

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Diagnostics Advisory Committee (DAC)

### Minutes of the Meeting on Tuesday 10 April 2018

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

#### **PRESENT:**

##### **Standing Committee members:**

Dr Mark Kroese – **Chair**  
Ms Liz Adair  
Mr John Bagshaw  
Professor Enitan Carrol  
Dr Owen Driskell  
Dr Steve Edwards  
Dr Jim Gray  
Professor Steve Halligan  
Mr John Hitchman  
Mr Patrick McGinley  
Mrs Alexandria Moseley  
Dr Nick Summerton  
Professor Anthony Wierzbicki

Professor Chris Hyde attended Part 1 as a member of the External Assessment Group

##### **Standing Committee apologies:**

Dr Simon Fleming  
Dr Michael Messenger  
Dr Dermot Neely  
Dr Shelley Rahman Haley  
Dr Simon Richards  
Professor Matt Stevenson  
Professor Mark Sculpher

##### **NICE staff in attendance:**

Mark Campbell, Acting Programme Director – Devices and Diagnostics  
Rebecca Albrow, Senior Technical Adviser, DAP  
Donna Barnes, Project Manager, DAP  
Jessica Maloney, (Technical lead) Technical Analyst, DAP  
Alexandra Sexton, Administrator, DAP

##### **Observing:**

Ann Greenwood, Senior Medical Editor, NICE  
Jane Lynn, Resource Impact Assessment Team  
Lydia Shears, Public Involvement Adviser, PIP  
Maria Olsen, Peninsula Technology Assessment Group (PenTAG)  
David Packman, Peninsula Technology Assessment Group (PenTAG)  
Jo Varley-Campbell, Peninsula Technology Assessment Group (PenTAG)

**1. Introduction to the meeting**

The Chair welcomed new committee members Liz Adair and Nick Summerton.

The Chair noted that Dr Steve Edwards was attending his last Diagnostics Advisory Committee meeting and thanked him for all his support, contributions and insights throughout his time on the committee.

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

**2. Any other business**

No other business was offered.

**3. Minutes from the last Committee meeting**

The Committee agreed the minutes from the 14 March 2018 committee meeting.

**4. NICE's advisory body guide to declaring a conflict of interest**

NICE's new [declaration of interest policy](#) was noted.

**5. Equality and Diversity**

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

**Assessment of biomarker tests to help diagnose preterm labour in women with intact membranes**

**External Assessment Group representatives: Peninsula Technology Assessment Group (PenTAG):**

Professor Christopher Hyde, Professor of Public Health and Clinical Epidemiology  
Sophie Dodman, Research Fellow  
Dr Ruben Mujica-Mota, Senior Lecturer

**Specialist Committee members:**

Ciara Curran, Lay Specialist Committee Member  
Dr Ruth Gottstein, Consultant Neonatologist  
Dr Meekai To, Consultant in Fetal Medicine and Obstetrics  
Nigel Simpson, Senior Lecturer and Honorary Consultant  
Alison Stanley, Lay Specialist Committee Member

**Specialist Committee members' apologies:**

David Wells, Head of Pathology Services Consolidation

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

### **Part 1 – Open session**

The Chair welcomed representatives from Hologic, Medix Biochemica and Parsagen Diagnostics Inc.

There were no public attendees as none had registered to attend the meeting.

Committee members had declared relevant interests as follows:

Liz Adair declared a direct financial interest as she is employed by Viapath Group LLP and one member of the topic research team (one of the authors of the Diagnostics Assessment Report) is employed by Guys & St Thomas' NHS Foundation Trust who are shareholders in Viapath Group LLP. She does not know this report author personally. This interest was reviewed by the Programme Director and it was agreed that she could participate in the meeting.

Professor Enitan Carrol declared an indirect interest as she has ongoing research collaborations with IVD manufacturers, Biomerieux, Thermofisher and Mologic. None of them manufacture tests to diagnose preterm labour. She has never received any fees from any of these companies and they have never paid any fees to her Institution. This interest was reviewed by the Programme Director and it was agreed that she could participate in the meeting.

Professor Chris Hyde declared an indirect interest as his institution has received research funding from NIHR to compile the Diagnostics Assessment Report for this topic. This interest was reviewed by the Programme Director and it was agreed that Professor Chris Hyde should be partially excluded from the meeting, only attending Part 1.

Dr Simon Richards declared a direct financial interest as he is employed by Abbott Rapid Diagnostics Division as Divisional Vice President, Regulatory Affairs. This interest was reviewed by the Programme Director and it was agreed this meant Dr Richards should be totally excluded from the meeting.

Ciara Curran noted she had made contact with Alere (now Abbott) in March 2018 regarding the Actim PROM test as her local maternity hospital did not stock them and she wanted to find out the cost of the tests; her consultant is taking forward the discussion. This interest was reviewed by the Programme Director and it was agreed that she could participate in the meeting.

Dr Nigel Simpson declared an indirect financial interest as his institution (the University of Leeds) had received an educational grant from Hologic to subsidise refreshments during the 3rd UK Preterm Birth Network held in Leeds on 7th/8th September 2017 which he co-organised. This interest was reviewed by the Programme Director. It was agreed that Dr Simpson could participate in the meeting.

Dr Meekai To declared an indirect interest as she is the investigator in a study in women who are high risk of preterm birth and is provided with free FFN kits from Hologic. This is not the population under consideration for this topic. The study is still recruiting. This interest was reviewed by the Programme Director and it was agreed that she could participate in the meeting.

The Committee proceeded to discuss the comments made during the public consultation for the assessment of biomarker tests to help diagnose preterm labour in women with intact membranes

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 2 – closed session**

Agreement on the content of the Diagnostic Guidance Document (DGD) was discussed by the committee.

## **End of Part 2**

## **Date, time and venue of next meeting**

**Wednesday 13 June 2018** at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BD