

Date and Time: Tuesday 13 July 10am.

Minutes Unconfirmed



Appraisals Committee Meeting

**National Institute for
Clinical Excellence**

Place: NICE
Midcity Place
71 High Holborn

Present:

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| 1. Dr Paul Ewings | |
| 2. Dr Peter Jackson | Present for notes 1 - 17 |
| 3. Dr Simon Mitchell | |
| 4. Dr Sunil Angris | |
| 5. Professor Ron Akehurst | Present for notes 1 - 17 |
| 6. Mr Mike Spencer | |
| 7. Mr Sanjay Gupta | Present for notes 1 - 12 |
| 8. Mrs Miranda Wheatley-Price | |
| 9. Professor David Barnett (Chair) | |
| 10. Professor John Cairns | |
| 11. Professor Norman Waugh | |
| 12. Dr Mike Laker | Present for notes 1 - 19 |
| 13. Dr Lindsay Smith | |
| 14. Professor Richard Lilford | |
| 15. Dr Stephen Saltissi | |
| 16. Professor Mary Watkins | |
| 17. Professor John Lumley | |
| 18. Dr Jane Adam | Present for notes 1 - 19 |
| 19. Dr Trevor Gibbs | |
| 20. Professor Philip Home (Vice chair) | |
| 21. Mr Terence Lewis | Present for notes 1 - 12 |

In attendance:

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| Miss Janet Robertson | Technical Advisor, NICE (Technical Lead) | Present for notes 17 - 21 |
| Dr Elisabeth George | Technical Analyst, NICE, (Technical Lead) | Present for notes 17 - 21 |
| Dr Sarah Garner | Technical Advisor, NICE (Technical Lead) | |
| Miss Eleanor Donegan | Technical Analyst, NICE | Present for notes 1 - 17 |
| Miss Rebecca Kirby | Technology Appraisals Administrator, NICE | |
| Miss Seren Philips | Associate Appraisals Programme Director, NICE | |
| Dr Ken Stein | Senior Lecturer, Peninsula Technology Assessment Group (PenTAG) (AG representative) | Present for notes 1 -17 |
| Ms Emaneula Castelnuovo | Research Fellow, PenTAG | Present for notes 1 -17 |
| Mr Steven Palmer | Senior research fellow, university of York (AG representative) | Present for notes 17 - 21 |
| Mrs Eddie Farrow | Patient Advocate, Cardiac Risk in the Young | Present for notes1 - 12 |
| Dr William Toff | Senior Lecturer in Cardiology, University Hospitals of Leicester NHS Trust, Clinical expert | Present for notes1 - 12 |
| Dr Janet McComb | President, British Pacing and Electrophysiology Group, Clinical expert | Present for notes1 - 12 |
| Dr Gerald Kaye | Consultant Cardiologist, Cochrane Heart Group, Clinical expert | Present for notes1 - 12 |
| Mr Anthony Roth | Patient advocate | Present for notes1 - 12 |

Notes

Welcome

Notes

1. The Chair welcomed all members of the Committee to the meeting. The Chair reviewed the agenda and timescales for the meeting, which included the appraisals of 1) dual chamber pacing and 2) clopidogrel and modified release dipyridamole in occlusive vascular events.
2. Apologies were received from:
Fiona Duncan
Ailsa Claire
Terry John
George Levvy
Christa Roberts
David Chadwick
Stirling Bryan
Lorna Duggan

Any other business

3. The Chair reminded the committee about the next education days to be held on the 22 July or 21 September, and that the topic would be health economics.
4. The chair informed the committee that Radio 4 were recording a documentary about NICE. As a part of this they were planning on recording a section of this meeting, but they have restricted access to the confidential discussion.
5. The representative from radio 4 introduced himself and answered any questions from the committee.

Appraisal of dual chamber pacing.

6. The Chair asked all Committee members to declare any relevant conflicts of interest.
 - 6.1. Dr Ewings, Dr Mitchell, Mr Spencer, Mr Gupta, Professor Barnett, Professor Cairns, Professor Waugh, Dr Laker, Professor Lilford, Dr Smith, Dr Jackson, Professor Akehurst, Mrs Wheatley–Price, Dr Saltissi, Professor Watkins, Professor Lumley, Dr Adam, Mr Lewis and Dr Gibbs all declared that they knew of no personal specific, personal non-specific, non-personal specific or non-personal non-specific interest for any of the technologies to be considered as part of the appraisal of dual chamber pacing.
 - 6.2. Dr Angris declared a non personal non specific interest as he had attended education days sponsored by the manufacturers.
 - 6.2.1. It was agreed that these declarations would not prevent Dr Angris from participating in this section of the meeting.

