Scottish Needs Assessment Programme

Needs Assessment
SNAP
A National Approach

Paediatric Cochlear Implantation

SCOTTISH FORUM FOR PUBLIC HEALTH MEDICINE

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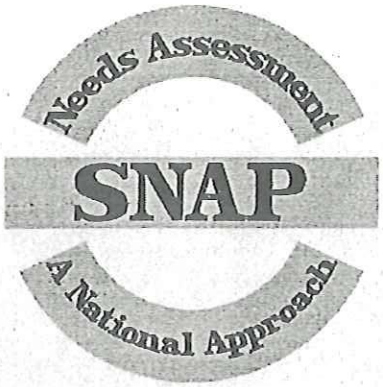
Scottish Needs Assessment Programme



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Acute Services Network

Paediatric Cochlear Implantation

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Further copies of this report are available from Ms Jackie Gregan, SNAP, 69 Oakfield Avenue, Glasgow G12 8QQ, tel: 0141 330 5607.

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EXECUTIVE SUMMARY

1 Cochlear implantation is a new technology based procedure for the restoration of hearing to profoundly deaf people.

2 An estimated 20 children per year in Scotland (range 14-24) may be suitable for the procedure. The indicative figure may rise to 27 (range 21-33) if the threshold for appropriate treatment is relaxed. There is, in addition, an estimated backlog of 100 children between the ages of 2-7 years who would be candidates according to the current audiometric criterion.

3 Evidence is accumulating that implantation in association with detailed assessment and prolonged rehabilitation is a safe and effective intervention in children, including those who have never acquired spoken language.

4 There is still a lack of data to detail the potential of implantation to enable full conventional communication and pursue a 'normal' hearing lifestyle. Educational attainment and measures of general well-being are long-term outcomes of particular interest which require further study. Successful implantation allows the majority of children to understand common phrases without lip-reading within six months - equivalent to mild impairment.

5 The implantation and associated care are costly - around £24 700 per case. For a fully funded programme meeting estimated need, this equates to £494 000 per annum at 1995/96 prices.

6 In view of the highly selective nature of the procedure and the potentially high level of expectation and demand it is necessary to have clear guidance on patient selection and the strategic development of the service. This guidance can be developed efficiently on a national basis.

7 In Scotland, the National Services Division contracted with North Ayrshire & Arran NHS Trust to implant four children for 1993/94 and ten in 1994/95. In addition, National Services Division understands that a further four children were referred for assessment to a centre in England in 1994.

8 Health Boards will wish to consider the future of cochlear implantation for Scottish children.

9 This paper draws on the full MRC Institute of Hearing Research Evaluation Study for cochlear implantation for both adults and children, partly funded by the Chief Scientist Office of the Scottish Office.

ISSUES FOR PURCHASERS

1 Purchasers should consider the number of cochlear implants required for local populations, based on the epidemiological and actual assessment of need.

2 The number and configuration of centres to fulfil the need will include the following possibilities:

   a) development of the existing Scottish service in Ayrshire.

   b) developing of a second centre, or alternative centre in Scotland - for example, Edinburgh.

   c) development of links with an English centre carrying out large numbers of implantations with demonstrably good outcomes.

Given the small numbers involved, and the early stages of paediatric evaluation, there is a shortage of published objective data to inform the purchasing process in this respect. However, established units achieving higher patient volumes offer the prospect of high quality outcomes.

While accepting the effectiveness of the intervention to the (hearing) professionals and grateful recipients, purchasers should pay heed to the debate within the deaf community about the desirability of imposing hearing on an otherwise 'normal' child.

Further purchasing considerations are:

1 increasing demand from referral of children for implantation, and the management of the process in response to need.

2 effective and comprehensive methods of consultation (see suggestions in section 6) including local providers of rehabilitation services.

3 more detailed financial data from the MRC evaluation study to compare with existing Scottish data.

4 full discussion of the evaluation study's findings.

5 the prospect of further evaluation data entering the published literature.

6 participation by providers in multicentre prospective studies as a method of validating existing data on effectiveness.

7 deriving ways of comparing the value of benefits gained from implantation compared to other interventions, against the substantial cost.

8 scrutiny of rehabilitation cost allocation, particularly where this may be borne by shared care locally.

1 INTRODUCTION

Cochlear implantation was introduced in the United Kingdom for children in 1989. The procedure describes the placement of electrodes in the inner ear, and is the central event in a complex process which includes sophisticated electronic devices and intensive clinical management. The implant is suitable for the profoundly deaf - that is, those who cannot benefit from conventional hearing aids.

Given that cochlear implantation is an expensive procedure, patients have been the subject of careful assessment prior to surgery and a lengthy programme of post-operative rehabilitation. In the United Kingdom, the process has been the subject of a MRC Institute of Hearing Research Evaluation co-funded by the Chief Scientist Office. The study was initially set up prospectively for adults and coordinated from the institute's headquarters in Nottingham. Evaluation of the procedure for children has been additional and parts are retrospective, although data collection has been rigorous and of a high quality. The coordinator and author of the study, Professor Quentin Summerfield, has kindly copied to National Services Division a draft of the paediatric chapter of the final report. Separate from the evaluation study, the largest programme of paediatric implantation in the United Kingdom is based in Nottingham at the Queen's Medical Centre, University Hospital.

Implantation in children became possible in the United States in 1990 following clearance by the Food and Drugs Administration (FDA) for use of the Nucleus 22-channel implant in children aged two years and over. Initially, implants were offered to children who had acquired and then lost ability to speak (post-lingual). Evidence recently has supported benefit in pre- or peri-lingual children - those who were deafened before acquiring spoken language. Worldwide, approximately 2500 implants have now been given to children under ten years old.

Adult cochlear implantation was first undertaken in 1984. Worldwide experience totals 11 500 implants. In the United Kingdom ten centres will have carried out about 600 implants by the end of 1995. Scotland has two units, in Crosshouse Hospital, Ayrshire and the Royal Infirmary of Edinburgh.

This assessment has been produced in response to steadily growing demand for paediatric cochlear implantation in Scotland, and the need to take account of the MRC Evaluation study findings in order to advance consultation among Health Boards, providers, interested professionals, the deaf community and carers.

2 PROFOUND DEAFNESS IN CHILDREN

Profound deafness is defined here as an average threshold in the better ear greater than 105 decibels (dB). At such a level, a child's hearing is not amenable to conventional hearing aids. A child who may benefit from cochlear implantation requires to have an intact inner ear (cochlea) capable of receiving an implant and the messages it transmits.

Such children are rare. One in 2439 (95% confidence interval 1:1961 to 1:3030) children have average losses greater than 95 dB, while one in 3226 (95% confidence interval 1:2703 to 1:4545) have average losses greater than 105 dB. Their deafness arises from a variety of causes:

- Congenital nerve deafness due to:

  a) a genetic disorder (one-third)
  b) infection with Rubella or Cytomegalo-virus, or anoxia and hyperbilirubinaemia in very premature babies (one-third)
  c) unknown causes (one third)

- Acquired deafness due to:

  a) infection (meningitis)
  b) trauma

Some 70% have congenital hearing impairment and therefore have 'pre-lingual' deafness. Most of the remainder have become deaf following meningitis. Prevention of meningitis through HIB vaccination may reduce the meningitis component of the cohort from 25% to 22% of deaf children. The majority of these children are also pre-lingually deaf.

Recent improved implants have, in adult patients, provided tangible benefit to people with deafness thresholds at 95 dB. If children with similar impairment were added to those currently deemed suitable for the intervention, the need for paediatric cochlear implantation would rise by approximately one third (all causes).

The need for Scottish children at the 105 dB threshold, based on these estimates, is for 20 implantations per year for the annual cohort (range 14-24). This concurs with referral experience to Lothian clinicians, extrapolated for Scotland. Reducing the threshold to 95 dB would increase the estimated need to 27 children. In the medium term (up to five years), there may be further demand for 'catch-up' due to a backlog of cases. This is estimated at 100 cases at the 105 dB threshold (providing all suitable children are referred).

3 THE COCHLEAR IMPLANT

The implant is either a single or 22-channel platinum based sensor, connected to an electronic pad under the skin behind the ear. This, in turn, apposes a transducer placed over the skin, connected to a sophisticated sound processor equivalent to a hearing aid. The Nucleus 22 channel device is currently the only established multi-channel implant on the market. There are, however, other multi-channel devices used in research that are awaiting FDA approval.

Single channel devices have poorer outcomes and should only be used in patients with damaged cochleas (ossification) or with morphological abnormalities of the mastoid. All devices require tuning which is carried out following connection of the external electronic system and is tailored to the individual.

4 MODEL OF EFFECTIVE CARE

4.1 Patient Assessment

This process is skilled and complex. The diagram on the following page shows the recommended sequence of prospective evaluation procedures. This process is extensive and may take several weeks. Note that discharge may occur at several points within the process. Professional consensus supports the view that proper assessment is crucial to the selection of appropriate patients, ultimate effectiveness, and the reputation of the intervention. In the United Kingdom over 90% of children were appropriately selected on the basis of average hearing levels. This is likely to be greater than 90% for the Scottish Unit given the use of conservative criteria (Professor Quentin Summerfield - personal communication).

4.2 Implantation

This is carried out by an ear, nose and throat (ENT) surgeon skilled and experienced in the procedure. The implant is positioned through a flap lifted behind the ear and through the mastoid bone. The inpatient episode takes 5-7 days. Approximately 4-6 weeks later, after healing of the flap, the patient returns for fitting of the transducer - 'switching on' - and to begin rehabilitation.

Complication rates for this operation are very low. The Nottingham Paediatric Cochlear Implantation Programme reports one middle-ear complication 18 months post-operatively, and one device failure necessitating implant removal after 15 months, of a series of 42 children.

With experience, total inpatient durations of stay will shorten below six days.

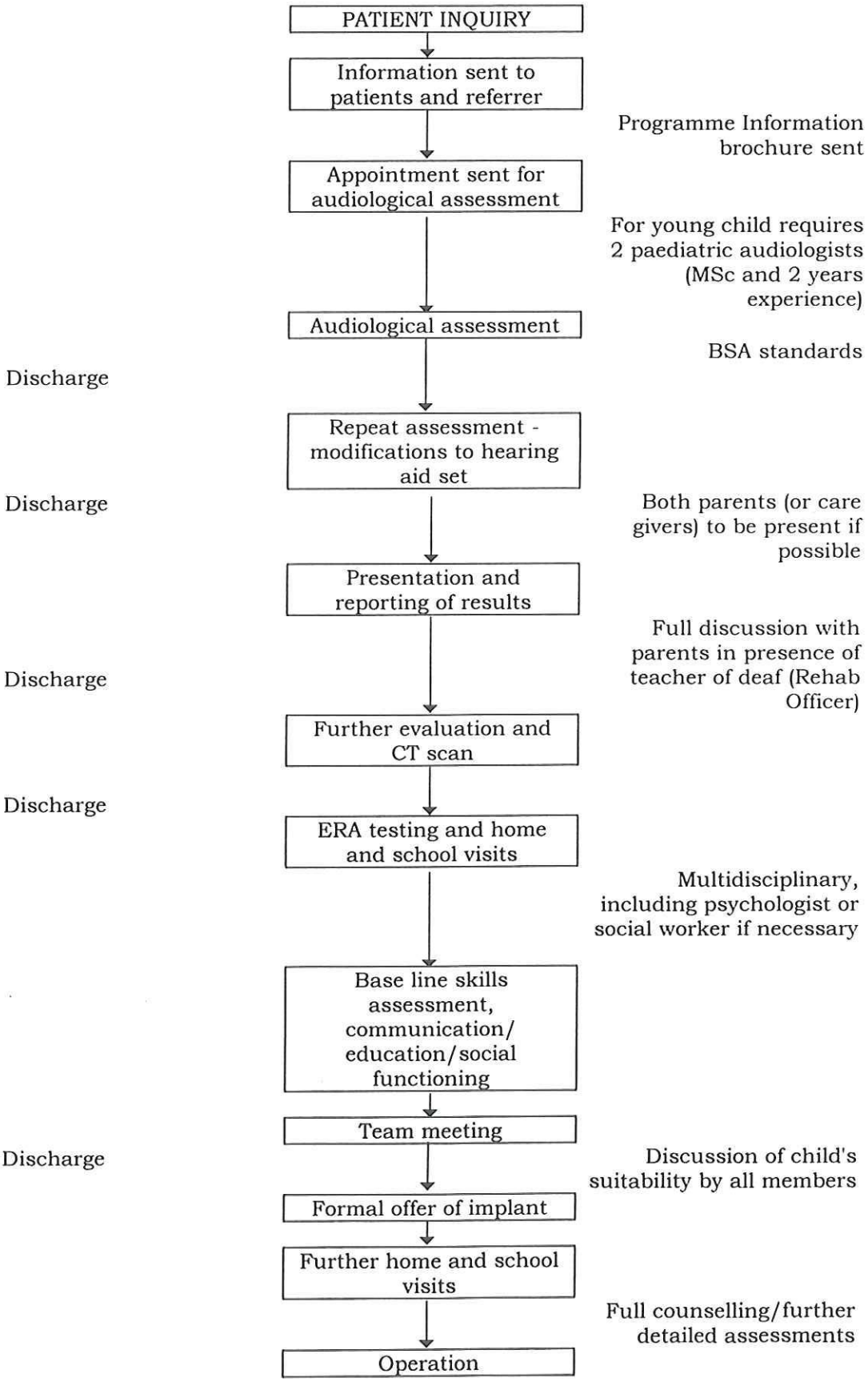
4.3 Rehabilitation

This is a multidisciplinary process on a continuing basis. Most centres around the world conduct rehabilitation at the implantation centre, and some provide residential facilities. The Scottish centre is developing a shared-care system to allow for large distances over which some patients have to travel, and to recognise the importance of training at home with the family.

The clinical team comprises:

- Surgeon
- Physicist (Audiological Scientist)
- Speech and Language Therapist
- Audiologist
- Teacher for the Deaf
- Hearing Therapist
- Administrative and Clerical Support

RECOMMENDED PATIENT CANDIDACY FLOW DIAGRAM



Eighty-five percent of children reaching six months in the study series (n=136) use their implant all the time. Poor compliance was associated with poor home support and late implantation - adolescents found learning to use their implant more troublesome than tried and tested means of communication.

Damage to external equipment is inevitable for this age group, especially when they enjoy the benefits of normal interaction with other children. The frequency of damage is approximately 0-6 times per child per year. Maintenance visits and costs and development of more robust processors by the manufacturer are, therefore, additional considerations.

4.4 Outcome

A good outcome from implantation reflects skilled communication, measured by change in linguistic status, and a high level of 'auditory receptive ability' - see table below. Children studied showed improved sign and speech ability, particularly the latter.

Auditory Receptive Ability

1	Displays no awareness of environmental sounds.
2	Is aware of environmental sounds.
3	Responds to speech sounds.
4	Recognises environmental sounds.
5	Discriminates at least two speech sounds.
6	Discriminates among five speech sounds.
7	Understands phrases without lip-reading.
8	Understands conversation without lip-reading.
9	Can use the telephone with a familiar talker.

The MRC study followed children for a limited time and, therefore, receptive abilities were skewed to the lower end of the table. It estimates a 90% chance that within four months of implantation, the child can respond to environmental sounds and speech. In contrast, a high level function such as conversation without lip-reading may be possible only after 40 months following implantation for 50%. Evidence is emerging that outcomes in pre-lingually deafened children are favourable, but significant improvements in hearing are only demonstrable over longer time periods.

In summary, the report states that outcomes are 'nearly always positive and sometimes impressive', often with rapid progress soon after implantation, although pre-lingual children may not show significant benefit fo up to two years. The majority of children should achieve level 7 ability by six months following implant (Appendix 3).

4.5 Prognostic indicators for good outcome

Established indicators include:

1 profound deafness, amenable anatomically and physiologically to intervention.

2 short period of deafness.

3 age of onset of profound deafness - better outcomes with younger age. Poorer outcomes result from implantation after the age of 7 for those deaf from early life.

4 larger number of tuned electrodes.

5 longer duration of implant use.

6 higher commitment to implantation (involvement, understanding and support) on the parts of parents and teachers.

There are no data on the effectiveness of multidisciplinary teams, or comparative data on centralised rather than shared care peripheral rehabilitation.

Outcomes for pre-lingual and post-lingual children are 'encouraging', although the rehabilitation input for the former group is greater.

