# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** Friday 16 December 2022

**Location:** Via Zoom

## Attendees

Committee members present

1. Brian Shine (Chair) Present for all items
2. Keith Abrams Present for all items
3. Rebecca Allcock Present for all items
4. Joy Allen Present for all items
5. John Cairns Present for all items
6. Diane Davies Present for all items
7. Rashmi Kumar Present for all items
8. Patrick McGinley Present for all items
9. Michael Messenger Present for all items
10. Karen Sennett Present for all items
11. Matt Stevenson Present for all items

NICE staff present

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

Programme (DAP)

Judith Short, Health Technology Assessment Adviser, DAP Present for all items

Jean Isaac, Health Technology Assessment Analyst, DAP Present for all items

Ying-Ying Wang, Health Technology Assessment Analyst, DAP Present for all items

Toni Gasse, Project Manager, DAP Present for all items

Alex Sexton, Administrator, DAP Present for all items

Thomas Lawrence, Data scientist, Managed Access Present for all items

Laura Marsden, Public Involvement Programme Present for items 1 – 1.1.5

Emma Gordon, Meetings in Public Present for items 1 – 1.1.5

External assessment group representatives present

Marie Westwood, Reviews Manager, Kleijnen Systematic Present for items 1 – 1.1.5

Reviews Ltd

Isaac Corro Ramos, Scientific researcher at the Present for items 1 – 1.1.5

Institute for Medical Technology Assessment, attending for KSR

**Specialist Committee Members present**

Rob Alcock, Consultant Radiologist, Salisbury District Hospital Present for all items

Sefina Arif, Lay Specialist Committee Member Present for all items

Anna Beatie, Consultant Cardiothoracic Radiologist, Present for all items

Newcastle upon Tyne NHS Hospitals Trust

Gerald Clesham, Consultant Cardiologist, Mid and South Essex Present for all items

NHS Foundation Trust

Timothy Fairbairn, Consultant Cardiologist, Liverpool Heart Present for all items

and Chest Hospital

Mani Motwani, Consultant Cardiologist, Manchester Heart Present for all items

Institute, Manchester Royal Infirmary, Manchester University   
NHS Foundation Trust

Rajesh Kharbanda, Consultant Cardiologist, Oxford Present for all items

University Hospitals NHS Foundation Trust

Jaydeep Sarma, Consultant Interventional Cardiologist, Present for all items

Manchester University Hospitals NHS Foundation Trust

Observers present

Alice Bell, Associate Health Technology Assessment Analyst Present for all items

Sophie Harrison, Associate Health Technology Assessment Present for all items

## Analyst

Emma McCarthy, Associate Health Technology Assessment Present for all items

## Analyst

Ruth Melville, Senior Medical Editor Present for all items

Louisa Regan, Implementation Adviser Present for all items

Vera Unwin, Health Technology Assessment Analyst Present for all items

Philip Williams, Finance/Business Analyst Present for all items

## Minutes

### Early Value Assessment of ‘CaRi-Heart for predicting cardiac risk in suspected coronary artery disease’

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

Rebecca Albrow noted that Early Values Assessments (EVAs) are currently being piloted by NICE, taking an initial look at technologies to provide an assessment of early value. Stakeholders are encouraged to provide feedback on the EVA pilots’ process.

The Chair noted apologies from standing committee members Sam Creavin, Neil Hawkins, Brendan Meyer, and Radha Ramachandran.

* 1. Part 1 – Open session

The Chair welcomed external assessment group representatives, members of the public, and company representatives from Caristo Diagnostics.

* + 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:

Keith Abrams declared a financial interest as he is a Partner and Director, Visible Analytics Limited, a HTA Consultancy company, but he has not been involved in any projects which involve a diagnostic technology. He also declared an indirect interest from funding to support a MRC Industrial PhD Studentship from Swiss Precision Diagnostics/Clearblue for a project on prediction of early miscarriage (interest ceased April 2022). 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. She also declared indirect interests as Roche Diagnostics manufacturer the following diagnostic cardiac biomarkers: Elecsys® Troponin T-high sensitive (TnT-hs) which is indicated to rule in and out acute non–ST-segment elevation myocardial infarction; Elecsys® NT-proBNP which is indicated to support heart failure diagnosis in both non-acute and acute settings. Roche Diagnostics also manufacture the cobas b 101 system, used in health screening for cholesterol measurement via a lipid panel. It was agreed that these interests would not prevent Joy Allen 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 structure, pricing and tariff developments. 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. He is also the Honorary Treasurer for the Association for Study of Obesity (ASO). He is also a member of the Obesity Policy Engagement Network UK (OPEN UK). 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. He also declared non-financial professional and personal interests as he is a Visiting Professor at the University of Leeds, and has been an unpaid expert/scientific adviser to the World Health Organisation (since 2022) and to the Department of Health and Social Care (including UKHSA and MHRA between 2020-2022). 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:

Robin Alcock declared non-financial professional and personal interests due to ongoing research collaboration with Swansea University Engineering and Computational Sciences Departments, researching computational techniques applied to CT Coronary Angiograms (et al) for modelling coronary arterial flows. His principal interest is academic research with main output of peer reviewed publications. He has received no personal funding to undertake this research, however research partners at Swansea University receive funding via engineering streams such as the Engineering and Physical Sciences Research Council to employ individual researchers. It was agreed that these interests would not prevent Robin Alcock from participating in the meeting.

Anna Beattie declared financial interests as she had received remuneration from HeartFlow (a company which uses routine CT data to assess whether narrowing of the arteries supplying the heart might be restricting blood flow) for teaching on a cardiac CT course, including travel and accommodation expenses and also for mentoring new sites adopting HeartFlow (£4261.50) in May/June 2022. She also declared an indirect interest as she is the radiology lead for NCIMI (National Consortium of Intelligent Medical Imaging) in Newcastle. Newcastle Hospitals and Caristo are both partner organizations of NCIMI, however to-date NCIMI have not collaborated with them on any research projects. It was agreed that these interests would not prevent Anna Beatie from participating in the meeting.

Timothy Fairbairn declared indirect interests due to work with Heartflow mentors bureau; he does not receive financial reimbursement but helps sites starting using the technology. He also declared that he is Guideline Committee Member of the Society Cardiovascular Computer Technology (SCCT). It was agreed that these interests would not prevent Timothy Fairbairn from participating in the meeting.

Rajesh Kharbanda declared that Oxford University Hospitals (OUH), his employer, received funding from the NHS England (via an NHS AI award) that funds the clinical deployment and real-world evaluation of CaRi-HEART in several NHS Hospitals. He has had no involvement in the development of Cari-Heart at the University of Oxford; neither he nor the clinical department have received funding from CaRi-Heart. It was agreed that these interests would not prevent Rajesh Kharbanda from participating in the meeting.

Manish Motwani declared financial interests as he undertakes clinical private practice. In private clinical practice, he has used and continues to use services from Caristo Diagnostics, specifically CaRiHeart scoring for a handful of patients in the last 6 months (from March 2022 - current). This is as an independent customer, not constituting any financial gain or professional gain, and not in the form of any advocacy for the company or its products. Patients are referred to Caristo for their scan processing and either pay directly to Caristo or are covered by their insurer (there is no financial gain or financial relationship to him). It was agreed that these interests would not prevent Manish Motwani from participating in the meeting.

Jaydeep Sarma declared financial interests as he undertakes private practice. He had previously received sponsorship to attend conferences funded by Abbott Vascular, BMS, Medtronic and Astra Zeneca (interest ceased February 2019); currently occasional refreshments are provided by industry before and after complex coronary structural interventions (coffee and snacks); and in November 2022 he attended a lecture on CT evaluation of Fat Attenuation Index, including dinner He also declared a non-financial professional and personal interest as he was a committee member, NICE ACS guidelines committee (interest ceased 2020). He also declared indirect interests as he was a programme committee member of the British Cardiovascular Society (interest ceased 2022) and he is clinical co-lead, Manchester Academic Health Sciences Collaboration. It was agreed that these interests would not prevent Jaydeep Sarma from participating in the meeting.

* + 1. The Committee proceeded to discuss ‘CaRi-Heart for predicting cardiac risk in suspected coronary artery disease’. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
    2. The Chair asked the manufacturer representatives 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 early value guidance consultation document. The committee decision was reached by consensus.
     3. The committee asked the NICE technical team to prepare the consultation document in line with their decisions.

### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (next topic) will be held on 18 January 2023.