

DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

PODCAST TRANSCRIPT OIG REVIEW OF HEPATITIS C VIRUS CARE WITHIN VETERANS HEALTH ADMINISTRATION MARCH 20, 2019

David Vibe:

I'm David Vibe, a Health System Specialist with the National Review Group in the Office of the Inspector General, Office of Healthcare Inspections. Today I am speaking with my colleagues Glenn Schubert, Health System Specialist with the National Review group, and Dr. Patrice Marcarelli, the primary medical consultant, regarding their recently published report *Review of Hepatitis C Virus Care within Veterans Health Administration*.

Dr. Marcarelli, can you give us a brief overview of hepatitis C and the effect it can have on a person's health?

Dr. Patrice Marcarelli:

Hepatitis C is a viral infection that causes inflammation of the liver. It is transmitted mainly through exposure to hepatitis C infected blood. People who inject drugs are at the highest risk of getting infected and intravenous drug abuse is the most common cause of hepatitis C transmission in the United States.

In 2013, researchers at the Centers for Disease Control and Prevention determined that 75 percent of people living with hepatitis C infection were born between 1945 and 1965.

This finding led to a recommendation for one-time hepatitis C virus screening among this population, referred to as the "birth cohort" whether or not they had any other known risk factors for contracting the disease. The numbers of veterans in both these groups are disproportionately high.

This contagious blood-borne disease is the leading cause of catastrophic liver damage, liver cancer, and liver transplants.

David Vibe:

Mr. Schubert, why was this review important to do?

Glenn Schubert

VHA is the nation's largest care provider for hepatitis C infection. Over 5 percent of veterans have hepatitis C infection, which is nearly triple the rate of the general population.

The review was prompted by two events, the introduction of new medications in 2014, called direct-acting antivirals, that can cure hepatitis C, and congressional appropriation of over 3 billion dollars to VHA to purchase these new medications.

David Vibe:

Dr. Marcarelli, how is someone diagnosed with hepatitis C infection?

Dr. Patrice Marcarelli:

A screening blood test looks for the antibody to the hepatitis C virus. If this test is reactive or positive, a second blood test is performed on the blood sample to confirm the presence of the genetic material of the virus.

This confirms the diagnosis of an active hepatitis C viral infection. A person who has cleared the virus would have a positive antibody but no genetic material of the virus in their blood.

David Vibe:

When it has been determined that someone is infected with the hepatitis C virus, what are the next steps?

Dr. Patrice Marcarelli:

A patient is then assessed for treatment. A blood test is obtained to identify the strain of the virus to direct treatment. Additional blood tests are needed to evaluate liver and kidney function as well as to identify other blood borne infections such as HIV and hepatitis B.

Providers would also assess for liver damage, alcohol and drug use, mental health issues and homelessness.

While not automatic exclusions for treating the hepatitis C virus, active substance abuse, mental health issues and homelessness need to be evaluated and addressed to increase compliance with medication regimen and follow-up appointments, which in turn lead to increased odds for the patient to successfully complete treatment.

Once the patient has been assessed, a team of multidisciplinary healthcare providers collaborate on the treatment regimen. When the treatment is completed, repeat testing for hepatitis C viral infection is done to evaluate if the patient has been cured.

David Vibe:

Mr. Schubert, what approach did the team take to review the care provided within VHA to veterans with hepatitis C infection?

Glenn Schubert

The OIG defined the study population as those patients who had a positive confirmatory test for hepatitis C virus infection during the study period from October 2017 through September 2018.

The OIG used the term "viremic", which means there is a presence of virus in the blood conferring infection, to describe the study population.

The study population was divided into two distinct groups with two objectives:

- Group 1 included viremic patients who did not receive direct-acting antivirals during the study period. This group accounted for about 55% of the overall study population.
- Group 2, which accounted for the other 45% of the overall study population, included viremic patients who did receive direct-acting antivirals during the study period.

The first objective was to assess VHA provider reasoning why viremic patients were not offered direct-acting antivirals.

The second objective was to assess if viremic patients treated with direct-acting antivirals received post-treatment blood tests to evaluate for cure of the patients' viral infection.

David Vibe:

What were the results of the analysis of the patients with confirmed hepatitis c virus infection who did not receive treatment with direct-acting antivirals?

Glenn Schubert:

The review evaluated and categorized reasoning VHA providers documented as to why patients were not offered treatment.

We feel such documentation is very important- and that it should be readily available in a patient's medical record.

That way, for all providers who are coordinating care from the moment of recognized infection and for years to come, there is no question that the patient was offered the appropriate education and opportunity to cure their disease.

The OIG defined categories of VHA providers' reasoning as acceptable, unacceptable, and unable to locate. The OIG estimated that in about 85% of viremic patients, VHA providers had documented acceptable reasons for not offering treatment.

Documentation of acceptable reasons suggested providers were educated on their options as part of the clinical decision-making process when choosing not to pursue treatment, for example the reasoning followed VHA treatment guidelines or were consistent with patients' preferences.

The OIG found no unacceptable reasoning documented by VHA providers for not offering treatment.

In the remaining 15% of patients, the OIG was unable to locate VHA providers' reasoning for not offering treatment.

These patients' electronic health records had no documented disease or medication exclusions, no hepatitis C related consultations or appointments, and no documentation of phone calls made or letters sent offering possible treatment.

Without a documented care plan, providers are unable to determine if the patient had ever been considered for initiation of treatment for their hepatitis C virus infection.

David Vibe:

What were the results of the analysis of the patients with confirmed hepatitis C virus infection who did receive treatment with direct-acting antivirals?

Glenn Schubert:

The OIG estimated that about 10% of patients treated with direct-acting antivirals did not have follow-up testing to determine if the treatment cured the patients' viral infection.

Without this critical data point, providers cannot determine treatment success or failure and patients will be unsure if they may be at risk for further complications from the disease or still risk transmitting the infection to others.

David Vibe:

Dr. Marcarelli, what recommendations does the OIG make to VHA on how to address the issues noted in the review?

Dr. Patrice Marcarelli:

The OIG recommended that VHA healthcare providers document evaluation, treatment and follow-up for hepatitis C patients. Documentation of these efforts in the electronic health record helps to ensure compliance with VHA treatment considerations and best practices.

The OIG also recommended that VHA healthcare providers ensure that testing is done after completing the course of direct-acting antiviral medication to determine if the patient was cured. This could lead to further assessment and treatment if the patient did not achieve a cure.

David Vibe:

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