# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 29 November 2022

**Location:** Via Zoom

## Attendees

Committee members present

1. Brian Shine (Chair) Present for all items
2. Liz Adair Present for all items
3. Rebecca Allcock Present for all items
4. Peter Baker Present for items 1 – 2.3.4
5. John Cairns Present for all items
6. Sam Creavin Present for all items
7. Justin Daniels Present for items 1 – 2.3.4
8. Diane Davies Present for all items
9. Ana Duarte Present for items 1 – 2.3.4
10. Neil Hawkins Present for items 3 – 3.2.3
11. Bernard Khoo Present for items 1 – 2.3.4
12. Rashmi Kumar Present for all items
13. Patrick McGinley Present for all items
14. Fiona MacPherson Smith Present for items 1 – 2.3.4
15. Michael Messenger Present for all items
16. Brendan Meyer Present for items 3 – 3.2.3
17. Hugo Pedder Present for items 1 – 2.3.4
18. Radha Ramachandran Present for all items
19. Gabriel Rogers Present for items 1 – 2.3.4
20. Karen Sennett Present for all items
21. Matt Stevenson Present for all items
22. Alasdair Taylor Present for all items

NICE staff present

Rebecca Albrow, Associate Director, Diagnostics Assessment Present for all items

Programme (DAP)

Frances Nixon, Health Technology Assessment Adviser, DAP Present for items 1 to 2.3.4

Thomas Walker, Health Technology Assessment Adviser, DAP Present for items 3 to 3.2.3

Simon Webster, Health Technology Assessment Analyst, DAP Present for items 1 to 2.3.4

Vera Unwin, Health Technology Assessment Analyst, DAP Present for items 3 – 3.2.3

Toni Gasse, Project Manager, DAP Present for all items

Alex Sexton, Administrator, DAP Present for all items

External assessment group representatives present

Lena Al -Khudairy, Associate Professor in Public Health Present for items 1 to 2.3.1
and Health Technology Assessment, Warwick Evidence

Ewen Cummins, Health Economist, attending for Warwick Present for items 1 to 2.3.1
Evidence

Mubarak Patel, Research Associate in Medical Statistics, Present for items 1 to 2.3.1

attending for Warwick Evidence

Ana Duarte, Research Fellow, Centre for Health Economics Present for items 3 – 3.1.5
University of York

Alexis Llewellyn, Research Fellow, Centre for Reviews Present for items 3 – 3.1.5
and Dissemination, University of York

Marta Soares, Professor, Centre for Health Economics, Present for items 3 – 3.1.5
University of York

**Experts present**

Nicola Birchmore, Paediatric Diabetes Nurse Specialist Present for items 1 to 2.2.6

Julie Brake, Nurse Consultant – Diabetes Present for items 1 to 2.2.6

Alison Finney, Lay expert Present for items 1 to 2.2.6

Jeff Foot, Lay expert Present for items 1 to 2.2.6

Peter Hindmarsh, Professor of Paediatric Endocrinology Present for items 1 to 2.2.6

Sufyan Hussain, Consultant Physician in Diabetes and Present for items 1 to 2.2.6
Endocrinology

Fiona Regan, Paediatric Diabetes Consultant Present for items 1 to 2.2.6

Joanne Richardson, Patient expert Present for items 1 to 2.2.6

Philip Weston, Consultant Physician in Diabetes Present for items 1 to 2.2.6

Partha Kar, Consultant Endocrinology / Diabetes Present for items 1 to 2.2.6

National Specialty Advisor, Diabetes, NHS England

Charlie Knell, Head of Continuity of Supply, NHSE Present for items 1 to 2.3.1

**Specialist Committee Members present**

Steve Allen, Lay specialist Present for items 3 to 3.2.3

Pauline Bagnall, Uro-oncology Nurse Specialist Present for items 3 to 3.2.3

Oliver Hulson, Consultant Radiologist Present for items 3 to 3.2.3

Sanjeev Madan, Consultant Urological Surgeon Present for items 3 to 3.2.3

Santhanam Sundar, Consultant Clinical Oncologist Present for items 3 to 3.2.3

Graeme Spencer, Lay specialist Present for items 3 to 3.2.3

Lillian White, Urology Oncology Advanced Nurse Present for items 3 to 3.2.3

Hide Yamamoto, Consultant Urologist Present for items 3 to 3.2.3

Observers present

Amanda Adler, Chair, NICE Antimicrobials Evaluation Committee Present for items 1 – 2.3.4

Alice Bell, Associate Health Technology Assessment Present for all items

Analyst

Lyn Davies, Coordinator, Meetings in Public Present for items 1 to 2.2.6 and items 3 to 3.1.5

Ben Gregory, Finance/Business Analyst Present for items 1 to 2.3.4

Emma McCarthy, Associate Health Technology Assessment Present for all items
Analyst

Laura Marsden, Public Involvement Adviser Present for all items

Edgar Masanga, Business Analyst Present for items 3 to 3.2.3

Judith Shore, Health Technology Assessment Adviser Present for all items

Anna Sparshatt, Senior Medical Editor Present for items 3 to 3.2.3

Olivia Waring, Senior Medical Editor Present for items 1 – 2.3.4

## Minutes

### The Chair welcomed members of the committee and other attendees present to the meeting. The Chair thanked Liz Adair, attending her last meeting, for all her work and contributions during her time as a standing committee member.

### Appraisal of Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

1. The Chair noted that Keith Abrams, Joy Allen, Neil Hawkins and Brendan Meyer were not attending due to conflicts of interest.
	1. The committee approved the minutes of the committee meeting held on 31 October 2022.
	2. Part 1 – Open session
		1. The Chair welcomed invited clinical, lay and NHS England experts, external assessment group representatives, members of the public, and company representatives from Air Liquide Healthcare Ltd, CamDiab Ltd, Dexcom, Medtronic, and Tandem Diabetes Care Inc.
		2. The Chair asked all committee members and experts to declare any new relevant interests in relation to the topic being considered in addition to those declared in advance of the meeting. 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 at 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. In addition, Visible Analytics is/has undertaken work for Lilly (which he has not been involved with) and Roche (which he has been involved with) but not in diabetes and regarding therapeutics and not diagnostics. It was agreed that these interests meant Keith Abrams could not participate in the discussions and he did not attend the meeting.

Liz Adair declared a non-financial professional and personal interest as she is a Trustee at Carers Network, a charity which supports unpaid carers in West London. She also declared an indirect interest as she is a Quality Director at Synnovis Group LLP. Roche and Abbott (comparator companies) supply pathology services, equipment and consumables to Synnovis Services LLP - present and ongoing. It was agreed that these interests would not prevent Liz Adair from participating in the meeting.

Joy Allen declared a financial interest as she is employed by Roche Diagnostics. It was agreed that this interest meant Joy Allen could not participate in the discussions and she did not attend the meeting.

John Cairns declared a financial interest as he had advised Astellas on an economic evaluation of a treatment for anaemia in people with CKD. It was agreed that this interest would not prevent John Cairns from participating in the meeting.

Ana Duarte declared a non-financial professional and personal interest as she is a member of the University of York Evidence Review and Assessment group, which regularly conducts research to inform NICE's technology appraisals and diagnostic assessments. It was agreed that this interest would not prevent Ana Duarte from participating in the meeting.

Bernard Khoo declared a financial interest as he practices privately as a Consultant in Endocrinology. He also declared an indirect interest as his spouse is a consultant and shareholder in Zihipp Ltd, an Imperial College spin out company that is developing treatments for obesity. It was agreed that these interests would not prevent Bernard Khoo from participating in the meeting.

Brendan Meyer declared a financial interest as he holds shares in Embecta, a diabetes management company. It was agreed that this interest meant Brendan Meyer could not participate in the discussions and he did not attend the meeting.

Patrick McGinley declared a financial interest as he is an employee of Maidstone and Tunbridge Wells NHS Trust. He is a Faculty Member of MTech Access, providing updates on NHS Finance regime and the impact of its changes to MTech Access. He also declared non-financial professional and personal interests as he is a Strategic Council member of the All-Party Parliamentary Group (APPG) on Obesity, providing advice on costs of the disease within NHS to the APPG. He is also 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.

Michael Messenger declared an indirect interest as Roche were a strategic partner of the NIHR Leeds MIC; they were involved with several projects but did not fund the MIC (interest ceased in 2020). He also declared non-financial professional and personal interests as he is a visiting Professor at the University of Leeds, and is or has been an unpaid expert/scientific advisor to the World Health Organisation (October 2022-current) and Department for Health and Social Care including UKHSA and MHRA (May 2020-September 2022). He also declared financial interests as he is a Director at Insightful Health Ltd, a UK based public health and regulatory consultancy firm. He has recently been a paid consultant for the European Union IMI programme (since 2018), World Health Organisation (since 2022), Bill and Melinda Gates Foundation (since 2022), FIND – the global alliance for diagnostics (since 2022), ACT-IVD (since 2022), PinPoint Data Science Ltd (interest ceased 2020) and Cepheid (interest ceased 2020). He is a co-inventor of the PinPoint Cancer Test (Pinpoint Data Science Ltd) and as such may be eligible for a share of royalties from any sales. It was agreed that these interests would not prevent Michael Messenger from participating in the meeting.

Gabriel Rogers declared a non-financial professional and personal interest as since August 2022 he has been involved in health economic evaluation of the FLASH-UK RCT - https://www.clinicaltrials.gov/ct2/show/NCT03815006 https://www.nejm.org/doi/full/10.1056/NEJMoa2205650 - which examined the effectiveness of intermittently scanned continuous glucose monitoring ('flash') compared with SMBG, including in a subgroup of people using continuous subcutaneous insulin infusion. This is an independent RCT (main funder is Diabetes UK); in particular, the device manufacturer had no involvement. It was agreed that this interest would not prevent Gabriel Rogers from participating in the meeting.

Matt Stevenson declared an indirect interest as he is on a grant funded by Roche Diagnostics in an unrelated disease area. It was agreed that this interest would not prevent Matt Stevenson from participating in the meeting.

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

Julie Brake declared a financial interest as she had done a paid education session for hypoglycaemia for her local diabetes team. It was agreed that this interest would not prevent Julie Brake from participating in the meeting as an invited clinical expert.

Alison Finney declared a non-financial professional and personal interest as she is a Member of Diabetes UK and advocate for improvements in diabetes care, speaking with other people with diabetes online about care options they have available to them and how to get the most out of them. It was agreed that these interests would not prevent Alison Finney from participating in the meeting as an invited patient expert.

Jeff Foot declared non-financial professional and personal interests as he is a lay member of the Scottish Diabetes Technology and Innovation Advisory Group, a lay member of the Scottish Diabetes Education Advisory Group, a member of Advisory Council of Diabetes Scotland and a patient representative on NHS Highland MCN for Diabetes. It was agreed that these interests would not prevent Jeff Foot from participating in the meeting as an invited patient expert.

Peter Hindmarsh declared a non-financial professional and personal interest as he is a member of MHRA Devices Expert Advisory Group. It was agreed that this interest would not prevent Peter Hindmarsh from participating in the meeting as an invited clinical expert.

Sufyan Hussain declared a financial interest as he had received personal payment for 1-hour non-promotional educational activity for industry (Novo Nordisk) to teach on “Fasting during Ramadan and type 2 Diabetes” (interest ceased 2020). He has an NHS role as a Diabetes Consultant with specialist expertise in diabetes technologies at Guy’s and St Thomas’ NHS Foundation Trust. The Trust has been confirmed as a site for the NHSE hybrid closed loop pilot for adults. As part of his usual NHS role, he will provide usual clinical support for NHS patients on closed loops in his Trust/clinic (this may include NHS patients enrolled in the pilot), education for healthcare professionals and supervising clinical audits. He will not be undertaking any activities for NHSE and will not receive any financial benefits from this other than his usual salary. He also declared non-financial professional and personal interests as he is a member of the Scientific Advisory Committee, Juvenile Diabetes Research Foundation UK (JDRF UK), a member of Association of British Clinical Diabetologist’s Diabetes Technology Network (ABCD DTN), a supervisor of a Medical Student BSc project and ongoing work “Review of evidence and real-world outcomes of automated insulin delivery systems” (unpaid role, potential for peer-reviewed publication, independent with no grant funding). It was agreed that these interests would not prevent Sufyan Hussain from participating in the meeting as an invited clinical expert.

Philip Weston declared non-financial professional and personal interests as he is a Visiting Professor, Hope University, Liverpool, Honorary Senior Lecturer, Liverpool University, and he leads the insulin team at the Royal Liverpool University Hospital that is one of the NHS England chosen sites for the hybrid closed loop audit programme. There are no personal payments for this but people with diabetes that he provides care for will receive NHS England funded continuous glucose monitoring supplies. It was agreed that these interests would not prevent Philip Weston from participating in the meeting as an invited clinical expert.

Partha Kar declared non-financial professional and personal interests as he is the National Specialty Advisor, Diabetes with NHS England and co-lead of Diabetes GIRFT with NHS Improvement. He is a Consultant in Diabetes and Endocrinology at Portsmouth Hospitals NHS Trust. He set up “T1D Rise of the Machines” a series of events across the UK between people with Diabetes, industry and NHS representatives. He has extensive publications in the area including a monthly blog for the BMJ, a personal blog (“Sugar and Spice: Wish all things were nice”) and a podcast (“Sweet Talking”), TED talks from those with Type 1 Diabetes, and co- creator of Type 1 Diabetes comic (Volume 1 and 2). Recent publications on which he has been co-author include: Misra S et al, Characteristics and care of young people with type 2 diabetes included in the national diabetes audit datasets for England. (August 2022). Mira S et al, Developing services to support the delivery of care to people with early-onset type 2 diabetes (July 2022). Valabhji J et al, Associations between reductions in routine care delivery and non-COVID-19-related mortality in people with diabetes in England during the COVID-19 pandemic: a population-based parallel cohort study (May 2022). Misra S et al, Temporal trends in emergency admissions for diabetic ketoacidosis in people with diabetes in England before and during the COVID-19 pandemic: a population-based study (Sept 2021). Valabhji J et al, Temporal Trends in Lower-Limb Major and Minor Amputation and Revascularization Procedures in People With Diabetes in England During the COVID-19 Pandemic (May 2021). It was agreed that these interests would not prevent Partha Kar from participating in the meeting as an NHSE expert.

* + 1. The Committee proceeded to discuss the clinical and cost effectiveness of ‘Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes’. 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 invited experts, manufacturer representatives, 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

 Part 2a:

* + 1. The committee continued their discussions; the Chair then thanked the EAG and the NHSE expert present and they left the meeting.

 Part 2b:

* + 1. The committee discussed confidential information submitted for this item.
		2. The committee discussed next steps.
		3. The committee asked the NICE technical team to prepare documentation in line with their decisions.

### Assessment of MRI fusion biopsy in people with suspected prostate cancer

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

The Chair noted apologies from standing committee member Keith Abrams and Joy Allen.

* 1. Part 1 – Open session

The Chair welcomed external assessment group representatives, members of the public, and company representatives from Exact Imaging, Healthcare Supply Solutions, Kebomed UK/Koelist and MedCom GmbH.

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

Liz Adair declared a non-financial professional and personal interest as she is a Trustee of Carers Network a charity based in West London which supports unpaid carers. It was agreed that this interest would not prevent Liz Adair from participating in the meeting

John Cairns declared a financial interest due to his participation in a double-blinded focus group organized by PwC Switzerland on an epilepsy treatment (interest ceased December 2021). It was agreed that this interest would not prevent John Cairns from participating in the meeting

Patrick McGinley declared a financial interest as he is a Faculty Member of MTech Access, providing updates on NHS Finance regime and the impact of its changes to MTech Access. He also declared non-financial professional and personal interests as he is a Strategic Council member of the All-Party Parliamentary Group (APPG) on Obesity, providing advice on costs of the disease within NHS to the APPG. He is also 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.

Michael Messenger declared financial interests as he is a Director at Insightful Health Ltd, a UK based public health and regulatory consultancy firm. He has also recently been a paid consultant for: The European Union IMI programme (since 2018), the World Health Organisation (since 2022), the

Bill and Melinda Gates Foundation (since 2022), FIND – the global alliance for diagnostics (since 2022), and ACT-IVD (since 2022). He is a co-inventor of the PinPoint Cancer Test (Pinpoint Data Science Ltd) and as such may be eligible for a share of royalties from any sales. It was agreed that these interests would not prevent Michael Messenger from participating in the meeting.

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

Pauline Bagnall declared financial interests as she had attended an education meeting funded by Bayer (interest ceased September 2021); she had participated in a team building event sponsored by MSD in May 2022, and she works for the Prostate Cancer Research as a Clinical Nurse Specialist one day a week. She also declared non-financial professional and personal interests as she is a trustee of the British Association of Urological Nursing, a member of the National Prostate Cancer Audit Clinical Reference Group and a member of Prostate Cancer Risk Management Programme. It was agreed that these interests would not prevent Pauline Bagnall from participating in the meeting.

Sanjeev Madan declared financial interest as he undertakes private practice; he had received remuneration for attending Bayer advisory board meetings and speaker engagements in February, March and August 2021; he had received speaker fees from Ipsen in June 2021; he had received speaker fees from Laborie in July 2021. It was agreed that these interests would not prevent Sanjeev Madan from participating in the meeting.

Santhanam Sundar declared financial interests as he had received registration fee sponsorship for the ESMO conference from BSM in September 2022; and he does private medical practice. He also declared non-financial professional and personal interests as he is a council member of Royal College of Radiology. It was agreed that these interests would not prevent Santhanam Sundar from participating in the meeting.

Hide Yamamoto declared financial interests as he had received travel and teaching costs from BK Medical to teach the transperineal biopsy technique using the BK grid to other urologists in NHS hospitals (interest ceased March 2021); 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 professional and personal 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 in 2020. He has non-monetised videos on the technique of transperineal biopsy using the BK grid system <https://www.youtube.com/watch?v=B3tBj2fMzuo>

 <https://vimeo.com/370722288>. It was agreed that these interests would not prevent Hide Yamamoto from participating in the meeting.

* + 1. The Committee proceeded to discuss the clinical and cost effectiveness of MRI fusion 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.

### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (next topic) will be held on 16 December 2022.