# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 28 July 2022

**Location:** Via Zoom

## Attendees

Committee members present

1. Brian Shine (Chair) Present for all items
2. Keith Abrams Present for all items
3. Joy Allen Present for all items
4. John Cairns Present for all items
5. Sam Creavin Present for all items
6. Diane Davies Present for all items
7. Patrick McGinley Present for all items
8. Michael Messenger Present for all items
9. Brendan Meyer Present for all items
10. Alexandria Moseley Present for all items
11. Radha Ramachandran Present for all items
12. Karen Sennett Present for all items
13. Matt Stevenson Present for all items

NICE staff present

Mark Chapman, Interim Director of Medical Technology Present for all items

Sarah Byron, Programme Manager - Devices, Diagnostics Present for all items
and Digital

Rebecca Albrow, Associate Director Present for all items

Frances Nixon, Health Technology Assessment Adviser Present for all items

Suvi Harmala, Health Technology Assessment Analyst Present for all items

Harriet Wilson, Project Manager Present for all items

Alex Sexton, Administrator Present for all items

External assessment centre representatives present

Khanh Ha Bui, Research Associate, King's Technology Present for items 1 to 1.3.6
Evaluation Centre ( KiTEC)

Julius Ohrnberger, Associate Director, Ipsos UK (attending Present for items 1 to 1.3.6
for KiTEC)

**Decision Support Unit (DSU) representative present**

Ben Kearns, Research Fellow, ScHARR, University of Sheffield Present for items 1 to 1.3.6

**Specialist Committee Members present**

Tim Betts, Consultant Cardiologist, Oxford University Hospitals Present for all items
NHS Foundation Trust

Rudolf Cardinal, Associate Professor of Clinical Informatics / Present for all items
Honorary consultant liaison psychiatrist, University of Cambridge,
Cambridgeshire and Peterborough NHS Foundation Trust
& Cambridge University Hospitals NHS Foundation Trust

George Crowther, Consultant Old Age Liaison Psychiatrist, Present for all items
Leeds and York Partnership NHS Foundation Trust

Mani Santhanakrishnan, Consultant in Old Age Psychiatry, Present for all items
Tees, Esk and Wear Valleys NHS Foundation Trust

Muzahair Tayebjee, Consultant Cardiologist, Leeds Present for all items
Teaching Hospitals

Emma Thompson, Service Development Manager, Present for all items
Tees, Esk and Wear Valleys NHS Foundation Trust

Katherine Barrett, Lay specialist committee member Present for all items

Felicity Sandys-Wood, Lay specialist committee member Present for all items

Observers present

Matthew Brown, Digital Media Manager, NICE Present for all items

Victoria Carter, Adoption and Impact, NICE Present for all items

Rachael Cazaly, Medical Editor, NICE Present for all items

Lyn Davies, Coordinator, NICE Present for items 1 – 1.3.6

Hayley Garnett, Senior Medical Editor, NICE Present for all items

Vandana Ayyar Gupta, Managed Access Team, NICE Present for all items

Thomas Lawrence, Managed Access Team, NICE Present for all items

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

Ian Mather, Business Analyst, NICE Present for all items

Judith Short, Technical Adviser, NICE Present for all items

## Minutes

### Evaluation of KardiaMobile 6L for measuring QT interval in people having antipsychotic medication Early Value Assessment

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

The Chair noted apologies from standing committee members Liz Adair, Rebecca Allcock, Neil Hawkins, Shelley Rahman Haley, and Alasdair Taylor.

* 1. The committee approved the minutes of the committee meeting held on 25 May 2022.
	2. Rebecca Albrow noted that Early Values Assessments (EVAs) are currently being piloted by NICE across ten MedTech topics. ‘KardiaMobile 6L for measuring QT interval in people having antipsychotic medication’ is the first pilot. EVAs take an initial look at technologies to provide an assessment of early value; for promising technologies a recommendation may be made for further data to be collected before they return to the committee for a full assessment. Attendees were encouraged to get in touch for any further information regarding EVAs, and committee to feedback on the process and decision-making for this pilot topic.
	3. Part 1 – Open session

The Chair welcomed external assessment centre (EAC) and Decision Support Unit (DSU) representatives, members of the public, and company representatives from AliveCor.

* + 1. The Chair asked all committee members to declare any new relevant interests in relation to the item 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 financial interests as he is a Partner and Director, Visible Analytics Limited, a health technology assessment consultancy company (various clients but the only diagnostics projects are FibroScan and he has not been involved with the project or discussed it with colleagues); he is an HTA Consultant for Pfizer Oncology, and he delivers short course for NICE/ABPI. He also declared non-financial professional and personal interests as he has received research funding from Duchenne UK as part of Project HERCLUES in DMD (from various pharma companies); he has received research funding from Swiss Precision Diagnostics/ClearBlue for PhD studentship in modelling miscarriage using biomarkers; he is a Member NICE Decision Support Unit; and he is an advisor to the NHS Accelerated Access Collaboration (AAC). It was agreed that these interests would not prevent Keith Abrams from participating in the meeting.

 John Cairns declared financial interests as he had advised Astellas on the economic of evaluation of Roxadustat (interest ceased May 2021), Takeda on the economic evaluation of maribavir (interest ceased August 2021) and he had participated in a double-blinded focus group on an epilepsy treatment 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 noted that his GP Practice has a KardiaMobile device, funded by the CCG. It was agreed that this interest would not prevent Sam Creavin 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 personal and professional 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 the Honorary Treasurer for the Association for Study of Obesity (ASO). He is a Member of 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 noted in the meeting that he has recently set up a consultancy company, which is not yet trading. It was agreed that this interest would not prevent Michael Messenger from participating in the meeting.

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

Tim Betts declared financial interests as he undertakes private practice, but none that has any relevance to this committee. He has received direct payments from the commercial sector to attend meetings, conference or event, over and above funding to support reasonable travel, accommodation and attendance costs, but nil related to this committee, and has received reasonable support for travel etc from Medtronic, Boston Scientific, Abbott, and Acutus Medical. He has received direct payments from the commercial sector to provide educational lectures to GPs and attendees at national and international conferences and symposia, from companies including Medtronic, Boston Scientific, Abbott, Acutus Medical, EBR Systems, Pfizer and Bristol Myers Sqibb; no payments have been related to the topic under consideration. He has received direct payments from the commercial sector for consultation fees relating to product development from Medtronic, Boston Scientific, Abbott, Acutus Medical and EBR Systems; no payments have been related to the topics covered by this committee. He also declared non-financial professional and personal interests as he is conducting research projects that involve the use of wearable technologies (Apple Watch and Skylabs CART-I ring) to detect the abnormal heart rhythm atrial fibrillation and prevent strokes; these projects are not related to the topic under consideration. It was agreed that these interests would not prevent Tim Betts from participating in the meeting.

Rudolf Cardinal declared financial interests due to software royalty income from the sales of Whisker and related software by licensee companies Cambridge Cognition Ltd, 2002–2004; Campden Instruments Ltd, 2004– (owned by the Lafayette Instrument Company Inc.). This is software for

controlling research apparatus, primarily used for behavioural neuroscience research. Royalties are paid via companies owned by the University of Cambridge (Cambridge University Technical Services Ltd; Cambridge Enterprise). He has also been paid as a consultant to Campden Instruments Ltd (2004–) and the University of Cambridge (2009–) regarding these software products. End users of the software include universities, companies, and government research organizations. He further declared financial interests due to book royalty income from Taylor & Francis Group, previously Lawrence Erlbaum Associates (2006–) (book: ANOVA for the Behavioural Sciences Researcher); Cambridge University Press (2011–) (book: The Diagnosis of Psychosis). He further declared non-financial professional and personal interests as he has published research in the general area of mortality and physical morbidity in psychiatric illness (e.g. dementias, PubMed IDs [PMIDs] 29101136, 30776008, 33113255; schizophrenia and related disorders, e.g. PMIDs 32049635, 32546415, 33035957, 34745650; more broadly, e.g. PMIDs 34039579, 34382242). He is an Associate Fellow of the British Psychological Society (2011–) and a Fellow of the Institute of Biomedical Science (2013–), Royal Society of Biology (2021–), Faculty of Clinical Informatics (2020–), and Royal College of Psychiatrists (2021–). He declared an indirect interest as his spouse is a member of the Animals in Science Committee (ASC: a statutory committee advising the UK Home Office). It was agreed that these interests would not prevent Rudolf Cardinal from participating in the meeting.

George Crowther declared financial interests as he is a shareholder in an investment company, John Edward Crowthers Ltd. This is a property company and has no connection with the topic under consideration, or any medical company. He declared non-financial professional and personal interests as he is a joint author of the research paper: Mohammad Azram, Noura Ahmed, Lucy Leese, Matthew Brigham, Robert Bowes, Stephen B Wheatcroft, Marcus Ngantcha, Berthold Stegemann, George Crowther, Muzahir H Tayebjee, Clinical validation and evaluation of a novel six-lead handheld electrocardiogram recorder compared to the 12-lead electrocardiogram in unselected cardiology patients (EVALECG Cardio), European Heart Journal - Digital Health, 2021. This work may be considered during the assessment. He is Joint Chief Investigator in the registered research trial ‘An Evaluation of the Safety and Clinical Utility of Handheld ECG Technology in Psychiatry’. This work may be considered during the assessment. He is a visiting senior lecturer at the University of Leeds. There is no financial or non-financial interest in this guideline generated by this post. It was agreed that these interests would not prevent George Crowther from participating in the meeting.

Mani Santhanakrishnan declared non-financial professional and personal interests as he is Chair, Faculty of Old Age Psychiatry, at the Royal College of Psychiatrists, and a Consultant in Old Age Psychiatry who did the initial pilot study of the ECG device during start of COVID pandemic in 2020. It was agreed that these interests would not prevent Mani Santhanakrishnan from participating in the meeting.

Muzahir Tayebjee declared financial interests due to research grants from Biosense Webster and Abbott Medical to fund MD fellows salary (interest ceased December 2021); proctoring for Biosense Webster; educational board membership for Biosense Webster; an unrestricted research grant from Medtronic for REVRAMP (interest ceased December 2021); and a research grant (equipment) from AliveCor. He also declared non-financial professional and personal interests as he is the Chief Investigator of LOCAL ECG, a study designed to use handled ECG recorders to obtain chest leads which is funded by Leeds Cares (local charity), and AliveCor (unrestricted grant- equipment support). Support from AliveCor was donation and transport of equipment including new software. This study is being conducted independently of AliveCor. He was the Chief Investigator on EVALECG , a study designed to validate the Kardia 6L ECG, funded from an unrestricted educational grant from Biosense Webster (interest ceased December 2021). He is a Council Member of the African Heart Association. It was agreed that these interests would not prevent Muzahir Tayebjee from participating in the meeting.

* + 1. The Committee proceeded to discuss the clinical effectiveness and cost and resource use considerations for KardiaMobile 6L for measuring QT interval in people having antipsychotic medication.
		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 EAC, DSU 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 discussed confidential information submitted for this item.
		2. The committee then agreed on the content of the Early Value Assessment document. The committee decision was reached by consensus.
		3. The committee asked the NICE technical team to prepare the Early Value Assessment 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 31 August 2022.