



A FRAMEWORK FOR GOOD PRACTICE:

Managing device failure within a cochlear implant service

Introduction

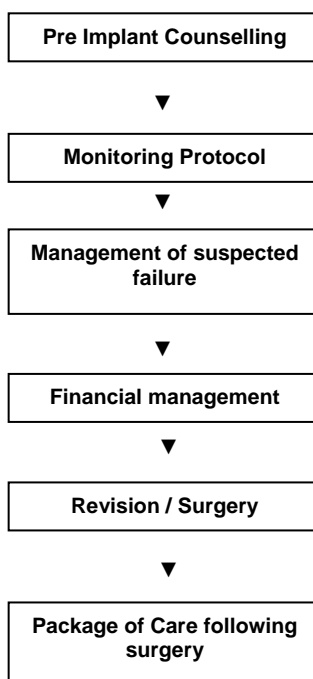
The identification and management of cochlear implant failures has been the subject of much discussion and a recent publication the European Consensus Statement on Cochlear Implant Failures and Explantations (Otol and Neurotol 2005) produced a common definition of device failure and how to report it. This described a number of categorisations for failures and explicit reporting principles. Balkany et al (2005) produced a Consensus Statement on cochlear implant soft failures or suspected implant malfunctions.

With this useful activity, it was felt that it was important to recognise that cochlear implants are technical systems that can fail and that the user may require further surgery during their lifetime. For implant programmes, with the increasing numbers of implantees, managing implant failures is likely to be a regular event. It was felt timely to explore the current ways in which implant programmes manage the needs of the users and their families. In addition, the implications for the organisations and for future planning was considered as well as the psycho-social impact of the experiences for users and families, support services and the implant team.

This protocol has been drawn up by CI co-ordinators, or their representatives, from the majority of UK implant teams and is designed to provide guidelines for implant centres in managing implant failure to promote consistency of practice and shared experience.

The following process map illustrates the care pathway:

Framework



FRAMEWORK FOR GOOD PRACTICE: MANAGING FAILURES IN A COCHLEAR IMPLANT SERVICE

Overview	Process	Information	Feedback	QS
PRE-IMPLANT COUNSELLING	Pre-implant meeting/appointment: <ul style="list-style-type: none"> - possibility of device failure should be discussed - written information on device failure should be issued 	Written and verbal information given to families/adults during the assessment process should include likelihood and management of device failure. Manufacturers should include device failure information in their counselling materials.	Team protocols. Record of information issued to patient Device failure to be included in the list of risks identified on the Operation Consent form. Written confirmation to patient/family that discussions have included the issue of device failure. Programme should provide written information on failure rates: <ul style="list-style-type: none"> - within own programme - UK data - manufacturer data 	Every centre should : <ul style="list-style-type: none"> - publish own failure experience on annual basis - record that written and verbal information has been given - classify failures according to internationally agreed protocol (See Otol. Neurotol)

<p>BASELINE MEASURES</p>	<p>Baseline Measures should include:</p> <ul style="list-style-type: none"> • Impedances checked following electrode conditioning in theatre • Intra-operative objective measures. Minimum of 3-4 channels (apical, medial and basal) • CT/X-ray: Confirmation of electrode positioning undertaken intra-operatively or prior to discharge 	<p>Identify initial device placement and function</p>	<p>Feedback to patient/family, at the time of operation, as appropriate</p> <p>Clinical reports regarding operation, radiology and objective test results to be distributed</p>	
<p>MONITORING PROTOCOL</p>	<p>Monitoring Protocol: The following measurements should be completed at set intervals, according to programme protocols:</p> <ul style="list-style-type: none"> • Impedances • Programming parameters • Sound field thresholds • Ling sounds testing • Speech perception testing • Objective measures • Performance outcome measures • Integrity testing 	<p>Monitor user performance and progress together with device function</p>	<p>Following every appointment, written clinical reports regarding assessment outcomes to be distributed to patient/family, referrer and all involved professionals as appropriate</p>	<p>Each team to have monitoring protocol in place</p>
<p>MANAGEMENT OF SUSPECTED FAILURE</p>	<p>Concern regarding device function identified by:</p> <ul style="list-style-type: none"> - Reporting of concern or observation to clinic from patient, parent or involved professional - identification of issue of concern within CI programme appointment <p>Arrange appropriate assessment investigation, eg:</p> <ul style="list-style-type: none"> - relevant monitoring protocol activities - integrity testing of implant system must be arranged without delay (in-house or by manufacturer as appropriate) - medical review - radiology - counselling (eg, discuss expectations and concerns) - device re-programming - request information from local services/families <p>If device failure is suspected cause of deterioration in performance or functioning:</p> <ul style="list-style-type: none"> - alert manufacturer - obtain confirmation from manufacturer regarding extent of device problem - discuss implications and options with patient/family, eg device choice, choice of ear <p>Agree patient management, eg:</p> <ul style="list-style-type: none"> - arrange explantation - re-implantation - continue monitoring protocol <p>Classify failure according to agreed definitions* Report to MRHA (www.mhra.gov.uk)</p>	<p>Concerns may include:</p> <ul style="list-style-type: none"> - reduction in awareness - decrease in understanding of speech - deterioration in quality of speech - discomfort or blinking to auditory signals - non-auditory sensations - inappropriate changes in programming parameter - failure to make appropriate progress, - unusually high levels of reports of external equipment problems <p>Test outcomes to inform patient and device management.</p> <p>Collation of outcomes of test results and discussions with patients/families. Arrange further case discussion as necessary</p>	<p>Full clinic reporting to be undertaken, copied to referrer, involved professionals and patient/parents.</p> <p>Written confirmation of device function (ie whether within specification) from manufacturer (need to identify timescales for this)</p> <p>Record on clinic database</p> <p>Report to MRHA as appropriate (www.mhra.gov.uk)</p>	<p>NDCS CI guidelines QS13</p> <p>NDCS CI guidelines QS45</p>

<p>FINANCIAL MANAGEMENT</p>	<p>Funding could be obtained by using one of the following methods:</p> <p>Explore funding (including guarantee) from the company to include:</p> <ul style="list-style-type: none"> • cost of implant • cost of external equipment <p>Apply to PCT/funding bodies to cover expenses of:</p> <ul style="list-style-type: none"> • medical review • additional radiology • implant system (where necessary) • surgery • after care <p>Factor costs associated with failures into business planning, eg staffing resources, theatre time, displacement of new patients</p>	<p>Relay of information from the centre/clinician to commissioning body/pct and visa versa</p> <ul style="list-style-type: none"> • Explanation to why re-implantation is necessary • Clinician to put forward case of need • Probable cost of the procedure (surgery/aftercare) • Confirmation of funding available of replacement device <ul style="list-style-type: none"> o From the manufacturer o from the PCT to centre o from centre to patient/family • Information to manufacturers/implant companies <p>Work out failure rate per 100 patients per programme per annum</p> <p>Cost each factor of process:</p> <ul style="list-style-type: none"> • Theatre time • Cost of new device, if not replaced by manufacturer • Surgical costs • Anaesthetics • Post-op xray • Tuning new device • Additional rehab costs 	<ul style="list-style-type: none"> • Feedback of costs to relevant agencies 	<p>Guidelines/ Recommendations</p> <p>Each centre to have strategic business plan to include explanation & re-implantation</p> <p>Quality standard required for timeline for reimplantation</p>
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REVISION SURGERY	<p>Follow centre's surgical protocol</p> <p>Book surgery slot (theatre, surgeon, anaesthesia, audiologist, equipment)</p> <p>Order equipment</p> <p>Remove old device if appropriate and send to manufacturer in accordance with instructions</p> <p>Insert new device and perform intra-operative testing</p> <p>Post-operative x-ray to confirm electrode placement</p> <p>Follow centre's post-operative protocol</p>	<p>Complete surgical record</p> <p>New device registration</p> <p>Send old device to manufacturers and record</p> <p>Results of intra-operative testing</p>	<p>Contact manufacturer with surgery date: discuss their presence</p> <p>Verbal information to patients/families as appropriate</p> <p>Written information to all relevant agencies</p>	<p>Follow surgical QS per BCIG/NDCS guidelines</p>
PACKAGE OF CARE FOLLOWING SURGERY	<p>Initial tuning of new device</p> <p>Rehabilitation and/or counselling sessions as appropriate</p> <p>Evaluate using centre's monitoring protocol</p> <p>Regular medical reviews (particularly in case of infection)</p> <p>If progress is satisfactory, return patient to standard programme protocol.</p> <p>If progress is not satisfactory, continue to review as above</p>	<p>Objective test measures</p> <p>Tuning information</p> <p>Speech perception and production results</p> <p>Information from families and local services</p> <p>Functional communication outcomes</p>	<p>Written information to all relevant agencies</p>	<p>Follow BCIG/NDCS QS and centre's own protocols</p>

