A Call to Action on Models of Care for NAFLD and NASH

Redefining care for people with fatty liver disease

Through this international call to action we aim to inspire change in how care pathways are designed and implemented for people with NAFLD by engaging with policymakers and practitioners to provide clear, evidence- based guidance on how healthcare settings can be restructured.

Why do we need a call to action?

NAFLD is the most prevalent liver disease in human history, with an estimated 2 billion people affected globally.[1] NAFLD is an umbrella term that describes a histological spectrum ranging from non-alcoholic fatty liver (NAFL) to the more aggressive non-alcoholic steatohepatitis (NASH). It is closely related to metabolic syndrome, obesity and type 2 diabetes[2] and is becoming an established risk factor for the 21st century's leading causes of death and disability including cancer, cardiovascular disease and type 2 diabetes. However, the phenotypes of NAFLD patients varies widely, with NAFLD also being observed in lean people, especially of Asian ethnicity.[3] NAFLD results in both metabolic and liver-specific complications making it a unique medical condition requiring complex care.[4] Left unaddressed, the burden of NAFLD is expected to grow over the next decade,[5] resulting in substantial economic and wellbeing losses and burdening healthcare systems.[6]

At present a holistic response to NAFLD is lacking, with limited attention paid to implementing public health prevention approaches or to improving the management of NAFLD patients within healthcare settings. Of 29 European countries surveys in 2019, none had a national strategy for addressing NAFLD, while only 35% had national clinical guidelines for management of the condition. NAFLD was also largely absent from the strategies aimed at addressing common co-morbidities including obesity, diabetes and nutrition. [7]

There is a clear unmet need related to care pathways for patients with NAFLD. In many healthcare setting no formal pathway exists, and where pathways are in place they are often not standardised according to best practices. As a result, health outcomes for patients with NAFLD vary widely between, and even within healthcare settings.

There is an urgent need to improve our understanding of how to provide patient-centred care to people with NAFLD, with multidisciplinary models of care (MoCs) tailored to their place on the disease spectrum. This will require concerted and collaborative efforts across clinical specialisations and the sharing of knowledge and ideas between organisations and across geographical boarders. Similar work has previously been undertaken for hepatitis C where

improved MoCs have resulted in more efficient and effective means of providing quality care to people in need.[8]

What EILF is doing to advance our understanding of models of care for NAFLD and NASH patients

The EASL International Liver Foundation (EILF) is working with a broad group of experts to advance our understanding of models of care for NAFLD patients. As part of this we are conducting a systematic review to identify published examples of comprehensive MoCs for NAFLD, and in partnership with Wilton Park will hold a series of consultations with experts from different global regions.

Through this work we aim to develop evidence-based guidance for healthcare providers and policymakers on what they need to do to provide effective care for these patients and to launch an inspirational global Call to Action.

Who should engage in this process?

EILF is seeking to engage with all stakeholders who have an interest in improving models of care for NAFLD patients, namely clinicians, researchers, patients and patient advocates, policymakers and civil society groups.

Critical discussions for redefining models of care for NAFLD and NASH

Our work centres on answering 4 key questions which are the foundation for designing quality models of care:

1) ***What services need to be provided?***

2) ***Where should services be delivered?***

3) ***Who should provide the services?***

4) ***How should all of the required services be integrated and coordinated within healthcare systems*?**

We have outlined a number of priority discussions areas for advancing our understanding of models of care for NAFLD and NASH patients to support healthcare providers in delivering care and to inform this Call to Action.

What services should be delivered?

1. **Define patient-centred pathways for NAFLD and NASH patients, which are tailored to their position on the disease spectrum and the presence of comorbid conditions**

The healthcare services required by NAFLD patients is dependent on their position on the disease spectrum. Establishing a clear management pathway that determines a patients' care needs and then links them to the appropriate services is the first critical step in developing effective MoCs for NAFLD.

There are several published examples such pathway. In Nottingham (UK) 4 clinical commissioning groups developed a pathway for the identification and risk stratification of liver disease–including NAFLD–in the community and referrals from primary to secondary care.[9] Further examples come from Oxfordshire (UK) and Camden and Islington (UK) where pathways have been established for the risk stratification of patients and criteria established for referrals to hepatologists.[10,11]

2. **Gain consensus on screening and testing strategies –including the use of on non-invasive testing (NIT)–which incorporate evidence-based best practices**

The majority of NAFLD patients are likely to first present within primary care settings, however primary care providers have limited awareness of the disease and their role in managing it.[12,13] Identifying patients with advanced fibrosis is particularly important given the increased risk of complications and the need for aggressive clinical management. Liver biopsy, the gold standard diagnostic tool for determining NASH, is not a practical tool for use in primary care settings. There are however a number of non-invasive tests (NITs) with high negative-predictive value which can detect advanced liver fibrosis. These tests are a central element for the development of care pathway such as those described above.

Equally critical is the establishment of screening guidance for settings outside of primary care where NAFLD patients are likely to represent, namely diabetes clinics. Such guidance should consider the practicalities of implementing different screening tools within various clinical settings and outline pathways through which patients are referred to liver specialists for further investigation and management.[14]

3. **Develop guidelines on treatment strategies for patients related to their position on the disease spectrum, ranging from lifestyle interventions to pharmacological treatments**

The clinical management strategies of NAFLD are specific to the position of the patient on the disease spectrum. The management of modifiable risk factors, including diet/nutrition and physical activity remain the cornerstone of treatment for all patients.[15] The current management of patients with advanced fibrosis is complicated by the limited number of pharmacological treatments currently available.[16] In addition to managing liver related complications, a proportion of patients with NAFLD also require services for the presence of comorbidities, including cardiovascular disease and diabetes. Clear guidance on what services are required by individual patients, and how these patients will be linked to the required these services is critical to the efficient and effective delivery of care.

4. **Outline actions for preventing disease progression in patients not requiring specialist hepatology care**

The majority of patients with NAFLD do not require intensive clinical management led by a hepatologist. Patients with NAFL or early stages of fibrosis can be managed in primary care with the aim of preventing disease progression or achieving remission. Prevalent non-communicable diseases such as obesity, T2DM, CVD and NAFLD, share a number of common risk factors, including poor diets and physical inactivity. This presents an opportunity for primary care and community interventions to collectively to address these risk factors and holistically address patient needs. This requires practitioners to outline the availability of primary care and community services, to identify which patients will benefit from access these services and to develop systems for linking patients with the services. These efforts will be central to lowering the prevalence of severe disease reducing the burden this placed on healthcare systems.

Where should services be delivered?

5. **Understand the roles of and interactions between primary, secondary and tertiary care providers**

Healthcare services for NAFLD patients will be delivered at different level within the health care system. Understanding which services will be delivered in primary, secondary and tertiary care and the interactions between primary, secondary and tertiary care providers is important to the delivery of coordinated, effective and efficient MoCs. For the majority of patients, the first stages of clinical assessment and risk stratification are likely to take place in primary care, followed by further assessment and a definitive diagnosis by specialists in

secondary care. Patients with advanced fibrosis, cirrhosis and end-stage liver disease will require more aggressive management by led by specilists,[17] and may require including transplantation. In the stages of NAFLD the hepatic component of the disease can generally be managed in primary care. Given the lack of awareness of NAFLD amongst primary care providers, educational activities will be needed to facilitate the scale up of interventions in primary care.

6. **Explore the benefits of co-locating NAFLD/NASH services with services for the treatment of common comorbidities**

The location of services is critical to the early diagnosis and effective management for NAFLD patients. Multi-disciplinary care clinics have numerous benefits in delivering coordinated care to NAFLD patients.[18] Co-location of specific services in strategic locations, such as diagnostic screening for NAFLD in diabetes clinics, can assist in the identification of previously undiagnosed NAFLD cases.[19] Decisions on where services can and should be co-located will be informed by the local healthcare system structures, in populous urban settings co-location may be more feasible than in rural areas. For services that do not require the physical presence of the patient (e.g. counselling sessions) virtual co-location of can also be considered.

Who should provide the services?

7. **Define the composition and structure of the multidisciplinary teams responsible for the management of patients with NAFLD and NASH**

It is clear that care for NAFLD patients requires a multidisciplinary team. It is important to define the composition of this team, such as the different specialist who need to be engaged, and to outline the structures needed to ensure the effective flow of information within the team and externally to other key stakeholders. According to the Birmingham (UK) experience a dedicated NAFLD clinic should incorporate inputs from hepatologists, diabetologists/weight loss physicians, diabetes specialist nurses (DSN), dieticians and practitioners proficient in the use of non-invasive diagnostic tools.[18] It will be important understand how the composition and structure of such a multidisciplinary team varies within and between different health system settings, and to understand the trade-offs that need to be made when devising a team considering factors including health system resourcing.

How should all of the required services be integrated?

8. **Establish effective systems for coordinating and integrating care across the healthcare system**

To deliver effective patient centred care for people with NAFLD patients it is critical to ensure close collaboration and coordination between service levels (primary, secondary and tertiary) and different specialities (e.g. hepatology, endocrinology and cardiology). Central to this is the flow of information between levels of care, different specialists and patients. Examples exist of multi-disciplinary hepatology clinics that facilitate connections between services.[10] A dedicated NAFLD clinic, as implemented in Birmingham, UK, is one strategy for providing multidisciplinary care which reduces the need for attendance at multiple clinics thus lessening the burden on patients.[18]

Next steps to redefine care for NAFLD

We actively encourage ministries of health and relevant agencies to improve care for patients with NAFLD. This Call to Action can help stakeholders to identify and outline national and subnational priorities and can be used as a blueprint for guiding action.

As a first step, countries can review current care pathways. While health systems vary widely, depending on the national or local context, the core elements of good care pathways, such as a clear articulation of the services being provided, who provides these services and how these services are integrated, remain constant across settings. Such a review should include a mapping of stakeholders who will be key to delivering sustained improvements in NAFLD care pathways.

Based on an understanding of how care is currently provided to patients with NAFLD, and guided by the 8 steps in this Call to Action, stakeholders can outline concrete steps for delivering improvements.

As we seek to develop optimal care models for NAFLD, we need to continue to grow the evidence based and address critical questions. This requires us to place knowledge management and information sharing at the centre of our efforts. A number of methods can be employed to generate evidence. Hospital audits of care pathways can provide detailed information on how new MoCs are being delivered and can help to identify systems barriers to optimal implementation, such as issues with linking patients to the required services. It is important that information flows efficiently within and between countries allowing for continuous improvement of care pathways based on emerging best practices. This will require dedicated structure for collating and sharing information at the national. regional and global level. Documenting the patient experience is also key to building patient-centred models that fit the

needs of affected people. Finally, but critically, we also need to understand how different models of care impact patient outcomes.

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Summary of the literature related to each discussion point

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