

Deploying a Consensus Metabolic Dysfunction-Associated Steatohepatitis (MASH) Care Pathway and Educational Pilot in Three U.S. Health Systems

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INTRODUCTION

Metabolic dysfunction-associated liver disease (MASLD), formerly referred to as nonalcoholic fatty liver disease, impacts 30% of the global population. Recent guideline updates regarding MASLD, including those from European Association for the Study of the Liver (EASL 2021) and American Association for the Study of Liver Diseases (AASLD 2023), recommend screening for advanced fibrosis in certain patients with increased risk for MASLD. This educational pilot focused on the role primary care providers will play in the delivery of guidelines-based metabolic dysfunction-associated steatohepatitis care.

AIMS

- Streamline early identification of patients with metabolic dysfunction-associated steatohepatitis (MASH) deployment of guidelines-based, consensus care pathways
- Engage primary care providers in peer-to-peer education around MASH care pathways
- Establish a foundation for future real-world evidence generation and quality improvement initiatives

METHODOLOGY

A panel of experts in hepatology were convened in November 2021 to develop a MASH consensus care pathway leveraging the American Gastroenterological Association (AGA) and EASL care guidelines. The care pathway has continued to be validated as additional guidelines have been released.

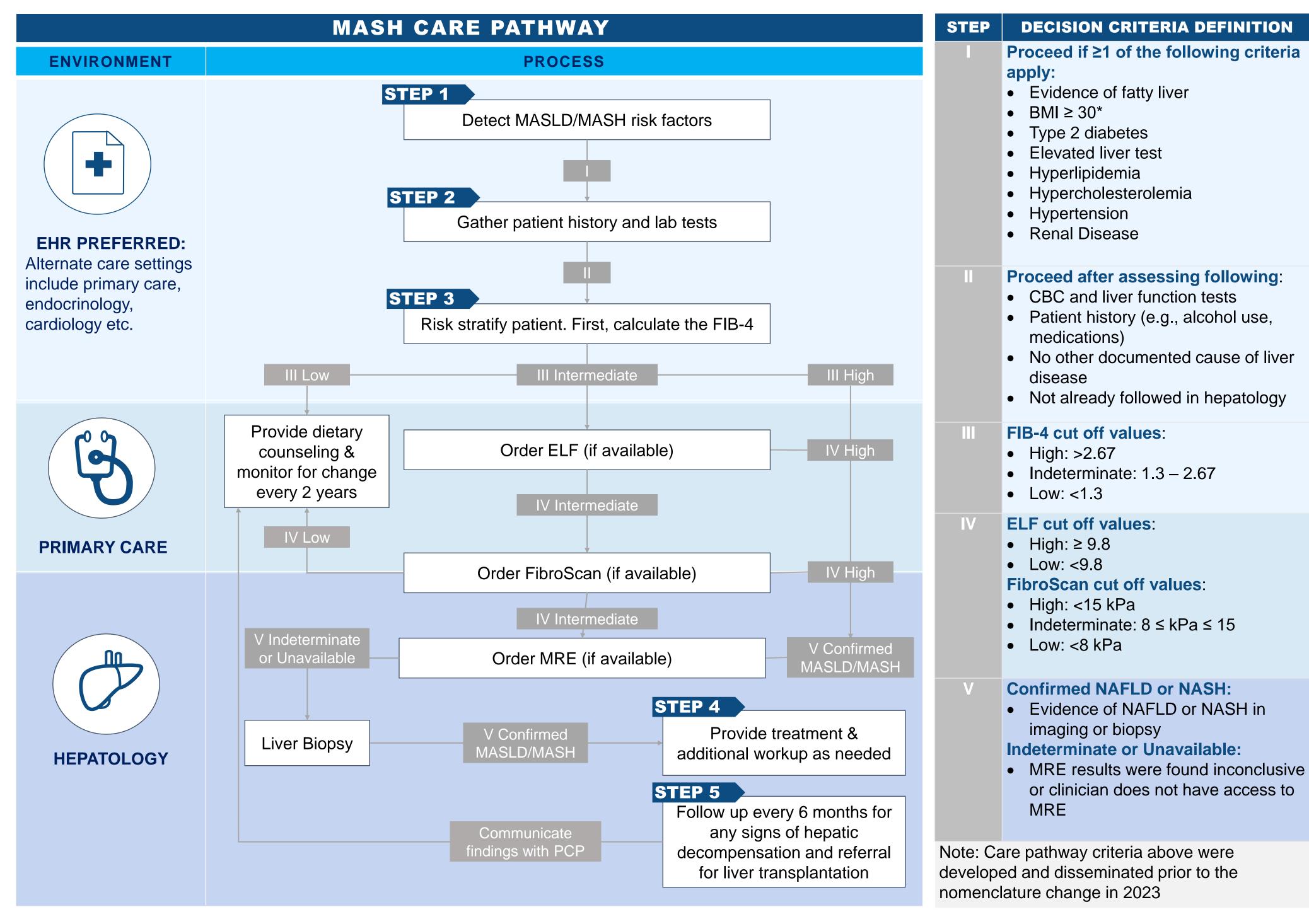
The consensus care pathway was deployed across three pilot sites:

- Boston Medical Center (BMC)
- Methodist Health System
- Weill Cornell Medicine

Investigators from each site conducted educational sessions with 19 eligible primary care providers (PCPs) at their respective sites, which included presenting a standardized 30-slide education deck, followed by a Q&A session. They then administered baseline, 2-month follow-up, and 4-month follow-up assessments. Responses were analyzed to understand any educational implications from pre- to post-interventional periods. The primary endpoint was to assess clinician-reported adherence to and satisfaction with the care pathway. The pilot was conducted from 2022-2023 and was deemed exempt by the Western Consensus Group Institutional Review Board (WCG-IRB). Education and surveys were conducted prior to the nomenclature update.

RESULTS

FIGURE 1: CONSENSUS-BASED CARE PATHWAY ROLLED OUT IN PILOT SITES



SURVEY RESULTS

Baseline Surveys

- 31.58% felt they had received sufficient training on when to refer to hepatology
- 78.95% were unsure or did not believe their institution had a formal referral protocol for patients suspected of MASLD/MASH
- 36.84% felt they had received sufficient training on the appropriate use of non-invasive tests (NITs) to inform MASLD/MASH referral decisions
- Within the past month:
 - 47.37% had not referred any patients suspected of MASLD/MASH to hepatology

Follow-Up Surveys

- Results from baseline to 4-months showed:
 - 48% increase in number of participants who either agreed or strongly agreed that they had received sufficient training on when to refer a patient suspected of MASLD/MASH to hepatology
 - 25.7% increase in self-reported adherence to the institution's referral guidelines
 - 20% increase in proportion of participants who had calculated a FIB-4 score within the past 12-months
 - NIT availability, unknown insurance coverage, and lack of EHR automation as barriers to protocol implementation

CONCLUSION

This pilot study demonstrated that continued engagement and education of PCPs will be essential to identifying and risk stratifying patients with MASLD/MASH further upstream, enabling management of lower acuity patients within primary care and referring potentially medically complex patients to hepatology for additional workup.

Learnings from the pilot initiative highlighted a few key takeaways:

- Knowledge gaps relating to the appropriate sequence of non-invasive diagnostics and best practices relating to referral guidelines persist amongst PCPs, but peer-to-peer education can improve provider confidence and adoption of guidelines-based care
- Barriers to implementation persist relating to diagnostic access and clinical workflow constraints; however, the authors hypothesize that these can be overcome through: integration of MASH care pathways within the EHR, simplification of actions required to maintain pathway adherence, transparency and awareness of insurance coverage for NITs

Additional evidence generation is needed to demonstrate the impact of care pathway implementation on clinical care outcomes across a wider range of care delivery settings (e.g., endocrinology, cardiology).

REFERENCES

- 1. Fernando, D. H., Forbes, J. M., Angus, P. W., & Herath, C. B. Development and progression of non-alcoholic fatty liver disease: the role of advanced glycation end products. International Journal of Molecular Sciences. 2019;20(20):5037.
- https://doi.org/10.3390/ijms20205037 2. Rinella, M.E. et al. A multisociety Delphi consensus statement on new fatty liver disease nomenclature. Annals of Hepatology. 2024;29(1):101133. https://doi.org/10.1016/j.aohep.2023.10113
- 3. American Liver Foundation. Nash definition & prevalence. 2022. https://liverfoundation.org/liver-diseases/fatty-liver-disease/nonalcoholic-steatohepatitis-nash/nash-definition-prevalence/#:~:text=NAFLD%20is%20the%20most%20common,of%20adults%20in
- %20the%20U.S 4. American Liver Foundation. Nonalcoholic fatty liver disease (NAFLD). 2023.

https://liverfoundation.org/liver-disease

- 5.Lee, Y.H. et al. "Nonalcoholic fatty liver disease in diabetes. Part I: epidemiology and diagnosis." Diabetes & Metabolism Journal. 2019;43(1):31-45. doi: 10.4093/dmj.2019.0011
- 6. Glass, L. M., Hunt, C. M., Fuchs, M., & Su, G. L. Comorbidities and nonalcoholic fatty liver disease: the chicken, the egg, or both? Federal practitioner: for the health care professionals of the VA, DoD, and PHS. 2019;36(2): 64-71.

 7. Intercept Pharmaceuticals, Inc. Intercept receives complete response letter from FDA for obeticholic acid as a treatment for pre-cirrhotic fibrosis due to NASH. 2023.
- receives-complete-response-letter-fda-obeticholic-0 8. Morris, Z. S., Wooding, S., & Grant, J. The answer is 17 years, what is the question: understanding time lags in translational research. Journal of the Royal Society of Medicine. 2011;104(12):510–520. https://doi.org/10.1258/jrsm.2011.110180

https://ir.interceptpharma.com/news-releases/news-release-details/intercept-

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