The clinical and cost effectiveness of advances in hearing aid technology

Report to the National Institute for Clinical Excellence

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ABBREVIATIONS

APHAB:	Abbreviated Profile of Hearing Benefit
AGC:	Automatic gain control
BEA:	Better ear average
BTA:	Behind the ear (hearing aid)
CIC:	Completely in the canal (hearing aid)
Db HL:	Decibel hearing level
DSP:	Digital signal processing
GHABP:	Glasgow Hearing Aid Benefit Profile
HHIE:	Hearing Handicap Inventory for the Elderly
HRQOL:	Health related quality of life
ITC:	In the canal (hearing aid)
ITE:	In the ear (hearing aid)
QALY:	Quality adjusted life year
RCT:	Randomised controlled trial
SPIN:	Speech Perception in Noise
WDRC:	Wide dynamic range compression

EXECUTIVE SUMMARY

Aim

The aim of this review is to assess the clinical and cost effectiveness of developments in hearing aid technology (in particular, digital hearing aids) in comparison to the current NHS analogue hearing aid range.

Methods

A search of electronic databases aimed at identifying randomised controlled trials, controlled randomised cross over trials and economic studies relating to digital hearing aid comparisons was undertaken; Medline, Embase, Science Citation Index, Cochrane Database of Systematic Reviews (CDSR), Cochrane Controlled Trials Register (CCTR) and the NHS Centre for Reviews and Dissemination databases (DARE, NHS EED, HTA). The publication lists and current research registers of health technology assessment (HTA) and guideline producing organisations, funding bodies, consumer groups, hearing research organisations were consulted and bibliographies from experts were obtained.

Clinical effectiveness studies were selected for inclusion if they met the following criteria: (1) used either randomised prospective controlled trial or randomised cross over study designs; (2) were undertaken on a population of hearing impaired individuals; (3) involved a comparison of two or more hearing aid technologies; and (4) used either an objective laboratory hearing/speech test or a self-report disability/quality of life questionnaire. For the purposes of the specific aim of this review, a detailed data extraction was undertaken for those studies that included a comparison of analogue versus digital hearing aids. All comparative studies of hearing aids that included a cost analysis or economic evaluation were data extracted. Quality of included studies was assessed and a detailed qualitative review of the evidence presented.

Results

This review identified a total of eight randomised controlled and cross over trials (involving a total of 378 individuals with mild to severe hearing impairment) that address the relative effectiveness of analogue versus digital hearing aids (and for which there no outstanding queries at the time of writing). These studies were small in size and of relatively poor methodological quality. There was no difference in analogue versus digital hearing aids in terms of the objective laboratory based tests of hearing for speech (or tests of speech perception). There was evidence of benefit of digital over analogue in a number of user self-report measures, although this was not a consistent pattern either within or across studies. Across the eight studies there was only one study which reported benefit of analogue over digital in one outcome. A further 41 studies were identified which made comparisons between hearing devices and that looked at issues such as monaural vs binaural, directional microphone technology and non-linear amplification.

Only three economic evaluations were identified. The first of these reported a possible range of incremental cost effectiveness ratios from US$ 59 to US$

1090 per unit gain of hearing benefit (as measured on either objective speech test or user self report measure) when comparing a digital to either linear or non-linear analogue aid. Two cost utility studies were undertaken that involved a comparison of a hearing aid versus no aid. These studies reported incremental cost per QALY ratios of $US 200 and 2,200 to 11,000 Euros respectively.

Conclusion

The evidence base comparing digital versus analogue hearing aids is small and of relatively poor quality. There appears to be little or no evidence from either laboratory or user-based outcomes of a clear consistent benefit of digital over analogue devices. Nevertheless the relatively small sample size of identified studies may reflect a lack of power rather than true evidence of a lack of effect. There are currently no direct 'head to head' cost utility studies comparing digital versus analogue hearing aids. The incremental cost effectiveness of digital devices (compared to analogue devices) is highly sensitive to their incremental cost and could range from less than £10,000 to more than £20,000 per QALY.

Further clinical research preferably in NHS service settings with well designed controlled trials measuring objective outcome (e.g., speech recognition) and validated measures of hearing specific quality of life is needed. There remains a need to systematically review the evidence of other technological advancements in hearing aids (such as binaural aids, directional microphones and methods of amplification).

1. INTRODUCTION

1.1 Background

1.1.1 Description of underlying health problem

Hearing can be impaired due to pathology in the outer ear, middle ear, cochlea, the ascending pathways and the cortex. In adults the most common pathology associated with permanent hearing impairment is damage to the cochlea (inner ear). Conductive hearing impairment occurs when sound waves are greatly attenuated on the way to the inner ear. This can be caused by a variety of problems including build-up of earwax (cerumen), infection, fluid in the middle ear (otitis media with effusion) or a punctured eardrum. Sensorineural loss occurs when the outer and inner hair cells in the cochlea are damaged and is most frequently the result of ageing or substantial noise exposure. It is also suspected that early adulthood (e.g. 40 to 50 year olds) sensorineural impairment might a have a significant genetic component. 2.1% (95% confidence interval: 1.8% to 2.5%) of the adult population has a hearing impairment with a conductive component and 13.8% has a sensorineural impairment alone. As hearing impairment becomes more severe, the proportion with a conductive component increases. Whilst conductive hearing impairment can often be beneficially treated with medical or surgical intervention, sensorineural impairment cannot presently be reversed.[1]
Hearing impairment is one of the most prevalent causes of disability.[2] Hearing impairment can have a profoundly negative influence on the individual, family and close associates. Reported functional disability is considerable and common. Adverse effects on physical, cognitive, emotional, behavioural and social functions, and employment status have been reported.[3-5] These effects are often regarded by the hearing impaired person as representing handicap even when the degree of audiological detectable hearing loss is relatively mild.
Only a small number of hearing studies have provided estimates of hearing impairment that are based on representative population samples and where impairment has been measured by standardised audiological methods[3]. In the UK, the current estimates of hearing impairment (and reported hearing disability) prevalence derives predominantly from the National Study of Hearing, which was conducted by the MRC Institute of Hearing Research in 1997[7]. There are a large number of measures of hearing impairment, the most general being the hearing threshold levels obtained for pure tones at different frequencies. In order to simplify the information available and obtain an index of ‘disability’ from the pattern of these thresholds over the frequency (the audiogram), an index of impairment has been used for the average hearing threshold level over the frequencies 0.5, 1, 2, and 4 kHz, in the better ear. This measure (better ear average, BEA) is probably one of the better predictors of overall hearing disability. The prevalence of BEA over a range of severity is presented in Table 1.
Davis has identified that 25 Db HL, 45 Db HL and 65 Db HL levels of average impairment correspond to the median impairment of those who report ‘mild’, ‘moderate’ and ‘severe’ impairment respectively[7]. The term ’profound deafness’ is used to describe hearing loss at 90 Db HL and higher.

Table 1. Estimate of prevalence of hearing impairment as a percentage of people in the UK, aged 18-80 years, with different degrees of severity of hearing impairment in the better ear (based on 2662 people).

Severity of hearing impairment (Db HL)	Prevalence Estimate (95% confidence interval)
25+	16. 1 (15.0 to 17.3)
35+	8.2 (7.4 to 9.1)
45+	3.9 (3.4 to 4.4)
55+	2.1 (1.7 to 2.5)
65+	1.1 (0.8 to 1.0)
75+	0.7 (0.5 to 1.0)
85+	0.4 (0.2 to 0.7)
95+	0.2 (< 0.1 to 0.5)
105+	0.1 (< 0.1 to 0.4)

Source: Davis, 1995[8]

Recent hearing impairment estimates in England and Wales are shown in Table 2.

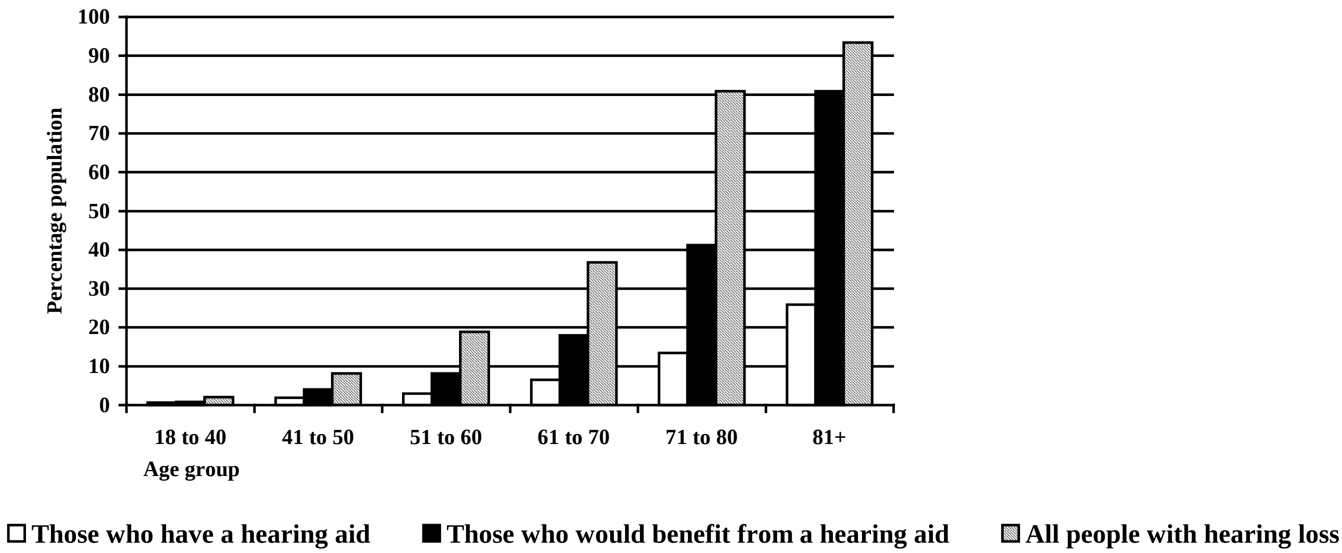
Table 2. Prevalence of hearing impairment by sex and age in England and Wales

Sex		women	men	both
18-64	**b25**	1165028	1630652	2753036
18-64	**b35**	510813	757995	1243390
18-64	**b65**	60290	134725	185671
65-79	**b25**	1665298	1743172	3389754
65-79	**b35**	1094951	921257	2002533
65-79	**b65**	130949	91687	223026
80+	**b25**	1364832	595418	1967243
80+	**b35**	1205066	497272	1706067
80+	**b65**	319429	150490	463376
All adults	**b25**	4195158	3969241	8110033
All adults	**b35**	2810829	2176524	4951990
All adults	**b65**	510668	376903	872073

Source: Davis personal communication[9]

The prevalence of hearing impairments is not greatly associated with noise exposure, gender, occupation or social class group, but predominantly with age[5,7]. The prevalence of hearing impairment (mild to severe) with age, is summarised in Figure 1.

Figure 1. Percentage of the population with hearing loss and the potential and actual hearing loss



From Richards & Gleeson, 1999[10]

Until the age of about 45 years, mild hearing problems are rare, so the prevalence estimates are small. Beyond age 50 the prevalence estimates are well over 10% approaching 50% by 70-74 years of age. It has been estimated that over the next two decades, due to increasing survival, the number of hearing-impaired people will probably rise by some 20%[8].
The report *Childhood Deafness in the European Community* puts the lower bound on hearing impairment around 1 per 1000 children with a BEA of 50Db HL born during 1969 and ascertained by 1977 (i.e. age 8 years of age) [11.] This is a good benchmark to take for birth cohorts in the 1980s and 1990s[8]. As with adults, as the severity criterion increases the prevalence decreases so that at 65+, 80+ and 95+ Db HL the estimates were 0.74, 0.48 and 0.29 per 1000 children.

1.1.2 Current treatment options and service provision

While hearing impairment may sometimes be remediated with medication or surgery if there is conductive pathology, and with the exception of cochlear implants as a surgical option only for those who have profound impairment at present, most hearing-impaired individuals are provided with a hearing aid alone to alleviate the problems with communication and orientation (but the hearing aid does not affect the underlying pathology or impairment). The benefit of wearing an aid is well established. For example, a large randomised controlled trial has reported significantly greater quality of life in those individuals wearing a hearing aid to those without an aid.[3]
Based on the figures in Table 2, 8.1 million individuals in England and Wales will have a hearing impairment in the better ear (i.e. ≥25 Db HL) of whom 2.8 million have an impairment (i.e. ≥45 Db HL) which confers substantial disability[12]. Of these approximately 1.4 million (3.4% of total population) are currently aided (in England & Wales), the proportion of which as not changed over the last 15 years. The Royal National Institute for Deaf People has

stated the need to increase the number of people who are aided and to set a target of 5.0% (i.e. 2.5 million users) so that 50% of those who could greatly benefit might be allowed to do so.

The reasons for this level of unmet need are well researched and were summarised in a recent Audit Commission report[4]. Factors include the stigma attached to hearing loss and wearing a hearing aid, people being unaware of hearing loss (e.g. family members may compensate imperceptibly), and that GPs may not refer or may delay referral.

The Medical Research Council Ear Nose & Throat (ENT) survey in1999 reported that 81% of users have NHS aids, 12% per cent have privately purchased aids, and 7% have both[13]. The NHS in England issues between 500,000 and 600,000 hearing aids per annum, of which approximately 220,000 are to new users and approximately 15,000 are to children.[4,14]

In 1997, the total NHS Audiology service cost was about £50 million per annum of which about £25 million represents the cost of hearing aids (and batteries), the remainder being staff, ENT costs (e.g. assessments) and other infrastructure. Of this £25 million, some £3.25 million (13%) is spent on hearing aids purchased outside of NHS Supplies.[15]

NHS hearing aid services are currently provided at 250 centres throughout the UK, which are attached mainly to ENT departments or Audiology departments of trusts. Audiology centres provide hearing aids that are purchased through NHS Supplies in over 90% of cases thus defining the 'NHS range' of hearing aids. The specification of the current 'NHS range' technology will be described in the next section. The average total cost of supplying an NHS hearing aid is about £90 of which about £40 is the cost of the hearing aid.[14]

Each year, approximately 150,000 aids are sold privately. The cost of a privately purchased hearing aid ranges from £250 to £3000.[4,16] This increased cost reflects the more recent technological developments of the hearing aids dispensed privately compared to NHS aids. The recent Audit Commission report identifies a twofold variation in the provision of hearing aids between former health authority areas, and an even greater intra-regional variation. Moreover this report also described a wide variation in waiting times for hearing aid fitting across UK. The average wait for an appointment to have an aid fitted is 19 weeks, and in one-fifth of health authority areas the average wait was reported to be longer than 6 months.

Finally, a number of reports have indicated that approximately one third of hearing aids are infrequently or never used. It is considered that this lack of usage is due to a combination of poor technology, inappropriate fitting and inadequate guidance and education of hearing aid users.[15,17]

1.1.3 Hearing aid technology – current NHS provision & developments in technology

A hearing aid is an electronic device consisting of a microphone, an electronic amplifier, a receiver and a battery. The microphone receives environmental sounds, the amplifier enhances a few or several frequencies (signal processing during this amplification stage can be via analogue or digital means), depending on the needs of the user, the receiver transmits the modified sounds to the middle ear, all powered by the battery. By manipulating and amplifying sound, hearing aids provide better hearing and speech comprehension. There is currently a wide variety of hearing aid types available. This range of devices and their technological basis is described below in the context of current NHS provision.

a. Current NHS Range

The ‘NHS range’ of hearing aids has been traditionally based on 1970s analogue behind the ear (BTE) technology. A basic analogue hearing aid provides the same amount of amplification, regardless of the intensity of sound entering it, so the technology is defined as linear. More recently, these devices have been updated to include some technological developments which provide non-linear amplification. These developments include compression that can involve both automatic gain control (AGC) and wide dynamic range compression (WDRC). Compression controls loudness (loud sounds are often uncomfortable to users), while still providing adequate amplification for soft sounds (which are not always heard with basic analogue devices). There is more amplification for softer sound than there is for louder sounds with compression hearing aids so that when a sound entering (or in some cases, exiting) the hearing aid reaches a critical level, the amplification of the compression hearing aid is reduced. In addition to compression, there has also been miniaturisation of analogue devices so that they can be fitted in the ear (ITE) and are therefore more cosmetically acceptable to users.

It is estimated that around 50% of NHS aids remain of the basic analogue BTE design. The average total cost of fitting a NHS hearing aid is about £90, which includes an average hearing aid cost of £40[16]. The most expensive NHS aids (i.e. WDRC) costs £144. NHS aids are usually fitted monaurally i.e. one hearing aid per user.

Currently NHS audiology service providers have discretion to make arrangements for supplying commercial (more technologically advanced) hearing aids if there is exceptional clinical need, and they are more likely to exercise this discretion if the hearing aid user is relatively young. However, the exercise of this discretion depends on local priorities and resources.

b. Developments in hearing aid technology

In recent years there has been a number of technological developments in hearing aid technology. These developments have included miniaturisation (i.e. ITE and ‘completely in the canal’ (CIC) devices), programmability (i.e. signal processing can be selectively adjusted to suit the user’s needs), compression (see above), and directional enhancement (i.e. various means by which sounds in front of the hearing aid user are emphasised, and sound from other directions suppressed).

Probably the single most publicised development in hearing aid technology has been the introduction of ‘digital’ aids in the mid 1990s. These aids use digital (as opposed to analogue) signal processing (DSP). With digital hearing devices, the incoming analogue signals received by the microphone are sent through a preamplifier to an analogue-to-digital (A/D) converter, where the signals are converted into numerical values (i.e. zeros and ones). The numbers are then changed by the DSP unit according to a set of algorithms that is either preset or programmed by the audiologist. A new set of numerical values is produced, which is then reconverted from digital-to-analogue (D/A) as it exits the loudspeaker in the hearing aid and enters the user’s ear canal.

Digital hearing aids have several important features potentially not available in a basic linear analogue aid, including fine-tuning frequency responses, active feedback control, use of multiple and directional microphones, and background noise reduction strategies. In allowing more parameters to be adjusted to suit the individual the fitting of a DSP aid is a complex and potentially more time consuming procedure than for a conventional aid. DSP fitting requires access to computer technology and specialist software[18]. The potential advantages described for DSP over conventional aids include:

(1) The extremely high precision with which frequency-gain characteristics can be specified and the use of this capability to study the effects.
(2) The use of memory and logical operations in the implementation of adaptive paired-comparison techniques for more effective hearing aid prescription
(3) The use of powerful signal processing techniques for noise reduction.
(4) The use of DSP aids as generalised hearing instruments which can be used for simulation, testing and prescription, as well as amplification.[19]

The first commercially successful DSP aid was produced by Widex (the Senso) in 1994 closely followed by Oticon's Digifocus the following year. Many manufacturers have followed this trend and now supply DSP aids. Since their arrival in the mid 1990s sales of DSP aids have grown rapidly in the private retail market and now account for some 25% of all private fittings in 1998. The average costfor a DSP aid can range from £250 to £3000, which includes an average cost of an aid of £600.[4,16]
Different countries have taken up DSP aids at different rates. For example, the USA is estimated to have an 82/18 split between traditional analogue and modern digital aids, of which 80% are the smaller ITE/ITC/CIC aids. However, Europe has a 65/35 split of analogue versus digital and only 30% are smaller aids with the remainder being BTE.[16] At present DSP aids are not supplied within the NHS. The Royal National Institute for Deaf People (RNID) has recommended that digital aids should be standard provision within 5 years[12].

In summary, considerable technological developments have taken place in hearing aid technology over the last two decades with a resultant substantial increase in sophistication. The hearing aid technology that is currently available through the NHS is considerably outdated compared to the miniaturised digital aids available in the private market. Digital aids provide a more technically advanced solution to hearing impaired users than conventional analogue aids. However, the extent to which this technological advancement results in better user outcomes has yet to be fully established and is therefore the focus of this review. The following section considers how user outcomes should be measured in order to assess the comparative benefit of different hearing aids.

1.1.4 Evaluating the benefits of hearing aid developments

Two key methodological factors in assessing the effectiveness of hearing aid development are study design and outcome selection.
As with other healthcare interventions, the randomised controlled trial represents the 'gold standard' when assessing clinical effectiveness of one hearing aid technology compared to another. The cross over study is a commonly used design in the area of hearing aid evaluation i.e. in the case of the comparison of hearing aids A and B, half the users are allocated to wearing hearing aid A followed by hearing aid B, while the other half are

allocated to wearing hearing aid B followed by A. The within individuals comparisons of a cross over design has the advantage of increasing statistical power and thereby reducing the number of users needed.[20] Cross over design requires chronic 'stable' diseases and can only study short-term effects. Evaluation of the impact of hearing aids for hearing impaired people is therefore well suited to such a study design. However, cross over designs have potential methodological problems, in particular, 'carry-over' (i.e. the effect of hearing aid continues after the cross over period) and 'order' (i.e. the magnitude of effect of hearing aid A will be altered if it either precedes or follows hearing aid B). In order to minimise an order effect, it is important that users are randomly allocated to hearing aid provision.[21]
Traditionally, much of the published research documenting hearing performance has used laboratory based objective tests of hearing/speech (i.e. electroacoustic testing). Such assessments have the advantage of objectivity, although there is also the recognition of the importance of assessing user benefit in terms of everyday living. Despite no formal consensus as to which particular categories of outcome assessment should be undertaken when assessing hearing aid benefit, a number of commentators[22,23] have suggested two broad categories of outcome assessment:

1. Laboratory based tests: i.e. use of objective tests of listening/hearing that mimic situations (i.e. speech tests in quiet and noise) that are frequently encountered in everyday life;
2. Disability/quality of life measures i.e. use of validated self-report questionnaires designed to assess disability/quality of life of hearing impaired individuals e.g. Glasgow Hearing Aid Benefit Profile (GHABP), Hearing Aid Performance Inventory.[22,23]

1.2 Aim of Review

The aim of this review is to assess the clinical and cost effectiveness of developments in hearing aid technology (in particular, digital hearing aids) in comparison to analogue hearing aids (in particular, the current NHS analogue range).

2. METHODS

An initial scoping literature search was undertaken which focussed on the identification of existing reviews and other key papers, as well as identification of randomised controlled trials and cross over trials likely to be included. Two previous systematic reviews were identified, the first being a review of effectiveness of bone anchored hearing aids (a device that does not use conventional air conduction methods) [24] and the other a review of the effectiveness of community based audiology services[25]. No systematic review of the comparative clinical and cost effectiveness of hearing aid devices was identified.

2.1 Search Strategy

The search strategy aimed to identify randomised controlled trials, randomised cross over trials and economic studies relating to digital hearing aids. Keyword strategies were developed based on terminology and indexing terms identified from studies retrieved in the scoping search and from information disseminated by the RNID. Keyword strategies did not include terms which would restrict results to specific comparisons or to specific populations. Keyword strategies were therefore sensitive enough to retrieve studies comparing digital hearing aids with any other type of hearing aid tested on any population. Searches of the following electronic databases were undertaken; Medline, Embase, Science Citation Index (SCI), Cochrane Database of Systematic Reviews (CDSR), Cochrane Controlled Trials Register (CCTR) and the NHS Centre for Reviews and Dissemination databases (DARE, NHS EED, HTA). Date and language restrictions were not used. The keyword strategy for Medline is in Appendix 1. Keyword strategies for all other databases are available.
Further searches were undertaken of current research registers (National Research Register (NRR), MRC Clinical Trials Register, Current Research in Britain (CRIB) and US National Institutes of Health (NIH) Clinical Trials Register. The publication lists and current research registers of health technology assessment (HTA) and guideline producing organisations, funding bodies, consumer groups and hearing research organisations were consulted. Bibliographies from experts were obtained. At the final stage of the review, citation searches using SCI search facility of included studies was undertaken. The reference lists of included studies were also checked.

2.2 Inclusion/exclusion criteria

Studies were selected for inclusion in the clinical effectiveness section of this review if they met the following criteria:

1. used either randomised prospective controlled trial or randomised cross over study designs;
2. were undertaken on a population of hearing impaired individuals;
3. involved a comparison of two or more hearing aid technologies;
4. used either an objective laboratory hearing/speech test or a self-report disability/quality of life questionnaire.

All comparative studies of hearing aids that were identified as including a cost analysis or economic evaluation were included within this review.
Two reviewers independently undertook study inclusion/exclusion decisions based on publication abstracts. Any disagreements regarding study selection between the two reviewers were resolved by consensus. Where insufficient information was available in the abstract to make a decision, the full study paper was obtained. In situations where there remained insufficient information (e.g. study design) the authors of the paper were contacted.

2.3 Quality assessment and data extraction of included studies

Detailed quality assessment and data extraction were undertaken for those studies which met the specific aim of the review i.e. for those studies where there was an explicit comparison of a digital vs analogue hearing aid. Other hearing aid comparisons which met the inclusion criteria but which did not include a direct comparison of a digital vs analogue hearing aid were categorised and listed by the nature of the comparison (e.g. digital vs digital, non-linear amplification, directional microphones etc.)

2.3.1 Quality assessment of included studies

The quality of studies comparing digital to analogue devices were assessed on the basis of:

1. was there an adequate description of the method of randomisation?;
2. was there blinding (i.e. at least blinding of outcome assessment)?;
3. was there a description of study withdrawals and was a percentage follow-up of 80% or more achieved?;
4. were the study outcomes analysed by intention to treat?;
5. was a formal pre-study power calculation performed?;
6. were validated outcome measures used?[26]

Study quality assessment was initially undertaken by one of the reviewers (RT) and checked by the other (SP).

2.3.2 Data extraction of included studies

For the purposes of the specific aim of this review, a detailed data extraction was undertaken for those studies where there was an explicit comparison of an analogue (or ‘conventional linear’) hearing aid versus a digital hearing aid. Data extraction was undertaken by one of the reviewers (RT) and checked by the other (SP).

2.4 Data analysis/presentation

Given the generally poor reporting of detailed numerical results and the heterogeneity in study outcomes it was considered inappropriate to pool the results across the studies. Instead a detailed qualitative analysis was undertaken.

Comparison of hearing aid technologies which did not include a digital vs analogue comparison are listed in Appendix 2. Studies where details of methodology were not available at the time of writing this report are listed in Appendix 3. Excluded studies are listed in Appendix 4.

3. RESULTS

3.1 Quantity of research available

The clinical effectiveness results of included studies that compare analogue hearing aids versus digital hearing aids and cost analysis/effectiveness results for all hearing aid comparisons are presented in this section. Randomised controlled trial and cross over studies of other hearing aid comparisons are listed in Appendix 2.

Table 3. Summary of study selection

Abstracts identified	260
Abstracts meeting inclusion criteria	112
Full papers meeting inclusion criteria	83
Included studies by comparison:	
Digital vs analogue	8* (12)**
Cost	8 (8)
Digital vs digital	6 (6)
Directional hearing aids	9 (10)
Mono vs binaural	4 (5)
Non-linear	19 (28)
Other	3 (9)
Total	57 (78)

* Numbers not in parentheses = studies definitely included
** Numbers in parentheses = studies definitely included + pending studies awaiting information from author

3.2 Assessment of clinical effectiveness

A total of eight randomised controlled trials and cross over studies, comparing digital versus analogue hearing aids, were identified. Study details and results are summarised in Tables 4 and 5. Given the generally poor reporting of detailed numerical results in the trial papers and the heterogeneity of study outcomes, it was decided to report these results qualitatively. The results for each study outcome were summarised as follows:

A = D i.e. no evidence of statistical difference in outcome between analogue and digital aid;

A > D i.e. outcome in analogue aid statistically superior (P < 0.05) to digital;

D > A i.e. outcome with digital aid is statistically superior (P < 0.05) to analogue.

3.3 Assessment of cost effectiveness

A total of eight cost analysis and cost effectiveness studies were identified for review. The details and results of these studies are summarised in Table 6.

Table 4. Study population, design, quality, intervention and comparison

Author (year) Citation Country	Design & quality†	Study population (N, severity, male/female, age)	Digital aid (make, fitting)	Analogue (make, fitting)	Comments
Arlinger et al, 1998 *Scand Audiol* 27:51-61[27] Arlinger & Billermark, 1999 *Br J Audiol* 33:223-232[28] Sweden	Cross over (1) N (2) N (3) C/T(?%) (4) C/T (5) N (6) Y	N = 33 (20 males) randomised Mean age: 62 yrs (19-76 yrs) Experienced users (6 months to 4 yrs current aid) Sensorineural loss? Mild to moderate hearing impairment	BTE Oticon DigiFocus Digital fitted either monaural or binaural (to match previous hearing aid experience)	'Own hearing aid' Various BTE (18 products): 8 K-amp circuitry 5 other non-linear signal processing (ASP, AVP, input controlled AGC) 7 multiprogrammable 3 selectable uni- or omni-directional microphone Monaural or binaural fitting to match hearing aid experience	• Pseudo randomisation by time i.e. first 16 patients received aids in order AB & next 17 in order BA. • Patients not blinded. No information on assessor blinding.
Berninger & Karlsson, 1999 *Scand Audiol* 28:117-25[29] Sweden	RCT (1) N (2) C/T (3) Y (88%) (4) C/T (5) N (6) Y	N = 200 (106 males) randomised Mean age: 73 yrs (18-92 yrs) First time users Sensironeural (6% mixed) Level of hearing impairment? N=94 analogue completers N=92 digital completers	Widex Senso BTE model (C8) Or Widex CIC (CX) Digital aid.	'Other aids' Analogue with no restriction on choice (29 aids from 10 manufacturers used)* Monaural or binaural fitting to match hearing aid experience	• * Products listed, specifications not given

Author (year) Citation Country	Design & quality†	Study population (N, severity, male/female, age)	Digital aid (make, fitting)	Analogue (make, fitting)	Comments
Bille et al., 1999 *Scand Audiol* 28: 127-35[30] Denmark	Cross over (1) N (2) Y (3) Y (89%) (4) C/T (5) N (6) Y	N = 28 (10 males) randomised Median age: 71 yrs (32-89 yrs) Experienced analogue aid users Sensironeural loss Mild to severe hearing impairment 25 completers	Widex Senso C8 Digital aid Either binaural or monarual	Widex Logo L8 & L12 Linear analogue aids Either binaural or monaural (matched)	• Aids tested identical in appearance thus users blinded. Assessors not blinded.
Boymans et al, 1999 *Audiology* 38:99-108[31] Netherlands	Cross over (1) N (2) N (3) C/T (4) C/T (5) N (6) Y	N = 27 randomised Median age: ? yrs (17-86 yrs) Experienced ITE aid users Sensironeural loss Level of hearing impairment?	Widex Senso Digital aid	'Reference aid' ITE analogue aids (19 aids from 7 manufacturers)*	• Study carried out in two clinical sites. • *Products listed, specifications not given but did not include multiprogrammable aids with remote control
Newman & Sandridge, 1998 *American Journal of Audiology* 7:115-128[32] United States	Cross over (1) N (2) C/T (3) Y (100%) (4) Y (5) N (6) Y	N = 25 (13 males) randomised Mean age = 69.2 yrs (47-84 yrs) Experienced (≥ 1 yr) users Sensorineural loss Severity of hearing impairment?	Oticion Digifocus BTE Seven band two channel digital aid Monaural or binaural (according to previous use)	*Oticon Personic 410 or 420 **Oticon MultiFocus Compact or Compact Mild *BTE One channel linear mini analogue aid (with AGC-I input limiting (410) or with active output limiting (420)) ** BTE Two channel mini analogue aid Monaural or binaural (matched)	• Authors contacted to confirm randomisation

Author (year) **Citation** **Country**	**Design & quality†**	**Study population** **(N, severity, male/female, age)**	**Digital aid** **(make, fitting)**	**Analogue** **(make, fitting)**	**Comments**
Ricketts & Dhar, 1999 *JAAA* 10(4):180-189[33] United States	Cross over (1) N (2) C/T (3) Y (100%) (4) Y (5) N (6) Y	N = 12 (? Males) randomised Median age = ? (adults) Experienced users? Sensorineural loss Mild to moderate / severe hearing impairment	Siemens Prisma with VAD or Widex Senso C8 & C9 Digital BTE Tested with directional and omnidirectional microphones	Phonak Piconet PS AZ Digitally programmable BTE analogue aid. Tested with directional and omnidirectional microphones	• Authors contacted to confirm randomisation • Pseudo-randomisation (counterbalanced) for first test condition. All other test conditions randomised
Yund et al, 1987 *J Rehab Res Devpt* 24(4):161-180[34] United States	Cross over (1) N (2) C/T (3) Y (69%) (4) C/T (5) N (6) Y	N = 29 (? males) randomised Mean age = ? 11 participants experienced users Sensorineural hearing loss Severity of impairment? N =20 completers	Experimental aid 8 channel compression with digital signal processing Monaural	'conventional aid' Various: 12 linear with peak clipping 2 output compression 6 input compression All monaural	• Author contacted to confirm randomisation
Wesselkamp, 1999 *Siemens technical report*, 15-Mar-99[35] Germany	Cross over (1) N (2) C/T (3) C/T (4) C/T (5) N (6) Y	N = 24 (? Males) randomised Mean age = 60 years (35 to 71 years) 12 new users, 12 experienced users Sensorineural hearing loss Severity of impairment?	(1) Siemens Prisma Digital aid with selectable microphones 6. 'Ref 2' Digital aid with non-directional microphone	* 'Ref 1 aid' Analogue aid with selectable non-directional / directional microphone	• Siemens Prisma also compared with another digital aid ('Ref 2 aid'). D vs A presented only

Y = criteria met, N= criteria not met, C/T= can't tell

†: Quality indicators: (1) was there an adequate description of the method of randomisation?; (2) was there blinding (i.e. at least blinding of outcome assessment)?; (3) was there a description of study withdrawals and what was the percentage follow-up of 80% or more achieved; (4) were the study outcomes analysed by intention to treat; and (5) was a formal pre-study power calculation performed; (6) were validated outcomes used ?: information not provided or unclear

Table 5. Study outcomes, follow up period & results

Author (year) Country	Study outcomes	Period of follow-up	Results (at follow up)	Comments
Arlinger 1998 Arlinger & Billermark, 1999	Laboratory measures 1. Speech recognition in noise Self report 2. APHAB 3. Gothenburg Profile 4. Perceived sound quality 5. Preference	1 month (with each aid)	1. A = D 2. D > A (3 subscales) 3. D > A 4. D > A or D = A† 5. D > A	• 1 year follow up on 29 of 33 who continued to use digital (i.e. non comparative) indicated further increase in outcome 1 and maintained levels of outcomes 2 to 5. Compliance of hearing aid use, doubled compared to during the period with own aid. • † D > A clearness / dullness, D = A softness / sharpness
Berninger & Karlsson, 1999	Laboratory measures 1. Hearing thresholds in sound field 2. Speech in competing speech Self-report 3. APHAB 4. usage Other 5. Fitting time	At least 3 weeks	1. A = D 2. A = D 3. D > A (1 category) 4. A = D 5. A = D	• Although no significant differences in outcomes 1, 2, 4 & 5, there was a trend of better outcomes for digital
Bille et al, 1998	Laboratory measures 1. Speech recognition in noise Self-report 2. Questionnaire of everyday function 3. Preference 4. Satisfaction	6-9 weeks	1. A = D 2. A = D 3. A = D 4. A = D	• Questionnaire carried out by interview. No outcome validation information provided.
Boymans et al, 1999	Laboratory measures 1. Speech recognition (various situations) 2. Loudness scaling Self report 3. Questionnaire rating general aid performance 4. Preference	4 weeks	1. A = D (in general) 2. A = D 3. A = D 4. D > A	• No validation information provided for questionnaire • Differences between aids appeared to differ across two clinical sites. • Consistent trend in improvement in questionnaire outcomes with digital.

Author (year) Country	**Study outcomes**	**Period of follow-up**	**Results (at follow up)**	**Comments**
Newman & Sandridge, 1998	Laboratory measures 1. Audibility Index 2. SPIN Self report measures 3. APHAB 4. HHIE 5. Knowles Hearing Aid Satisfaction Survey 6. Hearing daily use log 7. Preference rating	At least 4 weeks	1. A = D or A > D* 2. D > A 3. A = D 4. A = D 5. A = D 6. A = D 7. 7. A = D or A > D†	• Digital vs analogues differences reported • * No difference at 50dBHL but difference at 80dbHL • †A = D (cost of HAs not revealed) but A > D (cost of HAs revealed)
Ricketts & Dhar, 1999	Laboratory measures 1. speech recognition (in anechoic and 'typical living room' conditions)	None†	1. A = D*	• † Testing undertaken in the laboratory setting with no period of field familiarisation. • *Directional microphone > omnidirectional microphone whether digital or analogue in all test conditions
Yund et al, 1987	Laboratory measures 1. Signal to noise ratios at two noise levels	None†	1. A = D	• † Testing undertaken in the laboratory setting with no period of field familiarisation.
Wesselkamp, 1999	Laboratory measures 1. Speech in quiet 2. Speech in noise Self report measure 3. Sound quality rating	4 weeks	1. A = D 2. D > A or A = D* 3. D > A	*D > A in directional microphone mode, D = A (or A > D?) in non-directional mode

Table 6. Summary of cost analyses and economic evaluations

Author (year) Citation, Country	Type of study	Source of data	Hearing aid comparisons	Costs	Benefits	Cost effectiveness ratios	Comments
Davis et al, 1995 *MRC internal report*[14] United Kingdom	Cost analysis	1993 survey of all hearing aid clinics (198) in England & Wales	NHS range	1. £92.90 per aid			• Cost includes fitting & overheads (25%)
Lamden et al, 1995 *J Public Health Med* 17:445-9[36] United Kingdom	Cost analysis	Observational on 50 randomly selected users Single hospital in England June-Sept 1992	NHS range (monaural)	1. £ 25 aid 2. £ 13 clinic attendance for follow up			
Newman & Sanderbridge, 1998 *Am J Audiol* 7:115-128[32] United States	Cost effectiveness analysis	Randomised cross over study 25 users	A: linear analogue B: non-linear analogue C: digital	A: $1192 B: $1660 C: $3732	SPIN & HHIE Outcomes *	A: $49.67 to 98.51 B: $51.88 to $112.16 C: $109.76 to $223.47 AvsB: $58.5 to $173.33 BvsC: $1036.00 to $1090.00 AvsC: $254.00 to $552.17	• All costs in US$ • See Table 1 for further details • *Selected outcome which show benefit
Parving et al (1997) *Scand Audiol* 26:231-9[37] Denmark	Cost analysis	Randomised cross over trial 44 users	A: Resound Programmable WDRC ('Up-to-date aid') B: Linear/non-linear BTE ('Traditional aid')	A: £450 B: £270 Additional fitting costs of B over A: £150*			* includes fitting equipment & staff time

Author (year) Citation, Country	Type of study	Source of data	Hearing aid comparisons	Costs	Benefits	Cost effectiveness ratios	Comments
Joore (1999) *EHIMA Conference paper*[38] Netherlands	Cost utility analysis	1. Costs from a modelling of current Dutch hearing aid provision 2. HRQOL Utility assessment from pre-post study on 60 users over 16 weeks	Hearing aid vs no aid	Total cost of aid: 1295 Euros (includes GP referral, ENT specialist, Audiology centre & cost of aid)	Utility gain: EuroQol: 0.04-0.21 (CI?) Hearing aid QOL: 0.19 (95% CI 0.04? to 0.21)	Cost per QALY 2,200 to 11,000 Euros	• Assumes average life span of aid of 2.5 yrs • Discounting rate: 5% • £1.00 =1.54 Euros
Mulrow et al, 1990 *Ann Intern Med* 113:188-194[3] United States	Cost utility analysis	Randomised controlled trial 194 users	Analogue vs no aid	Total cost of aid: US$ 1000 (includes testing, fitting, and one follow up evaluation)		Cost per QALY* US$200	• *based on percent improvements in HHIE
Palmer et al, 1995 *Ear & Hearing* 16:587-598[39] United States	Willingness to pay	Controlled trial (Randomised?) 11 users	Comparison of 2 aids (details of aids not clear)		Lab test of sound quality	$6.75 per percentage point improvement in speech quality	• Users asked to make dollar value judgements on sound quality
Reeves et al, 2000 *Health Techol* Assess 4(4)[25] United Kingdom	Cost analysis	Systematic review of 11 studies of community audiology provision. (published 1981 to 1997)	BTE & ITE NHS aids	New hearing aid: £35.00 Accessories: £3.05 Exchange of hearing aid: £17.50 Ear mould: £6.00 Community clinic per attendance: £10.29 Hospital clinic per attendance: £8.69			

4. DISCUSSION

4.1 Clinical Effectiveness

This review identified a total of eight randomised controlled trials including cross over studies (involving a total of 378 individuals with mild to severe hearing impairment) that address the primary focus of this review i.e. the relative effectiveness of analogue versus digital hearing aids. These studies are small in size (on average 47 individuals) and of relatively poor methodological quality. In none of the studies was the method of randomisation described or a formal pre-study sample size calculation reported. The different physical characteristics of the hearing aid devices make user and clinician blinding difficult. Nevertheless blinding of outcome assessment is both possible and potentially important in order to reduce bias associated with laboratory based audiological testing. None of the studies reported that the assessors were blinded.

Across these eight studies there appeared to be no difference in analogue versus digital hearing aids in terms of objective laboratory based tests of hearing. Although there was evidence of benefit of digital over analogue devices in a number of user self-report measures, this was not a consistent pattern either within or across studies. Across the eight studies,only one study reported benefit of analogue over digital in one outcome.

There are number of methodological issues that need to be considered in interpreting these studies. Firstly, given the relatively small sample size of these studies, findings of 'no difference' may simply reflect the lack of power of the study rather a true lack of difference. However the two studies with the largest sample sizes (75 or over) both reported no difference between analogue and digital across all outcomes.

Second, although most of the studies used 'validated' outcomes it remains possible that these outcomes lack the sensitivity to detect the true underlying differences that might exist between these devices.

Third, in these studies, the period of familiarisation with each device ranged from 0 to 9 weeks. It may be that such a period of time is insufficient to allow the users to fully adapt and therefore benefit from the hearing device. In the case of the study by Arlinger and Billermark, an additional 12-month follow up was undertaken at which they reported an increased level of speech recognition ability compared to that at 1 month.

Fourthly, although in most cases the details of the 'comparator analogue aids' was inadequately reported, the analogue devices used across the majority of these studies generally appeared to be more sophisticated than a conventional linear ('NHS type') device. It therefore remains plausible that a more consistent pattern of improvement might have been observed if the digital devices had been compared with conventional linear analogue aids in these studies.

Finally, the interpretation of the findings of the comparisons undertaken by these studies cannot simply be interpreted on the basis of analogue versus digital signal processing alone. For instance the study by Ricketts and Dhar demonstrated no difference between digital and analogue devices in terms of signal processing (i.e. a digital versus analogue comparison).[33] However, there was significant benefit of directional versus omnidirectional microphones in all listening conditions irrespective of the whether the aid was digital or analogue. A full interpretation of the potential benefits of recent hearing aid developments is therefore also dependent upon the review of the of the evidence comparing the range of hearing aid technological developments, such as binaural fitting, directional microphones and methods of amplification (see Appendix 2). To date, no systematic review of these other technological comparisons has been undertaken.

4.2 Cost Effectiveness

Although a number of cost studies are reported in this review only three economic evaluations (i.e. comparison of both costs and consequences) were identified. The study of Newman and colleagues report in 1998 a possible range of incremental cost effectiveness ratios from US$ 58.50 to US$ 1090.00 per unit gain of hearing benefit (as measured by either objective speech test or user self report measure) when comparing a digital to either a linear or non-linear analogue aid. The hearing specific nature of the outcome makes interpretation (and comparison to other health care interventions) difficult.

Two cost utility studies were identified that involved a comparison of an hearing aid versus no aid. The study by Mulrow and colleagues reported an incremental cost per QALY ratio of $US 200 for the analogue aid. No incremental utility scores were reported in this study. Joore reported a range of incremental quality of life utility gain with a hearing aid of 4 to 21 percentage points. This range corresponds to an incremental cost per QALY of 2,200 to 11,000 Euros.

Although the incremental cost utility ratios of both these studies appear to be low, within the range usually considered to be acceptable within the NHS, these figures do not address the relevant comparison (i.e. digital vs analogue) in the context of this review. Given both the greater costs of the digital devices and their relatively small benefit in terms of clinical effectiveness in comparison to analogue aids (see Table 5), the incremental cost effectiveness of digital versus analogue hearing devices could be considerable. As described earlier in this report the private cost of a digital hearing aid may be as high as £3,000[16] (i.e. £2,910 more than a current NHS analogue device). However, in the ‘volume market’ of the NHS, the unit costs are likely to be considerably less. Two manufacturers have indicated in their submissions that the extra cost of introducing digital devices into the NHS is likely to be £250.

Table 7 illustrates the gains in quality of life that digital hearing aids would need to achieve in order to reach various incremental cost effectiveness ratios, under a range of assumptions about the incremental cost and expected life of digital aids.

This “what-if” analysis implies, for example, that at an additional cost of £250 a digital aid would need to achieve a 1.3 percentage point (or more) gain in quality of life (relative to an analogue aid) in order to attain an incremental cost effectiveness ratio of £10,000 per QALY (or less), assuming a 2 year hearing aid life. For the same incremental cost per QALY ratio, a digital aid with an additional cost of £3,000 and an expected life of 2 years, would need to achieve a gain in quality of life of 15 percentage points. To achieve an incremental cost effectivenes ratio of £20,000 per QALY, a digital hearing aid costing an additional £250 compared to an analogue aid, and with an expected life of 2 years, would only have to achieve a 0.6 percentage point improvement in quality of life. This simple analysis illustrates the sensitivity of the incremental cost-effectiveness ratio to the cost of digital aids, the expected life of aids, and to the mean gains in quality of life.

Table 7. Gains inquality of life required to achieve various incremental cost effectiveness ratios as a function of the incremental cost of a digital device (versus analogue) and the life time of the device.

Incremental cost (£)[1]	Expected life of aid (years)	Incremental cost-effectiveness ratio (£/QALY)			
		5,000	10,000	20,000	50,000
50	1	0.010	0.005	0.003	0.001
50	2	0.005	0.003	0.001	0.001
50	5	0.002	0.001	0.001	0.000
100	1	0.020	0.010	0.005	0.002
100	2	0.010	0.005	0.003	0.001
100	5	0.004	0.002	0.001	0.000
250	1	0.050	0.025	0.013	0.005
250	2	0.025	0.013	0.006	0.003
250	5	0.010	0.005	0.003	0.001
1000	1	0.200	0.100	0.050	0.020
1000	2	0.100	0.050	0.025	0.010
1000	5	0.040	0.020	0.010	0.004
3000	1	0.600	0.300	0.150	0.060
3000	2	0.300	0.150	0.075	0.030
3000	5	0.120	0.060	0.030	0.012

Notes:

1. Incremental cost includes the additional cost of a digital device versus an analogue device. The incremental cost does not include potential differences between device in terms of fitting, overheads and maintenance. No discounting of costs or benefits was undertaken. This was based on the assumption that the majority of costs will be incurred in the first year of the aid (so that discounting of costs is not necessary), and that discounting of QALYs would make little difference to the above estimates. With discounting at 1.5% pa (the current UK recommended rate for non-monetary outcomes) over five years (the maximum expected life of an aid) the gains in health related quality of life would have to be about 3% greater than the above estimates.

4.3 Current research

The NHS in March 2000 announced the launch of the Modernising Hearing Aids First Wave, a £4 million project to support 20 sites that will evaluate digital hearing aids. The main objectives of the project are to analyse the costs and efficacy of digital hearing aids, determine efficient and effective methods to distribute hearing aids, and to develop a modern hearing aid services for NHS users. NHS Trust have been invited to submit proposals to take part in the project, the sites are expected to be chosen in May 2000.[40] The RNID is currently funding an academic group at the University of Southampton to undertake an evaluation of the relative benefits of typical NHS amplification and advanced digital devices. This study involves a cross over trial where120 hearing impaired individuals are psuedo-randomised to one of three digital devices or an NHS analogue aid. This study has been powered for a within subject digital versus analogue comparison. Both laboratory and validated user self-report outcomes are being assessed. This study is due to fully report in October 2000. No results were available at the time of preparing this report.[41]

5. CONCLUSION

The evidence base comparing digital versus analogue hearing aids is small and of relatively poor quality. There appears to be little or no evidence from either laboratory or user-based outcomes of a consistent benefit of digital over analogue devices. There are currently no direct 'head to head' cost utility studies comparing digital versus analogue hearing aids. The incremental cost per QALY of digital (compared to analogue aids) is highly sensitive to their incremental cost. Further clinical research with well designed controlled trials measuring objective outcome (e.g., speech recognition), validated measures of hearing specific quality of life and costs, is needed.
The specific aim of this review was to assess the effectiveness and cost effectiveness of digital compared to analogue hearing devices. There remains a need to systematically review the evidence of other technological advancements (such as binaural aids, directional microphones and methods amplification) in hearing aids that have also taken place in recent years.

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Appendix 1. Search strategies for Medline

MEDLINE search strategy (using OVID BIOMED)
1966-

1 widex.tw.
2 senso.tw.
3 oticon.tw.
4 digilife.tw.
5 digifocus.tw.
6 prisma.tw.
7 d series.tw.
8 bernafon.tw.
9 dualine.tw.
10 starkey.tw.
11 cetera.tw.
12 resound.tw.
13 ic4.tw.
14 ensoniq.tw.
15 digital$.tw.
16 bone anchor$.tw.
17 baha.tw.
18 programable.tw.
19 programmable.tw.
20 wideband.tw.
21 wide band.tw.
22 non linear.tw.
23 nonlinear.tw.
24 signal process$.tw.
25 dsp.tw.
26 wide dynamic range compression.tw.
27 wdrc.tw.
28 or/1-27
29 Hearing aids/
30 hearing aid$.tw.
31 hearing device$.tw.
32 hearing instrument$.tw.
33 or/29-32
34 exp Hearing disorders/
35 Rehabilitation of hearing impaired/
36 34 or 35
37 Equipment design/
38 is.fs.
39 37 or 38
40 36 and 39
41 28 and 33
42 28 and 40
43 41 or 42
44 limit 43 to clinical trial
45 Cross-over studies/
46 43 and 45
47 44 or 46
48 Economics/
49 exp "Costs and cost analysis"/
50 Economic value of life/
51 exp Economics, hospital/
52 exp Economics, medical/
53 Economics, nursing/
54 exp models, economic/
55 Economics, pharmaceutical/

56 exp "Fees and charges"/
57 exp Budgets/
58 ec.fs.
59 (cost or costs or costed or costly or costing$).tw.
60 (economic$ or pharmacoeconomic$ or price$ or pricing).tw.
61 or/48-60
62 43 and 61
63 47 or 62

Appendix 2. Other comparisons

1. Non-linear amplification†

Reference	Nature of comparison
Biering-Sorensen M et al. A clinical comparative investigation of a non-linear versus linear hearing aid*. Scand Audiol* 1994;24:125-132. Parving A. *Comparative Investigation of Multifocus and Oticon E35F*. Oticon Internal report, 1993.	Oticon Multifocus (non-linear) vs Oticon E35F (linear) (Behind the ear aids)
Franck BAM, Sidonne C, et al. Evaluation of spectral enhancement in hearing aids, combined with phonemic compression. *J. Acoust. Soc Am* 1999;106(3):1452-1464.	Spectral enhancement with compression vs spectral enhancement without compression
Hawkins DB**.** Naidoo SV. Comparison of sound quality and clarity with asymmetrical peak clipping and output limiting compression. *J Am Acad Audiol.* 1193;4(4):221-8.	Peak clipping vs output limiting compression (Behind the ear hearing aids)
Humes LE, Christensen LA, Bess FH, Hedley-Williams A. A comparison of the benefit provided by well-fit linear hearing aids and instruments with automatic reductions of low-frequency gain. *J of Sp, Lang & Hear Res* 1997;40(3):666-85	Linear amplification vs BILL (base increase at low levels) processing (Dahlberg in the canal hearing aid with experimental BILL circuit fitted binaurally)
Jenstad LM, Seewald RC, Cornelisse L, Shantz J. Comparison of linear gain and wide dynamic range compression hearing aid circuits : aided speech perception measures. *Ear & Hearing* 1999;20:117-126.	Linear amplification vs single channel wide dynamic range compression (Siemens Viva 2Pro behind the ear hearing aid fitted monoaurally)
Lundh, P. *Field-test for the two channel hearing aid with compressor in low frequency channel. (Internal report 14-8-7)* .Oticon Research Unit, 1983	Low frequency compression vs no low frequency compression

	(Emulation of BTE Oticon Multifocus with and without low frequency compression)
Lutman ME, Payne E. *Comparison of alternative compression strategies in new and experienced hearing-aid users*. Institute of Sound and Vibration Research, University of Southampton, 1999, (ISVR Contract Report ; 99/31)	Multifocus compression vs wide dynamic range compression (Oticon DigiLife digital hearing aid)
Moore BCJ, Glasberg BR, et al. Optimization of a slow-acting automatic gain control system for use in hearing aids.*Br J Audiol* 1991;25:171-182.	Prototype dual front end automatic gain control (AGC) system vs commercially available behind the ear hearing aid with adaptable compression vs linear amplification
Moore BCJ, Glasberg BR. A comparison of four methods of implementing automatic gain control (AGC) in hearing aids. *Br J Audiol* 1988;22:93-104.	Three configurations of a prototype dual front automatic gain control (AGC) system vs dual channel AGC system vs linear amplification
Neuman AC, Bakke MH, et al. Effect of compression ratio in a slow-acting compression hearing aid: paired -comparison judgements of quality. *J Acoust Soc Am* 1994;96(3):1471-1478. Neuman AC, Bakke MH, et al. Effect of release time in compression hearing aids: paired- comparison judgements of quality. *J. Acoust Soc Am* 1995;98(6):3182-7.	Comparison of various compression algorithms (Computer simulated digital compression hearing aid)
Niklasson-Lovbacka K. *Speech intelligibility and sound quality with frequency dependent in AGC noise.* Gothenberg School of Rehabilitation, 1993	Automatic gain control (AGC) vs no AGC comparing three hearing aids (Single channel BTE with K-amp circuit, two channel hearing aid, conventional hearing with linear amplification)
Nilsson P, Vesterager V, Sibelle P, Sieck L, Christensen B. A double-blind cross-over study of a non-linear hearing aid. *Audiology,* 1997;36(6):325-38.	Compression (K-amp circuit) vs linear amplification (Rexton Setinette circuit)

	(Using in the ear hearing aids)
Parving A, Sorensen MS, Carver K, Christensen B, Sibelle P, Vesterager V. Hearing instruments and health technology--an evaluation. *Scand Audiol* 1997;26(4):231-9.	Subjects' own hearing aid vs programmable full-dynamic range compression (with compression) vs programmable full-dynamic range compression (linear mode) (Using behind the ear hearing aids)
Riko K, Pichor-Fuller MK, et al. Clinical evaluation of a two-channel amplitude compression hearing aid. *Laryngoscope* 1986;96:1226-1130.	Single channel vs two channel compression (Behind the ear hearing aids)
Sammeth CA, Tetzeli M, et al. Consonant recognition performance of hearing-impaired listeners using one linear and three nonlinear hearing aids. *J Am Acad Audiol* 1996;7:240-250.	Linear amplification (Argosy Linear Plus) vs three types of nonlinear amplification (2 types of BILL processing (Argosy Manhattan II with experimental modifications, Expander), peak clipping (Infinite Amplitude Clipper) (Behind the ear hearing aids under in the ear frequency conditions)
Stone MA, Moore BCJ, Alcantara JI, Glasberg BR. Comparison of different forms of compression using wearable digital hearing aids. *J Acoust Soc Am*. 1999;106(6):3603-3619	High frequency compression with automatic gain control (compression ratio 10:1) vs wide dynamic gain control (compression ration 2:1) vs linear amplification
Stone MA, Moore BCJ, et al. Effects of fast-acting high frequency compression on the intelligibility of speech in steady and fluctuating background sounds. *Br J Audiol* 1997;31:257-273	Automatic gain control (AGC) (compression ratio high) vs automatic gain control (compression ratio low) vs full dynamic range compression (FDRC) vs AGC (low) + FDRC (Audiologic Audallion digital hearing aid)

Valente M, Sammeth CA, Potts LG et al. Differences in performance between Oticon Multifocus Compact and ReSound BT2-E hearing aids. *Am Acad Audiol* 1997;8:280-93	Oticon Multifocus vs ReSound BT2-E (Digitally programmable analogue hearing aids fitted binaurally)
Yund EW, Buckles KM. Discrimination of multichannel-compressed speech in noise - long-term learning in hearing-impaired subjects. *Ear Hear*, 1995;16(4):417-427. Yund EW, Buckles KM. Enhanced speech perception at low signal-to-noise ratios with multichannel compression hearing aids. *J. Acoust Soc. Am* 1995;97(2):1224-1240. Yund EW, Buckles KM. Multichannel compression hearing aids: effect of number of channels on speech discrimination in noise. *J. Acoust Soc Am* 1995;97(2):1206-1223.	Multichannel compression vs linear amplification

† Can include digital vs digital or analogue vs analogue comparisons

2. Monoaural vs binaural comparisons†

Reference	Nature of comparison
Balfour PB, Hawkins DB. A comparison of sound quality judgments for monaural and binaural hearing aid processed stimuli. *Ear Hear* 1992;13(5):331-339.	Comparison using Phonic Ear 805CD2 hearing aid with omindirectional microphone
Festen JM, Plomp R. Speech-reception thresholds in noise with one and two hearing aids. *J. Acoust. Soc. Am* 1986;79(2):465-471.	With hearing aid vs hearing aid left ear vs hearing aid right ear vs hearing aid both ears (Subjects' own hearing aids)

Hawkins DB, Yacullo WS. Signal-to-noise ratio advantage of binaural hearing aids and directional microphones under different levels of reverberation. *J Speech Hear Dis* 1984;49:278-286.	Monaural vs binaural using both omnidirectional and directional microphone conditions
Schreurs KK, Olsen WO. Comparison of monaural and binaural hearing aid use on a trial period basis. *Ear Heari* 1985, 6(4): 198-202.	Field test

† Can include digital vs digital or analogue vs analogue comparisons

3. Digital vs digital comparisons†

Reference	Nature of comparison
Knebel S, Bentler R. Comparison of two digital hearing aids. *Ear Hear* 1998;19(4):280-289.	Oticon Digifocus vs Widex Senso
Naylor, G *E60-DYN5 vs MultiFocus Compact Field Test* Oticon Electronics A/S Research Unit, 1997	Oticon E60-DYN5 behind the ear (forerunner to Oticon Digifocus) vs Oticon MultiFocus Compact
Naylor, *G E63 SKI field test* Oticon, 1997	Comparison of two alternative SKI rationales (Used with subjects' own digital hearing aids)
Ricketts TA. Bentler RA. Comparison of two digitally programmable hearing aids. *Journal of the American Academy of Audiology.* 1992;3(2):101-12.	Widex Quattro vs Ensoniq Sound Selector

Warland A, Tvete O, Arntzen O, Traeland G, Skogstad W, Slethei K. Cited in *News from Oticon*, January 1998**.**	Oticon Digifocus vs Widex Senso
Wesselkamp, M. *Clinical study of PRISMA BTE at the University of Linköping.* (Siemens technical report 15-Mar-99). 1999	Siemens PRISMA vs 'Ref 2 aid' (with digital signal processing and non-directional microphone) (Also compares digital aid (PRISMA) vs analogue aid ('Ref 1 aid'). Included in digital vs analogue comparisons in this review)

† Comparisons of two or more digital devices

4. Directional microphone comparisons†

Reference	Nature of comparison
Gravel J, Fausel N, Liskow C, Chobot J. Children's speech recognition in noise using omnidirectional and dual-microphone hearing aid technology. *Ear Hear* 1999;20:1-11.	Omnidirectional microphone vs dual microphone (Phonak PiCS 332x worn binaurally in omnidirectional and dual (AutoZoom) conditions)
Hawkins DB, Yacullo WS. Signal-to-noise ratio advantage of binaural hearing aids and directional microphones under different levels of reverberation. *J Speech Hear Dis* 1984;49:278-286.	Monaural vs binaural using both omnidirectional and directional microphone conditions
Humes L and Bentler R. *Siemens Prisma clinical trial*. 1998	Omnidirectional vs directional microphone (Siemens Prisma in with and without voice activity detection (VAD) mode)

Mueller HG, Johnson RM. The effects of various front-to-back ratios on the performance of directional microphone hearing aids. *J Amer Audiol Soc* 1979;5:30-34.	Four directional microphone hearing aids with different front to back ratios
Nielsen HB, Ludvigsen C. Effects of hearing aids with directional microphones in different acoustic environments. *Scand Audiol* 1978;7:217-224.	Directional vs 'coventional' hearing aid (Oticon behind the ear 568 worn binaurally with directional and conventional microphone)
Nielsen HBA Comparison between hearing aids with a directional microphone and hearing aids with a conventional microphone. *Scand Audiol* 1973;2:173-.	Directional (Danavox 735 DV) vs omnidirectional (Danavox 735 V) hearing aids
Sung GS, Sung RJ, Angelelli RM. Directional microphone in hearing aids. *Arch Otolaryng* 1975;101:316-319.	Amount of directionality between three directional hearing aids (Behind the ear hearing aids)
Valente M, Fabry D, Potts L. Recognition of speech in noise with hearing aids using dual microphones. *J Amer Acad Audiol* 1995;6:440-449.	Directional vs omnidirectional microphones (using 'basic' and 'party' hearing aid programmes) (Phonak PiCS in conventional and AudioZoom conditions)
Voss T Clinical evaluation of multi-microphone hearing instruments. *Hear Rev* 1997;4(9):36,45-46,74.	Directional vs omnidirectional microphones (using 'basic' and 'party' hearing aid programmes) (Phonak PiCS in conventional and AudioZoom conditions)

† Can include digital vs digital or analogue vs analogue comparisons

5. Other comparisons†

Reference	Nature of comparison
Jerger J. Chmiel R. Florin E. Pirozzolo F. Wilson N. Comparison of conventional amplification and an assistive listening device in elderly persons. *Ear Heari.* 1996;17(6):490-504.	Hearing aid (Siemens Triton 3000 or 3M Memory Mate hearing aid worn monaurally) vs assistive listening device (Comtek Personal FM System)
Mulrow CD, Aguilar C, Endicott JE, Tuley MR, Velez R, Charlip WS, Rhodes MC, Hill JA, NeNino LA. Quality-of-life changes and hearing impairment, a randomized trial. *Ann Int Med* 1990;113:118-194	Hearing aid vs no hearing aid
Pumford J, Seewald R, Scollie S, Jenstad L Speech recognition with in-the-ear and behind-the-ear dual-microphone hearing instruments. *J Amer Acad Audiol* 2000;11(1):23-35.	Behind the ear hearing aid with dual microphone (Phonak PiCS AudioZoom) vs in the ear hearing aids with dual microphone (Phonak PiCS MicroZoom)

† Can include digital vs digital or analogue vs analogue comparisons

Appendix 3: Awaiting further information from authors/manufacturers

1. Digital vs analogue comparisons

Dillier N, Frolich T, Kompis M, Bogli H, Waikong L. Digital signal processing (DSP) applications for multiband loudness correction digital hearing aids and cochlear implants. *J Rehab Res* 1993;30(1): 95-109.

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Kuk FK, Kollofski C, Brown S Melum A, Rosenthal A. Use of a digital hearing aid with directional microphones in school-aged children. *J Am Acad Audiol*. 1999;10(10):535-48.

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4. Directional hearing aids

Wouters J, Litiere L, et al. Speech intelligibility in noisy environments with one-and two-microphone hearing aids. *Audiology* 1999; 38: 91-98.

5. Other comparisons

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