NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Diagnostics Advisory Committee (DAC)

**Minutes of the Meeting held on Thursday 6 August 2020**

**via Zoom**

**PRESENT:**

**Standing Committee members:**

Dr Mark Kroese (Chair)

Professor Keith Abrams

Ms Liz Adair

Ms Rebecca Allcock

Mr John Bagshaw

Professor John Cairns

Dr Jim Gray

Professor Steve Halligan

Professor Neil Hawkins (1st topic)

Mr Ross Maconachie

Mr Patrick McGinley

Dr Michael Messenger

Mrs Alexandria Moseley

Dr Brian Shine

**Standing Committee apologies:**

Professor Enitan Carrol

Dr Owen Driskell

Dr Sandeep Kapur

Dr Shelley Rahman Haley

Dr Alistair Reid

Professor Matt Stevenson

**NICE staff in attendance:**

Rebecca Albrow, Associate Director, Diagnostics Assessment Programme (DAP)

Frances Nixon, HTA Adviser, DAP (1st topic)

Tosin Oladapo, (Technical lead) HTA Analyst, DAP (1st topic)

Thomas Walker, HTA Adviser, DAP (2nd topic)

Donna Barnes, Project Manager, DAP

Alex Sexton, Administrator, DAP

Observing:

Mandy Brereton, Assistant Project Manager, CHTE

Emilene Coventry, Editor (1st topic)

Helen Crosbie, Public Involvement Adviser

Ann Greenwood, Editor (2nd topic)

Suvi Harmala, HTA Analyst, DAP

Charlie Hewitt, HTA Analyst, CHTE

Cheryl Hookway, Health Technology Adoption Manager

Ian Mather, Business Analyst – Resource Impact (2nd topic)

Laura Marsden, Coordinator, CHTE

Sophie McHugh, Administrator, CHTE

Gareth Murphy, Business Analyst – Resource Impact (1st topic)

Catherine Pank, Coordinator, Corporate Office

1. **Introduction to the meeting**

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

Apologies were noted.

1. **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.

1. **Any other business**

The Chair recorded the committee’s thanks to Dr Sandeep Kapur for all his work and contributions during his time as a member of the Diagnostics Advisory Committee.

1. **Minutes from the last Committee meeting**

The Committee agreed the minutes from the 3 June 2020 meeting.

1. **Equality and Diversity**

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

PredictSURE IBD and IBDX to guide personalised treatment of Crohn’s disease

External Assessment Group representatives: BMJ Technology Assessment Group:

Mariana Bacelar, Principal Health Economist

Dr Samantha Barton, Principal Health Technology Assessment

Analyst

Dr Steve Edwards, Director of Health Technology Assessment

**Specialist Committee members:**

Zehra Arkir, Consultant Clinical Scientist

Dr Rebecca Harmston, Lay specialist

Professor Shaji Sebastian, Consultant Gastroenterologist

Tracey Tyrrell, IBS Advanced Nurse Practitioner

**Specialist Committee members apologies:**

Dr Jenny Epstein, Consultant Paediatric Gastroenterologist

Professor Jack Satsangi, Professor of Gastroenterology

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

Part 1 – Open session

The Chair welcomed representatives from PredictImmune Ltd.

There were 4 public attendees.

The Chair asked Committee members to declare any relevant interests.

The following standing committee members had notified these interests in advance of the meeting:

Prof Keith Abrams had declared a financial interest as he is a Director of Visible Analytics Ltd, but this has no commercial interest in diagnostics relating to IBD. It was agreed that this interest did not preclude him from participating in the meeting.

John Bagshaw had declared a non-financial professional and personal 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 Steve Halligan had declared a non-financial professional and personal interest as he is the Principal Investigator (PI) for HTA 14/2010/07, a systematic review and meta-analysis of prognostic factors to identify patients at risk of future severe Crohn’s disease. The work started 2016 and is still ongoing, and a prognostic model is being developed. He had also declared an indirect interest in that he was Co-Investigator on the HTA funded METRIC study to investigate MRI / US imaging modalities for Crohn's disease, for which funding ceased in 2019. It was agreed that these interests required that Professor Halligan be partially excluded from the meeting and he therefore attended for the Part 1 discussions only.

Professor Neil Hawkins had declared a financial interest as a company (Visible Analytics Ltd) in which he has a financial interest (directorship) is currently conducting a systematic review for a manufacturer of pharmacological treatments for Crohn’s disease. The review does not concern diagnostics testing and is not commissioned by, and does not consider any products marketed by, PredictImmune Ltd or Glycominds, LLC. It was agreed that this interest did not preclude him from participating in the meeting.

Ross Maconachie had declared a financial interest as his company, Roche Diagnostics, manufacture the LightCycler analyser that the Predict-SURE IBD runs on. The company are using the LightCycler system independently of Roche and no licensing arrangements are in place. 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 (APPG) on Obesity and is a Trustee of the Association for Study of Obesity (ASO). He had also declared a financial interest as since April 2020 he has been a Faculty member of MTech Access, providing advisory features for emails and web conferences on the nature of NHS Finance, but had had no interaction with either PredictImmune Ltd, or Glycominds, LLC. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Michael Messenger had declared an indirect interest as he had provided free advice via the NIHR MIC to PredictImmune on their evidence generation approach; this interest had ceased in 2018. It was agreed that this interest did not preclude him from participating in the meeting.

The following specialist committee members had notified these interests in advance of the meeting:

Dr Rebecca Harmston had declared indirect interests as she is the lay representative JRCPTB Paediatric Cardiology Specialist Advisory Committee, the lay member of Pharmacy Research UK, the patient partner for Arthritis Research UK Centre for Epidemiology, the lay member of Technology Appraisal Committee D at NICE, a member of the Parent Carer Advisory Group of the Royal College of General Practitioners, the lay member of the NIHR and Imperial College Invitro Diagnostics panel, the public representative on the NHS Public and Patient Voices Panel with the Genomics Clinical Reference Group, the lay member on the ANTRUK Education Committee, and is a member of the HQIP Understanding Health Data Access Expert Advisory Group. It was agreed that these interests did not preclude her from taking part in the meeting.

Professor Shaji Sebastian had declared interests as he holds research grants from Takeda and from Tillots Pharma (not relevant /related to the technologies under discussion). In previous years (between 2014 and 2019) he had received speaker honoraria from Tillotts Pharma, AbbVie, Jansen and Takeda (not relevant/related to the product of this diagnostic advisory committee) as well travel / accommodation expenses for attending conferences from multiple pharma (not relevant/related to the technologies under discussion). It was agreed that these interests did not preclude him from participating in the meeting.

Tracey Tyrrell had declared interests as she had been the Royal College of Nursing special projects coordinator, attending central committee meetings and coordinating projects. In 2016/2017 she had received sponsorship to attend conferences (European Crohn’s and Colitis Organisation (ECCO, Ferring, AbbVie) which covered accommodation and travel. In previous years (to 2019) she had been a paid speaker for MSD, Ferring, Takeda and Norgine, presenting on the different topics related to IBD Nursing and chairing meetings. She is currently involved with the Quality Improvement Project (QIP), London North West University Healthcare Trust, looking at signposting patients to the right information from diagnosis. 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 PredictSURE IBD and IBDX to guide personalised treatment of Crohn’s disease.

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

The Chair thanked the manufacturer representatives for their attendance at the meeting.

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.

End of Part 1

Part 2 – closed session

Agreement on the content of the Diagnostics Consultation Document (DCD) was discussed by the committee.

End of Part 2

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

External Assessment Group representatives, Warwick Evidence:

Mary Jordan, Research Fellow

Dr Jason Madan, Professor in Health Economics

Dr Chris Stinton, Senior Research Fellow

**Specialist Committee members:**

Kate Daniels, Lay specialist

Dr Angela George, Consultant Medical Oncologist

Demetra Georgiou, Principal Genetic Counsellor

Dr Fiona Lalloo, Consultant in Clinical Genetics

Dr Tracie Miles, Clinical Nurse Specialist / Information Nurse Specialist

Gail Norbury, Consultant Clinical Scientist in Genetics

Dr Anca Oniscu, Consultant Pathologist

Professor Naveena Singh, Consultant Pathologist

Dr Katie Snape, Consultant Cancer Geneticist

**Specialist Committee members apologies:**

Prof Pierre Martin-Hirsch, Consultant Gynaecological Oncologist

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

Part 1 – Open session

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

There were 8 public attendees.

The Chair asked Committee members to declare any relevant interests.

The following standing committee members had notified these interests in advance of the meeting:

Professor Keith Abrams had declared a financial interest as he is a Director of Visible Analytics Limited but this has no commercial interests in testing strategies for Lynch syndrome in people with endometrial cancer. It was agreed that this interest did not preclude him from taking part in the meeting.

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.

Ross Maconachie had declared an interest as his company is Roche Diagnostics. They do not currently market a test for Lynch syndrome in endometrial cancer but, although not imminent, it is possible that they would in the future. Roche does market a test for Lynch syndrome in colorectal cancer. It was agreed that these interests did not preclude him from taking part 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). He had also declared a financial interest as since April 2020 he has been a Faculty member of MTech Access, providing advisory material for email briefings and web conferences on NHS funding. This covers a number of pharma companies but no known contact regarding Lynch syndrome. It was agreed that these interests did not preclude him from participating in the meeting.

The following specialist committee members had notified these interests in advance of the meeting:

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. She further declared that she is an ad hoc consultant for Atheneum consultants, providing an opinion on matters such as genetic counselling for hereditary conditions, but there has been no direct association with Lynch syndrome to date. She also declared that she is a reviewer for ‘Uptodate’, reviewing guidelines and documents for their medical library, commencing August 2020, reviewing Li fraumeni syndrome. She also declared a non-financial personal and professional interest as she is a committee member of Y-European Hereditary Tumour Group Active. She had also declared co-authorship of academic papers on hereditary cancer including Lynch syndrome. It was agreed that these interests did not preclude her from participating in the meeting.

Dr Fiona Lalloo 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 is a committee member of the Medical Genetics Clinical Reference Group. 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 non-financial personal and professional interests as she had been an expert witness in patent litigation regarding prenatal diagnostics (2017-2019). In 2016/17 she was an independent expert witness for a patent claim relating to no invasive prenatal testing UK. In 2017/18 she was an independent expert witness for a patent claim relating to no invasive prenatal testing Australia. Since January 2020 she has been a member of the NHSE Genomic Test Evaluation Working Group for rare and inherited disease. Since July 2020 she has been an independent expert witness for three defendants in a patent claim relating to sample preparation for free fetal DNA analysis UK. It was agreed that these interests did not preclude her from participating in the meeting.

Dr Anca Oniscu had declared the following financial interests: she had received an honorarium and a 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. She had further declared non-financial personal and professional interests as she is the Clinical Lead of the Molecular Pathology Consortium in Scotland, and author of the colorectal cancer molecular testing pathway business case in Scotland, “Molecular Pathology: Testing of Colorectal Cancer in Scotland: A Consensus Protocol for National Implementation.” It was agreed that these interests did not preclude her from participating in the meeting.

Professor 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 comments made during the public consultation for the ‘Testing strategies for Lynch syndrome in people with endometrial cancer’ topic.

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

The Chair thanked the topic notifier representative for attending the meeting.

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.

End of Part 1

Part 2 – closed session

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

End of Part 2

Date of next meeting (next topic): Thursday 3 September 2020.