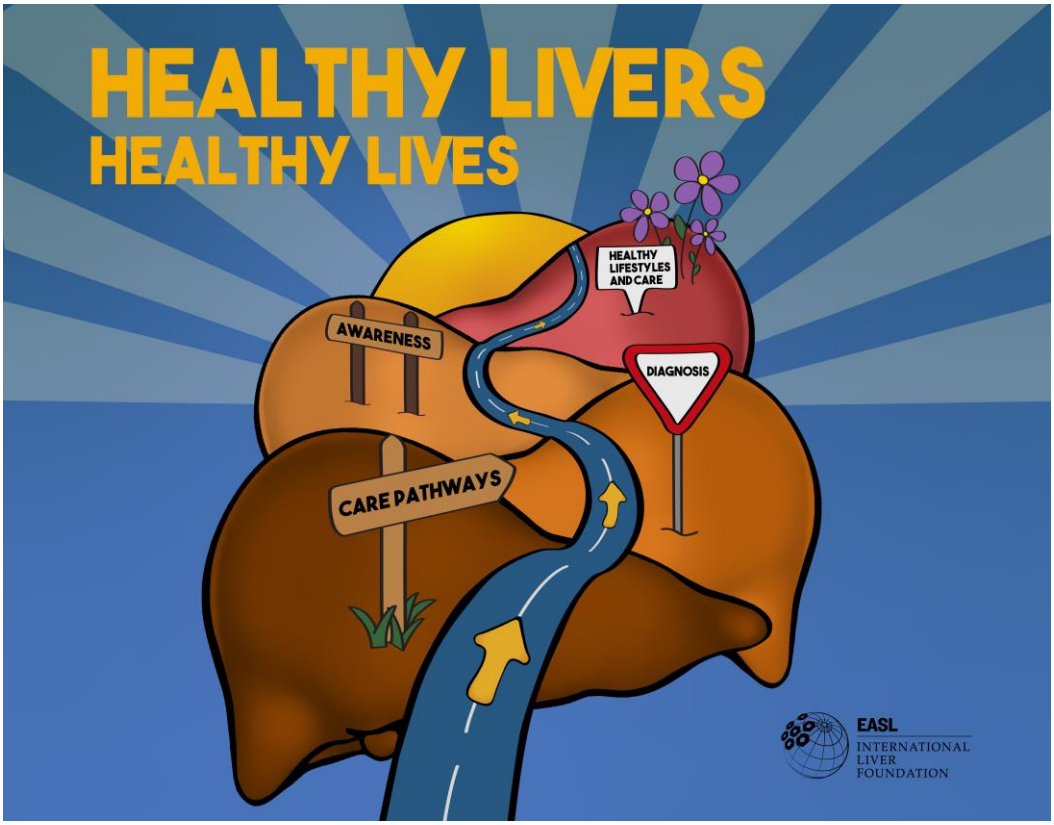
Wilton Park




Report

# Wilton Park virtual dialogue: Consensus for Care Pathways for NAFLD/NASH

Tuesday 16 June 2020 | WP1736V1

**In partnership with**

EASL
INTERNATIONAL LIVER FOUNDATION

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**In partnership with the EASL International Liver Foundation with support from Intercept.**

NAFLD- non alcoholic fatty liver disease- is a rapidly growing global health challenge. Despite affecting an estimated 2 billion people globally, the disease has received relatively little attention from policymakers, healthcare practitioners and global health experts. In 2020 and 2021 Wilton Park and the EASL International Liver Foundation (EILF) are partnering to hold a series of NAFLD dialogues which will holistically address a broad range of issues with the aim of advancing the global NAFLD agenda.

This first dialogue held virtually on June 16 2020 focused on the design and implementation of pathways of care for patients with NAFLD and NASH. There is a clear unmet need related to care pathways for patients with NAFLD with no formal pathways existing in many healthcare settings. Where pathways are in place these are often not standardised according to best practices. This event convened 27 leading clinicians, researchers and patient advocates from across Europe and north America for a detailed discussion on what concrete actions can be taken to improve models of care for NAFLD patients.

## Executive summary


- On 16 June 2020 Wilton Park, in partnership with EILF, hosted a dialogue to establish a broad consensus for evidence-based guidance for healthcare providers and policy-makers to determine optimal care pathways for effective care for NAFLD patients.
- Discussions were guided by a draft call to action which outlines eight recommendations for improving models of care, the recommendations centre around **what** services need to be provided, **where** the services should be provided, **who** should provide the services and **how** the services should be integrated.
- Through the meeting broad consensus was achieved related to the eight recommendations. The key themes and on-going issues to be addressed will be taken forward to subsequent dialogues which will focus on the implementation of pathways in national healthcare settings.
- The recommendations will provide clarity for policy makers and practitioners, and can be a compass for guiding and informing the design of optimal care pathways for NAFLD and NASH.

## Key themes across recommendations

- **Screening, risk stratification and simple pathways:** Targeted screening, clear risk stratification approaches and simple pathways are required to ensure patients are linked to appropriate care, this requires close collaboration with general practitioners and other clinical specialities.
- **Role of Primary care physicians:** Primary care physicians play a key role in identifying high risk patients, yet they are often overburdened and their knowledge of NAFLD is generally low, care pathways must be as simple and efficient as possible to make them feasible for GPs
- **Communication and education:** The liver health community should take the lead in educating both patients and practitioners about the disease. Communicating the impact of the disease to patient outcomes, including non-liver related outcomes, to other clinical specialists is important.
- **Collaboration:** Closer collaboration between disciplines is needed, but the liver community must be realistic and pragmatic in its approach to engaging other specialisations (e.g. endocrinology, cardiology) recognising health systems barriers that inhibit closer collaboration and developing strategies to overcome these.
- **Impact evidence:** The evidence base for NAFLD and NASH care models is limited, additional operational research to document successes stories of improving care across a range of health system settings is needed.
- **Patient centred design:** Ensuring care models and pathways are patient centred is critical, to achieve this patients and patient advocates must be included in discussions throughout the design and implementation process.

## Introduction

1. Historically, limited attention has been paid to the management of NAFLD patients within healthcare settings with few formal care pathways or standardised models for managing patients. As a result, health outcomes for patients with NAFLD and NASH tend to vary widely.
2. As a multi-system disease covering a wide spectrum–from simple steatosis to NASH and advanced fibrosis–multidisciplinary models of care are needed that are tailored to a patient's place on the disease spectrum. There is an imperative to better our understanding of what is required across varied healthcare settings to provide patient-centred care to people with NAFLD. This will require a concerted and collaborative effort across clinical specialisations and the sharing of knowledge and ideas between organisations and across geographical borders.
3. The first step in this process requires building consensus on evidence-based best practice which can guide healthcare providers and policymakers designing and implementing care pathways.
4. The discussions during dialogue were guided by a draft 'Call to Action on the models of care for NAFLD and NASH' (see appendix). The Call to Action is structured around four key questions which form the foundation of quality models of care: 1) **what** services need to be provided, 2) **where** the services should be provided, 3) **who** should provide the services and 4) **how** the services should be integrated.
5. The draft Call to Action was informed by an ongoing systematic review of published models of care for NAFLD and NASH which is being undertaken by EILF. The systematic review and Call to Action will be published in August 2020 with concrete recommendations that will be informed by the outcomes of this dialogue and other ongoing discussions.

6. The following report summarises the main discussions for each of the eight priority areas covered in the Call to Action.

## What services should be delivered?

**Recommendation 1: Patient-centred pathways for NAFLD and NASH patients, which are tailored to their position on the disease spectrum and the presence of comorbid conditions (medical algorithm)**

7. There was consensus that to deliver appropriate care it is critical to identify the status of the disease, referring patients in advanced stages to specialists for further assessment and management.

8. In developing a clear care pathway four questions should be addressed:

    i. who are we screening (at risk group such as diabetes patients or the general population)?

    ii. what are we screening for (fatty liver or liver fibrosis)?

    iii. how are you screening (what tools are being used)?

    iv. how can we build an algorithm with the information provided to guide patients through the pathway? A patient-centred algorithm can be built by understanding what services are prioritised by patients with NAFLD/NASH and ensuring that required services are both available and accessible.

9. Many patients will first present in primary care, we need to increase awareness and build the case for why primary care practitioners should be concerned about NAFLD. There is also a need to strengthen the flow of information between primary and secondary care and ensure sufficient information is provided to patients about the services that are available to them.

10. The substantial burden of NAFLD, and the limited resources available for treating patients, dictates that those at high risk are prioritised for screening. Diabetes patients are a group of interest given the poor prognosis for patients with diabetes and advanced fibrosis. Screening should also be guided by the local epidemiology and health system context. In areas where the prevalence of NAFLD and common co-morbid conditions is high, and there is capacity to treat all patients with advanced disease, screening efforts can be expanded.

