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because liver health matters

Understanding the Many Benefits of Comprehensive, Chronic Care Management of Liver Disease

Enhances patient outcomes, reduces costs associated with metabolic disease management, improves physician practice financial performance

FibroScan®, non-invasive technology that rapidly examines liver stiffness and fat at the point of care, integrates with MetaPhy Health's chronic care management programs.

Author: Dr. Reed Hogan, M.D., GI Associates (GIA) in Flowood, Mississippi

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Diabetes is one of the leading causes of disability and death in the United States. One in 10 Americans have diabetes – more than 30 million people – and another 84 million adults are at high risk of developing Type 2 diabetes.¹ Furthermore, the latest figures show that the obesity rate in the United States has reached 42.4%.²

Interventions to impact these conditions have traditionally been ineffective. Approaches like chronic care management (CCM) are recognized by CMS for reducing costs and improving outcomes to address chronic conditions, including Type 2 diabetes and obesity.

Nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) are highly prevalent in people living with metabolic syndrome (MetS) and are recognized not only as leading causes of liver disease, but also contributors to increased cardiovascular disease (CVD) mortality among people living with Type 2 diabetes.

MetaPhy and Echosens are collaborating to develop CCM programs that are more accessible and effective for clinicians, especially gastroenterologists, who are at the forefront of managing NAFLD and NASH.

When we look at the experience with the hepatitis C virus (HCV), the generalist referred patients to the liver specialist to cure HCV as an isolated medical condition. Because NAFLD and NASH are so tightly intertwined with obesity, diabetes and lifestyle, more coordinated engagement is needed to support behavioral changes that will result in better outcomes across the co-morbid conditions affecting the individual patient and the course of liver disease. CCM provides the opportunity to cost-effectively improve that coordination, with minimal impact on the practice model for both the specialist and the generalist.

While the current procedure-based model relies on a large pool of patients undergoing colon cancer evaluation every few years, there may be an opportunity to appropriately expand interim engagements with people with NAFLD who are at risk for advancing liver disease. The question is what role should gastroenterologists play in the management of chronic conditions?

As an ancillary program, an effective and efficient CCM program can mitigate the impact of NAFLD on metabolic comorbidities. With the introduction of new treatment options, including drugs that will soon be available, a targeted CCM program can integrate non-invasive, point of care liver examinations to leverage the launch of these drugs in a way that improves outcomes, lowers costs and enhances the physician practice income stream.

Understanding the Impact of NAFLD

NAFLD has become the most common chronic liver disease in the world and affects between 25% to 30% of adults in the United States.³ Comprised of a spectrum of disease severity, NAFLD ranges from simple steatosis to NASH and steatosis with hepatocyte inflammation, necrosis and fibrosis. About 20% of patients with NAFLD will progress to NASH, with around one-quarter of those developing liver fibrosis.⁴ Patients with NASH experience significantly increased mortality due to cirrhosis and hepatocellular carcinoma (HCC) and extrahepatic complications, such as CVD and malignancy.

For physicians, specialist practices and their patients, it is important to recognize NAFLD so that early intervention can be implemented. Lifestyle modifications and strict control of metabolic risk factors are the most effective treatment. Because disease progression is typically slow, patients can be managed well by primary care physicians. NAFLD patients with advanced liver fibrosis should be referred to specialist care for further assessment.⁵ While finding and managing fibrotic NASH is an important component to addressing liver disease, patients with steatosis alone are at a greater risk of cardiovascular mortality and morbidity.

Recent studies have suggested that NAFLD is often present as a comorbidity in patients with Type 2 diabetes. The mutual interrelationship between these conditions shows that Type 2 diabetes can exacerbate NAFLD by promoting progression to nonalcoholic steatohepatitis or NASH, while NAFLD causes the natural course of diabetic complications to worsen in Type 2 diabetes patients.⁶ NAFLD affects approximately 25% of the worldwide population and as many as 6% are affected by NASH, with NASH prevalence expected to increase by 63% by 2030.⁷

How CCM Addresses the Consequences of NAFLD

The increasing prevalence and incidence of NAFLD with advanced fibrosis is concerning because patients appear to experience higher non-liver-related morbidity and mortality than the general population. Recent clinical evidence suggests that NAFLD is directly associated with an increased risk of cardio-metabolic disorders.⁸

The MetaPhy Health Difference

In conjunction with the physician and the patient, MetaPhy Health's Comprehensive Chronic Disease Management (CCDM) program, including chronic care management and remote patient monitoring, can make weight management more effective in treating fatty liver and its underlying conditions. A CCDM program focused on lifestyle management will achieve a long-term impact and prompt rapid and potentially meaningful changes in liver fat as estimated by CAP™, which will further validate the program's lifestyle interventions.

MetaPhy prepares and implements a comprehensive telemedicine treatment plan focused on patient education, as well as dietary and medical concerns and behavioral challenges. Their clinical staff uses its technology platform to provide daily, weekly and monthly interactions, improving patient engagement, experience and outcomes.

With this additional level of care, they can document and report medical information and treatment progress, empowering the physician to stay connected to a patient at an unprecedented level.



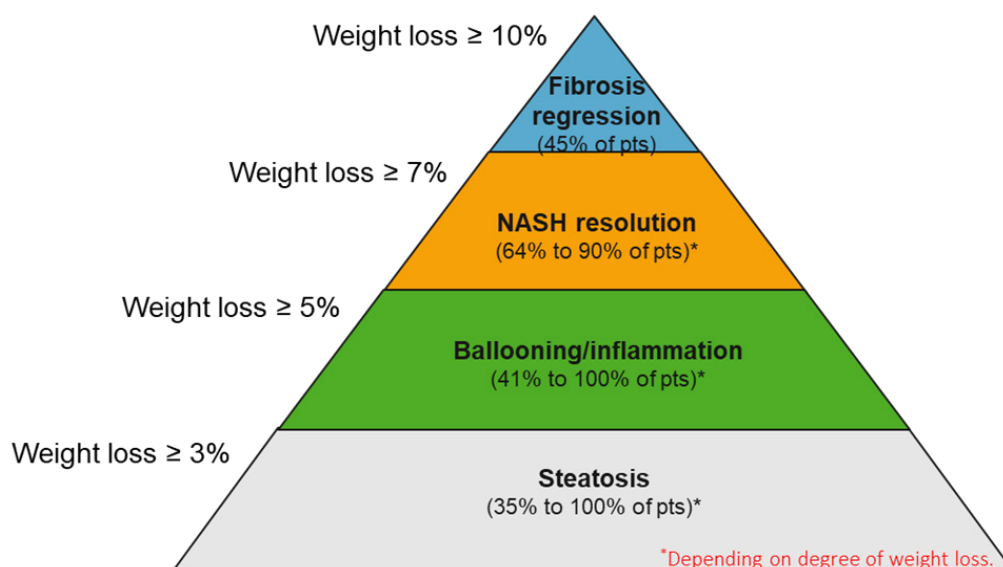
Chris Oubre, president and chief operating officer, MetaPhy, says, "The traditional approach of telling a patient that they need to change has not been adequate. Most patients want to change but may face barriers or challenges to achieving this in a meaningful and sustainable way. Our CCDM programs engage the patient to better understand their situation and tailor a plan that helps address their circumstances with high touch and compassionate care."

Kelsey Resch, telehealth care coordinator, MetaPhy Care, states, "As a telehealth care coordinator with MetaPhy's chronic disease management program, I am able to provide critical support and professional medical care to patients in need. My ability to provide extra support to patients outside of their regular physician appointments increases patient well-being and confidence in their health."

Implementing a CCDM program that targets liver health can address the broader needs of these patients and prevent them from developing NASH. In fact, this is a critical imperative given the costs and complications associated with NASH--a challenging, high-volume and chronic condition that lacks a standardized care delivery model. NASH has created a global treatment market projected to reach \$21.5 billion by 2025,⁹ and is on track to becoming the leading cause of liver transplantation in the United States. Although its progression rate may be slower than other types of liver disease, the incidence of NASH, and its sequela hyperlipidemia, hypertension, Type 2 diabetes, obesity and metabolic syndrome, is increasing throughout the world.¹⁰ Currently, new NASH/antifibrotic therapies are being evaluated in clinical trials and are expected to lead to even higher costs.¹¹

NAFLD is on target to quickly becoming the main indication for liver transplants in the country, with the number of healthy livers available for transplants likely to decline. Children as young as five are also developing fatty liver disease through over-consumption of sugars, sodas, fructose and corn syrup and lack of exercise. Liver transplant procedures are estimated to have an average cost of \$577,100, putting a tremendous burden on payers, especially self-funded employers.

NAFLD is reversible if caught in the early stages and accompanied by lifestyle change. In many patients, a 5-7% decrease in body weight is associated with a reduction in liver fat and inflammation.¹² Screening and early detection can help to prevent more serious conditions such as end-stage liver disease or liver cancer.



Treatment Options for NAFLD

The liver is the key to insulin resistance, but the good news is that fatty liver can be improved without drugs. In fact, weight loss is the best treatment option for NAFLD and the prevention of fibrosis progression.

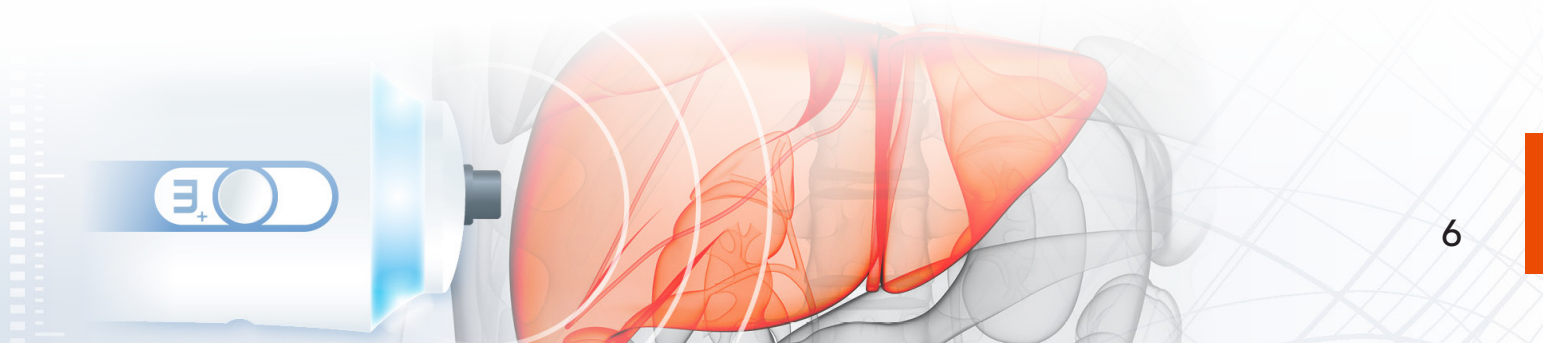
Obetacholic acid (OCA), the first FDA-approved treatment for fibrotic NASH, is expected to launch in 2020. OCA has demonstrated 40% efficacy¹³ and experts suggest an annual price tag of \$15,000 to \$20,000 to be cost effective.¹⁴ The use of OCA after 18 months saw 4 out of 10 patients showing improvement by at least one fibrosis stage, while 23% of those with no treatment experienced a similar reduction.¹⁵ For patients with earlier, but advancing fibrotic NASH, payers may require a “step edits,” including more intensive lifestyle modification prior to accessing pharmacological treatment. This is likely to dramatically increase the potential CCDM pool of NASH patients under collaborative GI/PCP care.

The efficacy of OCA, its high price tag and high placebo response reinforces the value of lifestyle modification as the primary treatment. If a patient loses 3% of weight this can lead to a 35% reversal in steatosis, with greater weight loss leading to lower inflammation, NASH resolution and, at 10% weight loss, fibrosis regression. This makes it clear that weight loss can be more efficient than drug intervention. CCDM programs that effectively impact lifestyle changes are critical and have significantly greater cost-savings if effectively implemented and weight loss is maintained. It also means a better use of time and resources and provides a substantial value proposition when OCA and other drugs are launched.

Investing in lifestyle modification for patients also improves comorbid conditions. The challenge is that lifestyle changes, while effective, are not always sustainable or efficient. This is where a liver examination, using FibroScan, combined with a CCDM program, like MetaPhy’s, can optimize a drug-free and highly effective way to reverse liver damage.

Liver Health First

In offering new recommendations for evaluating liver health in patients with Type 2 diabetes, the American Diabetes Association (ADA) suggests that noninvasive tests, such as elastography or fibrosis biomarkers, may be used to assess risk of fibrosis, but referral to a liver specialist and liver biopsy may be required for definitive diagnosis. Patients with Type 2 diabetes or prediabetes and elevated liver enzymes (alanine aminotransferase) or fatty liver on ultrasound should be evaluated for presence of NASH and liver fibrosis. Interventions that improve metabolic abnormalities in patients with diabetes—including weight loss, glycemic control, and treatment with specific drugs for hyperglycemia or dyslipidemia—are also beneficial for fatty liver disease.¹⁶



Value of FibroScan and MetaPhy for Leveraging OCA

Given the challenge of low compliance in lifestyle changes, MetaPhy's CCDM program can make weight management more effective in treating fatty liver and its underlying conditions. A CCDM program focused on lifestyle management will achieve a long-term impact and prompt rapid and potentially meaningful changes in liver fat as estimated by CAP™, which will further validate the CCDM program's lifestyle interventions.

It is estimated that of the 16.5 million Americans with fibrotic-NASH, approximately 1.5 million are currently under the care of gastroenterologists. Of these, approximately .5 million are potential candidates for drug treatment based on the degree of fibrotic-NASH. Another .7 million have earlier stage fibrotic disease and, while they have progressive disease, they may not be considered candidates for treatment.¹⁷ For gastroenterology and hepatology-gastroenterology practices, partnering with MetaPhy can improve efficiency around lifestyle modifications and tailored programs for each patient—with the hope of arresting or even reversing advancing liver disease. Moreover, adding a CCM capability as an ancillary service can improve the practice financial performance.

A core component of the Metaphy CCM program is FibroScan. FibroScan is a powerful tool supporting outcomes and providing valuable information on liver health. This information can support care management across key components of the metabolic syndrome – diabetes and hyperlipidemia.

As part of a patient-centered care model, FibroScan is designed to improve individual health outcomes, lower payer costs by avoiding expensive, invasive interventions and enhance the financial performance of practices.

This combination improves care coordination and develops and implements a comprehensive care plan for patients with NAFLD, NASH, Type 2 diabetes, obesity and/or the underlying metabolic syndrome conditions that contribute to the progression or risk of developing advanced liver disease. Many individuals with gastrointestinal issues are also living with other chronic diseases that can be improved through early detection, monitoring, patient education and engagement.

Real World Example

At GI Associates (GIA) in Flowood, Mississippi, we have successfully integrated our FibroScan capabilities with the MetaPhy CCDM programs. With this partnership, GIA is able to provide services to patients across the spectrum of NAFLD, leveraging FibroScan to monitor and engage patients. Effective lifestyle modification has been shown to cease and often reverse the progression of fibrotic NASH.

GIA is not only experiencing fiscal benefits from our NAFLD program, but also providing a valuable service to our community where viable treatment options for NAFLD have traditionally been scarce. In the GI setting where the volume of NAFLD/metabolic syndrome patients is overwhelming, the profitability of CCDM drives this ancillary.

Metabolic Syndrome and Women

Metabolic syndrome is the name for a group of risk factors that increases risk for heart disease and related problems, including diabetes, stroke, fatty liver disease and more. Risk increases as a person ages and is believed to affect one out of every six people. Polycystic ovarian syndrome (PCOS) is a condition in which women have imbalanced or decreased levels of the female hormones estrogen and progesterone. PCOS causes the growth of ovarian cysts, or other issues like irregular menstrual periods, excess hair on the face and chest, acne and, sometimes, infertility. Women with PCOS¹⁸ are often overweight or have diabetes, high blood pressure and high cholesterol levels. They may also be at a higher risk for NAFLD. Underneath all these connections is “metabolic syndrome,” a condition frequently present in those with NAFLD, PCOS and diabetes.

Closer Look at FibroScan

FibroScan is an innovative diagnostic tool to rapidly and non-invasively assess liver fat and stiffness. It assists in reducing unnecessary diagnostic procedures, additional treatments and cost associated with progressive liver disease. At point of care or in the primary care setting, physicians can provide liver stiffness and fat assessment as a component of a wellness visit rather than waiting for serious and more damaging symptoms to occur. FibroScan and a healthy diet, such as keto or Mediterranean diet, along with regular exercise, are essential for reversing liver damage and diabetes.

As part of an overall liver assessment, FibroScan can be performed by a medical assistant and interpreted by the physician, and it takes less than 10 minutes, including positioning the patient. FibroScan produces consistent numeric results for each liver stiffness and liver fat that can be easily interpreted by the clinician to assess and monitor these liver health metrics over time. What’s more, FibroScan is supported by 2,500+ peer-reviewed publications and is used as the reference for major association guidelines for non-invasive assessment of the majority of liver diseases.

Among its many benefits, FibroScan: provides consistency and evidence; standardizes care and provides patients and providers with state-of-the-art technology; is covered by CMS and most commercial insurance plans for diagnosing and monitoring chronic liver disease; and improves diagnostic accuracy for delegated risk contracts, such as Medicare Advantage (MA).



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About Echosens

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 2,500 peer-reviewed publications and examinations are covered by Medicare, Medicaid and many insurance plans. For more information, please visit <http://www.echosens.us> and follow us on Twitter (@echosensNA).

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