GLOBAL LIVER INSTITUTE

FINAL REPORT

NASH Externally-Led **Patient-Focused** Drug Development (EL-PFDD) Meeting

NOVEMBER 4TH 2021

CONTENTS

BACKGROUND

Global Liver Institute (GLI) is a 501(c)(3) tax-exempt not-for-profit organization, headquartered in Washington, D.C., United States, with offices in the U.S. and Europe. GLI's vision is for liver health to take its rightful place on the global public health agenda commensurate with its prevalence and impact. Central to this vision is responding to nonalcoholic steatohepatitis (NASH), the advanced form of fatty liver disease. In 2017, to advance this effort GLI created the NASH Council. There are currently more than 80 members of the NASH Council.

In 2020, GLI and the NASH Council released the resource, The Language of NASH: A Narrative to Guide Communication on NASH. This core NASH messaging framework was designed to establish consistent and meaningful terminology and messaging to be used as a foundation for communication in all areas around NASH. Following this release, in late 2020 GLI launched the U.S. NASH Action Plan. This action plan sets an actionable agenda and detailed roadmap with recommendations for each relevant impacted stakeholder group within the NASH community from patients and clinicians to regulators and policymakers.

With the goal of following through on one of the key recommendations within the U.S. NASH Action Plan, GLI and the liver patient advocacy community held a NASH EL-PFDD meeting on **November 4th, 2021.**

NONALCOHOLIC STEATOHEPATITIS (NASH) OVERVIEW

Nonalcoholic Fatty Liver Disease (NAFLD) describes a spectrum of liver disease including NASH through to cirrhosis.[1 2] NAFLD has commonly been described as fibrosis 0 – 4. The risk of adverse outcomes and mortality increases with fibrosis progression. Early stage NAFLD is when fat accumulates in the liver with little or no inflammation or liver cell damage. Left untreated, NAFLD can progress to NASH, which is characterized by the accumulation of fat in the liver, inflammation, and injury to the liver cells with or without scarring.

NASH is considered the most severe form of NAFLD. NASH has far-reaching public health effects that are not limited to the liver. The disease has shown significant concurrency with a variety of other conditions ranging from obesity, type 2 diabetes, cardiovascular disease (CVD), and chronic kidney disease.[3 4] Furthermore, NASH has a bidirectional relationship with type 2 diabetes. If NASH develops first, the patient is likely to develop type 2 diabetes. Conversely, in patients with type 2 diabetes initially, NASH is a common concurrent occurrence (37% of people with type 2 diabetes have NASH).[5]

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1 Younossi ZM, Koenig AB, Abdelatif D, et al. Global epidemiology of nonalcoholic fatty liver disease Meta-analytic assessment of prevalence, incidence, and outcomes. Hepatology. 2016; 64:73–84.

2 Banini BA and Sanyal AJ. Nonalcoholic Fatty Liver Disease: Epidemiology, Pathogenesis, Natural History, Diagnosis, and Current Treatment Options. Clin Med Insights Ther. 2016; 8:75–84.

3 Anstee QM, Targher G, Day CP. 2013. Progression of NAFLD to diabetes mellitus, cardiovascular disease or cirrhosis. Nature Reviews Gastroenterology & Hepatology 10(6): 330

4 Adams LA, Anstee QM, Tilg H, et al. 2017. Non-alcoholic fatty liver disease and its relationship with cardiovascular disease and other extrahepatic diseases. Gut 66(6): 1138-53

5 Younossi ZM, Golabi P, de Avila L, et al. The global epidemiology of NAFLD and NASH in patients with type 2 diabetes: A systematic review and meta-analysis. J Hepatol. 2019; 71:793–801.

NASH impacts anywhere from **148 million** to **444 million** people worldwide.[6 7] People with NASH have an overall mortality rate of 7.9% within seven years of diagnosis — almost twice that of the general population.[8] On top of this is that an estimated 10% of children in the United States also currently have NAFLD and run the risk of progressing to NASH.[9 1011] In 2015, it was estimated that there were 370,000 deaths among the NASH population; however, more than 90% of the deaths were classified as due to general background or excess cardiovascular.[12]

6 Spengler EK, Loomba R. Recommendations for diagnosis, referral for liver biopsy, and treatment of nonalcoholic fatty liver disease and nonalcoholic steatohepatitis. Mayo Clinic Proceedings. 2015;90(9):1233–1246.

7 Younossi ZM, Koenig AB, Abdelatif D, et al. Global epidemiology of nonalcoholic fatty liver disease meta-analytic assessment of prevalence, incidence, and outcomes. Hepatology. 2016; 64:73–84.

8 Anstee QM, Reeves HL, Kotsiliti E, et al. 2019. From NASH to HCC: current concepts and future challenges. Nature Reviews Gastroenterology & Hepatology: 1

9 J Pediatr. 2013;162(3):496–500.e1 Welsh JA, Karpen S, Vos MB. Increasing prevalence of nonalcoholic fatty liver disease among United States adolescents, 1988-1994 to 2007-2010.

10 Pediatrics. 2006;118(4): 1388–1393 Schwimmer JB, Deutsch R, Kahen T, Lavine JE, Stanley C, Behling C. Prevalence of fatty liver in children and Adolescents.

11 J Pediatr. 2018;200:174–180 Fernandes DM, Pantangi V, Azam M, et al. Pediatric nonalcoholic fatty liver disease in New York City: an autopsy study.

12 Estes C, Razavi H, Loomba R, Younossi Z, Sanyal AJ. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. Hepatology. 2018;67(1):123-133. doi:10.1002/hep.29466

MEETING OVERVIEW

GLI in partnership with the GLI's Liver Action Network, the NASH Council, and the liver advocacy community were proud to lead the first NASH Externally-Led Patient-Focused Drug Development Meeting (EL-PFDD) on November 4, 2021.

This meeting provided the U.S. Food and Drug Administration (FDA), and other relevant stakeholders have the opportunity to obtain a wide range of patients' and caregivers' input on NASH, including their perspectives on their condition, its impact on daily life, future therapy risk and benefit tradeoff, and the urgency around developing therapies.This meeting highlighted the FDA's willingness to form meaningful partnerships with the advocacy community that will contribute to the quality of the agency's regulatory decision-making and lends credibility to future NASH therapy review processes. The NASH EL-PFDD meeting also marked the continuation of a series of productive hepatology conversations that the liver advocacy community has had with the FDA throughout 2020, and 2021.

COLLABORATORS AND ATTENDEES

GLI collaborated with many other liver patient advocacy organizations (e.g., Fatty Liver Foundation, NASH knowvledge, Liver Coalition of San Diego, and Community Liver Alliance) and leadership in the NASH community to ensure the success of the event, including survey development, dissemination, promotion, and patient/caregiver participation. Additionally, GLI was pleased to see a wide spectrum of leaders outside of the liver patient community attend the event, including the American Association for the Study of Liver Diseases (AASLD), the Endocrine Society, the Obesity Action Center (OAC), the American Gastroenterological Association (AGA), the Liver Forum, Duke University School of Medicine, University of California San Francisco Medical Center, Massachusetts General Hospital/ Harvard Medical School: Fatty Liver Disease Clinic, and more. Also due to the variety of conditions that NASH is interconnected with, GLI appreciated the virtual attendance from multiple divisions within the FDA.

More than 100 stakeholders attended the meeting virtually with around 30% identifying themselves as patients or caregivers impacted by NASH. Although participants in this meeting may not fully represent the diverse population impacted by NASH, the input reflected a diverse set of experiences with the symptoms and treatments for this disease. More information, including the archived webcast and meeting transcript, is available on the meeting website: https://www.globalliver.org/news/global-liver-institute-externally-led-patient-focused-drug-development-meeting-nonalcoholic-steatohepatitis-nash

EXECUTIVE SUMMARY

This NASH EL-PFDD outcome report will provide an overview of the liver condition known as NASH, an overview of the EL-PFDD meeting that occurred on November 4th, 2021. It will summarize the input shared by panelists and attendees during the meeting, and include a summary of comments submitted to the NASH survey. To the extent possible, the terms used in this report to describe specific NASH symptoms, impacts, and treatment experiences reflect the words used by meeting attendees, or survey commenters. There may be symptoms, impacts, treatments, or other aspects of NASH that are not included in this report.

The input from the meeting and survey comments provided rich detail on the impact that NASH has on patients, caregivers, and family members. Participants highlighted the physical, emotional, and social toll NASH takes on daily life and focused on the need for new treatment options.

SEVERAL KEY THEMES EMERGED FROM THIS MEETING

- **Participants emphasized the lack of adequate educational support from their physicians and healthcare professionals who may also not think to screen for NASH, even in patients with more than one high-risk factor.**

- **Participants highlighted that due to the lack of public awareness of liver health and NASH, in particular, patients with NASH find it difficult to differentiate between symptoms related to NASH and other health issues.**

- **Participants shared in vivid detail the social, physical, and emotional impact that NASH has on their lives.**

- **They described how NASH is typically only detected once it has progressed to cirrhosis or liver cancer, therefore most of the participants have lived with the disease for years without being aware of the damage accumulating in their liver.**

- **Participants described how there remains a lack of a unified approach in early detection and management of NASH. They discussed how there are varying degrees of success in managing their symptoms with the methods currently available to address NASH like weight loss, and lifestyle interventions.**

- **Participants described the clinical features of NASH that they are most eager to have treatments, including their perspectives on the balance between potential future therapy risks and benefits, the value of having a solution for every stage of the condition, the value of stopping progression, and the risks they are willing to tolerate.**

- **Participants shared the challenges in getting diagnosed, and their experiences with liver biopsy including the burden associated with ,and the ineffectiveness of the diagnostic tool.**

- **Participants also stressed the need to improve NASH clinical trial design to improve access and create opportunities for them to participate. They also discussed the importance of shifting the thought process around clinical trial design including moving away from the focus on clinical adverse events.**

The input generated through this EL-PFDD meeting strengthened the community's understanding of the burden of NASH on patients and caregivers and the unmet medical need. Most importantly, we hope that FDA staff will carefully consider the findings from this meeting during the drug development process, including when advising sponsors on their drug development programs and when assessing products under review for marketing approval. Overall, the input gathered through this EL-PFDD meeting will provide the entire health community with clarity on the priorities and preferences for addressing NASH by individuals who have been impacted most by the serious chronic liver condition.

PANEL 1

General Theme: Awareness, Education, Impact on Function, Managing Care and Life, Progression and risks associated with NASH

The first panel focused on awareness, education, impact on function, managing care and life, progression, and risks associated with NASH. The key takeaways from this section of the meeting were centered around hearing directly from the panel on specific symptoms and impacts in their own words. The panel also expanded upon how NASH impacts their ability to live normally and perform activities as fully as they would like.

The conversation was moderated by Global Liver Institute CEO and Founder, Donna R. Cryer, JD, and included four panelists representing a variety of segments within the patient community, and highlighted the diverse impact of NASH.

The panel included:

- *Tony Villiotti*, a transplant recipient due to NASH, cirrhosis, and liver cancer. He is the founder of a nonprofit dedicated to raising awareness and providing education about nonalcoholic liver disease, NASH knowledge.
- *Megan Lazarone*, the daughter of a patient that passed away due to NASH. She cared for her mother as she experienced a range of symptoms over 10 years.
- *John Mahalchak*, a patient that was diagnosed with acute chronic pancreatitis in 2010 and underwent a total pancreatectomy with auto-islet transplant in 2013. Post-transplant he was diagnosed with gastroparesis and was placed on enteral nutrition and IV hydration. During a follow-up operation in 2019, a liver biopsy showed that he had fatty liver disease and fibrosis.
- *Terri Milton*, a patient that was diagnosed with NASH Cirrhosis in 2017 followed shortly afterward with a liver cancer diagnosis in 2018. She is currently on the transplant list waiting for a second chance of a life-giving liver.

The panelists' statements provided a vivid depiction of the burden of NASH on many aspects of daily life. Panelists emphasized the lack of awareness and how the symptoms of NASH, which may include fatigue, lethargy, abdominal pain, and sleeping problems, are non-specific so they can often be misinterpreted. They also highlighted the impacts of NASH on their personal, family, and social lives. They discussed how the rate of disease progression is not uniform; some people experience fast fibrosis progression while others follow a much slower course or may even experience regression. They also discussed how NASH care can look markedly different depending on when someone is diagnosed, and the unique complications experienced by each patient. They also discussed how due to NASH's strong link to obesity, weight loss is the most established approach to care; however, it can be difficult to accomplish and sustain.

Some of the key comments from the panel discussion are below:

“My experience has been that this lack of awareness [knowledge of the liver] extends even to many in the medical profession. Just taking my case as an example, I had two of the primary risk factors for fatty liver and cirrhosis. I was obese and I had diabetes. What if the monitoring of my disease had gone beyond the periodic routine blood tests and had included non-invasive testing that tracked the severity of the condition of my liver and what if on the day I was told I had a fatty liver I was also told that my condition might lead to cirrhosis. I feel strongly that if either of those had occurred I would at least have had the opportunity to control my condition and maybe avoid the transplant. I had nine years between my fatty liver and cirrhosis diagnosis. Nine years, I had eighteen doctors appointments during that time but as far as addressing my condition those nine years were wasted. My point here isn’t to be a Monday morning quarterback and talk about would haves and should haves, but just to point out that we need to do a better job of educating and monitoring those at risk.”

