Project scope: Intelligent Liver Function Testing (iLFT), including Enhanced Liver Fibrosis (ELF) testing, for the earlier diagnosis of chronic liver disease (CLD)

September 2025

Research question(s)

1. What is the clinical effectiveness, cost effectiveness, safety and experience of iLFT (including ELF testing) for the earlier diagnosis of CLD, compared with usual care in adults with suspected CLD?

Inclusion criteria

The selection of studies for inclusion in the literature review element of the project will be based on the following criteria:

Population	▪ Adults (aged 18 years and older), without a known diagnosis of CLD presenting to primary care where liver enzyme tests (known as Liver Function Tests [LFT]) are requested
Intervention	▪ An algorithm-based, automated system of laboratory analysis for LFTs (iLFT), with the addition of ELF testing as a second-line test for fibrosis
Comparator	▪ Usual care
Outcomes	Primary ▪ Diagnosis rate of liver disease ▪ Time to diagnosis ▪ Number of referrals to secondary care ▪ Number of patients who can be safely managed in primary care ▪ Quality of care ▪ Cost effectiveness Secondary ▪ Staging of liver disease

	▪ Performance (diagnostic and technical, including positive predictive value, negative predictive value, sensitivity, specificity) ▪ Number of GP consultations ▪ Hospital admissions ▪ Liver-related morbidity and mortality (eg decompensation) ▪ Health-related quality of life (HRQoL) ▪ Safety ▪ Experience (staff and patients with suspected CLD)
Setting	▪ Primary care
Limits	▪ English language

Exclusion criteria

The exclusion of studies from the literature review element of the project will be based on the following criteria:

Population	▪ Children and young people (younger than 18 years)
Intervention	▪ ELF only
Comparator	▪ -
Outcomes	▪ -
Setting	▪ Any other setting other than primary care
Limits	▪ Non-English language

Planned activities

SHTG have agreed on the following activities to support the development of SHTG Innovative Medical Technology Overview (IMTO) on ELF and iLFT testing:

- An evidence review of literature on clinical effectiveness, cost effectiveness, safety and experience
- Indicative cost / budget impact analysis.

End products

At the end of the project, SHTG will publish:

- An SHTG IMTO.

Timescales (approximate)

Publication in December 2025.