# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** Wednesday 18 January 2023

**Location:** Via Zoom

## Attendees

Committee members present

1. Brian Shine (Chair) Present for all items
2. Ghada Ahmed Present for all items
3. Rebecca Allcock Present for all items
4. Joy Allen Present for items 1 to 1.2.3
5. Sam Creavin Present for all items
6. Diane Davies Present for all items
7. Neil Hawkins Present for all items
8. Rashmi Kumar Present for all items
9. Patrick McGinley Present for all items
10. Michael Messenger Present for all items
11. Brendan Meyer Present for all items
12. Radha Ramachandran Present for all items
13. Jonathan Weir-McCall Present for all items

NICE staff present

Rebecca Albrow, Associate Director, Diagnostics Assessment Present for all items

Programme (DAP)

Frances Nixon, Health Technology Assessment Adviser, DAP Present for items 2 to 2.2.3

Judith Short, Health Technology Assessment Adviser, DAP Present for items 1 to 1.2.3

Suvi Harmala, Health Technology Assessment Analyst, DAP Present for items 2 to 2.2.3

Simon Webster Health Technology Assessment Analyst, DAP Present for items 1 to 1.2.3

Toni Gasse, Project Manager, DAP Present for items 2 to 2.2.3

Harriet Wilson, Project Manager, DAP Present for items 1 to 1.2.3

Alex Sexton, Administrator, DAP Present for all items

Thomas Lawrence, Data scientist, Managed Access Present for items 1 to 1.2.3

Helen Crosbie, Public Involvement Programme Present for items 1 to 1.2.3

Mark Rasburn, Public Involvement Programme Present for items 2 to 2.2.3

Rosalee Mason, Meetings in Public Present for items 1 to 1.1.5 and items 2 to 2.1.5

External assessment group representatives present

Ryan Kenny, Research Associate, Newcastle Technology Present for items 1 to 1.1.5  
Assessment Review Group

Nick Meader, Principal Research Associate, Newcastle Present for items 1 to 1.1.5

Technology Assessment Review Group

Hosein Shabaninejad, Senior Research Associate (Health Present for items 1 to 1.1.5

Economist), Newcastle Technology Assessment Review Group

Peter Auguste, Health Economist, Warwick Evidence Present for items 2 to 2.1.5

Yen-Fu Chen, Associate Professor, Warwick Evidence Present for items 2 to 2.1.5

Julia Geppert, Research Fellow, Warwick Evidence Present for items 2 to 2.1.5

**Specialist Committee Members present**

Emma Burkitt Wright, Consultant Clinical Geneticist Present for items 1 to 1.2.3

Susan Daniels, Lay specialist committee member Present for items 1 to 1.2.3

Jim Gray, Consultant Microbiologist, Birmingham Present for items 1 to 1.2.3  
Women's and Children's NHS Foundation Trust

Philippa May, Consultant Clinical Scientist, Great Ormond Present for items 1 to 1.2.3  
Street Hospital NHS Foundation Trust

Sam Oddie, Consultant Neonatologist, Bradford Teaching Present for items 1 to 1.2.3

Hospitals NHS Foundation Trust

Hayley Wickens, Consultant Pharmacist Genomic Present for items 1 to 1.2.3  
Medicine, Central and South Genomic Medicine Service

Alliance

Phil Crosbie, Senior Lecturer in Respiratory Medicine, Present for items 2 to 2.2.3  
University of Manchester

Sujal Desai, Consultant Radiologist, Royal Brompton Hospital Present for items 2 to 2.2.3  
Seamus Grundy, Consultant in Respiratory Medicine, Salford Present for items 2 to 2.2.3  
Royal NHS Foundation Trust

Emma O'Dowd, Consultant Respiratory Physician, Nottingham Present for items 2 to 2.2.3  
University Hospitals NHS Trust

Nagmi Qureshi, Consultant Radiologist, Royal Papworth Present for items 2 to 2.2.3  
Hospital NHS Foundation Trust

John Reynolds, Consultant Radiologist, University Hospitals Present for items 2 to 2.2.3  
Birmingham NHS FT

James Shambrook, Consultant Cardiothoracic Radiologist, Present for items 2 to 2.2.3  
University Hospital Southampton

Alan Thomas, Lay specialist committee member Present for items 2 to 2.2.3

Observers present

## Alice Bell, Associate Health Technology Assessment Analyst Present for items 2 to 2.2.3

## Matthew Brown, Digital Media Manager Present for all items

## Tara Chernick, Health Technology Adoption Manager Present for items 1 to 1.2.3

## Emilene Coventry, Senior Medical Editor Present for items 1 to 1.2.3

## Ann Greenwood, Market access analyst Present for items 1 to 1.2.3

Ben Gregory, Finance/Business Analyst Present for items 2 to 2.2.3

## Sophie Harrison, Associate Health Technology Assessment Present for items 1 to 1.2.3 Analyst

## Anam Khan, Health Technology Assessment Analyst Present for all items

Korn Knight, Senior Medical Editor Present for items 2 to 2.2.3

## Philip Williams, Finance/Business Analyst Present for items 1 to 1.2.3

## Minutes

### Early Value Assessment of ‘Genedrive MT-RNR1 ID Kit for detecting single nucleotide polymorphism m.1555A>G in neonates’

### The Chair welcomed members of the committee and other attendees present to the meeting.

The Chair welcomed Ghada Ahmed and Jonathan Weir-McCall as new standing committee members.

Rebecca Albrow noted that the topic had been routed into the Early Values Assessments (EVAs) pilots. EVAs are trialling a new approach to assessing those technologies that most reflect system need and demand, taking an initial look at technologies to provide an assessment of early value. Stakeholders are encouraged to provide feedback on the EVA pilots’ process.

The Chair noted apologies from standing committee members Keith Abrams, John Cairns, Anne Scott, Karen Sennett, and Matt Stevenson. In addition he noted apologies from specialist committee member Ruth Gottstein.

* 1. Part 1 – Open session

The Chair welcomed external assessment group representatives, members of the public, and company representatives from Genedrive Plc.

* + 1. The Chair asked all committee members to declare any new relevant interests in relation to the topic being considered in addition to those declared in advance of the meeting. The following standing committee members had notified these interests in advance of the meeting:

Joy Allen declared a financial interest as she is an employee of Roche Diagnostics.

John Cairns declared a financial interest due to his participation in a double-blinded focus group organized by PwC Switzerland on an epilepsy treatment (interest ceased December 2021). It was agreed that this interest would not prevent John Cairns from participating in the meeting.

Patrick McGinley declared a financial interest as he is a Faculty Member of MTech Access, providing advice on NHS finance structure, pricing and tariff developments. He also declared non-financial professional and personal interests as he is a Strategic Council member of the All-Party Parliamentary Group (APPG) on Obesity. He is the Honorary Treasurer for the Association for Study of Obesity (ASO). He is a member of the Obesity Policy Engagement Network UK (OPEN UK). It was agreed that these interests would not prevent Patrick McGinley from participating in the meeting.

Jonathan Weir-McCall declared financial interests due to private practice (Private Radiology Practice Group, Royal Papworth Radiology Group). He also declared non-financial professional and personal interests as he is Treasurer of British Society of Cardiovascular Imaging – Specialist Interest Group to the Royal College of Radiologists. He further declared indirect interests as he is on the Executive Committee of the British Society of Cardiovascular Magnetic Resonance, and he is on the Guideline Committee of the Society of Cardiovascular Computed Tomography. It was agreed that these interests would not prevent Jonathan Weir-McCall from participating in the meeting.

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

Emma Burkitt Wright had declared an indirect interest as she is a departmental colleague of Professor Newman and Dr McDermott, clinical developers of the Genedrive system. It was agreed that this interest would not prevent Emma Burkitt Wright from participating in the meeting.

Susan Daniels declared a non-financial professional and personal interest as she is Chair of NHS New Born Hearing Screening Programme Advisory Board and an indirect interest as she is CEO of the National Deaf Children’s Society. It was agreed that these interests would not prevent Susan Daniels from participating in the meeting.

Jim Gray declared a financial interest as he was Editor-in-Chief, Journal of Hospital Infection (and received income for this work from the Healthcare Infection Society) (interest ceased September 2022). It was agreed that this interest would not prevent Jim Gray from participating in the meeting.

Sam Oddie declared a non-financial professional and personal interest as he is Honorary Professor at Hull York medical School. It was agreed that this interest would not prevent Sam Oddie from participating in the meeting.

Hayley Wickens declared a financial interest as she had received occasional payments for speaking engagements at professional societies, including the Northern Ireland Centre for Pharmacy Learning and Development. She declared non-financial professional and personal interest as she is Chair, UK Clinical Pharmacy Association Genomics Committee (unpaid), a member of the Royal Pharmaceutical Society Genomics Expert Advisory Group (unpaid), and she has a professional interaction with companies providing genetic testing/technology (as part of her everyday work and not involving GeneDrive). She also declared that she works on a small part of the PROGRESS project, Pharmacogenetics Roll Out – Gauging Response to Service. The PROGRESS project looks to establish the feasibility of providing an NHS-wide diagnostic service to identify genetic changes associated with commonly prescribed drugs. Clinical Lead: Prof William Newman, Manchester University NHS Foundation Trust, and Dr John McDermott, University of Manchester. Both Prof Newman and Dr McDermott were leads on the PALOH trial. She had no involvement with the PALOH trial. The PROGRESS Project is led by the North West Genomic Medicine Service Alliance (GMSA), funded by NHSEI. Some funding has been paid from NWGMSA to her employer, Central and South GMSA, in order to back-fill her and colleagues’ time working on the project, but this does not benefit her personally. It was agreed that these interests would not prevent Hayley Wickens from participating in the meeting.

* + 1. The Committee proceeded to discuss ‘Genedrive MT-RNR1 ID Kit for detecting single nucleotide polymorphism m.1555A>G in neonates’. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
    2. The Chair asked the manufacturer representatives whether they wished to comment on any matters of factual accuracy.
    3. The Chair thanked the manufacturer representatives, the EAG and public observers for their attendance at the meeting.
    4. 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.
  1. Part 2 - Closed session
     1. The committee discussed confidential information submitted for this item.
     2. The committee then agreed on the content of the early value guidance consultation document. The committee decision was reached by consensus.
     3. The committee asked the NICE technical team to prepare the consultation document in line with their decisions.

### Assessment of ‘Software with artificial intelligence derived algorithms for automated detection and analysis of lung nodules from CT scan images’

### The Chair welcomed members of the committee and other attendees present to the meeting.

The Chair noted apologies from standing committee members John Cairns, Karen Sennett, Matt Stevenson, Anne Scott. In addition he noted that Joy Allen would not attend due to conflicts of interests.

* 1. Part 1 – Open session

The Chair welcomed external assessment group representatives, members of the public, and company representatives from Aidence BV, ContextFlow, Fujifilm Medical, Infervision UK Ltd, Riverain Technologies Inc, SynApps Solutions Limited/Mevis, and Varien/Siemens.

* + 1. The Chair asked all committee members to declare any new relevant interests in relation to the topic being considered in addition to those declared in advance of the meeting. The following standing committee members had notified these interests in advance of the meeting:

Joy Allen had declared a financial interest as she is an employee of Roche Diagnostics. Roche Diagnostics UK and Ireland are partners in the following research studies which are ongoing: (1) DART: The Integration and Analysis of Data using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases. (2) iDx Lung: Lung Health Checks in Wessex and Yorkshire: Integrated Biomarker Studies. She is not actively involved in either of these projects but members of her team (Access and Innovation) are. She also declared an indirect interest in that Roche is in partnership with Medial EarlySign who have developed an AI based clinical support tool, LungFlag for early flagging of potential patients for Lung Cancer Screening. It was agreed that these interest meant that Joy Allen could not participate in the meeting, and she did not attend.

John Cairns declared a financial interest due to his participation in a double-blinded focus group organized by PwC Switzerland on an epilepsy treatment (interest ceased December 2021). It was agreed that this interest would not prevent John Cairns from participating in the meeting

Neil Hawkins declared that alongside his academic role he has provided advice and undertaken analysis for a number of pharmaceutical and biotech companies related to HTA activities and is listed as a director of a company providing HTA services. He has not provided consultancy to any of the stakeholders listed for this assessment. It was agreed that these interests would not prevent Neil Hawkins from participating in the assessment.

Patrick McGinley declared a financial interest as he is a Faculty Member of MTech Access, providing advice on NHS finance structure, pricing and tariff developments. He also declared non-financial professional and personal interests as he is a Strategic Council member of the All-Party Parliamentary Group (APPG) on Obesity, Honorary Treasurer for the Association for Study of Obesity (ASO) and a Member of Obesity Policy Engagement Network UK (OPEN UK). It was agreed that these interests would not prevent Patrick McGinley from participating in the meeting.

Michael Messenger declared financial interests as he is a Director at Insightful Health Ltd, a UK based public health and regulatory consultancy firm. He is or has recently been a paid consultant for: The European Union IMI programme (since 2018), the World Health Organisation (since 2022) and is currently consulting for WHO on AI / TB; the Bill and Melinda Gates Foundation (since 2022); FIND – the global alliance for diagnostics (since 2022); ACT-IVD (since 2022); as well as PinPoint Data Science Ltd (interest ceased 2020) and Cepheid (interest ceased 2020). He is a co-inventor of the PinPoint Cancer Test (Pinpoint Data Science Ltd) and as such may be eligible for a share of royalties from any sales. He was previously a CI on the YCR funded Yorkshire Lung Screening trial from March 2018 to October 2020 and the iDX-LUNG trial from August 2019 to October 2020. It was agreed that these interests would not prevent Michael Messenger from participating in the meeting.

Jonathan Weir-McCall declared financial interests due to private practice (Private Radiology Practice Group, Royal Papworth Radiology Group). He also declared non-financial professional and personal interests as he is Treasurer of British Society of Cardiovascular Imaging – Specialist Interest Group to the Royal College of Radiologists. He further declared indirect interests as he is on the Executive Committee of the British Society of Cardiovascular Magnetic Resonance, and he is on the Guideline Committee of the Society of Cardiovascular Computed Tomography. It was agreed that these interests would not prevent Jonathan Weir-McCall from participating in the meeting.

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

Phil Crosbie declared financial interests due to consultancy fees and share options for lung cancer early detection and screening from Everest Detection, a biotechnology startup company (Everest Detection do not currently have a product); honoraria from Novartis for a lung cancer survey design (interest ceased 2020); and honoraria from AstraZeneca for a lung cancer screening talk and round table discussion (interest ceased 2020). He also declared non-financial professional and personal interests as he was the co-applicant on a grant submitted to NIHR involving commercial partner Infervision and AI approaches to chest CT interpretation (interest arose and ceased 2021), and he was co-applicant on a grant submitted to NIHR involving commercial partner Mindshare and AI approaches to chest CT interpretation (interest arose and ceased 2021), It was agreed that these interests would not prevent Phil Crosbie from participating in the meeting.

Seamus Grundy declared a financial interest as he is a Clinical Expert Reviewer for British Standards Institute. He provides expert opinion to the British Standards Institute for Respiratory Devices, however, he has not provided any opinion directly or indirectly related to the technology under review in this assessment. He also declared non-financial professional and personal interests as he is the Chief Investigator for Salford Lung Health Check Biomarker Study, collaborating with Everest Diagnostics Inc. The research relates to developing biomarkers to improve the early detection of lung cancer within lung cancer screening programs using blood and other biological samples such as urine or saliva. He also declared an NHSI grant application in collaboration with QURE for which he provided clinical expertise for the development of the grant proposal to evaluate the regional roll out of AI chest x-ray reporting across Greater Manchester. No financial or non-financial payment was received for this. It was agreed that these interests would not prevent Seamus Grundy from participating in the meeting.

Sujal Desai declared financial interests as he is the Founder/Co-Director, DMC-Radiology Reporting Ltd (out-sourced radiology reporting service); tutor, Boehringer-Ingelheim interstitial lung disease educational courses (paid honoraria & expenses), a consultant for Sensyne Healthcare Ltd (paid consultancy fee) but this company do not have any lung nodule products and focus only on ILD (interest now ceased); external expert/steering committee member for Astra Zeneca Phase III trial (paid consultancy fee). He also declared that he undertakes private practice (Cromwell Hospital, Royal Brompton Hospital, OneWelbeck Lung Health Group) (variable payments depending on workload). He also declared non-financial professional and personal interests as he is a Technical Adviser, Qure.AI, evaluating their nodule detection software and only advising on issues/deficiencies, as any potential user might. He has no financial relationship with Qure.AI and has never been paid by Qure.AI. He further declared that he is a Specialist Training Committee Member, Royal College of Radiologists, and an FRCR 2B examiner, Royal College of Radiologists. It was agreed that these interests would not prevent Sujal Desai from participating in the meeting.

James Shambrook declared non-financial professional and personal interests as he is President of the British Society of Cardiovascular Imaging/ British Society of Cardiovascular CT (this society does not advise on the management of pulmonary nodules). He also declared an indirect interest as he gave a presentation to the BIR conference in November 2020 about “The role of AI in developing the targeted lung health check programme”, he was invited to give this talk because of his institution’s use of Veye Chest from Aidence. No money was received for this talk. It was agreed that these interests would not prevent James Shambrook from participating in the meeting.

Emma O’Dowd declared non-financial professional and personal interests as she is the co-author on research looking at the role of artificial intelligence in pulmonary nodule risk stratification and co-author on editorials relating to nodules in lung cancer screening but these are not specifically related to the matter under review, there is no ongoing research related to this, and she does not have any affiliations related to this research. It was agreed that these interests would not prevent Emma O’Dowd from participating in the meeting.

* + 1. The Committee proceeded to discuss the clinical and cost effectiveness of ‘Software with artificial intelligence derived algorithms for automated detection and analysis of lung nodules from CT scan images’. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
    2. The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.
    3. The Chair thanked the manufacturer representatives, the EAG and public observers for their attendance at the meeting.
    4. 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.
  1. Part 2 - Closed session
     1. The committee discussed confidential information submitted for this item.
     2. The committee then agreed on the content of the Diagnostics Consultation Document (DCD). The committee decision was reached by consensus.
     3. The committee asked the NICE technical team to prepare the DCD in line with their decisions.

### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (next topic) will be held on 16 February 2023.