

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee (DAC)

Minutes of the Meeting held on Wednesday 27 November 2019

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

PRESENT:

Standing Committee members:

Dr Mark Kroese (Chair)
Ms Liz Adair
Dr Owen Driskell
Professor Steve Halligan
Professor Neil Hawkins
Mr John Hitchman
Professor Christopher Hyde
Mr Patrick McGinley
Professor Matt Stevenson
Professor Mark Sculpher

Standing Committee apologies:

Mr John Bagshaw
Professor Enitan Carrol
Dr Jim Gray
Dr Shelley Rahman Haley
Dr Sandeep Kapur
Dr Michael Messenger
Mrs Alexandria Moseley
Dr Simon Richards
Professor Anthony Wierzbicki

NICE staff in attendance:

Rebecca Albrow, Technical Adviser, DAP
Donna Barnes, Project Manager, DAP
Frances Nixon, Technical Adviser, DAP
Christopher Pomfrett, Technical Adviser (Research Commissioning), MTEP
Alex Sexton, Administrator, DAP

Observing:

Lorna Aucott, Aberdeen HTA Group (*first topic*)
Tara Chernick, Health Technology Adoption Manager, NICE
Emilene Coventry, Medical Editor, NICE (*second topic*)
Ann Greenwood, Senior Medical Editor, NICE (*first topic*)
Elisabet Jacobsen, Aberdeen HTA Group (*first topic*)
Tosin Oladapo, Health Technology Analyst, NICE (*first topic*)

Assessment of the ARCHITECT and Alinity i Urine NGAL assay, NephroCheck Test and NGAL Test to help assess the risk of acute kidney injury for people who are being considered for admission to critical care

1. Introduction to the meeting

The Chair welcomed Committee members, observers, members of the public and the company representatives. 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, observers and company representatives 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 20 August 2019 Committee meeting.

5. Equality and Diversity

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

External Assessment Group representatives, Aberdeen HTA Group:

Dr Miriam Brazelli, Reader
Dr Simon Sawhney, Clinical Lecturer
Dr Graham Scotland, Reader

Specialist Committee members:

Dr Banwari Agarwal, Consultant in Critical Care Medicine
Dr Sally Brady, Consultant Clinical Scientist
Dr Mark Devonald, Consultant Nephrologist
Guy Hill, Lay specialist
Dr Christopher Kirwan, Consultant in Critical Care and Renal Medicine
Dr Mark Thomas, Consultant Physician and Nephrologist
Dr Kay Tyerman, Consultant Paediatric Nephrologist

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

Part 1 – Open session

The Chair welcomed representatives from BioMérieux, BioPorto Diagnostics A/S, and Ortho Clinical Diagnostics.

There was 1 public attendee.

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

The following standing committee members had declared interests:

Liz Adair had declared an indirect interest as she is the Quality Director at Viapath Group LLP. Abbott and BioMerieux provide equipment and services to Viapath Services. It was agreed that this interest did not preclude her from participating in the meeting.

John Bagshaw had declared a non-financial professional and personal interest as since 2009 he has been a member of the Executive Board of the British In Vitro Diagnostics Association. It was agreed that this interest did not preclude him from participating in the meeting.

Prof Enitan Carrol had declared non-financial professional and personal interests as, since 2010, she has had a research interest in NGAL as a biomarker of bacterial infection, and has a manuscript under review evaluating several biomarkers of AKI including urinary and plasma NGAL. The urinary NGAL assays were performed on the Abbott ARCHITECT and the plasma using a commercial ELISA kit. It was agreed that these interests did not preclude her from participating in the meeting.

Dr Owen Driskell had declared non-financial professional and personal interests as he is a member of the ACB Scientific Committee since 2015, and a member of the Royal College of Pathologists Record Committee since 2018. He further declared an indirect interest as his wife is a health and safety professional for Astra Zeneca. It was agreed that these interests did not preclude him from participating in the meeting.

Prof Steve Halligan had declared financial interests as he has a private practice at the London Clinic, and a medicolegal expert reports company. It was agreed that these interests did not preclude him from participating in the meeting.

Prof Chris Hyde had 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.

Patrick McGinley had declared non-financial professional and personal interests as since September 2019 he has been a member of the Strategic Council for the All-Party Parliamentary Group on Obesity and he is a Trustee of the Association for the Study of Obesity (ASO). It was agreed that these interests did not preclude him from participating in the meeting.

Dr Mike Messenger had declared non-financial professional and personal interests as he is co-author on the following manuscripts: 'A comparison of the analytical performance of five commercially available assays for neutrophil gelatinase-associated lipocalin using urine' Annals of Clinical Biochemistry, 2013; and 'The future for diagnostic tests of acute kidney injury in critical care: evidence synthesis, care pathway analysis and research prioritisation' NIHR Journals Library, 2018. It was agreed that these interests precluded Dr Messenger from taking part in the discussions for this topic and he did not attend the meeting.

Dr Simon Richards had declared a financial interest as since October 2017 he has been employed by Abbott Rapid Diagnostics, a Division of Abbott, as VP, Divisional Regulatory Affairs. It was agreed that this interest precluded Dr Richards from taking part in the discussions for this topic and he did not attend the meeting.

Prof Anthony Wierzbicki had declared financial interests as he is the Clinical Lead, Blood Sciences Laboratory, Viapath, and undertakes private practice (lipids). He further declared non-financial professional and personal interests as since 2016 he has been a member of the Steering Committee STAREE trial. He had also declared the following indirect interests:

- Site clinical investigator: REGN-1500 trial (evinacumab in familial chylomicronemia syndrome) since April 2018
- Site clinical co-investigator VESALIUS trial: evolocumab (PCSK9) in patients with high cardiovascular risk since September 2019
- Chair: NICE kidney disease guidelines suite update since April 2019

It was agreed that these interests did not preclude him from participating in the meeting.

The following specialist committee members had declared interests:

Dr Sally Brady had declared non-financial professional and personal interests as she will be the Laboratory link for a study at Guy's and St Thomas' Trust for the use of Nephrocheck in the ICU, and the designated clinical scientist overseeing analysis of samples using the Nephrocheck POCT and laboratory systems. The study is not yet live and the start has been delayed to 2020. It was agreed that this interest did not preclude her from participating in the meeting.

Dr Mark Devonald had declared the following financial interests:

- Unconditional educational grants from Alexion, Stanningley Pharma, Vifor and Daiichi Sankyo to support the Nottingham Acute Kidney Injury Course March 2019 (for which he is the course director).
- Co-inventor (with Prof David Gardner) in patent application 'Biomarkers related to kidney function and methods involving their use'. International publication number: WO 2016/110701 A1 (international publication date 14 July 2016). Patent applicants: Nottingham University Hospitals NHS Trust and University of Nottingham.
- Medicolegal services, providing reports in field of nephrology and in particular acute kidney injury.
- Director of Active Kidney Innovation Ltd (currently concerned exclusively with provision of medicolegal reports).
- Some sessions of his NHS job are currently funded by a NIHR i4i grant supporting the development of a point of care test for early detection of acute kidney injury.

He had further declared the following non-financial interests:

- He leads the Nottingham Acute Kidney Injury Research Group, which has a research interest in identification and development of biomarkers for acute kidney injury.
- He has published research papers and given presentations in the field of nephrology, particularly acute kidney injury
- His research group collaborates with SureScreen Diagnostics Ltd and Trace2o Ltd in the development of a point of care test for acute kidney injury.
- He provides peer review for various journals and grant awarding bodies, particularly in the field of acute kidney injury.

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

Dr Kay Tyerman had declared a non-financial professional interest as from 2014-2017 she was a member of Member of NHS England 'Think Kidneys' Acute Kidney Injury Paediatric and Measurement Sub-group' and is the co-author of associated paediatric guideline. It was agreed that this interest did not preclude her from participating in the meeting.

The Committee proceeded to discuss the clinical and costs effectiveness for the ARCHITECT and Alinity i Urine NGAL assay, NephroCheck Test and NGAL Test to help assess the risk of acute kidney injury for people who are being considered for admission to critical care.

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 Consultant Document (DCD) was discussed by the committee.

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, members of the public and the company representatives. 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, observers and company representatives 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

Dr Victoria Wakefield, Principal Health Technology Assessment Analyst

NICE Decision Support Unit:

Dr Geoff Holmes, Research Associate, University of Sheffield

Specialist Committee members:

Dr Sreeman Andole, Consultant in Stroke

Joanna Denman, Lead Cardiology Advanced Clinical Practitioner

Dr Anand Dixit, Consultant Stroke Physician

Dr David Fox, Consultant Cardiologist

Jo Jerrome, Lay specialist committee member

Dr Justin Lee, Consultant Cardiac Electrophysiologist

Cara Mercer, Chief Cardiac Physiologist

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

Part 1 – Open session

The Chair welcomed representatives from Biotronik and Medtronic.

There were two public attendees.

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

The following standing committee members had declared interests:

Liz Adair had 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 had 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 had 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 had 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.

Patrick McGinley had declared non-financial professional and personal interests as since September 2019 he has been a member of the Strategic Council for the All-Party Parliamentary Group on Obesity and is a Trustee of the Association for the Study of Obesity (ASO). 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 had declared interests as he is part of the NICE committee for stroke, and previously acted as an Advisory Board member for rivaroxaban, dabigatran and apixiban. Since June 2019 he has been a member of the Clinical Reference Group for Neurosciences at NHS England. Since May 2018 he has been Assistant Medical Director, NHS England. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Anand Dixit had declared financial interests as he had attended (a one off) advisory committee meeting supported by Bayer plc on 'management of non-valvular AF in diabetics' and had received fees as an advisory board member. 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 had 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 had declared that he had received support (air travel/hotel accommodation) to attend scientific conferences from Medtronic, St Jude Medical (Abbott), and 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 had 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 Chair welcomed Dr Geoff Holmes from the NICE Decision Support Unit (DSU) and explained that the DSU provide a research and training resource to NICE. The DSU had been commissioned to provide an independent validation of the model for this topic.

The Committee proceeded to discuss the comments made during the public consultation on the Diagnostics Consultation Document and on the DSU critique of the model for this topic.

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

Date, time and venue of next meeting

Wednesday 29 January 2020 at the National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD.