SPONSORED VISIT TO THE NATIONAL PAEDIATRIC BILATERAL COCHLEAR IMPLANT AUDIT

UNIVERSITY OF SOUTHAMPTON AUDITORY IMPLANT SERVICE
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www.southampton.ac.uk/ais

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1. BACK-GROUND TO THE AUDIT: PROFESSOR GERRY O’DONAGHUE
(PROFESSOR OF OTOLOGY NOTTINGHAM)

The conference was opened by Professor Gerry O’Donaghue who contextualised the audit in reference to the NICE (National Institute on Clinical Excellence) guidelines following their recommendations of 2009 supporting the provision of two simultaneous cochlear implants to profoundly deaf children who fail to show sufficient audiological gains following a trial of three months of hearing aids.

Advances in technology need to be placed in context of the evidence to support their use and based on an infrastructure that provides timely early identification, assessment, and an early intervention service involving families, the education system and the myriad of health and hearing professionals who support these services.

“High quality and information give meaning to every thing we do in medicine” (Muir Gray 2007).

The NICE guidelines of 2009 stipulated that quality of life measures should be collected and that this would be reviewed in 2012 in order to provide ongoing policy based on good evidence.

This was strictly an audit although there is a close relationship between audit and research and further questions have arisen as result of this audit.

The National Biomedical Unit in Hearing were not in a position to do the audit so Southampton was chosen as it is one of the few Implant Centres based within an academic setting (University of Southampton).

Professor Gerry O’Donaghue was fortunate enough to be able to secure funding for the research through HQIP (The Heath Quality Improvement Partnership) The grant they supplied enabled the research to be completed and funded the salaries of the staff who worked on it part time over the three years. There was no commercial sponsorship.
The Domains of the audit included:

- Surgical safety
- Sound localisation
- Speech Perception and Production
- Speech in Noise
- Language
- Parental Perception
- Quality of Life

This was a collaborative Multi-Centre Audit whose brief was:

- Provide gold standard highest quality of evidence (Bandolier level 1)
- Disseminate the research
- Report back to NICE
- Reassure the Health Commissioners
- Advise families and the public that this is an appropriate use of taxpayers Vote Health
- Involve Multi-Centre-Localities

2. BILATERAL RESTORATION OF HEARING

Professor Anje Aschendorff: (Otolaryngologist Germany: University of Freiburg)

(a) Unilateral hearing loss (Single Sided Deafness)

The incidence of SSD had been unclear until the introduction of the Newborn Screening programme in Germany. Until NHS many of these children were undiagnosed as they still managed to function in a main-stream school and were mostly able to produce normal speech.

She spoke at some length about the aetiologies of SSD

She produced some research indicating that that up to 41% of SSD children require additional support in the classroom (Bess & Tharpe 1986) and up to 35% have to repeat a year of school (Bess & Tharpe 1986). Others have suggested that these children may have been misdiagnosed with Hyperactivity Disorders (Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder).

Further research needs to address the benefits of the treatment options for these children (ranging from no treatment, conventional hearing aids, BAHA and Cochlear Implantation) on a variety of outcomes.
Initial results appear to suggest that Cochlear Implantation may provide superior localisation and speech discrimination in all auditory conditions (following twelve months of device experience). However a caveat is that there is uncertainty of benefit with Cochlear Implantation with increasing Duration of SSD deafness prior to treatment. This outcome was even more pronounced with unaided speech understanding in noise in relation to duration of non-treatment of SSD deafness.

She indicated that health providers and hearing specialists in Germany are now more confident providing information on the benefits of Cochlear implantation for SSD to parents and families on the basis of this research.

**(b) Bilateral implantation versus binaural hearing**

Professor Ashendorrf raised the important issue of success obtaining binaural hearing in sequentially implanted children. Her presentation suggested there is a higher rate of rejection and non-use of the second implant after five years in SEQ children and additionally in teenagers (independent of the 5 years). Research indicates there is reduced benefit after 12 months interval (Gordon et al 2008). However this did not control for the method of rehabilitation of the newly implanted ear. There was some lively discussion in the audience about rehabilitation following the second implant and whether the recipient should have a daily period with only newly implanted tuned in. Some members of the audience felt it was an abuse of the child’s rights to remove the initial implant. From what I ascertained following discussion with the attendees the latter is not the usual practice in the UK. This, though, was the advice we received from our ITOD (anecdotally we have had a successful sequential implant after 5 years duration).

She reported that in Germany the majority of bilateral implants are still sequential with only 20% of implants being bilateral simultaneous (SIM). However the time delay between first and second implant has reduced. She suggests this is due to improved patient-centred counselling services to families and changes in insurance funding. Insurers in Germany have no consistent approach to funding of bilateral implants but they do have a recommendation to have the second implant within twelve months (at the moment only children with meningitis or obliterative disorders are consistently funded for the second implant).

She stressed the need for all hearing professionals to provide objective advice on treatment options to parents.

**3. PROTOCOL: UK NATIONAL PAEDIATRIC AUDIT**

*(Devyanne Bele)*

The audit consisted of 14 consortium centres over the UK and Northern Ireland and included

All children who received Bilateral CIs before age 18:
**SIM** (simultaneous): children who received both CIs on the same day

**SEQ** (sequential): children who received 2 implants at different times

Data was collected over three years from 2010 to 2012 and included 4 test intervals

This study is unique in time as the majority of children in the UK will now be **SIM** and so the comparison with the **SEQ** will eventually no longer be possible.

Initial testing of the **SEQ** Group was one CI and (+ or -) Hearing Aid whereas the **SIM** group was Hearing Aids

When interpreting the results therefore **SEQ** group have collectively a longer hearing age (*time in sound*) than the **SIM** group.

### OUTCOME MEASURES

**Three Categories**

1 **Performance Measures of the Child**
   - Sound field thresholds
   - Speech Perception
   - Localisation
   - British Picture Vocabulary Test

2 **Rating Scales**
   - Speech Intelligibility: 1 (low) - >5 (high)
   - Categories of Auditory Performance CAP 0 (low) -9 (high). This provides information about functional listening in daily life.

3 **Parental Questionnaires**
   - **Parent Outcome profile**: Explores issues important to parents
   - **Bilateral Listening Skills Profile**: Assessment of listening skills in complex environments
   - **Brief Assessment of Parental Perception**: Quality of life measures
4. SURGICAL SAFETY: Mr Stephen Broomfield: University Hospital Bristol

In summary 961 recipients were included in this study (with a total of 1397 implants) from the 14 consortium centres.

Overall major complications were 1.6 % and minor complications 6.5 %

The detailed presentation will be of interest to surgeons (available on the website www.southampton.ac.uk/ais)

Patients presenting with complications were spread evenly through the 14 consortium centres and there were no detectable differences between bilateral, simultaneous, sequential and unilateral implants. Suffice to say this is reassuring information to give to parents and guardians and important information for funders.

5. DEMOGRAPHICS

It is worth stating this that was an audit and not prospective study to address a specific research question. There children were not matched or controlled.

<table>
<thead>
<tr>
<th>10001 CHILDREN</th>
<th>465 SIM</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 Consortium centres</td>
<td>Range 6 months to 18 years at time of SIM</td>
</tr>
<tr>
<td>23 different home languages noted</td>
<td>Peak age 12 to 18 months</td>
</tr>
<tr>
<td>Included children with developmental delay and other medical conditions</td>
<td>536 SEQ</td>
</tr>
<tr>
<td></td>
<td>Range: Age first implant 12/12 to 18 years</td>
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<tr>
<td></td>
<td>Peak Age of Second CI 18 to 25 months</td>
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<td></td>
<td>Spread of 1-18 years between first and second CI</td>
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It is interesting to note that there were a quite a number of children in this audit who received bilateral implants in their mid to late teens. Some of these children may have had progressive hearing loss and may have been managing quite well with hearing aids up until implantation. There were also large numbers of children receiving their second CI after five years.
Many of the hearing specialists shared anecdotally during the pre-conference dinner that there was a current push to get unilaterally implanted children sequentially implanted prior to 18 (funded eligibility ends at 18).

This may create pressured decision making for parents and children. Over lunch I sat next to a 17 year old girl who was using BSL as her main method of communication (and had been a poor hearing aid wearer since childhood). She was facing the option of funded surgery within six months or not at all.

The audit recognises there are limitations in interpretation of the data in that children dropped in and out of the study and in the SIM group some of the children were too young to perform the test. What the audit does not address is the level of support to children and families and the habilitation methods used.

However the audit is unique in that it is a real population (not a sample) and it is providing a real assessment of what bilaterally implanted children can achieve in 2012.

6. OUTCOMES: SPEECH VOCABULARY AND FUNCTIONAL OUTCOMES (Presented by Julie Brinton)

The measures chosen were

- **CAP 11**

Both SIM and SEQ children show consistent improvement in **CAP 11** score with *time in sound* but by the three year follow-up the SIM children have overtaken the SEQ children. The mean improvement at one year in the **CAP 11** is higher in the SIM children the earlier the date of implantation.

- **SIR (Speech Intelligibility)**

SIM children had caught up with the SEQ children by three years of *time in sound* (more hearing experience) and showed higher mean improvements in the SIR Score. By three years of age the SIM children acquire mostly intelligible speech.

- **British Picture Vocabulary Test BPVS**

This is norm referenced and has been standardised on > 3000 children. By taking a score of 100 as the mean (with one Standard Deviation as 15: therefore range of 85-115 is 1 SD from the norm) SIM and SEQ children acquire ranges within 1 SD after one year of *time in sound* whereas Unilaterally Implanted children have mean scores of < 80 at three years of *time in sound*. 
It will be interesting to observe the changes over time and with increasing *time in sound* with CIs *(SEQ +SIM)*.

There was a lot of heated discussion following this talk. If scores do not increase for the Unilaterally Implanted children over further *time in sound* then obviously funders need to be aware of this as do parents of children who may be contemplating the second implant.

7. PARENT OUTCOME PROFILE QUESTIONNAIRE (Devyanne Bele)

The questionnaire was based in part on the work of Sue Archbold et al (2002) and was based on 74 questions on a variety of themes (communication, parental stress levels, sibling relationships etc) and is based on what parents value as important.

Thematic analysis suggested three major threads:

- Communication
- Education + Social Adjustment
- Family Relationships

The questionnaire addressed the *improvement in the above three* in relation to what was *attributable to the second implant alone*

**AND**

The relationship to the *improvement above* and the *age at which they received the second implant*

This part of the analysis did not address the time period between the first and second implant although one may infer that the younger the age of the child the shorter this time period.

*In summary for all three themes, children showed significant improvement with two CIs compared to one and those children who received the second CI < 5 years of age showed significant greater improvement than those children who received the second CI > 5 years of age*

However it is important to note there was wide variation in the distribution of results and this audit did not address the variables that may account for this.

There was lively discussion in the audience about those factors that may account for this wide variation in results and an acknowledgement that this is obviously an area for further scrutiny.
8. BRIEF ASSESSMENT OF PARENTAL PERCEPTION

This was presented by two clinical psychologists on behalf of the Clinical Psychologists UK special interest group looking specifically at Health - Related Quality of Life (HQRL)

Quality of life looks at those more generic quality of life issues rather than focusing on specific outcomes and has become an integral part of the assessment of emerging technologies in health.

Quality of Life issues vary across the spectrum of childhood with:

- **< 5** Focus on temperament and behaviour
- **>5 < 10** Focus on the ability to adapt to sound and preparation for surgery
- **>10** Focus on the ability to adapt to a “new physical appearance” and integration the new sound as well as the cognitive appreciation of future benefits

The aim of the BAPP (Brief Parental Perception) was to assess:

- Acceptance for second implant if **SEQ** (or **SIM** but some of the children were too young to assess )
- Assess impact on **HRQL**
- Assess Change in **HQRL** over time

Not all **SEQ** children had adapted to the second implant with ease. This audit did not study the reasons for this and it was acknowledged by the researchers and the audience that this is another area for further review. For adolescents, an emerging theme was the appearance of two visible devices on the head, and awareness that benefits may not be evident for some time.

To summarise:

- The majority of children (> 85%) wear their implants most of the time and there no significant difference between **SIM** and **SEQ**.
- The majority of children are either very of keen to wear their implants (>80%) with the **SIM** group showing more willingness than the **SEQ** at one and two years post-implant.
- Both groups show continuing improvement in **HRQL** (**SIM >SEQ**) up until the end of the study period.
• **SEQ** children have greater increases in **HRQL** if they receive their second implant < 4 years.

• As a caveat, we do not have any data beyond three years. This audit does not address the issues that adolescents may face as they mature into adult life.

• The majority of parents (**SEC +SIM**) would recommend a second implant to other parents.

• *This is a study of the parents’ perceptions of their child not the childrens’ experience of their lives. The latter would be an important but difficult question to answer.*

• *Implanted Adolescents’ perception of their lives would add perspective to this ethically difficult question of parents deciding on life altering surgery for children with a hearing impairment (in the absence of a medical “illness”).*

9. LOCALISATION AND SPEECH PERCEPTION
(Helen Cullington)

Localisation refers to the ability to decide on the direction and distance of sound. The main method for this comparison measures the signal at each ear in terms of level of sound (db) difference and the time difference between the two ears.

In order to complete this part of the research Professor Mark Lutman had to devise a sound localisation test. The localisation error = average error over 25 trials with 45 degrees taken as the baseline error.

In summary:

• Children with **SIM** localise significantly better than **unilateral** children.

• In fact the data suggests that up until 3 years of this study we cannot confidently say that **UNI** (unilateral) children localise

• Twelve months after the Second CI (**SEQ**) localisation improves: this *improvement* appears to *decrease* as the gap between the implants *increases*

• Speech perception in noise improves for the (**SEQ**) but this improvement appears to decrease as the gap between implants increases and the second ear is used less efficiently
• With increase in time of bilateral hearing children begin to use the second implant to help when noise is separated from speech

There is a wide variation of results in this audit. The rehabilitation of the second ear was not addressed in this audit.

10. BILATERAL LISTENING SKILLS PROFILE
(Devyanne Bele)

The purpose of this is to assess listening skills in adverse listening conditions.

It was developed by the Ear Foundation in Nottingham and is based on two scales which have been have been validated.

From the Analysis (factor analysis) three themes emerged

• Speech production + Understanding
• Localisation
• Quality of the Speech

Again there is a wide variation in results making prediction of benefit difficult for parents considering a sequential implant for their child.

However comparing BILAT with UNI across time in sound, the BILAT (SIM +SEQ) group perform significantly better then the UNI group.

MY CONCLUSIONS

In summary, the audit provided reassurance for funders and parents that SIM implantation is safe and effective. This information was the minimum required by NICE.

While there are wide variations in many of the outcomes the analysis of the audit gives evidence (within the audit period) of a number of superior outcomes for SIM over SEQ and BILAT over UNI but we cannot yet fully explain the reasons for this wide variation.

In the UK, UNI children less than 18 are now being offered and funded a second implant. Current information for parents suggests outcomes are unpredictable for any individual child.

Other issues that may now arise are potentially superior outcomes of children with BILAT (SIM+SEQ) over SSD. This may raise ethical questions about beneficence and justice for children with SSD who have either no treatment or unilateral aids.
Tricia Kemp who co-ordinates CICS: (Cochlear Implant Childrens’ Support Group) and (meets most of the families of newly diagnosed children) has anecdotally noted a marked reduction in both the interest in and use of Sign Language in these families over the last few years. Cochlear implantation is now being seen by these families as the logical and natural treatment option (personal correspondence).

As a result there is a risk that those implanted children whose functional outcomes are less favourable may be missing out on a valuable communication tool.

Dr. Sue Archbold (CEO of the Ear Foundation in Nottingham) has completed her PhD thesis on the topic (Deaf Education: Changed by Cochlear Implantation). I have yet to review this in depth.

In the introduction of this report I wrote:

Advances in technology need to be placed in context of the evidence to support their use and based on an infrastructure that provides timely early identification, assessment, and an early intervention service involving families, the education system and the myriad of health and hearing professionals who support these services.

Clearly without the infrastructure to support these children the technological advances will not be used to their full potential. The New Zealand Newborn Screen programme has already been marred by fraudulent and incorrect testing. ([http://www.stuff.co.nz/national/health/8101640/Eight-fired-over-baby-hearing-test-issues](http://www.stuff.co.nz/national/health/8101640/Eight-fired-over-baby-hearing-test-issues)

We have yet to study in depth the long-term educational and occupational outcomes of implanted children and the lived experiences of these implanted children as they move into adolescence and early adult life.

VISIT TO THE EAR INSTITUTE LONDON

On the last day of my visit I was able to spend some time with Dr. Debi Vickers a senior researcher and tutor who works at the Ear Institute in London at Grey Friars This gave me a valuable opportunity to discuss potential research questions and sources of information and contacts

GLOSSARY:

SIM: simultaneously implanted children

SEQ: sequentially implanted children

UNILATERAL: children with one implant
SSD: Unilateral hearing loss

CICS: (Cochlear Implant Childrens’ Support Group)

NICE: National Institute on Clinical Excellence in the UK. This sets the benchmark for a current evidence based treatment options on a variety of medical conditions

TUNED IN: The British equivalent of our “switch on”

TIME IN SOUND: length of time since “Tune In”

I finish with some questions raised from the concluding paragraph of my Master’s Thesis (2009): *Listening through Deaf Ears*

6.5 Conclusion

Doctors who conduct trials need equipoise: a belief that the two or more treatment options available have an equal chance of benefit and risk of harm. Yet it may be hard to find doctors who believe that it is ethical not to provide cochlear implants. For these reasons one could posit that doctors cannot fully inform parents with neutrality about the risks and benefits of cochlear implants. Questions about the ethics of such procedures may best be framed from the Socratic perspective “as to what constitutes a good life” (Frank, 2006) rather than a protectionist bio-ethics stance, which, while useful, may be more concerned with informed and voluntary consent and protecting practitioners from blame. In addition, such questions may lead parents to consider the potential collective effects of personal decisions. These more general issues are likely to affect the child’s future by taking this debate into a more societal context.
This chapter closes a question posed by Winkler (1998) to assist persons who are reflecting upon treatment options.

Does it enhance the whole person, or offer only a palliative substitute for wholeness? Does it serve our desire for completeness and connection, or pander to our anxieties about our short-sighted demands for control.