FACT SHEET

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The Prevalence and Clinical Management of Chronic Liver Disease

- Fatty liver disease is the fastest growing and largest segment of chronic liver disease, resulting in chronic illness for millions of people around the world and an annual US\$103 billion in direct healthcare costs in the United States alone.¹
- The liver is a critical organ that rids the body of harmful substances. Non-alcoholic Fatty Liver Disease (NAFLD) is an early stage form of fatty liver disease that occurs when there is an accumulation of fat in the liver, most commonly caused by obesity, diabetes and insulin resistance.
- NAFLD can progress to a more severe form of fatty liver disease called Non-alcoholic Steatohepatitis (NASH) characterized by inflammation and the formation of scar tissue. Left untreated, the disease can lead to chronic illness, organ failure, cancer and ultimately death. Early diagnosis is key to preventing – and reversing – disease progression and rising healthcare costs.



- Approximately 1 in 4 persons worldwide has fatty liver disease, a number that rises to 1 in 3 Americans (100 million) because of the greater prevalence of diabetes and obesity in the US.² Of this 100 million:
 - 50 million Americans with fatty liver disease are undiagnosed.³
 - 9.5 million Americans have NASH, the advanced form of the disease.⁴ By 2030, it is estimated that 27 million Americans will have NASH.⁵
- At least 20%–30% of patients with NAFLD develop NASH, which can lead to cirrhosis and associated complications, including hepatocellular cancer (HCC).⁶
- NASH is also associated with an increased risk of cardiovascular disease⁷ and increased cardiovascular and liver-related mortality.⁸⁻¹⁰
- NASH is already the number one indication for liver transplantation in women, patients older than 54 years, and Medicare recipients.¹¹
- MAFLD prevalence is highest among Hispanics, non-Hispanic whites and African Americans.¹²
- The upward trend in NAFLD/NASH incidence and prevalence underscores the importance and urgency of developing and implementing effective screening, diagnosis, and treatment strategies in the United States, particularly among emerging at-risk cohorts, such as patients with diabetes and obesity.

FACT SHEET



The Prevalence and Clinical Management of Chronic Liver Disease

- This growing epidemic puts a strain on both the healthcare system and clinical practices. The continued growth in patient cases and emergence of potential new treatments creates an urgent need for a cost-effective, quick and accurate solution to assist in the clinical management of patients with liver disease.
- 👐 Currently, physicians can assess liver tissue characteristics with a combination of blood tests, ultrasound, and MRI or biopsy.
 - While blood tests and general ultrasound are easy and inexpensive to administer, they are unable to provide reliable measurements on their own.
 - M On the other hand, while MRI and biopsy are considered the gold standard, they are expensive, invasive and inconvenient.
- Sonic Incytes has developed the first handheld 3D liver tissue assessment tool that measures liver stiffness and attenuation and can aid in the clinical management of patients with liver disease. It is accurate, accessible and affordable.
- M Accuracy: VelacurTM offers the following technical advances when compared to transient elastography:
 - 30x greater tissue sampling
 - 2x deeper tissue measurement
 - M 3D volumetric acquisition with live ultrasound image guidance
- Accessibility: VelacurTM is convenient and accessible for a variety of practice settings. This point of care solution is portable, can be operated by any healthcare professional, and produces real-time measurements of liver stiffness and attenuation.
- Affordability: Velacur[™] is more cost-effective than MRI, biopsy and other ultrasound tools, and provides a new revenue stream for clinicians.
- If the promising solution as an aid in the clinical management of patients with chronic liver disease.

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³ Polanco-Briceno, S., Glass, D., Stuntz, M. et al. Awareness of Nonalcoholic Steatohepatitis and Associated Practice Patterns of Primary Care Physicians and Specialists. BMC Res Notes 9, 157 (2016).

⁴ GlobalData. NASH: Current and Future Trends. GD Expert Presentations. October 2018.

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⁷ Wong CR, Lim JK. The association between nonalcoholic fatty liver disease and cardiovascular disease outcomes. Clin Liver Dis (Hoboken) 2018;12:39–44.

 ⁸ Younossi ZM, Stepanova M, Rafiq N, et al. Nonalcoholic steatofibrosis independently predicts mortality in nonalcoholic fatty liver disease. Hepatol Commun 2017;1:421–428.
⁹ C Dulai PS, Singh S, Patel J, et al. Increased risk of mortality by fibrosis stage in nonalcoholic fatty liver disease: systematic review and meta-analysis. Hepatology 2017; 65:1557–1565.

¹⁰ Stepanova M, Rafiq N, Makhlouf H, et al. Predictors of all-cause mortality and liver-related mortality in patients with non-alcoholic fatty liver disease (NAFLD). Dig Dis Sci 2013;58:3017–3023.

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¹² Younossi Z, et al. Hepatology. 2019;69(6):2672-2682; Younossi ZM et al. J Hepatol. 2019;70(3):531-544.