

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee (DAC)

Minutes of the Meeting on Tuesday 16 April 2019

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

PRESENT:

Standing Committee members:

Dr Mark Kroese (Chair)
Ms Liz Adair
Mr John Bagshaw
Dr Owen Driskell
Dr Simon Fleming
Dr Jim Gray
Prof Steve Halligan
Prof Neil Hawkins
Mr John Hitchman
Prof Christopher Hyde
Mrs Alexandria Moseley
Dr Shelly Rahman Haley
Prof Mark Sculpher
Prof Matt Stevenson
Prof Anthony Wierzbicki

Standing Committee apologies:

Prof Enitan Carrol
Dr Sandeep Kapur
Dr Michael Messenger
Mr Patrick McGinley
Dr Simon Richards
Dr Nick Summerton

NICE staff in attendance:

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

Observing:

Sarah Bromley, Editor, NICE
Tara Chernick, Health Technology Adoption Manager
Gareth Murphy, Business Analyst, NICE (*first topic*)
Mark Rasburn, Public Involvement Adviser
Katie Wyart, Health Technology Adoption Manager

1. Introduction to the meeting

The Chair welcomed Committee members, observers and members of the public.

The Chair noted that Dr Dermot Neely had retired and resigned from the committee. He recorded the committee's thanks to Dr Neely for his hard work and contributions over the past five years.

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.

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

External Assessment Group representatives: BMJ-TAG

Dr Steve Edwards, Director of Health Technology Assessment
Tracey Jhita, Health Economics Manager
Dr Victoria Wakefield, Principal Health Technology Assessment Analyst

Specialist Committee members:

Dr Sreeman Andole, Consultant in Stroke
Dr Anand Dixit, Consultant Stroke Physician
Joanna Denman, Lead Cardiology Advanced Clinical Practitioner
Jo Jerrome, Lay specialist
Dr Justin Lee, Consultant Cardiac Electrophysiologist
Cara Mercer, Chief Cardiac Physiologist

Specialist Committee members apologies:

Dr David Fox, Consultant Cardiologist

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

Part 1 – Open session

The Chair welcomed representatives from Biotronik, Medtronic Ltd and Abbott.

There were **5** public attendees.

The Chair asked Committee members to declare any relevant 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 would 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 would 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 would not preclude him 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 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 would 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 would 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 would 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 Advisory Board member for rivaroxaban, dabigatran and Apixiban. It was agreed that these interests would not preclude him from participating in the meeting.

Dr Anand Dixit had declared interests as he had received lecture fees for delivering lectures in conferences and being an advisory board member for Medtronic two years ago. He had also declared involvement 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. It was agreed that these interests would 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 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 him from participating in the meeting.

Dr Justin Lee had declared non-financial professional and personal interests as 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 had also declared that costs of organising room hire and meal for delegates for the 2018 South Yorkshire regional cardiac pacing meeting chaired by him were sponsored by Medtronic. It was agreed that these interests would not preclude him from participating in the meeting.

Cara Mercer had declared interests as 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 would 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 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, participation and contribution to the meeting.

End of Part 1

Part 2 – closed session

A decision on the content of the Diagnostics Consultation Document (DGD) was deferred pending additional analysis by the External Assessment Group (EAG).

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 13 February 2019 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
Dr Irina Tikhonova, Senior Research Fellow
Dr Huiqin Yang, Senior Research Fellow

Specialist Committee members:

Prof Anne Barton, Professor of Rheumatology
Prof John Isaacs, Professor of Clinical Rheumatology
Dr Frank McKenna, Consultant Physician and Rheumatologist
Susan Moore, Lay Specialist
Karl Nicholl, Biologics Nurse Specialist
Dr Martin Perry, Consultant Physician and Rheumatologist
Stephanie Turner, Lay Specialist

Specialist Committee members apologies:

Dr Mandy Perry, Clinical Scientist

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 and Theradiag

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 him from participating in the meeting.

Prof 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 him 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. It was agreed that this interest would not preclude him 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 him 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 him 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 him 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 him 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 him 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 Sanquin 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 Sanquin 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 him from participating in the meeting.

Dr 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 him 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 him 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 her 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 him from participating in the meeting.

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

End of Part 2

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

Wednesday 22 May 2019 at the National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD