News & Analysis

Medical News & Perspectives

VA Extends New Hepatitis C Drugs to All Veterans in Its Health System

Judith Graham

Aided by new funds from Congress, the Department of Veterans Affairs (VA) is extending new antiviral treatments to all veterans with hepatitis C treated within its sprawling health care system—regardless of the stage of their illness and whether they contracted these infections during military service.

The move puts the VA at the forefront of combatting the nation's deadliest infectious disease, which kills more people in the United States than HIV, tuberculosis, pneumoccocal disease, and dozens of other infectious conditions combined, according to the Centers for Disease Control and Prevention (CDC) (http://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html).

The government agency is now beginning hepatitis C antiviral therapy for 1100 patients a week—double the figure from a year ago—and hopes to increase that number to 2000 patients a week by the end of this year, said David Ross, MD, director of the VA's HIV, hepatitis, and public health pathogens programs. At the same time, the VA is trying to screen all veterans born between 1945 and 1965, who account for more than 75% of hepatitis C infections.

This "enormous effort" has required a redesign of care within the VA, Ross noted. Five medical centers in San Francisco; Ann Arbor, Michigan; Richmond, Virginia; Portland, Oregon; and West Haven, Connecticut, are leading that initiative, disseminating training and expert advice on hepatitis C throughout the VA, the nation's largest integrated health care system.

The goal is "to eradicate as much of the disease as we can," said Chester Good, MD, chair of the VA's medical advisory panel for pharmacy benefits management and an internist at the VA Pittsburgh Healthcare System.

High Prices a Barrier

The VA's new initiative follows a public outcry last year when the government agency began restricting the medications to veterans with advanced liver disease—a practice already followed by dozens of private insurers and state Medicaid programs across the country.

That controversial "prioritization" effort inspired a charge of "death panels" from Thomas Berger, PhD, executive director of the veterans health council for Vietnam Veterans of America, and a call from Sen Bernie Sanders (Ind, Vt), former chairman of the Senate Veterans Affairs Committee, to enlist manufacturers other than drugmakers holding the US patents to produce the medications for government use at lower prices (http://1.usa.gov/1FbJy5c).

The restrictions were driven by veterans' higher-than-expected demand for new hepatitis C therapies, the extraordinary cost of the medications, and a budget shortfall. The first drug in this category, Gilead Sciences' sofosbuvir (Sovaldi), carried a list price of $84 000 for a single course of treatment. With supplemental therapies, also required, the total cost soared to nearly $100 000.

Yet the medications have the potential to cure hepatitis C in almost everyone who takes them. The virus is eliminated in about 95% of cases after a 12-week or 24-week course of therapy, with minimal adverse effects. Previous therapies took twice as long, cured fewer than 50% of patients, and had significant adverse effects, causing many patients to discontinue treatment.

A quick calculation highlights the potential effect on the VA. Of veterans who seek care at its facilities, nearly 89 000 have a hepatitis C diagnosis but have not yet been treated, and another 40 000 may be infected but not diagnosed, according to data supplied by the agency.

Combine those figures (129 000 veterans with diagnosed but untreated or undiagnosed hepatitis C), multiply by $100 000 per treatment, and the total list price of hepatitis C drugs alone would come to $12.9 billion. Assume a 46% discount off the list price, the average reduction reported publicly, and the total drops to $7 billion.

The VA won't discuss the actual discounts it's received for new hepatitis C medications, but a report published last year indicates that it paid between $25 128 (for ombitasvir, paritaprevir, and ritonavir tablets copackaged with dasabuvir tablets and marketed as Viekira Pak) and $68 627 (for sofosbuvir) to treat all but 1% of patients. Two-thirds of the treatments involved giving patients ledipasvir and sofosbuvir, priced at $41 280.

This year, discounts may be even greater because Congress committed a bigger pot of funds to the VA for hepatitis C: $1.5 billion. About $1 billion of that amount pays for medications. A more substantial budget means more veterans can be treated, which gives drugmakers an incentive to negotiate favorable deals with the VA.

Next year's budget request from the VA also asks for $1.5 billion to treat about 35 000 patients with known or newly diagnosed hepatitis C infections. "VA will focus resources on the sickest patients and most complex cases and continue to build capacity for treatment through clinician training and use of telehealth platforms," according to a statement from Robert A. McDonald, Secretary of the VA.

Yet advocates remain concerned. "The fact is they don't have the money to treat everyone despite what they're promising," said Tricia Lupole, executive director of HCVets, which runs a website for veterans with this condition. She's concerned that veterans with infections that haven't progressed to serious liver disease will get short shrift, despite the effect on their quality of life and risk of complications.

Many Challenges Await

The cost of treatment is only one of several major challenges that the VA faces as it ramps up its hepatitis C program. The embattled agency, hit hard by allegations that some of its medical centers concealed the numbers of patients awaiting care, has made guaranteeing improved access to primary care a priority. But specialists needed to oversee the care of patients with advanced liver disease—hepatologists, gastroenterologists, and infectious disease physicians—are in short supply.

In a May report, the Office of Inspector General for the VA recommended that the agency ensure "adequate consultation" and "contingency plans for specialties with limited specialty provider availability" after investigating the case of a man in his 60s with hepatitis C who died after seeking care at Grand Junction Veterans Health Care System in Colorado. On several occasions, the physician responsible for the patient did not provide adequate care or "assess the patient thoroughly," investigators concluded. The Grand Junction center disagreed with the findings (http://1.usa.gov/28KsSJC).

Medical centers in the VA system with substantial hepatitis C expertise are trying to address the staffing issue through telehealth consults with patients, physicians, pharmacists, and nurses in smaller cities and rural areas. Laboratory tests can be administered and medications dispensed locally; expert advice and management is available from afar. "We can treat patients from San Francisco, but they don't have to come to San Francisco," said Alexander Monto, MD, director of the liver clinic at the San Francisco VA Medical Center.

Dixie Banner, a 54-year-old Navy veteran who lives an hour outside Anchorage, Alaska, believes she became infected with hepatitis C in boot camp in 1986. She started developing flu-like symptoms off and on in 1995, was diagnosed with advanced liver disease in 2014, and finally received telehealth treatment from a VA nurse specializing in hepatitis C later that year. "I got great care," Banner said. "I feel blessed."

The VA is also offering training in hepatitis C via videoconferencing to providers at smaller facilities and in rural areas through its Specialty Care Access Network–Extension for Community Healthcare Outcomes, otherwise known as SCAN-ECHO. Through that program, physicians, nurses, or clinical pharmacists sit in on a short hepatitis C lecture every week or two, present information about their patients, and get feedback from experts at a distance.

Unpublished data cited by Ross show that the median time to treatment from diagnosis was 6 months for patients seen by physicians who'd been through SCAN-ECHO training, compared with more than 2 years for those who hadn't had the training.

The intent is to offer the training to as many primary care clinicians as possible while trying not to overburden them, Ross said. But whether that will be sufficient to handle an escalating demand for care, and whether the quality of care delivered will be adequate, is far from certain, Lupole of HCVets noted.

Expanding Screening

A few years ago, each VA region established a hepatitis C team responsible for efforts to improve care in their geographic area. When those teams met for the first time, they identified screening more veterans for hepatitis C as a priority. Screening had previously been based on risk factors such as injection drug use or blood transfusions prior to 1992, when widespread testing of the blood supply was not routine. Over the past several years, the VA shifted its focus to all veterans in the baby boom generation, in line with recommendations from the CDC (http://1.usa.gov/RsajNk).

Each time a veteran born during that era comes in for care, the VA's electronic health record checks whether that person has been screened and issues an electronic reminder to perform a hepatitis C test if one has not been documented. Specific goals are being set for each VA region, and data will be published quarterly about their performance.

"No one wants to be on the bottom of that [performance] list," said Timothy Morgan, MD, chief of hepatology at VA Long Beach (California) Healthcare System, who's helping lead an effort to reengineer hepatitis C care within the VA. By the end of last year, 70% of veterans born between

1945 and 1965 had been screened for hepatitis C, with 7400 new infections identified nationwide in 2015 alone.

Morgan's region is one of several across the country that have created hepatitis C dashboards featuring information from patients' electronic medical records that is updated daily. The tool allows Morgan and colleagues to sort through patients by hepatitis C genotype, extent of liver disease, treatment status, and other factors. Last year, the Long Beach VA system used it to identify veterans with hepatitis C and advanced liver disease who hadn't yet been treated and send a letter inviting these veterans to come in for potentially curative therapy.

"If they don't call, we call them," Morgan said. During the previous 2 years, nearly 40% of veterans treated for hepatitis C at the Long Beach medical center had been diagnosed with advanced liver disease. Nationally, that figure is 21% of the 174 842 veterans within the VA health system who have been diagnosed with hepatitis C. More than 76 000 of these veterans have already received treatment, and more than 60 000 have been cured.

Educating Veterans

Once veterans are in treatment, managing their need for ongoing monitoring and education about hepatitis C is yet another challenge. In San Francisco, a solution is monthly group visits, where 4 to 8 veterans have their blood drawn, pick up a 30-day supply of medication, talk about their latest test results, and provide each other with peer support. A psychologist is typically present to deal with emotional issues that accompany treatment and hope for a cure.

Veterans with drug or alcohol addiction aren't automatically excluded from treatment at the VA, nor is there any specified abstinence requirement. But they won't be offered antiviral therapy if adherence problems are suspected, Ross said. The VA has extensive experience in treating veterans with HIV infection who also struggle with substance abuse, and the agency understands the need to address social and psychological issues that can complicate medical treatment, he noted.

As many as 1 of 10 Vietnam veterans have chronic hepatitis C—a rate 5 times that of the general population—and Vietnam Veterans of America has begun holding educational sessions around the country to encourage them to get tested and seek care if necessary. All are in the age group the VA is targeting, but the hepatitis C virus wasn't identified until 1989, years after the war ended. Meanwhile, the American Legion has also begun testing veterans for hepatitis C at community events through a partnership with AbbVie, which markets the Viekira Pak hepatitis C medication and has a financial interest in seeing more veterans treated for the disease.

Addressing the stigma associated with hepatitis C—which is closely associated with injection drug use and found disproportionately in people who are homeless and other marginalized populations—is an important part of these discussions. "When they came home, Vietnam vets were widely viewed as drug addicts or lazy good-for-nothings, and they haven't forgotten," said Berger. "Most of us were not involved in IV drug use; that's not how we acquired hepatitis C. But that's one of the reasons why so many of our people don't get tested, because of the stigma." ■

The JAMA Forum

The Partisan Divide on Health Care

Larry Levitt, MPP

Presidential elections rarely turn on debates over policy. They are typically influenced much more by the state of the economy, what is happening in the world, and the personal characteristics of the candidates. This year's campaign, which is atypical in so many respects, may be even less about policy than usual and more about perceptions of the personal qualities of the candidates.

But elections always have consequences for the future direction of policy. Now that the party platforms for the 2016 campaign are written and posted online, we can see that Republicans and Democrats are as far apart on health care as they have been for quite some time. Platforms are never implemented as written, and not all candidates endorse every plank in them. However, they signal which issues are important to the parties and, broadly speaking, what candidates aim to do about them.

Republican Platform

Not surprisingly, the centerpiece of the Republican health care agenda (http://bit.ly/2aKyxxa) is repeal of the Affordable Care Act (ACA). The more contentious question has been what policies Republicans would put in place of the ACA and what changes they might propose for Medicare and Medicaid.

Key elements of the Republican health care platform include:

- Protection from insurance discrimination for people with preexisting conditions who maintain continuous coverage. This would be a weaker safeguard than what's in the ACA, which guarantees access to insurance for everyone, even if they've had a gap in coverage, and requires that a minimum set of benefits be provided.

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- Allowing people to buy insurance across state lines. This would likely have the effect of insurers setting up shop in states