



January 21, 2020

Julie Zajac, MPH
Office of the Associate Director for Policy and Strategy
Community Guide Office
Centers for Disease Control and Prevention
1600 Clifton Road N.E., Mail Stop V25-5
Atlanta, GA 30329

RE: CDC Priority Topics for the Community Preventive Services Task Force (CPSTF); Request for Information (CDC–2019–0112)

Submitted via Regulations.gov

Dear Ms. Zajac,

The NASH Alliance appreciates the opportunity to submit comments in response to the Centers for Disease Control and Prevention (CDC) request for information (RFI) to identify priority topics for the Community Preventive Services Task Force (CPSTF).

The NASH Alliance is a coalition of clinical experts, patients, and life science innovators designed to educate the public and policymakers regarding NASH and its causes and treatments; advocate for responsible policies to improve access to diagnostic, preventive, and therapeutic services; and serve as a community for providers and patients.

Non-alcoholic fatty liver disease (NAFLD) occurs when an excess of fat lipids is stored in liver cells. Nonalcoholic steatohepatitis (NASH) is an advanced form of NAFLD in which tissue inflammation and liver cell damage is underway. NASH resembles alcoholic liver damage but often occurs in people who do not consume alcohol. If left untreated, NASH can worsen, resulting in fibrosis, cirrhosis, liver cancer and eventually liver failure.

The National Institutes of Health estimates that 30 to 40 percent of U.S. adults have NAFLD and three to 12 percent of adults have NASH.¹ An additional study estimates that 85 million people in the U.S. have

¹ <https://www.niddk.nih.gov/health-information/liver-disease/nafl-d-nash/definition-facts>

NAFLD, 17.3 million have NASH, and 3.6 million people have NASH with advanced fibrosis, with the potential for the prevalence of NASH to increase 56 percent between 2016 and 2030.²

There is an unprecedented need for the CDC to prioritize liver diseases, particularly NAFLD and NASH, as priority topics for the Community Preventive Services Task Force. These diseases have a high prevalence across the United States, yet many people are unaware of their causes that are linked to the obesity epidemic. Once a person becomes aware of their NASH diagnosis, irreversible liver damage often has been done and no pharmacologic treatment option currently exists. There is a need for the CDC invest in education, prevention, and surveillance efforts for NASH and NAFLD before people are diagnosed as well as to link them to care as new diagnostic and treatment options emerge.

Below are the NASH Alliance's responses to the questions included in the RFI:

1. What public health topics should be prioritized for CPSTF systematic reviews assessing the effectiveness and economic merits of public health programs, services, and other interventions?

The CDC should prioritize liver diseases, particularly NASH and NAFLD.

2. What is the rationale for choosing these topics?

There is a substantial unmet need for care and a large burden of disease. The causes of NAFLD and NASH have been highly linked to obesity, diabetes, hypertension, and hyperlipemia.³ One study estimates that the total financial burden associated with NASH is \$103 billion annually and the costs dramatically rise with liver decompensation.⁴ An additional study predicts that the 20-year costs for individuals with NAFLD in the United States will be \$55.8 billion, with 65,000 transplants, 1.37 million cardiovascular-related deaths, and 812,000 liver-related deaths over the next 20 years.⁵

While the prevalence of NAFLD and NASH is high across the country, it disproportionately affects Hispanic communities. One study found that NAFLD was more prevalent among Hispanics in the United States compared to non-Hispanic whites and non-Hispanic blacks.⁶ Additionally, the National Health and Nutrition Examination Survey has shown that Mexican-Americans have the highest prevalence of metabolic syndrome, a key risk factor for NAFLD and NASH development.⁷

An effort to prioritize NASH and NAFLD would align seamlessly with existing national efforts to improve the health, including Healthy People 2030. As previously mentioned, NASH and NAFLD are closely associated with obesity and diabetes, which have been identified as priority areas in the Healthy People 2030 proposed objectives for inclusion.⁸ If community-based interventions to reduce obesity and diabetes

² [https://www.journal-of-hepatology.eu/article/S0168-8278\(18\)32121-4/pdf](https://www.journal-of-hepatology.eu/article/S0168-8278(18)32121-4/pdf)

³ <https://www.ncbi.nlm.nih.gov/pubmed/26707365>

⁴ http://www.natap.org/2018/AASLD/AASLD_228.htm

⁵ <https://care.diabetesjournals.org/content/early/2020/01/02/dc19-1113>

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4838529/>

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4113166/>

⁸ <https://www.healthypeople.gov/sites/default/files/ObjectivesPublicComment508.pdf>

were combined with education addressing NAFLD and NASH, we may see a reduction in the prevalence of these liver diseases.

Even more concerning is that many more people are unaware that they have these liver diseases, due to NASH being asymptomatic in the early stages.⁹ Many patients remain undiagnosed until the condition worsens and irreversible liver damage starts to occur. Diagnosing NASH often involves performing invasive tests, such as liver biopsies, although non-invasive diagnostics including imaging are becoming available.¹⁰

The American Association for the Study of Liver Diseases (AASLD) guidelines suggest weight loss and exercise, cholesterol reduction, and diabetes control as ways to address the impacts of NASH.¹¹ These interventions are amenable to community-based preventive services, warranting prioritization by the CPSTF. Furthermore, as several promising therapeutic interventions are emerging, the availability of community-based preventive services may strengthen linkage to care for those eligible for treatment.

3. What are examples of published studies on interventions within these topics?

A variety of published evidence demonstrates the prevalence of NAFLD and NASH as well as opportunities to improve prevention. Selected findings include:

- *Modeling NAFLD Disease Burden in China, France, Germany, Italy, Japan, Spain, United Kingdom, and United States for the period 2016–2030*¹² — The study found the United States had the highest rate of NAFLD in 2016 at 26.3 percent and projected the U.S. NASH population to grow by 56 percent between 2016 to 2030. A community-based intervention approach is needed to address the underlying causes of the rapidly growing NAFLD and NASH populations.
- *The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance from the American Association for the Study of Liver Diseases*¹³ — Current guidance addresses lifestyle interventions consisting of diet, exercise, and weight loss. Such guidance reinforces the opportunity for community-based preventive services focused on nutrition and exercise to benefit patients who have or at risk for NAFLD and NASH.
- *Treatment of NAFLD with Diet, Physical Activity, and Exercise*¹⁴ — The study demonstrates the role of lifestyle interventions in treating NAFLD, with even modest weight loss of less than five percent producing “important benefits on the components of the NAFLD activity score.”¹⁵ The study specifically highlights the benefits of the Mediterranean diet, which can reduce liver fat even in the absence of weight loss.¹⁶

⁹ <https://www.niddk.nih.gov/health-information/liver-disease/nafl-d-nash/symptoms-causes>

¹⁰ <https://www.niddk.nih.gov/health-information/liver-disease/nafl-d-nash/diagnosis>

¹¹ <http://aasldv2019stg.aasld.org/sites/default/files/2019-06/NAFLD%20Guidance%202018.pdf>

¹² [https://www.journal-of-hepatology.eu/article/S0168-8278\(18\)32121-4/pdf](https://www.journal-of-hepatology.eu/article/S0168-8278(18)32121-4/pdf)

¹³ <http://aasldv2019stg.aasld.org/sites/default/files/2019-06/NAFLD%20Guidance%202018.pdf>

¹⁴ https://www.ncbi.nlm.nih.gov/pubmed/28545937#new_tab

¹⁵ Ibid.

¹⁶ Ibid.

In conclusion, we urge the CPSTF to adopt liver diseases, especially NAFLD and NASH, as a priority topic for its work over the next five years. We believe there is a significant opportunity to strengthen the delivery of community-based preventive services for liver diseases, including identifying those at risk, providing nutrition and exercise education, and providing linkage to care for those who need it. We would welcome the opportunity to discuss our comments with you. Please do not hesitate to contact me at bthornhill@nashalliance.org with any questions.

Sincerely,

Barrett Thornhill
Executive Director
NASH Alliance