NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 19 January 2022

**Location:** Via Zoom

## Attendees

Committee members present

1. Mark Kroese (Chair) Present for all items
2. John Cairns Present for items 3 – 3.4.2
3. Sam Creavin Present for all items
4. Diane Davies Present for all items
5. Jim Gray Present for items 1 – 2.4.3
6. Neil Hawkins Present for items 1 – 2.4.3
7. Stephen Habgood Present for items 3 – 3.4.2
8. Shaheen Hamdy Present for items 3 – 3.4.2
9. Emily Lam Present for items 3 – 3.4.2
10. Patrick McGinley Present for all items
11. Brendan Meyer Present for all items
12. Alexandria Moseley Present for all items
13. Karen Sennett Present for all items
14. Alasdair Taylor Present for all items
15. Brian Shine Present for all items
16. Matt Stevenson 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 – 2.4.3

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 – 2.4.3

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 – 2.3.6

Assessment Centre (SHTAC)

Jonathan Shepherd, Principal Research Fellow, SHTAC Present for items 1 – 2.3.6

Ines Souto Ribeiro, Consultant in Health Technology Present for items 1 – 2.3.6

 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

Hashim Ahmed, Professor of Urology, Imperial College Present for items 1 – 2.3.6

Healthcare NHS Trust

Tristan Barrett, Clinical Radiologist, Addenbrooke's Hospital, Present for items 1 – 2.4.3

Cambridge

Sanjeev Madaan, Consultant Urological Surgeon & Present for items 1 – 2.4.3

Lead Cancer Clinician, Darent Valley Hospital, Dartford

Jon Oxley, Consultant in Cellular Pathology, North Bristol Trust Present for items 1 – 2.4.3

Michele Pietrasik, Prostate Cancer Clinical Nurse Specialist, Present for items 1 – 2.4.3

Royal Surrey County Hospital NHS Foundation Trust

Graeme Spencer, Lay specialist committee member Present for items 1 – 2.4.3

Santhanam Sundar, Consultant Oncologist, Nottingham Present for items 1 – 2.4.3

University Hospitals NHS trust

David Wakefield, Lay specialist committee member Present for items 1 – 2.4.3

Hide Yamamoto, Consultant Urologist, Maidstone and Present for items 1 – 2.4.3

Tunbridge Wells NHS Trust

Experts present

Neil Guha, Professor of Hepatology, University of Present for items 3 – 3.3.7

Nottingham

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

Fiona Beyer, Senior Research Associate, Newcastle University Present for items 1 – 2.3.6 and

 and 3 - 3.3.7

Nawaraj Bhattarai, Health Economist, Newcastle University Present for items 1 – 2.3.6
Tara Chernick, Health Technology Adoption Present for 3 – 3.4.2
Manager, NICE

Emilene Coventry, Senior Medical Editor, NICE Present for items 1 – 2.4.3

Amy Crossley, Technical Adviser, NICE Present for items 1- 2.4.3

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

 and 3 - 3.3.7

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

Will Hollingworth, Professor of Health Economics, University Present for items 1 – 2.3.6 and

of Bristol and 3 - 3.3.7

Jean Isaac, Technical Analyst, NICE Present for all items

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

Ian Mather, Business Analyst, NICE Present for all items

Peslie Ngambi, Technical Analyst, NICE Present for items 3 – 3.4.2

Nicole O’Connor, Training Fellow in Evidence Synthesis, Present for items 1 – 2.3.6 and

Newcastle University and 3 - 3.3.7

Heather Stephens, Senior Medical Technology Implementation Present for items 1 – 2.4.3
Manager, NICE

Katie Thomson, Research Fellow, Newcastle University Present for items 3 – 3.3.7

Sheila Wallace, Research Fellow, Newcastle University Present for items 1 – 2.3.6 and

 and 3 - 3.3.7

Penny Whiting, Professor of Clinical Epidemiology, University Present for items 1 – 2.3.6
of Bristol

## Minutes

### Evaluation of Transperineal biopsy in people with suspected prostate cancer

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

* 1. The Chair noted apologies from standing committee members Keith Abrams, Liz Adair, Rebecca Allcock, Shelley Rahman Haley and Michael Messenger.
	2. The committee approved the minutes of the committee meeting held on 17 November 2021
	3. Part 1 – Open session
		1. The Chair welcomed external assessment group (EAG) representatives, members of the public and company representatives from BXTAccelyon, BK Medical, FujiFilm, JEB Technologies Ltd and Kebomed.
		2. 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:

 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.

Patrick McGinley declared a financial interest as he is a Faculty Member of MTech Access, advising on NHS finance flows, and receives an honorarium for this. He also declared non-financial personal and professional interests as he is a Strategic Council member of the All-Party Parliamentary Group (APPG) on Obesity, and is the Honorary Treasurer for the Association for Study of Obesity (ASO). It was agreed that these interests would not prevent Patrick McGinley from participating in the meeting.

Brendan Meyer declared a financial interest due to employment and stocks of Becton Dickinson, which offers solutions for bone, breast, prostate, sentinel lymph node and soft tissue biopsies, but he is employed within an unrelated business unit within the organisation. It was agreed that this interest would not prevent Brendan Meyer from participating in the meeting.

Michael Messenger declared a financial interest as he is a co-inventor of the PinPoint Cancer Test, a machine learning based blood test for the diagnosis of cancer, including prostate cancer. Although he has no shares or other interests in PinPoint DataScience Ltd, he may benefit personally from this technology via a commercialisation agreement they hold with the University of Leeds. He also declared non-financial professional and personal interests as he has previously received funding from Myriad Genetics Inc to evaluate their PROLARIS test for prostate cancer prognosis (interest ceased October 2020). It was agreed that these interests would not prevent Michael Messenger 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 specialist committee members had notified these interests in advance of the meeting:

Hashim Ahmed declared the following financial interests: Publication commissioned by Urology journal on a debate type article. He co-authored the ‘pro’ for transperineal biopsy in its generic form. He was a paid consultant and received institutional funds for a trial from Sophiris Biocorp to develop, conduct and manage their clinical trials in using a drug called PRX302 in treating localized prostate cancer (interest ceased January 2020). He has received payment from Boston Scientific for teaching other surgeons in techniques of Rezum water vapour therapy in benign enlarged prostates and cryotherapy in treating prostate cancer (prior to Boston’s takeover of BTG/Galil, this was through BTG/Galil). He has received funding from Sonacare Medical for teaching other surgeons in HIFU for prostate cancer treatment as well as paid lectures in courses and the travel and subsistence associated with these. He has received funding from Francis Medical for sitting on a Scientific Advisory Board to advise on the design and conduct of clinical trial in using water vapour therapy to treat prostate cancer. He has received funding from AXA PPP for time on a clinical advisory board for prostate pathway. He has received funding from Astra Zeneca for advisory committee membership on using routine data use of androgen deprivation therapy (interest ceased December 2020). University College London received funding from Trod Medical for a clinical trial (interest ceased April 2017). He undertakes private practice in London specializing in prostate diseases (benign enlargement, cancer).

He also declared non financial professional and personal interests as the Rapid Assessment and Prostate Imaging for Diagnosis (RAPID) programme is funded to deliver pre-biopsy MRI in patients with a suspicion of prostate cancer followed by targeted transperineal biopsy in those that require it. He has extensive publications in prostate biopsy within trials and retrospective large datasets. He has undertaken and is undertaking clinical trials evaluating various aspects of the prostate cancer diagnostic and treatment pathway. The IP7-PACIFIC trial specifically will evaluate bpMRI compared to mpMRI as well as image-fusion targeting versus cognitive/visual-estimation targeted for patients with a clinical suspicion. He is Chair, Focal Therapy UK, a group representing urologists carrying out focal therapy using any type of ablative device. He is on various advisory committees for the diagnostic pathway for prostate cancer coordinated by Prostate Cancer UK. He was Chair, NHS England’s Prostate Clinical Expert Group (interest ceased 2019). He is Chair, NCRI Prostate Research Group.

It was agreed that these interests meant that Hashim Ahmed should be precluded from part of the meeting, and he therefore only attended Part 1.

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 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 BXT Accelyon 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 has 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 clinical effectiveness and cost effectiveness of ‘Transperineal biopsy in people with suspected prostate cancer’. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
		2. The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.
		3. The Chair thanked the manufacturer representatives, the EAG and public observers for their attendance at the meeting.
		4. The Chair explained that “representatives of the press and other members of the public be 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 Consultation Document (DCD). The committee decision was reached by consensus.
		3. The committee asked the NICE technical team to prepare the DCD in line with their decisions.

### Evaluation of FibroScan for assessing liver fibrosis and cirrhosis outside secondary and specialist 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 Rebecca Allcock, Keith Abrams, Liz Adair, Jim Gray and Michael Messenger. He noted that Neil Hawkins was not attending due to a conflict 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:
* 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.
* Shaheen Hamdy declared financial interest in that he is Board Director, shareholder and CSO of Phagenesis Ltd (a company that works in the area of dysphagia care). There is no connection with the topic of Fibroscan. He is a shareholder of Anisys Ltd, a company working in the area of anorectal disorders. He also declared non-financial professional and personal interests as he is Professor of Neurogastroenterology, University of Manchester, Honorary Consultant Gastroenterologist, Northern Care Alliance (Salford Royal Hospital) and Interim Vice-Chair of the MTAC, NICE. It was agreed that these interests would not prevent Shaheen Hamdy from participating in 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.
* Patrick McGinley declared a financial interest as he is a Faculty Member of MTech Access, advising on NHS finance flows, and receives an honorarium for this. He also declared non-financial personal and professional interests as he is a Strategic Council member of the All-Party Parliamentary Group (APPG) on Obesity, and is the Honorary Treasurer for the Association for Study of Obesity (ASO). It was agreed that these interests would not prevent Patrick McGinley 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:

* Neil Guha declared a financial interest as he has a Gilead Sciences research grant for investigator led study on NAFLD (96K) given to University of Nottingham (PI). This is an epidemiological study to describe the severity of liver disease in the community setting and demographic factors associated with NAFLD. He also declared non-financial personal and professional interests as his research interest is in non-invasive markers and community liver disease. It was agreed that these interests would not prevent Neil Guha from participating in part 1 of the meeting as an invited expert.
* 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 Chair led a discussion of the evidence presented to the committee. This information was presented to the committee by Dr Alasdair Taylor and Patrick McGinley.
		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 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 be 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 then agreed on the content of the Diagnostics Consultation Document (DCD). The committee decision was reached by consensus.
		2. The committee asked the NICE technical team to prepare the DCD in line with their decisions.

### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (next topic) will be held on 23 February 2022.