# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 2 March 2023

**Location:** Via Zoom

## Attendees

Committee members present

1. Brian Shine (Chair) Present for all items
2. Keith Abrams Present for items 2 – 2.2.3
3. Ghada Ahmed Present for all items 1- 1.2.3
4. Rebecca Allcock Present for all items
5. John Cairns Present for items 1.2.3 - 2.2.3
6. Sam Creavin Present for all items
7. Diane Davies Present for all items
8. Neil Hawkins Present for items 1 – 1.2.3
9. Rashmi Kumar Present for all items
10. Brendan Meyer Present for items 1-1.2.3
11. Radha Ramachandran Present for all items
12. Anne Scott Present for all items
13. Karen Sennett Present for all items
14. Matt Stevenson Present for all items
15. 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 1 - 1.2.3

Thomas Walker, Health Technology Assessment Adviser, DAP Present for items 2 - 2.2.3

Thomas Lawrence, Data Scientist, Managed Access Present for all items

Vandana Gupta, Scientific Adviser, Managed Access Present for items 2 - 2.2.3

Peslie Ngambi, Health Technology Assessment Analyst Present for items 1 - 1.2.3

Amy Barr, Health Technology Assessment Analyst Present for items 2 – 2.2.3

Alice Bell, Associate Health Technology Assessment Analyst Present for items 1 – 1.2.3

Emma McCarthy, Associate Health Technology Assessment Present for items 2 – 2.2.3
Analyst

Toni Gasse, Project Manager, DAP Present for all items

Harriet Wilson, Project Manager, DAP Present for all items

Alex Sexton, Administrator, DAP Present for all items

External assessment group representatives present

Chris Stinton, Senior Research Fellow, Warwick Evidence Present for items 1 – 1.1.6

Jill Colquitt, Honorary Research Fellow, Warwick Evidence Present for items 1 – 1.1.6

Mary Jordan, Research Fellow, Warwick Evidence Present for items 1 – 1.1.6

Penny Whiting, Professor of Clinical Epidemiology, Bristol Present for items 2 – 2.1.6
Technology Assessment Group

Howard Thom, Senior Lecturer in Health Economics, Bristol Present for items 2 – 2.1.6
Technology Assessment Group

**Specialist Committee Members present**

Robin Alcock, Consultant Radiologist, Present for items 1 – 1.2.3

Salisbury District Hospital

Alberto Alonso, Consultant Thoracic Radiologist, Present for items 1 – 1.2.3

Manchester University NHS

Fergus Gleeson, Professor of Radiology, Consultant Present for items 1 – 1.1.6

Radiologist, Oxford University Hospitals

Christopher Johns, Consultant Thoracic Radiologist, Present for items 1 – 1.2.3

Northern General Hospital, Sheffield

Emma O’Dowd, Consultant Respiratory Physician, Present for items 1 – 1.2.3

Nottingham City Hospitals

Alan Thomas, Lay specialist committee member Present for items 1 – 1.2.3

Sarah-Louise Beford, Lay specialist committee member Present for items 2 – 2.2.3

Kiren Gill, Consultant Obstetrician and Present for items 2 – 2.2.3

Gynaecologist (Urogynaecology), Whittington Health NHS Trust

Christopher Harding, Consultant Urological Surgeon, Present for items 2 – 2.2.3

Freeman Hospital/Newcastle University

Gail Hayward, Associate Professor of Primary Care, Present for items 2 – 2.2.3

University of Oxford

Philip Howard, AMR Regional Antimicrobial Stewardship Present for items 2 – 2.2.3

Lead, NHSE North-East and Yorkshire

Lauren Rose, Specialist Clinical Pharmacist, Present for items 2 – 2.2.3

Nottingham University Hospitals

Alison Taylor, Lay specialist committee member Present for items 2 – 2.2.3

Martin Williams, Consultant in Microbiology and Present for items 2 – 2.2.3

Infectious Diseases, Bristol Royal Infirmary

Observers present

Oyewumi Afolabi, HTA Analyst Present for all items

Sarah Bromley, Senior Medical Editor Present for items 1 – 1.2.3

Matt Brown, Digital Media Manager Present for all items

Emilene Coventry, Senior Medical Editor Present for items 2 - 2.2.3

Emma Gordon, Coordinator, Meetings in Public Present for items 2 - 2.1.6

Ben Gregory, Finance/Business Analyst Present for items 1 - 1.2.3

Jo Heaney, Coordinator, Medical Technologies Evaluation Present for items 2- 2.2.3
Programme

Katie Holden, Project Manager Present for all items

Edgar Masanga, Business Analyst Present for items 2 - 2.2.3

Cheryl Pace, Implementation Manager Present for items 2-2.2.3

Mark Rasburn, Public Involvement Adviser Present for all items

## Louisa Regan, Implementation Adviser Present for items 1 – 1.2.3

Sandra Robinson, Assistant Project Manager, Meetings in Public Present for items 1 - 1.1.6

## Minutes

### Early Value Assessment of Artificial Intelligence software for analysing chest X-ray images to identify suspected lung cancer

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

The Chair noted apologies from standing committee members Keith Abrams, Michael Messenger and Patrick McGinley and from specialist committee member Ian Woolhouse. He also noted that standing committee member Joy Allen was not attending due to a conflict of interest.

Rebecca Albrow noted that Early Values Assessments (EVAs) are currently being piloted by NICE, taking an initial look at technologies to provide an assessment of early value. Stakeholders are encouraged to provide feedback on the EVA pilots’ process.

* 1. Part 1 – Open session
		1. The Chair welcomed external assessment group representatives, members of the public, and company representatives from Annalise.ai, Behold.ai, InferVision UK Ltd, Lunit and Siemens Healthineers.
		2. 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. She also declared non-financial professional and personal interests as Roche Diagnostics UK and Ireland are supporting/ participating in the following, ongoing research projects: 1) DART: The Integration and Analysis of Data using Artificial Intelligence to Improve Patient Outcomes with Thoracic Diseases. Using AI algorithms built on clinical, imaging, blood biomarker and molecular data to define a new set of standards for lung cancer screening. 2) iDx Lung: Lung Health Checks in Wessex and Yorkshire: Integrated Biomarker Studies - The primary purpose of the project is to determine whether adding blood or tissue biomarkers to low-dose CT scanning improves diagnostic performance in risk-stratified population screening for lung cancer, in comparison with currently-used risk prediction methods. She also declared that her spouse works for Siemens Gamesa, Wind Energy. It was agreed that these interests meant that Joy Allen could not participate in the meeting and she did not attend.

John Cairns declared a financial interest as he is providing advice to SOBI regarding the economic evaluation of loncastuximab teserine for treating DLBCL. It was agreed that this interest would not prevent John Cairns from participating in the meeting.

Neil Hawkins declared a financial interest as he is a director in a company providing HTA consultancy services for biotechnology and pharmaceutical companies. No services have been provided to stakeholders named in the current assessment or for related technologies. He also declared non financial professional and personal interests because as part of his university employment (at the University of Glasgow) he was a member of the TSET (Technology Specific Evaluation Team) that was assigned to perform an evaluation of the Behold.ai Red Dot technology as part of its Evaluation for Artificial Intelligence (AI) in Health and Care Award. However contracting was not completed and the University of Glasgow is no longer involved in this evaluation. He also declared that as part of his university employment he is involved in a proposal for funding (currently at proposal/bid stage) to evaluate an AI technology developed by Qure.ai. His university is partnering with Qure.ai to obtain funding. The project is financed by the Scottish Government and Qure.ai. The money is received by the University of Glasgow. It was agreed these interests would not prevent Neil Hawkins from participating in the meeting.

Patrick McGinley declared a financial interest as he is an employee of Maidstone and Tunbridge Wells NHS Trust. He is an Associate to MTechAccess, providing advice on NHS funding. 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 also the Honorary Treasurer for the Association for Study of Obesity (ASO). It was agreed that these interests would not prevent Patrick McGinley from participating in the meeting.

Karen Sennett declared a non-financial professional and personal interest as from 2015 to June 2022 she had been the GP advisory member of SUMMIT TRIAL UCLH regarding cat scans for detecting lung cancer early. It was agreed that this interest would not prevent Karen Sennett from participating in the meeting.

Jonathan Weir-McCall 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. It was agreed that these interests would not prevent Jonathan Weir-McCall from participating in the meeting.

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

Robin Alcock declared non-financial professional and personal interests due to ongoing research collaboration with Swansea University Engineering and Computational Sciences Departments, researching computational techniques applied to CT imaging. His principal interest is academic research with main output of peer reviewed publications. He receives no personal funding to undertake this research, however research partners at Swansea University receive funding via Engineering streams such as the Engineering and Physical Sciences Research Council to employ individual researchers. He further declared that he was a specialist committee member on the NICE diagnostics advisory committee considering CaRiHeart. It was agreed that these interest would not prevent Robin Alcock from participating in the meeting.

Albert Alsonso declared financial interests as he is an NHS Consultant Radiologist, and a Consultant Radiologist in private clinical practice - Heart and Lung Health Ltd: reporting radiologist; Atlas Diagnostics: reporting radiologist; Venturi Cardiology clinic: reporting radiologist; and Medica Reporting Services: reporting radiologist. It was agreed that these interests would not prevent Albert Alsono from participating in the meeting.

Fergus Gleeson declared a financial interest as he is a shareholder in Optellum Ltd, an AI company with a CT nodule characterization algorithm; and he is a co-founder of the company RAIQC Ltd, which provides a cloud based platform to enable image analysis and interpretation. RAIQC has worked with a number of companies to assess their AI algorithms for image interpretation. It provides this service at arms length to the companies and does not have ongoing commercial relationships with them. Each “reader study” is performed as a CRO and has specific contracts. The companies that RAAIQC has worked with are: GEHC, Lunit, CureAI, and Icometrix. He also declared non-financial professional and personal interests as he is PI for DART, and NIHR funded study into the development and utility of AI in Lung Cancer Screening. It was agreed that these interests meant that Fergus Gleeson could stay for the public part (Part 1) of the meeting only, and he did not attend for Part 2.

Christopher Johns declared a financial interest as he is a Consultant Chest Radiologist, Sheffield Teaching Hospitals NHS Foundation Trust. He also declared an indirect interest as his NHS Trust is trialling a number of AI solutions in this area: ALND, Vuno and Behold.ai. The Trust has received no financial incentive but have received trial licenses free of charge. It was agreed that these interests would not prevent Christopher Johns from participating in the meeting.

Emma O’Dowd declared non-financial professional and personal interests as she is 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 and there is no ongoing research related to this and she does not have any affiliations related to this research. She also declared that she is a co-applicant on a grant “Determining the impact of CT analysis software on lung nodule diagnosis (DOLCE)”, specifically evaluating Optellum lung cancer risk prediction tool (AI developed for use with CT scans) and comparing it to standard NHS practice. She has no financial interest in the tool or the company. It is an NHSX funded grant which has not yet started. This tool is not for use with CXR. It was agreed that these interests would not prevent Emma O’Dowd from participating in the meeting.

* + 1. The Committee proceeded to discuss the topic ‘Artificial Intelligence software for analysing chest X-ray images to identify suspected lung cancer’. 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 Early Value Guidance Consultation Document. The committee decision was reached by consensus.
		3. The committee asked the NICE technical team to prepare the Guidance Consultation Document in line with their decisions.

### Early Value Assessment of Point of care tests for urinary tract infections to reduce antimicrobial resistance

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

The Chair noted apologies from standing committee members Gadha Ahmed, Michael Messenger, Neil Hawkins and Patrick McGinley. He also noted that standing committee members Joy Allen and Brendan Meyer were not attending due to a conflict of interest.

Rebecca Albrow noted that Early Values Assessments (EVAs) are currently being piloted by NICE, taking an initial look at technologies to provide an assessment of early value. Stakeholders are encouraged to provide feedback on the EVA pilots’ process.

* 1. Part 1 – Open session
		1. The Chair welcomed external assessment group representatives, members of the public, and company representatives from Global Access Diagnostics, Llusern, and Sysmex/Astrego.
		2. 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:

Keith Abrams declared a financial interest as Visible Analytics Limited) of which he is a director is undertaking a project for Echosens on evaluating FibroScan for assessing liver fibrosis and cirrhosis in primary care. He is not involved in the project in any way and measures have been taken to avoid potential conflicts. Private HTA consultancy (regarding non-diagnostics) in the last 12 months has been provided to Abbvie (completed), AstraZeneca (completed), Bayer (completed), BMS (on-going) and Medtronic (completed). He also declared non-financial professional and personal interests due to 1) funding to support a MRC Industrial PhD Studentship from Swiss Precision Diagnostics/Clearblue for a project on prediction of early miscarriage (from October 2017 to April 2022); 2) £450K MRC/NIHR Methods Research Programme (from October 2021 for 3 years) S Bujkiewicz, RK Owen, KR Abrams, P Tappenden: HCD: Novel approaches of multi-parameter evidence synthesis and decision modelling for efficient evaluation of diagnostic health technologies in HTA decision making with use of electronic health records; 3) from October 2022 - date: NIHR I4I Application (Stage 2) with Cytecom Limited (a diagnostics company) via University of Warwick - technology uses combination of fluorescence microscopy imaging and electrical stimulation to quantify viable urine or bloodstream bacterial cells and antibiotic sensitivity results <30mins. If successful the money would go to his university department. It was agreed that these interests would not prevent Keith Abrams from participating in the meeting.

Joy Allen declared a financial interest as She is an employee of Roche Diagnostics UK and Ireland, since August 2021. Roche manufacturer: The Urisys 1100 urine analyzer - semi-automated hand held urine testing analyzer and Combur-Test® strip, Urine reagent strips. It was agreed that this interest meant that Joy Allen could not participate in the discussions and she did not attend the meeting.

John Cairns declared a financial interest due to advising SOBI (since January 2023) regarding the economic evaluation of loncastuximab teserine for treating DLBCL. 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 an employee of Maidstone and Tunbridge Wells NHS Trust. He is an Associate to MTechAccess, providing advice on NHS funding. 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 also the Honorary Treasurer for the Association for Study of Obesity (ASO). It was agreed that these interests would not prevent Patrick McGinley from participating in the meeting.

Brendan Meyer declared a financial interest due to employment and share holding for a Becton Dickinson business unit producing products for specimen collection and diagnostics, including culture and antimicrobial sensitivity testing with urine. It was agreed that this interest prevented Brendan Meyer from participating in the discussions and he did not attend the meeting.

Jonathan Weir-McCall 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. It was agreed that these interests would not prevent Jonathan Weir-McCall from participating in the meeting.

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

Sarah Louise Bedford declared non-financial professional and personal interests due to ad hoc work for the Care Quality Commission as an “expert by experience” and on “external advisory groups”. It was agreed that this interest would not prevent Sarah Bedford from participating in the meeting.

Karen Gill declared a financial interest due to private practice as a urogynaecologist, and indirect interests due to being a research committee member for British Society of Urogynaecology. It was agreed that these interests would not prevent Karen Gill from participating in the meeting.

Chris Harding declared financial interests due to having received speaker fees from Convatec and Medtronic, and due to advisory boards/consultancy from Teleflex Medical, Viatris and Convatec, an educational grant from Medtronic, and research grants from UK National Institute of Health and the Urology Foundation. He also declared non-financial professional and personal interests due to being on the following committees: EAU Female LUTS committee (Chair); ICS Urodynamics, Mesh Complications, Male LUTS committee (member). It was agreed that these interests would not prevent Chris Harding from participating in the meeting.

Gail Hayward declared financial interest as some of her salary comes from her role as Clinical Director of the NIHR Medtech and IVD Cooperative, which works with UTI diagnostics companies, including applying for collaborative grants to conduct research. These include Astrego Diagnostics, and Llusern Scientific as well as relationships with research groups interested in developing UTI diagnostics who are not yet at the stage of spin out. She also declared that she had previously held a EU funded grant with Astrego Diagnostics which had to closed before any research was conducted due to the pandemic. She further declared that she is CI of a diagnostic accuracy platform study which may include LLusern, Sysmex Astrego, Global Access Diagnostics, and ODx, and which will receive POCT tests and consumables from the companies to deliver this study. It will not receive any funding from the companies and they will have no input into study design or delivery. It was agreed that these interests would not prevent Gail Hayward from participating in the meeting.

Philip Howard declared non-financial professional and personal interests as he is a Leeds University academic and clinical pharmacist and has published extensively in the field <http://orcid.org/0000-0002-5096-0240>. He is on the Antimicrobial Expert Advisory Board, which provides advice to RPS about AMR and antimicrobial stewardship. He is President (and was formerly Vice President) of British Society of Antimicrobial Chemotherapy. BSAC provides free education and research funding on the responsible use of antibiotics to healthcare professionals, public and Parliamentarians within its charitable goals at a global level. Part of BSAC’s income is from the pharmaceutical and diagnostics industry through unrestricted education grants. All financial elements dealt with by CEO and Treasurer. He is Co-investigator: NIHR COVID Learning and Recovery call ref XP NIHR 132254 (PEACH study) - procalcitonin evaluation of antibiotic use in COVID-19 hospitalised patients. He is co-author “Use of Procalcitonin during the First Wave of COVID-19 in the Acute NHS Hospitals: A Retrospective Observational Study” Antibiotics 10 (5), 516. He is Co-investigator NIHR HTA Sepsis call 17/136/13 PROcalcitonin and NEWS evaluation for timely identification of sepsis and Optimal use of antibiotics in the Emergency Department (PRONTO) £1.968m. He is co-lead for Europe for the International Pharmacy Federation (FIP) Development Goal 17 on Antimicrobial Stewardship. He is Co-investigator NIHR-PGfR (Ref number RP-PG-1214-20007) £2,459,665 Penicillin allergy status and its effect on antimicrobial prescribing, patient outcomes, and antimicrobial resistance. In 2018 and 2020, £32k Health Education England, PI. & $100k BSAC Grant: Educational intervention to improve implementation of the Royal Pharmaceutical Society Antibiotic Checklist for community pharmacies. He is co-author on the following publications: “Mixed-Method Evaluation of a Community Pharmacy Antimicrobial Stewardship Intervention (PAMSI)”, Healthcare 10 (7), 1288; “PROcalcitonin and NEWS2 evaluation for Timely identification of sepsis and Optimal use of antibiotics in the emergency department (PRONTO)“ BMJ open 12 (6), e06342; “Global resilience and new strategies needed for antimicrobial stewardship during the COVID‐19 pandemic and beyond” Journal of the American College of Clinical Pharmacy; “Impact of introducing procalcitonin testing on antibiotic usage in acute NHS hospitals during the first wave of COVID-19 in the UK: a controlled interrupted time series …” Journal of Antimicrobial Chemotherapy 77 (4), 1189-1196; “Development and randomized controlled trial of an animated film aimed at reducing behaviours for acquiring antibiotics” JAC-Antimicrobial Resistance 3 (2), dlab083; “Using health literacy techniques to develop patient information for counselling on antibiotics courses” Access Microbiology 2 (2), 15 2020; “Using health literacy techniques to support pharmacist practice when counselling on antibiotics courses” Access Microbiology 2 (2), 16; “Encouraging Day Three Reviews via a Pharmacist-led Antimicrobial Stewardship Ward Round” Access Microbiology 2 (2), 89 1 2020; “Carbapenem stewardship in a large teaching English hospital-are we improving” Access Microbiology 2 (2), 164. He also reported an indirect interest due to involvement with the Global Respiratory Infection partnership (GRIP) which co-ordinates the webinars and workshops around the International Pharmacy Federation (FIP) Development Goal 17 on Antimicrobial Stewardship. He further declared that he attended a European Network on antimicrobial stewardship with point of care test (ENASPOC) which focussed on POC CRP in Brussels on 29 November 2022. The travel and accommodation were underwritten by an educational grant from Abbott Rapid Diagnostics. Cardiometabolic supported the event and MindGap healthcare market research and consultancy organised and moderated the event. It was agreed that these interests would not prevent Philip Howard from participating in the meeting.

Lauren Rose declared a financial interest as she is employed as a Specialist Antimicrobial Pharmacist at Nottingham University Hospitals NHS Trust. It was agreed that this interest would not prevent Lauren Rose from participating in the meeting.

Alison Taylor declared non-financial professional and personal interests as she is an unpaid volunteer for the Chronic Urinary Tract Infection Campaign (CUTIC), a not for profit organisation campaigning for recognition of Chronic UTI. She helps to run and contribute to their adult and parents support group. She also declared that she liaises and occasionally work with Bladder Health UK, supporting patients especially parents/children. It was agreed that these interests would not prevent Alison Taylor from participating in the meeting.

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### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (next topic) will be held on 23 March 2023.