Managing device failure will become a regular occurrence in clinic practice. This protocol is designed to support clinics in dealing with this sensitive area. We should remember that there are many dimensions of device failure and that it impacts on not only the user but their wider network. These include:

Dimensions of Failure

Implant user (adult or child):

Deafness, psychological impact, increased clinic attendance, loss of schooling or employment, disillusionment, risk of non-use,

Parent/carer/partner:

Anxiety, disillusionment, anger, clinic visits, time off work, costs,

Teachers/ employer:

Absence from school/work, loss of confidence in technology, negative attitudes, effect of non-use

Implant team:

Urgent appointment, rescheduling, time, expertise, counselling, funding implications, loss of confidence in technology

Purchasers:

Purchase of new implant, concerns re safety and cost-effectiveness, implications of non-use

Industry:

Regulatory requirements, recall implications, device modification, trust, implications for market share, making facts explicit

Deaf Community:

Increase antagonism, fuel suspicions

Public perception:

Diminish confidence and undermine support

Appendix:

Agreed definitions (European consensus statement: Otol and Neurotol, 2005)

- **Device failure:**
 - A device with characteristics outside the manufacturer's specification resulting in a loss of clinical benefit.
 - Re-implantation may be recommended, and all such failures should be reported to the competent authority.
- **Characteristics decrement:**
 - A device with measured characteristics outside the manufacturer's specification, but still of benefit to the patient.
 - Such failures do not need reporting. The implant team would decide if or when reimplantation becomes necessary. The device would then be deemed to have incurred a device failure and should be reported as such.
- **Performance decrement**
 - Unexplained but documented decrement in performance or a device that causes non-auditory sensations necessitating explanation.
 - Testing of the device may not show any failure; if reimplantation restores function or abolishes non-auditory sensations, the implant should be considered to have had a device failure and reported as such. If the new device fails to do so, the episode should be considered as a medical explanation.
- **Loss to follow up**
 - Implanted patients which have been lost to surveillance.

- **Medical reasons**

- Devices that are believed to be functioning normally but that need to be removed for medical reasons eg infection, biological failure etc.

- **Failure categories**

A Normal functioning device

B1 Characteristics Decrement: replacement of device not necessary as long as clinical benefit is preserved

B2 Performance Decrement: Explantation and reimplantation recommended

C Device failure: Explantation and reimplantation recommended. Report to competent authority and manufacturer is mandatory. Goes to cumulative survival rate calculation.

D Medical reason: Explantation due to medical problem (ie infections, electrode misplacement etc) Shall be reported to future European databank.

E Population of implantees who no longer show up for aftercare. Shall be reported to future European databank.

References:

Balkany T, Hodges AV, Buchman CA, Luxford WM, Pillsbury CH, Roland PS, Shallop JK, Backous DD, Franz D, Graham JM, Hirsch B, LUntz M, Niparko JK, Patrick J, Payne SL, Staller S, Telischi FF, Tobey EA, Truy E (2005) Cochlear implant soft failures. Consensus Development conference statement. *Cochlear Implants International* **6 (3)** 105-122

European Consensus Statement on Cochlear Implant Failures and Explantations: *Otology and Neurotology*, **26**: 1097-1099 2005

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