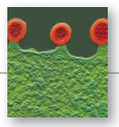


Improving Veteran Access to Treatment for Hepatitis C Virus Infection

Breanne S. Fleming, PharmD, BCACP; Amanda P. Ifeachor, PharmD, MPH, BCPS; Audrey M. Andres, PharmD, BCACP; Lindsey J. Reese, MD, MS; Elizabeth E. Davis, LCSW; Suthat Liangpunsakul, MD, MPH; Christina A. White, PharmD, MBA, BCPS; and Cassandra M. Ruoff, PharmD, BCPS

Addressing social issues and treatment barriers significantly increases access to HCV care, and many veterans successfully start therapy with the help of additional support staff.

In the U.S., 2.7 to 3.9 million people are chronically infected with the hepatitis C virus (HCV).[1] Survey data suggest that HCV infection is more prevalent in patients enrolled in the VA health care system than it is in civilian health care systems.[2] Studies have shown that Vietnam veterans, veterans with mental health and substance abuse disorders, and veterans without stable housing are more likely to be infected with HCV.[3] Data from the VA HCV Clinical Case Registry (CCR) for 2015 showed that 174,842 veterans with chronic HCV infection receieved care within the VHA, which makes the VA the single largest HCV care provider in the nation.[4]

The VA is dedicated to providing treatment to veterans with HCV infection. For fiscal year (FY) 2016, the VA allocated $1 billion to HCV care, and in February 2016 it began offering treatment to all veterans with HCV, regardless of degree of fibrosis or severity of underlying liver disease.[3,5] Each VAMC was tasked with improving veterans' access to HCV treatment.

Dr. Fleming, Dr. Ifeachor, and **Dr. Andres** are clinical pharmacy specialists; **Dr. Reese** is the chief of medicine and an internal medicine and infectious disease physician; **Ms. Davis** is a licensed clinical social worker; **Dr. Liangpunsakul** is an internal medicine and gastroenterology/hepatology physician; and **Dr. White** is assistant chief of pharmacy service, all at Richard L. Roudebush VAMC in Indianapolis, Indiana. Dr. Liangpunsakul also is an associate professor of medicine, biochemistry, and molecular biology at Indiana University School of Medicine in Indianapolis. **Dr. Ruoff** was formerly a clinical pharmacy specialist at Richard L. Roudebush VAMC and currently practices as a clinical pharmacy specialist at VA Great Lakes Healthcare System in Green Bay, Wisconsin.

In an effort to engage patients in HCV care, the multidisciplinary HCV team at the Richard L. Roudebush VAMC (RLRVAMC) in Indianapolis, Indiana, launched a 2-phase improvement process in 2016. The goal in phase 1 was to increase patient access to HCV clinics, and the goal in phase 2 was to recruit patients for direct-acting antiviral (DAA) therapy for HCV. These efforts were designed to increase screening, identification, and linkage to care for HCV and to expand clinic access for the treatment and cure of all identified veterans who pursued treatment.

Patients with HCV infection, referred from primary care clinics, initially were evaluated by HCV clinic providers (hepatologists, infectious disease specialists, gastroenterology fellows, or nurse practitioners) for eligibility to receive DAA therapy for HCV. Eligible patients then were referred to a pharmacist-run HCV clinic, which had been established at RLRVAMC in 2011. At the start of FY 2016, the clinic, staffed by 3 pharmacists, operated 5 half-days per week and accommodated up to 35 weekly patient appointments.

In this clinic, patients received initial education and medication reconciliation for potential drug interactions with DAAs. Once the HCV treatment was initiated, patients were evaluated in the clinic every 2 weeks for medication refills and assessment for tolerability, adherence, and laboratory abnormalities until end of treatment (8-24 weeks, depending on HCV genotype,

experiences with prior HCV treatment, and presence/absence of cirrhosis). Twelve weeks after completion of treatment, viral load was obtained to determine sustained virologic response (SVR12).

METHODS

Phase 1: Improve Clinic Access

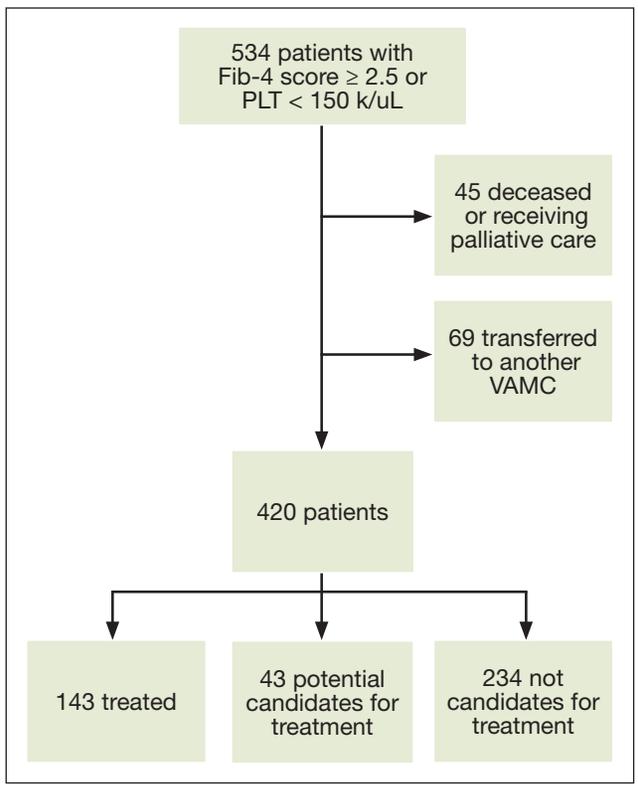
During FY 2016, methods for expanding clinic access to accommodate a large influx of treatment-eligible patients were reviewed and implemented.

In the first intervention, unneeded follow-up visits were eliminated to make room for additional new patient appointments. In general, patients treated with ribavirin require close monitoring, given the risk for anemia.[6] With the release of newer DAAs, however, more patients became eligible for treatment with ribavirin-free regimens.[7] As a result, follow-up appointments for these patients were extended to 4-week intervals instead of every 2 weeks. A patient with a history of nonadherence to medication use or clinic visits was still maintained on a 2-week schedule of follow-up for close monitoring.

In the second intervention, opportunities for switching those who completed treatment from face-to-face clinic visits to telephone were identified. These patients historically were seen in clinic for a brief interview and for a blood test used to determine end-of-treatment viral load. Improving access for new patients in the clinic involved moving more existing patients from in-clinic visits to telephone. At the end of the treatment plan, existing patients received an order for laboratory tests that included viral load. When all laboratory results were ready, patients were contacted by telephone. Recruiting a registered nurse to the treatment team who assisted with telephone visits further improved clinic efficiency.

The third intervention was inspired by successful results at other VA sites and launched a group treatment clinic for patients who were starting ribavirin-free DAA regimens.[7] Group visits were run by 2 pharmacists and accommodated up to 10 veterans. Patients underwent testing for HCV genotype and viral load before the initial group visit. At check-in, patients received a short questionnaire and consent form for group participation. The questionnaire reviewed patient history of drug and alcohol use and potential barriers to medication adherence. Patients also were encouraged to write down any questions they had about the treatment. During the initial group visit, pharmacists provided general education about the medications, potential adverse effects, treatment expectations, and the monitoring plan. Follow-up visits were conducted in a group setting as well.

Figure 1. Patient Selection From Clinical Case Registry Database

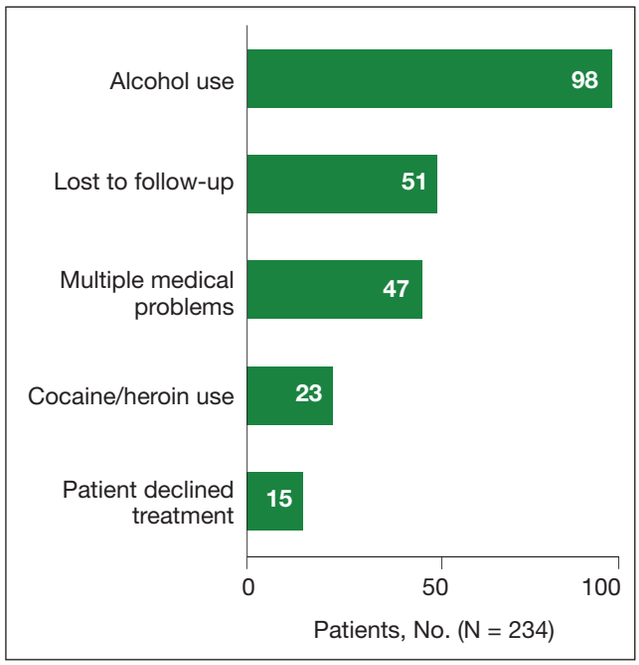


Abbreviations: Fib-4, Fibrosis-4 Index for Liver Fibrosis; PLT, platelet count.

Phase 2: Increase Recruitment

The records of 534 patients with advanced liver disease (F3-F4 fibrosis on the Fibrosis-4 Index for Liver Fibrosis) and HCV infection were identified in the CCR database for the period August 2015 to December 2015 (Figure 1).[8] Patients were excluded if they were deceased, were receiving palliative care (n = 45), or if they had transferred their care to another VA facility (n = 69). Of the 420 patients in the study reviewed, 234 (56%) had not previously been referred to an HCV clinic or been started on treatment because of a variety of social issues, including active substance use (Figure 2).

Figure 2. Barriers to Treatment of Hepatitis C Virus Infection



Many of the patients were difficult to engage because the clinic could not effectively assist them in achieving sobriety and lacked support personnel who could address their complex social issues. Given the availability of all-oral HCV treatments, the VA Public Health Department issued guidance allowing all HCV-infected patients to receive DAA treatment regardless of ongoing drug or alcohol use disorders.[9] Substance use was not to be considered a contraindication to therapy. It was suggested that health care providers determine these patients' treatment eligibility on a case-by-case basis. An official VA memorandum supporting this initiative was released in September 2016.[10]

Interventions

In an effort to engage all HCV-infected patients, the CCR review was expanded to include patients without advanced liver disease. All patients were contacted by mail. Any patient registered for secure messaging through MyHealth*e*Vet also received a secure message. Patients were informed about the newly approved DAA therapies and were connected directly with specialized HCV clinic schedulers at RLRVAMC. Patients who responded were scheduled for a group education class facilitated by 2 members of the HCV treatment team. Unlike patients in the group treatment clinic, patients in the education class had not completed the necessary workup for treatment initiation. In the class, patients received education on new HCV treatments and were linked to social work care if needed to streamline the referral process. All baseline laboratory test results also were obtained.

Another intervention implemented to recruit patients in this difficult-to-treat population was the addition of a social worker to the treatment team. Beginning in late June 2016, high-risk patients were referred to the social worker by HCV providers or pharmacists. For each referred patient, the social worker performed a psychosocial assessment to identify potential barriers to successful treatment and then connected the patient with either VA or community resources for support.

The social worker linked patients to mental health or substance use-related services, empowered them to access transportation resources for clinic appointments, orchestrated assistance with medication adherence from a home health nurse, and reached out to patients in person or by telephone to address specific needs that might limit their ability to attend appointments. The social worker also provided harm reduction planning and goal setting support to help patients with substance use disorders achieve sobriety or reduce substance use while on HCV treatment. All efforts were made to ensure that patients adhered to their clinic visits and medication use. In addition, during social work assessment, factors such as housing concerns, travel barriers, and loss and grief were identified and promptly addressed.

RESULTS

After the phase 1 intervention, 730 additional appointments were added in FY 2016 (Figure 3). As a result, 409 patients with HCV infection were started on treatment in FY 2016 compared with 192 in FY 2015. More important, the rapid increase in capacity and treatment initiation did not sacrifice the quality of care provided. Ninety-eight percent of patients who started treatment in FY 2016 successfully completed their treatment course. The overall SVR12 rate was 96% for all genotype 1 patients treated with ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir plus dasabuvir, or elbasvir/grazoprevir with or without ribavirin. In addition, the SVR12 rate was 82% for genotype 2 patients (almost all cirrhotic) treated with sofosbuvir plus ribavirin and 93% for genotype 3 patients treated with daclatasvir, sofosbuvir, and ribavirin.

Phase 2: Increase Recruitment

The expanded CCR review identified 234 patients with advanced liver disease and 546 patients without advanced disease. As this was a rolling review, 58 patients were linked to care before being contacted. Of the 722 patients in the cohort, 528 were contacted by mail and 194 both by mail and by MyHealtheVet messaging. One hundred forty-one patients responded: 129 by mail and 12 by MyHealtheVet messaging (eFigure 1, available at fedprac.com). Of the respondents, 101 were scheduled for the group education class, and another 16 were connected directly with an HCV provider. The remaining 24 were not scheduled for treatment, for various reasons: successful treatment at an outside facility (n = 8), absence of chronic HCV infection (n = 3), DAA treatment declined (n = 2), or other or unknown reasons (n = 11).

Of the 101 patients scheduled for group education, 43 attended education in FY 2016 (eFigure 2, available at fedprac.com). Four patients who had previously been seen in HCV clinic and had been lost to follow-up were reconnected with their providers. Twenty-eight patients were evaluated by HCV providers for the first time. In total, 23 were referred to pharmacy clinic for treatment initiation.

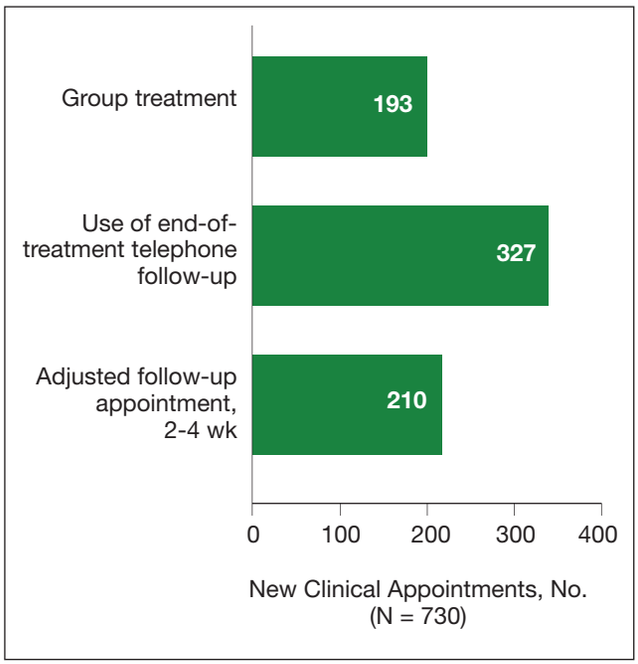
In June 2016, a social worker was added to the treatment team in an effort to improve recruitment in this difficult to treat population (Figure 2). Between June 2016 and end of FY 2016, 48 patients were referred to the social worker for evaluation. The primary reasons for referral were ongoing substance/alcohol use or high risk for relapse (n = 22); appointment adherence barriers, including problems with transportation (n = 16); underlying mental health disorders (n = 4); barriers to medication adherence (n = 3); and unstable housing (n = 3). Of these 48 patients, 31 received a single social worker intervention to connect with resources; the other 17 were recommended for intensive case management for ongoing support during preparation for HCV treatment and during therapy. As a result of social work involvement, 31 out of 48 referred patients were successfully started on treatment in FY 2016.

DISCUSSION

The VA continues focusing its efforts and resources on treating HCV infection in FY 2017. To further expand outreach, RLRVAMC is working on several additional process improvements. One reason for the lower than expected number of patients who did not see a provider after attending the group education class is that these patients were difficult to reach for scheduling. A medical support assistant is now attending these classes; immediately after a class ends and before leaving the facility, this assistant schedules patients for appointments with HCV providers. The team social worker continues to help prepare patients for treatment and targets interventions for patients early in their HCV workup so that resources are allocated before treatment initiation. In the first 2 months of FY 2017, about 10 more patients who were referred to the social worker for assessment and support started treatment.

Outreach letter responses identified almost 600 potential candidates for treatment. Pharmacists telephoned these patients in another effort to connect them with VA services. Interested patients were scheduled for a group education visit. Also, pharmacists reached out to all primary care clinics and community-based outpatient clinics connected with the facility to provide education on VA policies regarding HCV treatment eligibility and to encourage providers to refer all patients with HCV infection to the HCV clinic. This education was provided at primary care team meetings, and providers not in attendance receive individual

Figure 3. Newly Created Clinic Appointments After Intervention



outreach by pharmacists. Primary care providers also received a pocket card that summarized recommendations for HCV screening and referrals. These efforts and initiatives are expected to increase veterans' access to care for HCV infection within the catchment area.

CONCLUSION

Treatment team interventions in FY 2016 significantly increased veterans' access to RLRVAMC HCV care. The number of patients who started treatment more than doubled since the previous year. Many of these patients had complex social issues or treatment barriers but successfully started therapy with the help of additional support staff.

Author disclosures

This study was supported in part by a Hepatitis Innovation Team (HIT) grant to the hepatitis C care team at the Richard L. Roudebush VAMC and by VA Merit Award 1I01CX000361-01 to Dr. Liangpunsakul from the VA Office of Research and Development.

Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect those of Federal Practitioner, *Frontline Medical Communications Inc., the U.S. Government, or any of its agencies. This article may discuss unlabeled or investigational use of certain drugs. Please review the complete prescribing information for specific drugs or drug combinations—including indications, contraindications, warnings, and adverse effects—before administering pharmacologic therapy to patients.*

REFERENCES

1. Centers for Disease Control and Prevention. Hepatitis C FAQs for health professionals. https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm. Updated January 27, 2017. Accessed May 9, 2017.
2. U.S. Department of Veterans Affairs. Epidemiology of hepatitis C. http://www.hepatitis.va.gov/provider/reviews/epidemiology.asp. Updated August 26, 2016. Accessed May 9, 2017.
3. U.S. Department of Veterans Affairs, Office of Research and Development. VA research on hepatitis C. http://www.research.va.gov/topics/hep-c.cfm. Updated October 14, 2016. Accessed May 9, 2017.
4. U.S. Department of Veterans Affairs. HIV, hepatitis, and public health pathogens programs annual stakeholders report: 2015. https://www.hepatitis.va.gov/pdf/stakeholders-report-2015.pdf. Published May 2015. Accessed May 10, 2017.
5. Lynch TG, McCarthy MF; US Department of Veterans Affairs. Hepatitis C virus (HCV) funding and prioritization status update [memorandum]. http://www.hepatitis.va.gov/pdf/choice-prioritization-update.pdf. Published February 24, 2016. Accessed May 9, 2017.
6. Fried MW. Side effects of therapy of hepatitis C and their management. *Hepatology.* 2002;36(5 suppl 1):S237-S244.
7. AASLD/IDSA HCV Guidance Panel. Hepatitis C guidance: AASLD-IDSA recommendations for testing, managing, and treating adults infected with hepatitis C virus. *Hepatology.* 2015;62(3):932-954.
8. Vallet-Pichard A, Mallet V, Nalpas B, et al. Fib-4: an inexpensive and accurate marker of fibrosis in HCV infection. Comparison with liver biopsy and fibrotest. *Hepatology.* 2007;46(1):32-36.
9. U.S. Department of Veterans Affairs National Hepatitis C Resource Center Program and National Viral Hepatitis Program the HIV, Hepatitis, and Related Conditions Program in the Office of Specialty Care Services. Chronic hepatitis C virus (HCV) infection: treatment considerations. https://www.hepatitis.va.gov/pdf/treatment-considerations-2017-03-08.pdf. Updated March 8, 2017. Accessed May 9, 2017.
10. Lynch TG; U.S. Department of Veterans Affairs. Evaluation and treatment of veterans with hepatitis C (HCV) and co-occurring substance use or mental health concerns [memorandum]. http://www.hepatitis.va.gov/pdf/memo-HCV-and -mental-health.pdf. Published September 9, 2016. Accessed May 9, 2017.