NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Diagnostics Advisory Committee (DAC)

**Minutes of the Meeting held on Wednesday 3 June 2020**

**The meeting was held via Zoom**

**PRESENT:**

**Standing Committee members:**

Dr Mark Kroese (Chair)

Ms Liz Adair

Ms Rebecca Allcock

Professor Enitan Carrol

Dr Owen Driskell

Dr Jim Gray

Professor Neil Hawkins

Mr John Hitchman

Professor Christopher Hyde

Mr Patrick McGinley

Dr Michael Messenger

Mrs Alexandria Moseley

Dr Brian Shine

Professor Matt Stevenson

**Standing Committee apologies:**

Mr John Bagshaw

Dr Shelley Rahman Haley

Professor Steve Halligan

Dr Sandeep Kapur

Dr Alistair Reid

**NICE staff in attendance:**

Mirella Marlow, Programme Director, Centre for Health Technology Evaluation

Rebecca Albrow, Associate Director, DAP

Frances Nixon, Technical Adviser, DAP

Simon Webster, Health Technology Assessment Analyst, DAP

Christopher Pomfrett, Technical Adviser (Research Commissioning), MTEP

Donna Barnes, Project Manager, DAP

Alex Sexton, Administrator, DAP

Observing:

Sara Buckner, Technical Adviser, Centre for Guidelines

Emilene Coventry, Editor

Craig Grimes, Quality Standards

Rick Keen, Quality Standards

Hugh McIntyre, QSAC, Chair

Ian Mather, Business Analyst – Resource Impact

Peter O’Neill, Technical Adviser, DAP

Tosin Oladapo, Technical Analyst, DAP

Catherine Pank, Meetings in Public

Sandra Robinson, Meetings in Public

Daniel Smithson, Technical Analyst, QSAC

Katie Wyart, Health Technology Adoption Manager

**Assessment of High-sensitivity troponin for the early rule out of acute myocardial infarction**

1. **Introduction to the meeting**

The Chair welcomed Committee members, observers, members of the public and the company representatives. 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, observers and company representatives attending this meeting.

1. **Committee membership**

The Chair thanked John Hitchman and Prof Chris Hyde, who were attending their last committee meeting, for their tremendous hard work and valuable contributions during their time as members of the Committee.

The Chair also recorded the Committee’s thanks to Mirella Marlow, the Programme Director, who was attending her last meeting. He noted that she had been pivotal in setting up the Diagnostics Assessment Programme and providing the leadership and valuable guidance since its inception, and recorded the Committee’s gratitude for this legacy.

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

The Committee agreed the minutes from the 2 April 2020meeting.

1. **Equality and Diversity**

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

External Assessment Group representatives, Kleijnen Systematic Reviews Ltd:

Bram Ramaekers, Senior Health Economist

Marie Westwood, Review Manager

**Specialist Committee members:**

Professor Richard Body, Clinical Professor of Emergency Medicine

Mr Antony Chuter, Lay specialist

Professor Paul Collinson, Professor of Cardiovascular Biomarkers

Professor Nicholas Mills, Chair of Cardiology and Consultant Cardiologist

Mr Alan Reid, Principal Clinical Scientist and Scheme Organiser for UK NEQAS Cardiac Markers

Professor Adam Timmis, Professor of Clinical Cardiology

Mrs Helen Titu, Advanced Practitioner Emergency Medicine/Cardiology

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

Part 1 – Open session

The Chair welcomed representatives from Abbott Laboratories - Abbott Diagnostic Diagnostics Division, Beckman Coulter, Quidel Ireland, Ortho Clinical Diagnostics, Roche Diagnostics Ltd and Siemens Healthineers.

There were 12 public attendees.

The Chair asked Committee members to declare any changes to their declaration of interests; there were no further updates to those that had been declared prior to the meeting as noted below.

The following standing committee members had declared interests:

Liz Adair had declared an indirect interest as she is the Quality Director for Viapath Group LLP. Abbott Diagnostics, Beckman Coulter, Biomérieux, Roche, Siemens Healthineers all provide products/equipment/services to Viapath Services LLP. It was agreed that this interest did not preclude her from participating in the meeting.

Rebecca Allcock had declared a non-financial professional and personal interest as her employing Trust has applied for funding from the Accelerated Access Collaborative Pathway Transformation Fund to improve the patient pathway for patients presenting to ED with chest pain. It was agreed that this interest did not preclude her from participating in the meeting.

John Bagshaw had declared a non-financial personal and professional interest as he has been a Member of the Executive Board of the British In Vitro Diagnostic Association (BIVDA) since 2010. It was agreed that this interest did not preclude him from participating in the meeting.

Professor Enitan Carrol had declared non-financial personal and professional interests that arose in 2017 as she is a collaborator of Biomérieux in the HTA funded BATCH trial ( PCT in children with infection in hospital) and also as part of the H2020 PERFORM consortium (biomarkers to differentiate bacterial/viral infection in children). It was agreed that these interests did not preclude her from participating in the meeting.

Professor Neil Hawkins had declared a financial interest as he has provided consultancy services to Roche Ltd (Pharmaceuticals section) in an unrelated clinical area and not related to the product under consideration between August and November 2019. It was agreed that this interest did not preclude him from participating in the meeting.

Dr Sandeep Kapur had declared non-financial professional and personal interests as he works at the Mayo clinic healthcare in partnership with Oxford University Clinic, and since 2018 has been a 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 indirect interests as he is a member of the Strategic Council of the All-Party Parliamentary Group on Obesity, and a Trustee of the Association for the Study of Obesity. In addition, he had been appointed to the Faculty of MTech Access in April 2020, for which he receives an honorarium for advice on NHS Finance. The work has not involved any of the companies and/or the tests included in the assessment. It was agreed that these interests did not preclude him from participating in the meeting.

Dr Michael Messenger had declared non-financial personal and professional interests as Roche Diagnostics Ltd are a partner on a UK government grant, providing in-kind investment in terms of free kits not related to the field of Troponin (September 2019- present). In addition, Siemens Healthineers hold the pathology management service contract for Leeds Teaching Hospitals NHS Trust where he holds an honorary contract of employment (August 2016-present). It was agreed that these interests did not preclude him from participating in the meeting.

Dr Brian Shine had declared a non-financial personal and professional interest as he is on the steering committee for the Oxford MedTech and In Vitro Diagnostics Cooperative, funded by the NIHR. He had also declared an indirect interest as his Trust has a large pathology equipment contract with Abbott (since 2015), and previously with Siemens (2006-2015). It was agreed that these interests did not preclude him from participating in the meeting.

Professor Matt Stevenson declared a financial interest as he is part of a research bid run by the University of Sheffield funded by Roche Diagnostics to assess the potential use of biomarkers in patients with mild brain injury. This started in January 2020 and is anticipated to last 12 months. He also declared a non-financial personal and professional interest as he is co-author on one of the identified papers in the Diagnostics Assessment Report (DAR) related to cost-effectiveness of the tests (Thokala et al, Heart 2012). It was agreed that these interests did not preclude him from participating in the meeting.

The following specialist committee members had declared interests:

Professor Richard Body had declared financial interests as he had attended a steering group meeting for LumiraDx in June 2019; he had attended a Medical Advisory Board for Creavo, and chaired the Trial Steering Committee for a clinical study for the same manufacturer in around 2017; and he had attended an Advisory Board for Abbott Point of Care (biomarkers of traumatic brain injury) in 2019.

He had also declared non-financial personal and professional interests as follows:

* Since 2004 he has published multiple (approximately 100) papers regarding high-sensitivity troponin and the early diagnosis of acute coronary syndromes. In the discussion sections of the manuscripts, the group of authors may have described what could be perceived to be opinions. He had provided one unpublished manuscript to NICE as ‘academic in confidence’, relating to this assessment.
* Since 2016 he has sat on the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC) Committee for Clinical Applications of Cardiac Biomarkers, which provides educational material relating to the clinical use of cardiac biomarkers.
* Since February 2020 he has been a National Clinical Champion for the NHS England/AHSN project to implement high-sensitivity troponin rule-out strategies for acute myocardial infarction, a project which is based on the previous recommendations set out in DG15. His employer receives back fill for 2 hours per week of his time while he is fulfilling that role.
* Since 2017 he has been the Clinical Lead for the implementation of the T-MACS decision aid across Greater Manchester, which involves implementing rapid rule-out pathways for acute myocardial infarction across the region.
* Since 2018 he has been the Chief Investigator for the Pre-hospital Evaluation of Sensitive Troponin (PRESTO) study, which is funded via the NIHR RfPB scheme. The study also receives donation of reagents from Roche (and is due to receive donation of reagents from LumiraDx). Some limited additional funding has been provided for consumables from Abbott Point of Care.
* Since 2015 he has been the Chief Investigator for the Bedside Evaluation of Sensitive Troponin (BEST) study, which evaluated rapid rule-out pathways for acute myocardial infarction. The study received donation of reagents from Siemens in 2018; funding from Abbott Point of Care (approx. 2017); a European Union Horizon-2020 grant via FABPulous BV (which manufactures a point of care assay for heart-type fatty acid binding protein); and a contract has been signed (but no work completed to date) to run the Beckman troponin assay in stored samples. Singulex also donated reagents for use during the study.
* In August 2019 he had spoken about IFCC recommendations for using high-sensitivity troponin assays at the American Association for Clinical Chemistry conference. Travel expenses and accommodation costs were covered by the IFCC. The session was industry-sponsored by several diagnostic companies (Roche, Abbott, Siemens, Beckman, Ortho, ET Healthcare) but he did not take an honorarium and the session was delivered independently of the companies (as an initiative for the Committee for Clinical Applications of Cardiac Biomarkers).
* He is the Director of DiTA (the Manchester University NHS Foundation Trust Diagnostics & Technology Accelerator) and in this role frequently meet with diagnostic companies to discuss potential research studies. In that capacity he liaised with Quidel and its UK distributor, Una Health. Discussions were held concerning conducting an investigator-initiated study to evaluate the diagnostic accuracy of the Quidel troponin assay, although no agreement to proceed has been reached.

It was agreed that these interests did not preclude Professor Body from participating in the meeting.

Antony Chuter had declared the following financial interests:

* He spoke about living with pain to Executives from Pfizer (and received an honorarium in line with ABPI code) in 2017.
* He was a judge for the Grunenthal Pain Awards (and received an honorarium in line with ABPI code) in 2015.
* In 2017 and 2018 he advised on the editing of lay summaries (re cancer treatments) for Envision
* He attended advisory boards for Pfizer regarding Chronic Pain in 2018 and 2019.
* He spoke about living with pain in a video for internal use only in Pfizer (and received an honorarium in line with ABPI code) in 2017.
* In 2015 he attended the Q Research Advisory Board as a lay member.
* Lancaster University NIHR funding for a fit for Joint replacement surgery programme in 2019.
* For Ono he attended a 2-day workshop in 2019 on painful rare conditions, acting as a patient representative. For the same company he commented on internal patient involvement guide in 2019.
* ePAMS+ University of Edinburgh NIHR Programme grant looking at Antimicrobial Stewardship using electronic prescribing systems in hospitals in England in 2019.
* British Pain Society funded Clulow award Pain & HTLV1 looking at how pain effects people living with HTLV1 and how better to treat the symptoms in 2018.
* In 2018 he advised the editing of lay summaries (all regarding cancer treatments) for Envision.

He had also declared indirect interest as follows:

* In September 2019 he attended the European Federation of Pain Conference and spoke as a panel member as chair of Pain UK at a session re coproduction with patients of research in pain for which he received reasonable expenses.
* In May 2016 as chair of the Patient Liaison committee at the British Pain Society, he was lead for ‘Understanding and managing pain after surgery’ an information booklet for patients.
* Since 2013 he has been Chair of the Charity Pain UK, and from 2012 – 2017 was Chair of the Patient Liaison Committee at the British Pain Society.

It was agreed that these interests did not preclude Antony Chuter from participating in the meeting.

Professor Paul Collinson had declared non-financial personal and professional interests as in 2017 he had been a consultant to the International Federation of Clinical Chemists Committee on Clinical Applications of Cardiac Bio-Markers (C-CB), and in 2012 had been a member of the steering committee High-Sensitivity Troponin in the Evaluation of Patients With Acute Coronary Syndrome (High-STEACS) trial, a randomized controlled trial of hs Troponin in routine clinical practice (NCT01852123). He had also declared an indirect interest as he had written an independent editorial for the Journal of The American College of Cardiology to place a paper by Boeddinghaus J et I. J Am Coll Cardiol 2020;75:1111–24.al in current clinical and analytical context. It was agreed that this interest required Professor Collinson to be partially excluded for the meeting and he therefore attended Part 1 only of the meeting.

Professor Nicholas Mills had declared the following financial interests which had arisen in 2019: he participated in an Advisory Board for Siemens Healthineers on various cardiology products including cardiac troponin; he gave a seminar on early rule-out pathways in a session sponsored by Siemens Healthineers at the EuroMedLab IFCC meeting in Barcelona; he participated in a steering committee meeting for LumiraDx who wish to develop a troponin Assay; and he chaired a session on risk stratification in coronary heart disease at a meeting sponsored by Roche Diagnostics (ProCardio 2019).

He had also declared an indirect interest as the University of Edinburgh received in March 2019 an investigator-initiated research grant from Siemens Healthineers to evaluate the use of a cardiac troponin test for predicting risk in the general population.

He had also declared a non-financial personal and professional interest as from 2016-2019 he was the Chief Investigator for a 31,492-patient randomised trial funded by the British Heart Foundation to evaluate the safety and efficacy of an early rule-out pathway (ClinicalTrials.gov:

NCT03005158) that could be used with a number of troponin assays (Abbott, Roche, Siemens).

It was agreed that these interests did not preclude Professor Mills from participating in the meeting.

Professor Adam Timmis has declared a financial interest due to private practice work since 1990. It was agreed that this interest did not preclude him from participating in the meeting.

The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of High-sensitivity troponin for the early rule out of acute myocardial infarction.

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.

Date and time of next meeting: Thursday 6 August 2020