NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Diagnostics Advisory Committee (DAC)

**Minutes of the Meeting held on Wednesday 7 October 2020**

**via Zoom**

**PRESENT:**

**Standing Committee members:**

Dr Mark Kroese (Chair)

Ms Liz Adair

Ms Rebecca Allcock

Mr John Bagshaw

Professor John Cairns

Ms Diane Davies

Dr Owen Driskell

Dr Jim Gray *(1st topic only)*

Professor Neil Hawkins

Mr Patrick McGinley

Mr Ross Maconachie

Dr Michael Messenger *(attended for 1st topic only, as EAG)*

Mrs Alexandria Moseley

Dr Shelley Rahman Haley *(1st topic only)*

Dr Alistair Reid

Dr Karen Sennett

Dr Brian Shine

Professor Matt Stevenson *(attended for 1st topic only, as EAG)*

**Standing Committee apologies:**

Professor Keith Abrams

**NICE staff in attendance:**

Rebecca Albrow, Associate Director, DAP

Frances Nixon, HTA Adviser, DAP

Thomas Walker, HTA Adviser, DAP

Tosin Oladapo, Technical lead, HTA Analyst, DAP

Donna Barnes, Project Manager, DAP

Alex Sexton, Administrator, DAP

Observing:

Emilene Coventry, Editor

Helen Crosbie, Public Involvement Adviser

Suvi Harmala, HTA Analyst, DAP

Jean Isaac, HTA Analyst, DAP

Laura Marsden, Coordinator, CHTE

Edgar Masanga, Business Analyst – Resource Impact

Sandra Robinson, Coordinator, Corporate Office

Katie Wyart, Health Technology Adoption Manager *(2nd topic only)*

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 welcomed new committee members, Diane Davies and Dr Karen Sennett, who were attending their first meeting.

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

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

1. **Equality and Diversity**

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

Exploratory economic modelling of SARS-CoV-2 viral detection point of care tests and serology tests

External Assessment Group representatives:

Andrew Metry, Research Associate, School of Health and Related Research (ScHARR), The University of Sheffield

Prof Matt Stevenson, Professor of Health Technology Assessment, School of Health and Related Research (ScHARR), The University of Sheffield

Dr Mike Messenger, Visiting Professor, University of Leeds

**Specialist Committee members:**

Prof Rick Body, Professor of Emergency Medicine, University of Manchester

Dr Michael Caley, GP, South Warwickshire GP Federation

Prof Paul Dark, Chair of Critical Care Medicine, University of Manchester

Ms Tasneem Dhanji, Lay specialist

Dr Dominic Horne, GP Principal, Much Birch Surgery

Prof Will Irving, Professor of Virology, University of Nottingham

Dr Clare Leeds, Consultant Occupational Health Physician, County Durham and Darlington NHS Foundation Trust

Mrs Stella O’Brien, Lay specialist

Prof Anthony Rowbottom, Clinical Director for Pathology, Lancashire Teaching Hospitals

Mr Mike Sandys, Director of Public Health, Leicestershire County Council

Dr Alison Watt, Consultant Clinical Scientist Virology, Regional Virus Laboratory Belfast Health and Social Care Trust

**Specialist Committee members apologies:**

Dr Tolani Osunsanya, Consultant Occupational Physician

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

Part 1 – Open session

There were 12 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 has not been involved in any projects which involve a diagnostic technology. He also declared non-financial personal and professional interests as he has funding to support a MRC Industrial PhD Studentship from Swiss Precision Diagnostics/Clearblue for a project on prediction of early miscarriage. Since July 2020 he has been COI on UKRI-NIHR-funded UK-REACH study looking at effect of ethnicity on morbidity and mortality due to COVID in UK health care workers. Since July 2020 he has been the COI for Leicester Life Sciences Accelerator - Evaluating feasibility of workplace testing using Elephant Kiosk in SMEs. Since March 2020 he has been the COI on various HDR UK supported studies on diagnosis and prognosis of COVID-19 in UK. He also declared indirect interests as since March 2020 he has been a member of the Leicester COVID-19 Taskforce, and of the HDR-UKRI-SAGE COVID-19 Taskforce. It was agreed that these interests did not preclude him from participating in the meeting.

Liz Adair declared an indirect interest as she is the Quality Director of Viapath Group LLP. Viapath Analytics are undertaking diagnostic testing services which includes SARS-CoV-2. It was agreed that this interest did not preclude her 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.

Jim Gray had declared indirect interests as in August 2020 he led the procurement of VITA PCR (rtPCT for POC COVID-19 diagnosis) in his Trust. He is the co-applicant in the following grant application to the Healthcare Infection Society (submitted August 2020): ‘Maternity services response to the Covid-19 pandemic: how PHE guidance was implemented and what we can learn for the future’. It was agreed that these interests did not preclude him from participating in the assessment.

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 Treasurer 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 materials for email briefings and web conferences on NHS finance but with no link to any diagnostic manufacturers. It was agreed that these interests did not preclude him from participating in the meeting.

Ross Maconachie had declared a financial interest as his company, Roche Diagnostics, manufacture SARS-Cov-2 PCR tests and antibody tests and will shortly be launching a Rapid Antigen Test for viral detection in point of care settings. It is possible that additional tests or testing modalities will be launched in future. He also declared an indirect interest as his partner works for and has shares in Pfizer Ltd who are developing a coronavirus vaccine and treatments for coronavirus. It was agreed that these interests meant he should be excluded from Part 2 discussions.

Dr Mike Messenger declared interests as he has personal and professional affiliations with companies working in the field of COVID19 diagnostics, including:

* paid expert advisor to Cepheid Inc on the development of their Cancer test portfolio (ongoing);
* partner of Roche Diagnostics with current collaborations in the field of early cancer detection and diagnosis (ongoing);
* partner of SomaLogic Inc with current collaborations funded by them in the field of personalised health management of pre-diabetes (ongoing);
* Abbott have provided in-kind co-funding to a previous kidney research project (ceased 2019);
* Siemens Healthineers hold the pathology contract for Leeds Teaching Hospitals NHS Trust where he hold an honorary contract of employment;
* Avacta Life Sciences Ltd is a spin out company of the University of Leeds.

He also declared that from March – June 2020 he was a paid expert advisor to the European Union on COVID19 therapeutics and diagnostics. From May to September 2020 he was a seconded scientific advisor to the UK Department of Health and Social Care to support the COVID19 testing programme. He is currently a member of the UK Government Advisory Group for COVID19 Testing. He attended the meeting for part 1 only, as part of the EAG.

Karen Sennett declared a financial interest as she is a GP partner at NHS GP practice. It was agreed that this interest did not preclude her from participating in the meeting.

Prof Matt Stevenson declared that he is part of the EAG and receiving money for the work undertaken and had co-authored the EAG report for this assessment. He attended the meeting for part 1 only, as part of the EAG.

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

Richard Body declared non-financial personal and professional interests as he is the chief investigator for the FALCON (Facilitating AcceLerated Clinical validation Of Novel diagnostics for COVID-19) study and co-lead for the overarching CONDOR (COVID-19 National platform for Diagnostic evaluation and Research). This is a national platform study, funded by the NIHR, which evaluates new tests for COVID-19. Those tests are all commercially supplied and prioritized (for evaluation) by the Department of Health and Social Care. CONDOR provides analytical validation, in-context clinical validation, human factors evaluation and care pathway analysis.

He also declared that he is the Director of the Diagnostics & Technology Accelerator (DiTA) in Manchester, which works with companies to generate research evidence for new in vitro diagnostics and medical technologies. During the course of his duties he has held conversations with representatives of multiple companies that manufacture or are developing tests for COVID-19. Some (e.g. Eluceda, PhoenixDx) have been referred to the Virology Laboratory at Manchester University NHS Foundation Trust to try and secure access to samples in order to evaluate their tests. All companies are generally advised to submit their tests via the Department of Health and Social Care online portal.

He also declared an indirect interest as he had attended an advisory board meeting for Beckman Coulter in June 2020, for which his institution was remunerated. The focus was on cardiovascular biomarkers. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Michael Caley declared a financial interest as he is a GP Partner, Warwick Gates Family Health Centre and Medical Director, South Warwickshire GP Federation. It was agreed that this interest did not preclude him from participating in the meeting.

Prof Paul Dark declared non-financial professional and personal interests as he is a member of the Clinical Advisory Committee for DNAelectronics Ltd, London UK who are developing a rapid near-patient blood diagnostic for bacteria and fungi in the setting of sepsis. This work is performed on behalf of Salford Royal NHS Foundation Trust as part of his employment in the NHS.

He declared indirect interests as he is a member of the Steering Committee and co-investigator for the national NIHR Urgent Public Health clinical test bed platform for COVID-19, representing critical care nationally. He is a Member of the Research Committee of the Intensive Care Society UK. He is Respiratory Infection sub-theme lead, Manchester NIHR Biomedical Research Centre, University of Manchester. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Dominic Horne declared financial interests as he is GP Principal, Much Birch Surgery, Herefordshire, a salaried GP, Taurus Healthcare, Hereford, and NIHR CRN GP Research Champion, Herefordshire. He is the National Specialty Adviser for Public Health Screening at NHSE (one day a week). He also declared non-financial personal and professional interests as he is a member, Midland Faculty Board, RCGP; Honorary Senior Lecturer, University of Worcester; and Trustee and Board Member, Self Care Forum, London. He declared an indirect interest as a relative is an employee of Elekta, Stockholm. It was agreed that these interests did not preclude him from participating in the meeting.

Will Irving declared financial interests as in May 2020 he had been an Advisory Consultant, Source Bioscience. In 2019 he had been a Speaker/ Advisory Consultant for Gilead Sciences and he holds research grants from Gilead Sciences.

He also declared non-financial personal and professional interests as he is a member, Standing Advisory Committee on Microbiology and Virology, Royal College of Pathologists; a Member, Executive Committee, UK Clinical Virology Network; a Member, Advisory Committee, Safety of Blood Tissues and Organs; Chair, National Strategy Group for Viral Hepatitis; and Co-ordinator, UK Clinical Virology Network Advisory Group. He is a co-author on a letter to BMJ, ‘Rapid roll out of SARS-CoV-2 antibody testing-a concern’ (doi: 10.1136/bmj.m2420).

He is a co-applicant, UKRI grant: Medical Research Council: Transmission, pathogenesis and immunogenicity of SARS-CoV-2 in frontline healthcare workers: a national longitudinal cohort of 1320 participants. He is a co-author on ‘Potent anti-SARS-CoV-2 Antibody Responses are Associated with Better Prognosis in Hospital Inpatient COVID-19 Disease’ (https://www.medrxiv.org/content/10.1101/2020.08.22.20176834v1). It was agreed that these interests did not preclude him from participating in the meeting.

Dr Tolani Osunsanya had declared financial interests as he is Director of Goshen Health Solutions Ltd and of Leeds Health Solutions Ltd, both of which are occupational health services providers. He declared non-financial personal and professional interests as he is the Faculty of Occupational Medicine’s Regional Specialty Adviser (RSA) for Scotland, Examiner for the Faculty of Occupational Medicine Ireland, and an Examiner for the Faculty of Occupational Medicine UK. It was agreed that these interests did not preclude him from participating in the meeting.

Prof Anthony Rowbottom declared a financial interest and he works in private practice at Spire Healthcare. It was agreed that this interest did not preclude him from participating in the meeting.

Dr Alison Watt had declared financial interests as she had received a one-off payment of £300 from the Randox RIQAS panel (the interest ceased May 2020). The Panel’s primary objective is to advise Randox Laboratories on matters related to the external quality assessment of clinical pathology laboratories. She also declared non-financial personal and professional interests as she is Chair of UK Standards for Microbiology (UKSMI) Virology Serology working Group; a Member of the Executive Committee, UK Clinical Virology Network; a Virology Examiner, Royal College of Pathologists; and is on the UKNEQAS Microbiology Virology Specialist Advisory Group. It was agreed that these interests did not preclude her from participating in the meeting.

The Committee proceeded to discuss the exploratory economic modelling of point of care tests (POCTs) for detecting SARS-CoV-2 in a hospital setting.

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

The Chair thanked the EAG and public observers 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 Guidance Document (DGD) was discussed by the committee.

End of Part 2

PredictSURE IBD and IBDX to guide 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 Jenny Epstein, Consultant Paediatric Gastroenterologist

Dr Rebecca Harmston, Lay specialist

Tracey Tyrrell, IBS Advanced Nurse Practitioner

**Specialist Committee members apologies:**

Professor Jack Satsangi, Professor of Gastroenterology

Professor Shaji Sebastian, Consultant Gastroenterologist

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

Part 1 – Open session

The Chair welcomed representatives from PredictImmune Ltd and from Glycominds, LLC.

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 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 the Treasurer 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.

Dr Karen Sennett has declared a financial interest as she is a GP partner at NHS GP practice. It was agreed that this interest did not preclude her from participating in the meeting.

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

Zehra Arkir had declared that she leads the Anti-TNF drug and anti-drug antibody laboratory services in her local hospital for inflammatory diseases including Crohn’s disease. It was agreed that this interest did not preclude her from taking part in the meeting.

Dr Jenny Epstein declared financial interests as in 2018 she had received sponsorship from Abbvie to attend ECCO (European Crohn’s and Colitis) meeting, and she works in private practice (but does not see patients with Crohn’s disease in her private practice). She also declared non-financial professional interests as she is medical advisor to CICRA (Crohn’s in Childhood Research Association) and is a member of BSPGHAN (British Society of Paediatric Gastroenterology Hepatology and Nutrition) IBD working group. It was agreed that these interests did not preclude her from taking part in 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. She had further declared that she had recently joined a Patient Advisory Group with the company AlphaBiomics who have developed a diagnostic test RxSelexTM to predict whether or not patients with moderate to severe inflammatory bowel disease (IBD) are likely to respond positively to biologic drugs. It was agreed that these interests did not preclude her from taking part in the meeting.

Professor Jack Satsangi had declared non-financial professional and personal interests as he is research active in identifying biomarkers for test development for the disease area of this evaluation and similar target population, and he is co-author and provider of data for the paper “Transcription and DNA Methylation patterns of blood derived CD8+ T cells are associated with age and Inflammatory Bowel Disease but do not predict prognosis” (https://doi.org/10.1053/j.gastro.2020.08.017). He had also declared an indirect interest as he has a research interest in biomarker discovery. As the research publication he co-authored is of direct relevance to the technology being considered, it was agreed he should be excluded from Part 2 discussions.

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 comments made during the public consultation for the ‘PredictSURE IBD and IBDX to guide treatment of Crohn’s disease’ topic.

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

The Chair asked the manufacturer representatives whether they wished to comment on any matters of factual accuracy.

The Chair thanked the manufacturer representatives, EAG and public observers 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 Guidance Document (DGD) was discussed by the committee.

Date of next meeting (next topic): Thursday 5 November 2020.