NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Diagnostics Advisory Committee (DAC)

**Minutes of the Meeting held on 10 December 2020**

**via Zoom**

# PRESENT:

### Standing Committee members:

Dr Mark Kroese (Chair)

Professor Keith Abrams

Ms Rebecca Allcock

Mr John Bagshaw

Professor John Cairns

Dr Sam Creavin

Ms Diane Davies

Dr Owen Driskell

Mr Patrick McGinley

Mr Ross Maconachie

Dr Michael Messenger *(attended as EAG)*

Mrs Alexandria Moseley

Dr Shelley Rahman Haley

Dr Alistair Reid

Dr Karen Sennett

Dr Brian Shine

Professor Matt Stevenson *(attended as EAG)*

Dr Alasdair Taylor

### Standing Committee apologies:

Ms Liz Adair

Dr Jim Gray

Professor Neil Hawkins

### NICE staff in attendance:

Helen Knight, Programme Director

Rebecca Albrow, Associate Director, Diagnostics Assessment Programme

Thomas Walker, HTA Adviser, DAP

Suvi Harmala, Technical lead, HTA Analyst, DAP

Donna Barnes, Project Manager, DAP

Alex Sexton, Administrator, DAP

### Observing:

Helen Crosbie, Public Involvement Adviser

Hayley Garnett, Editor

Hannah Maiden, Public Health trainee

Maria Pitan, Project Manager, Corporate Office

Phil Williams, Business Analyst – Resource Impact

# Introduction to the meeting

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

Apologies were noted.

# 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.

# Any other business

The Chair welcomed new committee member Dr Alasdair Taylor, attending his first meeting.

# Minutes from the last Committee meeting

The Committee agreed the minutes from the 5 November 2020 meeting.

# Equality and Diversity

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

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

### External Assessment Group (EAG) 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, Principal Scientific Advisor for In Vitro Diagnostics,

 MHRA

### Specialist Committee members:

Prof Rick Body, Professor of Emergency Medicine

Prof Paul Dark, Chair of Critical Care Medicine

Ms Tasneem Dhanji, Lay specialist

Dr Dominic Horne, GP Principal

Prof Will Irving, Professor of Virology

Dr Clare Leeds, Consultant Occupational Health Physician

Mrs Stella O’Brien, Lay specialist

Dr Tolani Osunsanya, Consultant Occupational Physician

Prof Anthony Rowbottom, Clinical Director for Pathology

Mr Mike Sandys, Director of Public Health

Dr Alison Watt, Consultant Clinical Scientist Virology

### Specialist Committee members apologies:

Dr Michael Caley, GP

### Professional experts:

Joshna Mavji, Consultant in Public Health

Ruth O’Dea, Home Manager

Stephen Payne, Director of Operations

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

Part 1 – Open session

There were 20 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 an 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 the 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 the 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 further declared in the meeting that he is part of a research bid recently submitted looking at the impact of COVID-19 on the health care work force. 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.

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 and he therefore attended for Part 1 of the meeting only.

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 holds 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 had co-authored the EAG report for this assessment; his employer has received funding for the work undertaken. 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:

Prof 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 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.

Prof 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 residential care facilities.

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

The Chair thanked the experts, external assessment group representatives, 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 guidance was discussed by the committee.

### End of Part 2