THE EFFECTIVENESS AND COST-EFFECTIVENESS OF COCHLEAR IMPLANTS FOR SEVERE TO PROFOUND DEAFNESS IN CHILDREN AND ADULTS: A SYSTEMATIC REVIEW AND ECONOMIC MODEL

Introduction
The British Cochlear Implant Group (BCIG) is a professional body that represents all the different professional groups working in cochlear implant centres across the UK, including experts and scientists involved in research into implants and other professionals with an interest in cochlear implantation. This report has been prepared on behalf of the BCIG.

The Assessment Report is a comprehensive, detailed, thorough and well written document. The published literature on cochlear implants has clearly been well researched although it is disappointing to find that so many of the published papers initially identified were found to be of poor quality and hence not considered in the review. This is clearly an issue that needs to be addressed by implant professionals researching in this field.

The comments and conclusions of the authors seem fair; however the BCIG would like to make the following comments:

P2 "The evaluation...left 33 papers in the clinical effectiveness review." Of the 1,580 papers identified from the search only 33 were found to have usable information for the purposes of this report. Whilst it is accepted that there were valid reasons for the exclusion of such a high percentage of studies, many were rejected due to the small subject number. In a “High Cost Low Volume” treatment area such as this, it is very hard for centres to recruit large numbers of patients to research studies. Moreover the lack of Randomised Controlled Trials (RCTs) was criticised; however it would be unethical for NHS centres to withhold a
treatment known to give benefit from the control group. This makes it difficult for clinical centres to run RCTs in practice.

P28 “Further electrophysiological tests provide evidence of the candidates’ neurological condition.”

Electrophysiological tests are objective measures of the hearing pathway, from the VIIIth nerve to the brainstem or longer latency responses from the auditory cortex. They are specific to the auditory pathway and do not give evidence of the neurological condition in general.

P37 “…speech and motion processor (SMP)…”

This is not a term used in this field. To my knowledge there is neither SMP strategy nor a speech and motion processor. The term was not referenced so I am unable to find the source.

P39 Due to the exclusion of over 90% of the potential studies, only two of the possible eleven cochlear implant devices currently on the NHS contract were included in the studies: The Nucleus Freedom and the Nucleus double array, a specialist implant used in rare clinical cases of cochlea abnormality or ossification. Nine other devices on the NHS contract were not in the included studies including the two latest systems from the other leading manufactures (Advanced Bionics and Med-El). Exclusion of studies relating to these implant systems may have biased the evidence.

P67 “Measures of sensitivity to sound provide the strongest evidence to support the use of cochlear implants. Clear gains were made from 6 months post activation onwards, with PTA thresholds ranging from 32 to 44 dB HL post implantation.”

Clinically these measures are relatively unimportant, post-implantation. Soundfield thresholds are determined by the input dynamic range of the system and can be manipulated by adjustments in the processor controls or programming levels. It does not follow that improvement in soundfield thresholds are related to improvements in performance. Indeed if soundfield thresholds are set too low (i.e. better) this can be as detrimental to performance as very high (i.e. poor) thresholds.

P140 Bilateral cochlear implants vs. unilateral cochlear implants - adults

The three UK-based studies by Summerfield et al, Ramsden et al, and Verschuur et al, had an overlap of many of the same participants. Selection criteria for the Summerfield et al. and Ramsden et al. studies was that participants had reached a reasonable level of performance
with their first implant. Whilst significant binaural benefits were demonstrated in the Ramsden study, results were affected by the fact that performance with the first implanted ear was nearly always better than that with the second. This factor persisted throughout the duration of the study and could have diminished the measured binaural benefit. However, long term follow-up of some of the study participants has taken place in Birmingham and although unpublished, has shown that the second implanted ear does “catch up” with the first, but that this may take several years in sequentially implanted adults who were already good users of their first device. The long-term follow-up over several years after the second implant demonstrated greater binaural benefits for patients than reported in the Ramsden paper, although in a smaller group.

These studies were based on existing good users of a unilateral device who had no other co-morbidity e.g. additional handicap and who had used their first implant for at least 9 months. This group may not represent the population most likely to benefit from having a second implant sequentially after the first. Greater benefits may be observed for example in patients who demonstrate poor or deteriorating performance with the first device or who have additional disabilities.

**P204** "In a UK based multi-centre study by Verschuur and colleagues 150 of 20 individuals who underwent sequential implantation, the mean delay between the two operations was 35 months. The interval used in the model is therefore 3 years."

An interval of three years between first and second implants in sequentially implanted patients has been assumed. This figure was based on mean values identified in the study by Verschuur et al. It should be noted that the inclusion criteria for subjects participating in that study was that they had had their first implant for at least nine months, in order to have reached a plateau in performance with the first device. This patient group, therefore, may not be representative of the clinical population of sequentially bilaterally implanted patients. Research does suggest that the second ear should be implanted within twelve months to provide maximum binaural benefit (Kuhn-Inacker et al, 2004)

**P211** Speech processor upgrades "...are assumed to take place every ten years..."

Most UK programmes endeavour to upgrade the external speech processor every 4-5 years.

**P264** "...at a willingness to pay threshold of £30,000/QALY for simultaneous..."
bilateral implant to become cost-effective a discount of approximately 75% on the cost of the second implant system is required.”
Since it is shown that the clinical benefit of bilateral implants exceeds that of unilateral implantation, clearly the onus is now on manufacturers to consider significant cost reduction of implant systems in order to achieve cost-effectiveness. However consideration has not been given to the fact that a cost saving may be made on auditory rehabilitation of these patients, as both “ears” can be rehabilitated in the same session. Twice the number of rehabilitation appointments would not be required and this would represent a cost saving.

P280 “...changes towards service provision from a larger number of more general audiology departments...”
This is not generally accepted as being a desirable model of patient care. Quality of service provision is dependent on the highly specialist skills, required throughout the multi-disciplinary team, developing through experience of large numbers of implanted patients. Devolution of care to local audiology departments would have enormous implications for training and resources. Provision of parity of care throughout the UK would be difficult to maintain across large numbers of centres, many of which may manage potentially small numbers of implant patients. This model is actively discouraged by the BCIG in favour of the expansion of existing specialist centres or a move towards a hub-and-spoke model of care.

P283 “The purpose of this report is to assess the effectiveness and cost-effectiveness of cochlear implants for children and adults with severe to profound deafness.”
This statement, and indeed the title of the report, refers to severe to profound deafness. However other terminology relating to severity of deafness is used throughout the report and this is inconsistent:

- P285: “profoundly deaf adults and profoundly deaf children.”
  “...profoundly or severely deaf people....”
- P295: “We have only modelled the profoundly deaf (AHL >95)”. Also the statement that follows that effectiveness data relates to patients with higher levels of profound deafness (AHL >110) is not very meaningful from a clinical perspective. From an audiological point of view they are both profoundly deaf (you cannot be “very” profoundly deaf) and would be managed in the same way.
- P298: the concluding paragraph 13.1 refers to the “profoundly deaf” and not to the severe to profoundly deaf. This could potentially restrict the scope of the Assessment Report.
P292 “Our utility estimates were chosen on the basis of a systematic review of all empirical studies reporting the health-related quality of life impacts, or elicited utility values of being severely or profoundly deaf, or receiving a cochlear implant.”

The following statement then appears on P294:

“Due primarily to the lack of valid and reliable utility estimates, we were unable to assess the cost-effectiveness of unilateral implantation in several potentially important subgroups of deaf people:

- in severely deaf adults or children”

These two statements appear to be contradictory.

P296: “There is a paucity of high quality long term outcome data...”

This refers to the lack of long term outcome data, particularly regarding device failure rates for recent models. If a device has only been in clinical use for a short time, it is not possible to measure long-term results. Cochlear implants have only been in wider clinical use for the past 15 years and so unsurprisingly there is no data beyond this time frame.

P297: The idea of a national research registry is a good one and will be addressed by the BCIG.

**Conclusions**

The conclusions of the Assessment Report appear to be fair and positive in general about the clinical benefits of cochlear implants and in the cost effectiveness of unilateral implantation in adults and children. Cost-effectiveness has not yet been firmly established in bilateral implantation of adults and children, although this may be achievable with simultaneous bilateral implantation. This is largely due to the device costs involved in two systems, where manufacturers discounts are not yet sufficient to bring costs down to an acceptable level. Moreover the report also highlights the lack of high quality research, particularly with regard to bilateral implantation in children. It is hoped that this aspect of implantation will be reviewed again once further research has been undertaken.

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References:

