

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee (DAC)

Minutes of the Meeting on Tuesday 20 November 2018

Level 1A City Tower, Piccadilly Plaza, Manchester M1 4BD

PRESENT:

Standing Committee members:

Dr Mark Kroese (Chair)
Ms Liz Adair
Mr John Bagshaw
Dr Simon Fleming
Dr Jim Gray
Professor Steve Halligan
Dr Neil Hawkins
Mr John Hitchman
Professor Christopher Hyde
Dr Sandeep Kapur
Mr Patrick McGinley
Dr Michael Messenger
Mrs Alexandria Moseley
Dr Dermot Neely
Dr Shelly Rahman Haley
Dr Simon Richards
Professor Mark Sculpher
Professor Matt Stevenson
Dr Nick Summerton
Professor Anthony Wierzbicki

Standing Committee apologies:

Professor Enitan Carroll
Dr Owen Driskell

NICE staff in attendance:

Mark Campbell, Acting Programme Director – Devices and Diagnostic systems
Rebecca Albrow, Senior Technical Adviser, DAP
Frances Nixon, Technical Adviser, DAP
Thomas Walker, (Technical lead) Technical Analyst, DAP
Donna Barnes, Project Manager, DAP
Alex Sexton Administrator, DAP
Christopher Pomfrett, Technical Adviser, MTEP

Observing:

Sarah Bromley, Editor, NICE
Dr Josh Carlson, University of Washington (for Part 1 only)
Sophie Cooper, Scientific Adviser
Ciara Donnelly, Business Analyst, NICE

Ann Greenwood, Editor
Suzie Panek, Payroll Liaison Officer, NICE
Katie Wyart, Health Technology Adoption Manager

1. Introduction to the meeting

The Chair welcomed Committee members, observers and members of the public.

Apologies were noted.

2. Code of conduct for members of the public attending the meeting

The Chair explained the code of conduct to the members of the public attending this meeting.

3. Any other business

No other business was offered.

4. Minutes from the last Committee meeting

The Committee agreed the minutes from the 17 July 2018 Committee meeting.

5. Equality and Diversity

The Chair reminded the Committee to raise any potential equality issues related to the topic under discussion.

Lead-I electrocardiogram (ECG) devices for detecting atrial fibrillation using single time point testing in primary care

External Assessment Group representatives: Liverpool Reviews and Implementation Group

Rui Duarte, Senior Research Fellow
James Mahon, Director, Coldingham Analytical Services
Angela Stainthorpe, Research Associate

Specialist Committee members:

Dr Richard Blakey, GPSI Cardiology
Dr Matthew Fay, GP
Dr David Fox, Consultant Cardiologist
Catherine Ross, Clinical Leadership Lead, NHS England
Dr Mark Tanner, Consultant Cardiologist

Specialist Committee members apologies:

Dr Stuart Bennett, GPSI Cardiology
Rebecca Gardner, Lay specialist committee member

PART 1 AND PART 2 (open and closed parts of the meeting).

Part 1 – Open session

The Chair welcomed representatives from AliveCor, MyDiagnostick Medical BV, Cardiocity Ltd, and Plessey Semiconductors Ltd.

There were 5 public attendees.

The Chair asked Committee members to declare any relevant interests.

The following standing committee members had declared interests:

Dr Sandeep Kapur had declared he is a GP CQC special advisor, Digital Lead for Bromley CCG, GMC PLAB examiner and BNF Joint Formulary committee member. It was agreed that these interests would not prevent Dr Kapur from participating in the meeting.

Dr Simon Richards declared an indirect interest as he is employed as VP regulatory affairs for Abbott Rapid Diagnostics. This is a division of Abbott as is Abbott Medical UK which is involved in the area of arrhythmia management. It was agreed that this interest would not prevent Dr Simon Richards from participating in the meeting.

Professor Anthony Wierzbicki declared two ongoing interests as he is a Trial Investigator for Akcea and Clinical Registry Investigator for Chiesi. It was agreed that these interests would not prevent Professor Anthony Wierzbicki from participating in the meeting.

The following specialist committee members had declared interests:

Dr Richard Blakey declared a non-financial interest as he had undertaken unpaid consultancy (one hour) for AliveCor in 2016. He also declared indirect interests as in 2017 AliveCor supplied four devices free of charge to the KSS AHSN and he has taught healthcare providers how to use the AliveCor device; his community cardiology service uses AliveCor devices (purchased at full price) in clinic; he gave an interview about the implementation of AliveCor devices in East Sussex for the NHS Innovation Accelerator research programme; and in February 2017 he was present at teaching sessions by Zenicor for the use of the devices in nursing homes. It was agreed that these interests would not prevent Dr Richard Blakey from participating in the meeting.

Dr Matthew Fay declared ongoing financial interests as he works at the GP partnership Affinity Care, with the GP provider company Westcliffe Health Innovations, and with Westcliffe Medical Services. He also declared non-financial interests as he is a Trustee for the AF Association and for Thrombosis UK, he is on the Executive for Arrhythmia Alliance, he is a Faculty member for Heart Valve Voice and for AF Screen, he is a member of Cardiovascular Intelligence Network, an honorary Clinical Lecturer at Warwick Medical School, and Local Principal Investigator of the ETNA study. He also declared indirect interests as the Affinity Care partnership and Westcliffe Health Innovations have been reimbursed for his time out of practice for presentations and consultancy work for Bayer, Boehringer-Ingelheim, Bristol Myers Squib, Daiichi Sankyo, Lumira DX, Oberoi Consulting, Pfizer and MGP Guidelines; he is a Faculty

Confirmed

member of the SAFER study, and his AHSN is involved with the deployment of the Kardia device. It was agreed that these interests would not prevent Dr Matthew Fay from participating in the meeting.

Dr David Fox declared the following interests: he is a quality control consultant for Broomwell Healthwatch, he is director of the cardiac diagnostic company HPL Ltd, and he has received payment for delivering lectures to GPs paid for by Boehringer, Pfizer and Bayer pharmaceuticals. It was agreed that these interests would not prevent Dr David Fox from participating in the meeting.

Dr Mark Tanner declared non-financial professional and personal interests as he is the co-author of a publication related to the utility of the Alivecor/Kardia Lead I ECG recorder, and he has received a single unit of the Kardia device for clinical use from Alivecor. It was agreed that these interests would not prevent Dr Mark Tanner from participating in the meeting.

The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Lead-I electrocardiogram (ECG) devices for detecting atrial fibrillation using single time point testing in primary care.

The company representative from Cardiocity left the meeting.

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

The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.

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.

The Chair thanked the manufacturer representatives for their attendance, participation and contribution to the meeting.

End of Part 1**Part 2 – closed session**

Agreement on the content of the Diagnostic Consultation Document (DCD) was discussed by the committee.

End of Part 2**Date, time and venue of next meeting**

Tuesday 15 January 2019 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD