DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Review of Hepatitis C Virus Care within the Veterans Health Administration

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Executive Summary

The VA Office of Inspector General (OIG) conducted a review to assess Veterans Health Administration (VHA) facilities' care of patients with chronic hepatitis C virus (hepatitis C) infection.[1]

VHA is the nation's largest care provider for chronic hepatitis C infection with over 180,000 confirmed patients.[2] VHA patients are disproportionately affected by hepatitis C infection, with rates about three times the national average.[3] The OIG studied those VHA patients with hepatitis C infection as demonstrated by confirmatory laboratory testing in fiscal year (FY) 2017 as the group of patients who should have been assessed for treatment with direct-acting antivirals (DAA). The introduction of DAAs, which can cure chronic hepatitis C infection, and congressional appropriation of over $3 billion in FYs 2015, 2016, and 2017 for VHA patients to receive DAA treatment, prompted the review.[4]

The OIG identified three overall objectives and two study populations. The OIG defined study population A as patients with hepatitis C infection who did not receive DAA treatment and patients who did receive DAA treatment. The two specific objectives for study population A were to

1. Assess reasons why patients with chronic hepatitis C infection were not treated with DAAs.
2. Assess pre- and post-DAA treatment testing in patients with chronic hepatitis C infection.

The OIG defined study population B as those patients with positive hepatitis C antibody (Ab) results without evidence of confirmatory hepatitis C ribonucleic acid (RNA) testing in

[1] Hepatitis C is a viral infection of the liver.

2 Pamela Belperio et al., "Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs," Annals of Internal Medicine 167, no. 7 (October 3, 2017): 499–504.

3 Lauren Beste and George Ioannou, "Prevalence and Treatment of Chronic Hepatitis C Virus Infection in the US Department of Veterans Affairs," Epidemiologic Reviews 37, no. 1 (January 2015): 131-143.

4 Breanne Flemming et al., "Improving Veteran Access to Treatment for Hepatitis C Virus Infection: 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," Federal Practitioner 34, Suppl 4 (June 2017): S24-S28. H. Report 114-640, Conference Report to accompany H.R. 2577, Departments of Transportation, and Housing and Urban Development, and Related Agencies for the Fiscal Year Ending September 30, 2016, and for other purposes.

VHA Corporate Data Warehouse (CDW) administrative data in FY 2017. The specific objective for study population B was to

3. Assess whether patients with a positive screening test for the hepatitis C Ab received confirmatory hepatitis C RNA testing.

Objective 1: Assess the Reasons Why VHA Patients with Chronic Hepatitis C Infection Were Not Treated with DAA Medications

For patients in study population A who did not receive DAAs, the OIG reviewed a random sample of 415 patient electronic health records (EHRs) to assess if VHA providers' EHR documentation followed VHA hepatitis C treatment considerations.[5]

The OIG defined acceptable reasons VHA providers would not provide DAA treatment and estimated that in 85.5 percent of patients, EHR documentation reflected acceptable reasons (see Appendix A).[6] The OIG also defined unacceptable reasons VHA providers would not offer DAA treatment. The OIG did not identify EHR documentation that reflected unacceptable reasons.[7]

The OIG estimated that in 11.6 percent of patients, the OIG team was unable to identify VHA provider reasons for not offering DAA treatment. Patient EHRs contained no documented medication or disease exclusions and no hepatitis C related consults, appointments, documented phone calls, or documentation of letters sent pertaining to possible treatment.

The OIG estimated that 2.9 percent of patients had indeterminate reasoning for not being offered DAA treatment. The most common scenarios the OIG identified were ongoing patient substance abuse issues that interfered with a DAA treatment plan and concerns related to patient homelessness.

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[5] VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf (The website was accessed on November 1, 2017.). These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language on chronic HCV treatment considerations.

[6] The OIG defined acceptable reasons for not providing treatment with DAA medications to include: receiving treatment outside VHA, patient deferring or declining DAA treatment, and inaction by patient in response to contact attempts by VHA; VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf (The website was accessed on November 1, 2017.). These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language on chronic HCV treatment considerations.

[7] The OIG defined unacceptable reasons for not offering treatment with DAA medications to include: prior HCV treatment failure and HIV co-infection.

Objective 2: Assess Pre- and Post-DAA Treatment Testing in VHA Patients with Chronic Hepatitis C Infection

For patients treated with DAA medications, the OIG used VHA CDW administrative data to assess if patients received pre- and post-DAA treatment testing as outlined in VHA treatment considerations.[8]

The OIG was unable to fully assess pre-DAA treatment testing because there is no universally accepted time frame that dictates when the pretreatment testing must be done prior to starting a DAA medication regimen.

The OIG found 9.6 percent of patients who completed DAA treatment in the first six months of FY 2017 did not have posttreatment hepatitis C RNA tests. Without this critical data point, providers cannot determine hepatitis C treatment success or failure, or provide a pathway for retreatment.

Objective 3: Assess Whether Patients with a Positive Screening Test for the Hepatitis C Ab Received Confirmation RNA Testing

For patients with positive HCV Ab results without evidence of confirmatory HCV RNA testing in VHA CDW administrative data, the OIG reviewed a random sample of 405 patient EHRs to determine if confirmatory hepatitis C RNA testing was done. On March 10, 2017, VHA issued Directive 1299, *Reflex Confirmatory Testing for Hepatitis C Virus Infection*. This directive stated, "Among individuals who do not have a prior positive hepatitis C RNA result, it is VHA policy that reflex confirmatory testing using hepatitis C RNA testing be performed on all specimens that are reactive by initial serologic testing for hepatitis C antibodies."[9] For the specific subgroup of patients in study population B who had hepatitis C Ab tests performed after March 10, 2017, the OIG estimated 99.1 percent had confirmatory hepatitis C RNA testing performed.

The OIG made two recommendations.

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[8] VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf (The website was accessed on November 1, 2017.). These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language related to pre-and post-DAA treatment testing.

[9] VHA Directive 1299, *Reflex Confirmatory Testing for Chronic Hepatitis C Virus Infection*, March 10, 2017. This directive was in effect for the time frame of events discussed in objective 3. VHA Directive 1299 was rescinded and replaced by VHA Directive 1300.01, *National Viral Hepatitis Program*, May 23, 2018. The 2018 directive contains the same or similar language regarding reflex confirmatory RNA testing as the 2017 directive.

1. The Under Secretary for Health ensures that patients with confirmed positive chronic hepatitis C infection have provider documentation to address treatment considerations entered in their EHRs.
2. The Under Secretary for Health ensures that providers obtain posttreatment hepatitis C RNA tests to evaluate patient response to DAA treatment in alignment with VA National Viral Hepatitis Program Guidelines.

Comments

The Executive in Charge, Office of the Under Secretary for Health, concurred with the recommendations. (See Appendix D, pages 29–32 for the comments of the Executive in Charge.) The OIG will follow up on the recommendations and the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
for Healthcare Inspections

Contents

Abbreviations

Ab	antibody
CDC	Centers for Disease Control and Prevention
CDW	Corporate Data Warehouse
DAA	Direct-Acting Antiviral
EHR	electronic health record
FDA	U.S. Food and Drug Administration
FY	fiscal year
HIV	Human Immunodeficiency Virus
IFN	Interferon drugs
OIG	Office of Inspector General
RNA	ribonucleic acid
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a review to assess Veterans Health Administration (VHA) facilities' care of patients with chronic hepatitis C virus (hepatitis C) infection.[10] VHA is the nation's largest care provider for chronic hepatitis C infection with over 180,000 confirmed patients.[11] The OIG studied those VHA patients with hepatitis C infection as demonstrated by confirmatory laboratory testing in fiscal year (FY) 2017 as the group of patients who should have been assessed for treatment with direct-acting antivirals (DAAs). The introduction of DAAs, which can cure chronic hepatitis C infection, and congressional appropriation of over $3 billion in FYs 2015, 2016, and 2017 for VHA patients to receive DAA treatment, prompted the review.[12]

The OIG identified three overall objectives and two study populations. The OIG-defined study population A as VHA patients with hepatitis C infection who did not receive DAA treatment (objective 1) and patients who received DAA treatment (objective 2). The two specific objectives for study population A were to

1. Assess reasons why patients with chronic hepatitis C infection were not treated with DAAs.
2. Assess pre- and post-DAA treatment testing in patients with chronic hepatitis C infection.

The OIG-defined study population B as those patients with positive hepatitis C antibody (Ab) results without evidence of confirmatory hepatitis C ribonucleic acid (RNA) testing in VHA Corporate Data Warehouse (CDW) administrative data in FY 2017 (objective 3). The specific objective for study population B was to

[10] Hepatitis C is a viral infection of the liver.

[11] Pamela Belperio et al., "Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs," *Annals of Internal Medicine* 167, no. 7 (October 3, 2017): 499–504.

[12] Breanne Flemming et al., "Improving Veteran Access to Treatment for Hepatitis C Virus Infection: 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," *Federal Practitioner* 34, Suppl 4 (June 2017): S24-S28; H. Report 114-640, Conference Report to accompany H.R. 2577, Departments of Transportation, and Housing and Urban Development, and Related Agencies for the Fiscal Year Ending September 30, 2016, and for other purposes.

3. Assess whether patients with a positive screening test for the hepatitis C Ab received confirmatory hepatitis C RNA testing.

Background

In 2016, the Centers for Disease Control and Prevention (CDC) reported that hepatitis C infection was estimated to affect 3.5 million Americans and was responsible for more deaths than any other infectious disease.[13] Inflammation of the liver, also known as hepatitis, is most often caused by a virus and impairs the ability of the liver to perform its normal functions. Normal functions of the liver include storing nutrients; filtering and processing of chemicals found in food, alcohol, and medications; and removing waste products from the blood. The most common types of the hepatitis virus in the United States are hepatitis A, hepatitis B, and hepatitis C (see Appendix C for definitions). Hepatitis C is the focus of this report.[14]

Timeline and Transmission of Hepatitis C

Hepatitis C is transmitted when the blood or body fluids of a person with hepatitis C infection comes into contact with the blood or body fluids of a person who is not infected.[15] In the 1970s, a virus, known as "non-A, non-B," was suspected to be responsible for cases of hepatitis in up to 10 percent of patients who received blood transfusions.[16] In 1989, scientists isolated the responsible virus and named it hepatitis C.[17] In 1991, the U.S. Public Health Service published guidelines for screening donors of blood and blood products for hepatitis C.[18] According to the CDC, advanced screening tests for hepatitis C in blood and blood products have virtually eliminated hepatitis C from blood banks in the United States.[19]

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[13] Centers for Disease Control and Prevention "Hepatitis C Kills More Americans than Any Other Infectious Disease," news release May 4, 2016. https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html

[14] Centers for Disease Control and Prevention, "What is Viral Hepatitis" fact sheet April 19, 2018. https://www.cdc.gov/hepatitis/abc/index.htm (The website was accessed on May 10, 2018.)

[15] *National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online*, s.v. "Bloodborne pathogens", https://medlineplus.gov/ency/patientinstructions/000453.htm. (The website was accessed on November 6, 2017.)

[16] Leslie Tobler and Michael Busch, "History of posttransfusion hepatitis," *Clinical Chemistry* 43, no. 8 (August 1997): 1487-1493.

[17] Qui-Lim Choo et al., "Isolation of cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatitis Genome," *Science* 244, (April 21, 1989): 359-362.

[18] Miriam Alter et al., "Public Health Service Inter-Agency Guidelines for Screening Donors of Blood, Plasma, Organs, Tissues, and Semen for Evidence of Hepatitis B and Hepatitis C," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report* 40, no. RR-4 (April 19, 1991): 1-17.

[19] Centers for Disease Control and Prevention "Know More Hepatitis," August 22, 2014. https://www.cdc.gov/knowmorehepatitis/timeline.htm (The website was accessed on October 4, 2017.)

Prior to 1992, people were most commonly infected with hepatitis C through blood transfusions or organ transplants. Other common ways people could become infected, before and after 1992, were through improperly cleaned instruments used in healthcare procedures, poor infection-control practices used during tattooing or body piercing, and being born to a mother with hepatitis C infection. Less common ways people could be infected were through sharing personal care items like toothbrushes or razors that may have come in contact with an infected person's blood and having sexual contact with someone who had hepatitis C.[20] As of 2016, the most common way people were infected with hepatitis C was by sharing contaminated needles or other equipment to inject drugs.[21]

Phases of Hepatitis C Infection

Hepatitis C infection can be broken down into two phases: acute and chronic. Acute hepatitis C infection occurs during the initial transmission of infected blood or body fluid. If symptoms appear after acute hepatitis C infection, they are generally mild and flu-like and can include feeling tired, and poor appetite.[22] The CDC estimates about 20 percent of individuals with an acute infection will successfully clear the virus without treatment. The remaining 80 percent will develop chronic hepatitis C infection.[23] Chronic hepatitis C infection stays active in the body for years and results in liver and liver-associated diseases, as well as contributing to other health problems.

Health Problems and Economic Burden

Untreated chronic hepatitis C infection can result in yellow discolorations of the skin and eyes, fluid build-up in the abdomen, liver failure, liver cancer, and possibly death.[24] Chronic hepatitis C infection frequently causes immune-related diseases and inflammatory-related problems in

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[20] Centers for Disease Control and Prevention, "Hepatitis C Questions and Answers for Health Professionals," January 27, 2017. https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (The website was accessed on November 7, 2017.); Centers for Disease Control and Prevention, "Hepatitis C Questions and Answers for the Public," June 12, 2018. https://www.cdc.gov/hepatitis/hcv/cfaq.htm (The website was accessed on August 30, 2018.); Julia Kovaleva et al., "Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy," Clinical Microbiology Review 26, no. 2 (April 2013): 231-254.

[21] Cecily Campbell et al., "State HCV Incidence and Policies Related to HCV Preventive and Treatment Services for Persons Who Inject Drugs – United States, 2015-2016," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report* 66, no. 18 (May 12, 2017) 465-469.

[22] Management of Acute HCV infection https://www.hcvguidelines.org/unique-populations/acute-infection last updated July 8, 2016. AASLD/IDSA guidance was updated on April 12, 2017 and on September 21, 2017. (The website was accessed on November 9, 2017.)

[23] Centers for Disease Control and Prevention, "Hepatitis C Questions and Answers for Health Professionals," January 27, 2017. https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (The website was accessed on November 7, 2017.)

[24] Centers for Disease Control and Prevention, "What is Viral Hepatitis" fact sheet April 19, 2018. https://www.cdc.gov/hepatitis/abc/index.htm (The website was accessed on May 10, 2018.)

other areas of the body outside of the liver.[25] One example of an immune-related disease is the development of abnormal proteins in the blood (cryoglobulinemia) which causes debilitating and/or life-threatening vascular conditions. Examples of inflammatory-related problems are type 2 diabetes and cardiovascular disease.[26]

The economic burden from untreated chronic hepatitis C infection are the costs associated with treating advanced liver diseases like irreversible scarring (cirrhosis) and cancer. In 2011, the annual estimated cost for the care of untreated hepatitis C infection in the United States was between $4.3 and $8.2 billion. By 2024, costs are expected to reach between $6.4 and $13.3 billion.[27] The reason for treating chronic hepatitis C infection is to reduce liver-related health complications and death.[28]

Screening and Identification

Early identification of hepatitis C infection is important to be able to provide treatment and decrease damage to the liver. In 1998, the CDC published recommendations for screening persons at risk for hepatitis C transmission, including those who (1) had injected drugs, (2) were on chronic hemodialysis, (3) received blood transfusions or organ transplants before July 1992, or (4) people with the bleeding disorder hemophilia who were treated with blood clotting factors that were produced before 1987.[29] The CDC closely monitors many infectious diseases like hepatitis C infection.[30] The CDC monitoring led to the observation that persons born from 1945 through 1965, also known as the birth cohort, had five times the number of people whose blood tested positive for hepatitis C infection versus people born before 1945 or after 1965. For this reason, the CDC added a recommendation for a one-time hepatitis C screening for persons in the

[25] Patrice Cacoub et al., "Extrahepatic manifestations of chronic hepatitis C virus infection," *Therapeutic Advances in Infectious Disease* 3 no.1, (February 2016): 3–14.

[26] Patrice Cacoub et al., "Extrahepatic manifestations of chronic hepatitis C virus infection," *Therapeutic Advances in Infectious Disease* 3 no.1, (February 2016): 3–14.

[27] Homie Razavi et al., "Chronic hepatitis C virus (HCV) disease burden and cost in the United States," *Hepatology* 57, no. 6 (June 2013): 2164-2170.

[28] American Association for the Study of Liver Diseases and Infectious Diseases Society of America "*HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. When and in Whom to Initiate HCV Therapy,"* July 8, 2016. (Page 30) https://www.hcvguidelines.org/evaluate/when-whom AASLD/IDSA guidance was updated on April 12, 2017 and on September 21, 2017. (The website was accessed on November 8, 2017.)

[29] Hemodialysis is a treatment for kidney failure that filters blood outside the body. Miriam Alter et al., "Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report* 47, no. RR-19 (October 16, 1998): 1-39.

[30] Centers for Disease Control and Prevention, "Mission, Role and Pledge," April 14, 2014. https://www.cdc.gov/about/organization/mission.htm (The website was accessed on August 30, 2018.)

birth cohort.[31] The American Association for the Study of Liver Diseases, the Infectious Disease Society of America, and the U.S. Preventive Services Task Force have also adopted and recommended the CDC screening guidelines for use by patient care providers.[32]

The method for hepatitis C screening involves drawing a blood sample to test for hepatitis C infection (see Figure 1).[33] Initially, an antibody screening test is performed to show whether hepatitis C Ab have developed.[34] If the blood sample is reactive for the hepatitis C Ab, a second test is performed to confirm the presence of hepatitis C RNA, the genetic material of the hepatitis C.[35] If hepatitis C RNA is detected, this results in a life-long positive hepatitis C Ab outcome for the patient.[36] Once the presence of hepatitis C RNA is confirmed, the patient should be linked to care and additional testing done, including a test to determine the hepatitis C genotype.[37] Knowledge of the hepatitis C genotype is important in the selection of the particular medication and regimen used to treat the patient. There are seven main hepatitis C genotypes with many

[31] Bryce Smith et al., "Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945-1965," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report* 61, no. 4 (August 17, 2012): 1-36.

[32] Virginia Moyer et al., "Screening for Hepatitis C Virus Infection in Adults: U.S. Preventive Services Task Force Recommendation Statement," *Annals of Internal Medicine* 159, no. 5 (September 3, 2013): 349–357; American Association for the Study of Liver Diseases and Infectious Diseases Society of America "*HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C,*" July 8, 2016. (Page 16) https://www.hcvguidelines.org (The website was accessed on November 8, 2017.) AASLD/IDSA guidance was updated on April 12, 2017, and on September 21, 2017.

[33] Jane Getchell et al., "Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report* 62, Early Release (May 7, 2013): 362-365.

[34] An antibody is "a protein produced by the immune system in response to a foreign substance such as a virus or bacterium." *National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online*, s.v. "Antibodies" accessed June 1, 2018 https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022035/; Jane Getchell et al., "Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report* 62, Early Release (May 7, 2013): 362-365.

[35] Jane Getchell et al., "Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians," *Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report* 62, Early Release (May 7, 2013): 362-365.

[36] U.S. Department of Health and Human Services Centers for Disease Control and Prevention "Hepatitis C Information on Testing & Diagnosis" Publication No. 220411.

[37] The CDC defines linkage to care as recommended medical evaluation and care after the diagnosis of HCV infection. Genotype is the complete set of genes or genetic material present in a cell or organism. American Association for the Study of Liver Diseases and Infectious Diseases Society of America "*HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. HCV Testing and Linkage to Care,"* July 8, 2016. https://www.hcvguidelines.org/evaluate/testing-and-linkage (The website was accessed on January 10, 2018.) AASLD/IDSA guidance was updated on April 12, 2017 and on September 21, 2017.

different subtypes.[38] In the United States, hepatitis C genotypes 1a and 1b are the most common for patients with hepatitis C infection.[39]

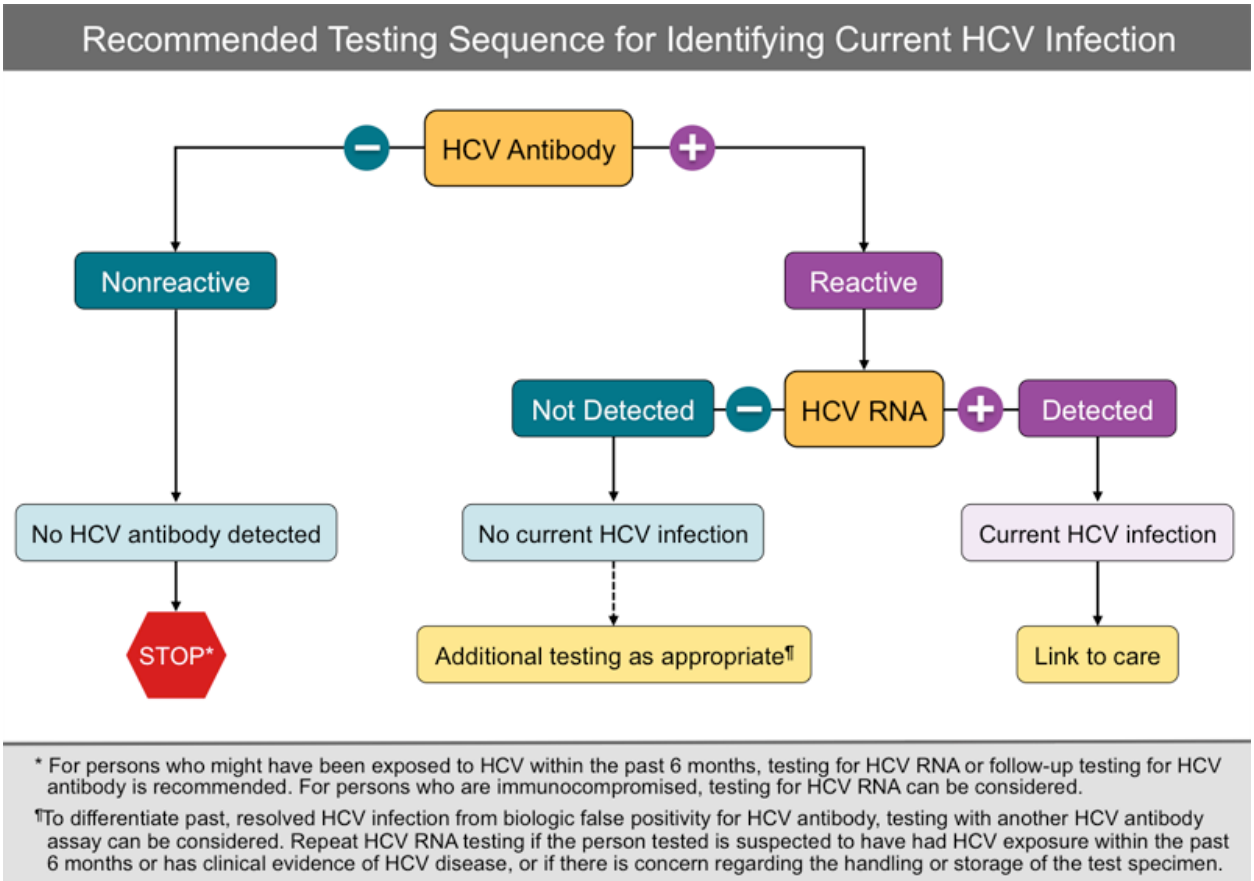

Figure 1. Recommended Testing Sequence for Identifying Current hepatitis C Infection.
Source: Centers for Disease Control and Prevention. Testing for hepatitis C infection: An update of guidance for clinicians and laboratorians. Morbidity and Mortality Weekly Report 62, (May 7, 2013): 1-4.

Treatment

While chronic hepatitis C infection can potentially lead to many serious medical problems, medications to eliminate hepatitis C have been developed. These medications interfere with the virus' ability to replicate. Stopping the virus from replicating means that chronic hepatitis C

[38] Jane Messina et al., "Global Distribution and Prevalence of Hepatitis C Virus Genotypes. *Hepatology* 61, (January 2015): 77-87.

[39] University of Washington and The University of Alabama at Birmingham, "Hepatitis C Online: HCV Epidemiology in the United States," September 5, 2016. https://cdn.hepatitisc.uw.edu/pdf/screening-diagnosis/epidemiology-us/core-concept/all (The website was accessed on January 31, 2018.)

infection could be cured.[40] A cure is defined as achievement of sustained virologic response by the patient remaining without detectable hepatitis C RNA found in their blood after treatment completion.[41]

The first class of hepatitis C treatment medications developed, interferon drugs (IFNs), required patients to have injections of the IFNs three times a week for 6–12 months.[42] The cure rate for patients treated using IFNs was approximately 5–20 percent.[43] The IFN treatment regimen had side effects such as depression and mood changes, fever, headache, fatigue, joint pain, and muscle pain that occurred in many patients.[44]

Subsequent treatments combined IFNs and another drug, ribavirin, to prevent replication of the hepatitis C. This new combination treatment increased the cure rate to 40–50 percent but patients continued to experience side effects.[45]

Scientists made additional breakthroughs into how hepatitis C replicated inside the body, leading to the development of a new class of medications, DAAs, which target hepatitis C in different ways to stop the virus from replicating.[46] First-generation DAAs were to be used in conjunction with IFN and ribavirin.[47] The DAAs worked by stopping the virus from continuing to produce new viral particles.[48] These triple drug treatments showed cure rates of 67–75 percent for patients who had not been previously treated for their chronic hepatitis C genotype 1 infection.[49]

Second-generation DAAs worked by attaching to hepatitis C genetic information to block the virus from continuing to produce new viral particles and were used in conjunction with IFN and

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[40] Jean-Michael Pawlotsky, "Therapy of Hepatitis C: From Empiricism to Eradication," *Hepatology* 43 (February 2006): S207–S220.

[41] Marc Ghany et al., "Diagnosis, Management, and Treatment of Hepatitis C: An Update." *Hepatology* 49, no. 4 (April 2009): 1335–1374.

[42] Doris Strader and Leonard Seeff, "A Brief History of the Treatment of Viral Hepatitis C," *Clinical Liver Disease* 1, no. 1 (February 2012): 6–11.

[43] M P Manns, H Wedemeyer, M Cornberg M, "Treating Viral Hepatitis C: Efficacy, Side Effects, and Complications," *Gut* 55, no. 9 (August 11, 2006): 1350-1359.

[44] Geoffrey Dusheiko, "Side Effects of Alpha Interferon in Chronic Hepatitis C. *Hepatology* 26, no. 3 Suppl. 1 (September 1997): 112S-121S.

[45] M P Manns, H Wedemeyer, M Cornberg M, "Treating Viral Hepatitis C: Efficacy, Side Effects, and Complications. *Gut* 55, no. 9 (August 11, 2006): 1350-1359.

[46] Paul Pockros, "New direct-acting antivirals in the development for hepatitis C virus infection," *Therapeutic Advances in Gastroenterology* 3, no. 3 (May 2010): 191-202.

[47] Jennifer Kiser and Charles Flexner, "Direct-Acting Antiviral Agents for Hepatitis C Virus Infection," *Annual Review of Pharmacology and Toxicology* 53, (January 2013): 427-449.

[48] Paul Pockros, "New direct-acting antivirals in the development for hepatitis C virus infection," *Therapeutic Advances in Gastroenterology* 3, no. 3 (May 2010): 191-202.

[49] Kyle Wilby et al., "Review of boceprevir and telaprevir for the treatment of chronic hepatitis C," *Canadian Journal of Gastroenterology* 26, no. 4 (April 2012): 205-210.

ribavirin.[50] These triple-drug treatments showed cure rates of 90 percent for patients who had never been treated for their chronic hepatitis C genotype 1 or 4 infections.[51] Early DAAs had side effects, especially mood swings and depression, when combined with IFN and ribavirin.[52]

The development of third-generation DAAs did not require IFN and had fewer side effects.[53] Third generation DAAs work by blocking a virus protein that hepatitis C needs to continue producing new viral particles.[54] These third-generation DAAs, with cure rates of 94–99 percent, were approved for the treatment of chronic hepatitis C infection for patients with all hepatitis C genotype infections.[55]

In less than four years, the first generation of DAA medications that were combined with IFNs and ribavirin have advanced to a third generation of all-oral single-tablet IFN-free DAA combinations that are indicated for all hepatitis C genotype infections.[56]

Barriers to Treatment

Two barriers to DAA treatment are (1) potentially life-threatening drug-drug interactions between DAAs and medications such as those used to treat cardiac arrhythmias, angina, psychoses, and gout, and (2) patient adherence to the treatment programs.[57] Patients on medications with the potential for drug interactions would generally need to be closely monitored by a team of specialists (that could include heart, mental health, infectious disease,

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[50] Paul Pockros, "New direct-acting antivirals in the development for hepatitis C virus infection," *Therapeutic Advances in Gastroenterology* 3, no. 3 (May 2010): 191-202.

[51] Eric Lawitz E et al., "Sofosbuvir for Previously Untreated Chronic Hepatitis C Infection," *New England Journal of Medicine* 368, (April 23, 2013): 1878-1887.

[52] Jordan Feld and Graham Foster, "Second generation direct-acting antivirals—Do we expect major improvements?" *Journal of Hepatology* 65, (2016): S130–S142.

[53] Julio Gutierrez, Eric Lawitz and Fred Poordad, "Interferon-free, direct acting antiviral therapy for chronic hepatitis C," *Journal of Viral Hepatitis* 22, no. 11 (November 2015): 861-870.

[54] University of Washington and The University of Alabama at Birmingham, "Hepatitis C Online: Antiretroviral Medications," https://www.hepatitisc.uw.edu/page/treatment/drugs/glecaprevir-pibrentasvir (The website was accessed on August 9, 2018.)

[55] Poonam Mishra, Jeffrey Murray and Debra Birnkrant, "Direct-Acting Antiviral Drug Approvals for Treatment of Chronic Hepatitis C Virus Infection: Scientific and Regulatory Approaches to Clinical Trial Designs," *Hepatology* 62, no. 4 (October 2015): 1298–1303.

[56] Jean-Michel Pawlotsky et al., "From non-A, non-B hepatitis to hepatitis C virus cure," *Journal of Hepatology* 62, no. 1S (April 2015): S87–S99.

[57] Kimberly Garrison et al., "The drug-drug interaction potential of antiviral agents for the treatment of chronic hepatitis C infection", Drug Metabolism and Disposition 46, no.8 (August 1, 2018): 1212-1225. *Cardiac arrhythmias* are an improper beating of the heart. *Angina* is chest pain caused by reduced blood flow to the heart. *Psychoses* are mental disorders characterized by a loss of contact with reality. *Gout* is a form of arthritis. University of Washington and The University of Alabama at Birmingham, "Hepatitis C Online: Addressing Adherence Prior to Initiating HCV Treatment," May 31, 2018. https://cdn.hepatitisc.uw.edu/pdf/screening-diagnosis/epidemiology-us/core-concept/all (The website was accessed on July 5, 2018.)

digestive system, or liver specialists) if they were going to be treated with DAAs. Problems adhering to the treatment program were often found in patients with intravenous drug use, alcohol abuse, and psychiatric disease.[58]

Pre-DAA Treatment Assessment

The American Association for the Study of Liver Diseases, the Infectious Diseases Society of America, and VHA all recommend performing a pretreatment assessment of the patient prior to starting a patient on DAA therapy. Pretreatment assessments are completed to confirm hepatitis C infection and guide the choice of the DAA prescribed, length of therapy, and urgency to treat.[59] Providers develop a care plan based on needs identified through the medical and psychosocial history. Clinical criteria, such as active substance abuse disorder, mental health disorders, or social issues such as homelessness should not be used to automatically exclude a patient from hepatitis C treatment. However, identifying clinical and social issues reveals the need for support from other medical, psychiatric, and social services so that the patient has the highest likelihood of completing treatment. The care plan may include interventions to support detox, co-management with specialists, or help from social services. If the VHA provider deems that the patient would not be a candidate for current treatment, a plan should be developed with the patient to address those issues precluding treatment and to re-examine those barriers at a future date.[60]

Post-DAA Treatment Assessment

The goal of DAA treatment is to eliminate hepatitis C. Effective treatment is defined as no detectable hepatitis C RNA in the blood 12 weeks after completing a course of treatment with

[58] University of Washington and The University of Alabama at Birmingham, "Hepatitis C Online: Addressing Adherence Prior to Initiating HCV Treatment," May 31, 2018. https://cdn.hepatitisc.uw.edu/pdf/screening-diagnosis/epidemiology-us/core-concept/all (The website was accessed on July 5, 2018.)

[59] American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. HCV Guidance Recommendations for Testing, Managing, and Treating Hepatitis C. (Pages 118-119.) Last updated July 8, 2016. http://hcvguidelines.org/ AASLD/IDSA guidance was updated on April 12, 2017 and on September 21, 2017. (The website was accessed on January 10, 2018.) VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf (The website was accessed on November 1, 2017.). These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language on chronic HCV treatment considerations.

[60] VHA Memorandum, "Evaluation and Treatment of Veterans with Hepatitis C (HCV) and Co-occurring Substance Use or Mental Health Concerns," September 9, 2016.

DAAs.[61] Providers cannot determine treatment success or failure, or provide a pathway for retreatment, without this critical data point. Despite the absence of detectable hepatitis C RNA, patients should be counseled about the risk for reinfection with future hepatitis C exposure.[62]

Delivery of Hepatitis C Treatment in VHA

VHA is the nation's largest care provider for chronic hepatitis C infection with over 180,000 confirmed patients.[63] VHA patients are disproportionately affected by hepatitis C infection, with rates about three times the national average.[64] VHA's overall prevalence of hepatitis C infection is 5.1 percent (2015) and is highest among patients who are homeless (hepatitis C prevalence of 13.4 percent in 2015) and those born from 1945–1965 (hepatitis C prevalence of 7.5 percent in 2016).[65]

In both 2015 and 2016, VHA memorandums to Veterans Integrated Service Network (VISN) leaders demonstrated that two of the challenges to providing hepatitis C treatment were the cost of the medications and VHA providers' misconceptions on patient eligibility.[66] VA's Assistant Deputy Under Secretary for Health for Clinical Operations issued a memorandum to VISN leaders in September 2016 reinforcing VHA's guidelines on the evaluation and effective treatment of patients infected with hepatitis C and co-occurring mental health and substance abuse disorders. A decision to disqualify a patient from receiving hepatitis C treatment "must be made on a case-by-case basis by individual providers in consultation with their patients." In

[61] Marc Ghany et al., "Diagnosis, Management, and Treatment of Hepatitis C: An Update. *Hepatology* 49, no. 4 (April 2009): 1335–1374; VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf. (The website was accessed on November 1, 2017.) These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language related to post-DAA treatment testing.

[62] Bryony Simmons et al., "Risk of Late Relapse or Reinfection with Hepatitis C Virus after Achieving a Sustained Virologic Response: A Systematic Review and Meta-analysis," *Clinical Infectious Diseases* 62, no.6 (January 19, 2016): 683-694.

[63] Pamela Belperio et al., "Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs," *Annals of Internal Medicine* 167, no. 7 (October 3, 2017): 499–504.

[64] Lauren Beste and George Ioannou, "Prevalence and Treatment of Chronic Hepatitis C Virus Infection in the US Department of Veterans Affairs," *Epidemiologic Reviews* 37, no. 1 (January 2015): 131-143.

[65] http://vaww.prevention.va.gov/CPS/Screening_for_Hepatitis_C.asp. (The website was accessed on September 4, 2018.) This website is not accessible to the public; Amanda Noska et al., "Engagement in the Hepatitis C Care Cascade Among Homeless Veterans, 2015," *Public Health Reports* 132, no. 2 (July 15, 2017): 136-139; https://vaww.vha.vaco.portal.va.gov/sites/PublicHealth/pophealth/hcvbirthcohort/default.aspx. (The website was accessed on November 8, 2017.)

[66] VHA Memorandum, "Provision of Hepatitis C Treatment – Clarification," August 13, 2015. VHA Memorandum, "Funding for Hepatitis C (HCV) Treatment in FY 16," November 10, 2015. VHA Memorandum, "Hepatitis C Virus (HCV) Funding and Prioritization Status," January 27, 2016.

addition, "if a patient is deferred for treatment based on problematic levels of alcohol or substance use, he/she should be referred for substance use treatment and must have a plan for re-evaluation for hepatitis C treatment eligibility within a reasonable time frame (e.g. 3–6 months)."[67]

In an October 2017 article, *Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs*, VHA leaders reported major barriers to hepatitis C treatment included "active alcohol or substance use, serious mental illness, documented nonadherence, unstable or uncontrolled medical co-morbidities, and an inability to be contacted."[68] VHA hepatitis C leaders noted that patients with drug or alcohol addiction should not be automatically excluded from hepatitis C treatment.[69]

VHA reported that between January 2014 and June 2017, a total of 92,000 hepatitis C-infected patients started DAA treatment, achieving cure rates exceeding 90 percent.[70] Increased congressional funding allowed VHA to allocate $696 million in FY 2015, $1 billion in FY 2016, and $1.5 billion in FY 2017 for treatment with DAAs.[71] In March 2016, the VA Under Secretary for Health commented that increased funding from Congress and reduced drug prices allowed VHA to fund care for all patients with hepatitis C regardless of the stage of the patient's liver disease.[72]

The article also highlighted VHA's success in curing hepatitis C infection due to the increased funding for drug treatment and infrastructure along with reduced drug prices. From January 4, 2017, through June 21, 2017, between 400 and 700 patients started hepatitis C treatment each

[67] VHA Memorandum, "Evaluation and Treatment of Veterans with Hepatitis C (HCV) and Co-occurring Substance Use or Mental Health Concerns," September 9, 2016.

[68] Pamela Belperio et al., "Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs," *Annals of Internal Medicine* 167, no. 7 (October 3, 2017): 499–504.

[69] Judith Graham, "VA Extends New Hepatitis C Drugs to All Veterans in Its Health System," *Journal of the American Medical Association* 316, no.9 (September 6, 2016): 913-915; VHA Memorandum, "Evaluation and Treatment of Veterans with Hepatitis C (HCV) and Co-occurring Substance Use or Mental Health Concerns," September 9, 2016.

[70] Pamela Belperio et al., "Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs," *Annals of Internal Medicine* 167, no. 7 (October 3, 2017): 499–504.

[71] Breanne Flemming et al., "Improving Veteran Access to Treatment for Hepatitis C Virus Infection: 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," *Federal Practitioner* 34, Suppl 4 (June 2017): S24-S28; H. Report 114-640, Conference Report to accompany H.R. 2577, Departments of Transportation, and Housing and Urban Development, and Related Agencies for the Fiscal Year Ending September 30, 2016, and for other purposes.

[72] VA News Release March 9, 2016 https://www.va.gov/opa/pressrel/includes/viewPDF.cfm?id=2762. (The website was accessed on October 25, 2017.)

week at VHA facilities. According to VHA, "as of July 2017, a total of 51,000 patients remain potentially eligible for treatment."[73]

Scope and Methodology

The OIG initiated the review in August 2017 and completed the work in July 2018.

The OIG reviewed prior OIG reports; VHA documents including directives, memorandums, and treatment considerations; peer-reviewed medical journals; U.S. Food and Drug Administration (FDA) announcements; and professional medical society guidelines. The OIG interviewed VHA leadership including the Chief Officer for Specialty Care Services; the Director, Human Immunodeficiency Virus, Hepatitis and Related Conditions, Office of Patient Care Services; the Director, National Hepatitis C Resource Program; and the Deputy Chief Consultant Measurement and Reporting.

The OIG defined study population A as active VHA patients who had confirmed detectable hepatitis C RNA tests (viremic) in FY 2017 (October 1, 2016, through September 30, 2017) and consisted of two distinct groups (see Figure 2):[74]

- Viremic patients who did not receive DAAs
- Viremic patients who did receive DAAs

In the viremic patient group who did not receive DAAs, the OIG reviewed a random sample of 415 patient electronic health records (EHR) to assess if VHA providers' documentation followed VHA hepatitis C treatment considerations.[75] Based on VHA treatment considerations, the OIG defined four categories (acceptable, unacceptable, unable to locate, and indeterminate) for VHA providers' documentation for not providing or offering patients DAA therapy (see Appendix A for OIG inspectors' criteria).[76]

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[73] Pamela Belperio et al., "Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs," *Annals of Internal Medicine* 167, no. 7 (October 3, 2017): 499–504.

[74] OIG defined active VHA patients as those patients who were seen at a VHA facility in FY 2017. Viremic is defined as the presence of virus in the blood conferring infection.

[75] VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf (The website was accessed on November 1, 2017.). These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language on chronic HCV treatment considerations.

[76] The OIG defined acceptable reasons for not providing treatment with DAA medications include: receiving treatment outside VHA, patient deferring or declining DAA treatment, and inaction by patient to contact attempts by VHA. The OIG defined unacceptable reasons for not offering treatment with DAA medications include: prior HCV treatment failure and HIV co-infection.

In the viremic group that received DAA treatment in FY 2017, the OIG used VHA CDW administrative data (see Appendix B for list of codes) to assess pre- and posttreatment hepatitis C RNA testing as outlined in VA hepatitis C Treatment Considerations.[77]

The OIG defined study population B (see Figure 2) as active VHA patients with a positive hepatitis C Ab result without evidence of confirmatory hepatitis C RNA testing in VHA CDW administrative data for FY 2017. The OIG reviewed EHRs for a random sample of 405 patients to determine if confirmatory hepatitis C RNA testing was done in accordance with VHA directives.[78]

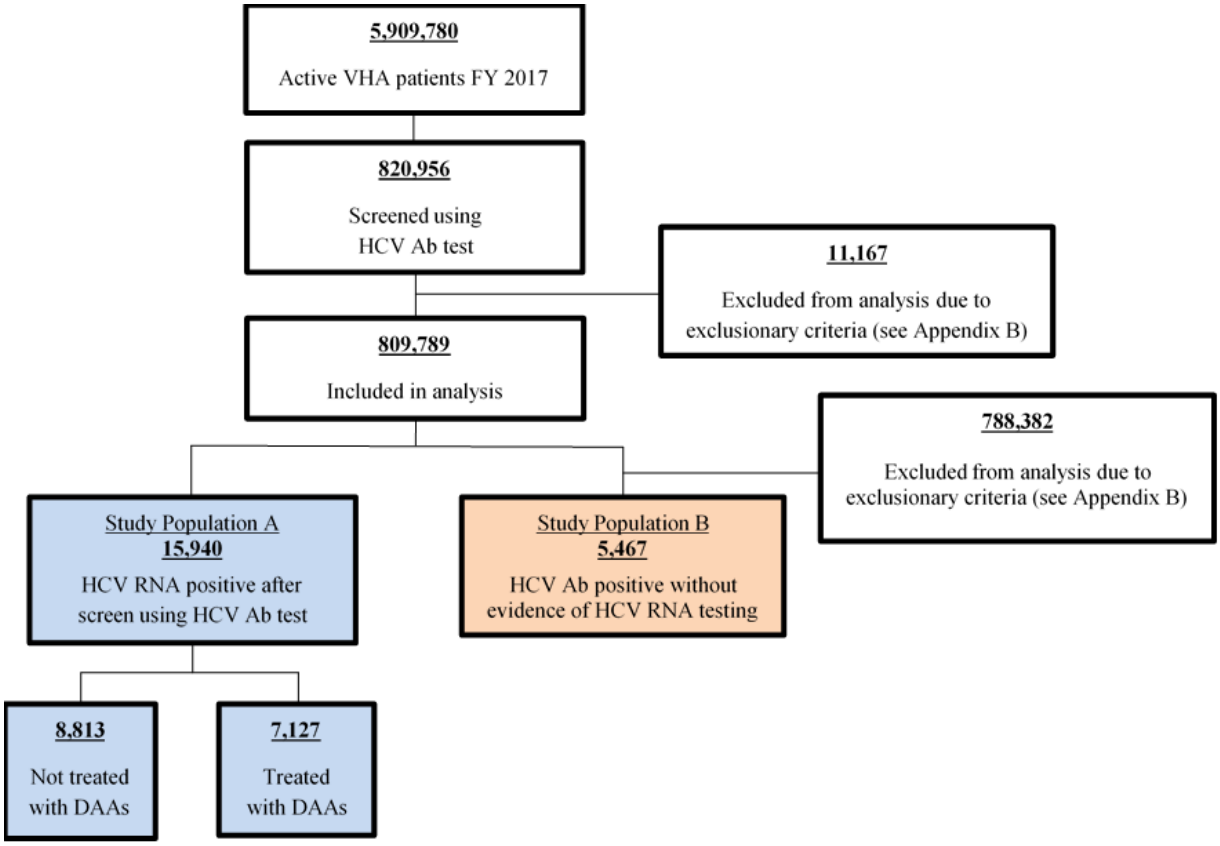

Figure 2. Flow diagram of active VHA patients in FY 2017 with OIG-defined populations.
Source: VA OIG analysis of CDW data

[77] VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf (The website was accessed on November 1, 2017.). These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language related to pre-and post-DAA treatment testing.

[78] VHA Directive 1299, *Reflex Confirmatory Testing for Hepatitis C Virus Infection*, March 10, 2017. This directive was in effect for the time frame of events discussed in objective 3. VHA Directive 1299 was rescinded and replaced by VHA Directive 1300.01, *National Viral Hepatitis Program*, May 23, 2018. The 2018 directive contains the same or similar language regarding reflex confirmatory RNA testing as the 2017 directive.

All data analyses were performed using SAS statistical software (SAS Institute, Inc., Cary, North Carolina), version 9.4.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Results

Characteristics of Study Population A

Chronic hepatitis C infection is a curable disease.[79] In a patient with confirmed chronic hepatitis C infection, evaluation for treatment with DAAs (1) gives the patient the best opportunity to rid their body of hepatitis C, and (2) decreases the risk for hepatitis C infection-related liver function problems. The OIG identified 15,940 active VHA patients with confirmed hepatitis C infection in FY 2017. The OIG team divided the patients into two groups: (1) patients who were not treated with DAAs, and (2) patients who were treated with DAAs. Table 1 shows baseline characteristics of study population A by DAA treatment status.

Table 1. Baseline Characteristics of Study Population A Patients with Confirmed Hepatitis C Infection in FY 2017, by DAA Treatment Status

Baseline Characteristic	Overall 15,940	Not Treated 8,813	Treated 7,127
Age, in years, at confirmation of hepatitis C infection – Mean (Med)	59.8 (62)	59.4 (62)	60.4 (62)
Male	96%	96%	97%
Year of birth occurred between 1945 and 1965 (birth cohort)	83%	80%	86%
Vietnam-era veteran	11%	11%	11%
Previously treated with DAAs *(measured from January 1, 2014, through confirmatory hepatitis C RNA test date in FY 2017)*	4%	1%	7%
Died in FY 2017	2%	2%	1%

Source: VA OIG analysis of CDW data

Mental health and substance abuse disorders are factors that have been associated with increased risk of hepatitis C infection.[80] In study population A, the OIG found approximately two out of three patients had been diagnosed with one or more mental health disorders and one in five patients had been treated for substance abuse disorders within the year prior to the date of their confirmed positive hepatitis C infection. Table 2 shows the mental health and substance abuse disorders diagnosed within the year prior to the date of study population A patients' confirmed positive hepatitis C infection.

[79] Pamela Belperio et al., "Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs," *Annals of Internal Medicine* 167, no. 7 (October 3, 2017): 499–504.

[80] Marin Schaefer, Rahul Sarkar, and Crisanto Diez-Quevedo, "Management of Mental Health Problems Prior to and During Treatment of Hepatitis C Virus Infection in Patients with Drug Addiction," *Clinical Infectious Diseases* 57, suppl. 2 (August 15, 2013): S111-S117.

