NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

# Diagnostics Advisory Committee (DAC) meeting minutes

**Minutes:** Confirmed

**Date and time:** 15 June 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. Jim Gray Present for all items
9. Neil Hawkins Present for all items
10. Patrick McGinley Present for all items
11. Ross Maconachie Present for items 1 - 4.2.3
12. Michael Messenger Present for all items
13. Alexandria Moseley Present for all items
14. Shelley Rahman Haley Present for all items
15. Brian Shine Present for items 1 - 4.2.3
16. Matt Stevenson Present for all items
17. Alasdair Taylor Present for all items

NICE staff present

Sarah Byron, Programme Director Present for all items

Rebecca Albrow, Technical Adviser Present for all items

Thomas Walker, Technical Adviser Present for items 5-6

Suvi Harmala, Technical Analyst Present for items 1 - 4.2.3

Simon Webster, Technical Analyst Present for items 5-6

Donna Barnes, Project Manager Present for all items

Alex Sexton, Administrator Present for all items

External assessment group representatives present

Isaac Corroramos, Health Economics Researcher Present for items 1 – 4.2.3
Kleijnen Systematic Reviews Ltd (KSR)

Marie Westwood, Reviews Manager Present for items 1 – 4.2.3
Kleijnen Systematic Reviews Ltd (KSR)

Keith Cooper, Senior Research Fellow in Present for items 5 -6
Health Economics, Southampton Health Technology
Assessments Centre (SHTAC)

Inês Souto Ribeiro, Senior Research Assistant, Present for items 5-6
SHTAC

Jonathan Shepherd, Principal Research Fellow, Present for items 5-6
SHTAC

Irina Tikhonova, Senior Research Fellow, Present for items 5-6
SHTAC

Specialist Committee Members present

Matthew Brookes, Consultant Gastroenterologist, Present for items 1- 4.2.3
Royal Wolverhampton NHS Trust

Fahmid Chowdhury, Consultant Radiologist Present for items 1 – 4.2.3
& Nuclear Medicine Physician,
Leeds Teaching Hospitals NHS Trust

Mark Follows, Clinical Lead Planned Present for items 1- 4.2.3
Care/ Gastroenterology, Norfolk and Waveney CCG

Nigel Horwood, Lay specialist committee Present for items 1 – 4.2.3
member

Yvonne McKenzie, Specialist Dietician Present for items 1 – 4.2.3

John McLaughlin, Professor of Gastroenterology Present for items 1 – 4.2.3
and Nutrition, University of Manchester
and Salford Royal Hospitals

Karen Slade, Lay specialist committee Present for items 1 – 4.2.3
member

Peter Whorwell, Professor of Medicine Present for items 1 – 4.2.3
and Gastroenterology, Wythenshawe Hospital

Sarah Findlay, Lay specialist committee Present for items 5 - 6
member

Joanna Girling, Consultant Obstetric Medicine, Present for items 5 - 6
Obstetrics and Gynaecology, West Middlesex
University Hospital and Chelsea &
Westminster Hospital NHS Foundation Trust

Shonagh Haslam, Principal Clinical Biochemist, Present for items 5 - 6
Lancashire Teaching Hospitals

Jenny Myers, Consultant Obstetrician / Present for items 5 - 6
Professor of Obstetrics & Maternal Medicine,
University of Manchester

Andrew Sharp, Senior Clinical Lecturer in Present for items 5 - 6
Obstetrics, University of Liverpool

Nigel Simpson, Senior Lecturer/Consultant Present for items 5 - 6
in Obstetrics & Gynaecology, University of Leeds
/Leeds Teaching Hospitals Trust

Elaine Sheehan, Specialist Midwife for Hypertension Present for items 5 - 6
and Maternal Medicine, St. George’s University
Hospitals NHS Foundation Trust

Manu Vatish, Professor of Obstetrics, Present for items 5 - 6
University of Oxford

Observers present

Emilene Coventry, Senior Medical Editor, NICE Present for items 5 - 6

Lucinda Evans, Coordinator, NICE Present for all items

Jacob Grant, Technical Analyst, NICE Present for all items

Ann Greenwood, Senior Medical Editor Present for items 1 – 4.2.3

Suvi Harmala, Technical Analyst, NICE Present for items 5 - 6

Laura Marsden, Public Involvement Adviser, NICE Present for all items

Ian Mather, Business Analyst, NICE Present for all items

Vera Unwin, Technical Analyst, NICE Present for all items

Milena Wobe, Technical Analyst, NICE Present for items 1 – 4.2.3

## 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 Karen Sennett.

### News and announcements

* 1. The chair recorded the committee’s thanks to John Bagshaw, Owen Driskell, and Alistair Reid for all their work and valuable contributions during their time as members of the Diagnostics Advisory Committee.

### Minutes from the last meeting

* 1. The committee approved the minutes of the committee meeting held on 10 December 2020.

### Evaluation of SeHCAT (tauroselcholic [75 selenium] acid) for the investigation of bile acid diarrhoea

* 1. Part 1 – Open session
		1. The chair welcomed external assessment group representatives, members of the public and company representatives from General Electric Healthcare.
		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, but he has not been involved in any projects which involve a diagnostic technology. He also declared a non-financial professional and personal interest as since 2017 he has funding to support an MRC Industrial PhD Studentship from Swiss Precision Diagnostics / Clearblue for a project on prediction of early miscarriage. It was agreed these interests would not prevent Keith Abrams from participating in the meeting.
* John Cairns declared a financial interest as he has been advising Astellas on health economic modelling for roxadustat for treating anaemia in people with chronic kidney disease (since October 2020). It was agreed that this interest would not prevent John Cairns from participating in the meeting.
* Sam Creavin declared a financial interest in that he is a GP Partner in an NHS practice. It was agreed that this interest would not prevent Sam Creavin from participating in the meeting.
* Patrick McGinley declared a financial interest as he is a Faculty Member of MTech Access, providing updates on the NHS finance regime and the impact of these changes to MTech Access and receive 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, providing advice on costs of the disease within NHS to the APPG. He is also the Hon Treasurer for the Association for Study of Obesity (ASO), and 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.
* Ross Maconachie declared a non-financial personal and professional interest in the meeting in that he is employed by Merck Sharp & Dohme Limited (MSD). As far as he is aware MSD do not make any drugs that could be used to treat bile acid diarrhoea. It was agreed that this interest would not prevent Ross Maconachie from participating in the meeting.

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

* Matthew Brookes declared financial interests due to earnings from private practice. He had received honoraria for an advisory board from Vifor Pharma (in 2019), and from Abbvie Pharma (in 2017). He also declared non-financial professional and personal interests in that he was Chief Investigator on a study to determine validity of faecal bile acid testing (interest ceased 2020), he was a Trustee of Guts UK! Charity (interest ceased 2019), was research chair for the British Society of Gastroenterology (interest ceased 2019), and is currently a member of the IBD UK Board. He also declared indirect interests as his research department has received grant funding from Tillotts Pharma (interest ceased 2020), and from Vifor Pharma (interest ceased 2020), and will receive grant funding from Norgine. It was agreed these interests would not prevent Matthew Brookes from participating in the meeting.
* Fahmid Chowdhury declared the following financial interests: national PET/CT contract reporting and auditing, Alliance Medical Limited; director, F&S Medical Imaging (12532293); designated member, Leeds Radiology Group (OC411908). He also declared receipt of speaker honoraria from GE Healthcare Limited, for presenting at reporter workshops about quantification of DaTSCAN in Parkinsonian syndromes (interest ceased 2020). It was agreed these interests would not prevent Fahmid Chowdhury from participating in the meeting.
* Mark Follows declared a financial interest due to funding from Reckitt Benckiser Healthcare for Upper GI Educational Hub RCGP/ Pulse GP training (interest ceased in 2019). It was agreed this interest would not prevent Mark Follows from participating in the meeting.
* Nigel Horwood declared a financial interest as he had been paid a nominal sum for patient and public involvement (PPI) work by Motilent in 2017. He also declared non-financial personal and professional interests as he is the patient representative on Guy’s and St Thomas’ Gastro Project Board; joint PPI lead on Osiris (optimising shared decision-making for high-risk major surgery) funded by the National Institute of Health Research (NIHR) and is involved with various studies being sponsored by Bowel Cancer UK charity. It was agreed these interests would not prevent Nigel Horwood from participating in the meeting.
* Yvonne McKenzie declared a financial interest as she is a clinical dietitian undertaking private practice. She also declared non- financial personal and professional interests due to her research project, ‘effectiveness of non-pharmacological therapies in the management of bile acid diarrhoea in adults: a protocol for a systematic review’ [https://www.crd.york.ac.uk/prospero/
display\_record.php?RecordID=188328](https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=188328). She is the Clinical Lead in IBS for the Gastroenterology Specialist Group of the British Dietetic Association. It was agreed these interests would not prevent Yvonne McKenzie from participating in the meeting.
* John McLaughlin declared non-financial professional and personal interests as in 2015-16 he co-chaired the NICE-funded multicentre prospective survey of SeHCAT provision and practice in the UK led by KITEC and subsequently published (Summers et al). He also declared that he is an active member of the UK Bile Acid Related Diarrhoea Network of clinicians and researchers, a trustee for Research and Deputy Clinical Chair, Guts UK charity, and Head of Division, Diabetes, Endocrinology and Gastroenterology, School of Medical Sciences, University of Manchester. It was agreed these interests would not prevent John McLaughlin from participating in the meeting.
* Peter Whorwell declared financial interests as he undertakes private practice. He has or had research funding from EnteroMed ltd (ongoing), 4D Pharma (ceased 2019), Ironwood Pharmaceuticals (ceased 2018), Danone (ceased 2018), and Salix Pharmaceuticals (ceased 2016). He was on an advisory board for Allergan UK (ceased 2019). He also declared non-financial professional and personal interests as he is an advisor to the IBS Network, an advisor to the International Foundation for Functional Gastrointestinal Disorders USA, and a member of the Rome International Working Team on Functional Gastrointestinal Disorders. It was agreed these interests would not prevent Peter Whorwell from participating in the meeting.
	+ 1. The Chair led a discussion of the evidence presented to the committee. This information was presented to the committee by Matthew Brookes, Brian Shine, and Karen Slade.
	1. Part 2 - Closed session (company representatives, external group representatives and members of the public were asked to leave the meeting):
		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 Diagnostics Consultation Document (DCD) in line with their decisions.

### Evaluation of PlGF-based testing to help diagnose suspected pre-eclampsia (update of DG23)

* 1. Part 1 – Open session
		1. The chair welcomed external assessment group representatives, members of the public and company representatives from Perkin Elmer, Quidel, Roche Diagnostics UK and Ireland and ThermoFisher.
		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:

* John Cairns declared a financial interest as, since October 2020, he has advised Astellas on health economic modelling for roxadustat for treating anaemia in people with chronic kidney disease. It was agreed this interest would not prevent John Cairns from participating in the meeting.
* Keith Abrams declared a financial interest as since May 2019 he has been a Partner and Director at Visible Analytics Limited, an HTA Consultancy, but has not been involved in any projects which involve a diagnostic technology. Via Visible Analytics he has advised Roche (Global, Basel) as regards a therapy (not diagnostics at all) for Spinal Muscular Atrophy (SMA). He also declared a non-financial personal and professional interest as he has received funding to support an MRC Industrial PhD Studentship from Swiss Precision Diagnostics/Clearblue for a project on prediction of early miscarriage. It was agreed that these interests would not prevent Keith Abrams from participating in the meeting.
* Liz Adair declared an indirect interest in that she is the Quality Director of Viapath Group LLP. All the manufactures involved in this assessment supply Viapath Services LLP with laboratory supplies and equipment. It was agreed that this interest would not prevent Liz Adair from participating in the meeting
* Matt Stevenson declared an indirect interest in that he is part of a research team that has received funding from Roche Diagnostics via the University of Sheffield to explore the impact of biomarkers in patients with head trauma. The interest arose early 2021 and the project is ongoing. It was agreed that this interest would not prevent Matt Stevenson from participating in the meeting
* Mike Messenger declared non-financial personal and professional interests as he was a collaborator on two oncology research programmes funded in kind by Roche Diagnostics between 2017-2020. The projects were IDX-LUNG integrated diagnostics for lung cancer screening, and a project to developing a machine learning based blood test for cancer. For both, he was co-investigator and Roche provided an in-kind contribution of biochemistry reagents. It was agreed that these interests would not prevent Mike Messenger from participating in the meeting.
* Neil Hawkins declared a financial interest in that he has personally received fees for consultancy services provided to the Pharmaceutical Division of Roche AG. No services were provided to the Diagnostics Division. The consultancy services provided were unrelated to the technologies being considered for PlGF. 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, providing updates on the NHS finance regime and the impact of these changes. 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, providing advice on costs of the disease within NHS to the APPG. He is also the Hon Treasurer for the Association for Study of Obesity (ASO), and 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.
* Ross Maconachie had declared a financial interest as he had been employed by Roche Diagnostics Limited, one of the companies involved in this assessment and he had done some work on market access and evidence generation for the Elecsys PlGF/s-Flt ratio test in the past, including contributing to submissions to NICE. It was agreed that these interests precluded Ross Maconachie from participating in the meeting and he did not attend.
* Sam Creavin declared a financial interest as he is a GP partner in an NHS practice. It was agreed that this interest would not prevent Sam Creavin from participating in the meeting.

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

* Sarah Findlay declared a financial interest as she is a medical publisher, the founder/CEO of Cedilla Publishing, and Section Editor for Women’s & Sexual Health at the BMJ Group. She also declared non-financial personal and professional interests as from 2018-19 she was the lay member/co-author of the NICE hypertensive disorders of pregnancy guideline, and the lay member of the James Lind Alliance Priority Setting Partnership on hypertensive disorders of pregnancy. Since 2019 she has been the lay member of the Trial Steering Committee (TSC) for the PARROT-2 study. It was agreed that these interests would not prevent Sarah Findlay from participating in the meeting.
* Joanna Girling declared a financial interest, as until 2018 she undertook private practice (not more than 10 patients annually, payment for services provided from Insurance company or ‘self pay’). She also declared non-financial personal and professional interests as she is the author and co-author of publications about placental growth factor published in peer-reviewed medical journals. Since 2020 she has been the Principal Investigator at her NHS Trust for CRN portfolio study, “Placental growth factor repeat sampling for reduction of adverse perinatal outcomes in suspected pre-eclampsia (PARROT-2)”. She is part of a network of experts available to give clinical consultations for women affected by pre eclampsia for APEC “Action on Pre eclampsia“ charity. In February 2021 she was asked to attend a meeting with Quidel (suppliers of PLGF to her hospital) to discuss with them the business plan and other arrangements for continuing to get PLGF into their unit. She also declared indirect interests as she is a close relative of the Chief Investigator of the PARROT study and co-Chief Investigator of the PARROT-2 study, peer reviewed, non- commercial CRN portfolio trials researching clinical applications of placental growth factor. It was agreed that these interests would not prevent Joanna Girling from participating in the meeting.
* Shonagh Haslam declared non-financial personal and professional interests as she is a member of the Association for Clinical Biochemistry (ACB) Scientific Committee. Her employer, Lancashire Teaching Hospitals (LTH), participated in the REMIT2 trial in 2018, and LTH will be participating in the PARROT2 trial. She presented for Roche Diagnostics at a UK meeting on pre-eclampsia markers in March 2021; no payment or hospitality were received. She presented for Roche Diagnostics at a Middle East meeting on SARS-CoV-2 antibody testing in November 2020; no payment or hospitality were received. It was agreed that these interests would not prevent Shonagh Haslam from participating in the meeting.
* Jenny Myers declared a non-financial personal and professional interests as from March 2020 – March 2021 she was the NHS England Clinical Champion for implementation of AAC/ITP PlGF-based testing for pre-eclampsia. It was agreed that this interest would not prevent Jenny Myers from participating in the meeting.
* Andrew Sharp declared financial interests as he had received an honorarium from Roche Diagnostics in 2018 and from Ferring Pharmaceuticals in 2017. He also declared non-financial personal and professional interests due to ongoing laboratory analysis of samples from a fetal growth study (Perkin-Elmer), but there is no direct financial involvement. It was agreed that these interests would not prevent Andrew Sharp from participating in the meeting.
* Nigel Simpson declared a non-financial personal and professional interests as over the past four years he was part of the study group which evaluated PlGF in the HTA-funded PARROT trial. He also declared indirect interests as he occasionally speaks (for free) at educational meetings run by Action on Pre-eclampsia. It was agreed that these interests would not prevent Nigel Simpson from participating in the meeting.
* Manu Vatish declared non-financial personal and professional interests as he is a Senior Clinical Academic at the University of Oxford, and has the following publications:
	+ Predictive Performance of PlGF (Placental Growth Factor) for Screening Preeclampsia in Asymptomatic Women: A Systematic Review and Meta-Analysis Hypertension 2019 74 (5):1124.
	+ Angiogenic factors: potential to change clinical practice in pre-eclampsia? BJOG 2018.
	+ Diagnostic utility of angiogenic biomarkers in pregnant women with suspected preeclampsia: A health economics review Pregnancy Hypertension 2019
	+ Temporal and external validation of the fullPIERS model for the prediction of adverse maternal outcomes in women with pre-eclampsia Pregnancy Hypertension 2019
	+ Soluble fms-Like Tyrosine Kinase-1-to-Placental Growth Factor Ratio and Time to Delivery in Women With Suspected Preeclampsia Obstet Gynecol 2016
	+ Placental Growth Factor as a Prognostic Tool in Women With Hypertensive Disorders of Pregnancy: A Systematic Review Hypertension 2017
	+ Implementation of the sFlt-1/PlGF ratio for prediction and diagnosis of pre-eclampsia in singleton pregnancy: implications for clinical practice Ultrasound Obstet Gynecol 2015
	+ Meta-Analysis and Systematic Review to Assess the Role of Soluble FMS-Like Tyrosine Kinase-1 and Placenta Growth Factor Ratio in Prediction of Preeclampsia: The SaPPPhirE Study – Hypertension 2018
	+ Predictive Value of the sFlt-1:PlGF Ratio in Women with Suspected Preeclampsia – New England Journal of Medicine 2016
	+ Randomized Interventional Study on Prediction of Preeclampsia/Eclampsia in Women With Suspected Preeclampsia: INSPIRE – Hypertension 2019

It was agreed that these interests would not prevent Manu Vatish from participating in the meeting.

* + 1. The Chair led a discussion of the evidence presented to the committee. This information was presented to the committee by Sarah Findlay, Mike Messenger, and Nigel Simpson.
	1. Part 2 – Closed session (company representatives, external assessment group representatives and members of the public were asked to leave the meeting).
		1. The committee discussed confidential information submitted for this item.
		2. A decision on the content of the Diagnostics Consultation Document was deferred pending further work on the economic model.

### Date of the next meeting

The next meeting of the Diagnostics Advisory Committee (DAC) will be held on Thursday 19 August 2021.