available indicate that people living with HIV (PLWH) who are on effective antiretroviral therapy (ART) have the same risk for COVID-19 as people who do not have HIV. But as COVID-19 made its way across the country in the first months of 2020, it soon became apparent that people of color were disproportionately affected, and that there was considerable overlap between the communities bearing most of the brunt of COVID-19 and HIV.

The role of systemic racism

These disparities are largely driven by the effects of structural or systemic racism. According to the authors of the O'Neill Institute report, Jeffrey S. Crowley and Sean E. Bland, systemic racism encompasses a broad range of disadvantages embedded in public policy, law, government, and culture. Systemic racism is also manifested in, and influenced by, social determinants of health, which include such areas as education, employment, the healthcare system, housing, income and wealth, the physical environment, public safety, social environments, and transportation, among other factors.

Experts writing over the past 18 months have identified factors contributing to increased vulnerability both to COVID-19 and to HIV. For example, Tonia Poteat and colleagues point to the high rates of pre-existing medical conditions, the fierce resistance to Medicaid expansion in the South, the lack of access to testing in low-income neighborhoods, and an over-representation among the essential workforce as factors that explain elevated risks for COVID-19 among people of color throughout the United States. These same factors also contribute to poor HIV-related health outcomes. Indeed, since Poteat and colleagues published their commentary in the spring of 2020, we have entered the era of COVID-19 vaccines, and here have seen disparities that closely parallel the disparity in access to, and uptake of, ART for HIV.

Racial segregation as a risk factor for HIV and COVID-19

Gregorio Millett, MPH, a prolific and influential epidemiologist who worked in the Obama White House and is now vice president and director of public policy at amfAR, recently wrote about differing HIV and COVID-19 outcomes and service delivery by race and ethnicity, and the crucial role of racial segregation in housing and homeownership. Using publicly available data from the U.S. Census Bureau, Millett and colleagues divided U.S. counties into quintiles by percentage of non-Hispanic white residents, and examined per capita (basically, on average per person) diagnoses of

Rather than separate conditions, Singer conceived of substance abuse, violence, and HIV as a closely interrelated complex of health and social crises that take an ongoing and significant toll on the lives and well-being of affected communities.

HIV and COVID-19. Their study found that HIV diagnoses decrease as the proportion of white residents increase across U.S. counties, with COVID-19 diagnoses following a similar pattern. Moreover, the study found that, compared to primarily non-Hispanic white counties in the U.S., fewer COVID-19 diagnoses have occurred in primarily white counties throughout the duration of the COVID-19 pandemic. As Millett and colleagues point out, other data contribute to the conclusion that racial segregation plays a part in disparate rates of infection and outcomes both for HIV and COVID-19. One recent study showed an association between redlining practices in Chicago and greater COVID-19 mortality in primarily Black neighborhoods. In another study, racial segregation accounted for 19% of HIV infections among Black people who inject drugs (PWID) compared to 3% of HIV infections in white or Latinx PWID. In addition, a study in New York reported that 65% of Black men diagnosed with HIV and 68% of new HIV diagnoses among Black men occurred in specific ZIP codes.

When it comes to HIV, the greatest disparities are for men who have sex with men (MSM) and transgender women. Across all risk groups, however, Black and Latinx people have a higher burden relative to non-Hispanic whites and other groups.

As Crowley and Bland note, researchers consistently observe racial and ethnic health disparities across many health conditions in the U.S. When it comes to HIV, the greatest disparities are for men who have sex with men (MSM) and transgender women. Across all risk groups, however, Black and Latinx people have a higher burden relative to non-Hispanic whites and other groups. They point to common factors that increase risk for HIV and COVID-19, including racism, trauma, poverty, stigma, residential segregation, housing insecurity (including both less access to housing and greater housing density), less access to health care and preventive services, incarceration, and immigration status.

George Floyd rekindles the racial justice movement

Within hours of George Floyd's murder at the hands of Minneapolis police officer Derek Chauvin, demonstrators began flooding streets in cities and towns across America, demanding an end to police violence against Black Americans in what became the largest mass protest movement in U.S. history. The slogan Black Lives Matter, which had emerged in 2013 after the acquittal of George Zimmerman in the shooting death of Trayvon Martin 17 months earlier, became the mantra of a nation grappling with Mr. Floyd's death. Over the next year, calls for racial justice grew to a scale not seen in the U.S. since the civil rights movement of the 1960s. And by most accounts, this incarnation of racial justice activism was more diverse and inclusive than any previously seen—a reflection, it would seem, of social, cultural, and demographic changes that had emerged during the first decades of the twenty-first century.

This resurgence of racial justice activism emerged in the midst of the COVID-19 pandemic, which had already begun to focus renewed attention on the health dimensions of the racial inequities that run throughout American history. Indeed, people of color were hardest hit not only by the health crisis itself, but by the economic devastation that came in the wake of the coronavirus. In addition, the murder of George Floyd occurred within months of the officer-involved deaths of Ahmaud Arbery and Breonna Taylor. For a time, at least, white Americans displayed previously unseen levels of support for the Black Lives Matter movement, identified racial discrimination as a major problem, and acknowledged that excessive police force disproportionately impacted Black people in this country.

Biden commits to racial equity in public health

On the campaign trail in 2020 and upon entering the White House in 2021, Joe Biden made addressing systemic racism one of his administration's four major priorities, and promised to center racial equity throughout his agenda, from combatting COVID-19 and revitalizing the economy to addressing climate change. In doing so, Biden make frequent reference to the murder of George Floyd, to the national reckoning with systemic racism, and to the centrality of racial equity to his agenda. This commitment has played out most noticeably in the rollout of the vaccination effort. While journalists continue to ask Biden's press secretary, Jen Psaki, to explain the lower rates of vaccination among people of color compared to whites, it seems clear that the administration's vaccination infrastructure, strategy, and tactics have consistently been designed and implemented with racial equity front and center.

Signalling commitment to race and HIV with key appointments

In addition to vaccination policies and other COVID-19–related strategies that appear to deliver on the administration's promise of centering racial equity, Biden has shown his commitment with several key appointments. Biden appointed Marcella Nunez-Smith, MD, MHS, an expert and leader in health equity research at Yale, to co-chair the Biden-Harris transition's COVID-19 advisory board, and then selected her to lead his administration's COVID-19 Equity Task Force.

To head the Centers for Disease Control and Prevention (CDC), Biden chose a renowned HIV expert, Rochelle P. Walensky, MD, MPH. In a statement marking the 40th anniversary of the report on Pneumocystis pneumonia in five previously healthy young gay men in Los Angeles in the Morbidity and Mortality Weekly Report (MMWR), Dr. Walensky underscored the disproportionate impact of HIV on specific communities, even in the face of extraordinary progress towards ending the HIV epidemic in the U.S. in recent years. Walensky notes that, while annual HIV infections in the U.S. decreased 73% from 1981 to 2019, some 37,000 people continue to be newly diagnosed with HIV each year. "Disparities in diagnoses and access to treatment and prevention persist," Walensky said. "Over half of new HIV infections are in the South, and new infections remain high among transgender women, people who inject drugs, and Black/African American and Hispanic/Latino gay and bisexual men."

Fauci personifies link between HIV and COVID-19

Perhaps the most dramatic symbol of the Biden administration's commitment not only to racial equity, but also to ending both the COVID-19 pandemic and the HIV epidemic, and to maintaining a fundamental commitment to science and fact-based decision making, is his reappointment of Dr. Anthony Fauci to head the National Institute of Allergy and Infectious Diseases (NIAID), a position Fauci has held under presidents both Democratic and Republican since

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1984. The ACT UP activists who confronted Fauci at the NIH in October 1988 ended up being given a literal seat at the table—the table in Fauci's conference room—later meeting with him regularly over red wine at the home of Fauci's deputy, James C. Hill, PhD, a gay man with a townhouse on Capitol Hill, where the virologist and the street activists would plan how to incorporate people with AIDS in the planning and execution of clinical trials for AIDS drugs.

Whither health equity?

At the annual meeting of the Presidential Advisory Council on HIV/AIDS (PACHA) in March 2021, Gregorio Millett gave a presentation on achieving health equity in HIV and COVID-19. Millett pointed out that both HIV and COVID-19 disproportionately impact communities of color, and stated that COVID-19 is part of a syndemic (alongside HIV, opioids, and hepatitis C) that magnifies health inequities by race. He noted that, while we are on track to end the HIV epidemic among white Americans, it will take much longer to end HIV in Black and Brown communities, due to COVID-19-related delays in implementing a national HIV strategy that is based on maximizing access to, and uptake of, HIV testing, treatment, and prevention by members of highly-affected communities, including people of color, where the impact of the lingering HIV epidemic is currently greatest.

Millett also discussed possible ways forward, including Medicaid expansion (which is currently gaining popularity in the states where it was initially rejected by governors and legislatures), ramped up HIV testing programs, and the use of algorithms and guidelines to address health inequities. Millett advocates declaring racism a public health issue, since that would allow it to be surveilled by the CDC, and "What gets measured gets managed."

In a 2020 commentary, Millet discusses why both COVID-19 and HIV remain prevalent in communities of color in the U.S., and explains the implications of these disparities for ending the HIV epidemic. As Millet notes, a recent report by the National Academy of Sciences estimated that as much as 70% of health outcomes are due to health access, socio-economic factors, and environmental conditions. Millett states that social determinants of health associated with greater HIV burden in Black and Brown communities have re-emerged in the wake of COVID-19, with disproportionate COVID-19 cases, hospitalizations, and deaths in communities of color.

"Just as HIV research expertise paved the way for a COVID vaccine, local and community efforts to address HIV disparities have also been instrumental in predicting and suggesting ways to address COVID-19 disparities," Millet said in comments provided for this article. "These range from identifying the scope of the problem and ways to address it through national and local strategies; to engaging most-impacted communities as equal partners to find viable solutions; and finding ways to guarantee access to new health innovations for marginalized groups in the U.S. and abroad."

"COVID-19 might temporarily set back our efforts to end HIV (and magnify racial disparities), but it will only strengthen the resolve of our community (advocates, scientists, and providers) to fight harder," Millett insisted. "That is what we did in the 1980s and 1990s, and that is what we are going to do today and into the near future." PA

MICHAEL BRODER is a gay, white, poz, Jewish, male, late-Boomer Brooklyn native (b. 1961). Columbia undergrad, MFA in creative writing from NYU, and PhD in classics from the CUNY Graduate Center. He tested HIV-positive in 1990, and started doing AIDS-related journalism while collecting unemployment insurance in 1991. He lives in Bed-Stuy with his husband and several feral backyard cats.

Social determinants of health associated with greater HIV burden in Black and Brown communities have re-emerged in the wake of COVID-19, with disproportionate COVID-19 cases, hospitalizations, and deaths in communities of color.

FRONT ROW: EDDIE MENDEZ AND JANICE BROCKMAN, WHO WERE SUCCESSFULLY TREATED FOR HEPATITIS C. BACK ROW: TOM AMBELANG, ALAA WASFI, BERNARD WHITEHEAD, AND SAM FORSYTHE

Living with Hepatitis C: Stories of stigma and getting cured

Everyone deserves to be looked in the face and understood—to the best of our abilities

BY **ALAA WASFI, RN, BSN** AND **SAM FORSYTHE**
PHOTOGRAPHY BY **JOHN GRESS**

Being the vulnerable human beings we all are, we assume things about chronic conditions such as hepatitis C. We assume it is a disease of Baby Boomers, of people who use needles. Ultimately, it's something that won't happen to us.

Because of such myths, many patients fall through the cracks. As health care providers, nurses, case managers, or whatever the title, we think of ourselves as "community educators." We talk and talk while patients look at us with wide eyes, nodding hesitantly. Are we really listening and processing their stories? What can we learn from them?

Hepatitis C in brief

As an infection of the liver that is caused by a virus transmitted through contaminated blood, hepatitis C (HCV), if left untreated, can lead to serious, and oftentimes irreversible, liver damage. Until a few years ago, hepatitis C treatment required weekly injections and oral medications that many people living with HCV could not take because of other health problems or unacceptable side effects. But with the bloom of drug options, chronic HCV is now promisingly curable with oral medications that are taken every day for two to three months with minimal side effects, if any.

Access to a cure, however, is still elusive.

Although 30% of people self-clear the virus spontaneously and antiviral medications are 98% effective in curing chronic infections, access to testing and treatment remain staggered. The World Health Organization (WHO) estimates that 71 million people have chronic HCV globally, with only 19% aware of their diagnosis. The U.S. Centers for Disease Control and Prevention (CDC) estimated 2.4 million people were living with HCV in the U.S. in 2014, and that the death toll associated with HCV reached 19,659. Because this figure was based on death certificates, which often underreport HCV, it is likely that the death toll is actually higher. These estimates reflect a mortality rate that surpasses the total number of deaths attributed to 60 other infectious diseases combined, including HIV, pneumococcal complications, and tuberculosis. These deaths are a testament to our systemic mistakes in the proper testing and swift treatment of HCV.

Although badly needed, HCV treatments are very expensive, costing about $84,000 for a full 12-course treatment of the latest drug. In one analysis, if all 300,000 Medicare patients projected to be diagnosed by 2015 were to seek treatment with the latest drugs after screening, the total expenditure could exceed $25 billion. That does not include the cost of lab appointments, doctor visits, and other fees. For those that are not eligible for insurance this is an impossible amount of money to pay.

Insurance no guarantee

These cost barriers are not altogether eliminated for those who are insured. Janice Brockman was diagnosed with HCV during a 2016 hospital visit. She was surprised by the news, but was immediately informed there was an effective treatment and given a referral for a specialist at a prominent Chicago hospital.

After a few months of follow-up visits and consultations, she was told she was not eligible for treatment because her insurance, an Illinois managed Medicaid plan, would not pay for it.

This story represents one of the primary barriers to HCV treatment in the U.S., the restrictions that plague access and often result in patients developing permanent liver damage before they receive treatment.

In 2019, these restrictions were lifted in Illinois as a result of legal advocates filing a lawsuit against the state, but prior to this point Medicaid plans would not pay for treatment unless a person completed additional testing, urine drug screens, and showed high levels of liver scarring and inflammation. Hepatitis C-related liver damage is typically a slow process, and these restrictions created systems where patients would wait for years to develop enough damage so they could qualify for treatment, leaving them with irreversible liver scarring that increased their risk of liver cancer. This is what happened to Brockman.

'I couldn't attend family functions'

After three attempts to get treatment from three different care centers, Brockman started her medications in 2020 through our clinic, Howard Brown Health, in Chicago. Shortly into her first round of treatment, she started showing significant side effects and was sent to the hospital, where she was discovered to have a cancerous tumor attached to her liver. The tumor caused the side effects, and having completed an ultrasound of her liver a few months prior, it was a decidedly recent development.

Brockman completed HCV treatment after seeing an oncologist, and today she is now cured of HCV and her cancer is in remission. However, this cancer was likely avoidable if she had been provided treatment soon after her HCV diagnosis. She also suffered through years of HCV-related symptoms that significantly impaired her life, including extreme fatigue and anemia, for which she was regularly hospitalized to receive blood transfusions.

Now that she's cured she realizes just how severely the HCV had affected her. "I feel incredible now, after years of feeling horrible. I couldn't attend family functions, parties, anything. I missed out

ON THE ROAD: BAYARMAA SHRAVDORJ WITH HER RIG.

COURTESY OF BAYARMAA SHARADORG

JANICE BROCKMAN AND EDDIE MENDEZ. SAYS MENDEZ:
'I wish [my previous provider] would have pushed me more, but I understand why he didn't. He completely left it in my court. And get a great team to help you. Be involved.'

on so much because all I wanted to do was lay up in bed."

Although Illinois lifted its Medicaid restrictions, the same restrictions still exist in many states and represent a huge disparity in who is able to access treatment, and sadly, who is more likely to die of liver disease.

A special collaboration

The many barriers affecting access to HCV treatment and cure are of special concern for people of immigrant experience. At Howard Brown, we strive to reduce the common language and insurance barriers experienced by this community. In part we've done this by partnering with Mongolian community representatives to better support Mongolian speakers specifically, because of their high rates of HCV and HBV.

Bayarmaa Shravdorj found she was living with HCV when she came in for a screening. Because HCV frequently shows no symptoms, she was unaware of her status, but unfortunately, she was painfully aware of what it meant. "I had some minor information about it from family and friends. My dad and younger siblings died from hepatitis viruses."

Shravdorj's loss is tragic, yet common. The majority of our Mongolian patients report the death of at least one immediate family member to hepatitis-related liver disease. It is because of this that the community is engaged in finding resources. However, many care facilities can't accommodate Mongolian speakers or treat individuals without insurance, and people have a hard time even getting screened.

Fortunately, we have been able to access medications for this group by using pharmaceutical assistance programs, which is how we were able to offer treatment immediately to Shravdorj.

"When I found out I had hepatitis C at Howard Brown Health … I felt overwhelmed," she said. "I didn't know what to do, but they told me they offered treatment and I embraced it with open arms and was very happy. I told my family I had hepatitis C and they were very supportive. Howard Brown Health told me it was fully treatable and they were very supportive too."

HIV/HCV co-infection

As for people living with HIV (PLWH), they are at a high risk for not only contracting HCV but also developing liver damage at a faster rate. The Department of Health and Human Services (DHHS) reports that of the PLWH in the U.S., about a quarter are co-infected with HCV, and those who are co-infected are over three times more likely to develop liver disease, liver failure, and liver-related death. For injection drug users living with HIV, the rate of HCV co-infection is about 75%.

Although we know the risk of co-infection, we still lack sufficient HCV screening among PLWH. At an STI clinic in Miami, only about 15% of participants were screened for HCV while 83% had been screened for HIV; and 98% of the participants had been previously screened for HIV as well.

For our co-infected community, universal screening and quick administration of treatment are particularly necessary. All PLWH should be screened for HCV upon entry into primary care, and providers should establish a testing routine based on the risk factors patients present.

Incarceration

Around the world, incarcerated people experience a higher incidence of HCV than the general population. However, they have routinely struggled to access medications and medical treatment.

The primary risk factor associated with this infection rate is injection drug use, followed by illicit tattooing, sexual behavior, and to a lesser extent, sharing of toiletries. People using drugs inside the prison system do not have access to sterile use supplies, contributing to the high transmission rate via injection use.

Of the participants Howard Brown has treated, multiple people have identified that their most likely exposures to HCV were during their time in prison, and all have attested to the

BROCKMAN WITH ALAA WASFI. SAYS BROCKMAN:
'I feel incredible now, after years of feeling horrible. I couldn't attend family functions, parties, anything. I missed out on so much because all I wanted to do was lay up in bed.'

lack of treatment available. The reasons reported for how and why our formerly incarcerated patients did not receive adequate HCV care vary. Some reported that testing for HCV was not available until they were about to leave or had just left prison. Other factors included lack of general access to medical care, being told they are not sick enough, and denial of medication requests due to the length of their sentence.

All of these have the same harmful effect: patients endure an unnecessary disease progression, and other inmates' risk of HCV exposure is increased.

Injection drug use

In the midst of an opioid epidemic, we must acknowledge the most considerable contributor to HCV transmission in the U.S., injection drug use. In 2018 the CDC HCV Surveillance Report showed that a majority of people are unable to identify how they were exposed, but of those who can, 72% report current or past injection drug use.

The opioid crisis has especially affected a younger age group, demonstrated by a 23% increase in new infections among people aged 20–39. In the city of Chicago alone, the infection rate among people who were born after 1986 increased by 288% between 2013–2017. Many state Medicaid systems require urine drug screens and six months of sobriety to be eligible for HCV treatment. People using drugs and alcohol are more likely to experience a lack of stability in housing and income, making strict eligibility criteria difficult to meet. There's also been a trend of hospitals and clinical practices imposing their own sobriety measures in pursuit of treating patients who they believe will be more successful.

It is important to note that there is no immunity gained by HCV treatment. We can cure the infection a person has, but they will not be immune moving forward and require education on how to avoid re-infection after treatment. This re-infection principle is the primary argument for not treating people who actively use drugs, in addition to the assumptions made by clinicians about their ability to engage in medical care.

However, current national HCV treatment guidelines recommend the treatment of patients using drugs. Even with the potential risk of re-infection, by treating everyone with HCV we are lowering the risk of community transmission and ensuring patients do not develop liver disease.

Our program

Effective HCV treatment requires an acceptance of all clients, and a multidisciplinary method of support. At Howard Brown we strive to maintain accessibility by offering treatment to everyone who comes in regardless of insurance, documentation, active drug and alcohol use, housing stability, or lapses in engagement. There is a long-established national trend of treatment denial based on these factors. If we have any hope of eliminating HCV, it's crucial to treat all patients. In order to see that all clients achieve a cure, our team consists of a pharmacist, nurse, and case managers who work to support clinicians in treating people with HCV, and assist those individuals in identifying and addressing barriers to treatment. By employing harm reduction, we adjust care plans to fit each person's feedback about what they need to make the treatment a success. We focus on educating clients about HCV and the treatment process so they can make informed decisions about their care.

One client, Eddie Mendez, says it best: "Have a good doctor, a great doctor. I wish [my previous provider] would have pushed me more, but I understand why he didn't. He completely left it in my court. And get a great team to help you. Be involved. Don't be ashamed. It's not a killer anymore. I feel so lucky. I've seen what it's done to people. It's testable and it's curable and that's pretty awesome." PA

ALAA WASFI, RN, BSN (she/they) is a primary care and sexual health Registered Nurse at Howard Brown Health since 2016. She presented on "Increasing HCV Treatment Through Reducing Stigma in an LGBTQ Health Setting" at the National Harm Reduction Conference, New Orleans 2018. Alaa was born and raised in Iraq. Her life's motto: "Everyone deserves to be looked in the face and understood—to the best of our abilities."

SAM FORSYTHE (she/her/hers) is an HCV Community Engagement Specialist at Howard Brown Health. She began working in HIV case management services for women of all ages and youth in 2015 and transitioned to HCV case management and outreach in 2018 where she has focused on engaging groups that experience significant barriers to hepatitis C treatment, including people with active use or a history of drug use, those of immigrant experience, and people without documentation.

HOWARD BROWN HEALTH's HCV team provides hepatitis C treatment and education to all individuals regardless of past denials, substance use, insurance, or documentation status, and aims to provide multidisciplinary support from diagnosis to cure. Howard Brown's mission is to eliminate the disparities in healthcare experienced by lesbian, gay, bisexual, and transgender people through research, education, and the provision of services that promote health and wellness.

POSITIVELY AWARE

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How to use this guide

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The POSITIVELY AWARE Viral Hepatitis Drug Guide includes medications for the treatment of hepatitis B (HBV) and hepatitis C (HCV) that are FDA approved. The information provided comes from the package labels, as well as sources such as the AASLD/IDSA Recommendations for Testing, Managing, and Treating Hepatitis C (HCV Guidance) and AASLD Hepatitis B Guidance.

Treatment
HCV treatment is a cure for hepatitis C. It is comprised of two or more medications—all pills—taken together. Most are a fixed-dose combination (FDC) that contains medications from two different classes in one pill. Some regimens may include weight-based ribavirin. Pegylated interferon is no longer used for HCV treatment.

HBV is treated with one medication at a time—either with an antiviral or with pegylated interferon. HBV treatment slows or prevents the progression of liver disease. It does not, currently, lead to a cure.

Drug names
Drug names can be confusing. We include the brand name, generic name, and an abbreviation. For example, Mavyret has a combination of glecaprevir and pibrentasvir, with the abbreviations of GLE/PIB.

Drug class
The "direct-acting antiviral" or DAA era of HCV treatment has seen the development of several different drug classes. Currently, there are five:

- Nucleoside analogs
- NS3/4A protease inhibitors
- Nucleotide NS5B polymerase inhibitors
- Non-nucleoside NS5B polymerase inhibitors
- NS5A inhibitors

Genotype (HCV-only)
Genotype (GT) refers to the strains or variations of HCV. For this guide we will only refer to GT 1–6. In the U.S., GT 1–4 are prevalent, with GT 1 the most common. Each genotype has subtypes indicated by numbers and letters (GT 1a, GT 1b, and so on). We list the genotypes that the HCV medication works against.

Average Wholesale Price (AWP)
The AWP is the measure used by insurance companies—both private and public—to determine the average cost of prescription drugs. HCV drugs can be expensive, and there is much concern over the burden these high costs place on programs such as Medicaid and Medicare, as well as the Veterans Administration and private insurance carriers. Each of the pharmaceutical companies has a Patient Assistance Program (PAP) to help people who are uninsured or underinsured cover all or part of the costs. There are also pharmaceutical co-pay programs and non-profit organizations that can help with some additional support for co-pays. A list of HCV drug patient assistance and co-pay programs appears on page 32.

Potential side effects and adverse events
This section offers information about side effects and adverse events associated with a drug. It's not an exhaustive list. Everyone experiences side effects differently: Just because it's listed doesn't mean you will necessarily get it. Talk to your medical provider about any side effects you may have during treatment, and get blood tests as directed.

Potential drug interactions
This section provides information about the variety of known and potential drug interactions. Again, it's not an exhaustive list. You can find a complete list in the package insert, but you should also talk with your medical provider and/or pharmacist about any medications (including over-the-counter ones) you are taking.

More information
This section contains information that is good to know.

A note on hepatitis B reactivation
In 2016 the FDA added a "Boxed Warning" about the potential risk of HBV reactivation in some patients taking any hepatitis C DAA. See page 37 for more information.

Special thanks to Brooke N. Stevens, PharmD, BCPS, AAHIVP, for reviewing the 2021 POSITIVELY AWARE Hepatitis Drug Guide.

Dr. Stevens is an HIV clinical pharmacist at the LifeCare Clinic at Methodist Hospital and The Ryan White Center for Pediatric Infectious Disease and Global Health at Riley Hospital for Children, both at Indiana University Health (IU Health) in Indianapolis. She currently trains pharmacy students, is on the clinical faculty of the Midwest AIDS Training and Education Center, and serves on the "hub team" for the HCV Project ECHO.

HCV FAQs

PA's hepatitis editor **Andrew Reynolds** answers frequently asked questions about hepatitis C—what you should know

1. What is hepatitis C?

"Hepatitis" means "inflammation of the liver." There are lots of things that can cause hepatitis, or liver inflammation, including certain medications, excessive amounts of alcohol, and other diseases as well as viruses. Hepatitis can be both short-lived (called "acute") or ongoing (called "chronic").

Hepatitis C virus (HCV) is transmitted from blood-to-blood contact that leads to either acute or chronic infection, and can lead to long-term liver damage. If chronically infected, HCV infects the cells of the liver, where it reproduces. Over time, this can lead to scarring and as more and more scarring occurs, it can lead to cirrhosis (where the scars build up and cause malfunction) and serious liver problems. Fortunately, HCV can be cured, preventing further liver damage and reducing the risk of developing liver cancer and other problems.

There are other hepatitis viruses. Hepatitis A and B are vaccine preventable, and hepatitis D and E are very rare in the U.S. There is no vaccine for HCV.

2. How is hepatitis C transmitted?

Hepatitis C is mainly transmitted from blood: When HCV-infected blood gets into you. The main way it is transmitted today is through the sharing of injection equipment: syringes, cookers, cotton, and water. If HCV infected blood gets in or on any of these injection items ("works"), they can transmit HCV to the next person who uses them.

Hepatitis C is not commonly transmitted through sex, especially in HIV-negative heterosexuals. In people living with HIV, especially men who have sex with men (MSM), the risk is higher and sexual transmission of HCV does happen in this group. HCV has been found in the semen and rectal fluids of HIV-positive MSM; sexual practices that can lead to bleeding, including but not limited to fisting and rough sex toy play, can transmit the virus during sex.

3. What are the symptoms of hepatitis C infection?

The most common symptom is actually no symptom! Hepatitis C is called "The Silent Epidemic" for a reason: most people who get infected with it, never know they have it. The only way to know for sure is to test for it.

That said, there are different symptoms for different stages. In the acute stage (early infection), there can be flu-like symptoms, dark urine, and clay-colored stools (poop). In the chronic stage (living with HCV until cured), there can be skin problems, cryoglobulinemia (blood disorder), and peripheral neuropathy (discomfort or pain in the hands and feet). In end-stage with cirrhosis (after living with HCV for 20-30+ years for most), there can be fluid retention (especially in the abdomen and legs), cognitive dysfunction or mental confusion, and severe itching. All stages experience fatigue, loss of appetite, and jaundice (yellowing of the skin or eyes). This list is not exhaustive.

Talk with your provider if you experience any symptoms. It's better to be safe than sorry! Many can be managed or treated, and once a person is cured, many of them can go away or become much less problematic.

4. How do I test for hepatitis C?

Hepatitis C testing is a two-step process: first, you take an HCV antibody test; and second, you confirm the result with a viral load (HCV RNA) test.

The HCV antibody test will come up either negative or positive. However, there's a window period before antibodies appear, similar to HIV. It may take up to 6 months to develop HCV antibodies after your most recent exposure. About 1 in 4 persons will clear hepatitis C on their own within six months of infection, but they'll still always show "positive" on an antibody test. Therefore, you'll need to get a viral load test too. If you clear HCV, these antibodies cannot protect you from another hepatitis C infection. So it's important to protect yourself from re-infection.

A viral load test confirms a positive antibody test. If it comes back positive, then you are chronically infected, meaning that you will have it for the rest of your life until you get cured.

A negative HCV antibody test result with a positive viral load test means (1) you were very recently infected and your body hasn't yet produced enough antibodies to come back antibody-positive, or (2) you have a weakened immune system (low CD4 cells) and your body may not be able to produce enough antibodies in response to HCV. In either situation, discuss this with your medical provider.

5. Who should get tested for hepatitis C?

This one is now easy to answer: Everyone! HCV testing is now recommended for everyone over the age of 18 without the need to ask about potential risk factors. Some people, such as those who inject drugs, will need to test routinely.

Risk factors

Anyone with risk factors for HCV should be tested on an ongoing basis if the risks continue. The frequency of testing should be at least once per year, but you may want to do it more frequently if you are injecting drugs or are living with HIV and sexually active.

The following risk behaviors or potential exposures call for routine HCV testing:

- injection drug use, even if just once in your life
- intranasal drug use (sniffing from a straw)
- any incarceration
- getting a tattoo in an unregulated setting
- long-term hemodialysis
- child born to a mother with HCV
- blood exposures on the job, including needle sticks or blood splashes to the eyes

Past medical procedures

Today's blood supply and blood products are very safe, as are organs for transplant. That said, HCV is a relatively recent discovery; we did not screen for it prior to July 1992. You should test for HCV if you received:

- a blood transfusion before July 1992
- an organ transplant before July 1992
- clotting factors before 1987 (clotting factors now have all viruses removed, including HCV by coincidence, hence the difference from blood transfusions or organ transplants)

Other conditions and circumstances
- HIV infection
- people starting PrEP (pre-exposure prophylaxis)
- people on PrEP (recommended monitoring)
- organ donors
- people with unexplained chronic liver disease

6. Can hepatitis C be cured?

Yes, and it is really pretty easy to cure these days! The old days of HCV treatment where you had to take pills every day and do an injection once a week for a year and maybe get lucky and get cured are long behind us. Today, HCV direct-acting antivirals, or DAAs, are all oral (pills only), and taken once per day for as little as 8-12 weeks (rarely 24 weeks). They are usually very well tolerated with few side effects, all of which are usually very mild. Once cured, your risk of ongoing HCV-related liver disease will stop and you'll likely reap a host of additional health benefits.

Benefits of HCV cure
- Negative HCV viral load for life
- Disappearance of HCV from the liver
- Normalization of AST, ALT, and GGT (liver function enzymes)
- Platelet increase in patients with thrombocytopenia
- Reduced risk of developing cirrhosis
- Reversion of fibrosis and, in some cases, cirrhosis
- Disappearance of esophageal varices (dilated blood vessels in the esophagus), which can burst
- Reduced risk of progression to liver cancer
- Reduced risk of decompensated liver disease
- Reduced risk of progression to liver failure and liver transplant
- Eliminates risk of transmission to drug using or sexual partners
- Eliminates risk of mother-to-child transmission
- Improved quality of life
- Reduction of psychological distress (anxiety, depression, etc.)
- Elimination of HCV-related stigma
- Lessens healthcare utilization and costs
- Return to the workforce and/or improved productivity

SOURCE: RUI MARINHO, 2014

HCV testing now free

According to the Hepatitis Plan (see Briefly), "In 2020, the U.S. Preventive Services Task Force (USPSTF) issued a Grade B recommendation that all adults aged 18–79 years be screened for hepatitis C, which will result in hepatitis C screening without cost-sharing [such as co-pays] for most people with Medicare, Medicaid, or private health insurance. These updated screening recommendations should result in greater numbers of adults being diagnosed with hepatitis C. However, these screening recommendations will only reach people engaged in the health care system."

Hepatitis C Direct-Acting Antivirals (DAAs)

Preferred regimens based on treatment guidelines from the American Association for the Study of Liver Diseases. Available at hcvguidelines.org
MEDICATIONS LISTED IN ALPHABETICAL ORDER

BRAND NAME	GENERIC (COMMON) NAME	MANUFACTURER	GENOTYPE	COPAY CARD	PATIENT ASSISTANCE PROGRAM	GENERIC AVAILABLE
Epclusa	**sofosbuvir/velpatasvir** (SOF/VEL)	Gilead AUTHORIZED GENERIC: Asegua Therapeutics LLC	1 2 3 4 5 6	✔*	✔	✔*
Harvoni	**sofosbuvir/ledipasvir** (SOF/LDV)	Gilead AUTHORIZED GENERIC: Asegua Therapeutics LLC	1 4 5 6	✔*	✔	✔*
Mavyret	**glecaprevir/ pibrentasvir** (GLE/PIB)	AbbVie	1 2 3 4 5 6	✔	✔	✘
Vosevi	**sofosbuvir/velpatasvir/ voxilaprevir** (SOF/VEL/VOX)	Gilead	1 2 3 4 5 6	✔	✔	✘
Zepatier	**grazoprevir/elbasvir** (GZR/EBR)	Merck	1 4	✘	✔	✘

* Authorized generic, with co-pay card, available

Epclusa

sofosbuvir/velpatasvir (SOF/VEL)

DRUG CLASS
sofosbuvir: Nucleotide analog NS5B polymerase inhibitor; **velpatasvir:** NS5A inhibitor

GENOTYPE
1 2 3 4 5 6

MANUFACTURER
BRAND: **Gilead Sciences**; AUTHORIZED GENERIC: **Asegua Therapeutics LLC**

AWP
BRAND (400/100 MG AND 250/50 mg TABLETS): **$29,904 / month**; AUTHORIZED GENERIC (400/100 mg TABLETS ONLY): **$9,600 / month**

DOSE

One tablet once daily with or without food. Pellets for pediatric use now available. Treatment is usually 12 weeks, but ribavirin may be added or treatment may be extended to 24 weeks for certain patients.

Each tablet used for adults contains 400 mg of sofosbuvir and 100 mg of velpatasvir. New oral pellet formulas approved in June (200 mg SOF/50 mg VEL or 150 mg SOF/37.5 mg VEL) now allow dosing in children age 3 and older (as opposed to age 6 and older previously), based on weight. (See Briefly, page 6.)

The brand name is dispensed in a bottle; the authorized generic is dispensed in a blister pack. The authorized generic was created to help lower cost and has identical ingredients as the brand name.

Take your missed dose as soon as possible unless it is less than 12 hours until your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Epclusa is a very well-tolerated medication with minimal side effects. Indeed, in clinical trials, very few people—0.2%— discontinued treatment due to side effects, and real-world experience has been similar. In patients without cirrhosis or in those with compensated cirrhosis, the most commonly reported side effects are headache and fatigue. Less frequently reported included nausea, insomnia, and asthenia (weakness). The majority of these side effects are considered to be mild and occurred at similar rates to placebo in clinical trials. Similar side effects can occur in patients with decompensated cirrhosis, in addition to diarrhea. Again, these are all considered mild to moderate in severity; very few people have to discontinue treatment because of them. Epclusa has not been studied in pregnant women or nursing mothers, so its impact on fetal development or nursing babies is unknown. Pregnant women or women who are trying to become pregnant should avoid use if the addition of ribavirin is required (see ribavirin page).

POTENTIAL DRUG INTERACTIONS

Before starting Epclusa, be sure to tell your medical provider or pharmacist about all of the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is important to report any changes to your medications as they happen during treatment. Epclusa should not be taken within 4 hours of antacids. If taking H2-receptor antagonists (used for heartburn), take Epclusa at the same time or separate by 12 hours at a dose that does not exceed doses comparable to famotidine 40 mg twice per day. Use of proton pump inhibitors (PPI) is not recommended, but if medically necessary, Epclusa should be taken with food and 4 hours before taking a PPI comparable to omeprazole 20 mg or lower. Epclusa should not be taken with the following HIV medications: efavirenz or tipranavir/ritonavir. Use caution and monitor renal function when taking Epclusa with tenofovir disoproxil fumarate (TDF). Avoid use of Epclusa if taking TDF with an HIV protease inhibitor, ritonavir, or cobicistat due to possible increase in TDF concentrations resulting in adverse reactions. It should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine, as they reduce the concentrations of both components of Epclusa and may reduce its effectiveness. It cannot be taken with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should determine if your statin should be continued or changed during treatment with Epclusa. No sofosbuvir-based HCV regimens may be used with amiodarone due to possible symptomatic bradycardia (slow heart rate). Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. Consult a medical provider should any of these symptoms occur.

MORE INFORMATION

Epclusa is a pangenotypic (active against all 6 genotypes), once-per-day regimen that has minimal side effects and high cure rates.

Epclusa can be used in several special populations. It can safely be used in people with kidney disease, including those on dialysis, with no need for dosage adjustment. Any child with HCV age 3 or older can now take Epclusa. It is also recommended for use in people after they receive a liver transplant.

Epclusa is taken for 12 weeks by people without cirrhosis or who have compensated cirrhosis. Ribavirin is added for people who have decompensated cirrhosis, or treatment is extended to 24 weeks if someone is not eligible for ribavirin.

See hcvguidelines.org for additional information on clinical studies and treatment recommendations.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Epclusa, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could worsen or reactivate during or after DAA treatment, potentially leading to serious liver problems, including liver failure or death. Patients with current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 37 for more information and consult your medical provider.

Harvoni

sofosbuvir/ledipasvir (SOF/LDV)

DRUG CLASS
sofosbuvir: Nucleotide analog NS5B polymerase inhibitor; **ledipasvir:** NS5A inhibitor

GENOTYPE
1 4 5 6

MANUFACTURER
BRAND: **Gilead Sciences**; AUTHORIZED GENERIC: **Asegua Therapeutics LLC**

AWP
BRAND (ALL AVAILABLE DOSES: **$37,800/ month**;
AUTHORIZED GENERIC 400/90mg TABLETS ONLY: **$14,400 / month**

DOSE

One tablet once daily with or without food. Treatment is usually 12 weeks, but ribavirin may be added or treatment may be extended to 24 weeks for certain patients. In some cases, an 8-week treatment duration is possible. See the first page of the package insert.

Each tablet used for adults contains 400 mg of sofosbuvir and 90 mg of ledipasvir. Dosing in children age 3 and older is based on body weight (see below), and smaller tablets as well as packets of pellets are available to use in pediatrics. The brand name is dispensed in a bottle; the authorized generic is dispensed in a blister pack. The authorized generic was created to help lower cost and has identical ingredients as the brand name.

Take missed dose as soon as possible unless it is less than 12 hours until your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Harvoni is generally well tolerated, and very few people need to discontinue treatment due to side effects. The most commonly reported side effects are fatigue, headache, nausea, diarrhea, and insomnia, and are all considered to be mild in severity. Additional side effects observed in patients with decompensated cirrhosis or after liver transplant were thought to be due to their medical condition rather than the medication. Harvoni has not been studied in pregnant or nursing women, so its impact on fetal development or nursing babies is unknown. Pregnant women or women who are trying to become pregnant should avoid use if the addition of ribavirin is required (see ribavirin page).

POTENTIAL DRUG INTERACTIONS

Before starting Harvoni, be sure to tell your medical provider or pharmacist about all of the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is also important to inform them of any changes to your medications as they happen during treatment. Harvoni should not be taken within 4 hours of antacids. If taking H2-receptor antagonists, take Harvoni at the same time or separate by 12 hours at a dose that does not exceed doses comparable to famotidine 40 mg twice per day. Use of proton pump inhibitors (PPI) is not recommended, but if medically necessary, Harvoni should be taken at the same time as a PPI comparable to omeprazole 20 mg or lower under fasted conditions (on an empty stomach). Harvoni should not be taken with the HIV medication tipranavir/ritonavir. Use caution and monitor renal function when taking Harvoni with tenofovir disoproxil fumarate (TDF). Avoid use if taking TDF with an HIV protease inhibitor, ritonavir, or cobicistat due to possible increase in TDF concentrations resulting in adverse reactions. It should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine, as they reduce the concentrations of both components of Harvoni and may reduce its effectiveness. Do not take Harvoni with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should decide if your statin should be continued or changed during treatment with Harvoni. No sofosbuvir-based HCV regimens are to be used with amiodarone due to possible symptomatic bradycardia (slow heart rate). Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. Consult a medical provider should any of these symptoms occur.

MORE INFORMATION

Harvoni was an exciting development for treating HCV in 2014 as it was the first one-pill, once-daily regimen with minimal side effects and high cure rates with treatment durations ranging from 8 to 24 weeks. Although there are now many treatment options available, Harvoni is still commonly used.

Harvoni can be used in several special populations. It can safely be used in people with kidney disease, including those on dialysis, with no need for dosage adjustment. It is FDA approved for use in children age 3 and older. It is also recommended to be used in people after they receive a liver transplant.

See hcvguidelines.org for additional information on clinical studies and treatment recommendations.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Harvoni, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could worsen or reactivate during or after DAA treatment, potentially leading to serious liver problems, including liver failure or death. People with current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 37 for more information and consult your medical provider.

Harvoni dosing

BODY WEIGHT	DOSING OF TABLETS OR ORAL PELLETS	HARVONI DAILY DOSE
At least 77 lbs. (35 kg)	One 400/90 mg tablet daily **or:** Two 200/45 mg tablets daily **or**: Two 200/45 mg packets of pellets daily	400/90 mg daily
37.4–77 lbs. (17 kg to less than 35 kg)	One 200/45 mg tablet daily **or**: One 200/45 mg packet of pellets daily	200/45 mg daily
Less than 37.4 lbs. (17 kg)	One 150/33.75 mg packet of pellets daily	150/33.75 mg daily

Zepatier

grazoprevir/elbasvir (GZR/EBR)

DRUG CLASS
grazoprevir: HCV NS3/4A protease inhibitor;
elbasvir: HCV NS5A inhibitor

GENOTYPE 1 4

MANUFACTURER
Merck

AWP
$8,736 / month

DOSE

One tablet once daily with or without food. Each tablet contains 100 mg of grazoprevir and 50 mg of elbasvir. The number of weeks on treatment depends on genotype, previous therapy, and presence of NS5A polymorphisms (mutations that may make the Zepatier less effective). Ribavirin may also be added in patients with certain baseline NS5A polymorphisms. See treatment duration tables at positivelyaware.com/drug-guides/zepatier.

Take missed dose as soon as possible unless it is less than 12 hours until your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Zepatier is very well tolerated with minimal side effects. In clinical trials, very few people —around 1%—discontinued treatment due to side effects. The most commonly reported side effects are fatigue and headaches. These side effects are considered mild and are comparable in patients with and without cirrhosis. Nausea, insomnia, and diarrhea have also been reported. Zepatier has not been studied in pregnant women or nursing mothers, so its impact on fetal development or nursing babies is unknown. Pregnant women or women who are trying to become pregnant should avoid use if the addition of ribavirin is required (see ribavirin page).

POTENTIAL DRUG INTERACTIONS

Before starting Zepatier, be sure to tell your medical provider or pharmacist about all of the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is important to report any changes to your medications as they happen during treatment. Zepatier should not be taken with HIV medications that require a booster (meaning they require another medication such as ritonavir or cobicistat to increase the drug levels in the body), such as atazanavir, darunavir, or elvitegravir. Zepatier should also not be taken with the HIV medications efavirenz or etravirine. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should determine if your statin may be continued or changed during treatment with Zepatier. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Unlike several of the other HCV medications, Zepatier does not interact with acid reducing agents. It should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine. It cannot be taken with St. John's wort; in general, herbal products should be avoided due to lack of information regarding potential for interaction.

MORE INFORMATION

Zepatier was an excellent medication upon its release, but it is not used much any longer as the other newer DAAs are preferred due to an additional lab test required, possible need for ribavirin addition, and limited genotypes (only 1 and 4) covered. If you have HCV genotype 1a, you will need to get an HCV drug resistance blood test before starting Zepatier. If your hepatitis C virus is resistant, you will have to add ribavirin and take the combination for an additional four weeks (16 weeks total). This improves its effectiveness and allows the medication to overcome resistance, dramatically improving your chances for cure.

It is an excellent regimen for patients with kidney disease, including those on hemodialysis, with 99% achieving a cure. NS3/4A protease inhibitors, such as grazoprevir, are contraindicated in people with moderate or severe liver impairment (Child-Pugh B/C), which is also called decompensated cirrhosis. Using Zepatier in decompensated cirrhosis may cause significantly higher amounts of grazoprevir in the blood and may increase ALT (a liver enzyme).

For more information, go to hcvguidelines.org.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Zepatier, a blood test is recommended to check for hepatitis B (HBV) infection. HBV infection could worsen or reactivate during or after DAA treatment, potentially leading to serious liver problems, including liver failure or death. Patients with current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 37 for more information and consult your medical provider.

RECOMMENDED TREATMENT REGIMEN AND DURATION in persons with HCV genotype 1 or 4

Genotype 1a, treatment-naïve or PegIFN/RBV-experienced* without baseline mutations**	Zepatier for 12 weeks
Genotype 1a, treatment-naïve or PegIFN/RBV-experienced* with baseline mutations**	Zepatier + ribavirin for 16 weeks
Genotype 1b, treatment-naïve or PegIFN/RBV-experienced*	Zepatier for 12 weeks
Genotype 1a or 1b, PegIFN/RBV/PI-experienced***	Zepatier + ribavirin for 12 weeks
Genotype 4, treatment-naïve	Zepatier for 12 weeks
Genotype 4, PegIFN/RBV-experienced*	Zepatier + ribavirin for 16 weeks

* Pegylated interferon + ribavirin
** NS5A polymorphisms at amino acid positions 28, 30, 31, 93
*** Pegylated interferon + ribavirin + NS3/4A protease inhibitor (boceprevir, telaprevir, simeprevir)

NOTES:
Testing for baseline NS5A polymorphisms is not required for genotype 1b or in patients on hemodialysis.
For patients with CrCl greater than 50 mL per minute, the recommended dosage of ribavirin is weight-based: less than 145 pounds (66 kg) = 800 mg per day; 146–176 pounds (66–80 kg) = 1,000 mg per day; 177–231 pounds (81–105 kg) = 1,200 mg per day; and greater than 231 pounds (105 kg) = 1,400 mg per day. All are administered in two divided doses with food.

Mavyret

glecaprevir/pibrentasvir (GLE/PIB)

DRUG CLASS
glecaprevir: NS3/4A protease inhibitor;
pibrentasvir: NS5A inhibitor

GENOTYPE 1 2 3 4 5 6

MANUFACTURER
AbbVie

AWP
$15,840 / month

DOSE

Three tablets once daily with food. Each tablet contains 100 mg of glecaprevir and 40 mg of pibrentasvir for a total daily dose of 300 mg/120 mg. It is important to take all three tablets at the same time—do not separate throughout the day. See treatment duration tables at positivelyaware.com/mavyret. The number of weeks on treatment depends on such things as cirrhosis status and previous therapy. New oral pellet formula approved in June now allows dosing in children age 3 and older (as opposed to age 12 and older previously), without cirrhosis or with compensated cirrhosis, based on weight. (See Briefly, page 6).

Take your missed dose as soon as possible unless it is less than 12 hours until your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Mavyret is a very well-tolerated medication with minimal side effects. In clinical trials, very few people (about 0.1%) discontinued Mavyret due to side effects. Only headaches and fatigue were reported by clinical trial participants at rates higher than 10% (16% and 11%, respectively), with even fewer reporting nausea or diarrhea. Rates of side effects are not affected by treatment duration, presence of cirrhosis, HIV/HCV co-infection, history of kidney transplant, or adolescence. There are no serious lab abnormalities expected. Mavyret has not been studied in pregnant women or nursing mothers, so its impact on fetal development or nursing babies is unknown.

POTENTIAL DRUG INTERACTIONS

Before starting Mavyret, be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is important to report any changes to your medications as they happen during treatment. Mavyret should not be taken with HIV medications that require ritonavir as a booster, such as atazanavir and darunavir, to increase drug levels. Mavyret should not be taken with the HIV medications efavirenz or etravirine. It should also not be taken with rifampin or carbamazepine due to decreased concentrations of both components of Mavyret. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should determine if your statin may be continued or changed during treatment with Mavyret. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Use of ethinyl estradiol (estrogen)-containing birth control is not recommended due to potential increase in ALT (a liver enzyme). Mavyret should not be used with cyclosporine doses higher than 100 mg daily. It cannot be taken with St. John's wort; in general, herbal products should be avoided due to lack of information regarding potential for interaction.

MORE INFORMATION

Mavyret is a pan-genotypic (active against all 6 genotypes) regimen that cures most people without ribavirin in as few as 8 weeks of treatment. Some people may need to take Mavyret for up to 16 weeks, depending on previous treatment experience and presence of cirrhosis. The overall cure rate (sustained virologic response, or SVR) across all genotypes was 97.5%. It is an excellent regimen for people with kidney disease, including patients on hemodialysis, curing 98% of patients with severe kidney disease in 12 weeks of treatment (EXPEDITION-4) as well as for patients who are post-liver or kidney transplant.

NS3/4A protease inhibitors, such as glecaprevir, are not recommended for people with moderate or severe liver impairment (Child-Pugh B/C), which is also called decompensated cirrhosis.

For more information, GO TO hcvguidelines.org.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Mavyret, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could worsen or reactivate during or after DAA treatment, potentially leading to serious liver problems, including liver failure or death. People with current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 37 for more information and consult your medical provider.

Treatment-naïve patients: If you've never taken HCV treatment before, you'll take it as follows

Genotype	No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1 2 3 4 5 6	8 weeks	8 weeks

Treatment-experienced patients: If you have taken HCV treatment before, you'll take it as follows

Genotype	Previous treatment regimen	No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1	**NS5A inhibitor*** without prior treatment with an NS3/4A protease inhibitor**	16 weeks	16 weeks
1	**NS3/4A protease inhibitor**** without prior treatment with an NS5A inhibitor*	12 weeks	12 weeks
1 2 4 5 6	**Prior treatment** with (peg) interferon, ribavirin and/or sofosbuvir but no other HCV treatment	8 weeks	12 weeks
3	**Prior treatment** with (peg) interferon, ribavirin, and/or sofosbuvir but no other HCV treatment	16 weeks	16 weeks

* In clinical studies, this included ledipasvir/sofosbuvir or daclatasvir + (peg)interferon + ribavirin. Other NS5A inhibitors include elbasvir, velpatasvir, and ombitasvir.

** In clinical studies, this included simeprevir + sofosbuvir, simeprevir, boceprevir, or telaprevir + (peg)interferon + ribavirin.

Vosevi

sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX)

DRUG CLASS
sofosbuvir: Nucleotide NS5B polymerase inhibitor;
velpatasvir: NS5A inhibitor; **voxilaprevir:** NS3/4A protease inhibitor

GENOTYPE 1 2 3 4 5 6

MANUFACTURER
Gilead Sciences

AWP
$29,904 / month

DOSE

One tablet once daily with food. Each tablet contains 400 mg of sofosbuvir, 100 mg of velpatasvir, and 100 mg of voxilaprevir.

Take missed dose as soon as possible unless it is less than 12 hours until your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Vosevi is very well tolerated with minimal side effects. In fact, in clinical trials, very few people—0.2%—discontinued treatment due to side effects. The most commonly reported side effects are headache, fatigue, diarrhea, and nausea. Asthenia (weakness), insomnia, rash, and depression have also been reported, but in less than 10% of people. All adverse events are generally mild to moderate in severity and similar between people with and without compensated cirrhosis. There are no significant lab abnormalities of concern. Vosevi has not been studied in pregnant women or nursing mothers, so its impact on fetal development or nursing babies is unknown.

POTENTIAL DRUG INTERACTIONS

Before starting Vosevi, be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbal products you take, whether they are prescribed, over-the-counter, or illicit. It is important to report any changes to your medications as they happen during treatment. Vosevi should not be taken within 4 hours of antacids. If taking H2-receptor antagonists (used for heartburn), take Vosevi at the same time or separate by 12 hours at a dose that does not exceed doses comparable to famotidine 40 mg twice per day. Use of proton pump inhibitors (PPI) is not recommended, but if medically necessary, Vosevi can be taken with a PPI comparable to omeprazole 20 mg or lower. Vosevi should not be taken with the following HIV medications: efavirenz, atazanavir, lopinavir/ritonavir, or tipranavir/ritonavir. Use caution and monitor renal function when taking Vosevi with tenofovir disoproxil fumarate (TDF). It should not be taken with the rifamycin antimicrobials, such as rifabutin, rifampin, or rifapentine, nor should it be taken with the anticonvulsants carbamazepine, phenytoin, phenobarbital, or oxcarbazepine. It cannot be taken with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction. There are no interactions with methadone or other common medications used for opioid, alcohol, or nicotine dependency. Use with certain statins (cholesterol medicine) may cause increased risk of muscle pain (myopathy) or muscle breakdown (rhabdomyolysis). Your doctor should determine if your statin should be continued or changed during treatment with Vosevi. No sofosbuvir-based HCV regimens may be used with amiodarone due to possible symptomatic bradycardia (slow heart rate). Signs of bradycardia include fainting, dizziness, lightheadedness, weakness, excessive fatigue, shortness of breath, chest pains, and confusion or memory problems. Consult a medical provider should any of these symptoms occur.

MORE INFORMATION

Approved in 2017, Vosevi marks the next generation of Gilead drugs for treatment of hepatitis C and will provide people whose previous treatment failed with a new option to get cured. Of particular importance is Vosevi's effectiveness in people with previous DAA treatment experience and HCV drug resistance. In POLARIS-1, 97% of people with GT1 achieved SVR12 (cure), and neither compensated cirrhosis nor presence of baseline resistance mutations appeared to affect outcomes. This is a wonderful achievement and offers hope to people living with HCV-associated cirrhosis.

NS3/4A protease inhibitors, such as voxilaprevir, are not recommended for patients with moderate or severe liver impairment (Child-Pugh B/C), which is also called decompensated cirrhosis. Using Vosevi in decompensated cirrhosis may cause significantly higher amounts of voxilaprevir in the blood and may increase ALT (a liver enzyme).

In 2019, the FDA approved Vosevi's use for people with kidney disease, including those on dialysis, with no need for dosage adjustment. Although it is not FDA approved for use in HIV co-infection, it may be considered if drug interactions are also assessed. Vosevi is currently only approved for use in adults.

See the chart below for general treatment recommendations and hcvguidelines.org for additional information.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Vosevi, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could worsen or reactivate during or after DAA treatment, potentially leading to serious liver problems, including liver failure or death. Patients with current or past HBV infection should be monitored during HCV DAA treatment, and some may need to take HBV treatment. See HBV Reactivation on page 37 for more information and consult your medical provider.

Genotype	Patients previously treated with an HCV regimen containing:	Length of treatment
1 2 3 4 5 6	NS5A inhibitor*	12 weeks
1a or 3	Sofosbuvir without an NS5A inhibitor**	12 weeks

* In clinical studies, this included daclatasvir, elbasvir, ledipasvir, ombitasvir, and velpatasvir

** In clinical studies, this included sofosbuvir alone or in combination with any of the following: peginterferon/ribavirin, ribavirin, boceprevir, simeprevir, or telaprevir

Ribavirin

ribavirin (RBV)

DRUG CLASS
Nucleoside analog

GENOTYPE
1 2 3 4 5 6

MANUFACTURER
GENERIC CAPSULES/TABLETS: **Manufacturers vary**

AWP (BASED ON 1,200 MG/DAY DOSING)
GENERIC 200 mg TABLET: **$1,389 / month**
GENERIC 200 mg CAPSULE: **$1,601–$1,668 / month**

DOSE

Ribavirin dosage depends on several factors, including indication for treatment, patient lab values, and patient tolerability. It is given in either fixed doses or in doses related to weight (weight-based). The dose range is 600 mg to 1,200 mg per day taken in two divided doses. Ribavirin is now only available as a generic tablet or capsule; other products have been discontinued. It must be taken with food. Ribavirin may be added to direct-acting antiviral (DAA) therapy in people that have severe hepatic impairment (decompensated cirrhosis) or in people who have certain resistance mutations that make the DAA less effective. It should never be taken by itself for treatment of hepatitis C. Use of ribavirin is contraindicated in people with creatinine clearance (CrCl) less than 50 mL/min.

Take missed dose as soon as possible unless it is less than 12 hours until your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

There are two very serious potential side effects associated with ribavirin: anemia and birth defects/miscarriage/stillbirth. The anemia caused by ribavirin can be very severe and can happen very quickly, usually within the first 1–2 weeks of starting treatment. Anemia can cause severe fatigue, dizziness, headaches, and shortness of breath; routine blood testing for anemia, neutropenia, and other blood conditions is recommended. The anemia may also cause or worsen cardiac conditions.

The other major side effect is birth defects or fetal death in pregnant women. Pregnant women, women who are trying to become pregnant, and males whose female partners are pregnant should not take ribavirin. Women of childbearing age and their male sexual partners must use two forms of birth control throughout treatment and for six months post-treatment. It is unknown if ribavirin passes through breast milk or the impact it could have on breastfeeding babies.

Other side effects that have been reported with ribavirin include rash and itching, and there is a small risk of pancreatitis. If you experience any symptoms related to pancreatitis (severe stomach pain that radiates to your back, nausea, vomiting, and/or diarrhea) you should call your advice nurse (when applicable) or go to an emergency department for evaluation. If you have renal (kidney) disease, talk with your medical provider about potential dosage adjustments as the levels of ribavirin can be increased dramatically. Some people who are taking ribavirin experience what is commonly called "riba-rage," that is they get easily irritated and get angry easier.

POTENTIAL DRUG INTERACTIONS

Ribavirin cannot be used with the HIV medication didanosine (Videx-EC, Videx, ddI) as this combination can lead to potentially fatal levels of ddI. Similarly, azathioprine (an immunosuppressive) cannot be used due to increased concentrations of azathioprine. Use caution if ribavirin is given with zidovudine, lamivudine, or stavudine (medications to treat HIV) due to potential for worsening side effects (anemia) and possible loss of HIV viral suppression (controversial if this actually occurs).

MORE INFORMATION

It's not entirely understood how ribavirin works against HCV. It previously played a major part in HCV treatment for years when used in combination with interferon but is now generally reserved for certain patient populations with severe hepatic impairment. We are essentially in the ribavirin-free era with many of the current HCV DAAs.

If you need to take ribavirin, the side effects can be difficult. If you become anemic while on ribavirin, your medical provider may need to adjust the dose accordingly. The anemia often happens quickly, so get blood tests to monitor it early in your treatment. "Riba-rage" is not a common occurrence, but it's good to be aware and (if disclosing HCV status is not an issue) telling the people around you about it so you can get the support you need to minimize its impact.

HEPATITIS C CO-PAY AND PATIENT ASSISTANCE PROGRAMS

Treatment for HCV can be expensive, but the good news is that help is out there. All of the pharmaceutical companies have a patient assistance program (PAP) to help uninsured people, and some also provide help for underinsured people to cover all or part of the costs of their drug. There are also pharmaceutical co-pay programs and non-profit organizations that can help with some additional support for co-pays. Check with each program for details.

Harbor Path
harborpath.org
Provides a single site for all patient assistance program applications for both HIV and HCV medications.

HealthWell Foundation
(800) 675-8416
HealthWellFoundation.org
Their newly formed hepatitis C co-pay assistance program can provide up to $30,000 to eligible patients who are insured and have an annual household income of up to 500% of the federal poverty level.

Link2Labs
Link2labs.com
A discount lab service for uninsured, low income and high deductible insured persons. They have lab services in all states except California, Massachusetts, New Jersey, New York, and Rhode Island. Their easy to use website allows you enter the labs you need, pay for them, find a lab near your zip code and receive your results securely online.

Medicine Assistance Tool
medicineassistancetool.org
A free, confidential program offered by the pharmaceutical industry, this serves as a one-stop shopping site for over 475 public and private patient assistance programs, including around 200 offered by the drug companies themselves. They also have a directory of over 10,000 free or low-cost clinics that can be searched by ZIP code.

Needy Meds
needymeds.com
Provides a one-stop site for patient assistance programs and other discount opportunities for a variety of pharmaceuticals; also has a very useful database to find free and low-cost medical clinics that can be searched by ZIP code.

Patient Access Network Foundation
(866) 316-7263
panfoundation.org
Has an HCV-specific program, and can offer up to $6,800 in financial assistance for eligible individuals.

DRUG NAME	MANUFACTURER	CONTACT INFORMATION
Harvoni	Gilead Sciences	(855-) 7-MYPATH (855) 769-7284 mysupportpath.com
Sovaldi	Gilead Sciences	(855) 7-MYPATH (855) 769-7284 mysupportpath.com
Epclusa	Gilead Sciences	(855) 7-MYPATH (855) 769-7284 mysupportpath.com
Vosevi	Gilead Sciences	(855) 7-MYPATH (855) 769-7284 mysupportpath.com
Mavyret	AbbVie	(800) 222-6885 abbvie.com/patients/patient-assistance.html
Zepatier	Merck	(800) 727-5400 merckhelps.com/zepatier

HEPATITIS C RESOURCES, SERVICES, AND INFORMATION

Caring Ambassadors
hepcchallenge.org
An education and advocacy organization whose website offers a wealth of information for people living with HCV. Their "Hepatitis C Choices" book offers a comprehensive overview of all aspects of the disease.

HELP-4-HEP
(877) 435-7443 toll-free
National hepatitis C support line staffed by peer counselors. Health education, resources, referrals for testing and treatment, and emotional support. Monday–Friday, 9 am–7pm EST.

Hep C Association
hepcassoc.org
An excellent source for HCV news and information.

Hepatitis C.net
hepatitisc.net
Provides education, tools and resources to help you manage your hepatitis C. Articles are written by people living with HCV (including some who have been cured), patient advocates, and medical providers.

HEP Mag
hepmag.com
An excellent resource for hepatitis B and C news and information. Their blog series, written by people living with HCV, and other HCV advocates, is a great source of practical information and inspiration.

The Hepatitis C Mentor and Support Group, Inc.
hepatitiscmsg.org
An excellent resource for HCV support groups throughout New York, with links to many other resources for people living with HCV. They publish an excellent newsletter, too.

infohep
infohep.org
Based in the U.K., this is an excellent resource for viral hepatitis news and education.

National AIDS Treatment Advocacy Project
natap.org
Easily the best website for scientific results from HIV and HCV conferences and academic articles.

Treatment Action Group
treatmentactiongroup.org
National advocacy, research, and policy think tank on HIV, hepatitis C, and tuberculosis. They produce fact sheets, policy papers and an annual Pipeline Report.

Hepatitis C treatment for HIV/HCV co-infected persons

It wasn't that long ago that treating hepatitis C in people living with HIV was limited to two drugs: pegylated interferon and ribavirin. These medications were very challenging: People had to take them for a year, injecting one of them, suffering severe side effects, and worst of all, they were not a very effective cure. Today, HCV treatment is easier than ever—for most people it can be completed in 8–12 weeks (although some people may need 24 weeks), with few pills (and no injections!), and manageable side effects that are usually quite mild. Best of all, there's a high cure rate—between 90 to 100%. These new treatments also work very well in people living with HIV. HIV infection might complicate treatment, but it's nothing that can't be managed, and you can still be cured of HCV.

Following are some key points for people living with HIV and HCV. This information comes from the recommendations from the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents and from AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C, the two leading sets of professional guidelines for managing and treating HIV and HCV. They inform your medical providers in their practice, and offer valuable information for you, too. Read more at hiv.nih.gov and hcvguidelines.org.

Managing HIV in co-infected persons

Managing and treating your HIV maintains your immune system and keeps your HIV viral load undetectable, but it's also good for your HCV. HIV treatment slows down liver damage and reduces the risk of liver-related problems for people who are co-infected.

There could be drug interactions between your HIV and HCV medications, however. In these cases, you may need to switch your HIV regimen to accommodate the HCV treatment. If you can't (or don't want) to switch, you may be able to try an HCV treatment that doesn't interact with your HIV meds. Make sure your HIV and HCV care providers both know about all the medications you're taking so they can help you manage any potential interactions.

The most important thing is that you should not stop taking your HIV medication in order to take HCV treatment. You can take both at the same time.

HCV treatment in persons who are co-infected

Everyone with HCV should get treated, regardless of the amount of liver damage; persons who are co-infected with HCV and HIV are no exception. In fact, AASLD/IDSA Guidance states that people who are co-infected can be treated and re-treated with the same DAAs as those who are living with HCV alone.

The cure rates for people who are HIV/HCV co-infected are extremely good, closely mirroring the rates of people who don't have HIV. Hepatitis C DAAs are easy to tolerate, and the medications have few side effects. There's never been a better time to treat HCV.

When to begin HCV treatment for co-infected persons

As soon as possible. Co-infected persons who are cured of HCV have a lower risk of liver problems down the line. The sooner you get cured, the less likely the liver damage. Even if you find out that your liver has more advanced damage, getting cured reduces the risk of long-term consequences. Additionally, depending upon how much damage there is, you might even be able to reverse it.

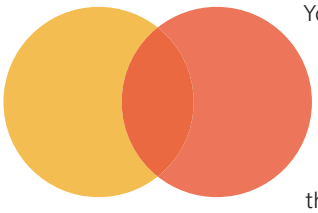
The only time you might consider holding off on HCV treatment is if your CD4 cells are below 200. If this is the case, it might make sense to wait a bit until your HIV medications can suppress the virus and give your immune system a chance to recover. Talk with your medical provider about the best course of action.

Maximizing treatment effectiveness

Adherence to your HIV medications is extremely important for keeping your viral load suppressed and to minimize the risk of developing drug resistance. The same is true for your HCV medications: The better you are at taking them, the better your chance at achieving the cure.

Adherence is more than just taking the pills every day. It includes taking them as prescribed to avoid drug interactions that might weaken the DAA's effectiveness. Check with your medical provider about everything you're taking—prescribed, over-the-counter, or recreational—to make sure you can take them safely and to maximize your chance at a cure.

Preventing reinfection after treatment



You can get hepatitis C more than once. After you've been cured, it will still be important to prevent re-infection with HCV. If you inject drugs, use new syringes and injecting equipment, and avoid sharing them. People who are HIV positive are more vulnerable to sexual transmission of HCV, so minimizing your risk of exposure to HCV through safer sex practices (condoms for anal sex and gloves for fisting, for example) and other forms of harm reduction can offer you protection from re-infection.

After you've been cured, and if you have ongoing risk that could lead to re-infection, you'll want to get tested by taking a viral load test (you'll always have HCV antibodies) to check for HCV.

Manage other potential liver conditions

People living with HIV are at great risk for having "non-alcoholic fatty liver disease," or "NAFLD," even in the absence of HCV or HBV. NAFLD is related to metabolic disorders that are common in people living with HIV, including diabetes, high cholesterol, and obesity (high body-mass index, or BMI; a clinical way of saying "overweight"). These lead to excess fat getting stored in a person's liver that can lead to problems over time, including cirrhosis and liver cancer. Talk to your medical provider about your risk of NAFLD and monitor liver health after you've been cured of HCV. There are no current treatments for NAFLD, but many are being studied. Follow Positively Aware for updates on NAFLD research news and its treatment.

Closing

We can end co-infection. Through improved HCV awareness, routine HCV testing, and expanding HCV treatment, the health and wellbeing of people living with HIV will improve. It's not easy, but we have the tools and the ability.

IF YOU HAVE QUESTIONS about HCV treatment, call The Support Partnership's national hepatitis C helpline: HELP-4-HEP, (877) 435-7443.

To treat, or not to treat?

The answer is *yes*—people who inject drugs should be treated for their hepatitis C

BY **KAITLYN JARRELL, PharmD**

The hepatitis C virus (HCV) affects 2–15% of people living with HIV. Of those affected, *up to 90% are people who inject drugs (PWID)*. This is not shocking given that injection drug use (IDU) is the most common risk factor for acquiring HCV infection. Substance use, past or present, can play a big role in a person's health and access to medical care. Likewise, substance use may impact one's access to HCV treatment.

For people living with HIV/HCV co-infection, this is especially concerning. HIV co-infection speeds up fibrosis (liver scarring) progression in those living with HCV, compared to people who have HCV alone. Thus, an unnecessary delay in therapy may lead to irreversible, yet avoidable, liver damage.

Barriers to HCV treatment in PWID

Studies published over the last decade show HCV treatment to be effective in PWID, but stigma surrounding IDU remains. Some healthcare providers may hesitate to prescribe treatment for PWID out of concern for poor outcomes. For example, poor medication adherence could lead to treatment failure. Continued IDU (without safe injection practices) could lead to re-infection after treatment.

Aside from these concerns, some insurance companies also require pre-treatment screening for drug and alcohol use. These companies may deny medication to people with current or recent use. However, there are no data to support this practice. Screening for drug use is not a reliable method of determining who will complete treatment successfully. Instead, these practices create barriers, increase health care costs, and exclude a population who could benefit from access to treatment. According to current practice guidelines, we should abandon all pre-treatment drug and alcohol screening.

Aside from these outside barriers, there are also internal barriers that can pose a challenge. Recently, I assisted a patient applying for insurance coverage for HCV treatment. The medication was approved, and he did not have a copay. We reviewed goals of therapy, administration, adherence, potential side effects, and pharmacy procedures. He expressed no concerns and there were no known issues to address.

A few weeks went by and when it would have been time for his first refill, he was unreachable by phone. Eventually, I discovered he had not started treatment. He wasn't answering his phone because he was afraid he would be in trouble. He admitted to ongoing IDU and thought it would be best to wait until later because "there was no point." For him, public stigma related to IDU had turned into self-stigma. He did not believe he deserved treatment because he believed he was "doomed" to re-infection even if treatment was successful. Additionally, he had no symptoms of HCV disease, so immediate treatment did not seem to him to be a priority.

Benefits of HCV treatment in PWID

Of course, there *is* a point to treating HCV in PWID. First, the longer HCV goes untreated, the greater the risk of permanent liver damage. Other personal risk factors can accelerate this damage (such as poor diet, alcohol use, HIV

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co-infection, genetics, and type of infection), so even if you have no symptoms, treatment is beneficial. Second, PWID can be successfully treated. IDU does not directly correlate with poor medication adherence or treatment failure, so this should not be used as a reason to deny treatment. Finally, after a person is cured of HCV, they can no longer transmit the virus to others. Thus, treating HCV in PWID also provides public health benefits.

Side note: Keep in mind, there are valid reasons to delay HCV treatment (these include major drug interactions and untreated HIV infection), so be sure to discuss this with your provider. If treatment needs to be delayed for any reason, it is important to stay engaged in care. Your provider can monitor disease progression and recommend treatment when appropriate.

New data supporting HCV treatment in PWID

In October 2020, *Clinical Infectious Diseases* published results from ANCHOR, a single-study evaluating treatment of HCV in PWID with chronic HCV, OUD (opioid use disorder), and IDU. The study was done by researchers at the University of Maryland. It took place at a harm reduction organization's drop-in center in Washington, D.C. In the study, 100 people living with HCV infection, opioid use disorder, and ongoing injection drug use were treated for HCV with direct-acting antivirals (DAAs). Study participants were mostly male (76%) and Black (93%). Of the participants, 58% injected opioids daily. All participants were prescribed 12 weeks of sofosbuvir/velpatasvir (brand name Epclusa) to treat HCV. They were all also offered opioid agonist therapy (OAT).

Opioid agonists (i.e., buprenorphine, methadone) are used to treat opioid use disorder. These therapies work by activating the same receptors as opioids, but to a lesser extent. This helps to reduce both cravings and withdrawal symptoms. Researchers wanted to offer OAT to help reduce risk for study participants, as OAT has been shown to reduce IDU, opioid use, infections, and death from overdose.

The purpose of the study was to find out if PWID could successfully be treated with DAAs. Researchers also wanted to know what percentage of participants would start and continue OAT therapy and determine what factors would affect treatment outcomes. Researchers looked at medication adherence rates, treatment completion rates, and cure or sustained virologic response (SVR) rates.

In the study, 82 of the 100 participants were cured despite imperfect adherence to medication. There were some known interruptions in therapy and many completed treatment more than one week late. In the study, neither on-treatment drug use nor imperfect adherence were associated with treatment failure. However, continuing OAT and completing two or more bottles of sofosbuvir/velpatasvir were associated with achieving cure.

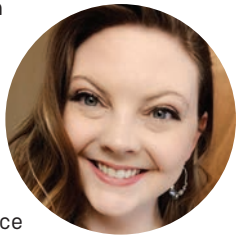
Researchers concluded that offering OAT with HCV treatment in PWID and opioid use disorder can result in high SVR rates while also reducing risks associated with drug use. Further, people who inject drugs can be successfully treated for HCV at rates comparable to those who do not use drugs, even if adherence is not perfect.

You can read the full article, "Concurrent Initiation of Hepatitis C and Opioid Use Disorder Treatment in People Who Inject Drugs," at ncbi.nlm.nih.gov/pmc/articles/PMC7755091/?report=reader.

Conclusion

As stated by current hepatitis C guidelines (hcvguidelines.org) from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), active or recent drug use or a concern for re-infection is *not* a reason in itself to deny HCV treatment. HCV treatment for PWID, in combination with harm reduction services (including syringe exchange programs, routine HCV testing, condom distribution, opioid agonist/antagonist therapies) will be vital to the elimination of HCV.

KAITLYN JARRELL, PharmD is an HCV clinical pharmacist at Indiana University Health (IU Health) in Indianapolis. She works closely with providers specializing in Hepatology and Infectious Diseases within the IU Health system (both in downtown Indy as well as smaller sites across the state) to assist with insurance approvals, patient education, adherence monitoring, and lab follow-up. In addition, she works with the physicians at IU Health Physicians Infectious Disease, primarily assisting with the management of care in patients living with HIV. Dr. Jarrell graduated from the University of Mississippi (Ole Miss) in 2018. After pharmacy school, she completed a two-year residency at IU Health, with her second year specializing in pharmacy administration. She is credentialed as a Board Certified Pharmacotherapy Specialist through the Board of Pharmacy Specialties as well as an HIV Specialist through the American Academy of HIV Medicine.



COVID-19 and viral hepatitis

It seems that treatment of COVID-19 in people with viral hepatitis is no different than for anyone else—unless they have cirrhosis.

"People with underlying cirrhosis of the liver, including those caused by viral hepatitis, may have the potential for a higher risk of developing severe COVID-19 illness and/or more problems from their existing liver disease if they get a COVID-19 infection, with prolonged hospitalization and increased mortality," writes the American Association for the Study of Liver Diseases (AASLD) in an educational flyer. "These patients need to take careful precautions to avoid COVID-19 infection. COVID-19 may affect the processes and procedures for screening, diagnosis, and treatment of viral hepatitis."

That said, there's actually not much known about the impact of COVID-19 on people living with hepatitis B or C, AASLD continued.

Stay on your medications, including those for HBV or HCV, unless your doctor tells you otherwise, both AASLD and the U.S. Centers for Disease Control and Prevention (CDC) say. And get vaccinated against COVID-19, hepatitis A, and hep B as well—this last includes babies.

And CDC wrote this in a separate announcement about substance use: "Why is there an increased risk of COVID-19 infection and complications for individuals with an addiction? Chronic substance use can harm or weaken the body, including the immune system, and make an individual more vulnerable to infection. The effect of certain types of substances used may present greater risks as well, particularly opioids, alcohol, nicotine, and methamphetamines present greater risks for patients to develop severe illness from COVID-19."

Read the four-page flyer from AASLD at aasld.org/sites/default/files/2020-10/COVID19-Flyer-ViralHepatitis.pdf. Read the CDC Q&A at cdc.gov/coronavirus/2019-ncov/need-extra-precautions/liver-disease.html.

Hepatitis B—An overview

A cheat sheet from **Andrew Reynolds** on the most common infectious disease in the world

Hepatitis B (HBV) is a virus that infects the liver, and it is the most common infectious disease in the world. In the United States, an estimated 850,000 to 2.2 million people live with HBV, and about 10% of people living with HIV are co-infected with HBV. In recent years there have been increases in HBV infections among people who inject drugs (PWID) and in mother-to-child transmission in the U.S., directly related to the opioid crisis. Screening, vaccination and prevention, and HBV treatment are essential tools for addressing this public health problem.

Hepatitis B transmission

Hepatitis B is transmitted in much the same way as HIV: It's spread when blood, semen, vaginal fluids, and other body fluids of a person get into a person who is not infected or not protected by immunity (through vaccination or cleared infection). It is also commonly transmitted from mother to child during birth. The following have been associated with risk of transmission:

- vertical (mother to child) transmission
- condomless sex with an infected partner
- sharing syringes and other drug-injection equipment (cookers, cotton, water, etc.)
- sharing household items such as razors or toothbrushes with an infected person
- other blood-to-blood contact
- occupational exposure from needlesticks or other risks of blood-to-blood contact.

Testing for hepatitis B

Most people who become infected with HBV don't know it because it rarely leads to signs or symptoms in the acute or chronic stages of infection. Over time, as the liver is damaged, noticeable symptoms may arise, but screening (testing) for the virus is the only way to determine if you have HBV.

Who should get tested:

Persons from endemic regions of the world:
- persons born in a country with HBV rates greater than 2%
- U.S.-born individuals who did not receive a vaccination, and whose parents were born in a country with HBV rates greater than 8%

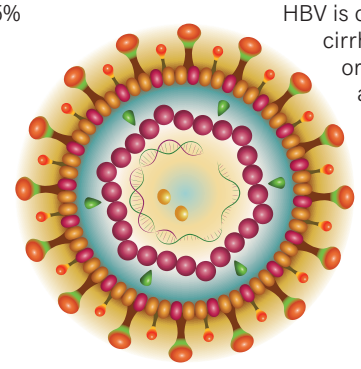
Persons with certain medical conditions:
- women who are pregnant
- babies born to mothers who are HBV-infected
- individuals on hemodialysis
- people needing immunosuppressive therapy (such as chemotherapy or those receiving organ transplants)
- people with chronic HCV infection before undergoing DAA therapy
- donors of blood, plasma, organs, tissues, or semen
- anyone with an unexplained elevated ALT/AST

Risk-based
- people who inject drugs
- men who have sex with men
- people living with HIV
- household, needle-sharing (including injection equipment), or sex partners of people with chronic HBV
- people who are the sources of blood or body fluids resulting in a potential HBV exposure (such as an occupational needle stick or blood splash or sexual assault) where post-exposure prophylaxis may be necessary

SOURCE: CENTERS FOR DISEASE CONTROL AND PREVENTION (cdc.gov/hepatitis)

Vaccination for hepatitis B

Hepatitis B is vaccine preventable. It is safe and highly effective in preventing HBV, successful over 95% of the time. After the first dose, the vaccine is administered one month and six months later. Adults may be eligible for two dose sequence, where the first dose is provided and the second one is given at least one month later (minimum of 28 days after the first one). The vaccine remains effective the rest of your life with no need for a booster shot ever.



MOONNOON-ISTOCK

Who should be vaccinated against HBV:
- all infants, beginning at birth
- all children under the age of 19 years who have not been vaccinated previously
- susceptible sex partners of hepatitis B surface antigen (HBsAg)-positive persons
- sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., more than one sex partner during the previous 6 months)
- anyone seeking care for a sexually transmitted disease
- men who have sex with men
- injection drug users
- susceptible household contacts of HBsAg-positive persons
- health care and public safety workers at risk for blood exposure
- anyone with end-stage renal disease
- residents and staff of facilities for developmentally disabled persons
- travelers to regions with intermediate or high rates of endemic HBV infection
- anyone with chronic liver disease
- anyone living with HIV
- adults with diabetes ages 19–59 years (at the discretion of clinicians for diabetics aged 60 and older)
- anyone seeking protection from HBV infection—acknowledgment of a risk factor is not required

If a person already has HBV, vaccination offers no protection against disease progression or risk of liver disease. Check for immunity or chronic infection before getting vaccinated.

Most people will clear HBV naturally and achieve immunity. Treatment for HBV is called for in anyone with cirrhosis, regardless of ALT or HBV viral load. Similarly, anyone living with chronic HBV who is undergoing immunosuppressive therapy should be treated to prevent an HBV flare-up. There are other scenarios where a person should be treated.

Hepatitis B medications

PREFERRED REGIMENS BASED ON AASLD TREATMENT GUIDELINES

CLASS	BRAND NAME	GENERIC/COMMON NAME	PREFERRED	MANUFACTURER
Nucleoside reverse transcriptase inhibitor (NRTI)	Epivir-HBV	lamivudine (3TC)	✘	GlaxoSmithKline
	Hepsera	adefovir (ADV)	✘	Gilead Sciences
	Baraclude	entecavir (ETV)	✔	Bristol-Myers Squibb
	Vemlidy	tenofovir alafenamide (TAF)	✔	Gilead Sciences
	Viread	tenofovir disoproxil fumarate (TDF)	✔	Gilead Sciences
Interferon-alfa	Intron A	interferon alfa-2b	✔ (in children)	Merck
	Pegasys	peginterferon alfa-2a	✔ (in adults)	Genentech

BLACK BOX WARNING

Hepatitis B reactivation

HBV reactivation has occurred in people co-infected with HCV/HBV while they were either on or shortly after HCV Direct-Acting Antiviral therapy, resulting in hepatic flares, and in some cases a liver transplant or death. This reactivation does not happen to everyone—there were 24 cases reported to the FDA over approximately 2.5 years—but it's a serious enough risk that several precautions should be taken:

People should be screened for HBV with both an HBsAg and an anti-HBc test before starting any HCV DAA (for more details on testing, see page 31).

People who test negative for HBV should be vaccinated against it.

People who test positive for HBV should be assessed to see if they need HBV treatment prior to starting HCV treatment.

People with HBV should be monitored with blood tests and clinically for signs of a hepatic flare-up or HBV reactivation.

People may need to take anti-HBV medications to treat active infection or reactivation.

In addition to these clinical measures taken by a medical provider, patients should watch for any signs or symptoms of HBV reactivation, including the following: **A yellowing of the eyes or skin** (jaundice), loss of appetite, nausea or vomiting, lighter colored stools, pain in the liver (right side of the belly, below the ribs), weakness, or fatigue. If you experience any of these symptoms, call your medical provider and let her/him know.

It's important to note that while this is a potentially serious adverse event that can be very frightening for someone living with HCV/HBV, it does not mean that they cannot be treated for HCV with DAAs. With proper monitoring and appropriate prevention measures, patients can be safely and successfully cured of HCV with no reactivation of HBV.

TACKTACK-ISTOCK

Baraclude

entecavir (ETV)

DRUG CLASS
Nucleoside reverse transcriptase inhibitor (NRTI), "nuke"

MANUFACTURER
Bristol-Myers Squibb

AWP
BRAND, 0.5 mg AND 1 mg TABLETS: **$1,647 / month**
GENERIC, 0.5 mg AND 1 mg TABLETS: **$1,332–1,800 / month**

DOSE

ADULTS (AGE 16 AND OLDER): **Treatment-naïve with no resistance, one 0.5 mg tablet once daily. If lamivudine (Epivir) or telbivudine (Tyzeka, discontinued since December 2016) resistant, one 1 mg tablet once daily.** ADULTS WITH DECOMPENSATED LIVER DISEASE (CHILD-PUGH B OR C): **one 1 mg tablet once daily. Baraclude should always be taken on an empty stomach (no food 2 hours before or 2 hours after taking pill).**

Dose adjustments needed for individuals with kidney disease (see chart below). Baraclude is safe to use in children age 2 years and older, weighing at least 22 pounds (10 kg) or more. Dosing for children is based on weight and should be done in consultation with an experienced medical provider. An oral solution (0.05 mg/mL) is also available to be used in children or for reduced doses in people with kidney disease

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Baraclude is a very well-tolerated medication with minimal side effects. When side effects do occur, they include headache, fatigue, dizziness, and nausea. Baraclude may lead to lactic acidosis, a build-up of lactic acid in the blood, which could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include: yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, and pain, achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen. Report any changes to your medications as they happen. Baraclude is safe to take with all HIV medications, with no drug interactions. Baraclude is eliminated by the kidneys, so it should be avoided with any medications that could negatively affect the kidneys, including chronic use or high doses of NSAIDS (non-steroidal anti-inflammatory drugs, such as Advil, Aleve, ibuprofen, naproxen, or Motrin).

MORE INFORMATION

Baraclude will not cure HBV—currently, no HBV medication will cure you—but it can decrease your risk of long-term complications such as cirrhosis or liver cancer. Baraclude is one of several preferred medications, including Vemlidy, Viread, and pegylated interferon, for the treatment of HBV in both mono- and HBV/HIV co-infected persons. If you are co-infected with HBV/HIV, you should not treat HBV without also treating your HIV. You should be checked for resistance to Epivir (lamivudine) before starting Baraclude. Epivir resistance decreases the effectiveness of Baraclude at the 0.5 mg dose, and it must be increased to 1 mg daily. For individuals with HBV/HCV co-infection, or people at risk of HBV reactivation while undergoing HCV DAA treatment, Baraclude may be one of the medications you could be prescribed to prevent it from happening and is safe to use while being treated for HCV. See **HBV Reactivation** on page 37 for more information and consult your medical provider.

Abrupt discontinuation of Baraclude may cause a severe, acute exacerbation of hepatitis B, which can result in hepatic decompensation and liver failure. If Baraclude is discontinued, your doctor should closely monitor you for symptoms of exacerbation. Do not stop this medication without talking to your doctor first.

DOSAGE REQUIREMENTS for patients with kidney disease

Creatinine clearance (mL/min)	Treatment-naive: 0.5 mg	Lamivudine-refractory, lamivudine/telbivudine resistant, or decompensated cirrhosis: 1 mg
50 or greater	0.5 mg once per day	1 mg once per day
30 to 49	0.25 mg once per day or 0.5 mg every 48 hours	0.5 mg once per day or 1 mg every 48 hours
10 to 29	0.15 mg once per day or 0.5 mg every 72 hours	0.3 mg once per day or 1 mg every 72 hours
Less than 10 or on dialysis	0.05 mg once per day or 0.5 mg every 7 days	0.1 mg once per day or 1 mg every 7 days

NOTES: Doses less than 0.5 mg daily should be given as the oral solution (liquid).
If a person is on hemodialysis, Baraclude should be given after the dialysis session.

Vemlidy

tenofovir alafenamide (TAF)

DRUG CLASS
Nucleoside reverse transcriptase inhibitor (NRTI), "nuke"

MANUFACTURER
Gilead Sciences

AWP
$1,474.50 / month

DOSE

One 25 mg tablet once per day, with food. Take your missed dose as soon as possible unless it is less than 12 hours until your next dose. Never double your dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Vemlidy is a very well-tolerated medication with minimal side effects. The most commonly reported side effects are headache, abdominal pain, fatigue, cough, nausea, and back pain. Not everyone experiences side effects, and among those who do, approximately only 1% stopped taking Vemlidy. Vemlidy is processed by the kidneys, so there is some risk of decreased kidney function. Before starting treatment, patients should have their creatinine clearance (CrCl) assessed. Routine monitoring of glucose and protein in the urine and of serum phosphorus should be standard of care too. If you experience any pain in the extremities, persistent or worsening bone achiness/pain, or fractures with or without muscular pain, consult your medical provider immediately. Although rare, Vemlidy may lead to lactic acidosis, a buildup of lactic acid in the blood, which could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, and pain, achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen. Report any changes in your medications as they happen. Because Vemlidy is related to Viread (tenofovir disoproxil fumarate, TDF), the two medications cannot be taken together. Similarly, Vemlidy cannot be taken with any of the following HIV combination medications, as they contain tenofovir (TDF or TAF): Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Descovy, Genvoya, Odefsey, Stribild, Symfi, Symfi Lo, Symtuza, or Truvada. If taken with the anticonvulsant carbamazepine, Vemlidy dosage should be increased to two tablets once per day. Vemlidy should not be taken with other anticonvulsants, such as oxcarbazepine, phenobarbital, or phenytoin. Vemlidy should also not be taken with the antimycobacterial medications, such as rifabutin, rifampin, and rifapentine, or St. John's wort.

MORE INFORMATION

Vemlidy will not cure HBV—currently, no HBV medication will cure you—but it can decrease your risk of long-term complications such as cirrhosis or liver cancer. Vemlidy is related to Viread but uses a smaller dose that is more efficiently delivered so the risks of kidney disease and loss of bone density appear to be less.

Before starting Vemlidy, you should be tested for HIV. If you are co-infected with HBV/HIV, you should not treat HBV without also treating your HIV to prevent resistance mutations in the HIV. In people with HBV/HIV co-infection, the combination of Emtriva and Vemlidy (or Viread) is the preferred regimen for treatment of HBV. If you have HBV/HIV, and need to switch from any tenofovir-containing regimen—such as Vemlidy—there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. Abrupt discontinuation of Vemlidy may cause a severe, acute exacerbation of hepatitis B, which can result in hepatic decompensation and liver failure. If Vemlidy is discontinued, your doctor should closely monitor you for symptoms of exacerbation. Do not stop this medication without talking to your doctor first. See **HBV Reactivation** on page 37 for more information and consult your medical provider. For individuals with HBV/HCV co-infection, or who are at risk of HBV reactivation while undergoing HCV DAA treatment, Vemlidy is one of the medications you could be prescribed to prevent this from happening and is safe to use while being treated for HCV.

There is no dosage requirement for people with kidney disease who have a CrCl greater than or equal to 15 mL per minute. For those with end stage kidney disease (those who have a CrCl below 15 mL per minute), they can take Vemlidy as long as they are undergoing dialysis. On days of dialysis, Vemlidy should be taken upon completion of dialysis. Vemlidy is safe for people with mild liver damage (Child-Pugh A), but it should not be used in patients with decompensated cirrhosis (Child-Pugh B or C). Vemlidy is currently only approved for use in adults.

Viread

tenofovir disoproxil fumarate (TDF)

DRUG CLASS
Nucleoside reverse transcriptase inhibitor (NRTI), "nuke"

MANUFACTURER
BRAND: **Gilead Sciences**

AWP
300 mg TABLET (BRAND): **$1,504 / month**
300 mg TABLET (GENERIC): **$110–$1,216 / month**
POWDER (BRAND ONLY): **$3,076 / month**

DOSE

One 300 mg tablet once per day (adults), with or without food. Oral powder and smaller, pediatric tablets are also available for children age 2 and older weighing at least 22 pounds. Take your missed dose as soon as possible unless it is less than 12 hours until your next dose. Never double your dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Viread is a very well-tolerated medication with minimal side effects. The most commonly reported side effects are diarrhea, nausea, asthenia (muscle weakness), headache, depression, and abdominal pain. Other, more rarely reported side effects include rash, excessive gas, and generalized pain and achiness, including back pain. Nervous system side effects include depression, insomnia, peripheral neuropathy, and dizziness. Viread may lead to decreases in bone mineral density (BMD); patients should be monitored for osteoporosis or osteopenia. Viread is processed by the kidneys so there is risk of kidney toxicity, including acute renal failure. Before starting treatment, patients should have their creatinine clearance (CrCl) assessed. Routine monitoring of glucose and protein in the urine and of serum phosphorus should be standard of care too. If you experience any pain in the extremities, persistent or worsening bone achiness/pain, or fractures with or without muscular pain, consult your medical provider immediately. Viread may lead to lactic acidosis, a buildup of lactic acid in the blood, which could be fatal. Signs and symptoms of lactic acidosis include feeling very weak or excessively fatigued, difficulty breathing, stomach pain with nausea and vomiting, feeling cold and chills (especially in arms and legs), dizziness and light-headedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately. Two liver conditions, hepatomegaly (enlarged liver) or steatosis (fatty liver), may occur. Signs and symptoms of these liver conditions include yellowing of the eyes and/or skin (jaundice), dark colored urine, light colored stools, nausea, loss of appetite, and pain, achiness or tenderness of the liver (lower right side of the belly, below the ribcage and next to the belly button).

POTENTIAL DRUG INTERACTIONS

Be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbs you take, whether they are prescribed, over-the-counter, or illicit, before starting this regimen. Report any changes to your medications as they happen. Do not take Viread with the HBV treatment Hepsera. Because Viread is related to Vemlidy (tenofovir alafenamide, TAF), the two medications cannot be taken together. Similarly, Viread cannot be taken with any of the following HIV combination medications, as they contain tenofovir (TDF or TAF): Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Descovy, Genvoya, Odefsey, Stribild, Symfi, Symfi Lo, Symtuza, or Truvada. Viread reduces the level of Reyataz, meaning that Reyataz 300mg must be boosted with Norvir 100 mg or Tybost 150 mg (taken with food) when used together. Kaletra, boosted Prezista and boosted Reyataz increase Viread levels but do not require dose adjustments. This interaction may increase Viread-related side effects; routine monitoring recommended. Viread should be avoided with any medications that could negatively affect the kidneys, including chronic use or high doses of NSAIDS (non-steroidal anti-inflammatory drugs, such as Advil, Aleve, ibuprofen, naproxen, or Motrin).

MORE INFORMATION

Viread will not cure HBV—currently, no HBV medication will cure you—but it can decrease your risk of long-term complications such as cirrhosis or liver cancer.

Viread (and its related drug Vemlidy) are also HIV medications. Before starting Viread, you should be tested for HIV. If you are co-infected with HBV/HIV, you should not treat HBV without also treating your HIV to prevent resistance mutations in the HIV. In people with HBV/HIV co-infection, the combination of Emtriva and Vemlidy (or Viread) is the preferred regimen for treatment of HBV. For individuals with HBV/HCV co-infection, or who are at risk of HBV reactivation while undergoing HCV DAA treatment, Viread is one of the medications you could be prescribed to prevent this from happening. Viread is safe to take with HCV DAAs, but you should be monitored for side effects if it is used with Epclusa, Harvoni, or Vosevi.

Viread is safe to use in children age 2 years and older, weighing at least 22 pounds (10 kg) or more. Dosing in children is based on weight and should be done in consultation with an experienced medical provider. For people with kidney disease, there may also be a need for dose adjustments. See the chart below for recommendations, and make sure you are routinely monitored by your medical provider while taking this treatment.

DOSAGE INTERVAL ADJUSTMENT for adults with altered creatinine clearance (mL/min)

	50 or greater	30-49	10-29	Hemodialysis patients
Recommended 300 mg dosing interval	Every 24 hours	Every 48 hours	Every 72–96 hours	Every 7 days or after approximately 12 hours of dialysis; doses are to be taken after dialysis

Pegasys; Intron A

peginterferon alfa-2a; interferon alfa-2b

DRUG CLASS
Interferon-alfa

MANUFACTURER
PEGASYS: **Genentech**
INTRON A: **Merck**

AWP
PEGASYS: **$ 1,225.79 / week**
INTRON A: **Varies based on product and weight-based dosing**

DOSE

Pegasys (preferred in adults)
In adults, 180 mcg injected subcutaneously once per week for 48 weeks.

Intron A (preferred in pediatrics)
PEDIATRICS (AGE 1 AND OLDER): 3 million IU/m2 subcutaneously three times a week (TIW) for the first week of therapy followed by dose escalation to 6 million IU/m2 subcutaneously TIW (maximum of 10 million IU TIW) injections.
ADULTS: 30–35 million IU/m2 subcutaneously as 5 million IU daily or 10 million IU TIW.

There are no food restrictions for either interferon product. Take your missed dose as soon as possible on the same day or the next day and then continue your regular dosing schedule. If multiple days are missed, check with your medical provider about what to do. Never double dose or take doses too close together.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Interferon has a high number of side effects associated with it: fatigue, headaches, nausea, chills, insomnia, anemia, pyrexia (fever), injection site reactions, loss of appetite, rash, myalgia (muscle pain), neutropenia, irritability, depression, alopecia (hair loss), dyspnea (shortness of breath), arthralgia (joint pain), pruritus (itching), flu-like feelings, dizziness, diarrhea, cough, weight loss, vomiting, unspecified pain, dry skin, anxiety, abdominal pain, leukopenia, and thrombocytopenia. In the case of the psychiatric/emotional side effects, interferon has been associated with depression, anxiety and, in rare cases, suicidal thoughts. If you have a history of any of these conditions, talk to your provider before starting HBV treatment with interferon. It does not mean you can't take interferon (or another HBV treatment), but you want to watch for signs of worsening depression and be able to take preventative actions ahead of time. As an injectable, injection site reactions (redness, swelling, and/or itching) and inflammation are common. If you have autoimmune hepatitis or are allergic to any of the ingredients in interferon, you should not take it.

POTENTIAL DRUG INTERACTIONS

There are few drug interactions with interferon. However, be sure to tell your medical provider or pharmacist about all the medications, supplements, and herbal products you take, whether prescribed, over-the-counter, or illicit, before starting this drug, and inform them of any changes to your medications as they happen. Caution is advised when taken with warfarin, phenytoin, or methadone. Methadone levels may increase due to interferon, so methadone levels and signs and symptoms of a stronger narcotic effect should be monitored. Use caution when taken in combination with other medications with similar side effects, such as neutropenia, as this could cause worsening symptoms.

MORE INFORMATION

Although interferon is no longer used in HCV treatment, it still has a potential role for treating HBV. That said, it is rarely used for HBV, and the World Health Organization does not include it in their HBV guidelines. Interferon will not cure HBV—currently, no HBV medication will cure you—but it can decrease your risk of long-term complications such as cirrhosis or liver cancer. It has some clinical advantages over the oral antivirals, as it's a finite therapy and it doesn't lead to HBV resistance, but it's a difficult medication to take (injection) and tolerate. Other medications are easier to take (oral) with fewer side effects. Interferon is less safe for people who have any level of cirrhosis and should never be used by someone with decompensated cirrhosis. The AASLD Guidelines for the Treatment of Hepatitis B do include pegylated interferon alfa, along with Baraclude (entecavir or ETV), Viread (tenofovir disoproxil fumarate or TDF), and Vemlidy (tenofovir alafenamide or TAF) as first-line agents in the treatment of HBV. If you need HBV treatment, talk to your medical provider about which option is best for you.

Hepatitis B Medication Patient Assistance Programs

You may have challenges accessing HBV treatments, but help is out there. All of the pharmaceutical companies that market HBV medications have a patient assistance program (PAP) to help uninsured or underinsured people cover all or part of the costs of their drug. If you are insured but have a high co-pay, there are co-pay assistance services, too. Additionally, there are non-profit organizations that can provide some support for co-pays. Check with each program for details.

The following organizations can help you find low-cost medical care, navigate the health care access and insurance field, or provide financial assistance to help with HBV costs and related health care expenses. These programs have different eligibility requirements, and some have limited funds each year. Call for more information:

HealthWell Foundation
(800) 675-8416
HealthWellFoundation.org
Currently does not have an HBV fund, but things may change as funding and donations come in. This is also a good resource for other diseases and conditions ranging from acute myeloid leukemia to urea cycle disorders.

Needy Meds
needymeds.com
A one-stop site of patient assistance programs and other discount opportunities for a variety of pharmaceuticals; also has a very useful database to find free and low-cost medical clinics that can be searched by ZIP code.

Partnership for Prescription Assistance
pparx.org
A free, confidential program offered by the pharmaceutical industry, this serves as a one-stop site for over 475 public and private patient assistance programs, including about 200 offered by the drug companies themselves. They also have a directory of over 10,000 free or low-cost clinics searchable by ZIP code.

Patient Access Network Foundation
(866) 316-7263
panfoundation.org
Does not have a current HBV program, but this may change, depending on new funding and donations to the organization. A great site for other resources and tips for managing prescription medication costs.

Patient Advocate Foundation
(800) 532-5274
copays.org/diseases/hepatitis-c
Does not have a current HBV program, but this may change, based on new funding and donations to the organization. They also assist patients with insurance denials and access to care issues.

Hepatitis B resources, services and information

American Liver Foundation
liverfoundation.org
Provides information and fact sheets on a wide range of liver diseases, including HBV and HCV. They have local chapters throughout the U.S. and often have educational and awareness events. Check their website for activities and events in your area.

Asian Liver Center, Stanford University
med.stanford.edu/liver
A world-renowned program working to eliminate the stigma of HBV, as well as prevent transmission and reduce deaths from liver disease among Asian Americans in the U.S. and among Asians throughout the world. It is an excellent resource for patients and providers.

Coalition Against Hepatitis for People of African Origin (CHIPO)
hepb.org research-and-programs/chipo
African immigrants have high rates of HBV, anywhere from 5% to 15%. CHIPO is a national community coalition comprised of organizations and individuals interested in addressing the high rates of hepatitis B among African communities in the U.S. CHIPO serves as a forum for sharing information and best practices, and improving national capacity to improve hepatitis B awareness, testing, vaccination and treatment among highly affected African communities.

Hepatitis B Foundation
hepB.org
Provides a wealth of information on HBV in all areas from awareness to prevention to treatment. They offer educational resources via fact sheets, videos, podcasts, and blog posts. They also have an excellent section on liver cancer via their Liver Cancer Connect program. Information is offered in a variety of languages.

HepB United
Hepbunited.org
A national coalition devoted to reducing the health disparities associated with hepatitis B by increasing awareness, screening, vaccination and linkage to care for high-risk communities across the U.S. This is an excellent site if you want to keep up with HBV news and updates, as well as policy and advocacy.

Know Hepatitis B
cdc.gov/knowhepatitisB/index.htm
An education and social campaign, Know Hepatitis B offers a number of materials including fact sheets, posters, videos and more on HBV in a wide variety of languages. There is also an excellent resource section for medical providers.

MEDICATION	MANUFACTURER	CONTACT INFORMATION
Viread (tenofovir disoproxil)	Gilead	(800) 226-2056 gileadadvancingaccess.com
Vemlidy (tenofovir alafenamide)	Gilead	(800) 226-2056 gileadadvancingaccess.com
Pegasys (pegylated interferon)	Genentech	(877) GENENTECH (877) 436-3683 gene.com/patients/medicines/pegasys

Hepatitis D: Wait...there's *another* hepatitis virus?

BY **ANDREW REYNOLDS**

You probably know a little something about hepatitis A, B, and C. I'm hoping you've been vaccinated against hep A and B, and if you're reading the Viral Hepatitis Drug Guide over the years, you know a lot about hep C. These really are the three types of viral hepatitis you should be most aware of as they are the most common types in the United States.

Worldwide, there is also hepatitis D (HDV) and E (HEV). Both are very rare in the U.S., but there has been an increase of HDV in recent years. Hepatitis D is most common in Eastern and Southern Europe, throughout the Mediterranean and Middle East, and parts of Asia and Africa. It is rare in the Americas, but it has been found in South America along the Amazon Basin.

This article provides a broad overview of HDV, and if you have any questions, check with your medical provider.

What is hepatitis D?
HDV, sometimes referred to as "hepatitis delta," is a liver infection caused by the hepatitis D virus. Hepatitis D is what's called a "satellite virus," that is, it needs something else to make you vulnerable to infection. In this case, only people with hepatitis B can acquire HDV. You can get both viruses at the same time (co-infection), or you can get HDV later after already having HBV (superinfection).

HBV/HDV co-infection: This is when a person acquires both viruses at the same time. Symptoms may be felt, but most people can fight both viruses off, and fewer than 5% of people will keep infection chronically where it will not go away.

HBV/HDV superinfection: This is when someone already has HBV, and then later acquires HDV. When this happens, the symptoms can be severe. In superinfection, HDV usually becomes chronic: About 90% of people who get HDV after already having HBV develop an HDV infection that will never go away. People with HBV/HDV superinfection are also more likely to have more severe liver damage over time.

How is hepatitis D transmitted?
Hepatitis D is transmitted much the same way as HBV or HIV: Through blood or sexual fluids. Vertical transmission (when the virus is passed from mother to child during pregnancy) of HDV is very rare. Hepatitis D can be transmitted the following ways:

- Condomless sex
- Sharing syringes or other injecting equipment
- Other blood to blood contact
- Sharing of personal items (such as razors)

You cannot get HDV through casual or household contact from things like sharing utensils or drinking glasses, hugging someone, or through airborne transmission.

What are the symptoms of hepatitis D?
When people first acquire HDV, also called acute infection, people generally experience the following symptoms:

- Fatigue
- Nausea and vomiting
- Loss of appetite
- Liver pain
- Jaundice (yellowing of eyes and skin)
- Light-colored stool
- Dark colored urine

After acute infection, symptoms tend to disappear, or you get used to them and just go about your life. Over time, however, HBV/HDV infection can lead to more and more scarring of the liver, eventually leading to cirrhosis and an increased risk for liver cancer or liver failure and the need for a liver transplant.

How to prevent hepatitis D?
There is no vaccine to prevent HDV, but since you need to have acquired HBV in order to be vulnerable to HDV infection, getting vaccinated against HBV will protect against HDV.

In the absence of the HBV vaccine, you can prevent HDV infection by doing some of the same things that are done to prevent HBV and HCV (and, for that matter, HIV):

- Don't share syringes or other injecting equipment
- Use condoms during sex
- Don't share razors, nail clippers, toothbrushes, or other household items that could have blood on them

Are there treatments or cures for hepatitis D?
There is no cure for HDV. There are treatments, but they can be difficult and are not very effective. Interferon can be used to treat HDV, but the impact on the course of disease is small and the side effects of the treatment can be very debilitating, making the risk-reward of taking it fairly low. There are medications that are under study, but nothing has been approved in the U.S.

While there are ineffective treatments and no cure, it is still important to stay engaged with your medical provider. You may benefit from HBV treatments, but it's also important to stay engaged with a medical provider so they can monitor the health of your liver, assess you for cirrhosis, and keep an eye on your health until cures become available.

Conclusions
Hepatitis D is very rare in the U.S., and you probably don't have anything to worry about in terms of having it or being at risk for it. That said, I believe in knowledge and empowering people to make educated choices about their healthcare and prevention needs. Remember, if you don't have HBV, you can't get HDV. Get vaccinated against HBV, and you're good and won't get HDV. If you're one of the rare folks who gets both HBV and HDV, stick with a medical provider for monitoring and evaluation, HBV treatment (when necessary), and to assess for liver damage.

YUOAK-ISTOCK

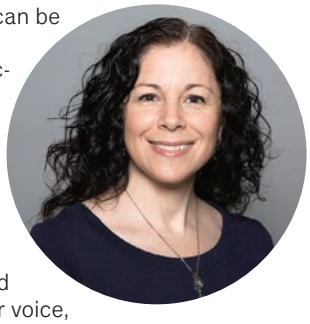
There are so many amazing people working to improve the lives of people living with viral hepatitis, including many of the authors of articles in this issue. We reached out to advocates and leaders in hepatitis B and C, and asked them for their views on what's needed to achieve viral hepatitis elimination. Here's a selection of their answers

What do you think is needed for the U.S. to

COMPILED BY **ANDREW REYNOLDS**

"To eliminate viral hepatitis, we must ensure that all individuals have equitable, stigma-free access to a cure. Access to the hepatitis C cure is restricted by discriminatory prior authorization criteria, while access to hepatitis B treatment is limited by discriminatory drug tiering policies. We must continue fighting for healthcare as a human right and holding insurance companies, pharmaceutical companies, and policymakers accountable. Viral hepatitis elimination will require a transformation in which we no longer view parts of humanity as disposable and everyone has the opportunity to achieve the health outcomes they want and deserve."

—Dr. Adrienne Simmons
Director of Programs,
National Viral Hepatitis Roundtable



"For me, this can be summed up in one word: voices. To achieve viral hepatitis elimination in the U.S., we need people living with chronic hepatitis B and C to raise their voice, share their viral hepatitis experiences, educate others, and demand action. This is the only way that viral hepatitis will be recognized as an urgent public health priority, which will lead to enhanced funding for research and public health programs to prevent, diagnose, and manage/treat viral hepatitis. Those of us working in viral hepatitis need to come together to create a safe space for people living with chronic hepatitis B and C to meaningfully and effectively share their voice and help create a movement so strong that it will lead to direct action."

—Chari Cohen, DrPH, MPH
Senior Vice President, Hepatitis B Foundation

"What the United States needs now to achieve viral hepatitis elimination are resources. We have the technical know-how necessary for elimination with vaccines, cures, and rapid and accurate testing, all of which have continued to improve and become more accessible for consumers. We have the implementation strategies that many different groups of brilliant minds across the government, academic, and non-profit fields have come together to draft. And we have an army of public health workers and advocates ready to put their lived experience and best practices to use, but they need the resources to do it. We need a significant and sustained investment in the infrastructure that supports viral hepatitis elimination, including staffing, from the national systems and agencies all the way to the point-of-care delivery in health centers, SSPs [syringe services programs], and other settings nationwide. Only when we have enough boots on the ground equipped with the tools they need to do the work laid out in the strategies, will we have what we need to eliminate viral hepatitis in the U.S."

—Frank Hood
Manager, Hepatitis Advocacy,
The AIDS Institute

"To achieve goals for hepatitis elimination in the U.S., there are at least five critical steps: 1) Remove all restrictions to HCV treatment; 2) Fully implement CDC/USPSTF [U.S. Preventive Services Task Force] recommendations to scale up HBV and HCV testing to the level necessary to reach elimination goals; 3) Meet international standards of harm reduction and HCV testing/treatment to eliminate HCV among persons who inject drugs; 4) Prioritize culturally appropriate prevention, testing, and treatment programs to eliminate hepatitis as a health disparity for racial/ethnic populations, the homeless, and other marginalized populations; 5) Through health diplomacy, the U.S. helps other countries improve hepatitis prevention, care, and treatment, reducing the burden of hepatitis globally and accelerating progress toward hepatitis elimination in the U.S.

"All of these efforts need reliable data to monitor implementation of vaccination, testing and treatment, and progress toward elimination goals."

—John W. Ward, MD
Director, Coalition for Global Hepatitis Elimination, The Task Force for Global Health

"In order to achieve viral hepatitis elimination, we need meaningful investment at the federal, state, and local government levels. We have a roadmap that details what it takes to eliminate viral hepatitis, and we have examples of countries that are way further ahead of the U.S. that we can emulate. What we don't have is the commitment of even a fraction of the resources necessary to make elimination a reality. And it is absolutely crucial that elimination strategies and resources defer to the wisdom and leadership of communities of people

achieve viral hepatitis elimination?

most impacted by viral hepatitis, including and especially people of color and people who use drugs."

—Katie Burk, MPH
SRO site liaison, Community Engagement and Mitigation Branch, San Francisco Department of Public Health

"All the things! The one thing I think is needed for the United States to achieve viral hepatitis elimination is the elimination of stigma against people living with hepatitis. If we eliminate all the other barriers, we still cannot eliminate hepatitis without eliminating stigma. Until we decide that people living with hepatitis should be treated with dignity and respect, regardless of how they live their lives, we will fail to deliver humane healthcare. Instead of asking people how they got hepatitis, our loving response should be, you have hep C? We have a cure, let's get started! Or, you have hep B or D? Let's create a plan to keep you as healthy as possible until we have a cure!

"I want healthcare to be humanized!"

—Robin Lord Smith
Community Engagement Coordinator, National Viral Hepatitis Roundtable

"With HCV infection rates increasing in the last decade, little attention has been placed on how hepatitis has impacted the pediatric population, particularly in adolescents and newborns. When traveling the United States, I see the lack of education and awareness about children and hepatitis C. There is a disconnect of information from when an infant is born to when they transition into the care of a pediatrician. While the United States has hepatitis C screening guidelines for young adults starting at 18 years of age, there are no guidelines for kids. This surge in cases is closely associated with the opioid crisis. In some states, admitting to drug use could jeopardize custody and may risk losing one's child. Incarcerated pregnant women with opioid use disorder frequently are denied essential medications and receive inadequate medical care.

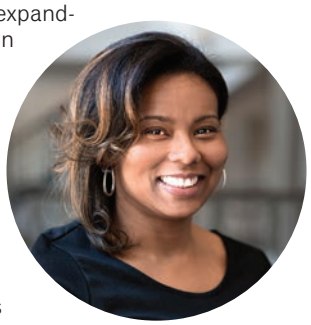
"Why should a child suffer from liver disease, risk cirrhosis if left untreated, when they can be treated and cured as early as three years of age? Pediatricians need to be better educated on hepatitis C in young patients. More awareness, more research, and more education on risks are needed for the public and communities most at risk. In order to truly achieve elimination we must focus efforts to include the pediatric population."

—Ronni Marks
Founder and Executive Director, Hepatitis C Mentor and Support Group

"I'm heartened by President Biden's National Viral Hepatitis Testing Day proclamation committing to the elimination of viral hepatitis by 2030. To make this a reality, the President must establish a high-level position within his administration (similar to previous "AIDS czars") whose sole responsibility is to oversee an elimination strategy. The President must also prioritize major increases in funding to implement the plan. Without leadership and funding, the United States will continue to fail to adequately address hepatitis B and C, let alone eliminate the diseases. With COVID, we've shown what can be achieved in a short period of time. If we approach the fight against viral hepatitis with the same urgency, we can end the unnecessary suffering and loss and secure one of the biggest public health victories ever."

