



U.S. NASH ACTION PLAN

2021 SCORECARD

2021 has been a pivotal year in addressing nonalcoholic steatohepatitis (NASH) in the United States. The U.S. NASH Action Plan, the only national NASH strategy, has been the logical next step in the work of the GLI NASH Council to take specific actions to address the multiple issues creating challenges and barriers to better NASH screening, diagnosis, and treatment. Each critical recommendation plays a vital role in elevating NASH to its rightful place on the national public health agenda commensurate with its prevalence and impact.

As a patient-driven multi-stakeholder community for whom addressing this disease is a life-and-death issue, we strongly believe that progress in addressing NASH is gauged through addressing four critical overriding issues to stop the rise of this life-threatening disease:

- Lack of awareness and education
- Lack of agreement on how to diagnose
- Lack of standardized patient management and treatment for NASH
- Lack of NASH-specific policy initiatives leading to poor health system preparedness

This year-end scorecard lists the accomplishments achieved according to the detailed agenda in the U.S. NASH Action Plan for each relevant stakeholder group – patients/care partners, clinicians, medical societies, patient advocacy organizations, industry, payors, health systems, regulators, and policymakers. While gaps and challenges remain, tracking and acknowledging NASH successes according to the U.S. NASH Action Plan is pivotal for the field to respond on a national scale in 2022 and beyond. The following is a summary of 2021 actions that help measure our progress collaboratively in filling these recommendations.

Patients & Caregivers

Education

GLI A3 Session: **Liz Helms, President and CEO of the CA Chronic Care Coalition and Founder of the TMJ (Common Temporomandibular Disorders) Society**, shared her story on how she began her journey as an advocate and used her voice as an advocate.



Diagnosis

Patient Management/Treatment

Policy Effort/Legislation

GLI-identified patients with NAFLD/NASH participated in patient advisory boards for **Boehringer Ingelheim** and **Pfizer Inc.**



Enrollment of patients with NAFLD/NASH and caregivers in **GLI's 2021 Advanced Advocacy Academy (A3)** held from September 21-23, 2021.



GLI A3 Session: Hepatologists **Dr. Nadge Gunn** and **Dr. Naim Alkhouri** delivered a briefing, *Clinical Trials: Are They For Me*, on the importance of clinical trials, giving patients a look into potential participation in clinical trials from the perspective of design, access and risk-benefit calculation.



GLI and **NutriStyle Inc.** partnered to create a personalized nutrition app for people living with liver disease, diabetes, and other chronic conditions or who want to maintain good liver health. The app allows users to create personalized meal plans to meet the specific requirements for people with NASH or a general interest in liver health.



Two groups of **patient panelists** testified at the first **NASH Externally-Led Patient-Focused Drug Development (EL-PFDD) Meeting** for the **U.S. Food and Drug Administration (FDA)** on November 4, 2021. These individuals provided their input on NASH, including their perspectives on their condition, its impact on daily life, and the urgency around developing therapies.



Clinicians

Education

GLI, in collaboration with NASH Council member, **Clinical Care Options**, launched the CME course, NASH Core Curriculum: A Comprehensive Online Resource Center to improve clinician understanding of foundational concepts in NASH diagnosis, management, and emerging pharmacologic treatment strategies.



Diagnosis

Patient Management/Treatment

Policy Effort/Legislation

The **American Gastroenterological Association (AGA)** worked with other professional societies, including the **American Diabetes Association (ADA)**, **American Osteopathic Association (AOA)**, **Endocrine Society**, and the **Obesity Society**, to develop a NAFLD/NASH Clinical Care Pathway that the groups say will facilitate “value-based, efficient, and safe care that is consistent with evidence-based guidelines, and setting the stage for future studies to examine the outcomes of such pathways.”



Medical Societies

Education

The **American Association for the Study of Liver Diseases (AASLD)**'s The Liver Meeting (TLMdx) was held from November 12-15, 2021. This conference offered NASH-related CME within and across specialties.



Diagnosis

The **European Association for the Study of Liver Diseases (EASL)** released updated guidelines on the use of non-invasive techniques for the evaluation of liver disease severity and prognosis, focusing on the topics for which relevant evidence has been published in the last five years.



Patient Management/Treatment

EASL published a patient guideline intended for all patients at risk of or living with NAFLD.



Policy Effort/Legislation

GLI's proposed coding revisions in **ICD-10-CM** were accepted. This will enable liver fibrosis to be classified more accurately and consistently with current clinical perspectives and documentation, and will enable enhanced tracking and research into progression of disease and the impact of treatment.



The **American Medical Association** Ed Hub online learning platform brings together education from trusted sources, and continually expands its offerings with outstanding education in the areas of Gastroenterology and Hepatology.



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Patient Advocacy Organizations

Education

Diagnosis

Patient Management/Treatment

Policy Effort/Legislation

Liver Wellness Foundation

presented a virtual educational *Meet Your Liver Doctors* Seminar on NAFLD and NASH.



The Fatty Liver Foundation

launched the NAFLD Screening Fund, a new five-year, multi-stakeholder, public-private partnership aimed at accelerating progress in the detection, diagnosis, staging, care, and research of NAFLD among at-risk and asymptomatic populations in the U.S.



The Fatty Liver Foundation

announced the publication of results of SUNN Study (Screening for Undiagnosed NAFLD and NASH) in PLOS ONE.



The Fatty Liver Alliance

collaborated with GLI to send out a letter to the **World Health Organization** urging them to prioritize a more focused approach on the impacts and risks of Type 2 diabetes on liver health, especially NAFLD and NASH.



Liver Coalition of San Diego

conducted webinars titled *Fatty Liver Disease, Diabetes and Obesity and Identifying and Managing NASH*.



GLI created a patient translation of the 2021 EASL Clinical Guidelines on Non-Invasive Tests for Evaluation of Liver Disease Severity and Prognosis.



GLI's LAN members led groups of patient advocates during A3's Hill Day in sessions with representatives across the U.S.



NASH KNOWledge and

Community Liver Alliance

hosted a discussion on fatty liver disease and NASH with leading healthcare professionals and advocates.



GLI's LAN members

attended the first NASH **EL-PFDD** for the **FDA** both as panelists and audience members who contributed to a robust Q&A session.



GLI's LAN sent a letter urging the **Centers for Medicare & Medicaid Services** to consider unmet needs in NASH and to support the FDA's Breakthrough Designation for IntraGastric Balloon as a treatment for NASH.



Industry

Education

Diagnosis

Patient Management/Treatment

Policy Effort/Legislation

GLI-identified patients with NAFLD/NASH participated in patient advisory boards for **Boehringer Ingelheim** and **Pfizer Inc.**



GLI applauded the actions of the **FDA** to grant breakthrough device designation for **Orbera® IntraGastric Balloon (IGB)** as a treatment for NASH.



Health Systems

Education

Diagnosis

Patient Management/Treatment

Policy Effort/Legislation

GLI's International NASH Day received participation from 120 partners representing 36 countries, (including 49 health care systems worldwide).



Payors

Education

Diagnosis

Patient Management/Treatment

Policy Effort/Legislation

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Regulators

Education

Diagnosis

Patient Management/Treatment

Policy Effort/Legislation

First ever **GLI NASH EL-PFDD** meeting with the **FDA** held on November 4, 2021, featuring community liver advocates.



Policymakers

Education

Diagnosis

Patient Management/Treatment

Policy Effort/Legislation

AASLD and **GLI** hosted a community educational Congressional Briefing on NASH.



GLI led input from the liver advocacy community to the **United States Preventive Services Task Force** following through on the recommendation to highlight the risks of NAFLD, NASH, and diabetes within their final recommendation statement for screening for prediabetes and Type 2 diabetes.



Senator Duckworth and **Representative Velázquez** reintroduced the **Liver Illness, Visibility, Education and Research Act (LIVER Act) H.R. 5675** and **S. 3041**.



Planned reintroduction of the **NASH Care Act** by **Representative Crenshaw** and **Representative Ruiz**.



Conclusion/Next Steps

Global Liver Institute thanks our NASH Council members for their continued dedication to patients with NASH and those at risk of fatty liver disease and NASH. With the many successes in the field, as outlined above, in the development of educational materials, care pathways, and policy/regulatory developments - there are still challenges that must be addressed by all NASH stakeholders.

GLI's U.S. NASH Action Plan identifies multiple issues that are still creating challenges and barriers to the NASH field. Gaps in addressing NASH and patient needs remain in all categories and can be addressed through the continued partnerships to create interventions tailored to the NASH patient's stage of disease, preferences, values, and circumstances. We believe strongly that the success of achieving our aims for NASH and our vision for the field is dependent on each stakeholder group's role and our collaboration with, and accountability to, each other.

As we build on our successes while addressing the challenges and gaps identified in the U.S. NASH Action Plan, we look forward to continuing to work together to prevent and address this life-threatening disease.