

Impact case study (REF3b)

Institution: University of York
Unit of Assessment: 4, Psychology, Psychiatry and Neuroscience
Title of case study: Impact on policy and practice in the provision of cochlear implants to deaf children and adults.
1. Summary of the impact

Our research on the clinical effectiveness and cost effectiveness of cochlear implantation has had two impacts. First, the research informed the decision by the National Institute for Health and Care Excellence (NICE) to issue guidance to the effect that the National Health Service (NHS) in England and Wales should provide cochlear implants *to both ears of deaf children, but to only one ear of deaf adults*. Those recommendations are binding on the NHS in England and Wales and have also been adopted in Scotland and Northern Ireland. Second, we translated tests of spatial hearing, which were developed in the course of the research, for use by clinicians. We incorporated the tests in a unique apparatus which is being produced commercially and used in clinics to monitor candidacy for, and outcomes from, cochlear implantation and other treatments.

2. Underpinning research

Background Cochlear implantation provides useful forms of hearing to two groups of people in particular: children born deaf and adults who become deaf after acquiring spoken language. An array of electrodes is implanted surgically in the inner ear with the aim of bypassing absent or malfunctioning parts of the auditory system and stimulating the nerve of hearing directly with electrical signals. Approximately 400 children and 400 adults receive implants in the UK each year. From 1991, when implantation was introduced to the NHS, until 2009, it was policy to provide a single implant in one ear ('unilateral' implantation). The cost of unilateral implantation is approximately £60,000 for a child and £34,000 for an adult. Unilateral implantation is an effective treatment: adults regain the ability to understand speech; children hear well enough to acquire spoken language.

Starting in 2000, controversy emerged over the issue of whether patients should, instead, receive two implants, one in each ear ('bilateral' implantation). The primary aim of bilateral implantation is to create skills in 'spatial hearing', such as the ability to work out where sounds are coming from and to attend to whichever ear conveys the clearer signal when there is background noise. The controversial issues were whether these benefits are large enough and are realised sufficiently consistently to justify the additional £30,000 which it costs to provide a patient with two implants rather than one and then maintain those implants. Our research has addressed those issues.

Research underpinning impact We claim impact stemming from three strands of research:

Strand 1: Bilateral implantation in adults The data-gathering phase of this strand took place before Summerfield joined the faculty of the University of York in 2004. The data were analysed and published in 2005-6 after he joined the University (publication [1] in the list in Section 3, below.). The study was a randomised controlled trial which compared outcomes from unilateral and bilateral implantation in adult patients. The outcomes of interest were self-reported measures of skills in spatial hearing in everyday life and measures of quality of life, including measures designed to provide the 'effectiveness' component of a cost-effectiveness analysis. The study demonstrated that bilateral implantation, compared with unilateral implantation, leads to significant improvements in self-reported abilities to localize sources of sound and to understand speech in noisy environments. However, the accompanying increments in quality of life are too small to justify the additional cost of two implants rather than one.

Strand 2: Bilateral implantation in children The data-gathering, analysis, and reporting phases of this strand were conducted between 2005 and 2010. The first study in this strand was a non-randomised comparison of children with unilateral and bilateral implants. Statistical control was exercised over confounding covariates. The outcomes of interest were measures of skills in spatial listening obtained by testing the children, and parental-proxy reports of the children's skills in spatial listening in everyday life. The study was larger and better controlled than previous comparisons of children with unilateral and bilateral implants. The results demonstrated that bilateral implantation, compared with unilateral implantation, is associated with significantly better skills in spatial listening, both in the laboratory and in everyday life (publication [2]). The second study in this strand obtained measures of the quality of life of hypothetical deaf children with none,

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one, or two implants from 180 adult informants using a formal method (the time trade-off technique) for assessing quality of life. The data were incorporated in probabilistic decision-analytic models of unilateral and bilateral implantation. The informants judged that deaf children received additional benefit from two implants. The difference was large enough to mean that bilateral implantation could be a cost-effective use of resources in the NHS (publication [3]).

Strand 3: The 'Crescent of Sound' In the third strand, we worked with clinicians to translate our laboratory tests of spatial hearing so that they could be used in clinics. First, we identified the tests which clinicians would need as a consequence of the change in policy that was introduced by NICE in 2009; that is, tests which can be used with children to inform judgements of candidacy for bilateral implantation and to monitor outcomes from bilateral implantation. Second, we extended the test battery to include tests suitable for adults and tests suitable for users of acoustic hearing aids. At the third step, we configured the software which controls the tests so as to minimise the cognitive demands on the tester; for example, the tester records only the response made by a participant; the software decides whether the response was correct or incorrect. This division of responsibilities is important because the tester will also be seeking to engage and maintain the interest and enthusiasm of the patient, who may be as young as 18 months. A further feature is that the software writes a report in plain English which compares the performance of the current participant with the performance of previous participants. We then worked with a firm of electrical engineers to design an apparatus to deliver the tests while meeting health and safety standards for use in hospitals with children.

The result is the 'Crescent of Sound'. It consists of a 180-degree arc of loudspeakers and associated digital video monitors. The monitors display movies and still images to control participants' attention, to provide feedback, and to reward engagement. The Crescent measures the ability of listeners to localize sources of sound, to track moving sounds, and to identify spoken words in the presence of interfering sounds, using the tests described in Publications [2], [4], and [5]. Many of the tests are implemented in a form which allows the difficulty of the listening task to adapt to the skill of the participant. In this way, the same test can be used both with children and with adults, and with users of implants, users of acoustic hearing aids, and participants with normal hearing. Publication [5] demonstrates that the tests can measure the ability of children with cochlear implants to localise sounds from as young as 2 years of age. Publication [6] demonstrates that the Crescent produces similar data to the laboratory apparatus from which it was derived.

Key researchers. The key researcher was Professor A. Q. Summerfield (2004- present).

3. References to the research

Note: Citation counts were taken from Scopus on 25th September 2013.

Strand 1

[1] Summerfield AQ, Barton GR, Toner J, McAnallen C, Proops D, Harries C, Cooper H, Court I, Gray R, Osborne J, Doran M, Ramsden R, Mawman D, O'Driscoll M, Graham J, Aleksy W, Meerton L, Verschure C, Ashcroft P, Pringle M. (2006). Self-reported benefits from successive bilateral cochlear implantation in post-lingually deafened adults: randomised controlled trial. *International Journal of Audiology*. Suppl: 99-107. doi: 10.1080/14992020600783079. 44 citations.

Strand 2

[2] Lovett RES, Kitterick PT, Hewitt CE, Summerfield AQ (2010). Bilateral or unilateral cochlear implantation for deaf children: an observational study. *Archives of Disease in Childhood*, 95, 107-112. doi: 10.1136/adc.2009.160325. 21 citations.

[3] Summerfield AQ, Lovett RES, Bellenger H, Batten G. (2010). Estimates of the cost-effectiveness of pediatric bilateral cochlear implantation. *Ear and Hearing*, 31, 611-624. doi: 10.1097/AUD.0b013e3181de40cd. 10 citations.

Strand 3

[4] Kitterick PT, Bailey PJ, Summerfield AQ (2010). Benefits of knowing who, when, and where in multi-talker listening. *Journal of the Acoustical Society of America*, 127, 2498-2508. doi: 10.1121/1.3327507. 6 citations.

[5] Lovett RES, Kitterick PT, Huang S, Summerfield AQ. (2012) The developmental trajectory of spatial listening skills in normally-hearing children. *Journal of Speech, Language, and Hearing Research*, 55, 865-878. doi: 10.1044/1092-4388(2011/11-0096). 2 citations.

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[6] Kitterick PT, Lovett RES, Goman AM, Summerfield AQ. (2011) The AB-York Crescent of Sound: an apparatus for assessing spatial-listening skills in children and adults. *Cochlear Implants International*, 12, 164-9. doi: 10.1044/1092-4388(2011/11-0096). 2 citations.

Grants

1. A.Q. Summerfield, "The bases of difficulties in spatial hearing for speech: investigations using psychoacoustic techniques and magneto-encephalography", Royal National Institute for the Deaf, Oct 2005 to Sept 2008, £60,770.
2. A.Q. Summerfield, "Spatial listening in children with normal hearing and children with bilateral cochlear implants", Deafness Research UK, Oct 2006-Dec 2009, £48,484.
3. A.Q. Summerfield, "Development and validation of the AB-York Crescent of Sound for measuring skills in spatial hearing in children and adults who use cochlear implants", Advanced Bionics SARL, Jan 2009-Dec 2010, £150,000.

Evidence of the quality of the research

Each publication and grant was peer-reviewed. In addition to presentations at conferences in the UK and mainland Europe, Summerfield reported the research in invited presentations at the 5th International Cochlear Implant Symposium (Charleston, NC, 2007), the International Hearing Aid Conference (Lake Tahoe, NV, 2008), the Conference on Implantable Auditory Prostheses (Lake Tahoe, NV, 2009, 2011), and the American Auditory Society (Scottsdale, AZ, 2012).

4. Details of the impact

Background Impact is claimed from research conducted by Summerfield for which the data were either analysed and published, or collected, analysed, and published, after he joined the staff of the University of York in October 2004.

Impact on health-care policy The first route to impact involved five stages: (1) Publications [1], [2], and [3], either after publication or, in some cases, before publication, were reviewed by health analysts and health economists at the Peninsular Technology Assessment Group (PenTAG) who assessed evidence of the clinical effectiveness and cost effectiveness of cochlear implantation for NICE. (2) Summerfield served as a member of PenTAG's Expert Advisory Group during this process. In that role, he gave advice by telephone and e-mail in response to questions posed by the analysts and economists. In July 2007, he sent written comments to PenTAG on a draft of the report that was subsequently published as Bond et al. (2009). (3) Data reported in the publications informed the conclusions reached by PenTAG about the clinical effectiveness and cost effectiveness of bilateral implantation compared with unilateral implantation. (4) PenTAG's conclusions informed the judgments of the Appraisal Committee at NICE which led to the recommendation in the NICE Guidance on Cochlear Implants (NICE, 2009) that newly-diagnosed young deaf children should receive bilateral implants whereas post-lingually deafened adults should receive unilateral implants. (5) As a result, health services in the UK have continued to provide implants unilaterally to post-lingually deafened adults but, since 2009, have provided implants bilaterally to newly-diagnosed young deaf children.

Economic benefit An estimate of the economic benefit to the UK of these decisions can be obtained by considering the Net Benefit associated with bilateral implantation in adults and children. Net Benefit can be calculated as the difference between the value of the quality of life gained from an intervention and the cost to the NHS of gaining it. According to this analysis, the provision of bilateral implants to an adult patient entails a *negative* net benefit of £7,500 (i.e. on average, the cost of provision exceeds the value of the gain in quality of life by £7,500), while the provision of bilateral implants to a child patient entails a *positive* net benefit of £10,000 (i.e. on average, the value of the gain in quality of life exceeds the cost of provision by £10,000). Thus, with 400 adults receiving implantation each year in the UK, the decision by NICE *not* to provide bilateral implants to adult patients *avoids* an annual loss of £3M. With 400 children receiving implantation each year in the UK, the decision to provide bilateral implants to child patients achieves an annual gain of £4M.

Beneficiaries One group of beneficiaries were the health analysts and health economists at PenTAG and the policy makers at NICE who received data that informed their judgments. A second group of beneficiaries were clinicians who were made aware of the types of performance test and questionnaires that can provide evidence of the clinical effectiveness of bilateral implantation. A third group of beneficiaries were deaf children who now receive two implants rather

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than one. Having two implants should help children to know where to look to see who is talking at home and at school, and to know where to move to avoid hazards outdoors. Further benefits to children (and their parents/carers) may arise from knowing that each implant can act as an insurance policy against the failure of the other implant.

Impact on health-care practice The second route to impact arose through the creation of the Crescent of Sound, thereby enabling clinicians to administer tests of spatial hearing which they would not otherwise have been able to use. The Crescent is a unique product whose hardware and software meet professional standards of safety, reliability, and ease of use. Its price (£35,000) reflects that quality. Its value to clinicians is evidenced by the fact that half of the paediatric implant centres in the UK and one in the Netherlands had acquired Crescents by October 2013. Clinicians are using Crescents to determine candidacy for, and to monitor outcomes from, cochlear implantation, hearing aids, and other treatments that improve spatial hearing across the life-span.

Beneficiaries One group of beneficiaries are clinicians who have a reliable ergonomic apparatus with which to administer tests that demonstrate whether a patient is benefitting from their cochlear implant(s) or acoustic hearing aid(s). As a result, patients and their carers can be informed about their performance and how it changes over time. A second group of beneficiaries are commissioners of health care who can receive information about candidacy for, and outcomes from, implantation and hearing-aid fitting measured with the same tests in different hospitals. A third beneficiary is the firm, Solutions Technology Ltd., which has earned £160,000 from constructing and installing Crescents.

5. Sources to corroborate the impact

1. Summerfield's role as a member of the Expert Advisory Group to PenTAG is acknowledged on page 161 of Bond et al. (2009).
2. The use by PenTAG of data from publication [1] is illustrated by discussions and analyses on pages 80, 105, 121, 135, and 152 of Bond et al. (2009).
3. Section 1 (pages 4 & 5) of the NICE Guidance on Cochlear Implantation (NICE, 2009) states that implants should be provided bilaterally to newly diagnosed young deaf children, but unilaterally to the majority of adult patients.
4. Paragraph 4.2.10 of the NICE Guidance on Cochlear Implantation (NICE, 2009) refers to estimates of the incremental gain in health utility arising from bilateral compared with unilateral implantation from publication [1].
4. In July 2008, Summerfield responded to a request from the Appraisal Committee at NICE by submitting unpublished data on the provision of bilateral and unilateral implantation to deaf children. The document that was submitted is available for audit. Those data formed the first and third datasets from consultees that are referred to in Paragraph 4.2.18 of the NICE Guidance on Cochlear Implantation (NICE, 2009). The data subsequently appeared in publications [2] and [3].
5. Contracts and order forms are available for audit which demonstrate the engagement of Solutions Technology Ltd. in the design of the Crescent of Sound, and in constructing and installing Crescents in clinics at the following sites: (i) Royal National Throat Nose and Ear Hospital, London; (ii) St Thomas' Hospital, London; (iii) Addenbrooke's Hospital, Cambridge; (iv) Royal Infirmary, Bradford; (v) Crosshouse Hospital, Kilmarnock; (vi) Children's Hospital, Birmingham; (vii) South of England Cochlear Implant Centre, University of Southampton; (viii) University Medical Centre, Utrecht, Netherlands. Photographs of some of these installations are at <http://www.york.ac.uk/psychology/research/facilities/aphhc/research/crescentofsound/>

References

- Bond M, Mealing S, Anderson R, Elston J, Weiner G, Taylor RS, Hoyle M, Liu Z, Price A, Stein K. (2009). The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults: a systematic review and economic model. *Health Technology Assessment* 13(44). <http://www.hta.ac.uk/fullmono/mon1344.pdf>
- NICE (2009). Cochlear implants for children and adults with severe to profound deafness. *NICE technology appraisal guidance* 166. <http://www.nice.org.uk/nicemedia/pdf/ta166guidancev2.pdf>