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WORKING GROUP ON ACUTE PURCHASING

THE USE OF COCHLEAR IMPLANTATION

December 1996

GUIDANCE NOTE FOR PURCHASERS 96/03

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The Institute:

- provides advice and support to NHS staff on undertaking Health Services Research (HSR);
- provides a consultancy service to NHS bodies on service problems;
- provides training in HSR for career researchers and for health service professionals;
- provides educational support to NHS staff in the application of the results of research;
- disseminates the results of research to influence the provision of health care.

The Directors of the Institute are: Professor R L Akehurst (Sheffield);
Professor C E D Chilvers (Nottingham); and
Professor M Clarke (Leicester).

Professor Akehurst currently undertakes the role of Institute Co-ordinator.

A Core Unit, which provides central administrative and co-ordinating services, is located in Regent Court within the University of Sheffield in conjunction with the School of Health and Related Research (ScHARR).

FOREWORD

Individuals or small groups in each District Health Authority in Trent have historically considered evidence on the likely effectiveness of new procedures or therapies in conjunction with their cost, making judgements on whether these should be supported. Since all or most Health Authorities face the same issues, there tends to be repetition in analysis and this can be wasteful of scarce professional expertise.

There are national attempts to remedy this situation by providing information on the effectiveness of interventions and these are welcomed. There remains, however, a significant gap between the results of research undertaken and their incorporation into contracts.

Following a request from purchasers, a network has been established in the Trent Region to allow purchasers to share research knowledge about the effectiveness of acute service interventions and to determine collectively their purchasing stance.

ScHARR, which houses the Sheffield Unit of the Trent Institute for Health Services Research, facilitates a Working Group on Acute Purchasing. A list of interventions for consideration is recommended by the purchasing authorities in Trent and approved by the Purchasing Authorities Chief Executives (PACE) and the Trent Development and Evaluation Committee (DEC). A public health consultant from a purchasing authority leads on each topic and is assisted, as necessary, by a support team from ScHARR which provides help including literature searching, health economics and modelling. A seminar is then led by the consultant on the particular intervention where purchasers and provider clinicians consider research evidence and agree provisional recommendations on purchasing policy. The guidance emanating from the seminars is reflected in this series of Guidance Notes.

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EXECUTIVE SUMMARY

Cochlear Implantation (CI) is a rapidly evolving health technology which restores useful forms of auditory sensation to people who are profoundly deaf, through electrical stimulation of the auditory nerve with electrodes implanted in the inner ear (the *cochlea*). The primary intention is to reduce disability and to improve the quality of life by increasing the capacity for using spoken language.

CI is suitable for two classes of client:
(a) children and adults who lost their hearing after learning spoken language; and
(b) young children who either lost their hearing before acquiring spoken language or who were born deaf.
There are approximately 4,000 suitable candidates for CI in the UK. Current uptake patterns suggest that 1,600 will seek and receive CI. A district with a population of 0.5 million would expect up to one new post-lingually deafened client every two years, and two new pre-lingually deafened clients per year. There would also be a backlog of up to 20 post-lingually deafened clients and up to 12 pre-lingually deafened clients.

The discounted cost of implantation and long-term management is £36,400 for adults and £57,400 for children. The cost per QALY for CI is £13,300 (range £10,200 to £30,500).

The cost effectiveness of CI is likely to be improved by ensuring that the intervention is provided by appropriately trained specialist teams, with sufficient workload to maintain their skills, operating in specialist centres. Patient selection should also be encouraged to ensure that CI is provided to those patients most likely to benefit.

It is recommended that, for patients meeting the candidature criteria set out in this guidance, purchasers should agree funding for the provision of CI in specialist Cochlear Implantation Centres, within agreed guidelines governing candidature and with the assurance that the results of audit are reported.

1. INTRODUCTION

1.1 Cochlear Implantation : Incidence and Pathology

Cochlear Implantation (CI) is a rapidly evolving health technology which restores useful forms of auditory sensation to people who are profoundly deaf, through electrical stimulation of the auditory nerve with electrodes implanted in the inner ear (the *cochlea*). The primary intention is to reduce disability and improve quality of life by increasing the capacity for using spoken language. CI was introduced to the NHS through a 4-year Government initiative (1990-1994) during which central funds partly underwrote the costs of provision by selected provider units.

(i) Implant Systems

Implant systems consist of external and internal components. Externally, a microphone, worn above the ear, is connected to a speech processor, typically carried on a belt or in a pocket, which in turn is linked to a transmitter coil placed on the outside of the head. The processor converts the signal from the microphone into a form suitable for radio-frequency transmission, through the scalp, to a receiver-stimulator package which is placed in a well fashioned surgically in the skull behind the ear. The receiver-stimulator decodes the radio-frequency signal and converts it into electrical pulses which are sent to an array of electrodes implanted surgically in the inner ear.

The preferred form of implant system is 'multi-channel'. Such systems divide the acoustic signal into a set of discrete frequency bands. The pattern of energy in different bands is represented by the pattern of electrical stimulation on different members of the array of implanted electrodes. In this way, the normal mapping between acoustical frequency and place of stimulation in the cochlea is partly restored.

(ii) Management of Patients

Management of patients involves four phases:
(a) pre-operative assessment and counselling, to determine suitability and to ensure informed consent to treatment;
(b) surgery;
(c) rehabilitation, including device tuning and speech/hearing therapy;

(d) long-term maintenance, to diagnose and remedy technical problems and, periodically, to upgrade processors.

(iii) Causes of Profound Deafness and Prospects for Prevention

Profound deafness has many causes. It may be present at birth or develop at any point in life. Prospects for prevention during the next decade of more than a small proportion of cases are limited. It is estimated [1] that there are 150,000 people in the UK with profound hearing impairment (an average reduction of sensitivity of 95 decibels (dB) or more compared with normal hearing in the ear which has better hearing; a person with this degree of hearing loss would be characterised as having a 'hearing level' of 95 dB).

(iv) Candidates for CI

CI is suitable for two classes of client:

(a) children and adults who lost their hearing after learning spoken language ('post-lingually' deafened clients); and
(b) young children who either lost their hearing before acquiring spoken language or who were born deaf ('pre-lingually' deafened clients).

1.1.1 Demand for CI

(i) Post-lingually-deafened Children and Adults

Candidature is defined by the intersection of :

(a) profound deafness;
(b) post-lingual acquisition;
(c) an inability to obtain material benefit from acoustic hearing aids;
(d) physical and intellectual fitness for surgery and rehabilitation; and
(e) a strong commitment to treatment.

The application of constraints (b)-(d) limits the number of candidates in the UK to approximately 4,000. Current patterns of uptake imply that 1,600 of them will seek and receive CI. [2]

(ii) Young Pre-lingually Deafened Children:

Candidature is defined by the intersection of:
(a) profound deafness;
(b) an inability to obtain material benefit from acoustic hearing aids; and
(c) a strong commitment to treatment on the part of parents and teachers.
Approximately 220 children are born with profound hearing loss each year in the UK. A further 80 lose this degree of hearing by the age of five, primarily as a result of meningitis.[3] It is estimated that CI will be sought on behalf of a high proportion of this population and that as many as two thirds will be clinically suitable to receive the service.

(iii) Uptake of Services to Date

Approximately 800 adults and 600 children have received CI in the UK. Approximately 15,000 people have received CI world-wide.

(iv) Expected Demand

Table 1 provides estimates of the demand for CI in the UK, developed from epidemiological data on the prevalence and incidence of profound deafness, and on the uptake of CI services. [2]

Table 1: Expected Demand for Cochlear Implantation in a District with a Total Population of 0.5m

CLIENT GROUP	BACKLOG	ANNUAL INCIDENCE
Post-lingually deafened clients (children and adults).	14 (range 11-20, minus cases already implanted)	0.5 cases (i.e. 1 case every 2 years) (range 0-2)
Pre-lingually deafened clients (children 2-6 years)	10 (range 7-12, minus cases already implanted)	2 cases (range 0-4)

2. COCHLEAR IMPLANTATION : SUMMARY OF EVIDENCE OF EFFECTIVENESS

2.1 Evidence of Effectiveness for Adults

Acquired profound deafness is a chronic condition for which CI is an elective treatment of last resort. As candidature for CI is defined partly by the inability to benefit from alternative therapies, randomised controlled trials (RCTs) comparing CI with other therapies have not been conducted. Instead, repeated-measures, involving tests on the same patients before and after implantation, have been used. These show consistent evidence of benefit in terms of improved communication skills and increased quality of life.

Table 2 summarises outcomes measured in the UK during the MRC evaluation of the National CI Programme.[2] These data were obtained from adults (18 years and older) who could not understand speech without lip-reading using acoustic hearing aids. The outcomes were first measured 9 months after implantation and were maintained without change when re-measured 18 months after implantation.

These levels of outcome were shown when patients were equipped with 2nd-generation implant systems. Similar levels have been shown elsewhere in the world by patients equipped with 2nd-generation systems. Higher levels are now reported from patients using 3rd-generation systems.

The single most important outcome from CI is continued use of the implant system, because patients have the option of ceasing to use the device if it brings no benefit. The asymptotic level of elective non-use, estimated by survival analysis 5 years after implantation, is 8%.[2] Thus, by this measure, the ratio of the number of patients benefiting to the number treated (0.92) is high in relation to many other treatments.

In addition to the outcomes listed in Table 2, the family and friends of patients reported:

- amelioration of major difficulties of communication in relationships;
- less need to simplify messages;
- less fatigue engendered in patients by the need to ensure that messages had been understood;
- less need to assist patients to communicate with others; and
- greater participation by patients in activities outside the home.

Table 2: Outcomes from Cochlear Implantation for Post-lingually Deafened Adults [2]

OUTCOME MEASURE	% PATIENTS DISPLAYING OUTCOME	COMMENTS
1. Suitable referral willing to proceed with treatment	50%	Sophisticated techniques for assessing candidature make improved accuracy of pre-referral assessment unlikely.
2. Evidence of use All day while awake At least 10 hours per day At least 4 hours per day	 50% 80% 90%	 Data from patients with multi-channel devices. Lower rates of use recorded from patients with single-channel devices.
3. Evidence of non-use 2 years after implantation 5 years after implantation	 3-5% (multi-channel) 10% (single-channel) 8% (multi-channel)	8% non-use rate at 5 years estimated by survival analysis to be the asymptotic rate of elective non-use. Half of patients who subsequently became non-users were implanted early in the Programme.
4. Identified some common environmental sounds	97%	25% of patients identified more than 75% of sounds correctly.
5. Identified more words correctly in sentences when using implant in combination with lip-reading than when lip-reading alone.	95%	
6. Greater benefit to lip-reading than achieved pre-operatively with acoustic hearing aid	80-90%	Data from sub-set of patients with sufficient residual hearing for pre-operative testing with hearing aid(s) to be feasible.
7. Identified some words correctly in sentences without lip-reading	50%	Score of 10% correct or greater; 15% of patients scored 50% or more correct. (>50% corresponds to useful ability to converse without lip-reading.)
Demonstrated some understanding of questions posed over the telephone by an unfamiliar talker	35%	Score of 10% correct or greater; 15% of patients scored more than 50% correct. (>50% correct corresponds to useful ability to converse using telephone.)
Improved quality and/or intelligibility of own speech	70%	Most of remaining 30% already produced speech of acceptable quality and/or intelligibility.
8. Tinnitus attenuated or eliminated	50%	Two-thirds of implanted patients experienced tinnitus pre-operatively; tinnitus was attenuated or eliminated in half of them.
9. Reduction in self-reported hearing handicap	90%	
10. Improvement in quality of life measured retrospectively with Glasgow Benefit Inventory	96%	Average change in quality of life is greater than that reported by moderately impaired patients

		managed with hearing aids.
11. Positive change in health-related quality of life measured retrospectively with EuroQol visual-analogue scales	94%	Average change +0.23 on scale where 1 and 0 correspond to best and worst imaginable states of health.
12. Occupational status	No change	40% were in paid employment pre- and post-operatively.
13. Satisfaction with job	No change	
14. Extent of unpaid work	No change	
15. Average no. of people on whom patients relied for help in overcoming problems of communication	6 (pre-op) 3.5 (post-op)	Average amount of help required from each helper was also reduced.
16. Medical/Surgical complications		
a) Mortality	nil	No. of operations monitored: 244 (adults) 136 (children)
b) Major problem	10% (adults) 7% (children)	Including: damage to VIIth nerve causing facial paralysis; infection or necrosis of skin flap; cholesteatomas; mispositioning or movement of the electrode array. All treated successfully by revision surgery or medical management. Probability of complications declines steeply over first 10 patients managed by a surgeon.
c) Failure of implanted device	1.6% (adults) 0.7% (children)	
d) Revision surgery	4.3% (adults) 2.2% (children)	
e) Minor problem	25% (adults and children)	Overcome by medical management or by retuning or replacing processors. High rate of technical problems due to lack of robustness of external components, notably Nucleus processors and Ineraid percutaneous connectors.

2.2 Evidence of Effectiveness for Children

For this client group, the immediate goal is to provide access to sound; the medium and long-term goals are to enable the acquisition or retention of useful forms of spoken

language leading first, to improved scholastic attainment and, then, to enhanced social independence and quality of life in adulthood.

An RCT, though theoretically desirable, would be of impractically long duration, and might now be considered unethical for clearly defined candidates. The most powerful research designs have involved longitudinal case-control comparisons of children with implants and children managed with hearing aids or tactile aids.[4,5] These studies have shown that children selected for CI typically have hearing levels exceeding 110 dB. With implants, these children function better than children with the same hearing levels who are managed with hearing aids or tactile aids. They function about as well as less impaired children with hearing levels of 90-100 dB who are equipped with hearing aids. Such children generally make good use of hearing aids and develop useful forms of spoken language. The linkage encourages the belief that children with implants will go on to develop spoken language.

Since 1991, paediatric CI in the UK has undergone radical changes in attitude and level of activity following the results of a trial in North America that led to the endorsement by the Food and Drug Administration of an implant system for use with children. The MRC Evaluation obtained observational data on initial outcomes from children implanted in the UK and reviewed the literature internationally, reaching the following conclusions:

- *Post-lingually deafened children:* Good outcomes are generally obtained for children of all ages, provided that there is a strong commitment to CI by the child, family, and teachers; outcomes are particularly good when implantation occurs soon after the onset of profound deafness; evidence of speech understanding is often displayed within a few months of implantation.

- *Pre-lingually deafened children:* Generally, there is evidence of the ability to detect and distinguish environmental sounds within a few months of implantation; evidence of the perception and production of speech emerges slowly, often not until the implant has been used for 1-3 years. The best outcomes are displayed when children are implanted before the age of 5 years; disappointing outcomes are often reported when children are implanted after the age of 10-13 years. A strong informed commitment to CI by family and teachers is essential.

Table 3 summarises evidence on effectiveness of CI in young children.

2.3 Conclusion on Direction of Evidence and its Quality

For *post-lingually deafened adults and children,* there is strong, statistically robust evidence of effectiveness for appropriately selected candidates.

For *pre-lingually deafened children,* there is strong evidence of positive initial outcomes for appropriately selected candidates. It is not yet clear what levels of skills in spoken language will be attained, nor to what extent these will be translated into enhanced scholastic achievements. Thus, **although initial outcomes are promising, further longitudinal evaluation of outcomes from implanting pre-lingually deafened children is necessary.** Similar conclusions were reached by an NIH Consensus Development Conference. [6]

