

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee (DAC)

Minutes of the Meeting held on Wednesday 29 January 2020

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

PRESENT:

Standing Committee members:

Dr Mark Kroese (Chair)
Ms Liz Adair
Mr John Bagshaw
Professor Enitan Carrol
Dr Jim Gray
Professor Steve Halligan
Professor Neil Hawkins
Mr John Hitchman
Professor Christopher Hyde
Mr Patrick McGinley
Mrs Alexandria Moseley
Dr Shelley Rahman Haley
Professor Matt Stevenson
Professor Mark Sculpher
Professor Anthony Wierzbicki

Standing Committee apologies:

Dr Owen Driskell
Dr Sandeep Kapur
Dr Michael Messenger
Dr Simon Richards

NICE staff in attendance:

Rebecca Albrow, Associate Director, DAP
Thomas Walker, Technical Analyst, DAP
Christopher Pomfrett, Technical Adviser (Research Commissioning), MTEP
Donna Barnes, Project Manager, DAP
Alex Sexton, Administrator, DAP

Observing:

Tara Chernick, Health Technology Adoption Manager, NICE
Ann Greenwood, Senior Medical Editor, NICE
Olivia Havercroft, Medical Editor, NICE
Ian Mather, Business Analyst – Resource Impact

Assessment of Tests to help assess risk of acute kidney injury for people being considered for critical care admission (ARCHITECT and Alinity i Urine NGAL assays, BioPorto NGAL test and NephroCheck test)

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 27 November 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
Dwayne Boyers, Health Economist

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 and BioPorto Diagnostics A/S.

There were no 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 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 comments made during the public consultation for the 'Tests to help assess risk of acute kidney injury for people being considered for critical care admission (ARCHITECT and Alinity i Urine NGAL assays, BioPorto NGAL test and NephroCheck test)' 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

The committee agreed the content of the Diagnostics Guidance Document (DGD).

Date, time and venue of next meeting

Thursday 27 February 2020 at the National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD.