Contralateral acoustic hearing aid use in adult unilateral cochlear implant recipients: Current provision, practice, and clinical experience in the UK

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Abstract

Objectives: The study surveyed practising cochlear implant audiologists with the aim of: (1) characterising UK clinical practice around the management and fitting of a contralateral hearing aid in adult unilateral cochlear implant users ('bimodal aiding'); (2) identifying factors that may limit the provision of bimodal aiding; and (3) ascertaining the views of audiologists on bimodal aiding.

Methods: An online survey was distributed to audiologists working at the 20 centres providing implantation services to adults in the UK.

Results: Responses were received from 19 of the 20 centres. The majority of centres reported evaluating hearing aids as part of the candidacy assessment for cochlear implantation. However, a majority also indicated that they do not take responsibility for the contralateral hearing aid following implantation, despite identifying few practical limiting factors. Bimodal aiding was viewed as more beneficial than wearing the implant alone, with most respondents actively encouraging bimodal listening where possible. Respondents reported that fitting bimodal devices to take account of each other's settings was potentially more beneficial than independently-fit devices, but such sympathetic fitting was not routine practice in any centre.

Discussion: The results highlight some potential inconsistencies in the provision of bimodal aiding across the UK as reported by practising audiologists. The views of audiologists about what is best practice appear to be at odds with the nature and structure of the services currently offered.

Conclusion: Stronger evidence that bimodal aiding can be beneficial for UK patients would be required in order for service providers to justify the routine provision of bimodal aiding and to inform guidelines to shape routine clinical practice.

Key Words: Cochlear Implants; Bimodal Aiding; Acoustic Hearing Aids; Clinical Practice of Bimodal Fitting; Binaural Hearing; Bimodal Benefits; Sympathetic Bimodal Fitting; Bimodal Listening.

Introduction

Cochlear implantation was originally devised as a method for restoring a sensation of sound in bilateral sensorineural hearing impairment where the degree of loss was total or profound (Ramsden, 2013). A consensus statement from the US National Institutes of Health (NIH) in the late 1980s demonstrated that cochlear implantation was largely restricted to individuals who could derive no real benefit from acoustic hearing aids and no open set speech discrimination (Kohut et al., 1988). A subsequent NIH consensus statement acknowledged that listening performance of some adults with a severe-to-profound hearing impairment was poorer than that of adults with a more profound impairment but who used a cochlear implant (Gates *et al*., 1995). As a result, a relaxation of candidacy criteria was recommended to include individuals with up to 30% open-set speech discrimination in their best aided condition in the US.

At approximately the same time in the UK, a national study group was evaluating outcomes following cochlear implantation in patients who either had no open-set speech discrimination before implantation ("traditional candidates") or who had some measurable discrimination ("marginal hearing aid users") (UKCISG, 2004a). The study group concluded that those patients who had some usable residual hearing pre-operatively (i.e. non-traditional candidates, or "marginal hearing aid users") can have favourable odds of benefitting from cochlear implantation, particularly those with shorter durations of deafness, and therefore should be considered as candidates for the treatment.

In 2009, the National Institute for Health and Care Excellence (NICE) in the UK reviewed the evidence for the effectiveness and cost-effectiveness of cochlear implantation in adults

(NICE, 2009). As a result of their appraisal of the evidence, NICE recommended unilateral cochlear implantation for adults with a bilateral severe-to-profound sensorineural hearing impairment who derive “insufficient” benefit from acoustic hearing aids. Insufficient benefit was defined as an inability to report at least 50% of words on an open-set test of speech discrimination in quiet while in their best-aided condition. The effective result of these recommendations was an expansion of the eligibility criteria which led to an associated increase in the number of hearing impaired individuals that would be suitable for the treatment. When the NICE guidance was published, approximately 900 adults were implanted each year across 14 hospitals (NHS, 2012), a level of activity which had increased to 1161 by 2014 across 19 implanting centres (BCIG, 2015). As candidacy criteria in the UK now permit candidates to have measurable open-set speech perception but still restrict implantation to one ear (thus retaining the audiological status of the non-implanted ear), many implant recipients in the UK now have measurable residual hearing and potentially aidable thresholds in their non-implanted ear.

Bimodal aiding is the practice of providing and fitting an acoustic hearing aid (HA) in one ear and a cochlear implant (CI) in the other ear. Improvements in listening abilities from using both devices over using the CI alone (bimodal benefits) have been widely documented, and are thought to reflect the integration of low frequency acoustic cues from the HA with higher frequency cues from the CI (Gantz and Turner, 2003). Despite the fact that unilateral cochlear implantation is the current treatment for adults with severe-to-profound hearing losses in the UK (NICE, 2009), the restoration of binaural hearing whether through bilateral implantation or bimodal listening has been recommended for this patient group (point 1.1; NHS, 2013).

A systematic review of the evidence for bimodal aiding in adults found that wearing a contralateral HA in addition to a CI can provide benefits to speech perception, particularly in the presence of background noise (Olson and Shinn, 2008). These bimodal benefits to speech perception have been observed even when the information accessible to the non-implanted ear cannot support any useful speech perception on its own (Zhang et al., 2010), suggesting that there may be supra-additive benefits from combining acoustic with electric hearing. Other studies have suggested that the benefits are not supra-additive but simply reflect the fact that CI users may be able to integrate electric and acoustic information optimally (Micheyl and Oxenham, 2012). Bimodal aiding has also been shown to improve music perception (Kong et al., 2004) and the naturalness of speech (Sucher and McDermott, 2009), and may improve sound localisation in some listeners (Dunn et al., 2005). The evidence has led some to recommend that bimodal aiding should be offered routinely when listeners are able to make some use of both devices (Ching et al., 2004).

The size of bimodal benefit that patients receive has been found to relate to the level of acoustic hearing in their non-implanted ear (Zhang et al., 2013). Accordingly, many studies that have demonstrated bimodal benefits have done so in patients who have access to a level of hearing in their non-implanted ear that is readily aidable using an acoustic hearing aid (Morera et al., 2005, Yoon et al., 2012) and therefore greater than that typically available to patients in the UK who meet NICE criteria. Despite this, there is evidence that UK patients report benefits from wearing a HA in addition to their CI and may derive benefits to speech perception from doing so (Visram, 2012). Other bimodal benefits that

have been observed in UK patients include some ability to distinguish emotions in spoken sentences and an improved ability to determine the location of sounds (Goman, 2014).

The importance of an appropriately fit HA for use in combination with a CI has been well documented (Ching et al., 2004, Dunn et al., 2005, Gifford et al., 2007, Kong et al., 2005, Mok et al., 2006, Gifford et al., 2010). To date, professional bodies in the UK including the British Cochlear Implant Group (BCIG), the British Society of Audiology (BSA) and the British Academy of Audiology (BAA) have yet to issue guidance on the provision of HAs that are to be used simultaneously with a CI in the other ear, and how the two devices should be fit to work sympathetically together. It is therefore unclear whether clinicians providing CI services in the UK undertake HA evaluations or consider the potential benefits of bimodal aiding when assessing candidacy, when considering which ear should be implanted to maximise benefit, when fitting the CI, or when reviewing progress following implantation. The aim of this study was therefore to survey audiologists across UK adult CI centres about their current practice around bimodal aiding. The objectives of the survey were:

1. To describe current clinical practice in the UK around bimodal aiding in adults
2. To identify factors potentially limiting clinical practice around bimodal aiding
3. To characterise audiologists' views of bimodal aiding

Methods

Design

The survey (Supplementary Material 1) was designed to characterise clinical practice around bimodal aiding by following the temporal progression of a patient through the care pathway

from candidacy assessment through to the choice of ear for implantation, initial activation of the CI, and post-implantation follow up. Questions types were varied and included: (i) scaling to estimate patient numbers or importance ratings; (ii) agreement/disagreement using a five-point Likert scale; (iii) frequency of occurrence using both yes/no and always/sometimes/rarely/never response sets (reflecting degree of certainty); and (iv) open-ended questions where free-text responses were permitted.

Most questions were designed to elicit a response, and respondents were not permitted to proceed to the next question until a response to the current question had been provided. Responses to open-ended questions were always optional. Conditional question pathways were included so that each respondent was presented with a set of questions that were deemed appropriate based on their previous responses. For example, questions about the manner in which HAs are fit at the candidacy assessment stage were not presented to respondents who had previously indicated that they never fit HAs at that stage of the care pathway.

Distribution

The survey was distributed online using the Survey Monkey software (https://www.surveymonkey.com/). The survey was targeted at audiologists working at CI centres within the UK. An invitation to complete the online survey was distributed to every BCIG member indicating it was for the attention of audiologists working with adult patients. The introductory text of the survey indicated that only those who work with adult patients

should complete the survey. No option was given to complete the survey on paper. Sixty-six audiologists were registered with audiology-related job titles on the BCIG mailing list at the time of mailing (January 2015), which included representatives from the 20 UK CI centres that work with adult patients. Programme coordinators were also invited to forward the survey to any audiologist who may not be a member of the BCIG. A follow up letter and poster for placement in communal areas such as staff rooms was sent to the coordinator of each CI centre one month after the initial invitation was sent. After a further three months, coordinators of CI centres who had not yet contributed were sent a reminder email or were contacted by telephone.

Procedure

Respondents were informed that the purpose of the survey was to investigate current practice around evaluating, fitting and reviewing patients who use (or could use) bimodal devices. Respondents were asked to name the CI centre in which they worked. This information was collected to determine the geographical distribution of responses and to assess whether the results were likely to be representative of current practice across the UK. Respondents were informed that their responses would be strictly anonymous. Accordingly, in reporting the results individual responses have not been associated with any particular CI centre. While acknowledging that every patient is an individual, respondents were asked to think about the things they would typically do and to focus on their practice within the last 5 years.

Analysis

The survey was divided into three sections based on relevance to the study objectives. Sections were not equal in length, given the greater complexity of certain aspects of clinical practice than others. No question contributed to more than one section. The number of responses varied across questions due to the use of conditional question pathways and the fact that respondents were not required to answer to all questions. Where possible, individual responses were converted to a binary outcome by grouping them into one of two categories (e.g. agree/disagree, yes/no, etc.). Responses were then summarised as the proportion of centres from which positive responses were received and as the proportion of individuals who responded positively. Ninety-five percent confidence intervals were calculated for each of these proportions (Newcombe, 1998).

The terms 'majority' and 'minority' were applied only to proportions that were found to be significantly greater than or less than 50% of respondents, respectively. For example, if data were available from 19 centres on a particular question, a proportion of 26% or less (5 centres or fewer) was interpreted as a 'minority' (upper 95% confidence interval of proportion = 48.8%) and a proportion of 74% or more (at least 14 centres) was interpreted as a 'majority' (lower 95% confidence interval of proportion = 51.2%). Where questions contained an estimation of the frequency of a clinical activity or procedure (always/often/sometimes/rarely/never), practice was considered routine if respondents selected the 'always' or 'often' options. The statistical significance of the difference between two proportions was calculated using McNemar's test (McNemar, 1947).

Results

Nineteen of the twenty centres contributed to the survey resulting in a centre response rate of 95%. Complete responses were received from 33 individual audiologists, representing an estimated individual response rate of 50% based on the number of registered BCIG members with audiology-related job titles. The centres that chose to participate and the numbers of completed surveys received from each are shown in Table 1. As the number of responses differed across centres, the interpretation of the results was based on summary statistics of responses at the centre level, rather than at the individual level. A further five respondents completed part of the survey but did not identify which centre they practiced at. Their responses were included when calculating summary statistics at the individual level.

Section 1: Current clinical practice in the UK

The proportion of centres who indicated undertaking activities in various parts of the care pathway and the associated confidence intervals are listed in Tables 2 and 3.

(a) Hearing aid management during candidacy assessment (Table 2)

Respondents estimated that 87% of patients who attend for candidacy assessment wear a HA in at least one ear (95% confidence interval: 83-92%). All but one centre reported that they do conduct HA evaluations as part of the candidacy assessment and a majority of those centres (14 out of 18) reported checking HA fittings routinely as part of this evaluation. The fact that some respondents in those 14 centres indicated that they do not check HA fittings routinely could suggest some level of inconsistency within centres but may also simply

reflect the division of responsibilities among staff. Eleven centres indicated that they would check the HA fitting in *every* patient who attended wearing HAs, but this did not represent a majority.

The need for HA fitting and evaluation appeared to be judged on an individual basis. When presented with the scenario of a CI candidate who does not wear HAs but has measurable hearing thresholds or a history of recent HA usage, a majority of centres (83%) indicated they would routinely attempt to fit HAs. When presented with an alternative scenario of a candidate attending wearing a single HA, the number of centres that reported routinely attempting a HA fitting in the unaided ear dropped to 61%, which did not represent a majority. Two respondents from a single CI centre commented that they would rarely attempt to fit a HA to the unaided ear as the result would be unlikely to affect the candidacy decision, where open-set speech discrimination scores in the quiet when in their best-aided condition must be <50% (NICE, 2009).

A variety of HA fitting and verification methods were reported including fitting to a prescription target (64%), Real Ear Measurement (61%), aided threshold measurement (50%) and speech discrimination testing (50%). The majority of centres reported using a combination of methods.

(b) Hearing aid management following implantation (Table 2)

Respondents estimated that 58% of patients who received their CI within the last 5 years wear a contralateral HA at initial activation of the CI (95% confidence interval: 51-64%), but hypothesised that only 41% of this group would still be wearing the HA after 5 years of implant use (mean decrease as a proportion of all CI users of 33%; 95% confidence interval 28-38%). Only a minority of centres indicated that they take full responsibility for the maintenance of the contralateral HA once the CI is activated despite the fact that the majority of centres reported routinely conducting HA reassessments prior to implantation, and may have fitted the aid during the assessment. Instead, a majority of centres indicated that they refer patients elsewhere for their ongoing hearing aid maintenance, usually the implant user's local audiology team, who may or may not have fitted the HA originally.

A minority of centres indicated that they routinely conduct a contralateral HA evaluation within the first 12 months of CI use, and only 3 centres reported routinely reviewing the HA fitting after 12 months of CI use. Six centres indicated that they would attempt to re-fit a contralateral HA that a CI user had stopped wearing following implantation but this represented a minority view. All centres indicated that they would not routinely fit a new HA in an unaided contralateral ear within the first 3 months after CI activation, even if it had potentially aidable thresholds, although nine centres indicated that they would consider it but only at the patient's request. The post-operative HA fitting and verification methods reported by respondents were notably different to the methods chosen pre-operatively, with only 33% of respondents selecting the same combination of methods at the two time intervals.

(c) Sympathetic bimodal fitting (Table 3)

At initial CI activation, only one centre reported an agreed protocol for "bimodal switch-on" in the clinic; i.e. consideration of both devices when creating the first CI programme. Four centres did report taking the HA parameters into account when first activating the CI, but no centre indicated making any attempt to match device parameters such as compression settings or frequency allocations at this stage. Eleven centres reported attempting to match the two devices for loudness at the CI fitting stage but this did not represent a majority.

There was minimal evidence that devices are fit sympathetically at subsequent CI review appointments. Only one centre, which notably was not the centre that reported using a bimodal switch-on procedure above, reported following a protocol for programming bimodal patients in the clinic. Only a minority of centres reported taking the parameters of the HA into account when deciding how to reprogramme the CI, and only one respondent was consistent in using these parameters at both switch-on and subsequent reviews. Only two centres indicated that they attempt to match device parameters such as compression settings or frequency allocations at CI review appointments. However, a majority of centres reported balancing loudness across the two devices at review appointments.

In summary, inconsistencies in practices relating to bimodal fitting at both initial and subsequent CI programming appointments were apparent. It would therefore appear likely that any programming adjustments related to improving bimodal listening are made to the

implant only and not to the HA, given that the majority of centres do not routinely adjust HA fittings post-implantation.

(d) Bimodal outcome measurement (Table 3)

When a bimodal listener attends for a performance review, all but one centre reported routinely measuring listening outcomes using the CI alone, 12 centres (not a majority) reported routinely measuring bimodal listening outcomes, while a minority of centres reported routinely measuring outcomes from the HA alone following implantation. Only seven centres reported that they follow an agreed protocol for measuring bimodal benefit in the clinic, and three centres reported rarely or never measuring bimodal outcomes.

Of the 12 centres that report measuring bimodal outcomes routinely, four indicated that they choose additional listening tests specifically to measure bimodal benefit that would not normally be used with a unilateral CI listener. A free text box was provided for respondents to list any test used specifically to measure bimodal benefit. The following tests were listed: BKB sentences in adaptive noise test, the Star^2 (Sentence Test with Adaptive Randomised Roving levels) test (Joffo and Boyle, 2010), multiple speaker sound localisation, and the CRM (Coordinate Response Measure) sentence test (Kitterick et al., 2010, Kitterick et al., 2011).

(e) Patient advice (Table 3)

When a patient attends for initial activation wearing a HA in the non-implanted ear, advice about how to use the HA in addition to the CI was inconsistent across centres. Only a minority of centres recommend that both devices be worn together from the first day that the CI is activated, with 68% recommending intermittent use of the HA at first to allow time for CI-only listening. A separate minority reported advising patients not to wear the HA until they have been using their CI for around 3 months. Four centres indicated that they would not make recommendations about contralateral HA use and would leave it to the patient to decide.

In spite of the uncertainties about HA use evident at initial CI activation, a majority of centres (95%) reported actively encouraging CI users to wear a contralateral HA once they had used their implant for at least 3 months. No respondent reported actively discouraging contralateral HA usage after an initial 3-month CI acclimatisation period.

Interim summary

An overview of the consistencies and inconsistencies of clinical practice derived from this section is shown in Table 4. Centres almost universally reported evaluating HAs during candidacy assessment, a practice that is consistent with national guidance that requires the speech perception abilities of candidates to be assessed in the best-aided condition (NICE, 2009). However, some variability in reported practice both within and between centres was apparent. The current reports suggest that most centres do not maintain the long term care of the contralateral HA, do not routinely optimise bimodal aiding through evaluating or re-

fitting the HA post-operatively, and do not practise sympathetic bimodal fitting. The focus of the audiologist seems primarily on optimising the CI. The two devices are therefore likely to be programmed independently after implantation, on separate occasions and not necessarily by the same person or at the same centre. Whilst there is reportedly some uncertainty about how to advise patients on bimodal listening at initial CI activation, most centres appear to actively encourage HA during later stages of CI use, implying a mismatch between their advice to listen bimodally and their clinical practice to optimise it.

Section 2: Factors limiting bimodal practice

Table 5 lists the proportion of CI centres and individual responses who agreed or disagreed with statements about factors that might limit the provision and optimisation of bimodal devices and their associated confidence intervals.

(a) Hearing aid management

A minority of centres indicated that a lack of time, rooms and equipment are significant factors limiting HA management during candidacy assessment. Six centres reported a shortage of available audiologists, and eight reported a lack of staff expertise in HA fittings. Only one centre suggested that insufficient residual hearing was a factor limiting HA fitting during candidacy assessment, which represented a minority view.

Three centres had at least one respondent report that they do not evaluate HAs as part of the candidacy assessment. The most frequent limiting factors cited by these respondents were a lack of staff expertise (3 centres), insufficient numbers of audiologists (3 centres) and a lack of rooms/equipment (2 centres). None of these centres indicated that time was a limiting factor. Further free text comments suggested that a lack of funding for HA provision at CI centres may be a contributing factor to the lack of HA evaluations during candidacy assessment.

During the initial CI activation period, a minority of centres indicated that lack of equipment was a limiting factor but 68% indicated that there was insufficient time to evaluate HAs in addition to the CI. The role of time, equipment, staffing or staff expertise in limiting HA management during subsequent routine CI review appointments were all listed as limiting factors, but were variable across centres suggesting that there is no single factor that presents a consistent barrier to the provision of bimodal aiding in established CI users.

(b) Bimodal outcome measurement

A minority of centres indicated that there is a lack of staff expertise within their centres to measure bimodal outcomes. Nine centres reported insufficient time to measure bimodal listening outcomes in addition to CI-only, and six centres reported insufficient equipment.

(c) Sympathetic bimodal fitting

Around half of all centres (58%) indicated that there is insufficient time to conduct sympathetic fitting of both devices in the same session. A similar number of centres agreed that there is a lack of guidance on how to optimise the two devices to work better together. Additionally, the fact that only a minority of centres reportedly retain responsibility for ongoing care of the contralateral HA post-implantation (Table 2) may also represent a significant factor limiting the provision of sympathetic bimodal fitting.

Interim summary

The pattern of responses suggests that in centres that currently undertake HA evaluations, resources for managing HAs both during candidacy assessment and after implantation are adequate. In centres that do not currently undertake HA evaluations as part of their service, there appear to be more limitations to overcome including lack of staff expertise, facilities, and possibly also a lack of funding. The fact that respondents from these centres indicated that time is not a limitation suggests that routine HA evaluations would be possible if these logistical factors were addressed. Measurements of bimodal outcomes would also appear to be feasible given the available resources and staff expertise reported by respondents, but longer review appointments may be necessary to ensure that they can be obtained consistently across all patients and centres. The sympathetic fitting of the CI and HA does not appear to be feasible at present due to the time constraints and lack of experience and guidance reported by respondents. Therefore, the data suggest that additional time may also be necessary during certain appointments to ensure that the HA and CI can be maintained and optimised at the same time.

403

404 **Section 3: Respondent views regarding bimodal issues**

405 Table 6 lists the proportion of CI centres and individual respondents who expressed
406 agreement with a range of statements about bimodal aiding and the associated confidence
407 intervals.

408

409 *(a) Hearing aid management*

410 A majority of centres (95%) indicated that it is beneficial both to attempt to optimise HAs
411 during the candidacy assessment stage and to optimise the contralateral HA post-
412 implantation. A majority of centres were also of the opinion that HA optimisation was
413 within the role of the CI audiologist both during candidacy assessment and post-operatively
414 (68% and 79%, respectively). Responses from individual audiologists about whether they
415 feel it is within their role to evaluate HA fittings were more mixed both when considering
416 candidacy assessment (42%) and post-operative appointments (61%). It is possible that this
417 apparent variability within centres may have reflected the division of responsibilities among
418 staff.

419

420 Respondents were invited to comment on the practicalities of maintaining both devices.
421 Common themes in the responses to this open-ended question indicated that: (i) managing
422 both devices may provide a smoother service for the patient throughout the care pathway;
423 (ii) there are logistical difficulties around HA maintenance as many patients do not live near

their CI centre and may prefer to access HA repair services locally; (iii) there are difficulties with funding as CI services may not be commissioned to support and manage HAs; and (iv) there is limited staff expertise of the range of available HAs, software, stock, and spares within CI centres.

(b) Bimodal benefit

When asked to consider both the positives and the negatives of contralateral HA use, the majority of centres (84%) agreed that bimodal aiding provides more benefit than wearing the CI alone. No respondent indicated that wearing the CI alone was more beneficial than bimodal aiding. The majority of centres (84%) reported taking the possibility of bimodal aiding into consideration when choosing which ear to implant, although at an individual level 64% of respondents reported doing so, which did not represent a majority. Respondents were asked to list up to three potential advantages and three potential disadvantages of wearing a contralateral HA in addition to a CI that they had directly observed or heard from patients during their clinical practice. Figure 1 shows the reported categories of bimodal advantage, the largest of which was sound localisation. Figure 2 shows the reported categories of bimodal disadvantage, the largest of which was related to wearing an earmould.

In spite of the majority of clinics not having an agreed protocol for measuring bimodal outcomes (Section 1d), the majority of centres (95%) reported that it is clinically useful to measure bimodal benefit. Respondents were asked to rate the most useful outcome

446 measures to demonstrate bimodal benefit and the proportion of respondents who selected
447 each category of test is shown in Figure 3. A majority of respondents indicated that
448 measuring speech discrimination in background noise was the most useful clinical measure
449 of bimodal benefit.

450

451 *(c) Sympathetic bimodal fitting*

452 When asked to compare sympathetic with independent bimodal device fittings, a majority
453 of centres (84%) felt that fitting the devices sympathetically (taking into account each
454 other's settings) could somehow improve bimodal outcomes over fitting the two devices
455 independently. A majority (79%) also rated a recently-refit contralateral HA as more
456 beneficial than one that has not been recently re-fit. However, 84% of centres
457 acknowledged that wearing a contralateral HA that was fit prior to receiving the CI may be
458 sufficient to provide some bimodal benefits. Thus, the responses imply that the use of a
459 contralateral HA, and not necessarily one that has been recently optimised, is better than
460 not using a HA at all.

461

462 *(d) Further guidance*

463 Respondents from 18 centres completed this section. Every centre indicated that they
464 would welcome guidance on: (1) how to maximise bimodal benefit; (2) how to optimise
465 bimodal fitting; (3) which patients would be most likely to benefit from a contralateral HA
466 fitting; (4) measuring bimodal benefit; and (5) how to advise patients about being a bimodal
467 listener. A majority of respondents (83%) were unsure as to the best time to reintroduce a

HA following CI activation, presumably attributable to concerns about CI acclimatisation discussed previously.

Interim summary

Respondents indicated that it may be in the best interests of the patient to have both devices managed by a single centre but acknowledged the practical limitations of this model. The general view that the optimisation of HA fittings following implantation is within the role of the CI audiologist appeared to suggest that what respondents reported as being their current practice is not always able to reflect what they believe to be optimal for the patient. Bimodal aiding was viewed as potentially more advantageous to the patient than wearing the CI alone, and sympathetic bimodal fitting was also viewed more favourably than devices that had not been sympathetically fit. Bimodal outcome measurements appear to be considered clinically useful, although it is unclear if and how these measurements inform HA optimisation. Respondents acknowledged that further guidance on aspects of bimodal fitting is required to implement changes in routine fitting practice.

Discussion

A survey of CI audiologists across the UK characterised their reported clinical practice around bimodal aiding, identified factors that may be limiting the provision of bimodal aiding, ascertained their views on bimodal aiding, and demonstrated consistencies and inconsistencies in practice across the UK.

Changing candidacy landscape

Until relatively recently, few individuals with useful residual hearing in the contralateral ear received a CI in the UK. A large-scale UK study that collated outcomes from adults implanted between 1998 and 2000 demonstrated that most were unable to derive benefit from acoustic amplification pre-operatively (UKCISG, 2004a). Even candidates who had some measurable speech understanding using HAs ('marginal HA users') were receiving only minimal benefit from amplification in their better ear and had an average open-set speech discrimination score of only 13%. Respondents to the current survey estimated that approximately half of those implanted within the last five years will continue to wear a HA even after their CI is activated, suggesting that contemporary CI recipients may receive additional benefits from contralateral acoustic amplification. This estimate is compatible with the results of a recent survey of CI users, which found that 48% of respondents who had been implanted in the UK in the five years between 2010-2015 reported using a contralateral HA (Fielden et al., 2016a). It would therefore appear as if there has been an increase in the number of CI candidates who have aidable residual hearing since both the last UK-wide outcomes study and the publication of NICE guidance (NICE, 2009).

One impact of this change in who is receiving cochlear implants in the UK is that a large proportion of recipients may no longer be monaural listeners whose outcomes are determined solely by a single implanted ear as was previously the case, but rather binaural listeners who may derive benefits from the combination of the CI and the HA. In these patients, CI audiologists have had to shift their focus away from considering an outcome solely in terms of a patient's capacity to use their CI and towards an outcome based on

binaural listening. However, this apparent change in practice has occurred in the absence of any guidance or training and is therefore likely to be based predominantly upon clinical experience. The disconnect apparent in the survey between the role of audiologists working in CI centres today and the evidence available to them with which to inform their practice may explain why the current provision of bimodal aiding appears to be inconsistent and at odds with the views of those who deliver it.

Estimates of sustained bimodal usage

While audiologists in the survey estimated that approximately half of those implanted within the last five years will wear a HA at activation, they also estimated that less than half of these patients will continue to wear their HA once they have used their implant for a further five years. This estimate of the proportion of longer-term bimodal users contrasts with previous estimates that have assumed a constant proportion of around 70% of implant recipients (Bond et al., 2009). The reasons for the estimated drop in the number of bimodal users over time are unclear, but at least five plausible explanations are apparent. First, the bimodal benefit perceived by the patient may lessen as they become more proficient at listening using the CI. Second, the amount of residual hearing may be so marginal that the natural progression of the hearing loss over time may reduce HA benefit leading to eventual non-use, perhaps because the better-hearing ear was selected for implantation. Third, the independent fitting of both devices may mean that some patients struggle to integrate the electric and acoustic signals and eventually stop using the HA. Fourth, as HAs are not typically maintained by CI centres there is a lack of cohesion between hearing services, and the bimodal patient may receive conflicting advice at each service or find it impractical to

access HA maintenance services over time. Finally, it is possible that only a small proportion of UK CI users can obtain consistent and useful bimodal benefits in spite of the previous four issues, and are therefore the ones to persist with contralateral HA usage. It is impossible to know which of these, if any, could potentially contribute to poor rates of sustained HA use. More research is needed to isolate the reasons that could contribute to non-use of contralateral HAs and to provide more direct evidence for the number and nature of patients who could receive ongoing bimodal benefits.

Nature of bimodal benefit

While the majority of audiologists agreed that bimodal aiding can be beneficial and encourage patients to wear a contralateral HA, the survey highlighted some uncertainty around best practice. For example, uncertainty was evident about who could benefit from bimodal aiding, when to introduce the HA after CI activation and how to fit devices sympathetically. This uncertainty may be a result of the limited available evidence for what aspects of hearing status determine the degree of bimodal benefit available to the patient. A systematic review of the effectiveness for cochlear implantation as a treatment for severe-profound deafness found that studies comparing bimodal aiding with unilateral CI or bilateral CI were poor in quality and low in number (Bond et al., 2009). To date, there is a lack of agreement in the literature as to what aspects of the HA signal delivery contribute to bimodal benefit with the possibilities including access to low frequency acoustic cues (Zhang et al., 2010), spectral modulation detection (Zhang et al., 2013), or how effectively the modalities integrate (Yoon et al., 2015). Notably, these and other studies that have demonstrated bimodal benefit have been conducted almost exclusively on patients

implanted outside the UK who have greater levels of residual hearing in the non-implanted ear than are typically accessible to UK patients. Therefore, further research on UK patients is needed to ascertain whether similar benefits are possible given the current candidacy criteria. However, even if the benefits can be realised there appears to be both a lack of consistency for how to identify who may benefit from bimodal aiding and how to optimise bimodal devices to maximise benefit.

Influence on the choice of ear to implant

Responses to the present survey suggest that audiologists are considering the potential benefits from preserving patients' access to residual acoustic hearing when recommending which ear to implant in at least some patients. Compatibly, a recent hypothetical decision-choice experiment suggested that clinicians may not always advise implanting the 'optimal' ear for CI outcomes in order to preserve residual hearing where possible (Fielden et al., 2016b). Given that little would be gained if residual hearing was preserved by recommending a physiologically-unresponsive ear for implantation, their willingness to consider residual hearing may suggest that centres are now seeing more patients in whom both ears are receptive to implantation; i.e. are likely to improve performance if implanted. The results may therefore suggest that audiologists are now able to be increasingly cautious about risking the loss of residual hearing in patients where the choice of ear is not strongly influenced by other factors. However, it remains unclear to what extent factors relating to residual hearing inform decision making around which ear to implant, how frequently, and in what proportion of patients. As the present results suggest that audiologists' practice remains focused on maximising outcome using the CI alone, it is likely that the choice of ear

582 is still influenced primarily by factors such as the physiological responsiveness and duration
583 of deafness of each ear, which can be used to estimate the likelihood that implanting a
584 particular ear will improve performance compared to the best-aided condition using HAs
585 alone (UKCISG, 2004b).

586

587 *Commissioning arrangements*

588 The disconnect between the apparent willingness of the respondents to encourage bimodal
589 aiding and the fact that services related to bimodal aiding are reportedly rarely provided
590 may be attributable, at least in part, to the manner in which implantation services are
591 commissioned in the UK. The guidance from NICE which informs current commissioning
592 arrangements was based on an assessment of the effectiveness and cost-effectiveness of
593 cochlear implantation in the UK that compared acoustic hearing aids to the provision of
594 either unilateral implantation or bilateral implantation (Bond et al., 2009). While the
595 economic evaluation did account for the fact that a subset of patients continue to use a HA
596 following cochlear implantation and therefore incur additional costs to the health service,
597 the evaluation did not assume any incremental benefit arising from the provision of a well-
598 fit acoustic hearing aid in the non-implanted ear. The decision to not account for any
599 bimodal benefit was based primarily on the lack of robust evidence for the impact that
600 bimodal aiding has on the overall health and well-being of patients. In the absence of such
601 evidence in UK patients and therefore evidence for the cost-effectiveness of bimodal aiding,
602 it is unlikely that funding arrangements will change to include maintenance provision of two
603 devices in those patients who may benefit from their use.

Practical considerations

The survey highlighted practical problems that would arise if a single service were to maintain both devices with respondents identifying issues related to staff time and funding as potential limiting factors. While an integrated model of service provision would likely provide a smoother service for the patient, create a more cohesive care pathway, and facilitate the sympathetic optimisation of the two devices, it may also be less convenient for the patient who may have to travel many miles to reach their nearest CI centre for minor adjustments to the HA or to obtain replacement parts. A more practical arrangement could be for the CI centre to take responsibility only for the fitting and reprogramming of HAs, while routine maintenance and spare parts continued to be provided by local audiology departments. A more radical approach would be for certain aspects of CI care to be undertaken by local audiology departments, perhaps with remote assistance from the CI centre. However, this approach would currently not meet the standard for quality of care as specified in the BCIG quality standards report (NICE 2007). This option would therefore require considerable investment to ensure that remote standards of care were achieved. Another option that is already being explored by CI centres nationally is the adoption of outreach clinics, which could be extended to support bimodal fittings.

Given the increasing numbers of CI users requiring ongoing maintenance and the numbers of patients who could now be aided bimodally, changes to the current model of service provision would appear to be inevitable. Audiologists generally appear to be willing to

consider changes in their practice to enhance the provision of bimodal aiding, but the lack of evidence with which to inform their practice and practical issues related to time and funding severely limit the nature and scope of any changes that could be made at the present time.

Recommendations for future research

This survey has demonstrated that UK audiologists are willing to consider changing their practice relating to bimodal aiding but have identified a need for guidance on best practice regarding: (a) the fitting and evaluation of HAs during candidacy assessment; (b) identifying who is likely to benefit from bimodal aiding; (c) providing advice on HA use at CI switch-on; (d) optimising bimodal aiding (including sympathetic bimodal fitting); and (e) using bimodal outcome measurement to both inform fitting and monitor changes in performance. The creation of guidance on these topics is currently hindered by a lack of evidence for the size and nature of bimodal benefits that are available to UK CI users and evidence for whether the methodologies that have been proposed for optimising the fitting of bimodal devices are applicable to clinical practice in the UK.

At the very least, the development of new guidance would require: (a) an up-to-date systematic review of the evidence for the effectiveness of bimodal aiding that includes patients with limited residual hearing similar to that of UK patients; (b) evidence that the provision of bimodal aiding is a cost-effective use of limited NHS resources; (c) evidence that existing bimodal fitting and assessment methods are appropriate for use UK patients; and (d) a consensus among clinicians on those aspects of bimodal fitting that are feasible to

implement and of benefit to patients. While the current survey has identified some aspects of practice and views that appear to be held consistently across UK CI centres, any consensus exercise to inform guidance would ideally be formed using an established methodology such as a Delphi process (Dalkey, 1969) and involve the broad range of healthcare professionals that deliver the current care pathway. Further research should also engage with UK CI recipients whose experience can contribute to a better understanding of the benefits and disadvantages of bimodal aiding, and why patients choose to use or not to use a contralateral HA.

Ultimately, an evaluation of the benefits that bimodal aiding provides to UK patients should be based on well-designed clinical controlled trials. It is only when such robust evidence is available that current clinical commissioning arrangements are likely to be amended to both recommend and fund bimodal aiding in the UK.

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Figure Captions

Figure 1. Categories of bimodal advantages reported by respondents from direct observation of patients. Error bars plot 95% confidence intervals. A proportion whose right error bar is entirely to the left of the 50% line demonstrates an observation that was observed only by a minority of respondents, whereas a proportion whose left error bar is entirely to the right of the 50% line represents the majority of respondents.

Figure 2. Categories of bimodal disadvantages reported by respondents from direct observation of patients. Error bars plot 95% confidence intervals. A proportion whose right error bar is entirely to the left of the 50% line demonstrates an observation that was observed only by a minority of respondents, whereas a proportion whose left error bar is entirely to the right of the 50% line represents the majority of respondents.

Figure 3. Outcome measures reported as being clinically useful in demonstrating benefit in bimodal listeners. Error bars plot 95% confidence intervals. A proportion whose right error bar is entirely to the left of the 50% line demonstrates an observation that was observed only by a minority of respondents, whereas a proportion whose left error bar is entirely to the right of the 50% line represents the majority of respondents.

Table captions

TABLE 1. A list of the UK adult cochlear implant centres which contributed to the survey dataset and the numbers of respondents from each. The 19 participating centres represents a response rate of 95%. The UK centre not listed either did not participate in the survey or did not complete the survey to the point where the centre name was requested.

TABLE 2. Mean responses to questions about current clinical practice in the UK relating to HA management. The number of CI centres from which positive responses were received to each question is reported together with the percentage and its 95% confidence interval. The table also lists the number of respondents who responded positively, also expressed as a percentage with 95% confidence intervals. The use of bold type indicates that a result represented a significant minority (<50%) or majority (>50%) of CI centres and/or respondents.

TABLE 3. Mean responses to questions about current clinical practice in the UK relating to bimodal fitting, outcome measurement, and advice. The number of CI centres from which positive responses were received to each question is reported together with the percentage and its 95% confidence interval. The table also lists the number of respondents who responded positively, also expressed as a percentage with 95% confidence intervals. The use of bold type indicates that a result represented a significant minority (<50%) or majority (>50%) of CI centres and/or respondents.

TABLE 4. A summary of clinical practice at different stages of the temporal clinical care pathway. A tick represents practice that is routine, i.e. conducted by a majority of respondents and centres; a cross represents practice that is not routine, i.e. conducted only by a minority of respondents and centres, and a question mark represents inconsistency in practice across respondents and centres. The table numbers that contain these data are shown in brackets.

TABLE 5. Mean responses to questions about factors that limit clinical practice in the UK relating to bimodal aiding. The number of CI centres from which positive responses were received to each question is reported together with the percentage and its 95% confidence interval. The table also lists the number of respondents who responded positively, also expressed as a percentage with 95% confidence intervals. The use of bold type indicates that a result represented a significant minority (<50%) or majority (>50%) of CI centres and/or respondents.

TABLE 6. Mean responses to questions about audiologists' views of bimodal aiding. The number of CI centres from which positive responses were received to each question is reported together with the percentage and its 95% confidence interval. The table also lists the number of respondents who responded positively, also expressed as a percentage with 95% confidence intervals. The use of bold type indicates that a result represented a significant minority (<50%) or majority (>50%) of CI centres and/or respondents.

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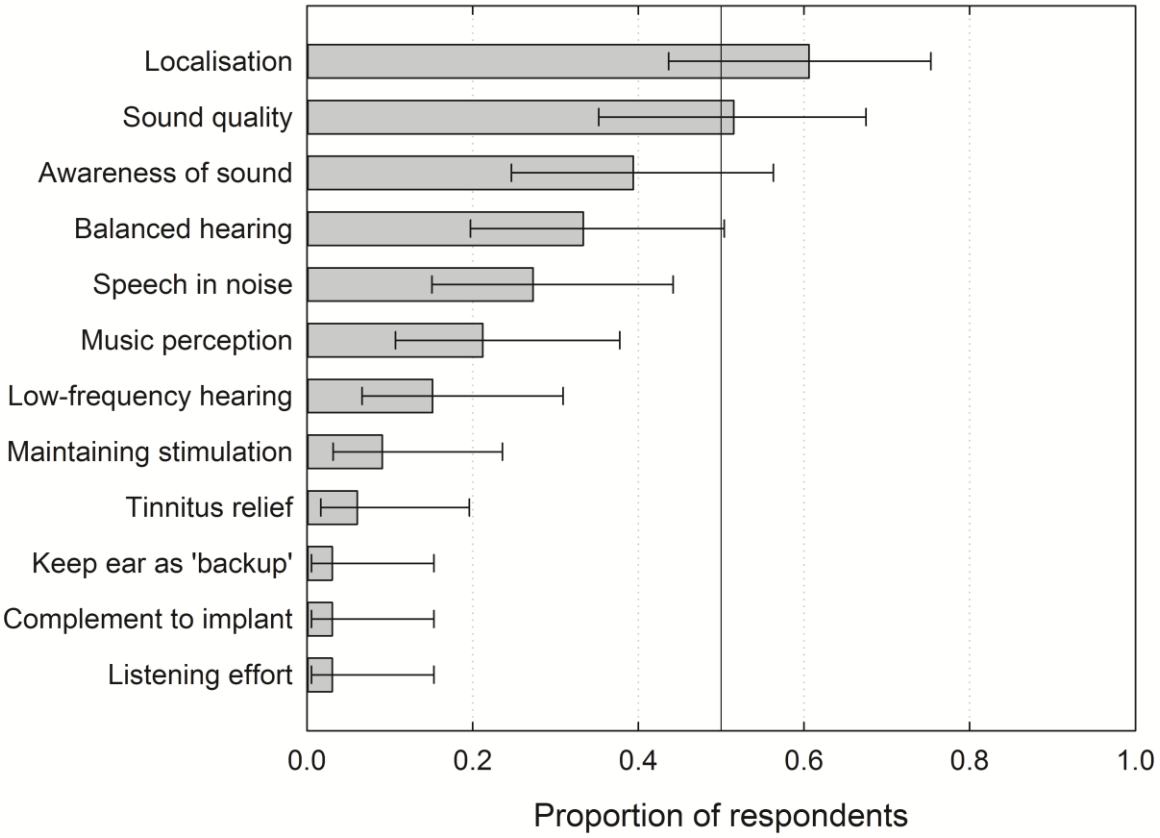
Localisation
Sound quality
Awareness of sound
Balanced hearing
Speech in noise
Music perception
Low-frequency hearing
Maintaining stimulation
Tinnitus relief
Keep ear as 'backup'
Complement to implant
Listening effort
0.0
0.2
0.4
0.6
0.8
1.0
Proportion of respondents

Figure 1

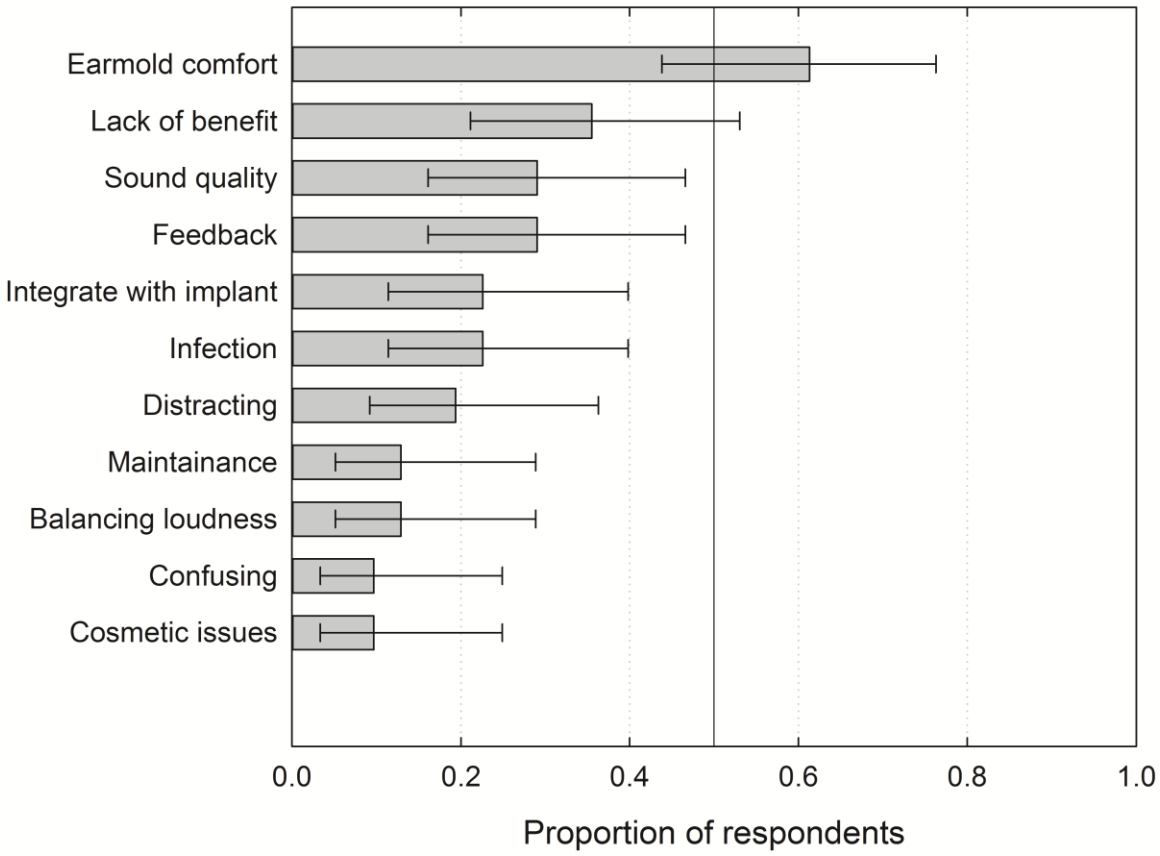
Earmold comfort
Lack of benefit
Sound quality
Feedback
Integrate with implant
Infection
Distracting
Maintainance
Balancing loudness
Confusing
Cosmetic issues
0.0
0.2
0.4
0.6
0.8
1.0
Proportion of respondents

Figure 2

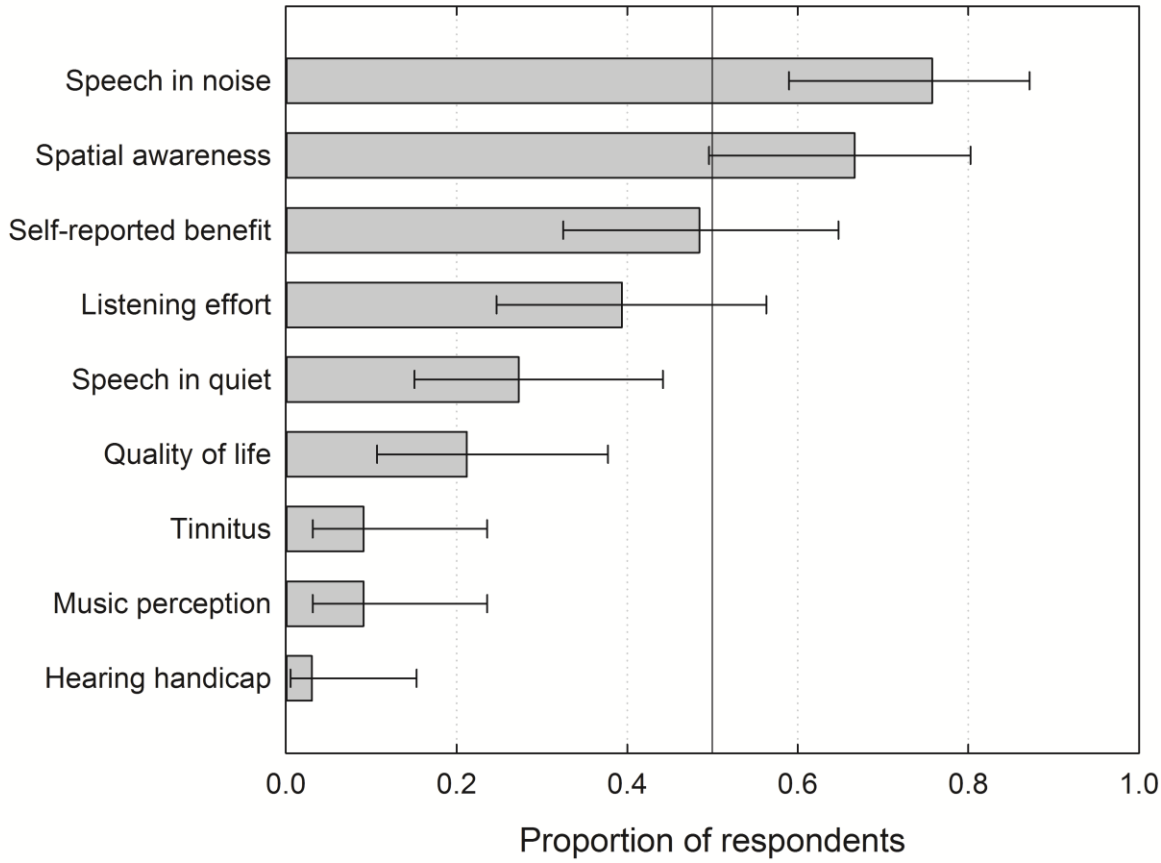
Speech in noise
Spatial awareness
Self-reported benefit
Listening effort
Speech in quiet
Quality of life
Tinnitus
Music perception
Hearing handicap
0.0
0.2
0.4
0.6
0.8
1.0
Proportion of respondents

Figure 3

Participating Centres	Number of responses
Belfast Cochlear Implant Centre	1
Cardiff Adult Cochlear Implant Programme	1
Dublin Cochlear Implant Programme	1
Emmeline Centre, Cambridge	1
The Richard Ramsden Centre for Hearing Implants (Manchester)	3
The Midlands Hearing Implant Programme (Adults' Service)	3
North Wales Cochlear Implant Programme	1
Nottingham Auditory Implant Programme	3
The Oxford Cochlear Implant Programme	1
Portland Hospital Cochlear Implant Programme	1
RNTNE Adult Implant Programme	1
Scottish Cochlear Implant Programme	2
South Wales Cochlear Implant Programme, Bridgend	1
St George's Hospital Auditory Implant Service	1
St Thomas' Hospital Hearing Implant Centre	1
University of Southampton Auditory Implant Service	7
West of England Hearing Implant Programme	2
Yorkshire Auditory Implant Service (Bradford)	1
Yorkshire Auditory Implant Service (Sheffield)	1
Total number of completed responses (with identifiable affiliation)	**33**
Total number of incomplete responses (without identifiable affiliation)	5
Total number of responses	**38**

	No. centres (%; 95% CI)	No. respondents (%; 95% CI)
HA management during candidacy assessment (Section 1a)		
Numbers who…		
conduct HA evaluations as part of the candidacy assessment	**18** (**95**; 75-99)	**28** (**74**; 58-85)
routinely check HA fittings in patients attending for assessment	**14** (**78**; 55-91)	**21** (**75**; 57-87)
check HA fittings in *every* HA user during assessment	11 (61; 39-80)	16 (57; 39-73)
routinely attempt a HA fitting in a candidate with no HAs	**15** (**83**; 61-94)	**24** (**86**; 69-94)
routinely attempt to fit a HA to a single non-aided ear	11 (61; 39-80)	14 (50; 33-67)
use a combination of HA evaluation methods	**17** (**94**; 74-99)	**23** (**82**; 64-92)
HA management following implantation (Section 1b)		
Numbers who…		
routinely take responsibility for the contralateral HA	**5** (**26**; 12-49)	**6** (**18**; 9-34)
would refer to a different audiologist for HA issues	**15** (**79**; 57-91)	**27** (**82**; 66-91)
evaluate the contralateral HA during the first 12m of CI use	8 (42; 23-64)	10 (30; 17-47)
attempt to re-fit a HA the patient had stopped wearing	**6** (**32**; 15-54)	**6** (**18**; 9-34)
routinely attempt a HA fitting in an unaided contralateral ear	**0** (**0**; 0-17)	**0** (**0**; 0-10)
only fit a HA to an unaided contralateral ear at patient request	9 (47; 27-68)	**10** (**30**; 17-47)
routinely review the HA fitting after 12m of CI use	**3** (**16**; 6-38)	**3** (**9**; 3-24)
use the same combination of HA evaluation methods as pre-CI	9 (47; 27-68)	10 (33; 19-51)

	No. centres (%; 95%CI)	No. respondents (%; 95%CI)
Sympathetic bimodal fitting (Section 1c)		
At initial activation: Numbers who…		
follow an agreed bimodal switch-on protocol	**1** (**5**; 1-25)	**1** (**3**; 1-15)
take HA parameters into account when programming the CI	**4** (**21**; 9-43)	**4** (**12**; 5-27)
match fitting parameters e.g. frequency ranges of HA and CI	**0** (**0**; 0-17)	**0** (**0**; 0-10)
balance the CI and HA for loudness	11 (58; 36-77)	12 (36; 22-53)
At subsequent review appointments: *Numbers who…*		
follow an agreed bimodal programming protocol	**1** (**5**; 1-25)	**2** (**6**; 2-20)
take HA parameters into account when programming the CI	**3** (**16**; 6-38)	**3** (**9**; 3-24)
match fitting parameters e.g. frequency ranges of HA and CI	**2** (**11**; 3-31)	**3** (**9**; 3-24)
balance the CI and HA for loudness	**15** (**79**; 57-91)	18 (55; 38-70)
Post-implant bimodal outcome measurement (Section 1d)		
Numbers who…		
follow an agreed protocol for measuring bimodal benefit	7 (37; 19-59)	**8** (**24**; 13-41)
routinely measure CI-only listening outcomes	**18** (**95**; 75-99)	**27** (**82**; 66-91)
routinely measure bimodal listening outcomes	12 (63; 41-81)	17 (52; 35-67)
routinely measure HA-only listening outcomes	**5** (**26**; 12-49)	**5** (**15**; 7-31)
choose specific outcome measures to measure bimodal benefit	4 (33; 14-61)	**4** (**24**; 10-47)
Advice given to patients (Section 1e)		
At initial activation: *Numbers who…*		
recommend intermittent use of the HA at first	13 (68; 46-85)	19 (58; 41-73)
recommend not wearing the HA until 3 months post-CI	**4** (**21**; 9-43)	**5** (**15**; 7-31)
recommend both devices be worn together from the start	**3** (**16**; 6-38)	**5** (**15**; 7-31)
leave it to the patient to decide if bimodal aiding is beneficial	**4** (**21**; 9-43)	**4** (**12**; 5-27)
At subsequent review appointments: *Numbers who…*		
actively encourage established CI users to wear a HA	**18** (**95**; 75-99)	**31** (**94**; 80-98)

Practice	Pre-implant	Initial activation	Post-implant
Hearing aid management	✓ (2)	✗ (2)	✗ (2)
Sympathetic bimodal fitting	--	✗ (3)	✗ (3)
Advice to patients on bimodal aiding	--	? (3)	✓ (3)
Bimodal outcome measurement	--	--	? (3)

	No. centres (%; 95%CI)	No. respondents (%; 95%CI)
HA management (Section 2a)		
During candidacy assessment. *Numbers who indicated…*		
a lack of staff expertise in HA fitting	8 (42; 23-64)	18 (50; 34-66)
a lack of time	**3** (**16**; 6-38)	**4** (**11**; 4-25)
a lack of available audiologists	6 (32; 15-54)	**8** (**22**; 12-38)
a lack of rooms/equipment	**5** (**26**; 12-49)	**9** (**25**; 14-41)
patients have insufficient residual hearing	**1** (**5**; 1-25)	**1** (**3**; 0-14)
During initial activation. *Numbers who indicated…*		
a lack of time	13 (68; 46-85)	17 (52; 35-67)
a lack of equipment	**5** (**26**; 12-49)	**10** (**30**; 10-47)
During subsequent reviews. *Numbers who indicated…*		
a lack of time	11 (58; 36-77)	15 (45; 30-62)
a lack of rooms/equipment	7 (37; 19-59)	11 (33; 20-50)
a lack of staff expertise in HA fitting	**5** (**26**; 12-49)	14 (42; 27-59)
a lack of available audiologists	9 (47; 27-68)	18 (55; 38-70)
Bimodal outcome measurement (Section 2b)		
Numbers who indicated…		
a lack of time	9 (47; 27-68)	12 (36; 22-53)
a lack of staff expertise	**4** (**21**; 9-43)	**5** (**15**; 7-31)
a lack of equipment	6 (32; 15-54)	**6** (**18**; 9-34)
Sympathetic bimodal fitting (Section 2c)		
Numbers who indicated…		
a lack of time to fit both devices in the same session	11 (58; 36-77)	17 (52; 35-67)
a lack of guidelines on optimising bimodal fittings	12 (63; 41-81)	18 (55; 38-70)

	No. centres (%; 95%CI)	No. respondents (%; 95%CI)
HA management (Section 3a)		
During candidacy assessment. *Numbers who indicated…*		
it is the role of the CI audiologist to evaluate HAs	**13** (**68**; 46-85)	15 (42; 27-58)
it is beneficial to optimise HAs	**18** (**95**; 75-99)	**33** (**92**; 78-97)
During subsequent reviews. *Numbers who indicated…*		
it is the role of the CI audiologist to evaluate contralateral HAs	**15** (**79**; 51-88)	20 (61; 50-80)
it is beneficial to optimise the contralateral HA	**18** (**95**; 75-99)	**30** (**91**; 76-97)
Bimodal benefit (section 3b)		
Numbers who indicated…		
Consideration of bimodal aiding when choosing the CI ear	**16** (**84**; 62-94)	21 (64; 47-48)
bimodal aiding is more beneficial than CI-alone	**16** (**84**; 62-94)	**28** (**85**; 69-93)
it is clinically useful to measure bimodal benefit	**18** (**95**; 75-99)	**30** (**91**; 76-97)
Sympathetic bimodal fitting (Section 3c)		
Numbers who indicated…		
sympathetic device fitting could improve outcomes	**16** (**84**; 62-94)	**27** (**82**; 66-91)
a recently re-fit HA is more beneficial than an older fitting	**15** (**79**; 57-91)	**26** (**79**; 62-89)
wearing a previously-fit HA can still provide bimodal benefits	**16** (**84**; 62-94)	**26** (**79**; 62-89)
Further guidance (section 3d)		
Numbers who indicated a need for guidance on…		
maximising bimodal benefit	**18** (**100**; 82-100)	**31** (**97**; 85-99)
optimising bimodal fitting	**16** (**89**; 67-97)	**29** (**91**; 76-97)
identifying bimodal candidates	**14** (**78**; 55-91)	**23** (**72**; 55-84)
measuring bimodal benefit	**16** (**89**; 67-97)	**28** (**88**; 72-95)
when to reintroduce the HA post-CI	**15** (**83**; 61-94)	**26** (**81**; 65-91)
how to advise patients on bimodal listening	**16** (**89**; 67-97)	**27** (**84**; 68-93)