

**Aligning with the Veterans
Administration to Battle
Chronic Liver Disease**

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Aligning with the Veterans Administration to Battle Chronic Liver Disease

High prevalence of non-alcoholic fatty liver disease (NAFLD) and its more serious subset non-alcoholic steatohepatitis (NASH) poses serious challenges to the Department of Veterans Affairs (VA).

Not long ago, the VA implemented an initiative to cure all VA patients with chronic hepatitis C virus (HCV). In 2019, they announced that they had healed nearly 100,000 veterans of the virus, with only 26,000 more to go.¹

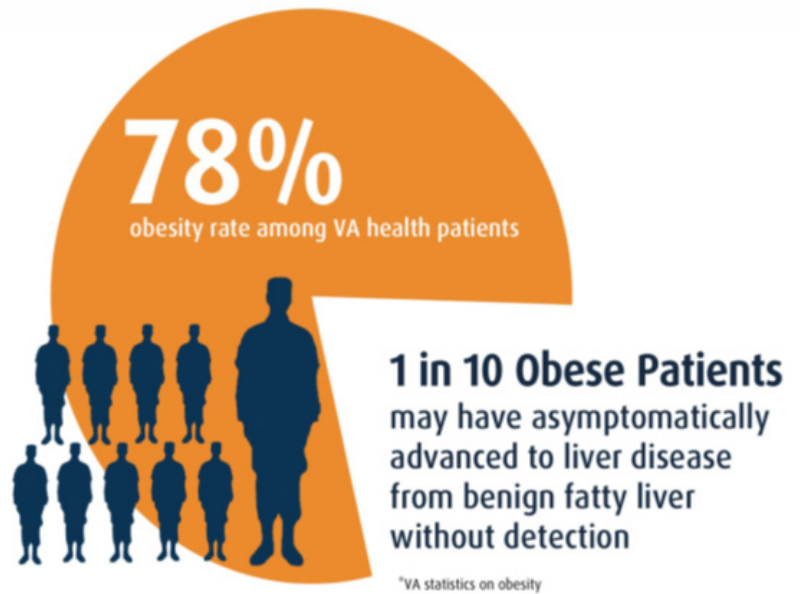
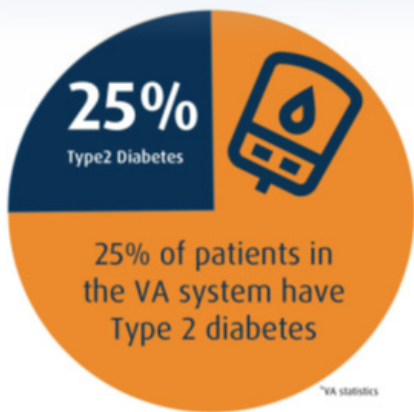
But their mission is not over. Because HCV infection can lead to advanced liver disease, the VA has set a new goal of addressing the risk for cirrhosis, liver failure, liver cancer and death among veterans. The VAs priority will be focused on enhancing prevention efforts and services for those at highest risk of acquiring a new infection or reinfection and veterans with advanced liver disease.

This includes ongoing efforts to tackle the epidemic of NAFLD, a potentially progressive liver disease that occurs in people with high blood sugar, obesity or high cholesterol. NAFLD is recognized as the most common chronic liver disease in the United States, and a disease that independently increases the risk of diabetes (by two-to-five fold), heart and kidney disease, cirrhosis, liver cancer and death.²

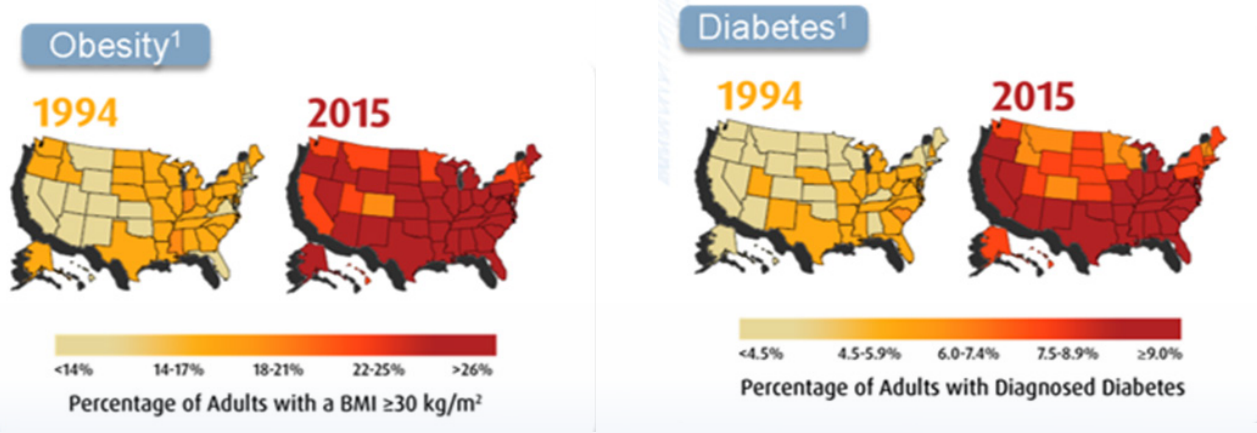
Approximately 30.3 million Americans have diabetes, including an estimated 7.2 million who have the disease but have not received a diagnosis.³ **Diabetes is significantly more prevalent among U.S. veterans, who make up 9% of the civilian U.S. population, than among the general population and affects nearly 25% of VA patients.**⁴

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The VA has estimated that 78% of veterans are overweight or obese.⁵ Adding to the problem of treating NAFLD, diabetes and other related chronic conditions, 3.2 million (35%) of enrolled veterans live in rural communities. Rural veterans and their caregivers face unique barriers to care, such as lack of public transportation, a paucity of broadband coverage, long travel distances to VA health care facilities and a shortage of care providers.⁶



Source: https://www.cdc.gov/diabetes/statistics/slides/maps_diabetesobesity_trends.pdf

It's important for the VA to reduce unused or missed appointments

as a metric for cost savings and patient outcomes. The Veterans Health Administration (VHA), one of the largest integrated healthcare delivery systems in the United States, has projected that approximately 18% of the scheduled annual VHA outpatient appointments (in 10 performance measure clinics) were unused in fiscal year 2008.⁷ The VHA estimates the cost of no-shows and unused appointments is approximately \$564 million annually. What's more, no-shows have been associated with structural barriers, such as distance to the clinic and lack of transportation.

Fortunately, the VA has been authorized to provide eligible veterans and other beneficiaries mileage reimbursement, common carrier reimbursement (plane, train, bus, taxi, light rail, etc.), when medically indicated "special mode" (ambulance, wheelchair van) transport for travel to and from VA, or VA authorized non-VA health examination, treatment or care.⁸ Furthermore, veterans who live as little as 30 minutes from a VA health care facility will be able to choose private care, a significant change in rules that addresses access to care.⁹

This white paper examines the **impact of NAFLD and NASH as both a medical and economic crisis among military and civilian populations, and highlights the VA's strategy to eradicate liver disease, including its broadened contract with Echosens to include the FibroScan® 430 mini+ portable technology.**

A "silent" disease with no symptoms, NAFLD requires early identification and intervention as a critical approach for reducing the burden of the disease and improving patient outcomes. Toward that end, VA has adopted portable technology from Echosens called FibroScan® to improve access to non-invasive liver assessment and early detection of liver disease across the veteran population.

NAFLD Among Active Service Members

The military has experienced a 12-fold increase in the number of active service members diagnosed with NAFLD.¹⁰ Service members with severe NAFLD resulting in impaired liver function are unable to perform their military duties and are disqualified from service. This once rare disorder was diagnosed in 19,069 service members between 2000 and 2017, but increased rapidly from 12.6 cases per 100,000 people in 2000 to 152.8 per 100,000 people in 2017.¹¹

The Air Force had the highest rate with 99.4 per 100,000 people. The Marine Corps holds the fewest incidences with a rate of 32.9 per 100,000. The Army and Navy had rates of 79.2 and 78.6 respectively.¹²

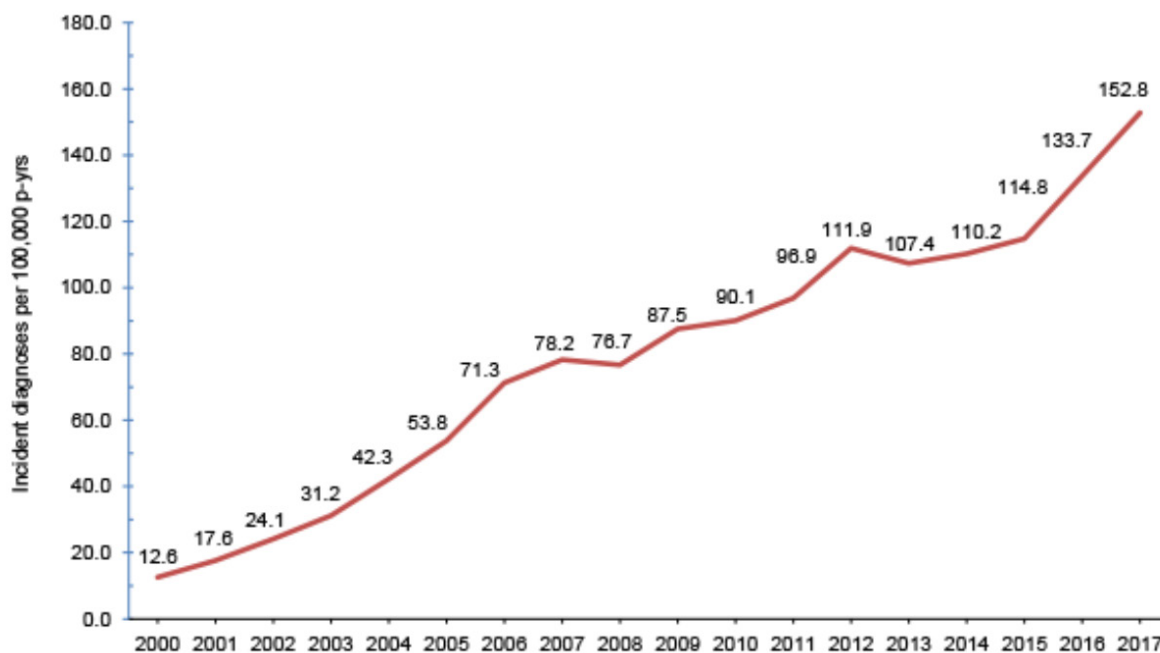
Overall rates have increased alongside the advancing ages of our troops. Within the ranks, warrant officers and senior officers had markedly higher rates than junior enlisted service members. Men were diagnosed at more than 1.5 times the rate of women.¹³

Link to Obesity

As obesity rates have increased in the general population, the military too has experienced higher rates of overweight troops in the ranks. In 2015, 7.8% of active duty service members were considered overweight, which was a 73% increase from 2011. While there is no cure for NAFLD, treatment is focused on preventing risk factors -- keeping a healthy body weight, eating plant-based diets and increasing daily exercise.¹⁴

Service members with severe NAFLD resulting in impaired liver function are unable to perform their military duties and are disqualified from service. **Cirrhosis related to NASH recently surpassed hepatic C virus-related cirrhosis as the leading indication for liver transplant in the United States.**¹⁵

FIGURE 1. Annual rates of incident NAFLD diagnoses, active component, U.S. Armed Forces, 2000–2017



Source: <https://health.mil/News/Articles/2019/01/01/NAFLD>



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Understanding the Impact of NAFLD

Liver disease is a silent epidemic, affecting millions of Americans and imposing significant financial burden on the U.S. healthcare system. NAFLD, which affects nearly 1 in 3 Americans, is most common in people living with diabetes (40-70%) or obesity (61-95%), with higher rates in older or Hispanic patients.¹⁶

Not simply a result of alcohol consumption, as many believe, NAFLD is the most common type of liver disease in the Western world as the result of poor eating habits and a sedentary lifestyle. In some cases, the fat in the liver cells builds up to the point where the liver cells swell and eventually cause inflammation. But there are usually no symptoms at this point.

As the inflammation continues, over time it leads to a condition that is called “non-alcoholic steatohepatitis” (NASH) – and its most troubling characteristic is its silence. The overall NASH prevalence in the adult population of developed countries has been estimated as high as 12%.

In some patients, persistent inflammation causes scar tissue to form in the liver, which is also known as “fibrosis.” This leads to a more serious stage of the disease called cirrhosis, a scarring of the liver that can lead to liver failure – the number one reason for liver transplants for end-stage liver disease or liver cancer.

High Costs of Liver Disease

NAFLD

The gravity of the liver disease health crisis is illustrated by this comparison to HCV:

PREVALENCE: HCV affects 3.5 million people and is curable with safe and effective treatments. NAFLD affects 85 million Americans and, as the disease advances, affects as many as seven million more who develop a related condition called NASH. Nevertheless, HCV has received considerably greater attention as a communicable disease.¹⁷

Cost of HCV: The costs of HCV are expected to reach \$9.5 billion by 2020, driven entirely by the costs associated with end-stage liver disease – decompensated cirrhosis, liver cancer and liver transplant.¹⁸ It is estimated that there are 6.65 million adults (18+ years old) with NASH in the United States and that there were 232,000 incident cases in 2017. Lifetime costs of all NASH patients in the United States in 2017 will be \$222.6 billion and the cost of the advanced NASH population will be \$95.4 billion.¹⁹

While outward signs of advancing liver disease are often associated with liver cirrhosis or liver cancer, if detected early, therapeutic interventions and lifestyle modifications can alter the course of NAFLD, improve prognosis and reduce costs.

Cost of Liver Cancer

In addition to progression to end-stage liver disease, NAFLD is associated with increased rates of liver cancer. A recent VA study suggested that the costs of HCC in cirrhotics three years post diagnosis was \$154,688 versus \$69,010 in matched cirrhotic controls. Diabetes and obesity have been shown to be independent risk factors for the development of HCC.²⁰

Economic Impact of NAFLD and NASH

NAFLD is costly to the U.S. healthcare system: \$32 billion annually, almost as much as the \$34 billion annual costs of stroke.²¹ The prevalence of NAFLD reflects the rising trend of obesity in the United States and, concurrently, the military population. NAFLD is the most common form of chronic liver disease,²² so it's important to identify its economic burden to underscore the need for readily available treatments and early detection to save money and lives among soldiers and civilians.

A challenging, high-volume and chronic condition that lacks a standardized care delivery model, NASH has created a global therapeutic treatment market projected to reach \$21.5 billion by 2025.²³ Although its progression rate may be slower than that of other types of liver disease, the incidence of NASH, and its interrelationship with hyperlipidemia, hypertension, liver cancer, Type 2 diabetes, obesity and metabolic syndrome, is increasing throughout the world.²⁴

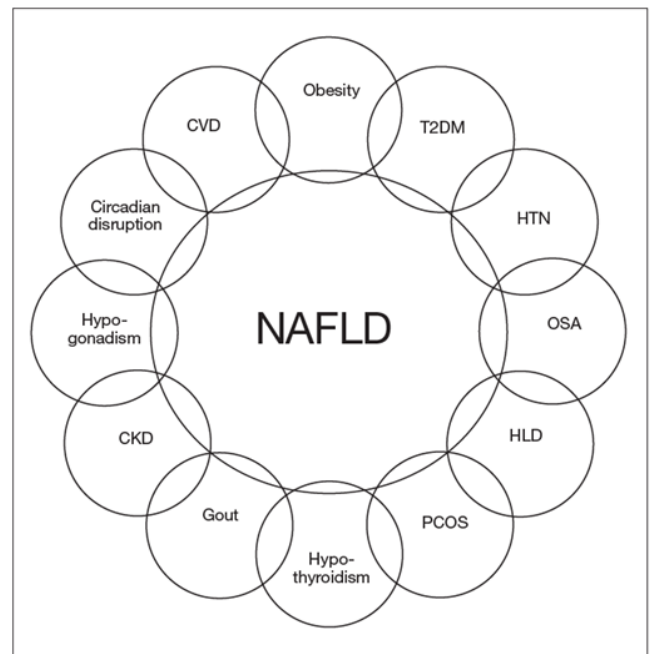
Liver Transplants

It is expected that by 2020, NASH will be the leading indication for liver transplant in the United States.²⁵ Increasing rates of NAFLD as indication for transplant (+140% over 10 years) vs 40-45% for HCV.

Heavier/sicker populations on the transplant lists may lead to poorer outcomes and increased management expenses medical costs – with hepatocellular carcinoma (HCC) management expenses and medical costs.²⁶

Compared with other etiologies, NAFLD cirrhosis is diagnosed at an older age, probably because of a slower fibrosis progression rate (on average one stage over 14 years) and decompensates later in life. Due to its silent course, liver failure is often the first presentation at diagnosis of NAFLD-related cirrhosis (38–45% of cases).²⁷

FIGURE 3 Metabolic Conditions and Complications Associated With NAFLD



Abbreviations: CKD, chronic kidney disease; CVD, cardiovascular disease; HLD, hyperlipidemia; HTN, hypertension; NAFLD, nonalcoholic fatty liver disease; OSA, obstructive sleep apnea; PCOS, polycystic ovary syndrome; T2DM, type 2 diabetes mellitus.

Source: <https://www.mdedge.com/fedprac/article/192463/mixed-topics/health-and-economic-burden-nonalcoholic-fatty-liver-disease/page/0/2>

Documenting the High Costs

In a recently published retrospective analysis of the OptumLabs Data Warehouse, claims for 108,420 patients diagnosed with NAFLD and 108,420 matched controls were evaluated both for peri-diagnosis period – one year pre-diagnosis through five years post diagnosis. For commercially insured patients diagnosed with NAFLD, the claims and costs prior to diagnosis were markedly higher than the controls, \$4,547 and \$2,298, respectively. This was primarily driven by increased costs for imaging diagnostics and hospitalizations.²⁸

In this study, the costs in the year of diagnosis spiked by 72% or \$3,257 (from \$4,547 to \$7,804) for patients covered by commercial insurance. The largest contributors to the cost increase were liver biopsies and hospitalizations. The study concluded that the costs associated with the care for NAFLD independent of its metabolic comorbidities are very high, especially at first diagnosis. Research efforts should focus on identification of underlying determinants of use, sources of excess cost and development of cost-effective diagnostics.²⁹

The same study examined medical records during a 10-year period (2005-2015) and identified 4,569 patients diagnosed with NAFLD. Researchers analyzed the healthcare costs per patient and overall costs per year in both groups, and extrapolated costs to a national scale to determine an economic burden of \$32 billion annually for the United States.³⁰

These results highlight a significant issue if healthcare leaders fail to address the causes of NAFLD or ignore preventive and effective screening methods. This study also reveals the potential reduction in healthcare costs if screening and treatments are put into place. The key is to determine which patients are at a higher risk of developing liver damage due to the disease in order to tackle this challenge at the population level.³¹ Clearly, the economic burden from NAFLD can be substantial, even without a definitive diagnosis.³²

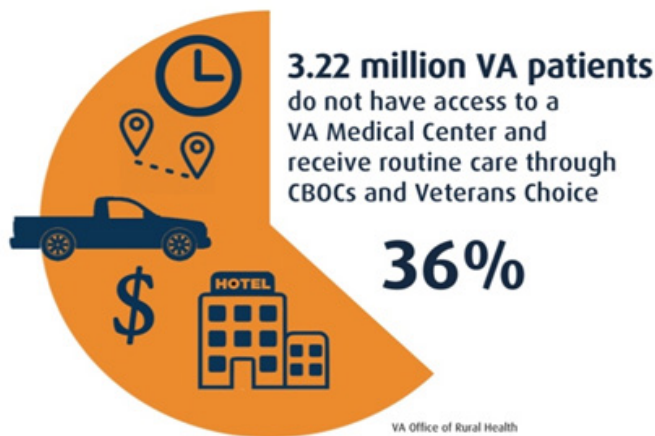
While prospective studies are needed, the authors suggest that as the NAFLD burden continues to increase, solutions are needed to promote healthcare delivery platforms to reduce costs and implement PCPs to optimally manage this complex patient population. An interpretation of this data suggests that (1) undiagnosed disease may be more resource intensive than post diagnosis and (2) screening strategies that rule out patients with liver disease due to NAFLD in primary care may be cost effective in reducing the number of patients subjected to specialist workup.

VA's Current Initiatives to Fight NAFLD

In the wake of its enormous success in the fight to eradicate HCV, the VA has adopted FibroScan® noninvasive liver diagnostic devices nationally to help assess their patients' liver conditions -- without painful and time-consuming liver biopsies.

While new drugs have effectively eradicated HCV in many patients, liver disease remains and these individuals still require ongoing monitoring for NAFLD and NASH. This is the focus of a recent study which suggests that fatty liver is present in 47.5% of patients who have cured their HCV infection, with some experiencing ongoing clinically significant fibrosis, despite normalizing liver enzymes.

This study reinforces the need to continue to monitor liver health in those patients with metabolic syndrome who are cured of HCV infection. NAFLD was identified in patients prior to treatment and persisted even after curing their HCV infection.



To requisition, reference #VA119-17-D-0033
For more information about FibroScan® and Echosens,
visit us at www.echosens.us or contact us at 781 790 9845

As part of an overall assessment, FibroScan® can help detect liver disease before it progresses and becomes symptomatic, reducing costs and improving outcomes.

These much-needed portable FibroScan® units will bring greater access to screening and earlier detection for many veterans who may be living with liver disease but are completely unaware of it. With one-third of veterans receiving their healthcare in community clinics and not the VA Medical Centers, the addition of the FibroScan® 430 mini+ provides greater access to care for these patients.

Data collected in examinations with FibroScan® can be sent back wirelessly to the Veterans Integrated Service Network (VISN) hub physicians, eliminating the need for VA patients to travel long distances to reach a main VA facility for care. The VA can now bring care to the Veterans through their Community Based Outreach Clinic (CBOC) infrastructure.

Physicians Treating Veterans

FibroScan® enhances physicians' ability to better diagnose and monitor veterans and their families for liver disease...no matter where they receive their care.

Diseases such as NAFLD and NASH are increasing in prevalence among the VA population. Cirrhosis related to NASH recently surpassed HCV-related cirrhosis as the leading indication for liver transplant in the United States. Earlier diagnosis—and risk stratification—of patients with underlying liver conditions presents a huge opportunity to impact outcomes for patients and reduce costs for the VA system. The ability to add this powerful diagnostic tool to assessment of liver disease, wherever it's needed, helps reduce costs and ease the burden on both physicians and patients. Patient satisfaction can also improve by cutting wait times and travel costs, and making it easier to get results painlessly and immediately.

An assessment with FibroScan® is a simple, non-invasive test that provides scores that can be used to diagnose and monitor liver health. The addition of portable FibroScan® systems will enable the VA to save time, money and, most importantly, help the veterans with HCV get follow-up assessments and halt the progression of NAFLD.



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Echosens, the developer of FibroScan®, is an innovative high-technology company offering a full range of products and services supporting physicians in their assessment and management of patients with chronic liver diseases. FibroScan® is supported by over 2,000 peer reviewed publications.

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