Table 2. Percentage of Study Population A Patients with Confirmatory Hepatitis C RNA Tests in FY 2017 Who Were Diagnosed with Mental Health Disorders or Treated for Substance Abuse Disorder within the Prior Year, by DAA Treatment Status

Mental Health or Substance Abuse Disorders	Overall 15,940	Not Treated 8,813	Treated 7,127
Mental Health Disorder	65%	69%	61%
Major Depressive Disorder	28%	30%	25%
Mood Disorders	33%	35%	30%
Posttraumatic Stress Disorder	19%	21%	17%
Substance Abuse Disorder	48%	52%	42%
Alcohol Abuse Disorder	15%	16%	12%
Treated for Substance Abuse Disorder	21%	24%	17%

Source: VA OIG analysis of CDW data

Objective 1: Assess the Reasons Why VHA Patients with Chronic Hepatitis C Infection Were Not Treated with DAA Medications

The OIG found that in study population A, 8,813 out of 15,940 patients (55.3 percent) who had a positive hepatitis C RNA test did not receive DAA treatment during FY 2017.

The OIG reviewed the EHRs of a random sample of 415 patients from the 8,813 patients. The EHR review evaluated and categorized the rationale VHA providers documented why patients did not receive DAA treatment. The OIG defined categories of VHA providers' reasoning as acceptable, unacceptable, unable to locate, and indeterminate when considering treatment for their hepatitis C infection. (See Appendix A.)

The following are examples of VHA provider documented rationale for not moving forward with DAA treatment:

- Medical comorbidities—cancers, lung disease, or other chronic medical conditions
- Mental health disorders—substance abuse and alcohol abuse
- Social circumstances—homelessness or compliance/adherence issues

The OIG estimated that in 85.5 percent (95% Confidence Interval (CI) 82.2–88.9 percent) of patients, VHA providers had documented in EHRs acceptable reasons for not providing DAA treatment that followed VHA hepatitis C treatment considerations or were consistent with patients' preferences. The most common situations the OIG identified were (1) patient inaction after VHA contact attempts, (2) patients in the process of obtaining pretreatment tests, referrals

for hepatitis C education or specialty care, and other evaluations that moved them toward receiving DAA treatment, and (3) patients declined or deferred DAA treatment VHA providers offered.

The OIG also defined unacceptable reasons VHA providers would not offer DAA treatment. The OIG did not identify documentation in patient EHRs that was consistent with defined unacceptable reasons.

The OIG estimated that in 11.6 percent (95% CI 8.6–14.6 percent) of patients, the OIG team was unable to identify VHA provider reasons for not offering DAA treatment. Patient EHRs contained no documented medication or disease exclusions, and no hepatitis C-related consults, appointments, documented phone calls, or documentation of letters sent pertaining to possible treatment.

The OIG estimated 2.9 percent (95% CI 1.3–4.5 percent) of patients had indeterminate reasoning for not being offered DAA treatment. The most common scenarios the OIG identified were ongoing patient substance abuse issues that interfered with a DAA treatment plan and concerns related to patient homelessness. Examples of provider comments were "need…to abstain from alcohol and drugs to be considered for treatment," "not a candidate due to…[substance use disorder] and multiple no shows," "consider treatment after 6 months of sobriety," and "not a candidate due to…unstable living situation."

Objective 2: Assess Pre- and Post-DAA Treatment Testing in VHA Patients with Chronic hepatitis C Infection

The OIG used CDW administrative data to assess select pre- and posttreatment testing performed on study population A. The CDC, other scientific bodies who promote guidelines for treatment of hepatitis C infection, and VHA consider pretreatment assessment an essential step in the DAA treatment pathway. Pretreatment assessment includes testing to evaluate liver function, kidney function, liver scarring, and other viral coinfections. These tests, in conjunction with clinical assessment, help to formulate the treatment plan for hepatitis C. The OIG was unable to fully assess pre-DAA treatment testing because there was no universally accepted time frame that dictates when the pretreatment testing must be done prior to starting DAA treatment. Table 3 shows the percentages of patients with tests performed in study population A within a year prior to treatment with DAAs. Appendix C provides the definitions for the tests listed in Table 3.

Table 3. Pretreatment Testing Status for DAA Treated Patients with Confirmatory Hepatitis C RNA in FY 2017 Within a Year Prior to Treatment with DAAs

Pretreatment Test	Percent of the 7,127 Patients Treated with DAA Who Received Pretreatment Testing
Evidence of evaluation of scarring in the liver	100%
Aspartate Aminotransaminase (AST)	100%
Alanine Aminotransaminase (ALT)	99%
Bilirubin	99%
Creatinine	99%
Glomerular Filtration Rate (GFR)	99%
Hepatitis B	88%
hepatitis C Genotype	80%
International Normalized Ratio (INR)	76%
Hepatitis A	71%
Human Immunodeficiency Virus (HIV)	61%

Source: VA OIG analysis of CDW data

VHA guidance, *Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations,* revised September 22, 2016, recommends posttreatment hepatitis C RNA testing to evaluate DAA treatment response.[81] Of the patients in study population A who received DAAs, more than one in three completed their DAA treatment within the first six months of FY 2017. The OIG excluded patients who had DAA treatment in the last six months of FY 2017 to account for hepatitis C RNA tests that may have been obtained after the end of FY 2017. The OIG used CDW administrative data to determine if a hepatitis C RNA level was drawn within at least six months after patients finished DAA treatment.

The OIG found 9.6 percent of patients who completed DAA treatment in the first six-months of FY 2017 did not have posttreatment hepatitis C RNA tests. However, the OIG was unable to determine the reason why a hepatitis C RNA test was not done. Patients' non-compliance with post-DAA treatment testing or simply being lost to follow-up could be explanations as to why the test was not done. Without post-DAA treatment hepatitis C RNA testing, a provider would

[81] VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf (The website was accessed on November 1, 2017.) These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language on chronic HCV treatment considerations.

not know whether a patient achieved a hepatitis C cure. A positive post-DAA treatment hepatitis C RNA test would guide the provider to further testing, evaluation, and treatment for the patient.

Objective 3: Assess Whether Patients with a Positive Screening Test for the hepatitis C Ab Received Confirmation RNA Testing

The OIG defined the study population B as active VHA patients with positive hepatitis C Ab results without evidence of confirmatory hepatitis C RNA testing in VHA CDW administrative data in FY 2017.[82] The OIG reviewed the EHRs of a random sample of 405 patients from the 5,467 patients in study population B to determine if confirmatory hepatitis C RNA testing was done.

Hepatitis C infection is confirmed by analyzing a sample of blood for the presence of hepatitis C RNA.

On March 10, 2017, VHA issued Directive 1299, *Reflex Confirmatory Testing for Hepatitis C Virus Infection*. This directive stated, "Among individuals who do not have a prior positive hepatitis C RNA result, it is VHA policy that reflex confirmatory testing using RNA testing be performed on all specimens that are reactive by initial serologic testing for hepatitis C antibodies."[83] For the specific subgroup of patients in study population B who had hepatitis C Ab tests performed after March 10, 2017, the OIG estimated 99.1 percent (95% CI 97.8–100 percent) had confirmatory hepatitis C RNA testing performed.

Conclusion

The OIG determined that 85.5 percent (95% Confidence Interval (CI) 82.2–88.9 percent) of patients who were not provided DAA treatment had acceptable reasons documented by providers in the EHR that followed VHA hepatitis C treatment considerations or were consistent with patients' preferences. In a small proportion of patients not offered DAA treatment, the OIG was unable to locate provider documentation that the patient declined treatment, was considered for treatment, or provided with a plan to address their hepatitis C infection. Without a documented care plan, the OIG was unable to evaluate providers' plan to offer patients treatment for their hepatitis C infection or refer them for specialty care in the future.

[82] Population B did not have an analysis of characteristics. This group of patients was identified during a review of VHA CDW administrative data for a positive HCV Ab result without evidence of HCV RNA testing in FY 2017. A random sample of patient EHRs were reviewed to assess whether confirmatory HCV RNA testing was obtained in population B.

[83] VHA Directive 1299, *Reflex Confirmatory Testing for Chronic Hepatitis C Virus Infection*, March 10, 2017. VHA Directive 1299 was rescinded and replaced by VHA Directive 1300.01, *National Viral Hepatitis Program*, May 23, 2018. The 2018 directive contains the same or similar language regarding reflex confirmatory RNA testing as the 2017 directive.

The OIG found 9.6 percent of patients who completed DAA treatment in the first six months of FY 2017 did not have posttreatment hepatitis C RNA tests to determine sustained viral response. Providers cannot determine treatment success or failure or provide a pathway for retreatment without this critical data point.

For the specific subgroup of patients in study population B who had hepatitis C Ab tests performed after March 10, 2017, the OIG estimated 99.1 percent (95% CI 97.8–100 percent) had confirmatory hepatitis C RNA testing performed.

Recommendations 1–2

1. The Under Secretary for Health ensures that patients with confirmed positive chronic hepatitis C virus infection have provider documentation to address treatment considerations entered in their electronic health records.
2. The Under Secretary for Health ensures that providers obtain posttreatment hepatitis C virus ribonucleic acid tests to evaluate patient response to direct-acting antiviral treatment in alignment with VA National Viral Hepatitis Program Guidelines.

Appendix A: Four OIG-Defined Reasoning Categories for Objective 1

1. Acceptable Reasons Why a Patient Was Not Considered for Evaluation for Hepatitis C Treatment

- The patient received DAA treatment outside VHA.
- The laboratory data did not provide evidence to proceed with treatment. This could be because the hepatitis C RNA was below a detectable threshold or the hepatitis C RNA resolved spontaneously.
- The patient deferred or declined DAA treatment during the study period.
- The patient did not respond to hepatitis C treatment contact attempts by VHA through letters, phone calls, or scheduled appointments.
- The patient was pregnant or nursing.
- The patient's life expectancy was less than 12 months. This could include a patient on hospice or palliative care, an end-stage disease, or late-stage cancer.
- Providers were concerned about a drug interaction with the patient's current medications.
- The patient's documented medical comorbidities precluded hepatitis C treatment.
- The patient's circumstances presented compliance or adherence challenges.
- The patient had a diagnosis of hepatocellular carcinoma (liver cancer).

2. Unacceptable Reasons Why a Patient Was Not Considered for Evaluation for hepatitis C Treatment

- HIV co-infection
- Prior treatment failure with interferon alone or the combination of interferon and ribavirin regimen
- Prior treatment failure with DAA

3. Unable to Locate EHR Documentation of Reasons Describing Why a Patient was Not Considered for Evaluation for Hepatitis C Treatment

4. Indeterminate Reasons Why a Patient Was Not Considered for Evaluation for Hepatitis C Treatment

- Substance abuse
- Severe mental health issues
- Homelessness

Appendix B: Pretreatment and Posttreatment Testing and Diagnostic Codes and Exclusion Criteria

Hepatitis C Screening

- Logical Observation Identifiers Names and Codes (LOINC): 75886-2, 13955-0, 16128-1, 16129-9, 16936-7, 22324-8, 22325-5, 22326-3, 22327-1, 22328-9, 22329-7, 40726-2, 42506-6, 44831-6, 47365-2, 47441-1, 48159-8, 51656-7, 51657-5, 51824-1, 5198-7, 53376-0, 57006-9, 72376-7, 33462-3, 34162-8, 39008-8, 5199-5
- Current Procedural Terminology (CPT) Codes: 86803, G0402, G0438, G0439, G0472

Hepatitis C RNA Tests

- LOINC: 75888-8, 10676-5, 11011-4, 11259-9, 20416-4, 20571-6, 29609-5, 34703-9, 34704-7, 38180-6, 38998-1, 42003-4, 42617-1, 47252-2, 48576-3, 49369-2, 49370-0, 49371-8, 49372-6, 49373-4, 49374-2, 49375-9, 49376-7, 49377-5, 49378-3, 49379-1, 49380-9, 49603-4, 49604-2, 49605-9, 49608-3, 49758-6, 50023-1, 5010-4, 5011-2, 5012-0, 51655-9, 53825-6, 59052-1, 11526-1, 6422-0

Diagnoses

- Liver Diseases
  - Liver Disease ICD-10: K70-K77 http://www.icd10data.com/ICD10CM/Codes/K00-K95/K70-K77
  - Alcoholic liver disease ICD-10: K70 http://www.icd10data.com/ICD10CM/Codes/K00-K95/K70-K77/K70-
  - Cirrhosis ICD-10-CM: K70.3, K71.7, K74 http://www.icd10data.com/ICD10CM/Codes/K00-K95/K70-K77
  - Non-alcoholic fatty liver ICD-10-CM: K76.0 http://www.icd10data.com/ICD10CM/Codes/K00-K95/K70-K77/K76-/K76.0
- Viral Hepatitis
  - Viral hepatitis excluding hepatitis C ICD-10-CM: B15-B19, excluding B17.1, B18.2, B19.2 http://www.icd10data.com/ICD10CM/Codes/A00-B99/B15-B19
  - Hepatitis A ICD-10-CM: B15 http://www.icd10data.com/ICD10CM/Codes/A00-B99/B15-B19/B15-
  - Hepatitis B ICD-10-CM: B16, B18.0, B18.1 http://www.icd10data.com/ICD10CM/Codes/A00-B99/B15-B19

- Mental Health Disorders
  - Mental health disorders ICD-10-cm: F01-F99
    http://www.icd10data.com/ICD10CM/Codes/F01-F99
  - Substance abuse disorder ICD-10-CM: F10-F19
    http://www.icd10data.com/ICD10CM/Codes/F01-F99/F10-F19
  - Alcohol abuse disorder ICD-10-CM: F10.1
    http://www.icd10data.com/ICD10CM/Codes/F01-F99/F10-F19/F10-/F10.1
  - Mood disorders ICD-10-CM: F30-F39
    http://www.icd10data.com/ICD10CM/Codes/F01-F99/F30-F39
  - Major depressive disorder ICD-10-CM: F32, F33
    http://www.icd10data.com/ICD10CM/Codes/F01-F99/F30-F39/F32-
    http://www.icd10data.com/ICD10CM/Codes/F01-F99/F30-F39/F33-
  - Post-traumatic stress disorder ICD-10-CM: F43.1
    http://www.icd10data.com/ICD10CM/Codes/F01-F99/F40-F48/F43-/F43.1
  - Treated for substance abuse disorder Stop codes: 513, 514, 519, 545, 547, 548, 560
    http://vaww.mcao.va.gov/DSS%20Documents/DSS%20Identifiers-Stopcodes/FY17%20Mid-Year%20Active%20Stop%20Codes.xlsx
- Other Conditions
  - Human immunodeficiency virus ICD-10-CM: B20, 098.7
    http://www.icd10data.com/ICD10CM/Codes/A00-B99/B20-B20/B20-/B20
  - Hemodialysis CPT: 90935, 90937, 90939, 90940, 99512, G8714, G8715, 90997, G8956

Exclusions for OIG-Defined Study Populations A and B

- Hospice/Palliative Care
  - International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM): Z51.5
  - CPT Codes: G9054, G0182, G0337, G0182, Q5001, Q5002, Q5003, Q5004, Q5005, Q5006, Q5007, Q5008, Q5008, Q5009, Q5010, S0255, S0271, S9126, T2042, T2043, T2045, T2046
  - Treating Specialty Codes: 96, 1F
  - Clinic Stop Codes: 351, 353
- Hepatocellular Carcinoma ICD-10-CM: C22.0

- Persistent Vegetative State ICD-10-CM: R40.3

Exclusions for OIG-Defined Study Population B

- Patients with hepatitis C Ab results that were unavailable (651,935), hepatitis C Ab negative (132,753), and canceled/pending/indeterminate (3,694) were excluded from the analysis of OIG-defined study population B.

Appendix C: Definitions

Alanine aminotransferase (ALT) and **Aspartate aminotransferase (AST)** are enzyme tests that may be elevated in irreversible scarring (cirrhosis) or liver injury. [84]

Bilirubin is an orange-yellow pigment formed in the liver by the breakdown of hemoglobin. An elevated bilirubin can cause yellowing of the skin and eyes (jaundice). Bilirubin levels can rise as irreversible scarring (cirrhosis) progresses.[85]

Creatinine is produced by the breakdown of creatine (important in producing energy in the muscles of the body) and is filtered out of the body through the kidneys. High levels of creatinine can warn of malfunction or failure of the kidneys.[86]

Glomerular Filtration Rate (GFR) is a measure of kidney function calculated by the level of creatinine in the blood and a person's age, race, and gender. Low GFR means that the kidneys are not working as well as they should.[87]

Hepatitis A Virus is a highly contagious viral infection of the liver. It can range in severity from mild to more severe but does not usually result in a chronic infection as can occur with hepatitis C and hepatitis B. Hepatitis A virus is spread from person to person through consumption of contaminated food or water. Hepatitis A blood tests check for antibodies to the Hepatitis A virus and remain positive for life once a patient has been exposed. Hepatitis A virus can be prevented with vaccination and the CDC recommends patients with chronic or long-term liver disease including hepatitis B or hepatitis C should be vaccinated.[88]

Hepatitis B Virus is a viral infection of the liver that can also cause liver damage. Blood can be tested to detect the hepatitis B virus or antibodies to the different parts of the virus. By analyzing the various hepatitis B virus blood tests, a provider can evaluate a patient for current or prior hepatitis B virus infection. Current or active hepatitis B virus infection will require medication to

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[84] *National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online*, s.v. "Alanine aminotransferase", https://medlineplus.gov/ency/article/003473.htm (The website was accessed on July 5, 2018.); *National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online*, s.v. "Aspartate aminotransferase", https://medlineplus.gov/ency/article/003472.htm (The website was accessed on July 5, 2018.)

[85] *National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online*, s.v. "Bilirubin", https://medlineplus.gov/ency/article/003479.htm (The website was accessed on July 5, 2018.)

[86] *National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online*, s.v. "Creatinine", https://medlineplus.gov/ency/article/003475.htm (The website was accessed on July 5, 2018.)

[87] *National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online*, s.v. "Glomerular Filtration Rate", https://medlineplus.gov/ency/article/007305.htm (The website was accessed on July 5, 2018.)

[88] https://www.cdc.gov/hepatitis/hav/profresourcesa.htm The ABCs of Hepatitis Fact Sheet. Last updated December 21, 2015. (The website was accessed on February 26, 2018.)

treat hepatitis B virus as well as DAAs for hepatitis C. In addition, if the patient does not have immunity to hepatitis B virus, the hepatitis B virus vaccine should be offered. On October 4, 2016, the FDA issued a Safety Alert for DAAs for hepatitis C. This Drug Safety Communication warned of the risk of hepatitis B reactivating (becoming an active infection again) in any patient with a current or previous infection with hepatitis B virus during or after hepatitis C DAA therapy. The FDA reported serious liver problems or death occurred in a few of these cases. The FDA recommended screening all patients for current or prior hepatitis B virus infections before starting treatment with DAA and monitoring for HBV flare-ups or reactivation during treatment.[89] Hepatitis B virus screening became a part of the VHA hepatitis C Treatment considerations in March 2017.[90]

Hepatitis C is a viral infection of the liver.

Hepatitis C can be divided into seven strains or **genotypes**, types 1 through 7, with type 1 divided into 1a and 1b.[91] The hepatitis C genotype guides the choice of DAA and the length of therapy.[92] American Association for the Study of Liver Diseases and Infectious Disease Society of America guidelines recommend genotype testing any time prior to starting DAA.[93] If a patient had prior successful hepatitis C treatment and, on retesting, had a positive hepatitis C RNA, retesting may be indicated to evaluate if a relapse of hepatitis C infection (same genotype) or

[89] MedWatch Safety Alerts for Human Medical Products. U.S. Food and Drug Administration. FDA warns about the risk of hepatitis B reactivating in some patients treated with direct-acting antivirals for hepatitis C. October 4, 2016.

[90] Department of Veterans Affairs National Hepatitis C Resource Center Program and the HIV, Hepatitis, and Related Conditions Program in the Office of Specialty Care Services. "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations Revised March 8, 2017" https://www.hepatitis.va.gov/pdf/treatment-considerations-2017-03-08.pdf (The website was accessed on November 1, 2017.). These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language on chronic HCV treatment considerations.

[91] Jane Messina et al., "Global Distribution and Prevalence of Hepatitis C Virus Genotypes. *Hepatology* 61, (January 2015): 77-87.

[92] American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. HCV Guidance Recommendations for Testing, Managing, and Treating Hepatitis C. (Pages 118-119.) Last updated July 8, 2016. http://hcvguidelines.org/ (The website was accessed on January 10, 2018.) AASLD/IDSA guidance was updated on April 12, 2017 and on September 21, 2017. VA National Hepatitis C Resource Center Program and the National Viral Hepatitis Program "Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations" Revised September 22, 2016 https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-09-22.pdf (The website was accessed on November 1, 2017.). These treatment considerations were in effect during the time frame of the events discussed in this report. On October 18, 2017, the Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations were updated and contain same or similar language on chronic HCV treatment considerations.

[93] American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. HCV Guidance Recommendations for Testing, Managing, and Treating Hepatitis C. Last updated July 8, 2016 http://hcvguidelines.org/ (The website was accessed on January 10, 2018.) AASLD/IDSA guidance was updated on April 12, 2017 and on September 21, 2017.

possible reinfection (if the same or different hepatitis C genotype) has occurred and posttreatment follow-up is needed.[94]

Human Immunodeficiency Virus (HIV) is a virus that causes a marked reduction in cells that fight infection. The mode of transmission of bloodborne pathogens, such as HIV, HBV, and hepatitis C can be the same, most commonly through exposure to infected blood and body fluid exposures.[95] Intravenous drug usage is a major risk for transmission of these bloodborne viral infections.[96] With 48 percent of study population A noted to have substance abuse disorder, this population has an increased risk of HIV coinfections.[97] hepatitis C patients with HIV coinfection have more liver related morbidity and mortality (disease and death) and higher mortality than patients with only hepatitis C infection.[98] Patients on antiretroviral medications for HIV can have drug interactions between DAAs and medications for HIV.[99]

International Normalized Ratio (INR) is a standardized measure of the time it takes blood to clot. A high INR means that the blood will clot too slowly and can indicate problems in the liver.[100]

[94] Bryony Simmons et al., "Risk of Late Relapse or Reinfection with Hepatitis C Virus After Achieving a Sustained Virologic Response: A Systematic Review and Meta-analysis," *Clinical Infectious Diseases* 62, no.6 (January 19, 2016): 683-694.

[95] CDC Blood/Body Fluid Exposure Option https://www.cdc.gov/nhsn/pdfs/hps-manual/exposure/3-hps-exposure-options.pdf Last updated January 1, 2013 (The website was accessed on January 29, 2018.)

[96] CDC Injection Drug Use and HIV Risk https://www.cdc.gov/hiv/risk/idu.html last updated August 3, 2018 (The website was accessed on September 10, 2018.)

[97] CDC HIV and Injection Drug Use https://www.cdc.gov/vitalsigns/hiv-drug-use/index.html last updated November 29, 2016 (The website was accessed on August 9, 2018.)

[98] American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. HCV Guidance Recommendations for Testing, Managing, and Treating Hepatitis C. Last updated July 8, 2016 http://hcvguidelines.org/ (The website was accessed on January 10, 2018.) AASLD/IDSA guidance was updated on April 12, 2017, and on September 21, 2017.

[99] American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. HCV Guidance Recommendations for Testing, Managing, and Treating Hepatitis C. Last updated July 8, 2016 http://hcvguidelines.org/ (The website was accessed on January 10, 2018.) AASLD/IDSA guidance was updated on April 12, 2017, and on September 21, 2017.

[100] American Association for Clinical Chemistry Lab Tests Online, s.v. "Prothrombin Time and International Normalized Ratio (PT/INR)," https://labtestsonline.org/tests/prothrombin-time-and-international-normalized-ratio-ptinr (The website was accessed on September 10, 2018.)

Appendix D: Executive in Charge Comments[101]

Department of Veterans Affairs Memorandum

Date: November 14, 2018, comments amended December 12, 2018[102]

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: Healthcare Inspection—Review of Hepatitis C Virus Care within Veterans Health Administration

To: Assistant Inspector General for Healthcare Inspections (54)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review the OIG draft report, Healthcare Inspection: Review of Hepatitis C Virus Care (HCV) within Veterans Health Administration. I have reviewed the draft report and concur. Attached is Veterans Health Administration's (VHA) corrective action plan. VHA completed corrective actions on recommendations 1 and 2, and requests OIG consider closure.

2. VHA is committed to continually improving HCV treatment for Veterans. Since the time of the OIG review, VHA has made steady progress in treatment considerations and post treatment of Veterans with HCV. Specific examples of this progress include the following:

a. Over 112,986 Veterans have been treated with oral HCV antivirals since these medications became available in January 2014.

b. 17,350 Veterans were started on HCV treatment in fiscal year 2018, including 117 who received treatment through the Choice program.

c. 7,920 of these Veterans had conditions which made them high-priority treatment candidates.

d. Among Veterans with sustained viral response (SVR) testing data available, overall SVR (cure) rate for the Nation with the oral HCV regimens is 96.8 percent.

e. It is estimated that there are approximately 30,267 Hepatitis C patients obtaining care in VA who still need to be treated for HCV.

[101] The recommendations for the Under Secretary for Health (USH) were submitted to the Executive in Charge who has the authority to perform the functions and duties of the USH.

[102] Footnotes 101, 102, and 103 delineates the changes between VHA's November 14 and December 12, 2018, action plans for recommendation 2.

f. 83.5 percent of Veterans in the 1945-1965 birth cohort have been screened for HCV. It is estimated that approximately 5,873 additional Veterans would be identified if all Veterans in the birth cohort were tested.

3. Thank you for the opportunity to review the draft report. If you have any questions, please email Karen Rasmussen, M.D., Director, GAO-OIG Accountability Liaison at VHA10E1DMRSAction@va.gov.

//original signed by://
Richard A. Stone, M.D.
Attachments

Comments to OIG's Report

Recommendation 1

The Under Secretary for Health ensures that patients with confirmed positive chronic hepatitis C virus infection have provider documentation to address treatment considerations entered in their electronic health records.

Concur

Target date for completion: September 2018

Executive in Charge Comments

VHA Comments: Concur.

As of September 30, 2018, over 112,986 Veterans have been treated with oral Hepatitis C virus (HCV) with Direct Acting Antiviral (DAA). As VHA continues to actively treat Veterans with HCV infection, the number of Veterans unwilling or unable to be treated remains relatively constant, while the overall number of Veterans that will require treatment will continue to decrease. VA continues to reach out to, and evaluate all Veterans with chronic HCV and treat all who are willing and able to be treated.

According to this OIG report, 85.5 percent of patients with HCV had documentation of acceptable reasons for not providing DAA therapy that followed VHA's HCV Treatment Considerations. VHA finds 85 percent compliance with documentation to be acceptable, and based on the findings in this report VHA has exceeded our compliance expectations. VHA encourages documentation of clinical decisions around HCV treatment in the health record. VHA requests OIG consider closure of this recommendation based on our excellent compliance with documentation.

Status: complete Completion Date: September 2018

OIG Comment: The OIG considers this recommendation open to allow time for the Executive in Charge, Under Secretary for Health to provide supporting documentation.

Recommendation 2

The Under Secretary for Health ensures that providers obtain posttreatment hepatitis C virus ribonucleic acid tests to evaluate patient response to direct-acting antiviral treatment in alignment with VA National Viral Hepatitis Program Guidelines.

Concur

Target date for completion: September 2018

Executive in Charge Comments

VHA Comments: Concur.

As of the first 6 months of FY 2017, OIG found that 90.4 percent of all patients who had received DAA treatment had a post-treatment Hepatitis C virus (HCV) Ribonucleic Acid (RNA) test to determine sustained viral response (SVR). VHA finds 90 percent compliance with post-treatment HCV RNA testing to be an acceptable compliance rate, and we currently are meeting that expectation.[103] The 10 percent allowance, accommodates patients' preferences regarding follow-up, repeat testing, patients' choice to use community providers, or inability to return due to relocation or other reasons.[104] VHA request OIG consider closure of this recommendation because we have met our compliance expectations.[105]

VHA submits the following documentation as evidence of completion for this recommendation:

1. VA has reported sustained viral response (SVR) testing rates since October 2015; since that time SVR testing has increased from 55.4 percent to 90.0 percent.
2. The SVR testing rate has remained constant between 87-90 percent for the past 18 months even with targeted outreach to patients who require SVR testing.

Status: complete Completion date: September 2018

OIG Comment: The OIG considers this recommendation open to allow time for the Executive in Charge, Under Secretary for Health to provide supporting documentation.

[103] VHA's original November 18, 2018, response stated, "VHA finds 90 percent compliance with post-treatment HCV RNA testing to be an acceptable compliance rate, and we currently are meeting that standard." (Change indicated by the underlined word.)

[104] VHA's original November 18, 2018, response stated, "The 10 percent allowance, accommodates patients' preferences regarding follow-up, repeat testing, local provider choices, or inability to return due to relocation or other reasons." (Change indicated by the underlined words.)

[105] VHA's original November 18, 2018, response stated, "VHA request OIG consider closure of this recommendation because we have met our expected compliance standard." (Change indicated by the underlined words.)

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Glenn B. Schubert, MPH, Team Leader Kelley Brendler-Hall, MSN, RN Patrice Marcarelli, MD Nathan McClafferty, MS Thomas Wong, DO Robert Yang, MD, MHA
Other Contributors	Elizabeth Bullock Felicia Burke, MS Jennifer Christensen, DPM Ronald Penny

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