

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

**Diagnostics Advisory Committee (DAC)**

**Minutes of the Meeting held on Monday 17 June 2019**

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

**PRESENT:**

**Standing Committee members:**

Dr Mark Kroese (Chair)  
Mr John Bagshaw  
Professor Enitan Carrol  
Dr Owen Driskell  
Dr Jim Gray  
Prof Neil Hawkins  
Mr John Hitchman  
Dr Sandeep Kapur (*first topic only*)  
Mr Patrick McGinley  
Mrs Alexandria Moseley  
Professor Mark Sculpher

**Standing Committee apologies:**

Ms Liz Adair  
Dr Shelley Rahman Haley  
Professor Steve Halligan  
Professor Christopher Hyde  
Dr Michael Messenger  
Dr Simon Richards  
Professor Matt Stevenson  
Professor Anthony Wierzbicki

**NICE staff in attendance:**

Sarah Byron, Associate Director, DAP  
Rebecca Albrow, Senior Technical Adviser, DAP  
Ewa Rupniewska (Technical lead) Technical Analyst, DAP (*first topic*)  
Thomas Walker (Technical lead) Technical Analyst, DAP (*second topic*)  
Christopher Pomfrett, Technical Adviser, MTEP  
Donna Barnes, Project Manager, DAP  
Alex Sexton, Administrator, DAP

**Observing:**

Sarah Bromley, Medical Editor, NICE  
Tara Chernwick, Medical Technology Implementation Manager, NICE (*first topic*)  
Ann Greenwood, Senior Medical Editor, NICE  
Vijitha Gunasekera, Warwick Evidence (*first topic*)  
Ian Mather, Business Analyst, NICE (*second topic*)  
Gareth Murphy, Business Analyst, NICE (*first topic*)  
Brian Shine, Technology Appraisal Committee member  
Katie Wyart, Medical Technology Implementation Manager, NICE (*second topic*)

**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 22 May 2019 Committee meeting.

**5. Equality and Diversity**

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

**Assessment of Rapid Tests for Group A Streptococcal infections in people with a sore throat**

**External Assessment Group representatives: Warwick Evidence**

Felix Achana, Senior Research Fellow  
Hema Mistry, Associate Professor  
Sian Taylor-Phillips, Associate Professor

**Specialist Committee members:**

Gillian Cross, Advanced Practitioner  
Keith Howell, Clinical Pharmacist  
Professor Michael Moore, Professor of Primary Care Research  
Dr Mitul Patel, Consultant Microbiologist  
Carole Pitkeathley, Lay specialist committee member  
Mohammed Rafiq, Clinical Pharmacist  
Derren Ready, Clinical Scientist

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

**Part 1 – Open session**

The Chair welcomed representatives from Abbott, nal von minden, Orion Diagnostica and Roche Diagnostics.

There were 3 public attendees.

The Chair asked Committee members to declare any updates to declared interests.

The following standing committee members had declared interests:

Liz Adair declared an indirect interest as Abbott, Becton Dickinson, Biomerieux, Roche diagnostics and Cepheid supply products and equipment to Viapath Services LLP where she is employed. It was agreed that this interest did not preclude her from participating in the meeting.

Prof Enitan Carroll declared non-financial professional interests as she is collaborating with Biomerieux on an H2020 grant, the PERFORM study (Personalised Risk assessment in febrile illness to optimise Real-life Management across the European Union) and on an NIHR grant for which she is the Chief Investigator, the 'Biomarker-guided duration of Antibiotic Treatment

in Children Hospitalised with confirmed or suspected bacterial infection' (BATCH) trial. It was agreed that these interests did not preclude her from participating in the meeting.

Dr Jim Gray reported non-financial professional and personal interests as he is the co-author of a paper, published in 2018, reporting on local experience of using rapid testing in a secondary care setting. He is co-investigator in two trials of group B streptococcus (GBS) diagnosis. Both trials include an arm where women are tested for GBS in rectovaginal swabs using the Cepheid GenExpert. He was not directly involved in negotiating the package (provision of test machines, consumables and training) provided by Cepheid for either trial. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Mark Kroese declared that Roche Products Ltd (pharmaceuticals) is the sponsor of the PHGF conference on 27 June 2019. It was agreed that this interest did not preclude him from participating in the meeting.

Dr Mike Messenger declared a financial interest as he was a paid consultant for Cepheid from October to December 2018. He also declared that Abbott provided co-funding to a research project from April 2016 to January 2019, and that Roche are a strategic partner of the NIHR Leeds MIC. It was agreed that these interests precluded Dr Messenger from taking part in the meeting and he did not attend.

Prof Mark Sculpher declared a financial interest as he had been a consultant to Roche Diagnostics but unrelated to rapid tests for Group A Streptococcal infections. It was agreed that this interest did not preclude him from participating in the meeting.

Dr Simon Richards declared a direct financial interest as he is employed by Abbott as VP Regulatory Affairs within its Rapid Diagnostics Division. It was agreed that this interest precluded Dr Richards from taking part in the meeting and he did not attend.

Prof Anthony Wierzbicki declared that he is the site investigator for clinical trial of volanesorsen (Akcea), and had been the site investigator for the clinical trial of evolucumab (Amgen), and for the clinical registry for familial chylomicronaemia syndrome (Chiesi). It was agreed that these interests did not preclude him from participating in the meeting.

The following specialist committee members had declared interests:

Keith Howell declared a non-financial professional interest as he is an ENT specialist mentor; it was agreed that this interest did not preclude him from taking part in the meeting.

Prof Michael Moore declared interests as he is undertaking active research in the area and has been in receipt of NIHR funding relating to research. In the meeting, he further declared that he is the co-author of a paper considered by the EAG as part of the Diagnostics Assessment Report for the topic under consideration. It was agreed that these interests did not preclude him from participating in the meeting.

Carole Pitkeathley declared interests as since April 2018 she has been a member of the Leadership Development in Postgraduate Medical Training National Leads Group, Health Education England with a paid honorarium; and she has undertaken paid consultancy work regarding development of leadership programmes for doctors in training and other health professionals for Health Education England Leadership Academy. It was agreed that these interests did not preclude her from participating in the meeting.

Dr Derren Ready declared interests as he is an Honorary Senior Lecturer, UCL Eastman Dental Institute, Honorary Lecturer, Queen Mary University of London, and Deputy-incident director, PHE for the Scarlet Fever & invasive Gp A Streptococcal Standard Response Incident Management. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Mitul Patel declared interests as in 2016, he had received assistance with travel and an honorarium for a lecture from Biofire/Biomerieux. He co-hosted 'Infection During Pregnancy' training days in 2017 and 2018 and room hire was sponsored by Gilead Pharma. In 2018 he had given a lecture presentation at the European Users Group Meeting, Portugal and received financial assistance with travel and accommodation (booked by Biofire) and an honorarium was paid to his Trust. He organised the Clinical Microbiology and Infection Workshop in December 2018, Ahmedabad, India, and travel and accommodation were covered.

He further reported that he has published an article on 'Utility of blood culture in sepsis diagnostics', and was co-author on the following publications: 'Fifteen-minute consultation: the agar plates your microbiology colleagues want you to be scared about', 'The Worldwide Antibiotic Resistance and Prescribing in European Children (ARPEC) point prevalence survey: developing hospital-quality indicators of antibiotic prescribing for children', and 'Combined infection training: should we be concerned about its impact on infection prevention and control training of microbiologists in the UK?'. In 2018 he was co-author on poster presentations on neonatal bacterial and fungal infections at the European Academy of Paediatric Societies conference. He had a poster at the Federation of Infection Societies 2018 conference on the effect on pre-admission antibiotics and implications on outcomes in cases of mastoiditis and was Chair, NICE Managing Common Infection Session on URTI and UTI at that conference.

He further noted that since 2016 he has been the Chair of the West Midlands Infection Group, with three scientific and business meetings per year sponsored by various pharmaceutical companies. Since May 2017 he worked with Aston University on a project regarding the application of Data Envelope Analysis for empyema patients.

It was agreed that these interests did not preclude Dr Patel from taking part in the meeting.

The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Rapid Tests for Group A Streptococcal infections in people with a sore throat.

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

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 at 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**

**Assessment of Implantable Cardiac Monitors (BioMonitor 2-AF, Confirm Rx insertable cardiac monitor and Reveal LINQ Cardiac Monitoring System) to detect atrial fibrillation after cryptogenic stroke)**

**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. Equality and Diversity**

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

**External Assessment Group representatives: BMJ-TAG**

Peter Cain, Senior Health Economist  
Tracey Jhita, Health Economics Manager  
Victoria Wakefield, Principal Health Technology Assessment Analyst

**Specialist Committee members:**

Joanna Denman, Lead Cardiology Advanced Clinical Practitioner  
Dr Anand Dixit, Consultant Stroke Physician  
Dr David Fox, Consultant Cardiologist  
Jo Jerome, Lay specialist committee member  
Dr Justin Lee, Consultant Cardiac Electrophysiologist  
Cara Mercer, Chief Cardiac Physiologist

**Specialist Committee members apologies:**

Dr Sreeman Andole, Consultant in Stroke

**Part 1 – Open session**

The Chair welcomed representatives from Biotronik and Medtronic Ltd.

There were 4 public attendees.

The Chair asked Committee members to declare any relevant interests.

The following standing committee members had declared interests:

Liz Adair declared an indirect interest as Abbott Medical UK supply pathology equipment and products to Viapath Analytics LLP where she is employed. It was agreed that this interest did not preclude her from participating in the meeting.

Dr Owen Driskell declared an indirect interest as his wife works for Astra Zeneca as health and safety professional. It was agreed that this interest did not preclude him from participating in the meeting.

Prof Chris Hyde declared an indirect financial interest as he works for a university which is an evidence contractor for NICE. The report for this guidance was not produced by this group. It was agreed that this interest did not preclude him from participating in the meeting.

Dr Sandeep Kapur declared indirect interests as he is a committee member of the BNM Joint Formulary Committee, a GMC PLAB examiner and CQC GP Adviser. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Michael Messenger had declared non-financial professional and personal interests as Abbott contributed reagents and equipment in kind to research projects he had been affiliated with between 2016 and 2018, not pertaining to implantable cardiac monitors. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Simon Richards had declared a direct financial interest as he is employed as VP regulatory affairs for Abbott Rapid Diagnostics. This is a division of Abbott as is Abbott Medical UK. It was agreed that this interest precluded him from participating in the meeting and he did not attend.

Prof Mark Sculpher had declared a financial interest as he had been a consultant to Medtronic but unrelated to this topic and not since 2015, and to Abbott but unrelated to this topic and not since 2014. It was agreed that these interests did not preclude him from participating in the meeting.

Prof Anthony Wierzbicki had declared indirect interests as he had been a Site Investigator for Akcea from 2017-2018, he is a Site Investigator for Regeneron, and he is Chair of the NICE chronic kidney disease guideline group. It was agreed that these interests did not preclude him from participating in the meeting.

The following specialist committee members had declared interests:

Dr Sreeman Andole declared interests as he is part of the NICE committee for Stroke, and previously acted as Advisory Board member for rivaroxaban, dabigatran and Apixiban. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Anand Dixit declared interests as he had received fees for delivering lectures in conferences and being an advisory board member for Medtronic around 2016. He had been involved in discussions regarding a joint academic and industry (Apoplex) research project around use of non-invasive monitoring for 7 days post stroke to avoid unnecessary use of ILRs. He had received lecture fees from Daiichi Sankyo in March 2019 for a lecture on 'anticoagulation in AF for the elderly patient.' It was agreed that these interests did not preclude him 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 had received payment for delivering lectures to GPs from Boehringer, Pfizer and Bayer pharmaceuticals. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Justin Lee declared that he had received support (air travel/hotel accommodation) to attend scientific conferences from Medtronic, St Jude Medical (Abbott), Daiichi-Sankyo. He had also received honoraria for speaking at educational meetings sponsored by Servier and Bayer. He also declared that costs of organising room hire and a meal for delegates for the 2018 South Yorkshire regional cardiac pacing meeting (which he chaired) were sponsored by Medtronic. It was agreed that these interests did not preclude him from participating in the meeting.

Cara Mercer declared that she had received payment from Medtronic for work on a policy for CPI nursing performing ILR implant in 2016, and had received a speaker fee from Medtronic for a talk at a syncope study day in 2017. She also declared a non-financial professional interest as she had given a talk at a nurses' study day in 2018. It was agreed that these interests did not preclude her from participating in the meeting.

The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Implantable cardiac monitors (BioMonitor 2-AF, Confirm Rx insertable cardiac monitor and

Reveal LINQ Insertable Cardiac Monitoring System) to detect atrial fibrillation after cryptogenic stroke.

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 had questions or 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 at 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.

### **Date, time and venue of next meeting**

Tuesday 20 August 2019 at the National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD.