

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

**Diagnostics Advisory Committee (DAC)**

**Minutes of the Meeting held on Tuesday 20 August 2019**

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

**PRESENT:**

**Standing Committee members:**

Dr Mark Kroese (Chair)  
Ms Liz Adair  
Dr Owen Driskell  
Dr Jim Gray  
Professor Steve Halligan  
Professor Neil Hawkins  
Mr John Hitchman  
Professor Christopher Hyde  
Mrs Alexandria Moseley  
Professor Matt Stevenson  
Professor Mark Sculpher

**Standing Committee apologies:**

Mr John Bagshaw  
Professor Enitan Carroll  
Dr Shelley Rahman Haley  
Dr Sandeep Kapur  
Mr Patrick McGinley  
Dr Michael Messenger  
Dr Simon Richards  
Professor Anthony Wierzbicki

**NICE staff in attendance:**

Rebecca Albrow, Technical Adviser, DAP  
Donna Barnes, Project Manager, DAP  
Sarah Byron, Associate Director, DAP  
Mirella Marlow, Programme Director, Centre for Health Technology Evaluation  
Frances Nixon, Technical Lead (*first topic*), DAP  
Christopher Pomfrett, Technical Adviser (Research Commissioning), MTEP  
(*present for first topic*)  
Ewa Rupniewska, Technical Lead (*second topic*), DAP  
Alex Sexton, Administrator, DAP

**Observing:**

Emilene Coventry, Medical Editor, NICE (*first topic*)  
Ann Greenwood, Senior Medical Editor, NICE (*second topic*)  
Leslie Hayes, Business Analyst, NICE

**Assessment of point-of-care creatinine tests to assess kidney function before administering intravenous contrast for computed tomography (CT) imaging**

**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 17 June 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: Centre for Reviews and Dissemination (CRD) and Centre for Health Economics (CHE), University of York**

Mark Corbett, Research Fellow, CRD, University of York,  
Professor Stephen Palmer, CHE, University of York

**Specialist Committee members:**

Dr Jane Belfield, Clinical Director, Radiology Department  
Anne Dawnay, Consultant Biochemist  
Dr Mark Devonald, Consultant Nephrologist  
Guy Hill, Lay specialist committee member  
Emily Lam, Lay specialist committee member  
Professor Beverly Snaith, Clinical Professor of Radiology  
Annette Thomas, Consultant Clinical Scientist

**Specialist Committee members apologies:**

Dr Andrew Lewington, Consultant Renal Physician

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

**Part 1 – Open session**

The Chair welcomed representatives from Abbott Diagnostics, Fujifilm UK Ltd, Radiometer Ltd, Nova Biomedical, and Siemens Healthcare Ltd.

There were 2 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 Diagnostics, Radiometer and Siemens Healthineers supply products and equipment to Viapath Services LLP where she is employed

## **Unconfirmed**

as the Quality Director. It was agreed that this interest did not preclude her from taking part in the meeting.

Dr Sandeep Kapur had declared interests as he is a BNF Joint Formulary Committee Member since August 2018; a GMC PLAB examiner since July 2018, and a CQC GP advisor since July 2018, and is a physician at the Mayo Clinic London in partnership with Oxford University Clinic since April 2019. It was agreed that these interests did not preclude him from involvement with the guidance.

Dr Michael Messenger had declared non-financial professional and personal interests as since August 2017 he has been the co-investigator on the “Bias Estimation Point of Care Creatinine” (BEPoCC ISRCTN 18805212) and “Streamlining cross-sectional imaging pathways” (SCIPs ISRCTN 67296844) studies. It was agreed that these interests did not preclude him from involvement with the guidance.

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

Professor Mark Sculpher declared in the meeting that he is based at the same university as the Evidence Assessment Group for this topic but he had no involvement with their work for this assessment. It was agreed that this interest did not preclude him from taking part in the meeting.

Prof Anthony Wierzbicki had declared he is a clinical trial investigator for Akcea since April 2016, and for Regeneron since October 2018. He had been a clinical trial investigator for Amgen from 2015-2018. He had been a clinical registry investigator for Chiesi from 2017-2019. Since July 2018 he has been Chair of the NICE kidney guidelines update. It was agreed that these interests did not preclude him from involvement with the guidance.

The following specialist committee members had declared interests:

Dr Mark Devonald had declared indirect interests as he had received unconditional educational grants from MSD, Alexion and Stanningley Pharma to support the Nottingham Acute Kidney Injury Course (for which he is the course director) but had not received any personal honoraria. He is co-inventor 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 owners: Nottingham University Hospitals NHS Trust and University of Nottingham). It was agreed that these interests did not preclude him from taking part in the meeting.

Dr Andrew Lewington had declared interests as, since January 2018, he is the Associate Clinical Director NIHR Leeds In Vitro Diagnostic Cooperative and in this role engages with industry to help the development and delivery of new IVDs for the NHS. Since January 2012 he is Co-Chair of the UK Kidney Research Consortium Acute Kidney Injury Clinical Study Group and engages with industry to discuss potential AKI studies that could be developed with potential funding from industry or through partnering on grant applications. He had also declared attendance at the following meetings:

- American Society of Nephrology Conference, San Diego, November 2018, for a poster presentation on ‘Outcomes for Patients with Short vs More Prolonged Inpatient Hospital Stay after Previous Inpatient Admission with an Episode of AKI’. Reasonable expenses were partially covered by NHIR Leeds MIC.
- Acute Dialysis Quality Initiative (ADQI) – Quality Improvement Conference, San Diego, November 2018, leading on prevention of AKI in the community. Expenses were received from ADQI to cover two nights’ accommodation.

- AKI and CRRT conference, San Diego, May 2019, to symposia around therapeutic challenges in AKI and CKD- managing hypo and hyperkalaemia, innovations in caring for patients with dysnatremias, and preventing AKI. Reasonable travel and accommodation expenses were paid by the conference.
- AKI conference, Coventry, March 2019, to give a lecture on AKI diagnostics. Reasonable travel expenses were paid by Coventry Hospitals.
- NIHR Leeds Sepsis and AKI workshop to identify unmet clinical need, May 2019, to lecture on AKI and sepsis and AKI diagnosis and treatment.
- AKI conference, Italy, May 2019, to give a lecture on AKI prevention standards. Reasonable travel and accommodation were paid by the conference.
- Renal Association and British Renal Society UK Kidney Week, Brighton, June 2019, to chair a session on AKI.
- UK Critical Care Research Group, Leeds, June 2019, to give a presentation on NIHR Leeds MIC.
- 'Leading in Innovations in Healthcare and Medical Education Harvard Macy Course', Boston, June 2019. Reasonable expenses (flight and accommodation) were funded by LTHT.
- NIHR/UKKRC Research Conference, London, July 2019. Travel and registration expenses were paid by Leeds MIC.

It was agreed that these interests did not preclude him from involvement with the topic.

Dr Beverley Snaith had declared non-financial interests as she is Chief investigator on research studies investigating the topic under review (and relevant publications) in receipt of grants from NHS England and Y&H AHSN. This includes loan of equipment from 3 device companies for investigation. She is the co-author on a paper considered by the EAG as part of the Diagnostics Assessment Report for the topic under consideration. She had been an expert commentator on NICE Medtech innovation briefing – MIB 136, POCT Creatinine use before contrast enhanced imaging from August 2017 to August 2018. It was agreed that these interests did not preclude her from taking part in the meeting.

Dr Annette Thomas had declared an indirect interest as she is employed by Cardiff and Vale UHB, which hosts WeQAS, which provides an EQA programme to monitor the performance of POCT creatinine devices across the UK. She also declared a non-financial professional interest as she had been an expert commentator on NICE Medtech innovation briefing – MIB 136, POCT Creatinine use before contrast enhanced imaging from August 2017 to August 2018. She further declared that she had received reasonable accommodation and travel expenses to present a lecture on 'hypoglycaemia in neonates' at Nova Biomedical User Group meetings in November 2018. She had also received reasonable travel and accommodation expenses to present a lecture on 'countrywide connectivity of POCT' at Siemens Healthineers User Group meetings in Brussels in October 2018. It was agreed that these interests did not preclude her from taking part in the meeting.

The Committee proceeded to discuss the comments made during the public consultation for point-of-care creatinine tests to assess kidney function before administering intravenous contrast for computed tomography (CT).

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 and participation in the meeting.

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

Agreement on the content of the Diagnostic Guidance Document (DGD) was discussed by the committee.

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

Felix Achana, Senior Research Fellow

Daniel Gallacher, Research Fellow

**Specialist Committee members:**

Gillian Cross, Advanced Practitioner

Professor Michael Moore, Professor of Primary Care Research

Dr Mitul Patel, Consultant Microbiologist

Carole Pitkeathley, Lay specialist committee member

Derren Ready, Clinical Scientist

**Specialist Committee members apologies:**

Keith Howell, Clinical Pharmacist

Mohammed Rafiq, Clinical Pharmacist

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

**Part 1 – Open session**

The Chair welcomed representatives from Abbott, Orion Diagnostica and Becton Dickinson UK Ltd.

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 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.

Professor Enitan Carroll declared non-financial professional interests as since 2016 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 this topic.

Dr Jim Gray had reported he is the co-author of a paper, published in 2018, reporting on local experience of using rapid testing in a secondary care setting. Since 2016 he is the 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) had sponsored 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 since July 2017 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.

Professor Mark Sculpher declared a financial interest as since 2017 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.

Professor Matt Stevenson declared at the meeting that Roche Diagnostics have signalled their intent to fund a project at ScHARR (where he is employed) in which he will have a role. The project is around evaluating the cost-effectiveness of biomarkers in patients with traumatic brain injury, no contracts have been signed. It was agreed that this interest did not preclude him from participating in the meeting.

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Professor Anthony Wierzbicki had declared that since April 2017 he is the site investigator for clinical trial of volanesorsen (Akcea), and he had been the site investigator for the clinical trial of evolocumab (Amgen) during 2017-2018. He had been the site investigator for the clinical registry for familial chylomicronaemia syndrome (Chiesi) from 2016-2018. It was agreed that these interests did not preclude him from participating in the topic.

The following specialist committee members had declared interests:

Keith Howell had declared a non-financial professional interest as he is an ENT specialist mentor since 2016; it was agreed that this interest did not preclude him from taking part in the meeting.

Professor Michael Moore had declared he is undertaking active research in the area and has been in receipt of NIHR funding relating to research. He further declared that he is the co-author of a paper (PRISM development work and trial funded by the HTA) 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 had declared interests as since December 2016 she has been the standing lay member for the Managing Common Infections Guidelines Committee at NICE for which she is paid an honorarium, and since November 2018 has been the lay member for the Shared Decision Making Guidelines Committee for which she was paid an honorarium. She had also noted that 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. Since April 2018 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. In the meeting she declared that she has been appointed (August 2019) to the NHSE Same Day Emergency Care Programme Board as a lay member and will receive an honorarium for this week. 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 since 2012, Honorary Lecturer, Queen Mary University of London since 2013, and Deputy-incident director, PHE for the Scarlet Fever & invasive Group A Streptococcal Standard Response Incident Management since 2018. 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' (2016), and was co-author on the following publications: 'Fifteen-minute consultation: the agar plates your microbiology colleagues want you to be scared about' (2016), 'The Worldwide Antibiotic Resistance and Prescribing in European Children (ARPEC) point prevalence survey: developing hospital-quality indicators of antibiotic prescribing for children' (2014), and 'Combined infection training: should we be concerned about its impact on infection prevention and control training of microbiologists in the UK?' (2015). 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 has worked with Aston University on a project regarding the application of Data Envelope Analysis for empyema patients.

He had further reported, July 2019, that he is co-organising the Clinical Microbiology Workshop in India, for which travel expenses may be covered, and he is the name local microbiologist for Birmingham Children's Hospital for an NIHR funded programme on the effect of rapid molecular diagnosis of HA-pneumonia on antimicrobial stewardship.

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

The Committee proceeded to discuss the comments made during the public consultation for 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 Guidance Document (DGD) was discussed by the committee.

**End of Part 2**

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

Thursday 26 September 2019 at the National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD.