Budget Impact Analysis of Introducing the Elecsys® PRO-C3 assay as part of the ADAPT Algorithm for Assessing the Severity of Hepatic Fibrosis in Patients with Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) in the UK

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Background

- MASLD (metabolic dysfunction-associated steatotic liver disease) is a condition defined by the presence of hepatic steatosis in people with metabolic risk factors such as obesity, diabetes, or high blood pressure[1]
  - o MASLD affects approximately 30–38% of the general population and is highly underdiagnosed[2-5]
- Metabolic dysfunction-associated steatohepatitis (MASH), a progressive form of MASLD that affects ~25% of MASLD patients, can lead to liver cirrhosis, hepatocellular carcinoma and cardiovascular outcomes[6-8]
- In the UK, MASLD is typically first assessed with the Fibrosis-4 Index (Fib-4), followed by more specific tests such as the Enhanced Liver Fibrosis (ELF) blood test, vibration-controlled transient elastography (VCTE; FiboScan® in the model), or acoustic radiation force impulse (ARFI), when needed
- Despite the availability of current diagnostic tools, there remains an unmet need for a simplified, accurate, and affordable approach that provides rapid assessment through decentralised blood-based testing, and eases burden on healthcare services, particularly in light of the projected global increase in disease burden[9]
- The Elecsys® PRO-C3, used with the ADAPT algorithm, is a CE marked test designed to assess hepatic fibrosis severity in patients showing signs or evidence of MASLD
  - o The ADAPT algorithm incorporates age, diabetic status, PRO-C3 (a type III collagen formation marker), and platelet count

Objective

To evaluate the budget impact of introducing ADAPT to assess hepatic fibrosis severity for patients with MASLD in the UK over a 5-year time horizon.

Methods

- An excel-based budget impact model (BIM) was developed to compare the costs of diagnostic pathways incorporating ADAPT with others representing current care
- Progression through test sequences was assumed following a positive test
- The BIM included initial and subsequent testing for hepatic fibrosis in primary and secondary care
- The base-case settings and model structure are represented in **Table 1** and **Figure 1**, respectively. **Table 2** presents a list of key inputs included in the analysis

Table 1 Decision problem

Component	Base case approach			
Population	Patients with suspected advanced liver fibrosis due to MASLD			
Testing sequence (market shares - clinician estimates)	World with ADAPT	• FIB-4 → ADAPT → VCTE (85%) • FIB-4 → ADAPT → ARFI (15%)	World without ADAPT	• FIB-4 → ELF → VCTE (42.5%) • FIB-4 → VCTE (42.5%) • FIB-4 → ELF → ARFI (7.5%) • FIB-4 → ARFI (7.5%)
Time Horizon	5 years			
Outcomes	Costs by year broken down by category (test costs, drug costs)			
Perspective	NHS and PSS in England and Wales (aligned with guidance from NICE[10])			

Figure 1 Model structure

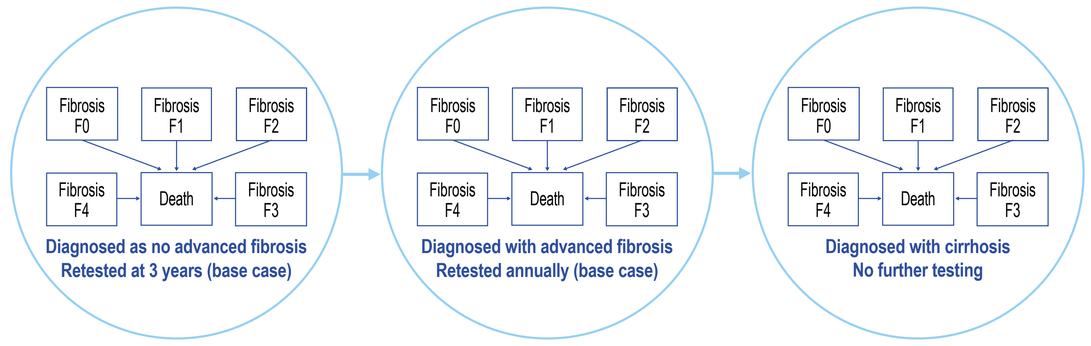

Table 2 Inputs included in the budget impact analysis

	ADAPT	ELF	VCTE	FIB-4	ARFI
Clinical data					
Advanced fibrosis diagnostic accuracy measures:					
Sensitivity	46%[11]	65%[12]	80%[13]	69%[14]	92%[15]
Specificity	90%[11]	86%[12]	77%[13]	64%[14]	85%[15]
Baseline characteristics	Mean age: 64 years[16]				
Mortality	Background mortality with MASLD adjustment[17]; HR: 1.32				
Cost data					
Testing costs	£31.50†	£42.00[18]	£65.00[19]	£4.40[19]	£65.00[20]
Consultation costs	GP surgery: £49.00[21] | Hepatology visit: £254.35[22]				
Drug acquisition costs	Resmetirom: £7.63 per 100 mg† (scenario) | Cardevilol: £0.73 per 87.50 mg[23]				

†Internal estimates

Results

- Assuming an increase in diagnosis of MASLD/MASH from 18% of patients in 2025 to 22% in 2029, projected tests were 254,447 in 2025, increasing to 286,410 by 2029 (**Table 3**)
- Over 5 years, testing cost totalled £282 million under current care, compared with £192 million with ADAPT, yielding total savings of £91 million (**Figure 2, Figure 3**)
- Scenario analyses explored the impact of different diagnostic sequences, showing net savings ranging from £33 million to £767 million (**Table 4**)

Figure 2 Total cost breakdown by category – 5-years

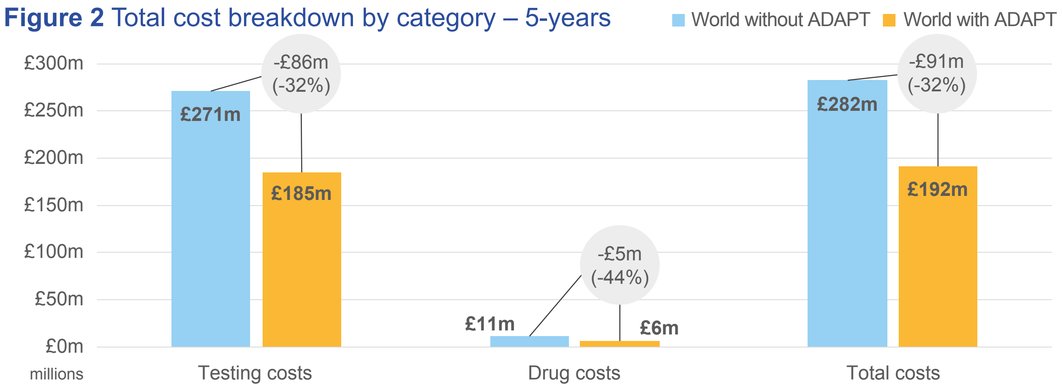

Figure 3 Disaggregated 5-year net cost savings

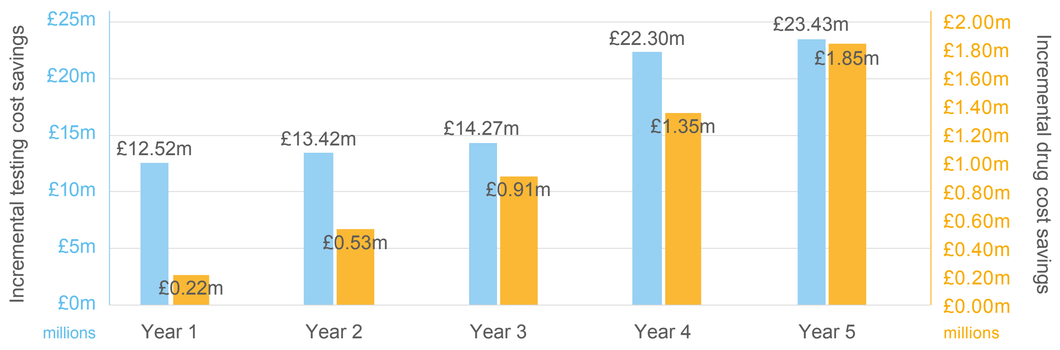

Table 3 Eligible patient population

	Calculation	Baseline: 2024	2025	2026	2027	2028	2029
Prevalent population	Linear interpolation: 2016–2030[24]	15,914,286	16,078,571	16,242,857	16,407,143	16,571,429	16,735,714
Proportion diagnosed	Lazarus et al., 2025[25] and projections	17%	18%	19%	20%	21%	22%
Total diagnosed	Prevalent population x % tested	2,705,429	2,894,143	3,086,143	3,281,429	3,480,000	3,681,857
Annual mortality rate	Based on Fu et al, 2023[17]	–	2.43%	2.43%	2.43%	2.43%	2.43%
Diagnosed patient deaths	Diagnosed in previous year x mortality rate	–	65,733	70,318	74,983	79,728	84,553
Diagnosed previously and alive	Diagnosed in previous year – deaths	–	2,639,695	2,823,825	3,011,160	3,201,700	3,395,447
Additional tests required to reach diagnosis rate	Total diagnosed – diagnosed previously and alive	–	254,447	262,318	270,269	278,300	286,410

Table 4 Scenario analyses

Scenarios	Cost savings	% change from base case
Biologic therapy (resmetirom) for treatment of stage F3 fibrosis	£767,427,264	745%
Proportion of patients diagnosed with MASLD rising at 2% (absolute) per year	£148,774,715	64%
Proportion of patients diagnosed with MASLD rising at 0% (absolute) per year	£32,835,313	–64%
Exclusion of correlation between different tests in sequences	£100,885,731	11%
Resmetirom price of £15 per 100 mg	£1,421,313,873	1,465%
Simulation of age distribution of cohort in place of reported data	£96,815,122	7%
FIB-4 not used in 20% of test sequences in world without ADAPT	£142,145,795	57%

Conclusion

MASLD testing is likely to rise over the next 5 years as availability of treatments increases. The introduction of ADAPT could substantially reduce the impact of testing on healthcare budgets, with testing specificity identified as the primary driver of potential savings.

Limitations

- Correlations between tests within sequences and repeated tests over time were captured. However, the extent of correlation was estimated in the absence of data
- The model did not allow for subsequent correction of false positive results
- Market share data for test sequences comprising current care were estimated based on clinical opinion
- Fibrosis progression was not modelled

Abbreviations: **ARFI**, acoustic radiation force impulse; **BIM**, budget impact model; **ELF**, Enhanced Liver Fibrosis; **FIB-4**, Fibrosis-4; **HR**, hazard ratio; **ICER,** incremental cost-effectiveness ratio; **MASH**, metabolic dysfunction-associated steatohepatitis; **MASLD**, metabolic dysfunction-associated steatotic liver disease; **NHS**, National Health Service; **NICE**, National Institute for Health and Care Excellence; **PSS**, personal social services; **QALY,** quality-adjusted life year; **UK**, United Kingdom; **VCTE**, vibration controlled transient elastography.

References

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