NETSCC, HTA

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Research Protocol

The clinical and cost-effectiveness of bone-anchored hearing aids (BAHAs) for people who are bilaterally deaf

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1 Title of the project:

The clinical and cost-effectiveness of bone-anchored hearing aids for people who are bilaterally deaf

2 Details of project team

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3 Plain English Summary

Most people with hearing loss can benefit from conventional air-conduction (AC) hearing aids, which work by amplifying sound which is passed along the ear canal to the eardrum making it vibrate. However, some people cannot wear these hearing aids or do not benefit fully from them because the conduction process (via air) is obstructed in someway. Instead, sound can be delivered though the skull by vibrations, missing out the outer and middle ears, using a bone-conduction (BC) hearing aid. The BC hearing aid is pressed firmly against the skin of the skull using a spring headband, but has several disadvantages. A bone-anchored hearing aid (BAHA[a]) also conducts sound through the bone, but uses a titanium fixture surgically implanted into the skull and an abutment which protrudes through the skin. Hearing loss can occur in both ears (bilateral). In these cases, BAHAs are usually fitted on just one side (unilaterally), but it has been suggested there may be benefits of bilateral BAHAs. The benefits and costs of bilateral compared with unilateral BAHAs and of BAHAs compared with conventional aids or surgery is not known.

We propose to bring together the most up to date and highest quality published and unpublished evidence on the benefits, harms and costs of BAHAs for people who have hearing loss in both ears. We will search for, review and assess the quality of studies of bilateral hearing loss that examine how effective BAHAs are compared with conventional AC and BC hearing aids, how effective bilateral BAHAs are compared with unilateral BAHAs, and how effective BAHAs are compared with surgical intervention. We will focus on the benefits of BAHAs in terms of improvements in quality of life, patient satisfaction and improvements in hearing measures, as well as the possible harms associated with BAHAs such as complications. This review will also look for studies that analyse the benefits and harms of BAHAs in relation to their costs. The review will be undertaken following a recognised, systematic and transparent approach, allowing people to understand and judge the process and

[a] **Baha** is a registered trademark of Cochlear Bone Anchored Solutions AB, a Cochlear group company. BAHA also relates to a range of bone conduction hearing aids where contact with the skull is maintained by surgical implant. Reference to BAHA in this proposal applies to all such devices and not to the manufacturer, supplier, or trade name.

methods we have used. We will summarise the findings of the review through a discussion and, if appropriate, by combining results statistically.

We will develop an economic model either through adapting an existing model or developing our own new economic model to examine the costs and benefits of BAHAs within the UK. This will use data from our review of studies, advice from clinicians and patient representatives and data from recognised sources (e.g. national published data, data from local hospitals' finance departments). We will also identify the areas where further research is needed.

4 Aim

The aim of this project is to conduct an evidence synthesis of the clinical and cost-effectiveness of: 1) unilateral BAHAs compared with bilateral BAHAs, 2) BAHAs compared with conventional AC and BC hearing aids and 3) BAHAs compared with surgical intervention for adults and children who are bilaterally deaf. Where evidence permits, we will aim to identify whether any beneficial effects of BAHAs differ between subgroups. Where appropriate an economic model will be devised by adapting an existing cost-effectiveness model or constructing a new one using the best available evidence to determine cost effectiveness in a UK setting. The research also aims to highlight deficiencies in current knowledge and to generate recommendations for future primary research.

4.1 Definition of the intervention

Unlike conventional AC hearing aids, which receive sound, amplify it and transmit it to the cochlear through the middle ear (via air), the BAHA allows sound to be conducted through the bone. It consists of a permanent titanium implant that is surgically placed in the mastoid bone behind the ear. An abutment, which protrudes through the skin, is fitted into the implanted fixture and a small detachable sound processor clips onto the abutment.

There are three BAHA models in current use, the BAHA Divino and Intenso which are entirely at head level, and the Cordelle II which has a body-style processor for greater power.[1] The BAHA Compact is an earlier version which is not currently sold in the UK; most patients who originally had a BAHA Compact fitted should have received an upgrade. Older devices include the BAHA Classic 300, HC 100, 200 and 30, the Branemark and the Xomed Audiant.

4.2 Relevant comparators

1) Air-conduction hearing aids

Some people with conductive or mixed hearing loss may use AC hearing though if there is a surgical option this is often preferred. For those with an infected ear, AC aids may prevent adequate ventilation of the ear and may thereby exacerbate the infection.[2] Congenital (present at birth) abnormality or atresia of the pinna (external ear) may prevent an AC aid being fitted.[2]

2) Bone-conduction hearing aids

BC hearing aids use a vibrator that is pressed firmly against the skin of the skull via a spring headband and conduct the sound directly to the inner ear, thus avoiding the middle ear.[3] However, there are several disadvantages and many people are unable to tolerate wearing the device, which can be uncomfortable, cause skin irritations and in some cases headaches.[4,5] The sound quality can also be poor as the skin acts as a barrier.[6] As a consequence, BC hearing devices are reported to be unpopular among people with hearing loss.[5]

3) Conventional ear surgery

Surgery to repair the middle ear hearing mechanism is known as tympanoplasty. Types of tympanoplasty include myringoplasty, which is the repair of a perforation in the eardrum, and ossiculoplasty, which is the repair of a defect in the ossicles of the middle ear.

A stapedectomy (or stapedotomy) is a surgical procedure for conductive hearing loss caused by a stapes footplate that is fixed in position, rather than being mobile. The two major causes of stapes fixation are otosclerosis (abnormal mineralisation of the temporal bone) and congenital malformation of the stapes.

4) Unilateral versus bilateral BAHAs

BAHAs may be fitted unilaterally or bilaterally in people with hearing loss in both ears. The vibratory patterns of bone-conducted sound would suggest that one BAHA should be sufficient for good hearing amplification in the bilaterally deaf.[7] However, several studies in adults[3] and one in children[7] have recently shown that there are benefits of fitting bilateral BAHAs in terms of improved ability to localise sound, speech recognition in quiet and noise, binaural hearing and greater satisfaction.[5] In a consensus statement from BAHA experts in 2005, bilateral application is advocated in young children with severe congenital conductive hearing impairment, but these guidelines state that thorough counselling is important.[8] Bilateral BAHAs may not always lead to improvements for individuals, and some prefer only one hearing aid. The application of bilateral BAHA systems is therefore still a subject of debate.[5]

4.3 Place of the intervention in the treatment pathway

All patients should be assessed by an ENT Surgeon in order to make a diagnosis and determine the appropriate management strategy (do nothing, surgery, AC hearing aid, BAHA etc.) According to the Quality Standards in Bone Anchored hearing Aids for Children and Young People,[2] a child with a significant hearing loss must be provided with suitable amplification soon after diagnosis, prior to the referral to the BAHA service. For some children, an AC aid may be tried in the first instance, although where a chronic conductive hearing loss is present, bone conduction (BC) hearing aids should always be considered, tried and evaluated.[2] All children meeting the selection criteria (see section 4.4) should be provided with the opportunity to be referred for assessment to the BAHA service, [2] although very young children (under around 3 years) are not suitable for a BAHA as their skull is not think enough to insert the fixture. These young children can wear a BAHA on a headband (soft band) until they are able to have the fixture inserted. Similarly, adults may have tried AC and BC aids before considering a BAHA, though this may be limited to a short trial of a soft band BC aid.

4.4 Population and relevant subgroups

There are two main types of hearing loss: sensorineural loss and conductive loss.[9] Sensorineural hearing loss (SNHL) occurs when there is damage to the outer and/or inner hair cells of the cochlea and/or the auditory nerve and involves is a loss of both acuity and discrimination. It is the most common form of hearing loss (approximately 95%) and is often attributed to natural deterioration with ageing and prolonged noise exposure.[9] Conductive hearing loss (CHL) is the result of damage or blockage in the outer or middle ear, for example from infection, fluid (otitis media with effusion), ostosclerosis (growth of extra bone tissue) or trauma or damage to the eardrum, and as a result is often amenable to surgical treatment.[2,9,10] With CHL there is a loss of acuity only.

CHL may also be caused by congenital abnormalities, which can affect any or all of the outer and middle ear structures.[2] The majority occur in isolation, but may be part of a syndrome such as Treacher Collins, Crouzons, Branchio-oto-renal syndrome or Goldenhaar syndrome.[11] Examples of CHL may also be found following mastoid surgery or in children with Down's syndrome,[12,13] although SNHL can also occur with Down's syndrome. The most common cause of CHL in children is otitis media with effusion; fortunately this is often only a temporary loss,[10] although it may be permanent in a very small number of children.[2]

The BAHA is indicated for patients who have a conductive or mixed hearing loss and can still benefit from sound amplification.[14] Otological indications include:

- Congenital malformation of the middle/external ear or microtia
- Chronically draining ear that does not allow use of an AC hearing aid (e.g. external otitis, draining mastoid activity)
- Patients with bilateral conductive hearing loss due to ossicular disease (and not appropriate for surgical correction) or unable to be aided by conventional air conducting hearing devices

The BAHA is also indicated for patients with single sided deafness, however the latter is excluded from this evaluation.

4.5 Key factors to be addressed

Clinical and cost outcomes

Some patients who are fitted with hearing aids may use them intermittently or never at all.[3] Therefore the acoustic benefits of hearing aids may not necessarily relate to improvements in a persons' quality-of-life (QOL).[3] For example, in a recent cohort study of recipients of BAHAs, previous users of a conventional BC hearing aids showed superior audiometric benefit and were very satisfied users of the aids.[15] However, this was not necessarily the case with those who had a previous AC aid.[16] In other studies, adults and children with BAHAs have been shown to have improved satisfaction compared with that prior to their BAHA on measures of self-rated QOL.[17,18] It is therefore important in evaluations of new devices that the acoustic benefits conferred from BAHAs are verified through outcome measures of QOL and satisfaction.

The BAHA surgery is minor but there are potential side effects with BAHAs, the most common being soft tissue reactions and loss of fixture.[19] In a 2002 HTA review for the Ontario Ministry of Health and Long-term Care, re-operation rates for tissue reduction or repositioning were generally under 10 per cent for adults but as high as 25 per cent for children.[20] In a 2007 review of 71 children with BAHA in the UK, younger age was associated with an adverse outcome such as requiring revision or experiencing fixture loss.[18] Failures in children tend to occur early after implantation as, relative to the adult skull, the infant skull is lower in mineral and higher in water content.[6]

Measures of cost-effectiveness include cost per quality adjusted life year (QALY) and cost per life year saved. It will be necessary to identify the resource implications of BAHAs and comparators, since these factors will help to inform the economic model. It is anticipated that the principal outcome of the economic model will be expressed in terms of incremental cost per QALY gained.

Further considerations

BAHA technology has improved over time, and it is likely that there will be less evidence available for the newer models.

5 Research methods for synthesis of evidence of clinical and cost-effectiveness

A systematic review will be undertaken in accordance with the NHS Centre for Reviews and Dissemination guidelines,[21] published guidelines on meta-analysis,[21] and criteria for appraising economic evaluations.[22]

5.1 Search strategy

A search strategy will be developed and tested by an experienced information scientist. Literature will be identified from several sources including electronic databases, bibliographies of articles, grey literature sources and hand searching of specialist journals. A comprehensive database of relevant published and unpublished articles will be constructed using Reference Manager software. Searches to identify studies will be carried out via a number of routes:

1) General health and biomedical databases including MEDLINE, EMBASE, Science Citation Index, BIOSIS;

2) Specialist electronic databases: DARE, the Cochrane library;
3) Grey literature and conference proceedings;
4) Contact with individuals with an interest in the field;
5) Checking of reference lists;
6) Research in progress databases: NIHR CRN Portfolio (formally UKCRN website), Current Controlled Trials (CCT), Clinical trials.gov

The draft search strategy for Medline is shown in Appendix 12.1. This will be adapted for other databases. All databases will be searched from inception to the current date with no language restrictions. Hand searching will focus on key meeting abstracts published in the past two years identified in consultation with experts and analysis of searches.

5.2 Planned inclusion/exclusion criteria

The planned inclusion/exclusion criteria for the systematic review are shown in Table 1.

Studies will be selected for inclusion through a two-stage process using the predefined and explicit criteria. The full literature search results will be screened by two reviewers to identify all citations that may meet the inclusion criteria. Full manuscripts of all selected citations will be retrieved and assessed by two reviewers against the inclusion criteria. An inclusion flow-chart will be developed and used for each paper assessed. Any disagreements over study inclusion will be resolved by consensus or if necessary by arbitration by a third reviewer.

Table 1 Inclusion criteria for systematic reviews

Participants	- Adults or children with bilateral deafness - Papers reporting both bilateral and unilateral hearing loss will be included if the groups are reported separately or if the majority of participants have bilateral hearing loss - Single sided deafness will be excluded
Interventions	- BAHAs (ie. attached to a surgically implanted titanium fixture)
Comparators	- Unilateral versus bilateral BAHAs - Conventional hearing aids (AC or BC) - Unaided - Ear surgery: tympanoplasty, myringoplasty, ossiculoplasty, stapedectomy, stapedotomy
Outcomes	- Validated measures of QOL, patient satisfaction and hearing measures, aided hearing thresholds, speech recognition scores; adverse events, complications. - Measures of cost effectiveness (e.g. cost per QALY, cost per life year saved); consequences to health service resources
Study design	- Clinical effectiveness: RCTs, controlled clinical trials, prospective cohort analytic studies (i.e. with control group), prospective cohort (one group pre and post) studies, and prospective case series. - For each comparator listed above: - where evidence from different types of study design is identified, only those studies with the most rigorous designs will be included; - where higher level evidence is limited to BAHA models no longer in current use, lower level evidence for models in current use (Divino, Intenso, Cordelle II)

	will also be considered. - Cost effectiveness studies (including measures of costs and consequences) - Studies published as abstracts or conference presentations will only be included if sufficient details are presented to allow an appraisal of the methodology and the assessment of results to be undertaken.

5.3 Data extraction and quality assessment

Data extraction and quality assessment will be undertaken by one reviewer and checked by a second reviewer using a pre-designed and piloted data extraction form to avoid any errors. The methodological quality of all included studies will be appraised using recognised quality assessment tools[23] and criteria for appraising economic evaluations.[22,24] The tool selected for assessing the quality of primary studies of clinical effectiveness has been recognised as one of the more comprehensive sets of criteria for assessing the quality of different study designs.[25] Where possible missing information will be obtained from investigators. Any disagreements between reviewers will be resolved by consensus or if necessary by arbitration by a third reviewer.

5.4 Data synthesis

Studies will be synthesized through a narrative review with tabulation of results of included studies. Where possible the results from individual studies will be synthesized through meta-analysis, with causes of heterogeneity of results examined. The specific methods for meta-analysis and for the detection and investigation of heterogeneity will depend upon the summary measure selected.

6 SHTAC Economic Model

If the systematic review of cost-effectiveness of BAHAs for people who are bilaterally deaf finds any relevant high quality economic evaluations, the feasibility of adapting and updating these existing models will be investigated. In the absence of relevant high quality, model-based economic evaluations, a *de novo* decision analytic model will be developed. The model will be structured using published evidence on the epidemiology and natural history of bilateral deafness, and will be informed by guidance from clinical advisors, to reflect the natural course of bilateral deafness and the impact of alternative interventions. Accepted guidelines for good practice in decision-analytic modelling and the general principles outlined in the NICE 'reference case'[24,26] will be followed. The model will be used to provide a cost-consequence analysis, reporting the costs of interventions included in the systematic review and their consequences in terms of hearing measures, QOL, complications, and health service resource use for bilaterally deaf patients receiving standard hearing aids (including BC hearing aids), surgery, unilateral BAHAs, and bilateral BAHAs. The model will also be used to estimate the longer term consequences in terms of quality adjusted life expectancy. The model will adopt a UK NHS and Personal Social Services perspective. The time horizon for the long-term model will be the patients' lifetime, with health outcomes expressed in terms of QALYs - costs and QALYs will be discounted at an annual rate of 3.5%.

Development of the structure of the model will be informed by several sources including previous models identified in the systematic review of cost effectiveness, evidence on the epidemiology and natural history of bilateral deafness and guidance from clinical and methodological advisors. The economic model will only include clinically-relevant comparators found to be clinically effective by the systematic review. Evidence of effectiveness will originate from the systematic review. Specific targeted literature searches will be required to populate other parameters in the model, including

baseline characteristics of the population requiring intervention, age/condition-specific life expectancy and the impact of deafness on patient satisfaction and health related QOL. Information on adverse events and complications will come from the systematic review of effectiveness.

Resource use and unit costs, including consultations (e.g. ear, nose and throat surgeon, audiologist), treatments, adverse events, and complications will be obtained from published evidence, official sources such as Unit Costs of Health & Social Care[27] and NHS Reference Costs,[28] and from the Costing Unit at Southampton General Hospital. Costs of hearing aids, both BAHAs and conventional devices, will be taken from published tariff prices for the UK.[29,30] Costs will be inflated to current prices as necessary. If no published data are available, we will consult with expert advisors to obtain estimates for the parameters relating to resource use.

The results of the economic model will be presented as a cost-consequence analysis, clearly specifying the direct costs associated with each intervention and consequences in terms of hearing, quality of life and adverse events of each intervention, and as a cost-utility analysis. The results of the cost-utility analysis will be presented as incremental cost-effectiveness ratios for the base case and using cost-effectiveness acceptability curves to show the probability of each device being cost-effective at different willingness to pay thresholds. Uncertainty will be examined using deterministic and probabilistic sensitivity analysis. The importance of the underlying model assumptions will be assessed through an analysis of different scenarios. Value of information analysis will be undertaken to help inform payback in terms of reduced parameter uncertainty from additional research, identifying which parameters most contribute to decision uncertainty and should therefore be the focus of future research.[31,32 33]

The model will be constructed in MS Excel to ensure transparency. All stages in the development of the model, analysis of data and interpretation of results will be undertaken by one health economist and checked by a second health economist. All model assumptions and data sources will be clearly specified and their effects on outcomes checked through sensitivity analysis, to ensure model results accurately reflect the inputs used. Internal consistency will also be assessed through the replication of the model in different software to compare results. External consistency will be assessed through comparing results with the previously published analyses.

7 Advisors

Representatives and other potential users of the review from different professional backgrounds and opinions, including academics, clinicians, health economists, commissioners, patient groups, professional organisations, will be invited to provide expert advice to support the project. Experts will be asked to provide comments on a version of the protocol and of the final report, as well as advising on the identification of relevant evidence. All experts will be asked to register competing interests and to keep the details of the report confidential. In addition, we have identified advisors at Cochlear (manufacturer of BAHAs) and at collaborating NHS hospital trusts, who have expertise and data on the costs and resources involved in supplying, implanting and managing BAHA devices and the comparator technologies.

Representatives from service users will be invited to join the advisory group to inform the review and will be involved as stated above. There are a number of potential UK societies such as The Royal National Institute for Deaf People (RNID) and Baha Users Support (Kent) (BUSK).

8 Competing interests of authors

DP has declared a potential competing interest.

9 Project management and milestones

Major Milestones	Date
Project Initiation	1 March 2009
Submission of progress report	1 September 2009
Submission and dissemination of report	1 March 2010

10 References

1. Spitzer JB, Ghossaini SN, Wazen JJ. Evolving applications in the use of bone-anchored hearing aids. *American Journal of Audiology* 2002;11, (2):96-103.

2. National Deaf Children's Society. *Quality standards in bone anchored hearing aids for children and young people*. London: NDCS; 2003.

3. Johnson CA, Danhauer JL, Reith AC, Latiolais LN. A systematic review of the nonacoustic benefits of bone-anchored hearing aids. *Ear Hear* 2006;27, 703-13.

4. Bance M, Abel SM, Papsin BC, Wade P, Vendramini J. A comparison of the audiometric performance of bone anchored hearing aids and air conduction hearing aids. *Otol Neurotol* 2002;23, 912-19.

5. Snik AF, Bosman AJ, Mylanus EA, Cremers CW. Candidacy for the bone-anchored hearing aid. [Review] [26 refs]. *Audiology & Neuro-Otology* 2004;9, (4):190-6.

6. Davids T, Gordon KA, Clutton D, Papsin BC. Bone-Anchored Hearing Aids in infants and children younger than 5 years. *Arch Otolaryngology Head & Neck Surgery* 2007;133, 51-5.

7. Priwin C, Jonsson R, Hultcrantz M, Granstrom G. BAHA in children and adolescents with unilateral or bilateral conductive hearing loss: A study of outcome. *Int J Ped Otorhinolaryngology* 2007;71, 135-45.

8. Snik AF, Mylanus EA, Proops DW, Wolfaardt JF, Hodgetts WE, Somers T, Niparko JK, Wazen JJ, Sterkers O, Cremers CW, Tjellstrom A. Consensus statements on the BAHA system: where do we stand at present?. [63 refs]. *Annals of Otology, Rhinology, & Laryngology - Supplement* 2005;195, 2-12.

9. Yueh B, Shapiro N, MacLean CH, Shekelle PG. Screening and Management of Adult Hearing Loss in Primary Care. *JAMA* 2003;289, 1976-85.

10. Nadol JB. Hearing loss. *NEJM* 1993;329, 1092-102.

11. Shprintzen R J. *Genetics,syndromes and communication disorders.* San Diego-London: Singular Publishing Group, Inc, 1997.

12. Miller J F, Leddy M, Leavitt L A. Evaluating communication to improve speech and language skills. *Improving the communication of people with Down's syndrome*, Baltimore: Paul H Brookes Publishing Co., 1999. p.119-32.

13. Roizen N. Hearing Loss in Children with Down's Syndrome: a review. *Down's Syndrome Quarterly* 1997;2, (4):1-4.

14. Entific Medical Systems. *Audiological manual. Selection criteria, evaluation and fitting procedures for BAHA*. 2000.

15. Browning GG, Gatehouse S. Estimation of the benefit of bone-anchored hearing aids. *Annals Otology, Rhinology & Laryngology* 1994;103, 872-78.

16. Mylanus EA, van der Pouw KC, Snik AF, Cremers C. Intraindividual comparison of the bone-anchored hearing aid and air-conduction hearing aids. *Arch Otolaryngology Head & Neck Surgery* 1998;124, 271-76.

17. Badran K, Bunston D, Arya AK, Suryanarayanan R, Mackinnon N. Patient satisfaction with the bone-anchored hearing aid: a 14 year experience. *Otol Neurotol* 2006;27, 659-66.

18. Lloyd S, Almeyda J, Sirimanna KS, Albert DM, Bailey CM. Updated surgical experience with bone-anchored hearing aids in children. *Journal Laryngol & Otology* 2007;121, 826-31.

19. Proops DW. The Birningham bone anchored hearing aid programme: surgical methods and complications. *Journal Laryngol & Otology* 1996;BAHA supplement, 7-12.

20. Ontario Ministry of Health and Long-Term Care. *Bone anchored hearing aid*. 2002.

21. NHS Centre for Reviews and Disseminaiton. *Undertaking systematic reviews of research on effectiveness*. York: NHS Centre for Reviews and Dissemination; 2001. No. 4 (2nd edition)

22. Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. *BMJ* 1996;313, 275-83.

23. Thomas BH, Ciliska D, Dobbins M, Micucci S. A process for systematically reviewing the literature: Provisding the research evidence for public health nursing interventions. *Worldviews on Evidence-Based Nursing* 2004;1, (3):176-84.

24. Philips Z, Ginnelly L, Sculpher M, Claxton K, Golder S, Riemsma R, Woolacoot N, Glanville J. Review of guidelines for good practice in decision-analytic modelling in health technology assessment. *Health Technology Assessment* 2004;8, (36):1-158.

25. Deeks J, Dinnes J, D'Amico R, Sowden A, Sakarovitch C, Song F, et al. Evaluating non-randomised intervention studies. *Health Technol Assess* 2003;7, (27).

26. NICE. *Guide to the methods of technology appraisal*. London: NICE; 2004.

27. Curtis L, Netten A. *Unit Costs of Health and Social Care*. Canterbury: PSSRU; 2006.

28. Department of Health. NHS reference costs 2006-07. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082571

29. Department of Health. National tariff 2006/07. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127649

30. *British National Formulary*. London: BMJ Publishing, 2008.

31. Claxton K, Ginnelly L, Sculpher M, Philips Z, Palmer S. A pilot study on the use of decision theory and value of information analysis as part of the NHS Technology Assessment Programme. *Health Technology Assessment* 2004;8, (31).

32. Girling AJ, Freeman G, Gordon J, Poole-Wilson P, Scott DA, Lilford R. Modelling payback from research into the efficacy of left-ventricular devices. *International Journal of Technology Assessment in Health Care* 2007;23, 269-77.

33. Eckermann S, Willan AR. Expected value of information and decision making in HTA. *Health Economics* 2007;16, 195-209.

11 Appendices

11.1 Draft search strategy for Medline

1 exp Deafness/ (20783)
2 ((mixed adj5 deaf*) or (mixed adj5 hearing adj loss*)).ti,ab. (392)
3 (sensorineural* adj5 deaf*).ti,ab. (1277)
4 (bilateral* adj5 deaf*).ti,ab. (724)
5 exp Hearing Loss/ (42445)
6 Hearing Disorders/ (12599)
7 Hearing Impaired Persons/ (689)
8 (hearing loss* adj5 bilateral*).ti,ab. (1301)
9 (hearing loss* adj5 conductive).ti,ab. (1506)
10 (hearing loss* adj5 sensorineural).ti,ab. (5810)
11 Hearing Loss, Sensorineural/ (9843)
12 Hearing Loss mixed conductive sensorineural/ (55)
13 Hearing Loss, Bilateral/ (1324)
14 Hearing Loss, Conductive/ (2348)
15 (hearing adj2 loss*).ti,ab. (21232)
16 hearing loss noise induced/ (5132)
17 "Rehabilitation of Hearing Impaired"/ (1203)
18 (hearing adj5 impair*).ti,ab. (8111)
19 or/1-18 (61735)
20 Bone Conduction/ (1998)
21 exp Osseointegration/ (4946)
22 osseointegrat*.ti,ab. (3525)
23 exp hearing aids/ (9717)
24 23 and (20 or 21 or 22) (320)
25 (divino or intenso or cordelle).ti,ab. (9)
26 (divino or intenso or cordelle).mp. (38)
27 (classic adj1 "300").ti,ab. (6)
28 (HC adj1 "300").ti,ab. (3)
29 (HC adj1 "100").ti,ab. (28)
30 (HC adj1 "200").ti,ab. (13)
31 (HC adj1 "210").ti,ab. (1)
32 (HC adj1 "220").ti,ab. (1)
33 (HC adj1 "300").ti,ab. (3)
34 (HC adj1 "360").ti,ab. (0)
35 (HC adj1 "380").ti,ab. (0)
36 (HC adj1 "400").ti,ab. (2)
37 temporal bone/ (7731)
38 prosthesis implantation/ (4922)
39 bone anchored.mp. (387)
40 23 and 37 (228)
41 23 and 38 and 39 (40)
42 or/24-36,40-41 (584)
43 19 and 42 (323)

44 (bone anchor* and (hear* or deaf*)).ti,ab. (259)
45 23 and (BAHA or BAHAs or "BAHA's").ti,ab. (164)
46 19 and (BAHA or BAHAs or "BAHA's").ti,ab. (138)
47 ((BAHA or BAHAs or "BAHA's") and (hear* or deaf*)).ti,ab. (172)
48 19 and 38 and 39 (28)
49 (bone anchor* adj5 hearing aid*).ti,ab. (246)
50 43 or 44 or 45 or 46 or 47 or 48 (470)
51 (letter or comment or editorial).pt. (769498)
52 50 not 51 (458)
53 limit 52 to humans (453)
54 from 53 keep 1-453 **(453)**

11.2 Draft data extraction form

Reviewer:		**Date:**	**Version:**
Reference and Design	**Intervention**	**Participants**	**Outcome measures**
First author *et al*., year [ref ID] Country *Design:* *Study setting:* *Number of centres:* *Follow-up*: xx months. Funding:	1. 2. *Duration of treatment:* *Other interventions used*:	*Indication for Treatment:* *Number of Participants:* *Sample attrition/dropout:* *Inclusion/exclusion criteria for study entry:*	*Primary outcomes:* *Secondary outcomes:* *Method of assessing outcomes:* *Length of follow-up:*

Characteristics of participants

	BAHA	**Comparator**	**P value**
Age, years			
Sex			

Results

Outcomes	**BAHA**	**Comparator**	**P Value**
Quality of life			
Comments			
Patient satisfaction			

Comments			
Hearing measure			
Comments			
Hearing measure			
Comments			
Adverse Effects			
Comments			
Resource Use			
Comments			

Note: If reviewer calculates a summary measure or confidence interval PLEASE INDICATE

Methodological comments

- Allocation to treatment groups:
- Blinding:
- Comparability of treatment groups:
- Method of data analysis:
- Sample size/power calculation:
- Attrition/drop-out:

General comments

- Generalisability:
- Outcome measures:
- Inter-centre variability:
- Conflict of interests: