

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee (DAC)

Minutes of the Meeting on Thursday 27 February 2020
Level 1A City Tower, Piccadilly Plaza, Manchester M1 4BD

PRESENT:

Standing Committee members:

Dr Mark Kroese (Chair)
Mr John Bagshaw
Professor Enitan Carrol
Dr Shelly Rahman Haley
Dr Neil Hawkins
Mr John Hitchman
Professor Christopher Hyde
Dr Sandeep Kapur
Dr Michael Messenger
Mrs Alexandria Moseley
Professor Mark Sculpher
Professor Matt Stevenson
Dr Simon Richards (*first topic only*)
Dr Brian Shine

Standing Committee apologies:

Ms Liz Adair
Dr Owen Driskell
Dr Jim Gray
Professor Steve Halligan
Mr Patrick McGinley
Professor Anthony Wierzbicki

NICE staff in attendance:

Rebecca Albrow, Associate Director, DAP
Thomas Walker, (Technical lead) Technical Analyst, DAP
Donna Barnes, Project Manager, DAP
Alex Sexton, Administrator, DAP

Observing:

Helen Crosbie, Public Involvement Adviser
Ann Greenwood, Editor, NICE
Gareth Murphy, Business Analyst – Resource Impact
Peter O'Neill, Technical Adviser, DAP
Tosin Oladapo, Health Technology Analyst, DAP
Katie Wyart, Health Technology Adoption Manager, NICE

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

The Chair noted that Dr Brian Shine had joined the committee and was attending his first meeting. The Chair thanked Dr Simon Richards, Professor Mark Sculpher and Professor Anthony Wierzbicki, at the end of their committee tenure, for their tremendous contributions during their time as members of the Diagnostics Advisory Committee.

4. Minutes from the last Committee meeting

The Committee agreed the minutes from the 29 January 2020 Committee meeting.

5. Equality and Diversity

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

Assessment of Testing strategies for Lynch syndrome in people with endometrial cancer

External Assessment Group representatives, Warwick Evidence:

Mary Jordan, Research Associate
Jason Madan, Associate Professor of Health Economics
Chris Stinton, Senior Research Fellow

Specialist Committee members:

Kate Daniels, Lay Specialist
Angela George, Consultant Medical Oncologist, Consultant in Oncogenetics
Fiona Lalloo, Consultant in Clinical Genetics
Pierre Martin-Hirsch, Consultant Gynaecological Oncologist
Tracie Miles, Clinical Nurse Specialist / Information Nurse Specialist
Gail Norbury, Consultant Clinical Scientist in Genetics
Naveena Singh, Consultant Pathologist
Katie Snape, Consultant Cancer Geneticist

Specialist Committee members apologies:

Demetra Georgiou, Principal Genetic Counsellor in Cancer
Anca Oniscu, Consultant Pathologist

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

Part 1 – Open session

The Chair welcomed representatives from the University of Manchester (the notifier of the topic).

There were no public attendees.

The Chair asked Committee members to declare any relevant interests.

The following standing committee members had notified the following interests:

Liz Adair had declared an indirect interest as she is the Quality Director for Viapath Group LLP. Viapath Analytics LLP provide pathology and testing services to the NHS which includes genetics. It was agreed that this interest did not preclude her from participating in the meeting.

John Bagshaw had declared an indirect interest as he is an Executive Board member of the British In Vitro Diagnostic Association (BIVDA). It was agreed that this interest did not preclude him from participating in the meeting.

Professor Chris Hyde had declared non financial personal and professional interests as he is part of an academic group who have published on the effectiveness and cost-effectiveness screening for Lynch syndrome. They have a continuing interest in this topic but are not currently in receipt of research grants funding this work. It was agreed that this interest did not preclude him from participating in the meeting.

Dr Sandeep Kapur had declared indirect interests as, since July 2019 he has worked at Mayo Clinic Healthcare in Partnership with Oxford University Clinic, and since April 2018 has been a committee member of the BNF Joint Formulary Committee. 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 Simon Richards declared a financial interest as, since 2017, he has been employed in Abbott Rapid Diagnostics as VP, Divisional Regulatory Affairs, and non-financial professional and personal interests as, since 2014, he is a committee member of the British In Vitro Diagnostic Association (BIVDA). It was agreed that these interests did not preclude him from participating in the meeting.

Professor Anthony Wierzbicki had declared non financial personal and professional interests: Site Clinical trial co -investigator, AKCEA volanesorsen in familial chylomicronemia syndrome (CS-7) (2017-20); Regeneron evinacumab in familial chylomicronemia syndrome (REGN-1500) (2019-2020); Amgen VESALIUS evolocumab in coronary heart disease (2019-ongoing). He had also declared that he is on the Clinical Trial steering committee for MRC Australia STAREE, statins in the elderly (2017- ongoing). He had further declared a financial interest as he works in private practice (lipids). It was agreed that these interests did not preclude him from participating in the meeting.

The following specialist committee members had declared interests:

Demetra Georgiou had declared a financial interest as since 2015 she has worked in private practice as a genetic counsellor, and an indirect interest as she is a charity advisor. It was agreed that these interests did not preclude her from participating in the meeting.

Dr Fiona Laloo had declared non-financial interests as she is a co-author of academic papers including consensus documents on Lynch syndrome; she is a member of an NHSE clinical expert group to advise around Lynch testing and implementation of NICE DG27, and has been a committee member of medical genetics CRG and has reapplied for membership. It was agreed that these interests did not preclude her from participating in the meeting.

Tracie Miles had declared that she is an information nurse specialist to the Eve Appeal Gynaecology Cancer Research Charity to improve public knowledge and awareness of gynaecological cancers. It was agreed that this interest did not preclude her from participating in the meeting.

Gail Norbury had declared she had been an expert witness in patient litigation regarding prenatal diagnostics (2017-2019). It was agreed that this interest did not preclude her from participating in the meeting.

Dr Anca Oniscu had declared the following financial interests: she had received honorarium and speaker fee from MSD to run PD-L1 training sessions in August 2018; she had attended an advisory board organised and funded by Bayer in September 2019, with the meeting not related to endometrial cancer or cancer predisposition syndromes, but a discussion around testing strategies for NTRK fusions (honorarium for participation); she had attended a European Expert PD-L1 advisory board meeting in Vienna sponsored by MSD (and received an honorarium for participation) in November 2019; and she was Chair of “Biomarker testing in Scotland: roundtable workshop event” organised by Bristol-Myers Squibb in January 2020 and received an honorarium for chairing the meeting. It was agreed that these interests did not preclude her from participating in the meeting.

Dr Naveena Singh had declared the following non-financial personal and professional interests: she was an invited member and co-author of the Manchester International Consensus Group (2017-2019); president of the British Association of Gynaecological Pathologists from June 2016 – June 2019; co-chair, Education Committee, International Society of Gynaecological Pathologists (since August 2019); and co-author on published papers on mismatch repair staining (published 2019). She gave an invited lecture, Biomarkers in Endometrial and Ovarian Carcinoma: p53 and mismatch repair immunohistochemistry, the International Society of Gynecological Pathologists (ISGyP) Symposium, USCAP, Vancouver in November 2017. She gave an invited lecture, Lynch syndrome UK practice, National Gynaecological Pathology EQA Academic meeting, Birmingham, November 2019. She gave an invited lecture, Mismatch repair defects in Gynaecological cancers, International Society of Gynecological Pathologists (ISGyP) Symposium, USCAP, Los Angeles, August 2019. She is the Lead Author for BAGP guidance on Interpretation of Mismatch Repair Protein Immunohistochemistry in Gynaecological Cancers. It was agreed that these interests did not preclude her from participating in the meeting.

Dr Katie Snape had declared financial interests as she had prepared and delivered a teaching session to GPs (February 2020) on breast and ovarian cancer and genetic testing panels for Everything Genetic. She also declared indirect interests as she had given talks on BRCA testing in ovarian cancer for Astra Zeneca in 2019; had attended a House of Lords Round Table hosted by Merck Serono Ltd on implementation of the national genomic medicine service in 2019; since 2018 had advised AXA-PPP intermittently on the clinical rationale with respect to their policy for genetics, with the advisory role being funded; and prepared and delivered materials for a training day for cancer health care works sponsored by Pfizer relating to communication of genetic test results in 2019. It was agreed that these interests did not preclude her from participating in the meeting.

The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Testing strategies for Lynch syndrome in people with endometrial cancer.

The Committee was asked if there were any specific equality issues to consider in relation to this assessment.

The Chair thanked the topic notifier 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

Assessment of Implantable cardiac monitors 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:

Tracey Jhita, Health Economics Manager
Victoria Wakefield, Principal Health Technology Assessment Analyst

Specialist Committee members:

Joanna Denman, Lead Cardiology Advanced Clinical Practitioner
Dr David Fox, Consultant Cardiologist
Jo Jerrome, Lay specialist committee member
Dr Justin Lee, Consultant Cardiac Electrophysiologist
Cara Mercer, Chief Cardiac Physiologist

Specialist Committee members apologies:

Dr Sreeman Andole, Consultant in Stroke
Dr Anand Dixit, Consultant Stroke Physician

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

Part 1 – Open session

The Chair welcomed representatives from Abbott Medical UK Ltd, Biotronik SE and Co KG, and Medtronic Ltd.

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.

Professor 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 since July 2019 he has worked at Mayo Clinic Healthcare in Partnership with Oxford University Clinic, and since April 2018 has been a committee member of the BNF Joint Formulary Committee. 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 (trial ended recruitment in April 2017, paper published Jan 2019). 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.

Professor 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.

Dr Brian Shine had declared an indirect interest as his laboratory has a large equipment contract with Abbott Laboratories. He was not involved in the procurement process and is not involved in the management of the contract. He has not received any material or other gain from the contract or from Abbott's dealings with his Trust. It was agreed that this interest 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. He also declared that he has participated in Delphi analysis conducted by Portolan Pharmaceuticals regarding an antidote for factor xa inhibitors. 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.

Jo Jerrome had declared a non-financial professional and personal interest as she is CEO of Thrombosis UK Ltd. It was agreed that this interest did not preclude her 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 Committee proceeded to discuss the comments made during the public consultation on the Diagnostics Consultation Document (second consultation).

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 of next meeting (next topic): Thursday 2 April 2020.