-Tony Villlotti

“I would also like to address the lack of a medical solution for those with NAFLD and NASH particularly the assessment of the safety of the drugs under development. I’m not a scientist and have really nothing to contribute to the medical assessment of drug safety but I do understand a patient perspective on this subject we also see tv commercials where the sales pitch for a drug is followed by a list of very scary side effects the choices are left to the patient in consultation with their doctor to weigh the risk and rewards of that drug. I would encourage the FDA to give those NASH patients that same choice when it comes to NASH drugs. Please don’t let perfection be the enemy of good having no drug for the treatment of NASH is a risk in and of itself as we sit here patients are continuing down the road to a transplant or even death the world was not standing still”

- Tony Villiotti

“I was lucky after a transplant and thankful that I did. I wouldn’t be alive today without it but I have to tell you that transplant is not a great solution, a transplant is not a get out of jail free card. The anti-rejection drugs I’ll be taking for the rest of my life have damaged my kidneys to the point where I’ve lost half my kidney function and my diabetes has gotten worse. It’s a price worth paying but it’ll be much better served if a medical solution has been available to slow down or stop the progression of my condition*”*

-Tony Villiotti

"...for many NASH patients their house is figuratively on fire and they're willing to take some risk so you know I'm being repetitive but I feel like I can't say it enough please consider the patient perspective during your evaluations..."

-Tony Villiotti

"I was seeing my doctor every six months for my diabetes. After some blood work, he told me that my liver enzymes were elevated and I had fatty liver. I never heard of that condition but he didn't make a big deal of it and so I didn't ask any questions. He told me I should lose weight but that didn't set off any warning bells as I heard that at every doctor's appointment. I walked out of that appointment not concerned at all by fatty liver; my focus continued to be on my diabetes" -*Tony Villiotti*

"...looking back on my experience the thing that struck me the most was how few people had heard of non-alcohol liver disease despite the fact that as many as 100 Americans have it just and overall there's a general lack of knowledge about the liver the survey I saw shortly after my transplant showed that about one-third of the surveyed thought you could live without a liver..."
-Tony Villiotti

"[My mother] was diagnosed with NASH for years. [She] felt unwell. She was often fatigued and because she was a nurse she knew something was wrong. She was a type 2 diabetic and she was overweight, but she continued to go to the doctor after doctor and in Alexandria, [Louisiana], being a small town there just weren't very many specialists so she ended up traveling all over Louisiana to find someone to correctly diagnose what was going on. They would often tell her she was depressed and just needed to try depression medicine but she knew she was not sad she was sick. This was very frustrating obviously because it spanned over a decade of her trying to get a correct diagnosis."

-Megan Lazarone

"...after it was over we were all shocked and dumbfounded. I knew she had a liver disease. I knew it was serious and I knew she was going to the doctors for it but I thought 'Didn't she say it was treatable?' 'Wasn't she fine?' 'Was this real?' We were all so shocked that we had an autopsy done. The autopsy showed that it was an abdominal bleed in her liver and spleen. It also showed her kidneys were in failure and her heart was also failing and we did not previously know that. I'm not sure if she was aware and did not tell us but I don't believe so. So this is why I'm here today. I'm here because there isn't a day that goes by that I don't miss her so much. I can feel it in my bones..."

- Megan Lazarone

"I want this disease to be talked about. I want it to have its own commercials. I want people to know that it's not caused by drinking. I want people to know that yes lifestyle changes can help but there has got to be some other treatments [...] my goal in being here today is not only just to honor my mom but just ultimately that we can get to a point where this is not something that people are dying from."

-Megan Lazarone

"I was having issues maintaining weight and I was having a lot of issues just functioning, in general, the pain was very severe, I was constantly nauseous, so in 2011, we decided to try placing a feeding tube. The goal being that we would kind of let my digestive system rest and kind of let everything try to heal on its own. Unfortunately, this didn't really help much and we found that my pancreas still had been atrophying this entire time. So in 2013, I underwent what's called a total pancreatectomy with autoisla transplant. Basically what they do is they go in, they take my pancreas out, they take all of the insulin-producing cells that live in my pancreas and they put them into my liver.
So now my liver is doing double duty. It has to function as a liver but it also now is functioning as a pancreas. I was in the hospital for about a month recovering and during this recovery I had to be placed on TPN. TPN is when they put a special catheter right in the tip of your heart and they use it to infuse nutrition if you're not able to eat so I would get fats and lipids and vitamins and sugars and everything that I needed to sustain myself would be injected right into my heart and we would do that every day. Being on TPN puts patients at a higher risk for developing fatty liver and is one of the most common complications associated with going on TPN. This is mainly because we're infusing fats or lipids directly into the bloodstream and then they're sent down to be filtered out by the liver. However TPN is a life-saving therapy and a life-extending therapy so the benefits far outweigh the risks for most patients."

- John Mahalchack

"... the liver biopsy is really looking for a needle in a haystack and for me probably the most interesting result from the liver biopsy was that the biopsies did not show any signs of having islet cells in my liver, but we knew that they had to be there because if not, I would have required insulin around the clock. The biopsy did show that I had fibrosis but that I had just a mild level of fat so as my hepatologist said it was not super consistent with the clinical picture so we just decided to start some vitamin E and monitor my liver more closely for a couple of months. After that, I continued to have issues with my feeding tube and it wouldn't stay in the correct spot so I had to have another surgery done where they were able to basically go from one feeding tube to two so I have one that's in my stomach and one that's in my intestines. This was necessary to get me the nutrition I needed that I wasn't able to do beforehand again since we were already in there they did obtain another intraoperative biopsy and this time it showed that there was minimal fibrosis but there were significant levels of fat which again did not mesh with the clinical picture."

- John Mahalchak

"...my liver journey started actually in 1998 because I had given blood to the American Red Cross and received a postcard in the mail afterward and it basically all it said was 'Oh, by the way, your liver enzymes are elevated. You probably need to go ahead and go see your doctor.' So I did and he sent me on to to a GI specialist who specialized in the liver and after many many tests as he said 'Terri, you have fatty liver' he says 'it's not a big deal... everybody has it.' So this is 1998...until 2017 I didn't worry about my liver..."

-Terri Milton

"I was diagnosed with a lot of different things but really not with what was going on. In August of 2017, we finally decided that possibly my gallbladder was giving me a lot of problems and I decided to do elective gallbladder surgery and during that surgery, my surgeon found that my liver was cirrhotic and so I went ahead and did a biopsy in three places [… and my doctor] says to me, 'Terri, you have cirrhosis of the liver and you also have something called NASH and that's what caused the cirrhosis' "

-Terri Milton

PANEL 2

General Theme: Path to Diagnosis (non-invasive diagnostics), Ideal Clinical Trials for patients; barriers to clinical trial participation, logistical issues, and how that informs the potential ideal clinical trial design

The second panel focused on the path to diagnosis (non-invasive diagnostics), ideal clinical trials for patients; barriers to clinical trial participation, logistical issues, and how that informs the potential ideal clinical trial design. The key takeaways from this section of the meeting were centered around the panel expanding upon the overreliance on liver biopsy for diagnosing NASH. A few of the panelists underlined how they feel liver biopsy is a risky, invasive procedure that can be subject to sampling variability. Many of these same comments were also highlighted throughout the input from patients and caregivers within the NASH survey.

Another point that was discussed is the issues around current NASH clinical trial design including the dependence on liver biopsy. A few panelists discussed how liver biopsy is rarely performed outside of a specialist setting, creating an access barrier and in some cases an extended wait time, contributing to misreporting and underdiagnosing of NASH. Some panelists even went so far as to say that they have decided to not participate in a NASH clinical trial because it would have required a liver biopsy.

The conversation was moderated by Global Liver Institute CEO and Founder, **Donna Cryer**, and included three panelists.

The panel included:

- *Bruce Dimmig*, a patient that was diagnosed with metabolic syndrome many years ago, but was never told that it could lead to liver disease. He finally received a correct diagnosis and has now been impacted by fatty liver disease and NASH for more than 10 years.
- *Suzanne Maisner*, a gerontologist and patient impacted by NASH. After multiple years of common blood count tests showing skyrocketing liver enzyme levels, she was finally sent to a specialist that uncovered that she
- has advanced NASH.
- *Wayne Eskridge*, a patient that had his gallbladder removed in 2010. He was shown a picture of his liver, and suddenly told he has stage 4 liver cirrhosis. He explained that it was a powerful and frightening moment – one that is seared into his memory. Wayne has founded the Fatty Liver Foundation, a nonprofit dedicated to identifying asymptomatic, undiagnosed Americans with liver fibrosis or early cirrhosis caused by fatty liver disease, and to educate them on the lifestyle changes needed to halt or minimize disease progression.

The panelists' statements provided a vivid depiction of the burden of NASH and the issues with getting an appropriate diagnosis. They highlighted that there are acceptable and commonly used non-invasive diagnostics that could address many of the issues associated with liver biopsy. They also explored how the current FDA clinical trial design guidelines may lead to unintended consequences.
For example, the requirement of a clinical outcomes trial approach is the only pathway of approval for the treatment of compensated NASH cirrhosis.

Some of the key comments from the panel discussion are below:

"I was diagnosed with metabolic syndrome many years ago before starting my liver journey which started with the bruises... but was never told that this could lead to liver disease"

- Bruce Dimmig

"I don't qualify for a lot of clinical trials because of some [of] the parameters, but there needs to be something done to be more inclusive of the not normal symptoms that people have. I just think they're a little too restrictive at times...I'd love to be able to take part in one. Like I was saying earlier, to me the risk would be worth it."

- Bruce Dimmig

"You know you see the commercials on TV for the cancer treatment centers of America where it's a team approach kind of thing. I would really love to see that in the broader disease population because everybody has their own little silo and they only treat that little silo [...] If I have heart issues I have metabolic issues, I have sleep apnea, I have kidney issues, and I've had the nephrologist and the hepatologist pointing fingers at each other going, no it's because of the liver, no it's because of the kidneys instead of getting together and going okay let's figure this out and let's do it as a team."

- Bruce Dimmig

"...after two years of common blood count tests showing skyrocketing liver enzyme levels my doctor conceded to send me to a specialist not a hepatologist but a GI [doctor]. Several weeks after taking a blood test his office called to say that I have stage three liver disease and that there is nothing more to be done."

- Suzanne Maisner

"I enrolled in a double blind study. Other than seeing the initial Fibroscan, I received no other information on my liver disease. I was unaware of any changes reflected in subsequent Fibroscans and blood tests for the duration of the study. The lack of transparency [within studies] is a problem. Study participants should know how the experimental drug affected them. I would have liked to have known if it stopped the disease or reversed it."

- Suzanne Maisner

"I have looked for further clinical trials so that I can get a Fibroscan to determine where my NASH level now is. All the trials that I have identified locally require a liver biopsy as a precondition for enrolling. There is no way that I would take on the risk of a liver biopsy due to the danger of the procedure unless I was in a critical situation. Requiring a liver biopsy to participate in NASH trials is overkill. I believe it will limit subject participation unless they are ill-informed. Imaging tests including MRE, MRI and Fibroscans can be used for diagnostics in various phases of the trials."

- Suzanne Maisner

"I think that at the end of the trial that information should be sent back to the individuals [...] I know that during the course of [the trial] they can't let you know, but certainly they can let you know at the end of the study what the outcome was because they have the information there and it's only one person's outcome. [That transparency] would have made it a lot better. If I had that information I would have known more about how to handle my disease."

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Suzanne Maisner

"Patients and providers need to urgently know that [a NASH diagnosis] is the beginning of a progressive serious disease and they need to stop it. I can tell you, I would have made more changes, not that I wasn't exercising or eating [...] but I would have been a lot more vigorous about it"

- Suzanne Maisner

"I really didn't think much about FDA at all until I found out that I was a cirrhosis patient and started to think about clinical trials and all of the things that go along with that. As I think about what the FDA [...] we want you [the FDA] to be our champions we want you to be our protectors we understand the need for the service that you do, which is to really care about us and to keep us well, give us an opportunity to have effective medications and that's really the vital relationship that's meaningful to us [...] We want you to be thoughtful [...] if we look behind us and we look at 10,000 deaths and we say oh that is terrible…and that's a statistic if we think about the future and 10,000 people who are dying now…what you do can have a tremendous impact"

- Wayne Eskridge

"My point is we're right there [...] I agree that there's places where biopsy needs to be done and I don't say do away with biopsy entirely, but we need to augment that whole process with these other [noninvasive] tools and not just make biopsy the be all and end all."

- Wayne Eskridge

"As we think about biopsy I get offended by the reference to biopsy as the gold standard now it's more like a tin standard, you know we started doing biopsies in the 1920s. We've been doing needle biopsies for 100 years, and that was the best we had and we learned a lot, but it is very difficult as a gold standard because you get two pathologists and they won't necessarily see them the same way. You won't necessarily get the same reading of the same slide from the same pathologist so the big variation that we see in reading of biopsies is just such a hazard to this whole development process [...] it historically was the best but it's quickly being replaced."

- Wayne Eskridge

Liver disease is such a continuum of diseases and variations of diseases and there's no silver bullet [...] so as the drug developers are trying to sort this out they do need to be able to get a population in their study that has characteristics that meet the criteria of the target that they're particularly looking at [...] we are on the brink of being able to do [find the appropriate populations] much better through new imaging technologies that are developing and the wet methods that are developing"

- Wayne Eskridge

"I really would like the FDA to not be as distant as they are. It's taken us a year to put this little program together you know we don't have much opportunity to engage in a way that is a dialogue I mean we're here talking at you and we hope you're out there listening and we don't know really know whether you are and if you're going to engage the patient community you know engagement is more than us just giving a speech now and then and telling our story and you going off and maybe you talk about it or whatever it is you do but if you want to engage us in your processes then you need to engage us and not just speak to us in the form of congressional testimony kinds of settings so I'd like to see you know more intimate engagement with FDA"

- ***Wayne Eskridge*** on what he desires to see from the FDA

"I want to underscore the points that were raised about the limitations and risks of biopsies, the evolution of noninvasive diagnostics, and the role that they should play in both research and clinical practice. I want to also really underscore the clarity with which patients participating today discussed the risks that they were willing to take to be able to have a treatment for the disease and the fact that it is our risk to take."

- Donna Cryer

Overall this panel highlighted multiple times that it is critical for patients impacted by NASH to have diagnostic alternatives to increase the number of diagnoses allowing more patients with NASH to be identified and treated. Also they urged the regulators, and drug developers to consider the value of having a solution for every stage of fibrosis. Most importantly, the panel urged action and stressed for the FDA to be open to the possibility of accelerated approval.

SURVEY RESULTS AND FINDINGS

To supplement the input gathered at the meeting, Global Liver Institute also conducted a Patient and Caregiver Survey on Benefits and Risks of Potential Treatments for Nonalcoholic Steatohepatitis (NASH), which was open until December 1, 2021. According to responses to the survey, 75% of the participants were female, and 75% were also over the age of 50. Participants represented a range of experiences with NASH. 15% of the respondents were caregivers, and more than 75% of the respondents indicated they had experienced abdominal pain and fatigue. 50% of the participants reported that fatigue had the greatest impact on their day-to-day life. Respondents also reported a variety of concurrent conditions with obesity at 66.67% being the most common reported condition. Some of the other key findings from the survey highlighted the concerns around liver biopsy (only 28% of respondents said they were not concerned about receiving a liver biopsy), and that more than 60% of respondents are not currently on a NASH treatment plan.

GLI utilized a variety of outreach mechanisms to reach a very broad cross-section of the community in a wide array of situations, demographics, socioeconomic circumstances, capacities, and geographic locations. The survey was designed to collect anonymous information about the priorities and preferences for addressing NASH including issues centered around diagnosis, clinical trial access, and available treatment options.

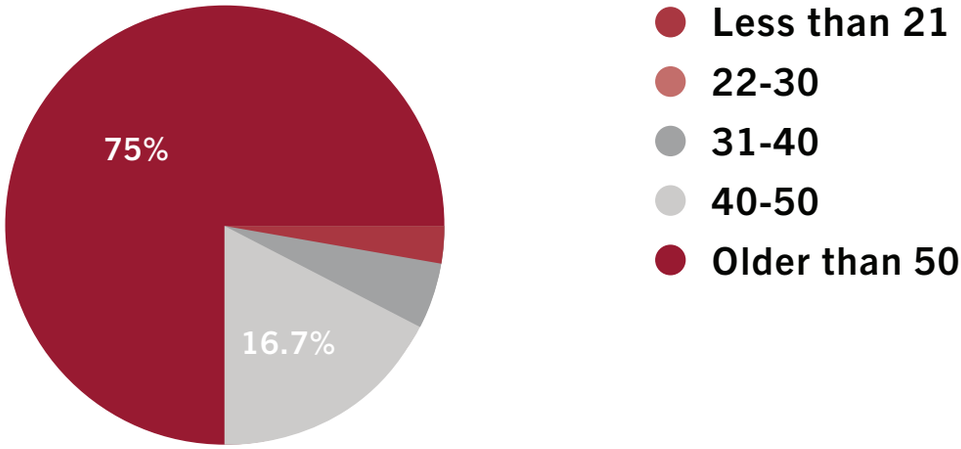
In summary, the survey examined patients' and caregivers' perspectives on their most significant symptoms, the impact of NASH on quality of life, and treatment options. Overall, the comments received in the docket reflected the experiences and perspectives shared during the virtual meeting. The following highlights of these comments, with a focus on experiences or perspectives that were not raised or addressed in detail at the meeting.

SURVEY HIGHLIGHTS

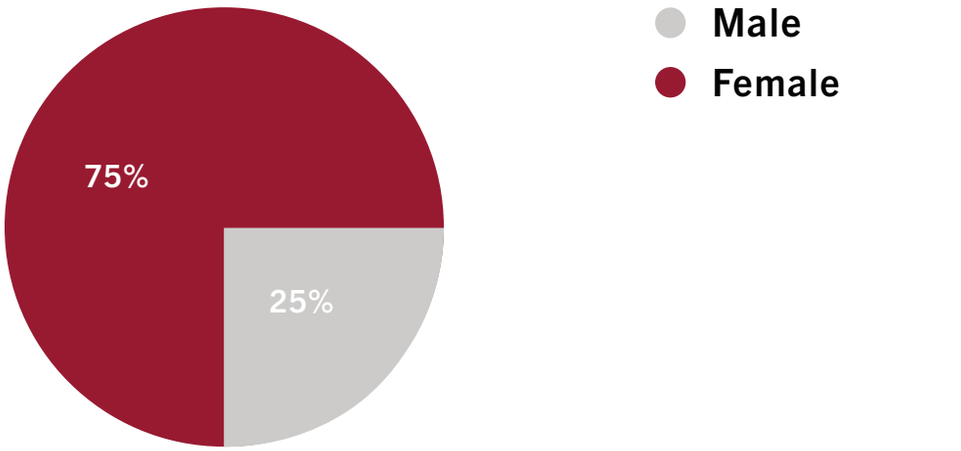
Demographic Questions

Your age. Reminder: Caregivers filling out this survey should provide this information about the person with NASH you care for.

36 RESPONSES

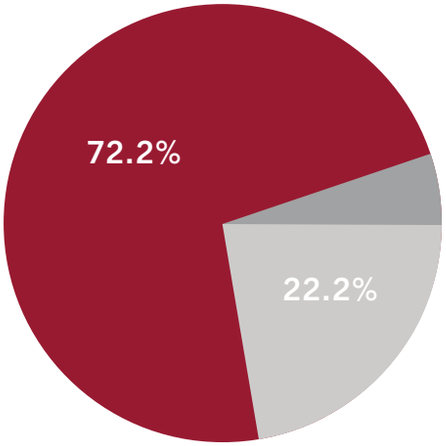


Your biological sex. Reminder: Caregivers filling out this survey should provide this information about the person with NASH you care for.

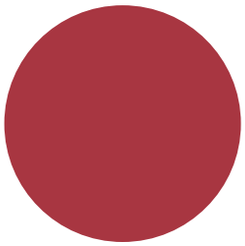


Your ethnicity. Reminder: Caregivers filling out this survey should provide this information about the person with NASH you care for.

36 RESPONSES



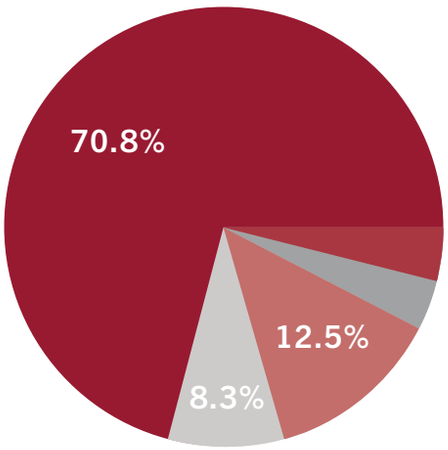
- Hispanic/Latino
- Non-Hispanic
- Do not wish to disclose



Patient and Caregiver Background Questions

When were you diagnosed with NASH?

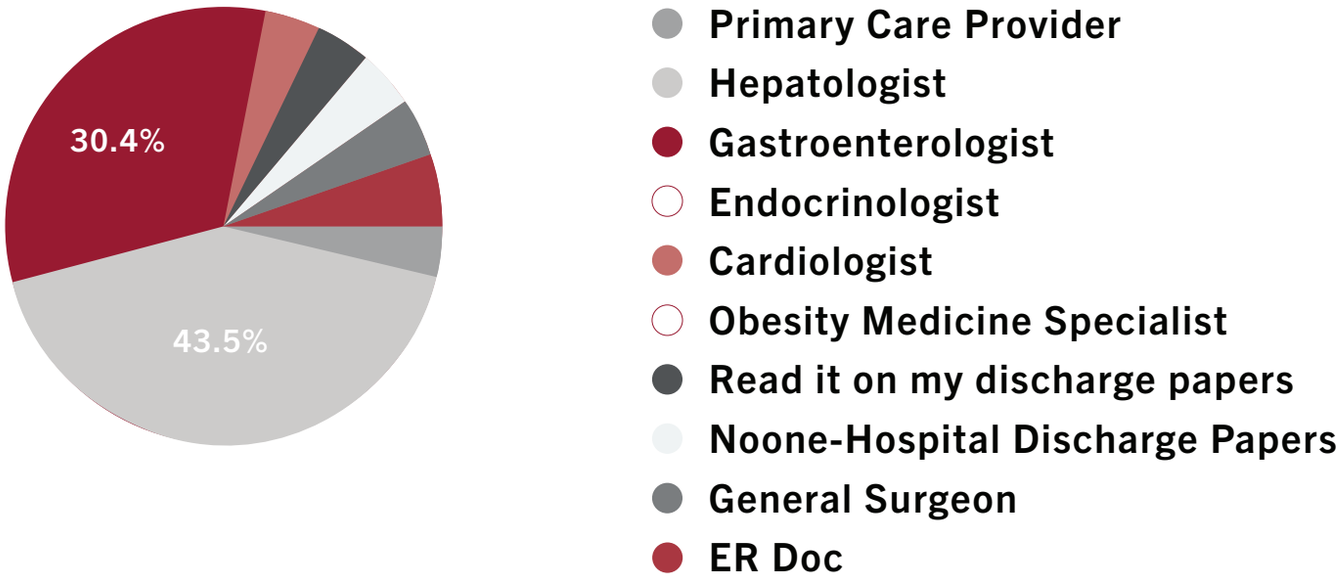
24 RESPONSES



- Within the last 10 days
- Between 10 days and one month ago
- Between one and six months ago
- Between six months and one year ago
- More than one year ago

What medical provider gave you the formal diagnosis for NASH?

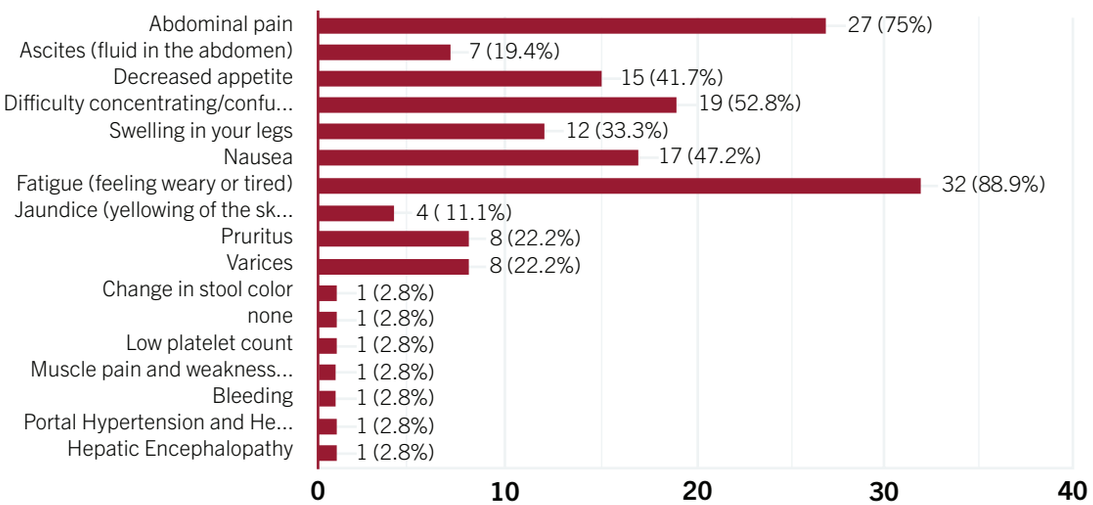
23 RESPONSES



Disease State and Symptoms Questions

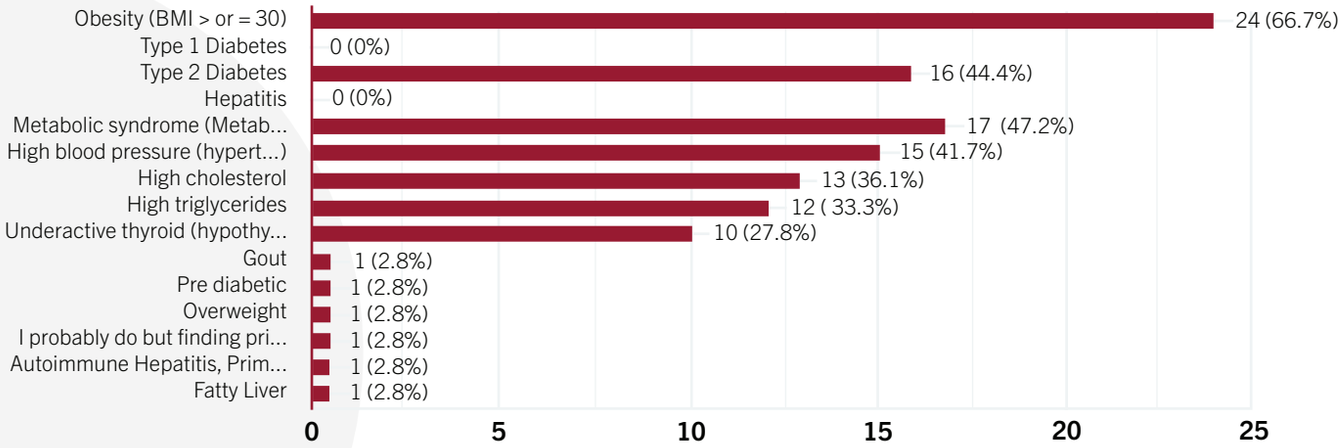
Do you currently have or have you previously had any of the following symptoms of NASH? Select all that apply.

36 RESPONSES



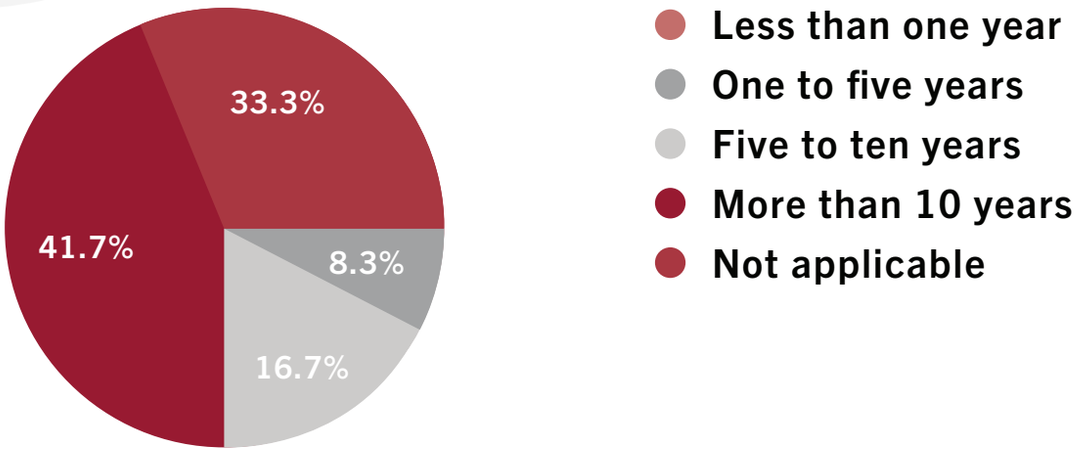
Have you previously had or do you currently have any of the following conditions? Select all that apply.

36 RESPONSES



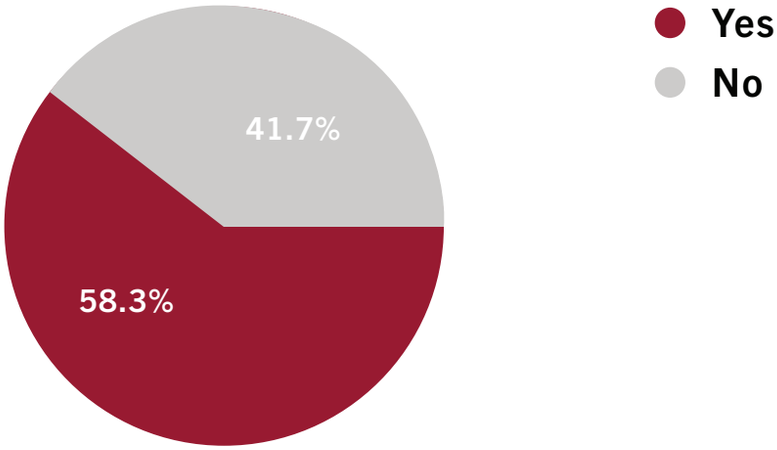
NASH can occur in people living with obesity. If you have been living with obesity, how long have you been living with obesity before you developed NASH?

36 RESPONSES



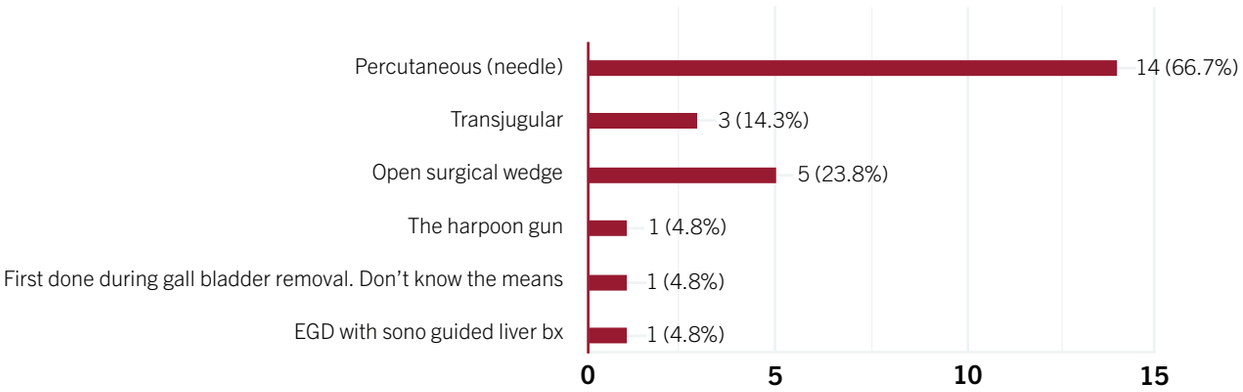
Have you ever had a liver biopsy?

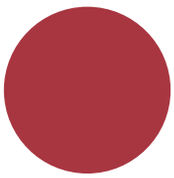
36 RESPONSES



What type of biopsy was your biopsy/biopsies? Check all that apply.

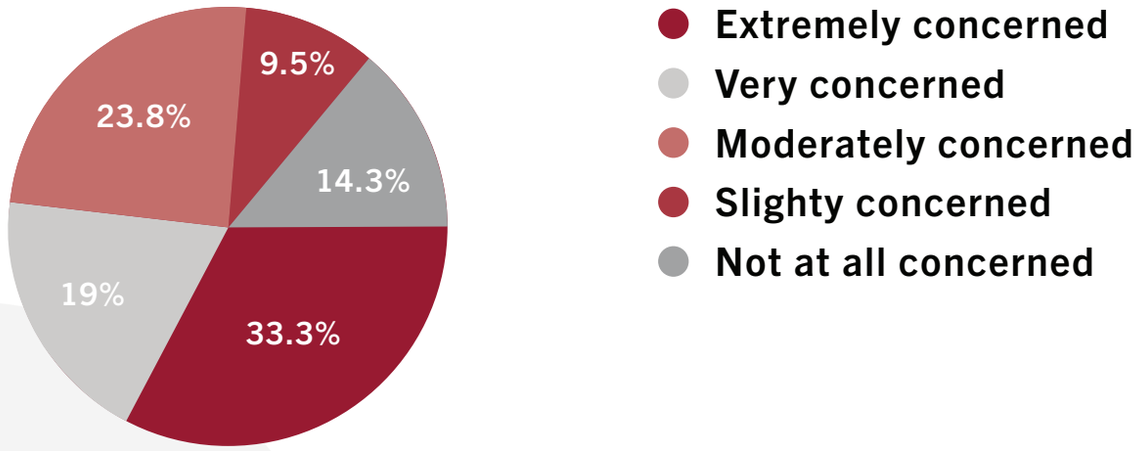
21 RESPONSES





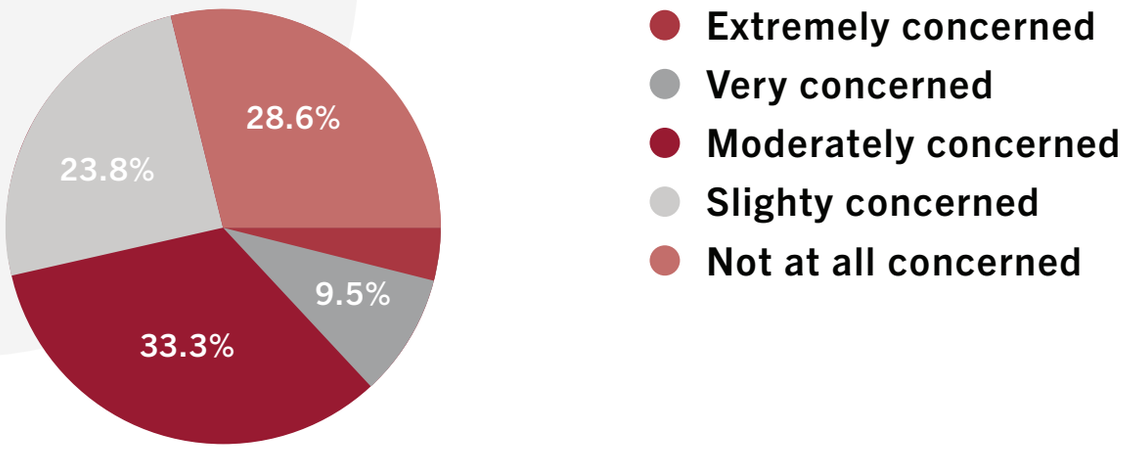
If you have had a liver biopsy, how concerned were you about getting a liver biopsy before the procedure?

21 RESPONSES



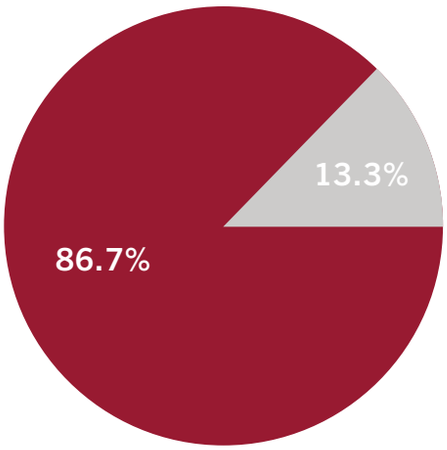
If you were concerned about your liver biopsy, compared to your level of concern before the biopsy procedure, to what extent are you concerned with a liver biopsy today?

21 RESPONSES



Was your diagnosis determined through a non-biopsy procedure?

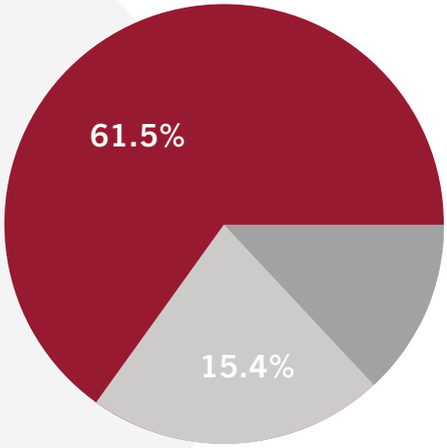
15 RESPONSES



- Yes
- No
- A combination of biopsy and non-biopsy procedure

What non-biopsy methods were used?

13 RESPONSES

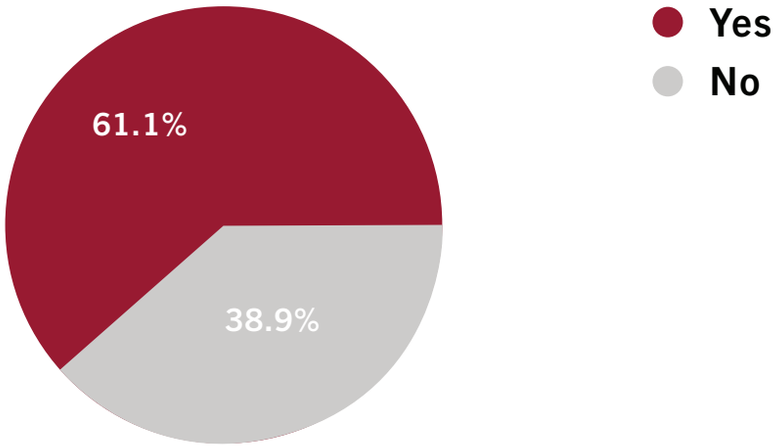


- Blood based tests (AST to Platelet Ratio Index (APRI), Fibrosis-4 Test (FIB-4),Enhanced Liver Fibrosis (ELF),and FibroTest)
- General imaging (CT, MRI, ultrasound)
- Magnetic resonance elastography (MRE)
- Transient elastography (FibroScan)

Treatment Options

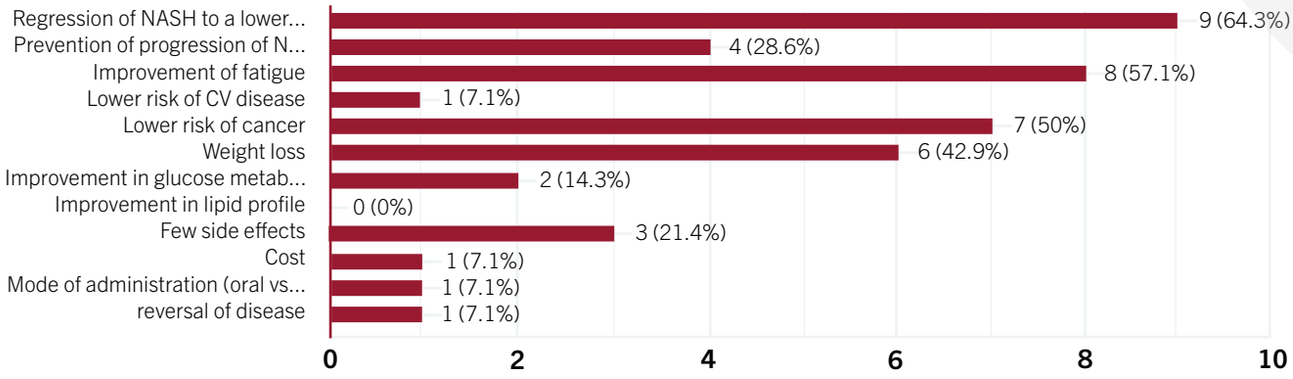
Are you currently on a NASH treatment plan?

36 RESPONSES



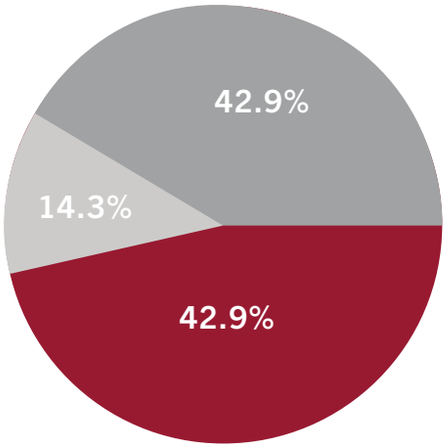
Other than a cure, what are the key benefits that would be most important to you in a new treatment for NASH? [please select the top 3 for you]

14 RESPONSES



Are there certain side effects that you would be willing to tolerate in order to address your NASH?

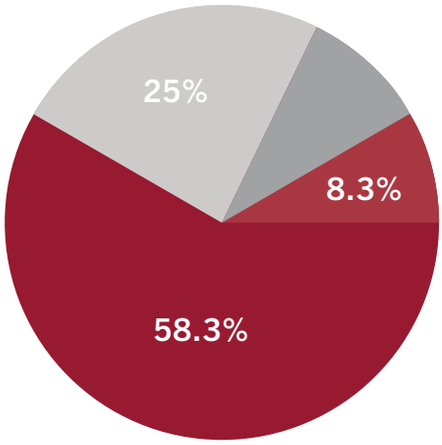
12 RESPONSES



- Yes
- No
- Maybe

What type of side effect?

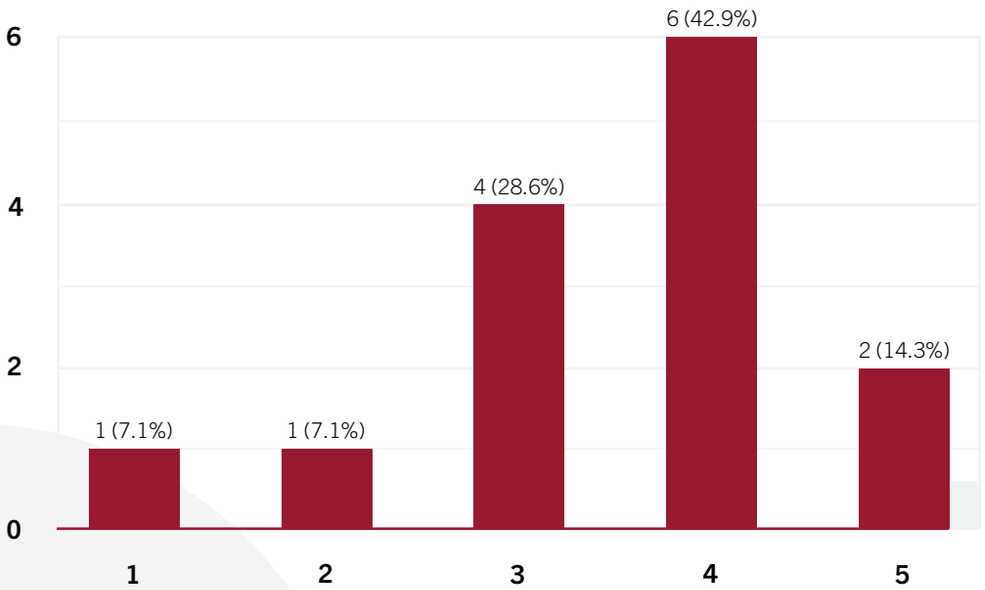
12 RESPONSES



- Itchiness
- Weight gain
- Elevation of cholesterol, low density lipoprotein (LDL) level or triglycerides
- None of these
- Depends on how effective the drug is and if the side effects resolve after end of treatment or if treatment is lifelong

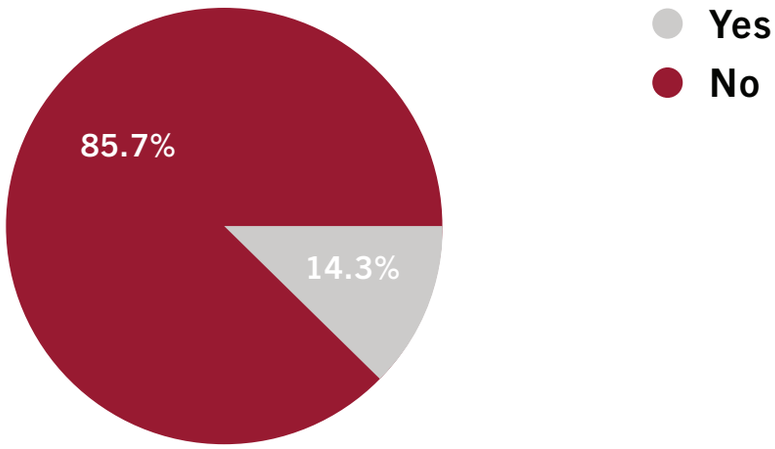
If you have had to make lifestyle (nutrition and exercise) adjustments, on a scale of 1 to 5, with 1 being easy and 5 being very challenging, how challenging are the lifestyle adjustments in your daily life?

14 RESPONSES



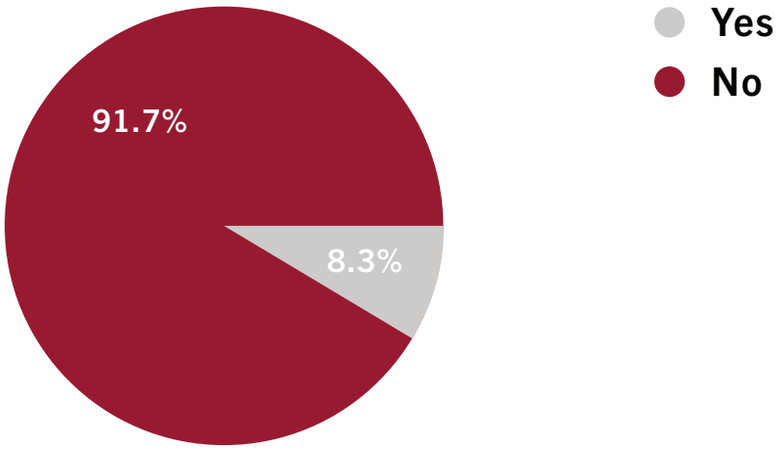
Have you been enrolled in a program that supports your lifestyle change?

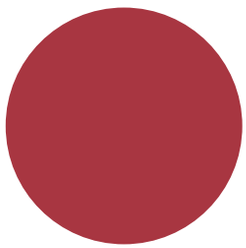
14 RESPONSES



Have you participated or are you currently participating in a clinical drug trial?

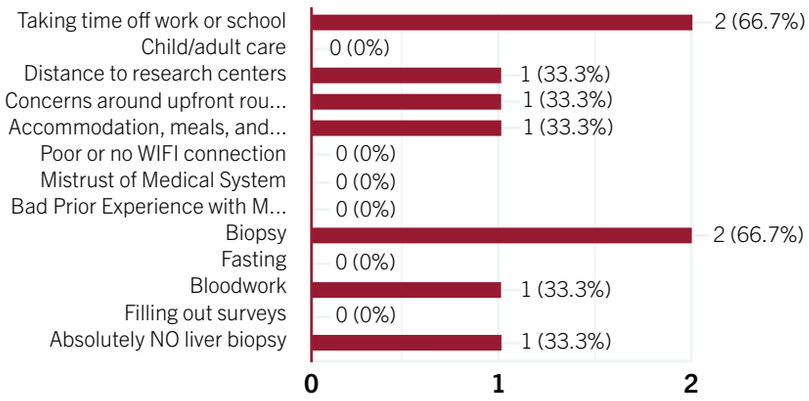
36 RESPONSES





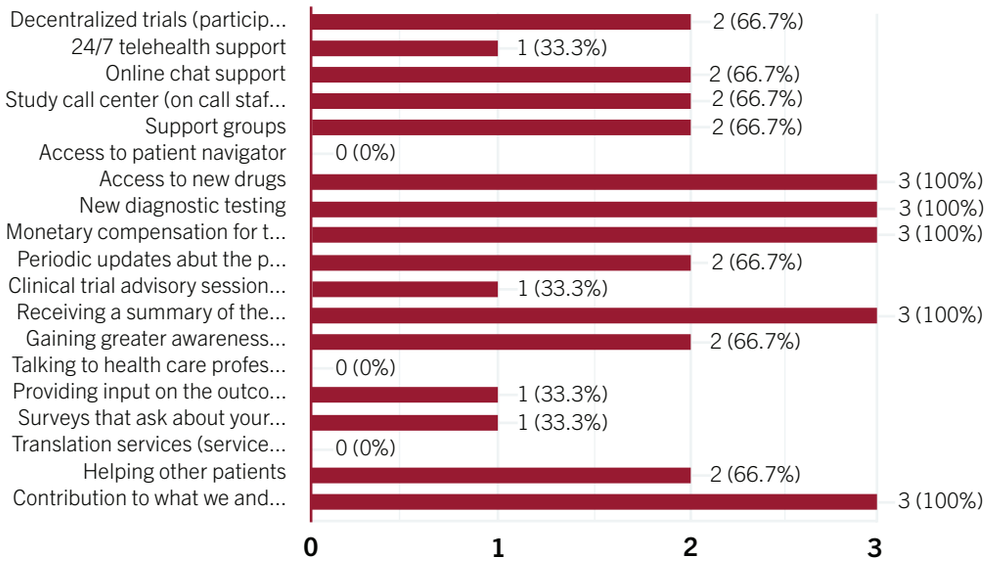
Are there any barriers that might prohibit you from participating in a NASH clinical trial? If yes, what are they? Check all that apply.

3 RESPONSES



What are some factors or support services that may make you more likely to participate in a NASH clinical trial? Check all that apply

3 RESPONSES



SUBMITTED COMMENTS *HIGHLIGHTS*

As a continuation of the survey findings and results, below please find some of the most relevant comments that were submitted in the survey. Comments submitted to the survey emphasized the psychological, physical, and economic impact of NASH. Survey commenters identified all the symptoms of NASH that were discussed during the virtual meeting as well as a robust list of additional symptoms. Survey comments also continued the virtual meeting conversation related to the impact of NASH patients' daily lives, and its significant toll on patients and their families. There was a high degree of frustration with the ineffectiveness of current NASH treatment management methods (lifestyle interventions), and the overreliance on liver biopsy. Survey commenters varied greatly on the ideal treatment effect, but listed a similar tolerance for many of the same side effects.

When thinking about how NASH impacts your day-to-day life or impacted your life when you had the condition, what is/was the biggest downside of the disease?

"The lack of energy constantly feeling exhausted"

"Fatigue"

"A total lifestyle change"

"Its unpredictability"

"Knowing it could lead to my death. Mother died of it."

"That it is largely preventable but there was no information, next steps, or awareness."

"Feeling sick and tired most of the time"

"Lose of control."

:Being told it was a death sentence, fatigue, all the symptoms, stigma of liver disease Uncertainty, feeling /looking very ill. No treatment, just trying to treat symptoms not the disease. Management depends on me/patient; wish there were networks of support for lifestyle changes in addition to drug development"

"Fear of dying:

"Loss of social interaction"

"Waiting"

"Having to rest and miss things."

"Feeling overwhelmed and no one believing you are sick"

"Fatigue"

"Daily attempts to watch fat intake"

"Strict changes, no cure, uncertainty."

"Being unclear on how best to try to treat it."

"Knowing I had the chance to lose weight when I was initially diagnosed with Fatty Liver and I chose to eat what I wanted to eat."

"stigma assumed alcoholic"

"It's hard to want to do things when you are so tired - simply cleaning the house is overwhelming"

"Diet restrictions & low energy."

"unknown, i wonder if it affects my energy levels"

"Need for a liver transplant."

"Not being able to drive because of my HE (hepatic encephalopathy)"

"GI Bleeding, almost died from blood loss"

"Everything you knew has to change. How you eat, cook, feel, enjoy life."

"That was 30 years ago. they only said try to lose weight"

"Recognizing the lifestyle changes that should be instituted"

"It's difficult to know if you are progressing"

"No cure."

"Radical changes to diet."

Describe your current NASH treatment plan (what have you and your doctor decided that you should do to manage your NASH.)

"I am following a Mediterranean diet and exercising when I can gather the energy. I also just began a clinical trial."

"No alcohol, which I haven't ever been a problem drinker and have not had alcohol for over 20 years, no processed foods and exercise."

“Weight loss, exercise, Mediterranean Diet”

“Diet modification, Urso, Vitamin E, Weight management, Stress Management”

“Lifestyle management, interval assessment via noninvasive tests,
weight management program, therapy/counseling”

“Mediterranean and exercise, just confirmed Type 2 Diabetes
and will be starting oral medication”

“Medications and low salt diet”

“Diet & exercise to lose 18 pounds, vitamin E daily regimen”

“Drastically reduce animal fats, refined and added sugar, starches, processed food, fast food, increase vegetable fats, fiber. Drink coffee I loved anyway, more water. Taking supplements of milk thistle, turmeric, flax, D3. Much better control of diabetes. Weight loss.”

“I see a Nutritionist and have a liver sonogram and an Endoscopy
every 6 months. I was also placed on Xifaxan and Linzess.”

“Diet low in sodium, exercise, lose weight”

“Change diet. Include fasting 12 hours nightly
& lose weight. Started on Ozempic to assist losing weight.”

“Lose 10% body weight, Mediterranean diet”

Describe your post-biopsy experience?

“no complications”

“I had it at the same time I had gastric stomach sleeve surgery. Was thankful
I was out for the biopsy. No issues afterwards.:

“I remember just resting. They did not have me hospitalized. I just laid flat for 6 hours.”

“My Gastro harpooned me once. He did not get a good sample. He asked if it was okay
if he did another one.”

“I told him, “You better do it now. Because you damn
well are not goingto have another chance.”

“The biopsy did not show anything bad.”

“After an ERCP, which I was only under twilight drugs, because they wanted me to be able to respond to commands/directions.”

“I was diagnosed with PSC, smoothly.”

“I was traumatized by the ERCP.”

“I became aware/conscious with the wedge in my mouth and hoses down my throat.”

“I became panicked.”

“It took a bit to get the hoses coughed up and out of me.”

“Being in the swimmers pose messed up my entire body alignment.”

“My blood pressure dropped, other than that, the expense and inconvenience of the length of time it took.”

“Post biopsy my blood pressure dropped too low.”

“It was part of my surgery”

“Relieved as the biopsy confirmed NASH 3, not cirrhosis as blood work stated.”

“It was really very simple. They did it in Interventional Radiology. The Radiologist had me place my arm over my head and numbed the area and then inserted the needle to take a portion of the liver under guided imagery.it was done in 15 minutes. He put on a pressure bandage.”

“Everything went well!”

“Done inpatient hospital endoscopy & was supposed to go home 4 hours later, but had severe abdominal pain & was kept overnight to observe cbc.”

“The worst was the second one where I had some bleeding and severe abdominal pain. Therefore they gave me pain medication which stopped my up and I was in the hospital for four (4) days until I could go to the bathroom again.”

“I had great pain post procedure causing order for a CT. No issues were found and I went home. A day or so of feeling like I’d been kicked in the gut by a mule and then just soreness for a week.”

“had to wait far to long for results GP gave me a print out and i took them home and went through them and diagnosed myself”

“Required rest to prevent complications”

If you were concerned about your liver biopsy, what specific concerns did you have about getting a liver biopsy before the procedure?

"The risk of bleeding"

"Bleeding."

"That it would be very painful. I had a kidney biopsy 5/1992. I had a roommate for my 24 hours laying still. She was carrying on moaning, crying, etc. She wanted to know what I was in for. She told me to never have a liver biopsy, it was much more painful than a kidney biopsy, in her experience."

"Bleeding, any other complications"

"Pain, complications, bad results"

"pain"

"Diagnosis"

"Results, not the procedure itself."

"Excess bleeding or finding out that I had liver cancer."

"Possible damage to other internal organs."

"Having bleeding problems after the procedure."

"Not being definitive enough for diagnosing my liver disease"

"I had tremendous pain after the first one during surgery so I didn't know how painful the second one would be."

"pain, bleeding, anesthesia"

"Potential complications"

BIOS

Moderator:

DONNA R. CRYER, JD
PRESIDENT AND CEO OF THE GLOBAL LIVER INSTITUTE

Donna R. Cryer, JD is Founder, President and Chief Executive Officer of the Global Liver Institute, the only patient-driven liver health nonprofit operating across the US, EU, and UK. GLI convenes the NASH, Liver Cancer and Pediatric and Rare Liver Disease Councils, as well as the Liver Action Network, collectively more than 200 organizations.

Mrs. Cryer has channeled her personal experience as a patient with inflammatory bowel disease and a 27-year liver transplant recipient into professional advocacy across a career in law, policy, consulting, public relations, clinical trial recruitment, and nonprofit management. She is the recipient of the 2021 Global Genes RARE Champions of Hope Founder's Award and the 2021 AASLD Distinguished Advocacy Service Award.

At GLI, Mrs. Cryer has raised more than $10 million for liver health initiatives. Among her many accomplishments with GLI, she developed a program featured by the White House on Solving Organ Shortage/Transplantation. She has launched numerous other successful programs at GLI, including the Cure Campaign, Advanced Advocacy Academy (A3), Liver Matters Blog, Liver Matters Health Policy Memo, the NASH Council, the Liver Cancers Council and the Pediatric and Rare Liver Diseases Council.

She is a frequent speaker on the topic of patient-centeredness and patient engagement in healthcare transformation and created a unique model for advocacy that mobilizes patients, influences policy, and coalesces clinicians to improve patient outcomes. In May 2021, she testified before the U.S. House Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, in a pivotal hearing on reforming the broken organ procurement system. Her testimony highlighted the racial disparities in organ transplantation. Thanks to consistent, fact-based advocacy from GLI, other allied groups, the media, and Congress, meaningful reforms to improve the system are finalized and forthcoming. Her advocacy for better representation of people of color in the organ procurement

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For almost a decade, Mrs. Cryer founded and led CryerHealth, a healthcare consulting firm providing strategic counsel to top biopharmaceutical companies, patient advocacy organizations and emerging technology firms on patient engagement in health information technology, drug discovery and clinical decision making.

Earlier in her career, Mrs. Cryer worked at the United Network for Organ Sharing in Richmond, Va., where she negotiated organ allocation regulations with the Department of Health and Human Services as part of the special executive staff/board member team. She also organized an immunosuppressive coalition of pharmaceutical companies, transplantation groups and key congressional offices, resulting in increased coverage of immunosuppressive medications under Medicare.

Mrs. Cryer serves on the Boards of Directors for the Council of Medical Specialty Societies, Sibley Memorial Hospital/Johns Hopkins Medicine, the Innovation and Value Initiative (IVI), and the Clinical Trials Transformation Initiative. She was the first patient to serve on the ABIM Gastroenterology Specialty Board, was one of the founding members of the AASLD Patient Advisory Committee and is the Community Representative on the AASLD NASH Task Force.

Previously, Mrs. Cryer served on the Executive Committee of the People-Centered Research Foundation. She was appointed by the U.S. Government Accountability Office to serve as the patient and consumer representative on the Health Information Technology Policy Committee, the federal advisory body to the National Coordinator for HIT. In addition, she served as a patient representative to the U.S. Food and Drug Administration, as a member of the Stakeholder Advisory Group to the NIH Learning Health System Research Collaboratory, as well as on the ABIM Gastroenterology Specialty Board and on an American Society of Clinical Oncology Guidelines Committee.

Mrs. Cryer was proud to serve as a member of the White House Task Force on e-health Equity in 2013. As part of the task force, she worked with a summit of experts on health disparities and health information technology to establish a framework to ensure that underserved populations benefit from advances in health technologies.

She has been named one of the Top Blacks in Healthcare by the Milken Institute at GW School vof Public Health and BlackDoctors.org, one of the Top 10 Patients Who Make An Impact by Health 2.0 and one of PharmaVoice's 100 Most Inspiring People. She is a frequent speaker on patient centricity in research and healthcare delivery at meetings of Biotechnology Innovation Organization (BIO), Pharmaceutical Research and Manufacturers of America (PhRMA), America's Health Insurance Plans (AHIP), National Quality Forum (NQF), American Association for Cancer Research (AACR), National Comprehensive Cancer Network® (NCCN®) and the National Academy of Medicine (NAM).

Mrs. Cryer received an undergraduate degree from Harvard and a Juris Doctorate from the Georgetown University Law Center.

Panelists:

TONY VILLIOTTI

Tony is a transplant recipient due to NASH, cirrhosis, and liver cancer. He lives in Pittsburgh, PA, and is the founder of NASH kNOWledge, https://www.nash-now.org/, a nonprofit dedicated to raising awareness and providing education about nonalcoholic liver disease.

MEGAN LAZARONE

Megan Lazarone is a resident of Baton Rouge, LA; but is originally from Alexandria, LA. She has been married to her husband Matt for 8 years and is a mother of an amazing 4-year-old daughter, Adair. Megan is a teacher of the visually impaired.

Megan's journey with Liver Disease began when her mother who was a registered nurse was diagnosed with NAFLD and then NASH, going to a number of different doctors in different cities for a span of 10 years experiencing symptoms that expressed to her something wasn't quite right with her health. Although Megan frantically research diseases of the livers and searched for solutions to help her mothers improve, Megan's mother informed her that her doctors said it was not that big of a deal. One day, however, it became apparent that it was indeed a big deal, resulting in the sudden death of Megan's mother. Megan now commits her time to advocate for early testing and treatments in honor of her mom and in hopes that liver disease is not something people have to die from.

JOHN MAHALCHAK

John has been dealing with chronic illness for over ten years, however, his journey with liver disease started in 2019. Briefly, he was diagnosed with acute chronic pancreatitis in 2010 and underwent a total pancreatectomy with auto-islet transplant in 2013. Post-transplant he was diagnosed with gastroparesis and was placed on enteral nutrition and IV hydration. During a follow-up operation in 2019, a liver biopsy showed that he had fatty liver disease and fibrosis.

He began pursuing patient advocacy after attending an FDA meeting in 2017. He has attended various medical conferences and events on Capitol Hill, with the goal of including the patient story in healthcare. He recently began serving on the Patient and Family Advisory Council at his local academic medical center and has been participating in a Zoom support group for those touched by liver disease.

He attended A3 for the first time last year, and aside from learning the latest updates in the field of liver disease, he looks forward to continuing to build a network of like-minded healthcare advocates!

TERRI MILTON

Terri is a 4th generation Texas native and enjoys exploring her state. She has been married to her husband Doug for almost 36 years. They have three adult children and seven grandkids. She enjoys gardening and reading. She and her husband also collect antiques and enjoy finding small shops in odd places.

In 2017, Terri was diagnosed with NASH Cirrhosis. In 2018, she was diagnosed with HCC and has had four localized regional treatments. She is currently on the transplant list waiting for a second chance of a life giving liver.

In 2018, she was invited to speak on a panel of NASH warriors at Liver Meeting in San Francisco. She is a graduate of Global Liver Institute's Advanced Advocacy Academy (A3) program. She has been a regular Patient Voice at several of Intercept Pharmaceutical events, along with a Patient Ambassador with Snow Company. She has also been featured in HEP magazine. and also has participated in a Satellite interview event with Intercept Pharmaceuticals. Currently, she manages a large Cirrhosis support Group on social media, is creator and administrator for CNU (Clean Nutrition University) also on social media, and several other smaller groups that deal with specific details of her journey with fatty liver disease and liver cancer. She remains an active liver health advocate with GLI, has recently become involved with the Texas Liver Foundation and will be part of an educational panel of speakers in October about the importance of nutrition and fatty liver disease.

BRUCE DIMMIG

Bruce has lived in the Phoenix metro area for over 25 years after having lived in the midwest and the east coast and was disabled from a long career as a commercial building architect by his liver disease, which has afflicted him for over ten years now and this is what has led him to now be a strong advocate for the care and support of people with all types of liver disease.

SUZANNE MAISNER

Suzanne Maisner retired to Tucson, Arizona six years ago. Most recently, she was a gerontologist and received her MA in Gerontology at USC. After studying economics at the University of California at Santa Cruz and The London School of Economics, she “fell” into the computer industry in Seattle. She was a co-founder of Share Communications, Inc. and principal of Zanne and Associates, a manufacturers representative firm marketing hardware and software.

WAYNE ESKRIDGE

On the morning of December 23, 2010, Wayne had his gallbladder removed, and was shown a picture of his liver and told he has stage 4 liver cirrhosis. It was a powerful and frightening moment – one that is seared into his memory. And one that began more than a half-decade of tests, misdiagnoses, and, eventually, lifestyle changes. Wayne lives in Idaho, and has founded the Fatty Liver Foundation, https://www.fattyliverfoundation.org/, a nonprofit dedicated to identifying asymptomatic, undiagnosed Americans with liver fibrosis or early cirrhosis caused by fatty liver disease, and to educate them on the lifestyle changes needed to halt or minimize disease progression.

CONCLUSION

This GLI led EL-PFDD meeting on NASH provided regulators and drug developers the invaluable opportunity to hear from patients and caregivers directly. They discussed the symptoms and health effects that matter most to patients, the impact that NASH has on daily life, the difficulties in getting an appropriate diagnosis, the issues with NASH clinical design preventing access for patients, and the factors patients consider when weighing the tradeoff between risks and benefits in selecting treatments.

NASH is a widespread serious chronic liver disease with physical, emotional, and social impacts. The ultimate aim of treatment for NASH is to reduce progression to cirrhosis or liver cancer and decrease fibrosis progression as well as NASH-related mortality. Patient perspectives play a critical role when considering how to best facilitate drug development.The liver advocacy community hopes that the FDA and drug developers recognize that patients have a unique ability to contribute to the understanding of their condition and treatment management.

The perspectives shared by participants at this meeting provided an in depth look at the challenges and burdens facing patients, and caregivers impacted by NASH. These discussions highlighted the harsh reality of the immense burden of NASH. As was discussed throughout the meeting, even with consistent clinical trials, progress for developing new therapies to treat NASH has been slow. This is why it is critical for regulators and drug developers to consider the real world burden of this life threatening condition. Panelists, and EL-PFDD survey participants urged regulators, and drug developers to consider the importance of patient-centric endpoints including the impact that stopping disease progression can have on a patient's life. They also expanded upon the access barriers, sampling variability, and burden associated with the requirement of liver biopsy within clinical trials. Most importantly, the NASH EL-PFDD meeting highlighted the urgency around developing NASH therapies

As Donna Cryer said during the conclusion of the meeting, "Just this time alone since we started planning this NASH EL-PFDD meeting to the conclusion of this event, there have been patients that have died, there are patients that have progressed from early stages of NASH to more advanced stages, there are patients that have progressed to liver cancer or to needing a liver transplant. The urgency that we all feel as patients and caregivers can not be overstated. If we can make regulatory time a little closer to patient time, that will serve everyone."

APPENDIX

Meeting Agenda

EXTERNALLY-LED PATIENT-FOCUSED DRUG DEVELOPMENT MEETING NONALCOHOLIC STEATOHEPATITIS (NASH)

Virtual

November 4, 2021

10:00 a.m. - 3:00 p.m. EST

Zoom

10:00 a.m. - 10:10 a.m.

Welcome, Opening Remarks & Introductions

DONNA R. CRYER, JD | *CEO and Founder of Global Liver Institute*

10:10 a.m. – 10:15 a.m.

EL-PFDD Overview and FDA Role

DIRECTOR JOE TOERNER | *Division of Hepatology and Nutrition*

COLLABORATORS: GLI'S LIVER ACTION NETWORK

General Theme: Awareness, Education, Impact on Function, Managing Care and Life, Progression and risks associated with

- *Tony Villiotti*
- *Megan Lazarone*
- *John Mahalchak*
- *Terri Milton*

12:00 p.m. – 12:15 p.m.

Q&A FOR PANEL 1

12:45 p.m. – 2:30 p.m.

PATIENT PANEL 2: TESTIMONIES

- *Bruce Dimmig*
- *Suzanne Maisner*
- *Wayne Eskridge*

General Theme: Path to Diagnosis (non-invasive diagnostics), Ideal Clinical Trials for patients; barriers to clinical trial participation, logistical issues and how that informs the potential ideal clinical trial design

2:30 p.m. – 2:45 p.m.

Q&A FOR PANEL 2

2:45 p.m - 3:00 p.m

CONCLUDING REMARKS

PANEL QUESTIONS

Theme: Managing NASH and Daily Life

Did you know you were at risk of NASH?

What symptom has the greatest impact on your day-to-day life?

When thinking about how NASH impacts your day-to-day life or impacted your life when you had the condition, what is/was the biggest downside of the disease?

Theme: Your Path to Diagnosis

Did you receive a formal diagnosis for NASH from a doctor? (Type of doctor?)

What were you told about the disease?

How was your diagnosis determined?

Have you ever had a biopsy? What are your concerns associated with liver biopsies?

Describe your experience getting a liver biopsy

Was your diagnosis determined through a non-biopsy procedure? If you have had biopsies as well, was the process with non-invasive diagnostics different for you?

Theme: Managing Care

What have you and your doctor decided that you should do to manage your NASH?
How has this plan affected your daily life? What are the challenges?

Are there certain side effects that you would be willing to tolerate in order to address your NASH?

Other than a cure, what are the key benefits that would be most important to you in a new treatment for NASH?

Theme: Your opinion on Clinical Trials (barriers, logistical issues)

Have you participated or are you currently participating in a clinical drug trial? What was your experience like?

Are there any barriers that might prohibit you from participating in a NASH clinical trial? If yes, what are they?

What are some factors or support services that may make you more likely to participate in a NASH clinical trial?

FULL SURVEY: PATIENT AND CAREGIVER SURVEY ON BENEFITS AND RISKS OF POTENTIAL TREATMENTS FOR NONALCOHOLIC STEATOHEPATITIS (NASH)

**indicates a required question*
BLUE text indicates logic/branching

Introduction and Consent

By most recent estimates, up to **444 million** people worldwide, including 40 million in the United States, are living with the progressive, chronic liver condition referred to as nonalcoholic steatohepatitis (NASH), the advanced form of fatty liver disease (NAFLD). Current estimates show that more than 1 in 4 adults have NAFLD (25–30%), and 2–6% have NASH yet these conditions are under-recognized, underdiagnosed, and undertreated.

On top of this is that an estimated 10% of children in the United States also currently have NASH.[14] [15] There are several reasons people may develop NASH including genetic predisposition and the presence of metabolic disorders, obesity, diabetes, chronic kidney disease, and cardiovascular disease (CVD).[16] [17] NASH is projected to rise in parallel to these diseases[18] and expected to increase in prevalence by over 50% by 2030 To learn more about NASH, please click here.

This survey is designed to collect information about your priorities and preferences for addressing nonalcoholic steatohepatitis (NASH). Data from this survey will be used by Global Liver Institute, a 501(c)3 patient advocacy and support organization, for research in our mission to help develop potential treatments for NASH. This information will also be shared with the U.S. Food and Drug Administration, and a variety of other stakeholders within the medical community to help them understand your thoughts and feelings about potential treatments for NASH.

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14 Pediatrics. 2006;118(4): 1388–1393 Schwimmer JB, Deutsch R, Kahen T, Lavine JE, Stanley C, Behling C. Prevalence of fatty liver in children and Adolescents.

15 J Pediatr. 2018;200:174–180 Fernandes DM, Pantangi V, Azam M, et al. Pediatric nonalcoholic fatty liver disease in New York City: an autopsy study.

16 Araujo AR, Rosso N, Bedogni G, et al. Global epidemiology of non-alcoholic fatty liver disease/nonalcoholic steatohepatitis: What we need in the future. Liver Int. 2018; 38 Suppl 1:47–51.

17 (EASO) EAftSotLEEAftSoDEEAftSoO. EASL-EASD-EASO Clinical Practice Guidelines for the management of non-alcoholic fatty liver disease. J Hepatol. 2016; 64:1388–1402.

18 Younossi ZM, Koenig AB, Abdelatif D, et al. Global epidemiology of nonalcoholic fatty liver disease meta-analytic assessment of prevalence, incidence, and outcomes. Hepatology. 2016; 64:73–84.

This survey is intended for people who currently have or previously had NASH or their caregiver if the person with NASH is unable to complete the survey on their own.

Your participation in this survey is optional and should take about 20 minutes. If you start the survey, you can stop at any time and come back later to finish it. We assure you that your responses will be kept confidential. Any data collected in this survey will only be shared in an anonymized fashion and the survey organizers will not contact you about your responses.

If you have questions or concerns about the survey, please contact [Name and email].

*BY SELECTING "**I CONSENT**" BELOW, YOU VOLUNTARILY AGREE TO PARTICIPATE IN THIS STUDY. YOUR RESPONSES (WITHOUT ANY IDENTIFYING INFORMATION ABOUT YOU) WILL BE SHARED WITHIN THE NASH EXTERNALLY-LED PATIENT-FOCUSED DRUG DEVELOPMENT MEETING. [RESPONDENTS WHO SELECT "I DO NOT CONSENT" WILL BE TAKEN TO THE DISQUALIFICATION PAGE]

I consent
I do not consent

Background Information

WHICH IS **TRUE** ABOUT YOU?

I currently have nonalcoholic steatohepatitis
I previously had nonalcoholic steatohepatitis
I care for a person who currently has or previously had nonalcoholic steatohepatitis
Other (please specify)

Patient Branch – For people who selected (a) or (b) on Q2

*DID YOU RECEIVE A FORMAL DIAGNOSIS FOR NASH FROM A DOCTOR?

Yes
No

[FOR PEOPLE WHO SELECTED (A) ON PREVIOUS QUESTION] *WHEN WERE YOU DIAGNOSED WITH NASH?

Within the last 10 days
Between 10 days and one month ago
Between one and six months ago
Between six months and one year ago
More than one year ago
What were you told about the disease?
Free Response
How often did your medical provider conduct follow ups with you?
Free Response

WHAT WERE YOU TOLD ABOUT THE DISEASE?

Free Response

HOW OFTEN DID YOUR MEDICAL PROVIDER CONDUCT FOLLOW UPS WITH YOU?

Free Response

Caregiver Branch – For people who selected (c) on Q2

DID THE PERSON YOU CARE FOR RECEIVE A FORMAL DIAGNOSIS OF NASH FROM A DOCTOR?

Yes

No

[FOR PEOPLE WHO SELECTED (A) ON PREVIOUS QUESTION] *WHEN WERE THEY DIAGNOSED WITH NASH?

Within the last 10 days

Between 10 days and one month ago

Between one and six months ago

Between six months and one year ago

More than one year ago

*HAS THE PERSON YOU CARE FOR WITH NASH PASSED AWAY?

Yes

No

[FOR PEOPLE WHO SELECTED (A) ON PREVIOUS QUESTION] *HOW LONG DID THE PERSON YOU CARED FOR LIVE AFTER THEIR NASH DIAGNOSIS?

Less than two weeks

Between two weeks and one month

Between one and three months

More than three months

[FOR PEOPLE WHO SELECTED (A) ON Q9] *IN WHAT SETTING DID THE PERSON YOU CARED FOR PASS AWAY?

Home

Hospice

Hospital

Other (Please Specify: _____)

Disease State and Symptoms

[Introductory text]

The rest of the survey includes questions about symptoms of and treatments for NASH and asks questions about your or your patient's preferences for potential future treatments. Caregivers taking this survey should answer these questions on behalf of the person who has NASH. Unless the question specifically says it is for caregivers, questions that say "you" are referring to the person with NASH. Caregivers should do their best to answer based on the preferences of the person with NASH, not their own.

DO YOU CURRENTLY HAVE OR HAVE YOU PREVIOUSLY HAD ANY OF THE FOLLOWING SYMPTOMS OF NASH? SELECT ALL THAT APPLY.

Abdominal pain
Ascites (fluid in the abdomen)
Decreased appetite
Difficulty concentrating/confusion
Swelling in your legs
Nausea
Fatigue (feeling weary or tired)
Jaundice (yellowing of the skin and whites of the eyes)
Pruritus
Varices
Other (please note _____)

WHAT ONE SYMPTOM HAS THE GREATEST IMPACT ON YOUR DAY-TO-DAY LIFE?
[choices shown based on responses to the previous question]

WHEN THINKING ABOUT HOW NASH IMPACTS YOUR DAY-TO-DAY LIFE OR IMPACTED YOUR LIFE WHEN YOU HAD THE CONDITION, WHAT IS/WAS THE BIGGEST DOWNSIDE OF THE DISEASE?
Free response

HAVE YOU PREVIOUSLY HAD OR DO YOU CURRENTLY HAVE ANY OF THE FOLLOWING CONDITIONS? SELECT ALL THAT APPLY.
OBESITY (BMI > OR = 30)

Type 1 Diabetes
Type 2 Diabetes
Hepatitis
Metabolic syndrome (Metabolic syndrome includes high blood pressure, high blood sugar, excess body fat around the waist, and abnormal cholesterol levels.)
High blood pressure (hypertension)
High cholesterol
High triglycerides
Underactive thyroid (hypothyroidism)
Other liver disease (please note: _____)
Other

[FOR PEOPLE WHO SELECTED (C) ON THE PREVIOUS QUESTION] NASH CAN OCCUR IN PEOPLE WHO HAVE TYPE 2 DIABETES. HOW LONG DID YOU HAVE DIABETES BEFORE YOU DEVELOPED NASH?

Less than one year
One to five years
Five to ten years
More than 10 years
Not applicable

[FOR PEOPLE WHO SELECTED (A) ON QUESTION 15] NASH CAN OCCUR IN PEOPLE LIVING WITH OBESITY. HOW LONG HAVE YOU BEEN LIVING WITH OBESITY BEFORE YOU DEVELOPED NASH?

Less than one year
One to five years
Five to ten years
More than ten years
Not applicable

Diagnosis and Treatments

HAVE YOU EVER HAD A LIVER BIOPSY?

Yes
No

Biopsy Branch – For respondents who select (a) on question 18

[FOR RESPONDENTS WHO SELECT (A) ON QUESTION 18] WHAT TYPE OF BIOPSY WAS YOUR BIOPSY?

Percutaneous (needle)
Transjugular
Open surgical wedge
Other

[FOR RESPONDENTS WHO SELECT (A) ON QUESTION 18] IF YOU HAVE HAD A LIVER BIOPSY, HOW CONCERNED WERE YOU ABOUT GETTING A LIVER BIOPSY BEFORE THE PROCEDURE?

Extremely concerned
Very concerned
Moderately concerned
Slightly concerned
Not at all concerned

IF YOU WERE CONCERNED ABOUT YOUR LIVER BIOPSY, WHAT SPECIFIC CONCERNS DID YOU HAVE ABOUT GETTING A LIVER BIOPSY BEFORE THE PROCEDURE?

Free Response

IF YOU WERE CONCERNED ABOUT YOUR LIVER BIOPSY, COMPARED TO YOUR LEVEL OF CONCERN BEFORE THE BIOPSY PROCEDURE, TO WHAT EXTENT ARE YOU CONCERNED WITH A LIVER BIOPSY TODAY?

Extremely concerned

Very concerned

Moderately concerned

Slightly concerned

Not at all concerned

[FOR RESPONDENTS WHO SELECT (A) ON QUESTION 18] DESCRIBE YOUR POST-BIOPSY EXPERIENCE?

Free response

Non-Biopsy Branch – For respondents who select (b) on question 18

[FOR RESPONDENTS WHO SELECT (B) ON QUESTION 18] WAS YOUR DIAGNOSIS DETERMINED THROUGH A NON-BIOPSY PROCEDURE?

Yes

No

A combination of biopsy and non-biopsy procedure

[FOR RESPONDENTS WHO SELECT (A) OR (C) ON QUESTION 24] WHAT NON-BIOPSY METHODS WERE USED?

Blood based tests (AST to Platelet Ratio Index (APRI), Fibrosis-4 Test (FIB-4), Enhanced Liver Fibrosis (ELF), and FibroTest)

General imaging (CT, MRI, ultrasound)

Magnetic resonance elastography (MRE)

Transient elastography (FibroScan)

Other_____

ARE YOU CURRENTLY ON A NASH TREATMENT PLAN?

Yes

No

Treatment Plan Questions Branch - For respondents who select (a) on question 26

DESCRIBE YOUR CURRENT NASH TREATMENT PLAN (WHAT HAVE YOU AND YOUR DOCTOR DECIDED THAT YOU SHOULD DO TO MANAGE YOUR NASH.)

Free response

Are there certain side effects that you would be willing to tolerate in order to address your NASH?

Yes

No

[FOR RESPONDENTS WHO SELECT (A) ON Q28] WHAT TYPE OF SIDE EFFECT?

Itchiness

Weight Gain

Elevation of cholesterol, low-density lipoprotein (LDL) level or triglycerides

Other (please specify _____)

IF A NEW DRUG HAS X SIDE EFFECT, BUT COULD IMPROVE Y OUTCOME, HOW LIKELY WOULD YOU BE ABLE TO TAKE THIS DRUG? [PROVIDE A SCALE]

OTHER THAN A CURE, WHAT ARE THE KEY BENEFITS THAT WOULD BE MOST IMPORTANT TO YOU IN A NEW TREATMENT FOR NASH? [PLEASE RATE FROM MOST IMPORTANT TO LEAST IMPORTANT]

Regression of NASH to a lower stage

Prevention of progression of NASH

Improvement of fatigue

Lower risk of CV disease

Lower risk of cancer

Weight loss

Improvement in glucose metabolism

Improvement in lipid profile

Few side effects

Cost

Mode of administration (oral vs. subcutaneous Injection)

Lifestyle Branch - For respondents who select (a) on question 26

ARE YOU CURRENTLY WORKING WITH A DIETITIAN/NUTRITIONIST?

Yes

No

ARE YOU CURRENTLY ON AN EXERCISE PLAN?

Yes

No

[FOR RESPONDENTS WHO SELECT (A) ON Q33] HOW OFTEN DO YOU EXERCISE EACH WEEK?

Less than two times per week

Two or more times per week

Every day

[FOR RESPONDENTS WHO SELECT (A) ON Q33] WHAT TYPE OF EXERCISE?

Cardio (ex: walking, biking, dancing to elevate your heart rate or perceived exertion)

Resistance (ex: weightlifting, yoga, bodyweight exercises)

[FOR RESPONDENTS WHO SELECT (A) ON Q33] HOW LONG DO YOU GENERALLY EXERCISE DURING A GIVEN SESSION?

0 - 15 minutes

15 - 30 minutes

30 minutes - 1 hour

More than 1 hour

IF YOU HAVE HAD TO MAKE LIFESTYLE (NUTRITION AND EXERCISE) ADJUSTMENTS, ON A SCALE OF 1 TO 5, WITH 1 BEING EASY AND 5 BEING VERY CHALLENGING, HOW CHALLENGING ARE THE LIFESTYLE ADJUSTMENTS IN YOUR DAILY LIFE?

1-5 choices or slider bar

(QUESTION FOR CAREGIVERS ONLY) IF YOU HAVE HAD TO URGE YOUR PATIENT TO MAKE LIFESTYLE (NUTRITION AND EXERCISE) ADJUSTMENTS, ON A SCALE OF 1 TO 5, WITH 1 BEING EASY AND 5 BEING VERY CHALLENGING, HOW CHALLENGING ARE THE CHANGES IN YOUR DAILY LIFE BECAUSE THE PERSON YOU CARE(D) FOR WAS REQUIRED TO MAKE LIFESTYLE (NUTRITION AND EXERCISE) ADJUSTMENTS?

1-5 choices or slider bar

WHAT ARE THE CHALLENGES OF YOUR SUGGESTED LIFESTYLE CHANGES?

Free response

HAVE YOU BEEN ENROLLED IN A PROGRAM THAT SUPPORTS YOUR LIFESTYLE CHANGE?
Yes
No

[FOR RESPONDENTS WHO SELECT (A) ON Q40] WHAT TYPE OF LIFESTYLE CHANGE SUPPORT PROGRAM WERE YOU ENROLLED IN?

Intensive behavioral therapy (IBT)
Cognitive behavioral therapy (CBT)
Wellness Coaching
Other (please specify _____)

[FOR RESPONDENTS WHO SELECT (A) ON Q40] HOW OFTEN HAVE YOU UTILIZED THESE LIFESTYLE CHANGE SUPPORT PROGRAMS?

1 time
1 - 5 times

5 - 10 times

More than 10 times

[FOR RESPONDENTS WHO SELECT (A) ON Q41] ON A SCALE OF 1 TO 5, WITH 1 BEING VERY LITTLE SUCCESS, HAVE YOU BEEN ABLE TO SUCCESSFULLY ACHIEVE WEIGHT LOSS GOALS THROUGH IBT?

1-5 choices or slider bar

HAVE YOU BEEN EVALUATED FOR A LIVER TRANSPLANT?

Yes

No [skip liver transplant questions]

[FOR PEOPLE WHO SELECTED (A) IN THE PREVIOUS QUESTION] WHAT IS THE HIGHEST MELD SCORE YOU HAVE EVER HAD? MELD, WHICH STANDS FOR MODEL FOR END-STAGE LIVER DISEASE, IS A SCORE BETWEEN 6 AND 40 THAT IS USED TO DESCRIBE THE LEVEL OF LIVER DISEASE.

I do not know

Highest MELD score: ___

HAVE YOU HAD A LIVER TRANSPLANT?

Yes

No [skip to liver transplant waiting list questions]

Liver Transplant Branch – For respondents who select (a) on Q44

WERE YOU TOLD THAT YOUR TRANSPLANT WAS A RESULT OF END-STAGE NASH (F4, NASH WITH CIRRHOSIS)?

Yes

No

LIVER TRANSPLANT WAITING LIST BRANCH – FOR RESPONDENTS WHO SELECT (B) ON QUESTION 46

How long after your NASH diagnosis did you go on the liver transplant waiting list?

1-3 months

3-6 months

6-12 months

over a year

ARE YOU CURRENTLY ON A WAITING LIST FOR A LIVER TRANSPLANT?

Yes

No

HOW LONG HAVE YOU BEEN ON A WAITING LIST FOR A LIVER TRANSPLANT?

1-3 months

3-6 months

6-12 months

over 1 year

Clinical Trial

HAVE YOU PARTICIPATED OR ARE YOU CURRENTLY PARTICIPATING IN A CLINICAL DRUG TRIAL?

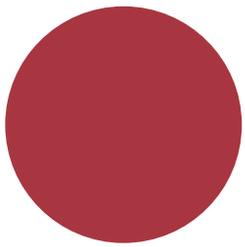
Yes

No

Clinical Trial Access Branch – For respondents who select (a) on Q51.

ARE THERE ANY BARRIERS THAT MIGHT PROHIBIT YOU FROM PARTICIPATING IN A NASH CLINICAL TRIAL? IF YES, WHAT ARE THEY? CHECK ALL THAT APPLY.

Taking time off work or school
Child/adult care
Distance to research centers
Concerns around upfront routine care costs
Accommodation, meals, and transportation costs
Poor or no WiFi connection
Mistrust of Medical System
Bad Prior Experience with Medical System
Biopsy
Fasting
Bloodwork
Filling out surveys
Other [free response]



WHAT ARE SOME FACTORS OR SUPPORT SERVICES THAT MAY MAKE YOU MORE LIKELY TO PARTICIPATE IN A NASH CLINICAL TRIAL? CHECK ALL THAT APPLY.

Decentralized trials (participation available remotely, parts done at home, by mail, phone video, or otherwise - not requiring you to come to research site or clinic)
24/7 telehealth support
Online chat support
Study call center (on call staff available to help)
Support groups
Access to patient navigator
Access to new drugs
New diagnostic testing
Monetary compensation for time, travel costs, and child/adult care

Periodic updates about the progress of the study

Clinical trial advisory sessions (with sponsors and health care professionals) to design the clinical study

Receiving a summary of the study results once the study is completed

Gaining greater awareness about NASH

Talking to health care professionals or clinical trial administrators about how they designed the clinical trials

Providing input on the outcomes (i.e., biochemical baseline measurements, median overall survival, duration of study) measured in the clinical trial

Surveys that ask about your preferences for treatments

Translation services (services translated into my language)

Helping other patients

Contribution to what we understand about NASH

Other (please note: _____)

Demographic Information

Race, ethnicity, gender, and sexuality are societal constructs that have a significant impact on American lives, particularly regarding health. Many different social structures place burdens, prejudices, and discriminations on many different groups of people which have severe negative consequences on health outcomes. This can unfortunately be seen in the high incidence, prevalence, and mortality rate of a countless number of liver diseases from viral hepatitis to NAFLD and NASH. Specifically, in the case of NASH, certain populations may even possess a gene variation, which has been associated with a heightened risk of NAFLD and NASH. This is why the next set of questions are especially important to educate the medical community about demographics impacted by NASH.

YOUR AGE. REMINDER: CAREGIVERS FILLING OUT THIS SURVEY SHOULD PROVIDE THIS INFORMATION ABOUT THE PERSON WITH NASH YOU CARE FOR.

Less than 21

22 - 30

31 - 40

40 - 50

Older than 50

*YOUR BIOLOGICAL SEX. REMINDER: CAREGIVERS FILLING OUT THIS SURVEY SHOULD PROVIDE THIS INFORMATION ABOUT THE PERSON WITH NASH YOU CARE FOR.

Male

Female

*YOUR GENDER IDENTITY. REMINDER: CAREGIVERS FILLING OUT THIS SURVEY SHOULD PROVIDE THIS INFORMATION ABOUT THE PERSON WITH NASH YOU CARE FOR.

Woman

Man

Transgender Woman / Trans Feminine

Non-Binary / Genderqueer / Gender Fluid

Two Spirit

Prefer to self describe: [Free response]

Do not wish to disclose

*YOUR ETHNICITY. REMINDER: CAREGIVERS FILLING OUT THIS SURVEY SHOULD PROVIDE THIS INFORMATION ABOUT THE PERSON WITH NASH YOU CARE FOR.

Hispanic/Latino

Non-Hispanic/Latino

Do not wish to disclose

*YOUR RACE (SELECT AS MANY AS APPLY). REMINDER: CAREGIVERS FILLING OUT THIS SURVEY SHOULD PROVIDE THIS INFORMATION ABOUT THE PERSON WITH NASH YOU CARE FOR.

American Indian or Alaska Native

Asian

Black or African American

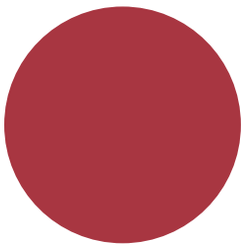
Native Hawaiian or Other Pacific Islander

White

Other_____

Do not wish to disclose

Location Information



*DO YOU LIVE IN THE UNITED STATES?

Yes

No

US BRANCH – FOR PEOPLE WHO RESPONDED “YES” TO THE PREVIOUS QUESTION

**Please enter your ZIP/postal code. _____*

OUS BRANCH – FOR PEOPLE WHO RESPONDED “NO” TO Q59

**Please enter the country where you live _____*

Survey Conclusion

We are very appreciative of you taking the time to complete this survey. Your answers will help us gather information that will help us in our critical effort to develop better advanced therapies for NASH. Any data collected here will only be shared in a summarized, anonymous manner. If you have any questions please do not hesitate to reach out to Andrew Scott, Global Liver Institute Policy Director, at ascott@globalliver.org.

www.GlobalLiver.org
@GlobalLiver
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Global Liver Institute (GLI) is a 501(c)(3) tax-exempt not-for-profit organization, headquartered in Washington, D.C., United States, with offices in the U.S. and Europe. GLI's vision is for liver health to take its place on the global public health agenda commensurate with its prevalence and impact. GLI's mission is to improve the lives of individuals and families impacted by liver disease through promoting innovation, encouraging collaboration, and supporting the scaling of optimal approaches to help eradicate liver diseases.