NICE time for a change in Cochlear Implant Eligibility Criteria
Debi Vickers, University College London

The British Cochlear Implant Group (BCIG) decided to look at candidacy criteria for cochlear implants in 2013 because members said it was the most important issue facing the field at the time. At that time the BCIG established a candidacy working group to acquire and evaluate evidence to determine what the indications for cochlear implantation should be. Evidence was compiled over the years and many individuals were involved with different activities. The information is stored on the BCIG website as well as being reported back to the BCIG council. The BCIG and the candidacy working group has worked closely with the Action Group for Adult Cochlear Implants together with other stakeholder organisations and a coherent set of evidence was compiled to request that the National Institute of Health and Care Excellence (NICE) review and update the current cochlear implant guidance.

The current NICE guidance came into play in 2009 and is based on data from adults implanted between 1998 and 2000. This group on average had higher hearing thresholds than the current cochlear implant recipients and also there were no data for children. Because of improvements in cochlear implant surgery approaches people with more residual hearing can be implanted and some people are able to use a hearing aid on the other side or in the same ear as the implant.

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NICE responded in December 2017 and said that there is sufficient evidence to suggest that the criteria could be changed but they were not going to do a full review but would look at the criteria for hearing loss and the speech perception aspects. Stakeholders were asked to respond. Various organisations wrote back with recommendations which they thought should be implemented. The evidence compiled by the BCIG candidacy working party has been helpful to support the cases put forwards by many stakeholders. Some of the evidence that has been used is:

1. Rosie Lovett, Quentin Summerfield and I conducted a paediatric study to determine whether the audiometric criteria was appropriate for children receiving cochlear implants. Forty three children with hearing aids and twenty eight with bilateral implants were compared on scores on two different speech tests in two types of noise. Analysis of the data using two frequencies indicated that we could adjust the threshold to greater than or equal to 80 dB HL instead of the current 90 dB HL cut off.

2. We asked clinicians to write about issues they faced on a day to day basis in terms of trying to give the right people cochlear implants. The articles that they wrote were compiled in a supplement for Cochlear Implants International and this can be accessed free of charge through the BCIG website. There are twenty articles covering a range of topics. For example, the importance of considering the use of contralateral hearing aids on the other ear, improvements in hearing preservation in the implanted ear, electro-acoustic devices where there is a hearing aid in the same ear that has an implant. One of the biggest problems clinicians face are people with different losses in each ear or those with low frequency losses who really struggle with speech perception but their audiograms fall outside the criteria. So the criteria appears to be too restrictive and a lot of articles suggested that the criteria for adults could also be lowered to 80dB HL.

We also compared what we are doing with other countries. Typically those with national funding like the UK have very strict guidelines but there is much more flexibility if there is private funding or insurance. We are the most conservative in terms of criteria; most countries have 70 to 80 dB HL as their criteria. In terms of speech testing, 24% of countries use sentence tests like the BKB alone and 76% actually use word tests at some point in the criteria.

3. The adult service evaluation is a data collection exercise that has involved cochlear implant centres across the UK sharing fully anonymised data on pre-implant and post-implant scores from adult cochlear implant recipients with the BCIG. The aim was to look at current day performance of cochlear implants to see if it has changed since the criteria was originally set up and also to ask if BKB sentences are appropriate for assessing adults or whether we should look at word tests. We looked at scores from the AB word test, which can be scored by whole words or by phonemes (individual sounds in a word) and the BKB sentences presented in quiet (scored by words correct). People are now on average achieving higher scores; originally the score at 12 months was 50% but now it is more like 80%. There is a strong relationship between the sentence test and the word test but the word test seems to better represent what speech sounds a person can hear.
4. The candidacy consensus was a big exercise to find out what people thought about the candidacy criteria and how or whether it should be changed. One hundred and sixty people responded to the initial questionnaire and we had a meeting in which 41 people attended to discuss candidacy. We looked to see whether there was consensus on various points such as which speech test to use for assessing candidacy. We gave people details of 600 potential patient profiles and asked them to say who they considered appropriate for an implant - appropriate means that the benefits outweigh any harm – and also if it was necessary. When people had a 90dB HL loss the criteria worked and the same was true when the hearing loss was 80dB HL but with a 70dB HL hearing loss there were a lot more problems and a large proportion of the profiles were considered inappropriate for an implant.

5. The final piece of evidence that was reviewed was the choice of frequencies to be included in the criteria. Currently we look at 2 and 4 kHz which are quite high frequencies but if you have a low frequency hearing loss but good hearing at 2 and 4kHz there can be a problem in terms of hearing speech. Literature says important speech regions are between 750 and 3000 Hz reflecting the fact that vowel information and a lot of speech cues are present in the low frequency region. A lot of other countries look at lower frequencies than we do in the UK.

Based on these five pieces of evidence the majority of stakeholders have recommended to NICE that the hearing threshold criteria should be amended to be greater than or equal to 80dB HL at two or more frequencies out of 500, 1000, 2000, 3000, or 4000 Hz bilaterally. We have requested that the speech criteria should be based the AB word test scored by phoneme rather than the BKB sentence test. We have suggested that the cut-off should be <50% on the AB phoneme score which is roughly equivalent to 70% on BKB sentences.

For children we don’t want to change the rule that the team decides whether the child’s listening skills and speech and language abilities are developing appropriately and for all candidates we strongly believe that the multi-disciplinary team should decide whether cochlear implantation will provide additional benefits beyond those of conventional hearing aids for each individual.

Going forwards we need to think about the areas of need that will not be covered by these amendments such as bilateral cochlear implants for adults or implants motivated to relieve tinnitus.

We hope that by the end of 2019 we will receive updated NICE guidance for cochlear implant criteria in the UK. This will be the result of hard work by many people.
Dr Newman talked about how the immune system and the nervous system interact and how this relates to hearing. Hearing is a part of the function of the nervous system and the cochlea is a little annex of the nervous system.

Southampton researchers have a long track record of looking at neuroimmunology and neurodegeneration in illnesses such as Alzheimer’s disease. In particular they have researched into how inflammation communicates with the brain and how this affects people with Alzheimer’s disease. They have found that the disease progresses more quickly, as the injury to the brain proceeds at a faster rate. Now the findings are being related to hearing loss. This work in collaboration with other hearing biologists is to understand ways to develop strategies for better hearing preservation.

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The immune system deals with infection or injury by generating a response to get rid of the pathogens such as bacteria, or the injured tissue. This is called the inflammatory response. The inflammatory response is part of what makes us feel tired and unwell when we have an infection. A healthy inflammatory response is one that resolves itself as the infection or injury is dealt with. However, inflammation is also found in many common conditions such as those that affect the circulatory system as we age including diabetes and coronary heart disease. A difference though is that in these conditions the low-level inflammation can become prolonged or chronic, rather than switching off (resolving) once the condition is dealt with. As has been seen in Alzheimer’s disease chronic inflammation may affect parts of the brain, including the regions and pathways responsible for hearing. If this is the case it may be that controlling inflammation may slow down the damage to the hearing pathways.

People with inflammation have a higher white blood cell count; in older people with hearing loss a higher white blood cell count has been associated with worse hearing loss. This is interesting as it suggests that the inflammation is affecting the rate of hearing loss. In a recent study in Southampton a group of older people with no particular hearing problems were recruited for a research project to explore whether hearing loss worsened more quickly in people who were more inflamed. In the first year of the study participants were asked to send in a monthly urine sample on the same day each month for twelve months. We searched for the molecule, neopterin, which indicates an inflammatory condition. Some people had very little inflammation during the year while another group had almost consistently high levels of inflammation. Hearing loss was greatest in the group with the greatest inflammation. Soon the data from three years will be available and we expect to see that those who had some hearing loss and were most inflamed during year 1 of the study have gone on to have the greatest hearing loss. This will be an important finding as it suggests that inflammation is contributing to the damage to the neurons and other cells in the hearing pathways.

The effectiveness of a cochlear implant is dependent on the health of the cells in the hearing pathways starting with the spirio-ganglion neurons. Central nervous system neurons once damaged are very poor at repairing themselves. We have evidence that sometimes implants do not work well for users although the implant itself is functioning correctly. This may include damage to the hearing pathways as the result of inflammation as we are seeing in the people with sensorineural hearing loss. The ambition for all people with cochlear implants is that their implants give them the best access to hearing that they can, ideally across their lifetime. If part of this relies on having a healthy nervous system then we should take steps to keep the nervous system as healthy and intact as possible. Our work suggests that any practical measures that can be taken are, to ensure that any inflammatory condition even as seemingly disconnected as a urinary tract infection are promptly dealt with. We hope to report the most recent of the work that has been discussed here in detail in the form of published scientific papers by the end of 2018.
Monica Sherratt’s story

I am writing in connection with the relaxation of the strict criteria which has held me back unnecessarily on my journey towards getting a CI. The problem with me has been that my hearing is worse for low frequency than for high frequency. The criteria is based on high frequency loss. I was first put forward as a candidate for a CI by the Hearing Therapist and Chief Audiologist at Gloucester Hospital in 2014. I had tests at Bristol and was accepted by the CI Team there for an implant provided it was approved by the Funding Panel. I did not meet their criteria and therefore was turned down. I wrote to my local MP who had a go at taking the matter up for me but he too drew a blank.

The good news is that I have now had an implant. Eventually my high frequency deteriorated sufficiently for me to qualify which has meant that my hearing loss by the time of the implant was making life very hard for me.

I have belonged to Gloucester Deafened and Cochlear Implant Support Group for seven years and it has been a great help to me to be able to discuss progress with others who have had implants and because of this I have not needed any further help preparing for the operation. I am now 84 and have spent four years suffering unnecessarily and increasingly because of the ruling which the Consultant at Bristol knew was unfair. Apparently because I am in the minority it seemed I was not worth considering. I was told by the Audiologist in Bristol that in her 25 years experience she had only come across one other case like mine.

The longed for day arrived and at the time of writing I was switched on four days ago, since when I have been in the land of Donald Duck! The sound at first was so funny I burst out laughing, or rather quacking! Then with the realisation that this duck in my head could talk and converse with the other ducks I was in tears at the implications. The audiologist was ready with tissues. This frequently happens. She assured me that everything I was experiencing was normal and good so off I went armed with training instructions and another appointment for re-tuning in just over a week’s time. Now I am beginning to enter the real world again but although my pal Donald Duck is helping me to hear I shall be grateful when he is able to leave me. I feel confident about the future but it is hard work and tiring.

I can’t speak highly enough about the treatment I have had in Bristol. The surgeon did a first class operation and the whole CI team is wonderful, full of smiles and encouragement. I feel very blessed already although I still have a long way to go.
Advanced Bionics Naída CI Q90 sound processor users will soon be able to have access to hands free phone calls to any mobile phone (1). Thanks to the SWORD™ chip technology from Sonova, connectivity to mobile phones regardless of the brand or operating system, including Android™, iPhone® and even feature phones becomes reality – with no body-worn device required (2). Naida CI Q90 users remain free to choose the brand of mobile phone of their preference.

Just like a Bluetooth® wireless headset calls will be heard ringing directly in the sound processor. Built-in microphones pick up the recipients’ voice. And with the simple touch of a button, users will be able to answer or reject calls when at a distance from the phone, or even from the other side of the room.

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To read more about the revolutionary SWORD technology, visit AdvancedBionics.com or email info.uk@AdvancedBionics.com

(1) with Bluetooth® 4.2 wireless technology and most older Bluetooth phones
(2) Bluetooth is a registered trademark owned by Bluetooth SIG, Inc.; Android™ is a registered trademark owned by Google, Inc.; iPhone® is a registered trademark of Apple, Inc.
Nucleus® 7 is now compatible with Android™ smartphones

Since the launch of the world’s first Made for iPhone cochlear implant sound processor in 2017 we have been working hard to extend the benefits of our industry leading technology to include Android smartphone users, whilst bringing new features to existing users, so we’ve got some very exciting updates.

• The Nucleus® 7 sound processor is now the world’s first Android compatible cochlear implant sound processor.

• New ForwardFocus feature allows users to ‘switch off’ background noise behind them to focus on a conversation.

• The Nucleus 7 Sound Processor is now available for the first time to those with a Nucleus 24 Series Implant.

In June this year we proudly announced the release of the Nucleus® Smart App for Android, offering greater connectivity than ever before. Users of our Nucleus 7 Sound Processor can now, not only control their hearing with the Nucleus Smart App* from a compatible Apple or Android device, but can also access a range of new features such as the ability to ‘switch off’ distracting background noise and focus on the conversation in front of them. From locating a lost or misplaced sound processor using the Find My Processor feature, through to confidently tracking progress with the Hearing Tracker feature, users can experience unprecedented connectivity and performance.

Along with the release of the Nucleus Smart App for Android, we have added a first-of-its kind control feature called ForwardFocus. This user-activated control feature allows the wearer to hear better in challenging listening environments such as a busy restaurant. When switched on, ForwardFocus reduces distracting noise coming from behind a person so they can more easily enjoy a face-to-face conversation.

And last, but by no means least, in our continuing strive to make our latest technology compatible with historic implants, the Nucleus 7 Sound Processor is now compatible with the Nucleus 24 Series Implant.

* The Nucleus Smart App is compatible with iPhone 5 (or later) and iPod 6th generation devices (or later) running iOS 10.0 or later. To use the Nucleus Smart App for Android, your device will need to run Android 5.0 (Lollipop) or later and support Bluetooth 4.0 or later. For a list of verified devices visit www.nucleussmartapp.com/android
From MED-EL

RONDO 2 with wireless charging and WaterWear

Now available in the UK, the RONDO 2 is the world’s only single-unit audio processor with rechargeable battery, wireless charging pad, one-touch activation, and automatic sound management that adapts to any environment. This makes RONDO 2 the natural choice if you prefer to forget about your cochlear implant and simply enjoy each day.

RONDO 2 wearers also benefit from never needing to use a drying kit, a splash proof design, and Bluetooth connectivity. A choice of a free connectivity kit or accessory kit makes the RONDO 2 perfect for every lifestyle.

Change your style not your battery

The revolutionary wireless charging pad recharges the RONDO 2 in just four hours; this provides 18 hours of battery life, giving you a full day of hearing from one overnight charge. Carrying and changing batteries is a thing of the past!

The only thing you need to think about is which design cover you want to wear today. Blend in with natural hair tone designs or stand out with fun and bright patterns. It’s completely up to you.

Swim or splash with WaterWear

A free WaterWear package is included as standard for all new RONDO 2 users. The brand-new accessory allows you to wear the RONDO 2 while bathing, swimming or taking part in other water sports.

WaterWear for the RONDO 2 consists of a tight transparent cover which is simply put over the processor and closed with an adhesive strip. The adhesive strip provides a tight seal and prevents any dust or water from entering the audio processor. WaterWear has an IP68 protection rating for water and dust, meaning it is fully submersible in natural, chlorinated or salt water.

WaterWear comes in a pack of three WaterWear covers and nine adhesive strips. Each WaterWear cover may be used up to three times; while the adhesive strips are designed for single-use.

Ask your audiologist about choosing RONDO 2 as part of your cochlear implant system, or next audio processor upgrade.

For more information about RONDO 2 visit medel.com/rondo2
Oticon Medical launches the smallest-ever BTE sound processor for CI

With the launch of Neuro 2, the smallest ever Behind-The-Ear (BTE) cochlear implant sound processor, Oticon Medical continues to bring expertise in micromechanics, sound processing and usability into the field of cochlear implants.

Award-winning design
Neuro 2 sets new aesthetic standards with an organic shape that is discreet and comfortable for users of all ages. Its design is characterised by an attention to detail that gives outstanding reliability and usability. This can be seen in its IP68 ranking – the highest protection in the CI industry against water and dust, reached without the need for any external accessories – the ultra-strong transparent cable, and features like the voice-activated microphone check and the battery door lock.

“Our uncompromising commitment to design excellence in the Neuro 2 has already resulted in a number of design awards, including the prestigious Red Dot Awards 2017 and 2018, the Good Design Award 2017, and the iF Design Award 2018,” says Jes Olsen, President of Oticon Medical.

Taking the strain out of hearing
In addition to the multi-awarded design, Neuro 2 features unique technologies based on BrainHearing™, the Oticon Medical philosophy to make listening and understanding as easy as possible and that frees up cognitive energy. These technologies include the surrounding mode with speech prioritization called Speech Omni, and the output compression system called Voice Guard, designed to preserve 95% of speech.

The perfect partner with Oticon hearing aids
For users who already use an Oticon hearing aid, the Neuro 2 provides the perfect match of sound processing technologies. Built on BrainHearing™, the two instruments share the same technologies and optimize the two acoustic inputs, so all important information is combined into a rich sound experience.

For more information, please visit www.oticonmedical.com/Neuro2
The Association has for many years been a subscribing member of the British Cochlear Implant Group. Each year BCIG holds an annual conference, usually hosted by one of the UK CI Centres, and whenever possible the Association aims to be represented. The 2018 conference was held at the Belfast Waterfront conference centre on the banks of the Lagan, and I attended on behalf of the Association. Tricia Kemp was also present, changing between her NCIUA and CICS hats as appropriate.

The great bulk of the presentations were aimed at the interests of the professionals working in the field, but some messages emerged of more immediate interests to adult implant users.

- Debi Vickers of UCL gave an update on the work going on to provide a consensus input to NICE’s review of the current UK implantation criteria.

- Harry Powell from Guy’s & St Thomas’s reported on their experience of fitting combined electro-acoustic stimulation [EAS] devices. Typically these devices aim to deliver an acoustic signal to take advantage of a patient’s surviving low frequency hearing, and use the CI part of the system to deliver higher frequency information. They are combined with “soft surgery” techniques to ensure that the patient’s residual low frequency hearing is not further damaged by the implant process. The bad news seems to be that when followed up for several years after the operation a significant number of patients saw further deterioration of their acoustic hearing. The good news is that with most of these patients their speech perception in electric-only mode showed little if any decline compared to their earlier scores in EAS mode, and continued to be far better than their pre-CI scores.

- Paul Goeverts from the EarGroup in Antwerp had been due to provide a presentation on the FOXR system [Fitting to Outcomes eXpert], which essentially uses artificial intelligence techniques to help the audiologist explore the plethora of possible maps for any given patient, and thence identify the optimal map as quickly as possible. Unfortunately Mr Goeverts was unable to get over to Belfast, and so delivered his presentation via a video link. This was in essence an update on a presentation made to the Bristol BCIG meeting a few years ago, since when the EarGroup have continued to refine their models and try them out on more patients. This really is very impressive work, and I’m sure it has to be the way forward for patient mapping.

- Helen Cullington from Southampton University gave a presentation at the Association’s 2017 Conference on the work being done on developing techniques to allow patients to undertake an element of remote testing and adjustment of their devices, and thence reduce the need for expensive and time-consuming visits to CI Centres. At Belfast she gave a further update on this ongoing study, and envisaged various remote tools being available for use nationally later this year. Again I’m sure this has to be the way forward for many patients, as the cumulative number of users continues to increase the resources just won’t be there to look after them all using the more traditional methods.

Paul N Tomlinson August 2018
September marks our first anniversary since our Facebook group started. We now proudly have over 135 members all supporting one another on line and at our regular socials. We have 3 volunteer administrators facilitating the group. Between them they have developed a lovely website for the group and established good links with the local Cochlear Implant Centre in Southampton (Adult Auditory Implant Service). The website contains information useful for anyone considering an implant, progressing through the assessment process or preparing for the operation itself. We also have an email address for those who don’t use Facebook.

Our group members are a rich mix of age. There are families and some who sign while others lipread, all come mostly from Dorset, West Sussex, Wiltshire and Hampshire. We also have a few Hearing Dog members too! Our group grew so strongly that we needed a third administrator to support the group and Sarah came to help us.

All 3 brands of cochlear implants are used in our group. We refrain from promoting one brand but we understand choosing which implant brand to have is a big decision to make. Attending one of our socials will give you the opportunity to chat to our members about their own implants. Most recipients of cochlear implants love to chat and share their experiences. Many people have said how useful they have found the gatherings and new friendships have formed. Our socials are roughly every 2-3 months. This summer we braved a picnic in the park and the sun shone. It was yet another brilliant day. Other socials have taken place so far in Southampton, Winchester, Portsmouth, Chichester and hopefully Salisbury soon.

We have been going for two years and continue to welcome more new members. In November we are proud to announce a joint venture with The Ear Foundation and The National Cochlear Implant Users Association. We are holding a Technology Day at AIS; Southampton on Saturday 3rd November. Representatives from the cochlear implant manufacturers will be there to answer our questions. Details about the Technology Day accompany this newsletter.

Further and fuller details on all the above can be found on our Facebook group: www.facebook.com/groups/cisoutherncounties

Disclaimer
Whilst the Association uses its best endeavours to provide accurate information on the subject of cochlear implants it does not provide medical advice or make recommendations with regard to any particular implant or equipment and no article in this newsletter should be construed as doing so.

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