Table 3: Outcomes from Cochlear Implantation for Pre-lingually Deafened Children

OUTCOME MEASURE	% PATIENTS DISPLAYING OUTCOME	COMMENTS
1. Evidence of use Full time: ≥10 hours per day Part time: 4-10 hours per day Non-users	 87% 10% 3%	 Data from Reference [2] obtained by surveying outcomes for ~130 children implanted in the UK by January 1994.
2. Auditory and linguistic skills 2.1 Six months after CI Ability to identify some environmental sounds. Ability to discriminate among a limited set of simple speech sounds. 2.2 Two years after CI Ability to understand simple phrases without lip-reading, provided that the talker is familiar and there is a strong constraining context. 2.3 Three years after CI Ability to participate in conversation with a familiar talker without lip-reading.	 70% 50% 50% 50%	Data from Reference [2] (i) Best outcomes are obtained for children implanted before the age of 5 years. (ii) Disappointing outcomes often reported if implantation occurs after the age of 10-13 years. (iii) Strong informed commitment to CI from family and teachers essential.
3. Medical/surgical complications	No more frequent than adults	See Section in Table 2.
4. Pre-verbal communicative behaviour. 5. Speech perception.	Similar to that of less impaired children managed with hearing aids who went on to develop useful forms of spoken language.	Data from Reference [4] Data from Reference [5]

3. COST AND BENEFIT IMPLICATIONS OF ADOPTING INTERVENTION

CI is a new health technology which does not replace a previous or alternative intervention. The costs of CI are, therefore, true additional costs. Savings are most likely to occur within the budgets of education and social services as a result of reduced dependency on special education, on special equipment for daily living, and on social support in adulthood.

3.1 Costs of Providing Cochlear Implantation

The MRC evaluation measured the costs of providing CI and estimated the future costs, listed in Table 4 (inflated to 1996 price levels). Costs of provision to adult clients were averaged over nine service providers. Costs of provision to children were measured in a single hospital and may not be representative of the cost of providing paediatric implantation generally. The costs of long-term management are listed twice, first with future costs discounted to present price levels at 6% per annum, and second with future costs not discounted. All sums in Table 4 include the cost of the implant system (£13,000).

Table 4: Costs of Cochlear Implantation and Long-term Management (1996 price levels)

TIME-PERIOD	ADULTS	CHILDREN
Assessment, implantation, rehabilitation in first year	£23,600	£27,300
Assessment, implantation, rehabilitation, and maintenance for a total of 12 years	£31,800 (future costs discounted) £33,000 (future costs *not* discounted)	£47,900 (future costs discounted) £53,000 (future costs *not* discounted)
Assessment, implantation, rehabilitation, and maintenance over life-time	£36,400 (future costs discounted) £49,700 (future costs *not* discounted)	£57,400 (future costs discounted) £119,600 (future costs *not* discounted)

Current charges for CI services by providers in Trent Region, or within easy access from Trent, are given in Tables 6 and 7

3.2 Cost-utility

The MRC evaluation estimated the cost-utility of CI for post-lingually deafened adults. Sensitivity analysis was used to set plausible limits on the range of estimates. Given that the average age at the time of implantation in the UK has been 49 years, future costs and benefits were aggregated over an expected further life-time of 26 years. Future costs were discounted to present price levels at 6% per annum. The results, inflated to 1996 price levels, are:

- £13,300 per QALY (range £10,200 - £30,500) if future benefits are discounted at 6% per annum.
- £6,600 per QALY (range £5,100 - £15,300) if future benefits are not discounted.

According to these estimates, the cost-utility of CI falls in the middle of the range of frequently quoted estimates for therapies in the UK (Table 5) and represents acceptable value for money.

These calculations were based on measurements made during the introduction of CI to the NHS. Technical improvements in implant systems leading to better outcomes, and increases in the efficiency of patient management, should improve cost-effectiveness. Further research is required to establish whether the expected changes occur.

Table 5: Cost/QALY of Cochlear Implantation and Other Therapies

THERAPY	**COST/QALY (£ 1996)**
Pacemaker insertion	1,300
Renal transplantation	5,700
Heart transplantation	9,500
Cochlear Implantation (adult)	**13,300**
Home haemodialysis	21,000
Hospital haemodialysis	26,700

Table 6: Charges for Adult Cochlear Implantation set by Hospitals in Trent or within Easy Reach of Trent

PROVIDER	CHARGES (£)						
	Assessment	Implantation + 1st Year	Years 2-3 (price / year)	Year 4+	Do follow up costs cover upgrades?	Total at 5 years (not discounted)	Total at 12 years (not discounted)
Queen's Medical Centre, Nottingham **1996/97** **1995/96**	 1,500 3,000	 24,500 24,500	 1,350 1,350	 1,350 1,350	 Yes Yes	 31,400 32,900	 40,850 42,350
University Hospital, Birmingham (formerly QEH)	483	24,584	1,416	1,416	Yes	30,731	40,643
Addenbrookes, Cambridge	1,215	22,860	1,700	1,700	Yes	30,875	42,775
Royal Infirmary, Bradford	670	25,142 + 227 yr 1	1,339	1,159	Yes	31,035	39,148
Royal Infirmary, Manchester	448	28,038	1,402	1,402	Yes	34,094	43,908
Royal Hallamshire, Sheffield	250	27,500	1,500	1,200	No	33,150	41,550

Table 7: Charges for Paediatric Cochlear Implantation Set by Hospitals in Trent or within Easy Reach of Trent

PROVIDER	CHARGES (£)						
	Assessment	Implantation + 1st Year	Years 2-3 (price / year)	Year 4+	Do follow up costs cover upgrades?	Total at 5 years (not discounted)	Total at 12 years (not discounted)
Queens Medical Centre, Nottingham	1,115	27,000 (includes assessment)	4,250 (covers both years)	2,000	Yes	35,250	49,250
Children's Hospital, Birmingham	1,585	26,476 (includes assessment) +2,660 yr 1	1,860	1,860	Yes	36,576	49,596
Addenbrookes, Cambridge	1,215	29,200 (includes assessment)	1,700	1,700	Yes	36,000	47,900
Royal Infirmary, Bradford	824	25,142 (excludes assessment) +490 yr 1	2,307 (yr 2) 2,153 (yr 3)	1,993	Yes	34,902	48,853
Royal Infirmary, Manchester	448	30,734	1,225	1,225	Unknown	36,082	44,657

3.3 Sustaining and Improving Cost-effectiveness

The following are the key considerations in sustaining and improving the cost-effectiveness of CI services.

3.3.1 Professional Composition of CI Teams

A multi-disciplinary team is required with training and experience appropriate to the age group of clients to whom services will be directed. Team members should have received specific training in their roles as specified by Summerfield and Marshall.[2] The size of a team should reflect its caseload. Teams should include:

- medical/surgical skills from an ENT surgeon with established interests in neuro-otology;
- scientific/technical skills from medical physicists or clinical audiologists;
- rehabilitative skills from professionals with experience in speech therapy, hearing therapy, and/or the teaching of deaf children;

- a programme co-ordinator from one of the above grades to whom the lead surgeon delegates responsibility for the day-to-day management of the programme.

In addition, access to a clinical psychologist is advisable.

3.3.2 Choice of Impant Systems

Modern multi-channel devices are strongly preferred. Devices should be of proven reliability and should be familiar to implant teams in order to minimise complication rates in surgery, failure rates of implanted components, time spent tuning, and time spent diagnosing problems. In choosing devices, teams should:

- obtain evidence of effectiveness and reliability from manufacturers and from the clinical scientific literature;
- obtain assurance of long-term support from manufacturers;
- select devices that have been awarded the CE mark of the European Union;
- develop a high level of expertise with each device they provide.

3.3.3 Maintaining Skills

Consensus of opinion suggests that **at least 12 new adult and/or child cases are required per CI centre per year for viability**. The incidence of medical/surgical complications falls with increasing experience of surgeons. There is no absolute number recommended to maintain skills.

3.3.4 Siting of CI Centres

CI is a low-volume treatment. A sustained throughput of patients is required to ensure the long-term viability of CI programmes. Provision should be concentrated in provider units located within easy access of the main population centres in the UK.

In view of the size of the backlog of patients, there may be proposals to establish additional provider units. However, the incidence of new candidates, according to current criteria, is unlikely to sustain all centres that already exist. Purchasers should consider the merits of concentrating purchasing on a small number of expert providers who manage high-volume programmes.

3.3.5 Criteria of Candidature

Cost-effectiveness will be optimised by selecting patients who are most likely to benefit, and least likely to develop complications or become non-users. The following criteria are relevant:

Adults

- Profound bilateral deafness of cochlear origin (average hearing level >95 dB);
- Onset of profound deafness after acquiring spoken language;
- No material benefit from acoustic hearing aids (average *aided* thresholds greater than about 60 dB(A));
- No material ability to understand speech using acoustic hearing aids (typically score less than 10% correct on a test requiring the identification of words in sentences without lip-reading);
- No morphological abnormality of the inner ear that would prevent the placement of electrodes close to surviving fibres of the auditory nerve;
- Intellectually fit and mentally alert (no major psychological contra-indications; IQ>70);
- Committed to their own health care and to the proposed treatment.

Outcomes from adult implantation are highly variable, although positive for the great majority of patients individually. Statistically, the best outcomes tend to be achieved by patients with three characteristics:

- Recent onset of profound deafness;
- Some measurable residual hearing;
- Proven skills in spoken language demonstrated by good lip-reading.

Children with post-lingual deafness

- The criteria listed above for adults apply here also.

Children with pre-lingual deafness

- Profound bilateral deafness of cochlear origin (average hearing level >95 dB);
- No material benefit from acoustic hearing aids (average *aided* thresholds greater than about 60 dB(A);
- Generally, age 2 years and older; CI may be indicated for some post-meningitics before the age of 2;
- No morphological abnormality of the inner ear that would prevent the placement of electrodes close to surviving fibres of the auditory nerve;

- Strong commitment to treatment and to spoken language on the part of parents and teachers;
- Implantation between the ages of 1 and 4 (i.e. before school entry) produces the best outcomes statistically. After the age of 10-13 years, outcomes are often poor and CI should not generally be encouraged; however, exceptional cases do arise, but should be justified on an individual basis.

3.3.6 Competition Between Manufacturers

Consortia of providers should be encouraged to negotiate favourable prices for bulk purchase of implant systems with established manufacturers.

3.3.7 Purchasing Strategy

To ensure that responsibilities are clearly located for:
(a) justifying decisions to treat in relation to criteria of candidature;
(b) furnishing audit and outcomes data; and
(c) long-term maintenance of patients and devices.
A complete service for an individual client should be purchased from a single provider. Primary providers may engage secondary providers located closer to patients' homes to provide aspects of pre-operative assessment and long-term maintenance.

3.4 Emerging Trends

3.4.1 Candidature

In the USA, outcomes achieved by traditional candidates using 3rd-generation implant systems exceed those achieved by less impaired patients who obtain measurable, but very slight, benefit from hearing aids.[5] As a result, criteria of candidature have been relaxed to include some of these 'marginal hearing-aid users'. One aim is to enable early provision to clients with progressive hearing losses. Further multi-centre research is needed in the UK to assess the cost-effectiveness of CI for this new group, and to specify revised protocols for assessing candidature. **For the immediate future purchasers should continue to use the criteria of candidature as set out in this Guidance Note.**

In the USA, cost-savings have been achieved in the management of patients by reducing in-patient stays to one night and by minimising the amount of therapeutic rehabilitation provided to adult patients. Further research is needed to establish whether these changes are compatible with sustained cost-effectiveness.

3.4.2 Developments in Technology

There is no alternative technology on the horizon. Within the next two years, smaller implant processors, styled like ‘behind-the-ear’ hearing aids, will appear. Over the next decade, totally implantable devices with advanced technical specifications may be developed, along with less advanced devices in which current levels of technology are consolidated at lower cost. Over the last decade, the real cost of implant hardware has fallen slightly, despite improvements in the technology. This trend should continue.

4. OPTIONS FOR PURCHASERS AND PROVIDERS

The following options were discussed during and after a seminar held by the Trent Institute's Working Group on Acute Purchasing:

Option 1 Purchasers should agree to fund only in the context of formal multi-centre clinical studies.

Option 2 Present arrangements should continue. Funding should be agreed for provision:

- In Cochlear Implantation centres;
- Within agreed guidelines governing candidature;
- With the assurance that the results of audit are reported.

Option 3 Funding should be agreed for widespread provision, extending beyond existing established provider units.

5. DISCUSSION AND CONCLUSION

After discussion at the Trent seminar between representatives of purchasers and providers of Cochlear Implantation, it was concluded that:

- There was strong evidence of the effectiveness of CI for adult and child clients meeting the criteria of candidature in this Guidance Note. (Those criteria are listed in the Summary Matrix overleaf). For this group of clients, Option 2 above should be adopted i.e., purchasing should continue as at present from established CI centres.
- For non-traditional candidates, i.e. patients who gain measurable but slight benefit from acoustic hearing aids, Option 1 above should be adopted i.e., purchasing should be agreed only in the context of formal multi-centre clinical studies.
- Prior to purchasing, evidence was required of:
    - levels of experience of the surgeon and other team members;
    - rationale for choice of devices;
    - number of clients implanted at the centre to date;
    - incidence of major complications, including those leading to decisions to explant devices;
    - incidence of elective non-use of devices by implanted clients.
- Purchasers should purchase the complete service for a client (assessment, implantation rehabilitation, and maintenance) from the same provider.
- Purchasing consortia should be considered in view of the small number of clients for each individual purchaser.
- Purchasers should consider the merits of concentrating purchasing on a small number of expert providers, who manage high volume programmes.
- Provider consortia should be encouraged to negotiate more favourable prices for bulk purchases of implant systems with established manufacturers.

6. COCHLEAR IMPLANTATION: SUMMARY MATRIX

CLIENT GROUP	CRITERIA OF CANDIDATURE	LIKELY UPPER LIMITS ON DEMAND IN A BENCH-MARK DISTRICT WITH A POPULATION OF 0.5 m		OPPORTUNITIES TO IMPROVE COST-EFFECTIVENESS	AUDIT
		BACKLOG	ANNUAL RECURRENT DEMAND		
All clients	• Profound bilateral deafness of cochlear origin (average hearing levels >95 dB). • No material benefit from acoustic hearing aids (average aided thresholds >60 db(A)). • No morphological abnormality of the inner ear that would prevent the placement of electrodes close to surviving fibres of the auditory nerve.			• Encourage concentration of services. • Ensure appropriately trained and experienced multi-disciplinary team. • Ensure at least 12 new patients implanted by centre per year. • Ensure provision of modern multichannel implant systems of proven effectiveness and reliability with which the team is familiar. • Encourage competition between manufacturers.	**Structure** • Composition, training, and experience of team. • Rationale for choice of devices. **Process** • Number of patients being implanted annually. • Arrangements for long-term maintenance of patients and devices. **Outcomes** • Incidence of major complications, including those leading to decisions to explant devices. • Incidence of elective non-use of devices by implanted clients.
Adults and	• Profound deafness	14 (range:	0.5 (range 0-2)	**Cost of treatment**	**Outcomes**

older children	acquired after learning spoken language. • No material ability to understand speech using acoustic hearing aids (typically score less than 10% correct on a test requiring the identification of words in sentences without lip-reading). • Intellectually fit and mentally alert (no major psychological contra-indications; IQ>70). • Committed to their own health care and to the proposed treatment.	11-20) (less patients already implanted).	(i.e. 1 patient every 2 years with a likely range from no patients to 2 patients per year).	**over 12 years:** ~£33,000 **Cost-utility:** £13,300/QALY (assuming 26 years of use, with upgrades, and future costs and benefits discounted at 6% per year)	• Gain in accuracy of speech-perception compared to pre-operative state. • Gain in quality-of-life compared to pre-operative state.
Younger children	• Profound deafness acquired either before or after learning spoken language. • Strong commitment to treatment and to spoken language by family and teachers, and, if possible to assess, the client. • Preferably under the age of 5 years, allowing implantation before school entry. • After the age of 10-13 years, outcomes are often poor and treatment should not be encouraged.	10 (range: 7-12) (less patients already implanted).	2 (range: 0-4) (i.e. 2 patients per year with a likely range from no patients to 4 patients per year).	**Cost of treatment over 12 years:** ~£53,000	**Outcomes** • Observational measures of performance.

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