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Appendices

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The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults: a systematic review and economic model

M Bond, S Mealing, R Anderson,
J Elston, G Weiner, RS Taylor, M Hoyle,
Z Liu, A Price and K Stein

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Appendix 1

Literature search strategies

A wide range of databases and other information resources were searched to locate details of both published and unpublished studies and other information on the clinical effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness.

All resources were searched from their inception to the most recent date available. There was no restriction on study by publication date. The search was limited to English language papers only. The bibliographies of retrieved references were checked for additional publications. The results of the searches were imported into Reference Manager 11 bibliographic management software and deduplicated. All initial searches were carried out in October 2006 and the update searches were rerun in July 2007.

The following databases were searched: MEDLINE (Ovid), EMBASE (Ovid), Ovid MEDLINE® In-Process & Other Non-Indexed Citations, ISI Science Citation Index, Cochrane Database of Systematic Reviews, CENTRAL, NHS EED, DARE, HTA (NHS-CRD), EconLit, Biosis Previews, ISI Proceedings, Current Controlled Trials, National Research Register and ClinicalTrials.gov.

Relevant internet sites were searched for information including the following regulatory sites: Medical Health and Regulatory Agency (MHRA), US Food and Drug Administration (FDA) and the European Regulatory Agency – Medical Device Safety Service (MDSS).

Full search strategies are listed in the following sections.

Search strategy: cochlear implants for severe to profound deafness in children and adults

Clinical searches: searched by Alison Price 12–19 October 2006, updated July 2007

Cochrane Library – CDSR – Issue 3/2006

#1. MeSH descriptor Hearing Loss explode all trees
#2. MeSH descriptor Deafness explode all trees
#3. MeSH descriptor Hearing Disorders explode all trees
#4. severe to profound deafness
#5. (severe NEAR/5 deaf*)
#6. (profound* NEAR/5 deaf*)
#7. deaf*
#8. (hear* NEAR/5 loss)
#9. (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8)
#10. MeSH descriptor Cochlear Implants explode all trees
#11. MeSH descriptor Cochlear Implantation explode all trees
#12. (cochlea* NEAR/10 (implant* or device* or prosthe*))
#13. (#10 OR #11 OR #12)
#14. (#9 AND #13)

Cochrane Library – CENTRAL – Issue 3/2006

As above

Ovid MEDLINE® – 1966 to October Week 1 2006

Searched 12 October 2006, saved as med-cochlear-clini-effect-final-all

1. exp hearing loss/(37541)
2. exp hearing loss, sensorineural/(14163)
3. "Hearing Loss, Bilateral"/(1190)
4. exp deafness/(17839)
5. severe to profound deafness.mp. (15)
6. (severe adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (327)
7. (profound adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (542)
8. Hearing Loss, Unilateral/(34)
9. exp Hearing Disorders/(49630)

10. deaf$.ti,ab. (19840)
11. (hear$adj5 loss).ti,ab. (19425)
12. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 (61873)
13. exp ear, middle/or exp ear, inner/(47537)
14. 12 or 13 (98248)
15. Cochlear Implants/(4019)
16. Cochlear Diseases/(557)
17. Cochlear Implantation/(1476)
18. (cochlear adj10 (implant$or device$)).ti,ab. (4660)
19. 15 or 16 or 17 or 18 (6089)
20. 14 and 19 (4964)
21. limit 20 to (humans and english language) (3781)
22. randomized controlled trial.pt. (238589)
23. controlled clinical trial.pt. (77157)
24. randomized controlled trials/(49082)
25. random allocation/(59319)
26. double-blind method/(91964)
27. single-blind method/(10803)
28. exp evaluation studies/(602476)
29. exp clinical trials/(196879)
30. clinical trial.pt. (463567)
31. (clin$adj5 trial$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (599913)
32. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 (1058607)
33. ((singl$or doubl$or tripl$or trebl$) adj5 (blind$or mask$)).tw. (89036)
34. exp placebos/(26048)
35. placebo$.tw. (102143)
36. random$.tw. (373635)
37. exp research design/(219553)
38. 33 or 34 or 35 or 36 or 37 (553879)
39. 32 or 38 (1269102)
40. limit 39 to human (1064650)
41. 21 and 40 (463)
42. (review or review-tutorial or review-academic).pt. (1271244)
43. (Medline or medlars or embase).ti,ab,sh. (22444)
44. (scisearch or psychinfo or psycinfo).ti,ab,sh. (1115)
45. (Psychlit or psyclit).ti,ab,sh. (704)
46. cinahl.ti,ab,sh. (1949)
47. ((hand adj59 search$) or (manual$adj9 search$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3717)
48. (electronic database$or bibliographic database$or computeri#ed database$or online database$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3852)
49. (pooling or pooled or mantel haenszel).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (25514)
50. (peto or dersimonian or der simonian or fixed effect).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1060)
51. 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 (50925)
52. 42 and 51 (18566)
53. meta-analysis.pt. (14472)
54. meta-analysis.sh. (7449)
55. (meta-analys$or meta analys$or metaanalys$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (26392)
56. (systematic$adj9 review$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (12274)
57. (systematic$adj9 overview$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (425)
58. (quantitativ$adj9 review$).mp. (1686)
59. (quantitativ$adj9 overview$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (151)
60. (quantitativ$adj9 synthesis$).mp. (1331)
61. (methodologic$adj9 review$).mp. (2451)
62. (methodologic$adj9 overview$).mp. (145)
63. (integrative research review$or research integration).mp. (49)
64. or/53–63 (39296)
65. 52 or 64 (51255)
66. 21 and 65 (10)
67. 41 not 66 (461)
68. Waiting Lists/(4600)
69. (wait$adj10 (surgery or operat$or implant$or list$or control$)).ti,ab. (5725)
70. exp case-control studies/or exp cohort studies/(889029)
71. 68 or 69 or 70 (895766)
72. 71 and 21 (726)
73. 72 not (66 or 67) (620)

EMBASE – 1980 to 2006 Week 41

Searched 16 October 2006

1. exp Hearing Impairment/(35069)
2. exp Congenital Deafness/(2186)
3. Perception Deafness/(6680)
4. hearing loss/or mixed hearing loss/or unilateral hearing loss/(10373)
5. exp ear disease/(47491)
6. severe to profound deafness.mp. (18)
7. (severe adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (272)

8. (profound adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (457)
9. deaf$.ti,ab. (13992)
10. (hear$adj5 loss).ti,ab. (16635)
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (76335)
12. cochlea prosthesis/(4375)
13. Implantation/(13919)
14. (cochlea$adj10 (implant$or device$or prosthe$)).ti,ab. (4396)
15. 12 or 13 or 14 (18264)
16. 11 and 15 (3683)
17. limit 16 to (humans and english language) (2934)
18. randomization/(20626)
19. controlled study/(2270014)
20. single blind procedure/(6140)
21. placebo/(90992)
22. double blind procedure/(61537)
23. clinical trial/(398197)
24. crossover procedure/(17930)
25. placebo$.tw. (94492)
26. blind$fashion.tw. (3499)
27. random$.tw. (317764)
28. clinical trial?.tw. (93827)
29. or/18–28 (2655359)
30. limit 29 to human (1686676)
31. 17 and 30 (801)
32. exp meta analysis/(27478)
33. meta#analy$.ab,sh,ti. (27479)
34. methodologic$review$.ab,sh,ti. (124)
35. methodologic$overview$.ab,sh,ti. (29)
36. (integrative research adj5 review$).mp. or research integration.ab,ti. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (24)
37. quantitat$synthesis.ab,sh,ti. (87)
38. quantitat$review$.ab,sh,ti. (245)
39. quantitat$overview$.ab,sh,ti. (58)
40. systematic$review$.ab,sh,ti. (19122)
41. systematic$overview$.ab,sh,ti. (276)
42. 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 (39054)
43. 17 and 42 (7)
44. 43 not 31 (4)
45. cohort analysis/(37235)
46. (wait$adj10 (surgery or operat$or implant$or list$or control$)).ti,ab. (4919)
47. 45 or 46 (42058)
48. 17 and 47 (25)
49. 48 not (44 or 31) (11)

Ovid MEDLINE® In-Process & Other Non-Indexed Citations – 13 October 2006

Searched 16 October 2006

1. severe to profound deafness.mp. (1)
2. (severe adj4 deaf$).mp. (10)
3. (profound adj4 deaf$).mp.
4. deaf$.ti,ab. (357)
5. (hear$adj5 loss).ti,ab. (613)
6. 1 or 2 or 3 or 4 or 5 (880)
7. (cochlear adj10 (implant$or device$)).ti,ab. (173)
8. 6 and 7 (82)
9. limit 8 to english language (69)
10. randomized controlled trial.pt. (282)
11. controlled clinical trial.pt. (20)
12. clinical trial.pt. (309)
13. (clin$adj5 trial$).mp. (3970)
14. 10 or 11 or 12 or 13 (4254)
15. ((singl$or doubl$or tripl$or trebl$) adj5 (blind$or mask$)).tw. (1668)
16. placebo$.tw. (2272)
17. random$.tw. (16771)
18. 15 or 16 or 17 (17799)
19. 14 or 18 (20448)
20. 19 and 9 (3)
21. (review or review-tutorial or review-academic).pt. (496)
22. meta-analysis.pt. (2)
23. (meta-analys$or meta analys$or metaanalys$).mp. [mp=title, original title, abstract, name of substance word] (912)
24. (systematic$adj9 review$).mp. [mp=title, original title, abstract, name of substance word] (990)
25. (systematic$adj9 overview$).mp. [mp=title, original title, abstract, name of substance word] (18)
26. (quantitativ$adj9 review$).mp. (76)
27. (quantitativ$adj9 overview$).mp. [mp=title, original title, abstract, name of substance word] (6)
28. (quantitativ$adj9 synthesis$).mp. (41)
29. (methodologic$adj9 review$).mp. (107)
30. (methodologic$adj9 overview$).mp. (9)
31. (integrative research review$or research integration).mp. (3)
32. or/21–31 (1891)
33. 32 and 9 (1)
34. (wait$adj10 (surgery or operat$or implant$or list$or control$)).ti,ab.
35. 34 and 9 (1)

Web of Knowledge (SCI-EXPANDED) – 1970 to present

#14	82	#13 AND #12 DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006
#13	>100,000	TS=(trial* or random*) DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006
#12	1699	#11 AND #6 DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006
#11	4048	#10 OR #9 OR #8 OR #7 DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#10	262	TS=(cochlea* SAME prosthe*) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#9	300	TS=(cochlea* SAME device*) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#8	3786	TS=(cochlea* SAME implant*) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#7	3945	TS=(Cochlea* Implant*) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#6	30,982	#5 OR #4 OR #3 OR #2 OR #1 DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#5	6563	TS=(hear* SAME/5 loss) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#4	15,103	TS=(deaf*) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#3	219	TS=(profound* SAME/5 deaf*) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#2	235	TS=(severe SAME/5 deaf*) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#1	20,949	TS=(Hearing Loss or Deafness or Hearing Disorders)

Web of Science Proceedings – 1990 to present

#7	8	#6 AND #5 DocType=All document types; Language=English; Database=STP; Timespan=2003–2006
#6	55,983	TS=(trial* or random*) DocType=All document types; Language=English; Database=STP; Timespan=2003–2006
#5	126	#4 AND #3 DocType=All document types; Language=English; Database=STP; Timespan=2003–2006
#4	302	TI=(cochlea* SAME (implant* or device* or prosthe*)) DocType=All document types; Language=English; Database=STP; Timespan=2003–2006
#3	1,129	#2 OR #1 DocType=All document types; Language=All languages; Database=STP; Timespan=2003–2006
#2	574	TS=(deaf*) DocType=All document types; Language=All languages; Database=STP; Timespan=2003–2006
#1	889	TS=(Hearing Loss or Deafness or Hearing Disorders)

Web of Knowledge BIOSIS Previews – 1990–2006

#9	4	#9 DocType=All document types; LitType=Meeting Abstract; Language=English; Taxa Notes=Humans; Database=BIOSIS Previews; Timespan=2003–2006
#8	20	#8 DocType=All document types; LitType=Meeting Abstract; Language=English; Taxa Notes=Humans; Database=BIOSIS Previews; Timespan=1990–2006
#7	63	#6 AND #5 DocType=All document types; LitType=All literature types; Language=English; Taxa Notes=All Taxa Notes; Database=BIOSIS Previews; Timespan=1990–2006
#6	>100,000	TS=(trial* or random*) DocType=All document types; LitType=All literature types; Language=English; Taxa Notes=All Taxa Notes; Database=BIOSIS Previews; Timespan=1990–2006
#5	2,007	#4 AND #1 DocType=All document types; LitType=All literature types; Language=English; Taxa Notes=All Taxa Notes; Database=BIOSIS Previews; Timespan=1990–2006
#4	35903	#3 OR #2 DocType=All document types; LitType=All literature types; Language=English; Taxa Notes=All Taxa Notes; Database=BIOSIS Previews; Timespan=1990–2006
#3	6966	TS=(hear* SAME/5 loss) DocType=All document types; LitType=All literature types; Language=English; Taxa Notes=All Taxa Notes; Database=BIOSIS Previews; Timespan=1990–2006
#2	29,809	TS=(deaf*) DocType=All document types; LitType=All literature types; Language=English; Taxa Notes=All Taxa Notes; Database=BIOSIS Previews; Timespan=1990–2006
#1	2916	TS=(cochlea* SAME (implant* or device* or prosthe*)) DocType=All document types; LitType=All literature types; Language=English; Taxa Notes=All Taxa Notes; Database=BIOSIS Previews; Timespan=1990–2006

DARE

(cochlea* AND (implant* or device* or prosthe*))

HTA database (on CRD databases)

(cochlea* SAME (implant* or device* or prosthe*))

NRR (National Research Register)

#1	(cochlea* near implant*)	177
#2	(cochlea* near device*)	8
#3	(cochlea* near prosthe*)	2
#4	(hearing near loss)	302
#5	deaf*	426
#6	(#1 or #2 or #3)	177
#7	(#4 or #5)	664
#8	(#7 and #6)	73

Current Controlled Trials including MRC Trials dB (http://controlled-trials.com/)

"Cochlear implants"

ClinicalTrials.gov (http://clinicaltrials.gov/)

Cochlear implant*

National Guidelines Clearinghouse

Cochlear implant*

FDA Center for Devices and Radiological Health (www.fda.gov)

Cochlear implant*

Medical Healthcare and Regulatory Authority

Cochlear implants

PsycINFO including PsycARTICLES – 1985 to present

1. severe to profound deafness.mp. (2)
2. (severe adj4 deaf$).mp. [mp=title, abstract, heading word, table of contents, key concepts] (52)
3. (profound adj4 deaf$).mp. [mp=title, abstract, heading word, table of contents, key concepts] (64)
4. exp Hearing Disorders/(6023)
5. deaf$.ti,ab. (4905)
6. (hear$adj5 loss).ti,ab. (1927)
7. 1 or 2 or 3 or 4 or 5 or 6 (7807)
8. Cochlear Implants/(506)
9. (cochlear adj10 (implant$or device$)).ti,ab. (641)
10. 8 or 9 (666)
11. 7 and 10 (458)
12. (random$or trial$).mp. [mp=title, abstract, heading word, table of contents, key concepts] (80452)
13. 11 and 12 (17)
14. limit 13 to (human and english language) (16)

Economics searches

Cochrane Library – CENTRAL – Issue 3/2006

#1. MeSH descriptor Hearing Loss explode all trees
#2. MeSH descriptor Deafness explode all trees
#3. MeSH descriptor Hearing Disorders explode all trees
#4. severe to profound deafness
#5. (severe NEAR/5 deaf*)
#6. (profound* NEAR/5 deaf*)
#7. deaf*
#8. (hear* NEAR/5 loss)
#9. (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8)
#10. #10 MeSH descriptor Cochlear Implants explode all trees
#11. MeSH descriptor Cochlear Implantation explode all trees
#12. (cochlea* NEAR/10 (implant* or device* or prosthe*))
#13. (#10 OR #11 OR #12)
#14. (#9 AND #13)
#15. MeSH descriptor Costs and Cost Analysis explode all trees
#16. MeSH descriptor Models, Economic explode all trees
#17. MeSH descriptor Cost-Benefit Analysis explode all trees
#18. (cost* NEAR (benefit* or utilit* or minim* or effective))
#19. (#15 OR #16 OR #17 OR #18)
#20. (#19 AND #14)

Ovid MEDLINE® – 1966 to October Week 1 2006

1. exp hearing loss/(37560)
2. exp hearing loss, sensorineural/(14170)
3. "Hearing Loss, Bilateral"/(1190)
4. exp deafness/(17844)
5. severe to profound deafness.mp. (15)
6. (severe adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (327)
7. (profound adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (542)
8. Hearing Loss, Unilateral/(34)
9. exp Hearing Disorders/(49653)
10. deaf$.ti,ab. (19850)

11. (hear$adj5 loss).ti,ab. (19438)
12. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 (61902)
13. exp ear, middle/or exp ear, inner/(47551)
14. 12 or 13 (98289)
15. Cochlear Implants/(4022)
16. Cochlear Diseases/(557)
17. Cochlear Implantation/(1477)
18. (cochlear adj10 (implant$or device$)).ti,ab. (4664)
19. cochleostomy.ti,ab. (105)
20. 15 or 16 or 17 or 18 or 19 (6114)
21. 14 and 20 (4988)
22. limit 21 to (humans and english language) (3791)
23. exp ECONOMICS/(363519)
24. exp ECONOMICS, HOSPITAL/(14374)
25. exp ECONOMICS, PHARMACEUTICAL/(1692)
26. exp ECONOMICS, NURSING/(3702)
27. exp ECONOMICS, DENTAL/(3386)
28. exp ECONOMICS, MEDICAL/(10144)
29. exp "Costs and Cost Analysis"/(128319)
30. Cost-Benefit Analysis/(39954)
31. VALUE OF LIFE/(4935)
32. exp MODELS, ECONOMIC/(4995)
33. exp FEES/and CHARGES/(7025)
34. exp BUDGETS/(9323)
35. (economic$or price$or pricing or financ$or fee$or pharmacoeconomic$or pharma economic$).tw. (315970)
36. (cost$or costly or costing$or costed).tw. (187673)
37. (cost$adj2 (benefit$or utilit$or minim$or effective$)).tw. (48482)
38. (expenditure$not energy).tw. (10092)
39. (value adj2 (money or monetary)).tw. (565)
40. budget$.tw. (10347)
41. (economic adj2 burden).tw. (1322)
42. "resource use".ti,ab. (2043)
43. or/23–41 (733772)
44. news.pt. (105429)
45. letter.pt. (582201)
46. editorial.pt. (199280)
47. comment.pt. (318112)
48. or/44–47 (924522)
49. 43 not 48 (677588)
50. 22 and 49 (148)
51. exp Hearing Disorders/ec [Economics] (132)
52. 23 or 29 or 30 or 31 or 32 or 33 or 34 (367556)
53. 51 and 52 (103)
54. limit 53 to english language (86)
55. 54 not 48 (75)
56. 55 or 50 (206)

EMBASE – 1980 to 2006 Week 41

1. exp Hearing Impairment/(35069)
2. exp Congenital Deafness/(2186)
3. Perception Deafness/(6680)
4. hearing loss/or mixed hearing loss/or unilateral hearing loss/(10373)
5. exp ear disease/(47491)
6. severe to profound deafness.mp. (18)
7. (severe adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (272)
8. (profound adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (457)
9. deaf$.ti,ab. (13992)
10. (hear$adj5 loss).ti,ab. (16635)
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (76335)
12. cochlea prosthesis/(4375)
13. Implantation/(13919)
14. (cochlea$adj10 (implant$or device$or prosthe$)).ti,ab. (4396)
15. 12 or 13 or 14 (18264)
16. 11 and 15 (3683)
17. limit 16 to (humans and english language) (2934)
18. (cost$adj2 effective$).ti,ab. (35195)
19. (cost$adj2 benefit$).ti,ab. (7330)
20. cost effectiveness analysis/(45567)
21. cost benefit analysis/(24596)
22. budget$.ti,ab. (7519)
23. cost$.ti. (33258)
24. (cost$adj2 (effective$or utilit$or benefit$or minimi$)).ab. (38347)
25. (economic$or pharmacoeconomic$or pharmaco economic$).ti. (12947)
26. (price$or pricing$).ti,ab. (9586)
27. (financial or finance or finances or financed).ti,ab. (19752)
28. (fee or fees).ti,ab. (4563)
29. cost/(18617)
30. cost minimization analysis/(1039)
31. cost of illness/(3417)
32. cost utility analysis/(1754)
33. drug cost/(27654)
34. health care cost/(49256)
35. health economics/(8752)
36. economic evaluation/(3338)
37. economics/(4999)
38. pharmacoeconomics/(875)
39. budget/(6673)
40. economic burden.ti,ab. (1284)
41. "resource use".ti,ab. (1791)
42. or/18–41 (203782)

43. (editorial or letter).pt. (495203)
44. 42 not 43 (181874)
45. 17 and 44 (95)
46. *"cost benefit analysis"/or *"cost effectiveness analysis"/or *"cost minimization analysis"/or *"cost of illness"/or *"cost utility analysis"/ (9260)
47. 11 and 46 (65)
48. 45 or 47 (152)
49. limit 48 to (human and english language) (141)

Ovid MEDLINE® In-Process & Other Non-Indexed Citations – 18 October 2006

1. severe to profound deafness.mp. (1)
2. (severe adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word] (10)
3. (profound adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word] (10)
4. deaf$.ti,ab. (360)
5. (hear$adj5 loss).ti,ab. (624)
6. (cochlear adj10 (implant$or device$)).ti,ab. (174)
7. 1 or 2 or 3 or 4 or 5 (894)
8. 6 and 7 (83)
9. limit 8 to english language (69)
10. (economic$or price$or pricing or pharmacoeconomic$or pharma economic$).tw. (3454)
11. (cost$or budget$).tw. (7154)
12. (cost$adj2 (benefit$or utilit$or minim$)).tw. (399)
13. (value adj2 (money or monetary)).tw. (23)
14. 10 or 11 or 12 or 13 (9666)
15. 9 and 14 (4)
16. 7 and 14 (22)
17. 15 or 16 (22)

SCI-EXPANDED – 1970–2006

#12	57	#11 AND #6 DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006
#11	1720	#10 AND #9 DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#10	3904	TS=(cochlea* SAME (implant* or device* or prosthes*)) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#9	26,686	#8 OR #7 DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#8	15,113	TS=(deaf*) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#7	14,551	TS=(hearing SAME (loss or disorders)) DocType=All document types; Language=All languages; Database=SCI-EXPANDED; Timespan=1970–2006
#6	>100,000	#5 OR #4 OR #3 OR #2 OR #1 DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006
#5	51,944	TS=(cost* SAME effective*) DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006
#4	818	TS=(value SAME (money or monetary)) DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006

#3	36,218	TS=(cost* SAME (benefit* or utilit* or minim*)) DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006
#2	>100,000	TS=(cost* or costly or costing* or costed) DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006
#1	>100,000	TS=(economic* or price* or pricing or pharmacoeconomic* or pharma economic*) DocType=All document types; Language=English; Database=SCI-EXPANDED; Timespan=1970–2006

NHS EED (CRD database)

(cochlea* SAME (implant* or device* or prosthe*))

EconLit

hearing disorder or deaf*

Epidemiology searches

Ovid MEDLINE® – 1966 to September Week 3 2006

1. exp hearing loss/(10251)
2. exp hearing loss, sensorineural/(7929)
3. "Hearing Loss, Bilateral"/(10251)
4. exp deafness/(34934)
5. Deafness/ep, et [Epidemiology, Etiology] (2073)
6. severe to profound deafness.mp. (18)
7. (severe adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (272)
8. (profound adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (456)
9. 7 or 8 (672)
10. or/1–9 (35041)
11. exp Incidence/(98905)
12. exp Prevalence/(111736)
13. incidence.ti. (28941)
14. prevalence.ti. (32779)
1. Risk Factors/(180965)
2. epidemiol$.ti. (38186)
3. etiolog$.ti. (10334)
4. aetiolog$.ti. (3549)
5. or/11–18 (411077)
6. *Epidemiology/(9142)
7. *Incidence/(1536)
8. *Prevalence/(2300)
9. incidence.ti. (28941)
10. prevalence.ti. (32779)
11. epidemiol$.ti. (38186)
12. etiolog$.ti. (10334)
13. aetiolog$.ti. (3549)
14. or/20–27 (116821)
15. (uk or united kingdom or england or scotland or britain or wales or great britain).in. (842631)
16. 10 and 19 and 29 (262)
17. united kingdom.cp. or united kingdom.sh. (2004975)
18. (uk or united kingdom or england or scotland or britain or wales or great britain).in,cp. (2306024)
19. 10 and 28 and 32 (161)
20. limit 33 to (human and english language) (155)
21. from 34 keep 3 (1)
22. exp hearing disorder/or exp hearing impairment/or hearing loss/or exp congenital deafness/or exp perception deafness/(43021)
23. hearing loss.ti,ab. (15512)
24. deafness.ti,ab. (7544)
25. (hearing adj5 disability).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (410)
26. 1 or 6 or 7 or 8 or 36 or 37 or 38 or 39 (46690)
27. 28 and 32 and 40 (188)
28. limit 41 to (human and english language) (180)

EMBASE – 1980 to 2006 Week 39

1. exp hearing loss/(10251)
2. exp hearing loss, sensorineural/(7929)
3. "Hearing Loss, Bilateral"/(10251)
4. exp deafness/(34934)
5. Deafness/ep, et [Epidemiology, Etiology] (2073)
6. severe to profound deafness.mp. (18)
7. (severe adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (272)
8. (profound adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (456)
9. 7 or 8 (672)
10. or/1–9 (35041)
11. exp Incidence/(98905)

12. exp Prevalence/(111736)
13. incidence.ti. (28941)
14. prevalence.ti. (32779)
15. Risk Factors/(180965)
16. epidemiol$.ti. (38186)
17. etiolog$.ti. (10334)
18. aetiolog$.ti. (3549)
19. or/11–18 (411077)
20. *Epidemiology/(9142)
21. *Incidence/(1536)
22. *Prevalence/(2300)
23. incidence.ti. (28941)
24. prevalence.ti. (32779)
25. epidemiol$.ti. (38186)
26. etiolog$.ti. (10334)
27. aetiolog$.ti. (3549)
28. or/20–27 (116821)
29. (uk or united kingdom or england or scotland or britain or wales or great britain).in. (842631)
30. 10 and 19 and 29 (262)
31. united kingdom.cp. or united kingdom.sh. (2004975)
32. (uk or united kingdom or england or scotland or britain or wales or great britain).in,cp. (2306024)
33. 10 and 28 and 32 (161)
34. limit 33 to (human and english language) (155)
35. from 34 keep 3 (1)
36. exp hearing disorder/or exp hearing impairment/or hearing loss/or exp congenital deafness/or exp perception deafness/(43021)
37. hearing loss.ti,ab. (15512)
38. deafness.ti,ab. (7544)
39. (hearing adj5 disability).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (410)
40. 1 or 6 or 7 or 8 or 36 or 37 or 38 or 39 (46690)
41. 28 and 32 and 40 (188)
42. limit 41 to (human and english language) (180)

Quality of life searches

Cochrane Library – CENTRAL – Issue 3/2006
Ovid MEDLINE® – 1966 to October Week 1 2006

1. exp hearing loss/(37541)
2. exp hearing loss, sensorineural/(14163)
3. "Hearing Loss, Bilateral"/(1190)
4. exp deafness/(17839)
5. severe to profound deafness.mp. (15)
6. (severe adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (327)
7. (profound adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (542)
8. Hearing Loss, Unilateral/(34)
9. exp Hearing Disorders/(49630)
10. deaf$.ti,ab. (19840)
11. (hear$adj5 loss).ti,ab. (19425)
12. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 (61873)
13. exp ear, middle/or exp ear, inner/(47537)
14. 12 or 13 (98248)
15. Cochlear Implants/(4019)
16. Cochlear Diseases/(557)
17. Cochlear Implantation/(1476)
18. (cochlear adj10 (implant$or device$)).ti,ab. (4660)
19. cochleostomy.ti,ab. (105)
20. 15 or 16 or 17 or 18 or 19 (6110)
21. 14 and 20 (4985)
22. limit 21 to (humans and english language) (3788)
23. exp ECONOMICS/(363215)
24. exp ECONOMICS, HOSPITAL/(14367)
25. exp ECONOMICS, PHARMACEUTICAL/(1688)
26. exp ECONOMICS, NURSING/(3702)
27. exp ECONOMICS, DENTAL/(3386)
28. exp ECONOMICS, MEDICAL/(10140)
29. exp "Costs and Cost Analysis"/(128174)
30. Cost-Benefit Analysis/(39904)
31. VALUE OF LIFE/(4933)
32. exp MODELS, ECONOMIC/(4990)
33. exp FEES/and CHARGES/(7018)
34. exp BUDGETS/(9317)
35. (economic$or price$or pricing or financ$or fee$or pharmacoeconomic$or pharma economic$).tw. (315608)
36. (cost$or costly or costing$or costed).tw. (187439)
37. (cost$adj2 (benefit$or utilit$or minim$or effective$)).tw. (48416)
38. (expenditure$not energy).tw. (10082)
39. (value adj2 (money or monetary)).tw. (565)
40. budget$.tw. (10335)
41. (economic adj2 burden).tw. (1320)
42. "resource use".ti,ab. (2035)
43. or/23–41 (733038)
44. news.pt. (105269)
45. letter.pt. (581686)
46. editorial.pt. (199009)
47. comment.pt. (317617)
48. or/44–47 (923485)
49. 43 not 48 (676925)
50. 22 and 49 (148)
51. 49 and 12 (1988)

52. limit 51 to (humans and english language) (1453)
53. 23 or 24 or 25 or 26 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 37 or 39 or 41 or 42 (392242)
54. 12 and 53 (714)
55. limit 54 to (humans and english language) (563)
56. 50 or 55 (644)
57. 54 not 50 (647)
58. 55 not 50 (496)
59. *"Hearing Loss"/(3032)
60. from 58 keep 12,14,17,21,27,47,50,53,61,71,73,87–88,90–91,93 (16)
61. exp Hearing Disorders/ec [Economics] (132)
62. (61 not 60) or 50 (257)
63. 61 not (60 or 50) (109)
64. limit 63 to (humans and english language) (86)
65. from 64 keep 16,18,20,26–27,31,34–37,41–42,51,57,59,64–65,77 (18)
66. exp Hearing Loss, Sensorineural/ec [Economics] (38)
67. limit 66 to (humans and english language) (30)
68. 67 not (64 or 60 or 50) (0)
69. 50 or 60 or 65 (182)
70. from 69 keep 1–182 (182)
71. value of life/(4933)
72. quality adjusted life year/(2787)
73. quality adjusted life.ti,ab. (2002)
74. (qaly$or qald$or qale$or qtime$).ti,ab. (1580)
75. disability adjusted life.ti,ab. (336)
76. daly$.ti,ab. (410)
77. health status indicators/(10691)
78. (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirstysix or shortform thirty six or short form thirty six or short form thirtysix or short form thirty six).ti,ab. (5977)
79. (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).ti,ab. (669)
80. (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab. (717)
81. (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab. (14)
82. (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab. (268)
83. (euroqol or euro qol or eq5d or eq 5d).ti,ab. (888)
84. (hql or hqol or h qol or hrqol or hr qol).ti,ab. (2089)
85. (hye or hyes).ti,ab. (51)
86. health$year$equivalent$.ti,ab. (31)
87. health utilit$.ab. (371)
88. (hui or hui1 or hui2 or hui3).ti,ab. (392)
89. disutil$.ti,ab. (76)
90. rosser.ti,ab. (59)
91. quality of well being.ti,ab. (204)
92. quality of wellbeing.ti,ab. (1)
93. qwb.ti,ab. (111)
94. willingness to pay.ti,ab. (740)
95. standard gamble$.ti,ab. (414)
96. time trade off.ti,ab. (353)
97. time tradeoff.ti,ab. (122)
98. tto.ti,ab. (235)
99. (index adj2 well being).mp. (257)
100. (quality adj2 well being).mp. (455)
101. (health adj3 utilitind).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (277)
102. ((multiattribute$or multi attribute$) adj3 (health ind$or theor$or health state$or utilit$or analys$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (148)
103. quality adjusted life year$.mp. (3647)
104. (15D or 15 dimension$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (556)
105. (12D or 12 dimension$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (184)
106. rating scale$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (49351)
107. linear scal$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (293)
108. linear analog$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (695)
109. visual analog$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (14155)
110. (categor$adj2 scal$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (695)
111. or/71–110 (92434)
112. (letter or editorial or comment).pt. (825243)
113. 111 not 112 (89676)
114. (Vertigo Symptom Scale or Hearing Disability Handicap Scale or Tinnitus Severity Questionnaire or Sense of Coherence Scale).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (78)

115. 113 or 114 (89735)
116. 22 and 115 (50)
117. 12 and 115 (340)
118. limit 117 to (humans and english language) (297)
119. 116 or 118 (297)
120. *"Quality of Life"/(24727)
121. from 119 keep 5 (1)
122. from 116 keep 1–50 (50)
123. 12 and 120 (143)
124. limit 123 to (humans and english language) (127)
125. 124 not 116 (116)
126. from 125 keep 1,3–4,6–7,10–15,17–18,20,23–26,28,30–31,33,37–43,45–49,53–55,58–59,61–63,65–71,73–76,78–80,82–84,86–88,91–93,95,97,100–104,109–110,112,115–116 (77)

EMBASE – 1980 to 2006 Week 42

1. exp Hearing Impairment/(35130)
2. exp Congenital Deafness/(2189)
3. Perception Deafness/(6698)
4. hearing loss/or mixed hearing loss/or unilateral hearing loss/(10402)
5. exp ear disease/(47570)
6. severe to profound deafness.mp. (18)
7. (severe adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (272)
8. (profound adj4 deaf$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (457)
9. deaf$.ti,ab. (14005)
10. (hear$adj5 loss).ti,ab. (16667)
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (76451)
12. cochlea prosthesis/(4382)
13. Implantation/(13947)
14. (cochlea$adj10 (implant$or device$or prosthe$)).ti,ab. (4402)
15. 12 or 13 or 14 (18298)
16. 11 and 15 (3685)
17. limit 16 to (humans and english language) (2935)
18. exp "quality of life"/(71508)
19. quality adjusted life year/(2694)
20. quality adjusted life.ti,ab. (1882)
21. (qaly$or qald$or qale$or qtime$).ti,ab. (1467)
22. disability adjusted life.ti,ab. (316)
23. daly$.ti,ab. (356)
24. (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirstysix or shortform thirty six or short form thirty six or short form thirtysix or short form thirty six).ti,ab. (5643)
25. (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).ti,ab. (758)
26. (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab. (655)
27. (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab. (11)
28. (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab. (177)
29. (euroqol or euro qol or eq5d or eq 5d).ti,ab. (869)
30. (hql or hqol or h qol or hrqol or hr qol).ti,ab. (1955)
31. (hye or hyes).ti,ab. (25)
32. health$year$equivalent$.ti,ab. (23)
33. ((health or cost) adj5 utilit$).ab,ti. (2116)
34. (hui or hui1 or hui2 or hui3).ti,ab. (298)
35. disutil$.ti,ab. (71)
36. rosser.ti,ab. (48)
37. quality of well being.ti,ab. (175)
38. quality of wellbeing.ti,ab. (5)
39. qwb.ti,ab. (96)
40. willingness to pay.ti,ab. (724)
41. standard gamble$.ti,ab. (373)
42. time trade off.ti,ab. (334)
43. time tradeoff.ti,ab. (115)
44. tto.ti,ab. (248)
45. (index adj2 well being).mp. (235)
46. (quality adj2 well being).mp. (417)
47. (health adj3 utilitind).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (255)
48. ((multiattribute$or multi attribute$) adj3 (health ind$or theor$or health state$or utilit$or analys$)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (134)49 quality adjusted life year$.mp. (3325)
49. (15D or 15 dimension$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (550)
50. (12D or 12 dimension$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (177)
51. rating scale$.mp. [mp=title, abstract, subject headings, heading word, drug trade name,

original title, device manufacturer, drug manufacturer name] (50552)
52. linear scal$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (245)
53. linear analog$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (641)
54. visual analog$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (15842)
55. (categor$adj2 scal$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (595)
56. or/18–56 (137020)
57. (letter or editorial or comment).pt. (496255)
58. 57 not 58 (128805)
59. 59 and 17 (141)

Ovid MEDLINE® In-Process & Other Non-Indexed Citations – 20 October 2006

1. severe to profound deafness.mp. (1)
2. (severe adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word] (10)
3. (profound adj4 deaf$).mp. [mp=title, original title, abstract, name of substance word] (10)
4. deaf$.ti,ab. (367)
5. (hear$adj5 loss).ti,ab. (645)
6. (cochlear adj10 (implant$or device$)).ti,ab. (177)
7. 1 or 2 or 3 or 4 or 5 (919)
8. 6 and 7 (86)
9. limit 8 to english language (71)
10. (economic$or price$or pricing or pharmacoeconomic$or pharma economic$).tw. (3526)
11. (cost$or budget$).tw. (7307)
12. (cost$adj2 (benefit$or utilit$or minim$)).tw. (407)
13. (value adj2 (money or monetary)).tw. (23)
14. 10 or 11 or 12 or 13 (9869)
15. 9 and 14 (4)
16. 7 and 14 (22)
17. 15 or 16 (22)
18. quality adjusted life.ti,ab. (114)
19. (qaly$or qald$or qale$or qtime$).ti,ab. (120)
20. disability adjusted life.ti,ab. (23)
21. daly$.ti,ab. (25)
22. (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirstysix or shortform thirty six or short form thirty six or short form thirtysix or short form thirty six).ti,ab. (358)
23. (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).ti,ab. (77)
24. (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab. (49)
25. (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab. (0)
26. (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab. (0)
27. (euroqol or euro qol or eq5d or eq 5d).ti,ab. (74)
28. (hql or hqol or h qol or hrqol or hr qol).ti,ab. (126)
29. (hye or hyes).ti,ab. (0)
30. health$year$equivalent$.ti,ab. (0)
31. health utilit$.ab. (13)
32. (hui or hui1 or hui2 or hui3).ti,ab. (27)
33. disutil$.ti,ab. (1)
34. rosser.ti,ab. (0)
35. quality of well being.ti,ab. (4)
36. quality of wellbeing.ti,ab. (1)
37. qwb.ti,ab. (2)
38. willingness to pay.ti,ab. (60)
39. standard gamble$.ti,ab. (14)
40. time trade off.ti,ab. (10)
41. time tradeoff.ti,ab. (3)
42. tto.ti,ab. (14)
43. (index adj2 well being).mp. (8)
44. (quality adj2 well being).mp. (17)
45. (health adj3 utilitind).mp. [mp=title, original title, abstract, name of substance word] (11)
46. ((multiattribute$or multi attribute$) adj3 (health ind$or theor$or health state$or utilit$or analys$)).mp. [mp=title, original title, abstract, name of substance word] (5)
47. quality adjusted life year$.mp. (113)
48. (15D or 15 dimension$).mp. [mp=title, original title, abstract, name of substance word] (40)
49. (12D or 12 dimension$).mp. [mp=title, original title, abstract, name of substance word] (18)
50. rating scale$.mp. [mp=title, original title, abstract, name of substance word] (621)
51. linear scal$.mp. [mp=title, original title, abstract, name of substance word] (97)
52. linear analog$.mp. [mp=title, original title, abstract, name of substance word] (23)
53. visual analog$.mp. [mp=title, original title, abstract, name of substance word] (592)

54. (categor$adj2 scal$).mp. [mp=title, original title, abstract, name of substance word] (20)
55. or/18–54 (2167)
56. (letter or editorial or comment).pt. (21716)
57. 55 not 56 (2150)
58. 9 and 57 (3)
59. 7 and 57 (10)
60. 59 or 58 (10)

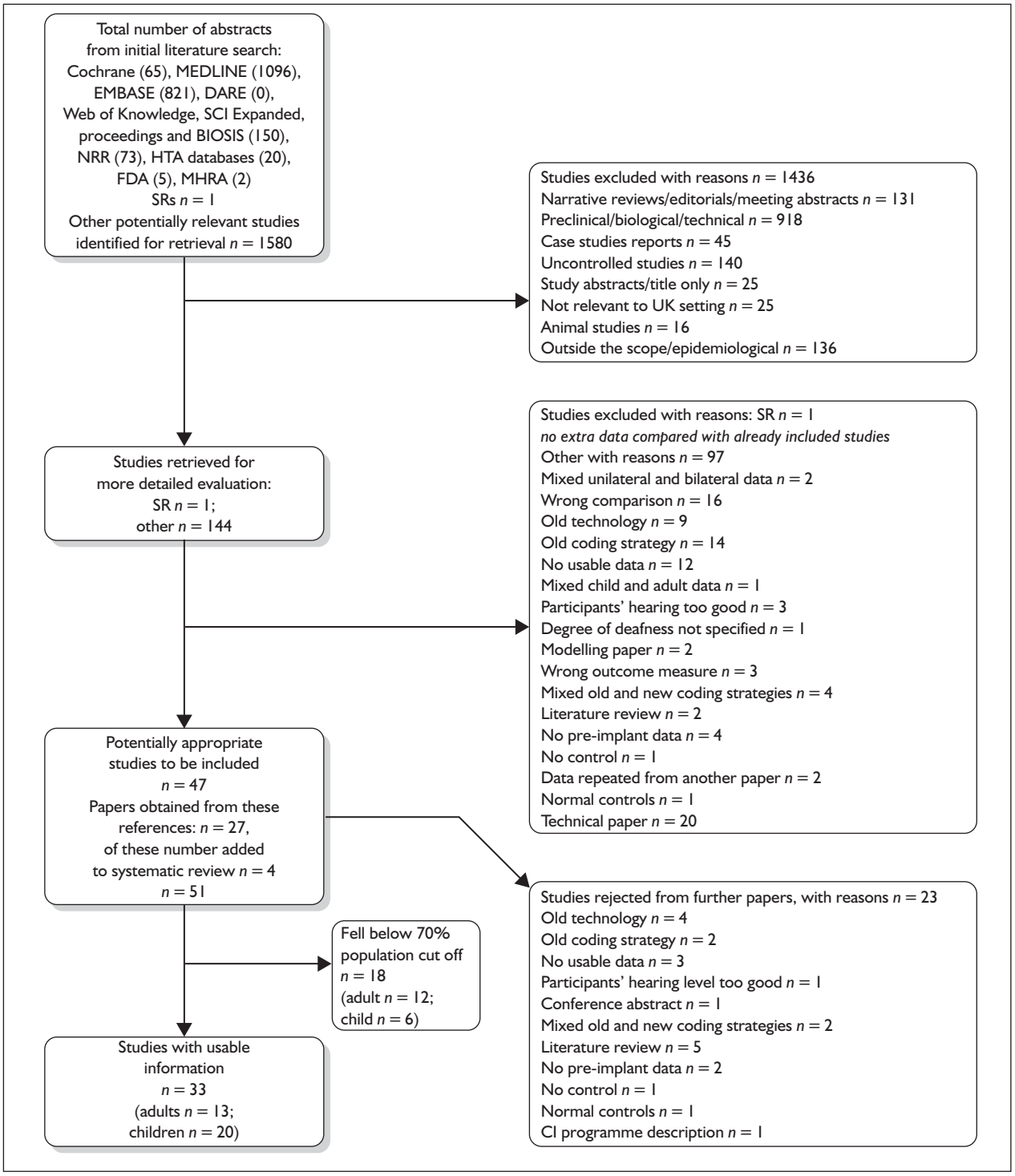
PsycINFO including PsycARTICLES – 1985 to present

1. severe to profound deafness.mp. (2)
2. (severe adj4 deaf$).mp. [mp=title, abstract, heading word, table of contents, key concepts] (52)
3. (profound adj4 deaf$).mp. [mp=title, abstract, heading word, table of contents, key concepts] (64)
4. exp Hearing Disorders/(6023)
5. deaf$.ti,ab. (4905)
6. (hear$adj5 loss).ti,ab. (1927)
7. 1 or 2 or 3 or 4 or 5 or 6 (7807)
8. Cochlear Implants/(506)
9. (cochlear adj10 (implant$or device$)).ti,ab. (641)
10. 8 or 9 (666)
11. 7 and 10 (458)
12. (random$or trial$).mp. [mp=title, abstract, heading word, table of contents, key concepts] (80452)
13. 11 and 12 (17)
14. limit 13 to (human and english language) (16)
15. from 14 keep 1–16 (16)
16. exp "quality of life"/(11199)
17. 11 and 16 (7)

Appendix 2

Quality assessment

QUOROM statement flow diagram for the quality of studies in this technology assessment review



Appendix 3

Summary of study characteristics and results tables

For definitions of outcome measures see *Tables 6–10*.

Children

TABLE 92 *Summary of study characteristics: unilateral cochlear implants vs non-technological support – children*

Study	Design	Participants	Intervention and control	Outcomes – auditory	Outcomes – speech
Harrison 2005[1] Canada Length of follow-up: 8 years	Pre/post retrospective longitudinal analysis Own control	$n = 82$ Age: 2–13 years Mean age at implant: 5.4 years Degree of deafness: severe to profound Prelingually deaf Mean time between deafness and implantation: 5.4 years	Nucleus multichannel cochlear implant Coding strategy: NR		Speech perception: closed set: TAC; open set: GASP, PB-K
Nikolopoulos 2004[2] UK Length of follow-up: 5 years	Pre/post prospective Repeated measures Own control	$n = 82$ Age: < 7 years at implantation Mean age at implant: NR Degree of deafness: profound Prelingually deaf Mean time between deafness and implantation: NR	Nucleus multichannel cochlear implant Coding strategy: NR		Speech perception: TROG
Manrique 2004[3] Spain Length of follow-up: 12 years	Pre/post prospective Repeated measures Own control	$n = 182$ Age: 0–14 years Mean age at implant: 4.8 years Degree of deafness: profound Prelingually deaf Mean time between deafness and implantation: NR	Multichannel cochlear implants: Nucleus 22, $n = 86$; Nucleus 24, $n = 96$ Coding: SPEAK	Auditory: PTA	

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Study	Design	Participants	Intervention and control	Outcomes – auditory	Outcomes – speech
Staller 2002[4] Canada Length of follow-up: 6 months Funded by Cochlear Corporation	Pre/post prospective Repeated measures Own control	*n* = 78 Age: 1–17 years Mean age at implant: ≥ 2 years = 1.5 years; 2–4 years = 3.4 years; > 5 years = 9.7 years Degree of deafness: profound Pre- and postlingually deaf Mean time between deafness and implantation: NR	Nucleus 24 cochlear implant Coding strategy: ACE, SPEAK, CIS	Auditory: 1–2 years: IT-MAIS ≥ 5 years: MAIS	Speech perception: 1–2 years: ESP, GASP, MLNT ≥ 5 years: ESP, GASP, LNT, HINT-C
MED-EL 2001[5] USA Length of follow-up: 6 months Funded by MED-EL for the FDA	Pre/post prospective Repeated measures Own control	*n* = 82 Age: 18 months–17 years Mean age at implant: 8.8 years Degree of deafness: profound Pre- and postlingually deaf Mean time between deafness and implantation: NR	COMBI 40+ cochlear implant Coding strategy: CIS PRO+	Auditory: < 5 years: IT-MAIS, auditory skills checklist, open set word recognition ≥ 5 years: IT-MAIS, auditory skills checklist, all communication skills checklist	Speech perception: < 5 years: ESP, GASP ≥ 5 years: ESP, MLNT, LNT, GASP, BKB
Nikolopoulos 1999[6] UK Length of follow-up: 6 years	Pre/post prospective Repeated measures Own control	*n* = 126 Age: > 7 years at implantation Mean age at implant: 4.2 years Degree of deafness: NR Pre- and postlingually deaf Mean time between deafness and implantation: NR	Nucleus multichannel cochlear implant Coding strategy: NR		Speech perception: closed set: IMST; open set: CDT, CAP Speech production: SIR

continued

TABLE 92 *Summary of study characteristics: unilateral cochlear implants vs non-technological support – children (continued)*

Study	Design	Participants	Intervention and control	Outcomes – auditory	Outcomes – speech
Illg 1999[7] Germany Length of follow-up: 3 years	Pre/post prospective Repeated measures Own control	*n* = 167 Age: 1.25–15 years Mean age at implant: NR Degree of deafness: severe to profound Pre- and postlingually deaf Mean time between deafness and implantation: NR	Cochlear implants CLARION 1.2 Coding: CIS		Speech perception: closed set: pattern perception, two-syllable word test, monosyllable word test, Minimal Pairs Test; open set: TAPS, monosyllable word test, GASP sentences, common phrases, Mr Potato Head
Kessler 1997[8] USA Length of follow-up: 6 months Funded by Advanced Bionics	Pre/post CLARION clinical trial, prospective Repeated measures Own control	*n* = 49 Age: ≥ 7 years Mean age at implant: NR Degree of deafness: not reported (assumed same as adult trial – profound) Pre- and postlingually deaf Mean time between deafness and implantation: NR	CLARION multistrategy cochlear implant system Coding strategy: CIS 93%; compressed analogue 7%	Auditory: MAIS	Speech perception: PB-K, ESP, GASP, common phrases, Mr Potato Head

NR, not reported.

TABLE 93 *Summary of study results: unilateral cochlear implants vs non-technological support – children*

	Audiological				Speech perception	
Study	**Outcome**	**Mean (%) (SD)**	***p*-value**	**Direction of change**	**Outcome**	**Mean (%)**
Harrison 2005[1] *n* = 82						% mean difference from baseline at 5 years
					TAC (*n* = 71)	6.36
					GASP (*n* = 71)	84.25
					PB-K words (*n* = 77)	48.28
					PB-K phonemes (*n* = 77)	65.85
Nikolopoulos 2004[2] *n* = 82					TROG	% mean difference from normal percentiles
					Preimplant:	
					< 1%	98
					1–25%	2
					25–75%	0
					75–100%	0
					Post 3 years:	
					< 1%	60
					1–25%	33
					25–75%	3.5
					75–100%	3.5
					Post 5 years:	
					< 1%	33
					1–25%	47
					25–75%	17
					75–100%	3
Manrique 2004[3] *n* = 182	PTA 1 year	Mean difference from baseline: 81.53 (5.00)	< 0.05	+		
Staller 2002[4] *n* = 78	12 months–2 years: IT-MAIS	No usable data reported				Total mean % difference between baseline and 3 months' follow-up
	3–17 years: MAIS (*n* = 20)	Total mean % difference between baseline and 6 months post activation: + 16	–	+ in favour of cochlear implants	3–17 years:	
					ESP:	
					Pattern (*n* = 25)	+ 37.0
					Spondee (*n* = 18)	+ 44.2

		Speech production					
p-value	Direction of change	Outcome	Mean (%) (SD)	*p*-value	Direction of change	*p*-value	Direction of change
–	+ early implant[a]						
–	+ early implant						
–	+ early implant						
–	+ early implant						
–	+ early implant						
–	+ early implant						
–	+ early implant						
–	+ early implant						
–	+ early implant						
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–	+ early implant						
–	+ early implant						
–	+ early implant						
–	+ early implant						
–	+ early implant						
–	+						
–	+						

continued

TABLE 93 *Summary of study results: unilateral cochlear implants vs non-technological support – children (continued)*

	Audiological				Speech perception	
Study	**Outcome**	**Mean (%) (SD)**	***p*-value**	**Direction of change**	**Outcome**	**Mean (%)**
					Monosyllable ($n = 17$)	+ 35.4
					6 months' follow-up	
					GASP ($n = 25$)	+ 37.1
					≥ 5–17 years:	
					LNT ($n = 43$)	+34.5
					HINT-C ($n = 21$)	+49.5
MED-EL 2001[5] $n = 82$; < 5 years = 35, ≥ 5 years = 47	Auditory skills checklist	Results not reported			< 5 years:	Total mean % difference between baseline and 6 months post activation
		Total mean % difference between baseline and 6 months post activation			ESP:	
					Pattern perception	70.0
					Spondee ID	50.0
					Monosyllable word ID	48.0
					GASP	59.0
	IT-MAIS	53.7	–	+	≥ 5 years:	
	MAIS	38.2	–	+	ESP:	
					Pattern perception	68.0
					Spondee ID	79.0
					Monosyllable word ID	68.0
					GASP	79.0
					MLNT	73.5
					LNT	76.0
					BKB sentences	53.0
					All ages:	
					Communicative skills checklist	39.5
Nikolopoulos 1999[6] $n = 126$		Correlation with age at implantation				Correlation with age at implantation
$n = 74$	Post 2 years:				Post 2 years:	
	CAP	–0.32	0.006	+ early implant	IOWA	+ 0.06
					CDT	+ 0.05

		Speech production					
***p*-value**	**Direction of change**	**Outcome**	**Mean (%) (SD)**	***p*-value**	**Direction of change**	***p*-value**	**Direction of change**
–	+						
–	+						
–	+						
–	+						
–	+						
–	+						
–	+						
–	+						
–	+						
–	+						
–	+						
–	+						
–	+						
			Correlation with age at implantation				
		Post 2 years:					
NS		SIR	–0.06	NS		NS	
NS							

continued

TABLE 93 *Summary of study results: unilateral cochlear implants vs non-technological support – children (continued)*

	Audiological				Speech perception	
Study	**Outcome**	**Mean (%) (SD)**	***p*-value**	**Direction of change**	**Outcome**	**Mean (%)**
n = 50	Post 3 years:				Post 3 years:	
	CAP	–0.48	0.0007	+ early implant	IOWA	–0.24
					CDT	–0.38
n = 29	Post 4 years:				Post 4 years:	
	CAP	–0.58	0.002	+ early implant	IOWA	–0.44
					CDT	–0.58
Illg 1999[7]					> 7 years:	2-year differences from baseline, mean % (SD)
n = 167						
					TAPS	56 (70.93)
					Monosyllable word test	54 (73.31)
					GASP sentences	8 (36.12)
					Mr Potato Head	22 (78.73)
					Pattern perception	59
					Two-syllable test	54
					One-syllable test	51
					Minimal Pairs Test	10
					7–15 years:	
					TAPS	37 (67.96)
					Monosyllable word test	36 (62.23)
					GASP sentences	23 (50.93)
					Common phrases	15 (43.09)
					Pattern perception	39
					Two-syllable test	25
					One-syllable test	35
					Minimal Pairs Test	15
Kessler 1997[8]		Total mean % difference between baseline and 6 months post activation				Total mean % difference between baseline and 6 months post activation
n = 49						
	MAIS (*n* = 14)	+ 20	–	+ in favour of cochlear implantation	PB-K (*n* = 49)	+ 31.5
					ESP (*n* = 49)	+ 54.0
					GASP (*n* = 49)	+ 33.0
					Mr Potato Head (*n* = 49)	+ 45.0

NS, not significant.
a All children showed benefit from cochlear implants; children implanted younger showed greater benefit.

		Speech production					
***p*-value**	**Direction of change**	**Outcome**	**Mean (%) (SD)**	***p*-value**	**Direction of change**	***p*-value**	**Direction of change**
		Post 3 years:					
NS		SIR	–0.49	NS		NS	
0.007	+ early implant						
		Post 4 years:					
0.02	+ early implant	SIR	–0.49	0.01	+ early implant	0.01	+ early implant
0.0008	+ early implant						
–	+						
–	+						
–	+						
–	+						
–	+						
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TABLE 94 *Summary of study characteristics: unilateral cochlear implants vs acoustic hearing aids – children*

Study	Design	Intervention group	Control group	Intervention and control	Outcomes – speech
Mildner 2006[9] Croatia $n = 49$ Length of follow-up: NA	Cross-sectional	$n = 29$ Age: mean 11.6 (7–15) years Degree of deafness: profound > 98 dB HL Mean age at implant: 8.2 (2–12) years Mean time between deafness and implantation: NR	$n = 20$ Age: mean 12.9 (7–15) years Degree of deafness: profound > 98 dB HL	Intervention: ESPrit 3G 45%, Tempo+ 24%, Spectra 21%, CIS PRO+ 7%, SPRINT 3% Coding strategy: ACE 48%, CIS 31%, SPEAK 21% Control: acoustic hearing aids	Speech perception: 52 one- and two-syllable words, words presented visually and orally, 34 word pairs, five nonsense words
Tomblin 1999[10] USA $n = 58$ Length of follow-up: 5 years	Non-randomised controlled prospective trial with cross-overs allowed	$n = 29$ Age, mean (SD): 10 (2.9) years Degree of deafness: profound Prelingually deaf Mean (SD, range) age at implant: 4.76 (1.57, 2–13) years Mean time between deafness and implantation: NR	$n = 29$ Age, mean (SD): 9 (3.65) years Degree of deafness: profound Prelingually deaf	Intervention: Nucleus 22 Coding strategy: NR Control: acoustic hearing aids	Speech perception: RITLS Speech production: expressive sentence usage, IPSyn
Osberger 1999[11] USA $n = 58$ Length of follow-up: 1.5 years	Pre/post prospective Repeated measures Own control	Participants $n = 58$ Age, mean: 5.4 years Degree of deafness: profound, mean = 110 dB HL Prelingually deaf Mean age at implant: 5.4 years Mean time between deafness and implantation: NR		Intervention: CLARION multistrategy implant Coding strategy: CIS Control: acoustic hearing aids	Speech perception: closed set: ESP; open set: GASP, PB-K Recognition of key words: Mr Potato Head, common phrases test

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Study	Design	Intervention group	Control group	Intervention and control	Outcomes – speech
Svirsky 1999[12] USA *n* = 297 Length of follow-up: 1.5 years	Non-randomised controlled retrospective trial	*n* = 222 Age, mean: 4.2 years Degree of deafness: profound Prelingually deaf Mean age at implant: 4.2 years Duration of implant use: NR Mean time between deafness and implantation: NR	*n* = 75 Age, mean: 8.4 years Degree of deafness: profound Prelingually deaf	Intervention: CLARION multistrategy implant Coding strategy: CIS Control: acoustic hearing aids	Speech perception: PB-K
Osberger 1998[13] USA *n* = 30 Length of follow-up: 0.5 years	Pre/post prospective Repeated measures Own control	*n* = 30 Age, mean: 9.0 years Degree of deafness: profound, mean 110 dB HL Prelingually deaf Mean age at implant: 9.0 years Duration of implant use: NR Mean time between deafness and implantation: 8.2 years		Intervention: CLARION multistrategy implant Coding strategy: CIS Control: acoustic hearing aids	Speech perception: closed set: ESP; open set: GASP, PB-K
van den Borne 1998[14] Netherlands *n* = 43 Length of follow-up: 3 years	Non-randomised controlled prospective trial	*n* = 20 Age, mean (range): 5.9 (3.3–9.3) years Degree of deafness: profound, ≥ 110 dB HL Prelingually deaf Mean age at implant: NR Mean time implant use: 3.4 (1.7–6.0) years Mean time (range) between deafness and implantation: 5.9 (1.5–8.6) years	*n* = 23 Age, mean: 3.6 years Degree of deafness: profound, ≥ 110 dB HL Prelingually deaf	Intervention: Nucleus multichannel Coding strategy: NR Control: acoustic hearing aids	Speech production: SECSHIC Auditory outcomes: basal auditory ability, average unaided pure-tone thresholds

NR, not reported.

TABLE 95 *Summary of results: unilateral cochlear implants vs acoustic hearing aids – children*

Study	Outcome	Cochlear implants		Acoustic hearing aids		Difference	*p*-value	Direction of change
Mildner 2006[9]	**Speech perception (one time point):**	***n***	**Mean (%)**	***n***	**Mean (%)**			
n = 49	Overall word scores	29	82.8	20	60.4	22.4	0.000	+
	Response to vowels:							+
	Nonsense words	29	57.5	20	31.6	25.9		+
	Minimal pairs	29	66.6	20	46.5	20.1	0.000	+
	Individual vowels	29	76.8	20	55.0	21.8	≤ 0001	+
	Individual vowel pairs	29	76.0	20	54.0	22.0		+
	Response to consonants:							
	According to features	29	61.0	20	41.4	19.6		+
	According to consonant category	29	61.0	20	39.3	21.7	< 0.01	+
Tomblin 1999[10]	**Speech perception:**	***n***	**Mean (SD)**	***n***	**Mean (SD)**			
n = 58	RITLS at latest visit	28	42.2 (15.7)	–				
	Speech production:							
	Difference in scores between baseline and 5-year follow-up			–				+
	IPSyn:							
	Total final score	29	60.3 (15.2)	29	40.7 (17.4)	19.6 (23.10)		+
	Subscale scores:							
	Noun phrase	29	17.8	29	13.8	4.1		+
	Verb phrase	29	18.1	29	11.0	7.1		+
	Negative question	29	1.9	29	1.0	0.9		+
	Sentence structure	29	21.5	29	15.4	6.1		+
	Correlation of age in regression analysis:							
	IPSyn score and age	29	0.4	–			< 0.03	+
	IPSyn score and months of cochlear implant use	29	0.6	–			< 0.0001	+
	IPSyn score and months of cochlear implant use with age partialled out	29	0.6	–			< 0.001	+

Study	Outcome	Cochlear implants		Acoustic hearing aids		Difference	*p*-value	Direction of change
Osberger 1999[11]	**Speech perception:**	***n***	**Mean**	***n***	**Mean**			
n = 58	Difference between preoperative scores with acoustic hearing aids and 18-month postoperative scores with cochlear implants:							
	ESP	58	83.2	58	26.7	56.5	< 0.0001	+
	GASP	58	55.0	58	9.7	45.3	< 0.0001	+
	Mr Potato Head	58	31.4	58	2.1	29.3	< 0.0001	+
	Common phrases	58	24.5	58	4.6	19.9	< 0.0001	+
	PK-B phonemes	58	47.1	58	4.3	42.8	< 0.0001	+
	PK-B words	58	27.6	58	0	27.6	< 0.0001	+
Svirsky 1999[12]	**Speech perception:**	***n***	**Mean (95% CI)**	***n***	**Mean (95% CI)**			
n = 297	Difference between preoperative and final scores: cochlear implant scores compared with predicted hearing aid scores:	Measured cochlear implants		Predicted acoustic hearing aid				
	PB-K words:			Insufficient data given to calculate the mean difference in scores				
	< 6 years at 18 months	222	6.3			–	–	+
	6–12 years at 12 months	222	6.5			–	–	+
Osberger 1998[13]	**Speech perception:**	***n***	**Mean % score at 6 months**	***n***	**Mean % score at baseline**			
n = 30	Difference between preoperative scores with acoustic hearing aids and 6-month scores postoperatively with cochlear implants:							
	ESP monosyllable words	30	62.7	30	26.8	35.9	–	+
	GASP words	30	60.1	30	15.7	44.4	–	+

continued

TABLE 95 *Summary of results: unilateral cochlear implants vs acoustic hearing aids – children (continued)*

Study	Outcome	Cochlear implants		Acoustic hearing aids		Difference	*p*-value	Direction of change
	GASP sentences	30	43.7	30	8.6	35.1	–	+
	PB-K phonemes	30	39.6	30	6.3	33.3	–	+
	PB-K words	30	49.6	30	0	49.6	–	+
van den Borne 1998[14] *n* = 43	**Auditory:**	***n***	**Mean**	***n***	**Mean**			
	Difference between preoperative scores and 24-month scores:							
	Basal sound identification	20	+3.5	23	+1.9	1.6	–	+
	Speech perception:							
	SECSHIC	20	+7.0	23	+6.9	0.1	–	+/–

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TABLE 96 *Summary of study characteristics: unilateral cochlear implant vs bilateral cochlear implants – children*

Study	Design	Participants 1	Participants 2	Intervention	Outcomes – speech
Peters 2007[15] USA Length of follow-up: NA Funded by Cochlear America	Cross-sectional Own control Sequential implants[a]	*n* = 30 Age range: 3–13 years; group 1: 3–5 years, group 2: 5.1–8 years, group 3: 8.1–13 years Mean age at implant: NR	Degree of deafness: severe to profound Prelingually deaf: NR Mean time between deafness and implantation: NR Time between implants: ≥ 5 years	First ear: Nucleus 22, 24 or 24 contour Coding strategy: NR Second ear: Nucleus 24 contour or Nucleus 24 contour advance	Speech perception: Group 1 MLNT words; group 2 LNT words; group 3 LNT words, HINT-C sentences, CRISP
Litovsky 2006[16] USA Length of follow-up: NA Funded by Cochlear America	Cross-sectional Own control Sequential implants	*n* = 13 Age range: 3–6 years Mean age at implant: NR Time between implants, mean (range): 4.6 (1.6–13.0) years	Degree of deafness: severe to profound Prelingually deaf: 12; postlingually deaf: 1 Time between deafness and implantation, mean (range): 3.1 (1.5–6.0) years	Nucleus 22 = 1; Nucleus 24 = 22; Nucleus 24 contour = 1; BI CLARION (platinum/auria) = 2 Coding strategy: NR	Auditory: MAA
Kuhn-Inacker 2004[17] Germany Length of follow-up: NA Funded by MED-EL	Cross-sectional Own control Timing of second implant: simultaneous[b] = 1; sequential = 17	*n* = 18 Age range: 2.11–9.1 years Age range at first implant: 2.0–6.11 years; age range at second implant: 2.1–8.0 years Time between implants: range 0 years–4 years 5 months	Degree of deafness: severe to profound Prelingually deaf: 14; postlingually deaf: 4 Mean time between deafness and implantation: NR	MED-EL COMBI 40, MED-EL COMBI 40+ Coding strategy: NR	Speech perception: discrimination in noise; discrimination in quiet: Gottinger test

NA, not applicable; NR, not reported.

a Devices were implanted at two different times.

b Devices were implanted in the same operation.

TABLE 97 *Summary of results: unilateral cochlear implants vs bilateral cochlear implants – children*

Study	Outcome	First side only	Second side only	Bilateral		*p*-value	Direction of change
Peters 2007[15] *n* = 30	**Speech perception:**	***n***	**Mean % (range)**	***n***	**Mean % (range)**		
	In quiet, differences between unilateral implant and bilateral implants at 12 months after the second implant:						
	MLNT words (group 1)	7	84.5 (71–96)	7	92.3 (71–100)	NS	+
	LNT words (group 2)	8	68.0	8	81.0	NS	+
	LNT words (group 3)	13	81.0	13	86.5	NS	+
	HINT-C sentences (group 3)	12	89	12	94.0	NS	+
	In noise, differences between unilateral implant and bilateral implants at 9 months after the second implant:	Difference					
		n	**Mean % (range)**				
	CRISP all participants:						
	Noise directed at the front	19	6.8 (62.1–68.9)			0.018	+
	Noise directed at first implant	15	13.2 (68.5–55.3)			0.0001	+
	Noise directed at second implant	18	– (72.2–79.0)			0.018	+

Study	Outcome	First side only		Second side only		Bilateral		*p*-value	Direction of change
Litovsky 2006[16] *n* = 13	**Auditory:**	***n***	**Mean % score**	***n***	**Mean % score**	***n***	**mean % score**		
	MAA in degrees azimuth (data are reported on the nine children who found the task easiest)	9	27.7	9	29.7	9	16.2	< 0.001	+
	Outcome	Left ear only		Right ear only		Bilateral		*p*-value	Direction of change
Kuhn-Inacker 2004[17] *n* = 18	**Speech perception:**	***n***	**Mean %**	***n***	**Mean %**	***n***			
	Discrimination in quiet – Gottinger test	18	70	18	71	18			+
		Unilateral				Bilateral		*p*-value	Direction of change
	Discrimination in noise	18	60			18			+

NS, not significant.

TABLE 98 *Summary of study characteristics: bilateral cochlear implants vs unilateral cochlear implant and an acoustic hearing aid – children*

Study	Design	Participants 1	Participants 2	Intervention	Outcomes
Peters 2007[15] USA Length of follow-up: 1 year *n* = 30 Funded by Cochlear America	Pre/post repeated measures Own control Sequential implants	*n* = 30 Age range: 3–13 years; group 1: 3–5 years, group 2: 5.1–8 years, group 3: 8.1–13 years Mean age at implant: NR Degree of deafness: severe to profound Prelingually deaf: NR Mean time between deafness and implantation: NR Time between implants: ≥ 5 years		First ear: Nucleus 22, 24 or 24 contour Coding strategy: NR Second ear: Nucleus 24 contour or Nucleus 24 contour advance Coding strategy: NR	Speech perception: group 1 MLNT words; group 2 LNT words; group 3 LNT words, HINT-C sentences
Litovsky 2006[16] USA *n* = 19 Length of follow-up: NA Participants had measures taken between one and three times. The latest time recorded was between 3 and 15 months after the second implant (mean 7 months) Funded by Cochlear America	Cross-sectional Sequential implants ≥ 1.6 years apart	Bilateral cochlear implant: *n* = 13 Age range: 3–6 years Mean age (range) at implant: 4.6 (1.6–13.0) years Time between implants, mean (range): 3.9 (1–11.6) years Degree of deafness: severe to profound Prelingually deaf: 12; postlingually deaf: 1 Time between deafness and implantation, mean (range): 3.1 (1.5–6.0) years	Cochlear implant + acoustic hearing aid: *n* = 6 Age range: 4–14 years Mean age (range) at implant: 5.6 (3.6–8.6) years Degree of deafness: severe to profound Prelingually deaf: NR; postlingually deaf: NR Time between deafness and implantation, mean (range): 5.3 (3.6–8.6) years	Bilateral cochlear implant group: Nucleus 22 = 1; Nucleus 24 = 22; Nucleus 24 contour = 1; Bi CLARION (platinum/auria) = 2 Coding strategy: NR Cochlear implant + acoustic hearing aid group: Nucleus 24 = 2; Nucleus 24 contour = 2; CLARION II HiFocus = 1; MED-EL C40+ = 1 Acoustic hearing aids Coding strategy: NR	Auditory: MAA

Study	Design	Participants 1	Participants 2	Intervention	Outcomes
Litovsky 2006[18] USA *n* = 20 Length of follow-up: NA Data collection varied between 3 and 26 months post second implant (mean 13.5 months)	Cross-sectional	Bilateral cochlear implants: *n* = 10 Age range: 3–14 years Mean age at implant: NR Time between implants: NR Degree of deafness: NR Prelingually deaf: NR; postlingually deaf: NR Time between deafness and implantation: NR	Cochlear implants and acoustic hearing aids: *n* = 10 Age range: 6–14 years Mean age at implant: NR Degree of deafness: NR Prelingually deaf: NR Postlingually deaf: NR Time between deafness and implantation: NR	Bilateral cochlear implant group: Nucleus 22 = 3; Nucleus 24 = 12; Nucleus 24 contour = 3; BI CLARION = 2 Coding strategy: NR Cochlear implant + acoustic hearing aid group: Nucleus 22 = 1; Nucleus 24 = 6; Nucleus Freedom = 1; MED-EL C40+ = 2 Acoustic hearing aids Coding strategy: NR	Auditory: MAA Speech production: CRISP

NR, not reported.

TABLE 99 *Summary of results: bilateral cochlear implants vs unilateral cochlear implant and an acoustic hearing aid – children*

Study	Outcome	One cochlear implant + acoustic hearing aid		Bilateral		*p*-value	Direction of change
Peters 2007[15]	**Speech perception:**	***n***	**Mean % (range)**	***n***	**Mean % (range)**		
n = 30	In quiet, differences between pre second implant and 1-year follow-up post second implant:						
	MLNT words (group 1)	7	67.3 (38–100)	7	92.3 (71–100)	0.003	+
	LNT words (group 2)	8	71.0	8	81.0	NS	+
	LNT words (group 3)	13	69.4	13	86.0	0.004	+
	HINT-C sentences (group 3)	12	88.0	13	94.0	NS	+
Litovsky 2006[16]	**Auditory:**	***n***	**Mean degrees azimuth**	***n***	**Mean degrees azimuth**		
n = 19	Differences in the ability to detect the direction of sound, MAA degrees azimuth	5	44.4	12	28.0	< 0.05	+
Litovsky 2006[18]	**Auditory:**	***n***	**Mean degrees azimuth (SD)**	***n***	**Mean degrees azimuth (SD)**		
n = 20	Differences in the ability to detect the direction of sound, MAA degrees azimuth	8	27.0 (± 23)	6	20.0 (± 10)	< 0.05	+
	Speech production:						
	CRISP test:	*n*	Mean % (range)	*n*	Mean % (range)		
	In quiet	10	–24.0 (–18 to –35)	10	–20.0 (–12 to –28)	< 0.0001	+
	In noise	10	–17.5 (–13 to –18)	10	–11.0 (–5 to –17)	< 0.005	+

NS, not significant.

TABLE 100 *Summary of study characteristics: children's quality of life with cochlear implants*

Study	Design	Participants – intervention	Participants – control	Outcomes
Damen 2006[19] Netherlands *n* = 9	Retrospective controlled study	Parents of children or children with Usher syndrome type 1: *n* = 7 Age, mean (SD): 12.4 (2.9) years Used cochlear implants	Parents of children or children with Usher syndrome type 1: *n* = 2 Age, mean: 15.4 years Without cochlear implants	NCIQ, ULS
Huber 2005[20] Austria *n* = 44	Cross-sectional survey	Children 8- to 16-years-old (*n* = 37) and their parents (*n* = 7) Used cochlear implants		KINDLr
Spahn 2004[21] Germany *n* = 94	Cross-sectional survey	Parents of children with cochlear implants: mothers: *n* = 52; fathers: *n* = 42		Symptom checklist 90-R, Everyday Life Questionnaire
Chmiel 2000[22] USA *n* = 22	Cross-sectional survey	Parents of children with cochlear implants: *n* = 11; age range: 3–20 years; length of cochlear implant use, mean years: 4.0 Children (same families) with cochlear implants: *n* = 11; age range: 6–20 years; length of cochlear implant use, mean years: 4.78		Quality of life questionnaire

TABLE 101 *Summary of study results: children's quality of life with cochlear implants*

Study	Quality of life outcomes			*p*-value	Direction of change
Damen 2006[19] *n* = 9		Intervention (*n* = 7), mean (range)	Control (*n* = 2), mean (range)		
	NCIQ – parents:				
	Sound perception – basic	75.4 (52.5–85.0)	21.3 (0–42.5)		+
	Sound perception – advanced	67.9 (32.5–95.0)	21.3 (10.0–32.5)		+
	Speech production	42.5 (22.5–57.5)	47.0 (20.0–75.0)		–
	Self-esteem	65.4 (40.0–90.0)	50.0 (47.5–52.5)		+
	Activity limitations	74.2 (63.9–88.9)	53.6 (47.2–60.0)		+
	Social interactions	70.9 (60.0–77.5)	53.8 (47.5–60.0)		+
		Intervention (*n* = 7), median (range)	Control (*n* = 2), median (range)		
	ULS:				
	Access to information	2.3 (1–4)	2.5 (2–4)		
	Communication	1.75 (0–5)	1.75 (0–2)		
	Mobility	0.5 (0–1)	1 (0–1)		
Huber 2005[20] *n* = 44 (children = 37; parents = 7		Cochlear implant children, mean (SD; 95% CI)	Hearing children, mean (SD)		
	KINDLr:				
	Age range 8–12 years (*n* = 18)	64.6 (8.9; 60.4–68.7); parents 80.8 (5.4; 78.4–83.3)	76.8 (8.6)	< 0.001	–
	Age range 13–16 years (*n* = 19)	72.1 (10.3; 66–78.1); parents 76.3 (10.2; 70.3–82.3)			
Spahn 2004[21] *n* = 94	SCL 90-R – distress	Parents (*n* = 94): global severity index: T = 78.7%	Norms: global severity index: T = 21.3%		
	EDLQ – quality of life	Cochlear implant parents, mean score = 168	Cardiac patients, mean score = 151	Students, mean score = 172	

Study	Quality of life outcomes			*p*-value	Direction of change
Chmiel 2000[22]		Parents ($n = 11$), mean score	Children ($n = 11$), mean score		
$n = 22$	Quality of life questionnaire mean benefit ratings, scale of 1–5 (5 is better):				
	Hearing environmental sounds	4.55	4.40		
	Imitate or produce speech	4.30	3.64		
	Speech-reading and understanding	4.00	3.89		
	Child's attitude or behaviour	3.64	4.00		
	Larger variety of activities	3.55	4.18		
	Make new friends	3.45	3.72		
	Child's level of frustration	3.45	3.55		
	Telephone use	3.18	3.73		
	Mean benefit rating	3.76	3.89		
	Mean problem ratings:				
	Extra care needed	2.36	2.64		
	Loud sounds bothersome	2.09	3.16		
	Cumbersome equipment	2.09	2.91		
	Acceptance by peers	2.00	2.20		
	Embarrassment from device	1.82	1.82		
	Child's resistance to wearing	1.55	1.70		
	Mean problem rating	1.99	2.40		

Adults

TABLE 102 *Summary of study characteristics: unilateral cochlear implants vs non-technological support – adults*

Study	Design	Participants 1	Participants 2	Intervention	Outcomes
UK Cochlear Implant Study Group 2004[23,24] UK Length of follow-up: 9 months	Prospective cohort Own control	*n* = 311: TC = 227; MHU = 84[a] Participants were defined by their preoperative BKB scores, MHUs aided acoustically and without lip-reading Age (range): 50.6 (16–82) years	Degree of deafness: profound Mean (range) dB HL: 115 (85–140); TC = 117.1 (116–119); MHU = 108.7 (107–111) Postlingually deaf mean (range) duration of deafness: TC = 14.2 (12.2–16.2) years; MHU = 10.6 (8.1–13.0) years	Nucleus CI 24 = 215; CLARION = 63; COMBI 40+ = 38 Coding strategy: CIS, SPEAK, compressed analogue	Speech perception: BKB sentences, AVGN, CUNY sentences Quality of life: HUI-3, GHSI, GBI
Mawman 2004[25] 2004 UK Length of follow-up: > 18 months	Retrospective pre/post analysis Own control	*n* = 214 Age at implantation, mean (SD): 50.4 (12.8) years	Degree of deafness: severe to profound Postlingually deaf Mean time (range) between deafness and implantation: 16.3 years (2 months–53 years)	Nucleus 22M = 88; Nucleus 24M = 56; Nucleus 24K Contour = 23; Nucleus 24K = 7; Nucleus 24 double array = 1; CLARION High Focus II = 1; MED-EL C40+ = 41; MED-EL C40 = 17; MED-EL S = 3; Ineraid = 2 Coding strategy: Nucleus: SPEAK or ACE; MED-EL: CIS; CLARION: MPS; Ineraid: CIS	Speech perception: BKB sentences, AB monosyllables
Parkinson 2002[26] USA Length of follow-up: 3 months	Pre/post repeated measures prospective Own control	*n* = 216 Age at implantation, mean (SD): 50.4 (12.8) years	Degree of deafness: severe to profound Postlingually deaf Mean time (SD) between deafness and implantation: 10.9 (11.8) years	Nucleus 24 contour Coding strategy: ACE, SPEAK, CIS	Speech perception: HINT sentences, CUNY, CNC
Kessler 1997[8] USA Length of follow-up: 24 months	Pre/post repeated measures prospective Own control	*n* = 238 Age at implantation, mean (range): 51 (18–81) years	Degree of deafness: profound Postlingually deaf Mean time (range) between deafness and implantation: 11 (0–73) years	CLARION multistrategy Coding strategy: CIS, 93%; CA, 7%	Speech perception: MAC vowels, MAC consonants, CUNY lip-reading, CUNY implant, NU-6 mono words, telephone sentences

a TC (traditional candidates) scored 0 on the BKB sentence test; MHU (marginal hearing aid users) are included in this table for completeness only as their preimplantation comparison is with acoustic hearing aids; their results are considered in the next comparison.

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TABLE 103 *Summary of study results: unilateral cochlear implants vs non-technological support – adults*

	Speech perception					Quality of life				
Study	**Outcome**	**Mean (95% CI)**		***p*-value**	**Direction of change**	**Outcome**	**Mean (95% CI)**		***p*-value**	**Direction of change**
UK Cochlear Implant Study Group 2004[23] *n* = 316	Mean difference between preimplant and 9-month postoperative scores:	TC	MHU			Mean difference between preimplant and 9-month postoperative scores:	TC	MHU		
	BKB	53.0 (48–58)	44.0 (37–51)	< 0.05	+	HUI-3	0.22(0.19, 0.24)	0.15 (0.11–0.19)	< 0.01	+
	AVGN	68.0 (63–71)	31.0 (26–37)	< 0.001	+	GHSI	0.17 (0.15–0.18)	0.19 (0.16–0.22)		+
						GBI	45.0 (43–48)	42.0 (37–47)		+
	Association with age at implantation at 9 months (*n* = 311):	All				Association with age at implantation at 9 months (*n* = 311):	All			
	< 30 years: BKB 39	58.0 (48–58)			+	< 30 years: HUI-3 39	0.24 (0.18–0.3)			+
	AVGN	50.0 (40–60)			+	GHSI	20.0 (16–24)			+
	< 30–40 years: BKB 35	49. 0 (35–62)			+	GBI	45 (38–52)			+
	AVGN	57.0 (45–69)			+	< 30–40 years: HUI-3 35	0.23 (0.16–0.29)			+
	< 40–50 years: BKB 59	49.0 (40–58)			+	GHSI	16.0 (12–20)			+
	AVGN	55.0 (45–64)			+	GBI	43 (36 to 49)			+
	< 50–60 years: BKB 75	53.0 (44–62)			+	< 40–50 years: HUI-3 59	0.21 (0.16–0.26)			+
	AVGN	51.5 (44–59)			+	GHSI	17.5 (13–22)			+
	< 60–70 years: BKB 70	47.5 (40–55)			+	GBI	42 (36–47)			+

continued

TABLE 103 *Summary of study results: unilateral cochlear implants vs non-technological support – adults (continued)*

	Speech perception				Quality of life			
Study	**Outcome**	**Mean (95% CI)**	***p*-value**	**Direction of change**	**Outcome**	**Mean (95% CI)**	***p*-value**	**Direction of change**
	AVGN	64.5 (57–72)		+	< 50–60 years: HUI-3 75	0.16 (0.11–0.20)		+
	≥ 70 years: BKB 33	46.0 (36–56)		+	GHSI	21.0 (16–23)		+
	AVGN	69.0 (59–79)		+	GBI	45 (39–50)		+
					< 60–70 years: HUI-3 70	0.20 (0.15–0.24)		+
					GHSI	18.0 (13–20)		+
					GBI	47 (42–52)		+
					≥ 70 years: HUI-3 33	0.17 (0.09–0.25)		+
					GHSI	12.0 (8–16)		+
					GBI	40 (34–45)		+
	Association with age, 9-month and preimplant scores:	Pearson correlation coefficients			Association with age, 9-month and preimplant scores:	Pearson correlation coefficients		
	BKB	$r = -0.062$	NS	+	HUI-3	$r = -0.108$	NS	+
	AVGN	$r = 0.164$	< 0.01	+	GHSI	$r = -0.114$	< 0.05	+
					GBI	$r = 0.003$	NS	+
	Association with duration of deafness in years, change at 9 months from baseline ($n = 311$)	All			Association with duration of deafness in years, change at 9 months from baseline ($n = 311$)	All		
	0 to < 10 years: BKB 168	58 (53–63)		+	0 to < 10 years: HUI-3 168	0.23 (0.2–0.25)		+
	AVGN	63 (58–67)		+	GHSI	20 (18–22)		+
	10 to < 20 years: BKB 64	49 (51–67)		+	GBI	47 (44–50)		+
	AVGN	56 (47–64)		+	10 to < 20 years: HUI-3 64	0.18 (0.14–0.21)		+

Study	Speech perception				Quality of life			
	Outcome	Mean (95% CI)	*p*-value	Direction of change	Outcome	Mean (95% CI)	*p*-value	Direction of change
	20 to < 30 years: BKB 29	43 (30–56)		+	GHSI	18 (15–20)		+
	AVGN	60 (50–70)		+	GBI	45 (40–50)		+
	30–40 years: BKB 24	26 (14–38)		+	20 to < 30 years: HUI-3 29	0.23 (0.15–0.30)		+
	AVGN	44 (27–60)		+	GHSI	16 (11–20)		+
	40–50 years: BKB 15	9 (–1 to 18)		+	GBI	42 (35–48)		+
	AVGN	32 (17–46)		+	30–40 years: HUI-3 24	0.13 (0.05–0.21)		+
	≥ 50 years: BKB 11	14 (–2 to 30)		+	GHSI	9 (4–14)		+
	AVGN	37 (13–60)		+	GBI	36 (28–43)		+
	Both measures declined significantly as duration of deafness increased	$r < -0.203$	< 0.01	+	40–50 years: HUI-3 15	0.90 (–0.03 to 0.21)		+
					GHSI	8 (0–15)		+
					GBI	31 (15–47)		+
					≥ 50 years: HUI-3 11	0.80 (–0.01 to 0.25)		+
					GHSI	12 (3–21)		+
					GBI	27 (11–38)		+
					Quality of life measures declined significantly as duration of deafness increased	$r < -0.203$	< 0.01	+

continued

TABLE 103 *Summary of study results: unilateral cochlear implants vs non-technological support – adults (continued)*

	Speech perception				Quality of life			
Study	**Outcome**	**Mean (95% CI)**	***p*-value**	**Direction of change**	**Outcome**	**Mean (95% CI)**	***p*-value**	**Direction of change**
	Outcome	***n*, mean (SD)**	***p*-value**	**Direction of change**				
Mawman 2004[25] $n = 214$	Difference in scores between preimplant and 18 months post implant:							
	BKB sentences	$n = 44$, 63.97 (42.96)		+				
	AB monosyllable words	$n = 43$, 49.91 (30.87)		+				
Parkinson 2002[26] $n = 216$	Difference in scores between preimplant and 3 months post implant:							
	Open set in quiet:							
	CUNY sentences	$n = 56$, 67.0 (33.69)	< 0.001	+				
	CUNY words	$n = 56$, 34.5 (23.12)	< 0.001	+				
	HINT sentences	$n = 56$, 57.0 (31.79)	< 0.001	+				
	Open set in noise:							
	CUNY sentences in noise (+10 dB SNR)	$n = 56$, 55.2 (35.60)	< 0.001	+				

	Speech perception				Quality of life			
Study	**Outcome**	**Mean (95% CI)**	***p*-value**	**Direction of change**	**Outcome**	**Mean (95% CI)**	***p*-value**	**Direction of change**
	Outcome	***n*, mean %**	***p*-value**	**Direction of change**				
Kessler 1997[8] *n* = 238	Difference in scores between preimplant and 12 months post implant:							
	MAC vowels	*n* = 120, 39		+				
	MAC consonants	*n* = 120, 39		+				
	CUNY sentences	*n* = 119, 42		+				
	Difference in scores between preimplant and 24 months post implant:	*n*, median %						
	CID sentences	*n* = 61, 89		+				
	NU-6 monosyllabic word test	*n* = 61, 36		+				
	Everyday telephone sentences	*n* = 61, 73		+				

MHU, marginal hearing aid users; NS, not significant; TC, traditional candidates.

TABLE 104 *Summary of study characteristics: unilateral implants vs acoustic hearing aids – adults*

Study	Design	Participants 1	Participants 2	Intervention and control	Outcomes
UK Cochlear Implant Study Group 2004[23a] UK *n* = 84 Length of follow-up: 9 months	Prospective cohort Own control	MHU = 84[b] Participants were defined by their preoperative BKB scores, aided acoustically and without lip-reading Age, mean (range): 50.6 (16–82) years	Degree of deafness: profound Mean (range) dB HL: 108.7 (107–111) Postlingually deaf mean duration of deafness: 10.6 (8.1–13.0) years	Nucleus CI 24 = 215; CLARION = 63; COMBI 40+ = 38 Coding strategy: CIS, SPEAK, compressed analogue	Speech perception: BKB sentences, AVGN Quality of life: HUI-3, GHSI, GBI
Ching 2004[27] Australia *n* = 21 Length of follow-up: NA	Cross-sectional Own control	Age, mean (range): 62 (25–84) years Degree of deafness: severe or profound: mean (SD) 83.3 (18.9) dB HL Postlingually deaf	Time between implantation and recruitment: > 6 months Duration of deafness, mean (range): 29 (8–62) years Duration of cochlear implant use, mean (range): 4 (1.0–8.8) years	*Intervention:* Nucleus CI 24 = 18; Nucleus CI 22 = 3 Coding strategy: ACE, SPEAK *Control:* Acoustic hearing aids	Auditory: direction of sound Speech perception: BKB/A sentences, functional performance, structured interview questionnaire
MED-EL 2001[5] USA *n* = 106 (fitted); efficacy *n* = 63, safety *n* = 50 Length of follow-up: 6 months Funded by MED-EL	Pre/post prospective repeated measures Own control	Degree of deafness: severe or profound: ≥ 70 dB HL Postlingually deaf: *n* = 45 Age at implantation, mean: 53 years Duration of deafness, mean: 28 years	Prelingually deaf: *n* = 18 Age at implantation: 37.4 years Duration of deafness, mean: 36.5 years	*Intervention:* COMBI 40+ Coding strategy: CIS PRO+ *Control:* Preoperative acoustic hearing aids	Speech perception: in quiet: HINT sentences, CUNY; in noise: HINT sentences, CNC words Speech production: telephone sentences, CID sentences Quality of life: questionnaire, adverse events
Hamzavi 2001[28] Austria *n* = 37 Length of follow-up: 36 months	Prospective cohort	Intervention group: *n* = 22 Age, mean (range): 53 (31–76) years Degree of deafness: severe/profound: mean (SD): 105 (5) dB HL Postlingually deaf Time between implantation and baseline measures: 36 months	Control group: *n* = 15 Age, mean (range): 53 (23–71) years Degree of deafness: severe/profound: mean (SD): 85 (10) dB HL	*Intervention:* COMBI 40/40+ Coding strategy: NR *Control:* Acoustic hearing aids	Speech perception: in quiet and noise: HSM sentences, open set

a This is the same study as reported in the previous section but with the marginal hearing aid user population.

b Marginal hearing aid users (MHU) scored > 0 with either ear on the BKB sentence test.

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TABLE 105 *Summary of study results: unilateral cochlear implant vs acoustic hearing aids – adult*

Study	Outcome	Cochlear implant		*p*-value	Direction of change
UK Cochlear Implant Study Group 2004[23] *n* = 84	**Speech perception:** Mean difference between preimplant scores with acoustic hearing aids and 9-month postoperative cochlear implant scores:				
	BKB	44.0 (37–51)			+
	AVGN	31.0 (26–37)			+
	Quality of life: Mean difference between preimplant scores with acoustic hearing aids and 9-month postoperative cochlear implant scores:				
	HUI-3	0.15 (0.11–0.19)			+
	GHSI	0.19 (0.16–0.22)			+
	GBI	42.0 (37.0–47.0)			+
	Outcome	**Cochlear implant**	**Acoustic hearing aid**	***p*-value**	**Direction of change**
	Auditory:	*n*, mean (95% CI)	*n*, mean (95% CI)		
Ching 2004[27] *n* = 21	Sound direction (averaged root mean squared errors, horizontal localization)	*n* = 18, 4.5 (4.1–4.9)	*n* = 18, 4.6 (4.3–4.9)	NS	+/–
	Speech perception:				
	BKB sentences in noise	*n* = 21, 39	*n* = 21, 2	< 0.001	
	Functional performance in real life, questionnaire scores:				
	Use	*n* = 20, 87 (83–92)	*n* = 20, 84 (78–90)	< 0.001	+
	Quiet	*n* = 20, 51 (40–62)	*n* = 20, 22 (12–31)	< 0.001	+
	Noise	*n* = 20, 45 (43–56)	*n* = 20, 18 (12–25)	< 0.001	+
	Environmental alertness	*n* = 20, 46 (40–52)	*n* = 20, 28 (22–34)	< 0.001	+
	Overall score	*n* = 20, 59 (52–65)	*n* = 20, 40 (36–44)	< 0.001	+

continued

TABLE 105 *Summary of study results: unilateral cochlear implants vs acoustic hearing aids – adult (continued)*

Study	Outcome	Cochlear implant		*p*-value	Direction of change
	Outcome	**≤ 25 years hearing loss**	**≥ 25 years hearing loss**	***p*-value**	**Direction of change**
MED-EL 2001[5]	**Speech perception:**	**Mean %**	**Mean %**		
n = 63	Changes between baseline with hearing aid and 6 months follow-up with cochlear implants:				
	Postlingually deaf (*n* = 45):				
	In quiet:				
	HINT sentences	+70	+50		+
	CUNY sentences	+72	+56		+
	In noise:				
	HINT sentences	+61	+41		
	CNC words	+40	+29		
	Prelingually deaf (*n* = 18):				
	In quiet:				
	HINT sentences	+19			+
	CUNY sentences	+ 21			+
	In noise:				
	HINT sentences	+ 12			+
	CNC words	+ 10			+
	CID sentences via telephone				
	Speech production:				+
	CID sentences via telephone, mean increase in ability between baseline and 6-month follow-up:				
	Postlingually deaf	+ 68	+ 42		+
	Prelingually deaf	+ 20			+
	Outcome	**All**		***p*-value**	**Direction of change**
	Quality of life:				
	Impact of the implant on lifestyle (*n* = 45):	% gaining benefit			
	Quite positive	40			+
	Very positive	44			+

Study	Outcome	Cochlear implant		*p*-value	Direction of change
	Quality of life questionnaire:				
	Postlingually deaf:				
	Impact of the implant on lifestyle ($n = 45$):	% gaining benefit			
	Quite positive	40			+
	Very positive	44			+
	Significant improvement shown on 18 items in the questionnaire			< 0.05	+
	Prelingually deaf ($n = 18$):	% gaining benefit			
	Quite positive	33			+
	Very positive	50			+
	Adverse events ($n = 106$)				
	Total adverse events (people/events)	20/22			+
	Medical events	7			+
	Device related	15			
	Outcome	**Cochlear implant**	**Acoustic hearing aid**	***p*-value**	**Direction of change**
Hamzavi 2001[28] $n = 37$	**Speech perception:**	***n*, mean (SD)**	***n*, mean (SD)**		
	Changes between preimplantation and 12 months post implantation:				
	HSM:				
	Numbers	$n = 22$, 90 (10)	$n = 15$, 35 (11.40)		+
	Monosyllables	$n = 22$, 43 (20)	$n = 15$, 18 (12.17)		+
	Changes between 12 months and 36 months post implantation:				
	HSM sentences:				
	In quiet:	$n = 22$, 16.2 (34.61)	$n = 15$, 0	< 0.001	+
	In noise:				
	SNR: 15 dB	$n = 22$, 14.4 (38.09)	$n = 15$, 0	< 0.007	+
	SNR: 10 dB	$n = 22$, 19.5 (30.69)	$n = 15$, 0	< 0.003	+
	SNR: 5 dB	$n = 22$, 13.0 (9.62)	$n = 15$, 0	< 0.006	+
	SNR: 0 dB	$n = 22$, 3.5 (4.68)	$n = 15$, 0	0.1	+

NS, not significant.

TABLE 106 *Summary of study characteristics: bilateral cochlear implants vs unilateral cochlear implants – adults*

Study	Design	Participants 1	Participants 2	Intervention	Outcomes – speech
Summerfield 2006[29] UK *n* = 24 Length of follow-up: 9 months	RCT Waiting list control subjects Sequential implants	Age, median (range): 56 (29–82) years Already use one implant	Postlingually deaf Degree of deafness: NR Length of time using one implant, median (IQR): 2.7 (1.7) years	*Intervention:* Nucleus CI 24 Coding strategy: SPEAK *Control:* Waiting list control subjects	Auditory: SSQ Quality of life, GHSI, HUI-3, VAS quality of life, EQ-5D, tinnitus questionnaire
Litovsky 2006[30] USA *n* = 37 Length of follow-up: 6 months Funded by Cochlear America	Pre/post prospective Repeated measures Own control Simultaneous implants	Age, median (range): 53.6 (26.6–86.6) years	Postlingually deaf Degree of deafness: severe to profound: > 70 dB HL Duration of deafness, mean (range): 5.6 (1 month–15 years) years	Nucleus CI 24 contour Coding strategy: SPEAK, ACE, CIS	Speech perception: in quiet: CNC, HINT; in noise: BKB Quality of life: APHAB
Ramsden 2005;[31] UK multicentre trial of bilateral cochlear implants UK *n* = 29 Length of follow-up: 9 months	RCT Waiting list control subjects Sequential implants	Age, mean (range): 57 (29–87) years Time between implants, mean (range): 36 (12–84) months	Degree of deafness: severe to profound: mean (range): 102.79 (67 to > 130) dB HL Duration of deafness, mean (range): 6.14 (1–15) years	Nucleus CI 24 (M or RST) Coding strategy: SPEAK, ACE	Speech perception: in quiet: CUNY, CNC; in noise: CUNY noise front, CUNY noise left, CUNY noise right Adverse events
Verschuur 2005[32] UK *n* = 20 Length of follow-up: NA Trial funded by Cochlear Ltd	Cross-section (from larger RCT) Own control Sequential implants	Age at first implant, mean (SD): 58.9 (12.67) years Time between implants, mean (SD): 37.0 (14.40) months	Degree of deafness: NR Postlingually deaf Duration of deafness (years): first ear, mean (SD): 7.9 (4.34); second ear, mean (SD): 10.0 (3.73)	Nucleus CI 24M, Nucleus CI 24K Coding strategy: SPEAK, ACE	Auditory: detection of sound direction
Laszig 2004[33] Germany and Switzerland *n* = 37 Length of follow-up: 6 months	Pre/post prospective Repeated measures Own control Simultaneous = 22; sequential = 15	Age: ≥18 years Age at bilateral implantation, mean (SD): 46 (11) years Time between sequential implants, mean (SD): 2.2 (1.4) years	Degree of deafness: profound Time between deafness and implantation, mean: 10 years	Nucleus CI 24 Coding strategy: SPEAK	Speech perception: in quiet and noise: HSM, OLSA; in quiet: FMWT

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TABLE 107 *(a) Summary of study results: unilateral cochlear implant vs bilateral cochlear implants – adults. Summerfield 2006[29] (n = 24)*

Outcome	Two cochlear implants			One cochlear implant			Direction of change		Pooled within groups pre/post		Direction of change
	Differences between measuring sessions, 9 months from 3 months and 3 months from 1 month preimplant										
Auditory:	***n***	**Mean (95% CI)**	***p*-value**	***n***	**Mean (95% CI)**	***p*-value**	***n***		**Mean (95% CI)**	***p*-value**	
SSQ: spatial hearing:											
3 months	12	1.46 (0.83–2.09)	< 0.01	12	–	NS	24	+	1.56 (0.95–2.17)	< 0.001	+
9 months	12	0.71 (0.08–1.33)	< 0.01	12	–	NS	24	+	2.00 (1.47–2.53)	< 0.001	+
Qualities of hearing:											
3 months	12	0.5 (–0.3 to 1.30)	NS	12	–	NS	24	+	0.9 (0.5–1.3)	< 0.05	+
9 months	12	1.76 (–0.6 to 2.8)	< 0.01	12	–	NS	24	+	0.7 (0.2–1.2)	< 0.05	+
Hearing for speech:											
3 months	12	1.1 (–1.00 to 2.3)	NS	12	–	NS	24	+	6.00 (0.00–12.00)	< 0.01	+
9 months	12	1.1 (–0.3 to 2.5)	NS	12	–	NS	24	+	9.00 (3.00–15.00)	< 0.01	+
Quality of life:											
GHSI:											
3 months	12	0.00 (–8.00 to 8.00)	NS	12	–	NS	24	+	3.00 (–1.00 to 6.00)	NS	+
9 months	12	6.00 (–7.00 to 13.00)	NS	12	–	Ns	24	+	4.00 (1.00 to 7.00)	< 0.05	+
HUI-3:											
3 months	12	0.1 (–0.1 to 0.3)	NS	12	–	NS	24	+	–0.03 (–0.11 to 0.08)	NS	–
9 months	12	0.11 (–0.08 to 0.29)	NS	12	–	NS	24	+	–0.01 (–0.1 to 0.08)	NS	–

continued

TABLE 107 *(a) Summary of study results: unilateral cochlear implant vs bilateral cochlear implants – adults. Summerfield 2006[29] (n = 24) (continued)*

Outcome	Two cochlear implants			One cochlear implant			Direction of change		Pooled within groups pre/post		Direction of change
VAS overall quality of life:											
3 months	12	–1.5 (–9.5 to 6.5)	NS	12	–	NS	24	+	–0.06 (–0.15 to 0.03)	NS	–
9 months	12	–3.0 (-9.0 to 3.0)	NS	12	–	NS	24	+	–0.06 (0.12–00)	NS	–
EQ-5D:											
3 months	12	–0.04 (–0.13 to 0.05)	NS	12	–	NS	24	+	–3.5 (–0.11 to 4.00)	NS	–
9 months	12	–0.01 (–0.09 to 0.07)	NS	12	–	NS	24	+	–4.5 (–12.0 to 3.0)	< 0.05	–
Tinnitus questionnaire:											
3 months	12	10 (–5.0 to 25.0)	NS	12	–	ns	24	+	12 (1.0 to 23)	< 0.05	+
9 months	12	14 (–1.0 to 29)	NS	12	–	NS	24	+	8 (–4.0 to 20)	NS	+

NS, not significant; SBNP, speech at better ear, noise at poorer; SPNB, speech at poorer ear, noise at better.

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TABLE 107 *(b) Summary of study results: unilateral cochlear implant vs bilateral cochlear implants – adults. Litovsky 2006[30] (n = 37)*

Outcome	*n*	Left ear alone	Right ear alone	Bilateral	*p*-value	Direction of change
Speech perception:						
Difference between preimplant and 6 months post activation:		**Mean %**	**Mean %**	**Mean %**		
In quiet:						
CNC	33	40.1	35.6	54	0.0001	+
HINT	33	66.0	66.9	76	0.0001	+
Difference between 3 and 6 months post activation:						
In noise:						
BKB:						
Noise left	29	–1.8	–2.7	–3.5	0.0001	+
Noise right	29	–0.8	–1.1	–1.1	0.0001	+
Noise front	29	–0.5	–1.3	0.02	0.0001	–
Speech in noise:						
Binaural redundancy effect	34	17.0 (3)	14.0 (3)	9.5 (3)		+
		Noise right, mean (SD)	**Noise left, mean (SD)**			
Head shadow effect	32	4.95 (3.6)	6.34 (3.8)		Binaural advantage $p < 0.0001$	
		Unilateral mean % (+1 SE)		Bilateral mean % (+1 SE)		
Quality of life:						
APHAB:						
Communication	30	4.4 (0.2)		5.7 (0.2)	< 0.0001	+
Reverberant conditions	30	3.0 (0.2)		4.4 (0.2)	< 0.0001	+
Background noise	30	3.1 (0.2)		4.4 (0.2)	< 0.0001	+
Aversion to sounds	30	3.2 (0.3)		3.0 (0.2)	> 0.05	+

NS, not significant; SBNP, speech at better ear, noise at poorer; SPNB, speech at poorer ear, noise at better.

TABLE 107 *(c) Summary of study results: unilateral cochlear implant vs bilateral cochlear implants – adults. Ramsden 2005,[31] UK multicentre trial of bilateral cochlear implants (n = 29)*

Outcome	n	First ear	*p*-value	*n*	Second ear	*p*-value	*n*	Bilateral	*p*-value	Direction of change
Speech perception – 3 months compared with pre second implant:										
In quiet:										
CNC words	24		NS	25		NS	26		NS	
CUNY sentences	25	6.5 ± 3.2	0.004	26		NS	26		NS	+
In noise:										
CUNY front	25		NS	25		NS	25		NS	
CUNY left	25		NS	25		NS	25		NS	
CUNY right	25		NS	25		NS	25		NS	
Outcome	***n***		***p*-value**	***n***		***p*-value**	***n***		***p*-value**	**Direction of change**
Speech perception:	**Bilateral compared with best monaural 9 months**			**Bilateral compared with first ear at 9 months**			**Bilateral compared with second ear at 9 months**			
Speech and noise from front speaker:										
CUNY sentences	7.7 ± 5.3%		< 0.002	12.6 ± 5.4%		< 0.001	–			+
Speech from front, noise into first ear:										
CUNY sentences				21 ± 6%		< 0.001	11.7 ± 6%		< 0.001	+
Head shadow effect	–		NS	–		NS	–		NS	
Speech from front, noise into second ear:										
CUNY sentences	–		NS	–		NS	49.8 ± 5.8%		< 0.001	+
First ear score compared with second ear score 9 months										
Head shadow effect	45.2 ± 5.8%		< 0.001							
Binaural squelch effect	–		NS							

NS, not significant; SBNP, speech at better ear, noise at poorer; SPNB, speech at poorer ear, noise at better.

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TABLE 107 *(d) Summary of study results: unilateral cochlear implant vs bilateral cochlear implants – adults. Verschuur 2005*[33] *(n = 20)*

Outcome	*n*	Right implant only	*n*	Left implant only	*n*	Bilateral	*p*-value for condition	*p*-value for bilateral	Direction of change
Auditory:	20		20		20				
Mean (SD) absolute angular error	67° (10) unilateral			67° (9)		24° (5)	< 0.001		
Speaker to the front, mean (SD) angular error	73°					23°	< 0.001	< 0.001	+
Speaker to the side, mean (SD) angular error	54°					26°	< 0.001	< 0.05	+
	Device opposite speaker		Device same side						
Mean error from left speaker as a function of listening condition	95°		33°			24°	< 0.001	< 0.05	+
Mean error from right speaker as a function of listening condition	96°		36°			24°	< 0.001	< 0.001	+

NS, not significant; SBNP, speech at better ear, noise at poorer; SPNB, speech at poorer ear, noise at better.

TABLE 107 *(e) Summary of study results: unilateral cochlear implant vs bilateral cochlear implants – adults. Laszig 2004[33] (n = 370)*

Outcome	*n*	Poorer ear – unilateral [mean % correct (SD)]	*p*-value	*n*	Better ear – unilateral [mean % correct (SD)]	*p*-value	*n*	Bilateral [mean % correct (SD)]	*p*-value	Direction of change
Speech perception:										
In quiet:										
FMW words:										
6-month score	30	49		30	58		30	58	0.00009[a]	+~
Difference between 6 and 3 months post second implant	30	17		30	11		30	48		+
HSM sentences:										
6-month score	14	78		14	80		14	81		+~
Difference between 6 and 3 months post second implant	14	10 (41.34)		14	0 (30.02)		14	–2 (35.38)	Poorer ear = 0.01; better ear = NS	+~
OLSA sentences:										
6-month score	19	72		19	74		19	78		+
Difference between 6 and 3 months post second implant	19	10		19	6		19	7		+
In noise:										
HSM sentences:										
6-month score:										
Sound front	23	29 (21)		23	50 (31)		23	54 (31)		+
SBNP	23	8 (14)		23	63 (32)		23	70 (32)		+
SPNB	23	13 (15)		23	55 (38)		23	59 (36)		+
OLSA sentences:[b]										
6-month score:										
Sound front	20	+0.46 (7.59)		20	–1.15 (4.14)	0.01	20	–2.76 (5.29)	0.04	+
SBNP	20	+7.36 (13.80)		20	–4.14 (8.97)		20	–5.06 (–11.04)		+

Outcome	*n*	Poorer ear – unilateral [mean % correct (SD)]	*p*-value	*n*	Better ear – unilateral [mean % correct (SD)]	*p*-value	*n*	Bilateral [mean % correct (SD)]	*p*-value	Direction of change
SPNB	20	+4.14 (11.73)		20	+5.98 (12.42)		20	–2.76 (9.43)		–
Bilateral head shadow effect:										
Better ear closer to noise	20				–11.4 dB (6 dB)	< 0.00001				+
Poorer ear closer to noise	20	–10 dB (8 dB)	< 0.00001							+

+~, results borderline positive; NS, not significant; SBNP, speech at better ear, noise at poorer; SPNB, speech at poorer ear, noise at better.

a Significant difference between poorer ear and bilateral.

b OLSA sentences in noise test scores represent the mean and SD of the critical signal to noise (SNR) required for 50% correct speech understanding scores for the group for each listening condition in each of the three test conditions. A negative SNR 50% shows that on average a 50% correct score was achievable with the speech level presented softer than the noise signal level (i.e. a more difficult SNR). A positive SNR 50% shows that on average a 50% correct score was achievable with the speech level presented louder than the noise signal level (i.e. an easier SNR).

TABLE 108 *Summary of study characteristics: quality of life with cochlear implants – adults*

Study	Design	Participants 1	Participants 2	Outcomes
Mo 2005[34] Norway $n = 27$ Length of follow-up: 15 months	Prospective Pre/post repeated measures Own control	Mean (SD) age adults: 57.6 (14.5) years Duration of deafness prior to surgery (SD): 8.5 (10.3) years	Postlingually deaf	PQLF, IRQF, SF-36
Vermeire 2005[35] Netherlands $n = 89$	Prospective Pre/post repeated measures Own control	Mean (SD) age adults: 58 (15) years Postlingually deaf Degree of deafness: profound		HHIA, GBI
Hallberg 2004[36] Sweden $n = 17$	Grounded theory Interviews	Mean (range) age adults: 56.5 (29–78) years Cochlear implant usage, mean (range): 4.1 (1–12) years		Emergent categories
Hawthorne 2004[37] Australia and New Zealand $n = 34$ Length of follow-up: 6 months Partly funded by Cochlear Ltd	Prospective Pre/post repeated measures Own control	Mean (SD) age adults: 49 (13) years Degree of deafness: profound	Years since hearing loss: from birth = 8; ≤ 6 years = 10; ≥ 5 years = 14	AQoL, HPS
Hogan 2001[38] Australia and New Zealand $n = 202$	Cross-sectional Non-randomised control	Intervention: $n = 148$ Cochlear implant user Time since implantation, mean (range): 4.9 (0–16) years	Control: $n = 54$ Cochlear implant candidate	AQoL
Palmer 1999[39] USA $n = 62$ Length of follow-up: 12 months Partly funded by Cochlear Corporation	Prospective Pre/post repeated measures	$n = 46$ Age at study, mean (SD): 49.0 (14.5) years Postlingually deaf Degree of deafness: severe or profound	$n = 16$ Age at study, mean (SD): 56.0 (15.4) years Postlingually deaf Degree of deafness: severe or profound	HUI-3

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TABLE 109 *Summary of study results: quality of life – adults*

Study	Outcome	Intervention	Control	*p*-value	Direction of change
Mo 2005[34]	PQLF total score:	Mean (SD)			
n = 27	Preimplant	2.94 (0.54)			
	Post implant	3.56 (0.44)			
	Difference	0.62 (0.47)		< 0.01	+
	IRQF total score:				
	Preimplant	3.35 (0.41)			
	Post implant	3.72 (0.44)			
	Difference	0.37 (0.39)		< 0.01	+
	SF-12 – general health:				
	Preimplant	72.6 (21.6)			
	Post implant	79.8 (21.4)			
	Difference	7.2 (14.5)		0.02	+
	Other SF-12 subscales were not significantly different				
Vermeire 2005[35]	HHIA:	Mean (SD)			
n = 89	Preoperative total score	69 (0.69)			
	Postoperative total score	48 (25.28)		< 0.001	+
	GBI:				
	Postoperative total score	35.16 (19.61)			

continued

TABLE 109 *Summary of study results: quality of life – adults (continued)*

Study	Outcome	Intervention	Control	*p*-value	Direction of change
Hawthorne 2004[37]	AQoL:	*n*, mean (SD)			
n = 34	Preimplant	*n* = 31, 0.36 (0.23)			
	6 months post implant	*n* = 31, 0.64 (0.28)			
	Difference	*n* = 31, 0.28 (0.36)		< 0.01	+
	HPS:				
	Preimplant	*n* = 34, 0.48 (0.15)			
	6 months post implant	*n* = 34, 0.68 (0.18)			
	Difference	*n* = 34, 0.20 (0.23)		< 0.01	+
Hogan 2001[38]		*n* = 46	*n* = 16		
n = 202	AQoL:	Mean (SD)	Mean (SD)		
	Illness	0.64 (0.35)	0.69 (0.32)	NS	-
	Independent living	0.89 (0.16)	0.87 (0.16)	NS	+
	Social relationships	0.84 (0.22)	0.82 (0.21)	NS	+
	Physical senses	0.78 (0.19)	0.58 (0.19)	< 0.01	+
	Psychological well-being	0.88 (0.17)	0.83 (0.19)	NS	+
	Utilities	0.57 (0.27)	0.38 (0.22)	< 0.01	+
Palmer 1999[39]		*n* = 62	*n* = 16		
n = 62	HUI-3	Mean (SD)	Mean (SD)		
	Preimplant	0.58 (0.17)	0.58 (0.20)		
	12 months post implant	0.78 (0.17)	0.58 (0.23)		+
	Utility gain	0.20 (0.24)			+
Hallberg 2004[36]	Reported above				
n = 17					

NS, not significant.

Appendix 4

Summary of audit of clinical practice in the UK by the British Cochlear Implant Group – criteria for candidacy

Referral recommendations (children and adults)

All programmes recommend referral of patients with severe to profound hearing loss for assessment for cochlear implantation. Referrals for lower levels of loss are accepted if functional hearing is poor.

Hearing aid trial (children and adults)

All programmes require a valid hearing aid trial to be undertaken, the majority recommending a 3-month trial unless the patient is post meningitic.

Unaided hearing level (children)

The most common current practice in the UK incorporates a guideline for unaided hearing levels of profound bilateral loss in the high frequencies (> 90 dB HL at 2 and 4 kHz) with the proviso that all programmes require the flexibility to implant at lower levels for individual patients with poor functional hearing as appropriate. A reliability (test–retest) margin of +/– 10 dB is applicable in paediatric testing. This is used in conjunction with a multidisciplinary functional hearing assessment.

Unaided hearing level (adults)

The most common current practice in the UK incorporates a guideline for unaided hearing levels of severe to profound bilateral loss across the frequency range, typically > 90 dB HL at 2 and 4 kHz, with the proviso that all programmes require the flexibility to implant at lower levels for individual patients with poor functional hearing as appropriate. This is used in conjunction with a functional hearing measure, most commonly a score of < 50% correct on BKB sentence testing in the best aided condition.

Aided hearing levels (children and adults)

No programme uses aided hearing thresholds as a criterion or guideline for cochlear implantation.

Functional hearing (children)

All programmes concur that they use functional hearing as the primary factor/indicator for implantation.

Factors include failure to develop, progress or maintain speech, language and listening skills appropriate to age, development and cognitive ability, measured by a multidisciplinary range of age-appropriate assessments and questionnaires. The child should also be likely to benefit from increased access to audition, with increased potential for improvement in linguistic and communication skills, monitoring own environment, and psychosocial factors.

The weight of influence of particular components of the assessment of functional hearing on whether to implant or not must be considered on an individual patient basis.

Functional hearing (adults)

All programmes use speech perception testing in conjunction with other assessments, most commonly a score of ≤ 50% correct on BKB sentence testing in the best aided condition, with the proviso that all programmes require the flexibility to implant at lower levels for individual patients with poor functional hearing as appropriate.

Other factors include consideration of the probability of benefit from increased access to audition in terms of likelihood of improvement in linguistic skills, communication skills, monitoring own environment, and psychosocial factors.

Additional needs (children and adults)

All programmes state that patients with additional or complex needs are considered on an individual basis, for both children and adults.

Age at implantation (children and adults)

No programme has a lower age limit for cochlear implantation in children, nor an upper age limit for adults. Some programmes will impose an upper limit to duration of profound deafness for both children and adults.

Guidelines/criteria (children and adults)

All programmes indicated that their guidelines are continuously evolving in line with developments in clinical experience, technology and peer-reviewed published evidence-based outcomes.

Funding issues (children and adults)

The majority of programmes experience funding problems for patients recommended for cochlear implantation.

Appendix 5

Outcome measures in reviewed studies

The outcome measures used in the included studies can be categorised as audiological, speech perception, speech production, quality of life and educational. Because of the large numbers of measures reported in the included studies ($n = 62$) they will be described in a series of tables.

Measures shaded dark grey were used with adults, those shaded light grey were used with adults and children and those unshaded were used with children. For details of references for included measures see *Tables 6–10*.

TABLE 110 *Hearing (sensitivity to sound) measures*

Measure	Description	No. of studies using each measure
Basal auditory ability (SRPx)	First detection of sounds is observed, then the ability to derive meaning from the sounds presented is assessed by finding out if the child can associate the sounds with their sources. These are everyday sounds presented randomly; the child is watched to see if they respond at all to the sound	1
MAA – Minimal audible angle (P)	This is the smallest change in the position of a sound source that can be reliably discriminated	3
PTA – Pure-tone audiometry (P)	Measures hearing sensitivity in laboratory conditions. This measure involves the peripheral and central auditory systems. Pure-tone thresholds indicate the softest sound audible to an individual at least 50% of the time. The average unaided threshold is taken	2
SSQ – Speech Hearing, Spatial Hearing and Qualities of Hearing questionnaires (SR)	This measure has three sections: spatial hearing, which is concerned with the location and tracking of sounds (17 questions); quality of hearing, which is about the clarity and naturalness of sounds (19 questions); hearing for speech, which assesses the capacity to focus attention on a single source and to divide attention between sources (14 items)	1

P, performance measure; SR, self-report; SRPx, self-report by proxy.

TABLE 111 *Speech perception measures*

Measure	Description	No. of studies using each measure
One-syllable test	Closed-set ad hoc test. The child has to recognise monosyllabic words	1
Two-syllable test	Closed-set ad hoc test. The child has to recognise familiar two-syllable words	1
AVGN – A normalised index	Using CUNY scores a normalised index (AVGN) can be calculated: $AVGN = 100 \times (CUNYAV_{pre} - CUNYV_{pre})/(100 - CUNYV_{pre})$. This is used to assess the arithmetically possible improvement in performance over lip-reading alone. Using AVGN scores before and after the intervention allows the change in performance to be evaluated ($AVGN_{pre} - AVGN_{post}$)	1
AB monosyllables – Arthur Boothroyd monosyllabic word test	Listener has to identify phonemes from a list of recorded words. Each list consists of 10 words and each word is constructed as consonant–vowel–consonant (CVC isophonemes). Score is based on the phonemes correct out of 30	1
BKB – Bamford–Kowal–Bench sentences	These are 21 lists of 16 sentences of simple syntactical structure presented in auditory alone conditions in quiet and noise of 10 dB signal to noise ratio. The listener repeats back what they have heard. Performance is scored as the number of key words reported correctly, using the loose key word scoring method	5
CAP – Categories of Auditory Performance	This measures real-life auditory receptive abilities and is a non-linear, hierarchical scale of auditory receptive abilities, from no awareness of environmental sounds to the ability to use a telephone with a known speaker	1
CDT – Connected discourse tracking	Measures open-set speech perception. Stories are read, phrase by phrase, to a child who repeats them back. This is done without lip-reading. The number of correct words per minute is calculated. Generic measure	1
CID sentences – Central Institute for the Deaf sentences	Subjects listen to a list of 20 sentences, varying in length and structure and spoken with minimal inflection. Sentences are drawn from 10 sets of 10 sentences, with 50 'target' words in each set. These are played at 70 dB (A) under different contextual conditions (i.e. with or without lip-reading). Subjects repeat the sentences or undertake a written task. Sentences are uncommon and not likely to be heard on a regular basis. Examples of typical sentences are 'The vacuum is in the back of the closet' or 'The book is on the top shelf next to the pencil'	1
CNC – Consonant Nucleus Consonant monosyllabic word test	This open-set word recognition test consists of 10 lists with 50 monosyllabic words in each list. Patients are scored for words correct and phonemes correct	4
Common Phrases Test	Open-set test. Assesses understanding of familiar phrases spoken in everyday situations. Ten simple phrases are repeated by the child and one mark is given for each correct answer	3
CUNY – City University of New York	Measure of the benefit of lip-reading from hearing, obtained by presenting high-quality audiovisual recordings of 12 sentences from 25 possible lists. Listeners have to report as many spoken words as possible in different conditions (background noise) and locations using lip-reading only ($CUNYV_{pre}$), audiovisual with the right ear aided ($CUNYAVR_{pre}$) and audiovisual with the left ear aided ($CUNYAVL_{pre}$). Performance is scored by the percentage of all words reported correctly. All of the tests are of a man's voice and are played at 70 dB	5
ESP – Early Speech Perception battery	Examines children's speech perception abilities according to four categories: no pattern perception, pattern perception, some word identification and consistent word identification. Pictures are identified by pointing after hearing spoken language	5
FMWT – Freiburger monosyllabic word test	This test comprises two lists of 20 German words for each listening condition (quiet and background noise), for which a percentage total word score is obtained. Words are presented at 70 dB	1

TABLE 111 *Speech perception measures*

Measure	Description	No. of studies using each measure
GASP – Glendonald Auditory Screening Procedure	Words: 12 words of different syllable numbers and/or stress patterns. The child repeats the word presented by the examiner. Sentences: 10 questions are asked; responses can be to repeat or answer the question by verbal/signed response	7
Gottinger speech lists	These are used in speech audiometry; they consist of two lists of bisyllabic words (30 words each) administered in an open-set format. Toddlers have a closed set (8 word list)	1
HINT – Hearing in Noise Test	This test measures sentence speech reception thresholds in quiet and noise. It consists of 13 lists of 10 sentences with all correctly identified words tabulated to derive a percentage score. A child version is also available	3
HINT-C – Hearing in Noise Test for Children	Measures sentence speech reception thresholds in quiet and noise. It consists of 13 lists of 10 sentences with all correctly identified words tabulated to derive a percentage score	3
HSM sentences – Hochmaier, Schultz and Moser sentence test	This test is specifically designed for cochlear implant users and is composed of 600 everyday sentences arranged in 30 lists of 20 sentences, each varying in structure and length and played at 80 dB. Lists are prepared with five different levels of noise in the background at various signal to noise ratios of between 15 dB and 0 dB	2
IMST – Iowa Matrix Sentence Test	Assesses closed-set speech perception. Controls for learning effects and consists of four 2×3 picture matrices. These word sentences are presented by voice but without lip-reading. The child responds by pointing to pictures or retelling the sentence	1
LNT – Lexical Neighbourhood Test	Open-set test of word recognition, based on word frequency and neighbourhood density, it uses words found in the vocabulary of children aged 3–5 years. The child repeats a spoken word. Can also be used for speech perception	2
MAC – Minimal Auditory Capabilities	A battery of tests graded in difficulty specifically targeted at cochlear implant patients. There are 14 subtests (13 audio and one video), which include gross sound identification, inflection detection, contrast detection, accent discrimination and word identification. Although designed for postlingual hearing loss it can be used to evaluate the hearing abilities of persons for whom traditional speech materials are too difficult. The second edition has been standardised	1
MAIS (IT-MAIS) – Meaningful Auditory Integration Scale (SRPx)	A parental rating scale of listening behaviours. There is also an infant/toddler version (IT-MAIS). Evaluates meaningful use of sound in everyday situations. It provides information about consistency of device use and response to sound in everyday listening using 10 questions, e.g. 'Do they respond to the doorbell?'	
Minimal Pairs Test	Assesses auditory discrimination skills for minimal pair words. Closed-set single word pairs differing by one feature (e.g. place, manner, articulation). The child has to find the picture corresponding to one or two similar words. Results are scored by feature errors	1
MLNT – Multisyllabic Lexical Neighbourhood Test	Similar to the LNT. Can also be used for speech production. Open-set test of word recognition, based on word frequency and neighbourhood density, it uses words found in the vocabulary of children aged 3–5 years. The child repeats a spoken word	2
Mr Potato Head	This is a modified open-set speech perception task. Children are asked to carry out 10 commands presented aurally to assemble the toy. A sentence score is given for the number of commands correctly carried out and a word score for the number of key words correctly identified, e.g. choosing the right colour shoes	3
NU-6 – Northwestern University Auditory Test number 6	Listeners repeat back a series of prerecorded phonetically balanced CNC monosyllabic words from four lists of 50 words, each recorded in four randomisations	1

continued

TABLE 111 *Speech perception measures (continued)*

Measure	Description	No. of studies using each measure
OLSA – Oldenburg sentence test	This test comprises two lists of 10 German sentences each consisting of 50 words. A percentage correct score is obtained for each listening condition (quiet and background noise)	1
PB-K – Phonetically Balanced Kindergarten Word List	Word identification test, with two levels, used to evaluate open-set word recognition. Includes 50 phonetically balanced words that are within the vocabularies of normal-hearing 5-year-olds. Scores indicate the numbers of words and phonemes correctly identified	5
RITLS – Rhode Island Test of Language Structure	This is a test of sentence comprehension. A sentence is presented in signed English or voice. The child chooses a picture from a set of three that best represents the sentence. The final score is the total number of sentences chosen in error	1
SECSHIC – Scales of Early Communication Skills for Hearing Impaired Children	Evaluates speech and language development in deaf children. There are four subscales: verbal receptive language, verbal expressive language, non-verbal receptive skills and non-verbal expressive skills (verbal receptive skills only used)	1
TAC – Test for Auditory Comprehension of Language	Measures the auditory comprehension of language with a battery of increasingly difficult auditory/speech discrimination tasks. Closed-set test	1
TAPS – Test for Auditory Perception and Speech	Designed for children with cochlear implants. It consists of six subtests: sound detection, synthetic syllables, syllable/word identification, phrases of different length and stress and sentences of similar length and stress. Open set	1
TROG – Test for the Reception of Grammar	An individually administered, multiple-choice test of understanding of English grammar for children aged 4–13 years. Includes 20 blocks of four items, each assessing a specific type of grammatical contrast. The child selects the correct picture from an array that corresponds to a word order or grammatical construction	1

SRPx, self-report by proxy.

TABLE 112 *Speech production measures*

Measure	Description	No. of studies using each measure
CRISP – Children's Realistic Intelligibility and Speech Perception test	Used to evaluate bilateral enhancement in noise. It uses known words to identify picture and sound combinations. Can be used to measure speech perception	2
IPSyn – Index of Productive Syntax	A system for scoring transcriptions of expressive language recorded on videotape. There are four grammatical domains: noun phrases, verb phrases, questions and negotiations, and simple and complex sentence forms. These are combined to give a total score	1
SIR – Speech Intelligibility RATING	This is a 5-point scale describing degrees of speech intelligibility, ranging from unintelligible speech to that understandable by all listeners (1 = least intelligible and 5 = most intelligible)	1

TABLE 113 *Quality of life measures*

Measure	Description	No. of studies using each measure
APHAB – Abbreviated Profile of Hearing Aid Benefit	This is a condition-specific 24-item self-assessment quality of life inventory in which patients report the amount of trouble that they are having with communication or noises in various everyday situations. Benefit is calculated by comparing the patient's reported difficulty in the unaided condition with their amount of difficulty when using amplification. It produces scores for four subscales: ease of communication (EC), reverberation (RV), background noise (BN) and aversiveness (AV)	1
AQoL – Assessment of Quality of Life	A multiattribute utility instrument designed for economic evaluation. It contains 15 items across five domains (illness, independent living, social relationships, physical senses and psychological well-being). The last four domains are combined using time trade-off weights derived from the Australian population to provide a utility score ranging from –0.04 (health state worse than death) to 1 (best health state)	2
Everyday Life Questionnaire	Ad hoc cochlear implant-specific questionnaire with most questions derived from Kelsay and Tyler (reference 99 in main reference list). Parent questionnaire has 54 questions assessing problems and benefits. A modified version has fewer items for children. Items are scored on a Likert scale, with higher scores indicating a better quality of life	1
EQ-5D – EuroQol 5 dimensions	This is a generic measure of health-related quality of life that contains five questions about the extent of problems in mobility, self-care, daily activities, pain and anxiety/depression. Each question has three possible responses: no problem, mild problem or severe problem. Each possible combination of responses to the five questions constitutes a 'health state'. The last section of the questionnaire also contains a visual analogue scale (VAS) (see below) on general health. States have been valued by a cross-section of the British public to allow a societal value to be assigned to a patient's health state on a scale in which 0 corresponds to death and 1 to full health	1
GBI – Glasgow Benefit Inventory	The GBI provides a direct self-reported measure of change in health status in relation to a specific event (e.g. an operation). It contains 18 questions covering three domains: psychological (optimism and self-confidence), social and emotional. Responses are made on a 5-point Likert scale and scored on a scale of –2 to +2. Scores are summed across questions and the total multiplied by 2.778 to give an aggregate score	2
GHSI – Glasgow Health Status Inventory	This (quasi)-generic profile measure assesses the effect of a health problem on a person's quality of life across five domains: overall life, general, physical, health and social support	2
HHIA – Hearing Handicap Inventory for Adults	This is a 25-item hearing-specific quality of life scale used to assess hearing handicap in adults. It has two subscales that measure the emotional and situational impact of hearing loss. The scale is scored from 0 to 100, with 100 representing the maximum handicap possible	1
HPS – Hearing Participation Scale	This is a shortened form of the GHSI with 11 items. It is scored from 0.00 to 1.00. A low score indicates that there are profound effects on quality of life due to deafness	1
HUI-3 – Health Utilities Index 3	This is a population-based instrument measuring quality of life on 9 domains: hearing, speech, vision, emotion, pain, ambulation, dexterity, cognition and self-care. Respondents are mapped onto a health state depending on functional capacity. Based on a 15-item questionnaire with specific questions related to hearing.[40] These assume that patients have no co-morbidity. Utilities are calculated for each domain and an overall utility value derived using an algorithm to weight each domain[41]	2
IRQF – Index Relative Questionnaire Form	This is a condition-specific health-related quality of life measure developed for cochlear implantation by the House Ear Institute, Los Angeles. It contains 31 questions relating to a relative's experience with the patient as hearing impaired, the effect of the handicap on their daily activities and the patient's adaptation to the implant. Answers are scaled from 1 to 5, where a low score may represent either a positive or a negative response	1
KINDLr – Munich Quality of Life Questionnaire for Children	This is a 24-item Likert-scaled generic questionnaire completed by children or adults, with different age versions. There are six dimensions: physical well-being, emotional well-being, self-esteem, family, friends and everyday functioning. These can be combined to produce a total score	1

continued

TABLE 113 *Quality of life measures (continued)*

Measure	Description	No. of studies using each measure
NCIQ – Nijmegen Cochlear Implant Questionnaire	This is a condition-specific instrument with questions in three domains, physical, psychological and social functioning, each containing 10 items. Scores range from 0 to 100 (optimal)	1
PQLF – Patient Quality of Life Form	This is a condition-specific health-related quality of life instrument for cochlear implantation developed by the House Ear Institute, Los Angeles. It contains 43 questions concerning patients' coping with their hearing loss, adaptation to the implant and emotional alteration since implantation. Answers are scaled from 1 to 5, where a low score may represent either a positive or a negative response	1
Quality of life questionnaire	This is a generic behaviour-oriented instrument. It has 42 items on a Likert scale, with subscales for the physical, psychological, social, medical treatment, well-being and functional components of quality of life. The total range of scores is from 42 to 210 with a high score showing a better quality of life	2
SF-36 – Short-Form 36	This is a widely used generic health-related quality of life instrument, which contains 36 questions across eight domains. Each domain focuses on different aspects of quality of life (physical functioning, role limitation because of health problems, bodily pain, social function, role–emotional, mental health, vitality), except for one domain, which provides an overall evaluation (general health). Responses to questions in each domain are summed to provide eight scores between 0 and 100, where a high score means a better result	1
Symptom Checklist 90-R	This measures psychological symptoms in the last 7 days. It contains 90 items on a Likert scale combining nine scales and a severity index to provide a measure of psychological distress	1
Tinnitus Questionnaire	This questionnaire provides an index of tinnitus-related distress and its degree of severity. It is a 52-item self-rating scale covering emotional and cognitive distress, intrusiveness, auditory perceptual difficulties, sleep disturbances and somatic complaints	1
ULS – Usher Lifestyle Questionnaire	This is a descriptive questionnaire consisting of nine main questions divided into subgroups. It covers domains of independence affected by deaf–blindness, communication, access to information and mobility	1
VAS quality of life scale – Visual analogue scale	This provides a summary of overall quality of life by asking subjects to indicate their quality of life on a 100-point visual analogue scale, ranging from 0 (the worst imaginable quality of life) to 100 (the best imaginable quality of life)	1

TABLE 114 *Educational measures*

Measure	Description	No. of studies using each measure
AMP – Assessment of Mainstream Performance	This is a deaf-specific measure which determines the skills that children need to possess to be successful in mainstream school. There is a 3- to 5-year-old version with 16 items and an older children's version with 22 items. It measures the child's ability to participate in a range of classroom activities and age-appropriate behaviours. Answers are coded as the percentage of time that a child spends doing an activity or behaviour	1
SIFTER – Screening Instrument for Targeting Educational Risk	This deaf-specific measure has had content and score reliability shown. It rates the child in comparison to others in the classroom on 15 items in five areas: academics, attention, communication, classroom participation and school behaviour. The scores are summed for each area to give a profile of failure, marginal or sufficient	1

Appendix 6

Data extraction tables for the systematic review of economic evaluations

TABLE 115 *Relevant economic evaluations of cochlear implants in children: study designs*

Study	Analysis type, year	Country, setting	Population	Comparators	Perspective	Time horizon, discounting	Costs	Effects for ICER	Sensitivity analyses
Barton, 2006[42]	Cross-sectional survey-based CUA; in 2001/2 UK pounds	UK, specialist cochlear implant centres	Children in the UK with permanent bilateral hearing impairment > 40 dB HL in the better-hearing ear. *n* = 8876, including 993 with cochlear implants (modal age at implantation 3 years, mean age at implantation 8 years), 3580 profoundly impaired and 1015 moderately impaired	Cochlear implant (presumed unilateral) No cochlear implant	UK NHS and societal	15 years and lifetime, discounted at 3% per annum for both cost and utility	Cost to the NHS of providing implant/ acoustic hearing aids Annual educational cost Cost to family of child's impaired hearing: out-of pocket expenditure, time away from usual activities by parents for accompanying child to clinical and hospital appointments	QALYs (adapted HUI-3, completed by parents; effect of cochlear implant estimated via regression analysis)	One way
Carter 1999[43]	Community survey and expert opinion exercise with decision model (project pathway)-based CUA; in 1994 Australian dollars	Australian implantation programmes	Deaf children (severity not reported)[a]	Cochlear implant (presumed unilateral) No cochlear implant	Australian government/ service provider	10 years, 15 years and 20 years; discounting rate at 5% for both costs and life-years	Ongoing costs for consecutive cohorts of patients (costs for recipients and their families are included only insofar as they are related to the funder/service provider perspective): selection of recipients, surgery/implantation, rehabilitation/implant maintenance over useful life of the implant Offsetting savings achieved through being able to attend ordinary schools rather than requiring special education[b]	QALYs (using the Sintonen HRQoL-15D instrument)	One way

Study	Analysis type, year	Country, setting	Population	Comparators	Perspective	Time horizon, discounting	Costs	Effects for ICER	Sensitivity analyses
Cheng 2000[44]	Retrospective before-and-after study-based CUA; in 1999 US dollars	Hearing clinic at a US academic medical centre	Profoundly deaf children (pre- or postlingually deaf not reported), average age 7.5 years, who received cochlear implant	Cochlear implant (unknown bilateral or unilateral) No cochlear implant (pre- vs post implantation)	US societal [= health care (Medicare) + patient + education + productivity]	73 remaining years of life; discounting rate at 3% for both cost and utility	*Direct costs*:[b] Preoperative costs Operative costs: implant device, hospital and surgery, medical complications if any Postoperative costs: audiology follow-up, rehabilitation, device failure if any, loss or damage insurance, extended warranty, external, special batteries, processor upgrade *Indirect costs*:[b] Time off from work Travel and parking Change in educational costs and future earnings Special equipment	QALY (using TTO, VAS and HUI – version not stated)[b]	One way
O'Neill 2001[45]	Simple calculation (no model)-based CUA; in 1997/8 UK pounds	UK, the Nottingham Paediatric Cochlear Implant Programme	Profoundly hearing-impaired children	Cochlear implant (unknown bilateral or unilateral) No cochlear implant	UK NHS	Lifetime; discounting rate at 6% for both costs and utility	Assessment Maintenance Rehabilitation Education cost savings[b]	QALY (assumed from HUI-2 generic health state of being deaf)[b]	Not reported

continued

TABLE 115 *Relevant economic evaluations of cochlear implants in children: study designs*

Study	Analysis type, year	Country, setting	Population	Comparators	Perspective	Time horizon, discounting	Costs	Effects for ICER	Sensitivity analyses
Summerfield 1997[46c]	Decision model-based CUA; in 1996 UK pounds	UK, Nottingham Paediatric Programme with three educational settings: school for deaf children, special unit attached to mainstream school, and mainstream school with support	Deaf children in the UK	Unilateral cochlear implant No cochlear implant (pre- vs post implantation)	British health-care system	Lifetime; discounting at 6% for both costs and benefits	Direct costs of medical and rehabilitative management: assessing referrals who prove unwilling or unsuitable to proceed to treatment, remedying medical/surgical/ technical complications, managing patients who subsequently become non-users, maintenance and upgrades for patients who continue to use their device	QALY (using HUI Index)	One way
O'Neill 2000[47]	Simple calculation (no model)-based CUA; in 1997/8 UK pounds	A major paediatric implant centre, alternative educational setting in the UK	Profoundly hearing-impaired children (hearing level > 95 dB) in the UK	Cochlear implant (unknown bilateral or unilateral) No cochlear implant	UK NHS (health authority purchaser + educational savings)	Compulsory school years (between age 4 and 16 years), and 70 years lifetime; discounting rate for costs at 6% (for benefits not reported)	Direct costs to purchasers of a paediatric cochlear implant over first 4 years Education costs: educating children with differing degrees of hearing impairment, communication needs, the number of extra teaching staff as opposed to non-teaching staff hours provided for the pupil, any single or recurrent cash allocations involved (e.g. for special equipment)	QALY (assumed from HUI-2 generic health state of being deaf)[b]	Not reported

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Study	Analysis type, year	Country, setting	Population	Comparators	Perspective	Time horizon, discounting	Costs	Effects for ICER	Sensitivity analyses
Schulze-Gattermann 2002[48]	Cost-offset analysis based on a retrospective analysis; in 1999 euros	At the centre for the hearing impaired at the Medical University of Hanover in Hildesheim in Germany; educational settings were used to measure for benefits	Congenitally deaf and prelingually deafened children aged 1–6.9 years, with a severe hearing impairment (click-evoked hearing level of approximately 95 dB)	Cochlear implant (unknown bilateral or unilateral) Hearing aid	Germany payers' perspective	Up to 16 years (end of education); discounting rate at 6% for costs and savings	Costs of medical and educational services that were related to the hearing impairment on an individual level: direct (medical) costs, indirect costs (e.g. travelling costs), educational expenses covered by public authorities	No ICER – educational costs (savings) offset against health-care costs	One way
Hutton 1995[49]	Simple calculation, CUA; 1992	UK, setting not stated	Children	Postlingually implanted Non-implanted	NHS and education sector	Lifetime, discounting at 6%	Implantation Rehabilitation Education cost/saving Special living equipment	QALY (assumed utility gain of 0.1)	None
Wong 2000[50]	CUA; in Hong Kong dollars, US dollars and UK pounds, year not stated	Hong Kong	Prelingually deafened children,[d] $n = 22$; mean age at implantation 6.42 years	Cochlear implant (unknown bilateral or unilateral) No cochlear implant	Service providers	Life expectancy of 75 years; discount rate at 6% for both costs and effects	Selection of implantees Provision of cochlear implants to the implantees Surgery including preoperative evaluations and postoperative medical care: rehabilitative measures; social, audiological and postoperation speech training and maintenance	QALY (using HRQoL 15-D instrument)	Not reported

CUA, cost–utility analysis; HRQoL, health-related quality of life; HUI, Health Utilities Index; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; TTO, time trade-off; VAS, visual analogue scale.

a The study also assessed cochlear implants in partially deafened adults and profoundly deafened adults. Data presented here are only for deaf children (severity of deafness not stated).

b No costs or effects/utility reported for the non-implanted comparator.

c The analysis extends the investigation of the study by Hutton *et al.*[49]

d The full study included both adults and children.

TABLE 116 *Relevant economic evaluations of cochlear implants in children: results*

Study	From treatment	To treatment	Incremental cost	Incremental effects	ICER (discounted)	ICER (not discounted)
Barton, 2006[42]	No cochlear implant	Cochlear implant	*Societal perspective:* Lifetime period: implanted at age 3 years: €119,591,[a] €102,373[b] and €92,525[c] implanted at age 6 years: €119,565,[a] €109,388[b] and €102,572[c] *Health sector:* Lifetime period: implanted at age 3 years: €13,040[a,b,c] implanted at age 6 years: €131,292[a,b,c]	Lifetime period: implanted at age 3 years: 4.894 QALYs,[a] 7.363 QALYs[b] and 8.569 QALYs[c] implanted at age 6 years: 4.073 QALYs,[a] 5.668 QALYs[b] and 6.447 QALYs[c]	*Societal perspective:* Lifetime period, cost per QALY: implanted at age 3 years: €24,436,[a] €13,904[b] and €10,798[c] implanted at age 6 years: €29,355,[a] €19,299[b] and €15,910[c] *Health sector:* Lifetime period, cost per QALY: implanted at age 3 years: €26,982,[a] €17,933[b] and €15,410[c] implanted at age 6 years: €32,235,[a] €23,164[b] and €20,366[c] (Cost per QALY from the perspective of health and education sectors combined was also reported)	
Carter 1999[43]	No cochlear implant	Cochlear implant	Not reported	Improvement in HRQoL-15D score: Low value:[d] 17% Middle value:[e] 26% High value:[f] 38%	Cost per QALY: 10-year period: A$13,020,[d] A$8440[e] and A$5940[f] 15-year period: A$11,100,[d] A$7480[e] and A$5070[f] 20-year period: A$3465,[d] A$2330[e] and A$1580[f]	
Cheng 2000[44]	No cochlear implant	Cochlear implant	Total direct costs: US$60,228 Total indirect costs: – US$113,426 Total costs: – US$53,198	TTO: 6.54 QALYs VAS: 8.03 QALYs HUI: 11.59 QALYs	Using direct medical costs: TTO: US$9209 per QALY VAS: US$7500 per QALY HUI: US$5197 per QALY Savings to society (using total costs): TTO: –$53,198	
O'Neill 2000[47]	No cochlear implant	Cochlear implant	Discounted value of savings attributable to cochlear implant: Cost over compulsory school years: $48,756.58	2.99 QALYs (discounted) 5.98 QALYs (undiscounted)	£2532 ($4051) per QALY	

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Study	From treatment	To treatment	Incremental cost	Incremental effects	ICER (discounted)	ICER (not discounted)
			Education savings: $26,781.36 Net cost over compulsory school years: $21,975.23 Costs over 70 years of life: $68,130.90 Net cost over 70 years of life: $41,349.55			
O'Neill 2001[45]	No treatment	Cochlear implant	Mean net discounted implantation costs by education authority type:[g] County: £33,241 London: £49,130 Metropolitan: £44,709 Unitary: £41,442	4 QALYs (assuming a child is implanted at age 4 years and lives for 75 years)	Net cost per QALY by education authority type:[g] County: £8310 London: £12,282 Metropolitan: £11,177 Unitary: £10,360	
Summerfield 1997[46]	No cochlear implant	Unilateral cochlear implant	Cumulative cost of medical and rehabilitative care: £60,000	Cumulative 3.8 QALYs	£15,600 per QALY £12,100 per QALY (taking into account saved costs in education) £10,000 per QALY (taking into account savings in costs for special equipment for daily living in adulthood)	
Schulze-Gattermann 2002[48]	Hearing aid	Cochlear implant	NA (cost-offset analysis)	NA (cost-offset analysis)	NA (cost-offset analysis)	
Hutton 1995[49]	Non-implanted	Unilateral cochlear implant	£59,343 (health-care cost) £15,906 (net saving after educational costs)	3.66 QALYs	£16,213	
Wong 2000[50]	Non-cochlear implantation	Postcochlear implantation	HK$250,628	Not reported	HK$183,100 or US$23,474 or £14,084 per QALY[h]	

AHL, average hearing level; HRQoL, health-related quality of life; HUI, Health Utilities Index; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; TTO, time trade-off; VAS, visual analogue scale.
a For children with a preoperative AHL of 105 dB.
b For children with a preoperative AHL of 115 dB.
c For children with a preoperative AHL of 125 dB.
d Low value: based on scores for four core dimensions – hearing, speech, usual activities and distress.
e Middle value: based on scores for the four core dimensions plus sleeping, depression and vitality.
f High value: based on scores for 12 of the 15 available dimensions.
g Presented in US dollars in the paper; converted by the authors of this review in August 2000 on an exchange rate of £1 = US$1.45.
h The exchange rate was HK$7.8 = US$1 and HK$13 = £1.

TABLE 117 *Relevant economic evaluations of cochlear implants in adults: study designs*

Study	Analysis type, year	Country, setting	Population	Comparators
Bichey 2002[51]	Retrospective cohort study-based CUA; year not stated	Indiana University Medical Center in the USA	Patients (both children and adults) with large vestibular aqueduct syndrome, at the medical centre, who were postlingually deafened and severely deaf: 10 with cochlear implants vs 10 with hearing aids	Cochlear implant (unknown bilateral or unilateral) Hearing aid
Carter 1999[43]	Community survey and expert opinion exercise with decision model (project pathway)-based CUA; in 1994 Australian dollars	Australian implantation programmes	Postlingually and profoundly deaf adults[b]	Cochlear implant (unknown bilateral or unilateral) No cochlear implant (pre- vs post implantation)
Lee 2006[52]	Small cohort study-based CUA, in 2002 $ (US?)	A hospital in Seoul in Korea	11 postlingually deaf adults who had received cochlear implants in that hospital between 1990 and 2002 and who had used the device for at least 1 year and were available for a direct interview Mean age at analysis 49.6 years Mean age at onset of deafness 33.4 years Mean time that the cochlear implant device was used 5.6 years	Cochlear implant (unknown bilateral or unilateral) No cochlear implant (pre- vs post implantation)
Palmer 1999[39c]	Comparative cohort study and calculation-based CUA; 1996 US$	One Canadian and 16 US implantation centres, i.e. hospital-based and patient resource clinics, from October 1994 to February 1996	Severely to profoundly hearing-impaired adult recipients of a cochlear implant ($n = 66$) and adults eligible for the device who had not yet received it ($n = 24$), aged ≥ 18 years	Nucleus 22-channel cochlear implant (unilateral) No cochlear implant
Summerfield 2002[53]	Empirical utility elicitation study and decision model-based CUA; in 2000 UK pounds	14 hospitals in the UK NHS and one Medical Research Council research unit	Normal-hearing adult volunteers ($n = 70$) and adults undergoing unilateral implantation who either did not benefit from acoustic hearing aids preoperatively ($n = 87$) or benefited marginally ($n = 115$)	Unilateral implant vs no intervention Unilateral implant vs hearing aids Unilateral implant vs simultaneous bilateral implants Provision of additional implant vs no additional intervention

Perspective	Time horizon, discounting	Costs	Effects for ICER	Sensitivity analyses
Not reported	Age 76 years; QALYs were discounted at 5%	Preoperative assessment costs Surgical fees Cost of anaesthesia Cost of hospitalisation Cost of implant Cost of postoperative audiological and communication assessments Cost of postoperative surgery[a]	QALYs (based on the Ontario HUI-3)[a]	One way
Australian government/ service provider	15 years; discounting rate at 5% for both costs and life-years	Ongoing costs for consecutive cohorts of patients (costs for recipients and their families are included only insofar as they are related to the funder/ service provider perspective): selection of recipients, surgery/implantation, rehabilitation/ implant maintenance over useful life of the implant[a]	QALYs (based on the Sintonen HRQoL-15D instrument)[a]	One way
Health sector	Expected lifetime (years not reported); discounting rate at both 0% and 5% for costs and annual discounting rate at 3% for QALYs	Preoperative: outpatient hospital fees, audiological and radiological evaluation Operative: costs of surgery, hospital accommodation, cochlear implant device, treatments for medical complications Postoperative: rehabilitation fees, audiological follow-up examinations during the first year following surgery, batteries for the device, processor upgrades, device failure from the second year following surgery until death Costs estimated based on the references; hospital data and other reports were also used[a]	QALY, using VAS (visual analogue scale), TTO (time trade-off), QWB (quality of well-being) index, EQ-5D (EuroQol) index[a]	One way
Canadian and US health sector	22 years; discounting rate at 3% for both costs and benefits	Assessments prior to surgery Facility charge (inpatient or day surgery) Cochlear implant device Surgery professional fee Anaesthesiology professional fee 1-year follow-up care[a]	QALY (using HUI scores)	One way
Health care	30 years; discounting rate at 6%	Staff Incidentals Accommodation and equipment CT and/or MRI Surgical session Inpatient stay Radiographic examination Implant system Spares and repairs[a]	QALY (using HUI-2)	One-way

continued

TABLE 117 *Relevant economic evaluations of cochlear implants in adults: study designs (continued)*

Study	Analysis type, year	Country, setting	Population	Comparators
Summerfield 1997[46d]	Decision model-based CUA; in 1996 UK pounds	UK	Profoundly deaf adults	Unilateral cochlear implant No cochlear implant (pre- vs post implantation)
Summerfield 1995[54]	CUA based on a UK national cochlear implantation programme (1990–4) and a decision model; costs are expressed in UK pounds at 1991–2 price levels	UK, the adult programmes at hospitals in England, Scotland and Northern Ireland	Profoundly postlingually deafened adults who received Nucleus 22-channel implant system under the programme	22-channel implant (unknown bilateral or unilateral) No treatment
UK Cochlear Implant Study Group 2004[40]	Before-and-after cohort study and decision tree-based CUA;[e] costs inflated to 2001/2 financial year levels and converted into euros (£1 = €1.54)	13 hospitals in the UK NHS	316 profoundly hearing-impaired postlingually deafened adults who received multichannel cochlear implants in 13 hospitals in the NHS between 1 June 1997 and 31 May 2000	Unilateral cochlear implantation No cochlear implantation
Wong 2000[50f]	Cohort study-based CUA in Hong Kong dollars, US dollars and UK pounds; year not stated	Hong Kong	Postlingually deafened adults, $n = 13$; mean age at implantation 41.2 years, average life of implantation 33.8 years	Cochlear implant (unknown bilateral or unilateral) No cochlear implant (pre- vs post implantation)
Francis 2002[55]	Cohort study-based CUA; study year for CUA not stated	Johns Hopkins Hospital in the USA	Pre- ($n = 6$) and postlingually ($n = 41$) deaf adults aged ≥ 50 years who have multiple channel cochlear implants received at the hospital between June 1989 and February 2000	Cochlear implant (unknown bilateral or unilateral) No cochlear implant (pre- vs post implantation)
Neilson 2006[56]	CUA based on a systemic review and a simple patient care pathway decision model; in 2005/6 Norwegian kroner	Norway	Severe to profoundly deaf adults	Unilateral cochlear implant No intervention (pre- vs post implantation)

Perspective	Time horizon, discounting	Costs	Effects for ICER	Sensitivity analyses
British health-care and education system	Remaining lifetime of 26 years; discounting at 6% for both costs and benefits	Direct costs of medical and rehabilitative management: assessing referrals who prove unwilling or unsuitable to proceed to treatment, remedying medical/surgical/technical complications, managing patients who subsequently become non-users, maintenance and upgrades for patients who continue to use their device[a]	QALY (using HUI scores)[a]	One way
UK's purchaser/provider of health care	26 years (remaining of lifetime); discounting rate at 6% per annum for the cost and utility	Salaries Salary overheads Accommodation Incidentals Capital equipment Radiology Surgery Hotel charges Implant hardware Maintenance and upgrades[a]	QALY (various derivation methods: VAS, Rosser Index, Ontario HUI)	One way
UK NHS	Lifetime; discounting rate at 6% for both costs and benefits	Cost of providing acoustic hearing aids when assigning the suitability of a subject for cochlear implantation Costs averted if acoustic hearing aids would not be provided to the subject after cochlear implantation Core cost of providing and maintaining implant Costs of managing medical/surgical complications Cost of replacing electrode arrays that fail[a]	QALY (based on HUI-3 scores)	One-way
US service providers	Mean 33.8 years of remaining life expectancy (to age 75 years); discount rate at 6% for both costs and effects	Selection of implantees Provision of cochlear implants to the implantees Surgery including preoperative evaluations and postoperative medical care Rehabilitative measures Social, audiological and postoperation speech training and maintenance[a]	QALY (using HRQoL 15-D instrument)[a]	Not reported
	21 years (remaining of 85 years life expectancy); discounting rate at 3% for both cost and utility	Costs associated with cochlear implantation: presurgical evaluation, cost of device, surgeon's and anaesthesiologist's fees, hospital costs, postoperative services including programming, insurance, extended warranty and miscellaneous hardware costs[a]	QALY (based on HUI-3 score)[a]	Not reported
Norwegian health-care system perspective, and perspective of patients	25 years of device/assumed remaining life expectancy; discounting rate at 4% for both cost and utility	Preimplant outpatient assessment and testing CT and/or MRI scan Hospitalisation, surgery and implanted device Postimplant outpatient follow-up and rehabilitation Cost of managing (major) complications with readmissions Ongoing periodic follow-up of patient's progress and equipment maintenance[a]	QALY	One way

continued

TABLE 117 *Relevant economic evaluations of cochlear implants in adults: study designs (continued)*

Study	Analysis type, year	Country, setting	Population	Comparators
Summerfield 1995[57] (short report)	CUA based on a UK national cochlear implantation programme (1990–4); costs are expressed in UK pounds at 1992–3 price levels	UK, the adult programmes at hospitals in England, Scotland and Northern Ireland	Profoundly postlingually deafened adults who received Nucleus 22-channel implant system under the programme	22-channel implant (unknown bilateral or unilateral) No treatment (pre- vs post implantation)
Wyatt 1996[58]	Comparative survey (for utilities) and decision-analytic model-based CUA; in 1993 US dollars	Johns Hopkins Hospital in USA	Adults with profound hearing loss (acquired or born deaf not reported) underwent cochlear implantation between July 1993 and June 1994 at the hospital	Nucleus 22-channel implant (unknown bilateral or unilateral) No cochlear implant (pre- vs post implantation or with cochlear implant vs awaiting cochlear implant?)
Wyatt 1995[59]	Decision-analytic model-based CUA; 1992 US dollars	USA	Profoundly deaf adults (acquired or born deaf not reported) who underwent cochlear implantation at the Johns Hopkins Hospital (USA) between February 1990 and May 1993. Mean age 45 years	Nucleus 22-channel implant (unknown bilateral or unilateral) No cochlear implant

CT, computerised tomography; CUA, cost–utility analysis; HRQoL, health-related quality of life; HUI, Health Utilities Index; ICER, incremental cost-effectiveness ratio; MRI, magnetic resonance imaging; QALY, quality-adjusted life-year.

a No costs (or effects) reported for the preimplantation or non-implanted comparator.

b The study population included partially deafened adults and children and profoundly deafened adults and children. Data presented here are for the profoundly deaf adults only.

c Results of the pilot study of the health-related quality of life assessment method have been previously reported by Wyatt *et al*.[58]

d The study included both adults and children; the analysis extends the investigation of the study by Hutton *et al.*[49]

e General linear models were used to predict the preoperative and 9-mo postoperative utilities with age at implantation and duration of profound deafness.

f The study included both children and adults. Data on children are extracted and reported in other sections.

Perspective	Time horizon, discounting	Costs	Effects for ICER	Sensitivity analyses
Not reported	12 years; discounting rate at 6% per annum for the cost and utility	Salaries Salary overheads Accommodation Incidentals Capital equipment Radiology Surgery Hotel charges Implant hardware Maintenance and upgrades[a]	QALY (VAS and ad hoc mapping to an unstated HRQoL measure)	Not reported
American third-party payors??	23 years of remaining life expectancy; discounting rate at 5% for both cost and utility	Direct medical costs: preoperative evaluation, surgery (hospital, surgeon's fee, anaesthesia), initial device, rehabilitation, follow-up, audiological testing and device maintenance, expected cost of a minor and a major complication[a]	QALY (using Ontario HUI score)[a]	One way
American third-party payors	33 years of remaining life expectancy; discounting rate at 5% for both cost and utility	Direct medical costs: preoperative evaluation, surgery (hospital, surgeon's fee, anaesthesia), initial device, rehabilitation, follow-up, audiological testing and device maintenance, expected cost of a minor and a major complication[a]	QALY(using the Ontario HUI-3)[a]	One way

TABLE 118 *Relevant economic evaluations of cochlear implants in adults with acquired deafness: results*

Study	From treatment	To treatment	Incremental cost	Incremental effects	ICER (discounted)	ICER (not discounted)
Bichey 2002[51]	Hearing aid	Cochlear implant	US$37,320 (mean charges for cochlear implant in the medical centre)	Average HUI score: 0.2 (SD 0.13, 95% CI 0.12–0.28)	US$12,774 per QALY[a]	US$6426 per QALY[a]
Carter 1999[43]	No cochlear implant	Cochlear implant	Not reported	Not reported	Cost per QALY (in A$): 10-year period: $45,630,[b] $22,045[c] and $14,115[d] 15-year period: $38,150,[b] $18,435[c] and $11,790[d] 20-year period: $35,250,[b] $16,825[c] and $10,895[d]	
Lee 2006[52]	No cochlear implant	Cochlear implant	Average lifetime discounted = $22,320 (base-case cost reported in *Table VIII* is different to this)	Gain in QALYs: VAS: 1.16 HUI: 1.28 EQ-5D: 0.91 QWB: 0.55 Mean = 0.98 (95% CI 0.66–1.2)	$ per QALY: VAS: 19,223 HUI: 17,387 EQ-5D: 24,604 QWB: 40,474 Mean = 25,424	
Palmer 1999[39]	No cochlear implant	Cochlear implant	$37,405; $34,460 after imputation of missing data	Gain in QALYs = 3.26 (calculated by the reviewers)	US$14,670 per QALY (95% CI US$8241–30,347)	
Summerfield 2002[53]	No intervention	Unilateral implant	£41,136	2.45 QALYs	£16,774	
	Hearing aids	Unilateral implant	£39,029	1.42 QALYs	£27,401	
	Unilateral implant	Simultaneous bilateral implant	£27,001	0.44 QALYs	£61,734	
	No additional intervention	Additional implant	£30,142	0.44 QALYs	£68,916	
	No additional intervention	Simultaneous bilateral implant	£68,137	2.89 QALYs	£23,578	
	Hearing aids	Simultaneous bilateral implant	£65,165	1.86 QALYs	£35,002	
Summerfield 1995[54]	No treatment	22-channel implant	£34,215	2.99 QALYs (discounted) 5.98 QALYs (undiscounted)	£11,440 per QALY	£5722 per QALY

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Study	From treatment	To treatment	Incremental cost	Incremental effects	ICER (discounted)	ICER (not discounted)
Summerfield 1997[46]	No cochlear implant	Cochlear implant (unilateral)	£40,000 accumulated costs of medical management	3 QALYs	£13,300 per QALY	
UK Cochlear Implant Study Group 2004[40]	No cochlear implant	Cochlear implant (unilateral)	All groups: €67,017 All TC: €67,076 TC-I: €66,808 TC-II: €67,439 All MHU: €66,854 MHU-I: €67,266 MHU-II: €66,206	QALYs gained: All groups: 2.46 All TC: 2.64 TC-I: 2.75 TC-II: 2.49 All MHU: 1.99 MHU-I: 1.73 MHU-II: 2.44	€ per QALY, calculated using 'net benefit approach': All groups: 27,142 All TC: 25,336 TC-I: 24,032 TC-II: 27,062 All MHU: 33,512 MHU-I: 39,009 MHU-II: 27,092	
Wong 2000[50]	No cochlear implant	Cochlear implant	HK$250,628	1.8 QALYs (calculated by the reviewers)	UK£10,237 or HK$133,087 or US$17,195 per QALY[e]	
Francis 2002[55]	No cochlear implant	Cochlear implant	US$36,025	3.78 QALYs	US$9530 per QALY	
Neilson 2006[56]	Unilateral cochlear implant	No intervention	Kr537,175	3.12 QALYs	Kr17,200 per QALY	
Summerfield 1995[57]	No cochlear implant	22-channel implant	£28,318	3.9 or 1.3 QALYs (0.3 or 0.1 utility gain for 26 years, discounted at 6%)	£8624 or £25,871	
Wyatt 1996[58]	No cochlear implant	Cochlear implant	US$53,838	2.83 QALYs (calculated by the reviewers)	US$15,928 per QALY	
Wyatt 1995[59]	No alternatives	Nucleus 22-channel cochlear implant	US$53,058	4.41 QALYs (calculated by the reviewers)	US$15,593 per QALY	
Wyatt 1995[60]	No cochlear implant	Nucleus 22-channel cochlear implant	Not reported	Mean difference in health status rating: 30.4% (95% CI 29.98–33.84)	US$9325 per QALY (unknown if this is discounted or undiscounted)	

EQ-5D, EuroQol 5 dimensions; HUI, Health Utilities Index; ICER, incremental cost-effectiveness ratio; MHU, marginal hearing aid users; QALY, quality-adjusted life-year; QWB, quality of well-being; TC, traditional candidates; VAS, visual analogue scale.

a Calculation cannot be checked (mean survival time post implantation not reported).
b Low value: based on scores for four core dimensions – hearing, speech, usual activities and distress.
c Middle value: based on scores for the four core dimensions plus sleeping, depression and vitality.
d Upper value: based on scores for 12 of the 15 available dimensions.
e The exchange rate was HK$7.8 = US$1 and HK$13 = UK£1.

Note: 95% CIs for the ICER shown only if they are reported.

Appendix 7

Quality assessment tables of UK-based economic evaluations and industry-submitted cost–utility analyses

TABLE 119 *Quality assessment of UK-based economic evaluations (using the CHEC criteria list)*

Criteria	Summerfield 1995[54]	Summerfield 1997[46a]	O'Neil 2000[47]	O'Neil 2001[45]	UKCISG 2004[40]	Barton 2006[42]	Summerfield 2002[53]
	Unilateral in adults	Unilateral in children	Unilateral in children	Unilateral in children	Unilateral in adults	Unilateral in children	Bilateral in adults
Is the study population clearly described?	Yes	Partly	Yes	Yes	Yes	Yes	Yes
Are competing alternatives clearly described?	Yes/no[b]	No	Yes	Yes	Yes	Yes	Yes
Is a well-defined research question posed in answerable form?	Yes	No	Yes	Yes	Yes	Yes	Yes
Is the economic study design appropriate to the stated objective?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is the chosen time horizon appropriate to include relevant costs and consequences?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Is the actual perspective chosen appropriate?	Yes	Yes[c]	Yes[d]	Yes[d]	Yes	Yes	Yes
Are all important and relevant costs for each alternative identified?	Yes/no[b]	Yes/no	Yes	Yes	Yes	Yes	Yes
Are all resources measured appropriately in physical units?	Yes	Yes	No[e]	No[e]	Yes	Yes	Yes
Are resources valued appropriately?	Yes	Yes	NA	NA	Yes	Yes	Yes
Are all important and relevant outcomes for each alternative identified?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Are all outcomes measured appropriately in physical units?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Are outcomes valued appropriately?	No[f]	No[f]	No[f]	No[f]	Yes (HUI-3)	Yes (HUI-3)	Yes (HUI-2)
Is an incremental analysis of costs and outcomes performed?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Are all future costs and outcomes discounted appropriately?	Yes (6%)	Yes (6%)[g]	Yes (6%)	Yes (6%)	Yes (6%)	Yes (6%)	Yes (6%)

Criteria	Summerfield 1995[54]	Summerfield 1997[46a]	O'Neil 2000[47]	O'Neil 2001[45]	UKCISG 2004[40]	Barton 2006[42]	Summerfield 2002[53]
Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis?	Yes (one way)	Yes	Yes	Yes	Yes	Yes	Mostly
Do the conclusions follow from the data reported?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Does the study discuss the generalisability of the results to other settings and patient/client groups?	Yes	No	No	No	Yes	Yes	Yes
Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)?	No	No	No	No	No	No	No
Are ethical and distributional issues discussed appropriately?	No[h]	No	No	Yes	No	No	No

HUI, Health Utilities Index; NA, not applicable.
The CHEC list for assessing quality of economic evaluations[61] incorporates all but one of the widely used critical appraisal questions recommended by Drummond *et al.*[62] (The missing question is 'Was the effectiveness of the programmes or services established?'.)
Two other UK-based studies[29,49] were not included in this table as, although they calculated incremental cost-effectiveness ratios, this was as part of the discussion section rather than as the main analysis of the paper.
a This is a short report (so contains less detail than a full paper).
b The cochlear implantation comparator is clearly described but the implicit comparator of no cochlear implantation is not.
c Results presented including both NHS only and NHS plus education costs.
d All cost-effectiveness results include estimated educational cost savings.
e Approximate annual costs sourced from Nottingham Paediatric Cochlear Implant Programme.
f Base-case estimate of utility gain was from a visual analogue scale.
g Assumed to be the same as the related 1995 analysis[54] in adult implant recipients.
h Ethical and distributional issues may have been discussed in other sections of the larger report.

TABLE 120 *Quality assessment of economic evaluation submitted by Cochlear Europe (using the CHEC criteria list)*

Criteria	Cochlear Europe	Assessment
Is the study population clearly described?	Yes	Yes
Are competing alternatives clearly described?	Yes	Yes
Is a well-defined research question posed in answerable form?	Yes	Not explicitly
Is the economic study design appropriate to the stated objective?	Yes	Yes
Is the chosen time horizon appropriate to include relevant costs and consequences?	Yes	Yes
Is the actual perspective chosen appropriate?	Yes	Yes
Are all important and relevant costs for each alternative identified?	Mostly, except not clear whether treatment of postsurgical complications was included. Omitted patient assessment costs of those ultimately not implanted. Also, assumed that 0% of device failures received a subsequent implant	Mostly, except not clear whether treatment of postsurgical complications was included, and omitted preimplantation assessment costs of those ultimately not implanted
Are all resources measured appropriately in physical units?	Yes	Yes
Are resources valued appropriately?	Yes	Yes
Are all important and relevant outcomes for each alternative identified?	Yes	Yes
Are all outcomes measured appropriately in physical units?	Yes (life-years)	Yes (life-years)
Are outcomes valued appropriately?	Yes (QALY weights from HUI-3)	Yes (QALY weights from HUI-3)
Is an incremental analysis of costs and outcomes performed?	Yes	Yes
Are all future costs and outcomes discounted appropriately?	Yes (at 3.5% pa)	Yes (at 3.5% pa)
Are all important variables, whose values are uncertain, appropriately subjected to sensitivity analysis?	Yes (one-way and PSA)	Yes (one-way and PSA)
Do the conclusions follow from the data reported?	Yes	Yes
Does the study discuss the generalisability of the results to other settings and patient/client groups?	Yes	Yes
Does the article indicate that there is no potential conflict of interest of study researcher(s) and funder(s)?	NA	NA
Are ethical and distributional issues discussed appropriately?	Yes/no	Yes/no

HUI, Health Utilities Index; NA, not applicable; PSA, probabilistic sensitivity analysis; QALY, quality-adjusted life-year.
The CHEC list for assessing quality of economic evaluations[61] incorporates all but one of the widely used critical appraisal questions recommended by Drummond *et al*.[62] (The missing question is 'Was the effectiveness of the programmes or services established?'.)

Appendix 8

Assessment of industry submissions to NICE

Industry-submitted economic evaluations

There were three industry submissions made to NICE as part of the appraisal process of cochlear implantation. These were from Cochlear Europe, Advanced Bionics Europe and MED-EL UK. Only those submissions from Cochlear Europe and Advanced Bionics Europe contained new economic analyses and we mainly focus on these below. The submission from MED-EL UK mainly summarised the results of the 2004 UKCISG paper (on adults)[40] and the 2006 paper by Barton and colleagues[42] on the cost-effectiveness of paediatric cochlear implantation.

Cost-effectiveness analyses from Cochlear Europe

This submission took a Markov model-based approach to evaluating the cost-effectiveness of unilateral and bilateral cochlear implantation compared with 'standard of care', from an NHS and Personal Social Services (PSS) perspective. They assessed the NICE decision problem in relation to their Nucleus® and Nucleus® Freedom™ implants, using costs and failure rates specific to these systems.

Costs included were those associated with assessment (imaging); surgery and inpatient stay; outpatient resources (years 1–20); the implant device; processor upgrade; and spares and repairs. However, their analyses omitted the assessment costs of those referred deaf people who ultimately did not receive a cochlear implant.

Outcomes were estimated as QALYs gained. The estimated utility gain resulting from unilateral cochlear implantation was 0.394 in adults and 0.224 in children.

In adults they reduced the baseline utility of being deaf and the utility gain due to implantation, as people in the model aged in proportion to the age-related decline in utility of the general population (using UK population age-specific EQ-5D utility weights). In this way both the utility associated with being deaf and that associated with implantation would be a fixed proportion of the population norm utility for that age. Without this adjustment – that is, with the same absolute utility gain at all ages – it is possible that implanted individuals might end up with greater utility than their normal-hearing peers (although this effect would occur only when people are very old).

In summary, with two notable exceptions, both the model structure and parameter estimates for effectiveness, resource use, costs and other assumptions were generally reasonable and evidence-based, and in most other respects the analyses met the reference case criteria stipulated in NICE methodological guidance (*Table 121*).

They produced two base-case ICERs (£ per QALY) for deaf adults and deaf children. These are reproduced in *Table 122*.

There are two aspects of the model's assumptions that are worth closer scrutiny, both of which favour the cost-effectiveness of cochlear implantation.

Estimation of utility gains

First, in preference to using directly derived utility gain values – which are available for unilateral implantation (in children and adults) and bilateral implantation (only in adults) – they chose to indirectly map word perception scores to predict utility gain as a percentage of age-adjusted normal utility. For adults the word perception score gains were from Balkany and colleagues[63] and cochlear 'data on file', and for children they were from Staller and colleagues.[4] Use of these particular studies was justified only on the basis of them including the 'most recently implanted patients'.

However, the logic used to map changes in sentence recognition scores to utility gains is the step in the process that appears most questionable. From correlation data on only 28 patients (about half of the patients studied in Francis and colleagues[55]) they assume that a 100% improvement in monosyllabic word scores is associated with a gain in utility of 0.73. This is on the basis of a weak correlation ($r = 0.55$), on a different word scoring system (monosyllabic sentences), and inspection of best fit lines. Furthermore, our inspection of the best fit lines in the publication suggests that the estimated HUI utility gain associated with a 100%

TABLE 121 *Compliance with NICE reference case requirements of the economic evaluation submitted by Cochlear Europe*

Reference case requirement		Reviewer comment
Decision problem: as per NICE project scope	Yes	Simultaneous bilateral implantation considered (not sequential or additional)
Comparator(s): alternative therapies routinely used in the UK	Yes	'Standard of care' with or without a hearing aid
Perspective on costs: NHS and PSS	Yes	But education costs included as sensitivity analysis
Perspective on outcomes: all health effects on individuals	Yes	
Type of economic evaluation: cost-effectiveness analysis	Yes	Cost per QALY
Adequate time horizon	Yes	
Synthesis of evidence on outcomes: based on a systematic review	Yes/no	No synthesis, but evidence of a review of some relevant studies before choice of utility estimate
Measure of health benefits: QALYs	Yes	
Description of health states for QALY calculations: use of a standardised and validated generic instrument	Yes/no	HUI-3 utility values mapped from speech recognition scores (not using an validated algorithm)
Method of preference elicitation for health state values: choice-based method (e.g. TTO, SG, not rating scale)	Yes	HUI-3 preference weights derived using standard gamble
Source of preference data: representative sample of the UK public	No	From Ontario general population
Evidence on costs: prices relevant to NHS and PSS	Yes	Recent NHS-based studies. Plausible assumptions used to estimate costs of bilateral implantation
Discount rate: 3.5% per annum for costs and health effects	Yes	

HUI, Health Utilities Index; QALY, quality-adjusted life-year; PSS, Personal Social Services; SG, standard gamble; TTO, time trade-off

TABLE 122 *Base-case incremental cost-effectiveness ratios reported in the Cochlear Europe submission*

Comparison	ICER	95% CI
In adults		
Unilateral implantation vs standard care	£7145	£5907–7794
Bilateral vs unilateral implantation	£32,909	£24,051–44,582
In children		
Unilateral implantation vs standard care	£10,542	£8804–12,655
Bilateral vs unilateral implantation	£39,049	£31,426–49,798

increase in monosyllabic sentence scores is 0.47 rather than 0.73.

Cost of treatment failures

Second, in the base-case analyses, the proportion of treatment failures that receive a subsequent implant was 0%. This seems highly implausible and notably contrasts with a statement in the Advanced Bionics Europe submission that 'reimplantation following [implant] failure is near universal' (p. 28), and information in the 2004 UKCISG study in which 11 of the 27 adults who experienced adverse events had either their electrode replaced or the other ear implanted.

Cost-effectiveness analyses from Advanced Bionics Europe

Methods

This submission also took a Markov model-based approach to evaluating the cost-effectiveness of unilateral cochlear implantation compared with no cochlear implant, from an NHS and PSS perspective. They produced reference case analyses for unilateral cochlear implantation versus no implantation in:

- prelingually deafened profoundly deaf children
- postlingually deafened profoundly deaf children
- postlingually deafened profoundly deaf adults (profoundly deaf for 10 years)
- postlingually deafened severely deaf adults.

They chose not to present any cost-effectiveness analysis of bilateral implantation in adults or children on the basis of a lack of sufficient current research evidence. For the same reason no analysis in severely deaf children was presented.

Costs included were those associated with preimplantation assessment; implant surgery; the implant device; programming and initial rehabilitation; ongoing support/maintenance; processor upgrade; and spares and repairs. The main data source for non-device costs was the 2003 study by Barton and colleagues[64] of the cost of paediatric implantation in 12 UK implantation programmes from the early 1990s to 1998/9. However, their analyses omitted the assessment costs of those referred deaf people who ultimately did not receive a cochlear implant.

They use these costs in their analyses of cochlear implantation in both children and adults and acknowledge that they consequently may have overestimated the cost of cochlear implants in adults. The hardware costs are from their own company records, notably including a zero cost for implant replacements (in the first 10 years) and a zero cost for processor replacement repair in the first 3 years (as per their current sales policy).

Outcomes were estimated as QALYs gained. Based directly on the related study by Barton and colleagues[42] the estimated long-term utility gains (4 years after implantation and onwards) due to unilateral cochlear implantation in children were 0.256 if implanted at age 3 years and 0.196 if implanted at age 6 years. The utility value used for assessment of the benefits of unilateral implantation for adults was 0.214, based on the large 2004 study by the UKCISG.[40] In adults, to reflect a documented inverse relationship between duration of deafness before implantation and utility gain from implantation, a utility decrement (of 0.002) was subtracted from the utility gain for each year of deafness.

In summary, both the model structure and parameter estimates that determine effectiveness (QALYs), resource use, costs and other assumptions appeared reasonable and evidence-based where possible, and in most other respects the analyses met the reference case criteria stipulated in NICE methodological guidance (*Table 123*).

Main results

The main probabilistic results for lifetime analyses are summarised in *Table 124*.

In addition they presented an analysis for prelingually deafened profoundly deaf children, implanted at age 3 years, which included estimated educational savings. This reduced the previous (health-care cost only) ICER by about £4500 to £8875 per QALY gained.

Cost-effectiveness analyses from MED-EL UK

The submission by Med-EL UK to NICE did not include an economic model and primarily takes the form of a narrative summary of a selection of the published literature on the efficacy, quality of life impacts and cost-effectiveness of cochlear implantation. Search strategies to identify the studies or any inclusion/exclusion criteria used to choose the final studies reviewed were not presented.

TABLE 123 *Compliance with NICE reference case requirements of the economic evaluation submitted by Advanced Bionics Europe*

Reference case requirement		Reviewer comment
Decision problem: as per NICE project scope	Yes	Except no estimation of cost-effectiveness of bilateral implantation. Analysis of technology in severely deaf actually uses data for profoundly deaf 'marginal hearing aid users' (as defined by UKCISG 2004)
Comparator(s): alternative therapies routinely used in the UK	Yes	
Perspective on costs: NHS and PSS	Yes	Education costs included in a sensitivity analysis
Perspective on outcomes: all health effects on individuals	Yes	
Type of economic evaluation: cost-effectiveness analysis	Yes	Cost per QALY
Adequate time horizon	Yes	
Synthesis of evidence on outcomes: based on a systematic review	Yes/no	No synthesis, but evidence of a review of some relevant studies before choice of utility estimate
Measure of health benefits: QALYs	Yes	
Description of health states for QALY calculations: use of a standardised and validated generic instrument	Yes	HUI-3 completed
Method of preference elicitation for health state values: choice-based method (e.g. TTO, SG, not rating scale)	Yes	HUI-3 preference weights derived using standard gamble
Source of preference data: representative sample of the UK public	No	From Ontario general population
Evidence on costs: prices relevant to NHS and PSS	Yes	A recent NHS-based study in children used as source of model costs for both children and adults
Discount rate: 3.5% per annum for costs and health effects	Yes	

HUI, Health Utilities Index; QALY, quality-adjusted life-year; PSS, Personal Social Services; SG, standard gamble; TTO, time trade-off

TABLE 124 *Base-case incremental cost-effectiveness ratios (ICERs) reported in the Advanced Bionic Europe submission*

Unilateral cochlear implantation compared with no implantation in:	ICER (£/QALY)	95% CI (£/QALY)	% of samples with ICER < £30,000/QALY
Prelingually deafened profoundly deaf children implanted at age 3 years	13,337	1945 – Dominated	87.8
Postlingually deafened profoundly deaf children implanted at age 6 years	17,210	2137 – Dominated	79.2
Postlingually deafened profoundly deaf adults implanted at age 50 years	20,027	2396 – Dominated	68.7
Postlingually deafened severely deaf adults implanted at age 50 years	37,012	2660 – Dominated	37.4

QALY, quality-adjusted life-year.

In relation to cost-effectiveness the submission described evidence relating to four different uses of cochlear implantation: unilateral implantation in children; unilateral implantation in adults; bilateral implantation in adults; and 'bimodal stimulation' in adults (unilateral cochlear implant with a contralateral hearing aid).

For unilateral implantation in adults separate results are presented for 'traditional implant candidates' (those who scored 0% without lip-reading on speech perception tests and who did not significantly improve when aided) and 'marginal hearing aid users' (those whose scores did significantly improve).

Cost-effectiveness results

The results presented in this submission that are most relevant to the UK NHS context are summarised in *Table 125*. The source papers from which cost-effectiveness results are quoted are those by UKCISG,[40] Barton and colleagues,[42] Summerfield and colleagues[53] and Summerfield and colleagues.[29] As these studies have been summarised in more detail elsewhere in this report we do not elaborate on their methods and other results here.

Major limitations

The major limitations of the economic evidence presented in this submission are that:

- the questions being answered are not well-defined and have to be inferred from the section headings; in most cases the comparator interventions are stated in the source paper but not in the submission
- the information presented is not based on a systematic review or on a rigorously informed decision model; any process of selecting studies cited and how their quality was judged are not described.

Summary of industry-submitted economic evaluations

Two of the manufacturers submitted original economic analyses that met most NICE reference case criteria, whereas a third manufacturer provided a narrative review of published economic evaluations.

The base-case cost-effectiveness ratios from submissions are summarised in *Table 126*. However, these results should be viewed with some caution. The cost–utility estimates from Cochlear Europe were based on an estimate of the utility gain from unilateral cochlear implantation in adults of 0.394, which is almost twice the typical estimate from other studies. This high estimate was derived from weak correlations between sentence recognition scores and utility scores in one small study. They also further assumed that no device failures would involve reimplantation of a new cochlear implant. The analyses by Advanced Bionics Europe were clear and comprehensive in terms of the range of costs and events captured in the model and the range of analyses conducted. However, they applied the same costs of assessment, surgery, tuning/rehabilitation and maintenance to both adults and children despite reliable evidence from the UK that most of these costs are lower for adults. Advanced Bionics Europe did not present an analysis of bilateral cochlear implantation, but suggested that this use of cochlear implantation be appraised after better evidence becomes available. Finally, neither the analysis submitted by Cochlear Europe nor that submitted by Advanced Bionics Europe included any costs for those referred and assessed for implantation but who ultimately did not receive a cochlear implant. *Table 126* summarises the main results of these two submissions.

Comparison of PenTAG's analysis with the industry-submitted analyses

For unilateral cochlear implantation there were relatively minor differences in the estimated ICERs; all base-case ICERs were less than £15,000 per QALY except for the Advanced Bionics Europe estimate for unilateral implantation in adults (mostly because they used relatively high paediatric costs in their analysis). The major difference between the industry-submitted and PenTAG economic analyses was for bilateral implantation in adults, for which Cochlear Europe's estimated ICER (of £32,900 per QALY) was some £17,000 lower than PenTAG's estimate (£49,500 per QALY). This difference is primarily due to the manufacturer using a substantially higher assumed utility gain from cochlear implantation (0.114) than that used in PenTAG's analysis, which was based on an estimated utility gain from bilateral implantation of 0.03.

TABLE 125 *Cost-effectiveness results from an NHS perspective (in 2001/2 euros or in 2005/6 pounds), corrected where miscited in the industry submission*

Comparison	ICER (€/QALY)	ICER (£/QALY)	Source paper
Unilateral implantation in children	€25,629		Barton 2006[42]
Unilateral implantation in adults (all)	€27,142	£20,595	UKCISG 2004[40]
Unilateral implantation in adults (traditional candidates)	€25,336	£19,224	UKCISG 2004[40]
Unilateral implantation in adults (marginal hearing aid users)	€33,512	£25,428	UKCISG 2004[40]

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.
These two ICERs are cited wrongly in the industry submission, and in pounds when they are in euros in the original source (see *Table 7* of UKCISG 2004[40]).
Currency conversion uses exchange rate of £1 = €1.54 (as used in original paper) and then inflated 4 years to 2005/6 prices using the inflators from Curtis L, Netten A. *Unit costs of health and social care 2006*. Canterbury, PSSRU: University of Kent; 2006.

TABLE 126 *Main results from industry-submitted economic analyses*

	Cochlear Europe		Advanced Bionics Europe	
Policy comparison assessed	**Base-case ICER**	**PSA % ICERs < £30,000/QALY**	**Base-case ICER**	**PSA % ICERs < £30,000/QALY**
In children				
Degree of deafness	Severe to profound		Profound	
Unilateral cochlear implantation vs none (profoundly deaf, aged 3 years)	£10,542	98%[a]	£13,337	87.8%
Unilateral cochlear implantation vs none (profoundly deaf, aged 6 years)			£17,210	79.2%
Bilateral vs unilateral implantation (profoundly deaf, aged 3 years)[b]	£39,049	24%[a]	NC	NC
In adults				
Degree of deafness	Severe to profound		Profound	
Unilateral cochlear implantation vs none (profoundly deaf, aged 50 years)	£7145	100%[a]	£20,027	68.7%
Unilateral cochlear implantation vs none (severely deaf, aged 50 years)			£37,012	37.4%
Bilateral vs unilateral implantation (profoundly deaf, aged 50 years)[b]	£32,909	32%[a]	NC	NC

ICER, incremental cost-effectiveness ratio; NC, not conducted; PSA, probabilistic sensitivity analysis; QALY, quality-adjusted life-year.
a As read off from cost-effectiveness acceptability curves in report submitted to NICE.
b All analyses comparing bilateral implantation were of simultaneous bilateral implantation.

Appendix 9

Probability trees used in the PenTAG model

The full probability trees used in the construction of the model are shown in *Figures 55–61*. In the base-case analyses a number of event probabilities were set to zero, meaning that several of the branches are redundant. Several of the trees are used to generate transition probabilities for multiple health states. *Table 127* summarises which trees correspond to which health states. The probability trees correspond to the full model and therefore include rare events.

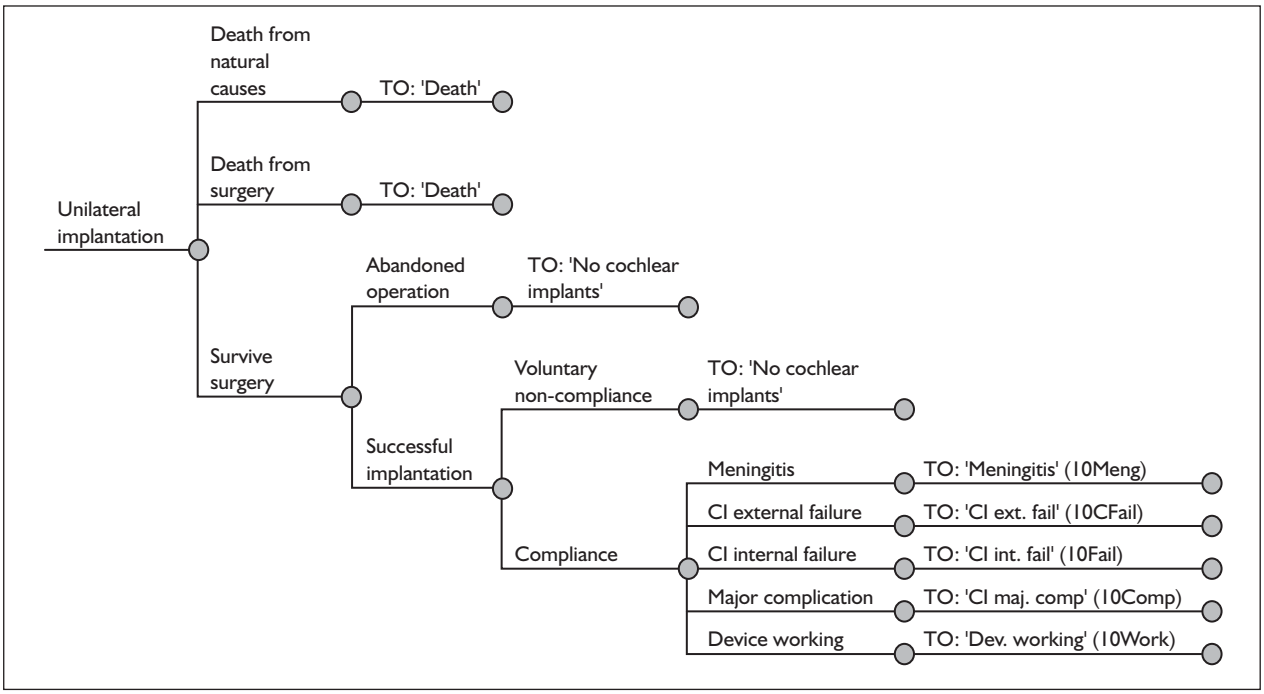

FIGURE 55 *Probability tree associated with the procedure to fit one cochlear implant. CI, cochlear implant.*

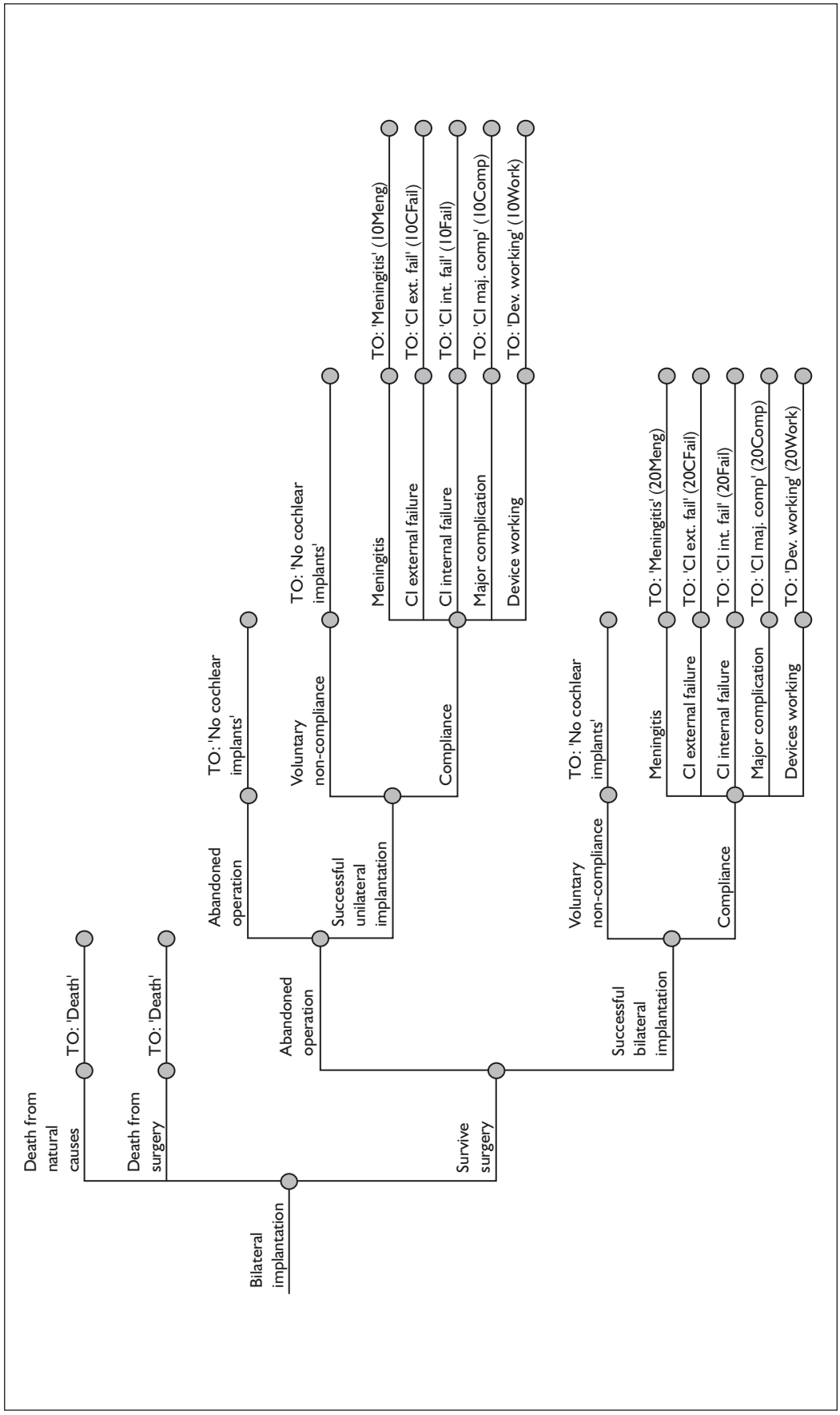

FIGURE 56 *Probability tree associated with the procedure to fit two cochlear implants simultaneously. CI, cochlear implant.*

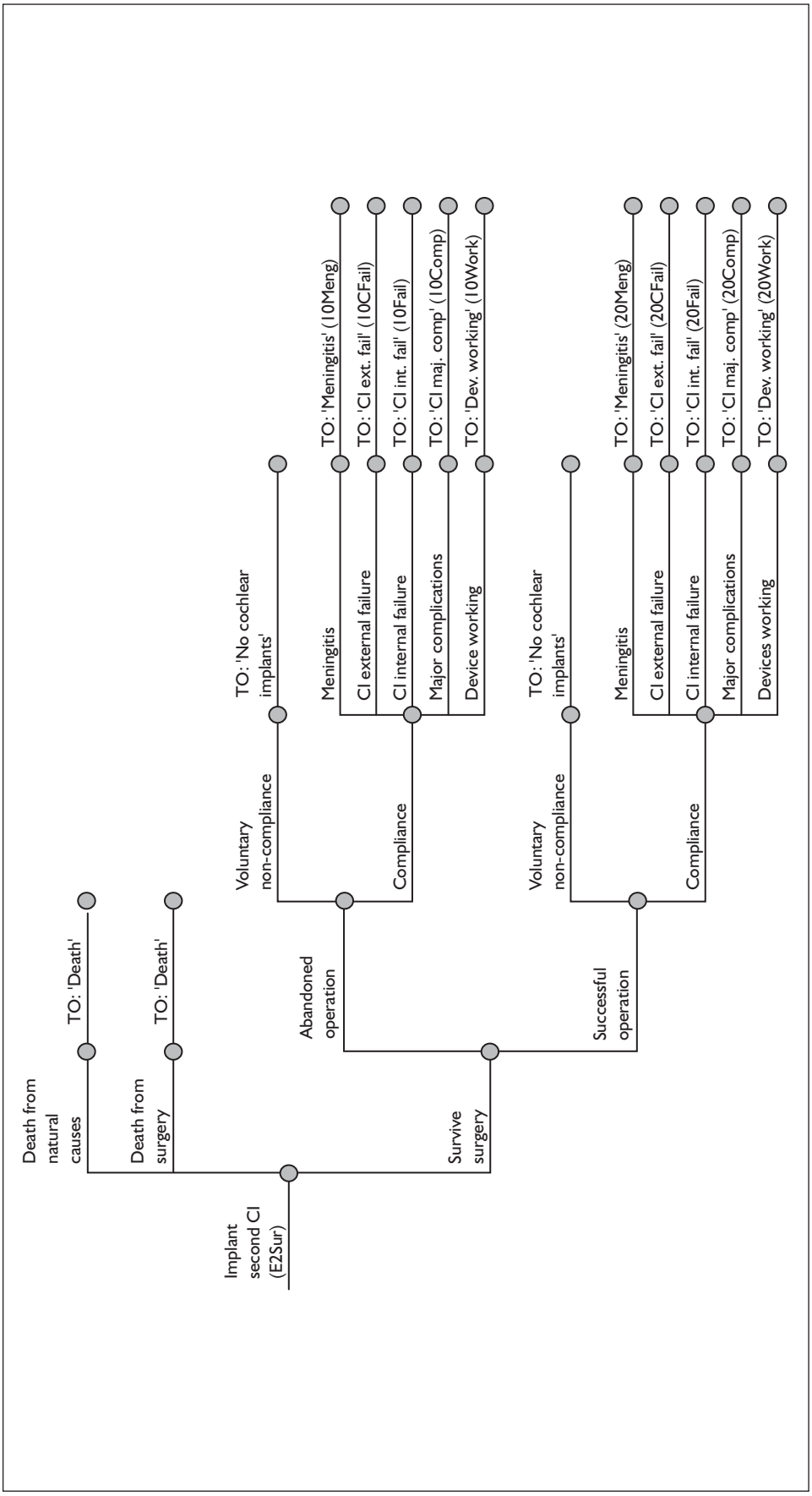

FIGURE 57 *Probability tree associated with the procedure to fit a second cochlear implant in individuals already using one. CI, cochlear implant.*

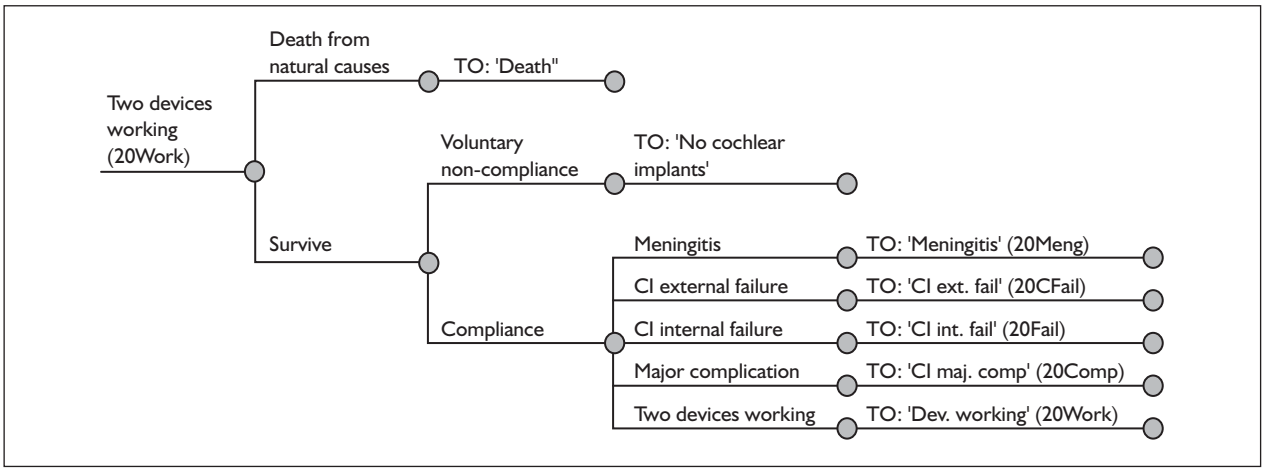

FIGURE 58 *Probability tree associated with health state '20Work'. CI, cochlear implant.*

TABLE 127 *Summary of health states and associated probability trees*

Probability tree	Health states in model using tree
Figure 55	UniSur, E3Sur
Figure 56	BiSur
Figure 57	E2Sur
Figure 58	20Work, 20CFail, 20Meng
Figure 59	20Comp, 20Fail
Figure 60	10Work, 10CFail, 10Meng
Figure 61	10Comp, 10Fail

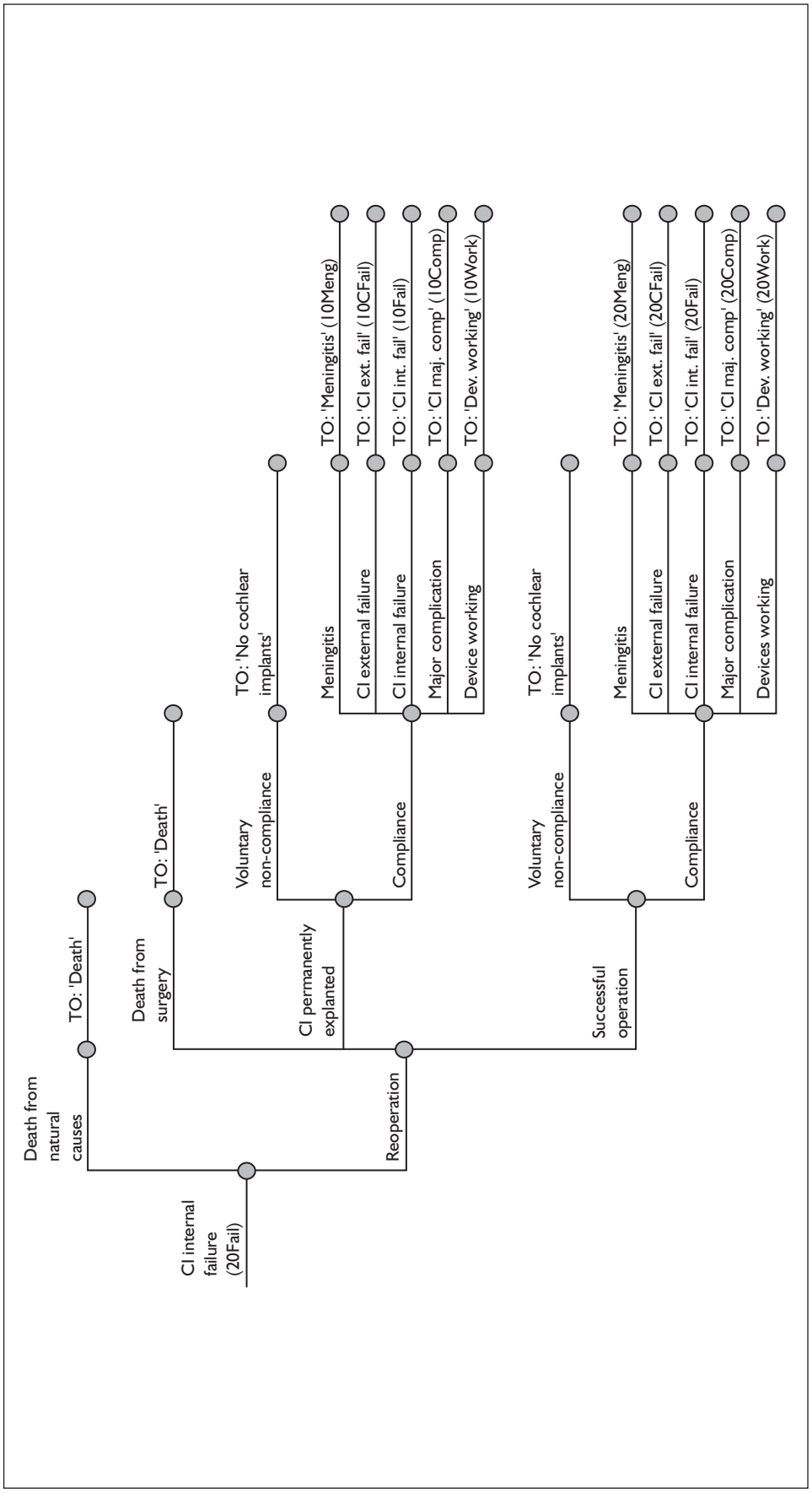

FIGURE 59 *Probability tree associated with health state '20Fail'. CI, cochlear implant.*

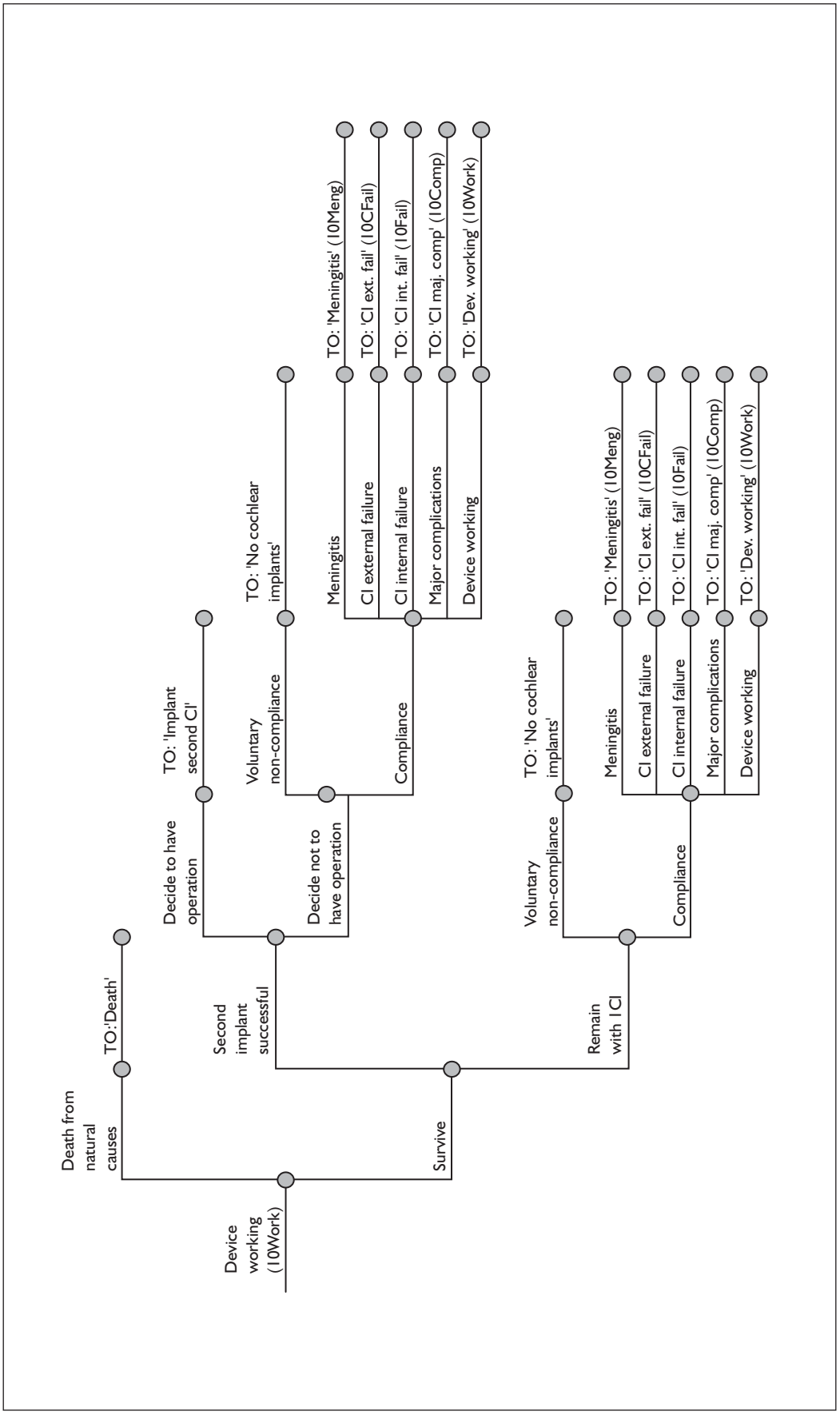

FIGURE 60 *Probability tree associated with health state '10Work'. CI, cochlear implant.*

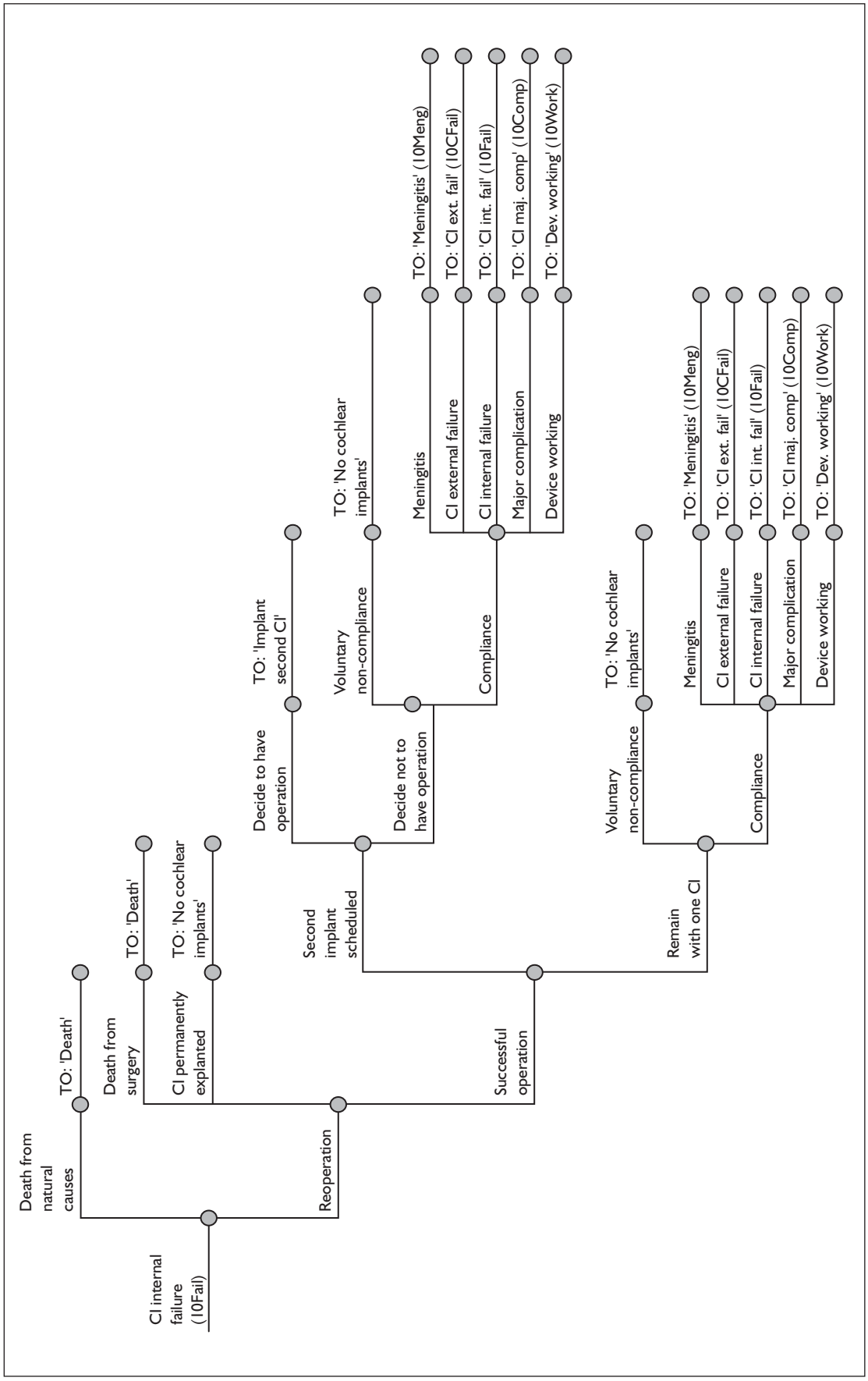

FIGURE 61 *Probability tree associated with health state '10Fail'. CI, cochlear implant.*

Appendix 10

Fitting parametric curves to survival data

General strategy

The initial stage of generating the survival curves used to model internal device failure was to find functional approximations to each of the individual curves reported in both the Cochlear Europe submission and Conboy and Gibbin.[65] For each published curve several different choices were explored (exponential, Weibull, Gompertz and linear), with goodness of fit assessed using the mean absolute percentage error (MAPE).[66]

An additional analysis of the numbers of each type of device implanted was also performed to generate a set of weights. Finally, these weights are used in combination with the values generated by the individual curves to produce a combined survival curve for the relevant patient group.

Calculation of MAPE

The method used is derived from that outlined in Makridakis and colleagues.[66] For each time point reported in one of the studies, the estimated value ($\hat{S}(t)$) and observed value ($S(t)$) were used to generate the percentage error using the formula:

$$PE_t = \left(\frac{S(t) - \hat{S}(t)}{S(t)} \right) * 100$$

From these values the MAPE is derived using the formula:

$$MAPE = \frac{1}{n} \sum_{t=1}^{n} \left| PE_t \right|$$

where n is the number of reported values for a particular survival curve.

Linear approximation

The general form of the survival function is:

$$\hat{S}(t) = \hat{\alpha} + \hat{\beta} * t$$

To generate estimates for the survival function, ordinary least squares (OLS) regression was performed with time as the independent variable to generate estimates for alpha and beta.

Exponential distribution

The exponential distribution is uniquely defined by a single parameter (lambda). In general:

$$\hat{\lambda} = \frac{-\ln\left\{\hat{S}(t)\right\}}{t}$$

where $S(t)$ represents the cumulative survival function.[67] To fit curves to published data an initial estimate of lambda (λ_{start}) is made. This estimate is used to generate estimates of the associated survivor function ($\hat{S}(t)$). Microsoft Solver® was then used to find the lambda value that minimises the MAPE.

Weibull distribution

The Weibull distribution is uniquely defined by two parameters (lambda and gamma). The general survivor function[67] can be written as:

$$\hat{S}(t) = \exp\left\{-\hat{\lambda} * t^{\hat{\gamma}}\right\}$$

Rearranging this gives:

$$\ln\left\{-\ln \hat{S}(t)\right\} = \ln \hat{\lambda} + \hat{\gamma} * \ln t$$

OLS regression analysis using transformed values for each time point and the corresponding cumulative regression is then performed to derive estimates for lambda and gamma.

Gompertz distribution

The Gompertz distribution is uniquely defined by two parameters (lambda and theta) and the general survivor function[67] can be written as:

$$\hat{S}(t) = \exp\left\{\frac{\hat{\lambda}}{\hat{\theta}}(1 - \exp^{\hat{\theta} * t})\right\}$$

Unfortunately there is no obvious transformation that can be performed to generate estimates for lambda and theta. Therefore, a solution was found in Microsoft Excel® using the Solver® function. Combinations of lambda and theta were analysed and the pair that minimised the MAPE was sought.

Survival analysis in children

The cumulative survival plots reported in the Cochlear Europe submission are reproduced in *Figure 62* alongside the data presented in Conboy and Gibbin.[65]

Table 128 summarises the curve-fitting process for paediatric cochlear implants.

Table 129 summarises the information concerning the numbers of paediatric implants.

The combined survival function used to model the cumulative survival of cochlear implants in children is therefore:

$$S(t) = 0.0095 \times F(t) + 0.2082 \times G(t) + 0.5047 \times H(t) + 0.2776 \times J(t)$$

Survival analysis in adults

The cumulative survival values for several different devices are reproduced in *Figure 63* and the fitting process summarised in *Table 130*. Published data for the CI24RE and CI24M post modification are

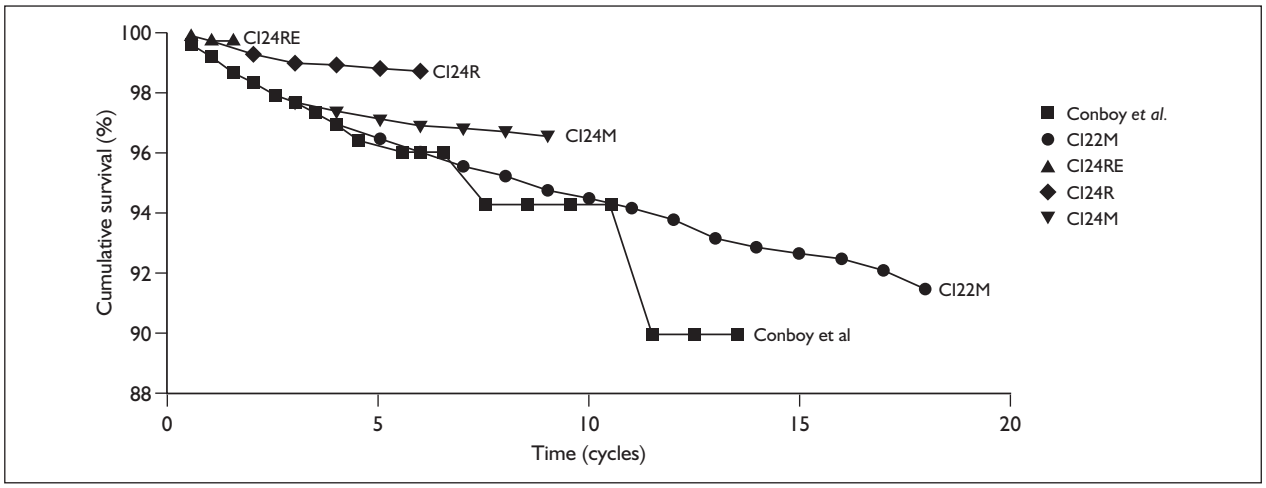

FIGURE 62 *Paediatric cumulative survival plots for a range of cochlear implants as reported by Cochlear Europe and Conboy and Gibbin.*[65]

TABLE 128 *Curve-fitting results for paediatric implants*

Receiver/stimulator or study	Functional approximation	Label	MAPE
Conboy 2004[65]	Exponential	$F(t)$	0.64%
CI22M	Weibull	$G(t)$	0.19%
CI24RE	NA		NA
CI24R	Weibull	$H(t)$	0.04%
CI24M (all)	Exponential	$J(t)$	0.48%
CI24M (post)	NA		NA

Note: Because information on cumulative survival for the CI24RE receiver/stimulator was only available for 1.5 years the fitting of a survival curve was unsuitable. Similarly, the number of CI24M receivers/stimulators used post modification was not reported. We therefore excluded these from the analysis of the numbers implanted (and therefore the curve-fitting process).

again not used for the same reason as in the child approximation. The values used to generate the weights are summarised in *Table 131*.

The function used to generate the combined cumulative survival curve for adult cochlear implant users is therefore:

$$S(t) = 0.3016 \times A(t) + 0.4777 \times B(t) + 0.2207 \times C(t)$$

TABLE 129 *Number of Nucleus® implants in children as reported in the Cochlear Europe submission*

Receiver/stimulator or study	Number implanted	Proportion of total implants
Conboy 2004[65]	377	0.95%
CI22M	8225	20.82%
CI24R	19,942	50.47%
CI24M (all)	10,968	27.76%
Total	39,512	100%

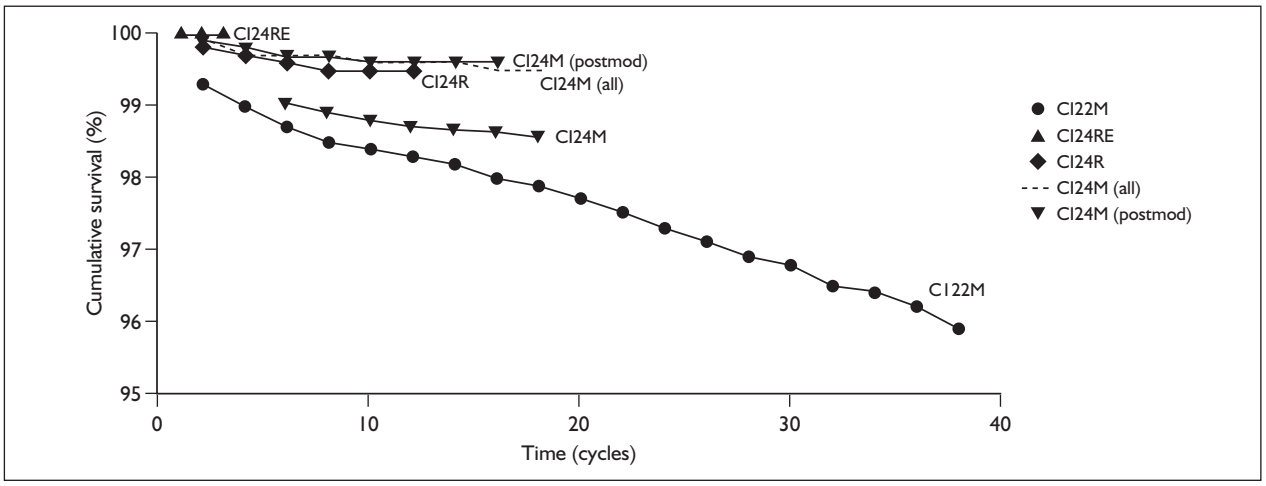

FIGURE 63 *Cumulative survival plots for a range of cochlear implants given to adults.*

TABLE 130 *Curve-fitting results for adult implants*

Receiver/stimulator	Functional approximation	Label	MAPE
CI22M	Linear	$A(t)$	0.09%
CI24R	Weibull	$B(t)$	0.02%
CI24M (all)	Weibull	$C(t)$	0.03%

TABLE 131 *Number of Nucleus® implants in adults as reported in the Cochlear Europe submission*

Receiver/stimulator	Number implanted	Proportion of total implants
CI22M	9940	30.16%
CI24R	15,743	47.77%
CI24M (all)	7272	22.07%
Total	32,955	100%

Appendix 11

Studies reviewed to identify utility values for model

The following is a complete list of the studies retrieved and examined to identify the most valid and reliable utility and utility gain estimates for use in the model:

1. Barton GR, Stacey PC, Fortnum HM, Summerfield AQ. Hearing-impaired children in the United Kingdom. IV: Cost-effectiveness of pediatric cochlear implantation. *Ear Hear* 2006;**27**:575–88.

2. Cheng AK, Rubin HR, Powe NR, Mellon NK, Francis HW, Niparko JK. Cost-utility analysis of the cochlear implant in children. *JAMA* 2000;**284**:850–6.

3. Francis HW, Chee N, Yeagle J, Cheng A, Niparko JK. Impact of cochlear implants on the functional health status of older adults. *Laryngoscope* 2002;**112**:1482–8.

4. Krabbe PF, Hinderink JB, Van Den Broek P. The effect of cochlear implant use in postlingually deaf adults. *Int J Technol Assess Health Care* 2000;**16**:864–73.

5. Lee HY, Park EC, Joong KH, Choi JY, Kim HN. Cost-utility analysis of cochlear implants in Korea using different measures of utility. *Acta Otolaryngol* 2006;**126**:817–23.

6. O'Neill C, O'Donoghue GM, Archbold SM, Normand C. A cost-utility analysis of pediatric cochlear implantation. *Laryngoscope* 2000;**110**:156–60.

7. O'Neill C, Archbold SM, O'Donoghue GM, McAlister DA, Nikolopoulos TP. Indirect costs, cost-utility variations and the funding of paediatric cochlear implantation. *Int J Pediatr Otorhinolaryngol* 2001;**58**:53–7.

8. Palmer CS, Niparko JK, Wyatt JR, Rothman M, de Lissovoy G. A prospective study of the cost-utility of the multichannel cochlear implant. *Arch Otolaryngol Head Neck Surg* 1999;**125**:1221–8.

9. Summerfield A, Stacey PC, Roberts KL, Fortnum H, Barton GR. Economic analysis and cochlear implantation. *Int Congr Ser* 2003;**1254**:313–19.

10. Summerfield AQ, Marshall DH, Archbold S. Cost-effectiveness considerations in pediatric cochlear implantation. *Am J Otol* 1997;**18**(6 Suppl.):S166–8.

11. Summerfield AQ, Marshall DH, Barton GR, Bloor KE. A cost-utility scenario analysis of bilateral cochlear implantation. *Arch Otolaryngol Head Neck Surg* 2002;**128**:1255–62.

12. Summerfield AQ, Barton GR, Toner J, McAnallen C, Proops D, Harries C, *et al*. Self-reported benefits from successive bilateral cochlear implantation in post-lingually deafened adults: randomised controlled trial. *Int J Audiol* 2006;**45**(Suppl. 1):S99–107.

13. UK Cochlear Implant Study Group. Criteria of candidacy for unilateral cochlear implantation is postlingually deafened adults. II: Cost-effectiveness analysis. *Ear Hear* 2004;**25**:336–60.

14. Wyatt JR, Niparko JK, Rothman ML, de Lissovoy G. Cost effectiveness of the multichannel cochlear implant. *Am J Otol* 1995;16:52–62.

15. Wyatt JR, Niparko JK, Rothman M, de Lissovoy G. Cost utility of the multichannel cochlear implant in 258 profoundly deaf individuals. *Laryngoscope* 1996;**106**:816–21.

Appendix 12

Ranges and distributions used in the probabilistic sensitivity analysis

TABLE 132 *Ranges and distributions used in the probabilistic sensitivity analysis*

Parameter	Subgroup	Available range	Source	Data type	Distribution
Utilities					
Profound deafness	Adults	(0.411–0.455)	UKCISG 2004[40]	95% CI	Beta
	Children	(0.393–0.452)	Barton 2006[42]	95% CI	Beta
Utility gain (one cochlear implant vs no cochlear implants)	Adults	(0.176–0.218)	UKCISG 2004[40]	95% CI	Beta
	Children, < 2 years post implant	(–0.013 to 0.144)	Barton 2006[42]	95% CI	Beta
	Children, 2–4 years post implant	(0.161–0.263)	Barton 2006[42]	95% CI	Modified beta
	Children, > 4 years post implant	(0.184–0.280)	Barton 2006[42]	95% CI	Modified beta
Utility gain (two cochlear implants vs one cochlear implant)	Adults	(–0.045 to 0.104)	Summerfield 2002[53]	95% CI	Initially 1-U transformation applied. Lognormal distribution used on transformed variable
	Children	None	Assumption that effect in children is identical to effect in adults made	Assumption	Initially 1-U transformation applied. Lognormal distribution used on transformed variable
Costs					
Presurgical candidacy	Adults	(£3169–4532) (–21% to +13%)	UKCISG 2004[40]	Min./max. values. Assumed to represent 99.9% CI	Lognormal
	Children	(£1194–5003) (–58% to +76%)	Barton 2006[42]	Min./max. values assumed to represent 99.9% CI	Lognormal
Unilateral implant (non-system)	Adults	(£928–6106) (–67% to +117%)	UKCISG 2004[40]	Min./max. values assumed to represent 99.9% CI	Lognormal
	Children	(£1427–4106) (–59% to +18%)	Barton 2006[42]	Min./max. values assumed to represent 99.9% CI	Lognormal
Bilateral implant (non-system)	Adults	(£1393–9160) (–67% to +117%)	UKCISG 2004[40]	Min./max. values assumed to represent 99.9% CI	Lognormal
	Children	(£2140–6160) (–59% to +18%)	Barton 2006[42]	Min./max. values assumed to represent 99.9% CI	Lognormal

Parameter	Subgroup	Available range	Source	Data type	Distribution
Tuning and maintenance (year 1)	Adults	(£4400–5300) (–12% to +6%)	UKCISG 2004[40]	Min./max. values assumed to represent 99.9% CI	Lognormal
Tuning (year 1)	Children	(£4025–17,473) (–56% to +91%)	Barton 2006[42]	Min./max. values assumed to represent 99.9% CI	Lognormal
Maintenance (year 1)	Children	(£1715–6443) (–59% to +54%)	Barton 2006[42]	Min./max. values assumed to represent 99.9% CI	Lognormal
Maintenance (year 2)	Adults	(£614–1165) (–23% to +46%)	UKCISG 2004[40]	Min./max. values assumed to represent 99.9% CI	Lognormal
	Children	(£932–6182) (–70% to +99%)	Barton 2006[42]	Min./max. values assumed to represent 99.9% CI	Lognormal
Maintenance (year 3)	Adults	(£318–1164) (–58% to +54%)	UKCISG 2004[40]	Min./max. values assumed to represent 99.9% CI	Log Normal
	Children	(£423–1896) (–69% to 39%)	Barton 2006[42]	Min./max. values assumed to represent 99.9% CI	Lognormal
Maintenance (year 4+)	Adults	(£317–875) (–47% to 46%)	UKCISG 2004[40]	Min./max. values assumed to represent 99.9% CI	Lognormal
	Children	(£423–1896) (–69% to +39%)	Barton 2006[42]	Min./max. values assumed to represent 99.9% CI	Lognormal
Digital hearing aid	Adults Children	(£62–152)	NHS Supply Chain	Min./max. values assumed to represent 99.9% CI	Lognormal
Cochlear implant internal failure (outside warranty)	Adults Children	NA	NA	Assumed to be the same as sampled value for non-implant system cost	NA
Cochlear implant external failure (in warranty)	Adults Children	(£0–100)	Values represent median cost of outpatient audiological appointment	Assumption. Assumed to represent 99.9% CI	Lognormal

continued

TABLE 132 *Ranges and distributions used in the probabilistic sensitivity analysis (continued)*

Parameter	Subgroup	Available range	Source	Data type	Distribution
Major complication (unilateral cochlear implant use)	Adults	(£7303–8532)	NA	Values a consequence of uncertainty in other parameters. Assumed to represent 99.9% CI	Lognormal
	Children	(£7421–8057)	NA	Values a consequence of uncertainty in other parameters. Assumed to represent 99.9% CI	Lognormal
Major complication (bilateral cochlear implant use)	Adults	(£5654–6883)	NA	Values a consequence of uncertainty in other parameters. Assumed to represent 99.9% CI	Lognormal
	Children	(£5709–6345)	NA	Values a consequence of uncertainty in other parameters. Assumed to represent 99.9% CI	Lognormal
Proportion internal failures outside warranty	Adults	(50–75%)	None	Assumption	Beta
	Children	(50–75%)	None	Assumption	Beta
Proportion external failures outside warranty	Adults	(99–99.9%)	None	Assumption	Beta
	Children	(99–99.9%)	None	Assumption	Beta
Event probabilities – internal device failure (adults)					
CI22M		Alpha: (0.9928–0.9945); beta: (–0.0009 to –0.0008)	Values derived by OLS regression using Cochlear Corporation reliability data	95% CI	Bivariate normal
CI24M (all)		Lambda: (0.0005–0.0014); gamma: (0.402–0.858)	Values derived by OLS regression using Cochlear Corporation reliability data	95% CI	Bivariate normal
CI24R		Lambda: (0.001–0.002); gamma: (0.391–0.712)	Values derived by OLS regression using Cochlear Corporation reliability data	95% CI	Bivariate normal

DOI: 10.3310/hta13440

Parameter	Subgroup	Available range	Source	Data type	Distribution
Proportion of above devices used to generate pooled survival curve			Baseline values derived from overall device use (Cochlear Corporation reliability data)	NA	Dirichlet
Event probabilities – internal device failure (children)					
Conboy 2004[65]		Lambda: (0.002–0.006)	Values derived by OLS regression using information derived from original source	95% CI	Truncated normal distribution
CI22M		Lambda: (0.005–0.0064); gamma: (0.735–0.822)	Values derived by OLS regression using Cochlear Corporation reliability data	95% CI	Bivariate normal
CI24R		Lambda: (0.002–0.004); gamma: (0.507 0.821)	Values derived by OLS regression using Cochlear Corporation reliability data	95% CI	Bivariate normal
CI24M		Lambda: (0.002–0.003)	Values derived by OLS regression using Cochlear Corporation reliability data	95% CI	Truncated normal distribution
Proportion of above devices used to generate pooled survival curve			Baseline values derived from overall device use (Cochlear Corporation reliability data)	NA	Dirichlet
Event probabilities – other					
Referrals not receiving an implant	Adults	None	SE assumed to be ¼ central estimate	Assumption	Beta
	Children	None	SE assumed to be ¼ central estimate	Assumption	Beta

continued

TABLE 132 *Ranges and distributions used in the probabilistic sensitivity analysis (continued)*

Parameter	Subgroup	Available range	Source	Data type	Distribution
Major complication (unilateral use)	Adults	None	SE assumed to be ¼ central estimate	Assumption	Beta
	Children	None	SE assumed to be ¼ central estimate	Assumption	Beta
Permanent device explantation during reoperation	Adults	(0.023–0.203)	Derived from meta-analysis of data presented in Dutt 2005,[68] Ray 2004,[69] Bhatia 2004,[70] Balkany 1999,[71] Stratigouleas 2006,[72] and Lassig 2005[73]	95% CI	Beta
	Children	(0.023–0.203)	Assumed to be same as for adults	Assumption	Beta
External cochlear implant failure (annual probability)	Adults	None	SE assumed to be ¼ central estimate	Assumption	Beta
	Children	None	SE assumed to be ¼ central estimate	Assumption	Beta
Elective (permanent) non-use	Adults	None	SE assumed to be ¼ central estimate	Assumption	Beta
	Children				
Risk modifiers					
Major complication (bilateral use compared with unilateral use)	Adults	None	SE assumed to be ¼ log mean value	Assumption	Constrained lognormal
	Children	None	SE assumed to be ¼ log mean value	Assumption	Constrained lognormal
Cochlear implant internal failure (bilateral use compared with unilateral use)	Adults	None	SE assumed to be ¼ log mean value	Assumption	Constrained lognormal
	Children	None	SE assumed to be ¼ log mean value	Assumption	Constrained lognormal
Cochlear implant external failure (bilateral use compared with unilateral use)	Adults	None	SE assumed to be ¼ log mean value	Assumption	Constrained lognormal
	Children	None	SE assumed to be ¼ log mean value	Assumption	Constrained lognormal

DOI: 10.3310/hta13440

Parameter	Subgroup	Available range	Source	Data type	Distribution
Device lifetimes					
Acoustic hearing aid	Adults	None	Variance assumed to be same as mean lifetime	Assumption. Need to generate an integer value	Poisson
	Children	None	Variance assumed to be same as mean lifetime	Assumption. Need to generate an integer value	Poisson
Cochlear implant speech processor	Adults	None	Variance assumed to be same as mean warranty	Assumption. Need to generate an integer value	Poisson
	Children	None	Variance assumed to be same as mean warranty	Assumption. Need to generate an integer value	Poisson
Other model parameters					
Delay between operations (sequential implantation)	Adults	None	Variance assumed to be same as mean	Assumption. Need to generate an integer value	Poisson
	Children	None	Variance assumed to be same as mean	Assumption. Need to generate an integer value	Poisson
Proportion of non-cochlear implant users gaining benefit from an acoustic hearing aid	Adults	None	SE assumed to be ¼ central estimate	Assumption	Beta
	Children	None	SE assumed to be ¼ central estimate	Assumption	Beta
Proportion of unilateral implantees using a contralateral acoustic hearing aid	Adults	None	SE assumed to be ¼ central estimate	Assumption	Beta
	Children	None	SE assumed to be ¼ central estimate	Assumption	Beta
Length of trial period before elective non-use	Adults	None	Variance assumed to be same as mean	Assumption. Need to generate an integer value	Poisson
	Children	None	Variance assumed to be same as mean	Assumption. Need to generate an integer value	Poisson

continued

TABLE 132 *Ranges and distributions used in the probabilistic sensitivity analysis (continued)*

Parameter	Subgroup	Available range	Source	Data type	Distribution
Proportion of initial costs incurred by unsuccessful referrals	Adults	None	SE assumed to be ¼ central estimate	Assumption	Beta
	Children	None	SE assumed to be ¼ central estimate	Assumption	Beta
Proportion of non-cochlear implant users who gain benefit from acoustic hearing aids only using one rather than two	Adults	None	SE assumed to be ¼ central estimate	Assumption	Beta
	Children	None	SE assumed to be ¼ central estimate	Assumption	Beta

OLS, ordinary least squares; SE, standard error.

Appendix 13

Speculative cost-effectiveness acceptability curves for a range of bilateral utility gain values

Children

As stated previously (see Chapter 5, Safety and reliability of cochlear implants – children and adults) our systematic review of utility values discovered no studies in children in which the incremental gain associated with using two cochlear implants versus one was measured or elicited. We therefore made the provisional modelling assumption that the utility gain in children would be the same as in adults.

This assumption is incorporated into the PSA outputs generated for the comparison of bilateral and unilateral cochlear implant use (see Chapter 7, Results of cost-effectiveness in prelingually implanted profoundly deaf children). We felt that because of the extreme uncertainty in this key parameter we would also generate a set of speculative, hypothetical CEACs corresponding to a range of possible estimates for this parameter.

In the absence of any data to inform this analysis we have assumed that the standard error is one-half of the central estimate and used these values to parameterise a range of beta distributions. The results for both early (implant age 1.5 years) simultaneous and early sequential bilateral implantation compared with unilateral implantation are presented graphically in *Figures 64* and *65* and tabulated in *Table 133*.

Adults

The systematic review of studies that produced utility estimates highlighted one study in which the incremental benefit associated with bilateral compared with unilateral implantation was elicited. This study was, however, very small ($n = 24$) and had a short-term follow-up period (9 months). The resultant parameter estimate is, therefore, subject to a high degree of uncertainty.

We therefore produced CEACs for a range of other possible parameter estimates for adults in the same way as for children. The results are summarised in *Table 134* numerically and in *Figures 66* and *67* graphically.

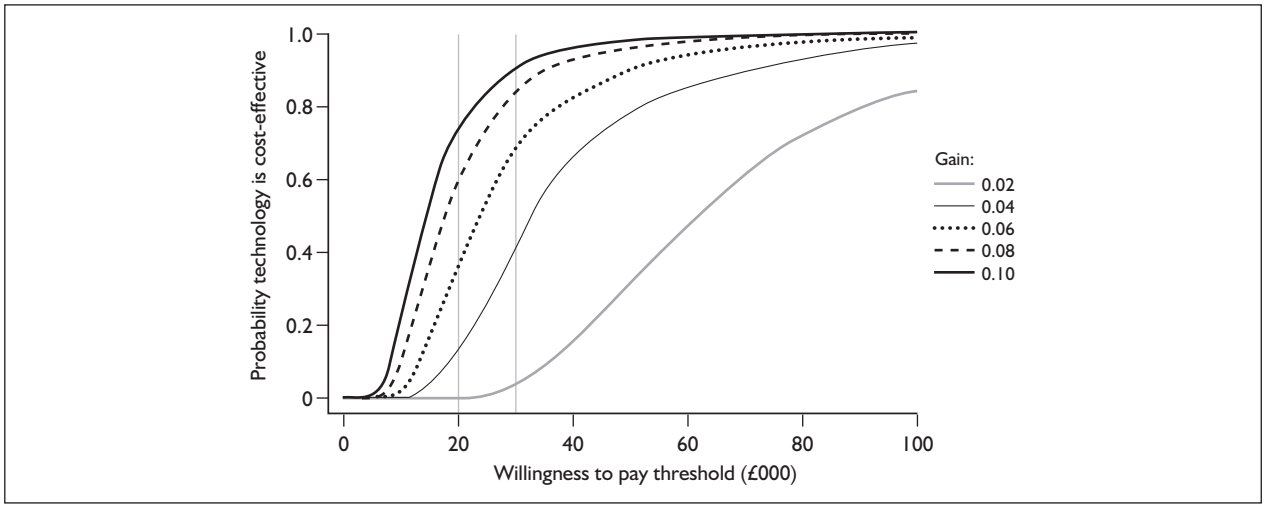

FIGURE 64 *Indicative cost-effectiveness acceptability curves for a range of utility gain values associated with simultaneous paediatric bilateral implantation.*

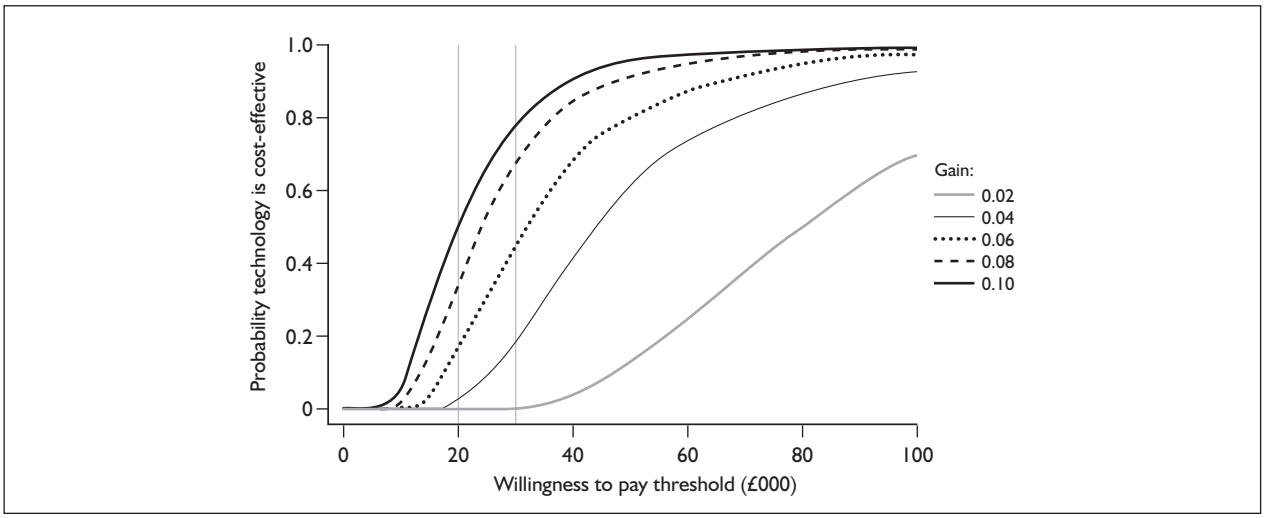

FIGURE 65 *Indicative cost-effectiveness acceptability curves for a range of utility gain values associated with sequential paediatric bilateral implantation.*

TABLE 133 *Indicative probabilistic sensitivity analysis outputs for a range of values associated with the incremental utility gain for paediatric bilateral cochlear implantation*

	Mean utility gain				
	0.02	**0.04**	**0.06**	**0.08**	**0.1**
Range used	0.0004–0.04	0.001–0.079	0.0012–0.112	0.002–0.158	0.002–0.198
Likelihood simultaneous implantation cost-effective at £20,000/QALY	0.2%	11.9%	35.2%	58.8%	72%
Likelihood simultaneous implantation cost-effective at £30,000/QALY	3.0%	40.1%	67.5%	83.9%	90.2%
Likelihood sequential implantation cost-effective at £20,000/QALY	0%	3.3%	15.4%	35.1%	49.0%
Likelihood sequential implantation cost-effective at £30,000/QALY	0.3%	19.8%	44.4%	66.5%	78.6%

TABLE 134 *Indicative probabilistic sensitivity analysis outputs for a range of values associated with the incremental utility gain for adult bilateral cochlear implantation*

	Mean utility gain				
	0.02	**0.04**	**0.06**	**0.08**	**0.1**
Range used	0.0004–0.034	0.001–0.079	0.0012–0.112	0.002–0.158	0.002–0.198
Likelihood simultaneous implantation cost-effective at £20,000/QALY	0%	5.0%	24.1%	42.5%	61.0%
Likelihood simultaneous implantation cost-effective at £30,000/QALY	1.0%	25.9%	55.5%	71.3%	82.8%
Likelihood sequential implantation cost-effective at £20,000/QALY	0%	1.2%	12.0%	27.5%	44.4%
Likelihood sequential implantation cost-effective at £30,000/QALY	0.2%	13.4%	38.7%	57.0%	73.5%

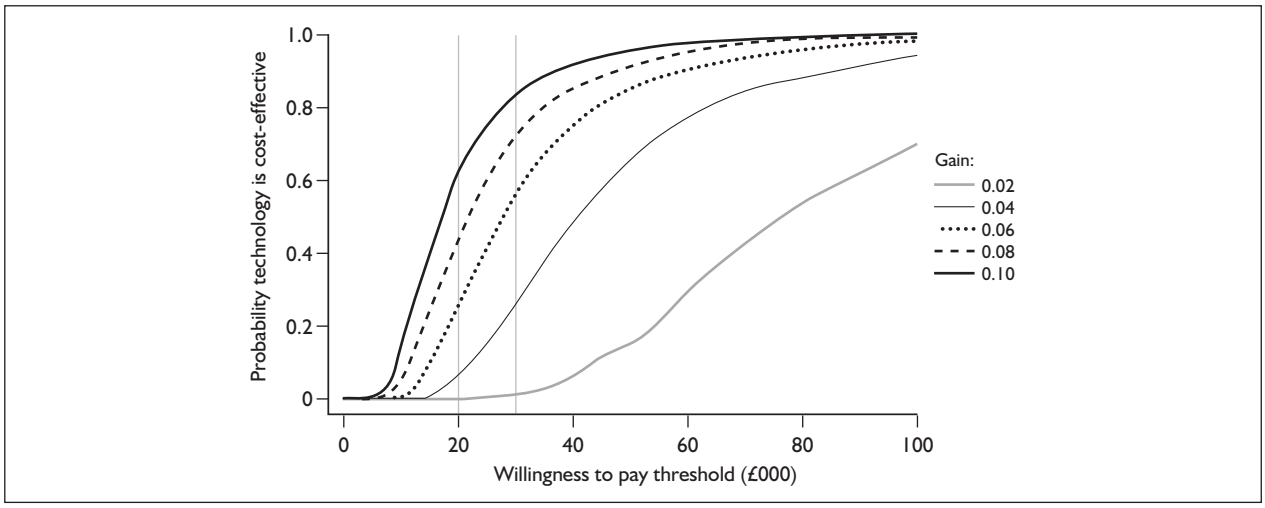

FIGURE 66 *Indicative cost-effectiveness acceptability curves for a range of utility gain values associated with simultaneous adult bilateral implantation.*

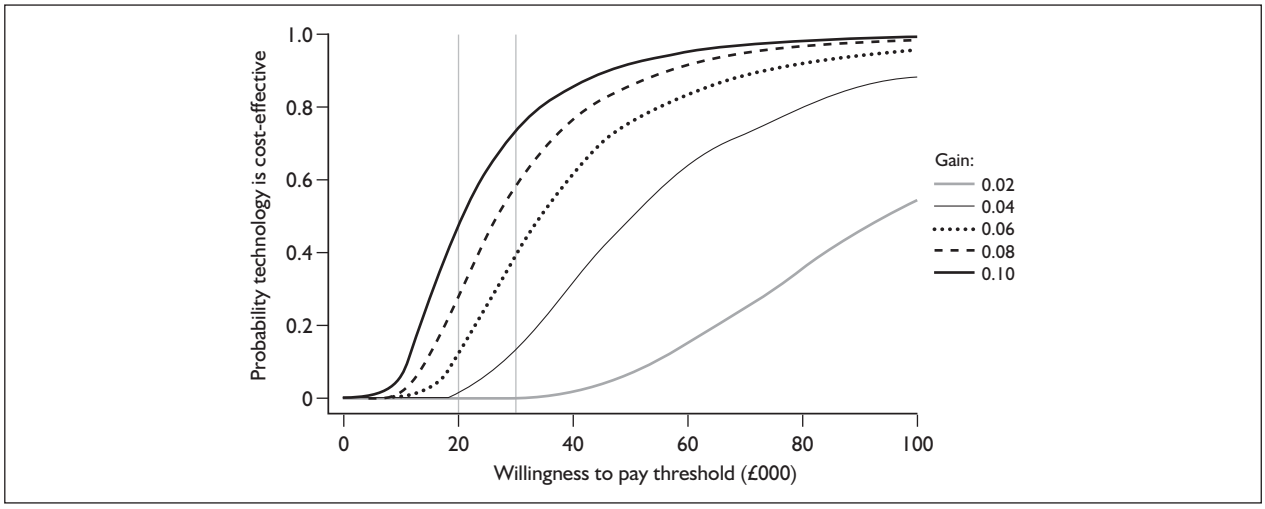

FIGURE 67 *Indicative cost-effectiveness acceptability curves for a range of utility gain values associated with sequential adult bilateral implantation.*

Appendix 14
Ongoing trials

Ongoing cochlear implant trials on the National Research Register, 18 October 2007

The NRR shows the following eight ongoing trials (see following section for details):

1. Candidacy of cochlear implants and hearing amplification devices in the Cambridgeshire area.
2. Cortical activity in cochlear implant users – a positron emission tomography study.
3. Maximising outcomes for adult cochlear implant users by auditory training (Bradford and Nottingham studies).
4. Quality of life of patients with binaural hearing aids and bilateral cochlear implants.
5. Health-related quality of life in children and adolescents with cochlear implants.
6. Improving outcomes for users of cochlear implants and bilateral cochlear implants by measuring primary psychophysical modifying speech processors and fitting schemes.
7. The effect of cochlear implantation on middle ear mechanics.

NRR multicentre ongoing trials
Record #1 of 1
TI:Candidacy of cochlear implants and hearing amplification devices in the Cambridgeshire area

PI:N0544194751

PR:Cambridge Consortium – Addenbrookes

RE:Eastern Regional Office

MR:We wish to calculate the prevalence of patient suitability (on audiological criteria) for cochlear implants and hearing amplification devices among patients who have undergone audiological investigations in hospitals in England.

MT:Aim: assessing the prevalence of candidacy for cochlear implants and hearing amplification devices among the patients previously assessed at audiology departments of selected hospitals

1− All patients in audiology database searched for audiological criteria for cochlear implants and hearing amplification devices.

2− Notes of patients fitting audiological criteria in certain/borderline cases are assessed for medical and otological exclusion criteria.

3− Outcome: suitability of patients grouped as candidates or not. This does not entail the device being offered because of resource restriction.

OU:Prevalence for candidacy for cochlear implants and hearing amplification devices in patients who have been investigated in selected hospitals' audiology departments.

MC:This record is from the lead centre of a multicentre study.

EC:06/MRE05/11

PC:Addenbrooke's Hospital

SD:3/8/2005

ED:3/8/2008

ST:Ongoing

AU:Mr Elias Koury

AD:ENT

F1:Own account

PK:MeSH terms not yet assigned

NRR participant centre ongoing trials
Record #1 of 4
TI:Cortical activity in cochlear implant users – a positron emission tomography study

PI:N0063116034

PR:Christie Hospital NHS Trust

RE:North West Regional Office

MR:Which areas of the auditory cortex are involved in patient response to cochlear implants?

MT:Neuroactivation study with FDG PET

OU:Patient response

MC:This record refers to a multicentre study led by another centre

LC:Manchester Royal Infirmary Hospital

SD:1/1/2002

ED:31/12/2008

ST:Ongoing

AU:Dr D Hastings

AD:North West Medical Physics, Christie Hospital NHS Trust, Wilmslow Road, Withington, Manchester, M20 4BX

PH:0161 446 3546

PN:RBV

PT:Greater Manchester Cancer Programme

F1:Royal College of Surgeons of Edinburgh

F3:140000

F4:NHS R&D Support Funding

F5:2007/08

PK:MeSH terms not yet assigned

Record #2 of 4
TI:Maximising outcomes for adult cochlear implant users by auditory training

PI:N0050182727

PR:Bradford Teaching Hospitals NHS Foundation Trust

RE:Northern/Yorkshire Regional Office

MR:Cochlear implantation is a surgical and therapeutic intervention that restores useful auditory sensations to people who are profoundly deaf and who do not benefit materially from acoustic hearing aids. The aim of this research is to measure the effectiveness of a computer-based, self-administered auditory training package designed to improve the speech perception abilities of adults who perform poorly with their cochlear implants. The training package will be implemented on laptop computers and used by patients in their own homes. If successful the training package will reduce the need for costly one-to-one speech and language therapy.

MT:The research planned with cochlear implant users follows on from work that has been carried out with normally hearing listeners who listen to speech through simulation of a cochlear implant system. The study has developed auditory training packages based around discriminating between quasi-minimal pairs of words and around discriminating words in sentences.

The study intends to evaluate the effectiveness of a training package that includes both word- and sentence-based auditory training. Participants will be eight cochlear implant users who have limited speech recognition abilities. An initial meeting between the investigators and each participant will take place at the local cochlear implant programme. Thereafter, all training and testing will be carried out in participants' own homes.

Participants will carry out extensive auditory training via laptop computers. Participants will be asked to complete an hour of training a day, 5 days a week, for a period of 3 weeks. They will be asked to complete half an hour of word training and half an hour of sentence training each day. Tests of speech perception will be administered on four occasions to allow the study to evaluate the effectiveness of auditory training.

SA:The lead surgeons at Nottingham and Yorkshire have agreed to identify suitable participants for this study. Suitable participants will be approached by clinicians at the cochlear implant programmes. The study intends to include participants who have limited speech perception abilities as they are seeking to develop a training package that will improve the speech perception skills of people who perform poorly with their implants. Participants will be native speakers of British English, as all of the tests of speech perception are administered in English. The study intends to recruit eight participants to this study; four will be recruited from the Bradford Teaching Hospitals NHS Trust.

OU:Improvement on a test of sentence recognition, which will be administered at baseline and after 1, 2 and 3 weeks of training.

AI:This research study is being undertaken as part of a PhD degree at the University of York. Educational supervisor is Professor Quentin Summerfield, Department of Psychology. Tel: 01904 432913. Email: aqs1@york.ac.uk.

MC:This record refers to a multicentre study led by another centre.

LC:University of York

EC:05/Q1205/258

SD:25/1/2006

ED:31/3/2008

ST:Ongoing

AU:Dr Paula Stacey

AD:Division of Psychology, Nottingham Trent University, Burton Street, Nottingham, NG1 4BU, UK

PH:07977 448415

EM:p.stacey@psychology.york.ac.uk

F1:Deafness Research UK (the Hearing Research Trust)

PK:MeSH terms not yet assigned

Record #3 of 4
TI:Maximising outcomes for adult cochlear implant users by auditory training

PI:N0192182458

PR:Nottingham University Hospitals NHS Trust

RE:Trent Regional Office

MR:Cochlear implantation is a surgical and therapeutic intervention that restores useful auditory sensations to people who are profoundly deaf and who do not benefit materially from acoustic hearing aids. The aim of this research is to measure the effectiveness of a computer-based, self-administered auditory training package designed to improve the speech perception abilities of adults who perform poorly with their cochlear implants. The training package will be implemented on laptop computers and used by patients in their own homes. If successful the training package will reduce the need for costly one-to-one speech and language therapy. Secondary research objectives: n/a.

MT:Case–control and questionnaire.

SA:Participants will be native speakers of British English who have limited speech perception abilities.

OU:Improvement on a test of sentence recognition, which will be administered at baseline and after 1, 2 and 3 weeks of training. Secondary outcome measures: improvement on tests of consonant and vowel recognition, which will be administered at baseline and after 1, 2 and 3 weeks of training.

MC:This record refers to a multicentre study led by another centre.

LC:University of York

SD:15/5/2006

ED:1/10/2007

ST:Ongoing

AU:Professor G O'Donoghue

AD:Queens Medical Centre, University Hospital Nottingham NHS Trust, Derby Road, Nottingham, NG7 2UH, UK

PH:0115 9249924

FA:0115 9249924

EM:g.o'donoghue@nottingham.ac.uk/

PN:RFKRA

PT:Optimising care for the management of common ENT conditions

F1:Deafness Research UK

F2:406:YOR:PS

F4:NHS R&D Support Funding

F5:2006/07

PK:MeSH terms not yet assigned

Record #4 of 4
TI:Quality of life of patients with binaural hearing aids and bilateral cochlear implants

PI:N0265147240

PR:University Hospital Birmingham NHS Foundation Trust

RE:West Midlands Regional Office

MR:To investigate the quality of life of patients with hinatmrai hearing aids and bilateral cochlear implants. To design and validate questionnaires that measure the quality of life of these patients.

MT:The study sample for this study will consist of patients from the UK National Health Service (NEd) who have received two hearing aids or cochlear implants. The clinicians at their own audiology centres will ask them if they would like to participate in the study and inform them that it will only involve filling in a questionnaire. It will also be emphasised that their participation or lack of it will not affect their treatment and that the only person who will know their responses will be the chief investigator as the questionnaires will be sent directly to the University of Southampton.

Patients agreeing to participate in the study will be given an envelope containing an information sheet (with the contact details of the chief investigator too), a consent form, an open-ended questionnaire and a prepaid envelope. The contents of the envelope are attached to the form. Patients will be able to fill in the questionnaires in their own homes. Questions will aim to prompt responses about the patients' views of how the second hearing aid or cochlear implant has changed their lifestyle, comparing their present quality of life to when they had only one aid or implant.

The responses from the open-ended questionnaire will then be used to develop a closed-ended questionnaire for the same purposes. These questionnaires will eventually be validated with the help of more patients from the NI-IS during the next stage of the PhD. It is envisaged that the same cochlear implantees will be used for the validation process of the implant questionnaire (as the number of bilateral implantees in the country is limited) but different patients will be asked to participate in the validation process of the hearing aid questionnaire. The validation of the closed-ended questionnaires will involve separate MREC approval.

SA:Hearing aid patients – some of these patients might be taking part in the Modernising Hearing Aid Services programme, which is happening across the UK. This involves filling in questionnaires, which do not affect the present study or vice versa. Cochlear implant patients – these patients are taking part in a multicentric study on the benefits of bilateral implantation. It involves studies on speech recognition in noise and the ability to localise sounds in an echo chamber. Once again these studies will not interfere with this study or vice versa.

OU:Unknown

MC:This record refers to a multicentre study led by another centre

EC:03/11/112

SD:7/8/2004

ED:7/8/2008

ST:Ongoing

AU:Mr H Cooper

AD:Audiology, Selly Oak Hospital, Birmingham, B29 6JD, UK

PH:0121 627 1627

PN:RRK

PT:Neurosciences and ageing

F1:Unfunded

F4:NHS R&D Support Funding

F5:2007/08

F6:12500.24

PK:MeSH terms not yet assigned

NRR single centre ongoing trials
Record #1 of 3
TI:Health-related quality of life in children and adolescents with cochlear implants

PI:N0013192684

PR:Guy's and St. Thomas' NHS Foundation Trust

RE:London Regional Office

MR:To evaluate the health-related quality of life of established paediatric cochlear implant users from St Thomas' Hospital Paediatric Cochlear Implant Programme, aged 4–16 years, via a generic, health-related quality of life questionnaire – KINDLr (Ravens-Sieberer U, Bullinger M. *Fragenbogen zur Erfassung der gesundheitsbezogenen Lebensqualitat bei Kindern und Jugendlichen*. Hamburg: University of Hamburg; 2000.)

MT:A qualitative cross-sectional study to investigate self-reported health-related quality of life questionnaire (HRQoL) ratings obtained from paediatric cochlear implant users and their parents using a standardised generic HRQoL questionnaire, and a qualitative component in which the key HRQoL issues for paediatric cochlear implant users will be explored through small focus groups containing children and adolescents with cochlear implants.

SA:71

OU:The primary outcome measure is the total score from the HRQoL questionnaire, the KINDLr. The raw total score will be transformed to a standardised score out of 100 so that total scores from the different versions of the KINDLr questionnaires can be compared. Domain scores will also be obtained for each domain within the questionnaire.

MC:This record refers to a single-centre study.

SD:4/12/2006

ED:4/11/2007

ST:Ongoing

AU:Miss Emma Stark

AD:St Thomas', Lambeth Palace Road, London, SE1 7EH

PH:020 7188 2197

EM:emma.stark@gstt.nhs.uk

PN:RJ1

PT:Improving children's health and quality of life

F1:Own account

F4:NHS R&D Support Funding

F5:2007/08

F6:7351

PK:MeSH terms not yet assigned

Record #2 of 3

TI:Improving outcomes for users of cochlear implants and bilateral cochlear implants by measuring primary psychophysical modifying speech processors and fitting schemes

PI:N0265147271

PR:University Hospital Birmingham NHS Foundation Trust

RE:West Midlands Regional Office

MR:Many users of unilateral cochlear implants can achieve a high degree of spoken word recognition when the speech is presented in quiet. However, even the most successful users experience difficulty in the presence of competing sounds and are poor at identifying where sounds come from. Our research aims to improve speech reception in noise. In one part of this we are investigating a new method for fitting bilateral implants, so that the same frequency band of speech results in stimulation of matched regions of the two cochleae. We have demonstrated that this matching is a necessary first step to allow patients to make full use of between-ear differences, in order to localise sounds and to extract speech from noisy backgrounds. We have also argued that the majority of existing cochlear implant speech processors, which preserve only the slowly varying 'envelope' information, are unlikely to permit full use of these binaural timing cues even when the electrodes are matched. To test this we have proposed a series of experiments to examine the conditions under which patients better hear speech in noisy situations and to localise sounds. The results should guide the selection of speech processing strategies used in monolateral and bilateral implants. We have funding from the Royal National Institute for Deaf People (RNID) for this project.

MT:Our overall strategy for the psychophysical experiments is to use stimuli that are relevant for the perception of speech whilst being sufficiently tightly controlled to allow generalisable conclusions

to be drawn from the results. Because the number of bilaterally implanted listeners, although growing, is still quite small, we focus on detailed measurements with about four implant users per experiment, backed up by parallel studies with normally hearing users. This dual approach has been very successful in unilateral studies that we have published, yielding similar results with acoustic and electric stimulation. This permits us to fine-tune experimental design using normal listeners, allowing the most efficient use of implant users' time. When appropriate, additional tests with monolaterally implanted users will be performed.

The psychophysical experiments with implant users will generally use 2 μs/phase biphasic pulse trains presented in monopolar ('MPI+2') mode, presented at a comfortable and loudness-matched level in each ear. There are 10 bilaterally implanted adult users of the Cochlear Limited C124 device seen at Birmingham Selly Oak Hospital. There are about 300 monolaterally implanted adult users of the Cochlear Limited C124 device seen there. Our psychophysical experiments use the SPEAR3 processor, which allows bilateral stimulation together with precise control of the timing between the two devices. This is controlled via specialised software.

The parallel psychoacoustic experiments will be performed at the Cambridge MRC-CBJJ and are covered by separate ethical approval.

SA:Clinicians in audiology at Selly Oak Hospital will identify prospective candidates who have a bilateral cochlear implant or a monolateral cochlear implant and a willingness to take part and the agreement of their audiologist and surgeon.

OU:Unknown

MC:This record refers to a single-centre study

SD:17/9/2004

ED:17/9/2008

ST:Ongoing

AU:Mr H Cooper

AD:Audiology, Selly Oak Hospital, Birmingham, B29 6JD

PH:0121 627 1627

PN:RRK

PT:Neurosciences and ageing

F1:Medical Research Council

F4:NHS R&D Support Funding

F5:2007/08

F6:12500.24

PK:MeSH terms not yet assigned

Record #3 of 3
TI:The effect of cochlear implantation on middle ear mechanics

PI:N0013164881

PR:Guy's and St. Thomas' NHS Foundation Trust

RE:London Regional Office

MR:Does a cochlear implant alter the mechanics of the middle ear?

MT:During implant operation the middle ear mechanics will be assessed by laser Doppler vibrometry.

SA:10 patients undergoing cochlear implants will be recruited into the study.

OU:Whether the mechanics of the middle ear are affected by the implant.

MC:This record refers to a single-centre study

SD:1/10/2006

ED:1/10/2009

ST:Ongoing

AU:Mr Alec Fitzgerald O'Connor

AD:Ear Nose & Throat, 2nd Floor, Lambeth Wing, St. Thomas' Hospital, Lambeth Palace Road, London, SE1 7EH, UK

PH:020 7188 2190

EM:Alec.FitzgeraldOConnor@gstt.nhs.uk

PN:RJ1

PT:Improving children's health and quality of life

F1:RNID

F3:64491

F4:NHS R&D Support Funding

F5:2007/08

F6:45963

PK:COCHLEAR IMPLANTS [adverse-effects]; EAR MIDDLE [injuries]

SK:HUMANS

Appendix 15

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Feedback

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We look forward to hearing from you.

NETSCC, Health Technology Assessment
Alpha House
University of Southampton Science Park
Southampton SO16 7NS, UK
Email: hta@hta.ac.uk
www.hta.ac.uk

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