TEST EVERYONE
FOR HEPATITIS C

OBSERVATIONS
OF AN HIV DOC

COVID-19
UNDERSCORES
DISPARITIES

UNTIL WE ARE
ALL FREE

ANDREA AND HASSAN
How their lives intersect
as survivors of hepatitis
and living with HIV

THE 8TH ANNUAL **POSITIVELY AWARE**

HEPATITIS DRUG GUIDE

POSITIVELY AWARE

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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.

ANDREA LAMOUR-HARRINGTON AND HASSAN J. GIBBS AT THE PHILADELPHIA MUSEUM OF ART, PHOTOGRAPHED BY HOLLY CLARK

INTERSECTING LIVES

BY **RICK GUASCO**

"WHEN THE photographer told me that I'd be doing the shoot with someone named Hassan, I was like, *nah, it can't be*," **Andrea Lamour-Harrington** says about being contacted by Philadelphia **photographer Holly Clark** to be featured on the cover of POSITIVELY AWARE's Hepatitis Drug Guide.

Andrea, 54, who identifies as trans, and **Hassan J. Gibbs**, 63, who is gay, are cousins who lost touch nearly five years ago, and each had been asked to take part in this issue's cover shoot. But this was more than a family reunion on the steps of the Philadelphia Museum of Art. Hassan had been Andrea's mentor years earlier at Philadelphia FIGHT, learning to live and thrive with HIV and hepatitis C.

"I discovered I was HIV positive on December 12, 1988," Andrea says. Pausing to reflect on that, she lets out an audible sigh. "It was around the time that Liberace died. I knew it was over for me, because if these rich people who could get good medicine could die, I knew with my poor self what my chances were."

To survive, she turned to sex work. "One night I was getting out of a trick's car, and I looked up at this billboard for something called Philadelphia FIGHT," she says. "And then I thought, *wait a minute—is that my cousin?* What's Hassan Gibbs doing on that billboard? At that moment, I said, I want to be a part of a positive message like that. I need to do that; I've got to take care of myself so I can do that."

SOON AFTER being honorably discharged from the army in 1979, having been a clinical tech, Hassan got a job in a hospital emergency room. Over the years, cleaning needles and other sharps, Hassan says he had sometimes been stuck by them. He was also sexually active and spent lots of money, "partying."

"I heard about HIV, that it was scary, but a lot of us thought it was a White boy thing," he says.

He had been selling his blood for extra cash when in March 1985 he received a letter notifying him that his blood would no longer be accepted because it was "contaminated with the HIV virus." He was advised to see a doctor as soon as possible.

Hassan says he was diagnosed with hep C in 1983, back when it didn't have a name and was only known as non-A, non-B hepatitis. He didn't see a doctor for a couple years, certainly not about his HCV, until he looked in the mirror one day and noticed that his eyes were jaundiced.

By 1991, he was told that his HIV had progressed to the point where he had six months to live. That's when he discovered Philadelphia FIGHT, a health services organization providing primary care, advocacy, and research. Through FIGHT, he found a doctor, and began taking AZT, the only HIV drug available at the time, though often considered toxic by many. Having heard how difficult interferon could be to tolerate, he held off getting HCV treatment.

As his health improved, Hassan joined the organization's Project TEACH (Treatment Education Activists Combating HIV) program as outreach coordinator, going on to be co-lead instructor. He was surprised to discover that his cousin Andrea

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would be in his class. Receiving medical care at FIGHT, she had been referred to the program. After graduating Project TEACH she started working at FIGHT through AmeriCorps, a volunteer public service organization. She was soon attending various events and presenting at conferences.

AROUND 2012, something didn't feel quite right to her, and Andrea got tested for hepatitis C. Through FIGHT, she enrolled in a clinical study with interferon.

After a year of weekly injections of interferon, Andrea was cured. Not long afterward, Sovaldi, the first one-pill-a-day treatment for hepatitis C was approved by the FDA in late 2013. "I'm not upset that they soon came up with better treatments," Andrea says philosophically. "In order to get to point C, you have to start at point A and then get to B."

HASSAN'S PERIODIC struggles with depression had gotten the better of him. Unhappy with work, he'd also lost touch with Andrea. Old habits returned.

"It started with beer," Hassan says. "The Millers turned to 45s, the 45s turned to rum and coke, and the rum and coke turned to crack. All within a six-month period."

Hassan was incarcerated for felony retail theft, first for three months, the second time for six months, most of which was awaiting trial, where he pled guilty. His parole officer helped him to get into rehab, and reconnected to care afterward. He decided to finally treat his hepatitis C.

Following a FibroScan to measure the amount of liver scarring, Hassan began a 12-week course of Epclusa last January and was cured. These days, he says he's "fabulous again," finding comfort from stress by tending to his plants.

"AS PEOPLE living with HIV, we need to be mindful of our mental health now more than ever," Hassan says. "Just an hour ago, I was going through a spell of depression, but I started taking care of my plants, and that lifted my spirits. We become so consumed by the news of all that's going on around us, but we need to stay focused on taking care of ourselves and living our lives."

The photo shoot was a warm, emotional reunion. "I had to hold back tears, because when I first came to Philadelphia FIGHT, and I did Project TEACH, my teacher was my cousin," Andrea says. "And here I am, more than 30 years [after my HIV diagnosis], and I'm on the steps of the art museum, having a photo shoot with the teacher who taught me how to stay alive. We're both here, thriving. HIV couldn't take us out, hep C couldn't take us out. I'm still here, because of what he taught me to do. Everything has come full circle."

THE CONVERSATION

'Living with this chronic condition'

FIRST BEING DIAGNOSED feels like you have been given a life sentence. You feel isolated and alone. You are left within the whirlwind of your thoughts and emotions. It is a mental and emotional roller-coaster of coming to terms with the new reality that you have HIV.

Though it can be seen as a life sentence in terms of it being a lifelong medical condition, you remain free. This is one of many chapters in your life; with much of the journey and its conclusion still to be written. It is a new chapter and a new beginning of self-awareness, individual purpose, and happiness.

Living with this chronic condition undoubtedly has its calm waters and turbulent storms, but it doesn't define who you are. You have the power to chart your course, on your journey through life. That being said, turn living with HIV from a perceived weakness into a strength. Recognize it for what it is, but also have the realization that it brought forth positive change in your life. I know this to be true, because I too am HIV positive. With one step forward at a time, let us enjoy this journey together.

—JAMES C.
STEUBENVILLE, OHIO

CLARIFICATION: A statement in an article in the May+June issue ("Struggling with COPD") implied that the medication Anoro Ellipta contains a steroid. It does not. The patient went back on Anoro and is doing well with her breathing once again.

JOIN IN THE CONVERSATION

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HOLLY CLARK

NOTE FROM THE HEPATITIS EDITOR
ANDREW REYNOLDS

Intersections of health and social disparities

Viral hepatitis, COVID-19, and police violence

Racism and inequality kill. This is an unimpeachable fact that has been highlighted all the more in 2020, first with the COVID-19 outbreak, and then with the renewed attention of police violence and the killings of Breonna Taylor, Tony McDade, George Floyd, and many others. We can also include viral hepatitis into this mix, with health disparities and suffering disproportionately affecting African Americans. This intersection of racism and White supremacy with health disparities has always been an important issue to fight—and indeed there are many individuals and organizations that have been fighting these problems for decades—but they are all the more important now as we are in the midst of this COVID-19 pandemic.

A brief snapshot of health disparities below gives us a sense of the urgency of the problem:

COVID-19
COVID-19 infections and deaths demonstrate yet again the sharp divide and health disparities we have here in the United States. African Americans make up about 13% of the U.S. population, but they make represent 25% of COVID-19 deaths. The death rate for COVID-19 in African Americans is over twice that of White people: 50.3 per 100,000 compared to 20.7 per 100,000.

Viral hepatitis
While COVID-19 is a new example that demonstrates health disparities, viral hepatitis is not. Hepatitis C and B are another in a long line of diseases and medical conditions that disproportionately impact African Americans. Once again, with 13% of the U.S. population, African Americans make up 25% of people living with HCV. African Americans have higher rates of infection, with liver disease ranked as a leading cause of death. Despite having effective cures for HCV, access to them remains elusive. A recent study found that African Americans are more likely to be considered ineligible for HCV treatment than any other racial group, even when controlling for other factors. Racism in healthcare kills, too.

The War on Drugs and Prisons
You cannot separate these high rates of infection and suffering without addressing policing and the war on drugs. The criminalization of drug use has resulted in the U.S. having the largest prison population in the world, as well as creating a situation where harm reduction tools—such as sterile syringes—are challenging for most people who inject drugs. Like health disparities, the war on drugs disproportionately impacts African Americans. We arrest and imprison African Americans at five times the rate of White people. Although African Americans and White people use drugs at approximately the same rates, African Americans are six times more likely to go to prison for drug charges than their White counterparts.

Racism and White supremacy, and the resulting suffering of African Americans, is as old as the founding of this nation. It is deeply rooted in American culture, and as such it will be difficult to change, and will require time to achieve. But it must change, and we can be the agents of this change. There is much to do.

POSITIVELY AWARE is committed to eliminating racial disparities in healthcare, and we have consistently written stories and features on key players in this fight. We will continue the fight, publishing articles on important topics and providing health education and pushing for health equity. Most recently, TPAN, the publisher of POSITIVELY AWARE, has joined hundreds of other organizations in calling for a change in policing in America, and shifting more resources to health and social services (positivelyaware.com/articles/tpan-calls-change-policing).

My commitment is to do more and try harder. I'll continue to fight for equal access to HCV testing and treatment. I'll continue to work to dismantle the war on drugs and the criminalization of people who use drugs. Most important, I'll follow the lead of People of Color in the harm reduction space, health care advocacy and economic justice, be an ally and partner with them to fight for change.

Journalism can be an important tool for activism and social change, and our commitment to you is to make sure we fulfill that promise.

What can you do? There's a lot, and most of it is beyond the scope of what I feel like I can tell people to do. But I can tell you what you can do for us. I can say that you can hold me and POSITIVELY AWARE accountable in our work. I know we want that. Pitch us story ideas about the ways race and health intersect in HIV and HCV. Let us know about important programs in your respective communities that work to address racism in healthcare. Tell us about important leaders doing work on these issues. We can and will write stories about all of these and more. Journalism can be an important tool for activism and social change, and our commitment to you is to make sure we fulfill that promise.

I'll close with a selection from TPAN's statement on the most recent spate of police violence:

Throughout its more than 30-year history TPAN has long fought for people who are marginalized and oppressed. We reaffirm our commitment today by standing together with everyone who fights racism, anti-Blackness and White supremacy in all its forms, and state unequivocally that:

Black Lives Matter.

Andrew

ENID VÁZQUEZ @ENIDVAZQUEZPA

BRIEFLY

PrEP progress

Injectable every 2 months works as well as Truvada in a study

A medication being studied for HIV prevention was found to be safe and effective in stopping the virus. Long-acting cabotegravir (CAB LA) was given as an injection once every eight weeks.

The HIV Prevention Trials Network (HPTN) was comparing CAB LA against Truvada as pre-exposure prophylaxis (PrEP). Truvada for PrEP is a once-daily pill already available on the market.

As a result of the decreased incidence of HIV seen with CAB LA, similar to that seen with the already-established Truvada for PrEP, the HPTN 083 study was unblinded in May.

This means that participants will now be told whether they are receiving CAB LA or Truvada. Those who want to change their PrEP from injection to Truvada, or vice versa, will be allowed to do so. A change to CAB LA is dependent on its availability.

HPTN 083 participants will also no longer have to take a placebo along with their PrEP medication.

"Demonstrating conclusively that long-acting injectable cabotegravir is highly effective almost two years earlier than originally expected is exciting news," said HPTN 083 protocol chair Raphael J. Landovitz, MD, MSc, in a press release from the research network. "It is inspiring that **we may soon have additional options for at-risk individuals who have difficulty with or prefer not to take pills**." Dr. Landovitz is a professor of medicine at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA) and associate director of the UCLA Center for Clinical AIDS Research & Education (CARE).

The international trial enrolled nearly 5,000 cisgender men and transgender women who have sex with men. Half of the U.S. participants identified as Black or African American.

"A long-acting injectable for PrEP that does not require adherence to an oral daily pill is a great addition to the HIV prevention toolbox. Prevention strategies have never been one-size-fits-all," said HPTN 083 protocol co-chair Beatriz Grinsztejn, MD, PhD, in the press release. Dr. Grinsztejn directs an HIV research center in Rio de Janeiro.

Kimberly Smith, MD, Head of Research and Development at ViiV Healthcare, which is developing cabotegravir, said in a company statement, "We are thrilled with the results not only because of the high efficacy of cabotegravir but also because we have demonstrated high efficacy in a study that adequately represents some of the populations most disproportionately impacted by HIV—Black MSM [men who have sex with men] in the U.S., young MSM globally, and transgender women."

A separate study, HPTN 084, is looking at CAB LA PrEP in cisgender women in sub-Saharan Africa. Truvada for PrEP is also being used as a comparator in that trial.

Truvada, usually as part of a single-tablet regimen (STR), is also available for the treatment of HIV. CAB LA is being studied for HIV treatment as well.

READ the HPTN release at hptn.org/news-and-events/press-releases/long-acting-injectable-cabotegravir-highly-effective-prevention-hiv. A statement from the HIV prevention advocates organization AVAC (formerly the AIDS Vaccine Advocacy Coalition) is at avac.org/press-release/trial-finds-long-acting-injectable-antiviral-safe-and-effective.

Dolutegravir infant dose approved

The FDA in June approved Tivicay PD, a dispersible form of dolutegravir (brand name Tivicay) for pediatric use in ages four weeks and up, and weighing at least 6.6 to 30.8 pounds (3–14 kg)

The **Tivicay PD tablets are dispersible in water (oral suspension) for pediatric doses**. Dolutegravir must be taken in combination with other HIV drugs.

In addition, the FDA expanded the use of the Tivicay 50 mg tablet to children weighing as low as 44 pounds (20 kg). The previous weight low was 77 pounds (35 kg).

Dolutegravir is from the drug class integrase strand transfer inhibitor (INSTI). INSTIs are the most used drugs for HIV treatment today. Dolutegravir, however, is one of the INSTIs being most implicated in weight gain. Nonetheless, new HIV treatment options for children are always welcome.

GO TO positivelyaware.com/tivicay.

HIV-to-HIV transplant

Two cases of organ donations from one person living with HIV to another were presented at the American Transplant Congress, held virtually in May.

The first such transplant in the United States was performed at Johns Hopkins University in March 2019. POSITIVELY AWARE has reported on that transplant, in which activist Nina Martinez donated a kidney to another positive person. Martinez has been living with HIV since she was six weeks old. She continues to do well, as does the man who received her kidney. Both remain on the HIV therapy they were taking before the transplant. Martinez is listed as an author on the research abstract on the two cases presented at the conference.

The report's conclusion states, "In the context of growing experience with HIV-to-HIV transplantation, **there is strong interest in living donation among the community of people living with HIV**. In fact, there is stronger interest in this population than the general population, particularly because of solidarity with the HIV community and a desire to help fellow individuals living with this condition. These two cases [the second was performed at Duke University] provide important proof-of-concept evidence that donation is possible for people living with HIV. Furthermore, the approaches used by both centers for evaluation, selection, informed consent, and follow-up are generalizable to other centers interested in expanding transplantation in this manner."

Martinez remains committed to promoting HIV-to-HIV organ transplants. **READ** her article in PA at positivelyaware.com/articles/where-there's-hope, which includes a list of resources.

International conferences update

The full program schedule for HIV2020 is now available online. The conference was originally set to be held in Mexico City, but because of the COVID-19 pandemic, will instead be conducted as a **series of two-hour sessions via Zoom video meetings from July to October**. **GO TO** HIV2020.org.

A community-based conference, HIV2020 was to coincide with the International AIDS Conference, which had been scheduled to take place in the Bay Area. Rebranded as *AIDS2020: Virtual*, the 23rd International AIDS Conference will run July 6–10. **GO TO** AIDS2020.org.

OI guidelines updated

The guidelines on opportunistic infections in HIV were updated in May.

In treatment of candidiasis, **important new information was added on miscarriages after any exposure to the anti-fungal fluconazole**, with even one dose. Other updates discuss azole resistance, the use of boric acid, and the use of gentian violet for oral candidiasis (thrush).

Herpes information has also been updated. Oral herpes is herpes simplex virus 1 (HSV-1) and genital herpes is HSV-2. There is new prevalence data for the country. HSV-1 as a cause of genital herpes is discussed, as well as prevention for HSV-2. There is additional information about interpreting HSV tests. Last but not least, there is information on treating acyclovir-resistant HSV.

The guidelines are produced by the U.S. Department of Health and Human Services (HHS). **READ THEM** at aidsinfo.nih.gov.

New resource for opioid use disorder

Essentials of Opioid Use Disorder: A Resource for Hepatologists and Infectious Disease Specialists Managing HCV and/or HIV Infection is a new guide from Clinical Care Options, in collaboration with the American Society of Addiction Medicine.

No heavy tome, the resource is a **handy-dandy guide in just four pages**. It packs a wallop, outlining:

- diagnostic criteria
- medications for OUD
- drug-drug interactions with HIV and HCV medications
- an algorithm on how to engage patients on potential drug use

DOWNLOAD the resource at bit.ly/OpioidUseDisorderResource.

Gilead sues U.S. over Truvada

Gilead Sciences has filed a breach of contract lawsuit

PHOTO COURTESY OF PHILIP NORMAL

BRITAIN'S FIRST HIV-POSITIVE MAYOR IS NORMAL: Artist and shop owner Philip Normal is believed to be the first openly HIV-positive mayor in the U.K.

"I don't know if this is true, but if it is, it is something none of us should feel pride in," Normal was quoted as saying in the Wadsworth Guardian. "Rather, it highlights the shame and stigma that has been associated with HIV for far too long."

Normal, 38, is the new mayor of Lambeth, a borough in south London. It has a large LGBTQ presence among its population of 300,000. Because of pandemic stay-at-home orders, Normal was appointed to the ceremonial position in May remotely from his home. A member of the U.K.'s Labor Party, he has been a councilman for the borough since 2018. He dedicates his charity work to the Albert Kennedy Trust, which supports homeless LGBTQ youth. **GET A PIECE** of history at philipnormal.co.uk/shop.

against the U.S. government over the company's drug Truvada. The company alleges that the Centers for Disease Control and Prevention (CDC) made four violations of agreements on HIV prevention research.

Last November 2019, the federal government filed a patent infringement lawsuit against Gilead on behalf of the U.S. Department of Health and Human Services (HHS), under which CDC operates. The suit sought "damages for Gilead's infringement of HHS patents related to pre-exposure prophylaxis (or PrEP) for HIV prevention. Despite multiple attempts by HHS to license its patents, Gilead has refused. ... The complaint further alleges that, as a result of such infringement, Gilead has profited from research funded by hundreds of millions of taxpayer dollars and reaped billions [in profits] from PrEP through the sale of Truvada and Descovy," HHS reported.

Gilead claims the patents should never have been granted to the government. The company's complaint alleges that it "has incurred unnecessary attorneys' fees and suffered reputational harm" as a result of the government's lawsuit. Gilead reported in April that through its contracts with the CDC, it agreed to "provide the CDC with significant quantities of Gilead compounds free of charge. The government, in return, agreed to promptly notify Gilead of any inventions, discoveries, or ideas that resulted from the research. In the case of the CTA [Clinical Trial Agreement], the government promised not to seek patent protection in connection with any alleged inventions that derive from the use of the study drug in the trial."

READ Gilead's announcement at bit.ly/lawsuitstatementGilead, and the HHS press release at bit.ly/lawsuitstatementDHHS.

Former Louisiana officer wins HIV discrimination case

A former Louisiana police officer who was denied a job as a sheriff's deputy, allegedly because he is living with HIV, has been awarded a $90,000 settlement. Lambda Legal announced in April that it reached the settlement with the Iberia Parish Sheriff Office, in New Iberia, Louisiana.

The settlement also mandates a number of nondiscrimination steps that the sheriff's office must take.

"This settlement is **a lesson to all employers across the country that HIV discrimination in the workplace is completely unlawful** and has no place anywhere. Someone's HIV status is absolutely irrelevant to their ability to safely perform a job, from the Iberia Parish Sheriff's Office to the U.S. Air Force [sued in a separate discrimination suit], and using it to deny employment or promotion is discrimination pure and simple," said Scott Schoettes, counsel and HIV Project Director at Lambda Legal, in a press release. "This settlement should also serve as a wakeup call to states and cities across the country to remove once and for all outdated and stigmatizing HIV criminalization laws that perpetuate discrimination and ignore current medical science."

Lambda filed a federal lawsuit against the sheriff's office in October 2017.

"I immediately knew that the sheriff's decision not to hire me was based on my HIV status, and though it was a long journey, it feels good to finally be vindicated," William "Liam" Pierce said in the release. "I hope that my case helps others avoid going through my experience and demonstrates to other employers that living with HIV has nothing to do with our ability to do any job."

READ the press release at bit.ly/sheriffdiscrimination.

Go low, San Antonio

It's a message everyone should know: people living with HIV who have an undetectable viral load cannot pass HIV on to their sex partners.

Now Bexar County, home to San Antonio, is telling everybody by using bright images and a simple message: "People on effective HIV treatment have ZERO risk of passing HIV to others."

"**When people with HIV take their HIV medications as prescribed, they can keep the amount of HIV in their body so low that it can't be passed on to others**," says Operation B.R.A.V.E. (Bexar County Response and Victory in Ending the Epidemic). "In clinical terms, this is called viral suppression."

"How Low Can You Go?" promotes "HIV treatment as a powerful tool for HIV prevention," Operation B.R.A.V.E. said in May when it launched the new media campaign.

"According to the Centers for Disease Control and Prevention, there is proven science supporting the campaign. In three different studies, including thousands of couples and many thousand acts of sex without a condom or other HIV prevention method, no HIV transmissions to an HIV-negative partner were observed when the HIV-positive person was virally suppressed," the campaign announcement noted.

It also mentioned the U = U campaign, which stands for "undetectable equals untransmittable." "U = U" has become the community-based catchphrase for the medical term, "treatment as prevention" (TasP). For prevention, undetectable is considered a viral load below 200 copies, on stable therapy for at least six months, and absent any other STI.

The campaign can be found online in English at GoLowSA.org and in Spanish at BajarSA.org.

READ the campaign announcement at bit.ly/2zuDlrc.

In it, Greg Casillas, HIV-positive for 20 years, says, "When I was diagnosed, taking meds felt like the beginning of the end of my life. It was very difficult for me to accept. When I learned new HIV meds could help me live a long, normal life, I confronted the internal stigma I had created and started care. Marrying the man of my dreams meant I needed to do it for him too. By taking my meds and staying healthy, I cannot pass HIV to him. It's not a cure for HIV, but it's the next best thing."

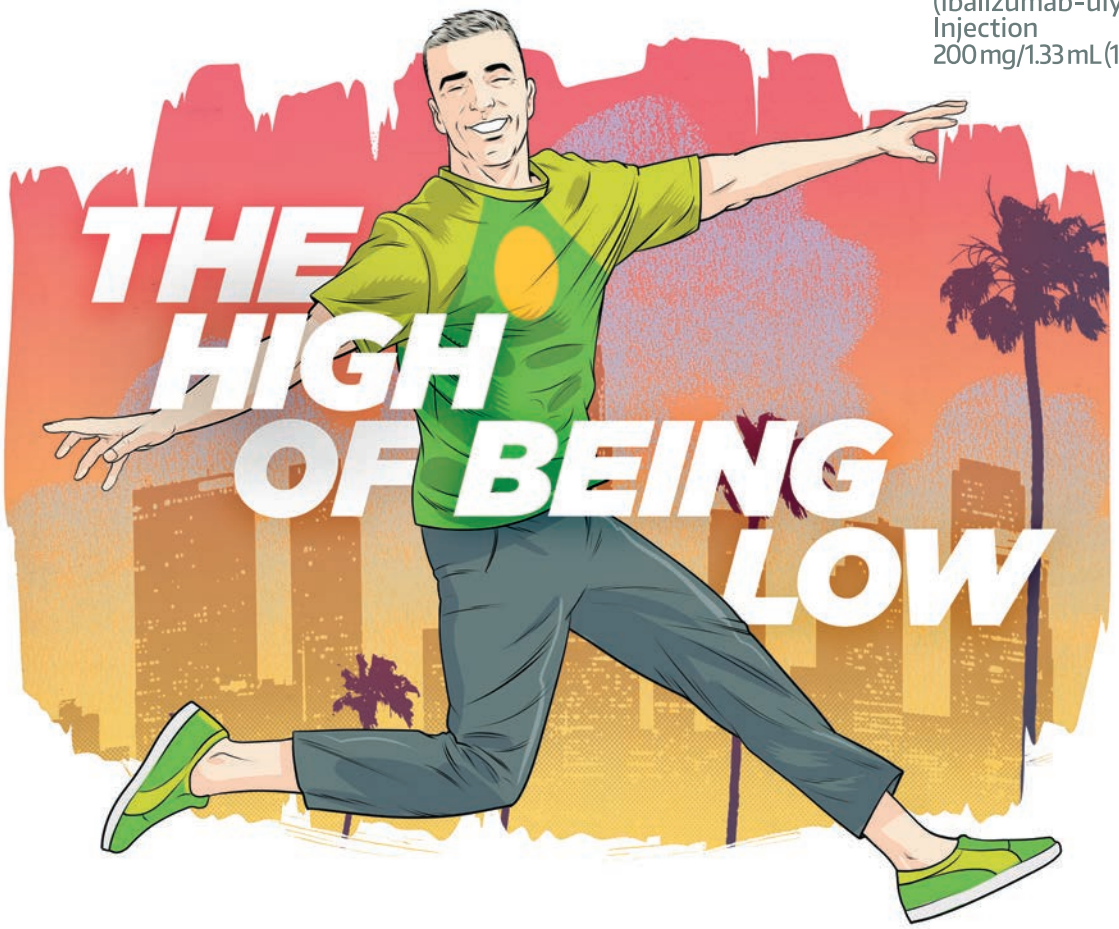
Operation B.R.A.V.E. noted that there's an estimated 37% of people with HIV in Bexar County who have not reached undetectable viral level due to a number of reasons. The group said it hopes to have 90% of people with HIV achieve undetectable by 2030.

Que tan bajos puedes llegar, San Antonio?

Orale!

OPERATION B.R.A.V.E.

Trogarzo®
(ibalizumab-uiyk)
Injection
200 mg/1.33 mL (150 mg/mL)



LOWER YOUR VIRAL LOAD. AND MAKE UNDETECTABLE A POSSIBILITY AGAIN.*

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

Ask your doctor about TROGARZO® – A breakthrough HIV-1 treatment designed specifically for those with treatment failures

TROGARZO.com

WHAT IS TROGARZO®?

TROGARZO® (ibalizumab-uiyk) is a prescription medicine that is used in combination with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults who:

- have received several anti-HIV-1 regimens in the past, and
- have HIV-1 virus that is resistant to many 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

TROGARZO® can cause serious side effects, including changes in your immune system (Immune Reconstitution Inflammatory Syndrome), which 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. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare 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®, tell your healthcare provider:

About all your medical conditions.

About all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

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®.

If you are breastfeeding or plan to breastfeed. Do not breastfeed if you are receiving TROGARZO® as it is not known if TROGARZO® passes into breast milk. You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

THERA technologies

719-01-01/20

‘We have to keep on being persistent.’

One man’s story of risk and resiliency

Veteran AIDS activist Matt Sharp, 63, is a leader in efforts to help long-term survivors, particularly through The Reunion Project, a national alliance and network. **Associate Editor Enid Vázquez** asked Sharp about facing the coronavirus pandemic from the perspective of a long-term survivor of HIV.

It’s been intense for me. I’m probably not different than a lot of people. I’ve had pneumonia so many times I lost count. So, I certainly am at risk for developing coronavirus disease. I had pneumonia just from getting seasonal flu a couple of years ago, and was in the hospital for two weeks. It was very serious.

So when I heard about the coronavirus being a respiratory illness, I became really fearful that I was going to get it. Because there was an outbreak here in the Bay Area early on. I knew immediately that I had to do some substantial things to change my life, really following the shelter-in-place rules that San Francisco and the Bay Area put into place early on—thankfully.

It’s hard sheltering-in-place at this point of my life, and especially living alone. I was already isolated, and now I am forced to isolate. But we’re coming up on four months, since March, and here in Berkeley where I live, I get out to walk my dog [his beloved rescue, Betty] and I’m starting to go to the grocery store.

Still, I’m being extremely careful. The double pneumonia I had two years ago happened because the seasonal flu turned out to be a very lethal one, causing people to get pneumonias, and I was one of them.

But I was fortunate to have a great doctor and system of care. You look at what’s going on across the country with the racial inequities in health care, and we’re seeing that people who don’t have access to health care are getting sick and dying more than those who do.

I was incredibly fortunate to have the care to get through that double pneumonia. Yet even if I got it this time I don’t know if that would save me. Once you get on a ventilator it’s hard to get off of it, and sometimes when you’re my age, when you have very little immune system left, and you have this propensity to get upper respiratory illness, there may not be much you can do to save yourself.

It’s been like a perfect storm of this viral disease hitting everyone globally, including long-term survivors who have already been impacted for years with sickness, growing older with HIV, isolation, and mental health issues related to survival. All of these together have placed an enormous burden on those of us who have survived.

We were also just beginning to mobilize as a nation and as local communities to address long-term survival. We couldn’t continue doing what we were doing to bring support programs to people who were in need.

The Reunion Project is bringing on a new diverse group of leaders and organizers to bring people together in creative ways to help move on and move past this—to *really* address our issues as long-term survivors, our issues of aging and HIV, plus our issues of mental health problems, coronavirus, and social and racial justice. In a way, there’s a silver lining there somewhere if you look deeply.

We know there is evidence that coronavirus is not impacting people with HIV like we first thought it would. That’s a tremendous relief. However, what’s the impact on our mental status going to be in the future—our mental health and our social health? We don’t know that yet.

But there are a lot of people who have a lot worse health issues than I do, so I try not to complain about being ill. We get enough of that already.

What I try to do is to get people to be collective in their thoughts around what we can do as a culture, as a community, as a network of long-term survivors to live healthy rather than focus on the deficits. To focus on the things that are positive. I’m involved in great things like The Reunion Project that I hope will build upon the strength of what we have.

We have to keep on being persistent. We’ve always said that as a community of people living with HIV we’re resilient and we take care of ourselves. That's one thing we have to remember no matter what hits us.

COURTESY OF MATT SHARP

Like HIV, COVID-19 underscores disparities

Another pandemic shows the effects of discrimination on vulnerable groups

BY ENID VÁZQUEZ

The COVID-19 crisis shows once again that good health is not equally available to all, health experts say.

Across the country, African Americans, Latinx, and Native Americans not only have higher rates of COVID-19, but also suffer greater severity of disease and disproportionately more deaths.

"The question is really, *Why?*" said Damani D. Piggott, MD, PhD.

The LGBTQ community and people with low income are among the many vulnerable communities experiencing worse health outcomes. Historically, these groups suffer from fewer resources. They also face discrimination that too often keeps them from accessing health care.

It's a challenge—once again, like HIV—to figure out how to protect the people most vulnerable to illness, which in turn will help protect everyone's health.

"The disparity impact of COVID-19 has placed a truly strong spotlight on longstanding vulnerabilities of key population groups to poor health," said Dr. Piggott. "And it highlights the [fact that] opportunity to obtain full health potential is still yet to be afforded to all."

Dr. Piggot, who is Assistant Dean for Graduate Biomedical Education and Graduate Student Diversity and Assistant Professor of Medicine at Johns Hopkins School of Medicine, spoke May 15 on "We Are Not All in This Together—COVID-19 and Communities of Color," along with Dr. Virginia D. Banks (see sidebar, "We had no idea"). They addressed reporters as part of a series of media briefings on the COVID-19 pandemic held by the Infectious Diseases Society of America (IDSA), an association of physicians, scientists, and public health experts.

'... it is becoming increasingly evident that COVID-19 is having a particularly ravaging impact on African American, Hispanic or Latinx, and Native American communities.'

"As data continue to emerge, it is becoming increasingly evident that COVID-19 is having a particularly ravaging impact on African American, Hispanic or Latinx, and Native American communities," Dr. Piggott reported. "Data from the Centers for Disease Control and Prevention as of yesterday show blacks, who make up just about 12% of the U.S. population, comprise 28% of identified COVID-19 cases in the U.S. for which race has been reported. The Hispanic or Latinx community, who make up 18% of the total U.S. population, also constitute 28% of U.S. COVID-19 cases in recent CDC data. There has also been increasing reports of COVID-19 in several Native American communities, including communities such as the Navajo Nation, which is experiencing among the highest per capita rates of COVID-19 across the entire U.S. ... Not only is more COVID-19 disease being seen in these communities, these communities are also experiencing more severe disease and more COVID-related death.

"A struggle to achieve health equity as a society really has been imbedded in key social determinants of health: socioeconomic, environmental, and many other key structural conditions in which we're born, live, work, and age," Dr. Piggot said, "and these factors include things such as:

- income
- employment
- housing
- food and water security
- educational opportunity
- transportation
- incarceration
- access to health systems and services, and
- multiple other determinants in our social and physical environment that have impacted our health for better or for worse over many generations."

Dr. Piggott also discussed socioeconomic conditions more common to people of color which contribute to greater problems given the realities of COVID-19. These include high-density housing arrangements, which preclude physical and social distancing.

The same goes for congregate settings, such as jails, prisons, detention centers, and shelters for those with unstable unhousing.

There's reduced access to medical care and medical insurance. Less access to financial resources also contributes to less health care access.

Language barriers and "other barriers to culturally congruent communication" further hurt access to health

Vulnerable populations

- People of color
- Persons with low income
- Immigrants
- Women
- Children
- Older adults
- Homeless or housing insecure
- Persons with chronic conditions
- LGBTQ
- Individuals with special needs
- Rural and urban residents
- Persons with low literacy and numeracy
- Persons in correctional institutions
- Residents of nursing homes and assisted living facilities

SOURCE: THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

care, as well as messages around disease prevention.

Not to mention a lack of trust in institutions that have historically caused harm to vulnerable people.

There are also underlying chronic conditions which are already more common and less controlled in people of color before the arrival of the pandemic, that contribute to greater severity of COVID-19 disease. Chief among them are diabetes, obesity, and heart disease.

Once again, an unequal health background creates an unequal health risk. Social determinants of health, like low income, further add to the excess risk.

Dr. Piggott started his discussion by pointing out the vulnerability that comes from working in essential jobs during a pandemic. Many of these are frontline jobs with low wages and high exposure to others.

Essential workers include any job where someone is being touched, said Lisa A. Cooper, MD, MPH. Dr. Cooper spoke about vulnerable communities in general (see list), in a webinar presented in May by the Center for Health Journalism (CHJ), "Covering Coronavirus: The Pandemic's Unequal Toll." Dr. Cooper Director of the Johns Hopkins Center for Health Equity and the Johns Hopkins Urban Health Institute.

"People who are caregivers of disabled people or older people have had to work during this time when everyone is being asked to stay at home or to engage in social distancing," Dr. Cooper continued. "They've had to go out and clean health facilities. They've had to drive buses and subway trains. And they've had to ride those public transportation options to get back and forth.

"Many of these groups also lack access to health care services—during a regular time. As you can imagine, during this time it's even harder to access health care services, when a lot of elective care procedures and routine visits are being postponed and people are being asked not to come in for care. So, you have folks who are not having access to regular care being asked to use, for example, telemedicine when they may not have access to broadband internet to be able to do that.

"And then you have an understandable mistrust of institutions and authority because of historical factors, mistreatment in the broader society, discrimination, and also disparities in health care as well as in research," said Dr. Cooper. "A number of different situations, even current situations, that make people in these communities suspicious of authorities, and so less likely to necessarily follow through on advice without getting it from trusted sources."

Dr. Cooper, with Joshua M. Sharfstein, also of Johns Hopkins, published a set of action steps for protecting vulnerable communities in the face of COVID-19, appearing on the *Politico* website in April. Recommended steps include ensuring sick leave and other health benefits, and promoting trust among communities of color.

"One of the things we said is that it's not going to be enough for us to just use Zoom [for video meetings online] and stay at home," Dr. Cooper explained. "And we also talk about why it's important that protecting the most vulnerable in our society is in the interest of all of us."

Among their other points, they wrote on the need for accurate data on race, ethnicity, and geography. Echoing Dr. Piggott, Dr. Cooper said, "It's not enough to say African Americans are more at risk, but why? It's not intrinsic to people being African American that they are being disproportionately impacted. Where are these infections clustering? Is it in certain neighborhoods where there are crowded housing conditions? Or where there's not enough access to food? Are these neighborhoods where there's an overrepresentation of multigenerational families or essential workers?

"We talked about the importance of leaders building trust and communicating frequently, authentically, and clearly with communities of color. This is particularly a challenge when leaders are not engaged with the community members who may be the trusted messengers in those communities."

"These are the groups that experience health disparities even when there's no pandemic," Dr. Cooper pointed out. "People not having access to running water, to wash their hands. On the Indian reservations, we've heard of that."

In summing up his talk, Dr. Piggott said, "As we continue to face this major pandemic and consider these factors, it is crucial for us to consider who has opportunity and who does not ... who has access and who does not ... and how do we close the opportunity and access gaps which spread to every corner of our globe. The virus has already shown us that we are all inextricably connected, and ensuring that everyone has opportunity for maximal health ultimately would be to the benefit of us all." PA

READ the Politico report at politico.com/news/agenda/2020/04/07/game-plan-to-help-those-most-vulnerable-to-covid-19-171863.

Health equity

The state in which everyone has the opportunity to obtain full health potential and no one is disadvantaged from achieving this potential because of their social position or any other socially defined circumstance.

SOURCE: THE NATIONAL ACADEMY OF SCIENCES, ENGINEERING, AND MEDICINE

'We had no idea'

WHEN I STARTED my infectious disease fellowship in the late '70s, somebody came up to me and said, "I don't know why you're going into infectious diseases. Everybody knows how to use penicillin and ampicillin."

Here we are now with a pandemic.

When in the early '80s, and through the '90s, I found myself taking care of HIV/AIDS patients and watching them die, those patients were my age.

And here I am now taking care of another group of patients close to my age who are also dying of a viral illness.

I'm on the front line, daily taking care of patients. When we first started taking care of patients coming in with COVID, the large onslaught in Ohio had started about the end of March. And we had heard about the cases that were in Washington state. But I don't think we had any idea of the impact that it was going to have with us in Northeast Ohio.

There are eight of us in our practice and four nurse practitioners. Many times on the weekends we would all be on call because we had so many patients coming in to the hospital.

Initially we were just trying to take care of patients as fast as we could. As fast as they came through the emergency room, we were just trying to basically keep people alive. Where we saw a grandfather who was bouncing a child on his knee a week before, now coming in a week later on a ventilator, and a week later he had died. This is the impact that this disease has had.

So we really didn't step back to look at race, ethnicity, or anything. It wasn't until really about April that we were now able to catch our breath and step back and look and say, "There's a disproportionate number of individuals from our society and community that are being heavily impacted with this disease."

—VIRGINIA D. BANKS, MD, MBA, FIDSA, FELLOW AND 2019 WATANAKUNAKORN CLINICIAN AWARD WINNER – IDSA, NORTHEAST OHIO INFECTIOUS DISEASE ASSOCIATES, YOUNGSTOWN, OHIO

Until we are all free

BY **AISHA N. DAVIS**

Na'Kia Crawford. Riah Milton. Dominique Fells. Nina Pop. Breonna Taylor. Priscilla Slater. Regis Korchinski-Paquet. Tony McDade. Oluwatoyin Salau. Rayshard Brooks. George Floyd. David McAtee. Ahmaud Arbery.

THESE THIRTEEN NAMES represent thirteen stories abruptly ended. Thirteen futures stalled. Thirteen unique lives, unique laughs, facing unique fears. Unique experiences gone.

But there is one common thread. These thirteen people were Black.

They are the names I know and speak in this moment. They are the names that many of us call to memory when we are demanding respect for Black lives.

Without a lens that centers our most marginalized, we cannot recognize and address the deepest harms facing our communities.

They have become part of a narrative threaded with white supremacy, forged over centuries, from the time Black people were forced into chattel slavery on this continent. In the aftermath of slavery, Black people have suffered being considered a fraction, lynching, gerrymandering, gentrification, divestment, and disenfranchised—and the ongoing state-sponsored violence we experience to this day.

All of this orchestrated harm, enforced by a nation built with broken promises on stolen land, littered with broken treaties.

And now, here we are.

And now, there is a global conversation about anti-Blackness. This moment has been called a revolution, an uprising, a protest. It has coalesced around George Floyd. The pain on his face contrasted with the deliberate indifference in the posture of the officers. A pain that is not new, but is sharp every time. Like when we learned Ahmaud Arbery was killed. Like when we learned Rayshard Brooks was shot in the back. This old, sharp pain feels like being impaled, like having the earth fall away from you, but instead of floating, you are met with the cold, hard edge of anti-Blackness.

And now, there is a global pandemic happening because of COVID-19. This moment has been named as one where all the pre-existing conditions of systemic racism are flaring up, where the social determinants of health are being laid bare, where we are not surprised by the disproportionate deaths in Black communities. It feels like having the air forced out of your lungs. While already being impaled. Like drowning, and boiling, and unable to scream.

And now, there is a spiral of violent quiet where women in Black communities are not remembered as much, not shouted by every voice, not fought for with as much vigor. Black women are being murdered in their beds, brutalized, and targeted. Breonna Taylor's killers have not been charged. Priscilla Slater died in police custody. It feels like everything that is happening—the drowning, the impaling—are happening, but no one will pay attention long enough to respond to it.

And now, there is a dangerous silence happening when the most marginalized in our Black communities are leading the charge, but are not being honored, respected, and rallied around in the same way. There are no suspects in Dominique Fell's murder. Riah Milton has been misgendered and dead-named. Tony McDade's killers have not been charged. It feels like no one is witnessing the harm—the drowning, the impaling. Not ignored—not even known.

Right now, there is no liberation if Black trans lives are not centered. Without a lens that centers our most marginalized, we cannot recognize and address the deepest harms facing our communities.

If we center the communities located at the intersection of all systems of oppression, we can build a future where everyone can meet their needs.

We must oppose policies that permit discrimination against trans and non-binary people—like those we saw handed down from the U.S. Departments of Health and Human Services (HHS) and Housing and Urban Development (HUD). Specifically, we must oppose HHS' stripping of gender discrimination protections for trans and non-binary people, previously protected in Section 1557 of the Affordable Care Act, as well as leaving a pathway for providers to deny reproductive health care. We must oppose HUD's policy permitting homeless shelters to deny services to trans and non-binary people.

We must recognize the bitter and the sweet that happen simultaneously. We should celebrate the protections in states like Illinois that cover the provisions of Section 1557, while we continue to fight for our trans and non-binary siblings in states that have not. We should celebrate the U.S. Supreme Court's decision in *Bostock v. Clayton County*, holding that Title VII of the Civil Rights Act prohibits employers from firing someone based on their sexual orientation or gender identity.

We should also recognize that the same court still refuses to take up the question of qualified immunity, which shields state actors—like the police—from accountability if they are acting in their official capacity. By centering the most marginalized, we can recognize that we must continue to fight. Can job security be enjoyed if a cop can kill you on your way home? We cannot celebrate Pride without demanding equity for our Black trans siblings.

We cannot have justice for George Floyd without justice for Breonna Taylor. For Riah Milton. For Dominique Fells. For Tony McDade.

To paraphrase Audre Lorde—we cannot be free when Black trans women are not free. Black lives do not matter to us all when Black trans women's lives do not matter to us all. Queer communities are not safe when Black trans women are not safe. Women do not have equity if Black trans women do not have equity. Immigrant communities can have no sanctuary if Black trans women have no sanctuary.

And we will keep working, and fighting, and protesting, and rising until we are all free.

ADAPTED from a blog that originally appeared on the website of AIDS Foundation Chicago. Reprinted with permission. aidschicago.org/page/news/all-news/until-we-are-all-free

New CDC recommendation: Test *everyone* for hepatitis C

Testing during pregnancy also becomes more important

BY ENID VÁZQUEZ

According to new U.S. data, the annual rate of acute (recently acquired) hepatitis C virus (HCV) cases tripled from 2008 to 2017.

Moreover, younger people now represent a significant number of those new cases. The highest rates of acute HCV infection were among those between the ages of 20 and 39.

Hepatitis C infection in many individuals frequently went undiagnosed, despite being potentially dangerous if it becomes chronic. Some of the data show that "only 61% of adults with hepatitis C knew they were infected."

Acute HCV often has no symptoms, which could be one reason for underdiagnosis, but stigma also plays a role in this lack of testing.

The new findings have led to two new recommendations for HCV testing from the U.S. Centers for Disease Control and Prevention (CDC).

- Everyone over the age of 18 should test for hepatitis C at least once in their lifetime.
- A test should be done during each and every pregnancy, regardless of age.

Previously, testing was recommended for people born between 1945–1965, the Baby Boomers, as well as anyone with risk factors for infection.

"Concurrent with the nation's opioid crisis, however, rapid increases in acute HCV infections among young adults, including reproductive aged persons, have put multiple U.S. generations at risk for chronic HCV infection," the CDC noted in its new surveillance data report, released in April.

The opioid epidemic is believed to be behind the higher rate of transmission to newborns of mothers with HCV, an increase of 39%.

The new report notes that more than 50% of acute cases progress to a chronic infection, "which can be life-threatening."

Further, "The number of newly reported chronic infections was approximately equal among younger and older adults in 2018."

Hepatitis C, the surveillance report noted, can be diagnosed with a blood test and is curable.

According to the report, "The annual rate of reported acute HCV cases per 100,000 population increased fourfold, from 0.3 in 2009 to 1.2 in 2018, and was highest among persons aged 20–29 (3.1) and 30–39 (2.6) in 2018."

The largest *proportion* of newly reported *chronic* HCV cases that year, however, occurred among people 20–39 and 50–69 years old.

As recommended previously, HCV testing should be done on a periodic basis as long as risk factors continue: At least annually for people who inject drugs, as well as for people with selected medical conditions, including those on maintenance hemodialysis.

The new recommendations note that HCV is "a major source" of disease and death in the U.S.

Yet, "[surveys conducted in 2013–2016] indicate only approximately 56% of persons with HCV infections reported having ever been told they had hepatitis. Therefore, strengthened guidance for universal HCV testing is warranted."

Overcoming barriers to therapy with direct-acting antivirals (DAA) for HCV are needed, the recommendations state. The success of more screening is tied to the availability of treatment.

Stigma within the health care system also needs to be addressed: "Any person who requests HCV testing should receive it regardless of disclosure of risk because many persons might be reluctant to disclose stigmatizing risks."

Most risk is related to injection drug use (IDU), but there are other risks as well.

"Although HCV infection is primarily associated with IDU, high-risk behaviors (e.g., anal sex without a condom), primarily among persons with HIV, are also important risk factors for transmission. Other possible exposures include sharing personal items contaminated with blood (e.g., razors or toothbrushes), unregulated tattooing, needlestick injuries among health care personnel, and birth to a mother with hepatitis C," the recommendations state.

The two reports were published in April. This is the first time the CDC has updated its hepatitis C recommendations since 2012.

SEE the recommendations at cdc.gov/mmwr/volumes/69/rr/rr6902a1.htm. The surveillance report can be viewed at cdc.gov/mmwr/volumes/69/wr/mm6914a2.htm.

Other groups make hepatitis C testing recommendations, which may differ to some degree: The U.S. Preventative Services Task Force (USPSTF), uspreventiveservices-taskforce.org/uspstf/recommendation/hepatitis-c-screening; the American Association for the Study of Liver Diseases (AASLD), hcvguidelines.org; and the Infectious Diseases Society of America (IDSA), idsociety.org/public-health/hepatitis-c/clinical-guidance.

IRINA STRELNIKOVA-ISTOCK

The information on this and the following page

comes from *CDC Recommendations for Hepatitis C Screening Among Adults—United States, 2020*

Hepatitis C overview

Hepatitis C is the most commonly reported bloodborne infection in the United States.

Hepatitis C is transmitted primarily through parenteral [non-oral] exposures to infectious blood or body fluids that contain blood, most commonly through injection drug use.

No vaccine against HCV exists, and no effective pre- or postexposure prophylaxis [PEP or PrEP] is available.

More than half of persons who contract HCV will develop chronic infection.

... more recent data suggest that spontaneous clearance might be as high as 46%, varying by age at the time of infection.

Spontaneous clearance is lower among persons co-infected with HIV. [See the recommendations for factors associated with spontaneous clearance.]

HCV antibodies (anti-HCV) can be detected 4–10 weeks after infection and are present in approximately 97% of persons by 6 months after exposure. HCV RNA can be detected as early as 1–2 weeks after exposure.

The course of chronic liver disease is usually insidious, progressing slowly without symptoms or physical signs in most persons during the first 20 years or more following infection.

Approximately 5%–25% of persons with chronic HCV will develop cirrhosis over 10–20 years.

Those with cirrhosis experience a 1%–4% annual risk for hepatocellular carcinoma.

Persons who are male, aged 50 years or older, use alcohol, have nonalcoholic fatty liver disease, have hepatitis B virus (HBV) or HIV co-infection, and who are undergoing immunosuppressive therapy have increased rates of progression to cirrhosis.

Direct-acting antiviral treatment can result in a virologic cure in most persons with 8–12 weeks of all oral medication regimens.

Hepatitis C treatment

Treatment for HCV infection has evolved substantially since the introduction of DAA [direct-acting antiviral] agents in 2011.

DAA therapy is better tolerated, of shorter duration, and more effective than interferon-based regimens used in the past.

Antivirals for hepatitis C treatment include next-generation DAAs, categorized as either protease inhibitors, nucleoside analog polymerase inhibitors, or nonstructural (NS5A) protein inhibitors. >>

Concerns during pregnancy and childhood

BECAUSE OF the increasing incidence of HCV infection among women of childbearing age, perinatal transmission (intrauterine or intrapartum) has become an increasingly important mode of HCV transmission. Among pregnant women from 2011 to 2016, hepatitis C virus testing increased by 135% (from 5.7% to 13.4%), and positivity increased by 39% (from 2.6% to 3.6%). The risk for perinatal transmission is informed by a systematic review and meta-analysis of studies conducted in multiple countries and is 5.8% for infants born to mothers who have HCV but not with HIV and doubles for infants born to mothers co-infected with HCV and HIV. Perinatal HCV transmission is almost always confined to infants born to mothers with detectable HCV RNA. Only approximately 20% of infants with perinatally acquired hepatitis C clear the infection, 50% have chronic asymptomatic infection, and 30% have chronic active infection. HCV-related liver disease rarely causes complications during childhood. Because fibrosis increases with disease duration, perinatally infected persons might develop severe disease as young adults.

The CDC's 2012 guidelines recommended that pregnant women be tested for hepatitis C only if they have known risk factors. However, in 2018, universal hepatitis C screening during pregnancy was recommended by the American Association for the Study of Liver Diseases and IDSA. This report expands hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection is <0.1%.

Despite their favorable safety profile, DAAs (direct-acting antivirals) are not yet approved for use during pregnancy. Safety data during pregnancy are preliminary and larger studies are required. A small study of seven pregnant women treated with ledipasvir/sofosbuvir [Harvoni] identified no safety concerns. Until DAAs become available for use during pregnancy, testing women during pregnancy for HCV infection still has benefits to both the mother and the infant. Many women only have access to health care during pregnancy and the immediate postpartum period. In 2017, 12.4% of women aged 19–44 years were not covered by public or private health insurance. Pregnancy is an opportune time for women to receive a hepatitis C test while simultaneously receiving other prenatal pathogen testing such as for HIV or hepatitis B. The post-partum period might represent a unique time to transition women who have had HCV infection diagnosed during pregnancy to treatment with DAAs. Treatment during the interconception (interpregnancy) period reduces the transmission risk for subsequent pregnancies. Identification of HCV infection during pregnancy can also inform pregnancy and delivery management issues that might reduce the likelihood of HCV transmission to the infant. The Society for Maternal-Fetal Medicine recommends a preference for amniocentesis over chorionic villus sampling when needed, and for avoiding internal fetal monitoring, prolonged rupture of the membranes, and episiotomy among HCV-infected women, unless it is unavoidable.

Testing during pregnancy allows for simultaneous identification of infected mothers and infants who should receive testing at a pediatric visit. Testing of infants consists of HCV RNA testing at or after age 2 months or anti-HCV testing at or after age 18 months. Although DAA treatment is not approved for children aged less than 3 years, infected children aged over 3 years should be monitored. In 2017, [Harvoni] became the first DAA approved for use in persons aged 12–17 years. In 2019 glecaprevir/pibrentasvir [Mavyret] became approved for use in children up to age 12, and [Harvoni] became approved for use in children up to age 3.

EDITOR'S NOTE: READ an article on HCV and perinatal syphilis from Hepatitis Editor Andrew Reynolds at positivelyaware.com/articles/twin-epidemics.

>> Many agents are pangenotypic, meaning they have antiviral activity against all genotypes.

A sustained virologic response (SVR) is a cure and is defined as the absence of detectable HCV RNA [aka "viral load"] 12 weeks after completion of treatment.

Approximately 90% [other experts, including the World Health Organization, put the percentage above 95%] of HCV-infected persons can be cured with 8–12 weeks of therapy, regardless of HCV genotype, prior treatment experience, fibrosis level, or presence of cirrhosis.

Hepatitis C epidemiology

National surveillance data revealed an increase in reported cases of acute HCV infection every year from 2009 through 2017.

The highest rates of acute infection are among persons aged 20–39 years.

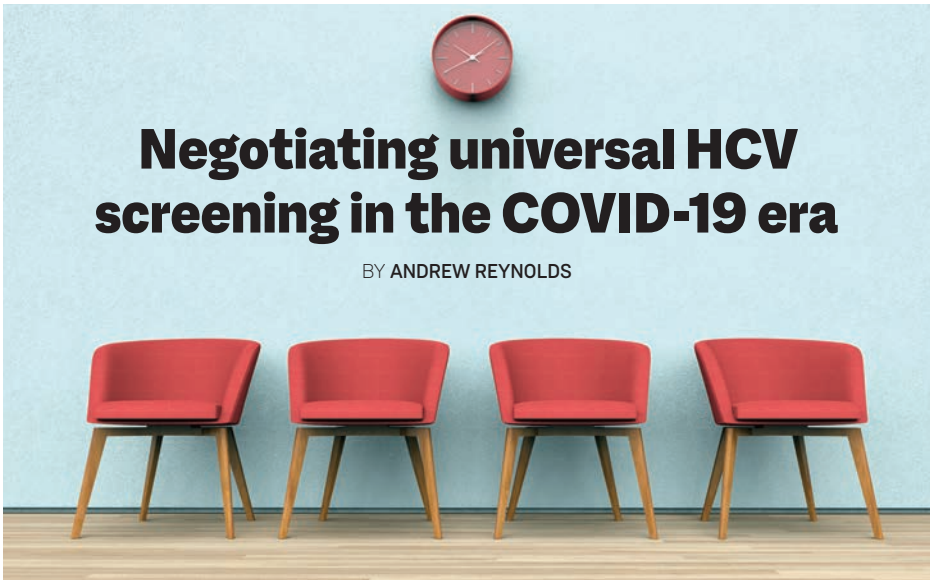
Surveys conducted during 2013–2016 indicated an estimated 2.4 million persons (1.0%) in the nation were living with hepatitis C.

As new HCV infections have increased among reproductive aged adults, rates of HCV infection nearly doubled during 2009–2014 among women with live births.

In 2017, 3,216 cases (1.0 per 100,000 population) of acute HCV infection were reported to CDC. The reported number of cases in any given year likely represents less than 10% of the actual number of cases because of underascertainment and underreporting. An estimated 44,700 new cases of HCV infection occurred in 2017.

Increased incidence of hepatitis C: 364%

During 2006–2012, the combined incidence of acute HCV infection in four states (Kentucky, Tennessee, Virginia, and West Virginia) increased 364% among persons aged 30 years or younger. Among cases in these states with identified risk information, IDU (injection drug use) was most commonly reported (73%). People who had HCV were primarily non-Hispanic white persons from nonurban areas.



Negotiating universal HCV screening in the COVID-19 era

BY **ANDREW REYNOLDS**

People living with hepatitis C, viral hepatitis activists, medical providers, and public health officials have advocated for universal HCV screening for years. We finally got our wish: On April 10, the Centers for Disease Control and Prevention recommended HCV testing for all adults age 18 and older without any requirement to talk about potential risk factors such as injection drug use that people are less likely to talk about due to stigma and fear of judgment. Universal screening is an excellent way to discover previously unknown HCV infections, and creates an opportunity for people who are living with HCV to find out their status and get connected to care, treatment and ultimately, cured.

Unfortunately, this recommendation fell smack in the middle of the COVID-19 outbreak when so many cities and states have instituted "shelter-in-place" (SiP) rules to minimize transmission of the coronavirus in public settings. The real challenge will be in finding a place to get a test due to safety concerns. We are starting to see testing facilities re-open, but many organizations that do community-based testing aren't doing it right now. Similarly, there is concern that many cities and states will experience a resurgence of COVID-19 cases after they've re-opened, and community-based organizations, clinics, and hospitals will have to limit services again to deal with a new onslaught of patients.

The importance of HCV (and other liver diseases) is great, but the urgency of coping with the COVID-19 public health emergency surpasses everything else at this time.

The good news, per the American Association for the Study of Liver Diseases (AASLD), is that there is no evidence that patients with chronic liver disease without advanced fibrosis due to hepatitis B and/or C are at greater risk of COVID-19 infection or for having worse health outcomes when infected. People with cirrhosis do appear vulnerable to the more serious negative health outcomes from COVID-19 infection, and they should take special precautions to stay safe and healthy. That said, we still want to get people tested and treated for HCV, but to do so as safely as possible.

There are AASLD recommendations for safely doing HCV care and treatment, a selection of which follow:

- When COVID-19 is prevalent in the community, severely limit outpatient visits to only patients who must be seen in person, even in areas without significant COVID-19 community spread.
- Follow CDC recommendations for PPE. If PPE is unavailable, keep a distance of at least 6 feet from the patient.
- Strongly consider phone visits or telemedicine as appropriate and available to replace in-person appointments.
- There is no contraindication to initiating treatment of hepatitis B and C in patients without COVID-19 as clinically warranted.

You may find places that are still doing HCV testing, but be prepared for lots of protective practices in place to prevent both you and the staff from getting COVID-19. Allow for extra time as a result. Your best bet to keep up with changes is to call ahead of time. Call HELP-4-HEP (877-4357443) for local HCV resources, and then follow up by calling those places to see if they are currently offering HCV testing and treatment.

SOURCE: aasld.org/sites/default/files/2020-06/AASLD-COVID19-ExpertPanelConsensusStatement-June42020-FINAL.pdf.

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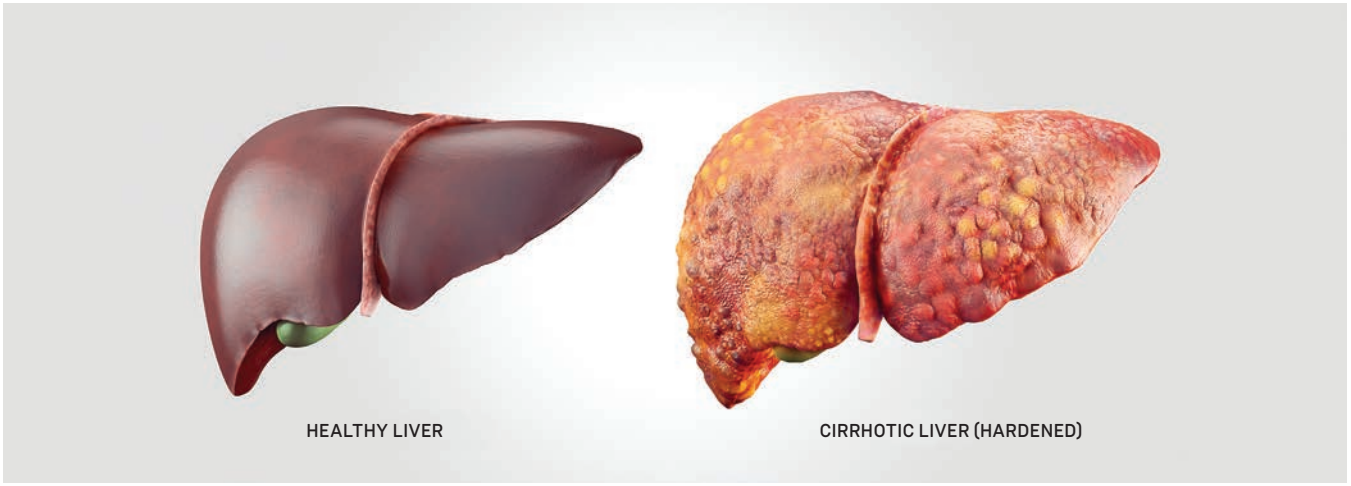
Your liver and hepatitis



HEALTHY LIVER

CIRRHOTIC LIVER (HARDENED)

The liver is the body's largest internal organ, and is responsible for over 500 vital functions. It's a remarkable organ that even has the ability to re-grow itself. The easiest way to think about the liver is as your body's filtering system and warehouse. The liver filters everything we eat, drink, breathe, or absorb through our skin. It also stores nutrients like vitamins, minerals, and iron.

Other functions of the liver include:

- clearing out alcohol and drugs (both legal and illicit)
- making bile and helps digest food
- managing fats and cholesterol
- managing sugars
- making platelets that help blood to clot

A healthy liver is essential for a healthy life. Getting cured of hepatitis C (HCV) will stop the damage done to the liver, and may even lead to a reversal back to a healthy one, including minimizing the risk of liver cancer. Beyond cure, there are many things you can do to help your liver stay healthy.

Fibrosis and cirrhosis

Over time, HCV can cause damage to the liver, leading to fibrosis and cirrhosis. For people living with HCV alone, the scarring process can be relatively slow: Without treatment, it takes an average of about 20–30 years for fibrosis to develop into cirrhosis. HIV/HCV co-infection can speed up liver damage dramatically.

Fibrosis

Chronic inflammation of the liver leads to the production of substances (collagen and other proteins) that can damage the liver's cells. Over time, this damage can lead to scarring. Fibrosis refers to the development of scar tissue in the liver. In the early stages of fibrosis, the liver is able to perform its functions with relative ease. Over time, the fibrosis grows and the scar tissue spreads, stressing the liver and its ability to do its job. As the fibrosis and scar tissue expands, it can eventually lead to cirrhosis. The speed with which fibrosis develops is different from person to person, with several other factors that can speed it up.

Factors that influence the rate of fibrosis progression:

- alcohol consumption
- age at time of infection
- co-infection with hepatitis B
- co-infection with HIV
- presence of other comorbid diseases (like diabetes)

There are many different ways for your medical provider to measure fibrosis and cirrhosis, ranging from a liver biopsy (not done as frequently as in the past, but still the gold standard of measurement) to blood tests. Increasingly, there is a non-invasive (that is, no blood needed) means of measuring liver scarring called "transient elastography" (aka FibroScan), which is painless, fast and easy. While each of these tests are different, they all report their results in a similar way (see following chart):

Fibrosis

SCORE	AMOUNT OF FIBROSIS
F0-F1	No to minimal fibrosis
F2	Significant fibrosis
F3	Severe fibrosis
F4	Cirrhosis

Cirrhosis

As the fibrosis progresses and the scarring covers more and more of the liver, it literally changes shape. This is called cirrhosis. Early cirrhosis, called compensated cirrhosis, can also be asymptomatic while the liver is still able to perform its functions. As the scarring gets more severe, the shape of the liver changes and it gets increasingly stiffer, reducing the blood flow and leading to a series of symptoms and complications. This is called decompensated cirrhosis, and it can be life-threatening without access to specialist health care.

Signs and symptoms of decompensated cirrhosis:

- severe fatigue
- loss of appetite
- nausea
- jaundice
- weight loss
- stomach pain
- fluid retention
- mental confusion

A person with decompensated cirrhosis should be in care with a liver specialist, routinely monitored for liver cancer and other serious problems, and be considered for a liver transplant.

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HCV's FAQs

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"). Besides hepatitis C, there are other hepatitis viruses: A, B, C, D, E. Hepatitis A and B are vaccine preventable, and hepatitis D and E are very rare in the United States. There is no vaccine for HCV.

Hepatitis C (HCV) is a virus that 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 and serious liver problems. Fortunately, HCV can be cured, preventing further liver damage and reducing the risk of developing liver cancer and other problems.

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/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. People often want to know what symptoms to look out for to see if they have HCV, but the only way to know for sure is to test for it. That said, there are some symptoms to look for and that are important to know about so you can make choices for how to manage them. There are different symptoms for different stages of HCV infection and we break them up on the next page by the acute stage (early infection), chronic stage (living with the virus until cured) and end-stage with cirrhosis (after living with HCV for 20-30+ years for most). This list is not exhaustive, but includes the most commonly experienced symptoms.

You should talk with your provider if you experience any of these symptoms, or if you aren't sure something you're currently feeling is related to HCV. It's better to be safe than sorry! Many of these symptoms can be managed and/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?

Testing for HCV is not a simple matter of doing the test and getting a positive or negative result. It can be a little complicated. It's also different from HIV, so that can be confusing as well. 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

The HCV antibody test will come up either negative or positive. If you're negative, you probably don't have HCV at this time. However, there's a "window period" with HCV antibodies similar to HIV. It may take up to 6 months to develop HCV antibodies. Therefore, if your most recent exposure for HCV occurred in the past 6 months, you will need to retest when you reach that 6 month point.

If your antibody test comes back

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positive, then you may have HCV, and "may" is the important word here. That's because about 25% (about 1 in 4) 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 (see below).

However, if you clear HCV like this during early infection, then these antibodies cannot protect you from another hepatitis C infection. People can be, and have been, re-infected! So it's important to protect yourself from re-infection.

THE HCV VIRAL LOAD TEST

If you get a positive HCV antibody test, the next step is to get a viral load test to confirm it. If your last possible HCV exposure was at least 6 months ago and your test comes back negative, then you've cleared the virus. If it comes back positive, then you are chronically infected with HCV, meaning that you will have it for the rest of your life until you get cured.

The other possibility is to have a negative HCV antibody test result with a positive viral load test. This means one of two things: (1) you were very recently infected with HCV 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, it's important to talk with your medical provider about what these results mean and what next steps you should take.

5. Who should get tested for hepatitis C?

This one is now easy to answer: *Everyone!* In 2020, HCV testing is now recommended for everyone over the age of 18 years old without the need to ask about potential risk factors: You just get a test! Most people will need to only get tested once in their life to rule out an infection. For others, such as people who inject drugs, they will need to test routinely. For more information on this update see CDC Recommendations, page 14.

RISK FACTORS

Anyone with risk factors for HCV should be tested on an on-going basis if the risks continued. 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 an HCV-infected mother
- blood exposures on the job, including needle sticks and/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. If you received any of the following, you should test for HCV:

- a blood transfusion before July 1992
- an organ transplant before July 1992
- clotting factors before 1987 (clotting factors 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
- 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, people living with HCV take medications called "direct-acting antivirals," or DAAs. These medications are all oral (pills-only), and are 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. There really isn't anyone who can't be treated and cured; with these medications and even if your first course of treatment doesn't work, there are options for re-treatment that you can try. Once cured, your risk of ongoing HCV-related liver disease will stop and you'll likely reap a host of additional health benefits:

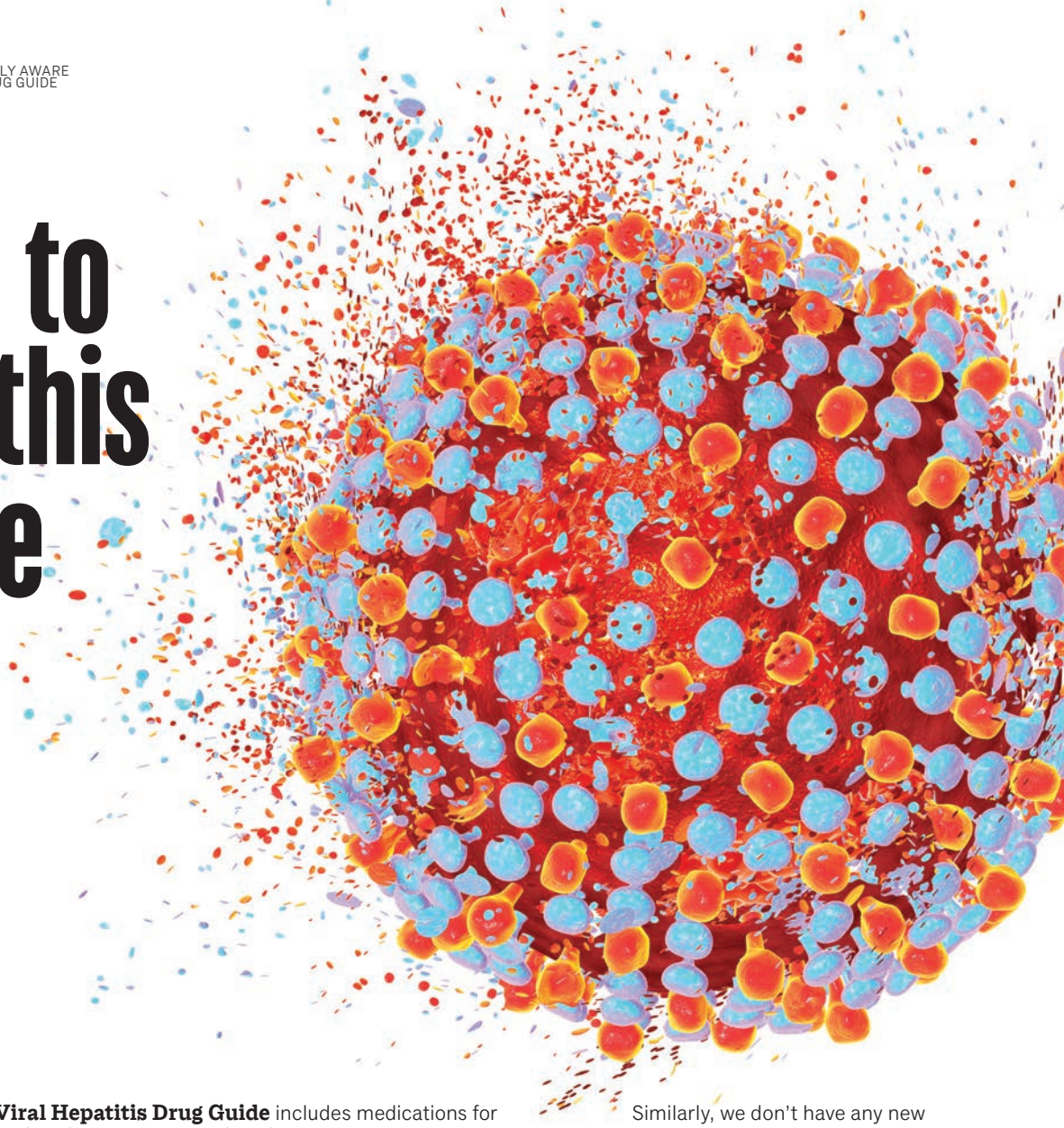
BENEFITS OF HCV CURE

- ✔ Negative HCV viral load for life
- ✔ Disappearance of HCV virus 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 varices (dilated blood vessels in the esophagus)
- ✔ 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

ACUTE HEPATITIS C	CHRONIC HEPATITIS C	END-STAGE LIVER DISEASE
Flu-like symptoms	**Fatigue** (mild to severe)	**Fatigue** (often severe)
Fatigue	**Fever**	**Nausea/vomiting**
Fever	**Depression**	**Fluid retention** (especially in the abdomen and legs)
Joint or muscle pain	**Joint or muscle pain**	**Jaundice**
Dark urine	**Nausea**	**Chronic pain**
Clay colored stools (poop)	**Loss of appetite**	**Cognitive dysfunction/ mental confusion**
Diarrhea	**Skin problems**	**Depression**
Nausea/vomiting	**Cryoglobulinemia** (blood disorder)	**Loss of appetite**
Loss of appetite	**Peripheral neuropathy**	**Skin problems**
Jaundice (yellowing of skin or eyes)		**Cryoglobulinemia** (blood disorder)
		Peripheral neuropathy
		Severe itching

How to use this guide



The Positively Aware Viral Hepatitis Drug Guide includes medications for the treatment of hepatitis B (HBV) and hepatitis C (HCV) that are FDA approved. Also included are medications that have an "off-label" recommendation—that is, treatment options that may not yet be FDA approved, but which are acceptable according to medical providers and other experts. The information provided on the FDA-approved drugs comes from the package labels, as well as other sources such as the AASLD/IDSA Recommendations for Testing, Managing, and Treating Hepatitis C (HCV Guidance); AASLD Hepatitis B Guidance; conference presentations; and medical journals.

Treatment

Treatment is comprised of two or more medications—all pills—taken together. Some treatments are a fixed-dose combination (FDC) that contains medications from at least two different classes in one pill. For example, Epclusa, which is one pill containing velpatasvir and sofosbuvir, or they may be two (or more) separate pills. Some regimens may include weight-based ribavirin. Pegylated interferon is no longer used for HCV treatment.

There are no combination therapies for Hepatitis B (HBV) at the moment, as it is treated with one medication at a time—either with an antiviral such as Viread (tenofovir), Epivir-HBV (lamivudine), or with pegylated interferon. The goal of HBV treatment is to slow or prevent the progression of liver disease. Hepatitis B treatment does not lead to a cure. Despite a concerted effort to develop a cure for HBV, we are many years away from achieving this goal.

What's new in 2020?

There are no new HCV drugs under development in the United States; we have all the HCV treatments needed to cure nearly everyone. The challenge is helping people access treatment due to insurance restrictions and other barriers. If the U.S. committed itself to treating and curing everyone with HCV, we have the medications to do it.

Similarly, we don't have any new drugs for HBV treatment that are close to reviewing. More than 50 HBV drugs and therapeutic vaccines are under development, but most are in the early stages of clinical trial development and are many years away from FDA approval. As new drugs are developed and get closer to FDA approval, Positively Aware will report on them and include them in future editions of the Drug Guide.

Each drug page will include, where applicable:

DRUG NAMES

Drug names can be confusing. We include the brand name, generic name, and an abbreviation. For example, Sovaldi is the brand name of sofosbuvir. Sovaldi can be abbreviated as SOV, and sofosbuvir is abbreviated as SOF. Additionally, HCV medications contain two or more drugs, so you may see several abbreviations and common names: Mavyret has a combination of glecaprevir and pibrentasvir, with the abbreviations of GLE/PIB. Drugs that have been

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FDA approved will appear under their brand name, while those that have not yet reached that stage will only have a generic (or common) name.

FDA STATUS
All medications in this year's Drug Guide are FDA approved.

DRUG CLASS
The "direct acting antiviral" or DAA era of HCV treatment has seen the development of several different classes of hepatitis medications. Currently, there are five classes of HCV drugs, and four multi-class fixed-dose combinations:

- 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. Worldwide, there are as many as 11 distinct genotypes, but 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 overall. Within each genotype, there are several subtypes that are indicated by numbers and letters (GT 1a, GT 1b, and so on). Although different genotypes can play a role in disease progression or severity, it is especially important to know one's genotype to determine the correct treatment. We will list the genotype(s) that the specific HCV medication works against, both those that are FDA approved as well as those that have enough evidence to be used "off-label."

APPROVED FOR HIV/HCV CO-INFECTION
Although all HCV antivirals can be used by people with HIV, only some are specifically FDA-approved for co-infection. The others are used off-label. We will note which drugs are which.

DOSAGE
HBV drugs are either oral tablets or an injectable. HCV drugs are all oral, may need to be taken at different times, and with differing food restrictions. Sometimes, the same drug is taken differently depending upon a variety of factors like genotype or liver health. This section will describe the dosage requirements for the drug, as well as provide details about restrictions and other relevant information.

MANUFACTURER
This section includes the name of the company that makes the drug.

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. Patients should never have to pay for medications at this price, but it's still important to know these costs when shopping for health insurance coverage. 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 30 of the HCV Drug Guide.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
This section offers information about side effects and adverse events associated with an HCV drug. It's not an exhaustive list, but rather a selection of the most commonly reported side effects. The information comes from the package insert and study data for the FDA-approved drugs, and clinical trial data for drugs that have yet to receive FDA approval. Since HCV medications are never taken alone, we'll cover potential side effects that are associated with the entire regimen, as opposed to a single drug. It may be hard to separate one cause of a side effect from another, and in the end, it doesn't really matter what the cause is, only that you are experiencing it. Everyone experiences side effects differently: Just because it's listed doesn't mean you will necessarily get it. Talk to your medical provider about side effects before starting treatment, communicate with them about any you may have during treatment, and get blood tests as directed to look for side effects.

POTENTIAL DRUG INTERACTIONS
This section provides information about the variety of known and potential drug interactions. Like the side effects section, it's not an exhaustive list of interactions, but rather a list of the most important ones. 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 medications) you are taking so you can minimize drug interactions. The information comes from the package insert and clinical trial data for FDA-approved drugs, and clinical trial data for the ones that have yet to receive FDA approval.

MORE INFORMATION
This section contains information that does not fit in any of the above sections, but is still important for you to know.

A note on the risk of hepatitis B reactivation in some patients treated with Direct Acting Antivirals (DAAs) for hepatitis C
On October 4, 2016 the FDA made a safety announcement, also known as a "Boxed Warning," about the potential risk of HBV reactivation in some patients taking **all hepatitis C DAAs**. A Boxed Warning is the most important warning the FDA can issue. In this case, there were a number of unexpected cases of hepatitis B reactivation among people who were cured of HCV using DAAs that led to hepatic flares, liver failure (requiring transplant) or in some cases, death. See page 33 for more information on this warning.

SPECIAL THANKS to Brooke N. Stevens, PharmD, BCPS, AAHIVP, for reviewing the 2020 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 serves as a clinical preceptor (training pharmacy students) at IU Health, and is on the clinical faculty of the Midwest AIDS Training and Education Center. She serves on the "hub team" for the HCV Project ECHO (Extension for Community Healthcare Outcomes) at the Richard M. Fairbanks School of Public Health (RMFSPH). And thanks to Walgreens Community Pharmacy in Chicago for reviewing the drug prices in this guide.

Hepatitis C Direct-Acting Antivirals (DAAs)

Preferred regimens based on AASLD treatment guidelines located 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	1 2 3 4 5 6	✔*	✔	✔*
Harvoni	**sofosbuvir/ledipasvir** (SOF/LDV)	Gilead	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: **$29,904 / month**; AUTHORIZED GENERIC: **$9,600 / month**

DOSE

One tablet once daily, usually for 12 weeks, with or without food. See treatment table at positivelyaware.com/epclusa. Each tablet contains 400 mg of sofosbuvir and 100 mg of velpatasvir. Dosage for children may be reduced based on body weight (see below). Ribavirin may be added or treatment duration extended in patients with decompensated cirrhosis. The brand name is dispensed in a bottle; the authorized generic is 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 closer to the time of 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, with the addition of 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 as they happen during treatment. Epclusa should not be taken within 4 hours of antacids. If taking H2-receptor antagonists, 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 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 sofosbuvir and may reduce its effectiveness. 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. 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 taken for 12 weeks without ribavirin (in most situations) that has minimal side effects and high cure rates. There were several updates to Epclusa prescribing during this past year:

In November, 2019, the FDA approved Epclusa's use in people with kidney disease, including those on dialysis, with no need for dosage adjustment.

In March, 2020, Epclusa was updated to include children. Any child with HCV age 6 or older, and weighing at least 37.5 pounds (17 kg) can take Epclusa.

Epclusa is taken for 12 weeks by people without cirrhosis or who have compensated cirrhosis; with ribavirin added for people who have decompensated cirrhosis (or extended for 24 weeks if not eligible for ribavirin). Treatment is for all genotypes and whether treatment-experienced or not (although this depends on what previous medicines were taken). 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 get worse 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 33 for more information and consult your medical provider.

Epclusa dosing

Body weight	Dosing of Epclusa	Epclusa daily dose
More than 66 pounds (30 kg)	One 400 mg/100 mg tablet once daily	400 mg/100 mg per day
37.5 to 66 pounds (17–30 kg)	One 200 mg/50 mg tablet once daily	200 mg/50 mg per day

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: **$37,800/ month**; AUTHORIZED GENERIC: **$14,400 / month**

DOSE

One tablet once daily with or without food. Tablet contains 400 mg of sofosbuvir and 90 mg of ledipasvir. Duration of therapy is 12 or 24 weeks, depending upon treatment experience and level of cirrhosis. In some cases, an 8-week treatment duration is possible. Ribavirin may be added in people with decompensated cirrhosis or liver transplant recipients with cirrhosis (compensated or decompensated). See treatment duration tables at positivelyaware.com/harvoni. The number of weeks on treatment depends on such things as cirrhosis status and previous therapy. Harvoni is FDA approved for use in children age 3 and older or weighing at least 37.4 pounds (17 kg), with oral pellets for children that age who weigh less (see below for more details).

Harvoni is now FDA approved for people with renal (kidney) disease, with no need to make any dosage adjustments.

Take missed dose as soon as possible, unless it is closer to the time of 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 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). Use caution and monitor renal function when taking Harvoni with tenofovir disoproxil fumarate (TDF). Avoid use if patient is taking TDF with an HIV protease inhibitor, ritonavir, or cobicistat due to possible increase in TDF concentrations resulting in adverse reactions. 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. 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 sofosbuvir and may reduce its effectiveness. 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 is FDA approved for use in children age 3 and older. The dosage amount depends on the weight of the child. The list is too long for inclusion here, but check out the HCV guidelines (hcvguidelines.org/unique-populations/children) for a list of approved treatments and dosage strength for children with HCV genotypes 1, 4, 5, and 6 with either no cirrhosis or compensated cirrhosis.

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 get worse 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 33 for more information and consult your medical provider.

Sovaldi

sofosbuvir (SOF)

DRUG CLASS
Nucleotide analog NS5B polymerase inhibitor

GENOTYPE
1 2 3 4

MANUFACTURER
Gilead Sciences

AWP
BRAND: $33,600 / month

DOSE

Sovaldi is almost never prescribed separately, but instead prescribed as part of co-formulated tablets that contain it with an additional DAA: Epclusa, Harvoni, and Vosevi. Sovaldi is taken as one 400 mg tablet once daily with or without food. Sovaldi should never be taken by itself and must be taken in combination with another DAA. Sovaldi is FDA approved for treatment of HCV genotypes 2 and 3 in pediatric patients down to 3 years old and there are recommendations for dosing in children weighing less than 37.4 pounds (17 kg).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS

Sofosbuvir is very well tolerated with minimal side effects. It is difficult to determine specific side effects of Sovaldi because it has been previously studied with ribavirin and pegylated interferon and documented side effects are likely due to those medications. When Sovaldi is taken with these medications (no longer recommended), the most common side effects reported are fatigue, headaches, nausea, fever, chills, and arthralgia (joint pain). Pegylated 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 it. Sovaldi is also present in several co-formulated tablets (Harvoni, Epclusa, and Vosevi). For more information on the side effects of these medications, see their respective drug pages.

Pregnant women or women who are trying to become pregnant should avoid use if the addition of ribavirin is required. Women of childbearing age and their male partners must use two forms of birth control throughout treatment and for six months after treatment with ribavirin. Changes in hematological (blood) values are also common, and routine blood testing to look for anemia, neutropenia, and other blood conditions is recommended.

POTENTIAL DRUG INTERACTIONS

Before starting sofosbuvir, 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 as they happen during treatment. No sofosbuvir-based HCV regimens are to be used with amiodarone due to possible symptomatic bradycardia. Signs of bradycardia (slow heart rate) 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 occur. Sovaldi cannot be taken with the HIV medication tipranavir/ritonavir but is safe to take with other HIV medications. Do not take Sovaldi with St. John's wort, and in general, herbal products should be avoided due to lack of information regarding potential for interaction. Sovaldi should not be taken with rifamycin antimicrobials, such as rifampin, rifabutin, rifapentine, or certain anticonvulsants, such as phenobarbital, carbamazepine, phenytoin, and oxcarbazepine, as they reduce the concentrations and its effectiveness.

MORE INFORMATION

Sovaldi is almost never prescribed. It is contained, however, in the co-formulated medications Epclusa, Harvoni, or Vosevi, which are very commonly used today. Approved in 2013, the original sofosbuvir dosage and duration is already pretty much obsolete when compared to other HCV treatments. Sovaldi is a drug with a lot of "firsts"—first drug of its class, first drug to receive FDA approval for use without interferon, and the first DAA to receive FDA approval for use in HIV/HCV co-infected patients.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Sovaldi, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse 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 33 for more information and consult your medical provider.

Available co-formulated tablets and their components

Harvoni	Ledipasvir + sofosbuvir
Epclusa	Velpatasvir + sofosbuvir
Vosevi	Velpatasvir + sofosbuvir + voxilaprevir

NOTES: Sovaldi may be used as an alternative regimen with Olysio (genotype 1) or Daklinza (genotypes 1, 2, 3). See hcvguidelines.org for more information on current recommendations. For pediatric patients, Sovaldi is still recommended in combination with weight-based ribavirin for treatment of genotypes 2 and 3.

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. Ribavirin may be added in patients with certain baseline NS5A polymorphisms (mutations that may make the Zepatier less effective).

Zepatier may be used in severe renal impairment, including patients on hemodialysis. NS3/4A protease inhibitors, such as grazoprevir, are contraindicated in patients 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 (liver enzyme).

Take missed dose as soon as possible, unless it is closer to the time of 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 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. That said, some insurance companies still prioritize its use because it is a lower cost drug in their respective plans. It is an excellent regimen for patients with kidney disease, including those on hemodialysis, with 99% achieving a cure. That said, it would not be surprising if Merck eventually discontinued its production.

If you have HCV genotype 1a, you will need to take 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.

BLACK BOX WARNING

Before starting treatment with any direct-acting antiviral (DAA), including Zepatier, patients should take a blood test to check for hepatitis B (HBV) infection. HBV infection could get worse 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 33 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 66 kg = 800 mg per day, 66–80 kg = 1000 mg per day, 81–105 kg = 1200 mg per day, greater than 105 kg = 1400 mg per day) 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 table at positivelyaware.com/mavyret. The number of weeks on treatment depends on such things as cirrhosis status and previous therapy. Mavyret is FDA approved for use in children age 12 and weighing at least 99 pounds (45 kg).

Mavyret can be used in severe renal impairment, including patients on hemodialysis. NS3/4A protease inhibitors, such as glecaprevir, are contraindicated for patients with moderate or severe liver impairment (Child-Pugh B, C), which is also called decompensated cirrhosis. Using Mavyret in decompensated cirrhosis may cause significantly higher amounts of glecaprevir in the blood and may increase ALT (a liver enzyme).

Take your missed dose as soon as possible, unless it is closer to the time of 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 as they happen during treatment. Mavyret should not be taken with HIV medications that require ritonavir as a booster to increase drug levels, such as atazanavir and darunavir. Mavyret should 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 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 the first pan-genotypic 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, curing 98% of patients with severe kidney disease in 12 weeks of treatment (EXPEDITION-4) as well as for patients post-liver or kidney transplant. Mavyret can be used for both adults and children who are liver and/or kidney transplant recipients. For all of this great news, Mavyret is not recommended for people with moderate to severe liver damage (Child-Pugh B or C), and alternative DAAs are better choices. For more information, see 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 get worse 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 33 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.

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).

Take missed dose as soon as possible, unless it is closer to the time of your next dose. Do not double up on your next dose.

Not FDA approved for use in HIV co-infection, but may be considered.

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

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 as they happen during treatment. Vosevi should not be taken within 4 hours before or after you take antacids. If taking H2-receptor antagonists, 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; 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 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

Approved in 2017, Vosevi marks the next generation of Gilead drugs for treatment of hepatitis C and will provide people who have been considered difficult to treat with a new option to get cured. A very important update for Vosevi occurred in November, 2019: The FDA approved Vosevi's use for people with kidney disease, including those on dialysis, with no need for dosage adjustment. Of particular importance is Vosevi's effectiveness in people with previous DAA treatment experience and HCV drug resistance. It is FDA approved for the re-treatment of HCV in people who are treatment-experienced, and although it can be used off-label for the initial treatment of HCV, it's best to use other options and save this one just in case it is needed later. In POLARIS-1, 97% of patients 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. 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 get worse 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 33 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, ledipasir, 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

Rebetol; ribavirin

ribavirin (RBV)

DRUG CLASS
Nucleoside analog

GENOTYPE
1 2 3 4 5 6

MANUFACTURER
REBETOL (SOLUTION): **Merck**
GENERIC CAPSULES/TABLETS: **Manufacturers vary**

AWP (BASED ON 1,200 MG/DAY DOSING)
REBETOL (SOLUTION): **$1,960 / month;**
GENERIC 200 MG TABLET: **$222–$1,670 / month**
GENERIC 200 MG CAPSULE: **$230–$1,668 / month**

DOSE

Ribavirin dosage depends on several factors, including the brand used, 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. Depending upon the manufacturer, tablets are available in 200 mg, 400 mg, 500 mg, and 600 mg. Ribavirin solution (liquid) and generic tablets are also available. The authorized generic was created to help lower cost and has identical ingredients as the brand name. 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.

Dose adjustment in patients with kidney dysfunction varies based on brand used. In general, 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 closer to the time of 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 or women who are trying to become pregnant cannot 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 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.

Additional financial assistance and access advocacy programs

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.

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.

Liver Health Connection
liverhealthconnection.org
Array of services for people throughout Colorado. Excellent site for news and information.

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.

DRUG NAME	MANUFACTURER	PHONE NUMBER	WEBSITE
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 treatment for HIV/HCV co-infected persons

It wasn't that long ago when 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, inject one of them, suffer severe side effects and worst of all, they were not very effective at curing people. Today, HCV treatment is easier than ever: For most people it can be completed in 8–12 weeks (some people may need 24 weeks), with few pills (and no injections!), and manageable side effects that are usually quite mild. Best of all, they cure people at very high rates, between 90 to 100% of the time. 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 *AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C*, the two leading professional guidelines for managing and treating HIV and HCV, respectively. They guide your medical providers in their practice, and offer valuable information for you, too.

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 co-infected people.

There could be drug interactions between your HIV and HCV medications, however. In these cases, there may be a need to switch your HIV regimen to accommodate the HCV ones. If you can't (or don't want) to switch them, you may be able to try an HCV treatment that doesn't interact with your HIV medications. Make sure you HIV provider and your HCV one 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 so that you can take HCV treatment. You can take both at the same time.

HCV treatment in co-infected persons

Everyone with HCV should be treated for it regardless of the amount of liver damage, and HIV/HCV co-infected persons are no exception. In fact, the 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. There may be some drug interactions between HIV and HCV meds, so make sure all your medical providers know what you're taking.

The cure rates for HIV/HCV co-infected people are extremely good, closely mirroring those of people who do not 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 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 problems. 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 so the 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 here.

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 of 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 and over-the-counter—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 reinfection with HCV. If you inject drugs, use new syringes and injecting equipment, and avoid sharing them. HIV-positive people are more vulnerable to sexual transmission of HCV, so minimizing your risk of exposure to HCV through safer sex practices (condoms for anal sex, gloves for fisting, for example) 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 for the virus 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 of 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 fancy 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. Stay tuned to 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 any questions about HCV treatment, call The Support Partnership's national hepatitis C helpline: HELP-4-HEP, (877) 435-7443.

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. Over 2 billion people worldwide have been infected with it at some point in their life, and approximately 240 million of those are chronically infected (living with HBV). Worldwide, it leads to over 780,000 deaths every year. 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. This brief article will provide you with HBV basic information.

Hepatitis B transmission

Hepatitis B is transmitted in much the same way as HIV: It's spread when the blood, semen, vaginal fluids, and other body fluids of a person infected with HBV get into a person who is not infected or who is not protected by immunity (through vaccination or cleared infection). It is also commonly transmitted from mother to child during birth. The following activities 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;
- 0ccupational 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.

Here's who should get tested for HBV:

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 SITUATIONS OR 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.

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 evaluation or treatment 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 exposure to blood or blood-contaminated body fluids
- anyone with end-stage renal disease, including pre-dialysis, hemodialysis, peritoneal dialysis, and home dialysis patients
- 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
- unvaccinated adults with diabetes mellitus ages 19–59 years (at the discretion of clinicians for unvaccinated adults with diabetes mellitus who are aged 60 years and older)
- anyone seeking protection from HBV infection—acknowledgment of a specific risk factor is not a requirement for vaccination

If a person already has HBV, the vaccination will offer no protection against disease progression or risk of liver disease. Sometimes, people get vaccinated without getting checked for chronic infection—ask your medical provider if you have been checked

for chronic HBV infection (or if you were exposed to the virus and then cleared it, and are thus naturally immune) before starting a vaccination schedule.

Treatments for hepatitis B

While HBV is vaccine preventable, to date there is no cure for it. There are treatments, however, that can help control and slow the virus from reproducing. These treatments can slow down the damage done to the liver and reduce the risk of long-term problems like cirrhosis or liver cancer.

While HBV is treatable, not everyone needs it. HBV treatment is not recommended for someone in the acute stage of infection; most people will clear it naturally and treatment doesn't look to improve the chances of clearing it. If someone is chronically infected, but has a normal liver function test called ALT or elevated ALT with low or undetectable HBV viral loads, then she/he does not need treatment. While they do not need treatment, they should be monitored routinely and engage in healthy liver behaviors and activities.

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 varied scenarios where a person should be treated for HBV, but those conversations are best to be had with a medical provider. If you're living with HBV and are concerned about whether or not you should take HBV treatment, talk with your medical provider.

Ten ways to love your liver

Health and wellness tips for living well with HBV

1. Learn about HBV. Hepatitis B can be complicated, from understanding the test results to managing chronic infection to making treatment decisions. There are excellent resources available to help you. Start here with this guide, and then check out the "Hepatitis B Resources" page (page 39) to learn more.

2. Get the hepatitis A vaccine. Hepatitis A is a viral infection of the liver. It's a short-term (also called "acute") infection that, while it will make you miserable, is rarely serious. However, if you live with HIV, HCV, or HBV, you should get vaccinated as it could make your liver disease worse. It's a two shot sequence: After your first shot, you get the second one 6 months later.

3. Test for hepatitis C (HCV) and HIV. Co-infection with either disease can increase the risk of liver damage in a shorter amount of time. Knowing your status for HCV and HIV is also important for treatment decisions for all three viruses.

4. Avoid alcohol. Ideally, people with HBV should not drink alcohol. Too much alcohol alone can be very hard on the liver, and alcohol and viral hepatitis are not a good mix: It speeds up AND worsens HBV-related liver damage. Changing drinking habits is hard, so get the help and support you need to reduce or quit safely.

5. Eat well. People with liver disease should minimize their fat intake, as well as watch their sugar and sodium. The more fresh fruits and vegetables you can eat the better. Do not eat raw or undercooked shellfish. Talk with your medical provider or pharmacist before starting any vitamins, minerals, or herbal supplements.

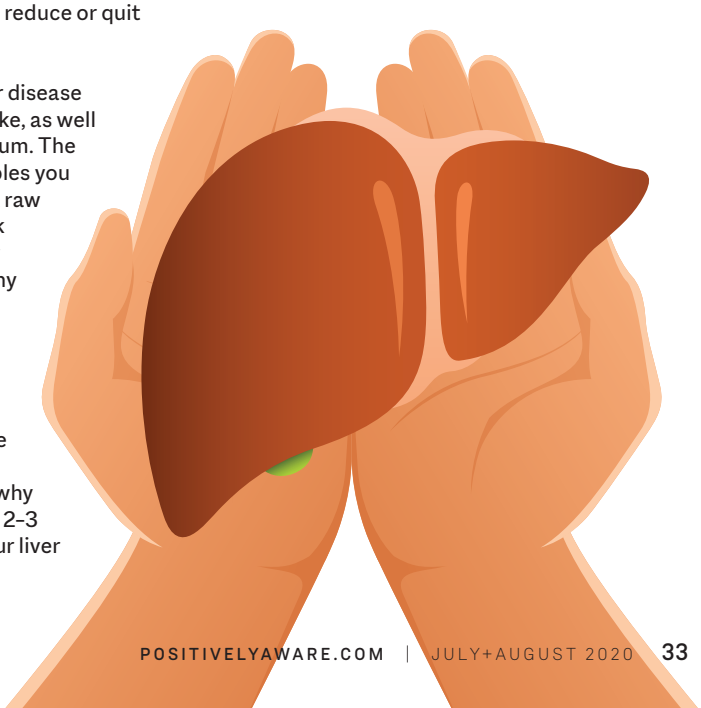
6. Drink coffee. Coffee has been shown to both slow down liver disease and reduce the risk of cirrhosis and liver cancer. It's not entirely clear why it works, but it does. Drinking 2–3 cups per day may improve your liver health.

7. Exercise. Check with your medical provider first to make sure it's safe to exercise. Exercise will burn calories and burn fat, maintain or lose weight, and lower stress. Exercise also helps against feeling tired and may even improve your mood. You don't have to do anything super difficult: Something as simple as 30 minutes a day can help.

8. Tell your sexual partners to test and see if they need to get vaccinated for HBV. As HBV can be transmitted sexually, talking to your sexual partners about HBV and preventing transmission is important. Sexual partners who have not been vaccinated against HBV should do so.

9. Practice safe injection and safe sex practices to avoid infecting others. As HBV can be transmitted through the sharing of injection equipment, talking to your drug-using partners about HBV and preventing transmission is important. Drug-sharing partners who have not been vaccinated against HBV should do so.

10. See your provider regularly and check for liver damage. You may not need HBV treatment; indeed, most people don't need it. It is still important to get regular checkups to monitor your liver.



AALTAZAR-ISTOCK

Hepatitis B medications

BY CLASS AND PREFERRED REGIMENS

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	✔	Merck
	Pegasys	peginterferon alfa-2a	✔	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:

Patients 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).

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

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

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

Patients 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.

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: **$1,300 / month**

DOSE

ADULT (AGE 16 AND OLDER): Treatment-naïve with no resistance, one 0.5 mg tablet once daily on an empty stomach (no food 2 hours before or 2 hours after taking pill); if lamivudine or telbivudine (brand name Tyzeka, discontinued since December 2016) resistant, 1 mg once daily on an empty stomach. Adult with decompensated liver disease: 1 mg once per day. Dose adjustments needed for individuals with kidney disease. See positivelyaware.com/baraclude and consult a medical provider for more detail.

PEDIATRIC (AGES 2–15): Weight-based dosing required. It's complicated, and should be managed in consultation with an experienced medical provider.

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. There are two potential serious side effects when taking Baraclude: (1) Lactic acidosis: The build-up of lactic acid in the blood that 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 lightheadedness, fast or irregular heartbeat, or unusual muscle pain. If you experience any of these symptoms contact your medical provider immediately; (2) 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 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—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 three preferred medications (including Viread and pegylated interferon) for the treatment of HBV in both mono- and HBV/HIV co-infected persons. Although Baraclude is not an HIV medication, it does have some activity against HIV. It should not be taken by itself if you are living with HIV. 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 must be increased to 1 mg.

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 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.
See pediatric treatment table online.

Vemlidy

tenofovir alafenamide (TAF)

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

MANUFACTURER
Gilead Sciences

AWP
$1,407 / month

DOSE

One 25 mg tablet once per day, with food. Take your missed dose as soon as possible, unless it is closer to the time of 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 were headache, abdominal pain, fatigue, cough, nausea, and back pain. Not everyone experiences side effects, and among those who do, approximately 1% have to stop taking Vemlidy. Vemlidy is processed by the kidneys, so there is some risk of kidney toxicity. 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. Vemlidy may lead to lactic acidosis, a buildup of lactic acid in the blood that 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 as they happen. Because Vemlidy is related to Viread (tenofovir DF), the two medications cannot be taken together. Similarly, it cannot be taken with any of the following HIV combination medications, as they contain tenofovir DF: Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Descovy, Odefsey, Stribild, Symfi, Symfi Lo, Symtuza, Genvoya, 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 oxcarbazepine, phenobarbital, or phenytoin. Vemlidy should not be taken with the antimycobacterial medications rifabutin, rifampin, and rifapentine. Vemlidy should not be taken with St. John's wort.

MORE INFORMATION

Vemlidy will not cure HBV—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, using 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. If you have HBV/HIV, and need to switch from any tenofovir-containing regimen, there is a risk of an HBV flare-up with signs and symptoms of acute HBV infection. For individuals with HBV/HCV co-infection, or those 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. There is no dosage requirement for people with kidney disease who have a creatinine clearance greater or equal to 15mL per minute. For those with end stage kidney disease (those who have a creatinine clearance below 15mL per minute), they can take Vemlidy as long as they undergo 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).

Viread

tenofovir disoproxil fumarate (TDF)

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

MANUFACTURER
BRAND: **Gilead Sciences**

AWP
TABLET (BRAND): **$1,504 / month**
TABLET (GENERIC): **$110–$1,216 / month**
POWDER (BRAND ONLY): **$2,934 / month**

DOSE

One 300 mg tablet once per day, with or without food. Oral powder is also available. Take your missed dose as soon as possible, unless it is closer to the time of 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. There are two potential serious side effects when taking Viread: (1) Lactic acidosis: The buildup of lactic acid in the blood that 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; (2) 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 as they happen. Do not take Viread with the HBV treatment Hepsera. Viread cannot be taken with any of the following HIV combination medications, as they contain tenofovir DF: Atripla, Biktarvy, Cimduo, Complera, Delstrigo, Descovy, Odefsey, Stribild, Symfi, Symfi Lo, Symtuza, Genvoya, 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, Prezista/Norvir, and Reyataz/Norvir increase Viread levels, but do not require dose adjustments. This interaction may increase Viread-related side effects; patients should be monitored for them and for kidney disorders. Viread should be avoided with any medications that could negatively affect the kidneys, including chronic use or high doses of NSAIDS (nonsteroidal anti-inflammatory drugs, such as Advil, Aleve, ibuprofen, naproxen, or Motrin). Viread is safe to take with HCV DAAs, but monitor for side effects if used with Epclusa, Harvoni, or Vosevi.

MORE INFORMATION

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. Another HIV medication—Epivir—also works against both HIV and HBV, and while it is an option for treatment, it's not preferred compared to several other choices. If you have HBV/HIV, and need to switch from any Viread-containing regimens, there is a risk of HBV flare-up with signs and symptoms of acute HBV infection. For individuals with HBV/HCV co-infection, or those 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 use in children age 2 and older, weighing at least 22 pounds (10kg) or more. Dose adjustments may be needed, 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—
ADULT: 180 mcg injected intramuscularly once per week, no food restrictions.

PEDIATRIC: Not recommended, but off-label use is possible. Consult with a medical provider for more information.

Intron A—
ADULTS AND PEDIATRICS (AGE 1 AND OLDER): 3 million IU/m^2 three times a week (TIW) for the first week of therapy followed by dose escalation to 6 million IU/m^2 TIW (maximum of 10 million IU TIW) injections. Treatment length is 16 weeks for adults and 16–24 weeks for pediatrics.

Take your missed dose as soon as possible on the same day or the next day and then continue on 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. It does not mean you can't take HBV treatment, you just want to watch for signs 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 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 used 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. The World Health Organization does not include it in their HBV guidelines. 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.html
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	WEBSITE	PHONE NUMBER
Baraclude (entecavir)	Bristol Myers Squibb	bms.com/patient-and-caregivers/get-help-paying-for-your-medicines.html	(800) 721-8909
Viread (tenofovir disoproxil)	Gilead	gileadadvancingaccess.com	(800) 226-2056
Vemlidy (tenofovir alafenamide)	Gilead	gileadadvancingaccess.com	(800) 226-2056
Intron A (interferon alfa)	Merck	No website.	(800) 727-5400
Pegasys (pegylated interferon)	Genentech	No website.	(888) 941-3331

Hepatitis A: What you need to know

It's not normally fatal, but hep A can lead to death for someone with liver disease

After years of decline, hepatitis A (HAV) outbreaks and infections have dramatically increased throughout the United States in recent years: From 2016 to 2018, the CDC reported a nearly 300% rise in HAV infections, with continued outbreaks reported in the years since. Many of these new infections are the result of contaminated food, but there have also been increases among men who have sex with men (MSM), people who inject drugs (PWID), and people who are homeless. Hepatitis A is not normally fatal, but for individuals with pre-existing liver disease, it can lead to death. Consequently, these recent outbreaks have led to a significant number of deaths. This page is designed to give you very basic information about HAV, including ways to prevent it so we can avoid this unnecessary loss of life from a vaccine-preventable disease.

What is hepatitis A?

Hepatitis A is a type of viral hepatitis. It is a virus that infects the liver, but it differs from hepatitis B (HBV) and C (HCV), in that it doesn't become chronic: Once infected, people will likely feel symptoms for around two months, with some people experiencing them for as long as six months. Like HBV, HAV is vaccine preventable.

Hepatitis A is transmitted from fecal to oral contact: When traces of poop (feces) are inadvertently eaten. It is commonly a food-borne illness, where someone eats something that has not been properly cleaned or cooked or hands have not been properly washed, but it can be sexually transmitted as well through oral to anal contact.

What are the symptoms of hepatitis A?

Once infected with HAV, it usually takes about 2–7 weeks for symptoms to appear. Whereas hepatitis B and C are usually asymptomatic (no symptoms), hepatitis A almost always has symptoms, some of which can feel quite severe:

- jaundice (yellowing of skin and eyes)
- fever
- fatigue
- loss of appetite
- nausea and/or vomiting
- abdominal pain
- diarrhea
- joint pain
- dark urine
- clay-colored stools (shit or poop)

These symptoms can last for 2–3 months, with some people experiencing them as long as six months. There is no treatment for hep A, but your symptoms may be treatable. However, don't take any medications—either over-the-counter or prescribed—to deal with symptoms without first consulting your medical provider. You don't want to put any added pressure on your liver, and some medications can do that.