—Ryan Clary
Clary Strategies

"The current state of viral hepatitis elimination strategies in the U.S. is under-resourced and piecemeal, and elimination cannot be achieved if this continues. I believe that an essential element needed to achieve viral hepatitis elimination in the U.S. is a systemic commitment to expanding health care resources to diagnose and treat more people, particularly those at greatest risk, such as people who use drugs, incarcerated persons, people experiencing homelessness, and the uninsured. This includes expanding Medicaid in more states, universal diagnosis and treatment in all correctional facilities, and expanding harm reduction programs such as syringe service programs, rather than the alarming current trend of reducing and eliminating these programs in many communities. These efforts require a consistent commitment of fiscal and personnel resources to provide these diagnostic and treatment services, as well as setting up a comprehensive data collection and surveillance system to identify best practices and monitor progress."



—Sonia L. Canzater, JD, MPH
Associate Director, Hepatitis Policy Project at the O'Neill Institute for National and Global Health Law, Georgetown University

POZ ADVOCATE
SCOTT SCHOETTES
@PozAdvocate

Knocking down myths regarding blood donation policy

In response to a significant drop in blood donations during the first few months of the COVID pandemic, the FDA modified its donor deferral policy to allow donations from gay and bisexual men who remained sexually abstinent for three months prior to donation—another step in the right direction, but still unrealistic for many. Happily, the FDA is currently conducting a study that would allow it to implement a policy based on individualized risk rather than sexual orientation or gender identity.

As we head toward a truly non-discriminatory blood donation policy (it's only taken three decades), it seems worthwhile to address some of the misplaced arguments and erroneous ideas that have been advanced by well-meaning celebrity advocates over the past couple of years. (As much of a consumer of celebrity/pop culture as anyone—and still imagining myself marrying one of these well-intentioned celebs—I am not going to name names.)

Myth #1: All donated blood is tested, so there is no risk of HIV transmission through blood donation.

While it is true that all donated blood is tested for a range of blood borne pathogens, including HIV, the FDA's donor deferral policy is designed to address the strong likelihood that a relatively recent infection would not be detected by these tests. People who point to the testing of blood donations as a reason to completely lift the deferral for gay and bisexual men misunderstand the purpose of the deferral.

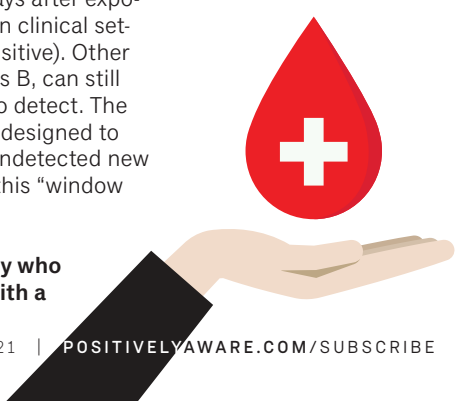
Blood donations have been tested for HIV—and other pathogens like hepatitis C—for decades. With early versions of the test, it took as long as six months for a new HIV infection to be detected. But the testing technologies have advanced over time, and now a new HIV infection can be detected within 9–11 days after exposure (note that testing in clinical settings may not be as sensitive). Other pathogens, like hepatitis B, can still take up to 20–25 days to detect. The donor deferral policy is designed to address the risk of an undetected new infection as a result of this "window period," as it is called.

Myth #2: A straight guy who had condomless sex with a woman a week before donating blood presents the same risk as a gay guy who had condomless sex with a guy a week before donating blood.

This is inaccurate for two reasons. First, not all sexual activities present the same degree of risk. In fact, the receptive partner during anal sex is at over 12 times greater risk than the insertive partner during anal sex or a receptive partner during vaginal sex. The insertive partner during vaginal sex has an even lower risk. The much higher risk through receptive anal sex helps explain why HIV is much more prevalent among gay and bisexual men.

The prevalence of HIV within the group of potential partners is the other major factor influencing the degree of risk of HIV acquisition. If 200 out of 1,000 potential partners is HIV-positive (approximate prevalence for gay men in major cities) versus four out of every 1,000 potential partners (approximate prevalence of HIV in the general population), then the risk is going to be 50 times higher for the gay guy in the example above. And that is before taking into account the relative risk of the sexual activity in which each guy has engaged.

While it is true that all donated blood is tested for a range of blood borne pathogens, including HIV, the FDA's donor deferral policy is designed to address the strong likelihood that a relatively recent infection would not be detected by these tests.



Myth #3: Monogamy would be a good criterion for allowing gay and bisexual men to donate blood without a deferral.

When I hear people suggest this, I want to say, "What are you thinking?!?" Unless they spend 24/7 with their partners, people do not *know* that they are in a monogamous relationship. And this is not a rap on gay and bisexual men, because a study on which the FDA has relied shows that 25% of heterosexual people who believed they were in a monogamous relationship were in fact not.

The criteria upon which the donor deferral policies rely should be things that are within the personal knowledge of the donor, such as the number of partners and the type of sexual activities in which the person has engaged. Perceived monogamy is not a good indicator of actual risk.

Myth #4: When the FDA implements a non-discriminatory donor deferral policy, all gay and bisexual men will be able to donate blood without restriction.

This misperception is the most anxiety producing, because it could lead to real disappointment on the part of sexually active gay and bisexual men when the policy finally changes. A non-discriminatory donor deferral policy would be based on an individual risk assessment using some of the criteria described above, such as number of partners and types of sexual activity in the month or two prior to donation. While that should bring a significant number of gay and bisexual men into the eligible donor pool, it will not be all gay and bisexual men.

A policy that excludes some gay and bisexual men—as well as some straight people—based on their individual risk is not discriminatory. It is the very thing we want—a policy that ensures the safety of the blood supply without relying upon stereotypes or generalizations about gay and bisexual men.

SCOTT SCHOETTES is an attorney and advocate who lives openly with HIV. He engages in impact litigation, public policy work, and education to protect, enhance, and advance the rights of everyone living with HIV.

ISTOCK

Pills

I'm going to go out on a limb and assume something. Don't get mad if I'm overstepping or overstating. I know it doesn't apply to everyone, but it's common enough. It's just a little something that I know to be true for me, and over time have found to be true for others. If you've been taking antiretroviral therapy (ART) for any longer than—let's say a year and a half or more—you've experienced some form of pill fatigue. Brand new to HIV or a long-term survivor, you've felt it, even if it was just a fleeting emotion. I'm using it as an all-encompassing term to include all sorts of emotions and feelings about HIV medication.

It could be that you're sick and tired of taking a pill that literally makes you sick and tired. Physical manifestations of HIV medication side effects are real. Maybe you have been taking multiple pills since the Bangles were walking like an Egyptian across the charts and you're just over it. A person having to hide medication from family and friends as you hide your status can create not only pill fatigue, but pill *anxiety* and adherence issues. Or, like me, you just feel a vague sense of resentment that you *have* to pop a pill to stay healthy. To say nothing of the agitation and irritation of dealing with refills, insurance, and co-pay melodrama. Mental and emotional side effects of ART therapy are real.

Mind you, not one of those things or examples mean that I don't feel grateful for the strides that have been made in HIV care. Don't think for one second that I don't appreciate and mourn for all who came before me who've succumbed before there were viable, less toxic options for helping us sustain healthy lives. It's not about that. I know even having the option to take them is a blessing! I'm just honest enough to admit that there have been times that I have been so tired of taking pills that I considered stopping.

I know I'm not alone in that, because I've had conversations with other survivors who feel the same way. Some of them (through no fault of their own) have made me feel ashamed of my resentment because of all of the things that they have been through. The side effects, the physical changes the medications have wrought on their bodies, the fact that they thrived on a particular medication while losing friends who did not. That is a different level of fatigue and it has my full respect.

The truth still stands though, that everything is relative. What is completely unimaginable and overwhelming for one person may be a walk in the park for another. Be it mild fatigue or full antipathy, it doesn't make you a bad person. It means you are human, and things are proportionate to your life experience and tolerance. Having said that, if you're a person who feels guilt over pill lassitude because you have survived and someone else did not, may I suggest that you release that guilt and accountability? It's not your burden to bear.

Science and the evolution of it, and the passion of the people behind it, have made it so that we have a number of medication options today that weren't available years ago. In between 2018 and 2021 alone more than nine medications were approved in the fight against HIV. Some were just updates and improvements on current meds, others have brand new mechanisms of action. They are new possibilities, right? Even if I'm not always ready to jump on them (I'm a fraidy cat about change), I love the idea that newly diagnosed people have choices. It's wonderful that people who have multiple viremic strains or medication class resistance still have options to stay healthy. It's that care overall is solution-based now rather than desperation-driven, if that makes sense. The new long-acting injectable alternative to a daily pill offers the prospect of even more freedom from the daily grind of adherence. It may even help eliminate some of this angst about taking your meds.

Forgive my presumption about your relationship with your medication. In case I'm right though—it's okay to feel that way. It's okay to admit it. It's not okay to get stuck in it and let it control you or keep you from your promise and potential. You've earned that. Do what I do. Roll your eyes and sigh deeply—BUT TAKE YOUR PILLS. Then move on with your day, and be happy another one was granted to you. Somebody needs somebody like you.

Be well. You matter.

What is completely unimaginable and overwhelming for one person may be a walk in the park for another. Be it mild fatigue or full antipathy, it doesn't make you a bad person. It means you are human, and things are proportionate to your life experience and tolerance.

Bridgette Picou is a licensed vocational nurse in Palm Springs, California. She is also an active HIV blogger and contributor to the CDC's "Treatment Works" public service campaign. Finding a voice in advocacy and activism is a natural progression, since she feels that every time she fights for someone else, she affirms her own life.

PICOU: CHAD SAIN · ILLUSTRATION: ANASTASIIA BORIAGINA -ISTOCK

Working it

The first National Convening on HIV and Employment

BY JEFF BERRY

The first National Convening on HIV and Employment was presented virtually April 20–21 by the National Working Positive Coalition (NWPC), in partnership with Pennsylvania State University and the U.S. People Living with HIV Caucus. The Convening "brought together an expert stakeholder group at the intersection of HIV and employment, including 69 leading policy experts, community advocates, service providers, researchers, and key federal and state government agency representatives," according to an NWPC press release.

"The convening was conceptualized in both an HIV care and prevention context, understanding how greatly employment, lack of employment, or underemployment contribute to our vulnerability to acquiring HIV, varying access to and quality of health care, treatment and housing, and quality of life, wellness, and well-being," says Mark Misrok, Executive Director of NWPC.

"Over the course of the two afternoons, I think something remarkable happened, in part, because we were super lucky to engage the diverse combination of experts most important to this particular conversation, including folks who've been very focused on employment as a priority, either from a service delivery or policy perspective, or a human rights perspective for people living with HIV. And also, people who really haven't focused on it a lot, but whose work makes it important for them to be involved and to be engaged."

Planning for the convening began in September of 2019. "Quite honestly, the community engagement in the two days of meetings was rare in my experience in terms of energy, passion, and brilliant brainstorming—the chat was absolutely on fire!"

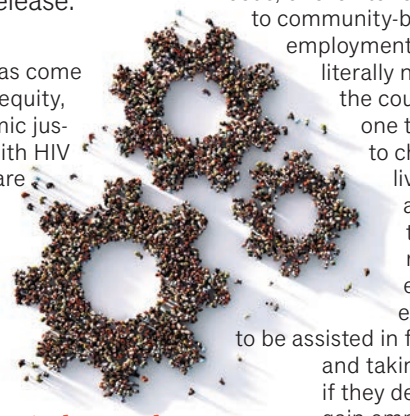
The transition to the new Biden administration was also a factor in helping to ensure the convening was a success.

"It felt like there was more of a threat to at least some people living with HIV, trying to advance employment initiatives in the previous administration, which had shown so much evidence of punitive action against people who utilize public programs, and such an inclination to impose mandated work requirements on public programs. So, we really did step gingerly. And certainly, we were more unleashed with that change. But also, the new administration has come in with a focus on health equity, racial justice, and economic justice, which all intersect with HIV and employment. Those are primary factors."

One of the important points of focus for Misrok has been working to effect change in the now decades-long blockage of using Ryan White funds for employment services. "It's been since the early- to mid-'90s that use of Ryan White supportive services funds has not been allowed to provide employment services," says Misrok. "For a very long time, we've observed how greatly that has influenced the lack of development in this area, because the providers who care the most about people living with HIV, who are the best connected to, and the most responsive to, people living with HIV, are so heavily influenced and defined by the Ryan White HIV/AIDS Program."

Misrok said that during a series of meetings prior to the convening with HIV policy folks, they were encouraged by seeing a shift in this area. "During the months leading up to the convening it seemed like there was a new openness among government leaders and policy advocates to discussion of removing that disallowance from Ryan White, that has seemed like the Berlin Wall for addressing employment needs of people living with HIV for so long."

Today in most parts of the country, including communities with large concentrations of people living with HIV on limited income who struggle to survive, there are no HIV-focused employment services, says Misrok. "HIV care and prevention service providers are not trained or equipped to address employment needs, or even to refer and link people to community-based mainstream employment programs. There's literally nothing in most of the country. So, the number one thing that we want to change is for people living with HIV to have access to information, services, and resources to consider their options for employment, and to be assisted in following through and taking steps when and if they decide they want to gain employment or change their jobs. And for people at greater vulnerability to HIV, for that vulnerability to not be exaggerated because of economic precariousness, for lack of sensitive, welcoming, affirming, and non-stigmatizing, non-discriminatory employment services."



'...the number one thing that we want to change is for people living with HIV to have access to information, services, and resources to consider their options for employment, and to be assisted in following through and taking steps when and if they decide they want to gain employment or change their jobs.'

It's this access to information, services, and resources that needs to change, says Misrok. "I think the political context changing in recent times has helped increase a readiness to respond to economic justice and racial justice and health equity issues, that entirely intersect at both HIV and employment. It's time to do this."

The group will be releasing a preliminary report this summer, with a full report including recommendations issued later this year.

FOR MORE INFORMATION, GO TO workingpositive.org.

Positively Aging is a collaboration among TPAN, POSITIVELY AWARE, The Reunion Project, and National Working Positive Coalition.

ISTOCK

If you are living with HIV, ask yourself the following questions:

Have I lost weight?

- [ ] Have I lost weight without trying?
- [ ] Does the change in my weight impact how I feel about myself or my health?
- [ ] Is my clothing looser than before because I have lost weight without trying?
- [ ] Have those I know mentioned that my appearance has changed?

Do I have less energy?

- [ ] Are any of my usual activities more difficult to perform?
- [ ] Am I exercising less than in the past?
- [ ] Do I need to take a break more often?
- [ ] Do I tire more easily after certain activities?

If you answered "yes" to any of these questions, take this questionnaire to your next appointment with your healthcare provider to start a conversation about HIV-associated wasting and to inquire about treatment. Together you can discuss next steps. To learn more about HIV-associated wasting, visit: **IsItWasting.com**

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* Undetectable viral load is defined as fewer than 50 copies of HIV per mL of blood.

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- have received anti-HIV-1 regimens in the past, and
- have HIV-1 virus that is resistant to antiretroviral medicines, and
- who are failing their current antiretroviral therapy

It is not known if TROGARZO® is safe and effective in children.

IMPORTANT SAFETY INFORMATION
Do not receive TROGARZO® if you have had an allergic reaction to TROGARZO® or any of the ingredients in TROGARZO®.

TROGARZO® can cause serious side effects, including:

- Allergic reactions. TROGARZO® can cause allergic reactions, including serious reactions, during and after infusion. Tell your healthcare provider or nurse, or get medical help right away if you get any of the following symptoms of an allergic reaction: trouble breathing, swelling in your throat, wheezing, chest pain, chest tightness, cough, hot flush, nausea or vomiting.
- Changes in your immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you start taking HIV-1 medicines. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your health care provider right away if you start having new symptoms after receiving TROGARZO®.

The most common side effects of TROGARZO® include diarrhea, dizziness, nausea, and rash. These are not all the possible side effects of TROGARZO®.

Before you receive TROGARZO® (ibalizumab-uiyk), tell your healthcare provider about all of your medical conditions, including if you are:

- **Pregnant or plan to become pregnant.** It is not known if TROGARZO® may harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with TROGARZO®.
- **Breastfeeding or plan to breastfeed.** You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. Do not breastfeed if you are receiving TROGARZO® as it is not known if TROGARZO® passes into breast milk. Talk with your healthcare provider about the best way to feed your baby during treatment with TROGARZO®.

Also tell your healthcare provider about all the medicines you take, including all prescription and over-the-counter medicines, vitamins, and herbal supplements.

For more information or medical advice about side effects, ask your healthcare provider. You may report side effects to the FDA at 1-800-FDA-1088 or the THERA patient support® program at 1-833-238-4372.

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