11. Rather than targeting all patients with NAFLD, the vast majority of whom will not have advanced disease or require intervention, there needs to be a more nuanced approach, with screening targeted at those with pre-existing conditions and at risk patients, such as those with diabetes, cardiovascular disease and lipid disorder patients.

12. Segmentation and stratification are critical for determining the services that a patient needs, we can consider concentric circles of care which are based on the services required and the intensity of a patient's care needs.

13. There is a real need for simpler screening processes, but a major barrier is a lack of clarity around what indicators should trigger a screening. Guidelines, such as the joint EU guidelines from EASL, EASD, EASO for screening, require updating with clear frameworks established for screening.

14. There was broad consensus that care pathways and management strategies should be patient centred. Patients should be actively involved in discussions about their care pathways, and empowered and informed to ask the right questions.

**Recommendation 2: National or regional guidelines on screening and testing including the use of on non-invasive testing (NIT)–which incorporate evidence-based best practices**

15. Non-invasive tests (NIT) are the principle tools through which patient centred pathways can be implemented, different NITs are being employed to varying degrees at different levels of the healthcare systems.
16. Clear guidance and adequate information are key for the successful implementation of NITs, including which tests should be used, when and by who and how the results are interpreted based on predefined referral pathways.
17. Greater clarity regarding the scale of the problem and the consequences for patients, coupled with clear messaging regarding what practitioners are testing for and what the possible outcomes may be, will facilitate the effective use of NITs.
18. Various serum biomarkers (used in the calculation of scores and ratios) and elastography techniques are used across different healthcare settings. FIB-4 has been validated in several contexts and is in relatively widespread use in routine practice, including in primary care. Elastography is most commonly used in secondary care facilities generally to confirm a diagnosis of liver disease following a referral.
19. To be feasible in primary care, any NITs need to be simple and efficient, where practicable calculation of scores and ratios should be automated. Care pathways should provide clear guidance on the next steps, allowing for easy interpretation of test results (e.g. further assessment and specialist referral).
20. Education for practitioners on interpreting NIT results is important for ensuring adequate care, and for increasing awareness that the absence of cirrhosis does not imply the absence of liver disease.

**Recommendation 3: Guidelines on treatment strategies for patients related to their position on the disease spectrum, ranging from lifestyle interventions to pharmacological treatments**

21. The increasing burden of NAFLD is mirrored by a growing burden of metabolic syndromes, including diabetes, with patients requiring complex care for multiple related comorbidity conditions.
22. Implementation of treatment strategies is not uniform. Clear guidelines on treatment strategies related to the patient's position on the disease spectrum are needed, this should flow directly from risk stratification approaches and is linked to the aforementioned concept of concentric circles of services needed and intensity.
23. There should be clearly defied pathways for treatment which outline the optimal clinical end point and include a focus on managing metabolic risk factors.
24. There should be better utilisation of existing data and wider undertaking of additional operational and implementation research to build the evidence base for effective lifestyle interventions (e.g. diet and physical activity).
25. In the absence of approved pharmacological therapies for NAFLD/NASH management options remain limited, lifestyle interventions and the management of metabolic complications remain the cornerstone of treatment. A lack of clarity on the intended end point for future pharmacological treatments is an ongoing challenge.

**Recommendation 4: Prevention programmes for patients who are not yet on the spectrum of NAFLD or NASH but who have risk factors (e.g. comorbidities such as obesity and type 2 diabetes)**

26. The involvement of primary care practitioners is crucial to enable effective prevention programmes, this requires awareness raising amongst GPs as to the risk for patients with untreated NAFLD. Risk groups who would benefit from early intervention should be clearly defined, such as those with type 2 diabetes or cardio-metabolic risk factors.

27. For those high-risk patients that are not yet on the disease spectrum there needs to be increased touch points with health services in order to provide an early diagnosis. This may require a re-structuring of how assessments are provided to make this process more efficient.

28. The indicators that place patients under the specialisation of hepatology need to be better defined. Better defining the roles and responsibilities of specialists, primary care physicians and community services is important for enhancing prevention efforts, this needs to consider the availability of services and the existing burden on health care providers.

29. Prevention for high-risk patents requires close collaboration with those working to address common comorbidities and risk factors, namely obesity, diet and physical activity. As part of these efforts, we should seek to understand ongoing efforts to address these conditions in primary care and the community.

## Where should services be delivered?

**Recommendation 5: The role of primary, secondary and tertiary care providers in the management of patients with NAFLD and NASH**

30. Following risk stratification care pathways should separate patients into low and high risk for fibrosis. Generally, those at low risk will be managed in primary care while those at high risk should be referred to a specialist at secondary care. This will be context specific, with primary and secondary care overlapping in some healthcare systems and will also be dependent on the existence of other comorbid conditions.

31. Primary care practitioners play a central role in screening patients and take on a significant responsibility for managing the disease in those patients not requiring specialist referral. Primary care practitioners also have a key role in educating patients about the disease and linking them to appropriate secondary health care services.

32. The lack of treatment options for patients with NASH and advanced fibrosis, including pharmacological treatments, contributes to limited interest in primary care settings.

33. Within secondary care, specialists outside hepatology and gastroenterology also play a role, notably endocrinologists and cardiologists who are likely to see patients with high risk for advanced fibrosis. There needs to be greater awareness amongst these groups, and clear guidance on what is required of them (use of routine NITs). Any messaging and guidance should be short, practical, easy and feasible to implement.

**Recommendation 6: The benefits of co-locating NAFLD/NASH services with services for the treatment of common comorbidities**

34. The co-location of services can be highly beneficial, ensuring efficiency in service delivery and convenience for patients.

35. There are several examples of multidisciplinary clinic models that offer a ‘one-stop shop’ for patients, providing assessments and clinical interventions for NAFLD and other co-morbidities (e.g. diabetes, cardiovascular disease) in one place at one time. Participants gave good examples of multidisciplinary clinics in the UK and Israel.

36. A multi-disciplinary clinic can provide a highly patient-centric approach. These models are most commonly found at large hospitals in populous urban areas, and are not practical in rural or low population locations.

37. The use of technology can also help to link people to services, bridging the divide when patients are not in close proximity to speciality care, for example tele-medicine or other virtual platforms can be utilised for consultations and for the provision of some services.

38. Where feasible certain services for NAFLD should be located in other specialist clinics, screening for advanced fibrosis in diabetes clinics with the NITs is a logical starting point.

## Who should deliver which services?

**Recommendation 7: The composition and structure of the multidisciplinary teams responsible for the management of patients with NAFLD and NASH**

39. The composition of a multidisciplinary NAFLD clinic should preferably include a hepatologist, a dietician or nutritionist, psychologist and a cardiovascular specialist or diabetologist. A specialist nurse could potentially offer support in navigating this team for patients and driving patient care.

40. At secondary and tertiary care level, focus should go beyond managing the liver, with attention also paid to other conditions including psychology, diet and nutrition.

41. It was suggested that pragmatism is needed when devising a multidisciplinary team, with patients' needs and the availability of resources being balanced. There were varied opinions as to which specialist would be most critical, with dietician and cardiovascular specialists most commonly named.

## Coordination and integration

**Recommendation 8: Strategies for ensuring the effective coordination of care between levels of service deliver and relevant specialties within specific hospitals and the broader healthcare system**

42. While there was broad consensus that services should be integrated, several challenges relating to the practical implementation of strategies were raised. Potential barriers noted were funding, country-specific insurance reimbursement practices, challenges adapting clinical practice guidelines and issues of data protection.

43. Given the vast differences in health services between countries, integration strategies need to be tailored to the local context and identify and address the specific healthy system barriers to coordination and integration.

44. Critical to care coordination is the timely and accurate flow of appropriate information between different levels of service delivery (primary to secondary care) and between relevant specialisations.

45. COVID-19 has led to the scale up of service delivery innovation such as video health and teleconsultations which aim to deliver care continuity. For NAFLD there was consensus that integration could be achieved in the absence of co-location through the use of service delivery innovations.

46. Operational and implementation research to monitor the implementation of innovate models of care will be key to building the evidence base and refining these approaches to deliver better patient outcomes.

## Conclusion

Broad consensus, relating to the eight recommendations outlined in the 'Call to Action', was achieved through this dialogue, particularly in key areas such as ensuring patient-centric approaches and integrating services. This consensus will offer much needed clarity for policy-makers and practitioners, helping to inform and shape future designs of optimal care pathways for NAFLD and NASH. The publication of the systematic review and a refined Call to Action in August will reflect the outcomes of this dialogue. The themes of this dialogue will be taken forward into ongoing discussions to inform the implementation of pathways in national care settings.

Future dialogues in this series will focus firstly, on the implementation of care pathways at country level and subsequently, the development of a broader roadmap for advancing the NAFLD agenda in relation to policy change and advocacy.

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Wilton Park | June 2020



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