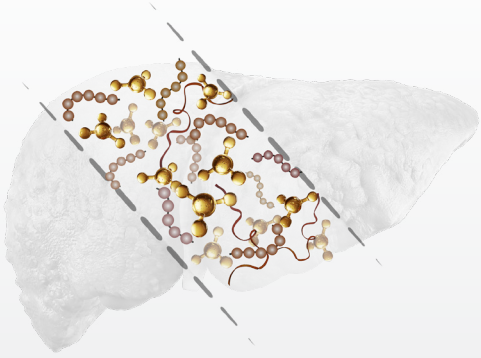
Enhanced Liver Fibrosis (ELF) Test

Expanded use of the ELF test can improve access to liver fibrosis testing and reduce carbon emissions: evidence from France



A novel spatial analysis shows sequential use of non-invasive blood tests in line with current international MASLD guidelines could overcome existing barriers to access in France and have a positive environmental impact compared with current clinical practice

Introduction

Metabolic dysfunction-associated steatotic liver disease (MASLD) is the most common cause of chronic liver disease, with a global estimated prevalence of 38% amongst adults for the period 2016–2019[2]. The rising prevalence of MASLD corresponds with increasing rates of obesity and type 2 diabetes; if current metabolic trends continue, over half of the adult population will have MASLD by 2040.[3] In France, MASLD represents a significant clinical and economic burden with an estimated 8.5 million individuals affected, including 79% of people with obesity.[4,5] The total healthcare costs associated with MASLD in France are estimated at 11.4–15.7 billion EUR, with costs and resource use driven by disease progression and comorbidity burden.[6,7]

Despite its high prevalence, MASLD remains markedly underdiagnosed, largely due to an asymptomatic disease course and limited awareness among both patients and healthcare professionals. Current guidelines recommend targeted case finding to identify individuals most likely to progress to more severe liver damage.[1,8] While liver biopsy is the gold standard for identifying metabolic dysfunction-associated steatohepatitis (MASH) and assessing fibrosis, it is not feasible for use in routine clinical practice given the scale of individuals with at-risk MASLD.

Table 1. Non-invasive tests for fibrosis in MASLD

Fibrosis-4 index (FIB-4)	Recommended first-line[1]
Enhanced liver fibrosis (ELF) test	Recommended second-line, if VCTE not available[1]
Vibration-controlled transient elastography (VCTE)	Recommended second-line[1]

Instead, sequential, non-invasive testing of at-risk patients is recommended to confirm or rule out presence of advanced fibrosis **(Table 1)**.[1] Simple blood tests, such as FIB-4, are useful for ruling out advanced fibrosis. Combining them with specialist tests, such as VCTE (or simply TE), to follow up on indeterminate scores results in good overall accuracy. However, TE availability is typically limited to specialist care settings. European guidelines recommend the ELF test as an alternative second-line test. ELF is a blood-based test that includes three direct fibrosis markers: hyaluronic acid, amino-terminal propeptide of type III procollagen, and tissue inhibitor of matrix metalloproteinase-1 (See section "About ELF test" below). Evidence from French clinical practice highlights how different fibrosis testing pathways, such as FIB-4 followed by TE or FIB-4 followed by ELF, are used in high-risk populations to guide clinical assessment.[9]

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While previous studies have demonstrated that a FIB-4/ELF testing pathway is cost-effective, improves detection, and reduces referral rates compared with standard care,[10–13] the wider societal consequences of introducing more accessible testing routes for individuals with MASLD have not been explored. A recent study has employed a novel approach to model the impact of a FIB-4/ELF testing pathway on travel times and carbon emissions.[14] Using publicly available data to map travel distance to fibrosis testing facilities in France, this is the first study to examine how increased use of FIB-4/ELF testing in primary care could result in patient- and environmental-level benefits.

Environmental sustainability and equality of access are increasingly relevant aspects of healthcare policy and decision-making. In France, the Haute Autorité de Santé's (HAS) environmental health roadmap supports incorporation of environmental criteria into health technology assessment and clinical guidelines.[15] There are also multiple policy initiatives aimed at addressing the well-documented challenges in accessing primary and specialist healthcare in France.[16–18] In this context, the current study is designed to address critical, previously unexamined aspects of MASLD care pathways, with implications for countries beyond France. Specifically, the accessibility and sustainability of liver fibrosis assessment in people with MASLD under the current testing paradigm (FIB-4 testing followed by TE for indeterminate cases) relative to a paradigm using the ELF test after indeterminate FIB-4 results was investigated.[14]

Spatial analysis: study design and methods

The study used a spatial analysis approach and public data to compare distances, times, and emissions associated with patient travel to general practitioners (GPs), laboratories, TE services, and hepatologists, for a TE-based versus an ELF-based confirmatory testing paradigm **(Figure 1)**.[14] 304 distinct TE service locations were available for analysis **(Figure 2)**. Importantly, reflex testing was assumed for the ELF test (same sample tested for FIB-4 and ELF test), reducing the need for a second laboratory visit. Non-invasive test accuracy and prevalence of advanced fibrosis were obtained from meta-analyses and French observational data, respectively.[19–21] The MASLD prevalence for each community was interpolated from regional-level data reported by the NASH-CO study.[22]

Travel times and duration were calculated at a community and department level using boundary and population data for June 2025. In total, 34,788 French communities were available for analysis. In communities that had more than one TE service available, synthetic subcommunities were created so that each TE service was associated with a specific catchment area.[14]

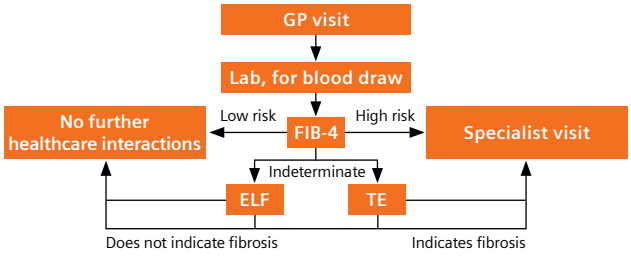

Figure 1. FIB-4/TE vs. FIB-4/ELF pathway modeled in the spatial analysis

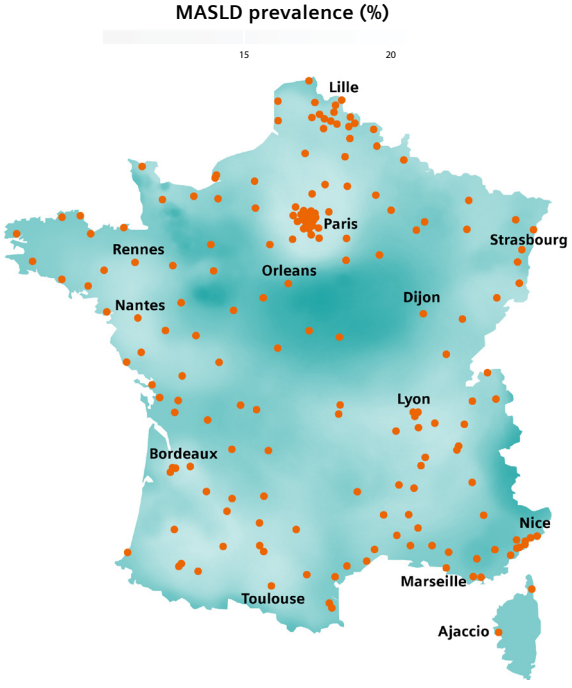

Figure 2. Per-capita availability of fibrosis-testing related healthcare services across France.

The Openrouteservice routing engine was used to obtain transport-dependent route information (car, cycle, and foot), while public transport routing was performed with the Google Maps Directions application programming interface. For modelling purposes, it was assumed the route to healthcare services originated at the approximate center point (the so-called "centroid") of each community.[14]

The split between the different modes of transport was informed by publicly available journey statistics for France[23] and factored in population density. CO_2 emissions for car and train journeys were sourced from published data.[24–26] Travel times, distances, and associated emissions for each confirmatory pathway were summarized across communities and departments using descriptive statistics (usually, means, medians, and standard deviations [SDs]).

Results

There is considerable variation in access to fibrosis testing-related services across France

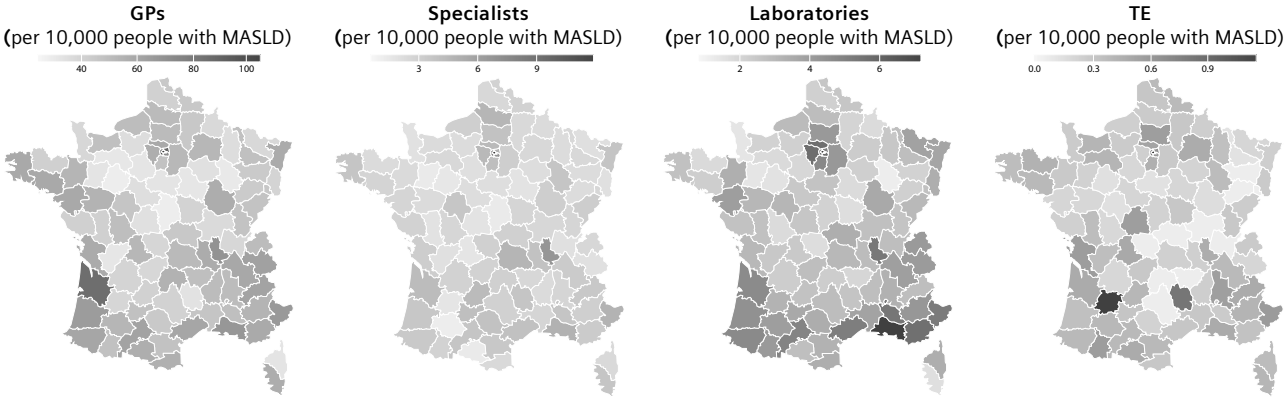

Figure 3. Per-capita availability of fibrosis-testing related healthcare services across France.

Service availability relative to MASLD population size varied across the country **(Figure 3)**, with pronounced differences observed in access to GPs, specialists, and TE services. The mean (SD; median) number of GPs per 10,000 population with MASLD was 44.4 (12.6; 44), ranging from 24.7 in Cher to 106.0 in Paris. Mean (SD; median) specialist availability was 2.48 (1.45; 2) per 10,000 people with MASLD (range: 0.648 to 11.8). Importantly, mean availability of TE services was 0.265 (0.20; 0.23) per 10,000 people with MASLD and higher in metropolitan areas such as Paris relative to departments in central and Eastern France. In contrast, laboratory availability was more equally distributed, with a mean (SD; median) of 2.87 (1.24; 3) laboratories per 10,000 people with MASLD.

In general, availability of services was higher in Southern France, Paris and Lyon compared with Central and Eastern France reflecting the rural-urban divide. Interestingly, the analysis revealed that the areas with the highest MASLD prevalence were comparatively underserved, while those areas with a lower proportion of affected individuals had better access to healthcare services **(Figure 4)**, indicating a suboptimal distribution of healthcare services across the country.

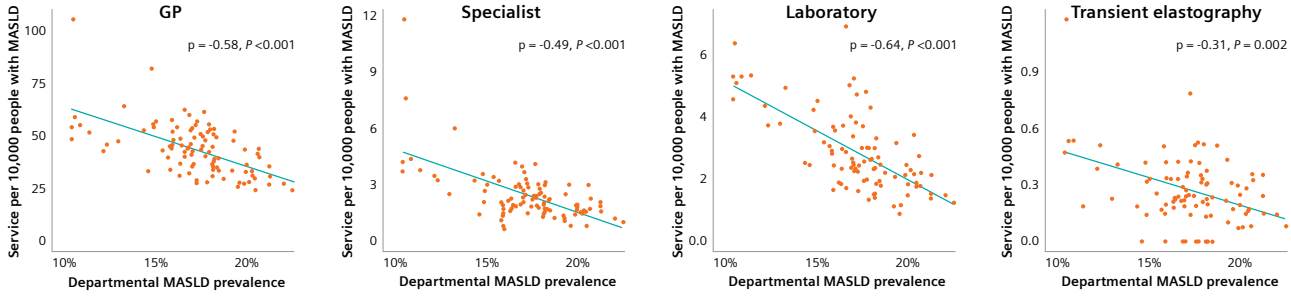

Figure 4. Correlation between departmental MASLD prevalence and service availability.

Accessing services, especially TE, imposes a significant travel burden on people with MASLD

An average roundtrip to the nearest TE service required 62 minutes travel time **(Figure 5)**, when weighted to the local MASLD population size, and was associated with 4,549 g CO_2 emissions **(Figure 6)**. In comparison, GPs were more accessible, with an average 16-minute journey and roundtrip CO_2 emission of 417 g.

Travel duration varied notably between regions in France—the mean travel duration, on a departmental level, to the nearest TE was 87 minutes, but ranged between 20 and 197 minutes. In departments in central France, the Vosges and Alps, and on Corsica, the average travel duration was the longest, with all twelve departments located in these regions requiring a mean TE travel duration of more than 2h in **(Figure 7)**.

GPs and laboratories were more accessible and could be reached within 60 minutes from 99% and 88% of communities' geographic centers, respectively. In contrast only 69% and 31% of communities could access specialist and TE services within 60 minutes, respectively, indicating long distances and travel durations to hepatologic healthcare services for a significant number of communities.

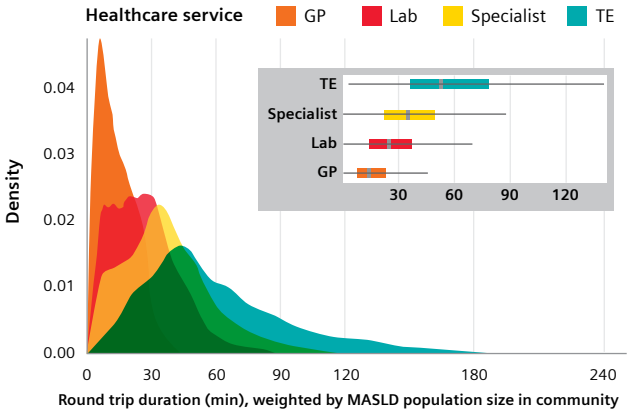

Figure 5. Travel duration to healthcare services, weighted by community populations with MASLD.

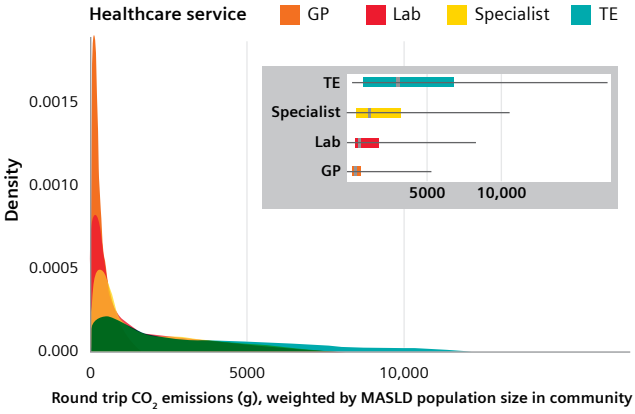

Figure 6. CO_2 emitted by travel to healthcare services, weighted by community populations with MASLD.

