

**Appeal ref:**

**BEFORE THE APPEAL PANEL OF THE NATIONAL INSTITUTE OF  
HEALTH AND CLINICAL EXCELLENCE APPEAL COMMITTEE**

**IN AN APPEAL AGAINST A HEALTH TECHNOLOGY APPRAISAL**

**BETWEEN:**

**SOUTH CENTRAL SPECIALISED COMMISSIONING GROUP**

**(managed by Hampshire Primary Care Trust)**

**YORKSHIRE & THE HUMBER SPECIALISED COMMISSIONING GROUP**

**(managed by Barnsley Primary Care Trust)**

**Appellants**

**-and-**

**NATIONAL INSTITUTE FOR HEALTH**

**AND CLINICAL EXCELLENCE**

**Respondent**

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## **GROUND OF APPEAL**

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1. This is the appeal of the South Central Specialised Commissioning Group and the Yorkshire & The Humber Specialised Commissioning Group against the Final Appraisal Determination (“FAD”) in respect of cochlear implants for children and adults with severe to profound deafness and the way in which the appraisal process was conducted. The FAD was published by NICE on 28<sup>th</sup> August 2008.

2. The South Central Specialised Commissioning Group is a committee comprising representatives of the nine Primary Care Trusts (known as 'Members') in NHS South Central. The Yorkshire & the Humber Specialised Commissioning Group is a committee comprising representatives of the 14 Primary Care Trusts (known as 'Members') in NHS Yorkshire & the Humber. Each specialised commissioning group (SCG) is established as a joint sub-committee of each of the Boards of Members in accordance with Regulations 9 and 10 of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administrative Arrangements) (England) Regulations 2002. One Member of each SCG is designated, by agreement, as the Host PCT; Hampshire PCT is the host for South Central SCG and Barnsley PCT is the host for Yorkshire & the Humber SCG.

*Aspects of the Guidance/Appraisal process being appealed against*

3. The Appellants appeal against the failure to act fairly and in accordance with the appraisal procedure set out in the Institute's Guide to the Methods of the Technology Appraisal Process, and against the FAD Guidance itself as set out at §§1.2 and 1.3 of the FAD, specifically that:-

*"1.2 Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids as defined in 1.4:*

- *children*
- *adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness....*

And

*"1.3 Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness. People who had a unilateral implant before publication of this guidance, and who fall into one of the categories described in 1.2, should have the option of an additional contralateral implant only if this is considered to provide sufficient benefit by*

*the responsible clinician after informed discussion with the individual person and their carers”*

### ***Grounds of Appeal***

4. The Appellants advance three grounds of appeal:

#### **Ground 1**

5. The Institute has failed to act fairly and in accordance with the appraisal procedure set out in the Institute’s *Guide to the Methods of Technology Appraisal* (April 2004)<sup>1</sup> Specifically:

- (a) Paragraphs 6.2.6.10 to 6.2.6.11 of the 2004 Guide, make plain that explicit reference should be made by the Committee as to the factors which justify the acceptability of the technology and that where the ICER is above £30,000/QALY the Committee is required to have an “increasingly strong” case for the recommendation and to explain its decision with reference to the factors taken into account. The Institute has failed to have regard to this Guide or the updated Guide (2008), has failed to act with appropriate caution, and failed to give any or any adequate explanation or reasons for its recommendation. The recommendation of simultaneous bilateral cochlear implantation in children and in individuals who are blind or have other disabilities (as set out at paragraph 1.2 of the FAD) is, given the high level of uncertainty with regard to the evidence base, inconsistent with the approach set out in the Guide.
- (b) The Institute has failed to provide any or any adequate reasons or explanation for recommending a technology with an incremental cost-effectiveness ratio (“ICER”) in excess of £30,000.

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<sup>1</sup> Although an updated Guide has now been produced by NICE dated June 2008, the Appellants consider that since this Appraisal was “initiated” prior to 25<sup>th</sup> June 2008, the 2004 Guidance is/was relevant, however, whichever guidance is relied on, the points remain the same.

### **Ground 2**

6. The Institute has prepared guidance which is perverse in the light of the evidence submitted. The Institute has irrationally and/or perversely recommended sequential contralateral cochlear implantation for patients with a pre-existing implant where this option is supported by the responsible clinician, despite its unequivocal statement that sequential bilateral implantation is not a cost effective use of NHS resources – see §4.3.17 *“The Committee noted that sequential implantation was associated with higher cost-effectiveness estimates than simultaneous bilateral implantation for both children and adults, and therefore concluded that sequential bilateral implantation is not an appropriate use of NHS resources”*.

### **Ground 3**

7. The recommendation is perverse, inadequately reasoned and/or made outside the powers of the Institute. The recommendation that bilateral implantation in children represents cost-effective use of NHS resources rests explicitly on an assumption of a minimum 40% discount in the price of the second implant. Even if that assumed discount is accepted, given the range list prices for these devices: £12,250 to £17,375, the required discount ranges from £4,900 to £6,950 which will in itself create substantially different ICER's for the technologies. The Institute has failed to give any or any adequate reasoning as to why the ICERs for these devices can be considered a cost-effective use of NHS resources. Moreover the recommendation made is premised on a recommendation as to the pricing of the technology to the NHS, which recommendation is outside the powers of the Committee– see Guide to the Methods of Technology Appraisal (April 2004) para. 6.1.8.

### ***Legal Background***

8. The function of NICE is to develop guidance covering all aspects of healthcare within the NHS. NICE's purpose is to encourage: (a) best clinical practice; (b) the

most efficient use of the NHS's finite resources; and (c) consistency of treatment throughout the NHS.

9. NICE was established by the National Institute for Clinical Excellence (Establishment and Constitution) Order (SI 1999/220) as a "special health authority" within the NHS with effect from April 1999.

10. By Regulation 10 of the 1999 Regulations, NICE is subject to the directions of the Secretary of State. Paragraph 2(1) of the current directions, 'Directions and Consolidating Directions to the National Institute for Health and Clinical Excellence 2005' provides that:

*"(1) the Secretary of State directs the Institute to exercise the following functions in connection with the promotion of clinical excellence and the effective use of available resources in the health service:*

*(a) to appraise the clinical benefits and the costs of such health care interventions as may be notified by the Secretary of State and to make recommendations;*

*(b) to develop guidelines providing advice on good practice in the management of such diseases and conditions as may be notified by the Secretary of State ... "*

11. Paragraph 2(4) directs NICE as to how to exercise the functions set out above, in these terms:

*"(4) In exercising the functions described in paragraphs (1)(a)-(d) and (3) above the Institute shall have regard to the following factors-*

*(a) the broad balance of clinical benefits and costs;*

*(b) the degree of clinical need of patients with the condition or disease under consideration;*

*(c) any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of the Institute by the Secretary of State and any guidance issued by the Secretary of State;*

*(d) the potential for long term benefits to the NHS of innovation."*

### *The status and effect of NICE Guidance and Guidelines*

12. NICE Guidance contains recommendations for the use of particular treatments (also referred to as "health technologies"). Where a treatment is recommended in clinical practice, NICE will generally give guidance as to the circumstances in which it should be used, or as to particular patient groups to whom it should be given. All NICE guidance contains an explanatory paragraph which indicates that healthcare professionals are expected to take the Guidance fully into account when exercising their clinical judgment, but it does not override the individual clinician's responsibility to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
  
13. On 11<sup>th</sup> December 2001, the Secretary of State directed that NHS Trusts should make the necessary funding available in respect of any treatment that is recommended by NICE. Further, since April 2005, NHS Core Standard C5 has provided that "*health care organisations [should] ensure that ... they conform to NICE technology appraisals ...*".
  
14. As part of the appraisal process an independent academic centre is commissioned to review and evaluate evidence on the health technology under appraisal. It produces a Technology Assessment Report (TAR) which presents an analysis of the cost-effectiveness of the health technology. In the present case, the TAR considered there was a high level of uncertainty in the evidence base in relation to bilateral cochlear implants
  
15. The key principle underlying NICE's approach to appraisals is that the NHS's limited resources should be targeted on those treatments which provide best value for money. As is explained in the "*Guide to the Methods of Technology Appraisal*" (April 2004)<sup>2</sup>, 6.2.6.1: "*The Institute is asked to take account of the overall resources available to the NHS when determining cost effectiveness.*"

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<sup>2</sup> It is considered the April 2004 Guide rather than the June 2008 guide is relevant. If the 2008 Guide is the relevant document, the point is the same.

*Therefore, decisions on the cost-effectiveness of a new technology must include judgments on the implications for healthcare programmes for other patient groups that may be displaced by the adoption of the new technology”.*

16. In determining whether particular treatments are cost-effective, NICE generally seeks to ascertain the incremental cost per quality adjusted life year (or "cost per QALY") of using a particular health technology . In broad terms, this is a standard measure of the cost of gaining a particular unit of utility through the use of the technology which can be applied across the whole spectrum of treatments appraised by NICE.

17. The general threshold for an "acceptable" cost per QALY is approximately an ICER of £20,000 per QALY: see 6.2.6.10 of NICE's '*Guide to the Methods of Technology Appraisal*' (April 2004).

18. By 6.2.6.10 of the 2004 Guide<sup>3</sup> it is stated that “*Above a most plausible ICER of £20,000/QALY, judgments about the acceptability of the technology as an effective use of NHS resources are more likely to make more explicit reference<sup>4</sup> to factors including:*

- *the degree of uncertainty surrounding the calculation of ICERs<sup>5</sup>*
- *the innovative nature of the technology*
- *the particular features of the condition and population receiving the technology*
- *where appropriate, the wider societal costs and benefits”*

19. Above an ICER of £30,000 per QALY, technologies are not normally recommended (para. 6.2.6.11 of the 2004 Guide<sup>6</sup>):

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<sup>3</sup> Now 6.2.23 of the updated 2008 Guide.

<sup>4</sup> It is noteworthy that in the 2008 Guide the wording of this section has been changed to ...judgments about the acceptability of the technology...will specifically take into account the following factors...” and the addition of the words “In particular the Committee will be more cautious about recommending a technology when they are less certain about the ICERs presented”.

<sup>5</sup> See footnote above.

*“Above an ICER of £30,000/QALY, the case for supporting the technology on these factors has to be increasingly strong. The reasoning for the Committee’s decision will be explained, with reference to the factors that have been taken into account in the “Considerations” section of the guidance”*

20. Further, in relation to the costs to the NHS, the “*Guide to the Methods of Technology Appraisal*” (April 2004) makes clear at 5.10.4.1

*“Where savings are anticipated, the extent to which these finances can actually be realized should be specified.”*

and goes on to specify at 6.1.8, that

*“the Committee is not able to make recommendations on the pricing of technologies to the NHS”*

#### ***The chronology of the appeal in the present case***

21. In December 2007 NICE produced its initial Appraisal consultation document with regard to Cochlear implants for children and adults with severe to profound deafness. The Appellants were formal consultees to the Appraisal consultation and submitted written responses to the NICE Appraisal Consultation Document (“ACD”). The written responses strongly disagreed with the recommendation in the 1<sup>st</sup> Appraisal Consultation Document that simultaneous bilateral implantation should be recommended for prelingual children and children and adults who are at risk of ossification of the cochlea.

22. Those responses were formally taken into account in a document entitled “*Comments received on the Appraisal Consultation Document*”.

23. In March 2008 NICE published a 2<sup>nd</sup> Appraisal Consultation document which appeared to take into account the formal responses of the Appellants. In particular, the Appraisal Committee’s preliminary recommendations in the 2<sup>nd</sup>

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<sup>6</sup> See 6.2.25 of the 2008 Guide.

Appraisal Consultation Document differed markedly from that in the 1<sup>st</sup> Appraisal consultation document with regard to the preliminary recommendations. By way of example, preliminary recommendation 1.3 read as follows:-

*“Bilateral cochlear implantation is not recommended for children and adults (other than those in 1.2<sup>7</sup>) except in the context of research designed to generate robust evidence about the benefits to functional hearing and health-related quality of life of simultaneous or sequential bilateral compared with unilateral cochlear implantation in those with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids.”*

24. The 2<sup>nd</sup> Appraisal Consultation Document concluded at §4.3.12:-

*“..it could not recommend bilateral implantation as a cost-effective use of NHS resources. The Committee also concluded that the potential for additional gains in quality of life for both pre- and post lingual children from bilateral implantation should be formally evaluated in a research environment”*

25. In May 2008 a further Committee meeting was convened to consider the appraisal in the light of the 2<sup>nd</sup> Consultation. The results of appraisal are set out in the Final Appraisal Determination dated 26<sup>th</sup> August 2008. Paragraphs 1.2-1.4 of the Final Consultation Document, differ significantly from the recommendations consulted upon and for the reasons set out below are perverse and/or procedurally flawed and/or ultra vires.

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<sup>7</sup> The category of persons in 1.2 of the 2<sup>nd</sup> ACD had been refined from “prelingual children, children and adults who are registered as blind, and children and adults who are at risk of ossification of the cochlear (for example after meningitis)” to exclude “prelingual children”.

## *Summary of basis of appeal*

### *Ground 1*

26. The Institute has failed to act fairly and in accordance with the appraisal procedure set out in the Institute's Guide to the Methods of Technology Appraisal Process. (April 2004)<sup>8</sup> Specifically:

(a) Paragraphs 6.2.6.10 to 6.2.6.11 of the 2004 Guide, make plain that explicit reference should be made by the Committee as to the factors which justify the acceptability of the technology and that where the ICER is above £30,000/QALY the Committee is required to have an "increasingly strong" case for the recommendation. Further the Committee is required to explain its decision with reference to the factors taken into account. The Institute has failed to have regard to either the 2004 Guide or the updated Guide (2008), and has failed to act with appropriate caution, and failed to give any or any adequate explanation or reasons for its recommendation. The recommendation of simultaneous bilateral cochlear implantation in children and in individuals who are blind or have other disabilities (as set out at paragraph 1.2 of the FAD) is, given the high level of uncertainty with regard to the evidence base, inconsistent with the approach set out in the Guide (2004) and/or its update in 2008.

(b) The Institute has failed to provide any or any adequate reasons or explanation for recommending a technology with an incremental cost-effectiveness ratio ("ICER") in excess of £30,000.

27. In particular the Committee's recommendation for simultaneous bilateral implantation in children is based upon the utility gain associated with the second

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<sup>8</sup> It is considered the April 2004 Guide rather than the June 2008 guide is relevant. If the 2008 Guide is the relevant document, the point is the same.

implant. There is no evidence to support the utility assumptions used by the Committee to identify an ICER below the £30,000 per QALY threshold for simultaneous bilateral implantation. The Committee has assumed (without evidence) a 33% greater utility gain in children than the utility gain in adults –see Considerations section at 4.3.13 to 4.3.14.

28. Further the Committee has failed properly to explain why or how the Committee has concluded that clinical opinion (usually the lowest level of evidence base in the hierarchy) was a sufficient basis to reject the conclusions of the TAR that bilateral implantation in these patient groups was not cost effective and has failed to make explicit reference to the key factors which might justify such a decision namely:

- *the degree of uncertainty surrounding the calculation of ICERs*
- *the innovative nature of the technology*
- *the particular features of the condition and population receiving the technology*
- *where appropriate, the wider societal costs and benefits”*

## Ground 2

29. The Institute has prepared guidance which is perverse in the light of the evidence submitted. The Institute has irrationally and/or perversely recommended sequential contralateral cochlear implantation for patients with a pre-existing implant where this option is supported by the responsible clinician, despite its unequivocal statement that sequential bilateral implantation is not a cost effective use of NHS resources – see §4.3.17 “*The Committee noted that sequential implantation was associated with higher cost-effectiveness estimates than simultaneous bilateral implantation for both children and adults, and therefore concluded that sequential bilateral implantation is not an appropriate use of NHS resources*”.

30. The FAD's purported justification for this recommendation is wholly inadequate having regard to the duties as set out in the Guide referred to above, and is contained at 4.3.17

*"The Committee was persuaded that in situations where the responsible clinician considers that an additional contralateral implant would provide sufficient benefit, people in the above two groups should have the option of an additional contralateral implant"*

31. No or no adequate reasons are given by the Committee for this conclusion, or how they were so persuaded. In particular it was incumbent on the Committee to have regard to 6.2.6.10 and 6.2.6.11 of the Guide (2004) and give its reasons for this conclusion. The Committee has failed to do so.

### Ground 3

32. The recommendation is perverse, inadequately reasoned and/or made outside the powers of the Institute. The recommendation that bilateral implants in children represents cost-effective use of NHS resources rests explicitly on an assumption of a minimum 40% discount in the price of the second implant. Even if that assumed discount is accepted, given the range list prices for these devices: £12,250 to £17,375, the required discount ranges from £4,900 to £6,950 which will in itself create substantially different ICER's for the technologies. The Institute has failed to give any or any adequate reasoning as to why the ICERs for these devices can be considered a cost-effective use of NHS resources.

33. In particular the Committee has taken no account of a difference of up to £3000 in the acquisition cost of the second implant device and a difference in the total acquisition cost of up to £8,200.

34. Moreover, it is perverse to assume that a difference of 40% in the acquisition cost of alternative systems will not lead to important differences in cost-effectiveness.

This is particularly so where the Committee expressly states that:

*“The Committee agreed that given the uncertainty over the magnitude of the additional quality of life gains associated with bilateral cochlear implantation in this group of people inclusion of a discount equivalent to 40% or more off the current list prices of the second implant could result in an acceptable cost-effectiveness estimate.”*

35. Moreover, while it may be appropriate for the Committee in its consideration of cost-effectiveness to take into account any anticipated savings (see 5.10.4.1 of the *Guide to the Methods of Technology Appraisal* (2004)) *“the extent to which these finances can actually be realized should be specified”*. The Committee has failed to do this. Rather than specify the financial savings that can actually be realized, the Committee appear to have been persuaded to make their recommendation on the speculation that *“if cochlear implants for bilateral implantation were acquired at the lowest price, which includes a discount on current list prices equivalent to 40% or more off the second implant, then it was appropriate to recommend bilateral implantation in this group as a cost-effective use of NHS resources.”*

36. This has resulted in a recommendation at 1.2 of the FAD that *“Acquisition of cochlear implant systems for bilateral implantation should be at the lowest cost and should include discount on current list prices equivalent to 40% or more for the second implant”*.

37. In doing so the Institute has made a recommendation outside its powers. As the 2004 Guide on the Methods of Technology Appraisal makes plain at 6.1.8:

*“The Committee is not able to make recommendations on the pricing of technologies to the NHS”*.

38. For all these reasons the Appellants consider that the FAD be remitted to the Appraisal Committee to reconsider the Appraisal in the light of the decision of the Appeal Panel.

26<sup>th</sup> September 2008

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**GROUNDS OF APPEAL**

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