NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 16 September 2021

**Location:** Via Zoom

## Attendees

Committee members present

1. Mark Kroese (Chair) Present for all items
2. Keith Abrams Present for all items
3. Liz Adair Present for all items
4. Rebecca Allcock Present for all items
5. John Cairns Present for all items
6. Sam Creavin Present for all items
7. Diane Davies Present for all items
8. Neil Hawkins Present for all items
9. Patrick McGinley Present for all items
10. Brendan Meyer Present for all items
11. Alexandria Moseley Present for all items
12. Alasdair Taylor Present for all items
13. Brian Shine Present for all items
14. Matt Stevenson Present for all items

NICE staff present

Sarah Byron, Programme Director Present for all items

Rebecca Albrow, Associate Director Present for all items

Frances Nixon, Technical Adviser Present for all items

Vera Unwin, Technical Analyst Present for all items

Donna Barnes, Project Manager Present for all items

Alex Sexton, Administrator Present for all items

External assessment group representatives present

Ana Duarte, Research Fellow, Present for items 1 – 3.1.7
Centre for Health Economics, University of York

Mark Simmonds, Senior Research Fellow, Present for items 1 – 3.1.7

Centre for Reviews and Dissemination, University of York

Marta Soares, Senior Research Fellow, Present for items 1 – 3.1.7
Centre for Health Economics, University of York

Specialist Committee Members present

Matthew Callister, Consultant Respiratory Physician, Present for all items

Leeds Teaching Hospital

Philip Crosbie, Senior Lecturer in Respiratory Medicine, Present for all items

University of Manchester

Jesme Fox, Lay specialist committee member Present for all items

Seamus Grundy, Consultant Respiratory Physician, Present for all items
Salford Royal Hospital

Helen Johnstone, Consultant Clinical Scientist, Present for all items
Epsom and St Helier Hospitals NHS Trust

Eric Lim, Professor of Thoracic Surgery, Present for all items
Royal Brompton Hospital

Emma O’Dowd, Consultant Respiratory Physician, Present for all items
Nottingham University Hospitals NHS Trust

James Wilson, Consultant Clinical Oncologist, UCLH Present for all items

Observers present

Diarmuid Coughlan, Research Associate, Present for all items
Newcastle University

Sophie Harrison, Associate Health Technology Present for all items
Assessment Analyst, NICE

Ryan Kenny, Research Associate, Present for all items
Newcastle University

Heidi Livingstone, Public Involvement Adviser, NICE Present for all items

Rosalee Mason, Coordinator, NICE Present for items 1 – 3.1.7

Ian Mather, Business Analyst, NICE Present for all items

Benjamin Pearce, Senior Medical Editor, NICE Present for all items

Louisa Regan, Implementation Adviser, NICE Present for all items

Nicky Welton, Professor of Statistical and Health Present for items 1 – 3.1.7
Economic Modelling, University of Bristol

## Minutes

### Introduction to the meeting

* 1. The Chair welcomed members of the committee and other attendees present to the meeting.
	2. The Chair noted apologies from standing committee members Jim Gray, Ross Maconachie, Michael Messenger, Shelley Rahman Hayley and Karen Sennett, and from specialist committee member Janette Rawlinson.

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meeting held on 19 August 2021.

### Evaluation of EarlyCDT Lung for lung cancer risk classification of solid pulmonary nodules

* 1. Part 1 – Open session
		1. The Chair welcomed external assessment group representatives, members of the public and company representatives from Oncimmune Ltd.
		2. The Chair asked all committee members to declare any relevant interests in relation to the item being considered. The following standing committee members had notified these interests in advance of the meeting:
* Keith Abrams declared financial interests as he is a Partner and Director, Visible Analytics Limited, a HTA consultancy company, with various clients but not including the company for this topic, and he is an HTA Consultant for Pfizer Oncology. He also declared a non-financial professional and personal interests as he had research funding from Duchenne UK as part of Project HERCLUES in DMD (interest ceased 31 December 2020); he has research funding from Swiss Precision Diagnostics/ClearBlue for a PhD studentship in modelling miscarriage using biomarkers; he is a Member of NICE Decision Support Unit, an Advisor to NHS Accelerated Access Collaboration, and a Member of NICE Technical Support Unit. It was agreed these interests would not prevent Keith Abrams from participating in the meeting.
* John Cairns declared financial interests as he had advised Astellas on health economic modelling for roxadustat (interest ceased May 2021) and Takeda on the economic evaluation of maribavir (interest ceased August 2021). It was agreed that these interests would not prevent John Cairns from participating in the meeting.
* Neil Hawkins declared a non-financial professional and personal interest since, as part of university employment, he may have potential involvement in a TSET (Technology Specific Evaluation Team). It was agreed that this interest would not prevent Neil Hawkins from participating in the meeting.
* Patrick McGinley declared a financial interest as he is a Faculty Member of MTech Access, advising on NHS finance flows, and receives an honorarium for this. He also declared non-financial personal and professional interests as he is a Strategic Council member of the All-Party Parliamentary Group (APPG) on Obesity, He is also the Hon 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.
* Alasdair Taylor declared non-financial professional and personal interests as he is a core member of his employing Trust's lung cancer MDT since 2016; he has no direct involvement in research relevant to the topic and has not published on the topic. He also declared an indirect interest as he is an elected member of the council of the Royal College of Radiologists, representing the faculty of clinical radiology. It was agreed that these interests would not prevent Alasdair Taylor from participating in the meeting.

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

* Matthew Callister declared non-financial professional and personal interests:
	+ He co-chaired the 2015 British Thoracic Society Pulmonary Nodule Guidelines. The role of biomarkers in discriminating benign from malignant nodules was considered and published evidence regarding EarlyCDT-Lung was reviewed. The GDG commented that "there are no reports evaluating the performance of this test in a cohort of patients with pulmonary nodules" and therefore concluded that its efficacy in discriminating malignant from benign nodules was unknown. The summary evidence statement was "Biomarkers do not offer sufficient accuracy to differentiate malignant from benign nodules" and the recommendation was "Do not use biomarkers in the assessment of pulmonary nodules" Grade D.
	+ He is Chief Investigator for the Yorkshire Lung Screening Trial (YLST), and a co-applicant on the YLST Biomarker Study (a nested sub-study within YLST - PI Dr Philip Crosbie, University of Manchester). As of December 2020 the study collaborated with Everest Diagnostics, a company developing circulating biomarkers of lung cancer. He has no personal connection with the company in question, has received no personal payments and owns no shareholdings of other investments in this company.
	+ The YLST biomarker company is now planning on being one site for IDx lung. The latter study is run by the University of Southampton, is funded by Innovate UK, and is testing a number of biomarkers in lung screening and nodule evaluation - one of which is Early CDT lung. He is not a listed co-investigator for IDx itself but will be a co-author on any paper published looking at the efficacy of these tests. He receives no personal payments for any of these collaborations.
	+ The EarlyCDT-Lung test has been proposed as a tool for identifying people at higher risk of lung cancer who might benefit from low-dose CT screening for lung cancer. This is a distinct indication for the test than the one under review here (discrimination of malignant from benign pulmonary nodules once detected). The former indication was the subject of the Early Detection of Lung Cancer in Scotland (ECLS), first presented in abstract form at the World Conference on Lung Cancer 2019 and shortly to be published in the European Respiratory Journal. He was asked to write a blog for the British Thoracic Oncology Group regarding lung cancer screening research presented at WCLC2019 (https://www.btog.org/blog/lung-cancer-screening-at-wclc-2019/), and has recently co-authored an editorial for publication in the European Respiratory Journal alongside the main trial paper. Both the blog and subsequent editorial raise some concerns about the design of ECLS and the way in which the performance of the test has been reported by the trial group. The recommendation in both is for further research to be undertaken to determine the role of EarlyCDT in this scenario. Use of EarlyCDT in this way is not the matter under consideration in this review.

It was agreed that these interests would not prevent Matthew Callister from participating in the meeting.

Philip Crosbie declared the following financial interests: Everest Detection, a biotechnology startup company - consultancy fees and share options for lung cancer early detection and screening. The company collaborate with the Yorkshire Lung Screening Trial biomarker study which he leads. Everest Detection do not currently have a product. He received an honoraria from Novartis for lung cancer survey design (interest ceased 2020), and from AstraZeneca for a lung cancer screening talk and round table discussion (interest ceased 2020). He also declared non-financial personal and professional interests as he contributed to NICE Medtech Innovation Briefing related to EarlyCDT-Lung; and he is chief investigator Yorkshire Lung Screening Trial Biomarker study (assess EarlyCDT-Lung in lung screening cohort). It was agreed that these interests would not prevent Philip Crosbie from participating in the meeting.

* Jesme Fox declared financial interests as her employer, Roy Castle Lung Cancer Foundation (RCLCF), has received grants/donations from multiple pharmaceutical and commercial businesses. These have been for specified projects (eg, conference organisation, patient information leaflets, Global Lung Cancer Coalition etc.) and not core funding. She has presented at many conferences and participated in advisory boards, organised by multiple pharmaceutical companies. Over the past year, she has participated in virtual Advisory Boards for Boehringer Ingelheim, BMS, AstraZeneca, Novartis, Debiopharma and Takeda (see dates below). In lieu of her time, donations have been given by the company to RCLCF. At no time has she personally accepted an honorarium. The dates were: Boehringer Ingelheim Advisory 26/02/21, BMS Advisory 09/12/20, 02/02/21, 12/03/21, 17/07/21, 22/07/21, AstraZeneca Advisory 12/03/21, Takeda Advisory 28/06/21, Novartis Advisory 10/12/20, Debiopharma 22/06/21, 07/09/21.

She also declared non-financial professional and personal interests as follows: she is the Medical Director, Roy Castle Lung Cancer Foundation; Branch President, Northwest Somerset Branch of Parkinsons' UK; Secretary, Global Lung Cancer Coalition; Member- British Thoracic Oncology Group; Member - International Association for the Study of Lung Cancer; Member -Lung Cancer and Mesothelioma Clinical Expert Group; Member - NHSE&I Early Detection 'Task and Finish Group'; Member - NHSE&I Lung Cancer Screening Advisory Group.

She also declared the following indirect interests: Roy Castle Lung Cancer Foundation is a registered charity, with an interest in ensuring equitable access to best practice diagnostics, treatment and care for all lung cancer patients. She represents the Global Lung Cancer Coalition on the Board of the Lung Ambition Alliance (the LAA currently receives funding from Astra Zeneca and Guardant Health). She represents the Global Lung Cancer Coalition on the Global Cancer Coalition Network.

It was agreed that these interests would not prevent Jesme Fox 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. He has not provided any opinion directly or indirectly related to the technology under review by this committee. He also declared non-financial professional and personal interests as he is the Chief Investigator for the Salford Lung Health Check Biomarker Study and is collaborating with Everest Detection Ltd. 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. It was agreed that these interests would not prevent Seamus Grundy from participating in the meeting.

Eric Lim declared the following financial interests: Abbott Molecular – consultancy (project-specific, not salaried position); Medtronic - consultancy and travel in line with public sector (economy class); Roche - educational presentations, advisory board payment, project specific; Medela - educational presentation, accommodation and travel in line with public sector and research funds to his institution; Johnson and Johnson - consultancy; Guardant Health - research funds to his institution; AstraZeneca - educational presentations, advisory board payment (project-specific, not salaried position); Bristol Meyers Squib - educational presentations ((project-specific, not salaried position). He also declared non-financial professional and personal interests as he is planning a research project (PhD) on use of earlyCDT for the evaluation of ground glass opacities, and is planning a RCT on the utility of blood based diagnosis for early surgical management. It was agreed these interest would not prevent Eric Lim from participating in the meeting.

* Emma O'Dowd declared a non-financial professional and personal interest 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. However, 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 this interest would not prevent Emma O’Dowd from participating in the meeting.
* James Wilson declared a financial interest due to private practice. It was agreed that this interest would not prevent James Wilson from participating in the meeting.
	+ 1. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of EarlyCDT Lung for lung cancer risk classification of solid pulmonary nodules.
		2. The Committee was asked if there were any specific equality issues to consider in relation to this assessment.
		3. The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.
		4. The Chair thanked the manufacturer representatives, the EAG and public observers for their attendance at the meeting.
		5. 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 20 October 2021.