High level hearing abilities does not necessarily mean that a child would cope in a mainstream educational setting. This phenomenon is an area for further study.

4.6 MRC study data on which the model is based

The total potential paediatric study cohort on which these data are based is 233 patients. Follow-up has been limited on some. Predictions and outcome variables have been based on data from 110-120 patients (based on completeness of data). As implantation experience developed, the mean age has dropped, and the case mix has shifted towards the congenitally deaf. The study cohort is, therefore, older and more likely to have acquired deafness than contemporary child cohorts.

4.7 Alternatives

Cochlear implantation is the treatment of choice for suitable children wishing to attain or recover a degree of hearing. For this group, there is no alternative of comparable effectiveness. However, debate will continue at lower thresholds of hearing impairment.

4.8 The value of implantation

While the professional community and a growing proportion of parents view the functioning implant with appropriate rehabilitation as a good and appropriate outcome, there remains debate within the deaf community that wider society is trying to 'normalise' a child within its own hearing set of

values. There remains resistance from deaf parents in particular that cochlear implantation is an inappropriate intervention. This view, however, is receding.

4.9 Value of benefit and cost

Paediatric cochlear implantation is a reasonably effective but costly intervention. Surgical complications are few and compliance is generally good. Much remains to be determined about long-term outcomes, models of the most effective rehabilitation and the most appropriate criteria for measurement. Most of all, there is no agreed value to measure the restoration of a useful degree of hearing from profound deafness. Nor is it simple to devise a consultation process which would adequately reflect opinions and derive a clear answer.

Expected benefits are in terms of:

1 disease specific

- auditory receptive ability tending towards high grades of achievement.
- other validated measurements of hearing, including audiometry.

2 social interaction with hearing children, other people and the environment.

3 towards normal educational and personal achievement.

4 towards fulfilling the potential of a child with all normally functioning senses and average abilities.

Data on the extent to which cochlear implantation can fulfil potential in all these respects is lacking, as are comparative studies. A recent economic analysis in the United States has estimated the cost per QALY for adult patients of £10 400 (range £8000 - £20 000). Disease specific data are accumulating to suggest effective outcomes. Local access to this service must be balanced against its highly specialised nature, the need for centres to develop expertise and the need for intensive and prolonged rehabilitation.

Year 1 clinical management costs include allowance for resources deployed for assessment when the child is ultimately deemed unsuitable. The ratio of those referred to those accepted is 2:1, although recent referral practice has met criteria more closely.

The current 1995/96 contract with North Ayrshire and Arran NHS Trust is a cost per case agreement and its value (for twelve cases) is £322 000:

Cost per child £26 800

42% of the cost is the implant and associated equipment (£11 980)

34% of the cost is staff

24% comprises supplies, core hospital costs and capital charges

The cost per case for a programme treating 16 or more children will fall to £24 700 reflecting the marginal cost and spreading fixed costs. Purchasers may wish to fund assessment separately. This would require identification in greater detail of clinical management costs in year 1.

The Nottingham cost breakdown is:

device costs	£12 930	(1994 contract costs)
management costs	£11 320	(end of year 1)
maintenance costs for 12 years (including upgrading)	£42 565	(future costs discounted to present at 6% per annum)

Processors are not expected to function after a protracted period, perhaps six years, which incurs approximately £6000 in replacement costs. There is, however, evidence that costs are coming down.

5 PRESENT SERVICE

The Crosshouse Hospital programme in Kilmarnock, under the leadership of Mr R J Singh, is one of the three longest established programmes in the United Kingdom (with Nottingham and Cambridge). There are now nine. Existing initially on charitable monies the Crosshouse programme is now funded through a National Contract managed by the National Services Division. The unit has undertaken 19 paediatric implantations.

The 1995/96 contract allows for twelve paediatric implantations funded by NSD. Pressures of demand and other external factors have increased implantation activity from four in 1993/94 and ten in 1994/95. One additional implantation was funded by charitable monies. We are, however, aware of four further children who have been referred to Nottingham during 1994 for assessment.

The waiting time for first assessment appointment at Crosshouse Hospital to implantation has risen from under one year to up to 24 months.

We are also aware of interest in providing a paediatric service by the second adult group working in Scotland (Royal Infirmary of Edinburgh through Edinburgh Sick Children's NHS Trust).

In England, eight centres planned to undertake 93 implantations in 1994. The crude intervention rate is currently some 60% higher, allowing for small numbers of patients and assuming no cross-border referrals from any country.

6 FRAMEWORK FOR CONSULTATION

The following tasks have already been undertaken.

1 Contemporary literature review.

2 Consultation with existing and potential providers.

3 Informal discussion with patients (two adults).

4 Extensive discussion with Professor Summerfield, coordinator of the Evaluation study and author of the report, the relevant chapter of which he kindly copied to us in draft, and on which much of this assessment is based.

5 Clinicians, and several public health physicians contemplating referral for assessment in England.

Other avenues for consultation include:

1 Other paediatric ENT clinicians, either representing potential providers or as sources of referral.

2 Clinicians in leading English institutions.

3 The full MRC study report.

4 A multidisciplinary group of specialist staff, including teachers.

5 GPs with previous experience of referral of a child.

6 Parents' support groups (a group already exists in Ayrshire).

7 Voluntary organisations for deaf people.

8 Local health councils and other statutory and non-statutory voluntary bodies.

7 AREAS FOR FURTHER DEVELOPMENT

Clearly, there is a gap between existing provision in Scotland for Scottish children and both demand and need identified through epidemiological advice contained in the MRC Evaluation study. The study recommends that no centre should be carrying out less than 10-12 implants per year, and they should be positioned appropriately for easy access for a large population (several million). However, even larger centres carrying out large numbers of implants and associated clinical management concentrate the skills of highly specialist multidisciplinary teams and offer the prospect of higher quality outcomes.

Balanced against the argument for one large centre is the need for local rehabilitation provision. The existing Ayrshire unit advocates shared care for distant rehabilitation, coupled with regular specialist centre assessment. Further consultation should address this issue, whether a comparative study would be appropriate and, meantime, whether the perception of a specialist centre equates with that of local clinicians and specialist staff.

8 OPTIONS

1 Maintain existing activity in Scotland, while recognising the demand for greater numbers of operations, some of whom will go to large English centres.

2 Increase the number of operations at the Ayrshire centre towards the lower end of estimates of need, pending improved outcomes data, comparative studies and growing awareness by the body of referring specialists. This arrangement may also recognise the need to refer to large English centres where demand exceeds supply.

3 Increase activity to the mid-range of expected need based on the 105 dB threshold.

4 Plan to meet need at the upper end of expectations, bearing in mind implant advances and widening indications for children with thresholds as low as 95 dB. Within this area there are two possibilities for Scotland - one or two units.

5 Any of the above options with competitive tendering between centres in Scotland for varying shares of the programme.

9 MONITORING

Purchasers might consider monitoring some of the following. Serial measures should be agreed with clinicians, using advice contained in the MRC Evaluation report following publication.

- Assessment criteria, possibly including domestic and local 'quality of involvement'. Referral by local clinicians fulfil the criteria in most cases.

- A suitable battery of baseline measurements for subsequent follow-up, covering a range of disease specific and wider measures.

- Skills, time spent and broad content of counselling of the child, parents, teachers and other local professional and lay carers.

- Activity statistics, measuring the number assessed, the criteria for those who fail assessment being deemed unsuitable, the number deemed suitable following assessment, the number undergoing implantation and 'switching on'.

- Process measures waiting times from secondary referral to first clinic visit/assessment; time span of visits to complete the assessment; waiting time acceptance to implantation; overall waiting time referral to implantation; length of inpatient stay; any complications; interval from implantation to 'switching on'; discharge arrangements and early rehabilitation management.

- Type of implant device.

- Audit of effective discharge planning.

- Audit of objective setting in rehabilitation to suit individual aptitudes.

- Proportion of patients entered into clinical trials, and type of trial.

- Six month and 18 month outcome measures using several serial parameters based on baseline assessment. Proportion of children at six months with level 7 auditory receptive ability.

- Comparative data on distant/local rehabilitation with central rehabilitation.

- Level of schooling and educational attainment standardised for age and duration following implantation.

- Parents' Views.

- GPs' Views.

Finance

- potential savings by bulk purchase of implants and replacement processors across the United Kingdom.

- containing rehabilitation costs, especially where local provision is a component.

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