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7. The Chair asked all other invited guests to advise the Committee of their relevant declarations of interests.
 - 7.1. Mr Roth declared he knew of no personal specific, personal non-specific, non-personal specific or non-personal non-specific interest for any of the technologies to be considered as part of the appraisal of dual chamber pacing.
 - 7.2. Dr McComb declared she had spoken at pacemaker meetings, and received funding to attend the meeting, and honoraria.
 - 7.3. Dr Toff declared he had received support and expenses from manufacturers to attend meetings.
 - 7.4. Dr Kaye declared he had received support and expenses from manufacturers to attend meetings.
 - 7.5. Mrs Farrow declared she had attend meetings for manufacturers but had received no financial contribution.
8. The Chair introduced the lead lead, Dr Steven Saltissi, and he gave a presentation on the clinical background, clinical effectiveness and general considerations on the appraisal of dual chamber pacing.
9. The Committee proceeded to discuss the clinical effectiveness of dual chamber pacing on the basis of the evidence before them. They sought clarification and advice from the experts present: Dr McComb, Dr Toff, Dr Kaye, Mr Roth and Mrs Farrow.
10. The Chair introduced the assessment group representative, Dr Ken Stein, and he gave a presentation on the cost effectiveness of dual chamber pacing.
11. The committee proceeded to discuss the cost effectiveness of dual chamber pacing with the help of the experts present.
12. The Chair thanked Dr McComb, Dr Toff, Dr Kaye, Mr Roth, and Mrs Farrow for their attendance, participation and contribution to the appraisal and they left the meeting.
13. The committee sought clarification from Dr Stein and Miss Castelnuovo on specific issues relating to their assessment report.
14. The committee continued to discuss the clinical effectiveness and cost effectiveness of dual chamber pacing.
15. In summary the discussion included:
 - 15.1. The evidence for the clinical effectiveness (and appropriateness) and cost effectiveness of dual chamber pacing compared to single chamber pacing.

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- 15.2. Extrapolation of data from mixed populations of Sick Sinus Syndrome (SSS) + Atrioventricular Block (AVB) to patients that have SSS or AVB alone.
 - 15.3. Rates of implants of dual chamber pace makers in elderly patients.
 - 15.4. Implantation in younger individuals: additional considerations and generalisability of data from RCTs in older patients.
 - 15.5. Expected device lifetime and complication rates associated with dual, and single chamber pacemakers.
 - 15.6. Pacemaker syndrome: incidence, symptoms, implications and disutility associated with it.
 - 15.7. The incidence and predictability of AVB in patients with SSS.
 - 15.8. The economic models submitted by the sponsors and Assessment Group including assumptions regarding the incidence, and utilities associated with mild and severe pacemaker syndrome
 - 15.9. Quality of life with dual compared to single chamber pacemakers.
 - 15.10. Current clinical guidelines and national adherence to their recommendations
 - 15.11. Rate responsive dual, and single chamber devices.
16. The Committee agreed the content of the guidance section of the Appraisal Consultation Document (ACD)

Appraisal of clopidogrel and modified release dipyridamole in occlusive vascular events.

17. The Chair asked all Committee members to declare any relevant conflicts of interest.
- 17.1. Dr Mitchell, Mr Spencer, Mr Gupta, Professor Barnett, Professor Cairns, Professor Waugh, Dr Laker, Professor Lilford, Dr Smith, Professor Watkins, Professor Lumley, Dr Adam, all declared that they knew of no personal specific, personal non-specific, non-personal specific or non-personal non-specific interest for any of the technologies to be considered as part of the appraisal of clopidogrel and modified release dipyridamole in occlusive vascular events.
 - 17.2. Mrs Wheatley-Price declared two non personal non specific interests. Firstly Sanofi-Synthelabo had given an educational grant to Colon Cancer Concern for a cancer awareness campaign. Secondly, her husband works for Boeringher Ingleheim, but on un-related topics, and they hold no shares in the company.
 - 17.2.1. It was agreed that this declaration would not prevent Mrs Wheatley Price from participating in this section of the meeting.
 - 17.3. Professor Home stated that, since previous meetings of the Committee on occlusive vascular events, Sanofi-Synthelabo had completed a take-over bid for Aventis Pharma, and that he had non-personal, non-specific interests (University Department, diabetes therapies) with Aventis Pharma.
 - 17.3.1. It was agreed that this declaration would not prevent Professor

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Home from participating in this section of the meeting.

- 17.4. Dr Angris declared a non-personal, non-specific interest as he had attended educational meetings sponsored by the manufacturers
 - 17.4.1. It was agreed that this declaration would not prevent Dr Angris from participating in the section of the meeting.
- 17.5. Dr Ewings declared a non personal non specific interest as he had received an educational grant from Sanofi-Synthelabo.
 - 17.5.1. It was agreed that this declaration would not prevent Dr Ewings from participating in the section of the meeting.
- 17.6. Dr Saltissi declared a non-personal, non-specific interest as his department had received an educational grant and research funding from Bristol Myers Squibb (BMS) for work unrelated to this appraisal.
 - 17.6.1. It was agreed that this declaration would not prevent Dr Saltissi from participating in the section of the meeting.
- 17.7. Dr Gibbs declared a non current interest that GSK would be involved in manufacturing drugs in acute coronary syndrome in future.
 - 17.7.1. It was agreed that this declaration would not prevent Dr Gibbs from participating in this section of the meeting.
- 18. The chair gave a presentation on the history of this appraisal, and on the consultee comments from the second ACD consultation.
- 19. The committee proceeded to discuss the comments on the ACD with the help of the assessment group representative, Mr Palmer.
- 20. In summary the discussions included:
 - 20.1. Review of appraisal milestones and current draft recommendations
 - 20.2. Discussion of consultee comments on the second ACD
 - 20.3. Discussion on 2 year treatment duration with the combination of MR dipyridamole and aspirin
 - 20.4. Risk of recurrent stroke and cardiovascular events
 - 20.5. Parameter values used in additional economic modeling
 - 20.6. Consideration of specific subgroups
 - 20.7. Definition of intolerance
 - 20.8. GI effects induced by study drugs
 - 20.9. Clarification of aspirin intolerance
- 21. The committee agreed the content of the Final Appraisal Determination (FAD).
Date, time and venue of the next meeting
- 22. Thursday 16 September, 10am, NICE