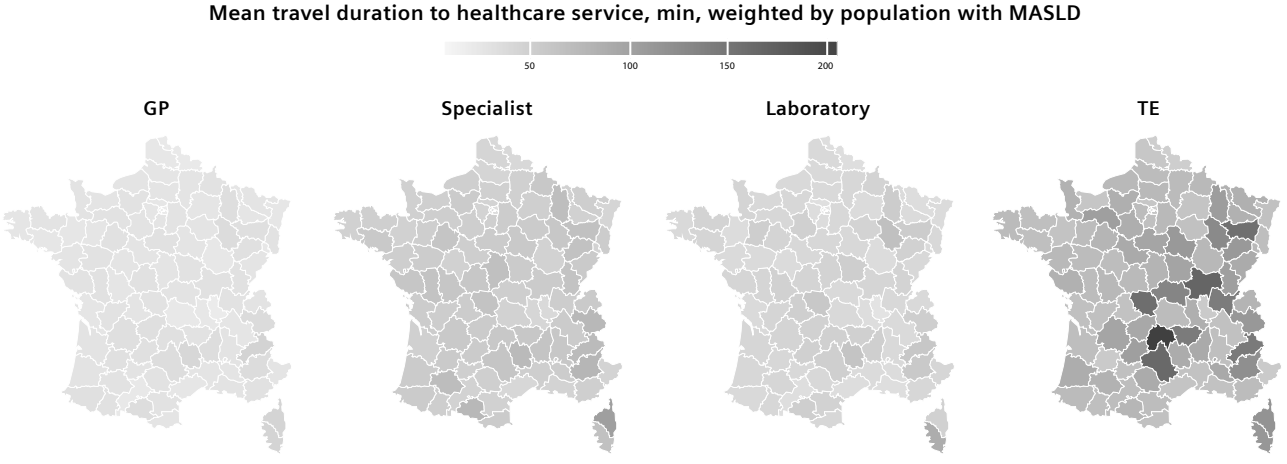

Figure 7. Travel duration to nearest healthcare service, weighted by community populations with MASLD and per department.

Implementing a FIB-4/ELF testing algorithm would result in benefits to the French healthcare system, patients and the environment

A total population size of 10,698,720 MASLD patients across France was simulated in the comparative analysis. The use of the ELF test following an indeterminate FIB-4 result instead of TE was predicted to result in 3.2 million fewer healthcare visits to GPs, specialists, TE services and laboratories, representing a 12% reduction compared to using TE after indeterminate FIB-4 **(Table 2**). The analysis revealed that almost 47,000 unnecessary follow-up visits with specialists could be avoided with the FIB-4/ELF pathway due to better filtering of indeterminate FIB-4 results. The reduction in healthcare visits was estimated to save nearly 3.3 million hours in travel time, equivalent to a 27% reduction versus the FIB-4/TE pathway. This reduction in travel with the FIB-4/ELF testing pathway was associated with a 41% reduction in carbon emissions, including nearly 100 tons saved from avoided visits. The FIB-4/ELF testing algorithm conferred travel and carbon emissions benefits over the FIB-4/TE pathway even in a scenario where half of the laboratories were assumed not to offer the ELF tests, confirming the robustness of the study findings. It is likely that not all laboratories would be equipped to perform the ELF test and would send samples to a central laboratory for processing. In this analysis, the CO_2 impact of transporting samples between laboratories was not modelled due to lack of data on laboratory organizational structure, however, the incremental effect of adding additional samples to scheduled courier services was assumed to be negligible.

Significance of findings

This study is the first to evaluate access to hepatology services across France and to model environmental and patient-relevant outcomes in relation to non-invasive testing for advanced fibrosis in MASLD.[14] This analysis revealed significant geographic disparities in access to specialists, and TE service, particularly in rural regions. These findings are consistent with the well documented problem of 'medical deserts' in France, and the regions identified in this analysis as having particularly poor access to healthcare services in relation to liver services correlate well with previously published reports on access to healthcare in general.[17,27]

Medical deserts in France are not solely defined by geographical remoteness but disproportionately affect socio economically disadvantaged and ageing populations. This is particularly relevant for MASLD, for which both disease prevalence and risk of progression are strongly linked to socioeconomic status.[28–30] The finding that spatial access to hepatology services is inversely related to the size of the MASLD population further underscores the role of socioeconomic factors in healthcare inequality. Although this study used travel distance and travel duration as proxies for healthcare accessibility, these findings suggest that populations living in medically underserved areas may experience a dual disadvantage, combining increased underlying risk of MASLD with greater structural and economic barriers to timely intervention. Note, however, that the study also has limitations, such as community centroids not necessarily reflecting population concentration (especially in rural communities) and healthcare

Table 2. Comparison of travel burden for FIB-4 / ELF and FIB-4 / TE testing pathways.

	Mean values		Absolute difference (ELF vs. TE)	% difference (ELF vs. TE)
	FIB-4/ELF	FIB-4/TE		
Visits, futile	607,879	654,828	–46,949	–7
Visits, all	23,004,661	26,246,543	–3,241,883	–12
Duration for futile healthcare travel (hours)	383,230	412,828	–29,598	–7
Duration for all healthcare travel (hours)	8,711,983	12,007,936	–3,295,954	–27
CO_2 emissions for futile healthcare travel (tons)	1275	1373	–98	–7
CO_2 emissions for all healthcare travel (tons)	21,024	35,351	–14,327	–41

location coding for GPs, laboratories, and specialists being based on Annuaire Santé speciality and activity codes (which may have overestimated specialist availability in particular).

Key policy objectives in high-income countries, including France, involve addressing increasing health inequalities as well as reducing CO_2 emissions. In this context, the current study not only identifies disparities in access but provides evidence supporting the increasing use of blood-based non-invasive tests in primary care.[14]

Real-world evidence indicates that sequential use of FIB-4 followed by ELF can be successfully implemented as part of primary and secondary clinical care pathways to help guide treatment decision-making in MASLD.[10–13,31] Furthermore, there is real-world and economic evidence demonstrating a beneficial impact of FIB-4/ELF test on referrals, healthcare resource use and costs versus standard care. For example, real-world adoption of a two-step testing pathway consisting of FIB-4 followed by the ELF test reduced unnecessary referrals by 80% compared with standard care in the UK.[10] The new spatial study now demonstrates a significant reduction in healthcare visits by using the ELF test rather than TE to confirm indeterminate FIB-4 results in France. They also suggest a meaningful impact on referral rate and healthcare resource use with increased use of the ELF test as a second-line test in primary care.

The reductions in travel burden associated with an ELF-based testing pathway could both improve access to and availability of fibrosis testing, without loss of accuracy.[14] These findings contribute to the ongoing debate in the liver community on the optimization of non-invasive testing pathways in light of the rapidly increasing prevalence of MASLD and the approval of novel MASH-specific therapies. While current guidelines recommend a sequential approach to fibrosis testing—typically FIB-4 / TE—it is evident that awareness and adoption amongst healthcare professionals remains suboptimal, in part due to inconsistencies amongst different guidelines and availability of certain tests.[32]

Conclusion

This new spatial analysis adds to the existing body of evidence supporting the use of FIB-4/ELF and provides novel evidence suggesting that reflex testing involving the ELF test could result in significant environmental benefits compared with a FIB-4/TE pathway. These findings resonate beyond France and align well with current global healthcare policy objectives in relation to equality of access to fibrosis testing, carbon footprint targets, and patient-centered care. This approach could be replicated in other countries to identify gaps in access to liver fibrosis testing for individuals with MASLD and estimate the environmental impact of incorporating the ELF test into sequential testing pathways in primary care.

About ELF test

Enhanced Liver Fibrosis (ELF) is an in vitro diagnostic test that measures three analytes of the extracellular matrix (hyaluronic acid, amino-terminal propeptide of type III procollagen, and tissue inhibitor of matrix metalloproteinase-1) that reflect active, dynamic fibrosis rather than the damage it has caused.

Outside the United States, ELF test is CE-marked for the assessment of liver fibrosis severity in patients with signs, symptoms, or risk factors of chronic liver disease to support diagnosis for fibrosis staging or prognosis for likelihood of progression to cirrhosis and liver-related clinical events. In the United States, ELF is indicated to aid prognostic evaluation of disease progression (to cirrhosis and liver-related clinical events) in NASH (MASH) patients with advanced liver fibrosis.

Interpretation of results

ELF score	Risk of disease progression (development of cirrhosis or liver-related events)
<9.80	Lower
≥9.80–<11.30	Mid[a]
≥11.30	Higher

[a]*In the Mid group, the risk of disease progression is similar to the pre-test risk. Pre-test risk refers to the likelihood of disease progression in the overall intended use population without considering the ELF score.*

Results should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Talk to your Siemens Healthineers representative to learn more about the ELF test and don't miss the opportunity to demonstrate the vital role and value of your clinical laboratory in MASLD patient management! Also, discover the comprehensive menu of solutions and tests Siemens Healthineers offers to manage chronic liver diseases.

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