

## Technology Appraisal Committee Meeting (Committee D)

**Minutes:** Confirmed

**Date and Time:** Tuesday 7 July 2015, 10 am to 5.30pm

**Venue:** National Institute for Health and Care Excellence  
Level 1A, City Tower  
Piccadilly Plaza  
Manchester  
M1 4BT

<b>Present:</b>	1. Professor Gary McVeigh (Chair)	Present for all notes
	2. Dr Lindsay Smith (Vice Chair)	Present for notes all notes
	3. Dr Andrew Black	Present for notes all notes
	4. Dr David Bowen	Present for notes all notes
	5. Dr Matthew Bradley	Present for notes all notes
	6. Dr Ian Davidson	Present for notes all notes
	7. Professor Simon Dixon	Present for notes all notes
	8. Mrs Susan Dutton	Present for notes all notes
	9. Mrs Gillian Ells	Present for notes all notes
	10. Professor Carol Haigh	Present for notes all notes
	11. Professor John Henderson	Present for notes all notes
	12. Dr Tim Kinnaird	Present for notes 5 to 43
	13. Dr Warren Linley	Present for notes all notes
	14. Dr Malcolm Oswald	Present for notes all notes
	15. Prof Oluwafemi Oyebode	Present for notes all notes
	16. Dr Mohit Sharma	Present for notes all notes
	17. Dr Murray Smith	Present for notes all notes

### In attendance:

Rob Anderson	Peninsula Technology Assessment Group (PenTAG)	Present for notes 5 to 14 and 18 to 27
Michael Breswick	Patient expert British Kidney Patient Association	Present for notes 18 to 27
Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Chris Chesters	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 31 to 43
Jacob Clarke	Patient expert nominated by Kidney Research UK	Present for notes 5 to 14
Danielle Conroy	Administrator, National Institute for Health and	Present for all notes

## Care Excellence

Dr Sally Doss	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 30
Simone Goren	Patient expert nominated by the Polycystic Kidney Disease Charity	Present for notes 31 to 40
Marcela Haasova	Peninsula Technology Assessment Group (PenTAG)	Present for notes 5 to 14 and 18 to 27
Paul Harden	Clinical expert nominated by the Royal College of Physicians	Present for notes 18 to 27 (by teleconference)
Sarah-Louise Harwood	Patient expert nominated by Kidney Research UK	Present for notes 18 to 27
Tracey Jones-Hughes	Peninsula Technology Assessment Group (PenTAG)	Present for notes 5 to 14 and 18 to 27
Helen Knight	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Dr Rosie Lovett	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 18 to 30
Fay McCracken	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 31 to 43
David Milford	Clinical expert nominated by the British Association of Paediatric Nephrology	Present for notes 18 to 27
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Ruben Mujica-Mota	Peninsula Technology Assessment Group (PenTAG)	Present for notes 5 to 14 and 18 to 27
Keith Pennington	Patient expert nominated by British Kidney Patient Association	Present for notes 5 to 14
Bram Ramaekers	Kleijnen Systematic Reviews Ltd	Present for notes 31 to 40
John Sayer	Clinical expert nominated by the Polycystic Kidney Disease Charity	Present for notes 31 to 40
Tristan Snowsill	Peninsula Technology Assessment Group	Present for notes 5 to 14 and 18 to 27

(PenTAG)

Robert Wolff	Kleijnen Systematic Reviews Ltd	Present for notes 31 to 40
Christopher Watson	Clinical expert nominated by Bristol-Myers Squibb	Present for notes 5 to 14
Ian Watson	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17
Theresa Williams	Patient expert nominated by the Polycystic Kidney Disease Charity	Present for notes 31 to 40
Colin Wilson	Clinical expert nominated by Cochrane Renal Group	Present for notes 5 to 14

**Non-public observers:**

Bethan Dorsett	Digital Editor, National Institute for Health and Clinical Excellence	Present for notes 1 to 30
Rob Hodgson	Centre for Reviews and Dissemination University of York	Present for notes 1 to 43

**Notes**

**Welcome**

1. The Chair welcomed all members of the Committee and other attendees present to the meeting. The Chair reviewed the agenda and timescales for the meeting, which included the appraisals of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85), immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99) and tolvaptan for treating autosomal dominant polycystic kidney disease.
2. The Chair informed the Committee of the non-public observers at this meeting: Bethan Dorset and Rob Hodgson
3. Apologies were received from Dr Aomesh Bhatt, Dr Ian Campbell, Mrs Tracey Cole, Dr Alexander Dyker, Professor Paula Ghaneh and Dr Susan Griffin

**Any other Business**

4. The Programme Director, Meindert Boysen updated the committee members on the progress with the appraisals of Ledipasvir-sofosbuvir for treating chronic hepatitis C [ID742], Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C [ID731] and Daclatasvir for treating chronic hepatitis C [ID766].

## **Appraisal of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85)**

### **Part 1 – Open session**

5. The Chair welcomed the invited experts: Rob Anderson Jacob Clarke, Marcela Haasova, Tracey Jones-Hughes, Ruben Mujica-Mota, Keith Pennington, Tristan Snowsill, Colin Wilson and Christopher Watson to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Astellas, Bristol-Myers Squibb, Novartis, Sandoz, Sanofi and Teva to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
  - 7.1. Dr Andrew Black, Dr David Bowden, Dr Matthew Bradley, Dr Ian Davidson, Mrs Susan Dutton, Mrs Gillian Ells, Professor Carol Haigh, Dr Tim Kinnaird, Mr Warren Linley, Professor Gary McVeigh (Chair), Dr Malcolm Oswald, Professor Femi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).
  - 7.2. Professor Simon Dixon declared a non-personal non-specific pecuniary interest as part of the team that he is Director of had undertaken research for two of the companies on unrelated topics.
    - 9.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.
  - 7.3. Professor John Henderson declared a non-personal non-specific pecuniary interest as the institute that he works for had received funding from one of the companies involved in the appraisal. He did not receive personal remuneration from this funding.
    - 9.3.1 It was agreed that this declaration would prevent Professor John Henderson from participating in this section of the meeting.
8. The Chair asked all NICE Staff to declare any relevant interests.
  - 8.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).
9. The Chair asked all other invited guests to declare their relevant interests.
  - 9.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary

interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).

10. The Chair introduced the lead team, Professor David Bowen and Dr Warren Linley who gave presentations on the clinical effectiveness and cost effectiveness of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).
11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85) on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
  - 11.1. The nature of immunosuppressive therapies for kidney transplantation in adults, and current clinical practice in this area
  - 11.2. The Assessment Group's systematic review of clinical effectiveness and evidence presented by the companies
  - 11.3. Economic models presented by the Assessment Group and 3 companies
  - 11.4. The overall clinical and cost effectiveness of immunosuppressive therapies for kidney transplantation in adults
12. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
13. 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.
14. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

15. Discussion on confidential information continued. This information was supplied by one of the companies.
16. The Committee continued to discuss the clinical and cost effectiveness of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).
17. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

## **Appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99)**

### **Part 1 – Open session**

18. The Chair welcomed the invited experts: Rob Anderson, Michael Breswick, Marcela Haasova, Paul Harden, Sarah-Louise Harwood, Tracey Jones-Hughes, David Milford, Ruben Mujica-Mota and Tristan Snowsill to the meeting and they introduced themselves to the Committee.
19. The Chair welcomed company representatives from Astellas, Novartis and Sanofi to the meeting.
20. The Chair asked all Committee members to declare any relevant interests
  - 20.1. Dr Andrew Black, Dr David Bowden, Dr Matthew Bradley, Dr Ian Davidson, Mrs Susan Dutton, Mrs Gillian Ells, Professor Carol Haigh, Dr Tim Kinnaird, Mr Warren Linley, Professor Gary McVeigh (Chair), Dr Malcolm Oswald, Professor Femi Oyeboode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
  - 20.2. Professor Simon Dixon declared a non-personal non-specific pecuniary interest as part of the team that he is Director of had undertaken research for two of the companies on unrelated topics.
    - 9.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.
  - 20.3. Professor John Henderson declared a non-personal non-specific pecuniary interest as the institute that he works for had received funding from one of the companies involved in the appraisal. He did not receive personal remuneration from this funding.
    - 9.3.1 It was agreed that this declaration would prevent Professor John Henderson from participating in this section of the meeting.
21. The Chair asked all NICE Staff to declare any relevant interests.
  - 21.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
22. The Chair asked all other invited guests to declare their relevant interests.
  - 22.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).

23. The Chair introduced the lead team, Dr Andrew Black and Professor John Henderson who gave presentations on the clinical effectiveness and cost effectiveness of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
24. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99) on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
  - 24.1. The aspects of immunosuppression that are especially important for children and adolescents, including side effects and adherence.
  - 24.2. The Assessment Group's systematic review of the clinical evidence.
  - 24.3. The effect of different dosing regimens on adherence.
  - 24.4. The assessments of cost effectiveness, including the model from the Assessment Group and the model from Astellas Pharma
25. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
26. 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.
27. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

28. Discussion on confidential information continued. This information was supplied by one of the companies.
29. The Committee continued to discuss the clinical and cost effectiveness of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
30. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

## **Appraisal of tolvaptan for treating autosomal dominant polycystic kidney disease**

### **Part 1 – Open session**

31. The Chair welcomed the invited experts: Simone Goren, Bram Ramaekers, John Sayer, Theresa Williams and Robert Wolff to the meeting and they introduced themselves to the Committee.
32. The Chair welcomed company representatives from Otsuka to the meeting.

33. The Chair asked all Committee members to declare any relevant interests
- 33.1. Dr Andrew Black, Dr David Bowden, Dr Matthew Bradley, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Mrs Gillian Ells, Professor Carol Haigh, Professor John Henderson, Dr Tim Kinnaird, Mr Warren Linley, Professor Gary McVeigh (Chair), Dr Malcolm Oswald, Professor Femi Oyeboade, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of tolvaptan for treating autosomal dominant polycystic kidney disease.
34. The Chair asked all NICE Staff to declare any relevant interests.
- 34.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of tolvaptan for treating autosomal dominant polycystic kidney disease.
35. The Chair asked all other invited guests to declare their relevant interests.
- 35.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Tolvaptan for treating autosomal dominant polycystic kidney disease.
36. The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.
37. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of tolvaptan for treating autosomal dominant polycystic kidney disease on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
- 37.1. The appropriateness of the subgroup with CKD stage 2 and 3
- 37.2. The company's revised base case including the revised assumptions used in the cost effectiveness model and how this differed to the preferred assumptions used by the ERG.
- 37.3. Discussions relating to quality of life, treatment-related utility decrements and health state utility values, including those presented from OVERTURE
- 37.4. The most plausible ICER
38. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.



39. 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.
40. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

41. The Committee continued to discuss the clinical and cost effectiveness of tolvaptan for treating autosomal dominant polycystic kidney disease.
42. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

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

43. Tuesday 4 August 2015, 10am to 5pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.