How is hepatitis A prevented?

There are two ways to completely prevent HAV: Get vaccinated, or take post-exposure prophylaxis after having been exposed (if you have not been vaccinated).

The HAV vaccine is a safe and effective way to prevent infection. The vaccine is a two-shot sequence, and you need them both to ensure long-lasting protection: You get the first one, and then follow up with the second shot six months later. Depending upon the brand of vaccine used, the second dose can happen as long as 12–18 months later. There are also vaccines that have both HAV and HBV in them. If a person misses the vaccination within the allotted time period, it's safe to start over as extra doses are not harmful. The HAV vaccine is safe for people with HIV, as well as those with HBV or HCV. Indeed, people living with any of these infections should be vaccinated against HAV.

If you have not been vaccinated, but think you've been exposed, call your medical provider immediately. You can take immune globulin or the HAV vaccine. It must be administered within the first two weeks of an exposure to be effective.

Other ways to prevent HAV include good hand washing, cooking food, and boiling water (note: in the U.S., drinking water is treated to kill HAV), and minimizing oral to fecal contact during sex.

Once a person has been infected with HAV, they will have natural immunity and need not worry about future infections.

Who should get vaccinated?

In the U.S., all children have been vaccinated since 2005. Some states started earlier. There are no recommendations to vaccinate all adults, so don't assume that you received the vaccine. The following should be vaccinated:

- all children at age 1 year
- people traveling to countries where hepatitis A is common
- family and caregivers of adoptees from countries where hepatitis A is common
- men who have sex with men
- people who use drugs, either injected or non-injected
- homeless persons
- people with chronic or long-term liver disease, including hepatitis B or hepatitis C
- people living with HIV
- people with clotting-factor disorders
- people with direct contact with others who have hepatitis A
- any person wishing to obtain protection from the virus

Hepatitis A is preventable. Don't assume you've been vaccinated—talk with a medical provider.

CHECK OUT the CDC's website on hepatitis A: cdc.gov/hepatitis/hav/afaq.htm.
TRACK hepatitis A outbreaks, with this interactive map from *Hep Mag*: hepmag.com/iframe/hepatitis-a-outbreak-map.

PREVENTING HEPATITIS A AND COVID-19

Handwashing when you have no sink—or home

Washing hands with soap and water is one of the best things to prevent any number of infections and diseases, including COVID-19. While washing or disinfecting hands with an alcohol-based hand sanitizer are the gold standard for disease prevention, it's not always easy to access the necessary resources, especially for people who use drugs and people without reliable housing. Here are a few suggested alternatives when soap, water or hand sanitizer are unavailable.

- Check for emergency housing.
- Check with service providers for handwashing supplies.
- Body wash and shampoo can substitute for soap. So can dish soap, but it may be irritating.
- Rubbing alcohol kills COVID-19. Drinkable alcohol does not. Alcohol wipes work—use one per finger, back of hand, and palm. Rub for at least 20 seconds.
- Look for places with water faucets you can use, such as parks and gas stations. Ask permission before using water hoses.
- Bottled water can be used for rinsing. Hands can air dry.

CONDENSED FROM vitalstrategies.org/resources/handwashing-and-covid-19-prevention-for-unhoused-people.

ISTOCK

Forgotten risk

Hepatitis B prevention for people who inject drugs

While the risk of HIV and hepatitis C infection from the sharing of syringes and related injection equipment gets the most attention, it is important to keep HBV at the forefront of our prevention efforts, too. Indeed, one of the first needle exchange programs was started in Amsterdam by a group of PWID and their allies in response to an HBV outbreak.

As the opioid crisis rages throughout the United States, we are seeing increases in HBV rates among PWID, and in pregnant women, which can lead to mother-to-child transmission if left unchecked. See below for some prevention and harm reduction tips to reduce the risk of infection among PWID.

HBV prevention tips for people who inject drugs

HBV vaccination. This is easily the most important recommendation: Get vaccinated and you don't have to worry about getting infected later. All PWID should be vaccinated against HBV. Test to make sure you don't already have it or are already immune to it (see page 32). If you're still at risk of infection, get vaccinated.

Safe injection practices. New, unused injecting equipment—syringes, cookers, cotton, water, etc.—for each injection is the best way to prevent HBV (as well as HCV and HIV). Check to see where you can get these in your local area: Syringe access sites may be available, or you may be able to purchase syringes from a pharmacy.

Other harm reduction practices. New, unused injection equipment is the gold standard for prevention, but if you have no access to them and have to share or re-use one, rinsing one with bleach is the next best thing. In lab settings, bleach has been shown to be effective in disinfecting and killing HIV, HCV, and HBV. You should rinse with cold water, draw up the bleach (ideally keep the bleach in there for 2 minutes), then rinse it out with cold water again.

FOR MORE INFORMATION on how to use bleach to disinfect a syringe, check out this video: harmreductionworks.org.uk/2_films/cleaning_syringes.html.

Reducing or stopping injection drug use. If you are ready for drug treatment or can get into opioid replacement therapy, you won't be injecting drugs any longer and thus not at risk. This is easier said than done, so if you're not ready, you may consider different, non-injecting, ways of taking your drug of choice. If you snort drugs, don't share straws. If you smoke them, don't share pipes, or do cover the mouthpiece to avoid any potential blood contact. If you choose to stop (or are forced to stop due to incarceration or other reasons), be mindful of the risk of opioid overdose should you use again. Be safe: If possible, don't use alone (each person using their own injecting equipment) and carry naloxone to reverse an overdose should one occur.

Practice safer sex and other prevention strategies. While preventing infection from injection drug use, don't forget about other ways to get it. Minimize your risk of sexual transmission through the use of condoms or other barriers.

After the cure: Taking care of your liver

A hepatitis C cure almost always results in improved liver health, but there is more to do to stay healthy

Today's HCV medications cure nearly everyone: People living with HCV who are in overall good health are cured over 95% of the time. Even those who aren't cured the first time can get cured at very high rates using different medications. Once cured, the virus won't bounce back: Less than 1% of people cured experience a return of the virus, so a sustained virologic response (SVR) is a true cure. That said, you'll still want to monitor your liver health and prevent the risk of getting re-infected with HCV.

Once you're cured, HCV-related liver disease progression almost always stops, even in those who have cirrhosis.

Liver health post-cure

Following your cure, AASLD/IDSA HCV Guidelines recommend the following:

People who have no cirrhosis:

- If you've been cured with little to no fibrosis (F0–F2), you should receive the same standard of care as if you never had HCV. You won't have to worry about your liver health any more than would someone who has never had HCV.
- Although HCV recurrence following cure is exceedingly rare, HCV re-infection can happen. If you don't have ongoing risk for HCV (for example, injection drug use), you don't need to screen for HCV routinely. If you do still have risk, a known exposure to HCV, or experience an unexpected rise in your liver enzyme tests, you should screen for HCV using a quantitative HCV RNA test (viral load) rather than an HCV antibody test to detect re-infection.
- If you have an unexpected flare-up in your liver enzymes after cure, your medical provider may order an HCV test to rule out re-infection while looking for other causes.

People who have cirrhosis:

Curing HCV, even when people have cirrhosis, leads to improved liver health. Risk of liver failure, liver cancer, and liver-related death drop dramatically for many people after they've been cured. If you have cirrhosis, especially decompensated cirrhosis, you will still want to monitor your liver health as follows:

- If you've been cured after developing more advanced liver disease (F3 or F4), you should be screened for hepatocellular carcinoma (HCC or liver cancer) with ultrasounds twice-yearly (every 6 months).
- If you've been cured after developing cirrhosis, you should get an endoscopy to check for varices (enlarged veins in the torso, which can burst). If varices are found, they can be treated appropriately and you will not likely get them again (it's rare for them to return after getting cured).
- If your liver function tests are consistently elevated and abnormal, your medical provider will assess you for other causes of liver disease.

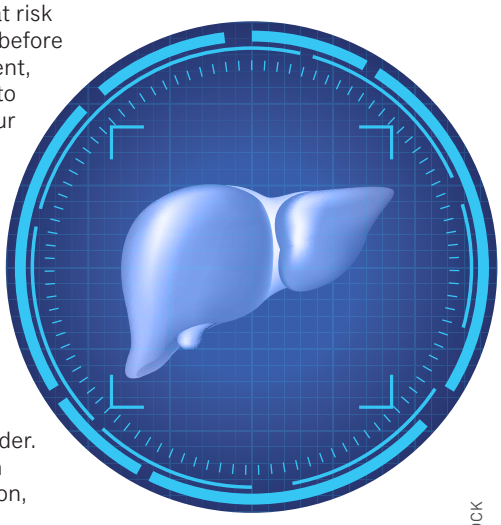
Other important considerations:

ALCOHOL USE Without the virus, it's common to wonder if it's safe to drink alcohol again. Alcohol, even drinking just 1–2 glasses per day, accelerates HCV disease and increases risk of cirrhosis and other liver complications. But what about after someone has been cured? We don't know. There has not been any research to help make an informed recommendation. If you have cirrhosis, you cannot drink alcohol safely. If you have more moderate levels of fibrosis you should talk with your medical providers; they know your liver health and other potential complications that may help you determine whether you can drink alcohol.

HEPATITIS B REACTIVATION If you were deemed at risk for HBV reactivation before starting HCV treatment, you should continue to stay in touch with your medical provider to monitor your liver health. If you are on HBV treatment, you may have to continue treatment for 3 months following completion of HCV DAA therapy. Do not stop taking HBV medication without consulting your provider. For more information about HBV reactivation, check out page 34.

HCV RE-INFECTION If you use drugs, don't share injection equipment (syringes, cookers, cotton filters, water, etc.), straws for snorting, or pipes from smoking. If you're HIV-positive, be mindful of sexual transmission of HCV, and use condoms and other practices that minimize risk of blood exposure during sex. Screen for HCV at least once a year, but you might want to do it more frequently to detect HCV re-infection as quickly as possible. For tips on reducing your risk for HCV re-infection, check out "Hepatitis C Prevention for People Who Inject Drugs" and "Hepatitis C Awareness for Gay Men."

FIBROSIS AND CIRRHOSIS These two conditions may reverse over time following a cure. Yes, your liver may return to normal. For more information, check out "Your Liver and Hepatitis."



ISTOCK

Defining champions

Celebrating 30 years of championing people affected by HIV

This year marks 30 years of POSITIVELY AWARE (PA) magazine. What started out as *TPA News*, a local newsletter for TPAN (the HIV service organization that publishes PA), became POSITIVELY AWARE and with the launch of the November 1990 issue went national. This year as we mark our 30th anniversary of publishing, we'll be looking back at some of the stories and people who helped make POSITIVELY AWARE what it is today: a vital resource for so many.

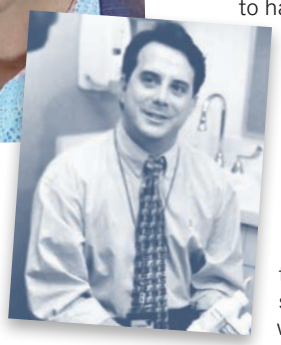
PA30 is a national campaign commemorating the 30th anniversary of POSITIVELY AWARE that will focus on leaders, influencers, and readers who stand out as champions for others affected by HIV. Our "**PA30 Champions**" will celebrate those who have helped pave the way for others and who help inspire the champion within each of us. PA30 Champions will be featured here in the magazine as well as in multimedia storytelling via email and social media. Through PA30, we invite readers and followers to share their stories and celebrate PA's impact on their treatment decisions and personal journey with HIV.

Meet **Glen Pietrandoni, RPh, AAHIVP**, someone who exemplifies the qualities of a PA30 Champion. Under Glen's leadership, Walgreens trained more than 3,000 pharmacists in HIV care in communities across the nation, including those with high HIV prevalence, to uniquely support HIV testing, education and care. In his personal life, Glen has been a tireless advocate and volunteer. He served on the board of TPAN, the publisher of POSITIVELY AWARE, and was a regular contributor to the magazine with his ongoing column "Medicine Chest". Glen's impact has extended to national policy and leadership circles, through his past work with the White House Office of AIDS Policy, the Centers for Disease Control and Prevention, and the U.S. Dept. of Health and Human Services.

In writing about the early days of the epidemic, Glen says, "In my mind, the history of HIV and my own history as a pharmacist are indelibly linked. I'd only been out of pharmacy school for a few years when the first AIDS case was documented in 1981, and as a gay man working in a predominantly LGBTQ community, the ensuing crisis felt deeply personal.

"At first, nobody knew what was happening; we just knew people were dying and there was no cure. There was a lot of stigma, fear and confusion in those days, and the community wasn't sure who they could trust. Along with other doctors, nurses, social workers, as pharmacists, we helped people ease their suffering with the limited options we had. We were all scared, but did what we could."

In a recent blog earlier this year announcing a new chapter in his life Glen says, "After almost 30 years, it's time to say goodbye to my Walgreens family. I have spent the vast majority of my professional career at Walgreens. It's been 50 years since I walked into the neighborhood Rexall drug store the summer before starting high school in 1970 and worked there through a pharmacy degree in 1979. In 1967, I wrote (see above) a school assignment that proclaimed my desire to become a "*pharmasist* [sic] and travel the earth." (We didn't have spell check back then.) In the '80s, with a business partner, I was co-owner of a number of drugstores that we eventually sold to Walgreens in 1989 and I have been here ever since. I am grateful for the friendships, mentors, and inspiring individuals that have been a part of my journey here at Walgreens for all these years.



'At first, nobody knew what was happening; we just knew people were dying and there was no cure. There was a lot of stigma, fear and confusion in those days, and the community wasn't sure who they could trust.'

—GLEN PIETRANDONI, TODAY, AND IN 1981

"I've had a series of unique opportunities at Walgreens as one of the first RxPress managers, the first onsite pharmacy manager at Howard Brown Health, first disease state lead for specialty, first provider sales team director, and first patient advocacy director. Along the way, I've been able to speak with patients in underserved urban communities in the United States, providers in rural China, numerous celebrities and government leaders and to countless team members in the field. I've been extremely fortunate to have traveled throughout the country and around the globe, all in an effort to accomplish our goal of helping people.

"Having said that, it did take some courage with brand and reputational risk, both from a large corporation and personally. In the early days, it was not easy to stand up for people who were ostracized by society, stigmatized by disease and lifestyle choices, and who did not have a voice. Together we have accomplished so much by focusing on serving our patients and delivering the best care possible with professionalism and without judgement.

For this honor and privilege, I am eternally grateful to have been a part of the Walgreens Company and its great tradition."

WE CELEBRATE and honor Glen as one of our PA30 Champions. He will be among the PA30 Honorees whose stories we will uplift this fall. **READ MORE** about Glen and our other PA30 Champions: positivelyaware.com/pa30.

COURTESY OF GLEN PIETRANDONI

ANTHONY MARTINEZ, MD, CLINICAL ASSOCIATE PROFESSOR, DEPARTMENT OF MEDICINE,
JACOBS SCHOOL OF MEDICINE AND BIOMEDICAL SCIENCES AT THE UNIVERSITY AT BUFFALO

MARTINEZ: SANDY KICMAN, JACOBS SCHOOL OF MEDICINE AND BIOMEDICAL SCIENCES AT UB · ECMC: M/E ENGINEERING

Not your basic bodega

An innovative hepatitis C clinic takes a different approach

BY **MICHELLE SIMEK**

Buffalo is having a moment. Buffalo is experiencing a renaissance. The second largest city in New York State is thriving thanks to public and private investments that are creating both new places to live and vibrant tourist destinations (such as Canalside, located at the 1825 terminus of the Erie Canal, which now has new restaurants and bars). Also thriving in Buffalo is perhaps the world's most unusual and dynamic hepatitis C (HCV) clinic: The Hepatology Clinic at the Erie County Medical Center (ECMC), otherwise known as *La Bodega*.

Founded in 2012 by Anthony "Tony" Martinez, MD, AAHIVS (HIV specialist), La Bodega is a community clinic that puts the needs of the community first. A medical doctor with the heart and soul of an activist, Tony moved to Buffalo from San Diego (although he is originally from Providence, Rhode Island) with a mission: "to help build the program and also contribute to the city's revitalization—which was a once-in-a-lifetime opportunity." Initially, "the clinic didn't have a space, still had paper charts, and didn't even have staff." ECMC offered Tony a space that used to be an orthopedic clinic. At the time, it was "a rag-tag forgotten area—like a bullpen with staff in the center and rooms all around. And the front window has a metal gate, just like you would see in a bodega in New York City."

Just like that, *La Bodega* earned its name. But instead of selling beer, cigarettes, and off-brand soda, this progressive Bodega follows a co-localized model and treats addiction and HCV simultaneously. Patients receive opioid substitution therapy (OST) at the same time as HCV treatment—no more draconian rules demanding that patients be clean and sober in order to save their livers and their lives. La Bodega has an astonishingly high HCV cure rate of 98.6%. "I was fortunately given a ton of freedom to build [La Bodega]," Tony says.

In addition to the bullpen vibe, La Bodega has a bell mounted on the wall that patients ring (loudly and proudly) once they are cured of HCV. (One patient rang it with such gusto, she pulled the triangle bell off the wall. It was replaced with a much more durable cowbell.) When that happens, everyone at the clinic comes out, claps and cheers for them. There is also space on the wall for patients to write their name and a message to the clinic staff and the world. Two large signs proclaim: "Come one, come all" and "La Bodega: Pirate Ships Don't Sink."

ERIE COUNTY MEDICAL CENTER (ECMC), HOME OF *LA BODEGA*

Patients are seen no matter if they walk in for the first time without an appointment or show up on the wrong day or time. Others are seen the same day that they are referred. La Bodega is staffed leanly but effectively and depends heavily upon their social worker. No one is hired if they don't embrace the clinic's core philosophy: "We live and die

MARTINEZ: 'WE'RE ALWAYS ON CALL.'

with our patients." The staff must have the same patient-centric philosophy and also agree to be on call 24/7 via cell phone, should a patient ever need help. "We are always on call," says Tony. "Patients need access to you. If they have that access, they feel more comfortable. If someone runs out of Suboxone on a Sunday, they can reach out to us." This is not your average clinic.

Tony has worked in addiction, HCV, and HIV for 18 years. "Liver disease and addiction are married to each other and they eventually merged in my career." He was treating a patient at La Bodega who was co-infected with HIV and HCV. The patient asked Tony if he could be his HIV specialist. "I then had to figure out how to add more to what I'm already doing. What do I have to do to become a specialist?" When he looked into AAHIVS—certification as an American Academy of HIV Medicine Specialist—he realized that he already met all of the training criteria, and was allowed to sit for the board exam and could add *AAHIVS* to his title after passing it. Tony remains the patient's HIV specialist to this day.

"Tony Martinez is one of my true 'Hep C heroes'," says Brian Risley, chair of the Hepatitis C Task Force and Manager of HIV/Hepatitis C Health Promotion at APLA Health in Los Angeles. "Tony knocked it out of the park when he spoke about his *bodega* clinic concept at the 16th Annual Hepatitis C Summit. La Bodega has created a family of providers and patients where successful treatment of HCV and addiction are as important as their life stories and successes. What Tony presented was a model for clinics everywhere to successfully treat each person's HCV and addiction holistically and empathetically."

And this model is being replicated in several states—California, Louisiana, Nevada, Texas, and Washington. Additionally, Tony has had discussions with health officials in Portugal and Saudi Arabia about assisting with HCV elimination plans in those countries.

Like all health care facilities, La Bodega had to make adjustments when the coronavirus pandemic hit the U.S. hard in March. While some patients had to be seen in person, La Bodega needed to convert to telemedicine—and quickly. During that "painful week," Tony's staff had to call every patient and convert their care to telemedicine. Some patients were technologically savvy enough to use the Zoom video conferencing platform, while others weren't, and Tony wanted options for all. "I wanted different platforms to let the patients choose what works for them and choose their scheduling. We had to make scheduling forgiving. Like our clinic model, one size does not fit all."

In an effort to facilitate easier patient communication, Tony and one of his staff members paid for their own subscriptions to various telemedicine services for their patients to use. Thanks to their nimble shift to telemedicine, La Bodega has seen 51 new HCV patients since March, and 43 of them have started hep C treatment. Twenty-one new patients have started opioid substitution therapy. The clinic has had 1,223 total patient visits since March 13, an astounding number.

On June 5, New York Governor Andrew Cuomo announced that the state had reached its lowest number of deaths and hospitalizations since the coronavirus epidemic started. As the state slowly reopens Tony continues to worry and "hopes it's not just COVID half-time. We can't sustain another round of this. We've got to flatten this thing out enough so that we can get ahead of it." And La Bodega's new challenge is that most patients really like telemedicine. "How do we integrate telemedicine as another communication tool while still maintaining that close, human interaction?"

Meanwhile, La Bodega is receiving national and international recognition. The team submitted numerous abstracts to last year's annual Liver Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston. One of the abstracts was included in the presidential plenary HCV wrap-up session (arguably the session with the most impactful abstracts). La Bodega's model was also presented last year at the International Conference on Hepatitis Care in Substance Users in Montreal. And this year, Tony presented at the International Hepatology Exchange in Amsterdam.

When he started his career, the majority of HCV patients were male baby boomers. Now, due to the opioid epidemic that has seeped into every state in the U.S., most of his patients are "frighteningly young," under the age of 30, and half are women. His female patients are of childbearing potential, and they can and do get pregnant. Babies are being born with HCV at the ever-growing rate of 6% (in comparison, HIV vertical transmission rates are 2%). And this has forced Tony and his Bodega to evolve again. They now offer testing for children born to HCV-positive mothers whom they have treated. La Bodega, in collaboration with the ECMC's Division of Family Medicine, also offers treatment to eligible children.

La Bodega, like the original stores in New York City, is "one-stop shopping" and open to all. PA

MICHELLE SIMEK has worked in HIV/AIDS for more than 20 years. She currently works at the UCLA Center for Clinical AIDS Research and Education (C.A.R.E.) and is a popular HIV/AIDS educational presenter, both locally and nationally. In her spare time, she is an actor, avid reader, enthusiastic concert-goer, and proud mom of Baxter, her rescue cat.

SANDY KICMAN, JACOBS SCHOOL OF MEDICINE AND BIOMEDICAL SCIENCES AT UB

OBSERVATIONS OF AN HIV DOC

HIV care focuses on healthy aging, not just younger people

BY **ENID VÁZQUEZ**

DR. FRANK PALELLA (BACK ROW, CENTER) APPEARED ON THE COVER OF POSITIVELY AWARE IN MAY 1993 WITH OTHER NORTHWESTERN PROVIDERS AND STAFF AS HOPS BEGAN.

We're told over and over again not to smoke. Thank—or blame—more than 5,000 men and women who signed up for a cohort study back in 1948 in Framingham, Massachusetts.

The Framingham Heart Study found that smoking is bad for us. That's the benefit of a cohort study. You follow a group of people to see what helps and what doesn't. Usually, participants have something in common, say, people with diabetes. Medical advances come from such work.

Enter HIV. Striking down young men and women in the prime of their life. And children.

Enter the HIV Outpatient Study, or HOPS, in 1993, at hospitals throughout the country. Not the first HIV cohort study in the world, but like the others, vital to health and wellbeing.

The thousands of men and women who enrolled in HOPS have helped track the astounding successes seen in the epidemic. They showed, for example, that life expectancy dramatically increased, and at the same time illness dramatically decreased, with new HIV treatments that became available in 1995–96.

Many other findings also contributed to improvements in HIV health care.

"These are observational data, which always precede the ability to do controlled trials. Because if you can observe it happening, that gives fuel to the process of constructing the randomized controlled trials [the gold standard in medical research]," said Frank J. Palella, Jr., MD, professor of medicine at Northwestern University Feinberg School of Medicine, in Chicago. "But first you have to have the observation."

Dr. Palella is principal investigator of the Northwestern HOPS site. Other sites around the country include Denver, Philadelphia, and Tampa, Florida.

Following are more observations from an observation study leader.

"It's interesting how our goals have changed. Back then our goal was to ... *keep ... people ... from ... dying*," Dr. Palella recalls. "Now, in a world where we can routinely suppress the virus, keep the immune system healthy, and extend survival, our goal has become completely different—happily. Today we usher people into old age and help them remain healthy. We talk about lifespan, and now we talk about healthspan as well. It's a newer word to use with HIV."

'Healthspan' refers to the times in life when someone is in reasonably good health. With the research findings and resulting medical advances, many of Dr. Palella's patients today are long-term survivors. And his younger patients are reassured that they too will live a long, healthy life by staying on treatment and in care.

I have patients who have literally been my patients for 30 *plus years*, many for more than 20 years. I have a big cadre of patients who are older: 50s, 60s, 70s, and beyond. I'm helping with their older age issues—their blood pressure, their diabetes. Their high cholesterol or their screening for cancer. Mobility, and frailty, and physical functioning issues that are age related.

And I have another big group of people who are young, and younger, and for whom the situation is so much better. Because they don't have to live a long period of time—or any period of time—without getting good therapy for HIV. It's there. It's publicly funded. You don't have to wait for good treatments to come along. *They're here.*

They didn't arrive overnight.

When we talk about the time in which the HOPS started, in 1993, it was the bad old days where we had no effective therapy for HIV. The focus back then was profiling how people with AIDS were doing, how long they were living, and what sort of opportunistic diseases they succumbed to, and what sort

MAY 1993 COVER PHOTO BY ROGER LEWIS

We learned that there is no such thing as treating HIV too early.

of things might palliate or even just marginally improve outcomes.

I can remember that in our in-patient hospice unit at Northwestern, which was primarily for people with cancer, over half of the patients in hospice were persons with AIDS at any given time from the late '80s and up to the mid-'90s . And they had a worse prognosis than people with cancer.

We saw so many young people, vital people, just talented people, people who had just embarked on their adult lives, taken from them, taken from us. We lost people who were important to us personally and professionally. That was very hard.

So when the triple drug protease inhibitor-based combination therapy first became available in late '95, early '96, it's clear that something dramatic happened. People ... stopped ... dying. People who had been losing weight and feeling awful, they're gaining weight, gaining strength. Their T cells went up, their viral loads went down. In the words of some of my patients, "These new medications have brought me back from the edge of the grave."' It gave people a second life.

One of my patients was featured in the *Chicago Tribune*. He talked about having been so ill with opportunistic infection after opportunistic infection. Then all of a sudden—he wasn't ill. And he felt so much better. One of his quotes was put in big, bold letters: "**All of a sudden I have to think about my future again.**" What a wonderful thing to have to think about again!

I'm happy to tell my patients now, especially my younger patients, "You stick with the program. Take your once-a-day pill. Come and see me every few months or even half year. Get screened for STDs. Keep your nose clean and stay away from things that are bad for you and you're going to live longer than me." And that's a wonderful thing to be able to say to people, something we couldn't say as recently as 20 years ago. Again, it's because we are so good at getting people into therapy, suppressed on therapy, and retained in care, so that HIV does not become the principle determinant of their lifespan or their healthspan. The menu of treatment options that we have available to us now is simply extraordinary.

So our goals now are to identify people with HIV, get them promptly into care and on therapy, virally suppressed, and maintained in care. Which are the five goals of the HIV continuum of care.

It was the evidence of HIV cohort studies along with other research that brought these options today.

We take it for granted now that everyone who's diagnosed with HIV should immediately start therapy so they can get suppressed on medication and remain in care. That in turn has informed the urgency of getting ... people ... tested. But so much of this initial incentivization comes from information that was evident from observational databases.

At the time the HIV Outpatient Study began, AIDS was the leading cause of death for men in the U.S., and more so for young men. As an infectious disease clinician, Dr. Palella was at the right place at the right time.

But beside the incredible death rate and lack of effective treatment, there was the stigma.

It was a very interesting and peculiar space to be in, because of an illness that was fatal and had no good therapies, which had a social stigma. It was a disease that implied a lifestyle status, and had financial, insurance coverage, and job implications, and familial alienation. Embracing HIV and AIDS as a disease state and persons with HIV as a population was a very brave and extraordinary thing to do.

In those days, even the medical providers who worked in HIV were shunned by other staff members.

Today, the stigma continues.

People of color, in addition, have to deal with the misinformation born of institutional mistrust. When Dr. Palella talks about a good prognosis for their disease, they're often surprised.

I think they hear my talk and take it to heart, but then they sometimes say, "I didn't know that," or "Wow, on the streets I'm hearing that that's not always the case for everyone. Maybe for my ethnic group or my racial group, that it doesn't work as well," being Black, Latino, or any other group. People hear things on the street which just ... *aren't ... true.*

Even as new findings continued to show the benefits of treatment, sometimes—but not always—there were racial differences. Some of those are due to socioeconomic differences, not the chemical compounds themselves.

Also seen were problems

HOPS HIV study at 25

THE HIV OUTPATIENT STUDY (HOPS) recognized its first 25 years of service with an article detailing its work and findings.

"The HOPS contributed to characterizing new conditions (e.g., lipodystrophy), demonstrated reduced mortality with earlier HIV treatment, uncovered associations between select antiretroviral therapy use and cardiovascular disease, and documented remarkable shifts in morbidity from AIDS opportunistic infections to chronic non-communicable diseases," the team reported in April.

HOPS is a cohort study, looking at outcomes in a group of people sharing a particular trait, in this case, HIV. HOPS was the first cohort group to report that HIV treatment with protease inhibitor drugs greatly reduced the risk of death and disease.

It was established by the Centers for Disease Control and Prevention (CDC) in 1993.

In 2017, its 25th year, 89% of HOPS participants had undetectable viral loads (less than 200). Nearly 11,000 participants enrolled in the study in that quarter of a century.

"Few sources of longitudinal data exist profiling people living with HIV (PLWH) spanning that period," the HOPS group noted. "Cohort data enable investigating new exposure and disease associations and monitoring progress along the HIV care continuum. ...

"During the past 25 years, HOPS participants and physicians have both witnessed and contributed to the advances and remarkable changes in the clinical epidemiology of treated HIV infection. The findings generated by clinical HIV research, including the HOPS, have informed both U.S. and international guidelines and recommendations shaping clinical practice today."

THE COMPLETE MANUSCRIPT, published in April 2020, is available from the journal *Open Forum Infectious Diseases* (OFID) at academic.oup.com/ofid/advance-article/doi/10.1093/ofid/ofaa123/5819208. OFID is an open-access journal from the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA).

like adverse events and high cost.

Those problems, however, provided the impetus for newer and better medications—safer and better tolerated.

All the while, the treatment benefits continued.

We learned that there is no such thing as treating HIV too early.

We were able to show from this work that starting earlier is better. There's not a T cell count—no CD4 cell count—above which we fail to demonstrate the benefits of therapy. This is both in terms of avoiding HIV-related illness, but also the aging-related illnesses like heart disease, kidney disease, liver disease, and cancer. Starting late will still save people's lives and bring them back from the brink of death. But death comes over the long term, over decades, when you ... start ... therapy ... as soon ... as possible.

As a big bonus we also learned over the last six or seven years that when you get somebody on therapy and virally suppress them you make them essentially incapable of sexually transmitting HIV. That is a huge part of prevention.

Undetectable equals untransmittable. Treatment equals prevention. It's true. The best prevention of HIV is identifying and treating people with HIV so they cannot transmit it sexually.

We have learned this over and over and over again, and it constitutes yet another important reason to identify people with HIV as soon as possible. Use universal screening and get them on the virally suppressive therapy. Not just for their own sake but for the sake of everyone whom they come in contact with, for the sake of the entire community, and all of society.

Undetectable equals untransmittable. Treatment equals prevention. It's true.

So, today Dr. Palella is taking care of patients as they age, expecting their lives to be as good as that of anyone else their age. And taking care of younger patients as well, with the expectation that they too will live long and healthy lives. Reminding all of them that taking care of their health benefits everyone.

I hope to keep my patients impassioned to stick with the program for themselves and for people they love. So we can keep everybody together regardless of HIV status. PA

Making history

"Mortality among the patients declined from 29.4 per 100 person-years in the first quarter of 1995 to 8.8 per 100 in the second quarter of 1997. There were reductions in mortality regardless of sex, race, age, and risk factors for transmission of HIV. The incidence of any of three major opportunistic infections (Pneumocystis carinii pneumonia, Mycobacterium avium complex disease, and cytomegalovirus retinitis) declined from 21.9 per 100 person-years in 1994 to 3.7 per 100 person-years by mid-1997."

—Palella FJ, Jr., Delaney KM, Moorman AC, et al. Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. HIV Outpatient Study Investigators. *New England Journal of Medicine* 1998; 338(13): 853-60.

Actual patient living with HIV.

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- *EGRIFTA SV™* is not for weight loss management.
- The long-term safety of *EGRIFTA SV™* **on the heart and blood vessels (cardiovascular) is not known**.
- It is not known whether taking *EGRIFTA SV™* helps improve how well you take your antiretroviral medications.
- It is not known if *EGRIFTA SV™* is safe and effective in children, do not use in children.

You should not take *EGRIFTA SV™* if you:

- Have a pituitary gland tumor, surgery, or other problems related to your pituitary gland, or have had radiation treatment to your head or head injury.
- Have active cancer.
- Are allergic to tesamorelin or any of the ingredients in *EGRIFTA SV™*.
- Are pregnant or become pregnant. If you become pregnant, stop using *EGRIFTA SV™* and talk with your healthcare provider.
- Are less than 18 years of age.

Before using *EGRIFTA SV™*, tell your healthcare provider if you:

- Have or have had cancer.
- Have problems with blood sugar or diabetes.
- Have scheduled heart or stomach surgery.
- Have breathing problems.
- Are breastfeeding or plan to breastfeed.
- Are taking any other prescription and non-prescription medicines, vitamins, and herbal supplements.

***EGRIFTA SV™* may cause serious side effects including:**

- **Increased risk of new cancer in HIV positive patients or your cancer coming back (reactivation).** Stop using *EGRIFTA SV™* if any cancer symptoms come back.
- **Increased levels of your insulin-like growth factor-1 (IGF-1).** Your healthcare provider will do blood tests to check your IGF-1 levels while you are taking *EGRIFTA SV™*.
- **Serious allergic reaction** such as rash or hives anywhere over the body or on the skin, swelling of the face or throat, shortness of breath or trouble breathing, fast heartbeat, feeling of faintness or fainting, itching and reddening or flushing of the skin. **If you have any of these symptoms, stop using *EGRIFTA SV™* and get emergency medical help right away.**
- **Swelling or fluid retention.** Call your healthcare provider if you have swelling, an increase in joint pain, or pain or numbness in your hands or wrist.
- **Increase in blood sugar (glucose) or diabetes.**
- **Injection site reactions.** Injection site reactions are a common side effect of *EGRIFTA SV™*, but may sometimes be serious.
- Increased risk of death in people who have critical illness because of heart or stomach surgery, trauma of serious breathing (respiratory) problems has happened when taking certain growth hormones.

The most common side effects of *EGRIFTA SV™* include:

- Pain in legs and arms
- Muscle pain

These are not all of the possible side effects of *EGRIFTA SV™*. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to **THERA patient support®** toll-free at 1-833-23THERA (1-833-238-4372).

This information is not intended to replace discussions with your doctor. For additional information about *EGRIFTA SV™*, go to: www.egriftasv.com for the full Prescribing Information, Patient Information and Patient Instructions for Use, and talk to your doctor. For more information about *EGRIFTA SV™* contact **THERA patient support®** toll-free at 1-833-23THERA (1-833-238-4372).

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