NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 22 March 2022

**Location:** Via Zoom

## Attendees

Committee members present

1. Mark Kroese (Chair) Present for all items
2. Keith Abrams Present for items 1 – 2.3.3
3. Liz Adair Present for items 3 – 3.4.2
4. Joy Allen Present for all items
5. Rebecca Allcock Present for all items
6. John Cairns Present for all items
7. Diane Davies Present for all items
8. Stephen Habgood Present for items 3 – 3.4.2
9. Neil Hawkins Present for items 1 – 2.3.3
10. Emily Lam Present for items 3 – 3.4.2
11. Michael Messenger Present for items 3 – 3.4.2
12. Brendan Meyer Present for all items
13. Radha Ramachandran Present for all items
14. Karen Sennett Present for items 1 – 2.3.3
15. Matt Stevenson Present for all items
16. 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

Frances Nixon, Health Technology Assessment Adviser Present for items 1 – 2.3.3

Thomas Walker, Health Technology Assessment Adviser Present for items 3 – 3.4.2

Jacob Grant, Health Technology Assessment Analyst Present for items 3 – 3.4.2

Simon Webster, Health Technology Assessment Analyst Present for items 1 – 2.3.3

Donna Barnes, Project Manager Present for all items

Alex Sexton, Administrator Present for all items

External assessment group representatives present

Jo Lord, Director, Southampton Health Technology Present for items 1 – 2.2.7

Assessment Centre (SHTAC)

Jonathan Shepherd, Principal Research Fellow, SHTAC Present for items 1 – 2.2.7

Ines Souto Ribeiro, Consultant in Health Technology Present for items 1 – 2.2.7

 and modelling, SHTAC

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

Specialist Committee Members present

Tristan Barrett, Clinical Radiologist, Addenbrooke's Hospital, Present for items 1 – 2.3.3

Cambridge

Sanjeev Madaan, Consultant Urological Surgeon & Present for items 1 – 2.3.3

Lead Cancer Clinician, Darent Valley Hospital, Dartford

Jon Oxley, Consultant in Cellular Pathology, North Bristol Trust Present for items 1 – 2.3.3

Michele Pietrasik, Prostate Cancer Clinical Nurse Specialist, Present for items 1 – 2.3.3

Royal Surrey County Hospital NHS Foundation Trust

Graeme Spencer, Lay specialist committee member Present for items 1 – 2.3.3

Santhanam Sundar, Consultant Oncologist, Nottingham Present for items 1 – 2.3.3

University Hospitals NHS trust

David Wakefield, Lay specialist committee member Present for items 1 – 2.3.3

Hide Yamamoto, Consultant Urologist, Maidstone and Present for items 1 – 2.3.3

Tunbridge Wells NHS Trust

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

Victoria Carter, Health Technology Adoption Present for all items
Manager, NICE

Hayley Garnett, Senior Medical Editor, NICE Present for items 3 – 3.4.2

Abigail Kinch, Media Team apprentice Present for all items

Elsa Marques, Health Economist, University of Bristol Present for items 1 – 2.2.7 and

 and 3 - 3.3.7

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

Rosalee Mason, Coordinator, NICE Present for items 1 – 2.2.7 and

 and 3 - 3.3.7

Ian Mather, Business Analyst, NICE Present for all items

Harriet Wilson, Project Manager, NICE Present for all items

## Minutes

### Evaluation of Transperineal biopsy for diagnosing prostate cancer

### The Chair welcomed members of the committee and other attendees present to the meeting

The Chair noted apologies from standing committee members Liz Adair, Sam Creavin, Jim Gray, Patrick McGinley, Michael Messenger, Alexandria Moseley, Shelley Rahman Hayley and Brian Shine, and from specialist committee member Hashim Ahmed.

* 1. The committee approved the minutes of the committee meeting held on 23 February 2022.
	2. Part 1 – Open session
		1. The Chair welcomed external assessment group (EAG) representatives, members of the public and company representatives from BXTAccelyon, BK Medical, Delta Surgical Ltd, FujiFilm, JEB Technologies Ltd and Kebomed.
		2. The Chair welcomed Joy Allen and Radha Ramachandran as new committee members. The Chair recorded the committee’s thanks to Jim Gray (at what would have been his last meeting) for his very valuable contributions during his time on the committee over the last six years, including his role as lead standing committee member on a number of topics.
		3. 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:

Keith Abrams declared financial interests as since May 2019 to date 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.

He also declared non-financial professional and personal interests:

* £750K MRC/NIHR Methods Research Programme January 2019 (3.5 years). Dias S, Abrams KR, et al: Inferring relative treatment effects from combined randomised and observational data.
* £450K MRC/NIHR Methods Research Programme Oct 2021 (3 years). S Bujkiewicz, RK Owen, KR Abrams, et al: HCD: Novel approaches of multi-parameter evidence synthesis and decision modelling for efficient evaluation of diagnostic health technologies in HTA decision making with use of electronic health records

 It was agreed that these interests would not prevent Keith Abrams from participating in the meeting.

Joy Allen declared a financial interest as she is an employee of Roche Diagnostics UK & Ireland. Roche manufacture a PSA test to aid in screening for prostate cancer. 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.

 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.

 Neil Hawkins declared a financial interest in that a company of which he is a director has provided consultancy services regarding health technology assessment issues to a company (not one involved in this assessment) developing a potential treatments for advanced prostate cancer. No consultancy was provided or requested regarding diagnostic technologies. It was agreed that this interest would not prevent Neil Hawkins from participating in the meeting.

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

Tristan Barrett declared a financial interest due to private practice at Nuffield Hospital Cambridge (2 hours per week). He also declared non-financial professional and personal interests as he is a Prostate Cancer UK Research Advisory Committee Member; he was a member of the National Cancer Research Institute Prostate Clinical Studies Group (interest ceased 2021); a management committee member of the British Society of Urogenital Radiology (BSUR); he was an Independent International Expert Clinical Reviewer for National Cancer Control Programme (NCCP) Evidence-Based Cancer Guideline in Ireland (interest ceased 2021); and a member of the European Society of Urogenital Radiology (ESUR). He also declared an indirect interest as his spouse is employed as Research Scientist, Drug Discovery at Astra Zeneca. It was agreed that these interests would not prevent Tristan Barrett from participating in the meeting.

Sanjeev Madaan declared financial interests as he undertakes private practice; he had received remuneration for attending Bayer round table meeting February 2021; he had received remuneration for GP teaching in June 2021 sponsored by Ipsen and for a flexible cystoscopy webinar in July 2021 from Laborie. It was agreed that these interests would not prevent Sanjeev Madaan from participating in the meeting.

Jon Oxley declared financial interests due to shareholdings – GSK, AstraZeneca, Smith&Nephew, private practice, and a one-off consultancy to AstraZeneca in 2021 looking at genetic testing in prostate cancer. It was agreed that these interests would not prevent Jon Oxley from participating in the meeting.

Michele Pietrasik declared a non-financial professional and personal interest as BXTAccelyon Precision Point Device is used in her NHS clinics. She does not receive any payment from the company. It was agreed that this interest would not prevent Michele Pietrasik from participating in the meeting.

Santhanam Sundar declared financial interests as he had received payments for speaking engagements and sitting on advisory boards from Bayer (in 2021) and conference registration fee sponsorship also from Bayer (in 2021) and he undertakes private practice. It was agreed that these interests would not prevent Santhanam Sundar from participating in the meeting.

David Wakefield declared a financial interest due to his involvement with Wise Owl Business Solutions Ltd, providing computer training in databases and business intelligence software, including training NHS staff. He also declared a non-financial personal and professional interests he reads posts on the Prostate Cancer UK forum and sometimes post opinions and his own experiences but he has never expressed any opinion on biopsy methods. It was agreed that these interests would not prevent David Wakefield from participating in the meeting.

Hide Yamamoto declared financial interests as he received travels costs from BK Medical in 2019 to teach the transperineal biopsy technique to other urologists in NHS hospitals; and he undertakes private practice where on occasions he will perform a prostate biopsy in patients with suspected prostate cancer. He also declared non-financial personal and professional interests as he is Co-investigator for the TRANSLATE study, an NIHR funded randomized controlled study which compares the cancer detection rate between transperineal biopsy and transrectal biopsy; he was a teaching faculty member for the transperineal biopsy course at the British Association of Urological Surgeons Conference 2020; a publication is planned of results of a large series of patients using the BK device performed in his NHS Trust. It was agreed that these interests would not prevent Hide Yamamoto from participating in the meeting.

* + 1. The Committee proceeded to discuss the comments made during the public consultation for ‘Transperineal biopsy for diagnosing prostate

cancer’ topic. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.

* + 1. The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.
		2. The Chair thanked the manufacturer representatives, the EAG and public observers for their attendance at the meeting.
		3. 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 Sam Creavin, Jim Gray, Patrick McGinley, Alexandria Moseley, Shelley Rahman Hayley, Karen Sennett and Brian Shine. He further noted that Keith Abrams and Neil Hawkins were not attending due to conflicts of interest.
	3. 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.

 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.

 Michael Messenger declared non-financial professional and personal interests as he has conducted and published NIHR funded research on the Siemens/iQUR Enhanced Liver Fibrosis test (interest ceased October 2020). It was agreed that this interest would not prevent Michael Messenger from participating in 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. It was agreed that this interest 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 comments made during the public consultation for the of 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. A decision on the content of the Diagnostics Guidance Document (DGD) was deferred pending additional analysis being provided.

### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (next topic) will be held on 26 April 2022.