



Chair: Louise Craddock
Vice Chair: Jeremy Lavy
Secretary: Deborah Mawman
Treasurer: John Briggs

Minutes of the BCIG Council Meeting
Date: 28th January 2010 Venue: RNTNE, London
Time: 11.00am – 3.00pm

Present

Louise Craddock (Chair)
Jeremy Lavy (Vice Chair)
John Briggs (Treasurer)
Deborah Mawman (Secretary)
Sheena Round (Membership Secretary)
Chris Raine (Council member)
Andrew Reid (Council member)

1) Agreement of previous Minutes

Minutes of the previous meeting were discussed and agreed.

2) Review of actions

Agenda items from the council meeting in June 2009 were discussed. No minutes were available.

Further discussion about the wording and interpretation of the NICE guidance is required at the next coordinators meeting to ensure that clinical practice is standardised throughout the UK. Currently different clinical criteria apply in different centres. **Action Coordinators.**

Guidance is now available to teams hosting the BCIG AGM. This has been forwarded to the Southampton team who are hosting the AGM in April.

3) Matters Arising

None

4) Membership update

Applications for new membership were approved:

| Name | Profession | Status | Affiliation |
|---------------|---------------------------|---------------|------------------------------------|
| Sian Edwards | Audiologist / PhD student | Full | UCL |
| Simon Lloyd | Surgeon | Full | Manchester CI programme |
| Shaza Saleh | Audiological Scientist | Full | RNTNE CI programme |
| Jackie Salter | Teacher of the Deaf | Full | Ear Foundation |
| K Tzifa | Surgeon | Full | Birmingham Children's CI programme |
| Debi Vickers | Tutor and Lecturer | Full | UCL |
| Peter Walsh | Surgeon | Full | Dublin CI programme |

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A discussion was held about whether there was a need to change how honorary membership is awarded. A system of nominating and voting for individuals was considered. A decision was made to continue with the current system of awarding honorary membership to the keynote international speaker at the BCIG AGM or to retiring professionals who have made a significant contribution to the field of cochlear implantation. This will be reviewed at the AGM.

5) CI numbers data collection

Currently there is no coordinated data collection / national database regarding the number of implants being performed in the UK and device failures. In the past the MRC IHR in Nottingham collected this data and published it on their website. At present the National Cochlear Implant Users Group (NCIUG) request this information from coordinators on an annual basis. It was felt that data sets of this type may be something that could be collected by a national clinical research facility details of which are outlined in item 11 below. **Action BCIG Council.**

6) Awareness campaign

Lynn Tapper, speech and language therapist from the Bradford CI team emailed the BCIG council to ask whether BCIG would help in launching a cochlear implant awareness campaign. Her concern is that a number of adults who come forward for a cochlear implant assessment may have had a stable profound hearing loss for several years prior to their first visit to the implant centres. It was agreed that a working group should be established to move this forward. A meeting is being planned with Lynn Tapper to discuss an awareness campaign. **Action DM/JB/SR**

7) Correspondence

Freedom of Information Request

A freedom of information request had been received from the Islington Deaf Society requesting information about the numbers of patients suffering adverse events following implantation. LC has responded stating that BCIG do not have this data and as a private organisation is not required to provide data of this nature.

NICE letter

Julie Brinton forwarded a copy of a letter written by NICE to the parents of a child who has had funding declined for a sequential cochlear implant. The letter outlines the current NICE guidance and outlines the legal position of NICE in terms of implementing the guidance.

8) Commissioners meeting / Cost of provision of CI services in the UK

Chris Raine met with David Kelmsley (now retired) who was the pan London commissioner for cochlear implants to discuss funding for sequential implants and new implant centres. The new commissioner for London is Lorna McDougal. CR outlined the importance of maintaining dialogue between commissioners and implant centres particularly in relation to funding of sequential implants. Data collated by Tracey Twomey (Nottingham) indicates that the cost providing CI services varies throughout the country. It was felt that costs should be the same throughout the UK and that it may be helpful to meet with the heads of the 9 specialist commissioning groups (SCG's) at a BCIG council meeting. **Action LC / CR**

9) BCIG bursary for adult rehabilitation

Richard Byrne of the NCIUG has written to council to ask if some of the money held in the BCIG account could be used to fund an MSc or PhD research student to investigate adult rehabilitation. Council agreed to examine the BCIG account to determine whether, after all required costs were

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accounted for, there was enough money to fund such a post as an on-going commitment. The treasurer's accounts will be presented at the Southampton AGM in April.

10) New publishers for Cochlear Implants International

Rosie Sheridan from Maney publishers was invited to the council meeting to discuss the changes to the Cochlear Implant International journal which is the official journal of the BCIG and other international affiliated cochlear implant groups. She outlined the design and layout of the new cover. The first issue to be published by Maney should be mailed to members in mid-February.

There was a discussion about a membership link to establish online access to the journal on the website. BCIG members could be given a username and password when they log onto the website so that they can read the journal online. All the journals will be backdated to the first publication. Establishing online access to CI international will involve additional costs to set up a "member area" on the website.

Maney plan to have a stand at the BCIG AGM in Southampton and they have been asked to sponsor a prize.

11) Coordinated research in the UK

David McAlpine (Professor of Auditory Neuroscience and Director of the UCL Ear Institute) was invited to the council meeting to discuss his proposal (see appendix 1) to establish a national unit to coordinate clinical cochlear implant research projects in the UK similar to the Cancer UK organisation. It was agreed that the next step in this process would be to convene a meeting of interested parties to develop a document to circulate to CI community. It was felt this was something that could be discussed at the next coordinators meeting and at the BCIG AGM.

Action LC

12) Website update

Minutes of previous meeting and a link to the BCIG AGM in Southampton are on the website. It was felt that the website is currently being underused and should be more up to date with forthcoming meetings, online membership applications and forthcoming meetings. Council considered a password protected section on BCIG so that members could access the journal online. JL to investigate costs of this and ongoing maintenance. In addition links to the ENT UK / BAA / BSA websites would be helpful. **Action JL**

13) NDCS / BCIG QS for children

The final version has been agreed and will be posted on the website. Consider launching these at the April BCIG meeting. **(Action JL/LC)**

14) ABI working group

The minutes of the 1st UK ABI meeting held in Manchester in December 2009 were discussed. It was agreed that there should be a section on the BCIG website about the ABI and a discussion about whether the ABI group should be part of the BCIG. The next UK ABI meeting in June will be in London in June 2010.

15) AOB

A vacancy has arisen on BCIG council for membership secretary.

Date / time of next meetings

Wednesday 21st pm or Thursday 22nd April am Southampton.
Autumn meeting – Thursday Sept 23rd

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Appendix 1:

Developing a National Clinical Trials Unit in ENT Medicine – prepared by David McAlpine

Importance

Communication is an important aspect of what it means to be human. Understanding speech and making oneself understood, appreciating music, the ability to feel connected to the surrounding environment and to respond appropriately; all rely on the ability to hear. By far the greatest single contributing factor leading to hearing loss is damage to the irreplaceable sensory cells of the cochlea, the hearing organ in the inner ear. Whether through developmental or genetic causes, as a consequence of drug therapy (e.g. anti-cancer agents), presbycusis (age-related hearing loss) or through exposure to loud sounds (increasingly prevalent in modern societies), damage to these cells, and the deafness that results, hampers an individual's ability to communicate. Deaf and hard-of-hearing people are often socially isolated, preferring not to mix in social gatherings where background noise makes communication impossible. For children, developmental delays due to auditory deprivation, impaired language acquisition, access to education and reduced social interaction with family and peers can impact over a life-time. The consequences of hearing loss, including its financial and health (including emotional health) costs to society, is becoming increasingly evident. *Nevertheless, despite this importance for human health and well-being, the UK suffers from an acute lack of high quality clinical research in hearing therapies. No national unit exists for clinical trials, and clinical research is poorly co-ordinated UK-wide. An urgent need exists for a more coherent, focused and strategic programme of ensuring patients undergoing hearing therapies benefit from placement into research programmes designed specifically to test outcomes of existing and developing therapies.*

Timeliness and the *status quo*

One area for which developing a nationwide programme of clinical trials is particularly timely is cochlear implantation. Cochlear implants (CIs) are the most successful sensory prosthetic device developed to date; it remains little short of miraculous that inserting electrodes into deafened ears, to stimulate directly the auditory nerves with electrical currents, can restore or imbue hearing function to the extent that some recipients are able to conduct conversations over the telephone. No other sensory prosthesis comes close to rivalling the success of CIs, as judged by the ability to enhance sensory and motor function (hearing and speech). Compared with attempts to restore vision in the blind or movement following spinal injury, the restoration of hearing by cochlear implantation is considerably advanced. Nevertheless, significant progress will be required if CI listeners are to be provided with hearing abilities that allow them to operate in most every-day listening environments, where multiple sound sources that must be attended to exist against a background of interfering acoustic signals (noise). The importance of improving outcomes of CI has recently been recognised by the National Institute for Health and Clinical Excellence (NICE) who recommended bilateral (compared to unilateral) implants be funded through the NHS. NICE's requirement to audit bilateral implantation (surgically and in terms of

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benefits) has brought to light the urgent need to develop a more coherent, focused and strategic research programme in cochlear implantation in the UK, with the aim of ensuring that basic laboratory findings make their way to clinical settings, and that the primary research model of CI – which remains the human implantee – is effectively directed and employed to relevant research studies designed to benefit implant users. The UK contains some of the world's leading researchers and clinicians in CI, and has a historic and ongoing strong international profile in basic studies in hearing and deafness, providing considerable scope for advancing the development of new procedures and therapies in implantation. Despite this, CI research is relatively poorly funded, the majority of funding being the result of charitable income (often through hearing/deafness charities with relatively modest funding streams), or through (sometimes casual) interactions with the leading implant companies. In part, this is the result of the early success of implantation (the first implant in the UK was carried out some 25 years ago), occurring as it did at a time when strategic development of research (and research funding) into sensory therapies was less considered. In this circumstance, CI was ahead of its time. The 25 years since, however, has seen a revolution in our understanding of the inner ear and auditory brain, the emergence of genetically-modified mice as a tool of investigation in studies of hearing and deafness, and the prospect of gene-therapies to correct sensory or communication deficits (already a reality in the treatment of blindness).

Currently, no national centre exists through which clinical research in hearing therapies is co-ordinated UK-wide. The national audit of bilateral implantation required by NICE, for example, is proceeding *ad hoc*, with no dedicated, funded national centre for co-ordinating projects and no dedicated administrative or technical support to train NHS clinics in the appropriate gathering of scientific data for understanding present and future hearing therapies. Whilst NICE's recommendations have led to NIHR-funded research into the efficacy of bilateral versus unilateral implantation (Professor Quentin Summerfield, University of York) in a randomized control trial of adults and children, a pro-active perspective on translational research in hearing and deafness, comprising a strategic, research-led programme, is highly desirable, and currently lacking. Without such, future benefits in implantation and other hearing and ENT therapies will be retarded.

We propose rectifying this situation by establishing a National Clinical Studies Programme in ENT Practice, using the broad field area of cochlear implantation as the pilot programme from which to develop further programme areas as the benefits of this approach become apparent to basic and clinical scientists and health-care providers. The presumed efficacy of bilateral over unilateral implantation is just one area of research in CI that requires a more co-ordinated approach to its investigation. Within the broader field of CI, the importance of preserving acoustic hearing upon implantation, whether that hearing is unaided or aided by conventional means (i.e. with a hearing aid), the impact of electrical stimulation in electro-acoustical stimulation (EAS - combining electrical and acoustical stimulation either within or across the ears), the degree to which implantation compromises residual hearing function following cochlear implantation as implant criteria are relaxed (and implant companies develop 'partial-insertion' devices), and the potential for combined prosthetic/biological therapies in CI are all currently the subject of considerable research and clinical interest. Developments in these areas, as they

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arise, will require close co-operation between basic scientists and increasingly diverse teams of surgeons, audiologists and therapists. Additionally, ethical issues associated with data sharing, the development of standard metrics of hearing ability that are easily and rapidly made (given the time constraints of clinical settings in which assessments are made) and competing financial pressures of health-care providers (here, the NHS) and companies marketing cochlear implants championing implantation from a purely commercial perspective, all require a co-ordinated approach to the subject.

Specific aims of the proposed Partnership

- 1) To develop and co-ordinate a national research strategy for cochlear implantation that will ensure CI users are directed to appropriate research studies, including future clinical trials. This will include monitoring and storing securely relevant data, and facilitating access to those data by appropriate groups of clinicians and researchers.
- 2) To provide the infra-structure necessary to develop cross-centre research programmes requiring co-operation between a broad range of scientists and clinicians with interests in CI.
- 3) To provide a base from which future biological developments in hearing therapies, including those relevant to CI, may be assessed and researched in human populations.
- 4) To use the proposed CI programme as a pilot framework through which a Clinical Trials Unit in ENT Medicine might eventually be established in the UK.

A successful outcome will be evidenced by researchers interacting with patients and patient data-bases whilst complying fully with regulatory requirements, the engenderment of stronger links between research undertaken in academic centres, NHS staff, patients and 'user' groups, the development of a central repository of information for the benefit of researchers in the field and, for studies conducted by NHS staff or researchers within a hospital setting, knowledge of those patients prepared to take part in clinical and basic research projects. Additional benefits will include extending the current UK-wide interest in auditing the impact and efficacy of bilateral implantation to possible clinical trials in other hearing/ENT therapies, providing a model by which such trials might be developed, and the development of new diagnostics, therapies and interventions as basic and clinical research endeavours in the field of hearing and deafness become more closely aligned.

Participants

The proposed Partnership encompasses Academic and NHS partners across the UK. For several reasons it is proposed that the project be co-ordinated and managed from the UCL Ear Institute and its associated hospital, the Royal National Throat Nose and Ear Hospital (RNTNEH). The Ear Institute constitutes one of the largest groupings of auditory scientists, clinicians and audiologists in Europe, housed in a purpose-built research centre that was made possible by an £11 million grant awarded by the Wellcome Trust. The Institute's research excellence was recognised in UCL's outstanding return in UoA4, RAE2008 with 70% of staff rated 4* and 3* (40% and 30%). Relevant recent recruits to the Ear Institute including Dr Deborah Vickers, formerly Head of European Clinical Trials for Advanced Bionics, one of the major implant manufacturers and Shakeel Saeed, Professor of Otology/Neuro-

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otology, providing academic leadership to the well-established Cochlear Implantation at the RNTNEH. In addition, the Ear Institute is a short walking distance to Great Ormond Street Hospital, the site of a major paediatric implant programme ([Dr Kaukab Rajput](#)). Other UCL-based partners include the Centre for Human Communication (CHC – [Professor Stuart Rosen](#), [Dr Andrew Faulkner](#)), London-based sites with implant programmes such as Guy's and St Thomas's hospital and St George's Hospital, and other major UK sites involved in CI research - the Hearing and Balance Centre at the University of Southampton ([Professor Mark Lutman](#)), the Division of Human Communication & Deafness at University of Manchester ([Professor Colette McKay](#)), the Auditory Perception and Hearing Health Care Research Group, University of York ([Professor Quentin Summerfield](#)), the University of Nottingham ([Professor Gerard O'Donogue](#)) and University Hospital Birmingham NHS Trust ([Louise Craddock](#); Chair of the British Cochlear Implant Group).

Benefits of the Ear Institute for Managing the Project

The Ear Institute has played an integral part in developing the national audit of paediatric bilateral implantation, working closely with other centres (notably Southampton and Nottingham) in developing scientific tests that can be applied to a clinical setting. The Ear Institute comprises faculty include several senior figures in ENT and Audiovestibular Medicine (e.g [Professor Linda Luxon](#)), is an integral part of Europe's largest Biomedical Research Centre (with Academic Health Science Centre status), and can call on support and expert advice from well-established centres such as the UCL Partners Clinical Trials Unit ([Professor Monty Mythen](#)) and the Cancer Research UK (CRUK) Clinical Trials Centre hosted at the UCL Cancer Institute ([Professor Chris Boshoff](#)). The central London location of the Ear Institute (a few minutes' walk from King's Cross, St Pancras and Euston Stations) make it an ideal location from which to co-ordinate a national programme. Already the Ear Institute regularly hosts meetings of interested parties, including the BCIG, research charities such as Deafness Research UK, Royal National Institute for the Deaf and the British Tinnitus Association, council meetings of the British Society of Audiology and the British Academy of Audiology, and a programme of ENT- and Audiology-related training programmes.

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