NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 28 September 2022

**Location:** Via Zoom

## Attendees

Committee members present

1. Brian Shine (Chair) Present for all items
2. Keith Abrams Present for items 1 – 2.4.3
3. Joy Allen Present for all items
4. Rebecca Allcock Present for items 3 – 3.4.2
5. Katherine Boylan Present for items 3 – 3.4.2
6. John Cairns Present for all items
7. Sam Creavin Present for all items
8. Diane Davies Present for all items
9. Stephen Habgood Present for items 3 – 3.4.2
10. Neil Hawkins Present for items 1 – 2.4.3
11. Emily Lam Present for items 3 – 3.4.2
12. Avril McCarthy Present for items 3 – 3.4.2
13. Alexandria Moseley Present for all items
14. Radha Ramachandran Present for all items
15. Karen Sennett Present for items 3 – 3.4.2
16. Matt Stevenson Present for all items
17. Alasdair Taylor Present for all items

NICE staff present

Sarah Byron, Programme Director Present for items 3 – 3.4.2

Rebecca Albrow, Associate Director Present for all items

Thomas Walker, Health Technology Assessment Adviser Present for all items

Jacob Grant, Health Technology Assessment Analyst Present for items 1 – 2.4.3

Suvi Harmala, Health Technology Assessment Analyst Present for items 3 – 3.4.2

Toni Gasse, Project Manager Present for all items

Alex Sexton, Administrator Present for all items

External assessment group representatives present

Rebecca Bresnahan, Research Associate, Present for items 1 – 2.3.6

Liverpool Reviews & Implementation Group

James Mahon, Director, Coldingham Analytical Services Present for items 1 – 2.3.6

External assessment centre representatives present

Andrew Sims, Centre Director, Newcastle External Assessment Present for items 3 – 3.3.7
Centre

Kim Keltie, Lead Healthcare Scientist, Newcastle External Present for items 3 – 3.3.7
Assessment Centre

Luke Vale, Professor of Health Economics, Newcastle University Present for items 3 – 3.3.7

Specialist Committee Members present

Heather Boult, Lay specialist committee member Present for items 1 – 2.4.3

Pinelopi Manousou, Consultant in hepatology, Present for items 1 – 2.4.3

Imperial College NHS Trust

Alistair O'Brien, Professor and honorary consultant Present for items 1 – 2.4.3

hepatologist, UCLH & The Royal Free Hospitals

Jeremy Shearman, Consultant gastroenterologist Present for items 1 – 2.4.3
and hepatologist, Warwick Hospital

Experts present

Vanessa Hebditch, Director of communications & policy, Present for items 3 – 3.3.7

British Liver Trust

Helen Jarvis, GP Partner, NIHR clinical doctoral Present for items 3 – 3.3.7

research fellow, Newcastle University

Janisha Patel, Consultant hepatologist, University Present for items 3 – 3.3.7

Hospital Southampton

Observers present

Tara Chernick, Health Technology Adoption Manager Present for items 3 – 3.4.2

Lyn Davies, Coordinator, NICE Present for items 1 – 2.3.6 and

 and 3 - 3.3.7

Laura Marsden, Public Involvement Adviser, NICE Present for all items

Edgar Masanga, Business Analyst, NICE - Present for items 1 – 2.4.3

Ian Mather, Business Analyst, NICE Present for items 3 – 3.3.7

Matthew Brown, Digital Media Manager, NICE Present for items 1 – 2.4.3

Jean Isaac, Health Technology Assessment Analyst Present for all items

## Minutes

### The Chair welcomed members of the committee and other attendees to the meeting. The Chair thanked Alexandria Moseley, attending her last committee meeting, for all her work and contributions during her time as a lay standing committee member. He also thanked Shelley Rahman Hayley, who was not able to attend the meeting, and who was now standing down as a member of the committee, for her input and contributions.

### Evaluation of MRI-based technologies for assessing non-alcoholic fatty liver disease

* 1. The Chair noted apologies from standing committee members Liz Adair, Brendan Meyer, Michael Messenger, Patrick McGinley, and Karen Sennett.

He also noted that Rebecca Allcock was not attending because of a conflict of interest.

He further noted apologies from specialist committee members Raneem Albazaz and David Breen.

* 1. The committee approved the minutes of the committee meeting held on Wednesday 31 August 2022.
	2. Part 1 – Open session

The Chair welcomed external assessment group (EAG) representatives, members of the public, and company representatives from Perspectum Ltd and Resoundant Inc.

* + 1. The Chair asked all committee members to declare any new relevant interests in relation to the item being considered. The following standing committee members had notified these interests in advance of the meeting:

Rebecca Allcock declared an indirect interest as her spouse is employed by GE Healthcare, as the UKI Public Private Partnerships Service Manager, although he has no direct involvement in any projects that cover MRI-based technologies for the assessment of NAFLD. It was agreed that this interest meant Rebecca Allcock could not participate in the discussions and she did not attend the meeting.

 Joy Allen declared a financial interest as she is an employee of Roche Diagnostics UK and Ireland (since August 2021). Roche manufactures the commercially available Elecsys® GAAD test for the aid in diagnosis of early-stage HCC. She also declared an indirect interest as her spouse is employed by Siemens Gamesa (renewable energy manufacturer), majority shareholder being Siemens. Siemens Healthineers and Siemens are separate businesses. It was agreed that these interests would not prevent Joy Allen from participating in the meeting.

 John Cairns declared financial interests as he had advised Takeda on the economic evaluation of maribavir (interest ceased August 2021) and he had provided advice on HTA of epilepsy treatments at a meeting organised by PWC Switzerland (completed Dec 2021). It was agreed that these interests would not prevent John Cairns from participating in the meeting.

Sam Creavin declared a financial interest as, in March 2022, he had attended a one-off one-hour session from the commercial sector to discuss the general process for diagnostics tests, including for liver problems (no specific companies were named). It was agreed that this interest would not prevent Sam Creavin from participating in the meeting.

Neil Hawkins declared that a company of which he is a director has provided consultancy services to Echosens, the manufacturers of the Fibroscan transient elastography device which is indicated in the diagnosis of fibrosis and cirrhosis. It was agreed that this interest would not prevent him from participating in the meeting.

Alasdair Taylor declared indirect interests as he is a Member of the British Society of GI and Abdominal Radiologists (since 2000), and an elected member of the governing council of the Royal College of Radiologists (since September 2020). It was agreed that these interests would not prevent Alasdair Taylor from participating in the meeting.

The following specialist committee members had notified these interests in advance of the meeting:

Heather Boult declared non-financial professional and personal interests as she is a lay member of the Pelvic Floor Dysfunction NICE guidelines committee; a member of the Children’s Liver Foundation; a member of the Peninsula Public Engagement Group (PenPEG) at Exeter Medical School, Exeter University; and a member of the Patient Participation and Involvement (PPI) Advisory Group, in the Academy of Nursing, University of Exeter. It was agreed that these interests would not prevent Heather Boult from attending the meeting.

Alastair O’Brien declared financial interests as he undertakes private practice at The London Clinic and will transfer to The Cleveland Clinic, London from September 2021. He has no input on the selection of liver MRI software or other equipment for either organisation. It was agreed that this interest would not prevent Alastair O’Brien from participating in the meeting.

Jeremy Shearman declared a financial interest as he undertakes private medical consultations (as Shearman & Haggett Medical Limited). He also declared non-financial professional and personal interests as he is a trustee of the Shakespeare Hospice, Stratford-upon-Avon. He also declared an indirect as he is chair of the clinical advisory panel of the patient charity Haemochromatosis UK. It was agreed that these interests would not prevent Jeremy Shearman from participating in the meeting.

* + 1. The Committee proceeded to discuss the comments made during the public consultation for the ‘MRI-based technologies for assessing non-alcoholic fatty liver disease’ topic.
		2. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
		3. The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.
		4. The Chair thanked the manufacturer representatives, the EAG and public observers for their attendance at the meeting.
		5. The Chair explained that representatives of the press and other members of the public were excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest (Section 1(2) Public Bodies (Admission to Meetings) Act 1960) and all public attendees left the meeting.
	1. Part 2 - Closed session
		1. The committee discussed confidential information submitted for this item.
		2. The committee then agreed on the content of the Diagnostics Guidance Document (DGD). The committee decision was reached by consensus.
		3. The committee asked the NICE technical team to prepare the DGD in line with their decisions.

### Evaluation of FibroScan for assessing liver fibrosis and cirrhosis in primary or community care

* 1. The Chair welcomed members of the committee and other attendees present to the meeting.
	2. The Chair noted apologies from standing committee members Liz Adair, Brendan Meyer, Michael Messenger and Patrick McGinley.

He further noted that Keith Abrams and Neil Hawkins were not attending due to conflicts of interest.

* 1. Part 1 – Open session
		1. The Chair welcomed the invited patient and professional experts, external group representatives, members of the public, and company representatives from Echosens.
		2. The Chair asked all committee members and invited experts to declare any new relevant interests in relation to the item being considered. The following standing committee members had notified these interests in advance of the meeting:

Keith Abrams declared a financial interest as he is a Partner and Director, Visible Analytics Limited, a HTA Consultancy company, but has not been involved in any projects which involve a diagnostic technology. However, Visible Analytics is undertaking a project for Echosens on evaluating FibroScan for assessing liver fibrosis and cirrhosis in primary care. He is not involved in the project in any way and measures have been taken to avoid potential conflicts. It was agreed that this interest meant Keith Abrams should be excluded from the discussions and he did not attend the meeting.

Joy Allen declared a financial interest as she is an employee of Roche Diagnostics UK & Ireland. Roche manufactures the commercially available Elecsys® GAAD test for the aid in diagnosis of early-stage HCC. She declared non-financial personal and professional interests as she has Guest Researcher status, Newcastle University, for collaborations with the NIHR In Vitro Diagnostics Co-operative on diagnostic test evaluation methodology. She is co-author on a number of publications describing evaluation of diagnostic test evaluations, some of which include commercially supplied tests. All evaluations which she undertook during her time at the NIHR Diagnostic Evidence Co-operative and more recently at the Newcastle In Vitro Diagnostics Co-operative were independent investigator- initiated studies. Range of funding as co-applicant or PI in her previous roles:

* + - * Co-applicant on NIHR i4i Connect Award: ‘GlycoScore: Superior prostate cancer diagnosis using a simple blood test’. Role: Lead on the care pathway analysis and early economic modelling studies. Feb 2021 – April 2022. Award Value: £150K
			* Co-Investigator on UKRI funded ‘COVID-19 National Diagnostic Research and Evaluation platform (CONDOR)’. This is study is on the Urgent Public Health Portfolio. Role: Lead the Care Pathway Analysis workstream. May 2020- June 2021. Award Value: £1.3m
			* Co-applicant on NIHR Product Development Award ‘Development of RxSelex: A microbiome-based predictive diagnostic of IBD biologics treatment outcome’. Role: Lead on barriers to adoptions studies. . Jan 2019 – Aug 2021 Award value: £1.2m
			* Co-applicant on MRC CIC funded ‘GlycoScore: Validation of a non-invasive diagnostic test to distinguish benign and aggressive prostate cancer’

Role: Lead Early feasibility pathway studies. Jan 2020 – Sept 2020. Award Value: £80K

* + - * Co-applicant on HTA commissioned call entitled `Primary care management of lower urinary tract symptoms in men: Development and validation of a diagnostic and decision-making aid (The PriMUS Study)’. Role: Lead in the development of the prototype decision aid and mathematically modelling the effect of the tool on secondary care referral rates. May 2017 – April 2020. Award value: ~£1.56m
			* Co-applicant on HTA commissioned call entitled `Antifungal stewardship opportunities with rapid tests: The A-Stop Study’. Role: Lead on novel statistical analyses to overcome imperfect reference standard. April 2017 – March 2021. Award value: ~£1.5m

It was agreed that these interests would not prevent Joy Allen from participating in the meeting.

Katherine Boylan declared a non-financial professional and personal interest as Manchester University NHS Foundation Trust (MFT) [her employer] is part of a project (ID-LIVER) funded by Innovate UK, led by the University of Manchester, around the early detection of liver disease. Echosens is not a partner on the bid, but MFT entered into a loan agreement to get access to the Fibroscan to allow the technology to be used within the community liver assessment clinics that have been set up as part of the ID-LIVER project. In return, MFT will share fully anonymised scan data and basic patient demographics. There is no financial recompense or other value negotiated (in either direction). It was agreed that this interest would not prevent Katherine Boylan from participating in the meeting.

 John Cairns declared financial interests as he had advised Astellas on health economic modelling for roxadustat (interest ceased May 2021) and Takeda on the economic evaluation of maribavir (interest ceased August 2021). It was agreed that these interests would not prevent John Cairns from participating in the meeting.

 Stephen Habgood declared non-financial personal and professional interests as he is a member of the NICE Medical Technology Advisory Group. He is Director of a Community Interest Company, ‘Making Families Count’, which delivers workshops to NHS managers about involving families in the investigation into such events as suicides and homicides, for which he is paid expenses and an attendance fee. He was Chairman of the national charity PAPYRUS Prevention of Young Suicide (interest ceased June 2019). He was a lay member of the Midlands Therapeutics Review and Advisory Committee (MTRAC) (interest ceased April 2021). He was on a Nice Quality Standards Advisory Committee, developing Quality Standards for the Guideline for Suicide Prevention in the Community and Custody Settings (interest ceased 2019). He is Assistant Priest, Parish of Eccleshall in the Diocese of Lichfield. He was Advisor to the Board of Trustees of the charity Survivors of Bereavement by Suicide (interest ceased 2021). It was agreed that these interests would not prevent Stephen Habgood from participating in the meeting.

Neil Hawkins declared a financial interest as he is a director of an HTA consultancy providing consultancy services to Echosens. He has no personal involvement in the provision of these services. It was agreed that this interest meant Neil Hawkins should be excluded from the discussions and he did not attend the meeting.

 Matt Stevenson declared a non-financial professional and personal interest as he undertook the pilot Diagnostics topic, which included FibroScan for the detection of liver fibrosis in patients with suspected alcohol-related liver disease. This work was published as an HTA monograph (Health Technology Assessment 2012: 16) and concluded that further data was needed before a robust estimate of the cost-effectiveness could be made. It was agreed that this interest would not prevent Matt Stevenson from participating in the meeting.

 Alasdair Taylor declared an indirect interest as he is an elected member of the council of the Royal College of Radiologists, representing the faculty of clinical radiology. It was agreed that this interest would not prevent Alasdair Taylor from participating in the meeting.

The following invited experts had notified these interests in advance of the meeting:

Vanessa Hebditch declared an indirect interest as Echosens provide a long-term loan of two FibroScan machines for the British Liver Trust to use as part of the charity’s ‘Love Your Liver’ roadshow events. She further declared that in June 2022 Echosens provided a grant of Euro10,000 (£8,565) towards the charity’s liver health awareness raising work. This goes towards the charities unrestricted funds. Echosens have no influence or input into any activity or content. It was agreed that these interests would not prevent Vanessa Hebditch from participating in part 1 of the meeting as an invited expert.

Helen Jarvis declared a financial interest as she is a GP partner owning business. She also declared non-financial personal and professional interests as she is on the clinical advisory board - British Liver Trust; clinical advisor for the Royal College of General Practitioners (RCGP); co-investigator on the SOLID study (MRC/NIHR funded study assessing biomarkers and FibroScan in the early detection of liver disease in the primary care setting) and author of a study assessing the availability of community pathways for liver disease including the use of FibroScan: <https://doi.org/10.3399/BJGPO.2021.0085>. It was agreed that these interests would not prevent Helen Jarvis from participating in part 1 of the meeting as an invited expert.

Janisha Patel declared a financial interest as in September 2021 she had attended the Echosens Liver Health Platform Focus group workshop. Payment was to her, declared to her institution. She also declared a non-financial personal and professional interest due to a pilot study in 2019: the University of Southampton NHS Foundation Trust owned FibroScan machine was taken to two different GP practices once a month to provide a community FibroScan service. The service was provided by an UHS employed nurse practitioner. She further declared a non-financial personal and professional interest due to the pay per scan FibroScan service commissioned by Hampshire and Southampton CCG which is ongoing. It was agreed that these interests would not prevent Janisha Patel from participating in part 1 of the meeting as an invited expert.

* + 1. The Committee proceeded to discuss the additional analyses submitted by the company for the ‘FibroScan for assessing liver fibrosis and cirrhosis in primary or community care’ topic.
		2. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
		3. The Chair asked the representatives of the manufacturer whether they wished to comment on any matters of factual accuracy.
		4. The Chair thanked the experts, the manufacturer representatives, the external group representatives and public observers for their attendance at the meeting.
		5. The Chair explained that representatives of the press and other members of the public were excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)” and all public attendees left the meeting.
	1. Part 2 - Closed session
		1. The committee and asked the NICE technical team to prepare documentation in line with their decisions.

### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (next topic) will be held on 31 October 2022.