

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee (DAC)

Minutes of the Meeting on Wednesday 13 February 2019

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

PRESENT:

Standing Committee members:

Dr Mark Kroese (Chair)
Professor Enitan Carrol
Dr Owen Driskell
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
Professor Anthony Wierzbicki

Standing Committee apologies:

Ms Liz Adair
Mr John Bagshaw
Dr Nick Summerton

NICE staff in attendance:

Mark Campbell, Acting Programme Director – Devices and Diagnostic systems
Sarah Byron, Associate Director, DAP
Frances Nixon, Technical Adviser, DAP (*first topic*)
Ewa Rupniewska, (Technical lead) Technical Analyst, DAP (*first topic*)
Rebecca Albrow, Senior Technical Adviser, DAP (*second topic*)
Thomas Walker, (Technical lead) Technical Analyst, DAP (*second topic*)
Donna Barnes, Project Manager, DAP
Alex Sexton, Administrator, DAP
Christopher Pomfrett, Technical Adviser, MTEP

Observing:

Ciara Donnelly, Business Analyst, NICE (*first topic*)
Katie Wyart, Health Technology Adoption Manager

Therapeutic monitoring of TNF-alpha inhibitors in rheumatoid arthritis

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 20 November 2018 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: Peninsula Technology Assessment Group (PenTAG)

Prof Stuart Logan, Cerebra Professor of Paediatric Epidemiology,
University of Exeter Medical School
Irina Tikhonova, Senior Research Fellow
Huiqin Yang, Senior Research Fellow

Specialist Committee members:

Prof Anne Barton, Professor of Rheumatology
Prof John Isaacs, Professor of Clinical Rheumatology
Karl Nicholl, Biologics Nurse Specialist
Dr Mandy Perry, Clinical Scientist
Dr Martin Perry, Consultant Physician and Rheumatologist
Stephanie Turner, Lay Specialist Committee Member

Specialist Committee members apologies:

Prof Frank McKenna, Consultant Physician and Rheumatologist
Susan Moore, 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 Grifols UK Ltd, Biohit Healthcare Ltd, Immundiagnostik AG, Theradiag, Cambridge Life Sciences, R-Biopharm, and Sanquin Diagnostic Services B.V.

There were **3** public attendees.

The Chair asked Committee members to declare any relevant interests.

The following standing committee members had declared interests:

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 would not preclude Dr Driskell from participating in the meeting.

Dr Neil Hawkins had declared an indirect interest in that he has provided consultancy regarding unrelated products in a different therapeutic area to Janssen Ltd, a manufacturer of one of the TNF-alpha inhibitors used in the treatment of rheumatoid arthritis. It was agreed that this interest would not preclude Dr Hawkins from participating in the meeting.

Prof Chris Hyde had declared an indirect interest in that he is based at the University of Exeter Medical School, but no longer actively helps PenTAG with its reports. In the meeting he noted that he had not been involved with the Diagnostics Assessment Report for this topic. It was agreed that this interest would not preclude Prof Hyde from participating in the meeting.

Dr Sandeep Kapur had declared indirect interests in that 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 would not preclude Dr Kapur from attending the meeting.

Dr Michael Messenger had declared non-financial professional and personal interests as his employer, the NIHR MIC Leeds, has conducted collaborative research with Alpha Laboratories concerning other product lines. It was agreed that these interests would not preclude Dr Messenger from participating in the meeting.

Dr Simon Richards had declared an indirect interest as he is employed by Abbott Rapid Diagnostics, which is a division of Abbott Laboratories. Another separate division of Abbott Laboratories markets a TNF inhibitor. It was agreed that this interest would not preclude Dr Richards from attending the meeting.

Prof Matt Stevenson had declared indirect interests in that he has published papers on rheumatoid arthritis, the model he helped construct for a NICE MTA has been regularly used as a starting point by manufacturers of RA interventions, and he has stated publicly that he does not believe that biologics are cost-effective at current prices. It was agreed that these interests would not preclude Prof Stevenson from participating in the meeting.

Prof Anthony Wierzbicki had declared indirect interests as he had been a Trial Investigator for Akcea and Clinical Registry Investigator for Chiesi. In the meeting he noted a further interest in that he is the Clinical Director of Blood Sciences at Viapath, which has responsibility for anti-TNF α and anti-drug antibody testing. It was agreed that these interests would not preclude Prof Wierzbicki from participating in the meeting.

The following specialist committee members had declared interests:

Prof John Isaacs had declared direct financial interests as he had received consultancy fees from companies producing biologic drugs which are measured by the technology, Abbvie, Janssen, Celltrion, Roche, Merck & Co and Amgen. He had received honorarium for lectures, including on anti-drug antibodies, from Pfizer, and had received hospitality at the European League Against Rheumatism AGM paid for by Sanqin Diagnostics Services B.V. He had also declared direct non-financial interests as he had conducted research into therapeutic drug monitoring funded by Pfizer which allowed for the purchasing of Promonitor kits. He had attended a meeting of the EULAR Study Group on Therapeutic Drug Monitoring at the HQ of Sanqin Diagnostics Services B.V. He had published papers on biosimilars, including immunogenicity measurements and is writing a review supported by Celltrion. He also declared an indirect financial interest as he had done consultancy work for Pfizer, and the fee had been paid to his employers. It was agreed that these interests would not preclude Prof Isaacs from participating in the meeting.

Prof Frank McKenna had declared the following direct financial interests: he had received an honorarium from Sandoz for attending an etanercept advisory board; he had also received an honorarium for an invited lecture on depression in RA given at Janssen satellite in EULAR 2016, and an honorarium for attending the 'Medical Education Therapy Area Steering Committee for RA' Janssen-Cilag Ltd. It was agreed that these interests would not preclude Prof McKenna from participating in the meeting.

Karl Nicholl had declared indirect financial interests as he had received speaker fees from Abbvie for a 'Back in Focus' meeting in February 2018, and from Eli Lilly for a 'Response Forum' in November 2017 and November 2018. It was agreed that these interests would not preclude Karl Nicholl from participating in the meeting

Dr Mandy Perry had declared a direct financial interest as her employer had undertaken a comparison of assays manufactured by different companies and this work was supported by one of the manufacturers (Grifols), in that the laboratory received remuneration for the laboratory staff time to undertake the work. It was agreed that this interest would not preclude Dr Perry from participating in the meeting.

Dr Martin Perry had declared direct financial interests as his employer had received an educational grant from Grifols for a biologic drug monitoring conference, and he had attended a conference in Spain with transport, accommodation and hospitality from Grifols (but had not received payment personally). He further declared direct non-financial interests as Grifols had also provided promonitor assay kits to undertake a pilot study. He had also received personal payment from Eli Lilly for an advisory board and travel, accommodation, conference registration fees and hospitality from Celgene. Biogen and Abbvie had also provided an education grant for a biologic drug monitoring conference but had not received a personal fee or payment. It was agreed that these interests would not preclude Dr Perry from participating in the meeting.

The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of therapeutic monitoring of TNF-alpha inhibitors in rheumatoid arthritis.

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

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

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: Liverpool Reviews and Implementation Group

Rui Duarte, Senior Research Fellow
Angela Stainthorpe, Research Associate

Specialist Committee members:

Dr Stuart Bennett, GPSI Cardiology
Dr Richard Blakey, GPSI Cardiology
Dr David Fox, Consultant Cardiologist
Rebecca Gardner, Lay specialist committee member
Catherine Ross, Clinical Leadership Lead, NHS England
Dr Mark Tanner, Consultant Cardiologist

Specialist Committee members apologies:

Dr Matthew Fay, GP

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

Part 1 – Open session

The Chair welcomed representatives from AliveCor Ltd and Mydiagnostick Medical bv. No attendees had registered for the public gallery.

The Chair asked Committee members to declare any relevant interests.

The following standing committee members had declared interests:

Dr Sandeep Kapur had declared indirect interests as 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 preclude Dr Kapur from participating in the meeting.

Dr Simon Richards had 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 preclude Dr Richards from participating in the meeting.

Prof Anthony Wierzbicki had 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 preclude Prof Wierzbicki from participating in the meeting.

The following specialist committee members had declared interests:

Dr Richard Blakey had 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 preclude Dr Blakey from participating in the meeting.

Dr Matthew Fay had 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 Squibb, Daiichi Sankyo, Lumira DX, Oberoi Consulting, Pfizer and MGP Guidelines; he is a Faculty 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 preclude Dr Fay 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 has received payment for delivering lectures to GPs paid for by Boehringer, Pfizer and Bayer pharmaceuticals. It was agreed that these interests would not preclude Dr Fox from participating in the meeting.

Dr Mark Tanner had 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 preclude Dr Tanner from participating in the meeting.

The Associate Director (DAP) updated the committee that RhythmPad GP made by Cardiocity is no longer in scope due to a change to the CE mark.

The Committee proceeded to discuss the comments made during the public consultation for the Lead-I electrocardiogram (ECG) devices for detecting atrial fibrillation using single time point testing in primary care 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 Guidance Document (DGD) was discussed by the committee.

End of Part 2

Date, time and venue of next meeting (next topic)

Tuesday 16 April 2019 at the National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD