

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Diagnostics Advisory Committee (DAC)

Minutes of the Meeting on Wednesday 13 June 2018

Level 1A City Tower, Piccadilly Plaza, Manchester M1 4BD

PRESENT:

Standing Committee members:

Dr Mark Kroese – **Chair**
Ms Liz Adair
Mr John Bagshaw
Dr Owen Driskell
Dr Simon Fleming
Dr Jim Gray
Mr John Hitchman
Professor Christopher Hyde
Mr Patrick McGinley
Dr Michael Messenger
Mrs Alexandria Moseley
Dr Shelley Rahman Haley
Dr Simon Richards
Professor Mark Sculpher
Professor Matt Stevenson
Dr Nick Summerton

Standing Committee apologies:

Professor Enitan Carrol
Professor Steve Halligan
Dr Dermot Neely
Professor Anthony Wierzbicki

NICE staff in attendance:

Mark Campbell, Acting Programme Director – Devices and Diagnostics
Rebecca Albrow, Senior Technical Adviser, DAP
Donna Barnes, Project Manager, DAP
Frances Nixon, (Technical lead) Technical Analyst, DAP
Christopher Pomfrett, Technical Adviser, MTEP
Alexandra Sexton, Administrator, DAP

Observing:

Clare Harland, Project Manager, CHTE 2020, NICE
Ann Greenwood, Senior Medical Editor, NICE
Ian Mather, Resource Impact Assessment, NICE (*morning*)
Adam Storrow, Resource Impact Assessment, NICE (*afternoon*)
Katie Wyart, Adoption and Impact, NICE

1. Introduction to the meeting

The Chair welcomed Committee members, observers and members of the public.

Apologies were noted.

2. Code of conduct for members of the public attending the meeting

The Chair explained the code of conduct to the members of the public attending this meeting.

3. Any other business

No other business was offered.

4. Minutes from the last Committee meeting

The Committee agreed the minutes from the 10 April 2018 committee meeting.

5. Equality and Diversity

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

Assessment of tumour profiling tests to guide adjuvant chemotherapy decisions in people with breast cancer (update of DG10)

External Assessment Group (EAG) representatives: School of Health and Related Research (SchARR), the University of Sheffield:

Dr Alice Bessey, Research Assistant
Dr Sue Harnan, Research Fellow
Dr Katy Cooper, Research Fellow
Dr Paul Tappenden, Reader

Specialist Committee members:

Dr Maria Bramley, Breast Surgeon
Dr John Graham, Consultant Oncologist
Linda Pepper, Lay member
Ursula Van Mann, Lay member

Specialist Committee members' apologies:

Dr Deirdre Ryan, Consultant Cellular Pathologist
Dr Britta Stordal, Consultant Clinical Scientist
Professor Andrew Wardley, Consultant & MAHSC Professor in Medical Oncology

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

Part 1 – Open session

The Chair welcomed representatives from Agendia N.V., Genomic Health, Myriad Genetics, and NanoString Technologies.

There were 12 public attendees.

Committee members present had declared relevant interests as below and no further updates to these interests were declared at the meeting:

Liz Adair declared an indirect interest as Roche Diagnostics supply products and equipment to Viapath Services LLP and she is the Quality Director of Viapath Group LLP. This interest was reviewed by the Programme Director and it was agreed that she could participate in the meeting.

Dr Owen Driskell declared an indirect personal interest as his wife works as a Health and Safety professional at AstraZeneca's Macclesfield site. This interest was reviewed by the Programme Director and it was agreed that he could participate in the meeting.

Professor Chris Hyde declared an indirect financial interest as he works for a university which is an evidence contractor for NICE (PenTAG at the University of Exeter). The report for the topic under discussion was not produced by this group. This interest was reviewed by the Programme Director and it was agreed that he could participate in the meeting.

Dr Michael Messenger declared a direct non-financial interest as he is a co-investigator on a recent Myriad Genetics funded health economics evaluation at the University of Leeds, evaluating the impact of an unrelated test, Prolaris for prostate cancer prognosis. As part of this, Myriad Genetics paid for his lunch (<£20) on 3rd October 2017 to discuss the Prolaris project. He also declared an indirect non-financial interest as colleagues within the NIHR MIC in Leeds, for which he is the Deputy Director, are co-investigators on the OPTIMA trial. He also declared a direct non-financial interest as Myriad Genetics had approached him in March 2014 about a potential future evaluation of EndoPredict; he said he would not discuss this with them until the revision of the topic under discussion is complete. He further declared an indirect financial interest as Myriad Genetics, Roche Diagnostics and Genomic Health sponsored the NIHR Leeds In Vitro Diagnostic Launch event in March 2018. These interests were reviewed by the Programme Director and it was agreed that he could participate in the meeting.

Dr Simon Richards declared a financial interest as he is employed as RA Vice President by Abbott who are a direct competitor to Roche Diagnostics. This interest was reviewed by the Programme Director and it was agreed that he could participate in the meeting.

Professor Mark Sculpher declared a direct financial interest as he had received a consultancy fee from Roche Diagnostics for ongoing work unrelated to the products under consideration or breast cancer. This interest was reviewed by the Programme Director and it was agreed that he could participate in the meeting.

Professor Matt Stevenson declared non-financial professional and personal interests as he is the Director of SchARR-TAG who have been allocated to undertake the Diagnostics Assessment Report (DAR) for the topic under discussion. These interests were reviewed by the Programme Director and it was agreed that he could participate in the meeting

Specialist committee members present had declared relevant interests as below and no further updates to these interests were declared at the meeting:

Professor John Graham declared the following direct financial interests:

- He gave an invited presentation in September 2017 on the use of tamoxifen for the prevention of breast cancer to the Medicines and Healthcare products Regulatory Agency and received an honorarium of £200 plus travel expenses.
- He gave an invited lecture in June 2017 at the American Society of Clinical Oncology Annual Meeting in Chicago and received an honorarium of \$500 plus conference fee, travel and accommodation expenses.

- He attended the ASCO Genito-Urinary Cancer Conference in February 2017, Orlando, Florida; the conference fee, travel and accommodation were paid by Bayer Health Care.
- He attended a trial investigator meeting in Berlin in June 2018 for a planned bladder cancer trial with rogaratinib. Accommodation and travel expenses were paid by Bayer Pharmaceuticals
- Private practice in the non-surgical management of breast and urological cancer (external beam radiotherapy and chemotherapy).

He further declared direct non-financial interests as follows:

- He is the principal investigator for the following ongoing commercially funded clinical trials in prostate cancer:
 - Radium-223 funded by Bayer Health Care
 - Rucaparib funded by Clovis Oncology
- He is the principal or co-investigator for the following ongoing non-commercially funded clinical trials in prostate cancer:
 - Stampede
 - The UK Genetic Prostate Cancer Study
 - Prompts
 - TOPARP
 - CTC Stop
- He is a member of the trial management group for the RT01 trial of external beam radiotherapy for prostate cancer.
- He is a member of the trial management group for the CHHIP trial of external beam radiotherapy for prostate cancer.

These interests were reviewed by the Programme Director and it was agreed that he could participate in the meeting.

The Committee proceeded to discuss the comments made during the second public consultation for the assessment of tumour profiling tests to guide adjuvant chemotherapy decisions in people with breast cancer (update of DG10). All committee members had seen the full consultation comments submitted during the first and second consultations.

The Committee was asked if there were any specific equality issues to consider in relation to this assessment.

The Chair asked the representatives of the manufacturers whether they wished to comment on any matters of factual accuracy.

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, participation and contribution to the meeting.

End of Part 1

Part 2a – closed session

Manufacturer representatives who had submitted additional confidential information were separately invited back into the meeting for further discussion with the committee.

The Chair thanked the manufacturer representatives and they left the meeting.

Part 2b – closed session

A decision on the content of the Diagnostics Guidance Document (DGD) was deferred pending additional analysis by the External Assessment Group (EAG).

End of Part 2

Date, time and venue of next meeting

Tuesday 17 July 2018 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD